Anhang 4-G: Ergänzende Unterlagen

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Anhang 4-G1: Weitere Analysen der Studie MONARCH-2

Anhang 4-G1.1: Postprogressionstherapien

Tabelle 4-112 (Anhang): Liste der Postprogressionstherapien (MONARCH-2)

Tabelle 2: Übersicht der Postprogressionstherapien - Monarch-2

	Ohne vorangegangene endokrine Therapie (Erstlinie) (A1)			Mit vorangegangener endokriner Therapie (Zweitlinie) (B1)		
	Abemaciclib+ Fulvestrant (N=246)	**Placebo+ Fulvestrant (N=128)**	**Gesamt (N=374)**	**Abemaciclib+ Fulvestrant (N=144)**	**Placebo+ Fulvestrant (N=66)**	**Gesamt (N=210)**
Patientinnen, die einen Progress hatten, n (%)	202 (82,1)	123 (96,1)	325 (86,9)	127 (88,2)	65 (98,5)	192 (91,4)
Systemische Therapie, n (%) [1]						
Insgesamt	152 (75,2)	92 (74,8)	244 (75,1)	101 (79,5)	60 (92,3)	161 (83,9)
Chemotherapie	104 (51,5)	68 (55,3)	172 (52,9)	66 (52,0)	47 (72,3)	113 (58,9)
Endokrine Therapie	108 (53,5)	64 (52,0)	172 (52,9)	63 (49,6)	43 (66,2)	106 (55,2)
Andere systemische Therapie	24 (11,9)	16 (13,0)	40 (12,3)	8 (6,3)	7 (10,8)	15 (7,8)
Zielgerichtete Therapie	68 (33,7)	46 (37,4)	114 (35,1)	46 (36,2)	32 (49,2)	78 (40,6)
Erste Folgetherapie	152 (75,2)	92 (74,8)	244 (75,1)	101 (79,5)	60 (92,3)	161 (83,9)
Chemotherapie	64 (31,7)	40 (32,5)	104 (32,0)	45 (35,4)	28 (43,1)	73 (38,0)
Endokrine Therapie	84 (41,6)	51 (41,5)	135 (41,5)	52 (40,9)	32 (49,2)	84 (43,8)
Andere systemische Therapie	16 (7,9)	6 (4,9)	22 (6,8)	6 (4,7)	4 (6,2)	10 (5,2)
Zielgerichtete Therapie	47 (23,3)	30 (24,4)	77 (23,7)	31 (24,4)	20 (30,8)	51 (26,6)
Operativer Eingriff, n (%) [1]	13 (6,4)	5 (4,1)	18 (5,5)	7 (5,5)	2 (3,1)	9 (4,7)
Strahlentherapie, n (%) [1]	29 (14,4)	24 (19,5)	53 (16,3)	26 (20,5)	11 (16,9)	37 (19,3)

Datenschnitt: 20.06.2019, ITT-Population
[1] Prozentzahlen basieren auf der Gesamtzahl der Patientinnen mit Progress.
Abkürzungen: A1: Postmenopausale Patientinnen ohne vorangegangene endokrine Therapie (Erstlinie); B1: Postmenopausale Patientinnen mit vorangegangener endokriner Therapie (Zweitlinie); RCT: Randomisierte kontrollierte Studie; ITT: Intention to treat; N: Gesamtzahl der Patientinnen in der Analyse; n: Anzahl der Patientinnen

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Anhang 4-G1.2: Ergebnisse des Gesamtüberlebens - Postmenopausale Patientinnen

Tabelle 4-113 (Anhang): Ergebnisse des Gesamtüberlebens (MONARCH-2)

Tabelle 019: Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel - stratifizierte Analyse, Postmenopausale Patientinnen (MONARCH-2; Datenschnitt: 20.06.2019)

	Abemaciclib+Fulvestrant		**Placebo+Fulvestrant**		
Population	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert**
Gesamtüberleben					
ITT Population[2]	189/390 (48,5)	44,9 [38,56; 52,24]	112/194 (57,7)	36,4 [32,22; 41,72]	0,775 [0,611; 0,981] 0,0340[3] 0,2641[4]

Datenschnitt: 20.06.2019
ITT-Population
1: In Monaten; 2: Für postmenopausale Patientinnen (Subpopulationen A1 und B1) wird gemäß Protokoll und CSR die stratifizierte Analyse angegeben; 3: Aus Log-rank-Test; 4: p-Wert aus dem Modell mit Interaktion zwischen Behandlungsgruppe und Subpopulation (A1 vs. B1).
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; n: Anzahl verstorbener Patienten; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar/nicht erreicht.

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Tabelle 4-114 (Anhang): Ergebnisse des Gesamtüberlebens - unstratifiziert (MONARCH-2)

Tabelle 020: Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel - unstratifizierte Analyse, Postmenopausale Patientinnen (MONARCH-2; Datenschnitt: 20.06.2019)

	Abemaciclib+Fulvestrant		**Placebo+Fulvestrant**		
Population	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert**
Gesamtüberleben					
ITT Population[2]	189/390 (48,5)	44,9 [38,56; 52,24]	112/194 (57,7)	36,4 [32,22; 41,72]	0,756 [0,598; 0,955] 0,0188[3] 0,3522[4]

Datenschnitt: 20.06.2019
ITT-Population
1: In Monaten; 2: Postmenopausale Patientinnen (Subpopulationen A1 und B1); 3: Aus Log-rank-Test; 4: p-Wert aus dem Modell mit Interaktion zwischen Behandlungsgruppe und Subpopulation (A1 vs. B1).
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; n: Anzahl verstorbener Patienten; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar/nicht erreicht.

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Anhang 4-G1.3: Kaplan-Meier-Kurven für die Ergebnisse der Endpunkte Symptomatik, Gesundheitszustand, gesundheitsbezogene Lebensqualität und unerwünschte Ereignisse

Abbildung 149 (Anhang): Kaplan-Meier-Kurven für Symptomatik, Gesundheitszustand und gesundheitsbezogene Lebensqualität (MONARCH-2)

Symptomatik – RCT

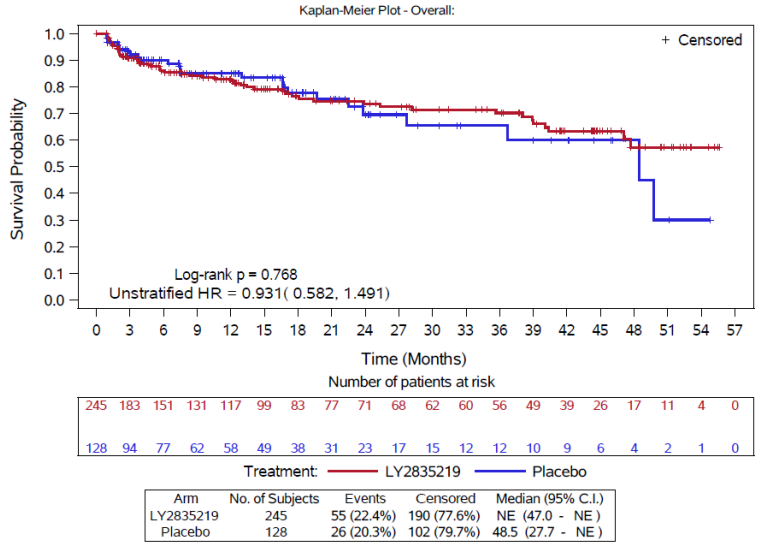


Abbildung 4-25: Kaplan-Meier-Kurve für Appetitlosigkeit (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

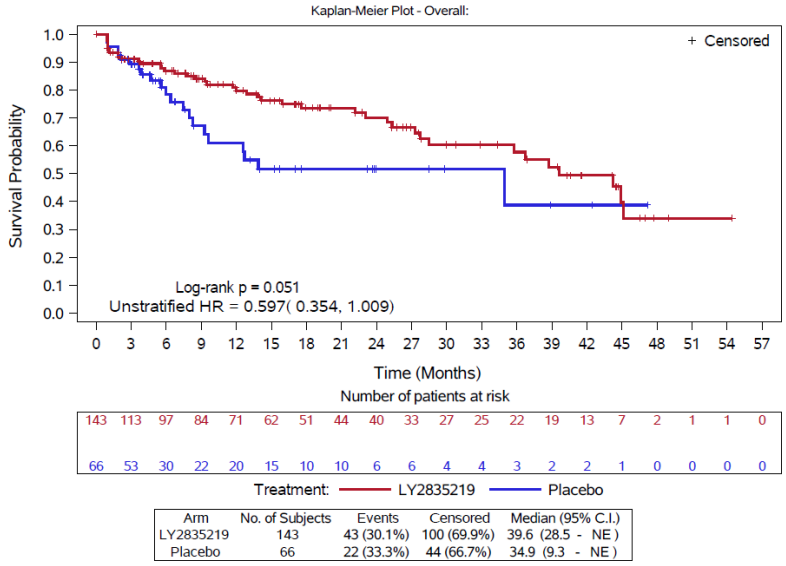


Abbildung 4-26: Kaplan-Meier-Kurve für Appetitlosigkeit (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

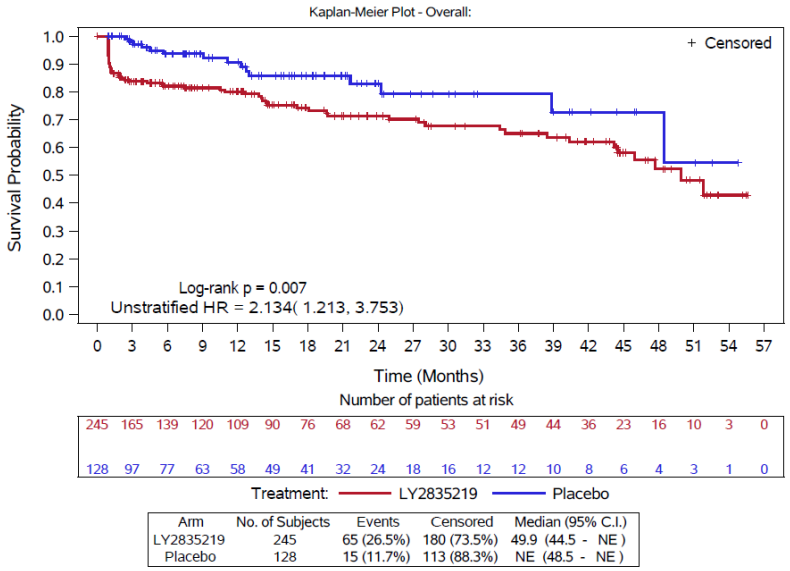


Abbildung 4-27: Kaplan-Meier-Kurve für Diarrhö (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

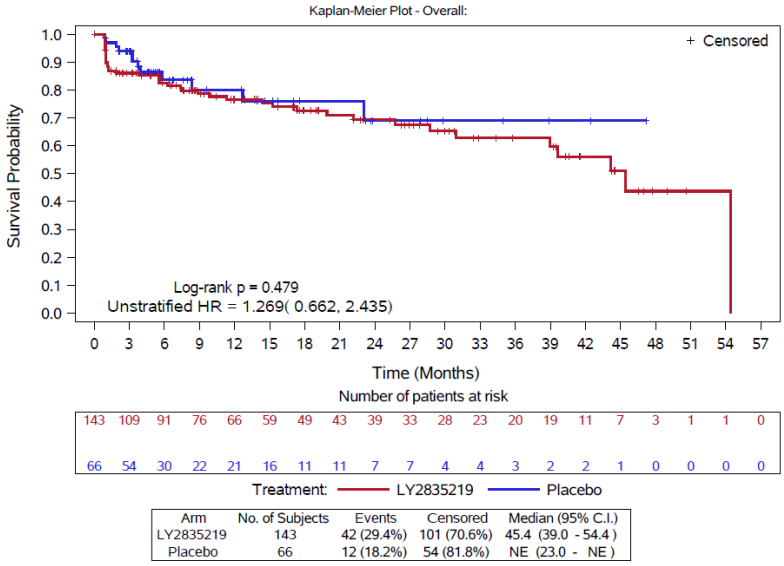


Abbildung 4-28: Kaplan-Meier-Kurve für Diarrhö (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

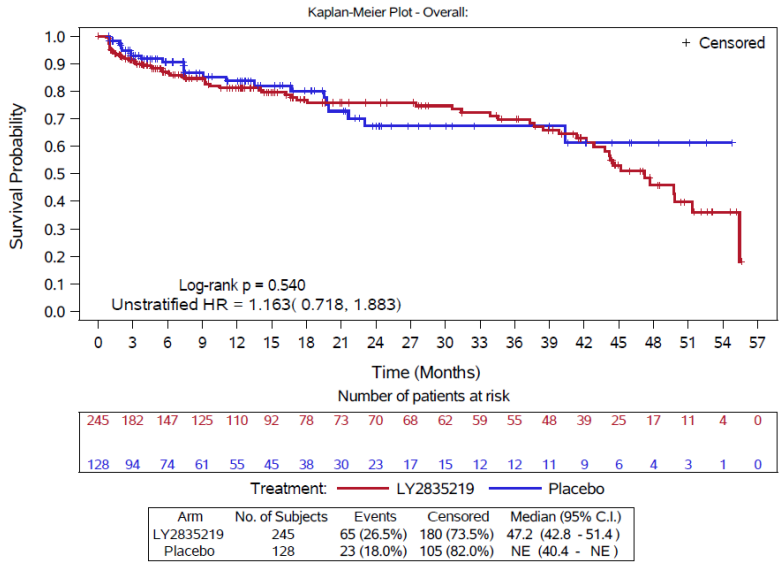


Abbildung 4-29: Kaplan-Meier-Kurve für Dyspnoe (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

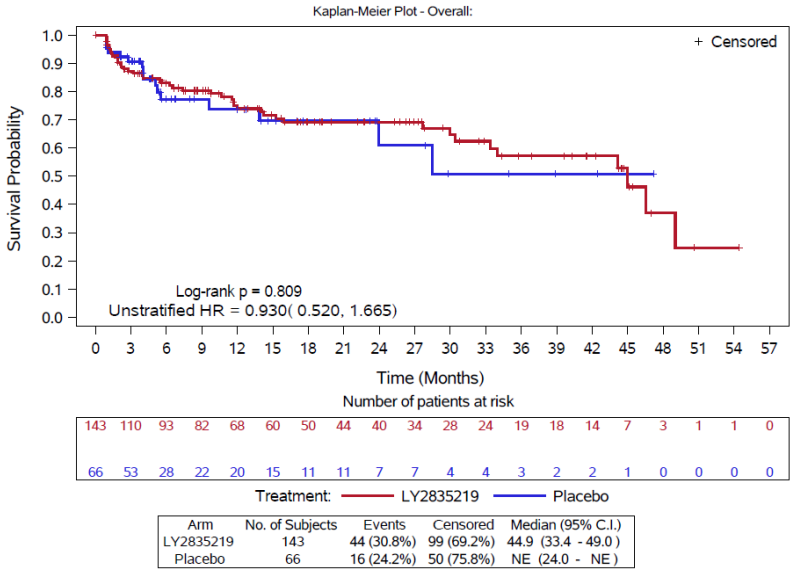


Abbildung 4-30: Kaplan-Meier-Kurve für Dyspnoe (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

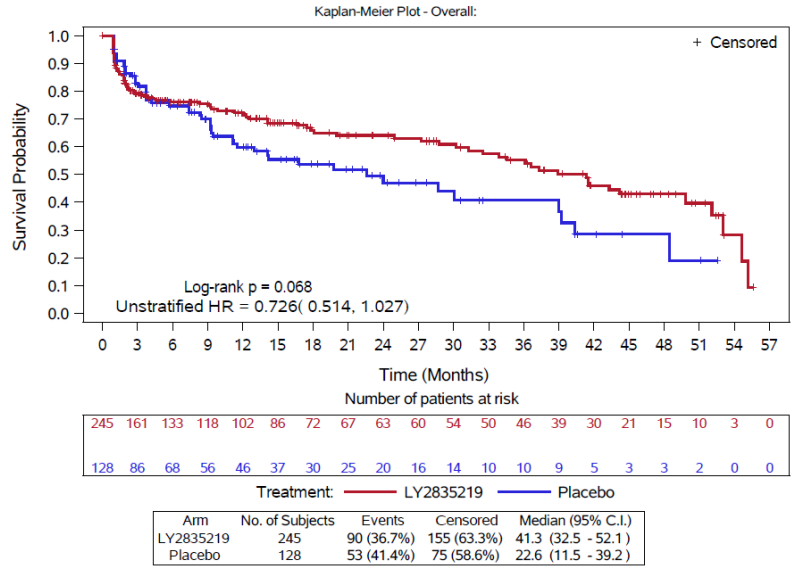


Abbildung 4-31: Kaplan-Meier-Kurve für Fatigue (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

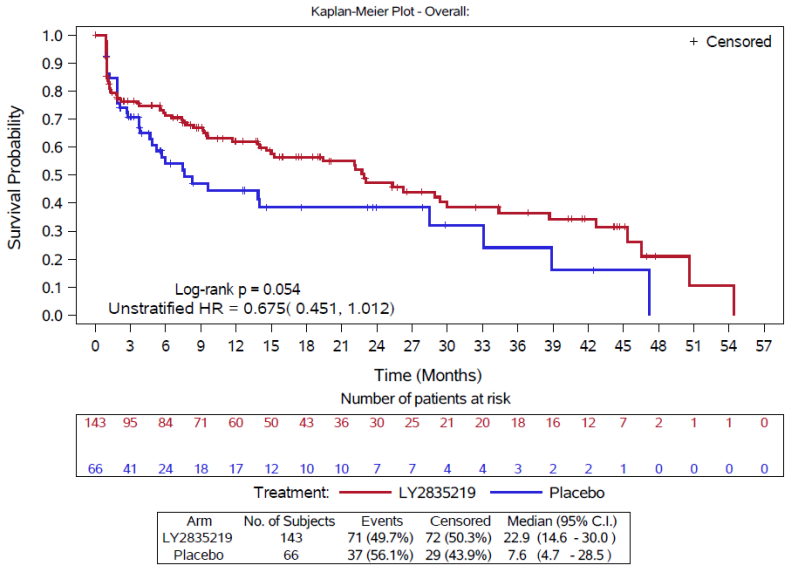


Abbildung 4-32: Kaplan-Meier-Kurve für Fatigue (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

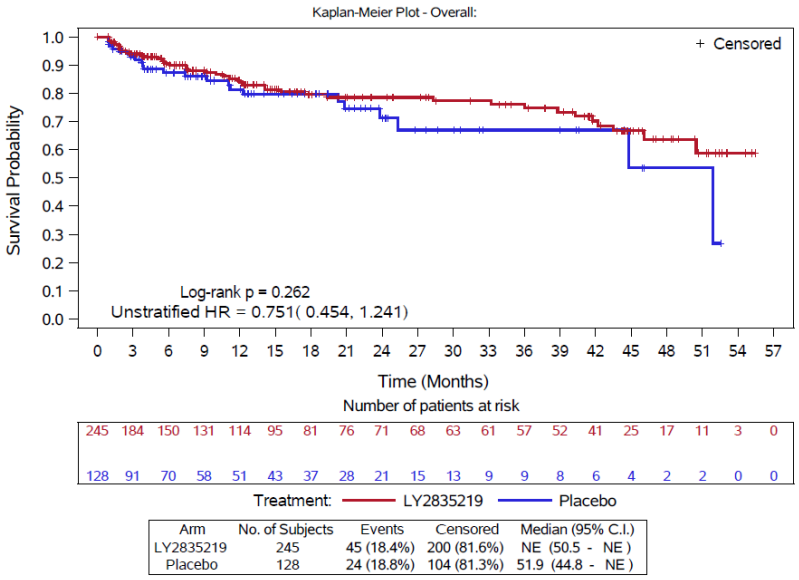


Abbildung 4-33: Kaplan-Meier-Kurve für Finanzielle Schwierigkeiten (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

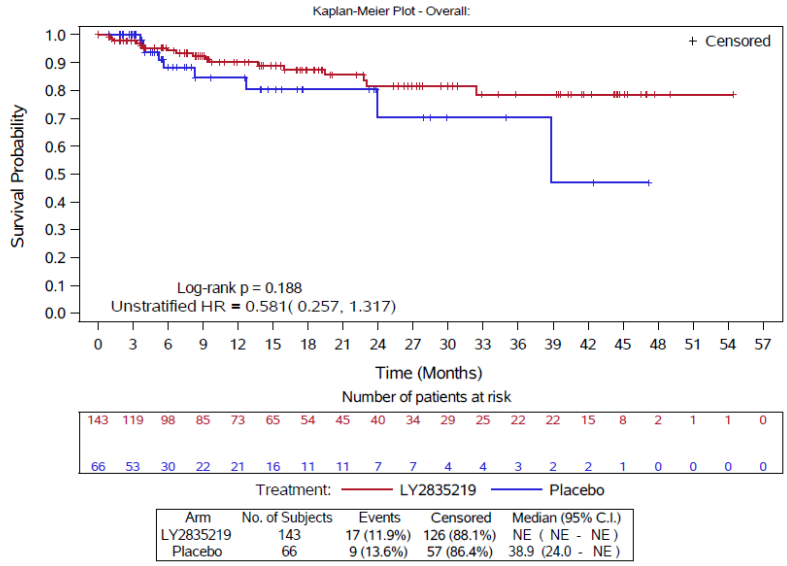


Abbildung 4-34: Kaplan-Meier-Kurve für Finanzielle Schwierigkeiten (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

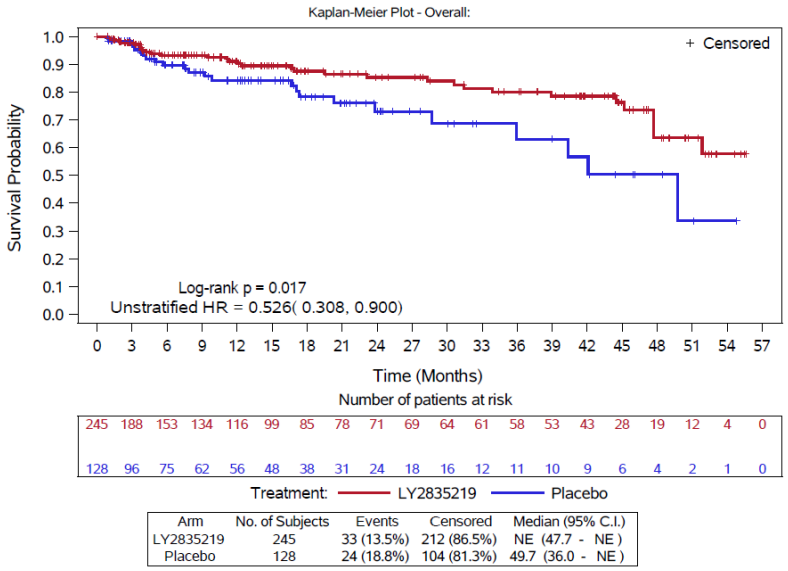


Abbildung 4-35: Kaplan-Meier-Kurve für Verstopfung (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

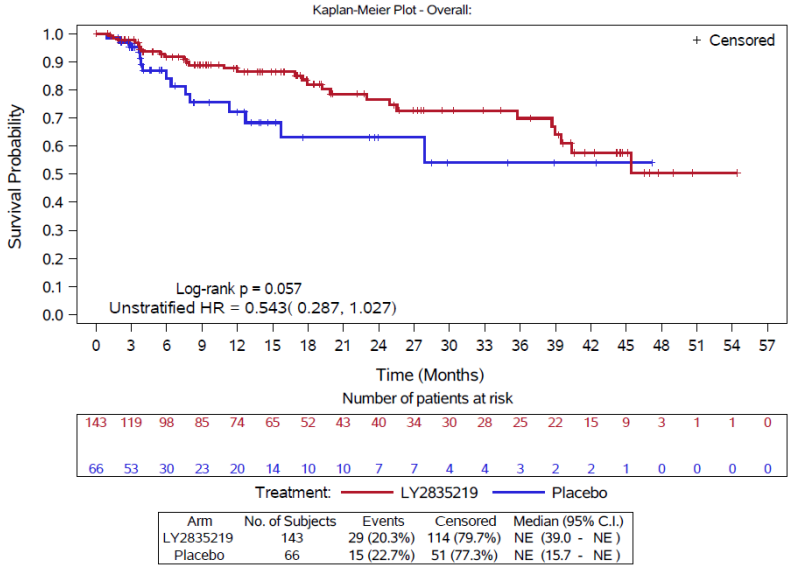


Abbildung 4-36: Kaplan-Meier-Kurve für Verstopfung (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

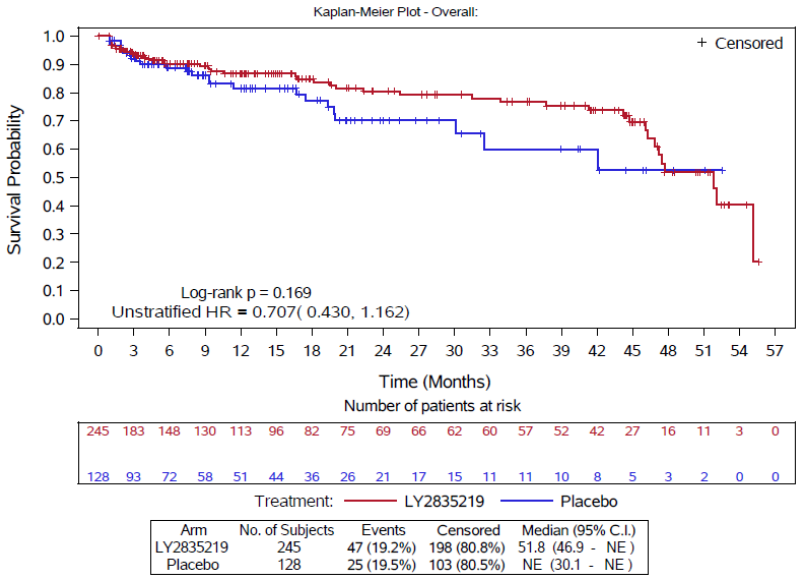


Abbildung 4-37: Kaplan-Meier-Kurve für Schlaflosigkeit (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

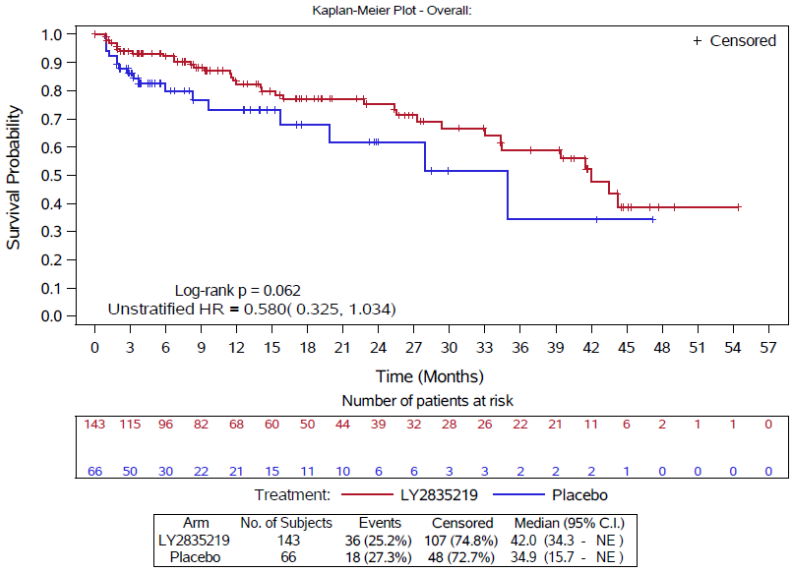


Abbildung 4-38: Kaplan-Meier-Kurve für Schlaflosigkeit (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

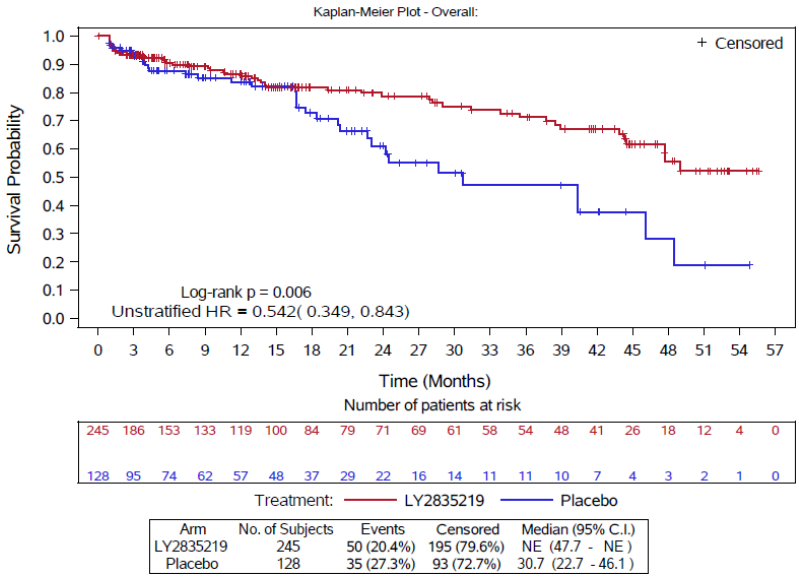
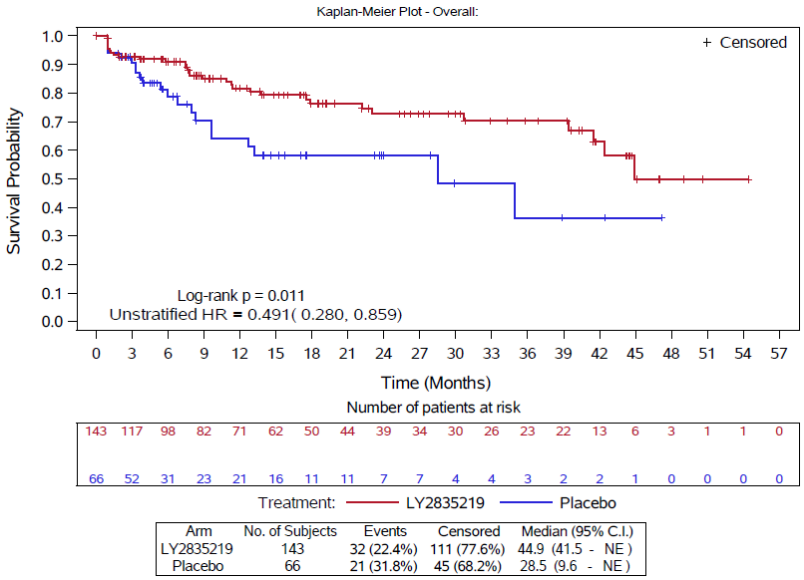
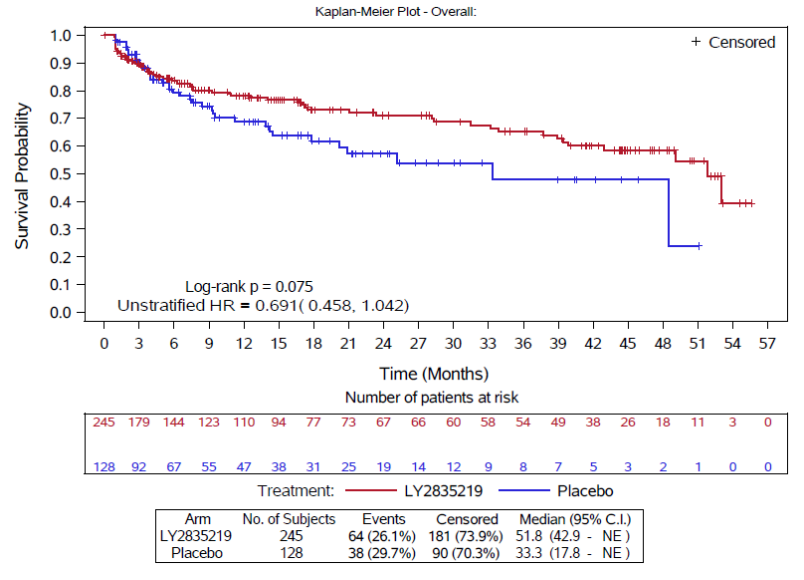


Abbildung 4-39: Kaplan-Meier-Kurve für Übelkeit und Erbrechen (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)



Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	143	32 (22.4%)	111 (77.6%)	44.9 (41.5 - NE)
Placebo	66	21 (31.8%)	45 (68.2%)	28.5 (9.6 - NE)

Abbildung 4-40: Kaplan-Meier-Kurve für Übelkeit und Erbrechen (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)



Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	245	64 (26.1%)	181 (73.9%)	51.8 (42.9 - NE)
Placebo	128	38 (29.7%)	90 (70.3%)	33.3 (17.8 - NE)

Abbildung 4-41: Kaplan-Meier-Kurve für Schmerz (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

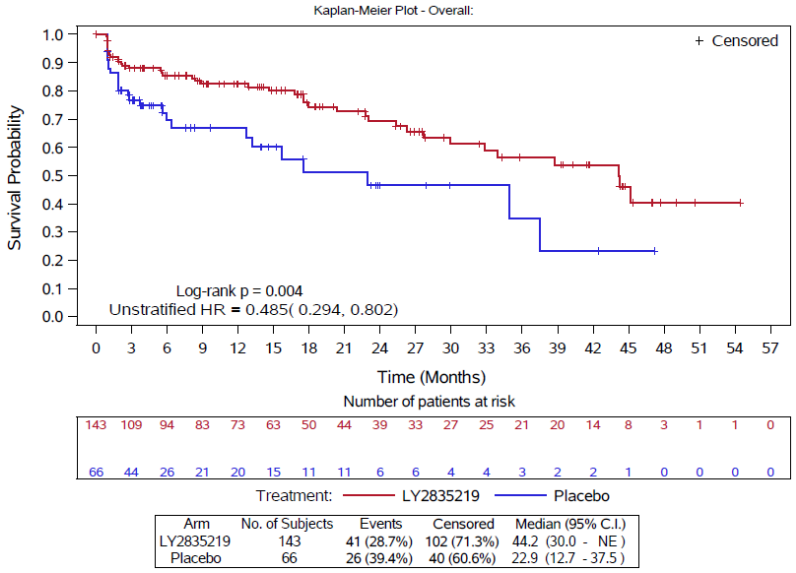


Abbildung 4-42: Kaplan-Meier-Kurve für Schmerz (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

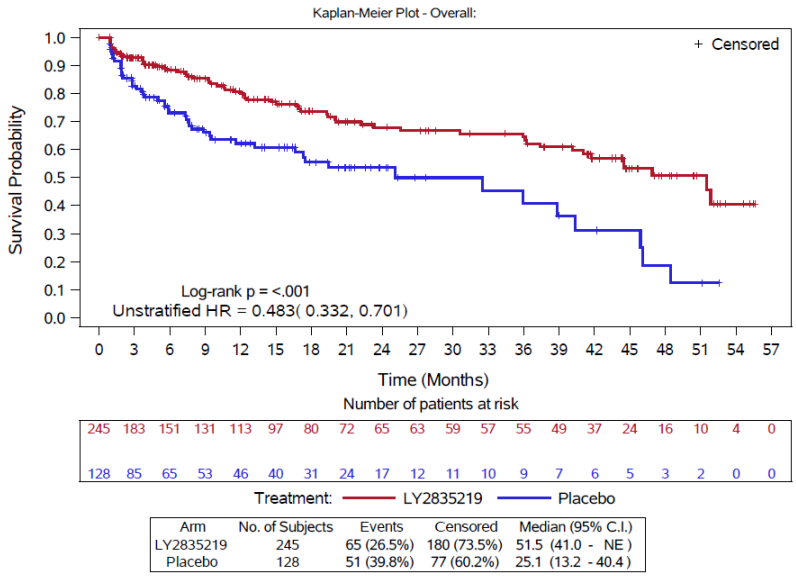


Abbildung 4-43: Kaplan-Meier-Kurve für Symptome im Armbereich (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

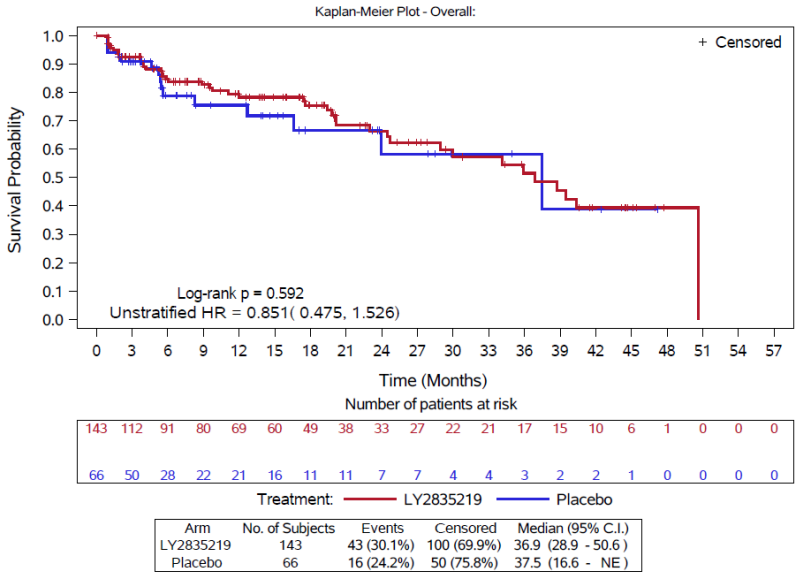


Abbildung 4-44: Kaplan-Meier-Kurve für Symptome im Armbereich (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

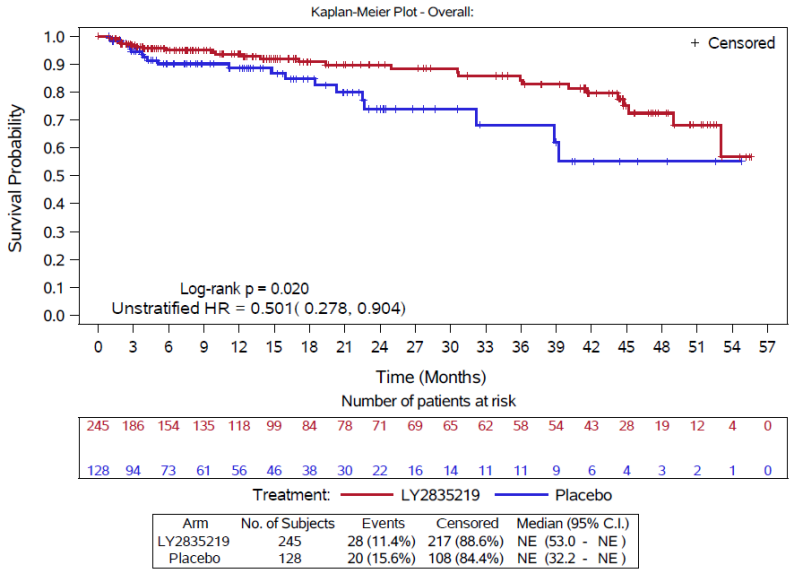


Abbildung 4-45: Kaplan-Meier-Kurve für Symptome im Brustbereich (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

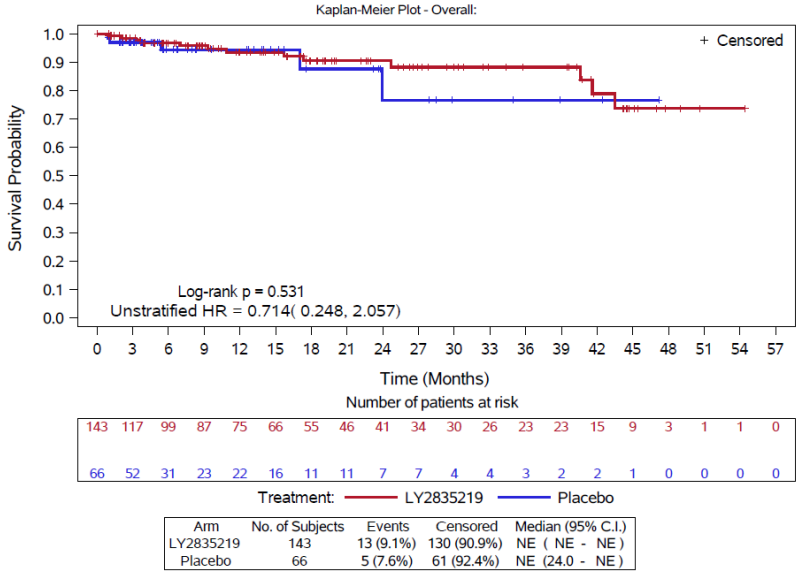


Abbildung 4-46: Kaplan-Meier-Kurve für Symptome im Brustbereich (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

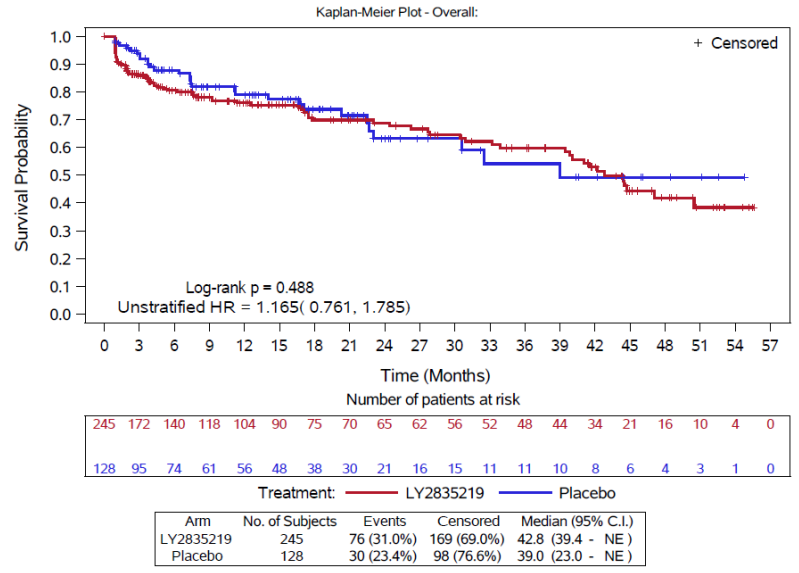


Abbildung 4-47: Kaplan-Meier-Kurve für Nebenwirkungen der systemischen Therapie (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

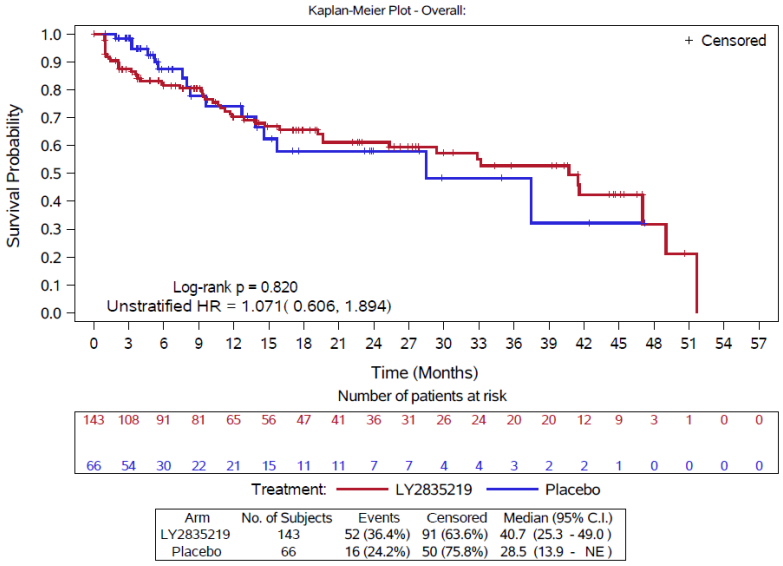


Abbildung 4-48: Kaplan-Meier-Kurve für Nebenwirkungen der systemischen Therapie (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

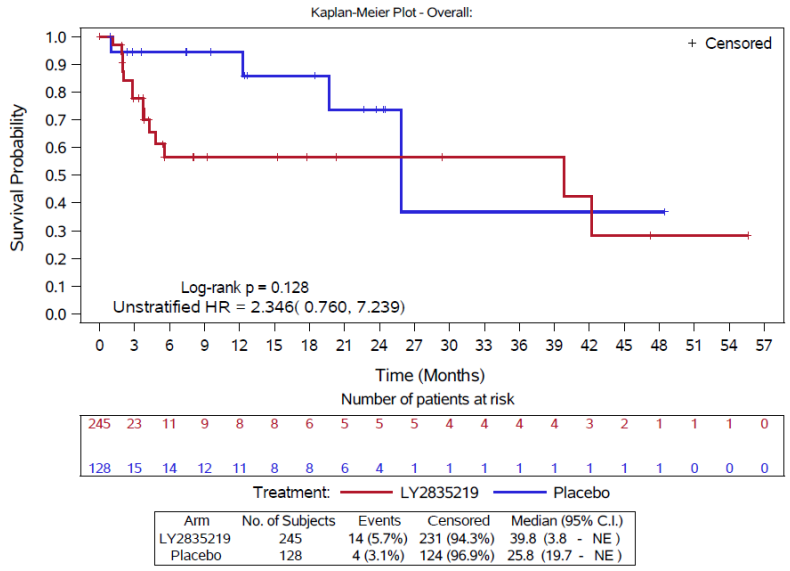


Abbildung 4-49: Kaplan-Meier-Kurve für Belastung durch Haarausfall (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

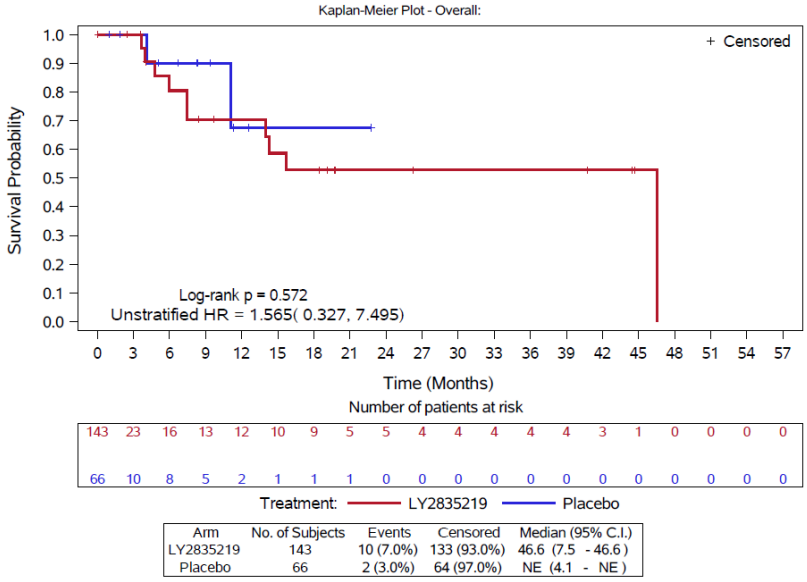


Abbildung 4-50: Kaplan-Meier-Kurve für Belastung durch Haarausfall (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

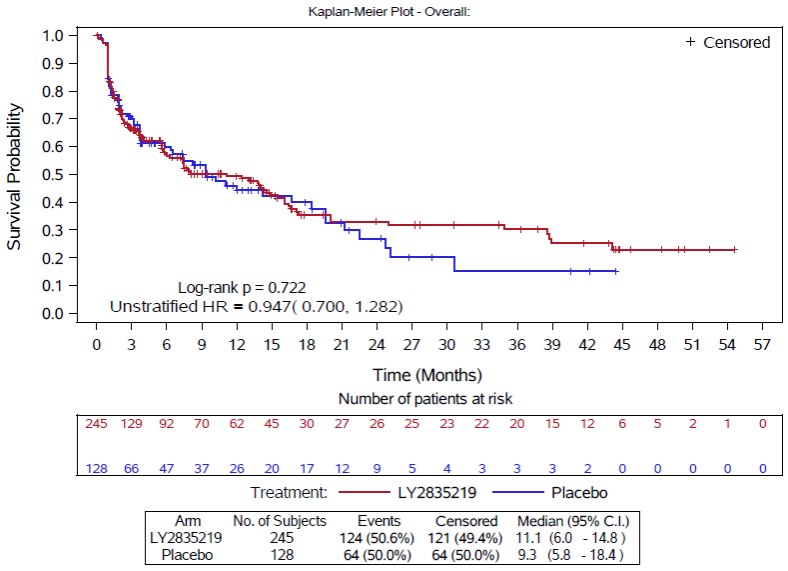


Abbildung 4-51: Kaplan-Meier-Kurve für Stärkster Schmerz in den letzten 24 Stunden (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

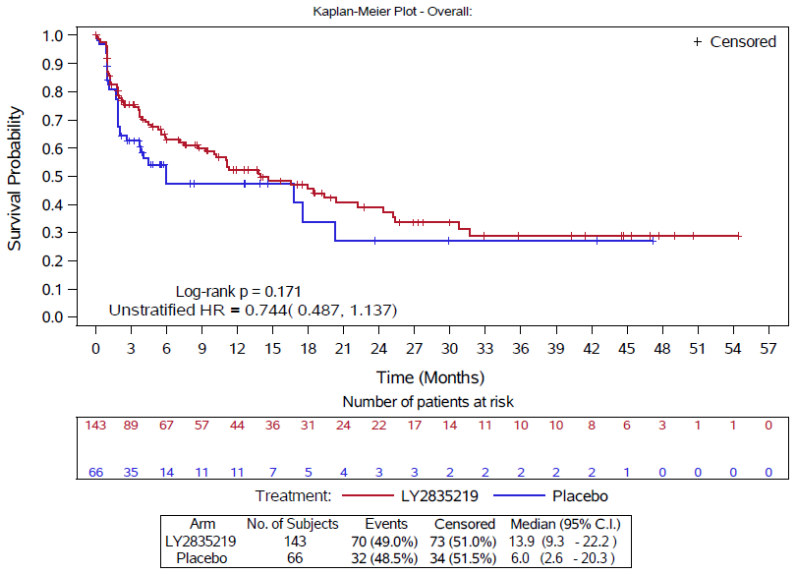


Abbildung 4-52: Kaplan-Meier-Kurve für Stärkster Schmerz in den letzten 24 Stunden (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

Gesundheitszustand – RCT

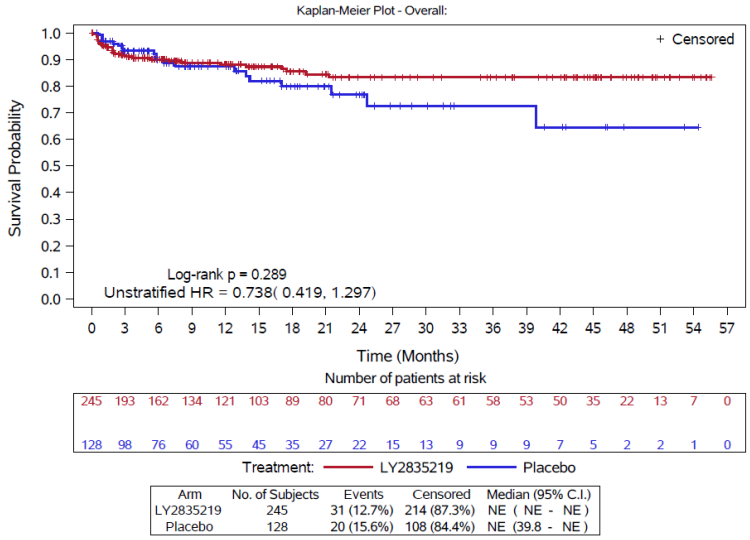


Abbildung 4-53: Kaplan-Meier-Kurve für Zeit bis zur Verschlechterung des ECOG-PS auf ≥2 (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

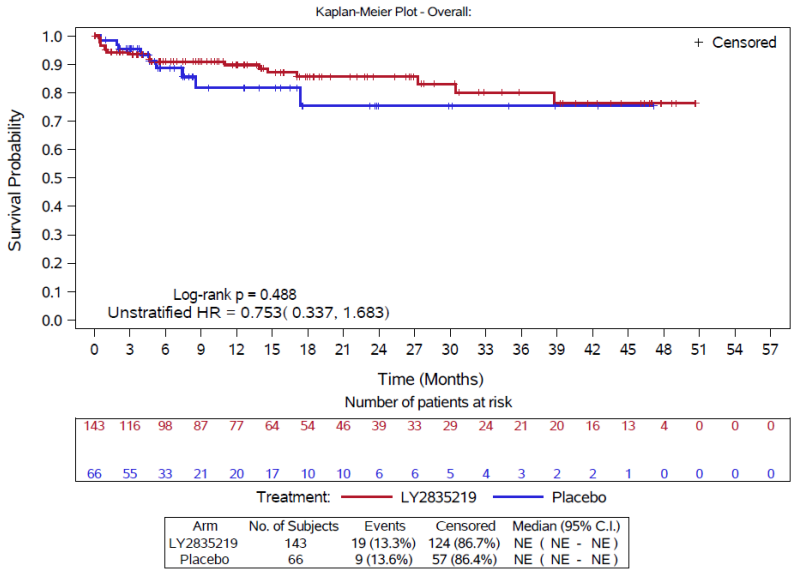


Abbildung 4-54: Kaplan-Meier-Kurve für Zeit bis zur Verschlechterung des ECOG-PS auf ≥2 (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

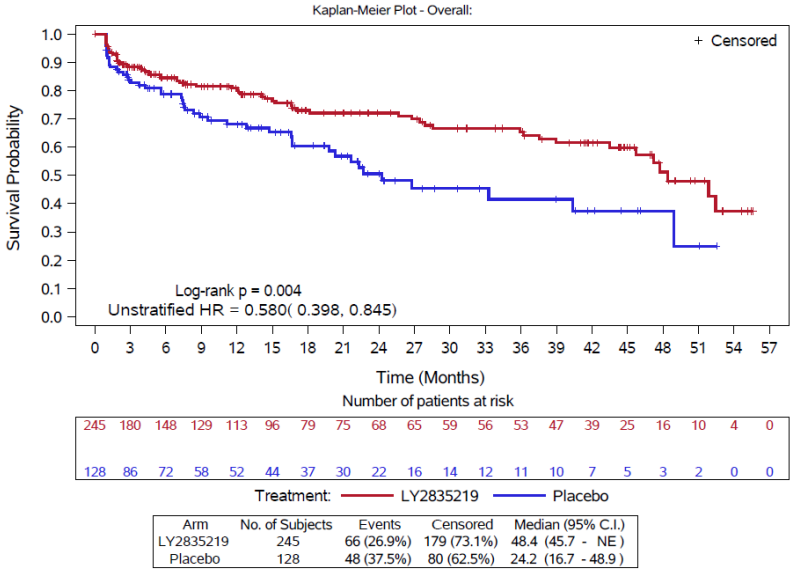


Abbildung 4-55: Kaplan-Meier-Kurve für Zeit bis zur dauerhaften Verschlechterung der EQ-5D VAS (7 Punkte) (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

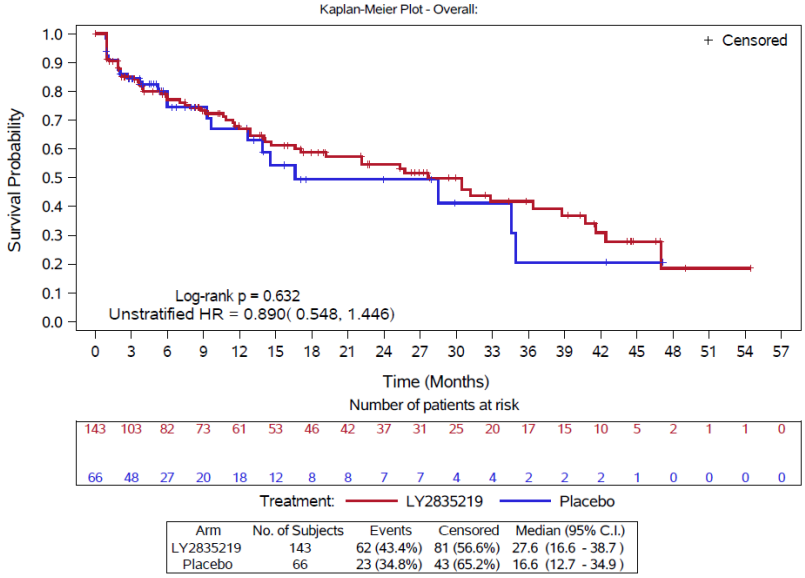


Abbildung 4-56: Kaplan-Meier-Kurve für Zeit bis zur dauerhaften Verschlechterung der EQ-5D VAS (7 Punkte) (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

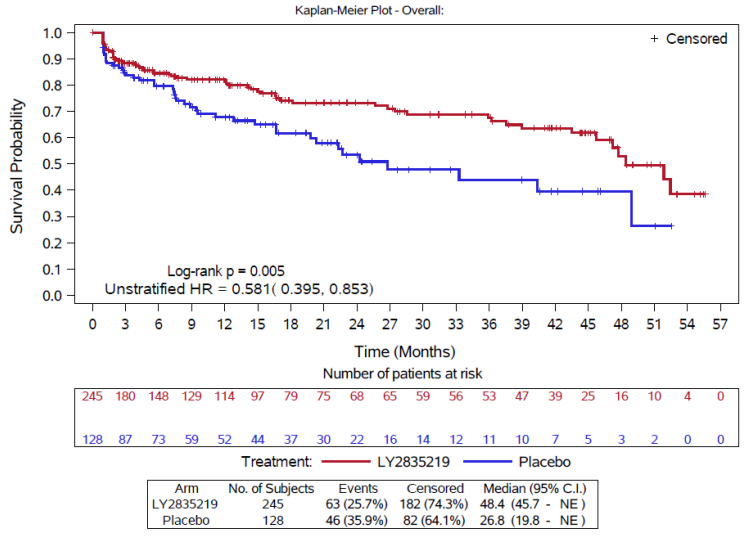


Abbildung 4-57: Kaplan-Meier-Kurve für Zeit bis zur dauerhaften Verschlechterung der EQ-5D VAS (10 Punkte) (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

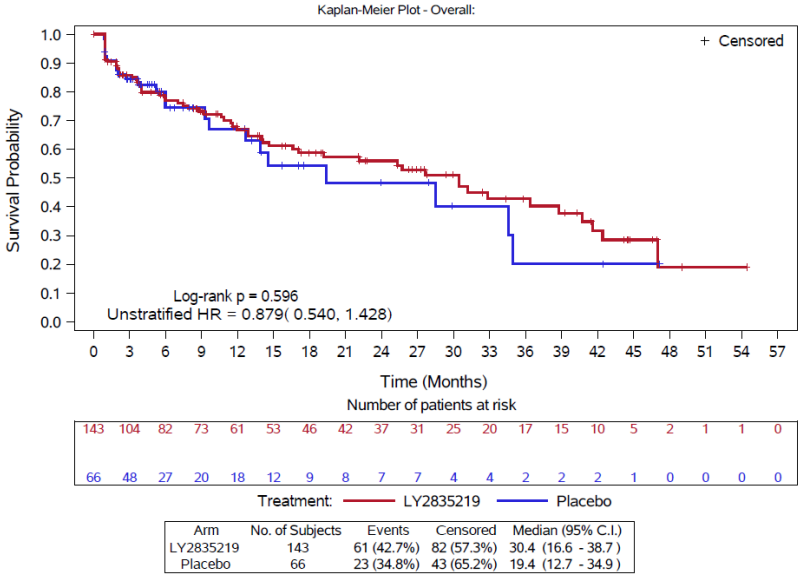


Abbildung 4-58: Kaplan-Meier-Kurve für Zeit bis zur dauerhaften Verschlechterung der EQ-5D VAS (10 Punkte) (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

Gesundheitsbezogene Lebensqualität – RCT

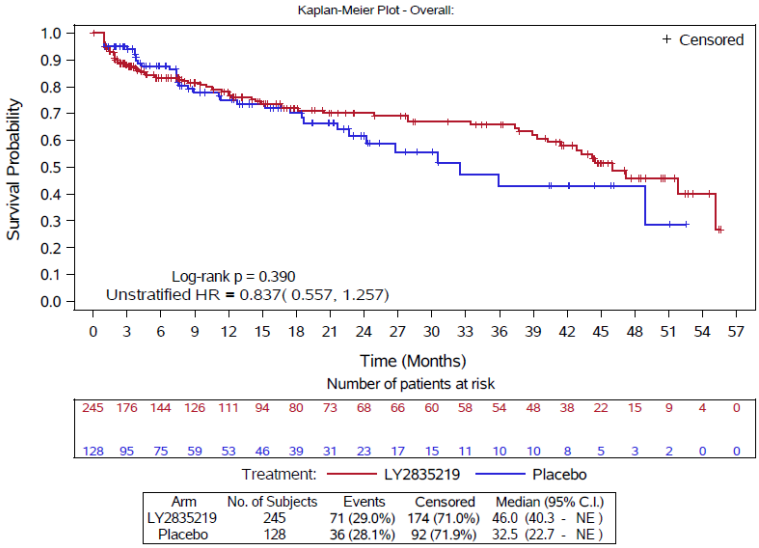


Abbildung 4-59: Kaplan-Meier-Kurve für Globaler Gesundheitsstatus (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

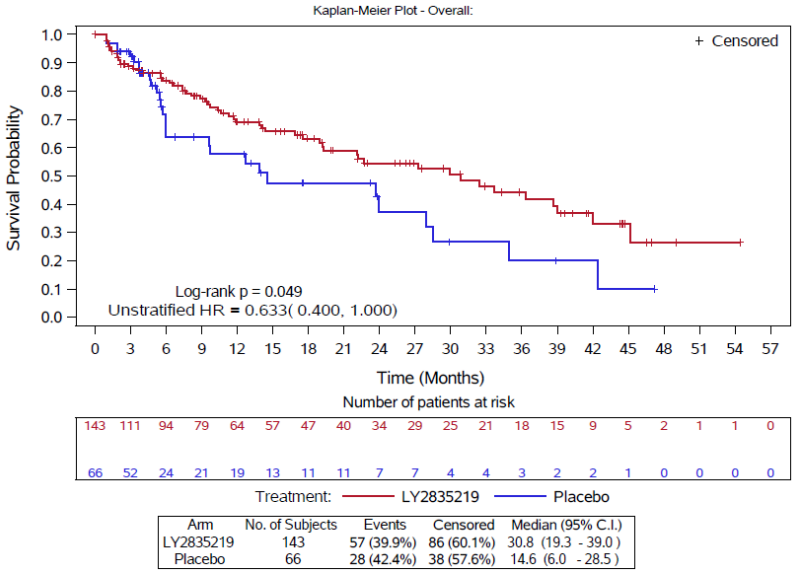


Abbildung 4-60: Kaplan-Meier-Kurve für Globaler Gesundheitsstatus (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

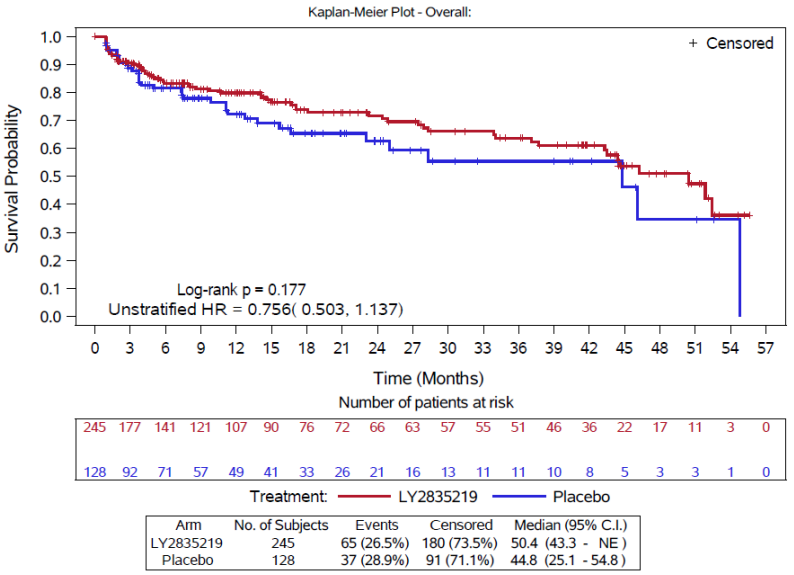


Abbildung 4-61: Kaplan-Meier-Kurve für Kognitive Funktion (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

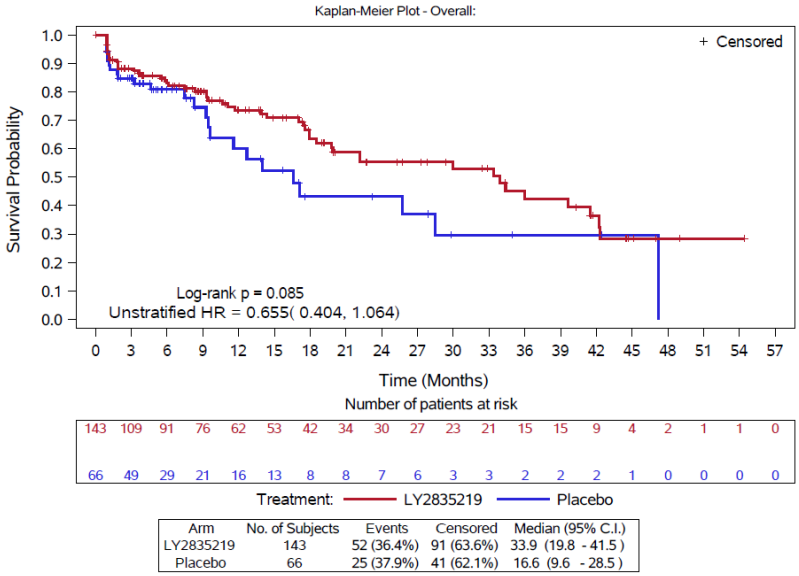


Abbildung 4-62: Kaplan-Meier-Kurve für Kognitive Funktion (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

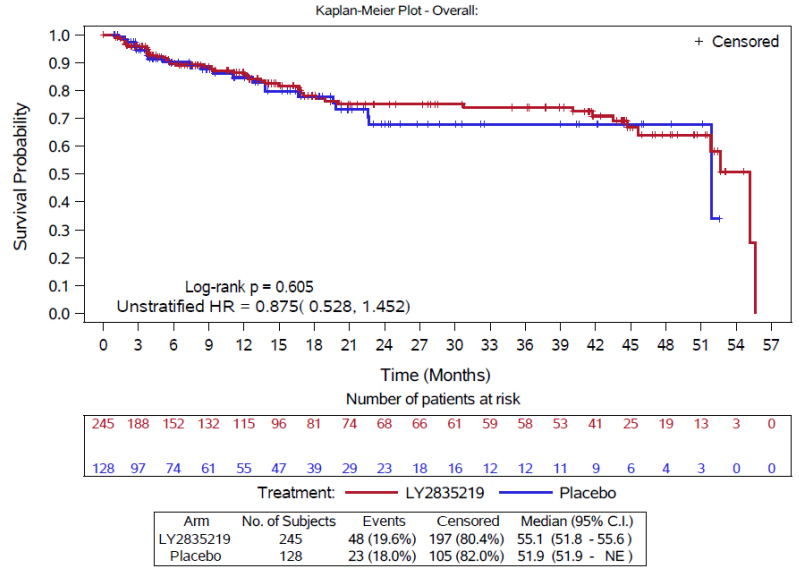


Abbildung 4-63: Kaplan-Meier-Kurve für Emotionale Funktion (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

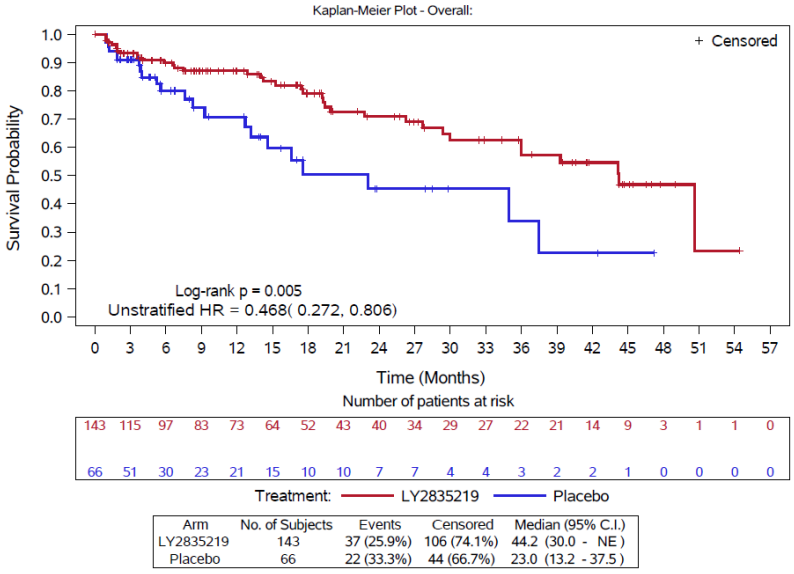


Abbildung 4-64: Kaplan-Meier-Kurve für Emotionale Funktion (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

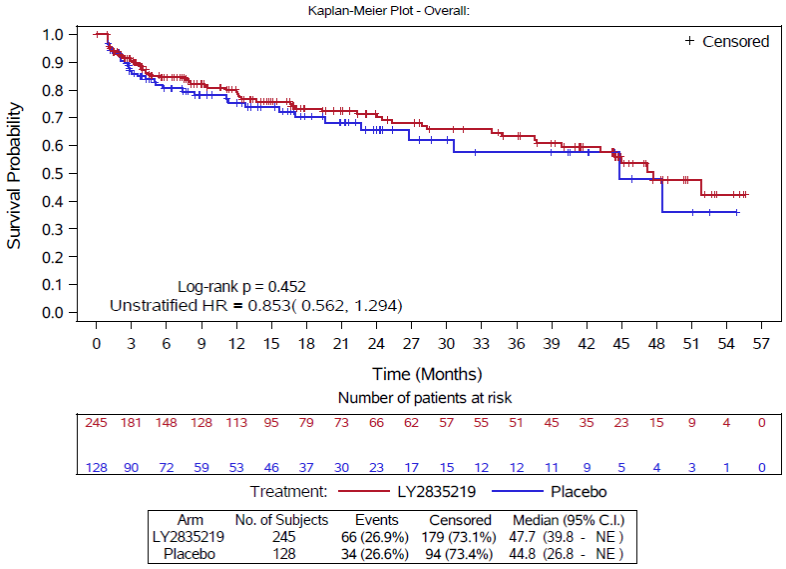
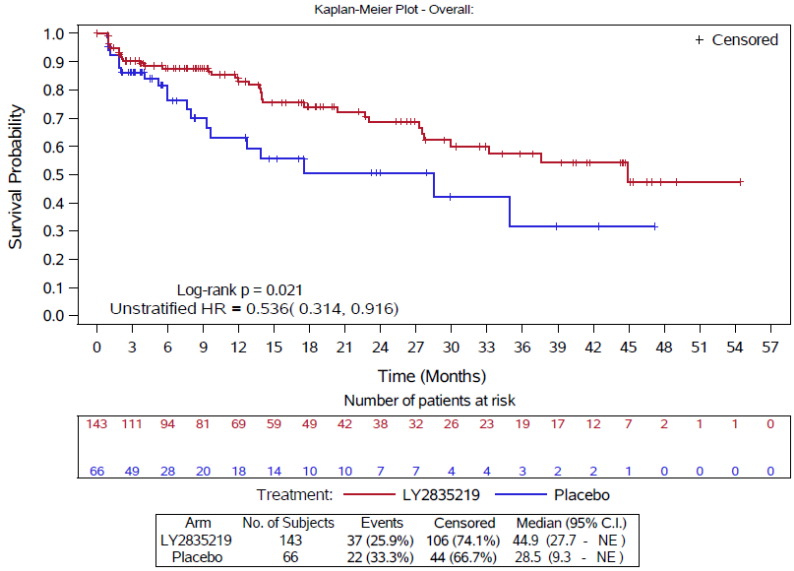
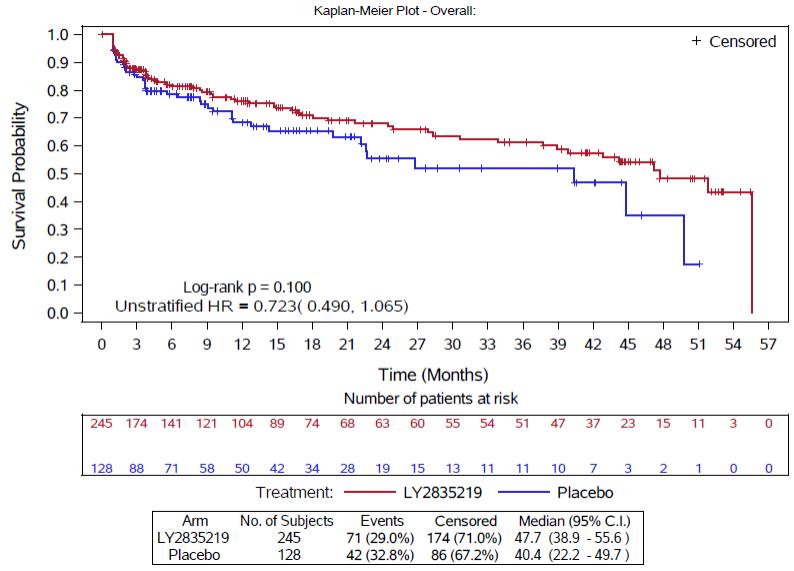


Abbildung 4-65: Kaplan-Meier-Kurve für Körperliche Funktion (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)



Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	143	37 (25.9%)	106 (74.1%)	44.9 (27.7 - NE)
Placebo	66	22 (33.3%)	44 (66.7%)	28.5 (9.3 - NE)

Abbildung 4-66: Kaplan-Meier-Kurve für Körperliche Funktion (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)



Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	245	71 (29.0%)	174 (71.0%)	47.7 (38.9 - 55.6)
Placebo	128	42 (32.8%)	86 (67.2%)	40.4 (22.2 - 49.7)

Abbildung 4-67: Kaplan-Meier-Kurve für Rollenfunktion (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

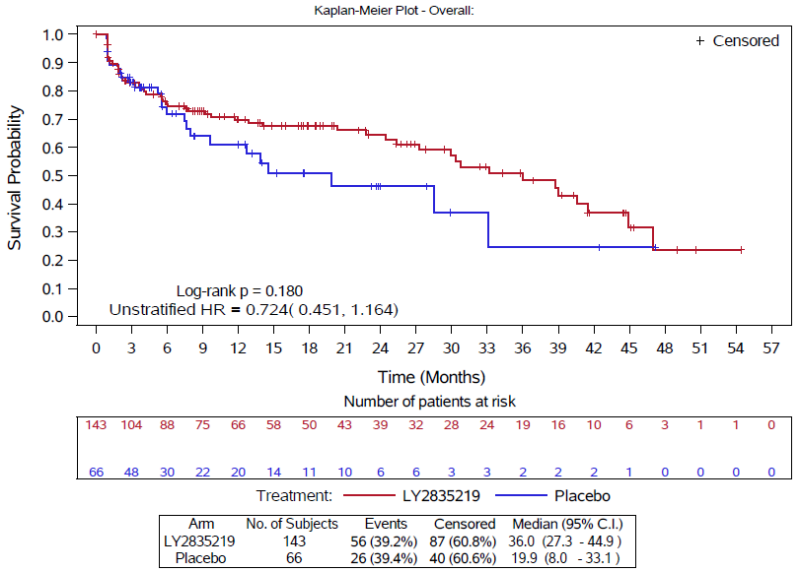


Abbildung 4-68: Kaplan-Meier-Kurve für Rollenfunktion (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

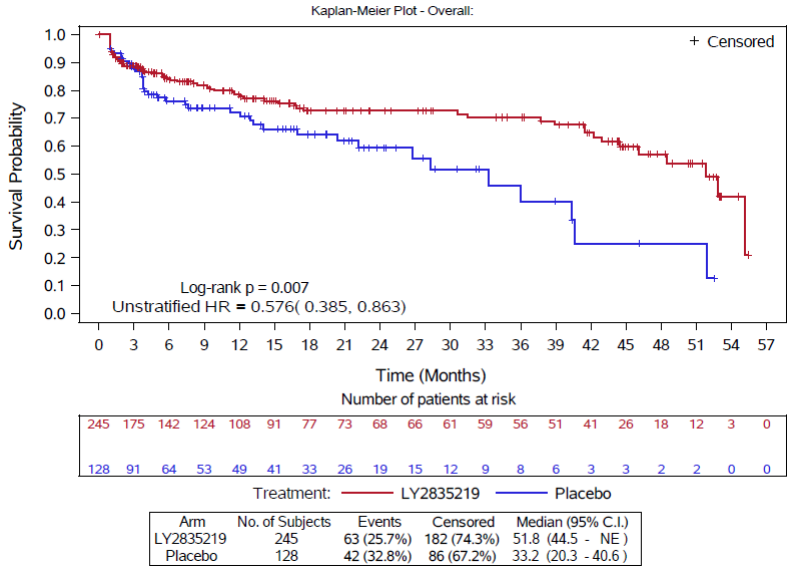


Abbildung 4-69: Kaplan-Meier-Kurve für Soziale Funktion (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

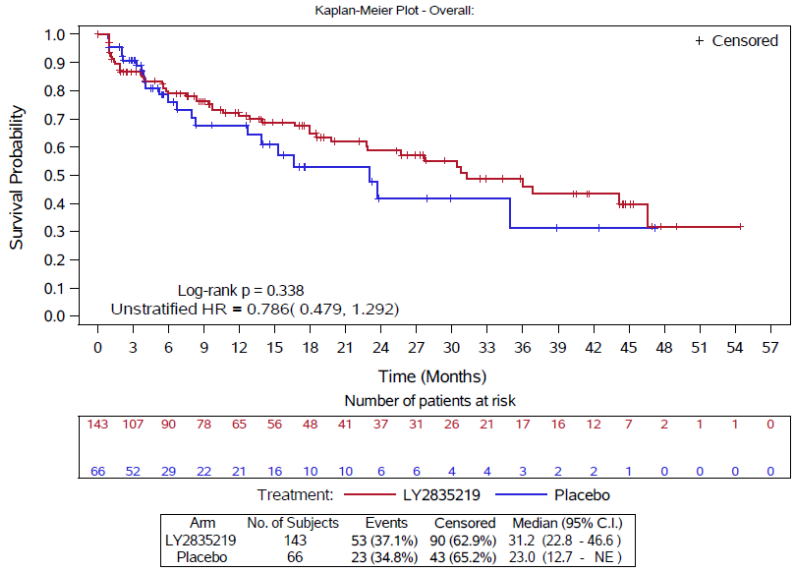


Abbildung 4-70: Kaplan-Meier-Kurve für Soziale Funktion (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

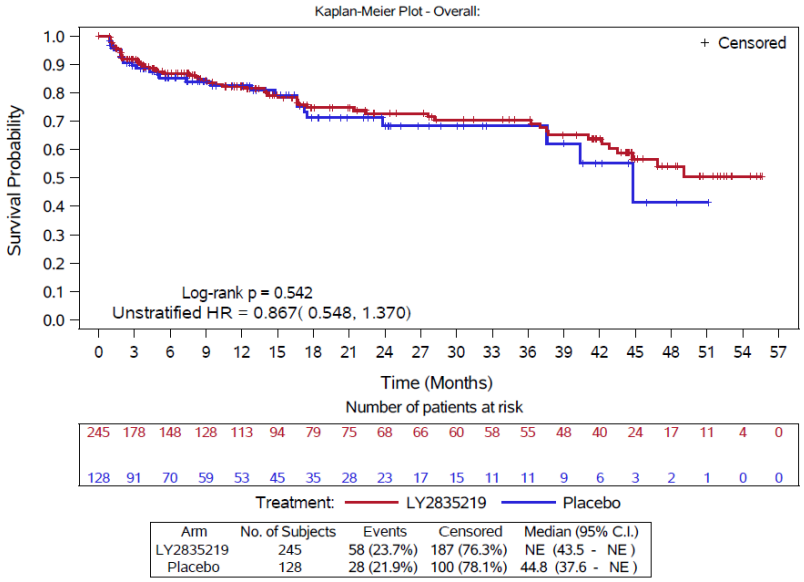


Abbildung 4-71: Kaplan-Meier-Kurve für Körperbild (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

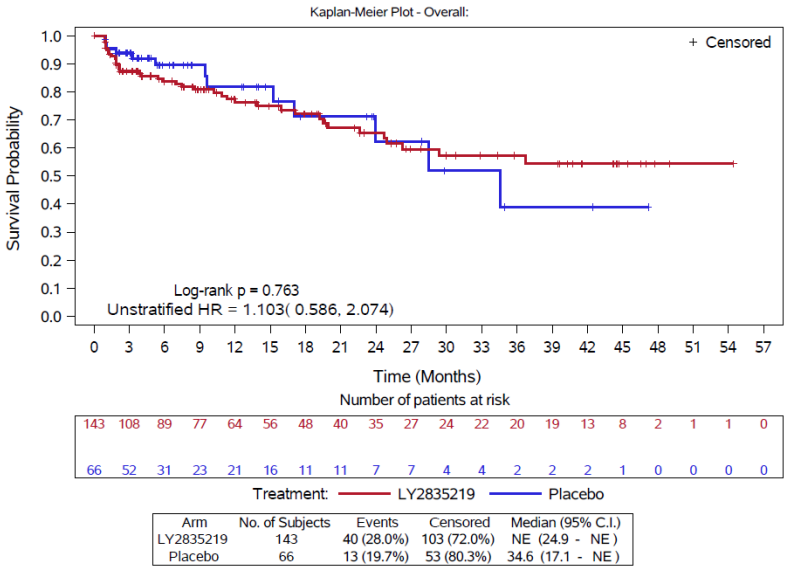


Abbildung 4-72: Kaplan-Meier-Kurve für Körperbild (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

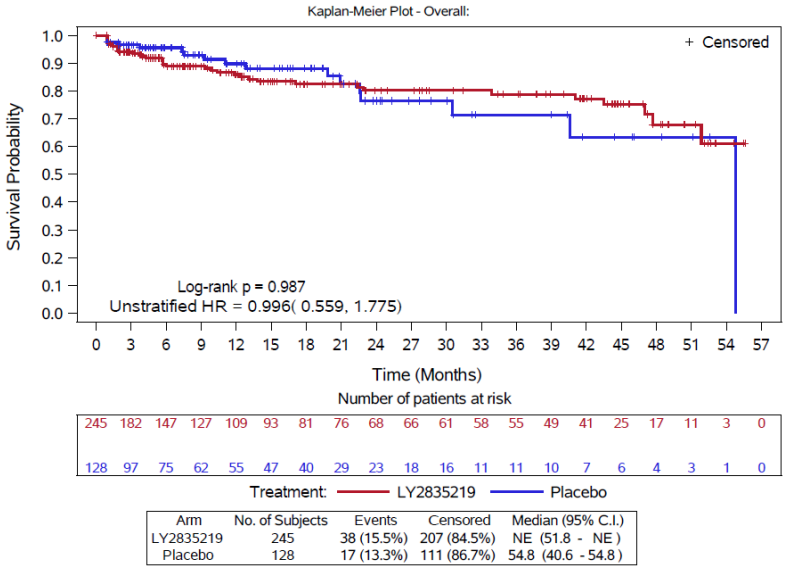


Abbildung 4-73: Kaplan-Meier-Kurve für Zukunftsperspektive (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

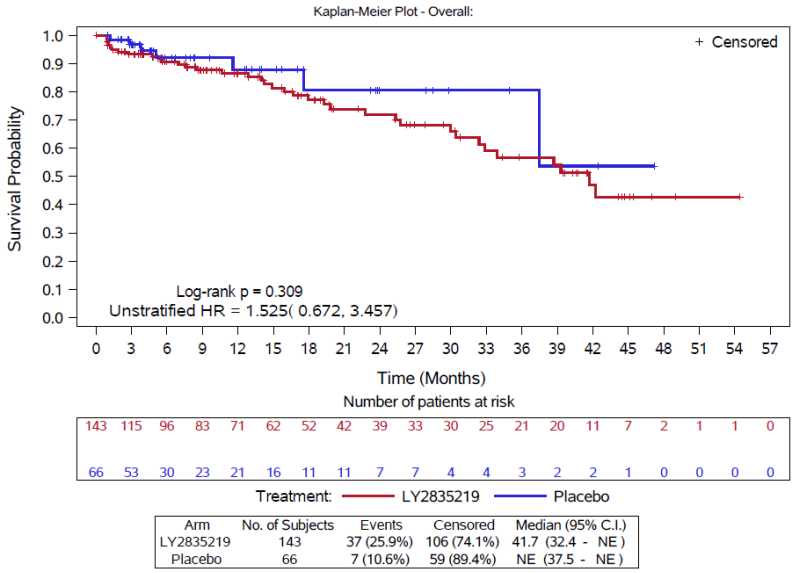


Abbildung 4-74: Kaplan-Meier-Kurve für Zukunftsperspektive (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

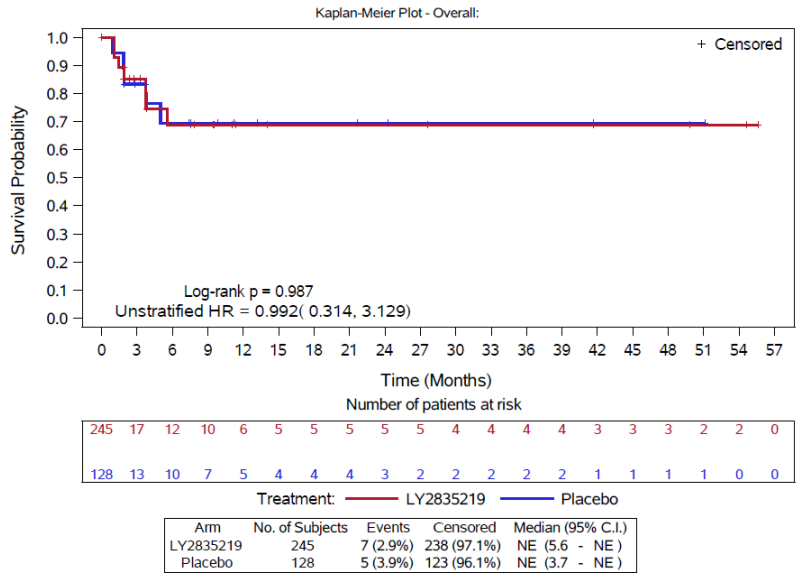


Abbildung 4-75: Kaplan-Meier-Kurve für Freude an Sex (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

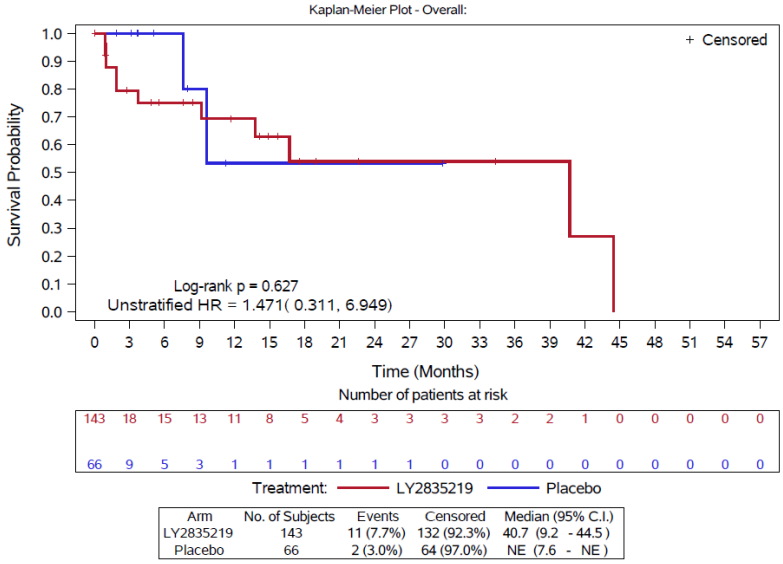


Abbildung 4-76: Kaplan-Meier-Kurve für Freude an Sex (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

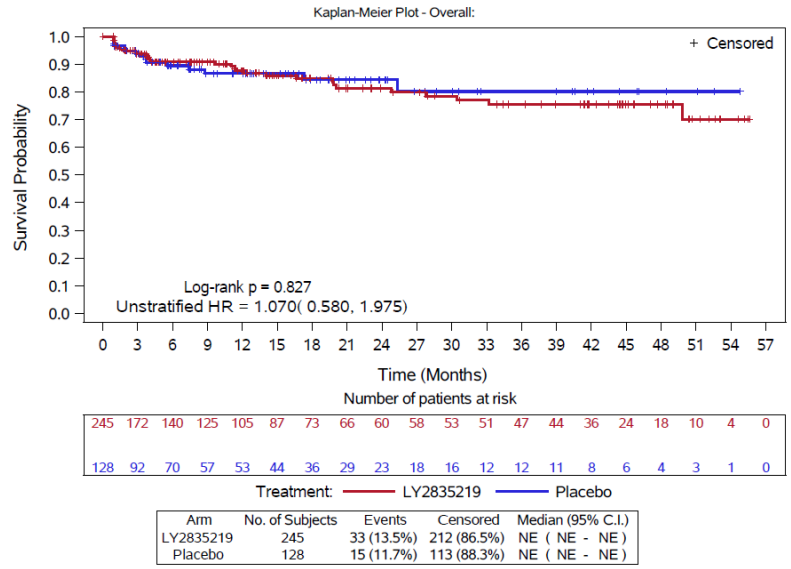


Abbildung 4-77: Kaplan-Meier-Kurve für Sexuelle Aktivität (postmenopausale Patientinnen ohne vorangegangene endokrine Therapie, A1)

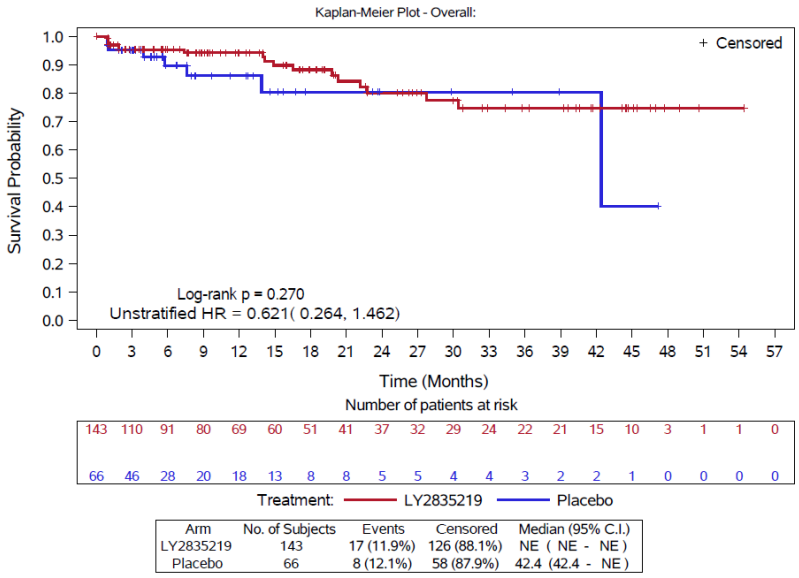
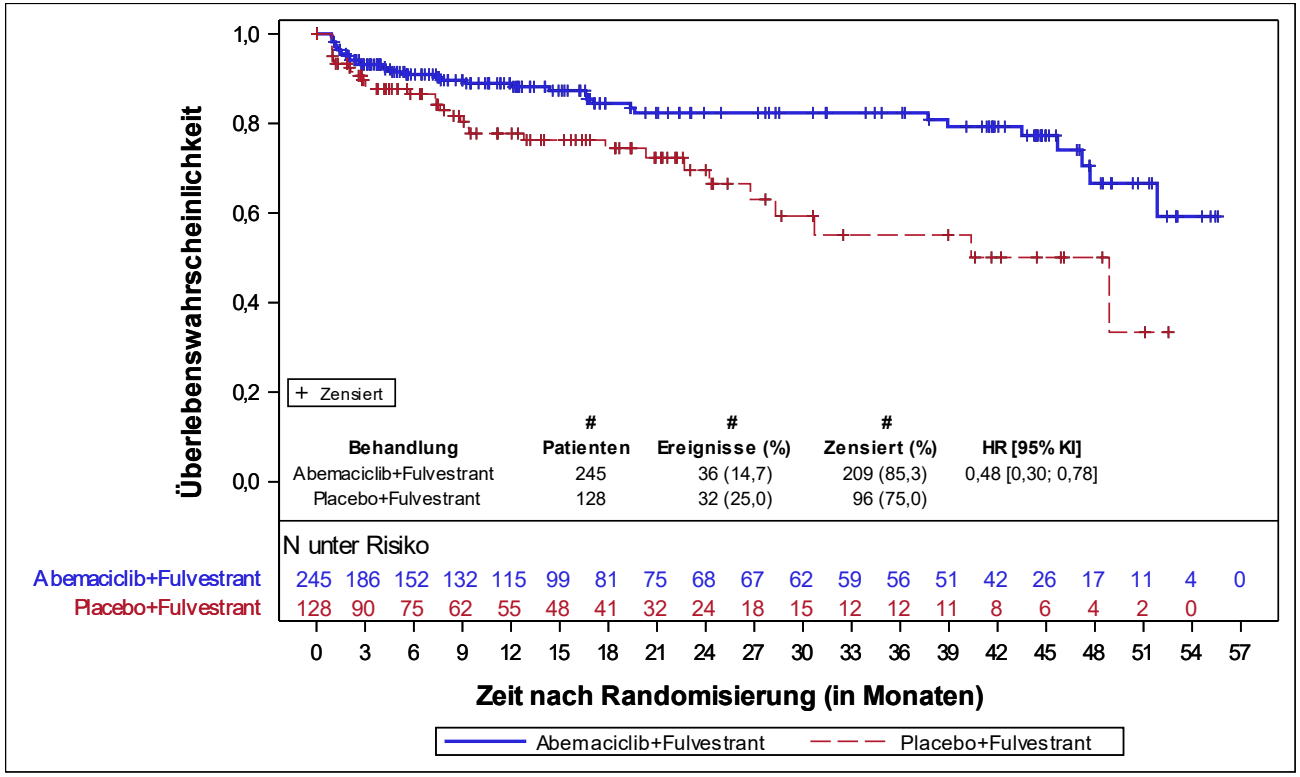


Abbildung 4-78: Kaplan-Meier-Kurve für Sexuelle Aktivität (postmenopausale Patientinnen mit vorangegangener endokriner Therapie, B1)

Abbildung 286: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EQ-5D VAS (≥15 Punkte)
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: EQ-5D: European Quality of Life Questionnaire 5 Dimensions; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; VAS: Visuelle Analogskala; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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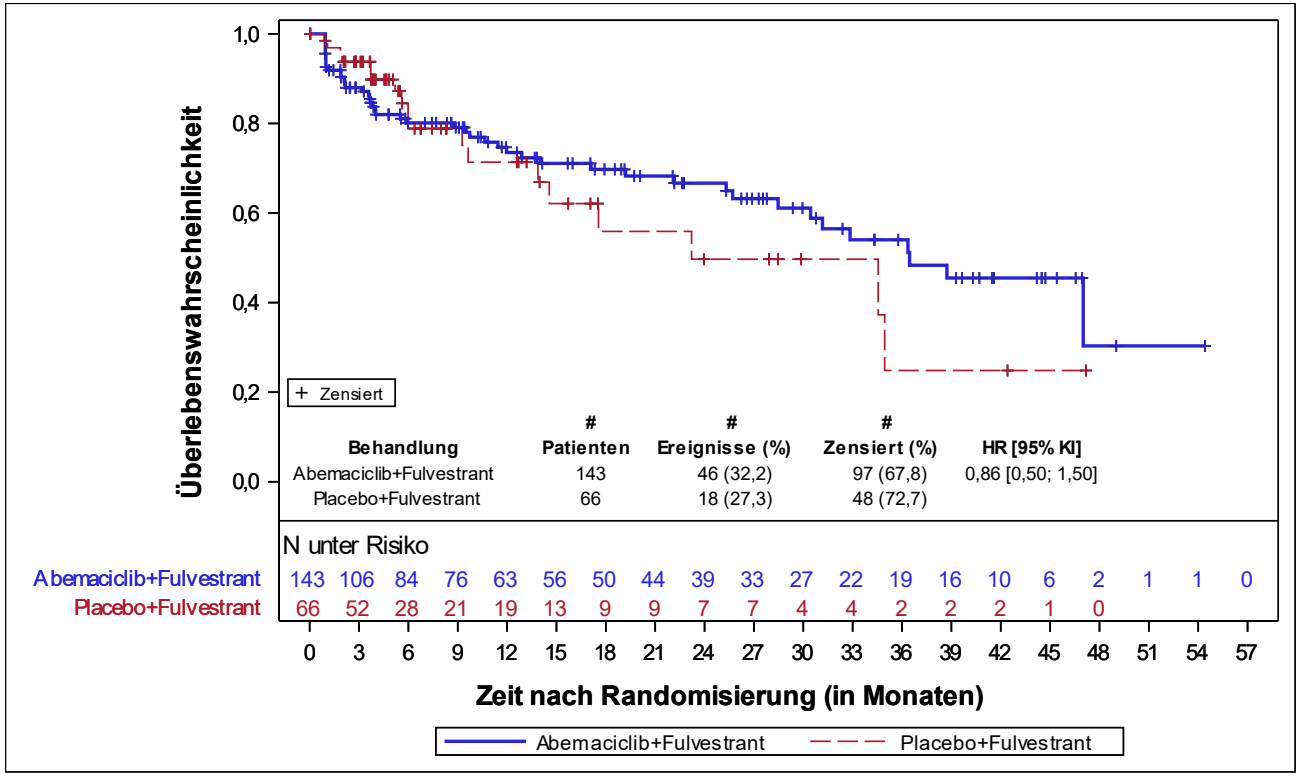
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttevasdp15_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
20JUL2021 / 03:42

Abbildung 287: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EQ-5D VAS (≥15 Punkte)
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: EQ-5D: European Quality of Life Questionnaire 5 Dimensions; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; VAS: Visuelle Analogskala; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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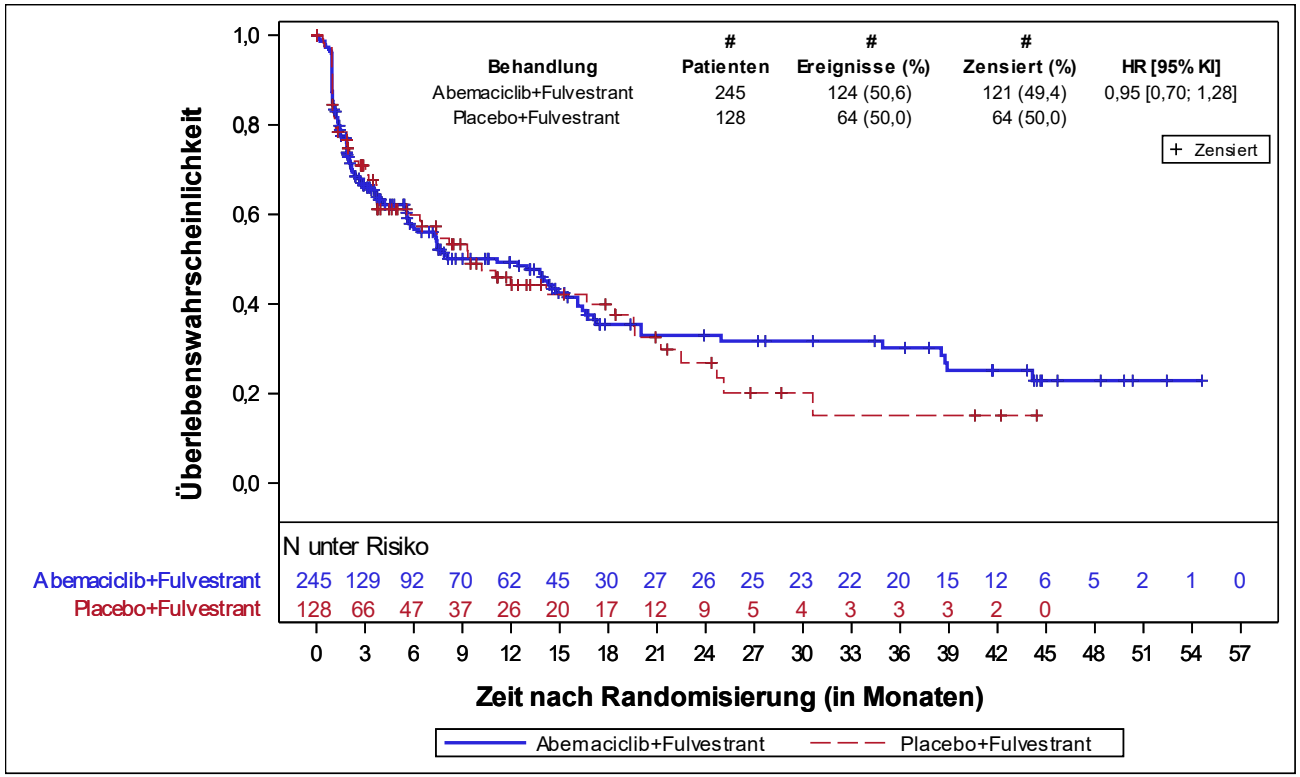
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttevasdp15_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
20JUL2021 / 03:42

Abbildung 288: Kaplan-Meier-Kurven - Stärkster Schmerz in den letzten 24 Stunden - Anstieg des Scores um ≥2 Punkte gegenüber der Baseline oder ein Anstieg des Schmerzmittelgebrauchs um mindestens eine Größenordnung
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Brief Pain Inventory; N: Anzahl der Patienten; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_eff_tte.sas
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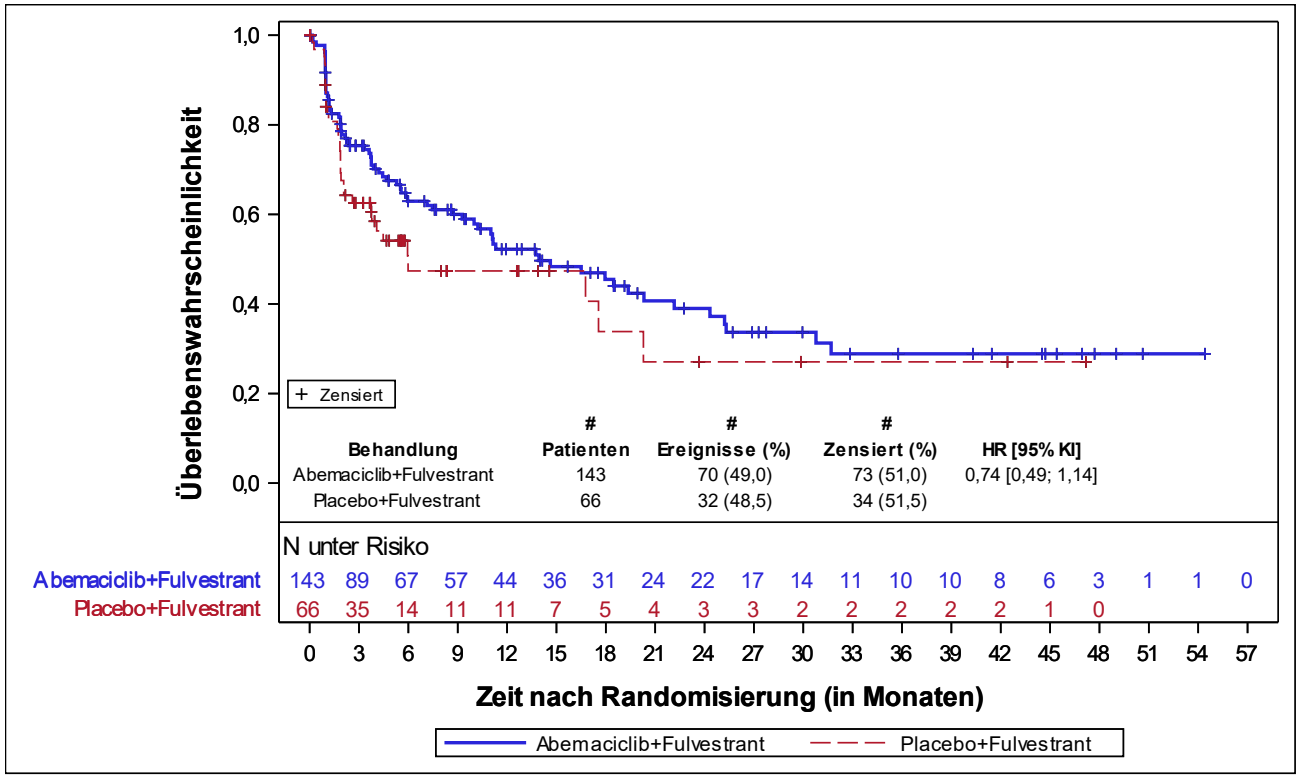
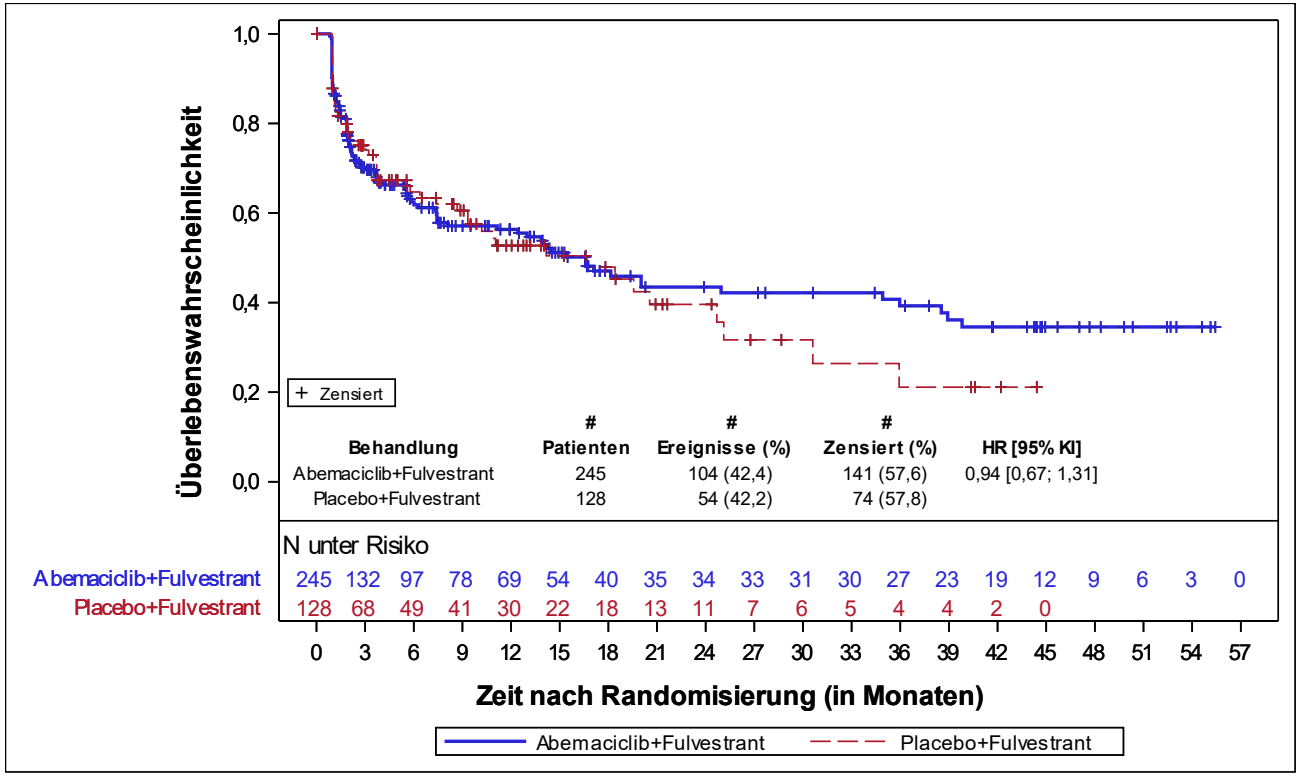
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
20JUL2021 / 03:42

Abbildung 289: Kaplan-Meier-Kurven - Stärkster Schmerz in den letzten 24 Stunden - Anstieg des Scores um ≥2 Punkte gegenüber der Baseline oder ein Anstieg des Schmerzmittelgebrauchs um mindestens eine Größenordnung
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Brief Pain Inventory; N: Anzahl der Patienten; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_eff_tte.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttwpadc_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
20JUL2021 / 03:42

Abbildung 290: Kaplan-Meier-Kurven - Stärkster Schmerz in den letzten 24 Stunden - Anstieg des Scores um ≥2 Punkte gegenüber der Baseline Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Brief Pain Inventory; N: Anzahl der Patienten; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_eff_tte.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttwpa2dc_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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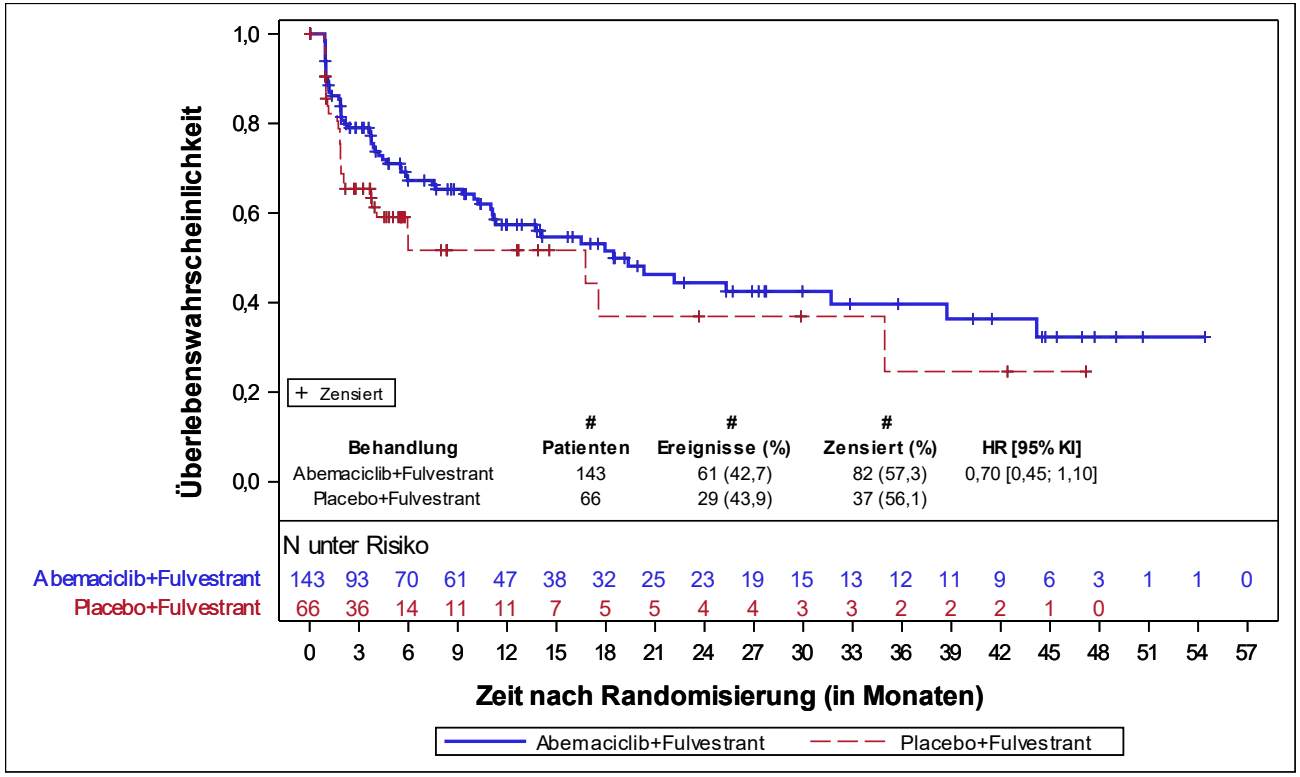
Abbildung 291: Kaplan-Meier-Kurven - Stärkster Schmerz in den letzten 24 Stunden - Anstieg des Scores um ≥2 Punkte gegenüber der Baseline Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Brief Pain Inventory; N: Anzahl der Patienten; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_eff_tte.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttwpa2dc_popa2.rtf
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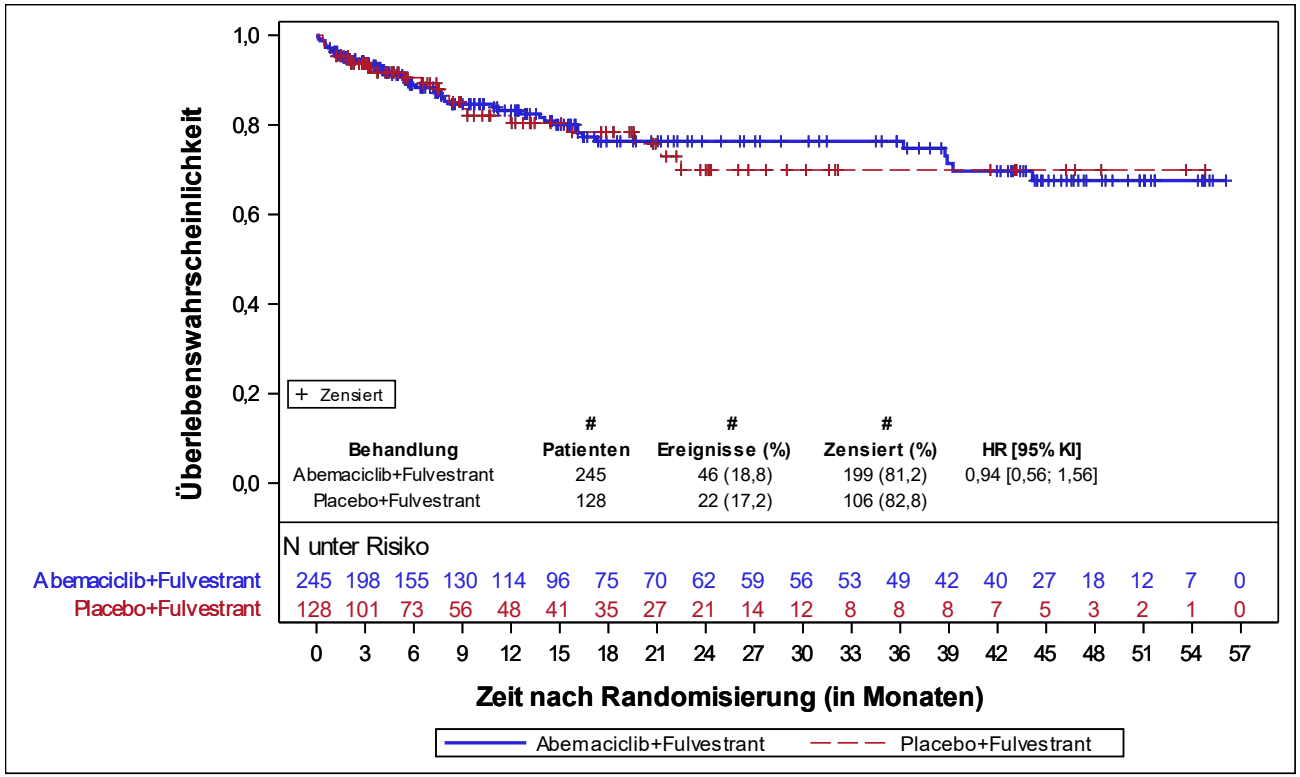
Abbildung 292: Kaplan-Meier-Kurven - Stärkster Schmerz in den letzten 24 Stunden - Anstieg des Schmerzmittelgebrauchs um mindestens eine Größenordnung
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Brief Pain Inventory; N: Anzahl der Patienten; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_eff_tte.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttaddc_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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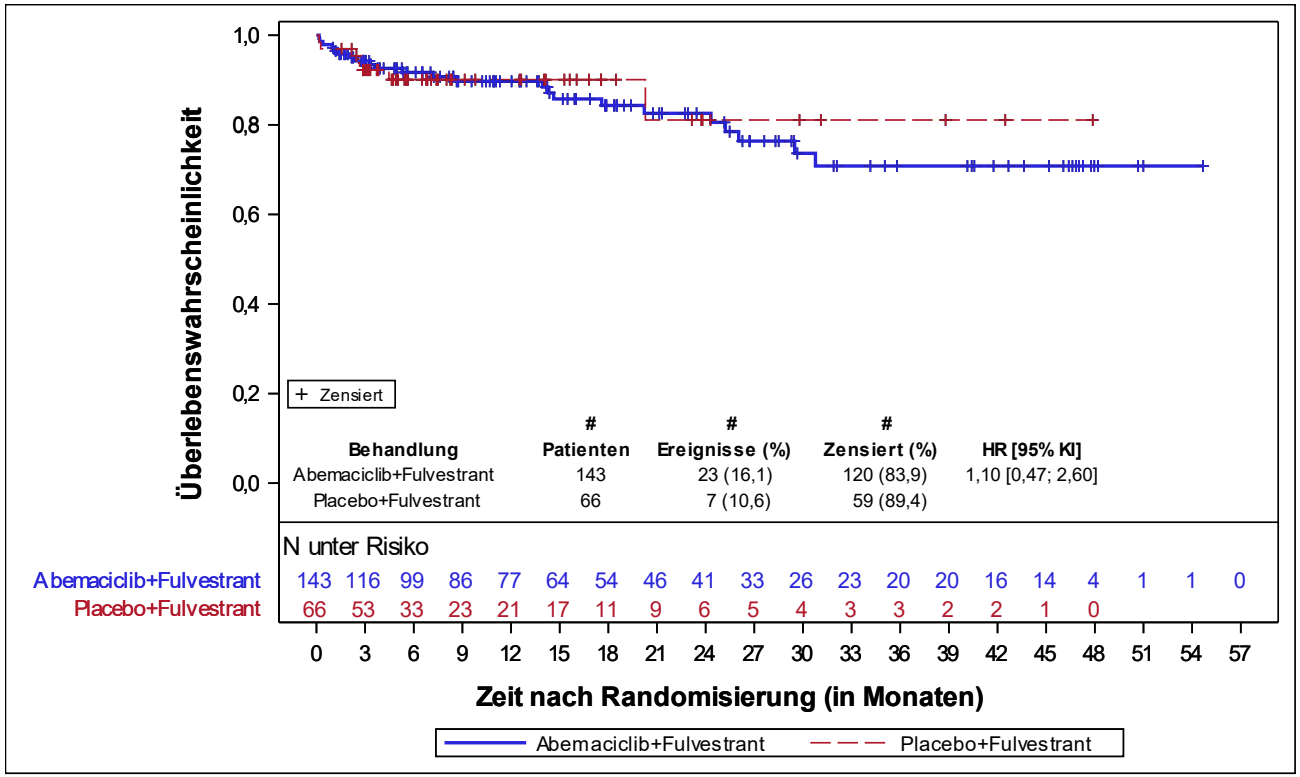
Abbildung 293: Kaplan-Meier-Kurven - Stärkster Schmerz in den letzten 24 Stunden - Anstieg des Schmerzmittelgebrauchs um mindestens eine Größenordnung
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Brief Pain Inventory; N: Anzahl der Patienten; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_eff_tte.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttaddc_popa2.rtf
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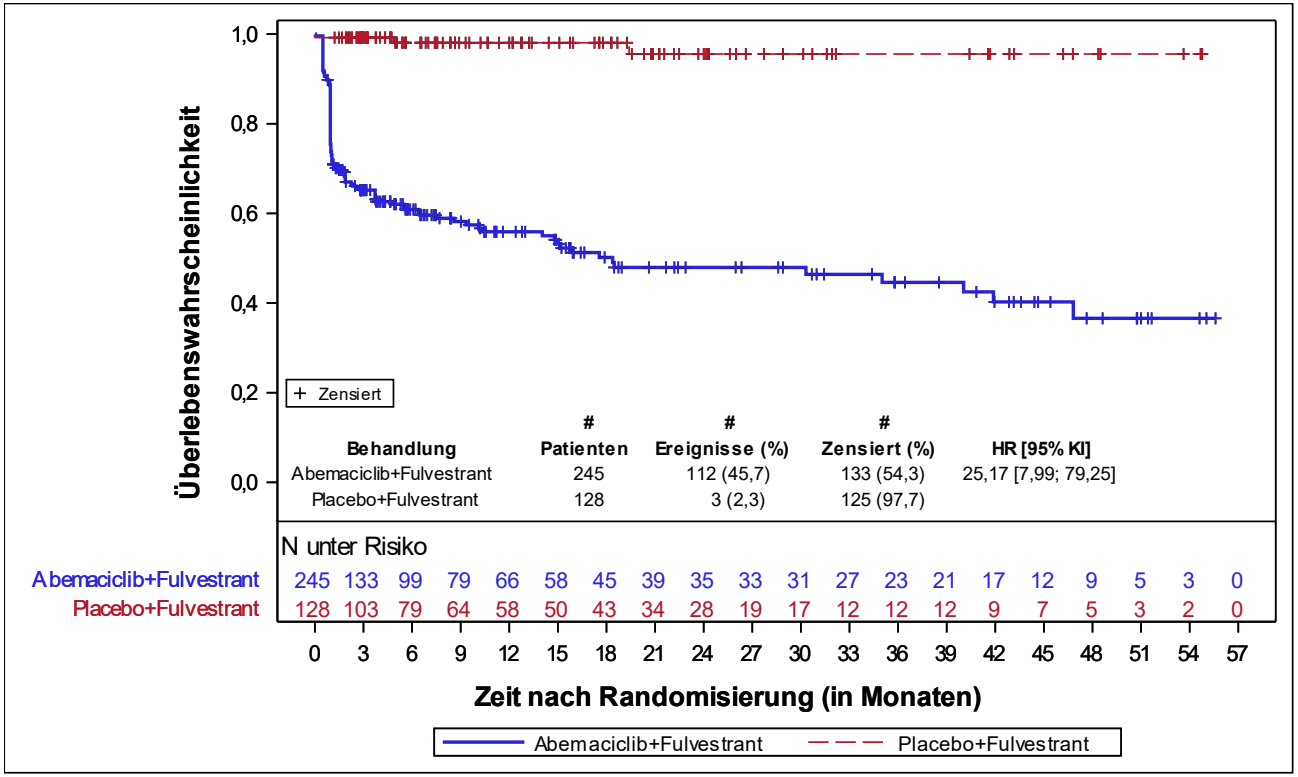
Abbildung 150 (Anhang): Kaplan-Meier-Kurven für UESI (MONARCH-plus)

Abbildung 001: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad)
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttnpaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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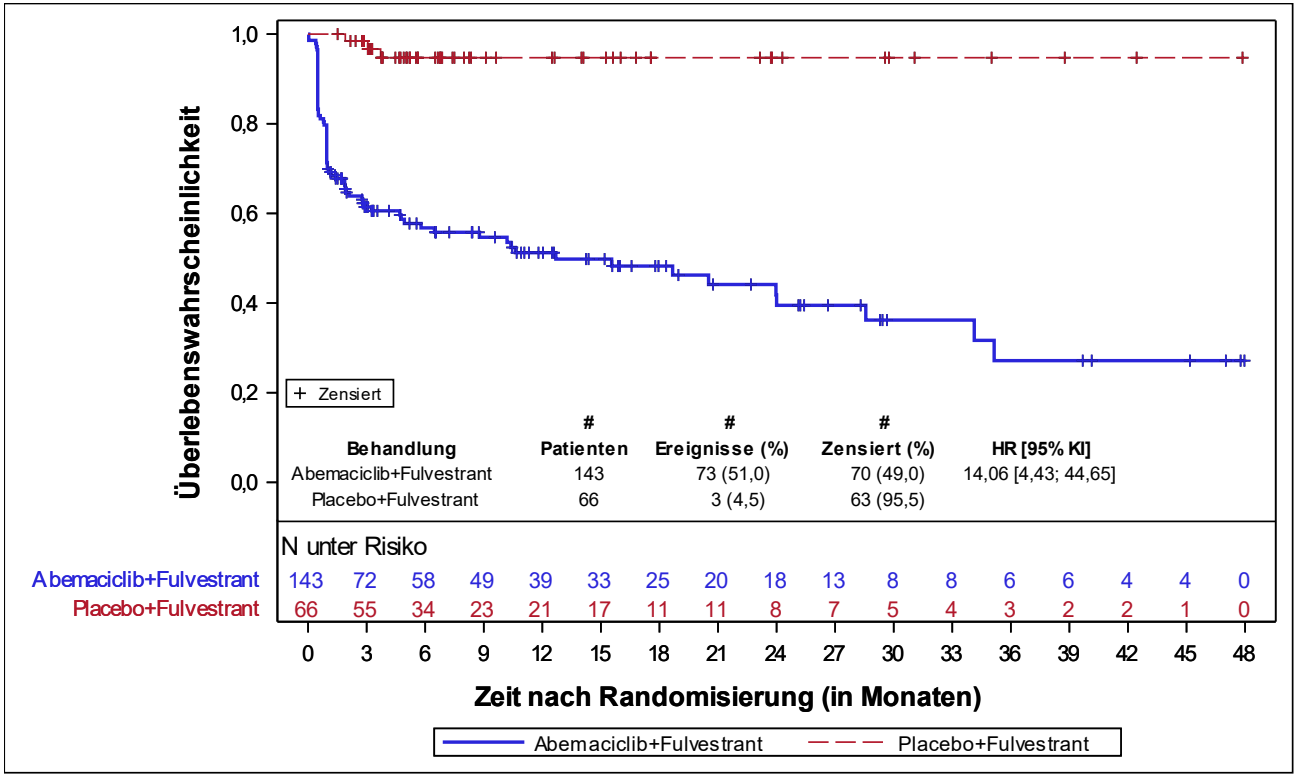
Abbildung 002: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad)
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttnpaesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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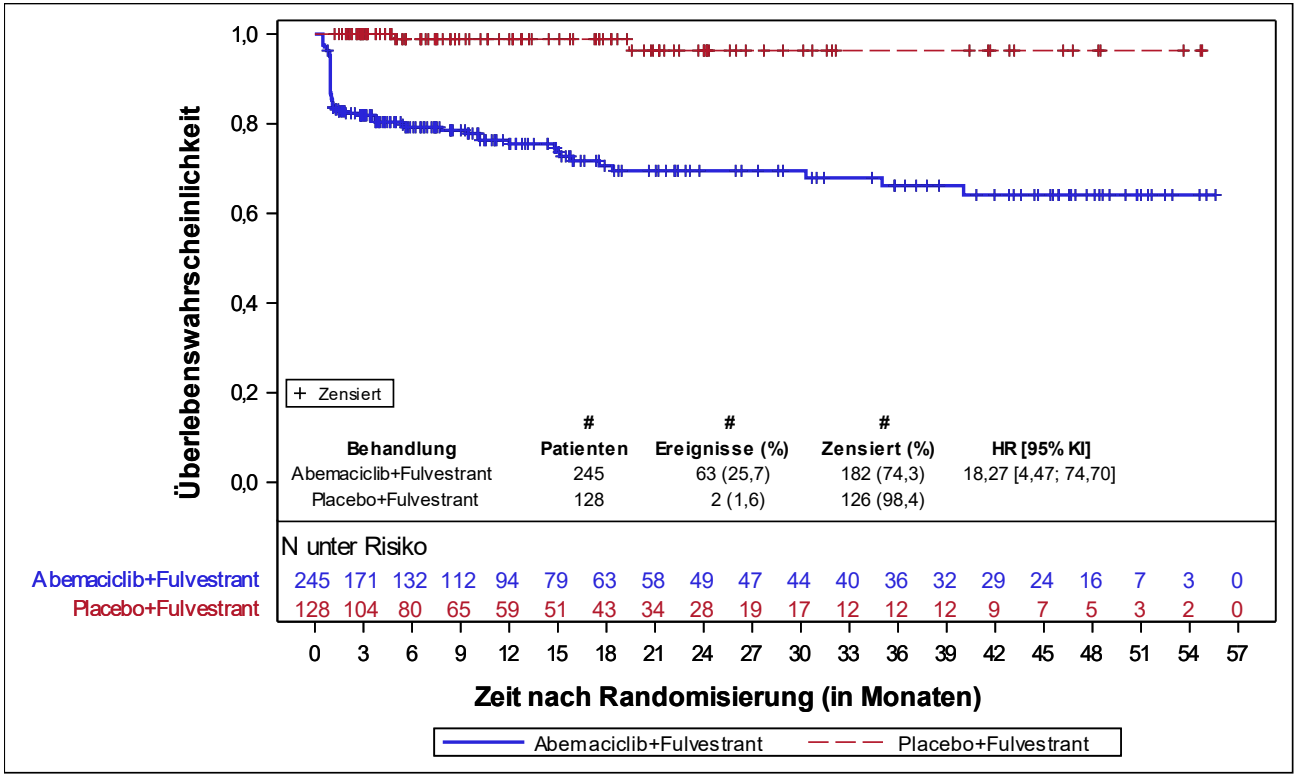
Abbildung 003: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttnp3aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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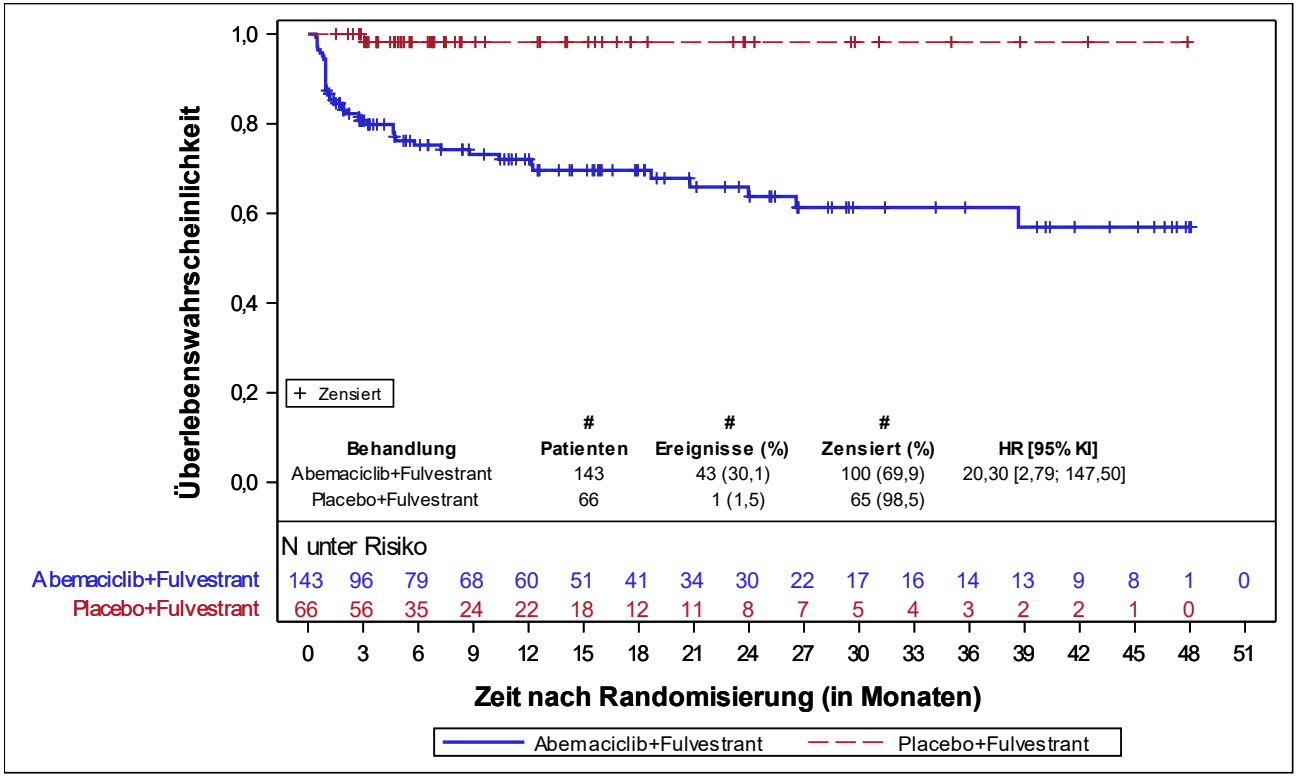
Abbildung 004: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttnp3aesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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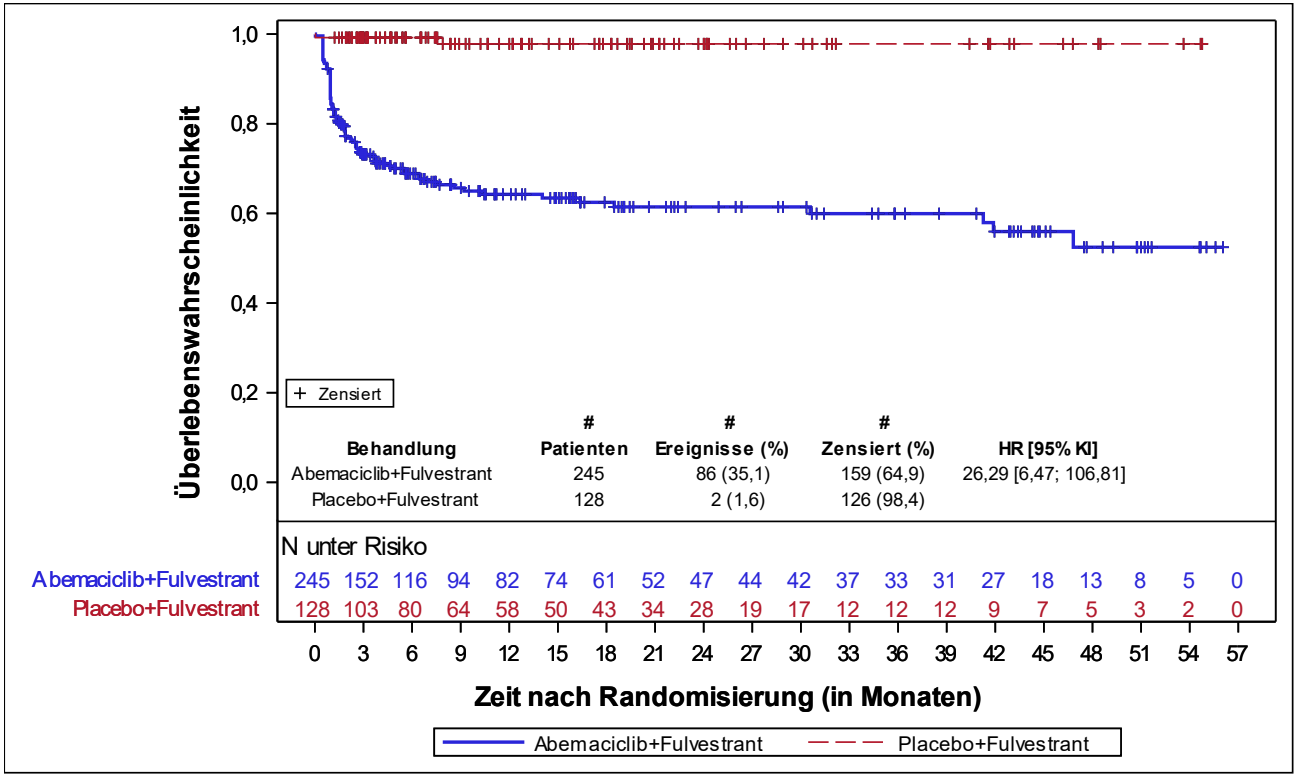
Abbildung 005: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttnp2aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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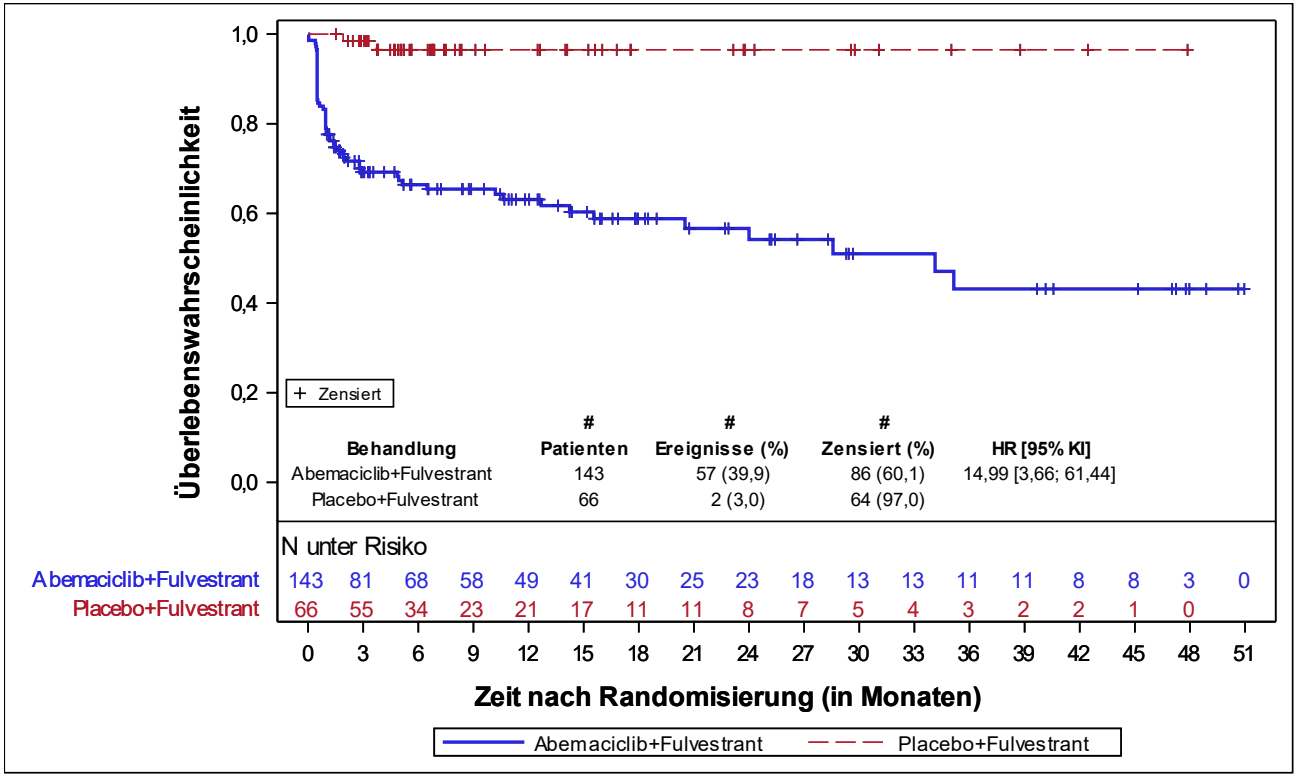
Abbildung 006: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttnp2aesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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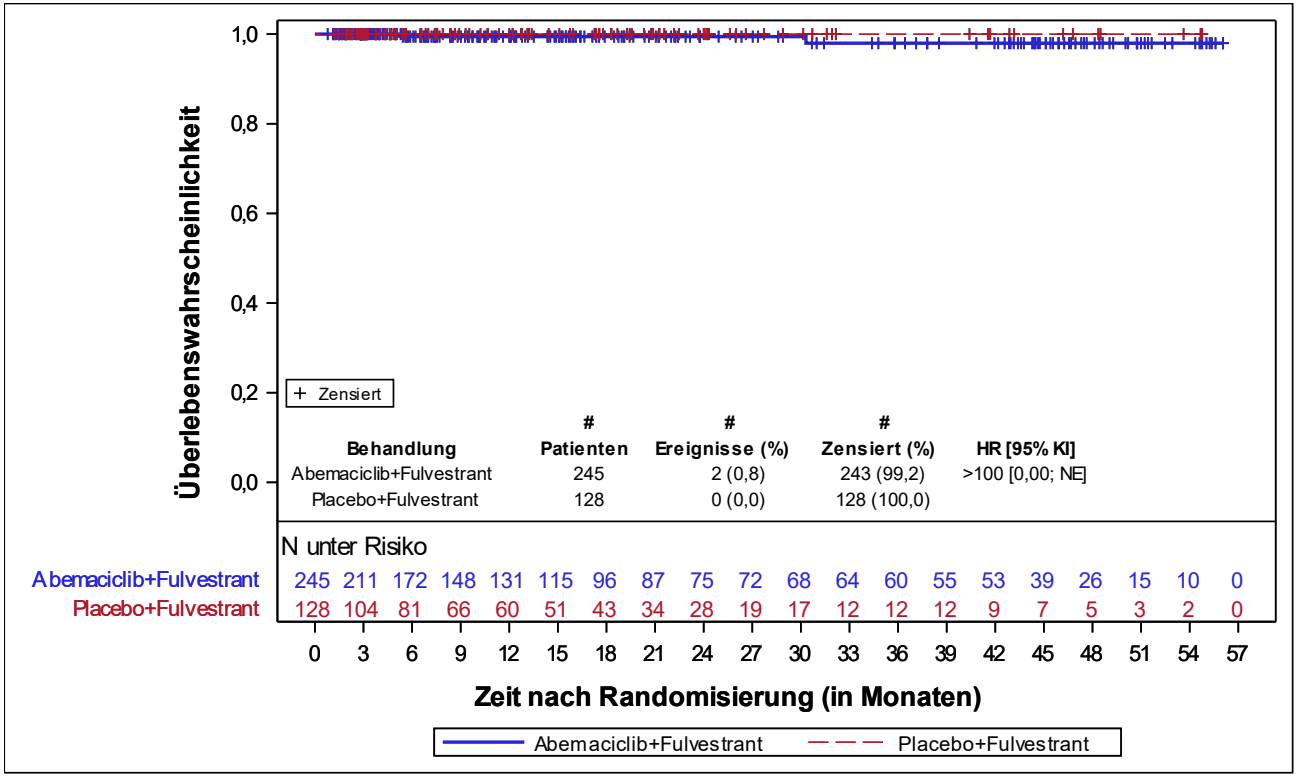
Abbildung 007: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: Neutropenie Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttnpsaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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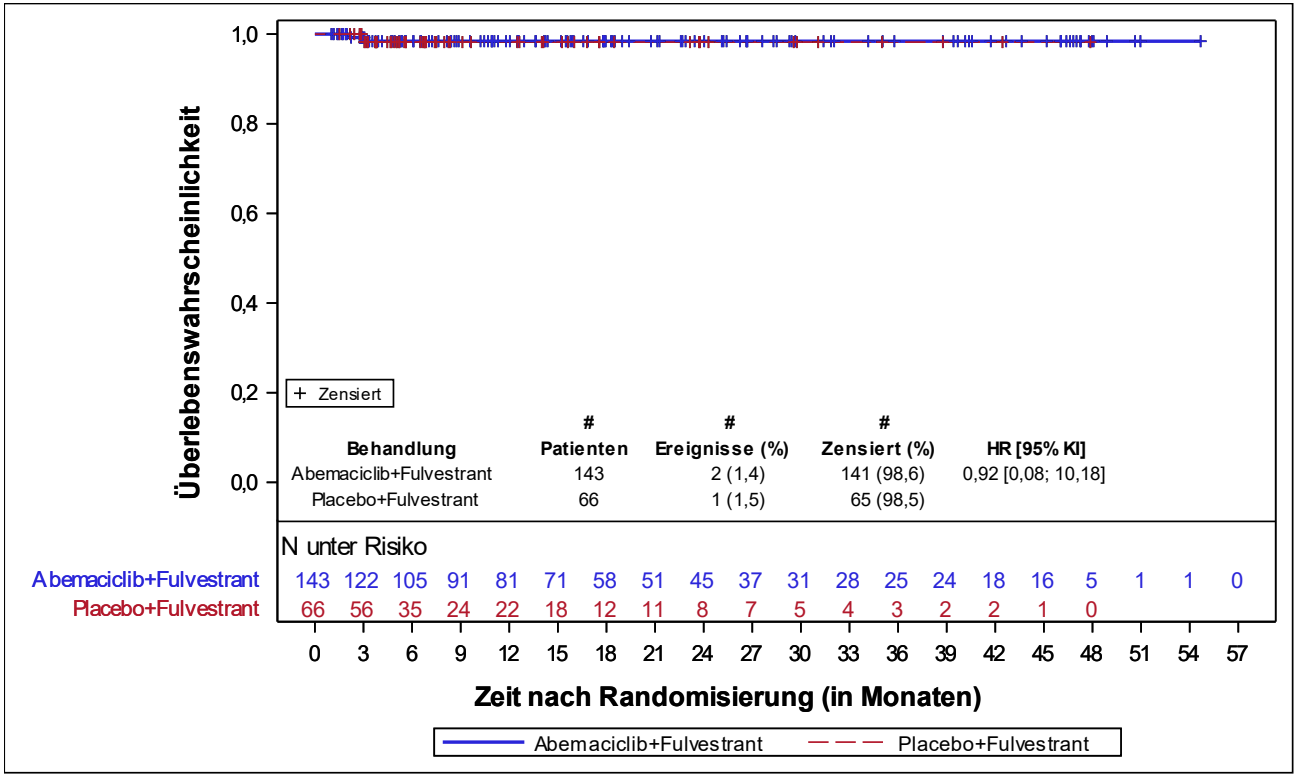
Abbildung 008: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: Neutropenie Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttnpsaesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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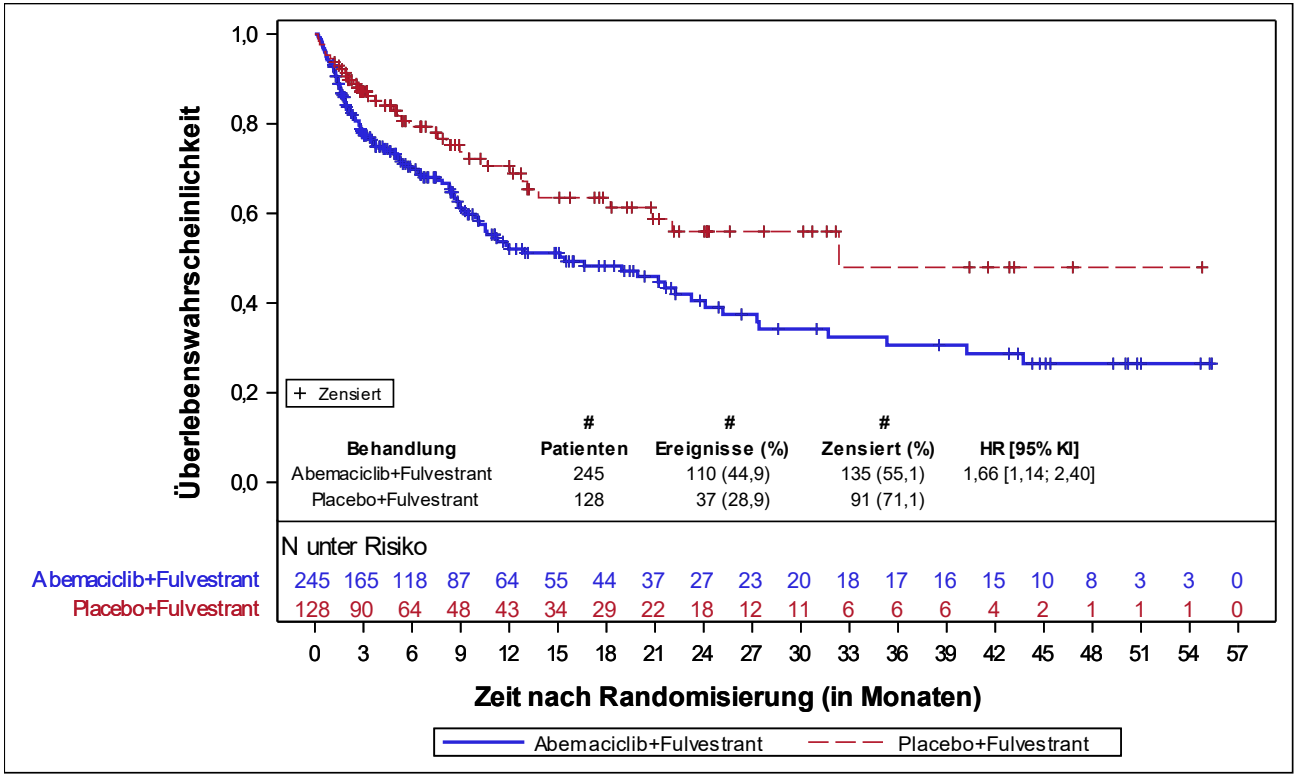
Abbildung 009: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad)
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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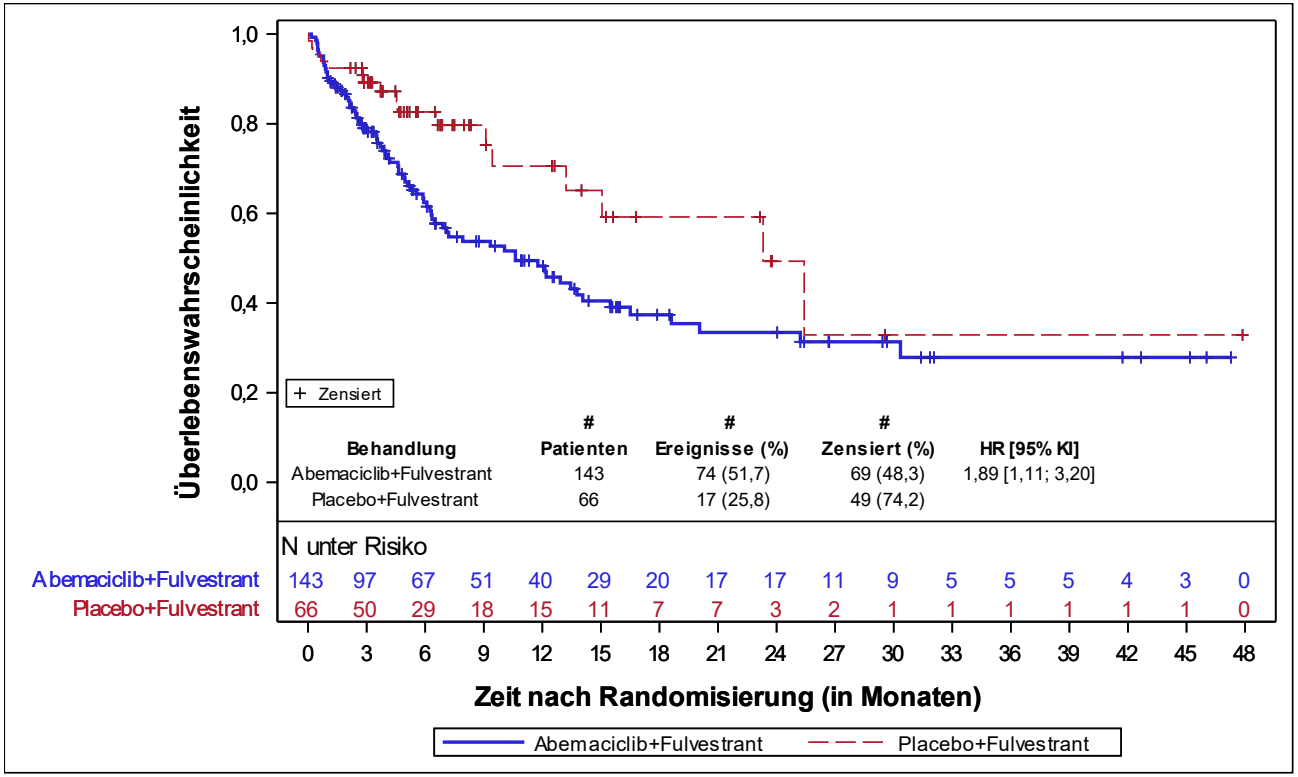
Abbildung 010: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttifaesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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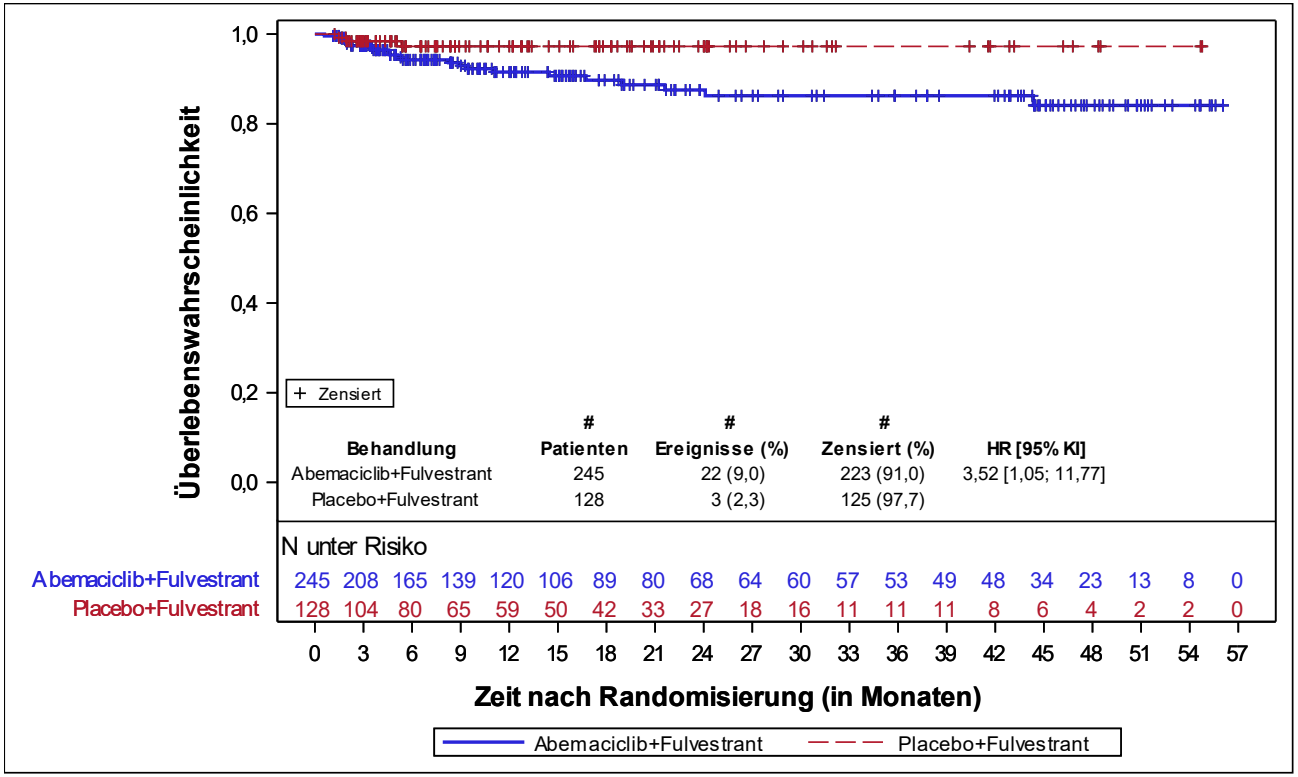
Abbildung 011: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttif3aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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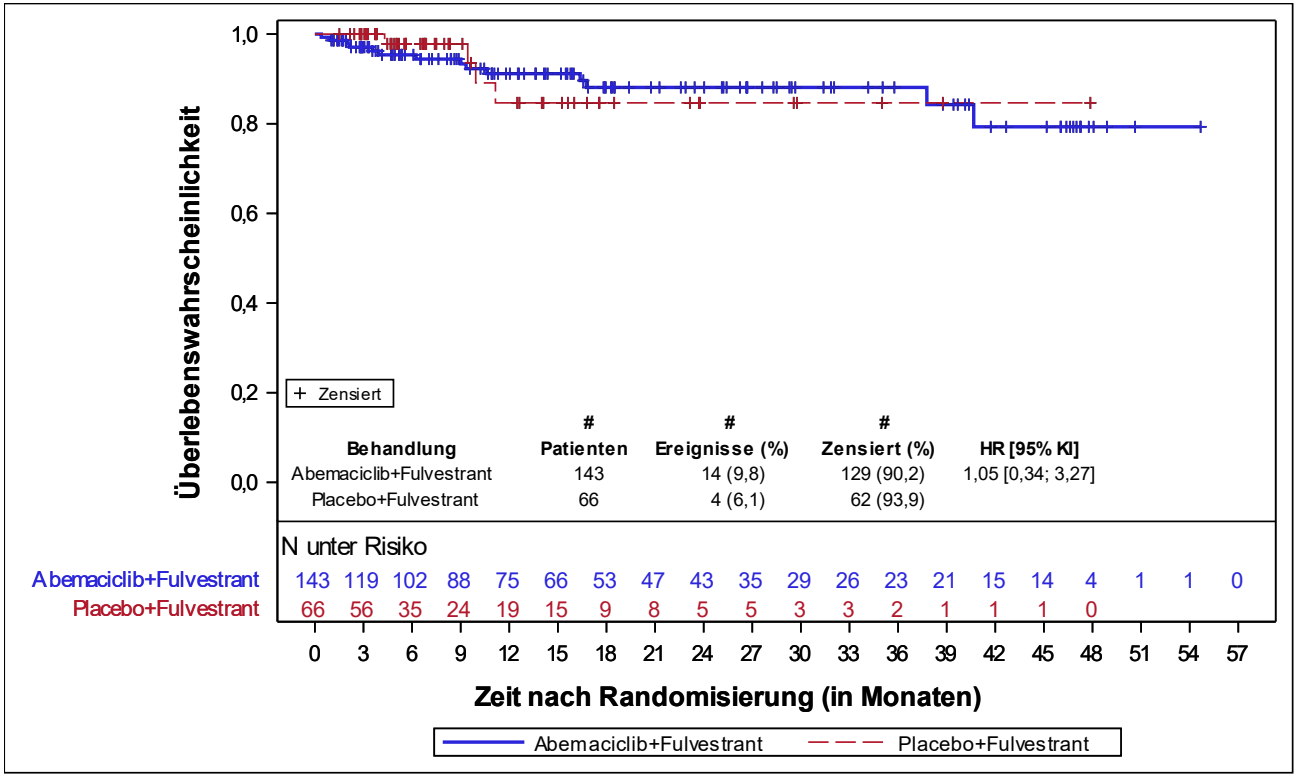
Abbildung 012: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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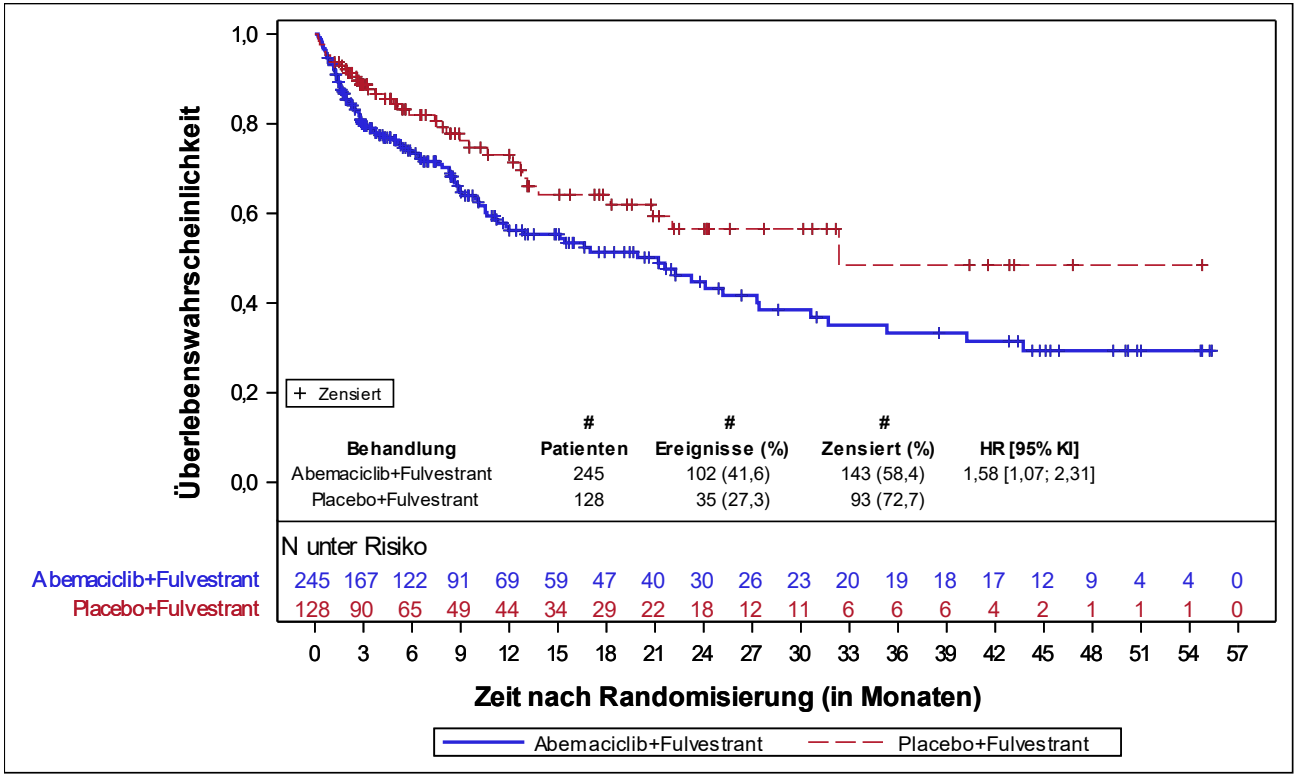
Abbildung 013: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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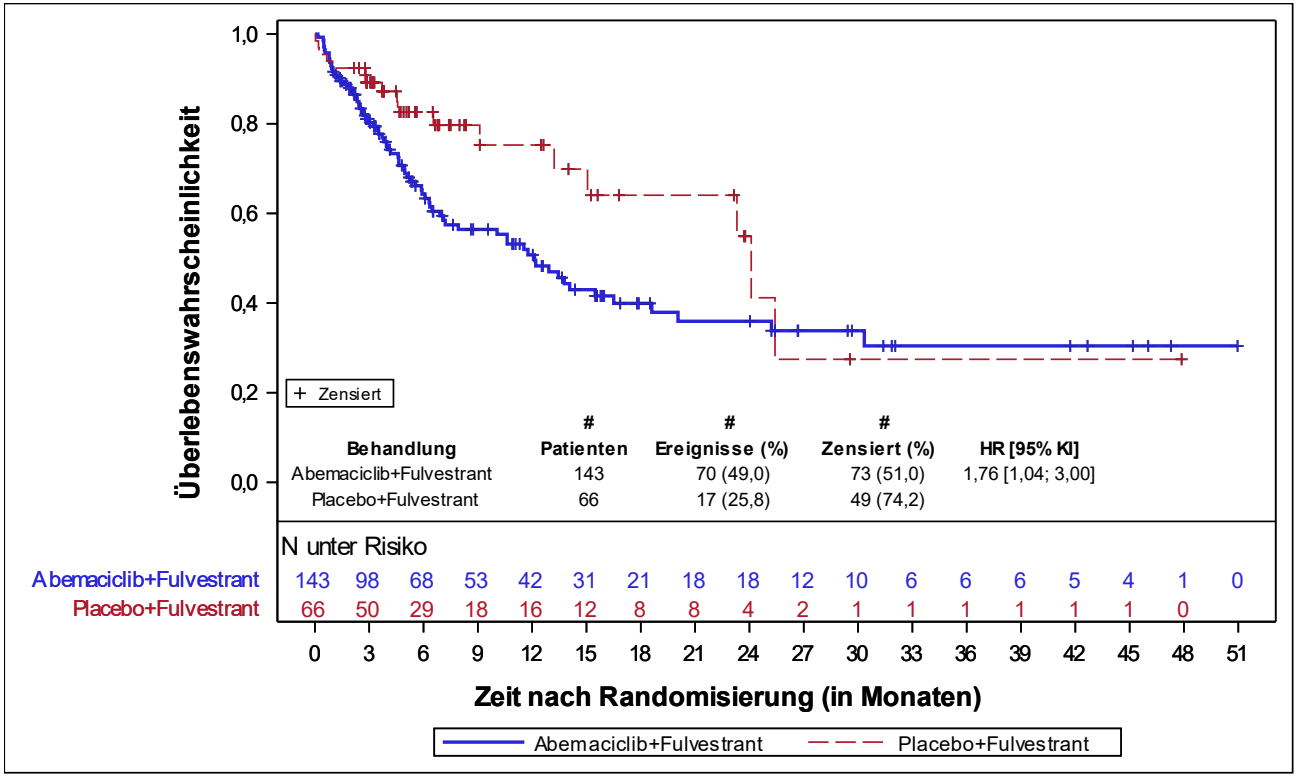
Abbildung 014: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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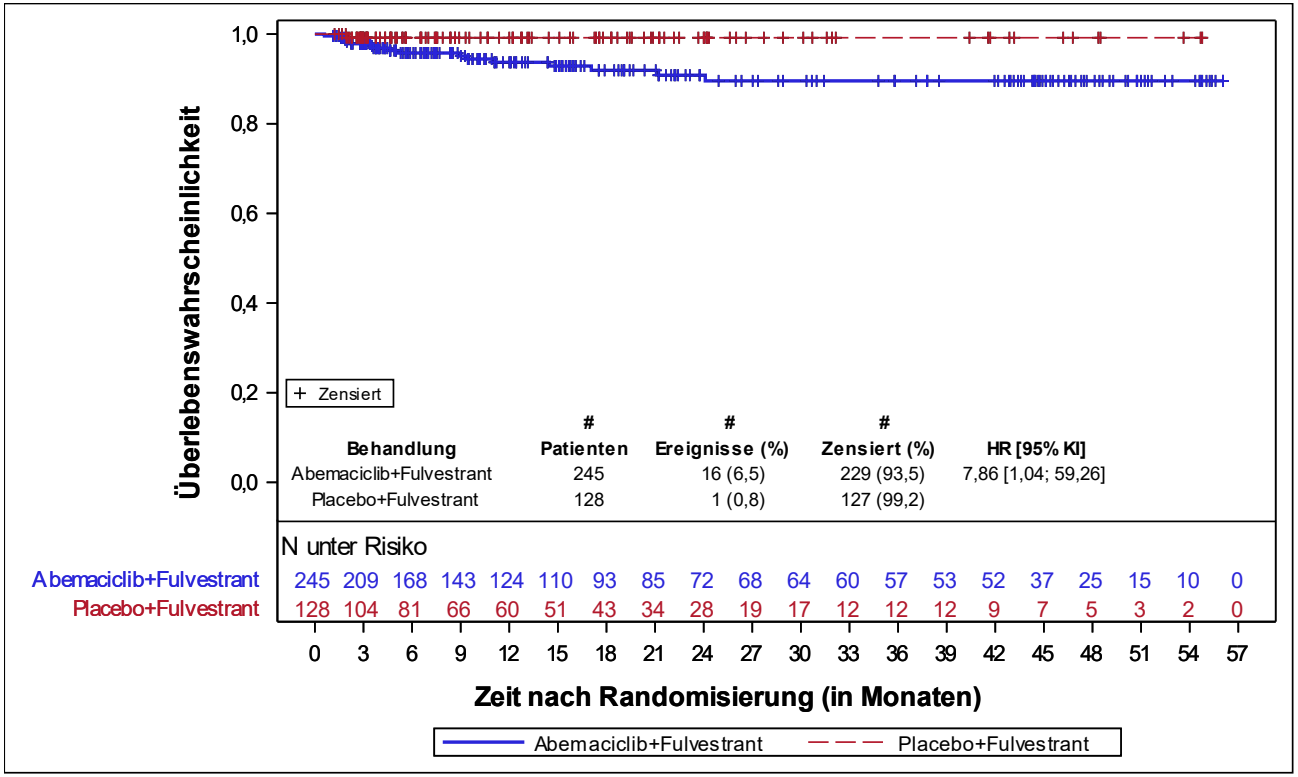
Abbildung 015: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttifsaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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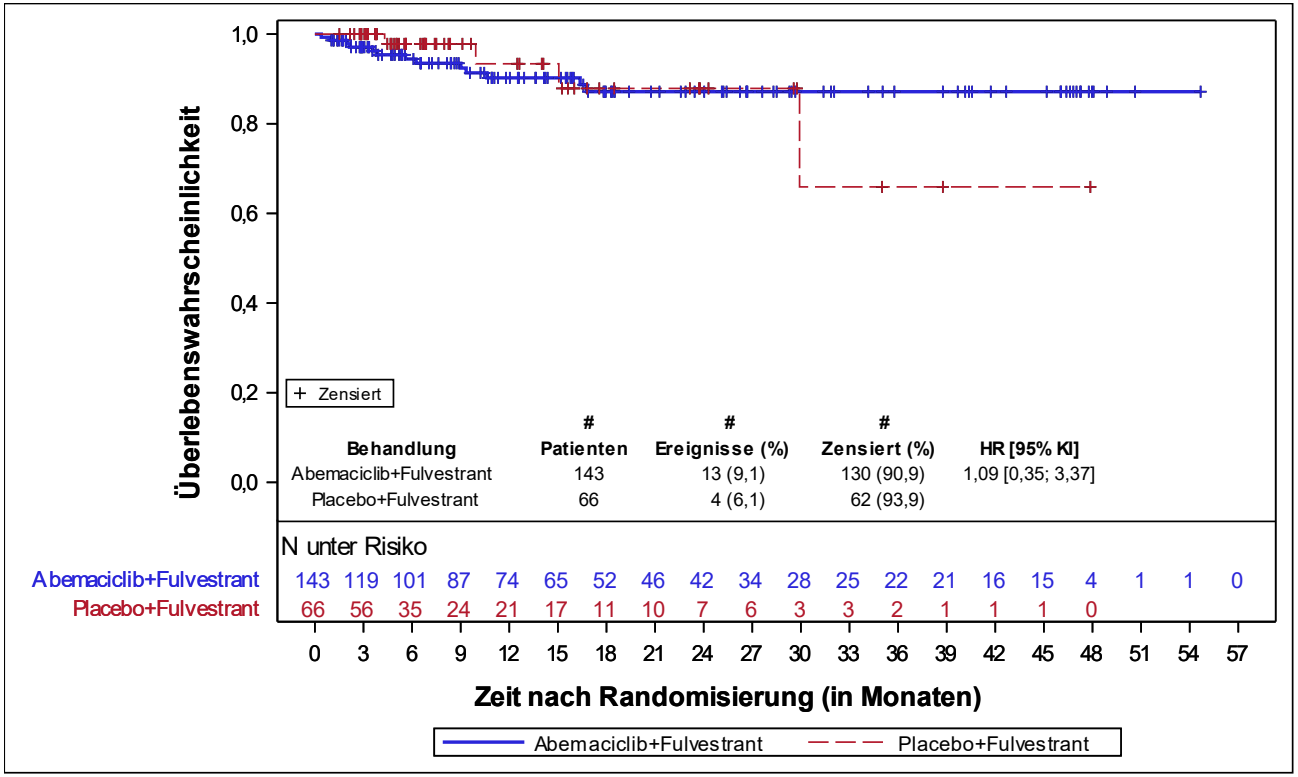
Abbildung 016: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttifsaesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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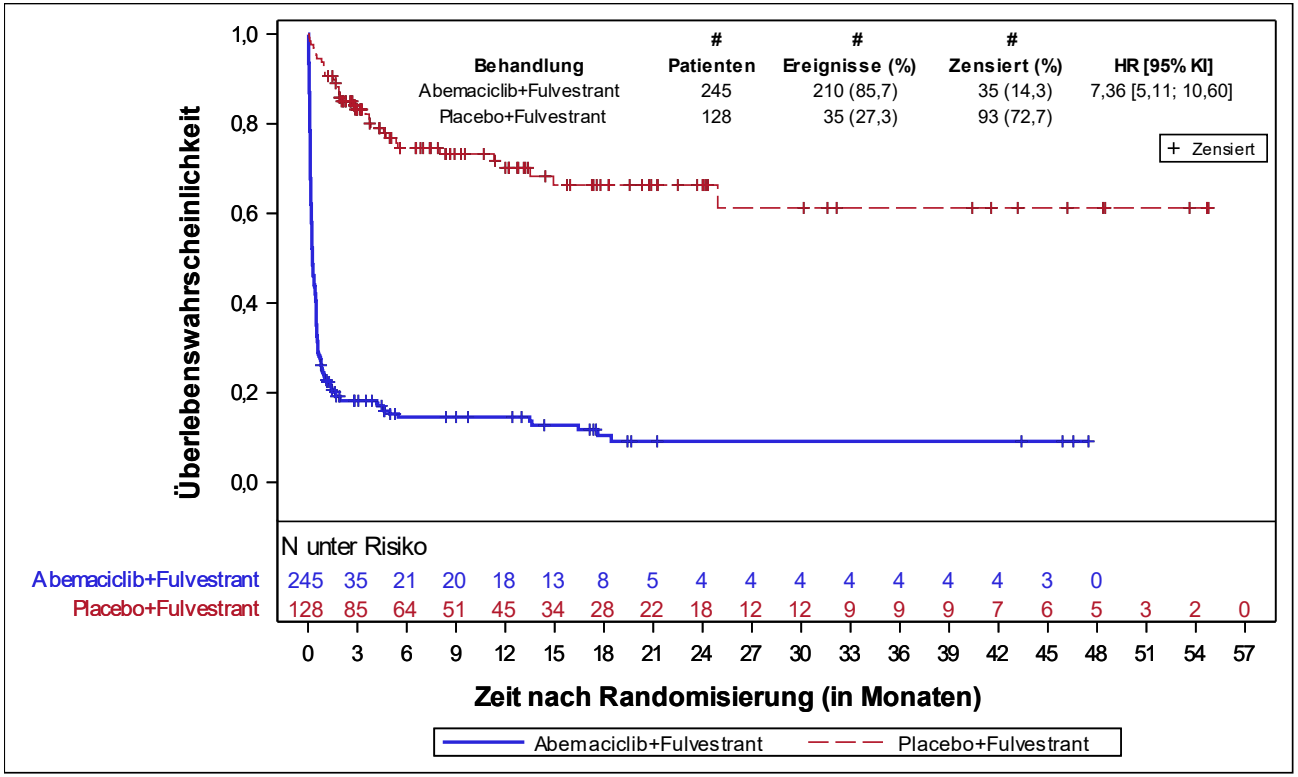
Abbildung 017: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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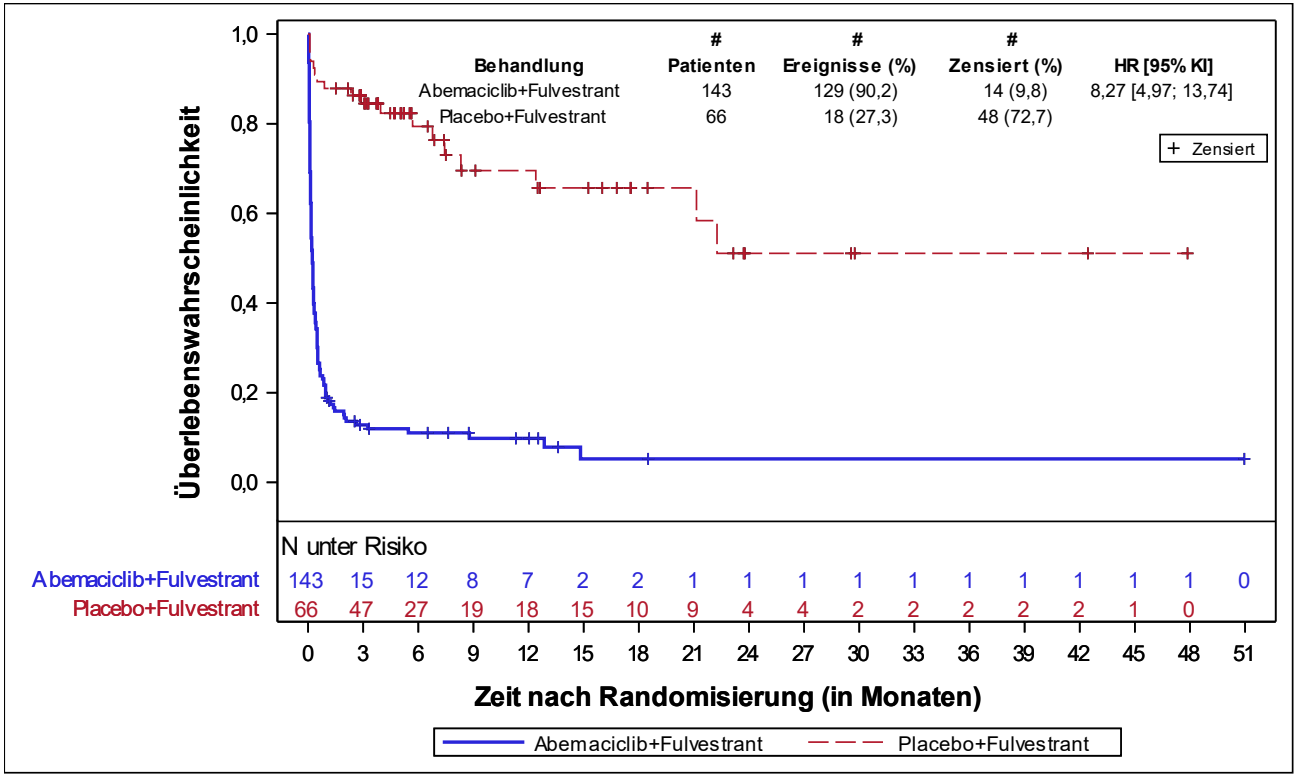
Abbildung 018: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad)
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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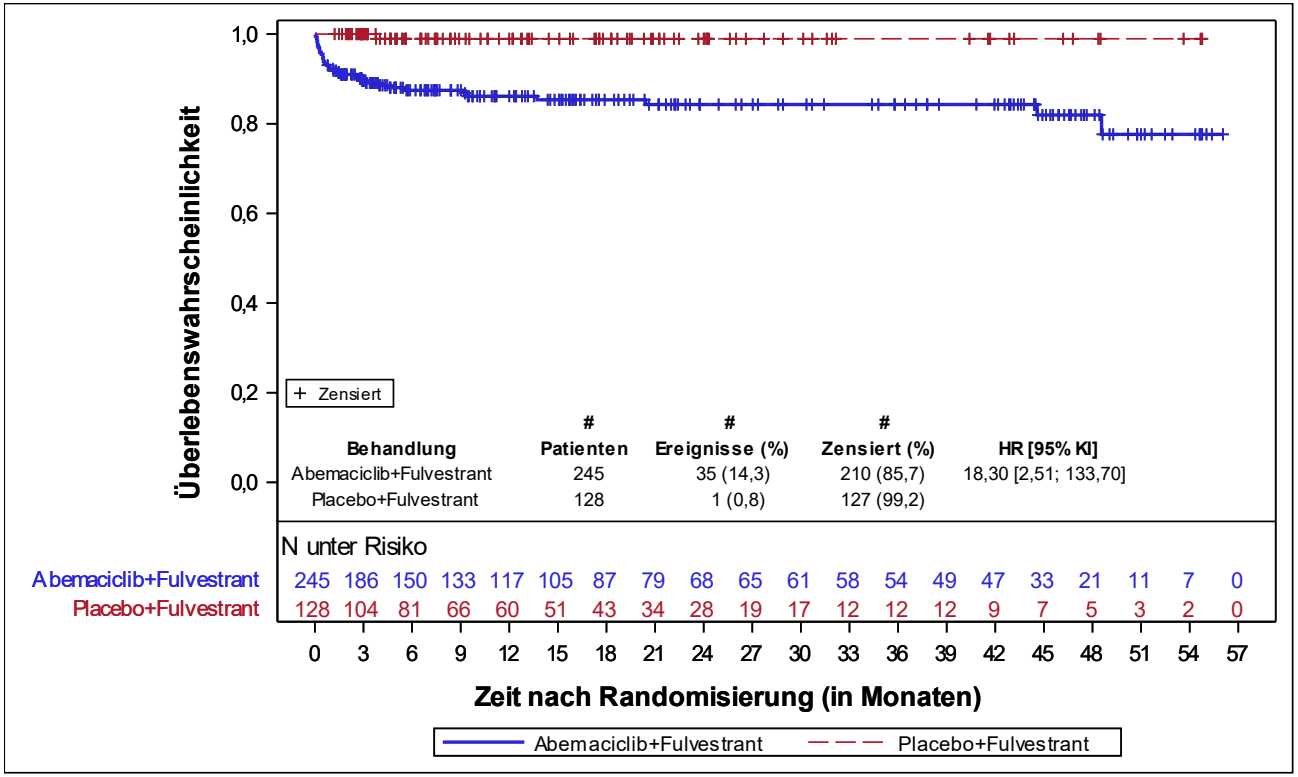
Abbildung 019: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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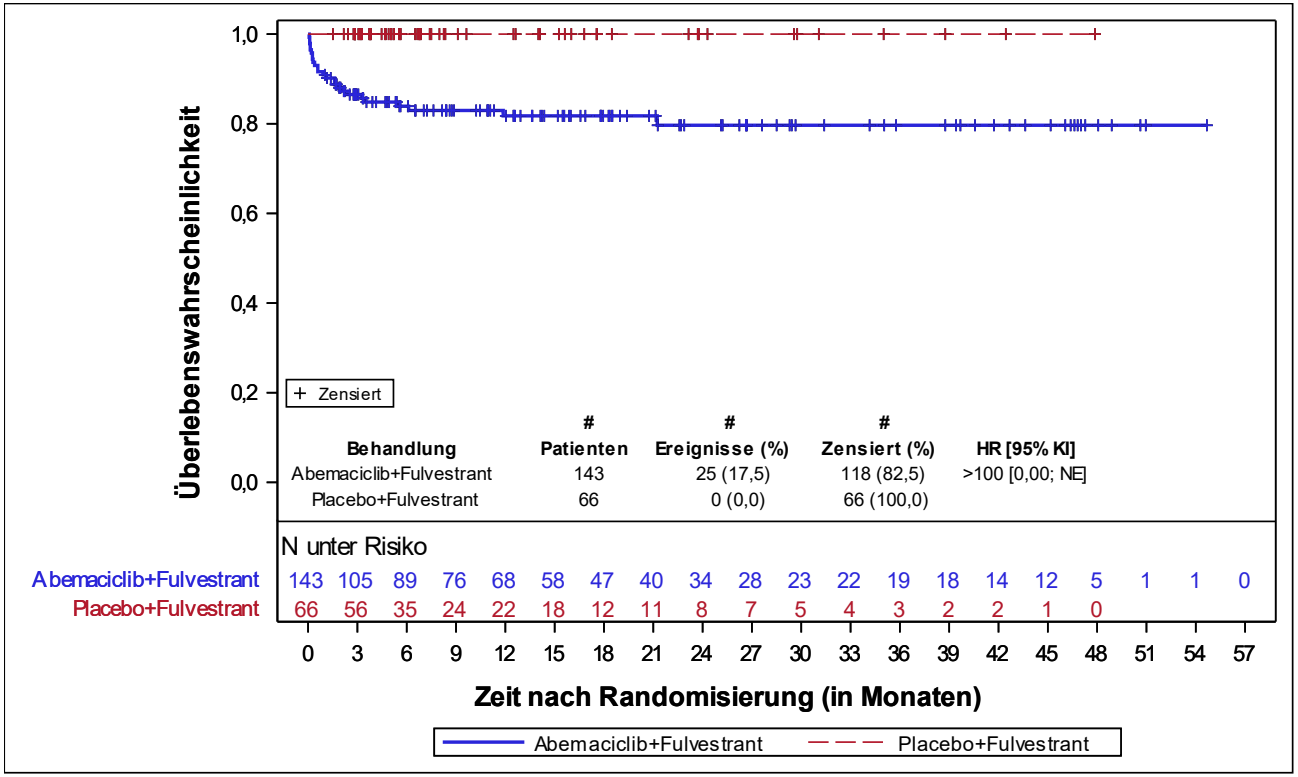
Abbildung 020: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttdi3aesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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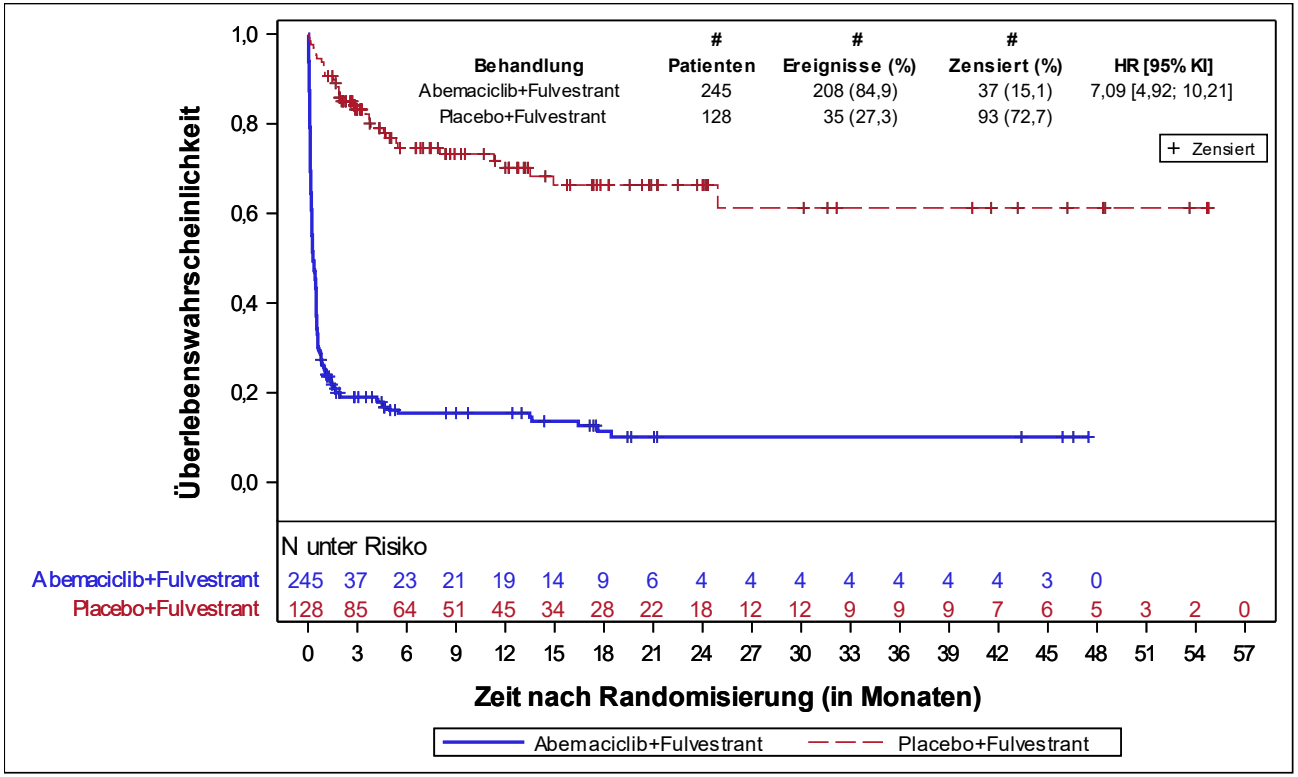
Abbildung 021: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttdi2aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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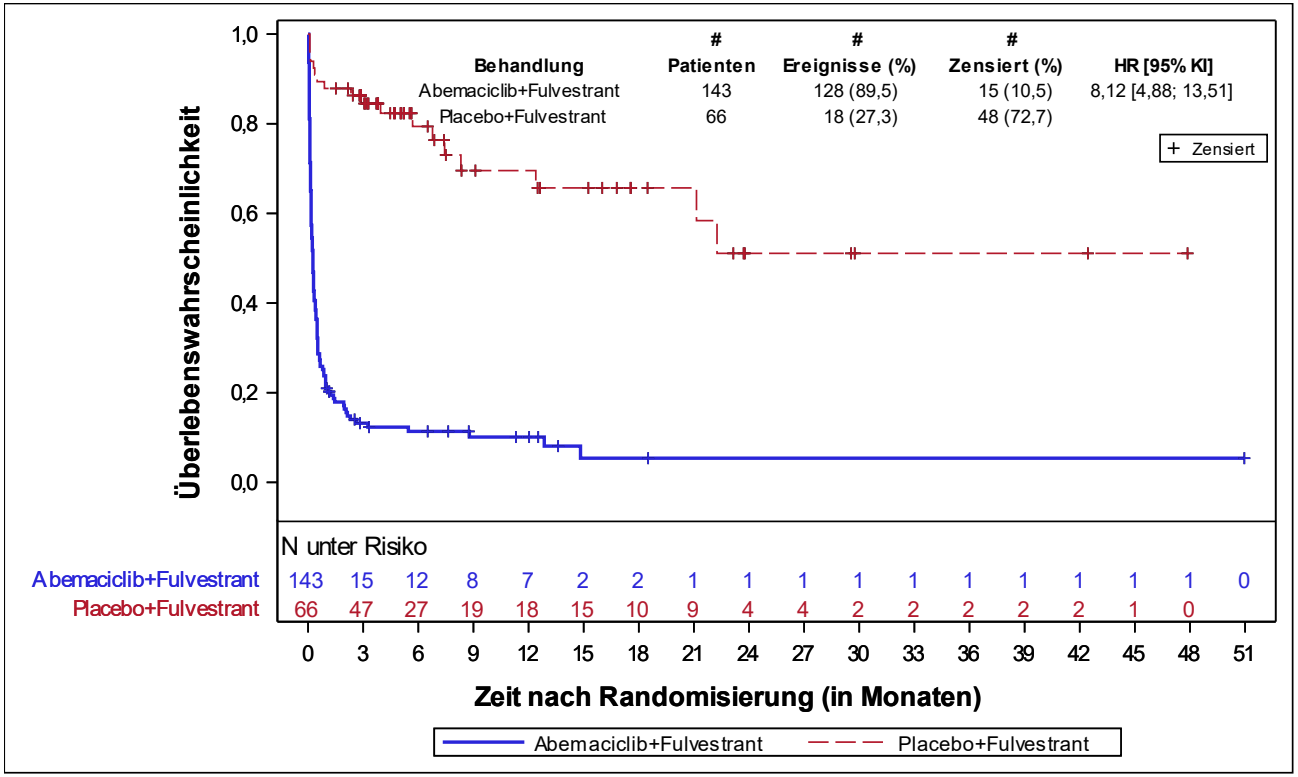
Abbildung 022: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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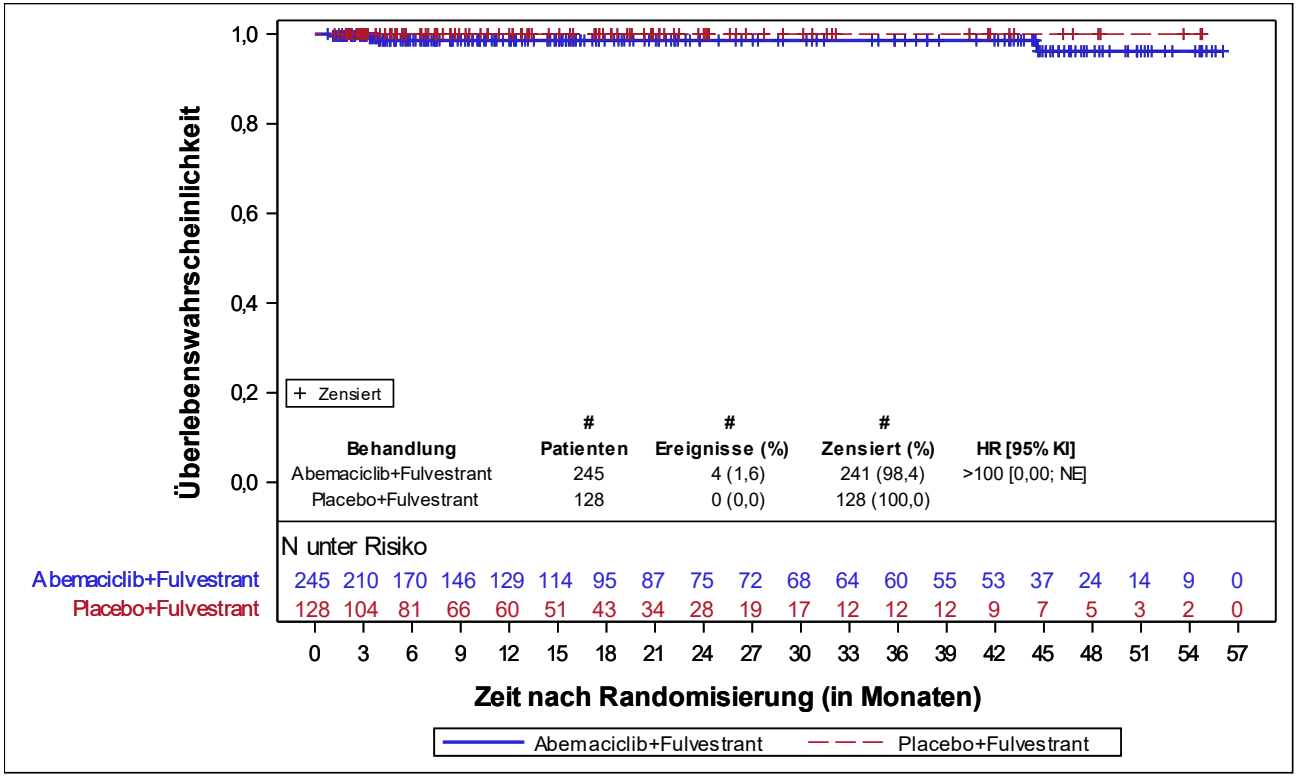
Abbildung 023: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Diarrhoe
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttdisaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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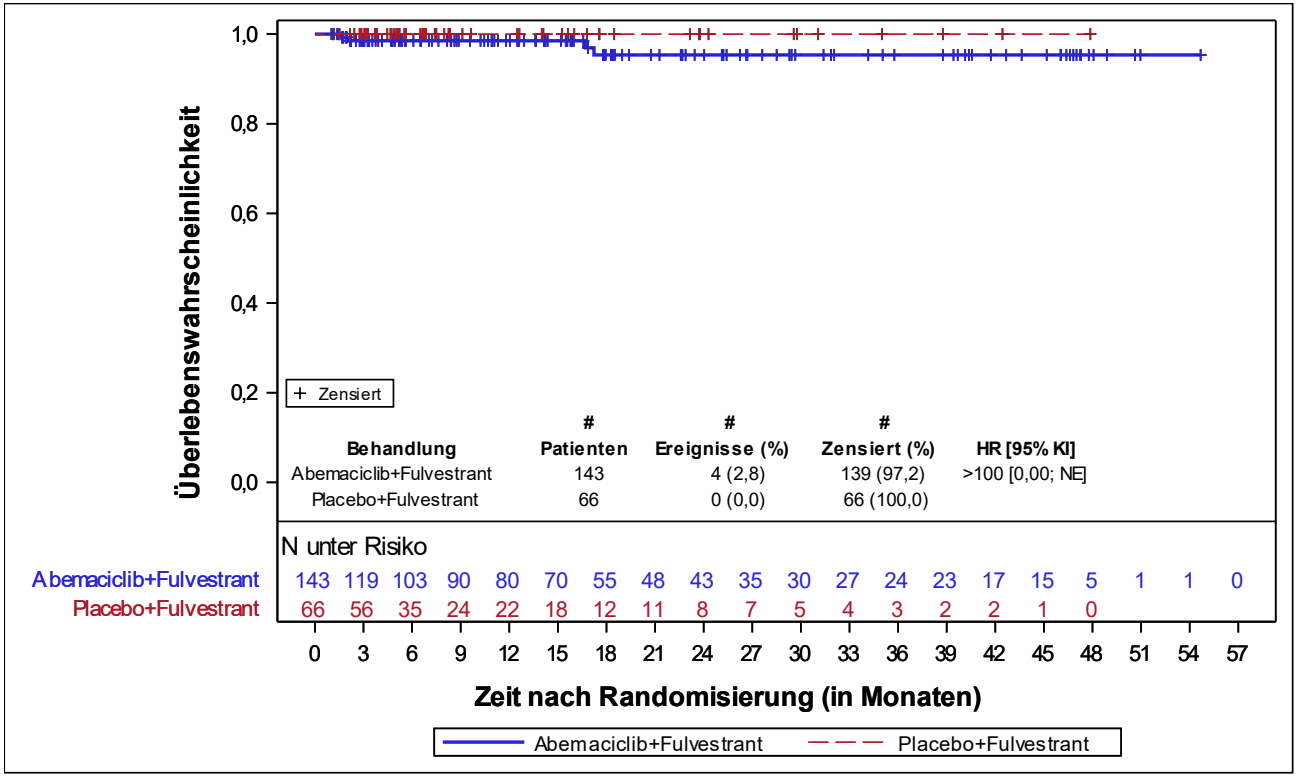
Abbildung 024: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Diarrhoe Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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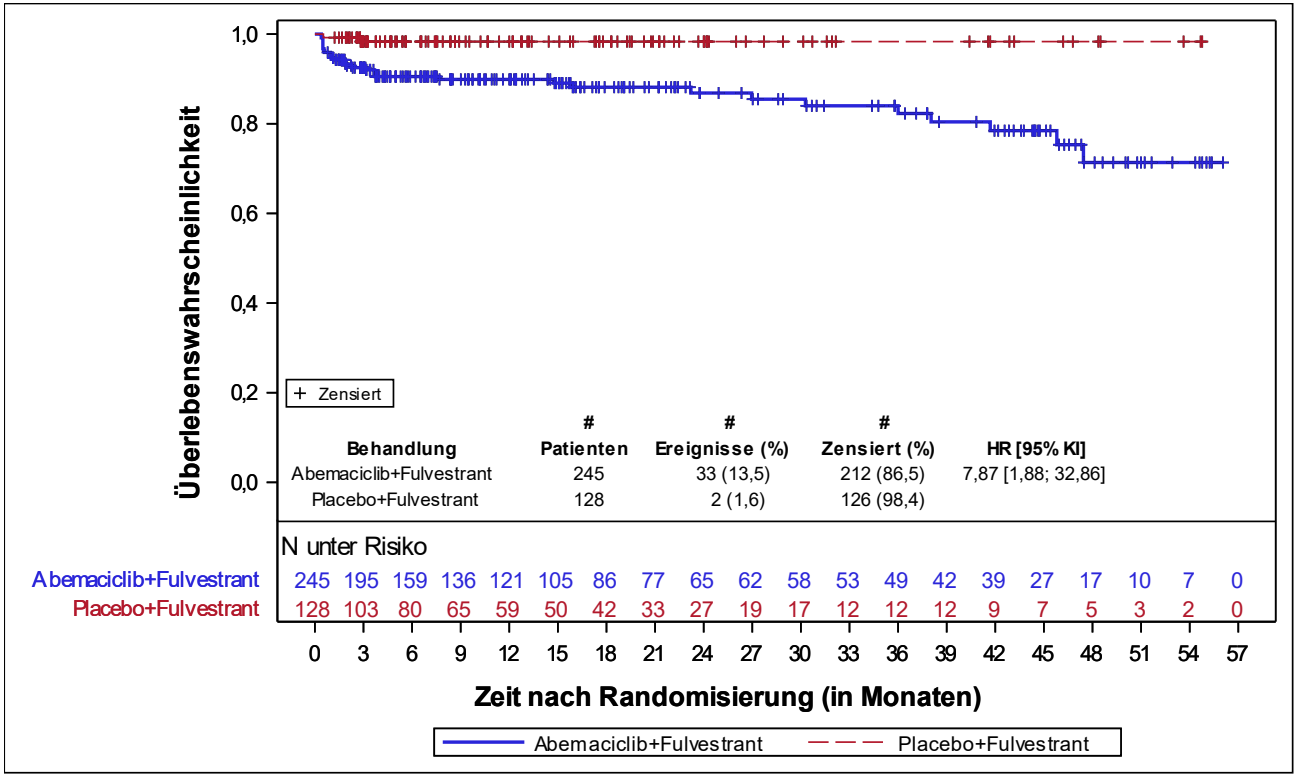
Abbildung 025: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad)
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttcraesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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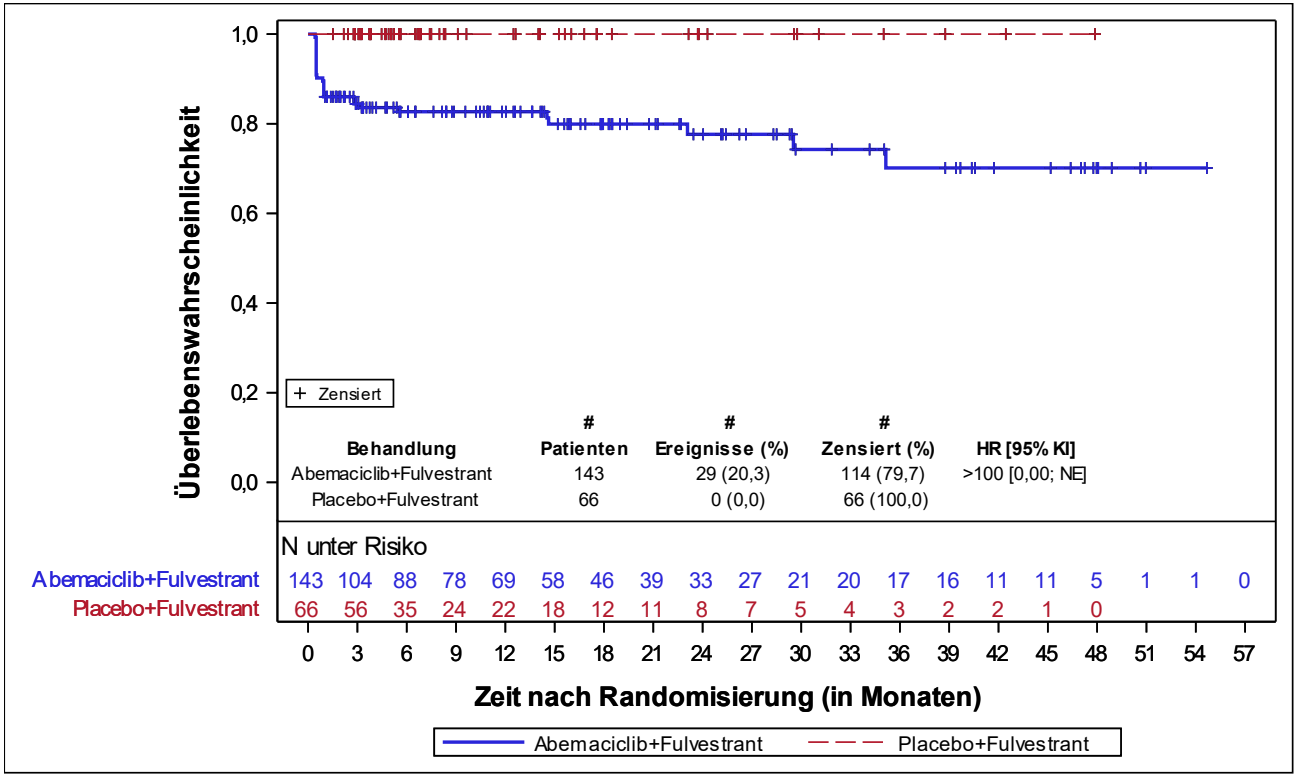
Abbildung 026: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad)
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttcraesi_popa2.rtf
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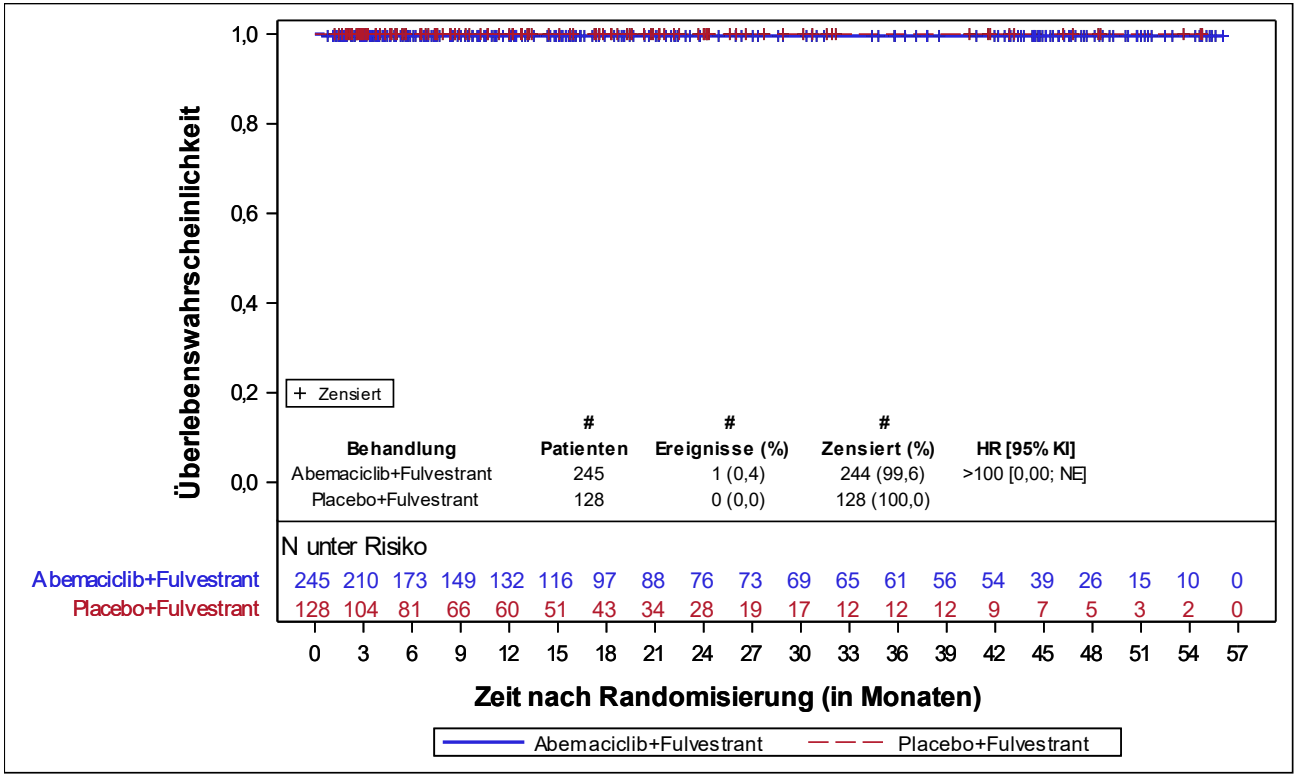
Abbildung 027: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Kreatinin im Blut erhöht Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttcr3aesi_popa1.rtf
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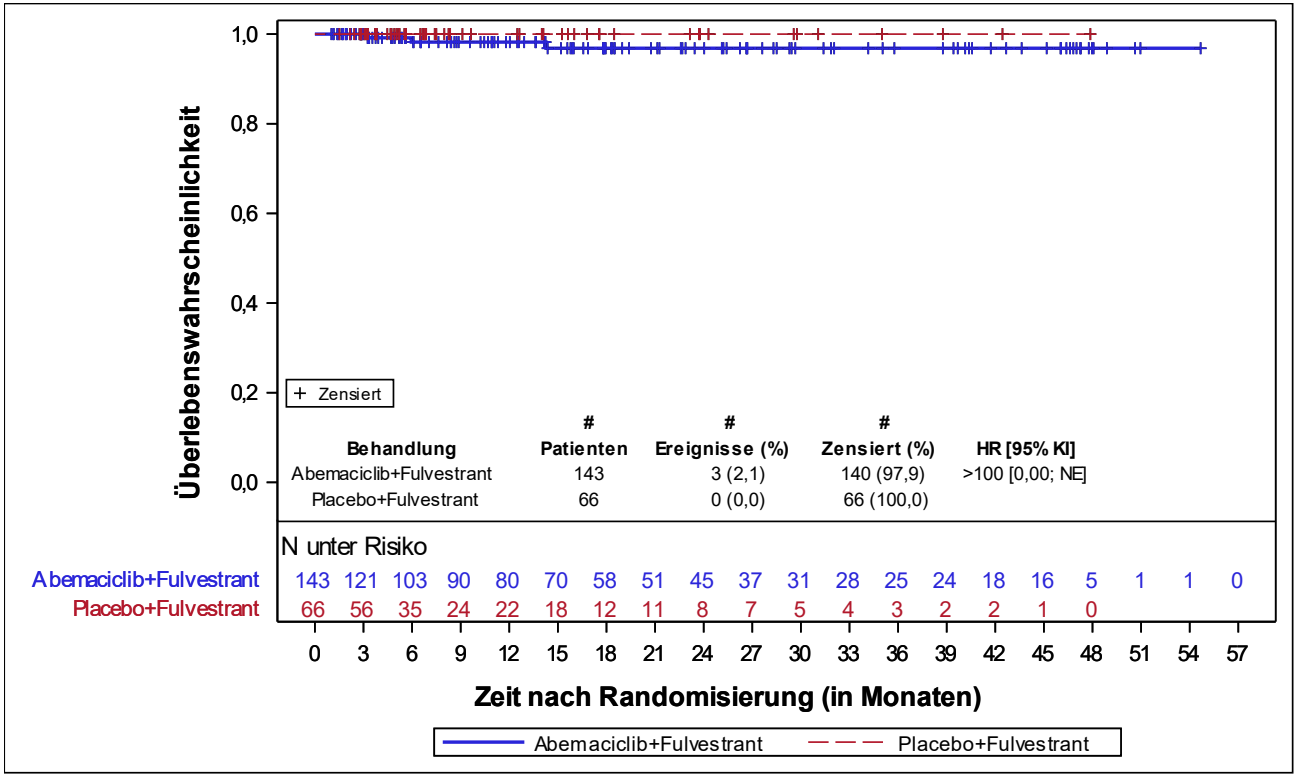
Abbildung 028: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Kreatinin im Blut erhöht Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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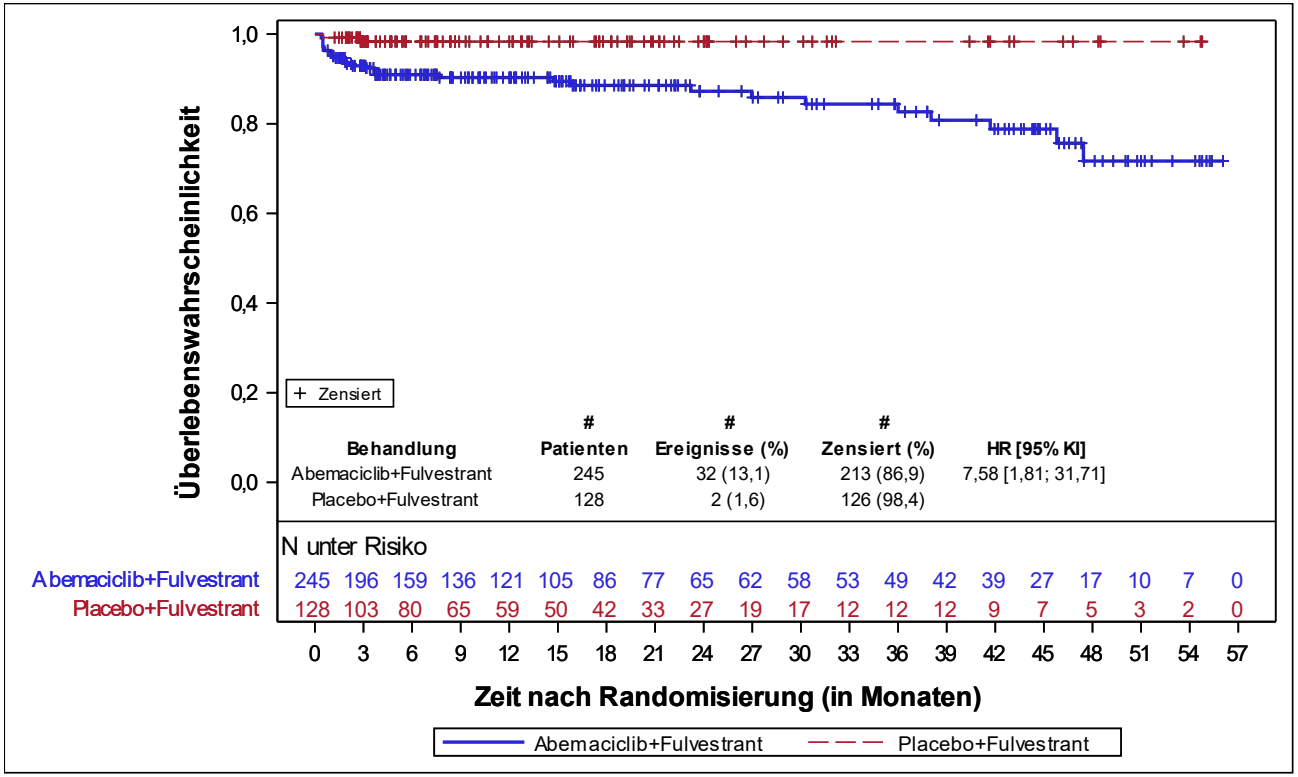
Abbildung 029: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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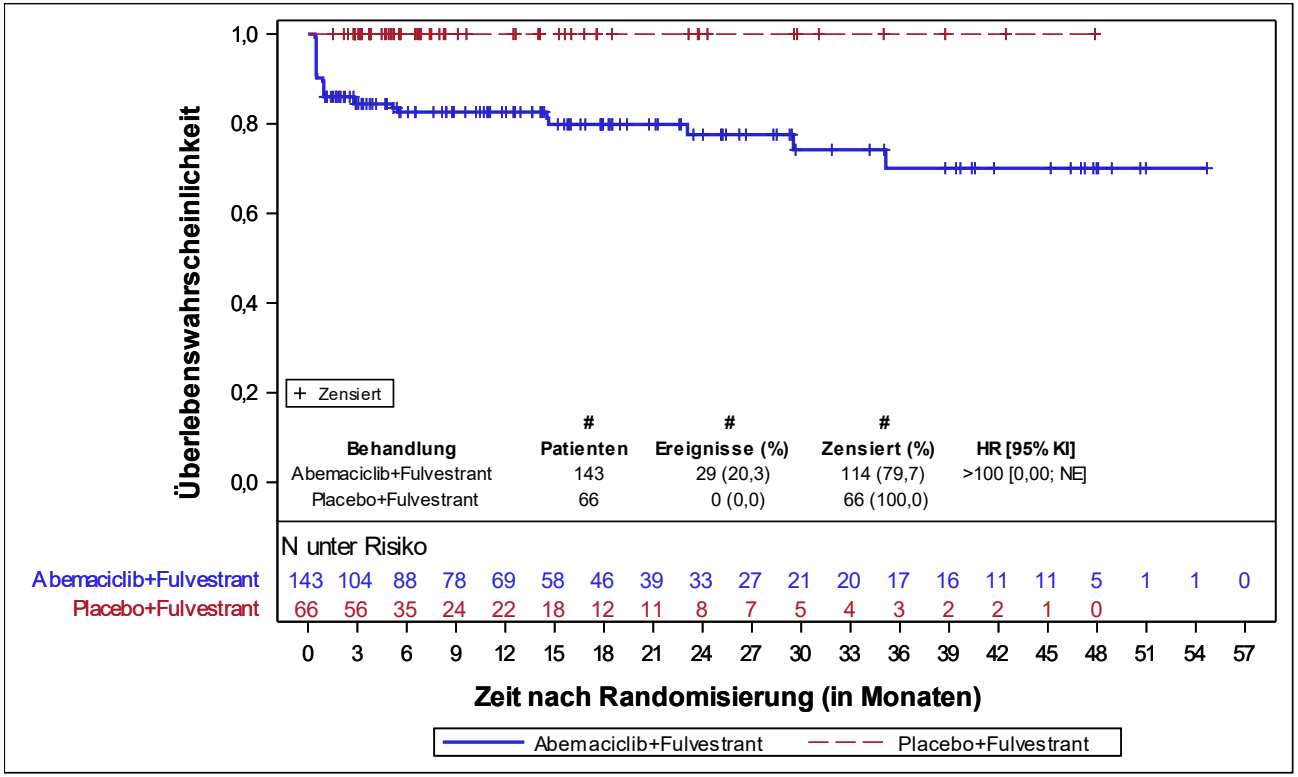
Abbildung 030: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttcr2aesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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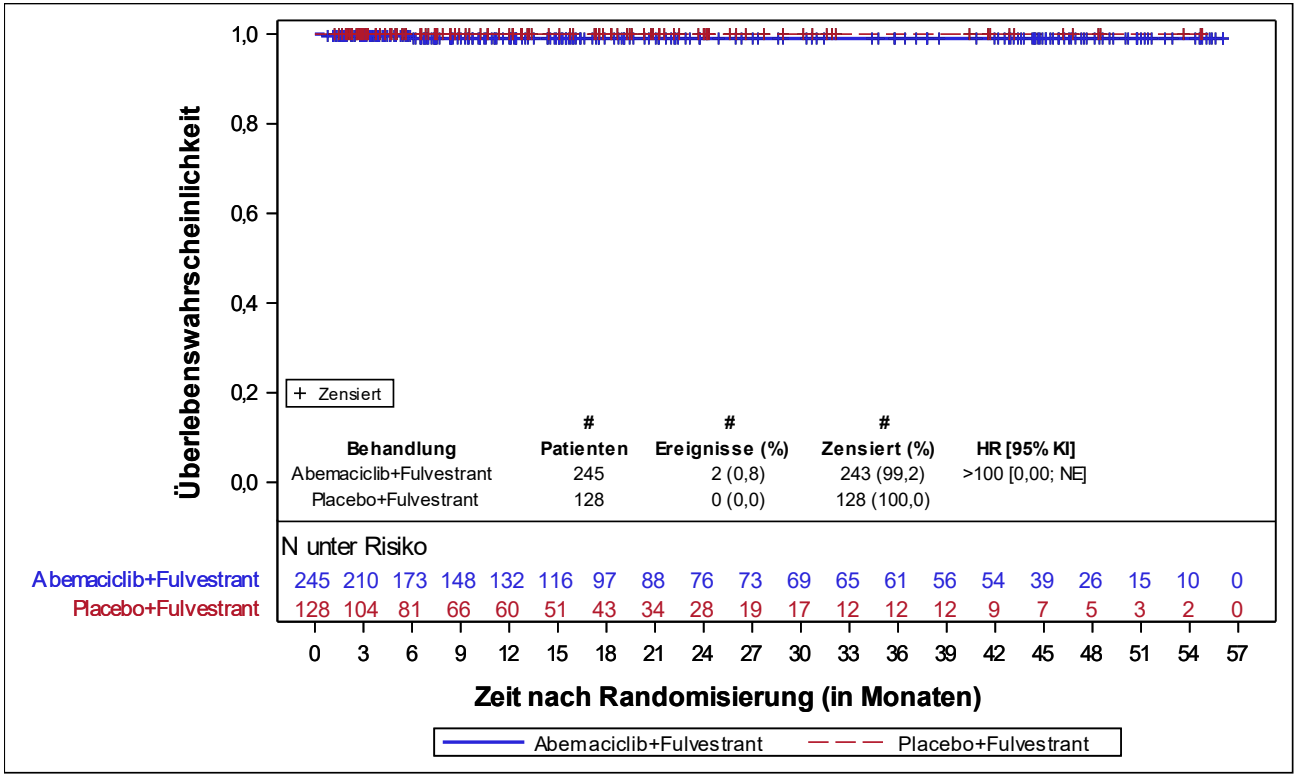
Abbildung 031: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Kreatinin im Blut erhöht Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttcrsaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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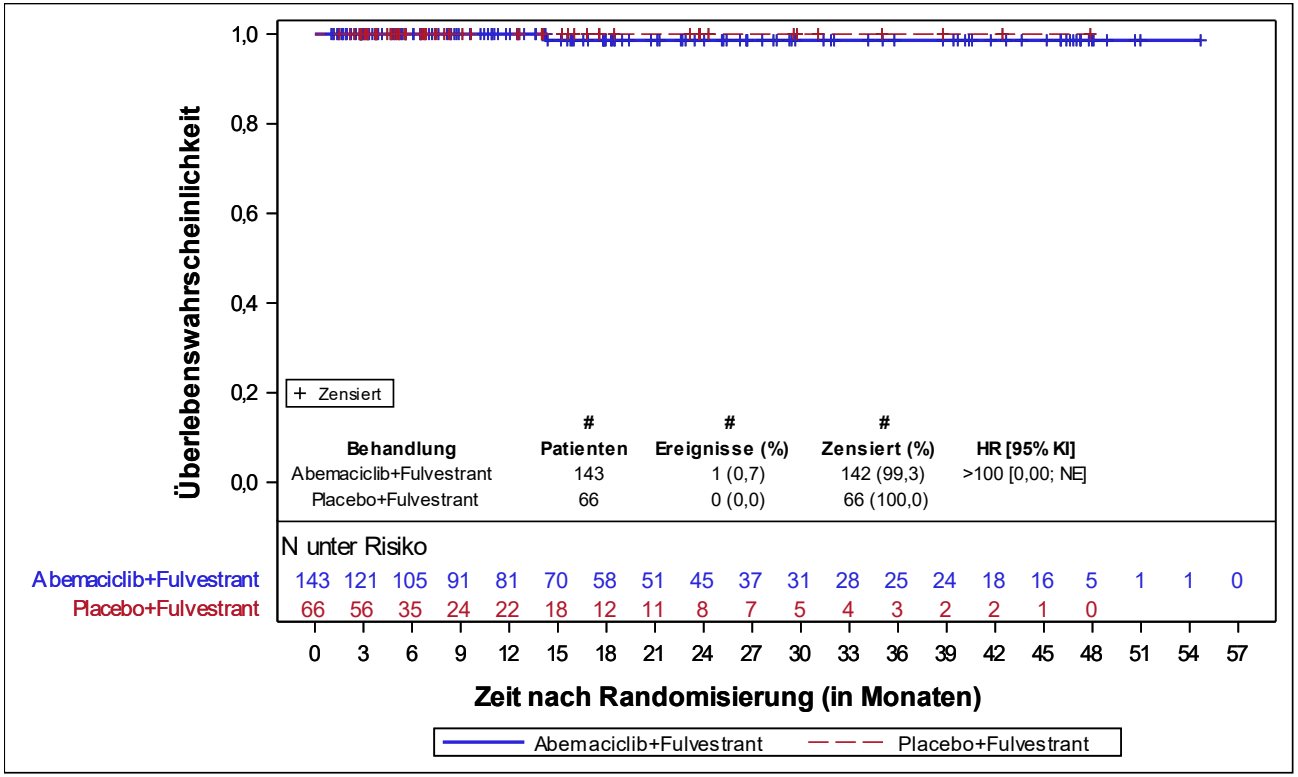
Abbildung 032: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Kreatinin im Blut erhöht Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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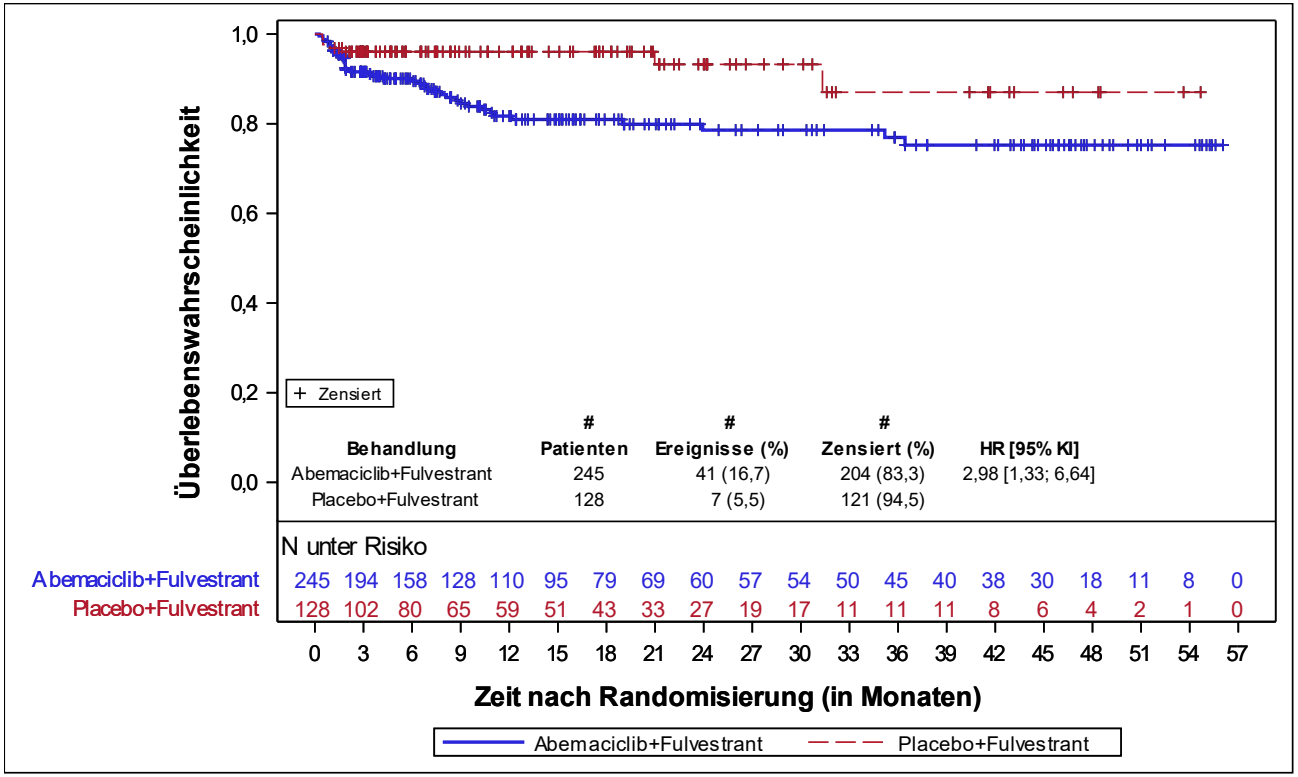
Abbildung 033: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttalaesi_popa1.rtf
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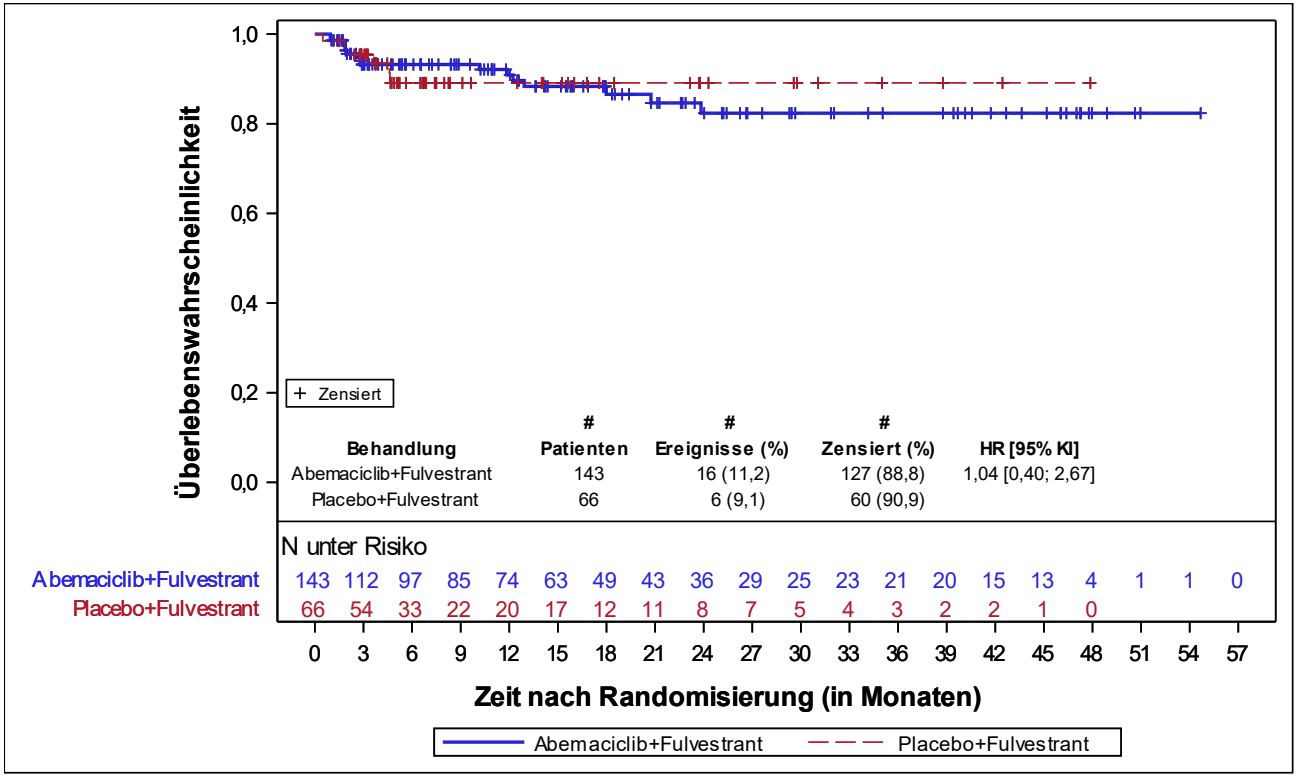
Abbildung 034: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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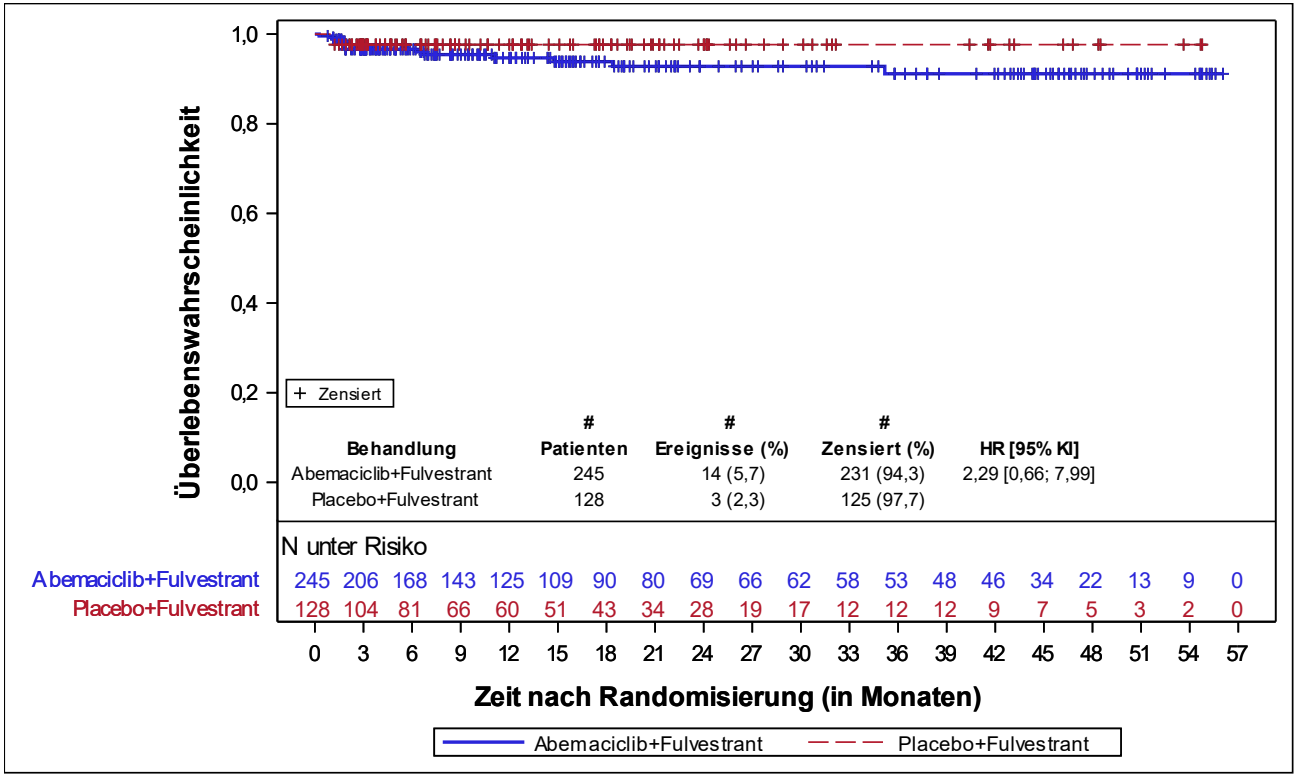
Abbildung 035: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttal3aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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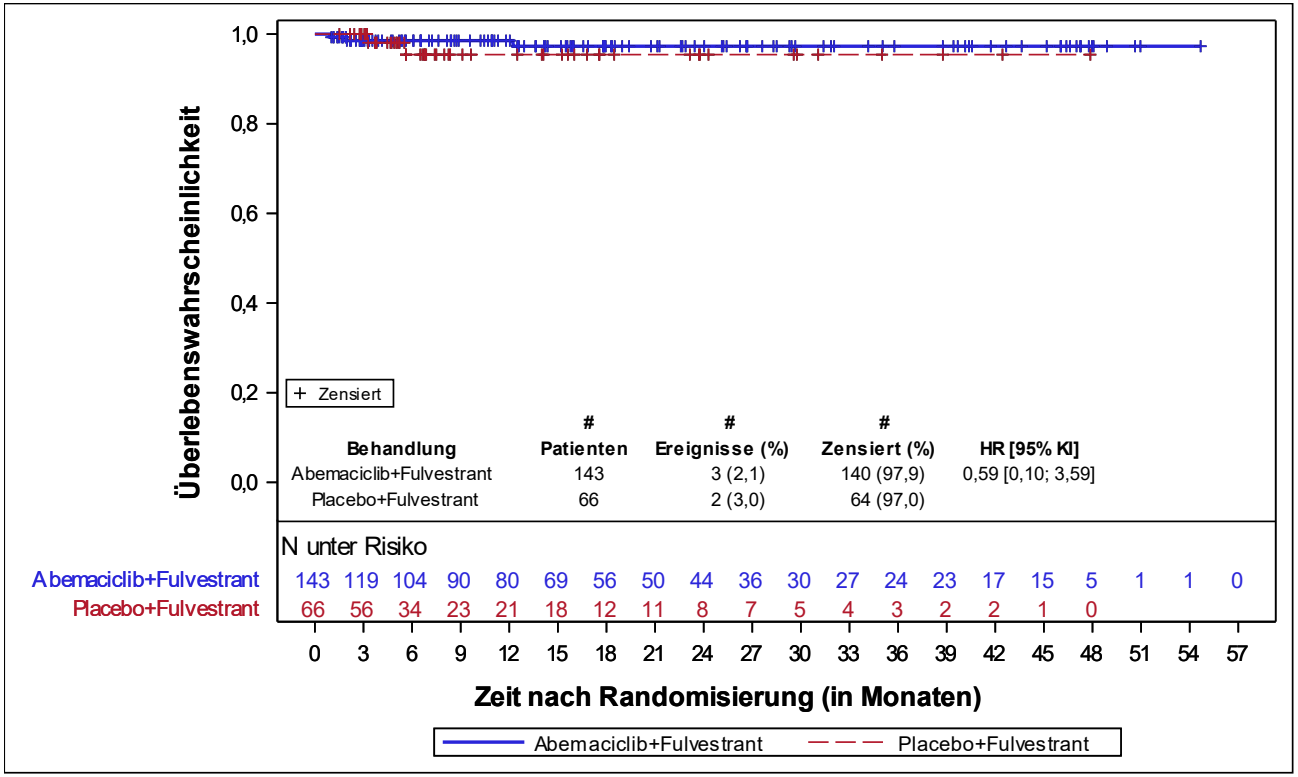
Abbildung 036: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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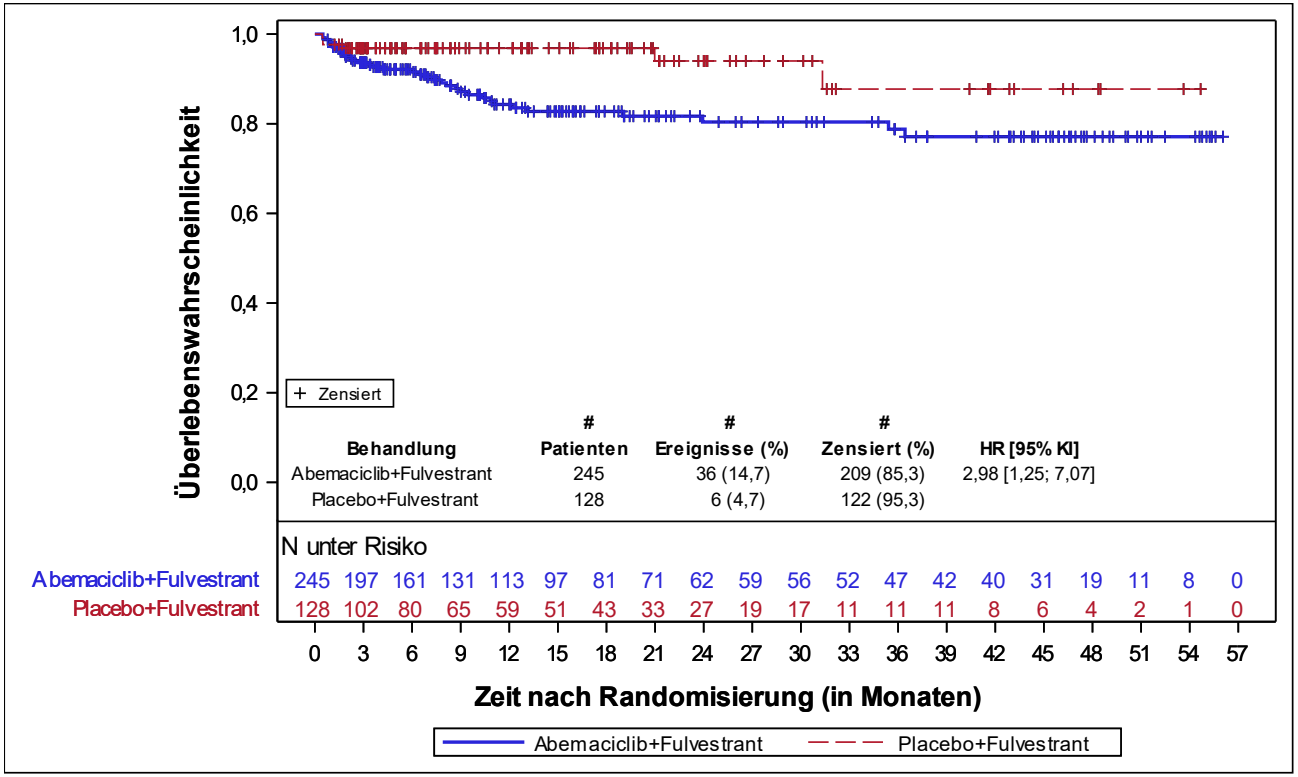
Abbildung 037: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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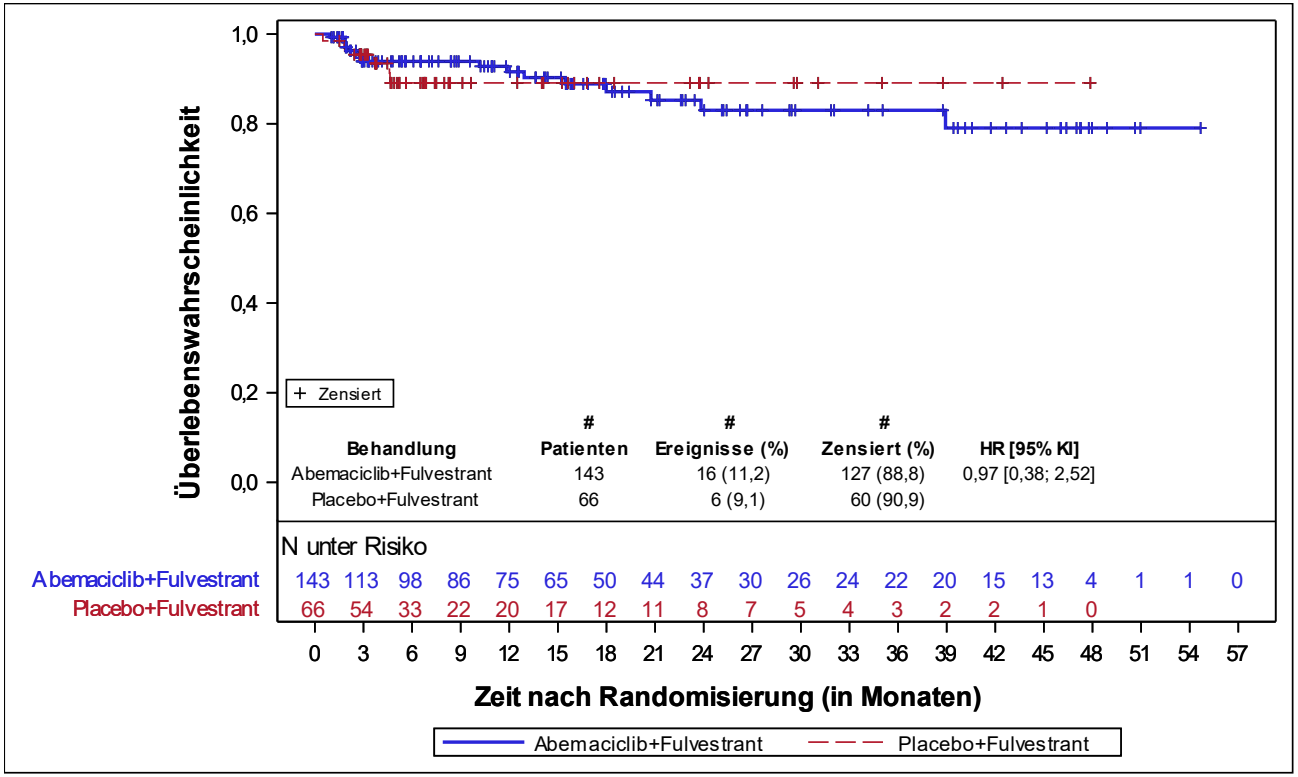
Abbildung 038: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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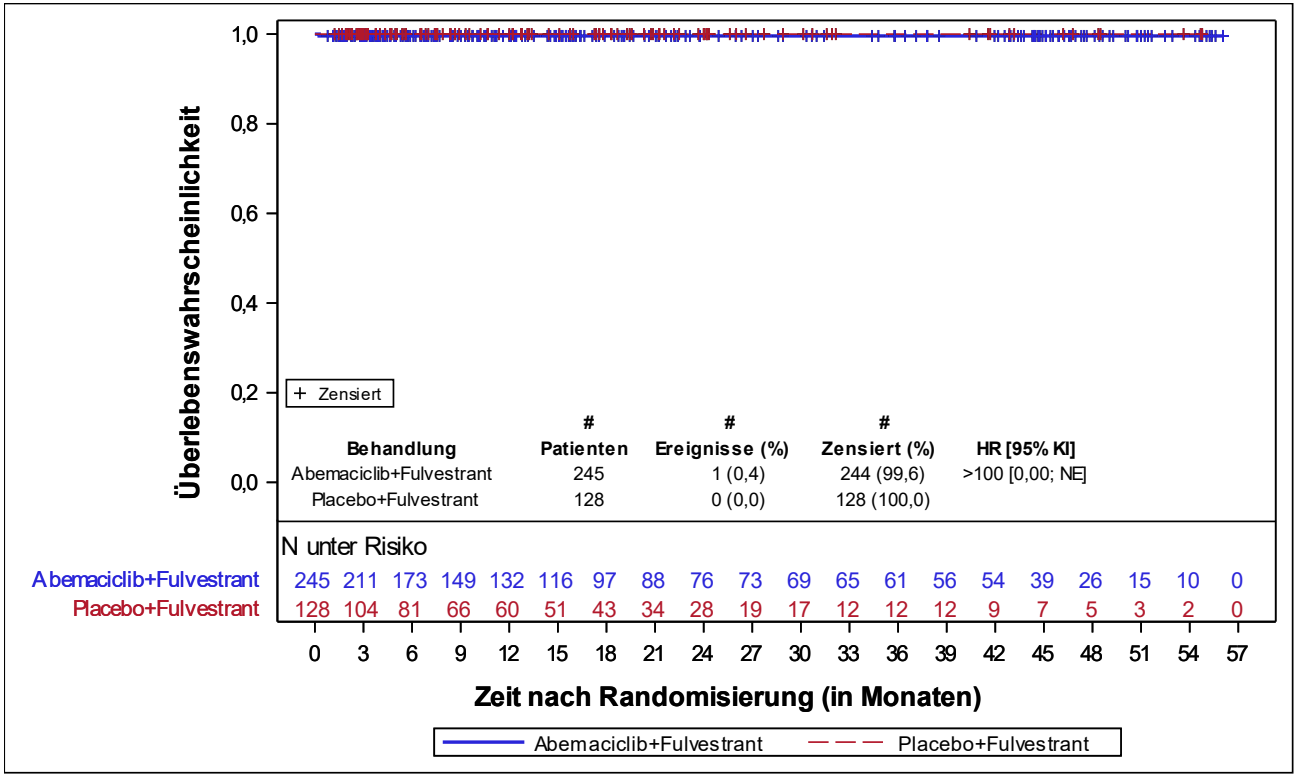
Abbildung 039: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alaninaminotransferase erhöht Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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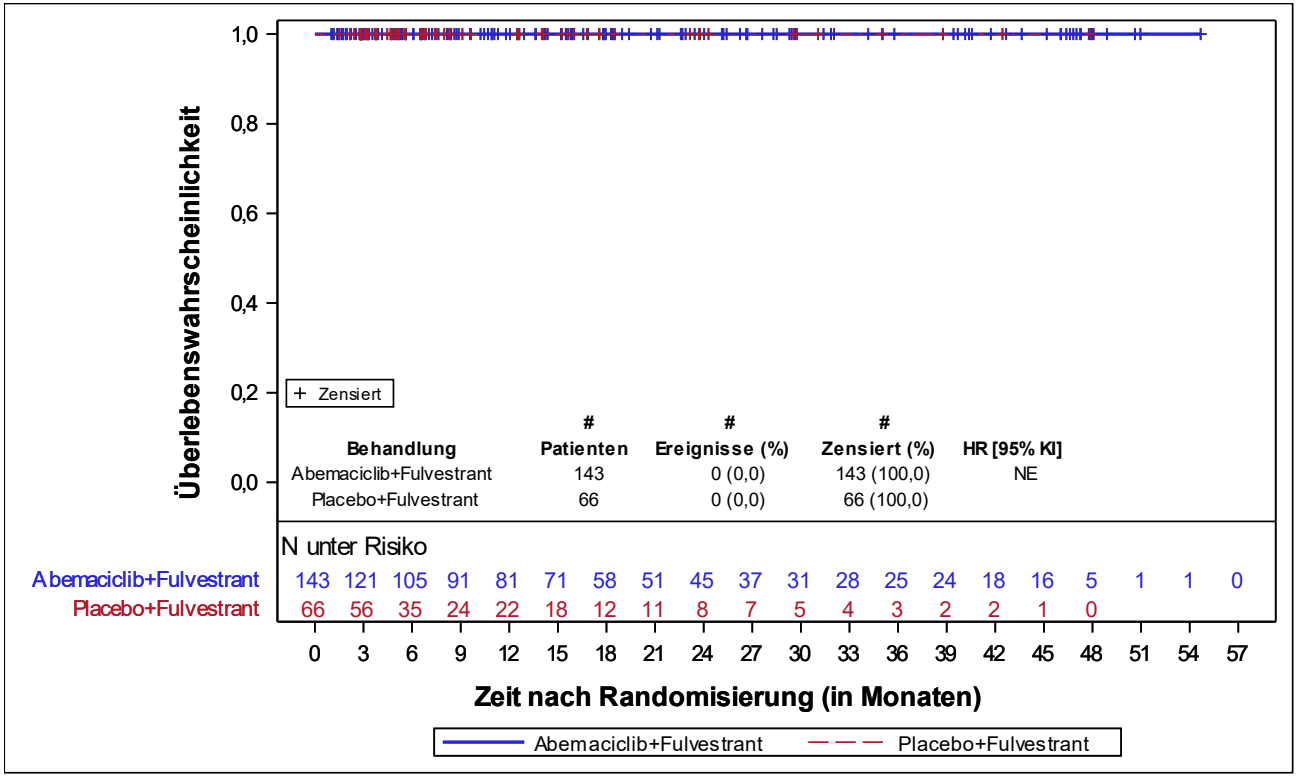
Abbildung 040: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alaninaminotransferase erhöht Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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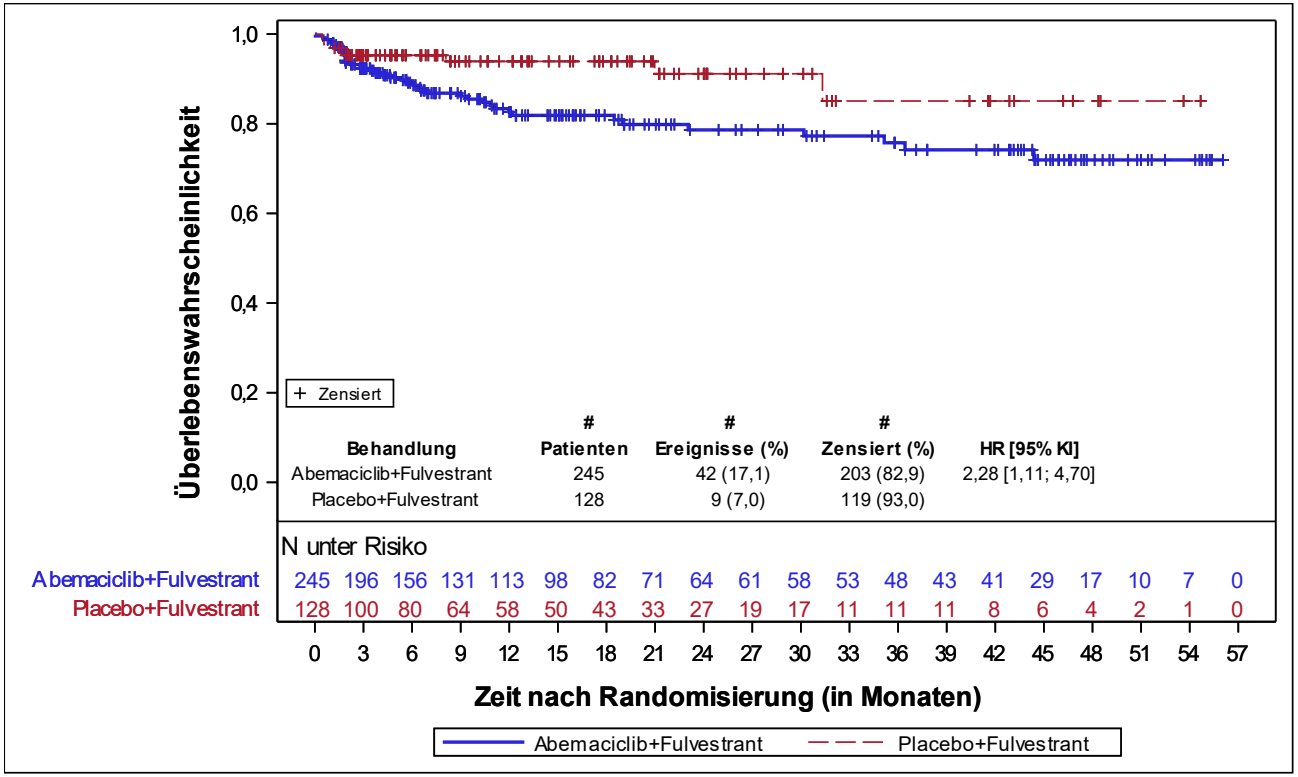
Abbildung 041: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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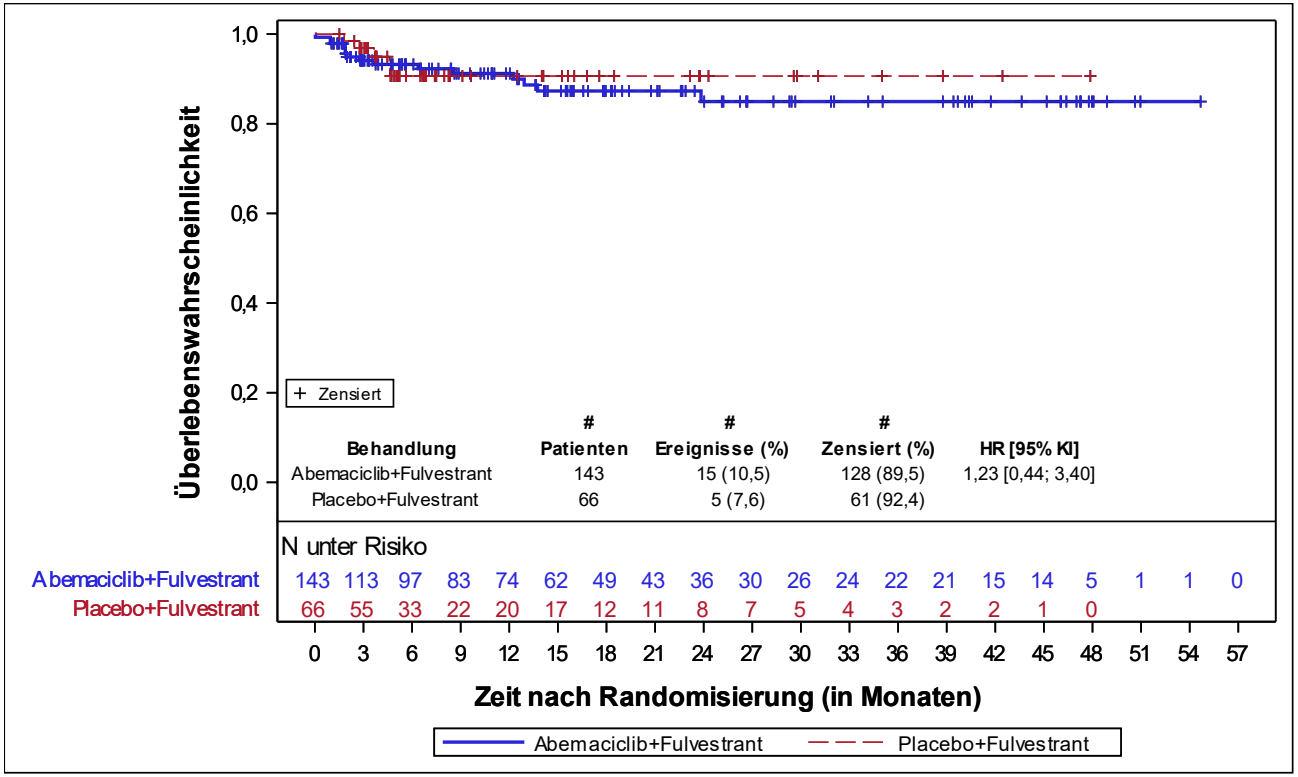
Abbildung 042: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttasaesi_popa2.rtf
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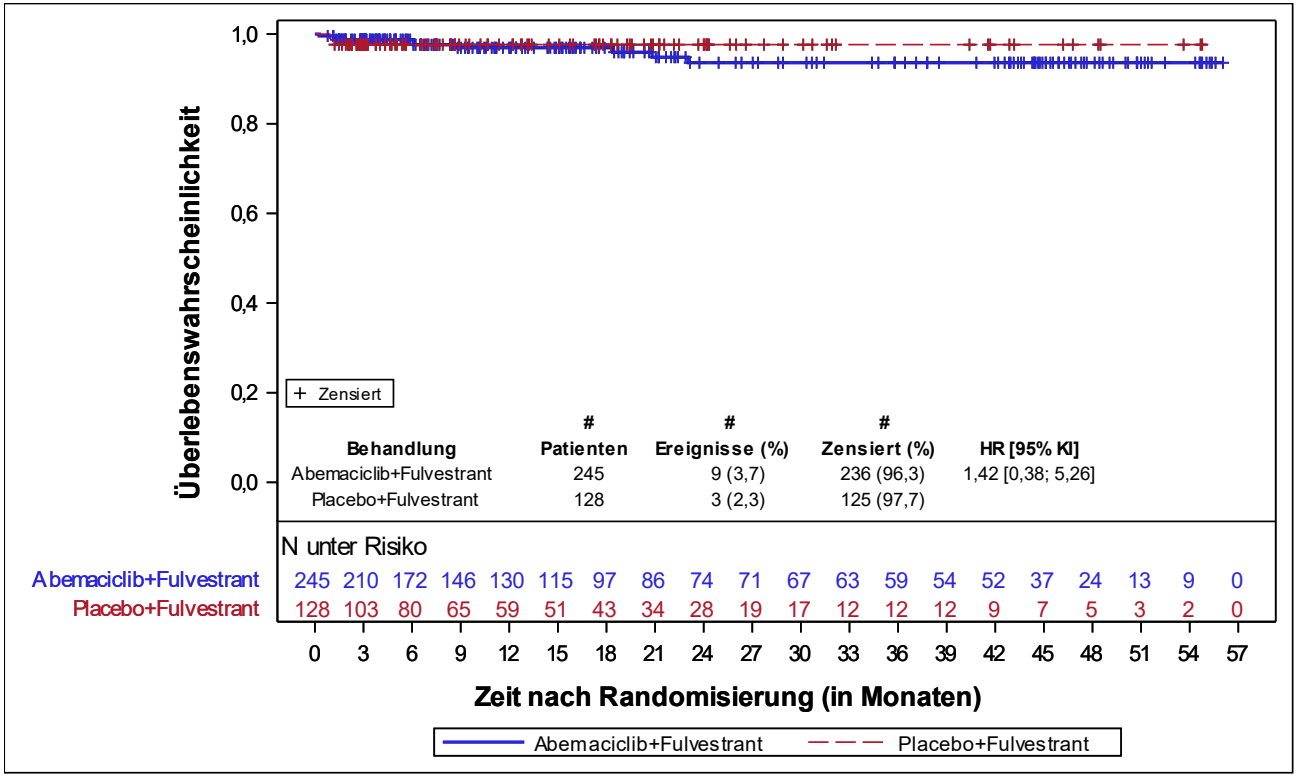
Abbildung 043: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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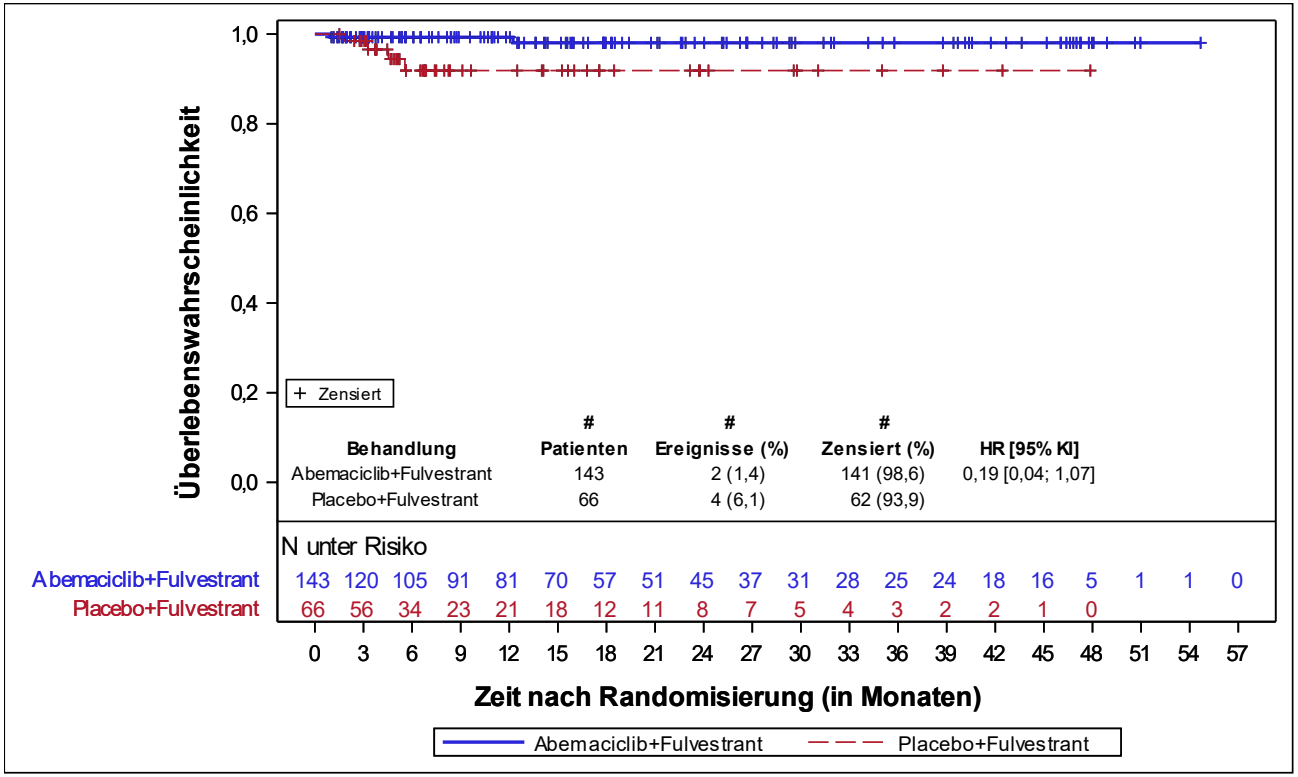
Abbildung 044: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttas3aesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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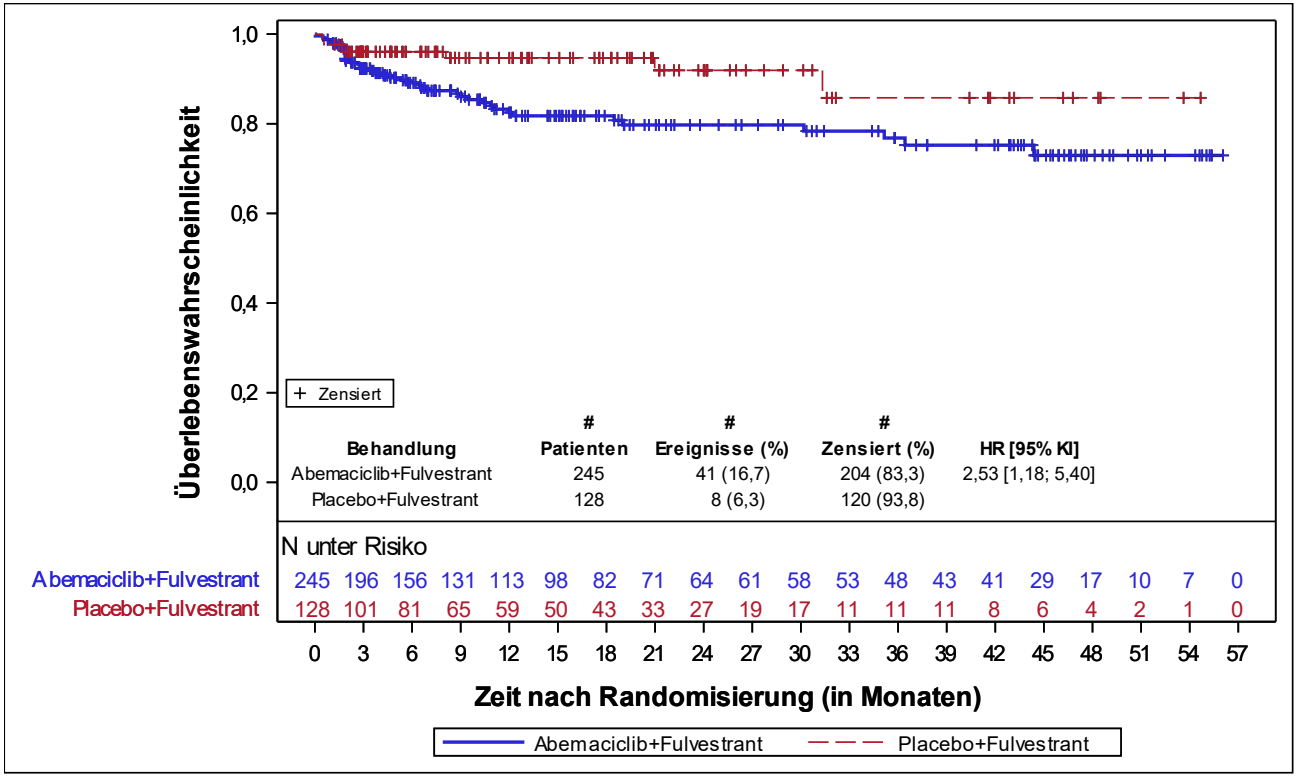
Abbildung 045: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttas2aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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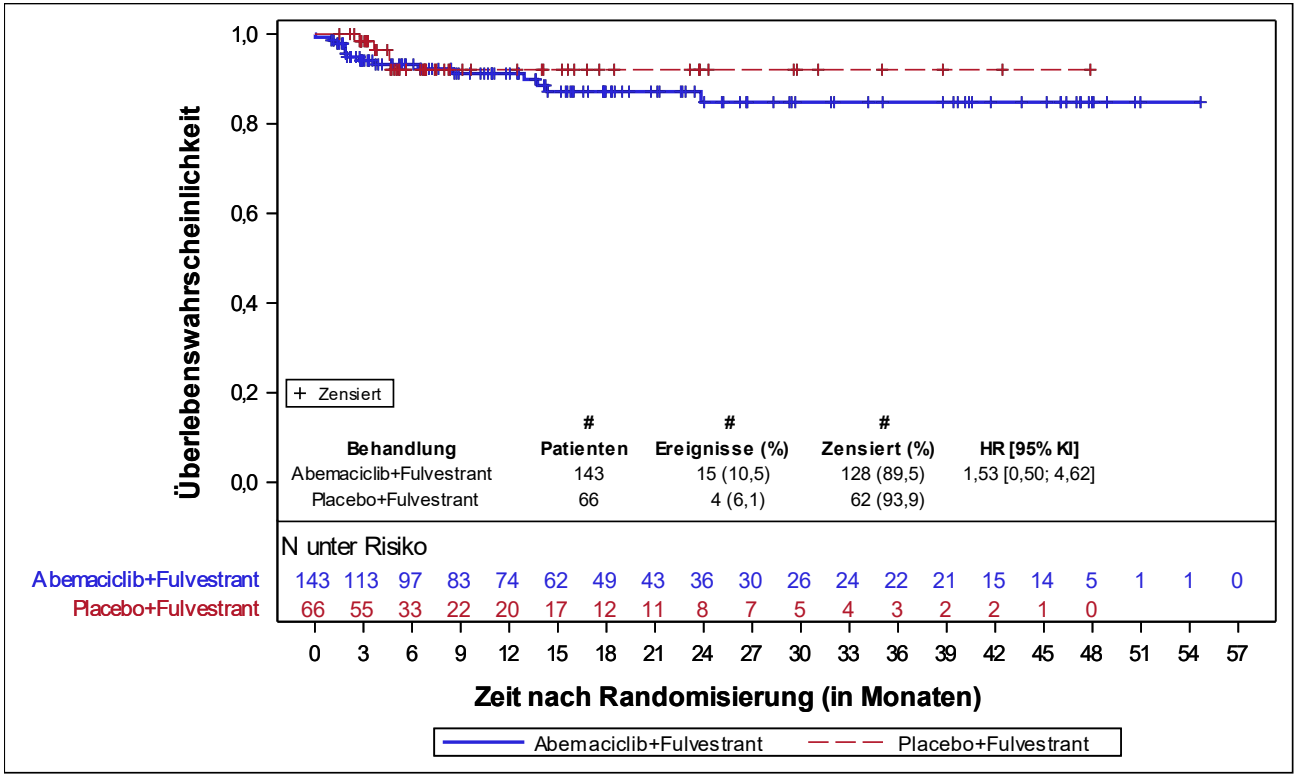
Abbildung 046: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttas2aesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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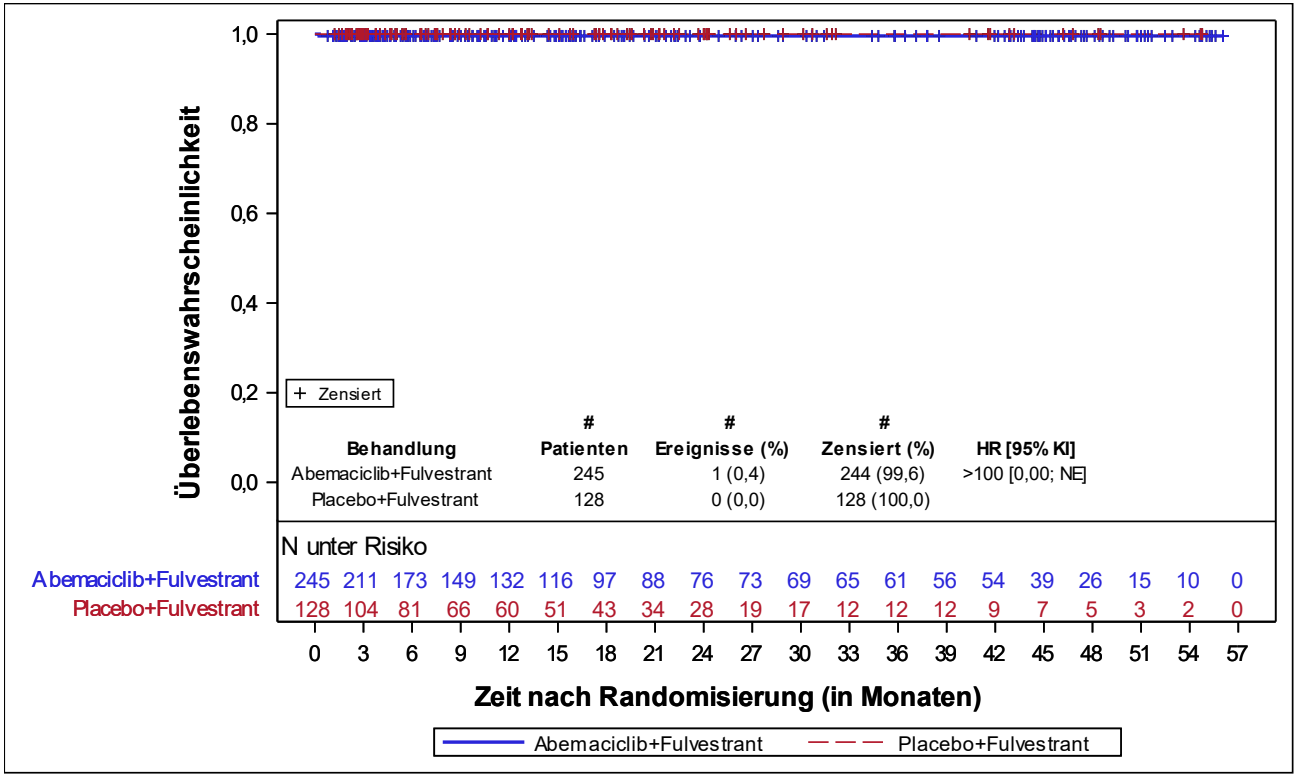
Abbildung 047: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Aspartataminotransferase erhöht Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttassaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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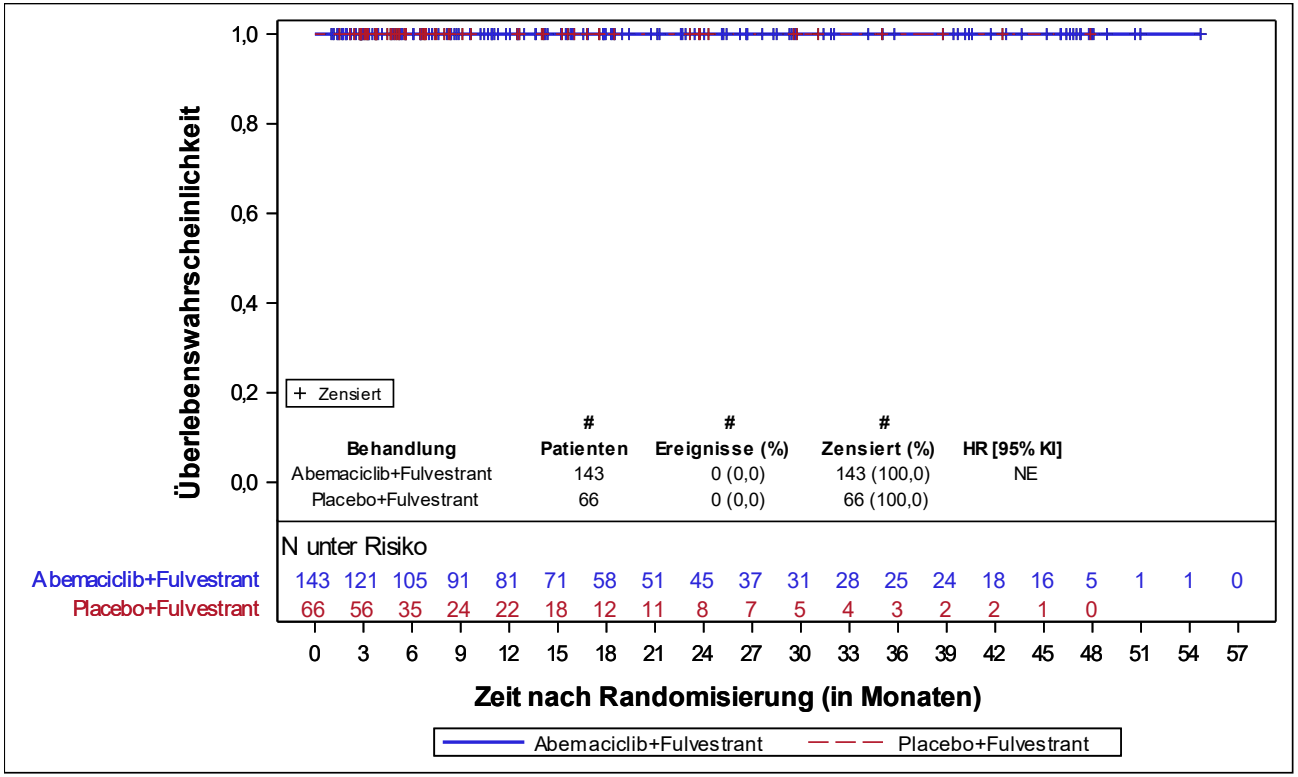
Abbildung 048: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Aspartataminotransferase erhöht Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttassaesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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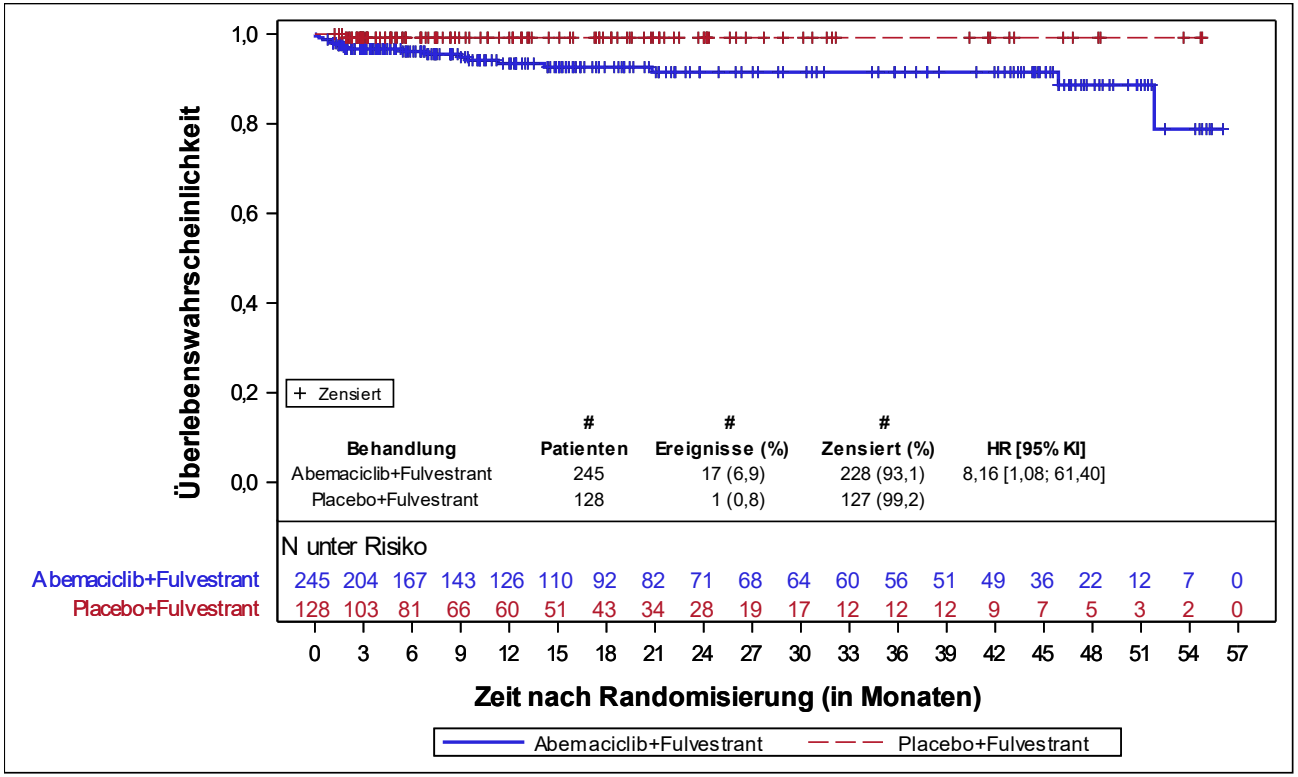
Abbildung 049: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttapaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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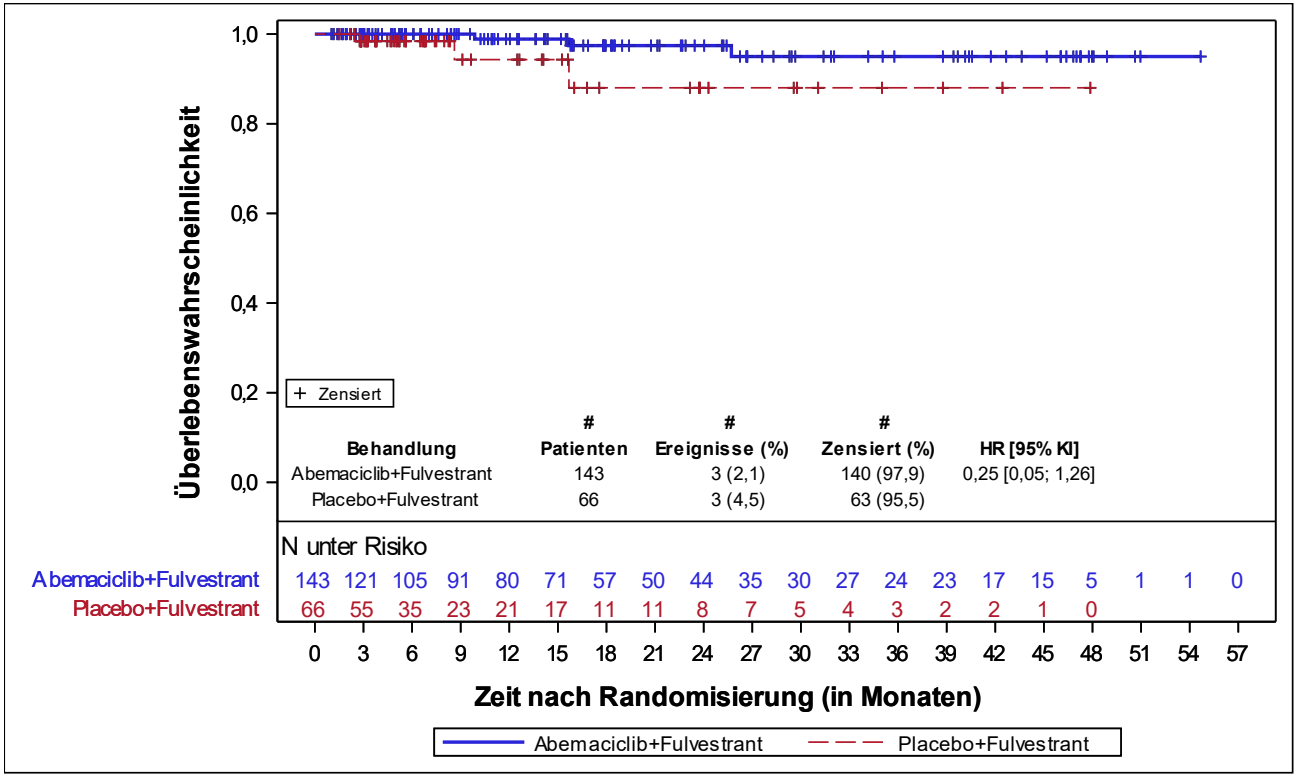
Abbildung 050: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttapaesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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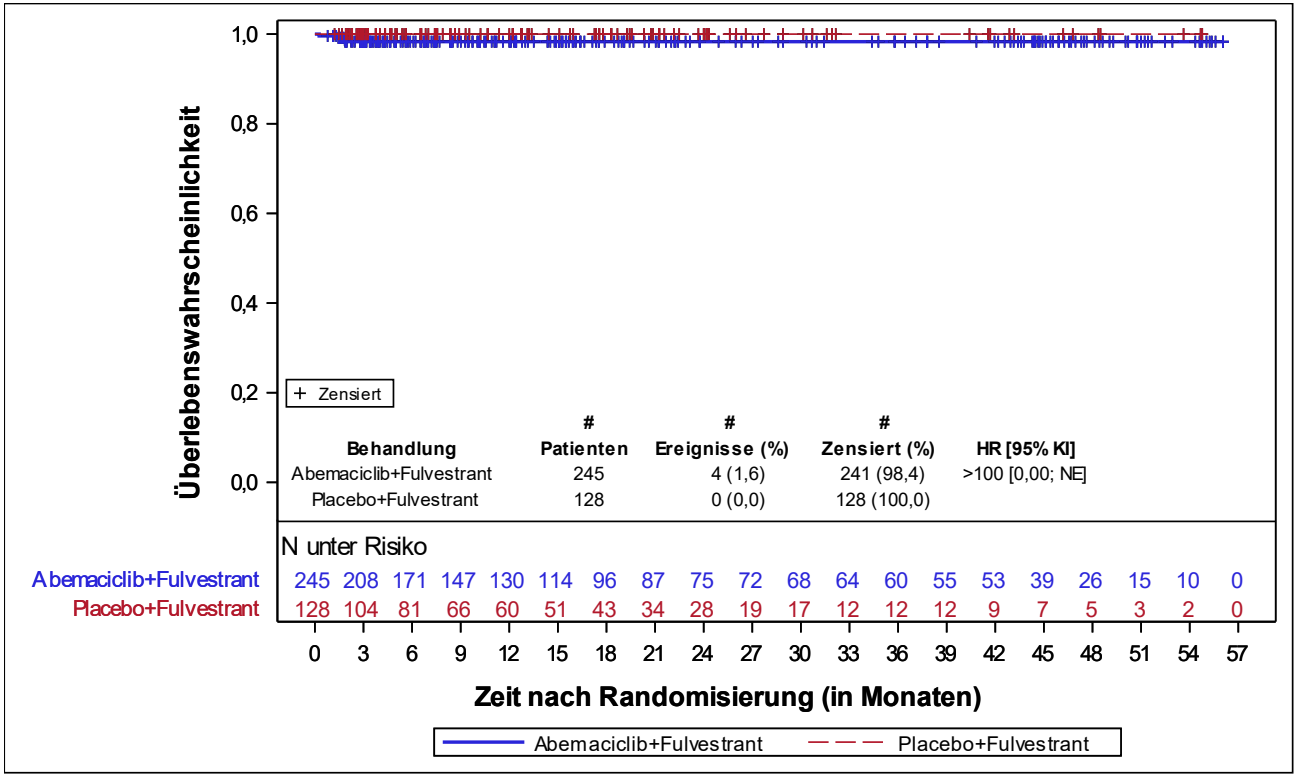
Abbildung 051: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alkalische Phosphatase erhöht Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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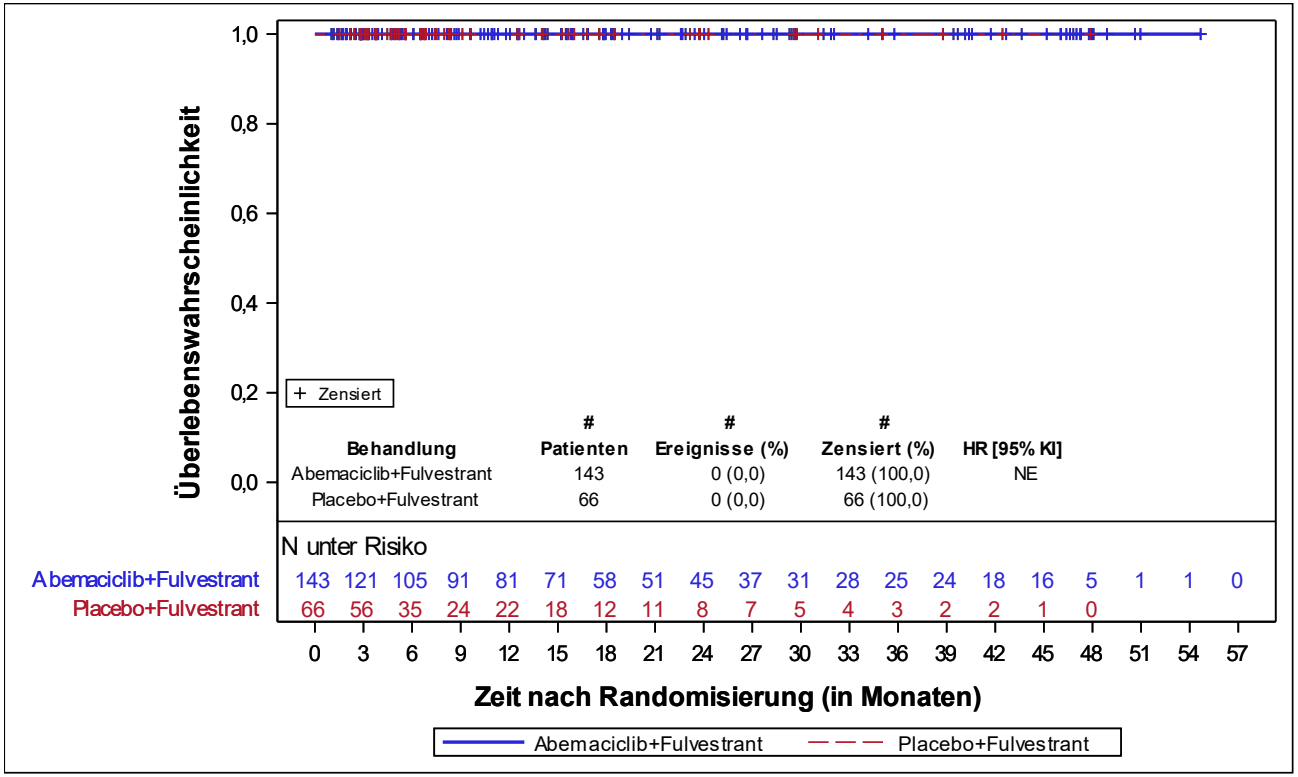
Abbildung 052: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alkalische Phosphatase erhöht Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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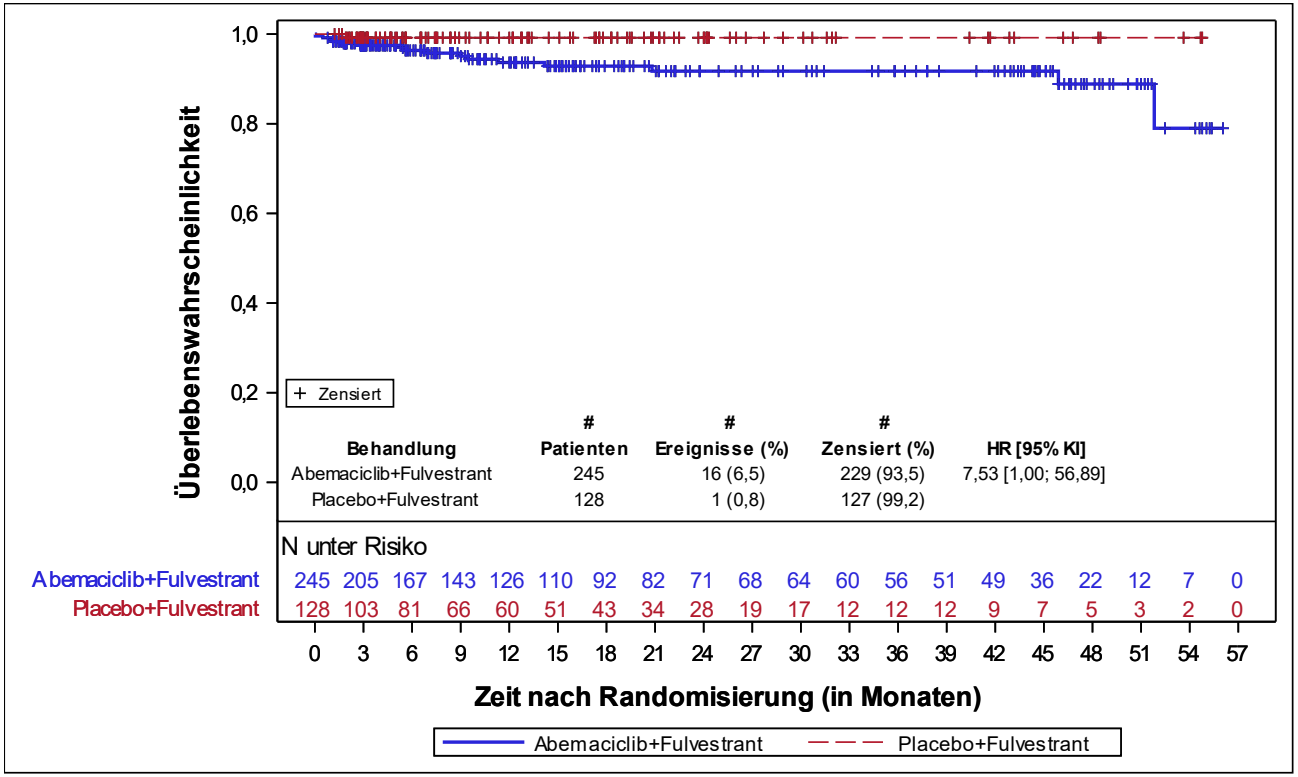
Abbildung 053: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttap2aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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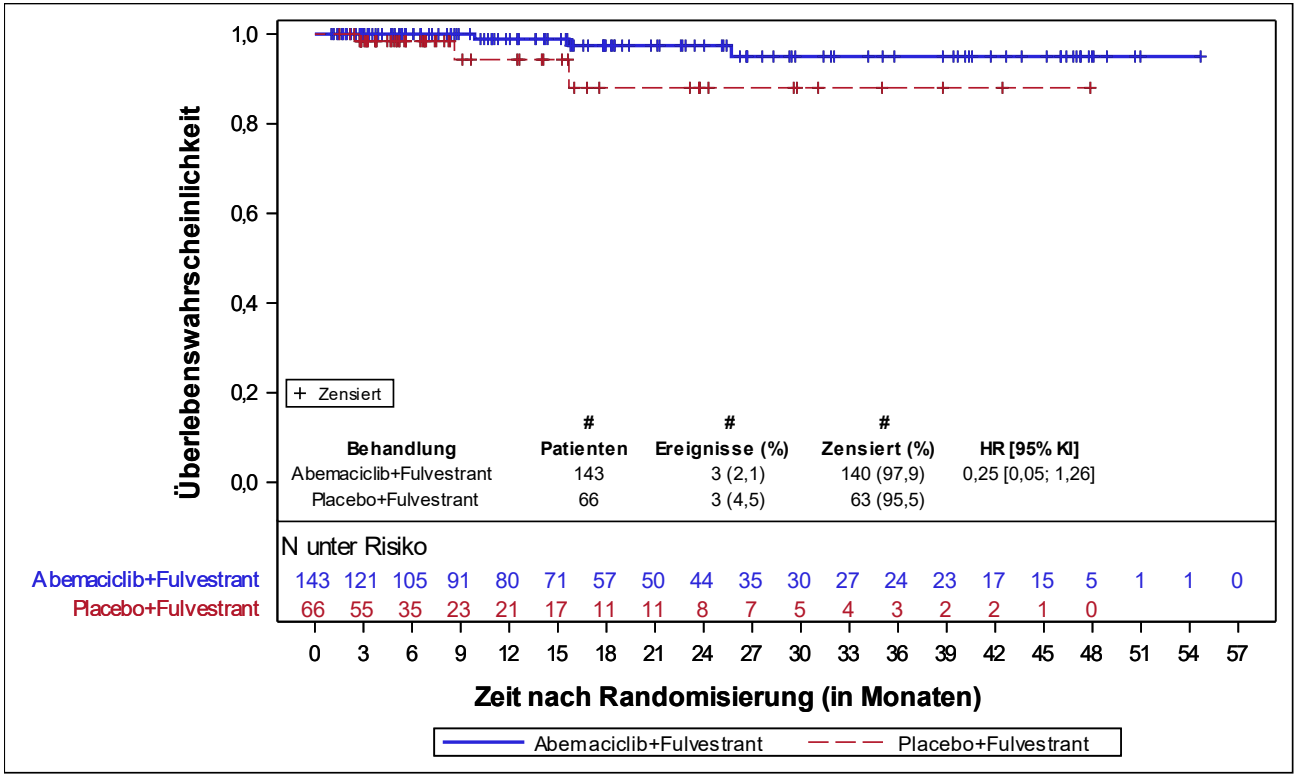
Abbildung 054: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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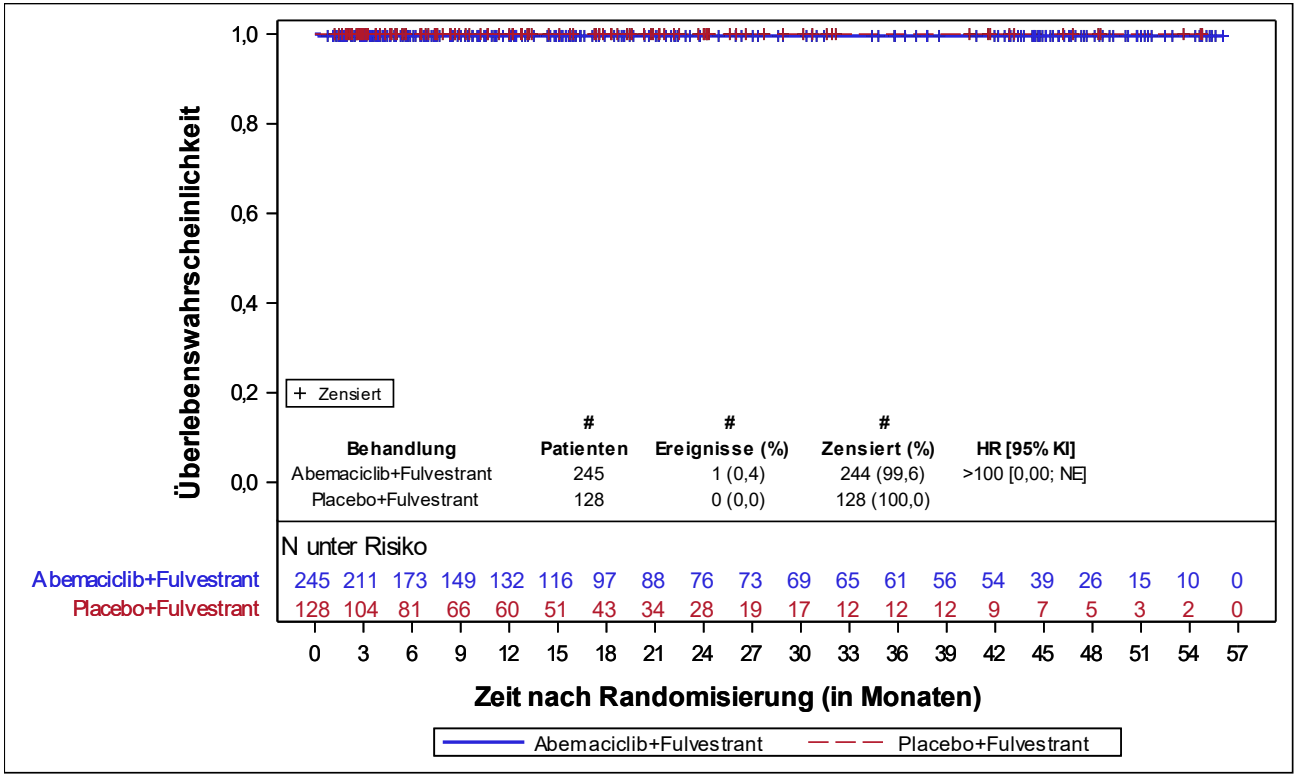
Abbildung 055: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alkalische Phosphatase erhöht Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttapsaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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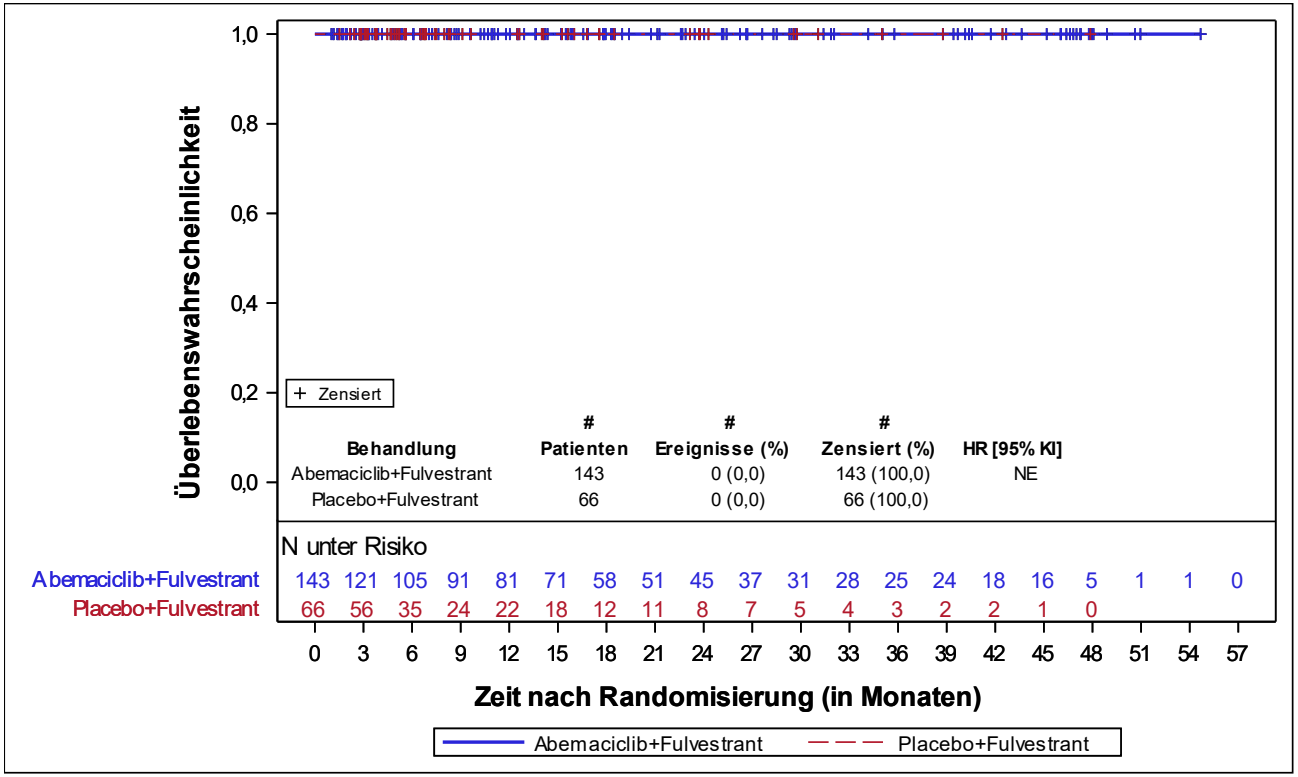
Abbildung 056: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alkalische Phosphatase erhöht Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttapsaesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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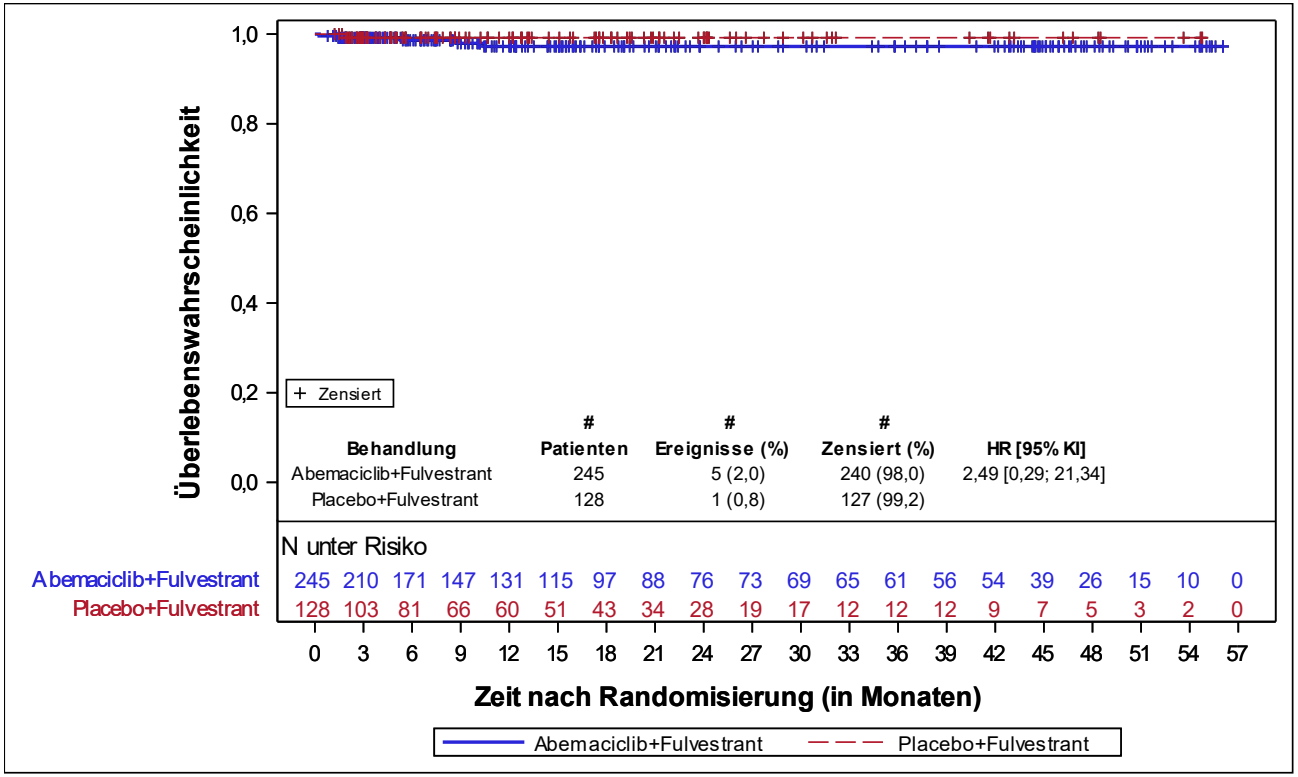
Abbildung 057: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Bilirubin im Blut erhöht (jeglicher Schweregrad)
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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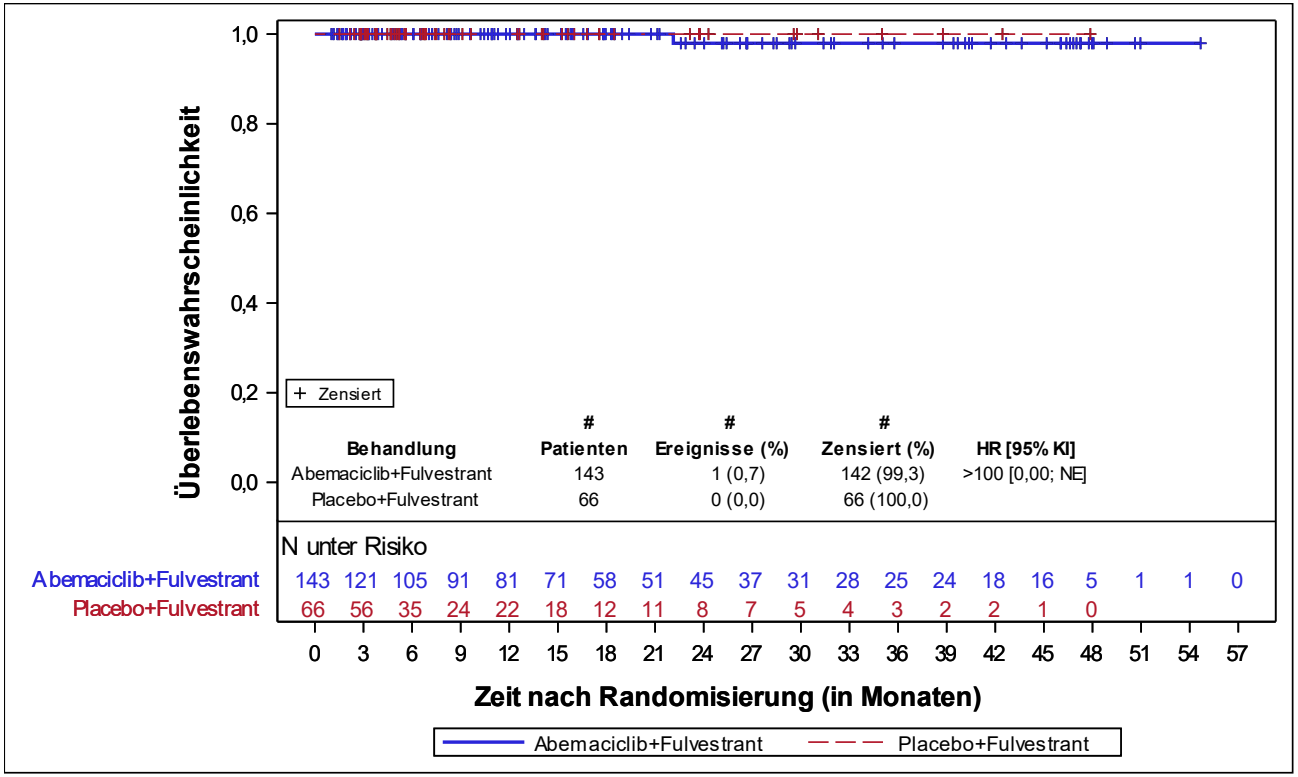
Abbildung 058: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Bilirubin im Blut erhöht (jeglicher Schweregrad) Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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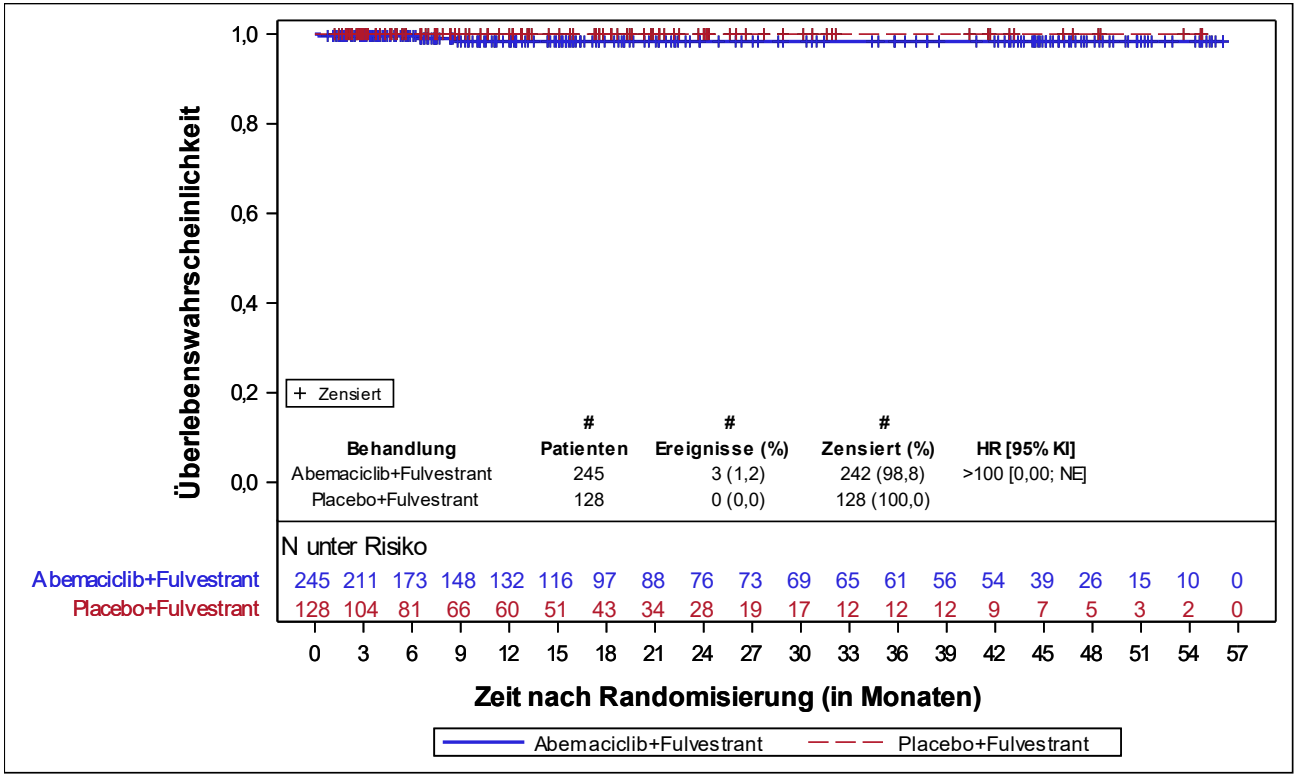
Abbildung 059: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Bilirubin im Blut erhöht Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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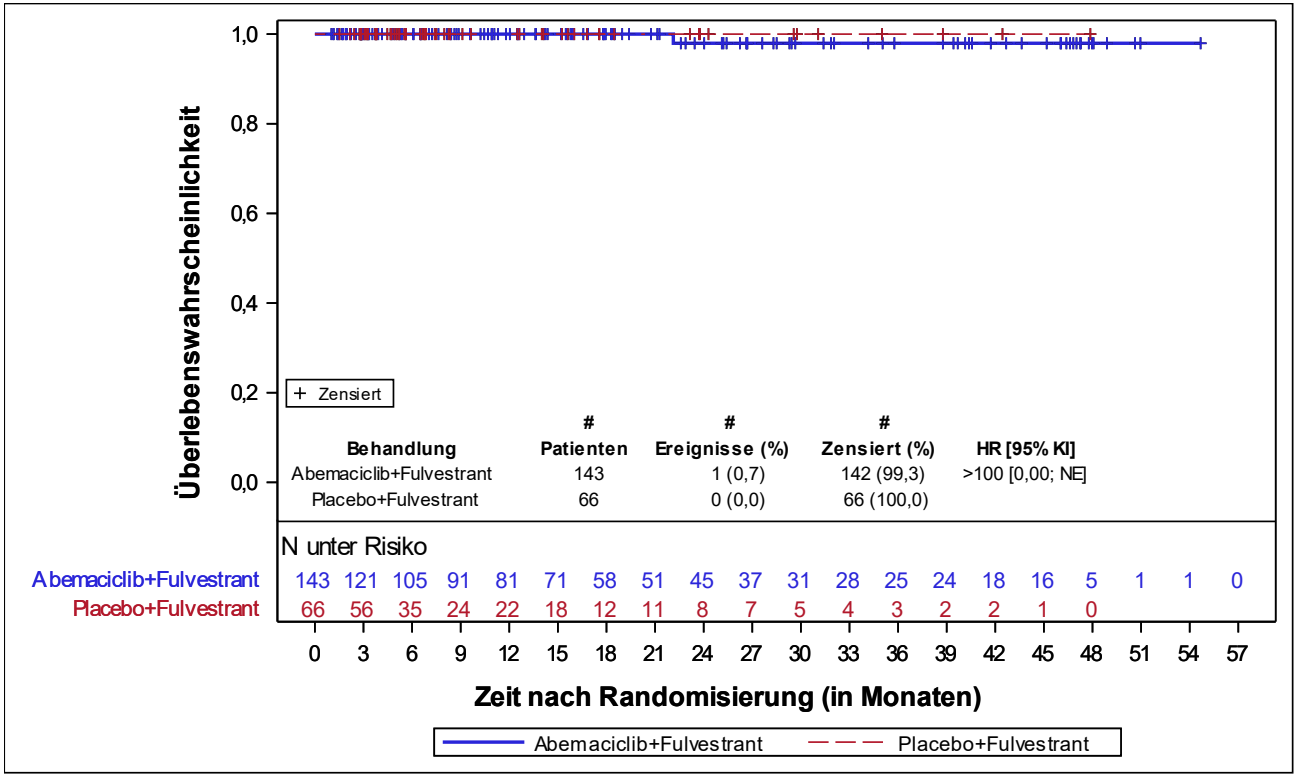
Abbildung 060: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Bilirubin im Blut erhöht Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttbi3aesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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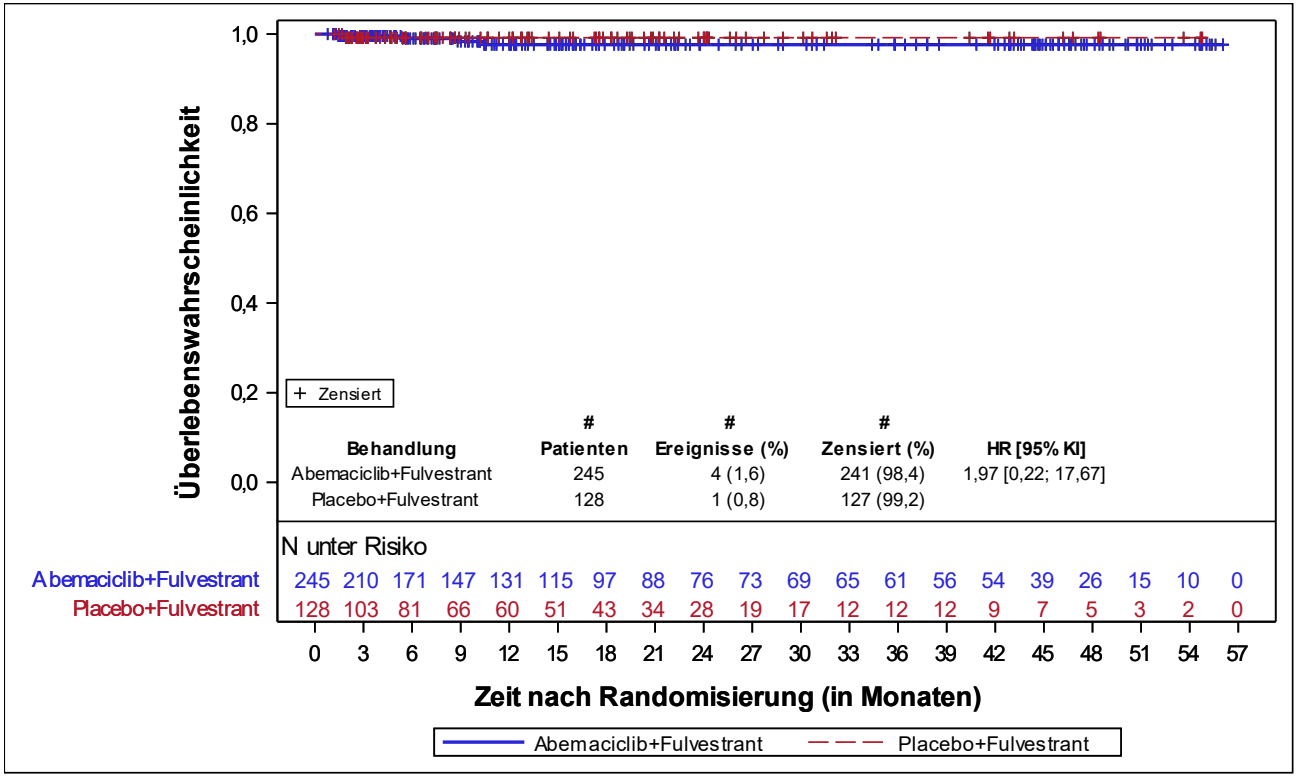
Abbildung 061: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Bilirubin im Blut erhöht Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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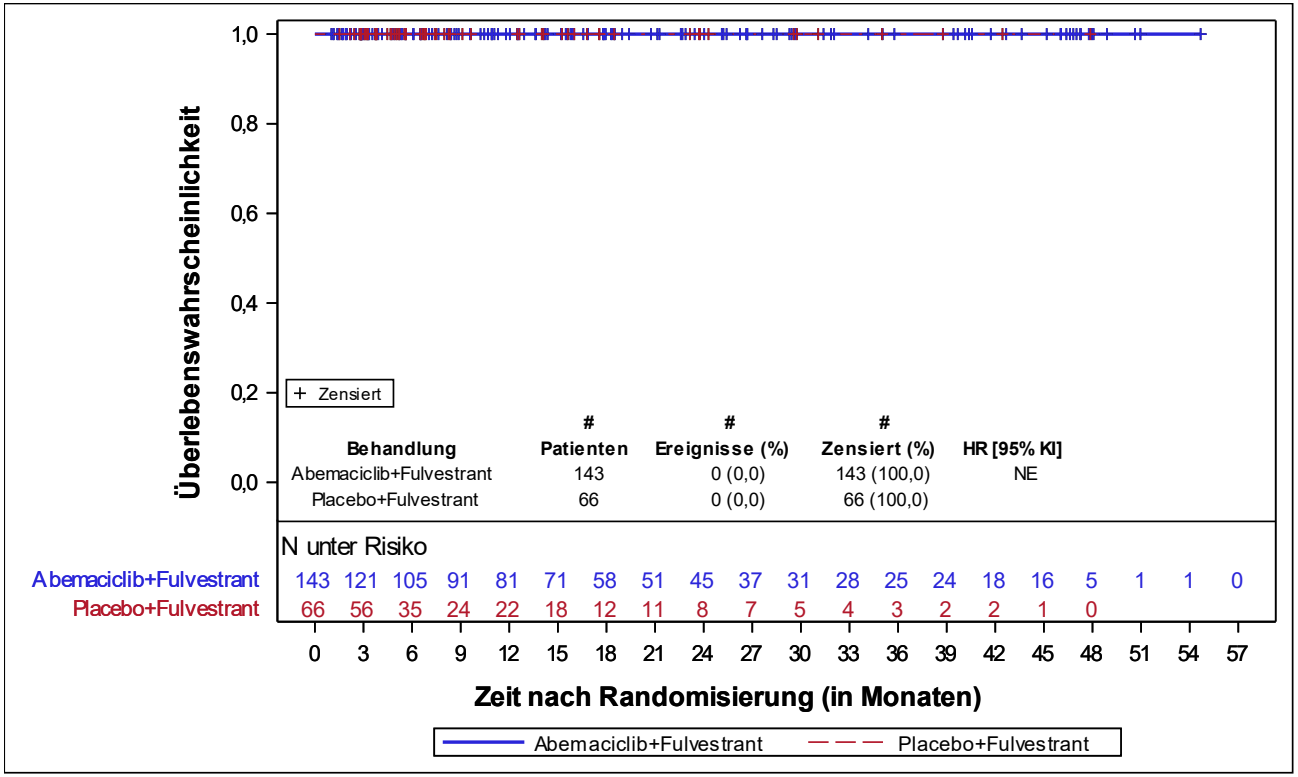
Abbildung 062: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Bilirubin im Blut erhöht Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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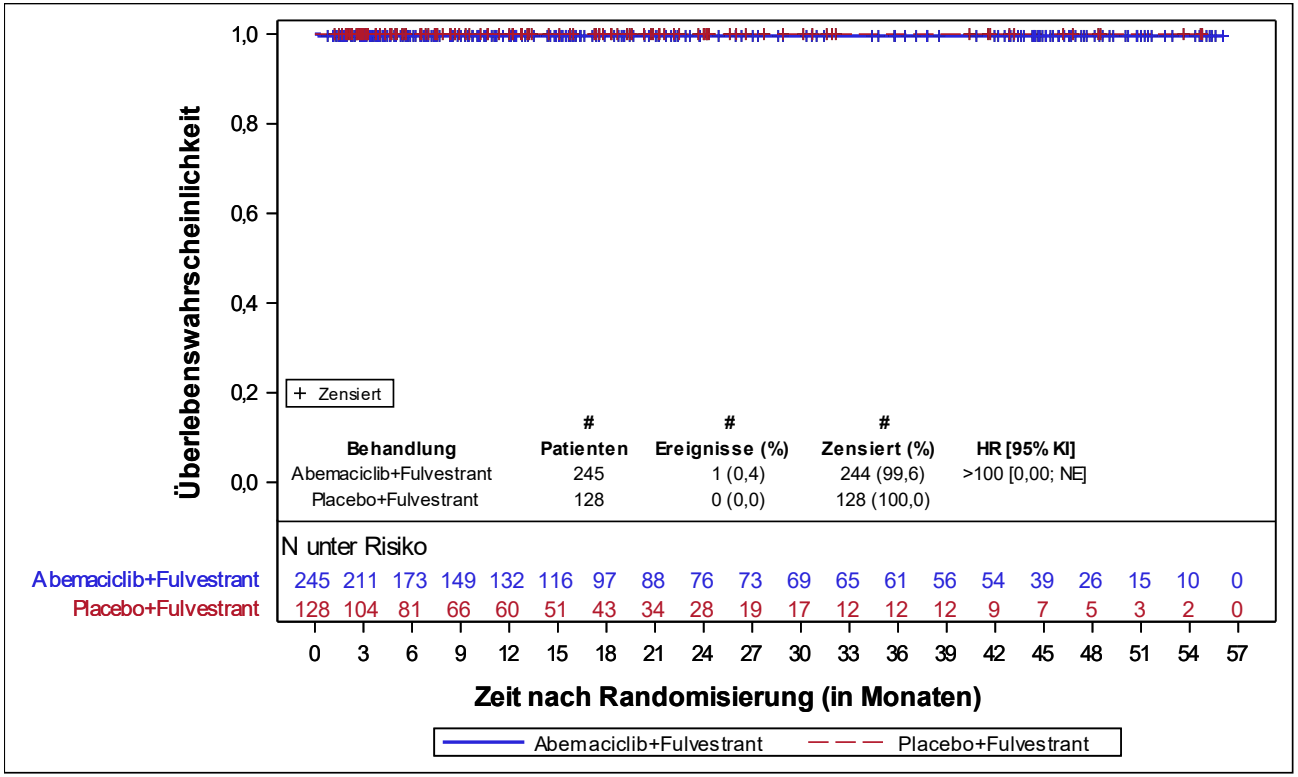
Abbildung 063: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Bilirubin im Blut erhöht Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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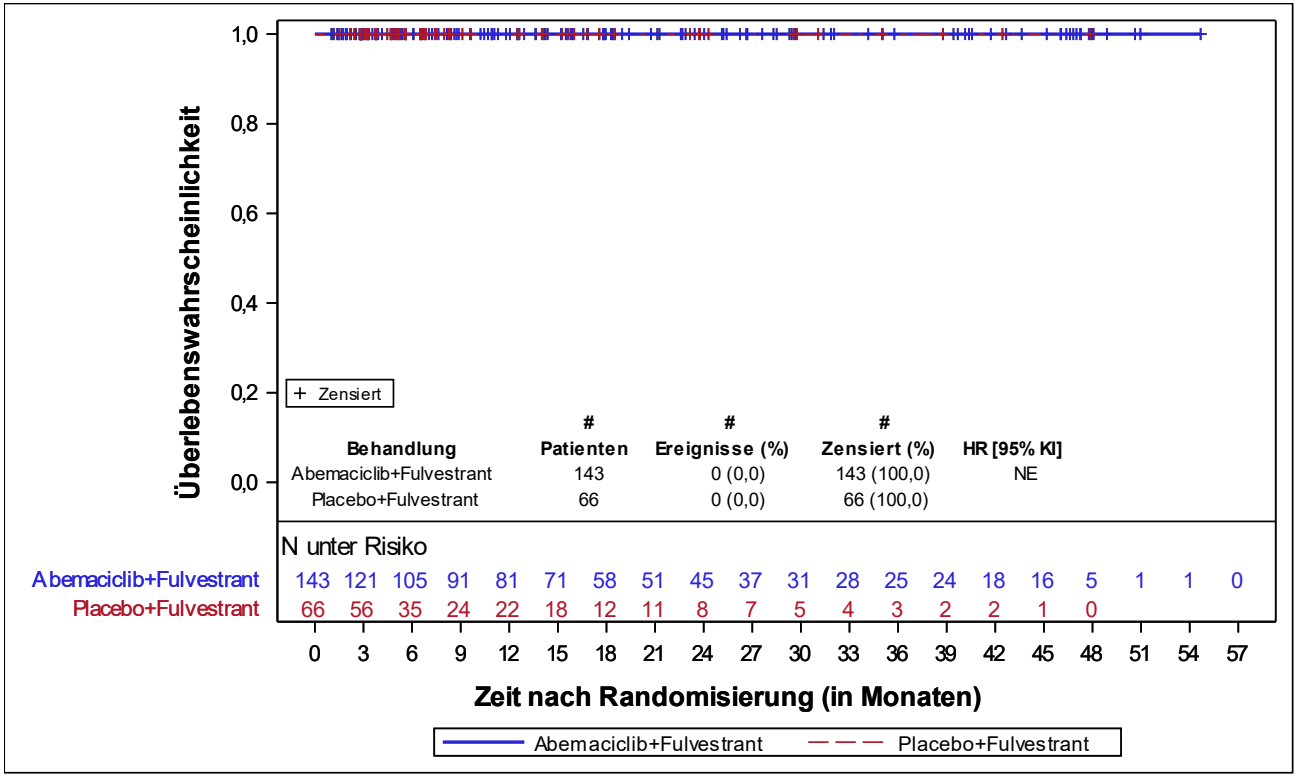
Abbildung 064: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Bilirubin im Blut erhöht Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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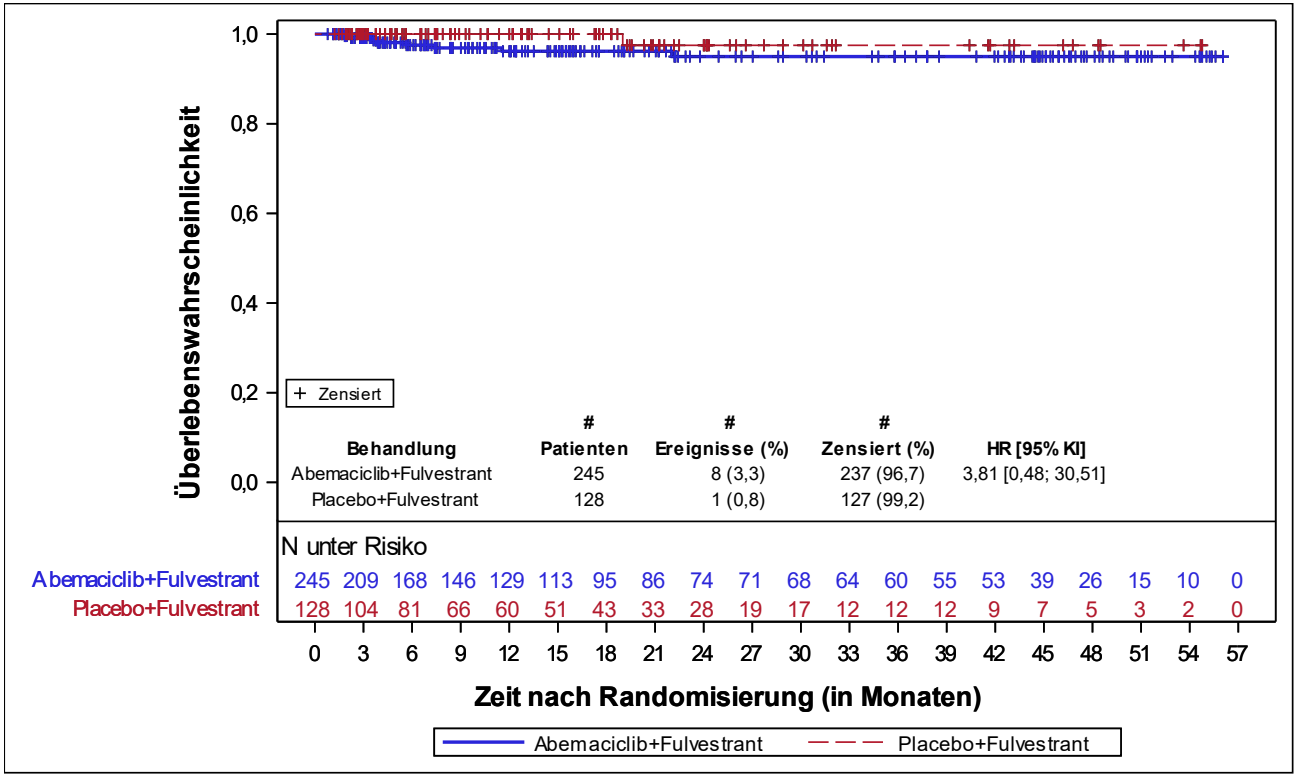
Abbildung 065: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Pneumonitis (jeglicher Schweregrad) Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttpnaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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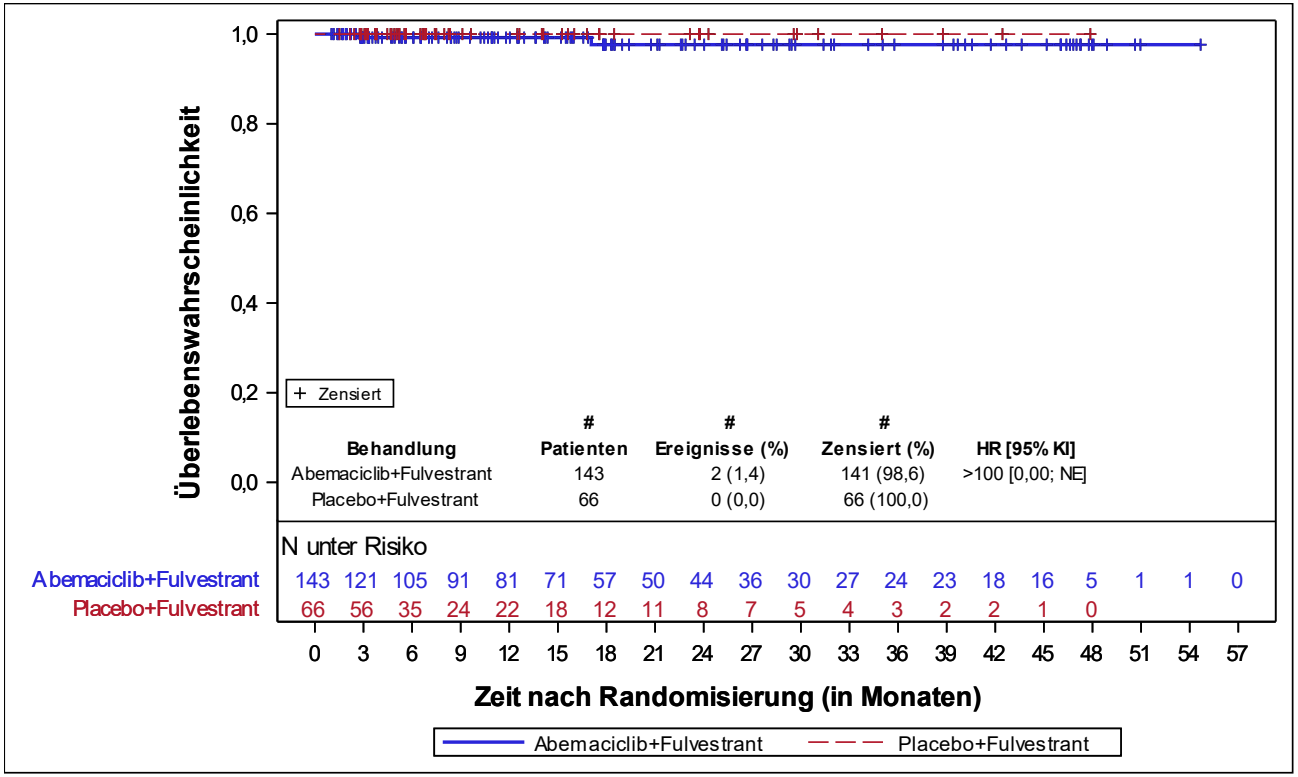
Abbildung 066: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Pneumonitis (jeglicher Schweregrad) Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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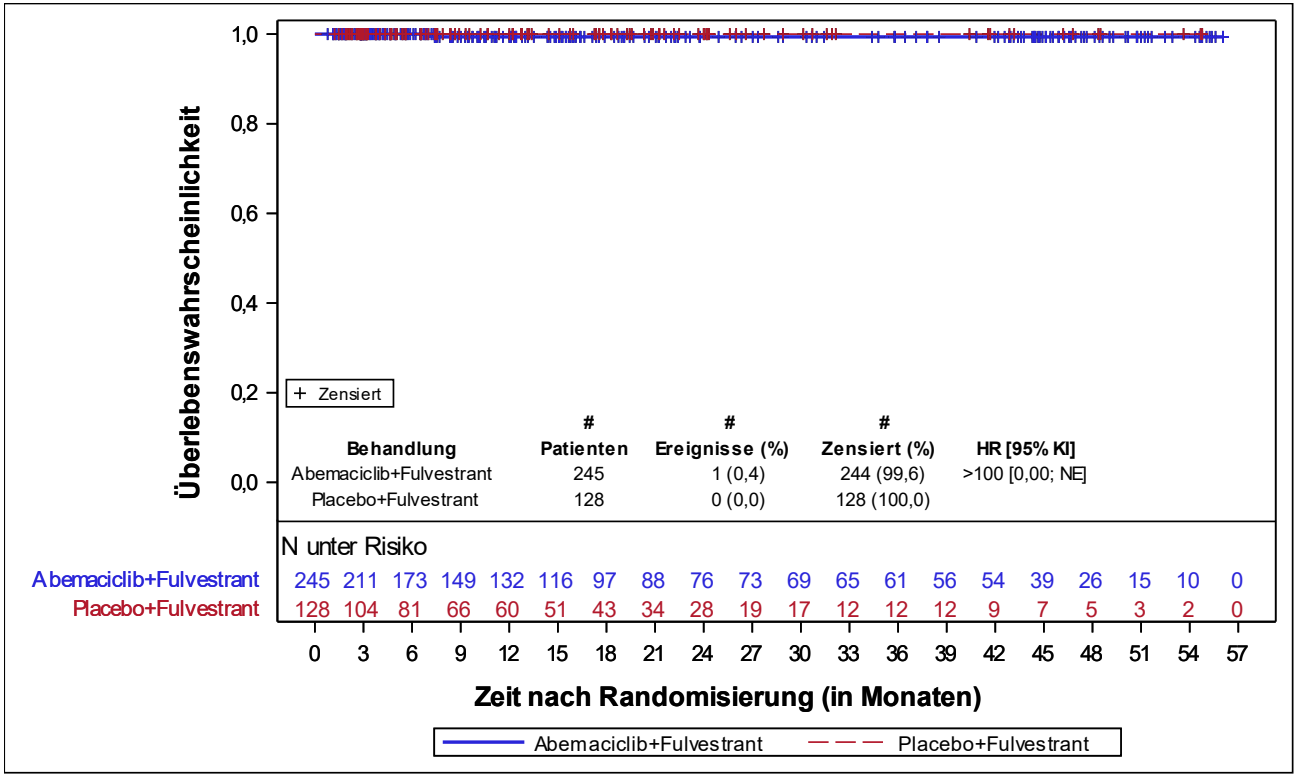
Abbildung 067: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Pneumonitis Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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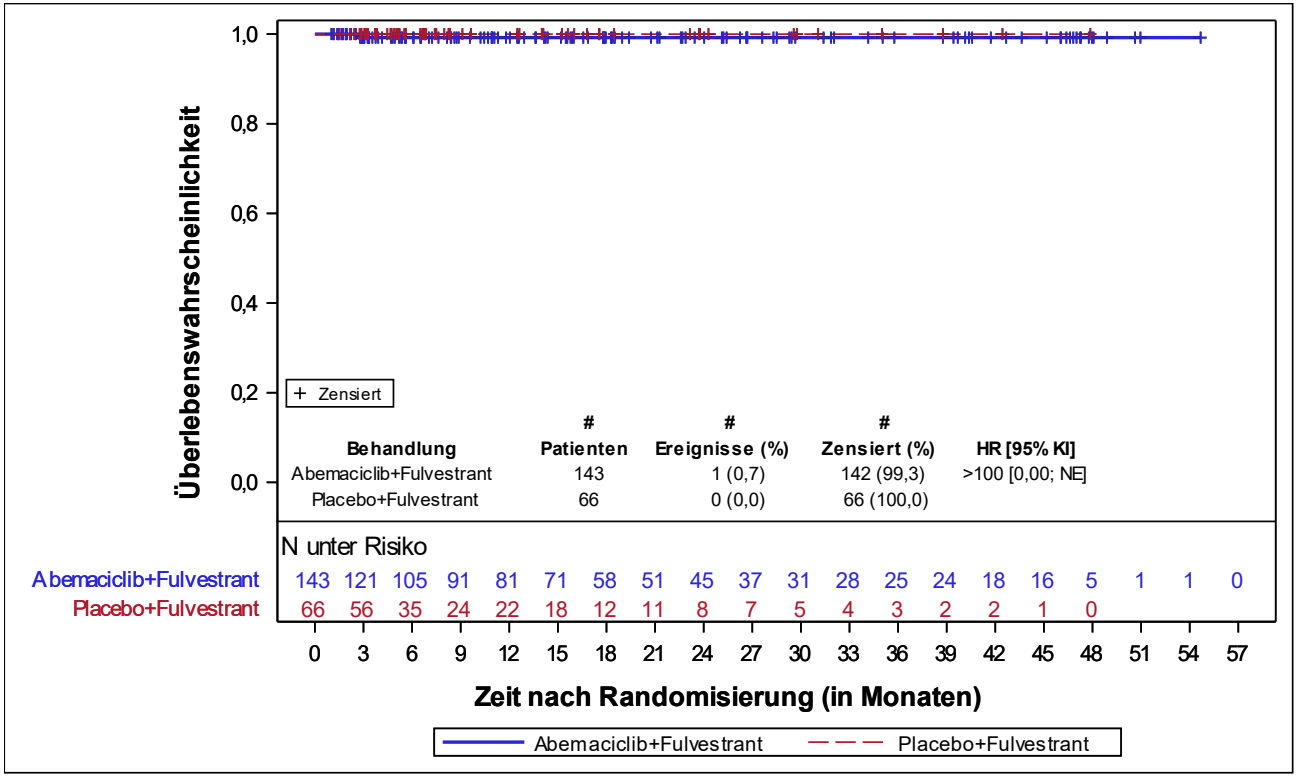
Abbildung 068: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Pneumonitis Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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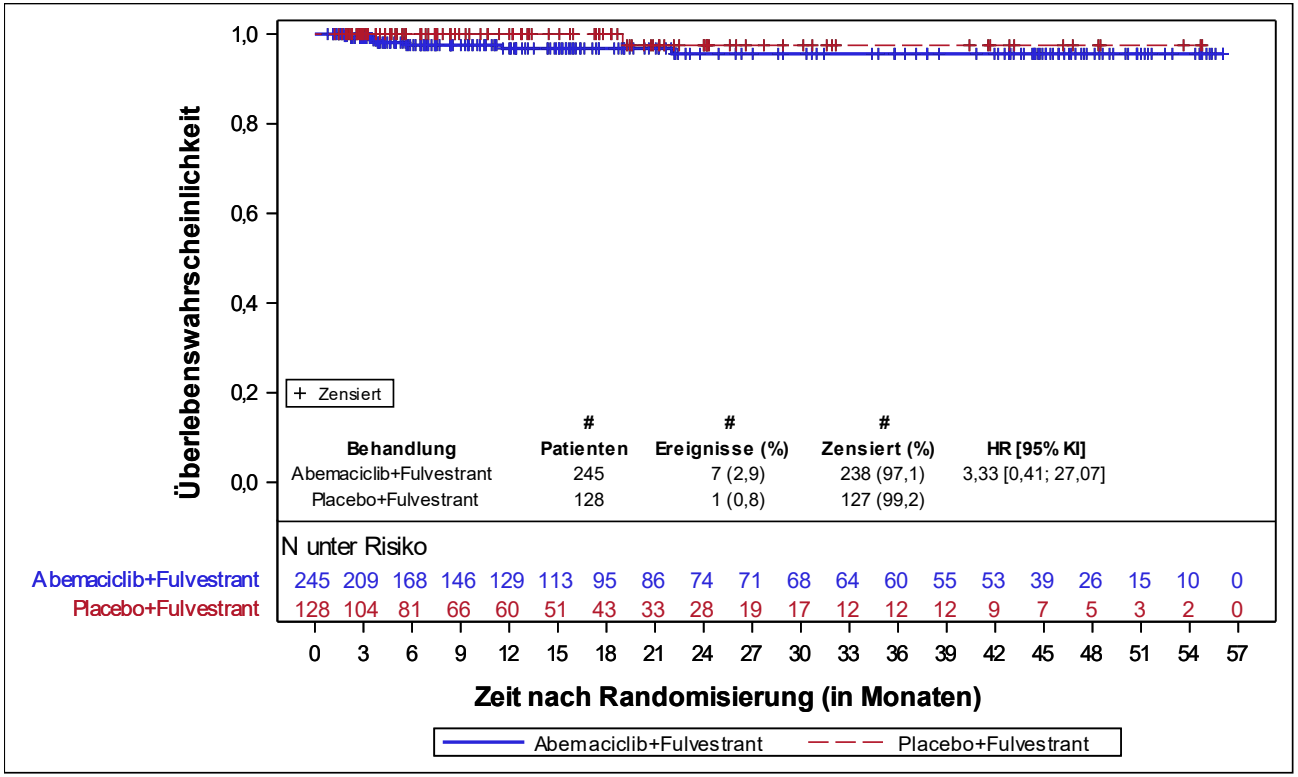
Abbildung 069: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Pneumonitis Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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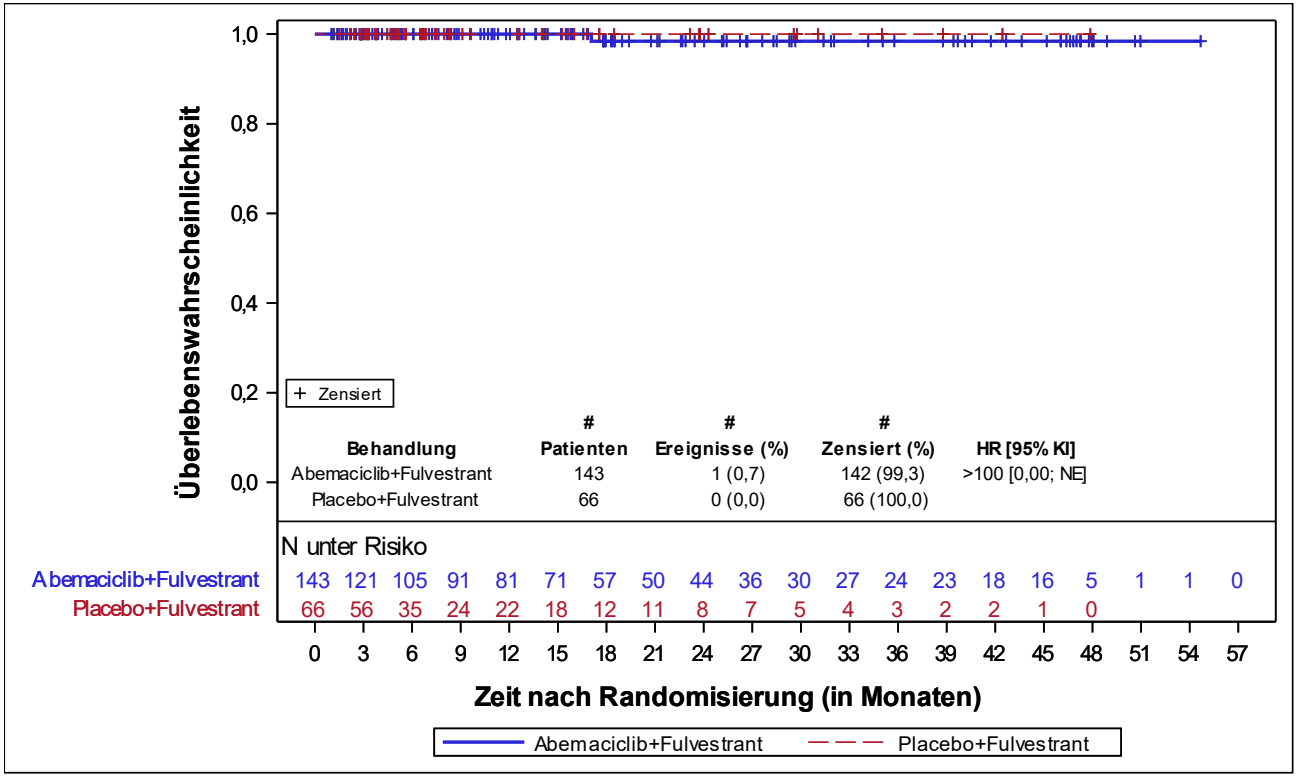
Abbildung 070: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Pneumonitis Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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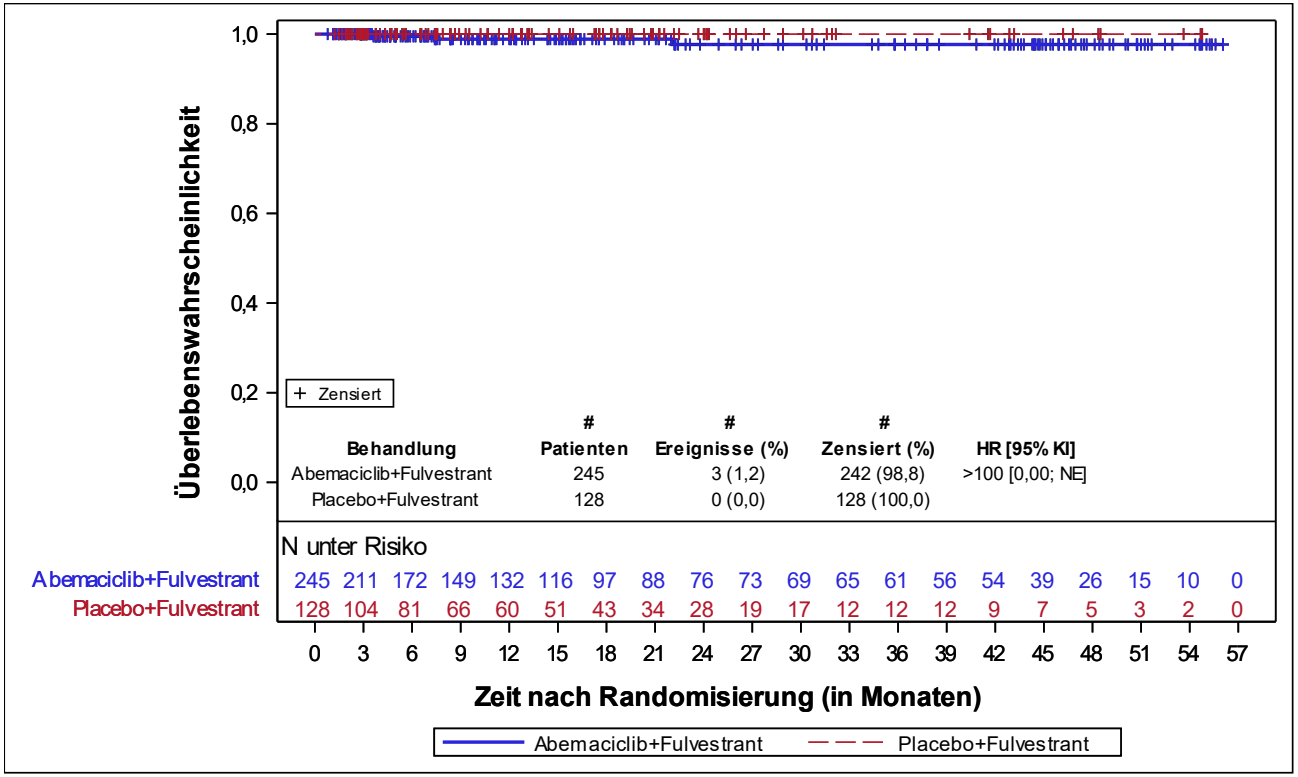
Abbildung 071: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Pneumonitis Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttpnsaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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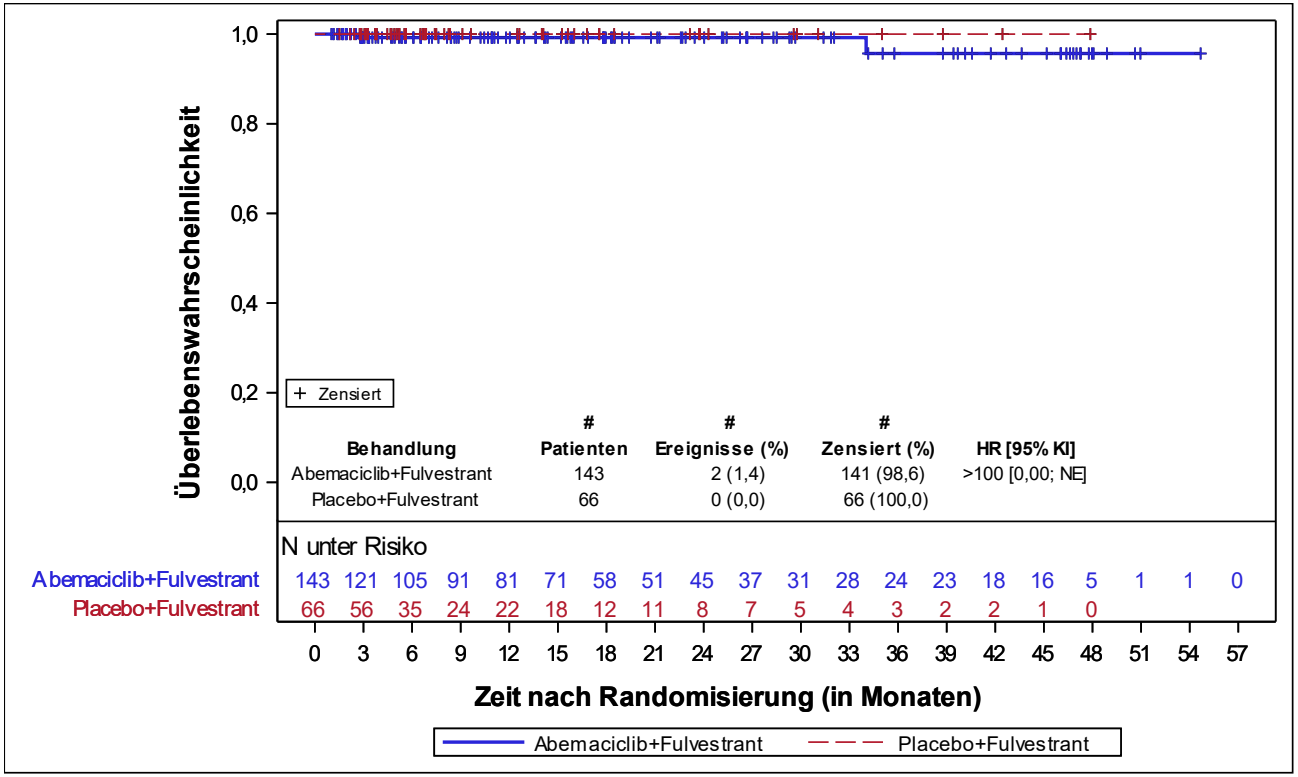
Abbildung 072: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Pneumonitis Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttpnsaesi_popa2.rtf
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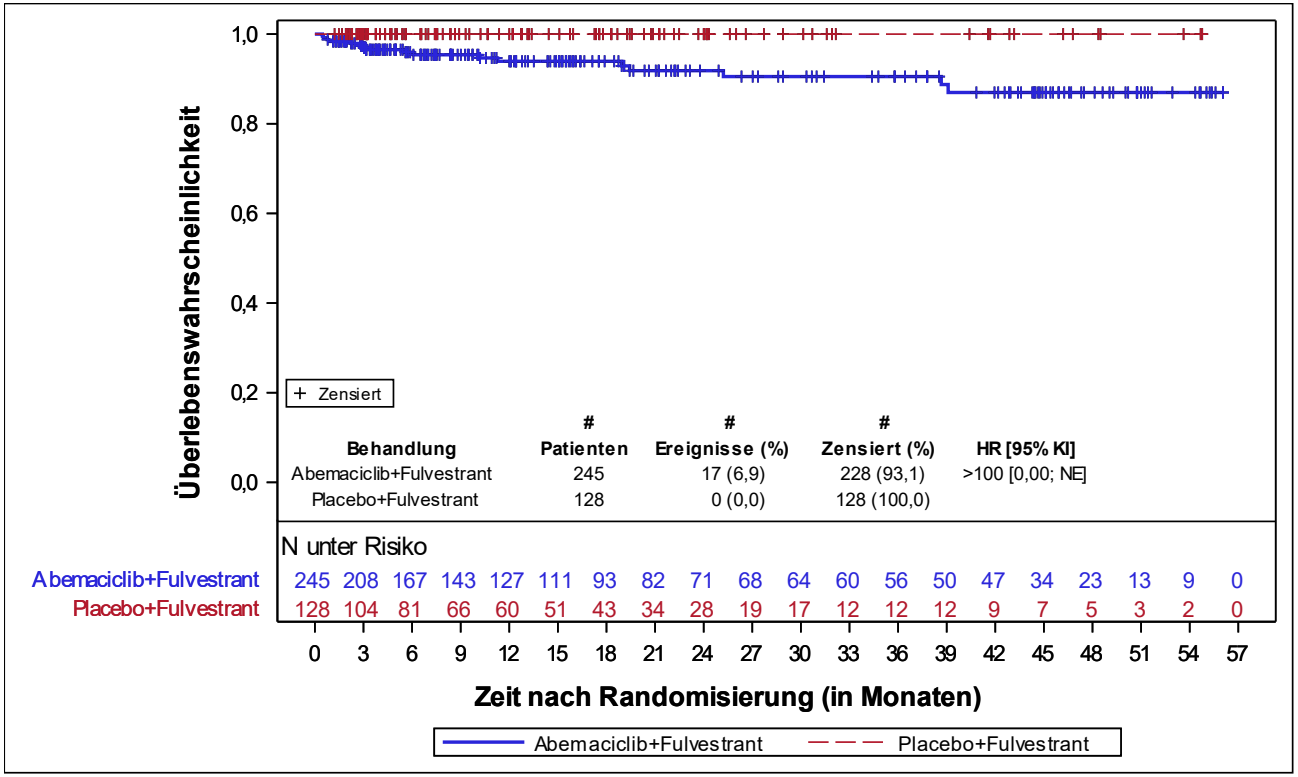
Abbildung 073: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad)
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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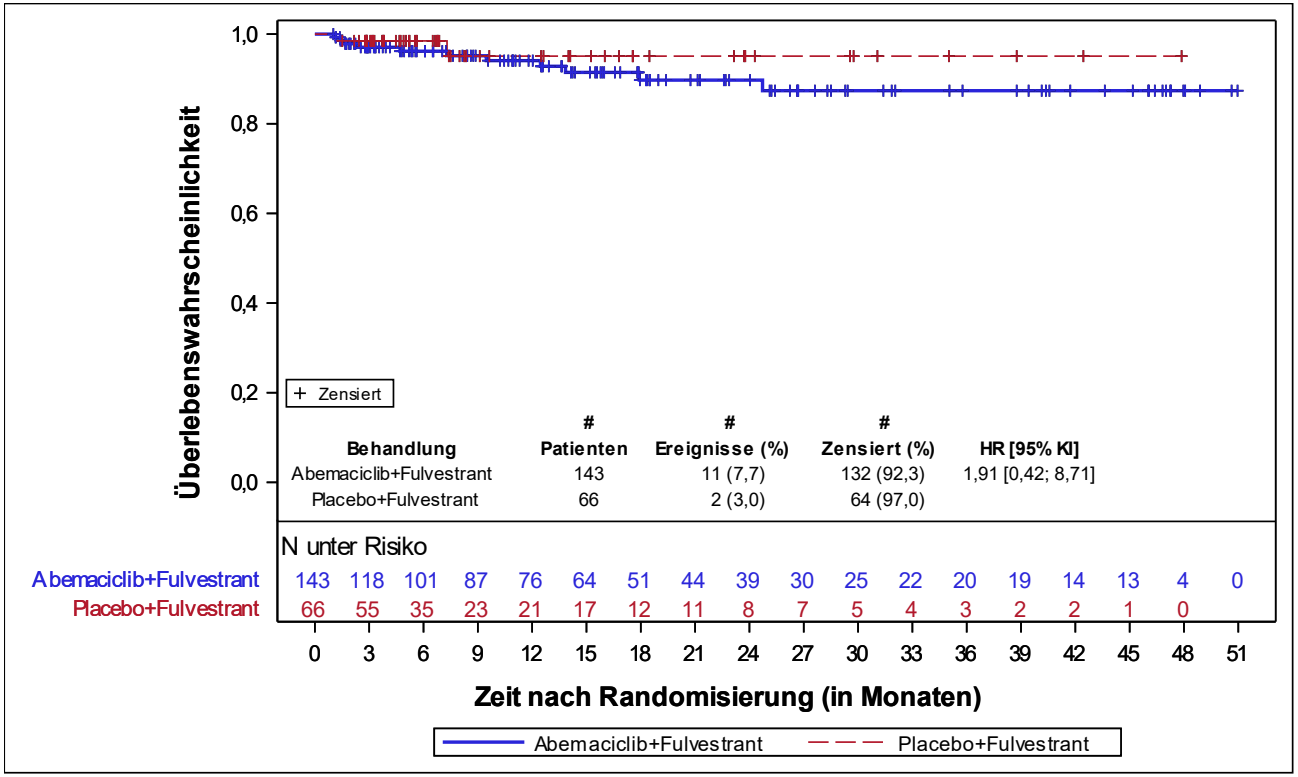
Abbildung 074: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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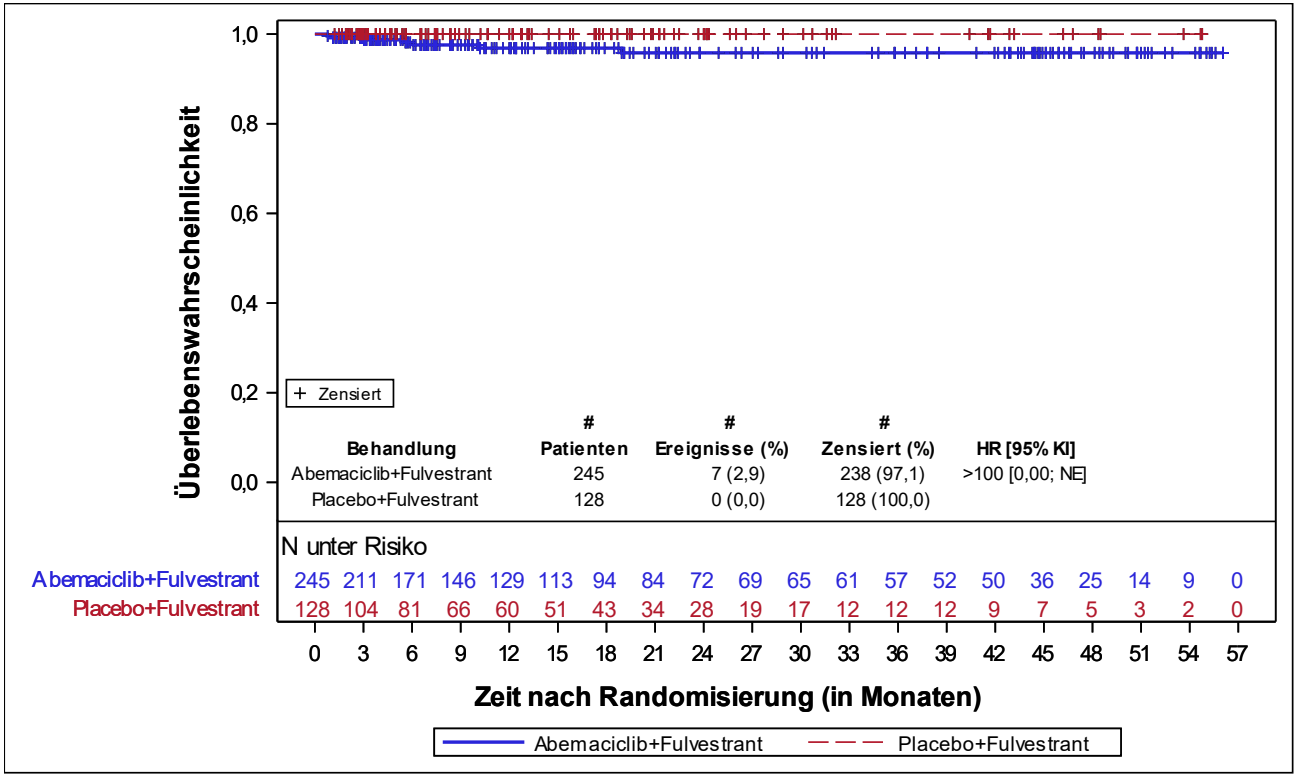
Abbildung 075: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Venöse Thromboembolie Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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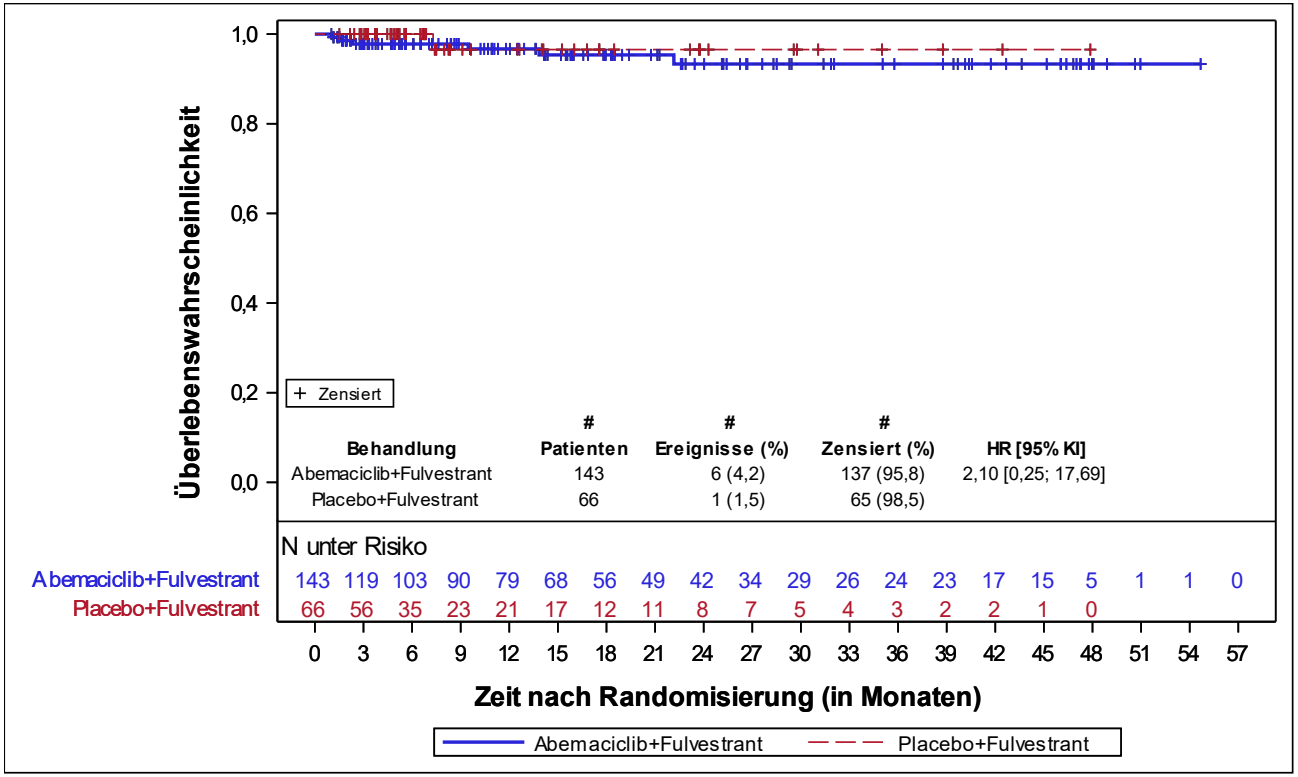
Abbildung 076: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Venöse Thromboembolie Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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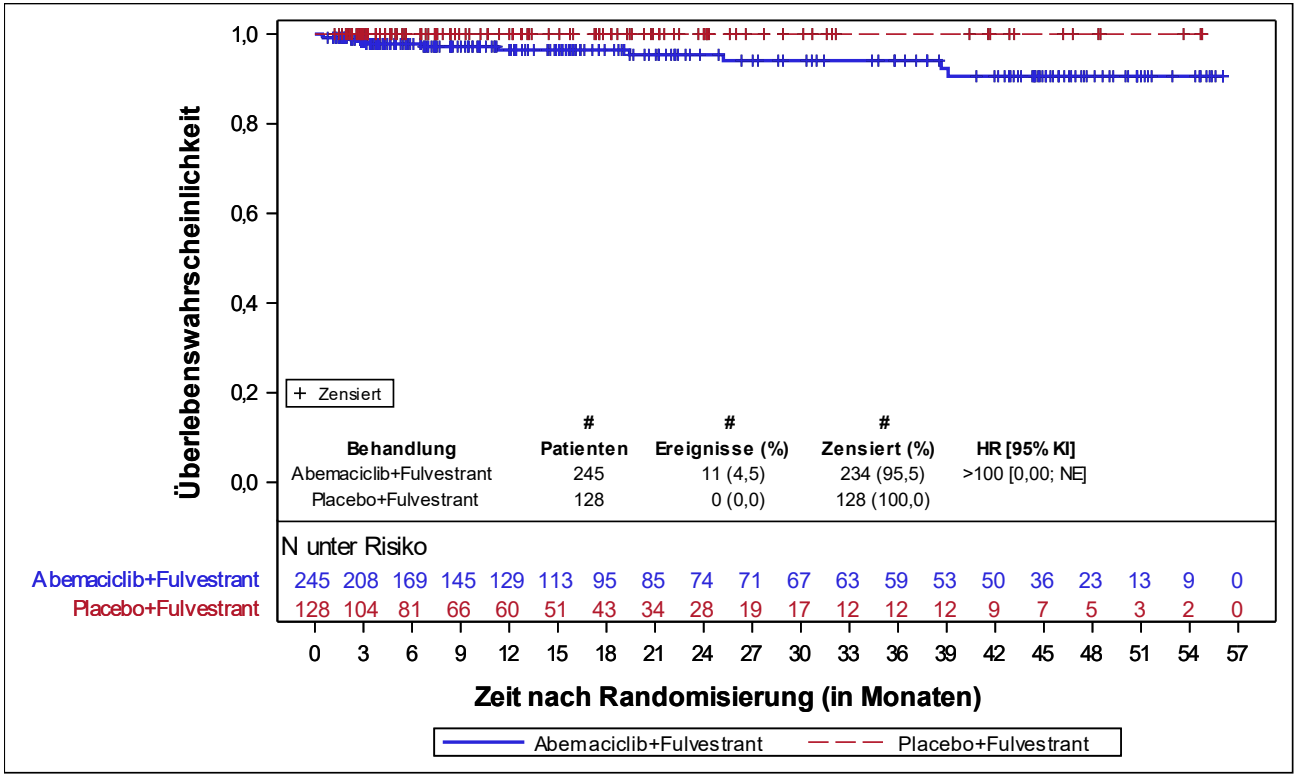
Abbildung 077: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Venöse Thromboembolie Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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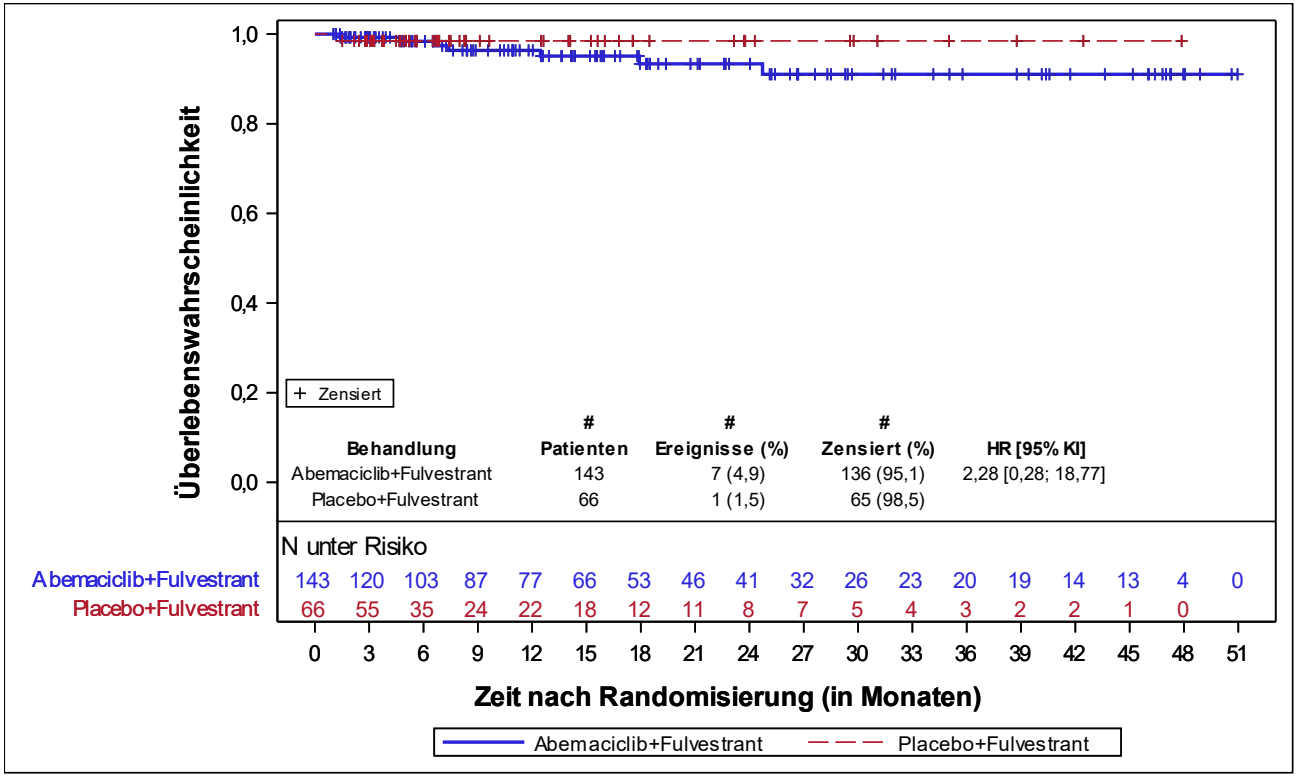
Abbildung 078: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Venöse Thromboembolie Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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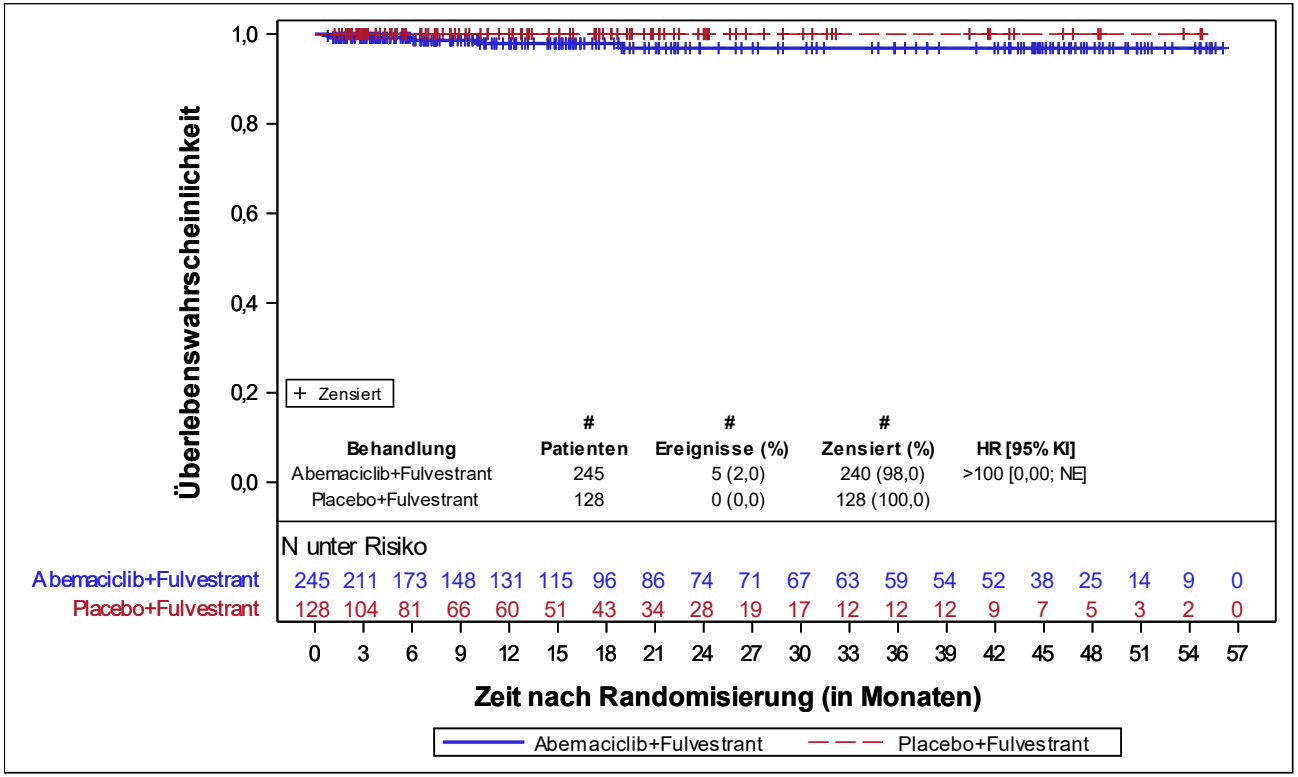
Abbildung 079: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: Venöse Thromboembolie Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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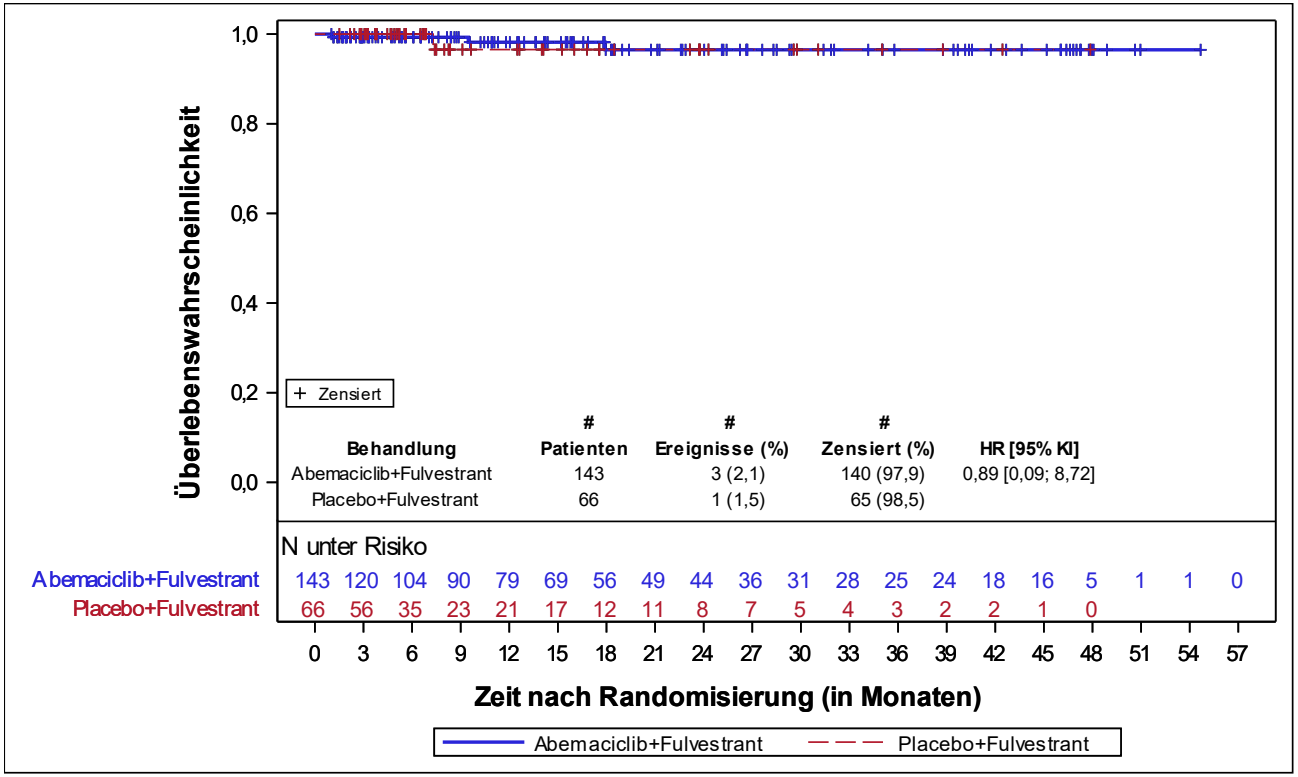
Abbildung 080: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: Venöse Thromboembolie Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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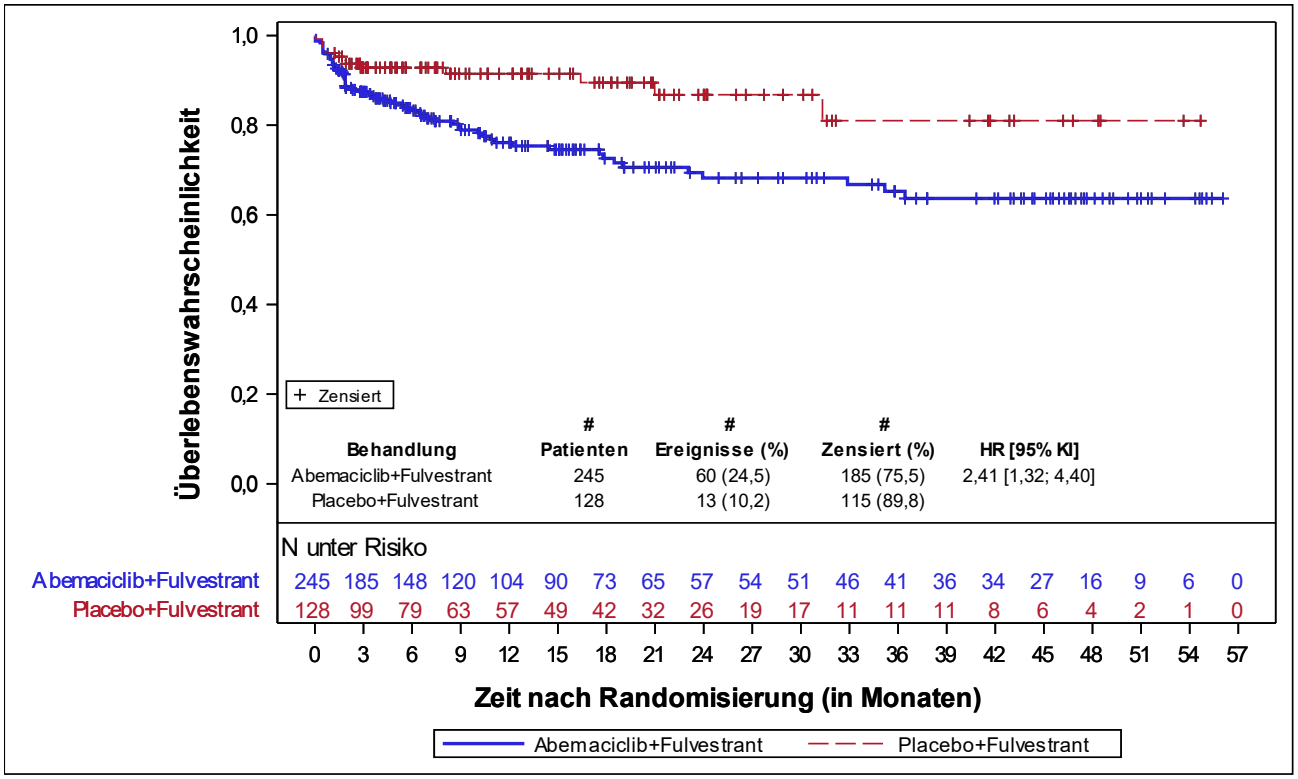
Abbildung 081: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad)
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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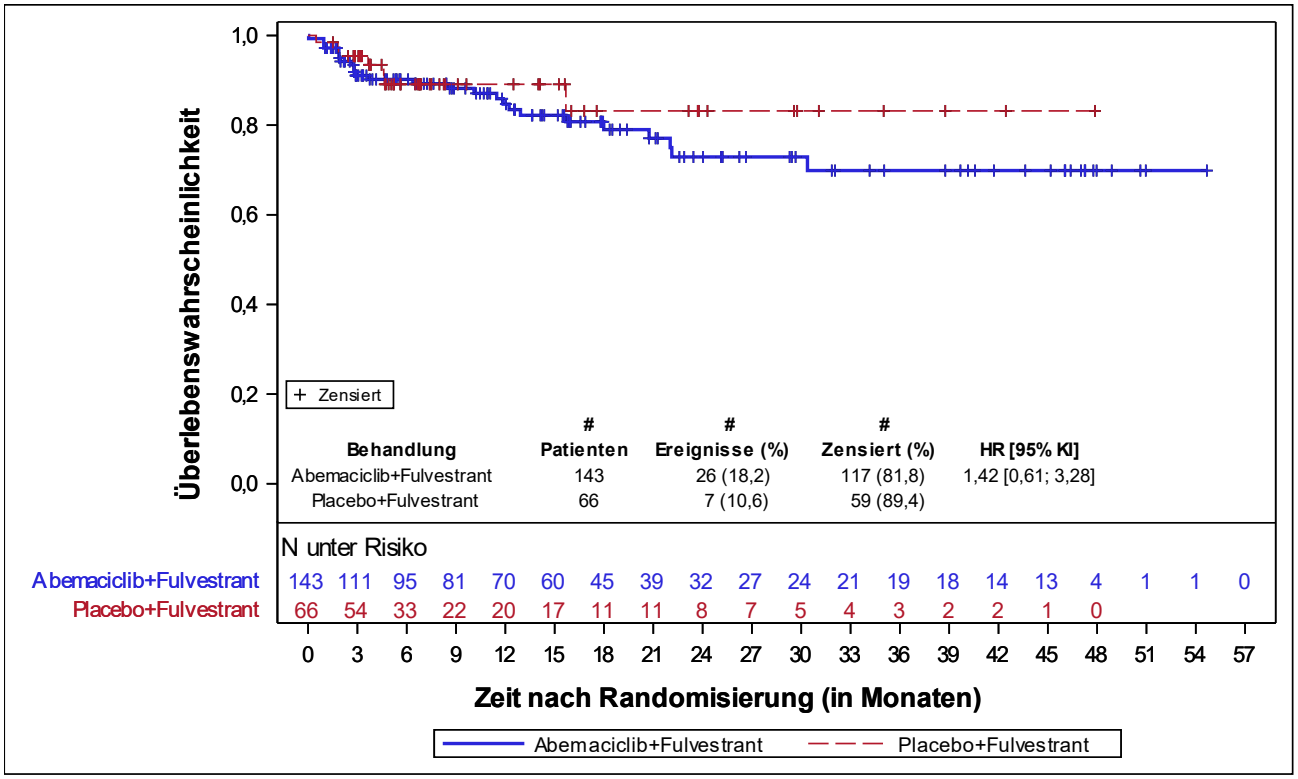
Abbildung 082: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad)
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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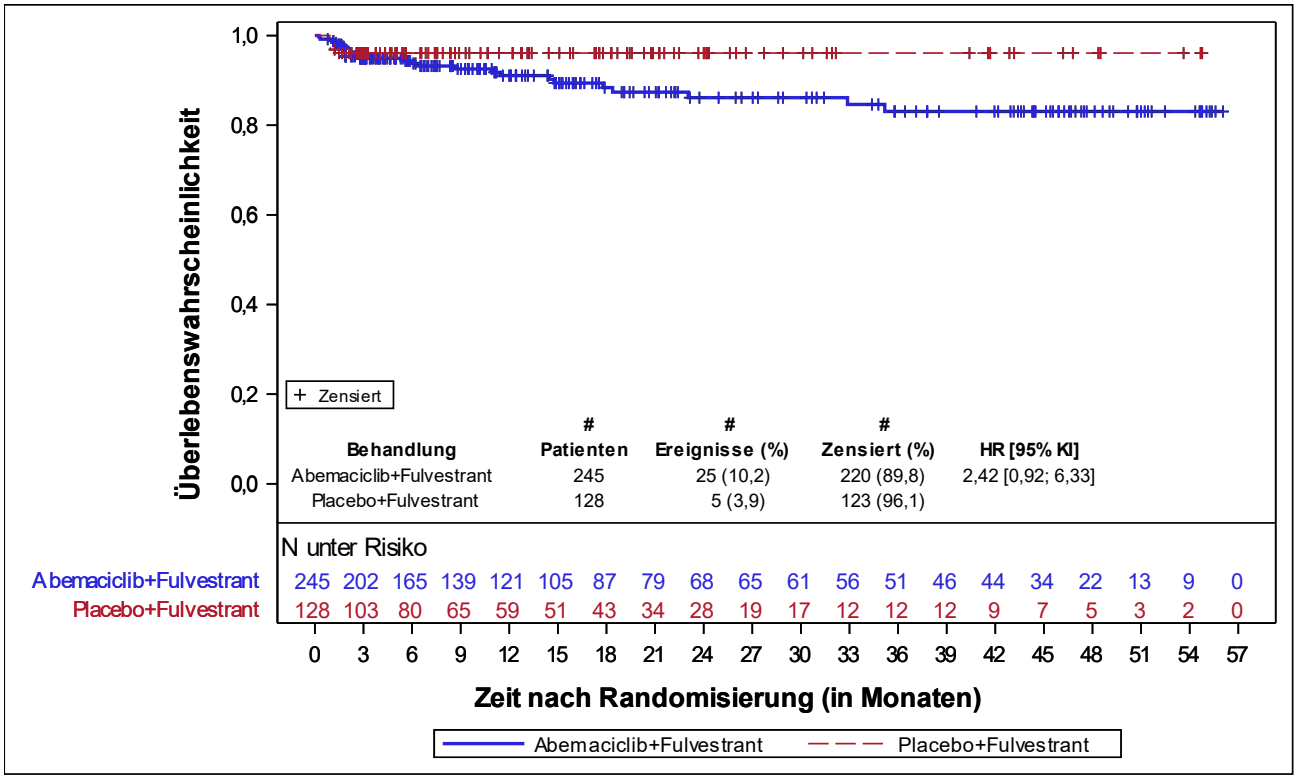
Abbildung 083: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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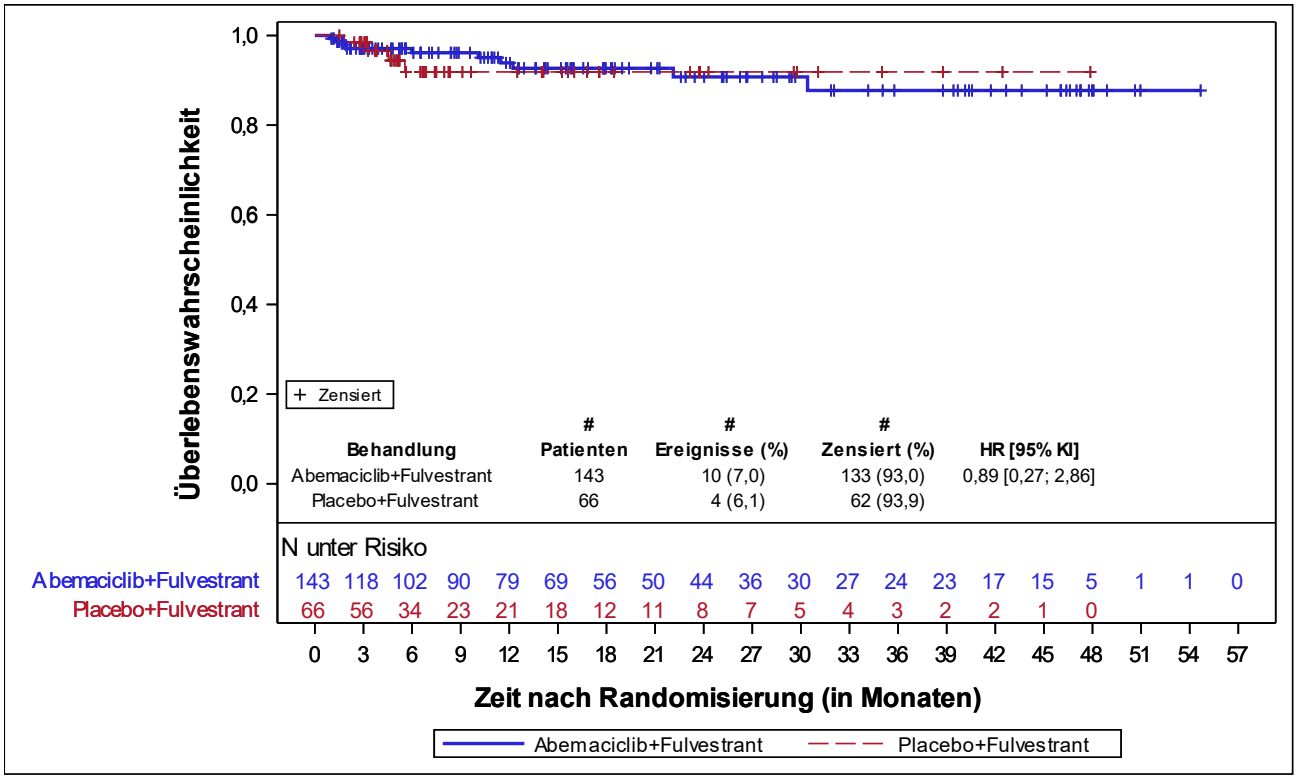
Abbildung 084: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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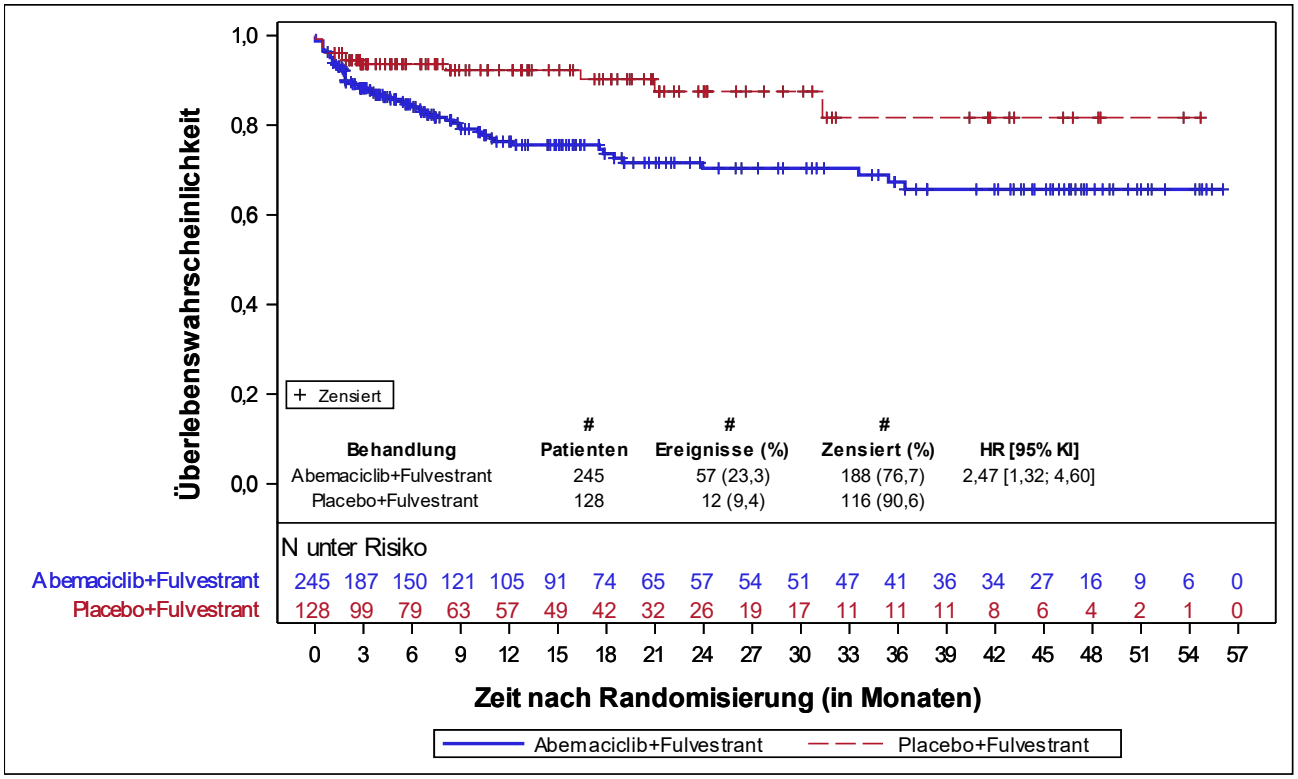
Abbildung 085: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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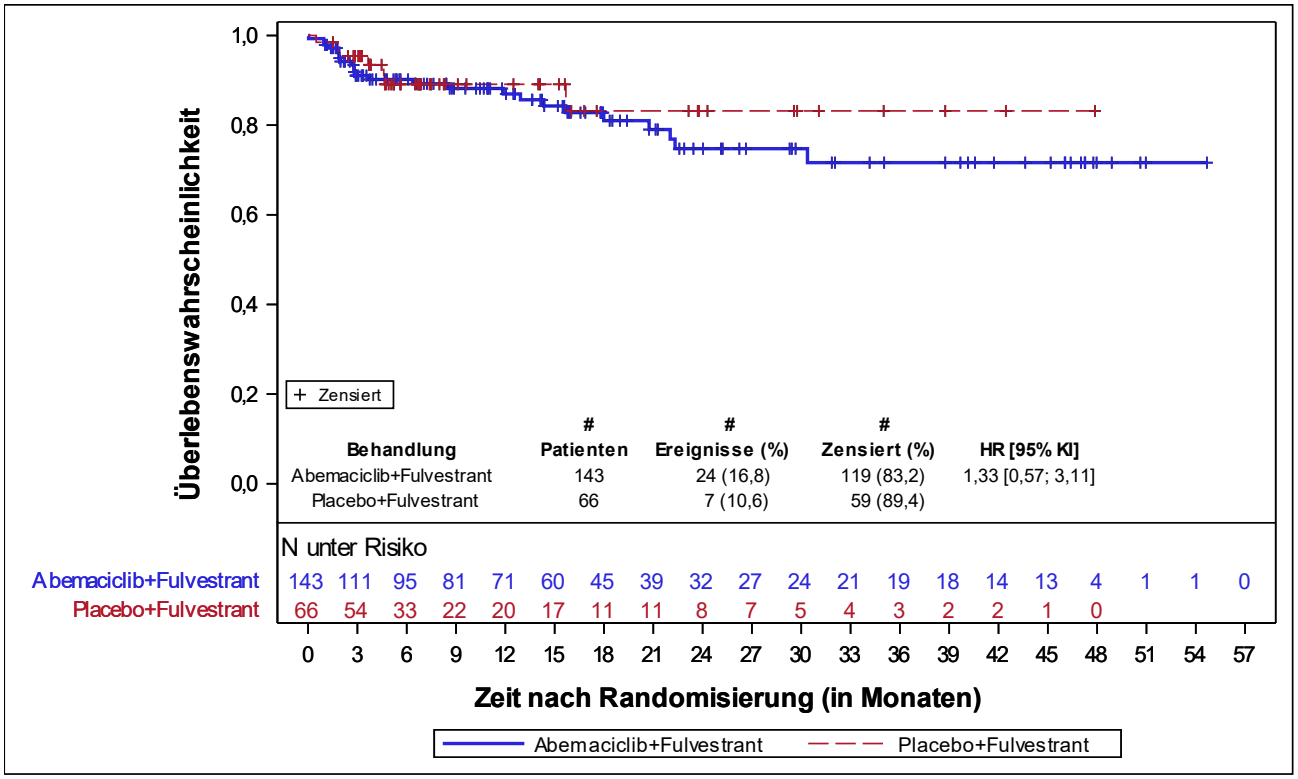
Abbildung 086: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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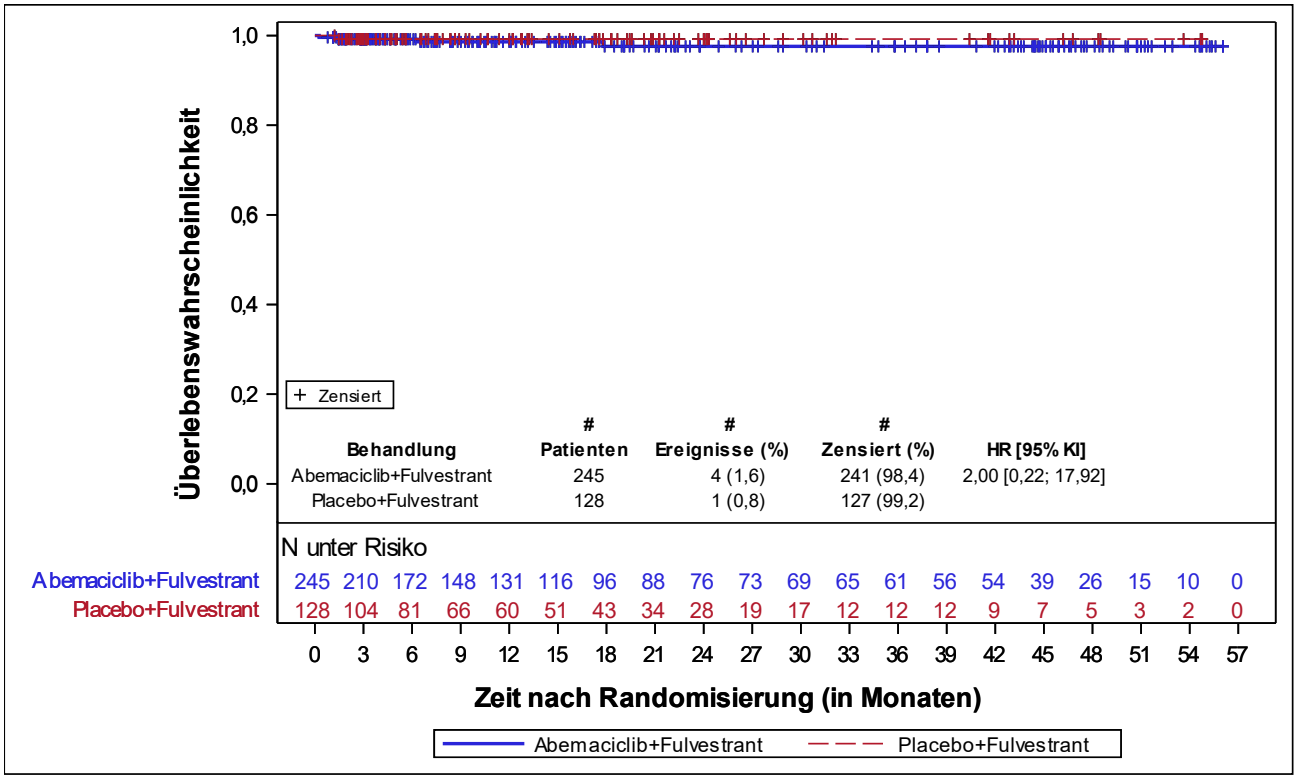
Abbildung 087: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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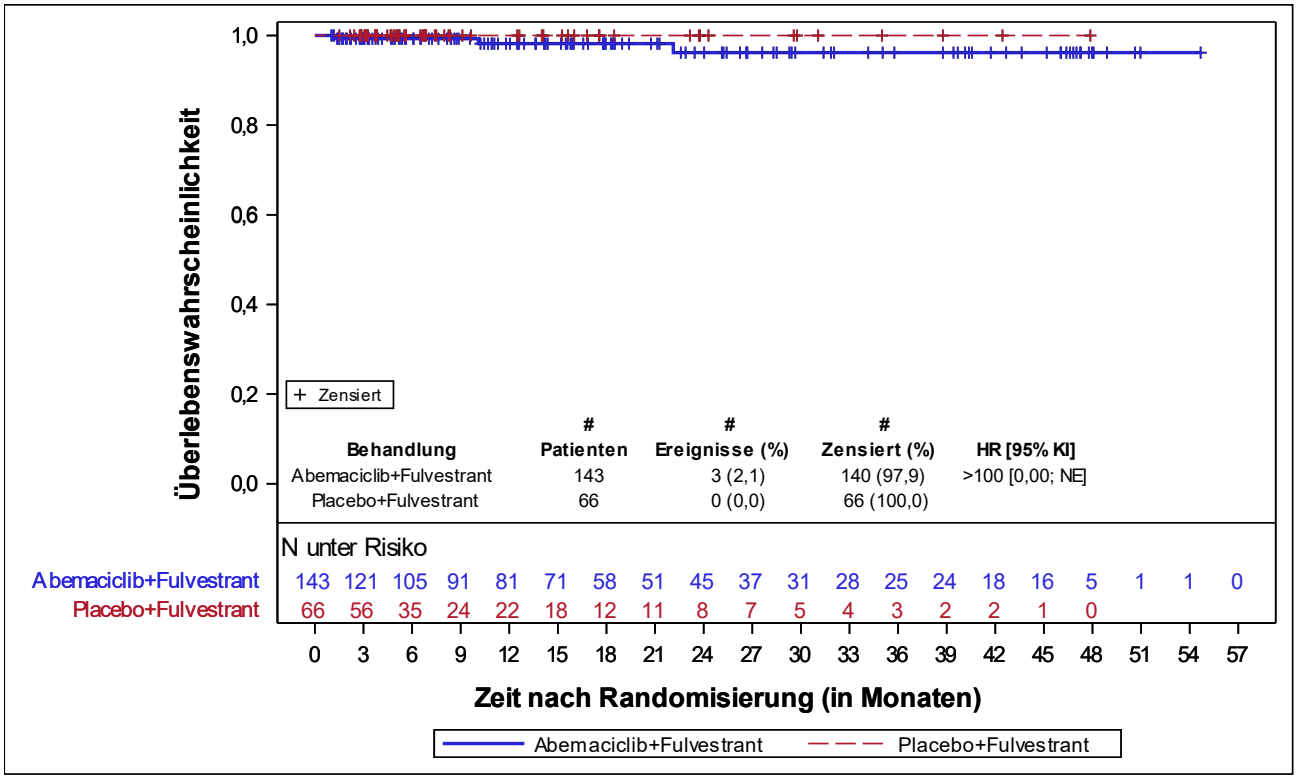
Abbildung 088: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km.sas
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Anhang 4-G1.4: Häufige unerwünschte Ereignisse nach SOC und PT - Safety-Population

Anhang 4-G1.4.1: Häufige unerwünschte Ereignisse jeglichen Schweregrades (Ereignisse die bei $\geq$ 10 % der Patienten oder mindestens 10 Patienten und $\geq$ 1% in mindestens einem Behandlungsarm auftraten)

Tabelle 4-115 (Anhang): Ergebnisse für UE jeglichen Grades nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (MONARCH-2, A1)

Table 012.1: Results for adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Gastrointestinal disorders	232/245 (94,7)	0,2 [0,13; 0,23]	81/128 (63,3)	3,7 [2,30; 7,96]	3,87 [2,97; 5,04] <,0001
Diarrhoea	210/245 (85,7)	0,3 [0,23; 0,39]	35/128 (27,3)	NE [24,92; NE]	7,36 [5,11; 10,60] <,0001
Nausea	125/245 (51,0)	16,1 [3,62; 31,33]	32/128 (25,0)	NE [39,42; NE]	2,46 [1,67; 3,63] <,0001
Abdominal pain	89/245 (36,3)	NE [34,22; NE]	23/128 (18,0)	49,8 [49,81; NE]	2,28 [1,44; 3,60] 0,0003
Vomiting	71/245 (29,0)	NE [50,37; NE]	15/128 (11,7)	NE [NE; NE]	2,60 [1,49; 4,55] 0,0005
Stomatitis	44/245 (18,0)	NE [NE; NE]	11/128 (8,6)	NE [NE; NE]	1,96 [1,01; 3,81] 0,0419
Constipation	36/245 (14,7)	NE [NE; NE]	20/128 (15,6)	NE [36,95; NE]	0,81 [0,47; 1,40] 0,4476
Dyspepsia	25/245 (10,2)	NE [NE; NE]	10/128 (7,8)	NE [NE; NE]	1,13 [0,54; 2,37] 0,7422
Dry mouth	21/245 (8,6)	NE [NE; NE]	5/128 (3,9)	NE [NE; NE]	2,14 [0,81; 5,68] 0,1187

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Gastrooesophageal reflux disease	17/245 (6,9)	NE [NE; NE]	4/128 (3,1)	NE [NE; NE]	2,04 [0,68; 6,07] 0,1922
Abdominal distension	11/245 (4,5)	NE [NE; NE]	2/128 (1,6)	NE [NE; NE]	2,52 [0,55; 11,41] 0,2161
General disorders and administration site conditions	168/245 (68,6)	4,7 [2,60; 6,97]	60/128 (46,9)	13,2 [6,21; 39,42]	1,64 [1,22; 2,21] 0,0008
Fatigue	120/245 (49,0)	14,8 [7,50; 36,85]	39/128 (30,5)	46,5 [42,18; NE]	1,74 [1,21; 2,49] 0,0025
Oedema peripheral	39/245 (15,9)	NE [NE; NE]	10/128 (7,8)	NE [NE; NE]	1,88 [0,93; 3,77] 0,0721
Pyrexia	31/245 (12,7)	NE [NE; NE]	8/128 (6,3)	NE [NE; NE]	1,78 [0,82; 3,89] 0,1410
Influenza like illness	21/245 (8,6)	NE [NE; NE]	7/128 (5,5)	NE [NE; NE]	1,31 [0,56; 3,10] 0,5332
Chills	19/245 (7,8)	NE [NE; NE]	1/128 (0,8)	NE [NE; NE]	9,58 [1,28; 71,51] 0,0069
Pain	17/245 (6,9)	NE [NE; NE]	7/128 (5,5)	NE [NE; NE]	1,03 [0,43; 2,49] 0,9479
Injection site reaction	16/245 (6,5)	NE [NE; NE]	9/128 (7,0)	NE [NE; NE]	0,85 [0,37; 1,92] 0,6930

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Non-cardiac chest pain	14/245 (5,7)	NE [NE; NE]	5/128 (3,9)	NE [NE; NE]	1,15 [0,41; 3,24] 0,7879
Localised oedema	10/245 (4,1)	NE [NE; NE]	2/128 (1,6)	NE [NE; NE]	2,11 [0,46; 9,73] 0,3265
Blood and lymphatic system disorders	142/245 (58,0)	5,5 [2,56; 14,04]	14/128 (10,9)	51,6 [40,57; NE]	7,92 [4,57; 13,74] <,0001
Neutropenia	111/245 (45,3)	18,4 [10,36; 46,82]	3/128 (2,3)	NE [NE; NE]	24,77 [7,87; 78,02] <,0001
Anaemia	77/245 (31,4)	42,2 [36,82; NE]	7/128 (5,5)	NE [51,55; NE]	6,09 [2,81; 13,21] <,0001
Leukopenia	73/245 (29,8)	NE [41,26; NE]	2/128 (1,6)	NE [NE; NE]	20,45 [5,02; 83,34] <,0001
Thrombocytopenia	37/245 (15,1)	NE [NE; NE]	3/128 (2,3)	NE [NE; NE]	6,45 [1,99; 20,95] 0,0003
Lymphopenia	22/245 (9,0)	NE [NE; NE]	1/128 (0,8)	NE [NE; NE]	9,73 [1,31; 72,35] 0,0064
Nervous system disorders	121/245 (49,4)	17,1 [8,32; 26,40]	40/128 (31,3)	31,5 [19,36; NE]	1,65 [1,15; 2,36] 0,0056
Headache	54/245 (22,0)	NE [NE; NE]	14/128 (10,9)	NE [NE; NE]	1,87 [1,04; 3,38] 0,0345

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Dysgeusia	46/245 (18,8)	NE [NE; NE]	4/128 (3,1)	NE [NE; NE]	6,47 [2,33; 17,97] <,0001
Dizziness	45/245 (18,4)	NE [NE; NE]	12/128 (9,4)	NE [NE; NE]	1,81 [0,95; 3,43] 0,0663
Neuropathy	24/245 (9,8)	NE [NE; NE]	13/128 (10,2)	NE [NE; NE]	0,82 [0,42; 1,63] 0,5788
Musculoskeletal and connective tissue disorders	118/245 (48,2)	13,4 [8,22; 21,86]	57/128 (44,5)	15,6 [7,86; 25,84]	0,99 [0,72; 1,36] 0,9614
Arthralgia	43/245 (17,6)	NE [NE; NE]	16/128 (12,5)	NE [NE; NE]	1,21 [0,68; 2,16] 0,5088
Back pain	32/245 (13,1)	NE [NE; NE]	20/128 (15,6)	NE [35,70; NE]	0,65 [0,37; 1,15] 0,1366
Muscular weakness	32/245 (13,1)	NE [NE; NE]	9/128 (7,0)	NE [NE; NE]	1,76 [0,84; 3,70] 0,1284
Pain in extremity	32/245 (13,1)	NE [NE; NE]	8/128 (6,3)	NE [NE; NE]	1,94 [0,89; 4,21] 0,0882
Myalgia	24/245 (9,8)	NE [NE; NE]	9/128 (7,0)	NE [NE; NE]	1,30 [0,61; 2,81] 0,4968
Bone pain	12/245 (4,9)	NE [NE; NE]	10/128 (7,8)	NE [NE; NE]	0,51 [0,22; 1,20] 0,1156

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Skin and subcutaneous tissue disorders	117/245 (47,8)	8,5 [6,31; 19,04]	29/128 (22,7)	NE [33,30; NE]	2,38 [1,58; 3,57] <,0001
Alopecia	46/245 (18,8)	NE [NE; NE]	4/128 (3,1)	NE [NE; NE]	6,14 [2,21; 17,06] <,0001
Rash	34/245 (13,9)	NE [NE; NE]	7/128 (5,5)	NE [NE; NE]	2,47 [1,09; 5,58] 0,0245
Pruritus	28/245 (11,4)	NE [NE; NE]	10/128 (7,8)	NE [NE; NE]	1,39 [0,67; 2,86] 0,3716
Dry skin	22/245 (9,0)	NE [NE; NE]	5/128 (3,9)	NE [NE; NE]	1,90 [0,71; 5,05] 0,1935
Dermatitis acneiform	11/245 (4,5)	NE [NE; NE]	5/128 (3,9)	NE [NE; NE]	1,06 [0,37; 3,08] 0,9098
Nail ridging	11/245 (4,5)	NE [NE; NE]	1/128 (0,8)	NE [NE; NE]	5,09 [0,66; 39,46] 0,0830
Metabolism and nutrition disorders	114/245 (46,5)	18,8 [12,07; 39,75]	30/128 (23,4)	NE [38,30; NE]	2,22 [1,48; 3,32] <,0001
Decreased appetite	78/245 (31,8)	NE [36,13; NE]	17/128 (13,3)	NE [NE; NE]	2,55 [1,51; 4,32] 0,0003
Hypokalaemia	25/245 (10,2)	NE [NE; NE]	3/128 (2,3)	NE [NE; NE]	4,00 [1,20; 13,26] 0,0143

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Dehydration	18/245 (7,3)	NE [NE; NE]	2/128 (1,6)	NE [42,51; NE]	4,23 [0,98; 18,31] 0,0357
Infections and infestations	110/245 (44,9)	15,4 [10,13; 23,24]	37/128 (28,9)	32,4 [18,25; NE]	1,66 [1,14; 2,40] 0,0074
Upper respiratory tract infection	41/245 (16,7)	NE [NE; NE]	10/128 (7,8)	NE [NE; NE]	1,95 [0,98; 3,91] 0,0536
Urinary tract infection	24/245 (9,8)	NE [NE; NE]	4/128 (3,1)	NE [NE; NE]	2,99 [1,04; 8,63] 0,0331
Sinusitis	13/245 (5,3)	NE [NE; NE]	3/128 (2,3)	NE [NE; NE]	1,86 [0,53; 6,56] 0,3260
Lung infection	12/245 (4,9)	NE [NE; NE]	1/128 (0,8)	NE [NE; NE]	5,49 [0,71; 42,38] 0,0661
Pharyngitis	11/245 (4,5)	NE [NE; NE]	2/128 (1,6)	NE [NE; NE]	2,34 [0,51; 10,64] 0,2587
Skin infection	11/245 (4,5)	NE [NE; NE]	4/128 (3,1)	NE [NE; NE]	1,22 [0,39; 3,86] 0,7355
Investigations	109/245 (44,5)	23,0 [11,08; 38,04]	24/128 (18,8)	NE [31,33; NE]	2,70 [1,74; 4,20] <,0001
Aspartate aminotransferase increased	42/245 (17,1)	NE [NE; NE]	9/128 (7,0)	NE [NE; NE]	2,28 [1,11; 4,70] 0,0212

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Alanine aminotransferase increased	41/245 (16,7)	NE [NE; NE]	7/128 (5,5)	NE [NE; NE]	2,98 [1,33; 6,64] 0,0051
Weight decreased	41/245 (16,7)	NE [NE; NE]	6/128 (4,7)	NE [NE; NE]	3,57 [1,51; 8,41] 0,0019
Blood creatinine increased	33/245 (13,5)	NE [NE; NE]	2/128 (1,6)	NE [NE; NE]	7,87 [1,88; 32,86] 0,0008
Blood alkaline phosphatase increased	17/245 (6,9)	NE [NE; NE]	1/128 (0,8)	NE [NE; NE]	8,16 [1,08; 61,40] 0,0150
Gamma-glutamyltransferase increased	13/245 (5,3)	NE [NE; NE]	1/128 (0,8)	NE [NE; NE]	5,95 [0,77; 45,66] 0,0514
Respiratory, thoracic and mediastinal disorders	105/245 (42,9)	22,1 [14,43; 37,02]	38/128 (29,7)	47,5 [20,02; NE]	1,41 [0,97; 2,04] 0,0724
Cough	43/245 (17,6)	NE [NE; NE]	17/128 (13,3)	NE [NE; NE]	1,10 [0,62; 1,94] 0,7440
Dyspnoea	29/245 (11,8)	NE [NE; NE]	19/128 (14,8)	NE [42,51; NE]	0,72 [0,40; 1,29] 0,2628
Rhinitis allergic	13/245 (5,3)	NE [NE; NE]	1/128 (0,8)	NE [NE; NE]	5,67 [0,74; 43,52] 0,0598
Oropharyngeal pain	12/245 (4,9)	NE [NE; NE]	7/128 (5,5)	NE [NE; NE]	0,69 [0,27; 1,78] 0,4411

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Epistaxis	11/245 (4,5)	NE [NE; NE]	3/128 (2,3)	NE [NE; NE]	1,70 [0,47; 6,16] 0,4104
Vascular disorders	72/245 (29,4)	NE [NE; NE]	23/128 (18,0)	50,6 [45,70; NE]	1,64 [1,02; 2,62] 0,0376
Hot flush	35/245 (14,3)	NE [NE; NE]	15/128 (11,7)	NE [NE; NE]	1,15 [0,63; 2,12] 0,6399
Embolism	17/245 (6,9)	NE [NE; NE]	0/128 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0054
Lymphoedema	13/245 (5,3)	NE [NE; NE]	2/128 (1,6)	NE [NE; NE]	2,77 [0,62; 12,36] 0,1646
Hypertension	11/245 (4,5)	NE [NE; NE]	4/128 (3,1)	NE [50,63; NE]	1,07 [0,33; 3,41] 0,9158
Eye disorders	48/245 (19,6)	NE [NE; NE]	9/128 (7,0)	NE [NE; NE]	2,65 [1,30; 5,40] 0,0054
Lacrimation increased	22/245 (9,0)	NE [NE; NE]	3/128 (2,3)	NE [NE; NE]	3,47 [1,04; 11,63] 0,0314
Vision blurred	11/245 (4,5)	NE [NE; NE]	4/128 (3,1)	NE [NE; NE]	1,19 [0,38; 3,78] 0,7653
Psychiatric disorders	46/245 (18,8)	NE [NE; NE]	22/128 (17,2)	NE [25,61; NE]	0,96 [0,58; 1,60] 0,8814

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Depression	22/245 (9,0)	NE [NE; NE]	6/128 (4,7)	NE [NE; NE]	1,80 [0,73; 4,44] 0,1979
Insomnia	20/245 (8,2)	NE [NE; NE]	12/128 (9,4)	NE [NE; NE]	0,71 [0,34; 1,46] 0,3489
Anxiety	13/245 (5,3)	NE [NE; NE]	1/128 (0,8)	NE [NE; NE]	5,71 [0,74; 43,80] 0,0583
Injury, poisoning and procedural complications	44/245 (18,0)	NE [45,27; NE]	13/128 (10,2)	NE [35,70; NE]	1,51 [0,81; 2,82] 0,1875
Fall	21/245 (8,6)	NE [NE; NE]	6/128 (4,7)	NE [NE; NE]	1,44 [0,58; 3,60] 0,4314
Contusion	12/245 (4,9)	NE [NE; NE]	2/128 (1,6)	NE [NE; NE]	2,49 [0,55; 11,23] 0,2193
Renal and urinary disorders	36/245 (14,7)	NE [NE; NE]	5/128 (3,9)	NE [NE; NE]	3,35 [1,31; 8,58] 0,0074
Cardiac disorders	21/245 (8,6)	NE [NE; NE]	12/128 (9,4)	NE [NE; NE]	0,75 [0,36; 1,53] 0,4249
Reproductive system and breast disorders	14/245 (5,7)	NE [NE; NE]	7/128 (5,5)	NE [NE; NE]	0,88 [0,35; 2,20] 0,7873
Not coded	13/245 (5,3)	NE [NE; NE]	2/128 (1,6)	NE [NE; NE]	1,89 [0,42; 8,50] 0,3973

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Not coded	13/245 (5,3)	NE [NE; NE]	2/128 (1,6)	NE [NE; NE]	1,89 [0,42; 8,50] 0,3973
Immune system disorders	12/245 (4,9)	NE [NE; NE]	3/128 (2,3)	NE [NE; NE]	1,67 [0,47; 5,97] 0,4278
Hypersensitivity	11/245 (4,5)	NE [NE; NE]	3/128 (2,3)	NE [NE; NE]	1,50 [0,41; 5,46] 0,5314
Ear and labyrinth disorders	11/245 (4,5)	NE [NE; NE]	8/128 (6,3)	NE [NE; NE]	0,58 [0,23; 1,46] 0,2409
Surgical and medical procedures	11/245 (4,5)	NE [NE; NE]	8/128 (6,3)	NE [NE; NE]	0,56 [0,22; 1,40] 0,2073

Data cut-off: 20.06.2019, Safety Population - Postmenopausal (1st line)
1: In months; 2: From Log-rank-Test
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; n: Number of patients with event; N: Total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; SOC: System Organ Class

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Tabelle 4-116 (Anhang): Ergebnisse für UE jeglichen Grades nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (MONARCH-2, B1)

Table 012.2: Results for adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Gastrointestinal disorders	134/143 (93,7)	0,1 [0,10; 0,20]	43/66 (65,2)	3,6 [1,64; 5,56]	4,00 [2,78; 5,76] <,0001
Diarrhoea	129/143 (90,2)	0,2 [0,16; 0,30]	18/66 (27,3)	NE [12,39; NE]	8,27 [4,97; 13,74] <,0001
Nausea	76/143 (53,1)	5,4 [0,99; NE]	16/66 (24,2)	NE [28,44; NE]	2,81 [1,63; 4,82] <,0001
Abdominal pain	56/143 (39,2)	NE [14,79; NE]	12/66 (18,2)	NE [NE; NE]	2,33 [1,25; 4,35] 0,0064
Vomiting	40/143 (28,0)	NE [NE; NE]	9/66 (13,6)	NE [NE; NE]	2,09 [1,01; 4,32] 0,0417
Constipation	23/143 (16,1)	NE [NE; NE]	10/66 (15,2)	NE [NE; NE]	0,92 [0,44; 1,95] 0,8355
Stomatitis	22/143 (15,4)	NE [NE; NE]	3/66 (4,5)	NE [NE; NE]	2,80 [0,83; 9,42] 0,0831
Dry mouth	12/143 (8,4)	NE [NE; NE]	8/66 (12,1)	NE [NE; NE]	0,61 [0,25; 1,51] 0,2834
Abdominal distension	10/143 (7,0)	NE [NE; NE]	0/66 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0673

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Dyspepsia	10/143 (7,0)	NE [NE; NE]	3/66 (4,5)	NE [NE; NE]	1,23 [0,34; 4,52] 0,7563
General disorders and administration site conditions	98/143 (68,5)	2,5 [1,15; 4,93]	34/66 (51,5)	7,4 [3,91; 11,47]	1,45 [0,98; 2,15] 0,0622
Fatigue	70/143 (49,0)	14,2 [4,57; NE]	18/66 (27,3)	NE [10,32; NE]	1,97 [1,17; 3,31] 0,0093
Injection site reaction	14/143 (9,8)	NE [NE; NE]	10/66 (15,2)	NE [NE; NE]	0,53 [0,23; 1,21] 0,1264
Oedema peripheral	14/143 (9,8)	NE [NE; NE]	6/66 (9,1)	NE [NE; NE]	0,81 [0,31; 2,13] 0,6681
Pyrexia	14/143 (9,8)	NE [NE; NE]	2/66 (3,0)	NE [NE; NE]	2,80 [0,63; 12,40] 0,1561
Influenza like illness	13/143 (9,1)	NE [NE; NE]	4/66 (6,1)	NE [NE; NE]	1,00 [0,32; 3,14] 0,9983
Non-cardiac chest pain	12/143 (8,4)	NE [NE; NE]	4/66 (6,1)	NE [30,38; NE]	1,09 [0,35; 3,41] 0,8858
Blood and lymphatic system disorders	88/143 (61,5)	3,7 [1,87; 10,19]	7/66 (10,6)	NE [NE; NE]	8,38 [3,88; 18,11] <,0001
Neutropenia	71/143 (49,7)	15,6 [4,93; 34,13]	3/66 (4,5)	NE [NE; NE]	13,63 [4,29; 43,29] <,0001

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Anaemia	52/143 (36,4)	24,0 [14,27; NE]	2/66 (3,0)	NE [NE; NE]	12,99 [3,16; 53,35] <,0001
Leukopenia	47/143 (32,9)	NE [26,79; NE]	0/66 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Thrombocytopenia	31/143 (21,7)	NE [NE; NE]	3/66 (4,5)	NE [NE; NE]	4,75 [1,45; 15,57] 0,0046
Lymphopenia	18/143 (12,6)	NE [NE; NE]	0/66 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0138
Infections and infestations	74/143 (51,7)	10,6 [6,35; 14,07]	17/66 (25,8)	23,3 [13,22; NE]	1,89 [1,11; 3,20] 0,0167
Upper respiratory tract infection	30/143 (21,0)	NE [34,45; NE]	5/66 (7,6)	NE [NE; NE]	1,89 [0,73; 4,90] 0,1827
Urinary tract infection	16/143 (11,2)	NE [NE; NE]	6/66 (9,1)	NE [24,10; NE]	1,00 [0,39; 2,58] 0,9970
Skin infection	11/143 (7,7)	NE [NE; NE]	1/66 (1,5)	NE [NE; NE]	3,33 [0,43; 26,04] 0,2242
Nervous system disorders	74/143 (51,7)	10,4 [4,31; 37,45]	18/66 (27,3)	NE [18,64; NE]	1,99 [1,19; 3,35] 0,0078
Dysgeusia	33/143 (23,1)	NE [NE; NE]	2/66 (3,0)	NE [NE; NE]	8,10 [1,94; 33,77] 0,0006

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Headache	28/143 (19,6)	NE [NE; NE]	9/66 (13,6)	NE [NE; NE]	1,29 [0,61; 2,74] 0,5074
Dizziness	20/143 (14,0)	NE [NE; NE]	3/66 (4,5)	NE [34,39; NE]	2,68 [0,79; 9,08] 0,0986
Neuropathy	14/143 (9,8)	NE [NE; NE]	8/66 (12,1)	NE [NE; NE]	0,57 [0,24; 1,38] 0,2104
Metabolism and nutrition disorders	73/143 (51,0)	17,1 [4,64; 37,78]	17/66 (25,8)	34,6 [33,44; NE]	2,17 [1,28; 3,69] 0,0032
Decreased appetite	50/143 (35,0)	NE [27,16; NE]	9/66 (13,6)	NE [33,44; NE]	2,86 [1,41; 5,83] 0,0024
Hypokalaemia	15/143 (10,5)	NE [NE; NE]	3/66 (4,5)	NE [34,55; NE]	1,82 [0,52; 6,37] 0,3408
Skin and subcutaneous tissue disorders	72/143 (50,3)	9,7 [6,05; 18,31]	15/66 (22,7)	NE [11,74; NE]	2,38 [1,36; 4,17] 0,0017
Alopecia	26/143 (18,2)	NE [NE; NE]	1/66 (1,5)	NE [NE; NE]	11,11 [1,51; 81,94] 0,0030
Pruritus	23/143 (16,1)	NE [NE; NE]	4/66 (6,1)	NE [NE; NE]	2,26 [0,78; 6,56] 0,1248
Dry skin	15/143 (10,5)	NE [NE; NE]	1/66 (1,5)	NE [NE; NE]	5,36 [0,71; 40,73] 0,0690

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Rash	11/143 (7,7)	NE [NE; NE]	3/66 (4,5)	NE [NE; NE]	1,52 [0,42; 5,46] 0,5221
Musculoskeletal and connective tissue disorders	67/143 (46,9)	22,8 [10,42; 31,79]	28/66 (42,4)	9,2 [5,85; NE]	0,85 [0,54; 1,33] 0,4722
Arthralgia	18/143 (12,6)	NE [NE; NE]	13/66 (19,7)	NE [15,75; NE]	0,52 [0,25; 1,06] 0,0670
Back pain	18/143 (12,6)	NE [NE; NE]	9/66 (13,6)	NE [NE; NE]	0,67 [0,30; 1,50] 0,3238
Pain in extremity	17/143 (11,9)	NE [NE; NE]	1/66 (1,5)	NE [NE; NE]	6,18 [0,82; 46,62] 0,0437
Muscular weakness	15/143 (10,5)	NE [NE; NE]	2/66 (3,0)	NE [NE; NE]	3,31 [0,75; 14,50] 0,0921
Bone pain	13/143 (9,1)	NE [NE; NE]	5/66 (7,6)	NE [NE; NE]	0,93 [0,33; 2,62] 0,8846
Respiratory, thoracic and mediastinal disorders	58/143 (40,6)	17,5 [13,71; NE]	24/66 (36,4)	27,9 [8,19; NE]	0,90 [0,56; 1,46] 0,6837
Cough	27/143 (18,9)	NE [NE; NE]	10/66 (15,2)	NE [27,91; NE]	0,96 [0,46; 2,00] 0,9237
Dyspnoea	25/143 (17,5)	NE [NE; NE]	9/66 (13,6)	NE [NE; NE]	1,06 [0,49; 2,29] 0,8804

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Oropharyngeal pain	12/143 (8,4)	NE [NE; NE]	5/66 (7,6)	NE [NE; NE]	0,88 [0,31; 2,53] 0,8187
Investigations	52/143 (36,4)	35,1 [20,98; NE]	8/66 (12,1)	NE [NE; NE]	3,14 [1,49; 6,62] 0,0015
Blood creatinine increased	29/143 (20,3)	NE [NE; NE]	0/66 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0002
Alanine aminotransferase increased	16/143 (11,2)	NE [NE; NE]	6/66 (9,1)	NE [NE; NE]	1,04 [0,40; 2,67] 0,9399
Aspartate aminotransferase increased	15/143 (10,5)	NE [NE; NE]	5/66 (7,6)	NE [NE; NE]	1,23 [0,44; 3,40] 0,6943
Weight decreased	14/143 (9,8)	NE [NE; NE]	1/66 (1,5)	NE [NE; NE]	5,97 [0,78; 45,46] 0,0497
Vascular disorders	36/143 (25,2)	NE [NE; NE]	17/66 (25,8)	NE [12,00; NE]	0,82 [0,46; 1,48] 0,5072
Hot flush	14/143 (9,8)	NE [NE; NE]	8/66 (12,1)	NE [NE; NE]	0,75 [0,31; 1,79] 0,5133
Embolism	11/143 (7,7)	NE [NE; NE]	2/66 (3,0)	NE [NE; NE]	1,91 [0,42; 8,71] 0,3931
Psychiatric disorders	27/143 (18,9)	NE [NE; NE]	11/66 (16,7)	NE [21,63; NE]	1,00 [0,50; 2,03] 0,9929

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Insomnia	18/143 (12,6)	NE [NE; NE]	4/66 (6,1)	NE [NE; NE]	1,90 [0,64; 5,65] 0,2378
Eye disorders	26/143 (18,2)	NE [NE; NE]	6/66 (9,1)	NE [19,96; NE]	1,53 [0,63; 3,75] 0,3463
Injury, poisoning and procedural complications	16/143 (11,2)	NE [NE; NE]	6/66 (9,1)	NE [21,01; NE]	0,73 [0,28; 1,90] 0,5180
Renal and urinary disorders	14/143 (9,8)	NE [NE; NE]	4/66 (6,1)	NE [26,93; NE]	1,11 [0,36; 3,44] 0,8612
Reproductive system and breast disorders	11/143 (7,7)	NE [NE; NE]	2/66 (3,0)	NE [33,11; NE]	1,83 [0,40; 8,34] 0,4278
Cardiac disorders	10/143 (7,0)	NE [NE; NE]	5/66 (7,6)	NE [NE; NE]	0,69 [0,23; 2,05] 0,5034

Data cut-off: 20.06.2019, Safety Population - Postmenopausal (2nd line)
1: In months; 2: From Log-rank-Test
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; n: Number of patients with event; N: Total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; SOC: System Organ Class

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Anhang 4-G1.4.2: Häufige schwerwiegende unerwünschte Ereignisse (Ereignisse die bei $\geq$ 5 % der Patienten oder mindestens 10 Patienten und $\geq$ 1% in mindestens einem Behandlungsarm auftraten)

Tabelle 4-117 (Anhang): Ergebnisse für SUE nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (MONARCH-2, A1)

Table 013.1: Results for serious adverse events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Infections and infestations	16/245 (6,5)	NE [NE; NE]	1/128 (0,8)	NE [NE; NE]	7,86 [1,04; 59,26] 0,0177
Gastrointestinal disorders	15/245 (6,1)	NE [NE; NE]	3/128 (2,3)	NE [42,51; NE]	2,36 [0,68; 8,20] 0,1635
Respiratory, thoracic and mediastinal disorders	10/245 (4,1)	NE [NE; NE]	4/128 (3,1)	NE [NE; NE]	1,16 [0,36; 3,71] 0,8005

Data cut-off: 20.06.2019, Safety Population - Postmenopausal (1st line)
1: In months; 2: From Log-rank-Test
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; n: Number of patients with event; N: Total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; SOC: System Organ Class

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Tabelle 4-118 (Anhang): Ergebnisse für SUE nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (MONARCH-2, B1)

Table 013.2: Results for serious adverse events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Infections and infestations	13/143 (9,1)	NE [NE; NE]	4/66 (6,1)	NE [29,92; NE]	1,09 [0,35; 3,37] 0,8834
Gastrointestinal disorders	9/143 (6,3)	NE [NE; NE]	2/66 (3,0)	NE [NE; NE]	1,42 [0,30; 6,74] 0,6588
Respiratory, thoracic and mediastinal disorders	5/143 (3,5)	NE [NE; NE]	5/66 (7,6)	NE [27,98; NE]	0,31 [0,09; 1,12] 0,0598

Data cut-off: 20.06.2019, Safety Population - Postmenopausal (2nd line)
1: In months; 2: From Log-rank-Test
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; n: Number of patients with event; N: Total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; SOC: System Organ Class

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Anhang 4-G1.4.3: Häufige unerwünschte Ereignisse CTCAE Grad $\geq$ 3 (Ereignisse die bei $\geq$ 5 % der Patienten oder mindestens 10 Patienten und $\geq$ 1% in mindestens einem Behandlungsarm auftraten)

Tabelle 4-119 (Anhang): Ergebnisse für UE (CTCAE Grad $\geq$ 3) nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (MONARCH-2, A1)

Table 014.1: Results for adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Blood and lymphatic system disorders	82/245 (33,5)	41,3 [29,00; NE]	4/128 (3,1)	NE [NE; NE]	12,34 [4,52; 33,68] <,0001
Neutropenia	62/245 (25,3)	NE [NE; NE]	2/128 (1,6)	NE [NE; NE]	17,72 [4,33; 72,48] <,0001
Leukopenia	21/245 (8,6)	NE [NE; NE]	0/128 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0013
Anaemia	19/245 (7,8)	NE [NE; NE]	2/128 (1,6)	NE [NE; NE]	4,15 [0,96; 17,89] 0,0383
Lymphopenia	10/245 (4,1)	NE [NE; NE]	1/128 (0,8)	NE [NE; NE]	3,98 [0,51; 31,34] 0,1564
Gastrointestinal disorders	52/245 (21,2)	NE [50,30; NE]	9/128 (7,0)	NE [NE; NE]	3,03 [1,49; 6,15] 0,0013
Diarrhoea	35/245 (14,3)	NE [NE; NE]	1/128 (0,8)	NE [NE; NE]	18,30 [2,51; 133,70] <,0001
Investigations	30/245 (12,2)	NE [NE; NE]	7/128 (5,5)	NE [NE; NE]	2,09 [0,92; 4,77] 0,0722
Alanine aminotransferase increased	14/245 (5,7)	NE [NE; NE]	3/128 (2,3)	NE [NE; NE]	2,29 [0,66; 7,99] 0,1812

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Metabolism and nutrition disorders	23/245 (9,4)	NE [NE; NE]	7/128 (5,5)	NE [42,51; NE]	1,54 [0,66; 3,59] 0,3186
Hypokalaemia	12/245 (4,9)	NE [NE; NE]	1/128 (0,8)	NE [NE; NE]	5,46 [0,71; 42,17] 0,0678
Infections and infestations	22/245 (9,0)	NE [NE; NE]	3/128 (2,3)	NE [NE; NE]	3,52 [1,05; 11,77] 0,0294
General disorders and administration site conditions	17/245 (6,9)	NE [NE; NE]	6/128 (4,7)	NE [48,33; NE]	1,25 [0,49; 3,20] 0,6385
Respiratory, thoracic and mediastinal disorders	13/245 (5,3)	NE [NE; NE]	7/128 (5,5)	NE [47,51; NE]	0,80 [0,32; 2,03] 0,6448
Vascular disorders	12/245 (4,9)	NE [NE; NE]	2/128 (1,6)	NE [NE; NE]	2,80 [0,62; 12,57] 0,1600
Nervous system disorders	10/245 (4,1)	NE [NE; NE]	5/128 (3,9)	NE [NE; NE]	0,79 [0,27; 2,35] 0,6734

Data cut-off: 20.06.2019, Safety Population - Postmenopausal (1st line)
1: In months; 2: From Log-rank-Test
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; n: Number of patients with event; N: Total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; SOC: System Organ Class

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Tabelle 4-120 (Anhang): Ergebnisse für UE (CTCAE Grad $\geq$ 3) nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (MONARCH-2, B1)

Table 014.2: Results for adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Blood and lymphatic system disorders	52/143 (36,4)	38,7 [20,78; NE]	2/66 (3,0)	NE [NE; NE]	12,69 [3,09; 52,13] <,0001
Neutropenia	42/143 (29,4)	NE [38,66; NE]	1/66 (1,5)	NE [NE; NE]	19,77 [2,72; 143,75] <,0001
Leukopenia	13/143 (9,1)	NE [NE; NE]	0/66 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0216
Anaemia	12/143 (8,4)	NE [NE; NE]	1/66 (1,5)	NE [NE; NE]	4,34 [0,56; 33,65] 0,1253
Gastrointestinal disorders	38/143 (26,6)	NE [NE; NE]	2/66 (3,0)	NE [NE; NE]	8,59 [2,07; 35,66] 0,0004
Diarrhoea	25/143 (17,5)	NE [NE; NE]	0/66 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0006
Abdominal pain	8/143 (5,6)	NE [NE; NE]	0/66 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1074
Infections and infestations	14/143 (9,8)	NE [NE; NE]	4/66 (6,1)	NE [NE; NE]	1,05 [0,34; 3,27] 0,9263
Metabolism and nutrition disorders	13/143 (9,1)	NE [NE; NE]	4/66 (6,1)	NE [34,55; NE]	1,15 [0,37; 3,57] 0,8110

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
General disorders and administration site conditions	12/143 (8,4)	NE [NE; NE]	1/66 (1,5)	NE [NE; NE]	4,15 [0,53; 32,30] 0,1402
Fatigue	9/143 (6,3)	NE [NE; NE]	1/66 (1,5)	NE [NE; NE]	3,27 [0,41; 26,12] 0,2368
Investigations	11/143 (7,7)	NE [NE; NE]	4/66 (6,1)	NE [NE; NE]	0,96 [0,30; 3,04] 0,9387
Aspartate aminotransferase increased	2/143 (1,4)	NE [NE; NE]	4/66 (6,1)	NE [NE; NE]	0,19 [0,04; 1,07] 0,0366
Vascular disorders	10/143 (7,0)	NE [NE; NE]	2/66 (3,0)	NE [NE; NE]	1,70 [0,37; 7,90] 0,4904
Musculoskeletal and connective tissue disorders	9/143 (6,3)	NE [NE; NE]	3/66 (4,5)	NE [NE; NE]	0,96 [0,26; 3,62] 0,9572
Respiratory, thoracic and mediastinal disorders	4/143 (2,8)	NE [NE; NE]	5/66 (7,6)	NE [27,98; NE]	0,27 [0,07; 1,03] 0,0415

Data cut-off: 20.06.2019, Safety Population - Postmenopausal (2nd line)
1: In months; 2: From Log-rank-Test
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; n: Number of patients with event; N: Total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; SOC: System Organ Class

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t014_ttirgr3_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:39

Anhang 4-G1.4.4: Unerwünschte Ereignisse, die zum Behandlungsabbruch führten nach SOC und PT

Tabelle 4-121 (Anhang): Ergebnisse für UE, die zum Behandlungsabbruch mindestens eines der beiden Medikamente führten nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (MONARCH-2, A1)

Any AE by SOC and PT leading to discontinuation of any (1 or both) study treatment — Page 1 of 4
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line) — 13:22 25JUN2021
Safety Population — TDTM
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019

	LY 2835219 (N =245)		Placebo (N =128)	
	n	(%)	n	(%)
Subjects with >= 1 TEAE leading to discontinuation of any study drug	52	(21.2)	7	(5.5)
Blood and lymphatic system disorders	10	(4.1)	0	(0.0)
Neutropenia	8	(3.3)	0	(0.0)
Leukopenia	1	(0.4)	0	(0.0)
Thrombocytopenia	1	(0.4)	0	(0.0)
Investigations	10	(4.1)	1	(0.8)
Alanine aminotransferase increased	3	(1.2)	0	(0.0)
Weight decreased	2	(0.8)	0	(0.0)
Aspartate aminotransferase increased	1	(0.4)	1	(0.8)
Blood alkaline phosphatase increased	1	(0.4)	0	(0.0)
Blood bilirubin increased	1	(0.4)	0	(0.0)
Blood creatinine increased	1	(0.4)	0	(0.0)
Gamma-glutamyltransferase increased	1	(0.4)	0	(0.0)
Gastrointestinal disorders	9	(3.7)	0	(0.0)
Diarrhoea	5	(2.0)	0	(0.0)
Abdominal distension	1	(0.4)	0	(0.0)
Abdominal pain	1	(0.4)	0	(0.0)
Gastritis	1	(0.4)	0	(0.0)
Nausea	1	(0.4)	0	(0.0)

Abbreviations: N = number of subjects in population ; n = number of subjects in the specified category; CTCAE = Common Terminology Criteria for Adverse Events; TEAE = Treatment-Emergent Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities.
MedDRA Version 22.0 CTCAE Version V4

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_teae_pt_soc_discf.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/t_teae_pt_soc_discf_popa1.rtf
Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Any AE by SOC and PT leading to discontinuation of any (1 or both) study treatment — Page 2 of 4
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line) — 13:22 25JUN2021
Safety Population — TDTM
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019

	LY 2835219 (N =245)		Placebo (N =128)	
	n	(%)	n	(%)
Cardiac disorders	4	(1.6)	1	(0.8)
Myocardial infarction	1	(0.4)	0	(0.0)
Palpitations	1	(0.4)	0	(0.0)
Supraventricular tachycardia	1	(0.4)	0	(0.0)
Ventricular tachycardia	1	(0.4)	0	(0.0)
Cardiac arrest	0	(0.0)	1	(0.8)
Infections and infestations	4	(1.6)	0	(0.0)
Sepsis	2	(0.8)	0	(0.0)
Enterocolitis infectious	1	(0.4)	0	(0.0)
Lung infection	1	(0.4)	0	(0.0)
Renal and urinary disorders	3	(1.2)	0	(0.0)
Acute kidney injury	2	(0.8)	0	(0.0)
Hydronephrosis	1	(0.4)	0	(0.0)
Hepatobiliary disorders	2	(0.8)	0	(0.0)
Hepatic failure	1	(0.4)	0	(0.0)
Hepatic function abnormal	1	(0.4)	0	(0.0)
Injury, poisoning and procedural complications	2	(0.8)	1	(0.8)
Fracture	1	(0.4)	0	(0.0)
Limb injury	1	(0.4)	0	(0.0)

Abbreviations: N = number of subjects in population ; n = number of subjects in the specified category; CTCAE = Common Terminology Criteria for Adverse Events; TEAE = Treatment-Emergent Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities.
MedDRA Version 22.0 CTCAE Version V4

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_teae_pt_soc_discf.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/t_teae_pt_soc_discf_popa1.rtf
Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Any AE by SOC and PT leading to discontinuation of any (1 or both) study treatment
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019

	LY 2835219 (N =245)		Placebo (N =128)	
	n	(%)	n	(%)
Hip fracture	0	(0.0)	1	(0.8)
Respiratory, thoracic and mediastinal disorders	2	(0.8)	0	(0.0)
Pneumonitis	1	(0.4)	0	(0.0)
Respiratory failure	1	(0.4)	0	(0.0)
Vascular disorders	2	(0.8)	0	(0.0)
Embolism	2	(0.8)	0	(0.0)
General disorders and administration site conditions	1	(0.4)	0	(0.0)
Multiple organ dysfunction syndrome	1	(0.4)	0	(0.0)
Metabolism and nutrition disorders	1	(0.4)	2	(1.6)
Decreased appetite	1	(0.4)	1	(0.8)
Hyponatraemia	0	(0.0)	1	(0.8)
Musculoskeletal and connective tissue disorders	1	(0.4)	0	(0.0)
Muscular weakness	1	(0.4)	0	(0.0)
Nervous system disorders	1	(0.4)	1	(0.8)
Cerebrovascular accident	1	(0.4)	0	(0.0)
Headache	0	(0.0)	1	(0.8)

Abbreviations: N = number of subjects in population ; n = number of subjects in the specified category; CTCAE = Common Terminology Criteria for Adverse Events; TEAE = Treatment-Emergent Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities.
MedDRA Version 22.0 CTCAE Version V4

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_teae_pt_soc_discf.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/t_teae_pt_soc_discf_popa1.rtf
Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Any AE by SOC and PT leading to discontinuation of any (1 or both) study treatment — Page 4 of 4
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line) — 13:22 25JUN2021
Safety Population — TDTM
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019

	LY 2835219 (N =245)		Placebo (N =128)	
	n	(%)	n	(%)
Not coded	1	(0.4)	0	(0.0)
Not coded	1	(0.4)	0	(0.0)
Skin and subcutaneous tissue disorders	0	(0.0)	1	(0.8)
Skin ulcer	0	(0.0)	1	(0.8)

Abbreviations: N = number of subjects in population ; n = number of subjects in the specified category; CTCAE = Common Terminology Criteria for Adverse Events; TEAE = Treatment-Emergent Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities.
MedDRA Version 22.0 CTCAE Version V4

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_teae_pt_soc_discf.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/t_teae_pt_soc_discf_popa1.rtf
Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Tabelle 4-122 (Anhang): Ergebnisse für UE, die zum Behandlungsabbruch mindestens eines der beiden Medikamente führten nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (MONARCH-2, B1)

Any AE by SOC and PT leading to discontinuation of any (1 or both) study treatment — Page 1 of 3
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line) — 13:22 25JUN2021
Safety Population — TDTM
B1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019

	LY 2835219 (N =143)		Placebo (N =66)	
	n	(%)	n	(%)
Subjects with >= 1 TEAE leading to discontinuation of any study drug	34	(23.8)	2	(3.0)
Blood and lymphatic system disorders	9	(6.3)	0	(0.0)
Anaemia	3	(2.1)	0	(0.0)
Neutropenia	3	(2.1)	0	(0.0)
Leukopenia	2	(1.4)	0	(0.0)
Lymphopenia	1	(0.7)	0	(0.0)
Gastrointestinal disorders	8	(5.6)	0	(0.0)
Diarrhoea	7	(4.9)	0	(0.0)
Nausea	1	(0.7)	0	(0.0)
Investigations	3	(2.1)	1	(1.5)
Alanine aminotransferase increased	1	(0.7)	1	(1.5)
Aspartate aminotransferase increased	1	(0.7)	0	(0.0)

Abbreviations: N = number of subjects in population ; n = number of subjects in the specified category; CTCAE = Common Terminology Criteria for Adverse Events; TEAE = Treatment-Emergent Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities.
MedDRA Version 22.0 CTCAE Version V4

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_teae_pt_soc_discf.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/t_teae_pt_soc_discf_popa2.rtf
Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Any AE by SOC and PT leading to discontinuation of any (1 or both) study treatment
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
B1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019

	LY 2835219 (N =143)		Placebo (N =66)	
	n	(%)	n	(%)
Gamma-glutamyltransferase increased	1	(0.7)	0	(0.0)
Hepatobiliary disorders	2	(1.4)	0	(0.0)
Cholecystitis	1	(0.7)	0	(0.0)
Drug-induced liver injury	1	(0.7)	0	(0.0)
Infections and infestations	2	(1.4)	0	(0.0)
Sepsis	2	(1.4)	0	(0.0)
Musculoskeletal and connective tissue disorders	2	(1.4)	0	(0.0)
Muscular weakness	2	(1.4)	0	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2	(1.4)	0	(0.0)
Colon cancer	1	(0.7)	0	(0.0)
Tumour pain	1	(0.7)	0	(0.0)

Abbreviations: N = number of subjects in population ; n = number of subjects in the specified category; CTCAE = Common Terminology Criteria for Adverse Events; TEAE = Treatment-Emergent Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities.
MedDRA Version 22.0 CTCAE Version V4

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_teae_pt_soc_discf.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/t_teae_pt_soc_discf_popa2.rtf
Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Any AE by SOC and PT leading to discontinuation of any (1 or both) study treatment
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
B1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019

	LY 2835219 (N =143)		Placebo (N =66)	
	n	(%)	n	(%)
Nervous system disorders	2	(1.4)	0	(0.0)
Cerebral infarction	1	(0.7)	0	(0.0)
Cognitive disorder	1	(0.7)	0	(0.0)
Respiratory, thoracic and mediastinal disorders	2	(1.4)	0	(0.0)
Pneumonitis	2	(1.4)	0	(0.0)
Skin and subcutaneous tissue disorders	2	(1.4)	0	(0.0)
Rash	2	(1.4)	0	(0.0)
General disorders and administration site conditions	1	(0.7)	0	(0.0)
Fatigue	1	(0.7)	0	(0.0)
Psychiatric disorders	0	(0.0)	1	(1.5)
Depression	0	(0.0)	1	(1.5)

Abbreviations: N = number of subjects in population ; n = number of subjects in the specified category; CTCAE = Common Terminology Criteria for Adverse Events; TEAE = Treatment-Emergent Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities.
MedDRA Version 22.0 CTCAE Version V4

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_teae_pt_soc_discf.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/t_teae_pt_soc_discf_popa2.rtf
Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Tabelle 4-123 (Anhang): Ergebnisse für UE, die zum kompletten Behandlungsabbruch führten nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (MONARCH-2, A1)

Any AE by SOC and PT leading to discontinuation of complete study therapy — Page 1 of 3
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line) — 13:24 25JUN2021
Safety Population — TDTM
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019

	LY 2835219 (N =245)		Placebo (N =128)	
	n	(%)	n	(%)
Subjects with >= 1 TEAE leading to discontinuation of complete study therapy	29	(11.8)	6	(4.7)
Investigations	6	(2.4)	1	(0.8)
Alanine aminotransferase increased	2	(0.8)	0	(0.0)
Aspartate aminotransferase increased	1	(0.4)	1	(0.8)
Blood alkaline phosphatase increased	1	(0.4)	0	(0.0)
Blood bilirubin increased	1	(0.4)	0	(0.0)
Weight decreased	1	(0.4)	0	(0.0)
Gastrointestinal disorders	4	(1.6)	0	(0.0)
Abdominal pain	1	(0.4)	0	(0.0)
Diarrhoea	1	(0.4)	0	(0.0)
Gastritis	1	(0.4)	0	(0.0)
Nausea	1	(0.4)	0	(0.0)
Infections and infestations	4	(1.6)	0	(0.0)
Sepsis	2	(0.8)	0	(0.0)
Enterocolitis infectious	1	(0.4)	0	(0.0)
Lung infection	1	(0.4)	0	(0.0)
Cardiac disorders	3	(1.2)	1	(0.8)
Myocardial infarction	1	(0.4)	0	(0.0)
Supraventricular tachycardia	1	(0.4)	0	(0.0)

Abbreviations: N = number of subjects in population ; n = number of subjects in the specified category; CTCAE = Common Terminology Criteria for Adverse Events; TEAE = Treatment-Emergent Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities.
MedDRA Version 22.0 CTCAE Version V4

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_teae_pt_soc_disca.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/t_teae_pt_soc_disca_popa1.rtf
Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Any AE by SOC and PT leading to discontinuation of complete study therapy
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line) 13:24 25JUN2021
Safety Population TDTM
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019

	LY 2835219 (N =245)		Placebo (N =128)	
	n	(%)	n	(%)
Ventricular tachycardia	1	(0.4)	0	(0.0)
Cardiac arrest	0	(0.0)	1	(0.8)
Injury, poisoning and procedural complications	2	(0.8)	1	(0.8)
Fracture	1	(0.4)	0	(0.0)
Limb injury	1	(0.4)	0	(0.0)
Hip fracture	0	(0.0)	1	(0.8)
Renal and urinary disorders	2	(0.8)	0	(0.0)
Acute kidney injury	1	(0.4)	0	(0.0)
Hydronephrosis	1	(0.4)	0	(0.0)
Respiratory, thoracic and mediastinal disorders	2	(0.8)	0	(0.0)
Pneumonitis	1	(0.4)	0	(0.0)
Respiratory failure	1	(0.4)	0	(0.0)
Blood and lymphatic system disorders	1	(0.4)	0	(0.0)
Neutropenia	1	(0.4)	0	(0.0)
General disorders and administration site conditions	1	(0.4)	0	(0.0)
Multiple organ dysfunction syndrome	1	(0.4)	0	(0.0)
Hepatobiliary disorders	1	(0.4)	0	(0.0)

Abbreviations: N = number of subjects in population ; n = number of subjects in the specified category; CTCAE = Common Terminology Criteria for Adverse Events; TEAE = Treatment-Emergent Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities.
MedDRA Version 22.0 CTCAE Version V4

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_teae_pt_soc_disca.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/t_teae_pt_soc_disca_popa1.rtf
Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Any AE by SOC and PT leading to discontinuation of complete study therapy — Page 3 of 3
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line) — 13:24 25JUN2021
Safety Population — TDTM
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019

	LY 2835219 (N =245)		Placebo (N =128)	
	n	(%)	n	(%)
Hepatic failure	1	(0.4)	0	(0.0)
Musculoskeletal and connective tissue disorders	1	(0.4)	0	(0.0)
Muscular weakness	1	(0.4)	0	(0.0)
Nervous system disorders	1	(0.4)	1	(0.8)
Cerebrovascular accident	1	(0.4)	0	(0.0)
Headache	0	(0.0)	1	(0.8)
Vascular disorders	1	(0.4)	0	(0.0)
Embolism	1	(0.4)	0	(0.0)
Metabolism and nutrition disorders	0	(0.0)	2	(1.6)
Decreased appetite	0	(0.0)	1	(0.8)
Hyponatraemia	0	(0.0)	1	(0.8)

Abbreviations: N = number of subjects in population ; n = number of subjects in the specified category; CTCAE = Common Terminology Criteria for Adverse Events; TEAE = Treatment-Emergent Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities.
MedDRA Version 22.0 CTCAE Version V4

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_teae_pt_soc_disca.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/t_teae_pt_soc_disca_popa1.rtf
Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Tabelle 4-124 (Anhang): Ergebnisse für UE, die zum kompletten Behandlungsabbruch führten nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (MONARCH-2, B1)

	LY 2835219 (N =143)		Placebo (N =66)	
	n	(%)	n	(%)
Subjects with >= 1 TEAE leading to discontinuation of complete study therapy	16	(11.2)	2	(3.0)
Gastrointestinal disorders	4	(2.8)	0	(0.0)
Diarrhoea	4	(2.8)	0	(0.0)
Blood and lymphatic system disorders	2	(1.4)	0	(0.0)
Anaemia	2	(1.4)	0	(0.0)
Hepatobiliary disorders	2	(1.4)	0	(0.0)
Cholecystitis	1	(0.7)	0	(0.0)
Drug-induced liver injury	1	(0.7)	0	(0.0)
Infections and infestations	2	(1.4)	0	(0.0)
Sepsis	2	(1.4)	0	(0.0)

Abbreviations: N = number of subjects in population ; n = number of subjects in the specified category; CTCAE = Common Terminology Criteria for Adverse Events; TEAE = Treatment-Emergent Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities.
MedDRA Version 22.0 CTCAE Version V4

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_teae_pt_soc_disca.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/t_teae_pt_soc_disca_popa2.rtf
Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Any AE by SOC and PT leading to discontinuation of complete study therapy
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
B1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019

	LY 2835219 (N =143)		Placebo (N =66)	
	n	(%)	n	(%)
Musculoskeletal and connective tissue disorders	2	(1.4)	0	(0.0)
Muscular weakness	2	(1.4)	0	(0.0)
General disorders and administration site conditions	1	(0.7)	0	(0.0)
Fatigue	1	(0.7)	0	(0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	(0.7)	0	(0.0)
Tumour pain	1	(0.7)	0	(0.0)
Nervous system disorders	1	(0.7)	0	(0.0)
Cerebral infarction	1	(0.7)	0	(0.0)
Respiratory, thoracic and mediastinal disorders	1	(0.7)	0	(0.0)
Pneumonitis	1	(0.7)	0	(0.0)

Abbreviations: N = number of subjects in population ; n = number of subjects in the specified category; CTCAE = Common Terminology Criteria for Adverse Events; TEAE = Treatment-Emergent Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities.
MedDRA Version 22.0 CTCAE Version V4

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_teae_pt_soc_disca.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/t_teae_pt_soc_disca_popa2.rtf
Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Any AE by SOC and PT leading to discontinuation of complete study therapy
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
B1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019

	LY 2835219 (N =143)		Placebo (N =66)	
	n	(%)	n	(%)
Investigations	0	(0.0)	1	(1.5)
Alanine aminotransferase increased	0	(0.0)	1	(1.5)
Psychiatric disorders	0	(0.0)	1	(1.5)
Depression	0	(0.0)	1	(1.5)

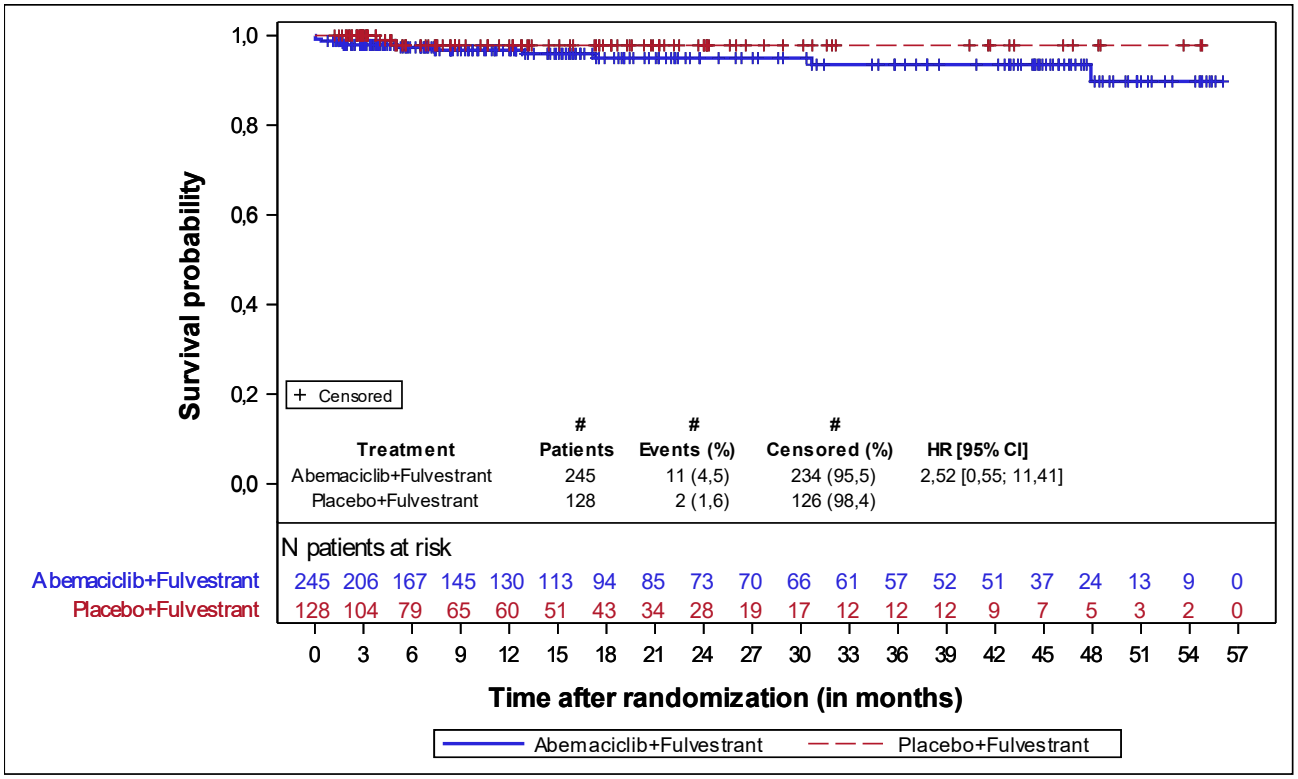
Abbreviations: N = number of subjects in population ; n = number of subjects in the specified category; CTCAE = Common Terminology Criteria for Adverse Events; TEAE = Treatment-Emergent Adverse Event; MedDRA = Medical Dictionary for Regulatory Activities.
MedDRA Version 22.0 CTCAE Version V4

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_teae_pt_soc_disca.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/t_teae_pt_soc_disca_popa2.rtf
Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Anhang 4-G1.4.5: Kaplan-Meier-Kurven

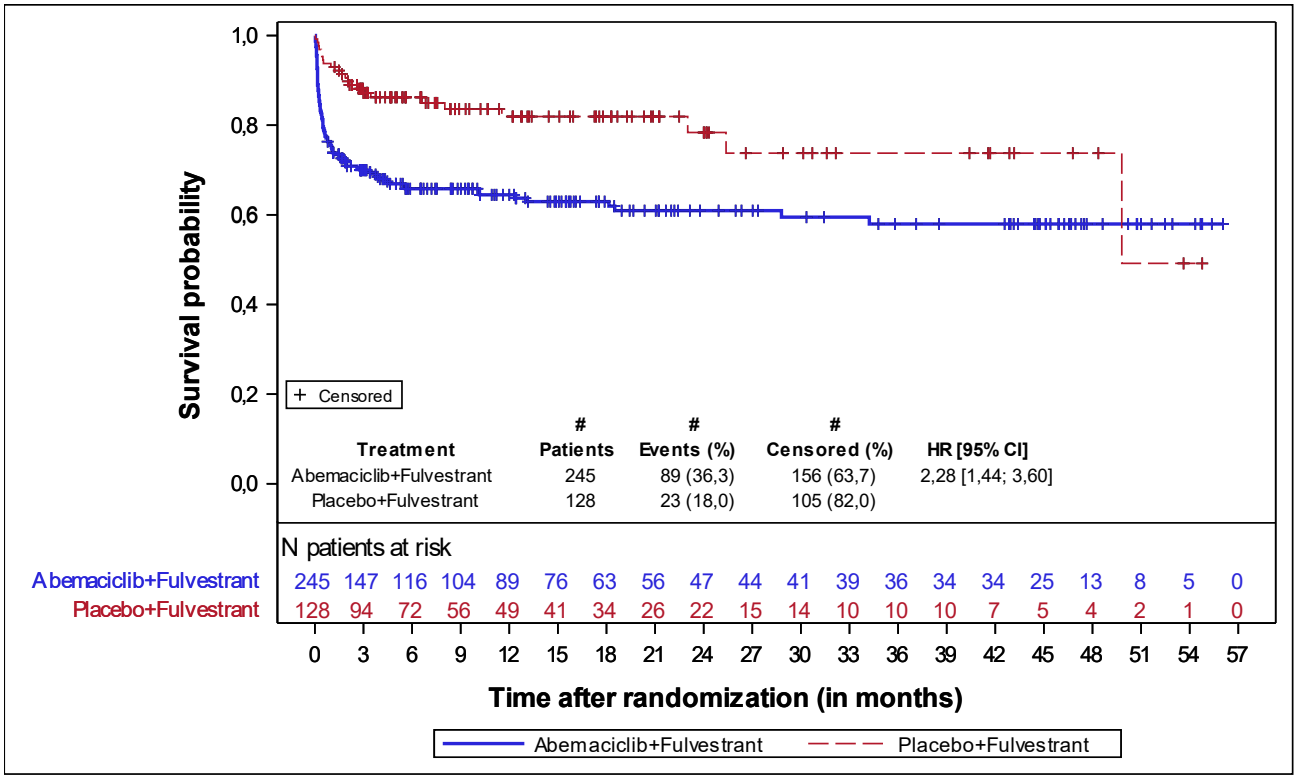
Abbildung 151 (Anhang): Kaplan-Meier-Kurven für Symptomatik, Gesundheitszustand und gesundheitsbezogene Lebensqualität (MONARCH 2)

Figure 089: Kaplan-Meier curves for adverse events according PT - Gastrointestinal disorders / Abdominal distension
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraep001_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 090: Kaplan-Meier curves for adverse events according PT - Gastrointestinal disorders / Abdominal pain
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraep002_popa1.rtf
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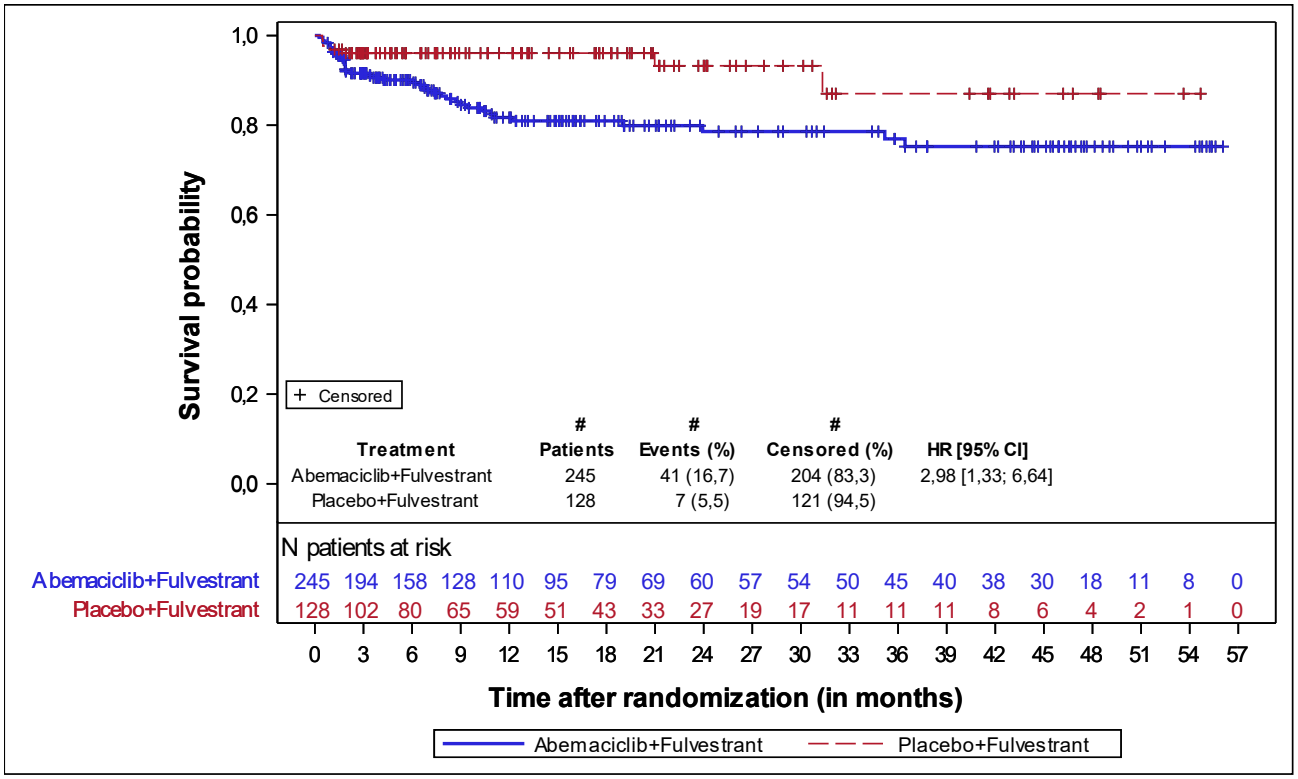
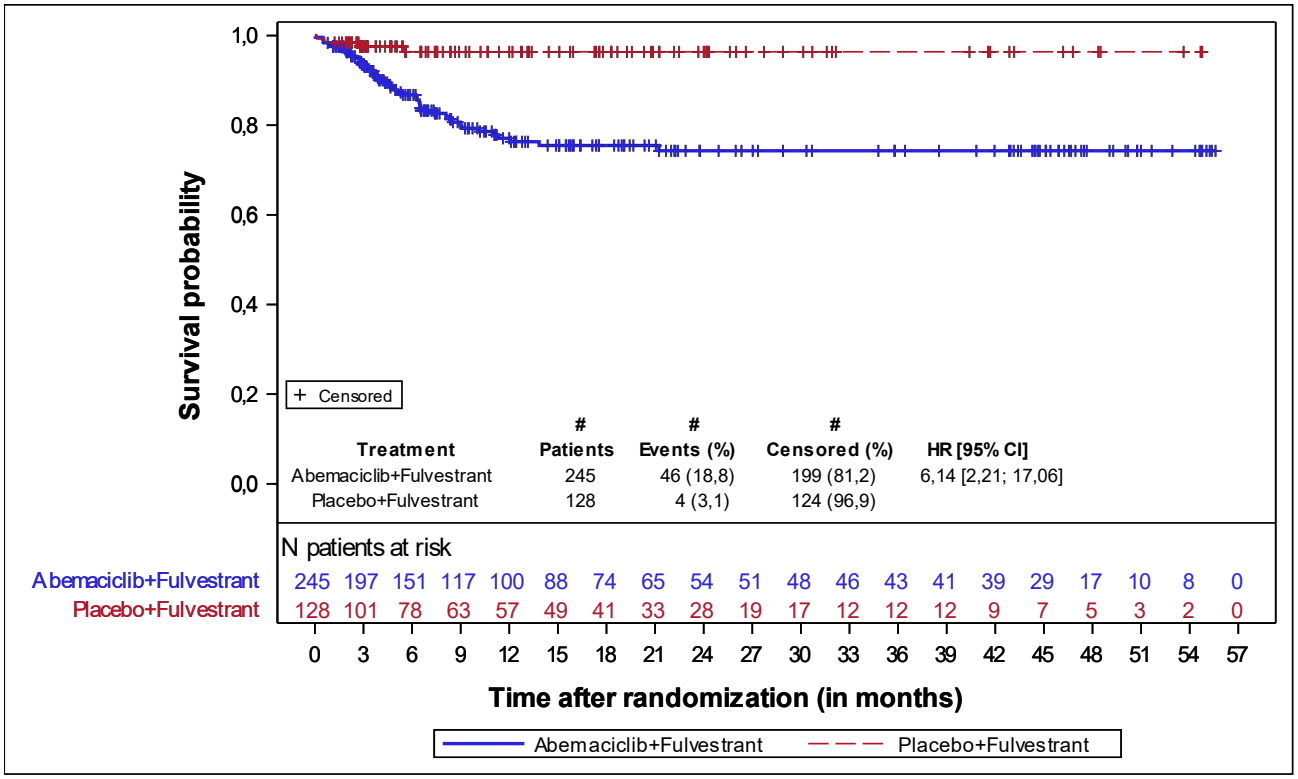
08JUL2021 / 02:43

Figure 091: Kaplan-Meier curves for adverse events according PT - Investigations / Alanine aminotransferase increased
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraep003_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 092: Kaplan-Meier curves for adverse events according PT - Skin and subcutaneous tissue disorders / Alopecia Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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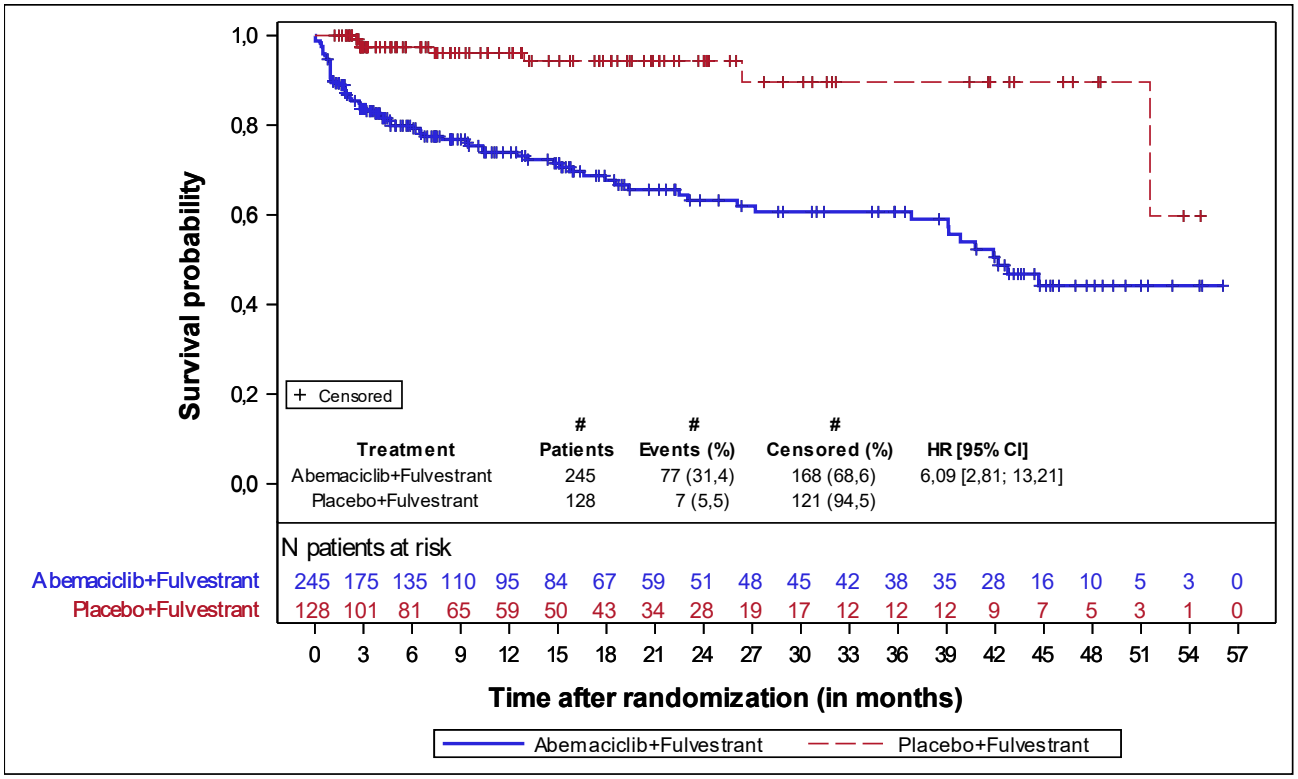
08JUL2021 / 02:43

Figure 093: Kaplan-Meier curves for adverse events according PT - Blood and lymphatic system disorders / Anaemia Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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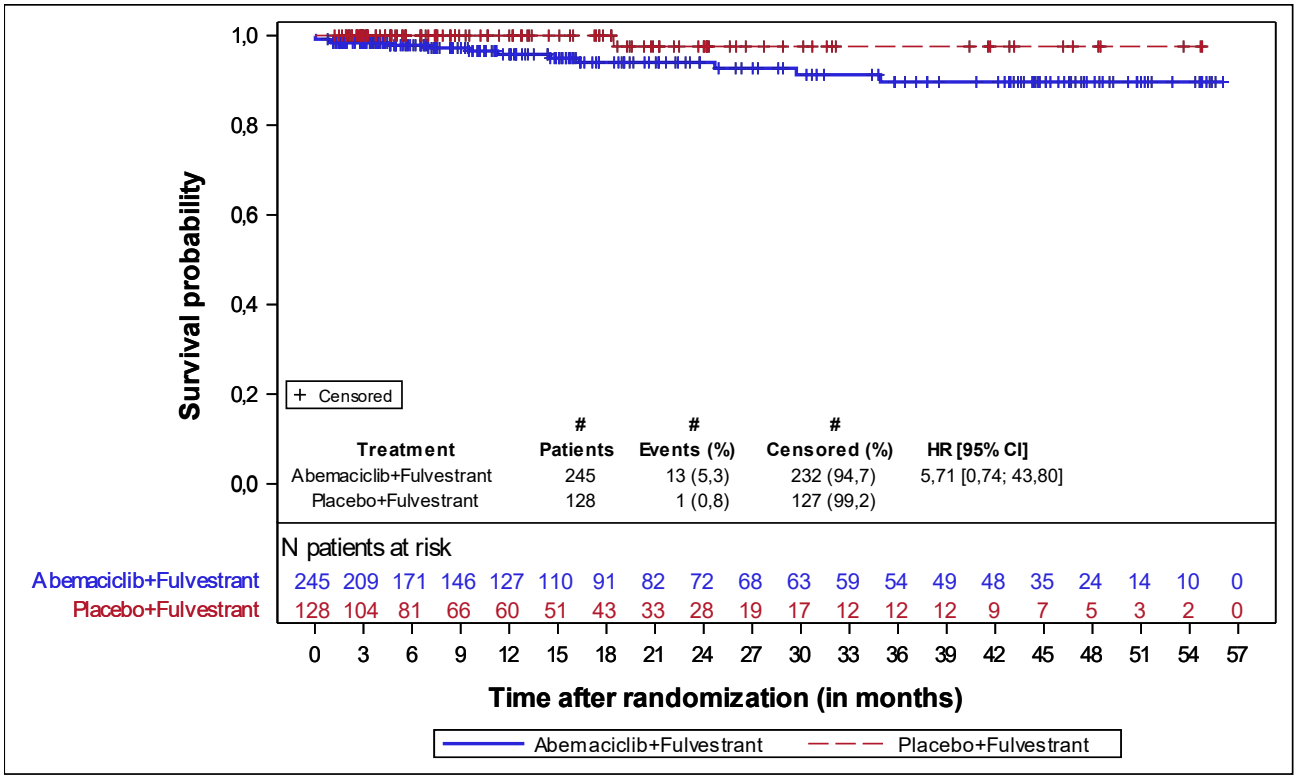
Figure 094: Kaplan-Meier curves for adverse events according PT - Psychiatric disorders / Anxiety
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraep006_popa1.rtf
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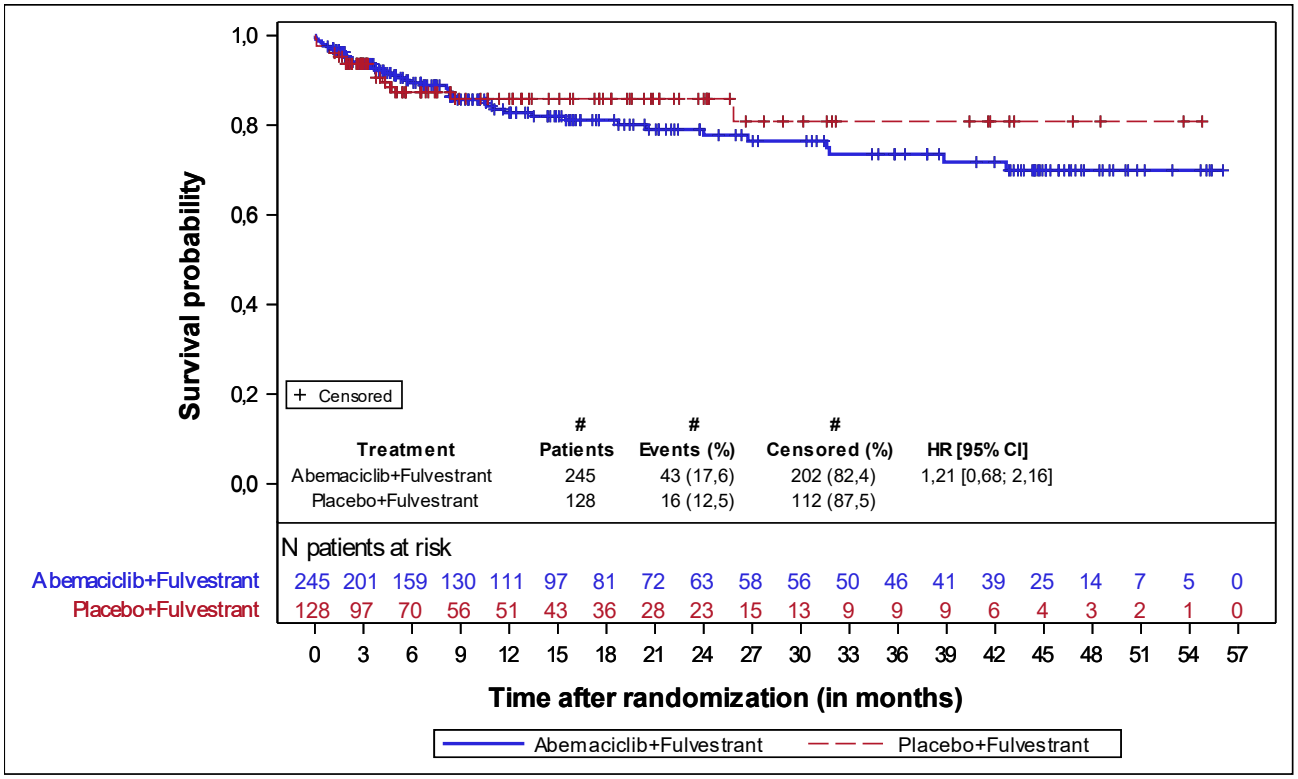
Figure 095: Kaplan-Meier curves for adverse events according PT - Musculoskeletal and connective tissue disorders / Arthralgia
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraep007_popa1.rtf
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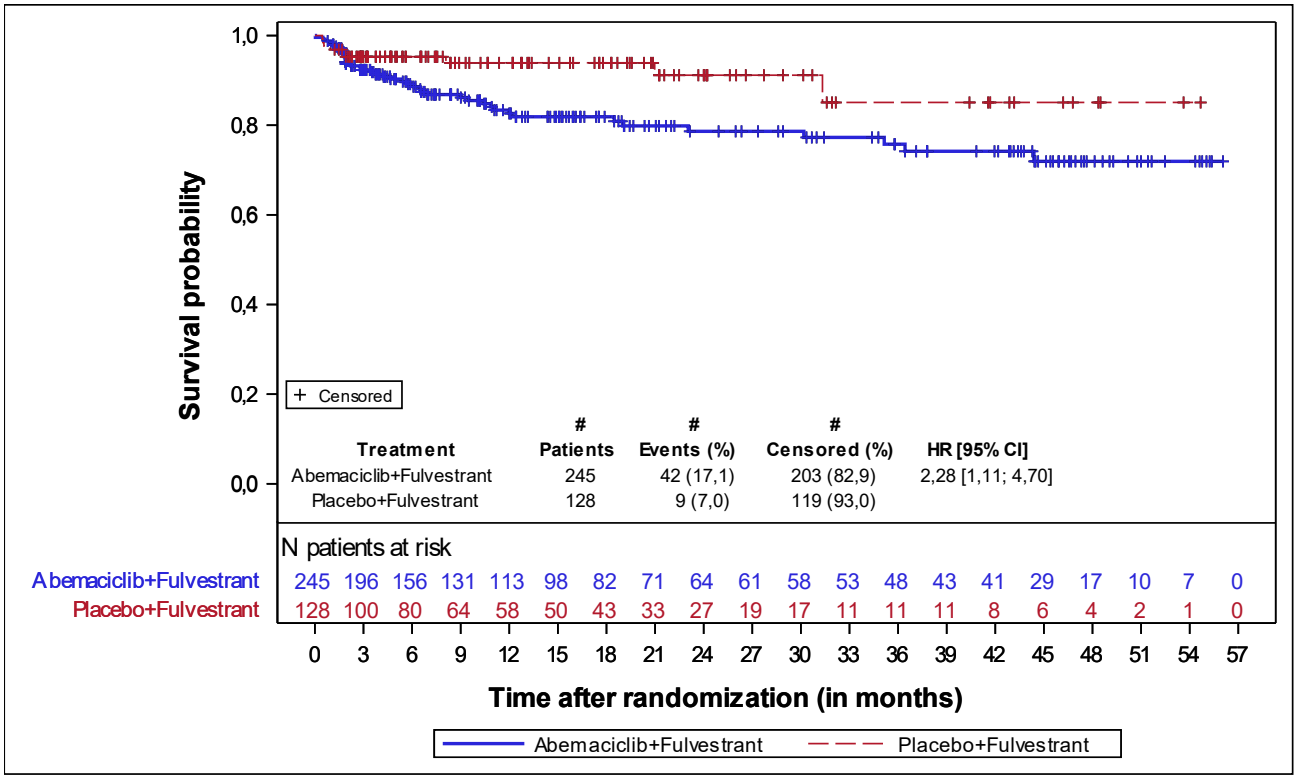
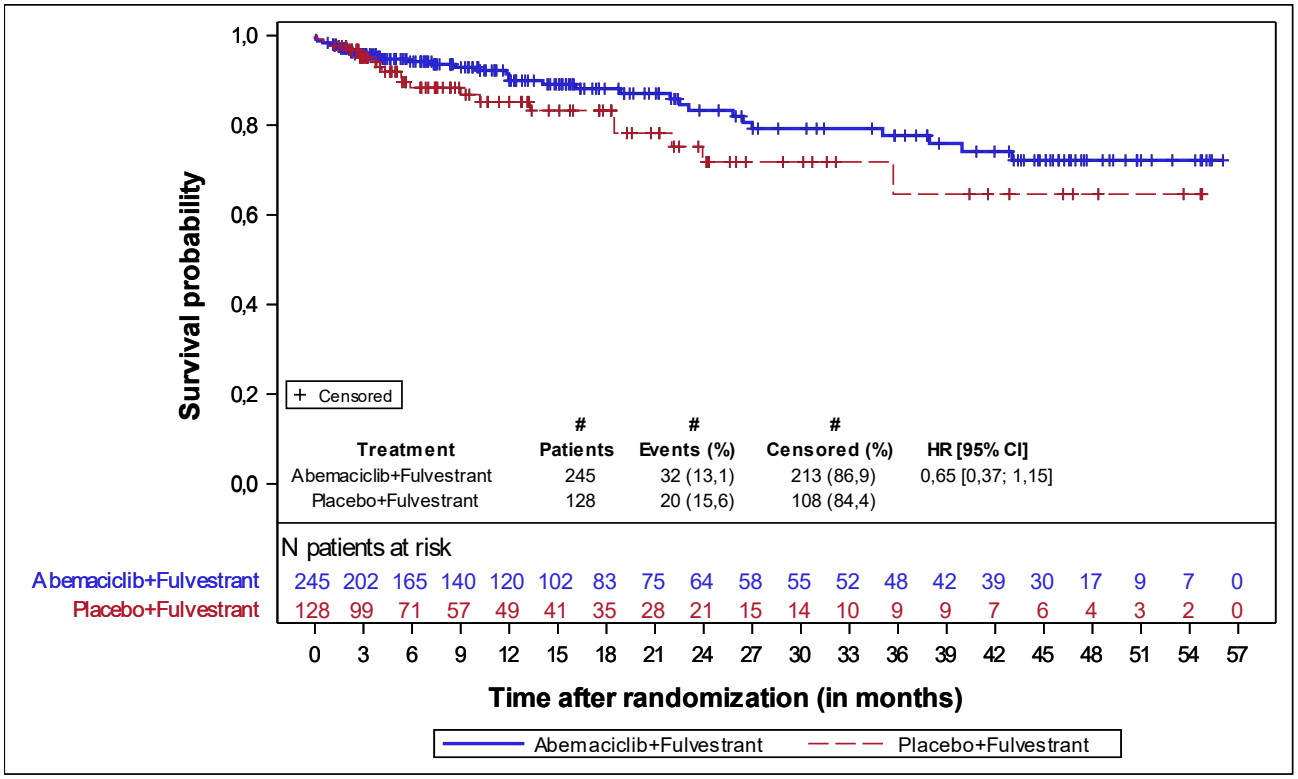
Figure 096: Kaplan-Meier curves for adverse events according PT - Investigations / Aspartate aminotransferase increased
Safety Population - Postmenopausal (1st line)



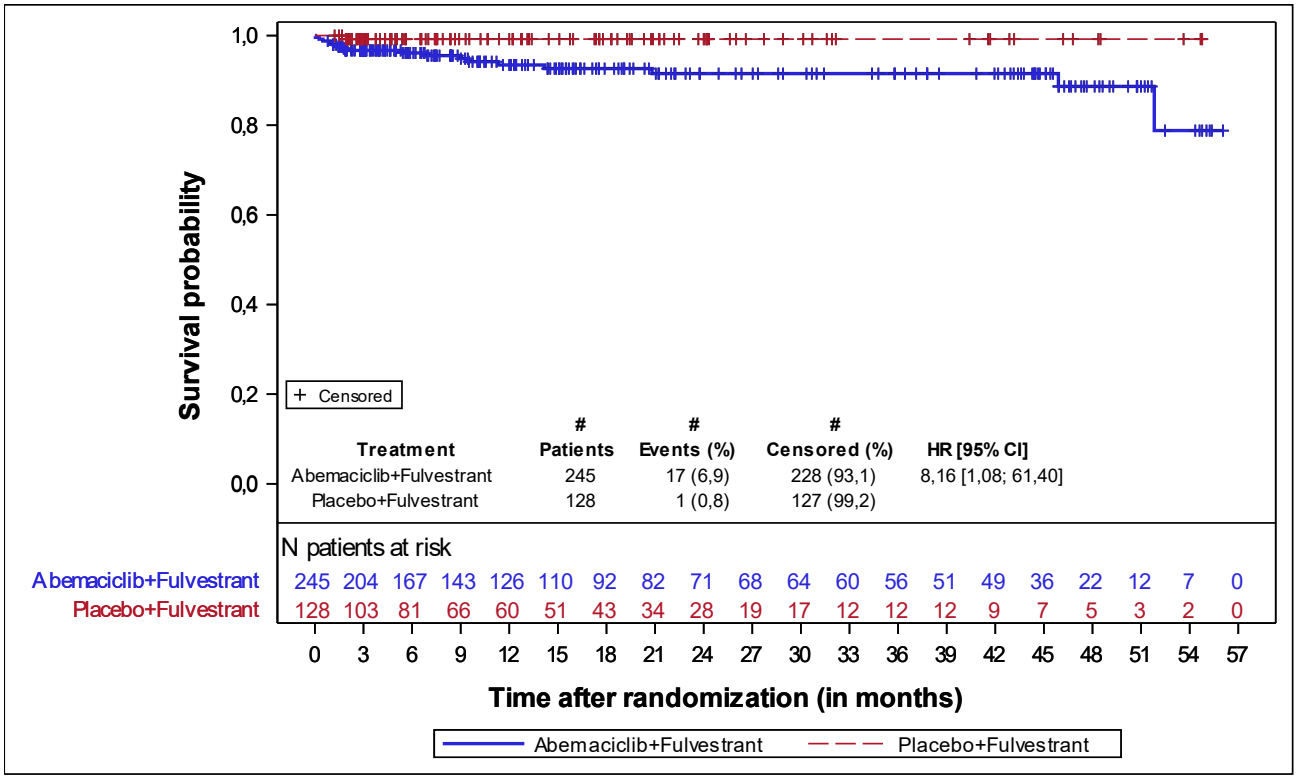
Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraep008_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 097: Kaplan-Meier curves for adverse events according PT - Musculoskeletal and connective tissue disorders / Back pain
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraep009_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 098: Kaplan-Meier curves for adverse events according PT - Investigations / Blood alkaline phosphatase increased
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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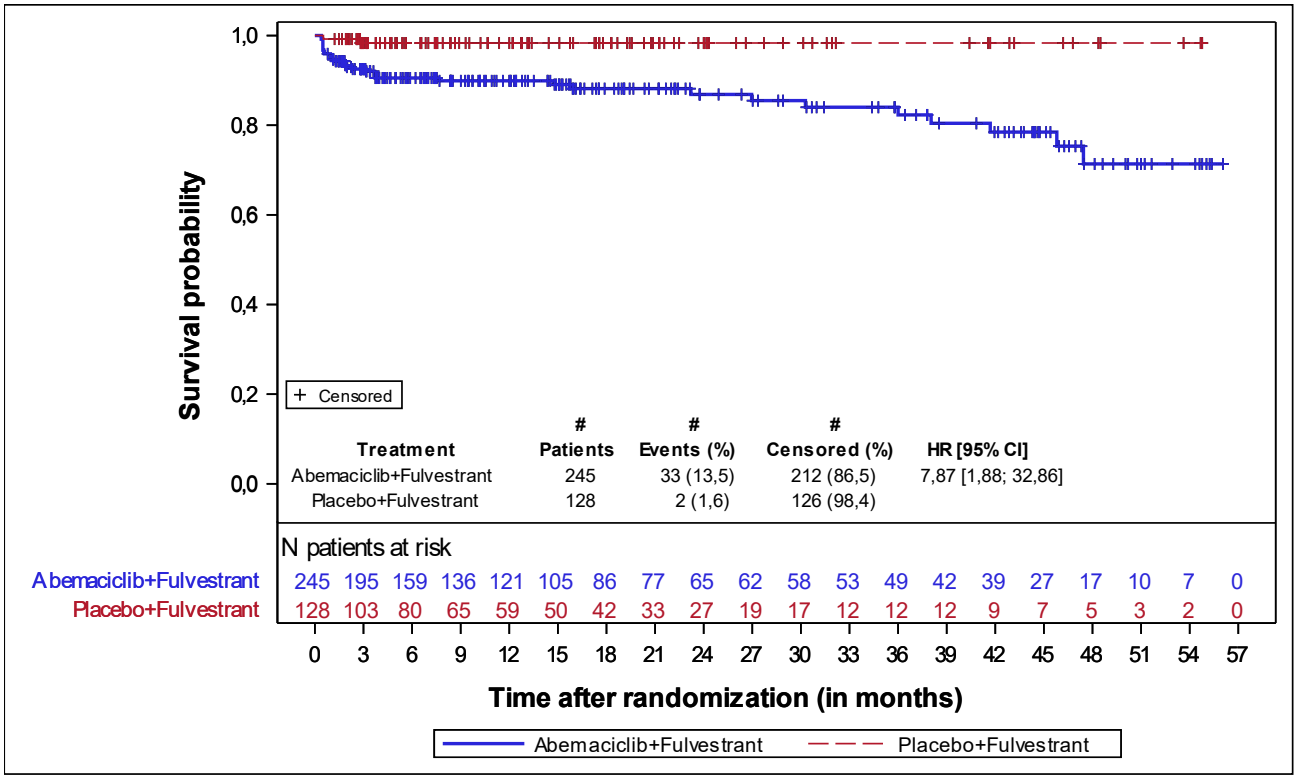
08JUL2021 / 02:43

Figure 099: Kaplan-Meier curves for adverse events according PT - Investigations / Blood creatinine increased
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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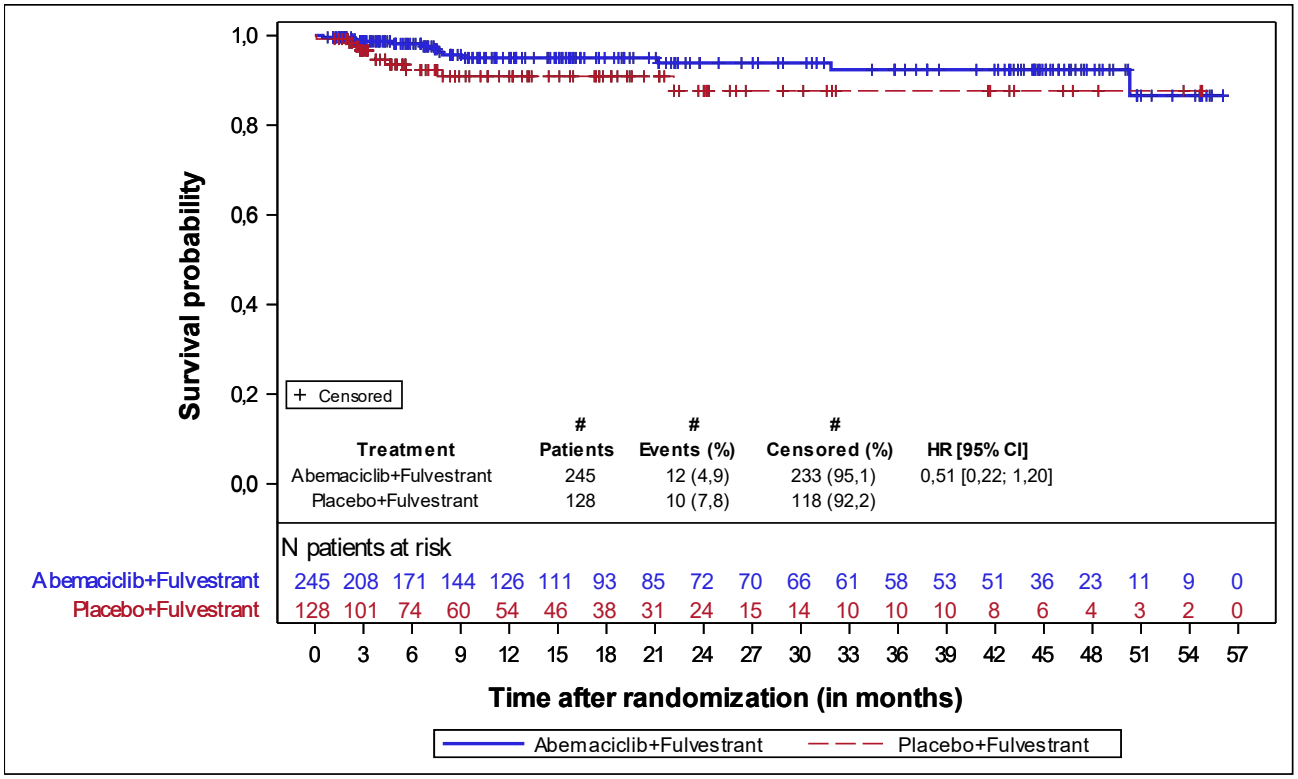
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 100: Kaplan-Meier curves for adverse events according PT - Musculoskeletal and connective tissue disorders / Bone pain
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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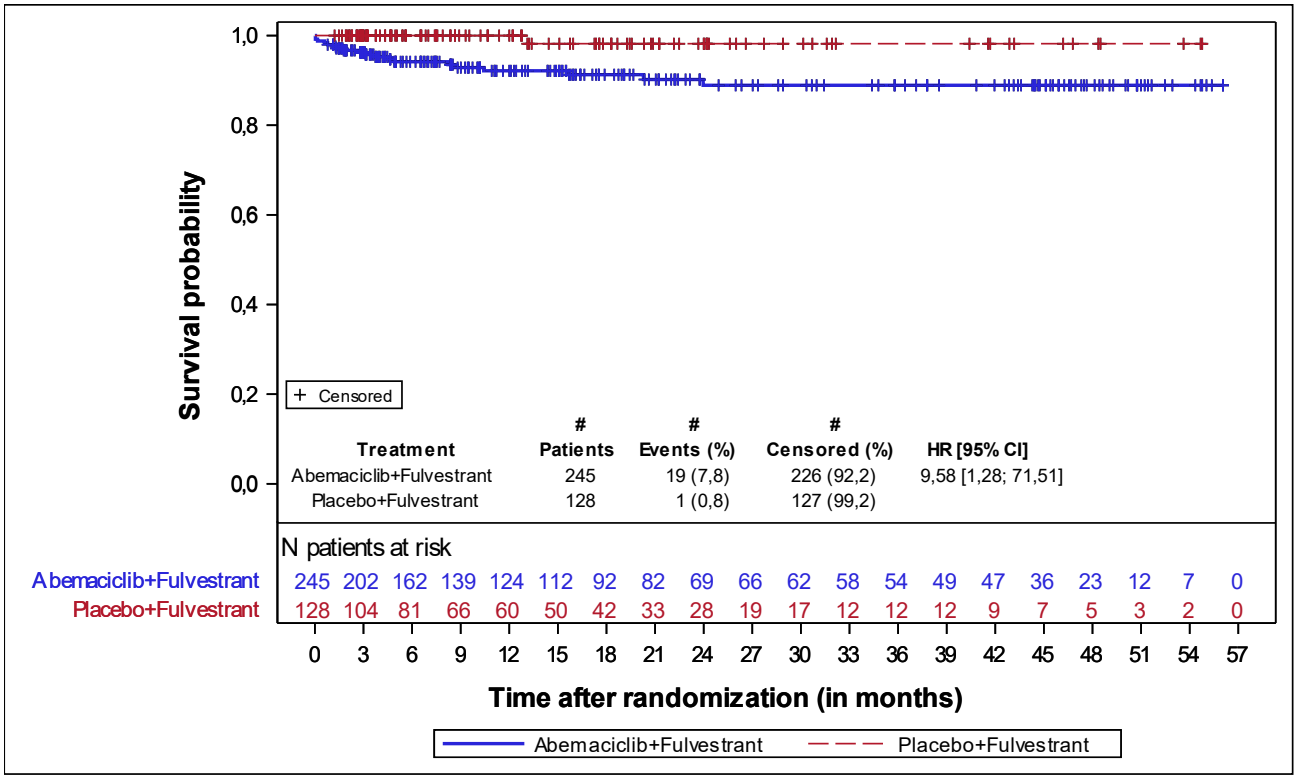
08JUL2021 / 02:43

Figure 101: Kaplan-Meier curves for adverse events according PT - General disorders and administration site conditions / Chills Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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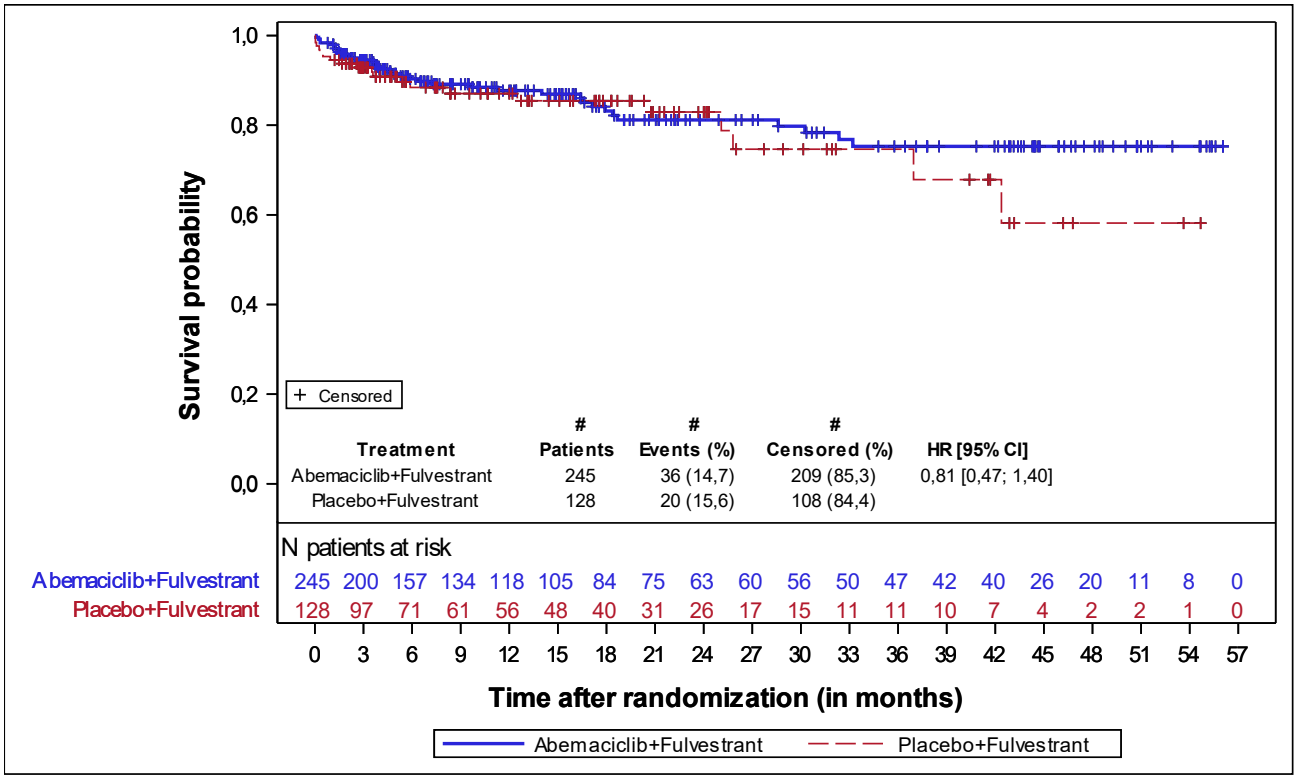
08JUL2021 / 02:43

Figure 102: Kaplan-Meier curves for adverse events according PT - Gastrointestinal disorders / Constipation
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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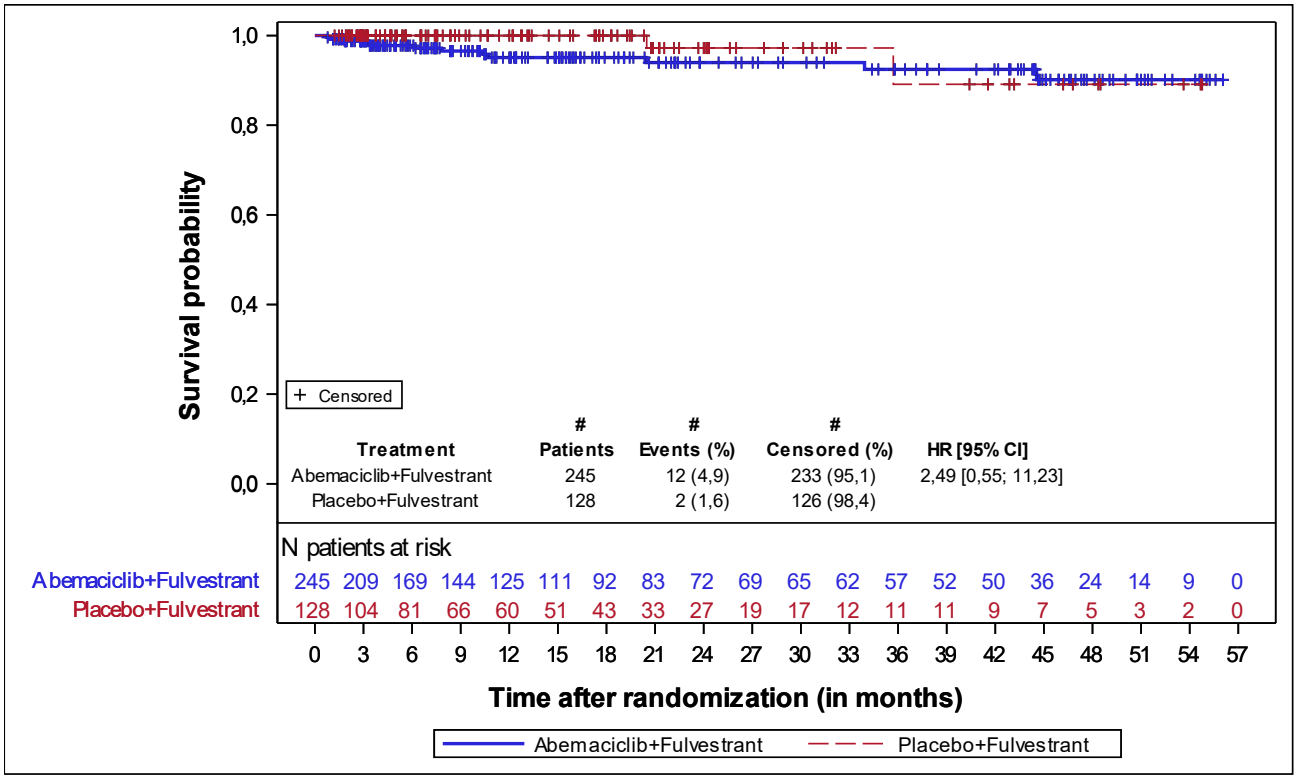
08JUL2021 / 02:43

Figure 103: Kaplan-Meier curves for adverse events according PT - Injury, poisoning and procedural complications / Contusion Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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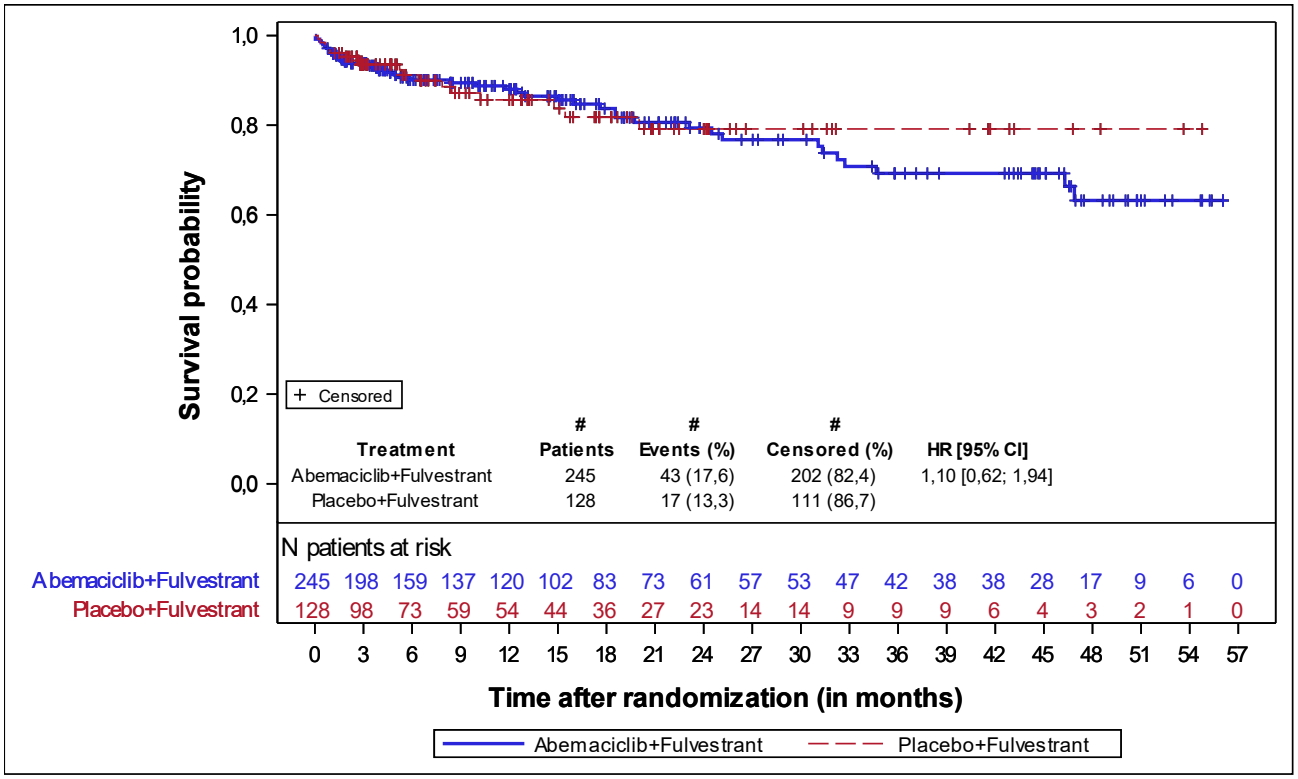
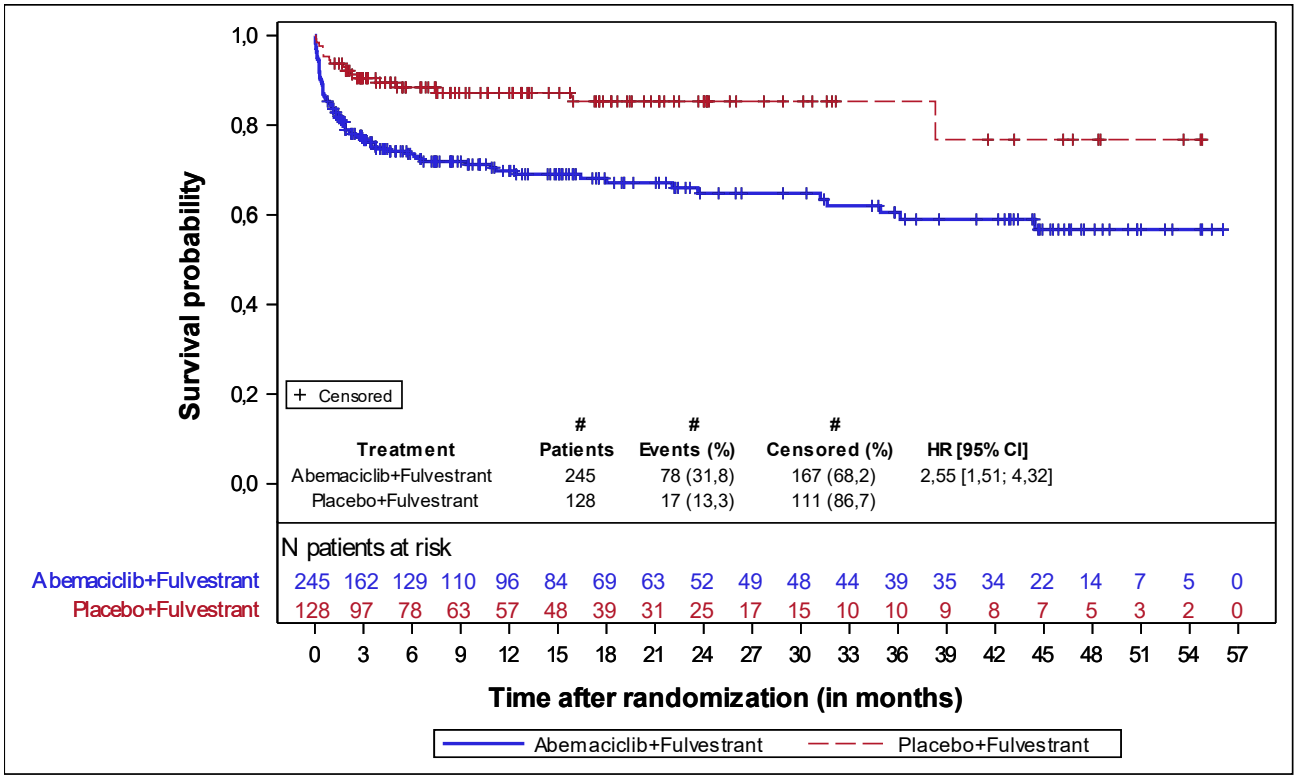
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 104: Kaplan-Meier curves for adverse events according PT - Respiratory, thoracic and mediastinal disorders / Cough
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraep016_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 105: Kaplan-Meier curves for adverse events according PT - Metabolism and nutrition disorders / Decreased appetite Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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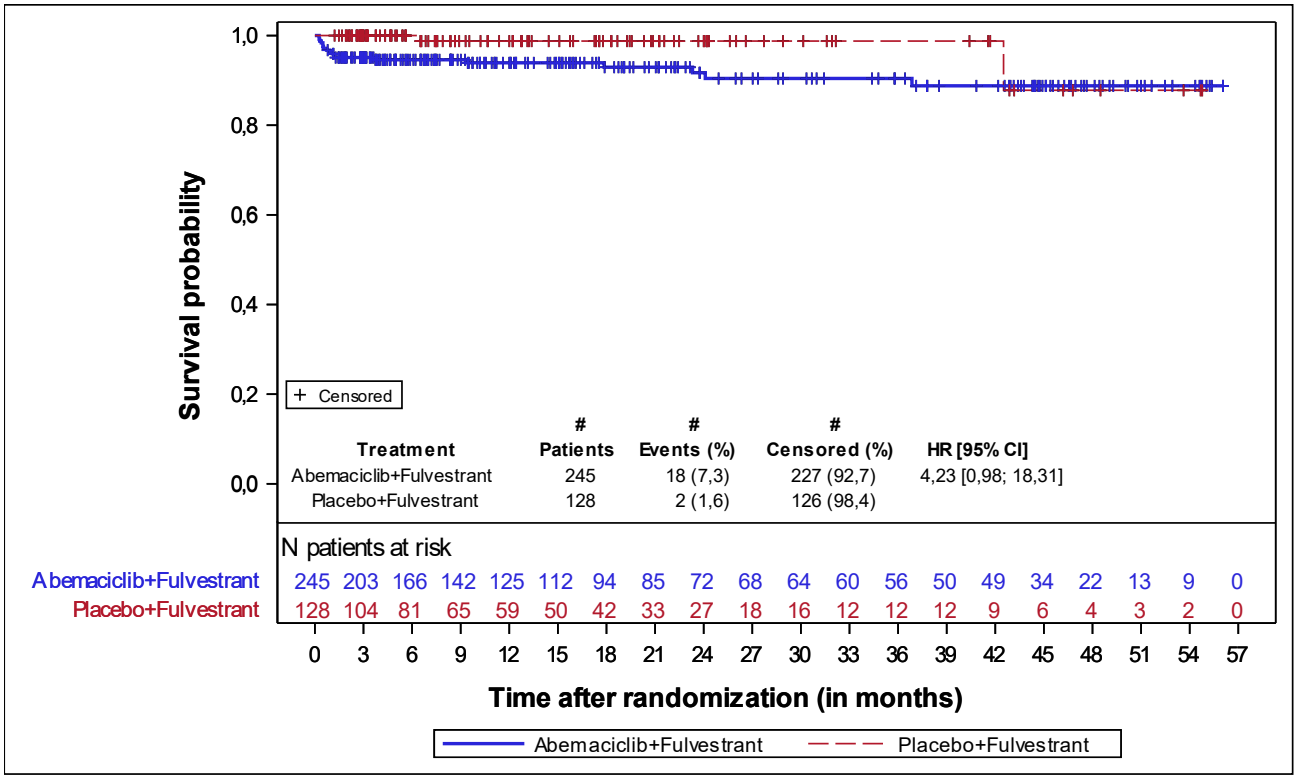
Figure 106: Kaplan-Meier curves for adverse events according PT - Metabolism and nutrition disorders / Dehydration
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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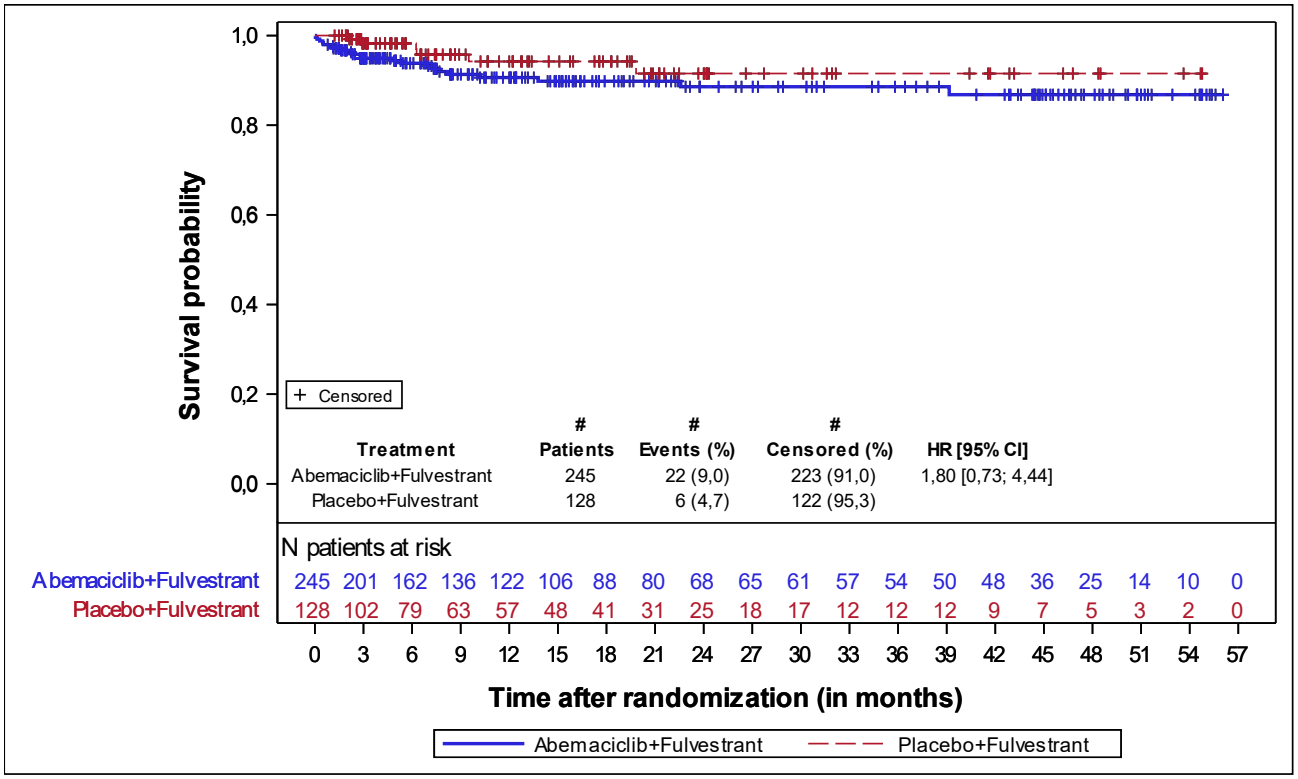
Figure 107: Kaplan-Meier curves for adverse events according PT - Psychiatric disorders / Depression
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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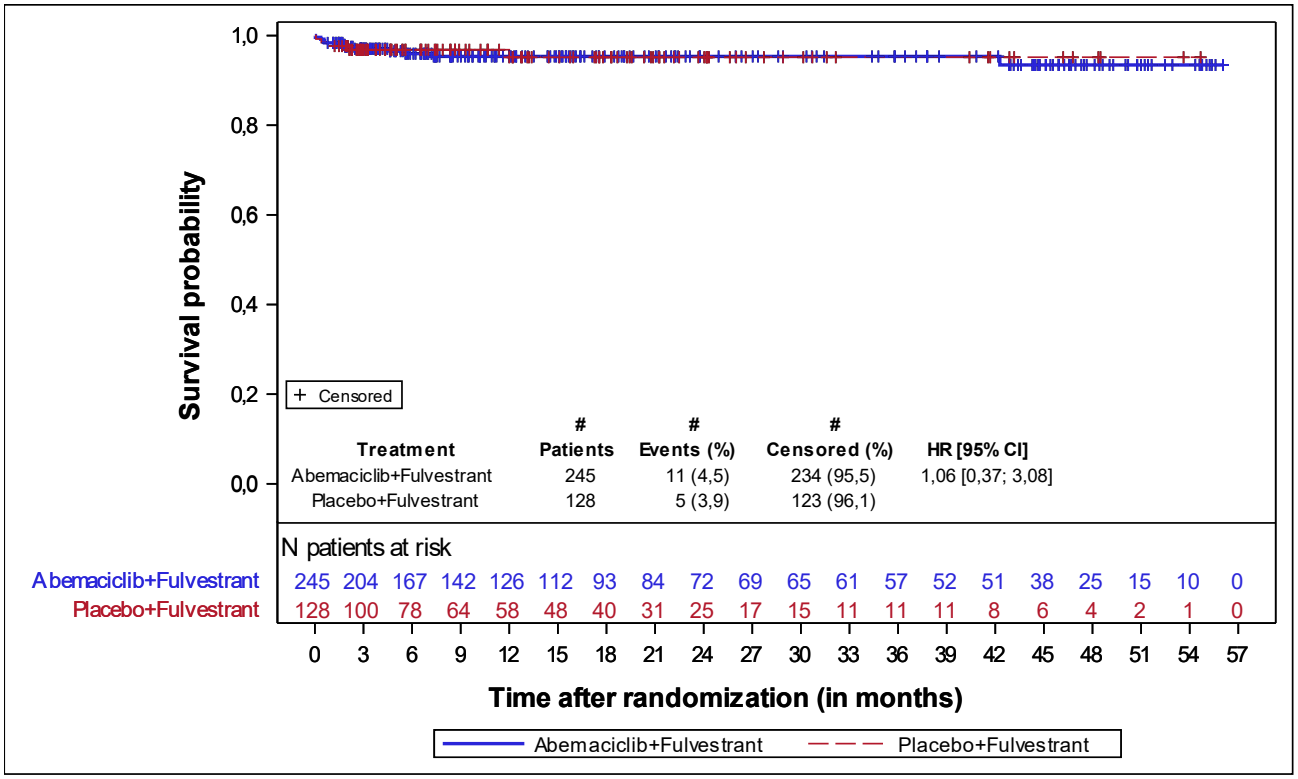
Figure 108: Kaplan-Meier curves for adverse events according PT - Skin and subcutaneous tissue disorders / Dermatitis acneiform Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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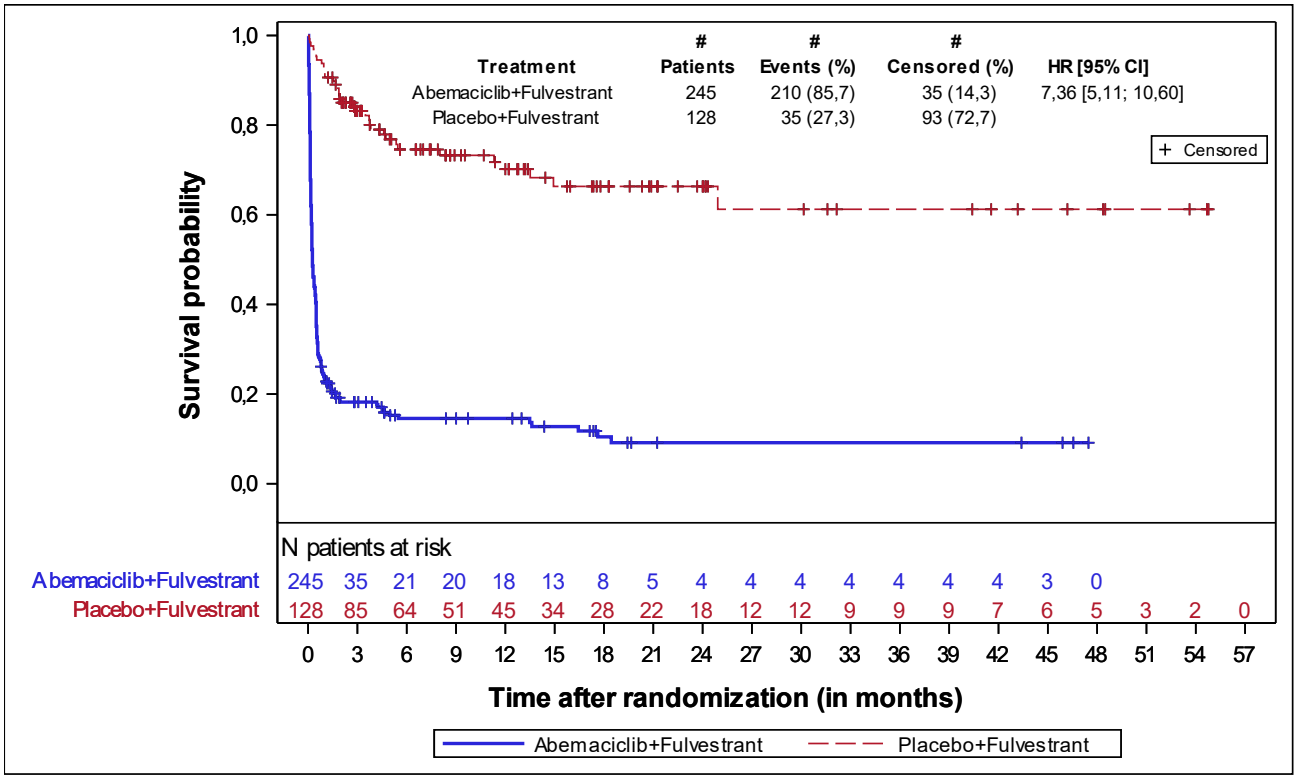
Figure 109: Kaplan-Meier curves for adverse events according PT - Gastrointestinal disorders / Diarrhoea
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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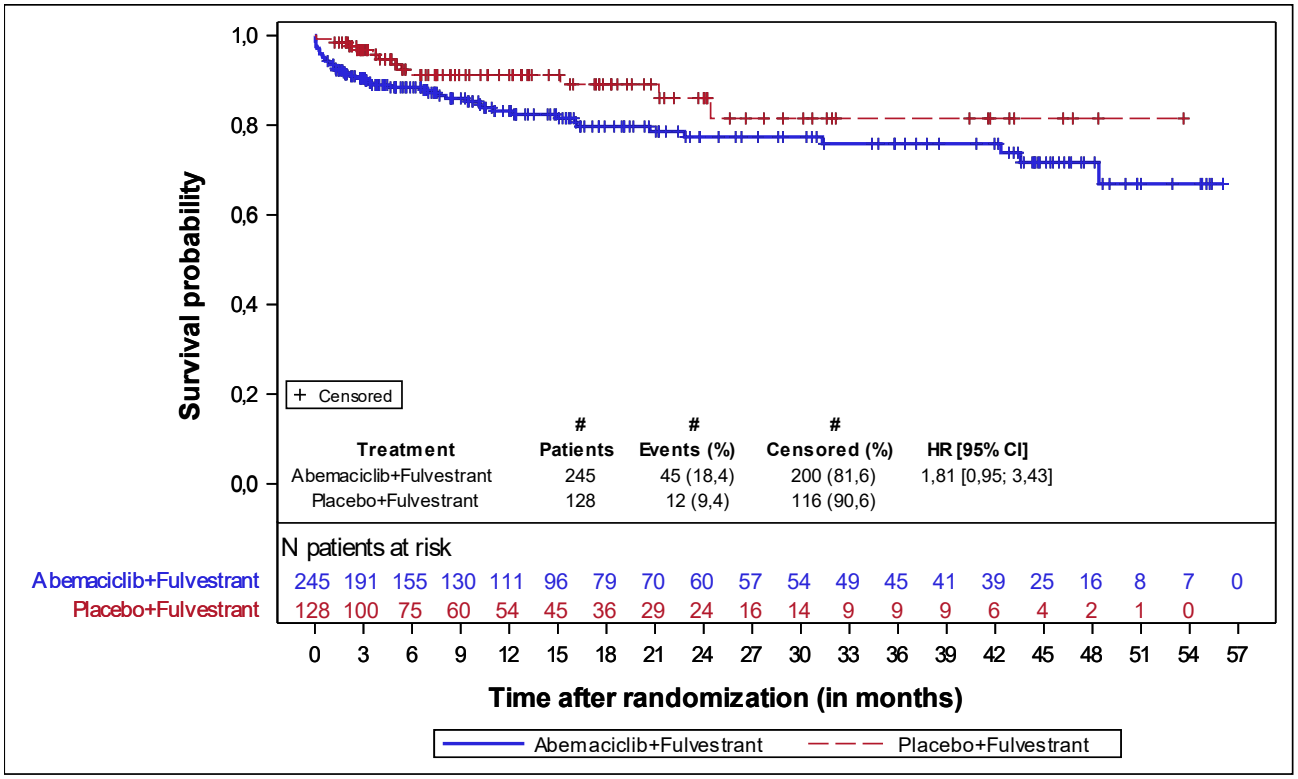
Figure 110: Kaplan-Meier curves for adverse events according PT - Nervous system disorders / Dizziness
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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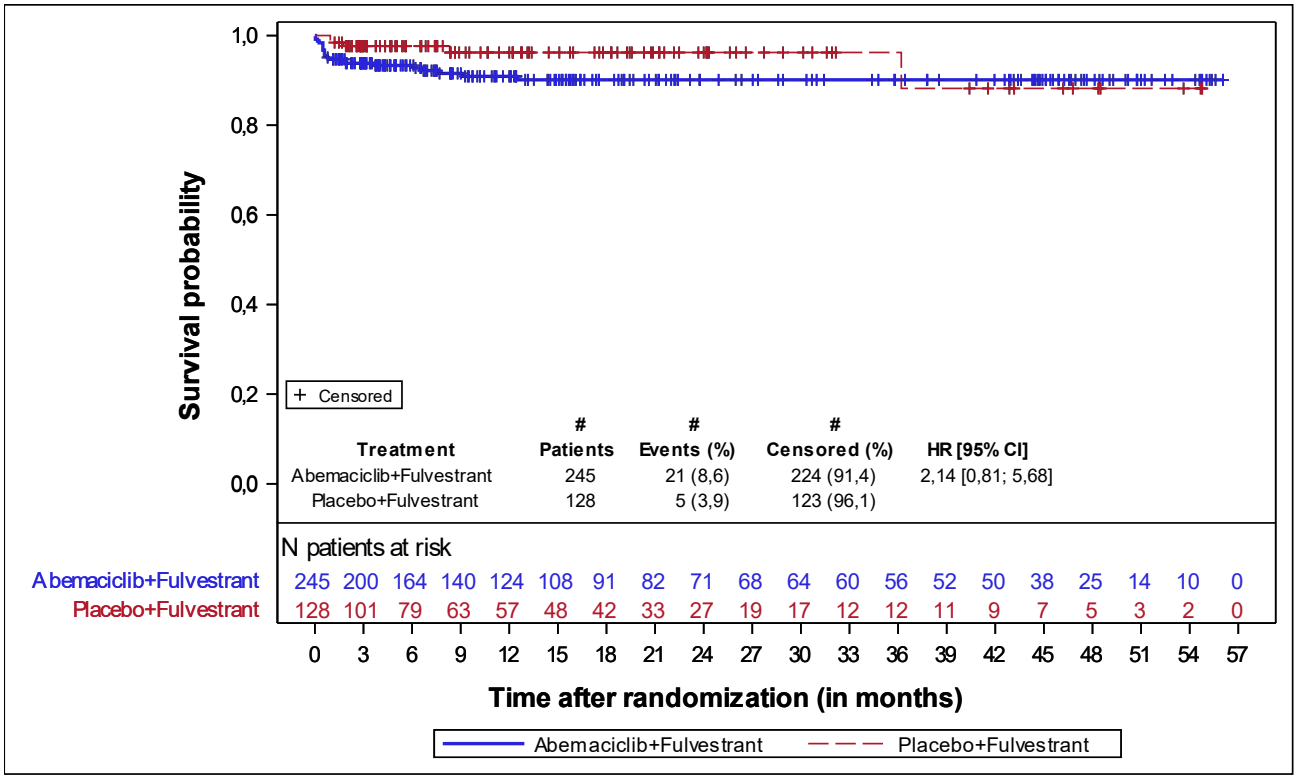
Figure 111: Kaplan-Meier curves for adverse events according PT - Gastrointestinal disorders / Dry mouth
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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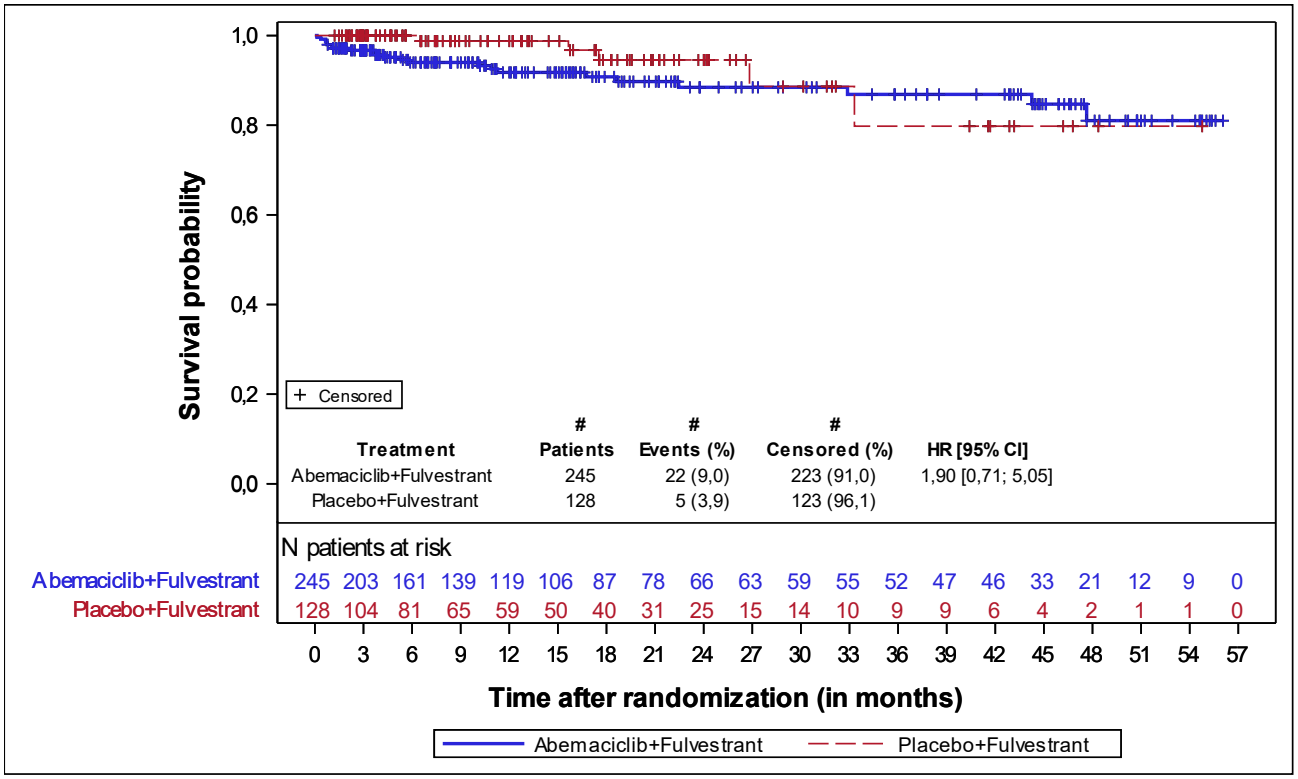
Figure 112: Kaplan-Meier curves for adverse events according PT - Skin and subcutaneous tissue disorders / Dry skin Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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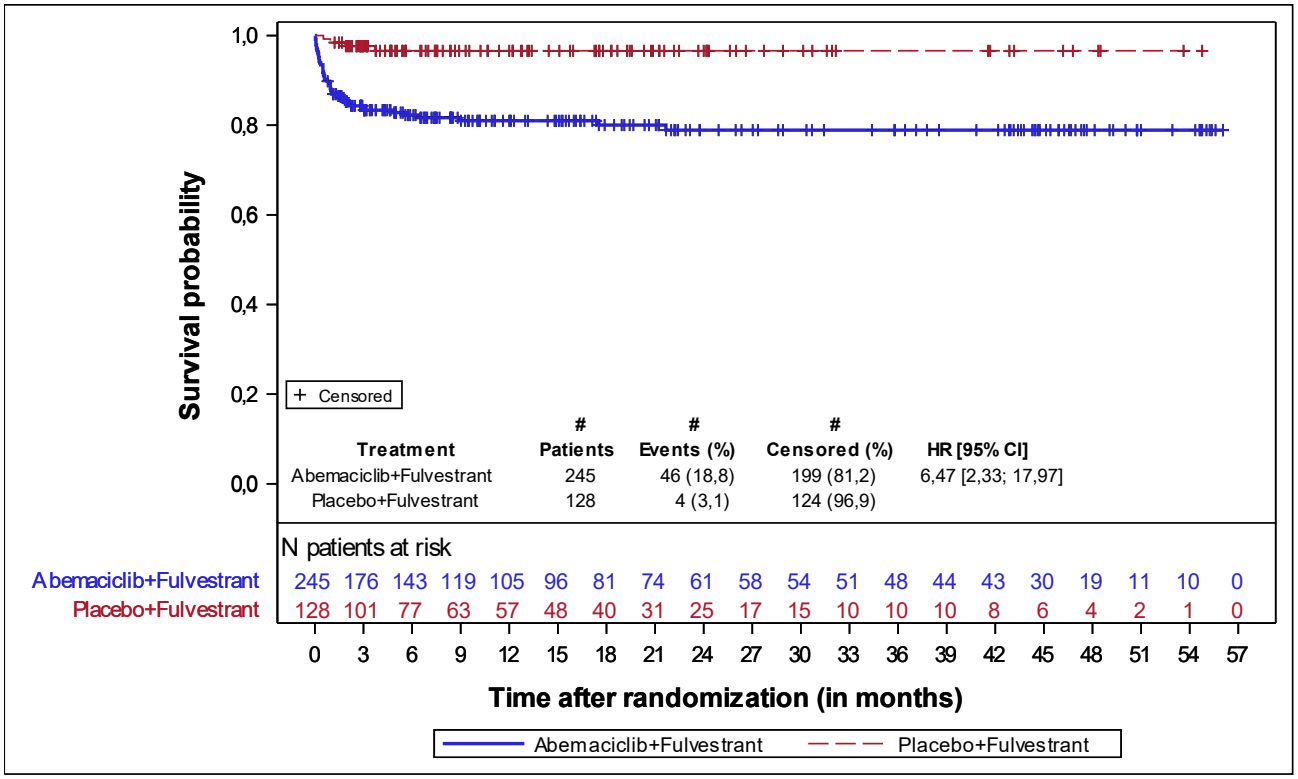
Figure 113: Kaplan-Meier curves for adverse events according PT - Nervous system disorders / Dysgeusia
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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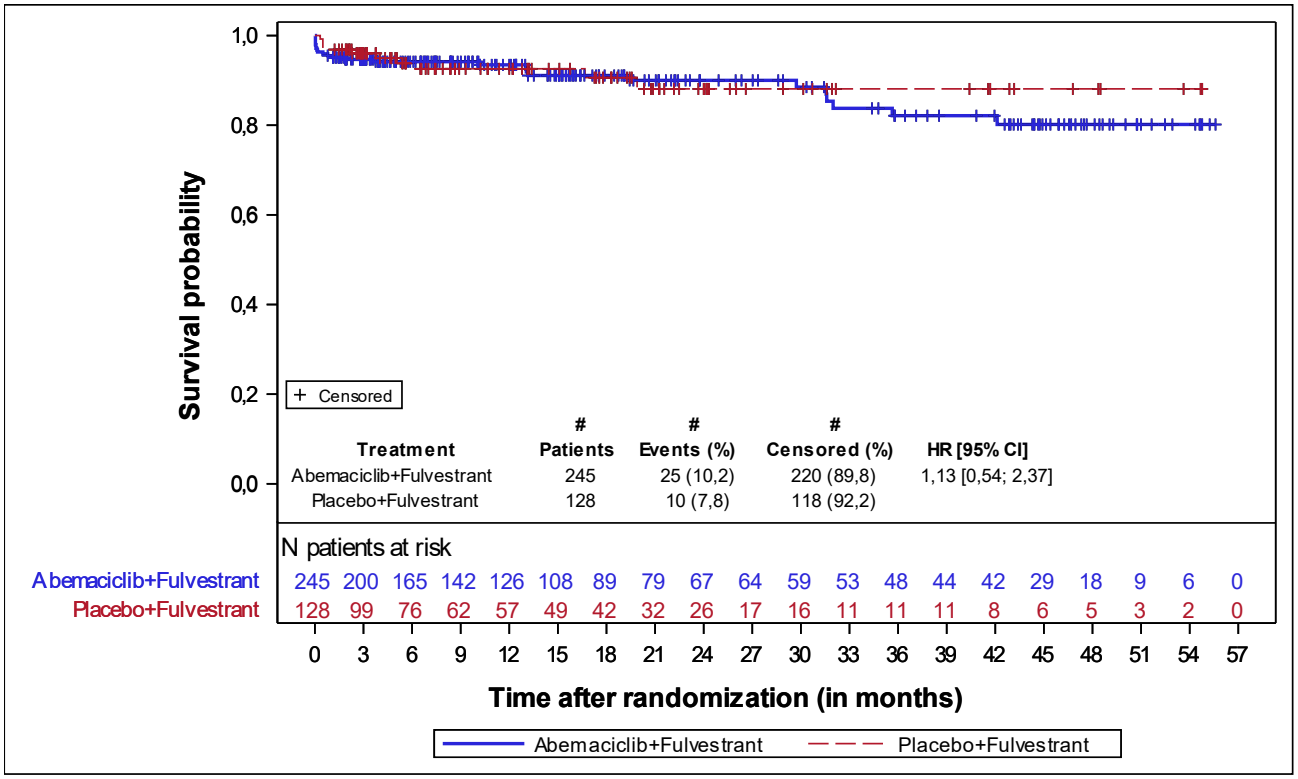
Figure 114: Kaplan-Meier curves for adverse events according PT - Gastrointestinal disorders / Dyspepsia
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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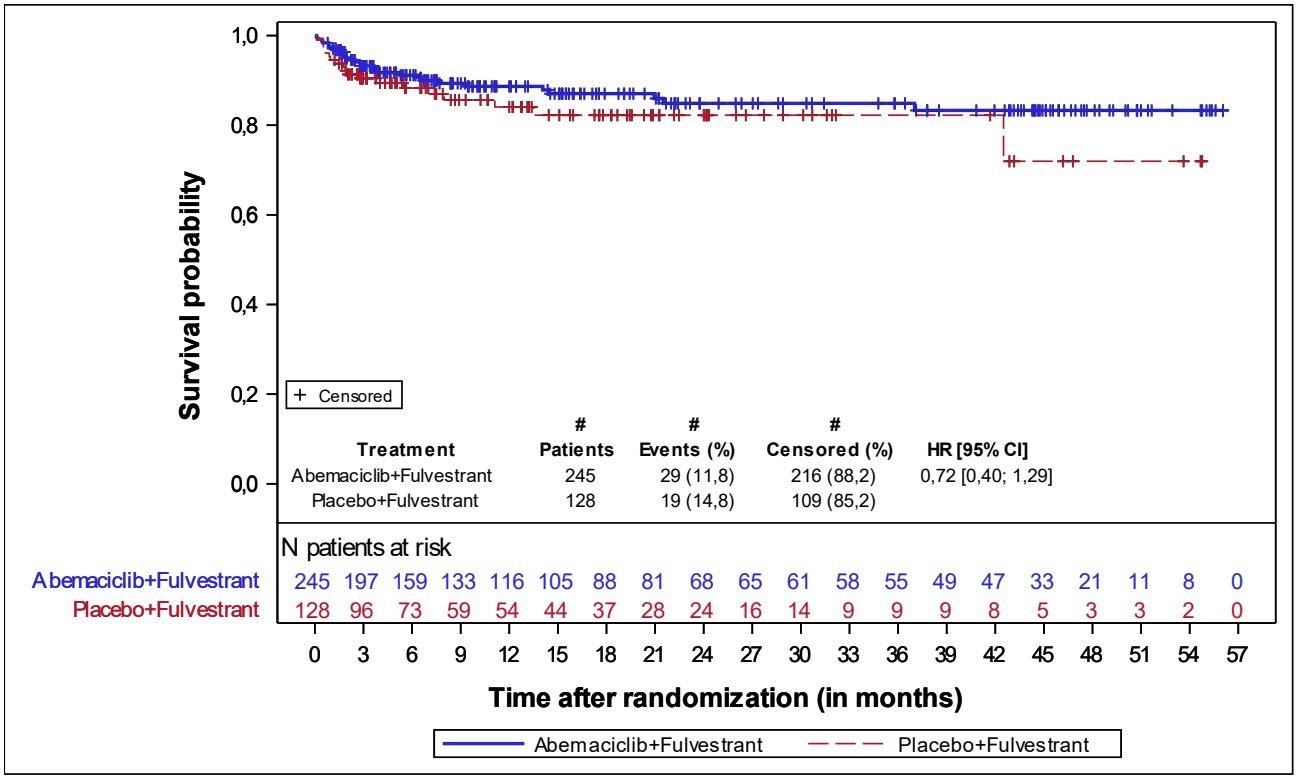
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 115: Kaplan-Meier curves for adverse events according PT - Respiratory, thoracic and mediastinal disorders / Dyspnoea Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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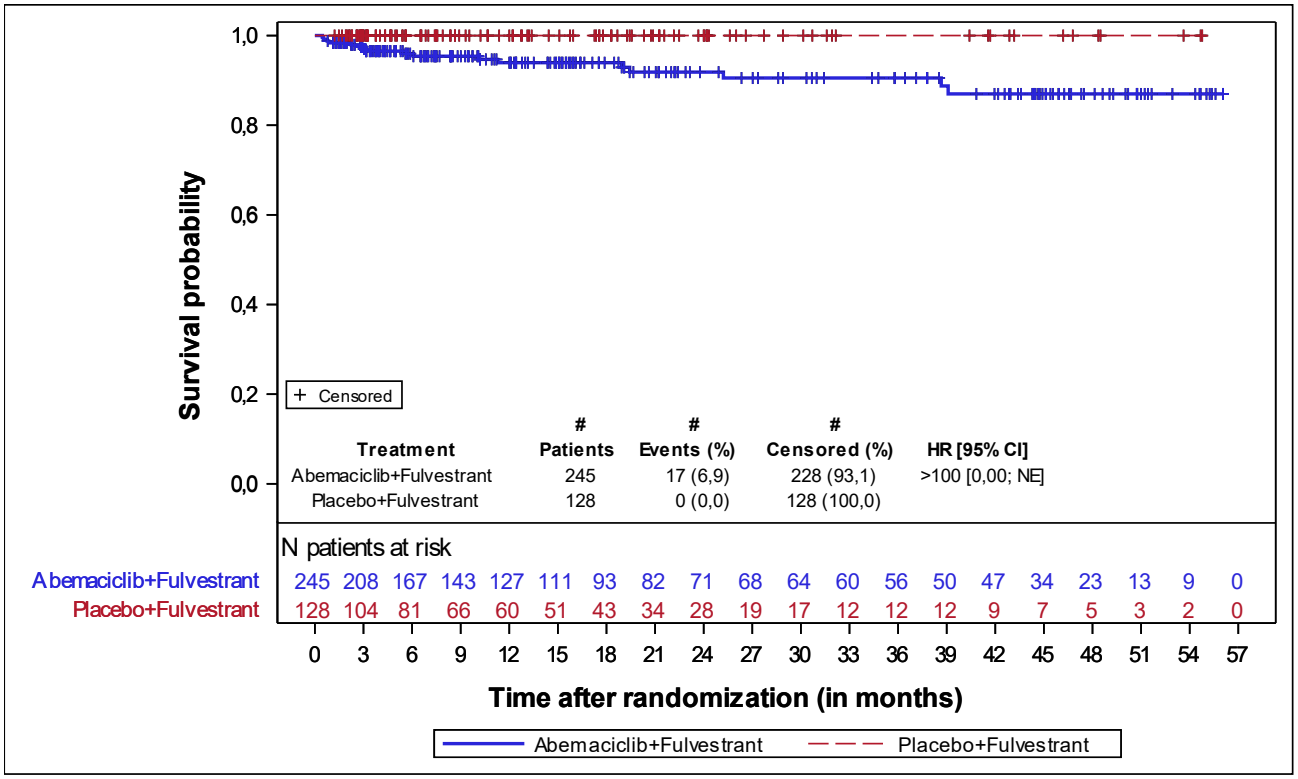
Figure 116: Kaplan-Meier curves for adverse events according PT - Vascular disorders / Embolism
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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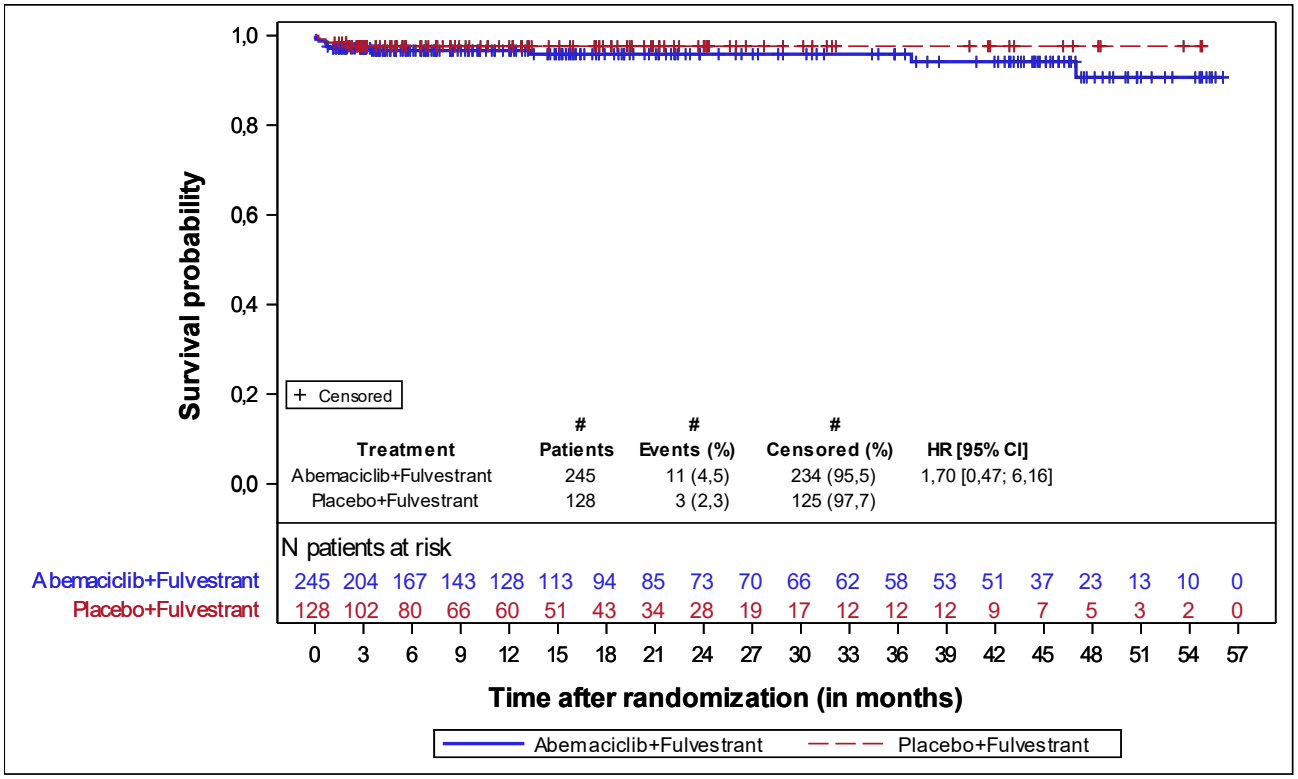
Figure 117: Kaplan-Meier curves for adverse events according PT - Respiratory, thoracic and mediastinal disorders / Epistaxis Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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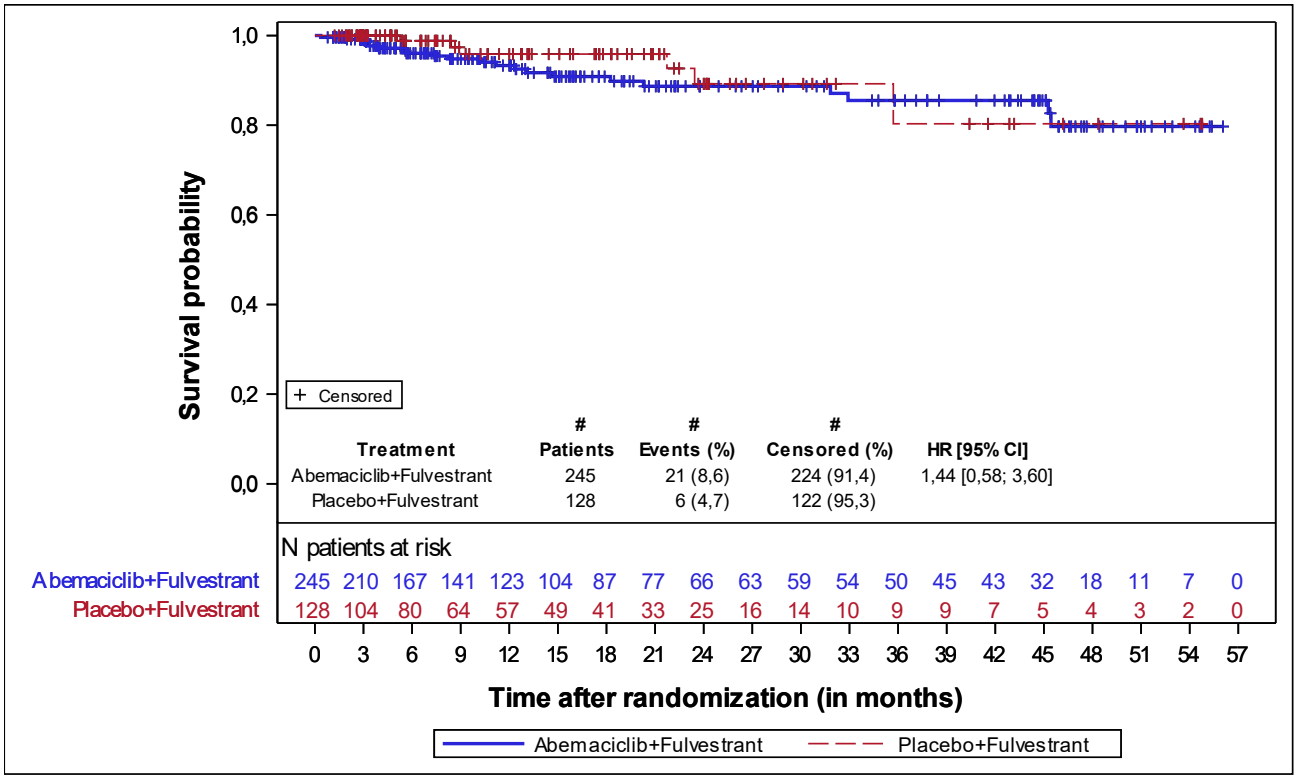
Figure 118: Kaplan-Meier curves for adverse events according PT - Injury, poisoning and procedural complications / Fall Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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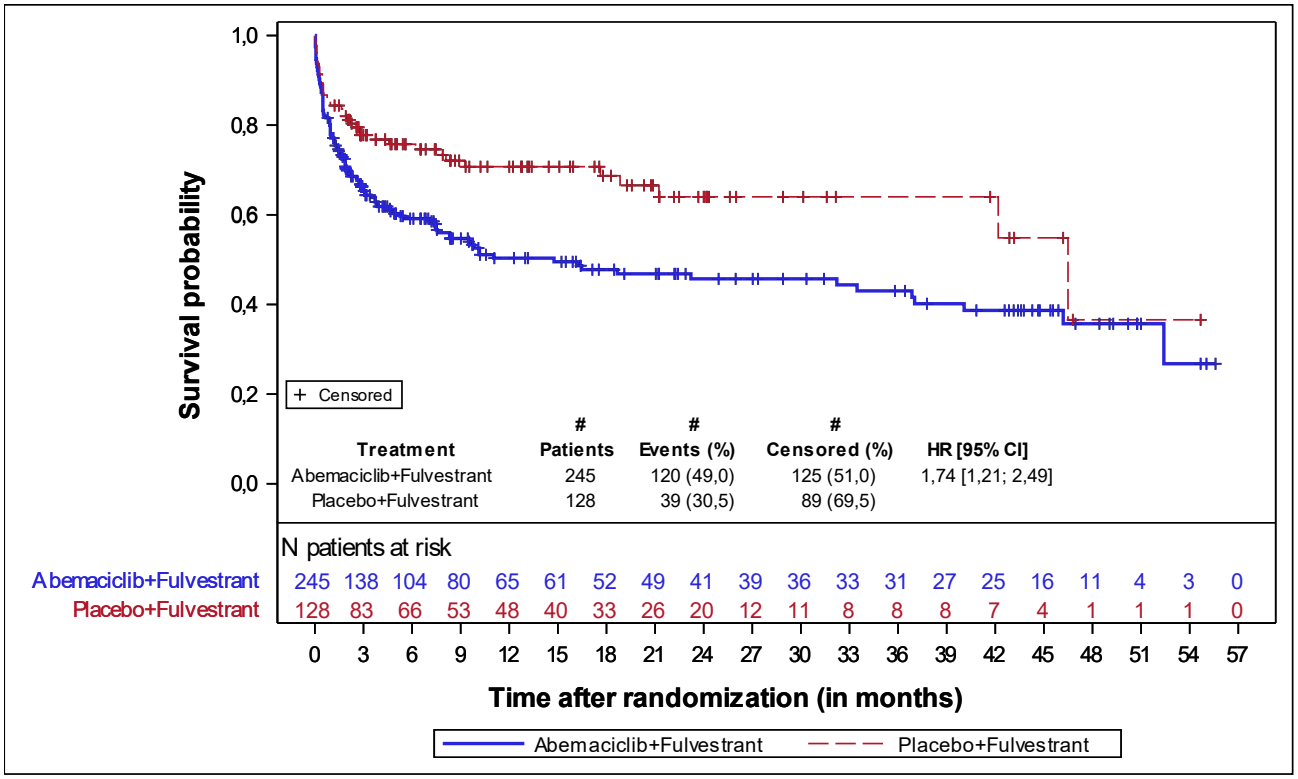
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 119: Kaplan-Meier curves for adverse events according PT - General disorders and administration site conditions / Fatigue Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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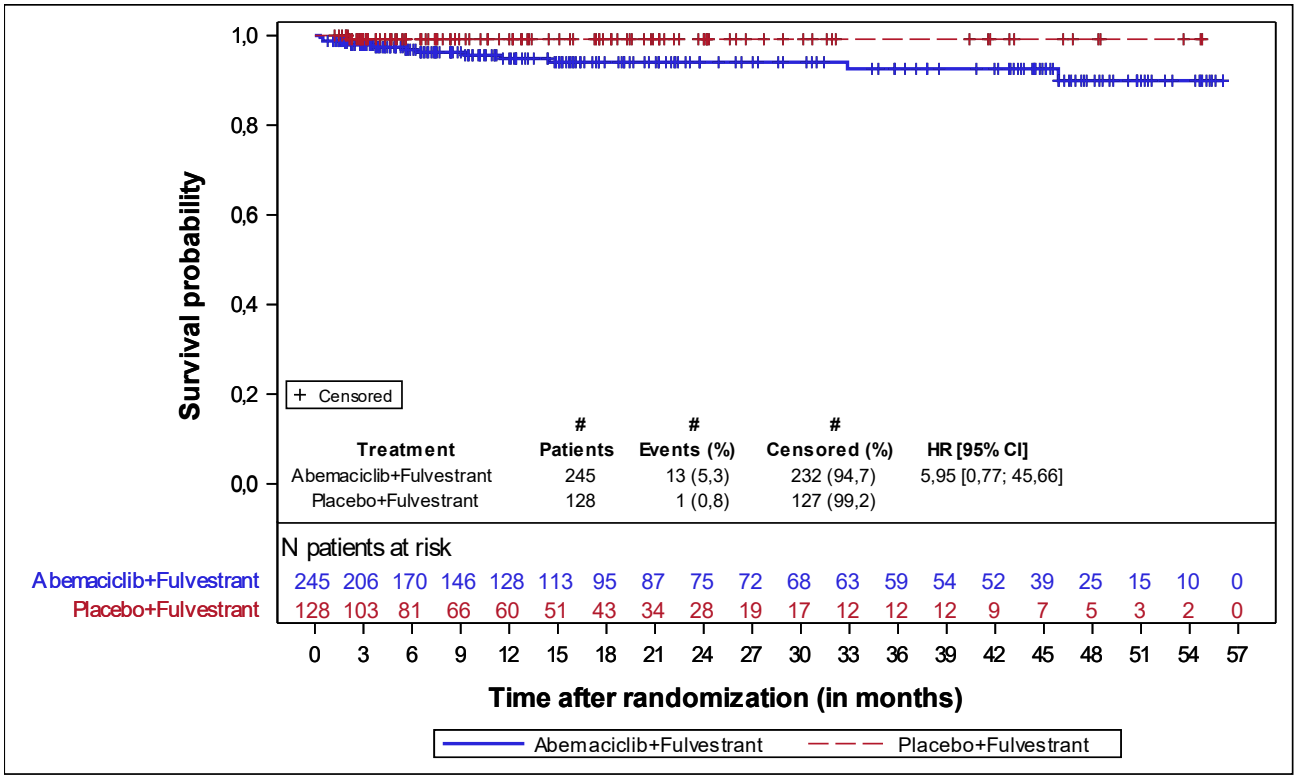
08JUL2021 / 02:43

Figure 120: Kaplan-Meier curves for adverse events according PT - Investigations / Gamma-glutamyltransferase increased
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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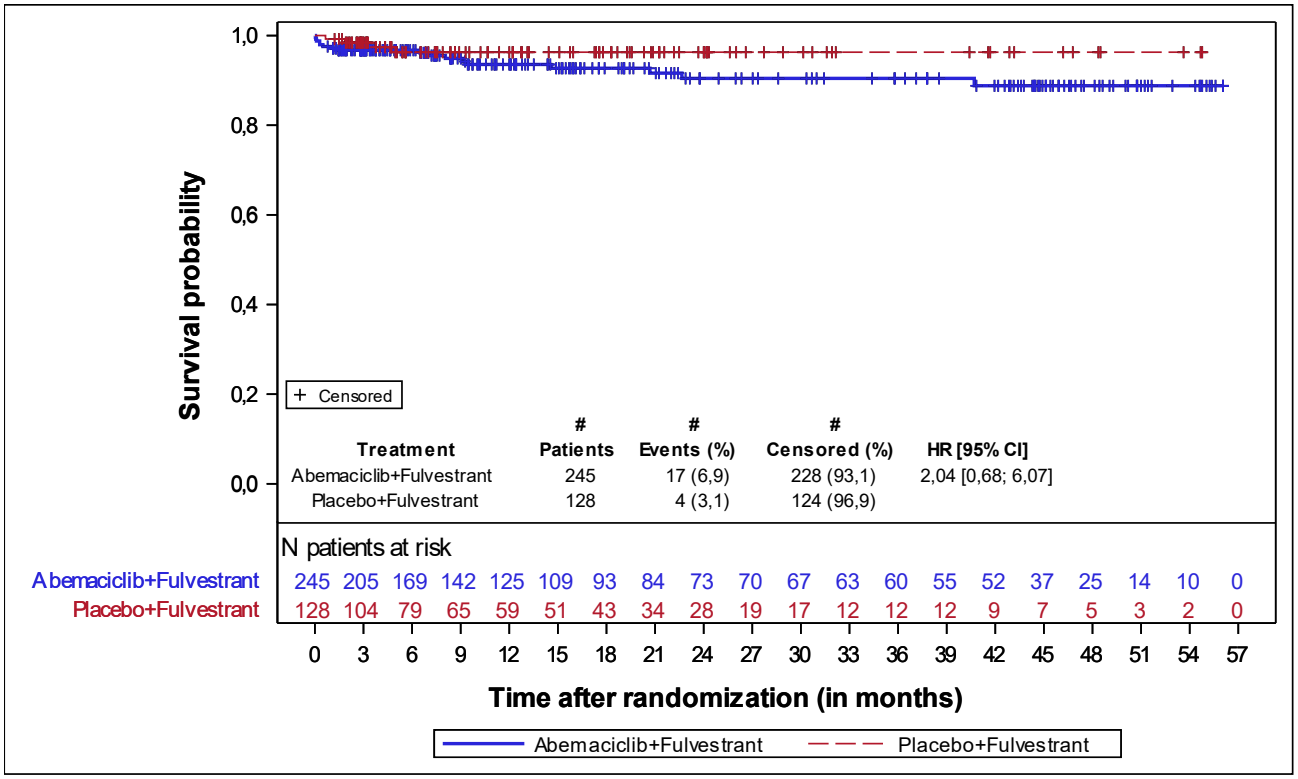
08JUL2021 / 02:43

Figure 121: Kaplan-Meier curves for adverse events according PT - Gastrointestinal disorders / Gastrooesophageal reflux disease Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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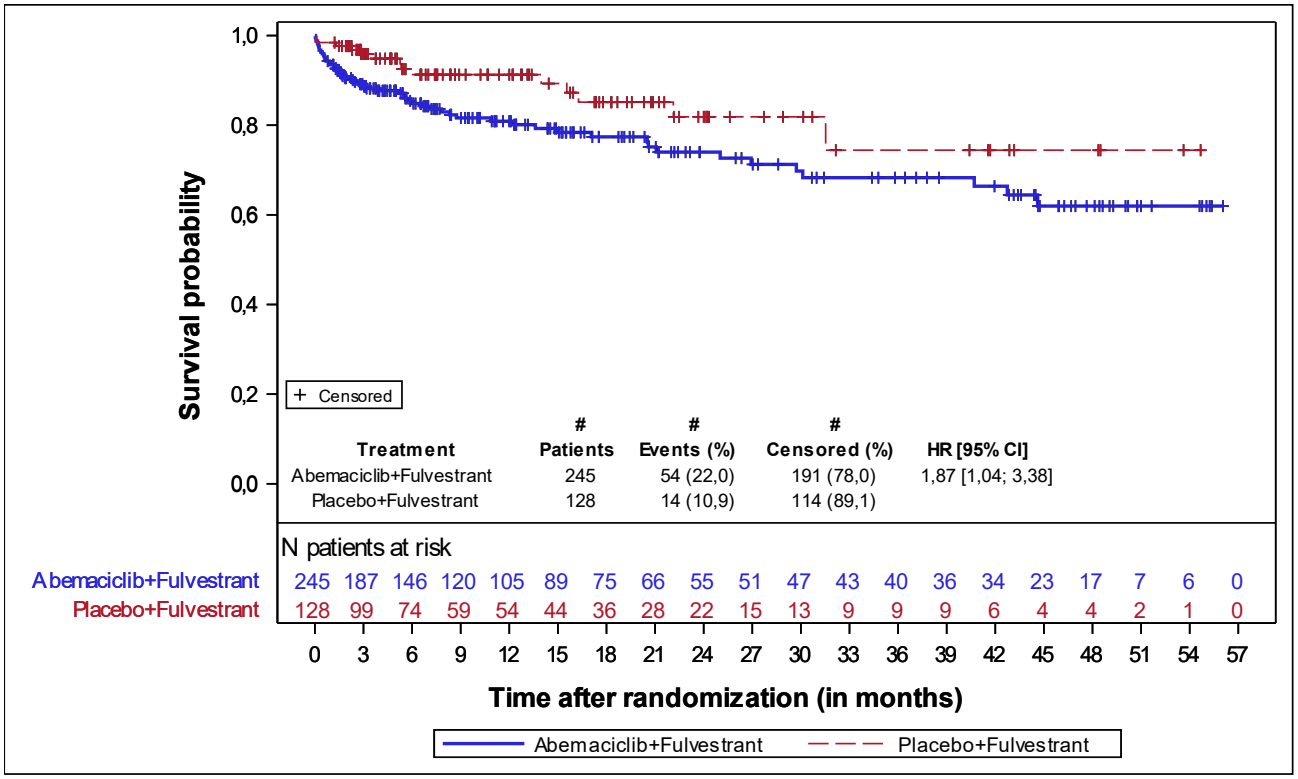
08JUL2021 / 02:43

Figure 122: Kaplan-Meier curves for adverse events according PT - Nervous system disorders / Headache
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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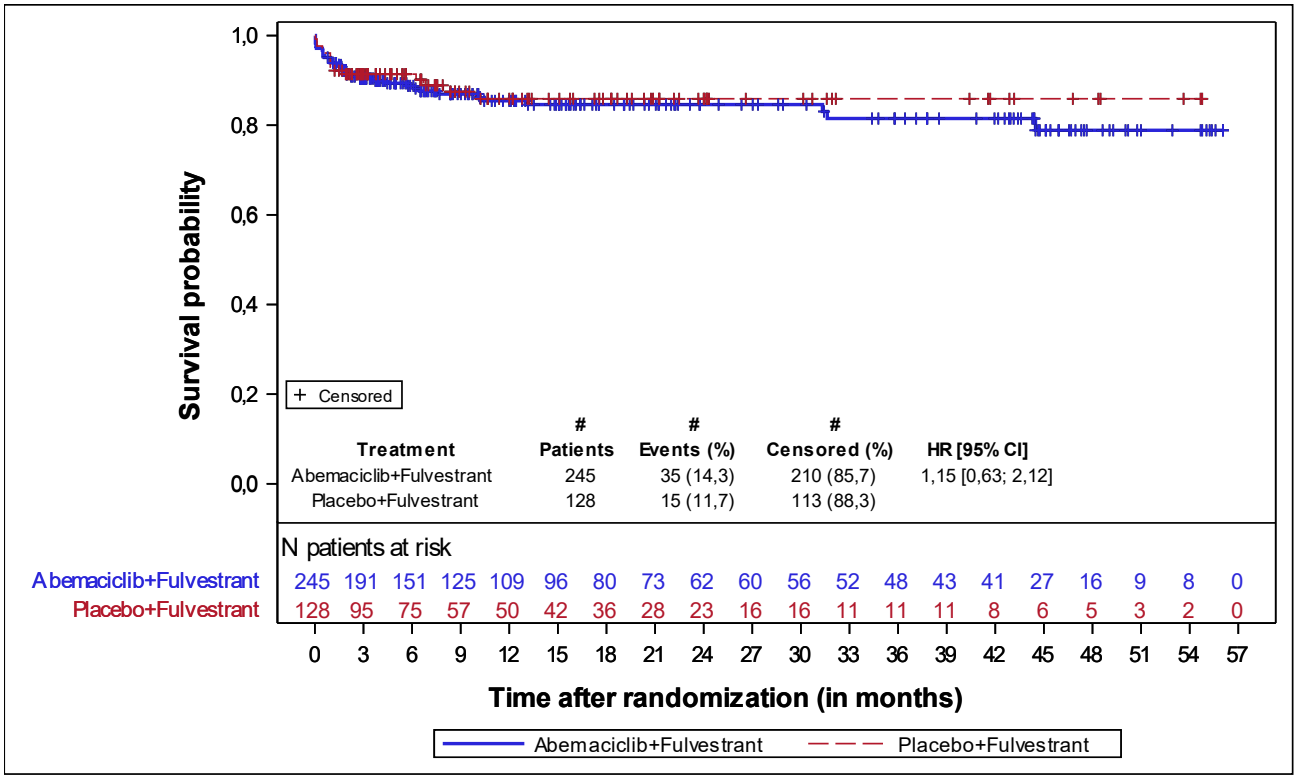
Figure 123: Kaplan-Meier curves for adverse events according PT - Vascular disorders / Hot flush
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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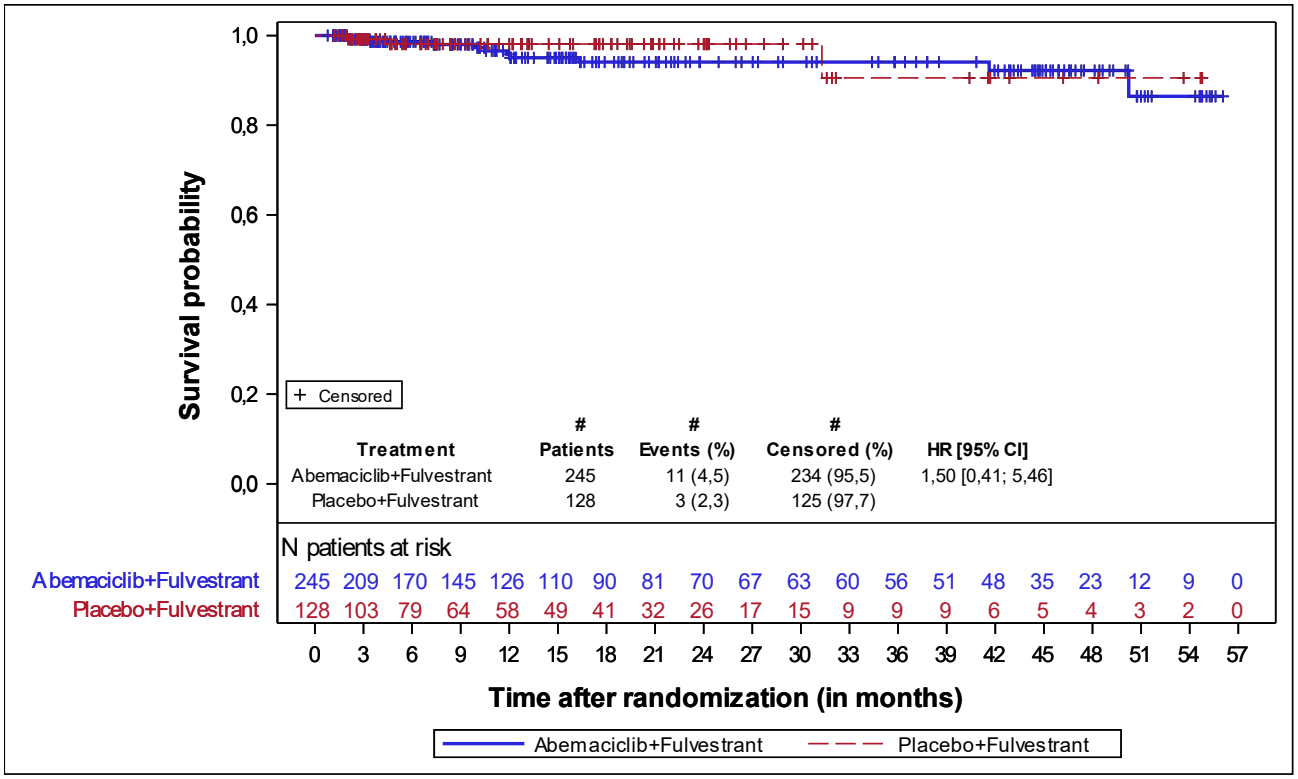
Figure 124: Kaplan-Meier curves for adverse events according PT - Immune system disorders / Hypersensitivity
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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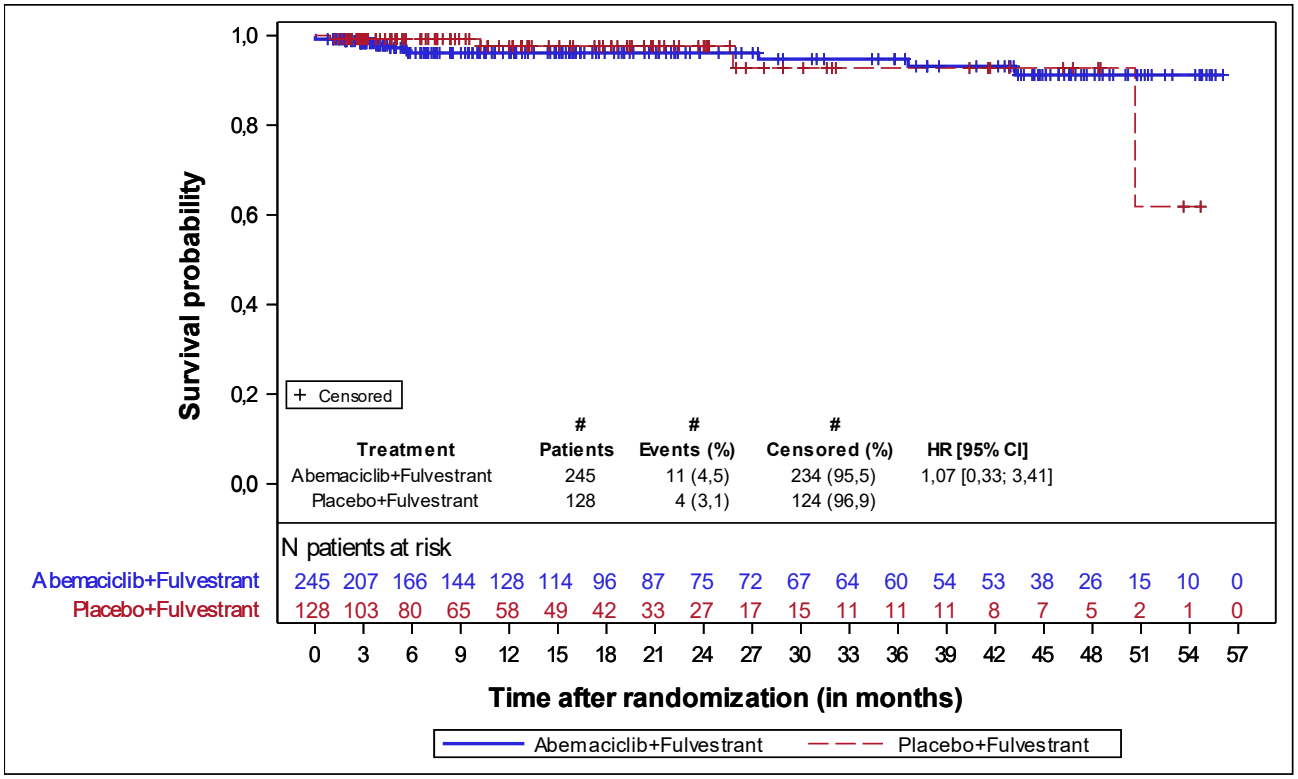
Figure 125: Kaplan-Meier curves for adverse events according PT - Vascular disorders / Hypertension
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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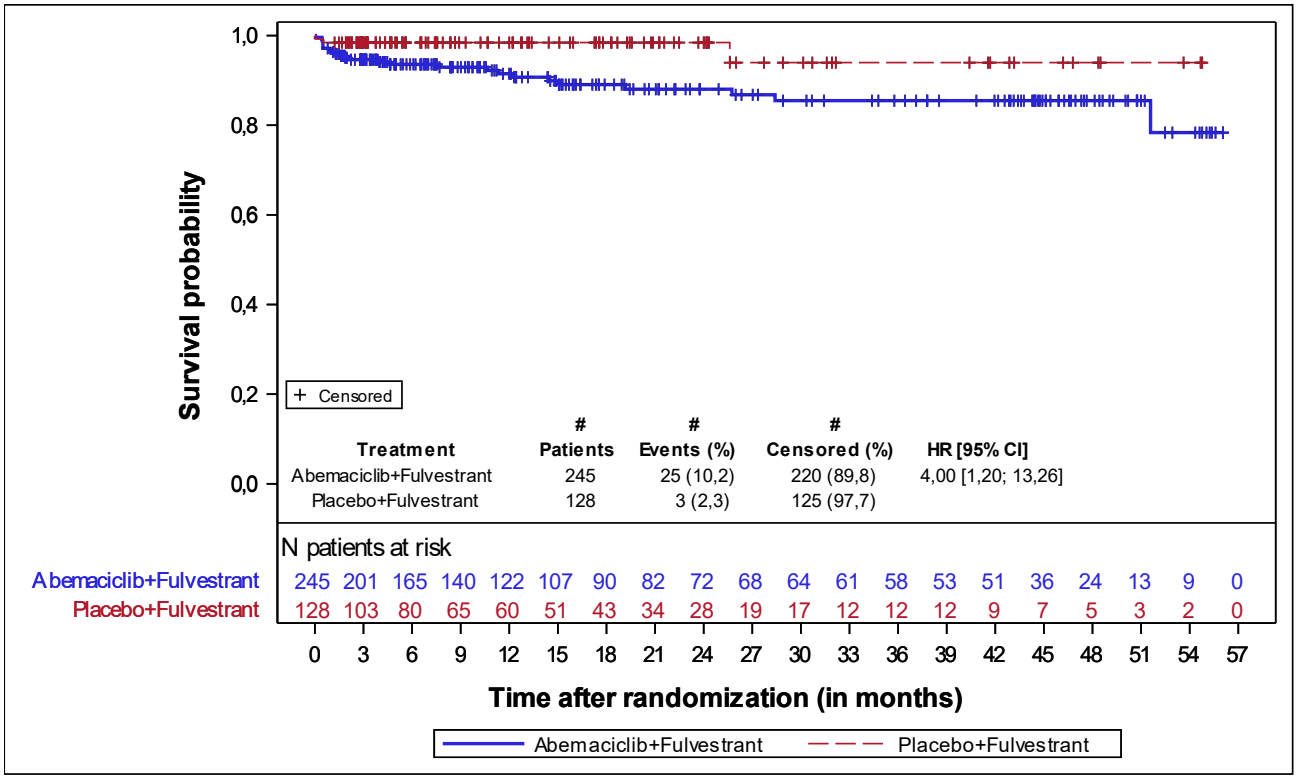
Figure 126: Kaplan-Meier curves for adverse events according PT - Metabolism and nutrition disorders / Hypokalaemia
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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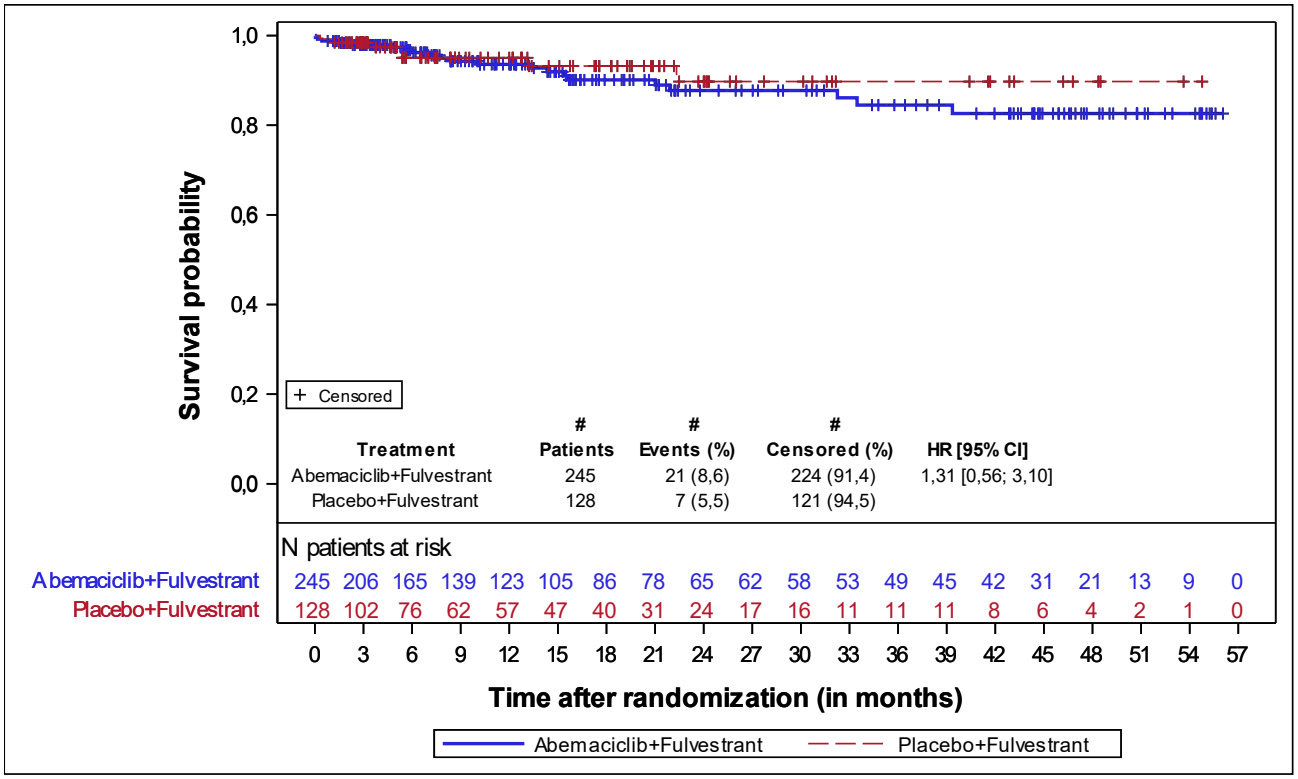
Figure 127: Kaplan-Meier curves for adverse events according PT - General disorders and administration site conditions / Influenza like illness Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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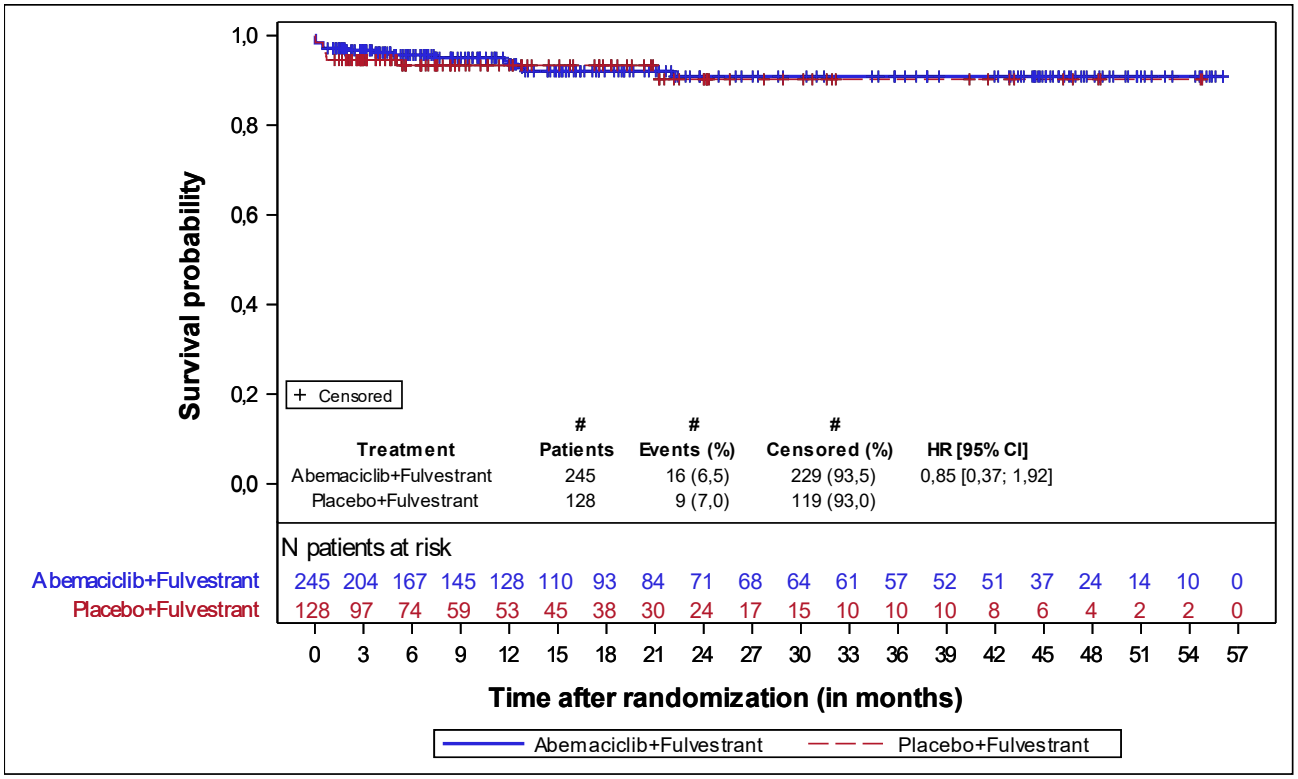
Figure 128: Kaplan-Meier curves for adverse events according PT - General disorders and administration site conditions / Injection site reaction Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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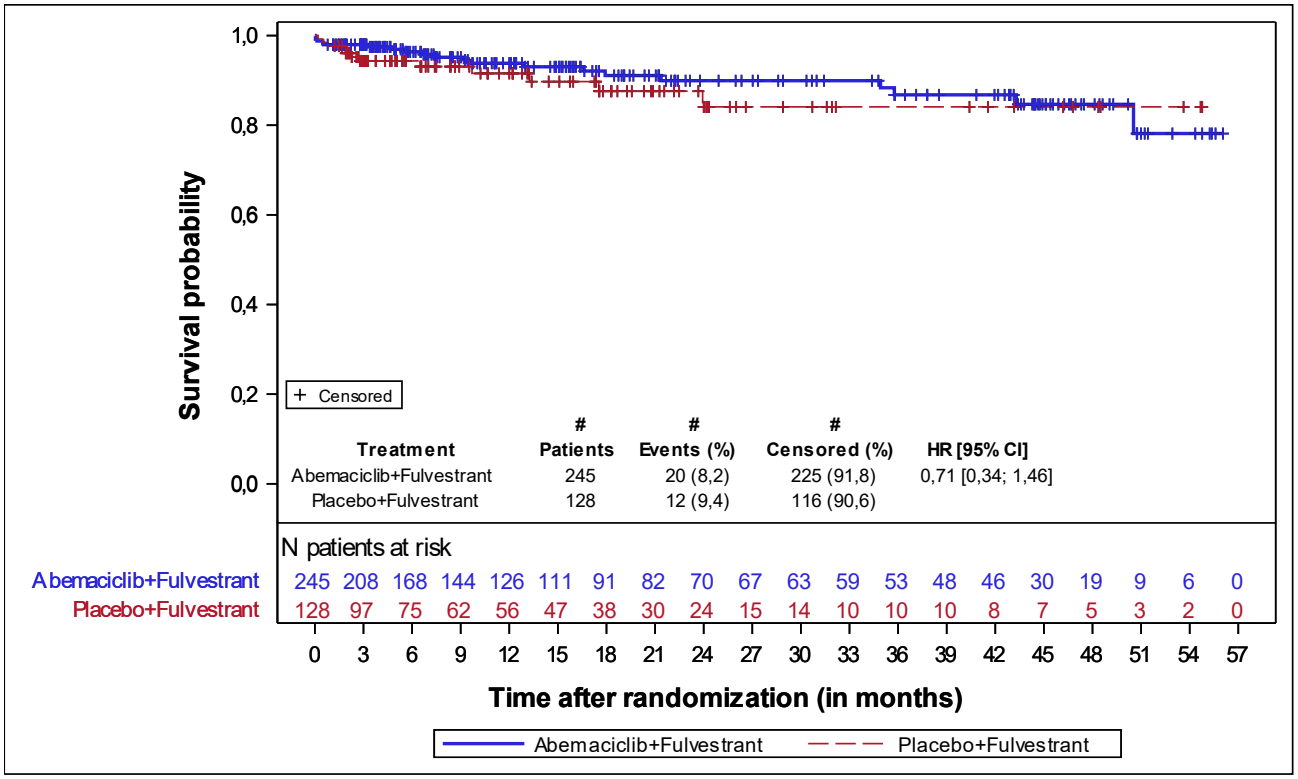
Figure 129: Kaplan-Meier curves for adverse events according PT - Psychiatric disorders / Insomnia
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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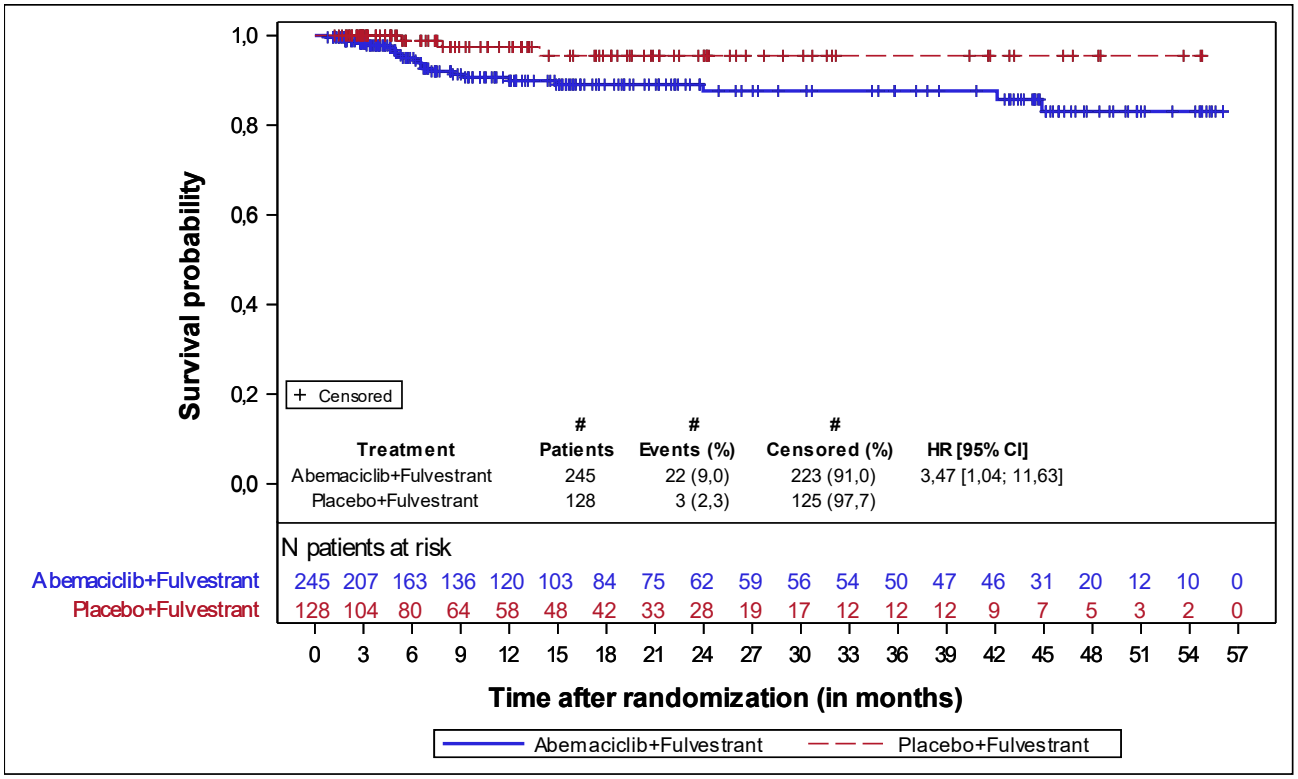
**Figure 130: Kaplan-Meier curves for adverse events according PT -
Eye disorders / Lacrimation increased
Safety Population - Postmenopausal (1st line)**



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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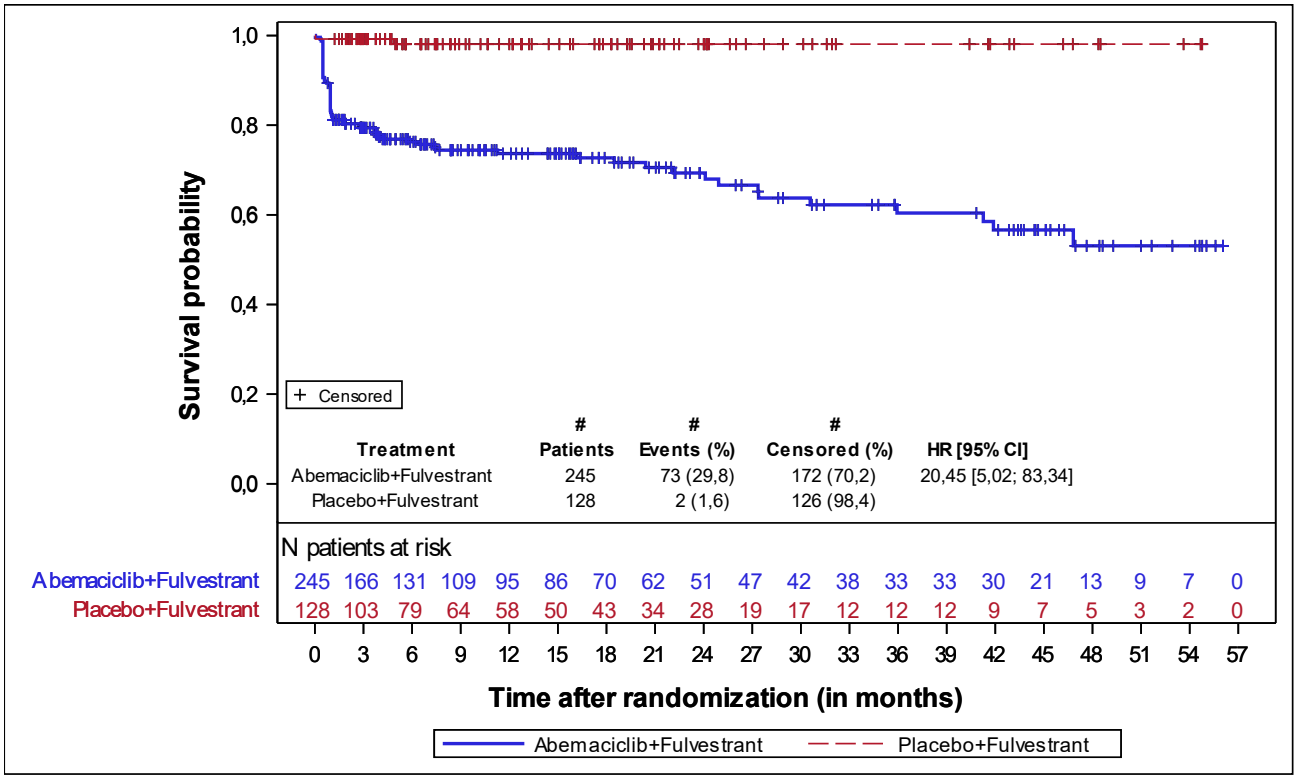
08JUL2021 / 02:43

Figure 131: Kaplan-Meier curves for adverse events according PT - Blood and lymphatic system disorders / Leukopenia Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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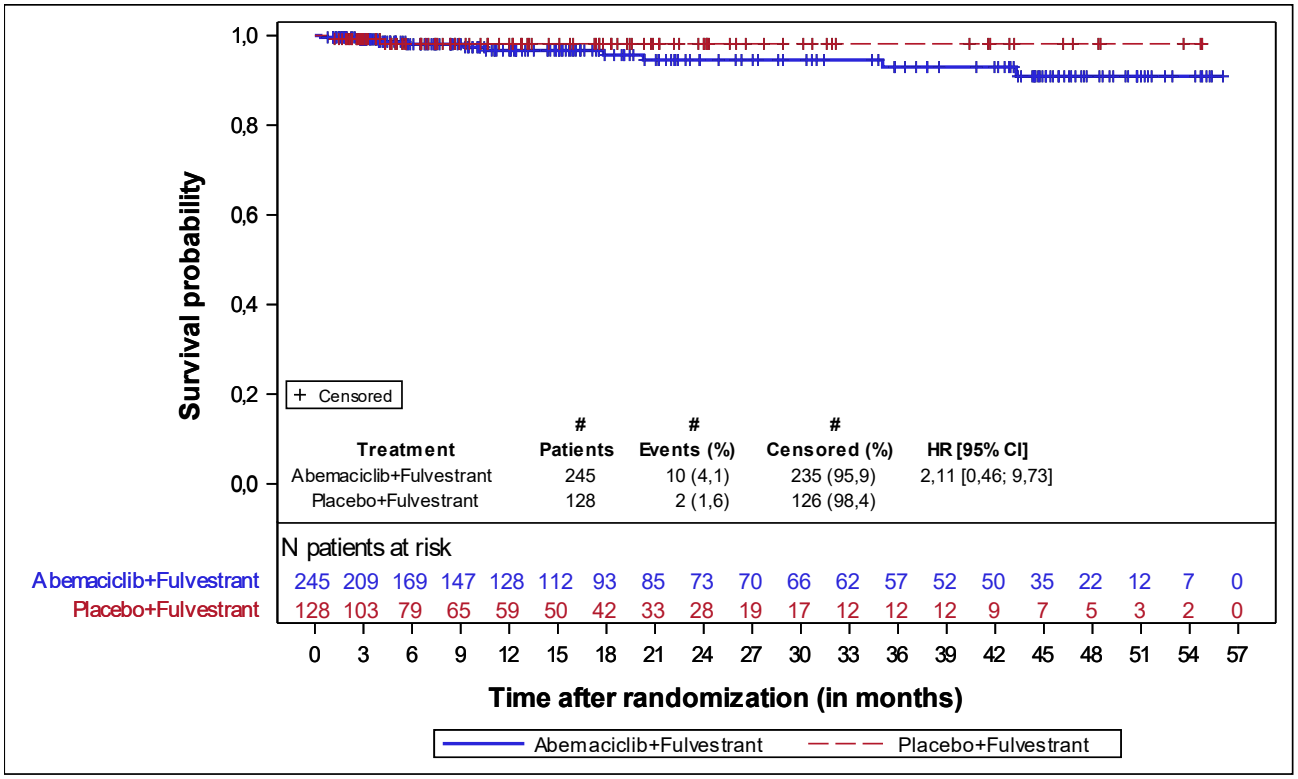
08JUL2021 / 02:43

Figure 132: Kaplan-Meier curves for adverse events according PT - General disorders and administration site conditions / Localised oedema Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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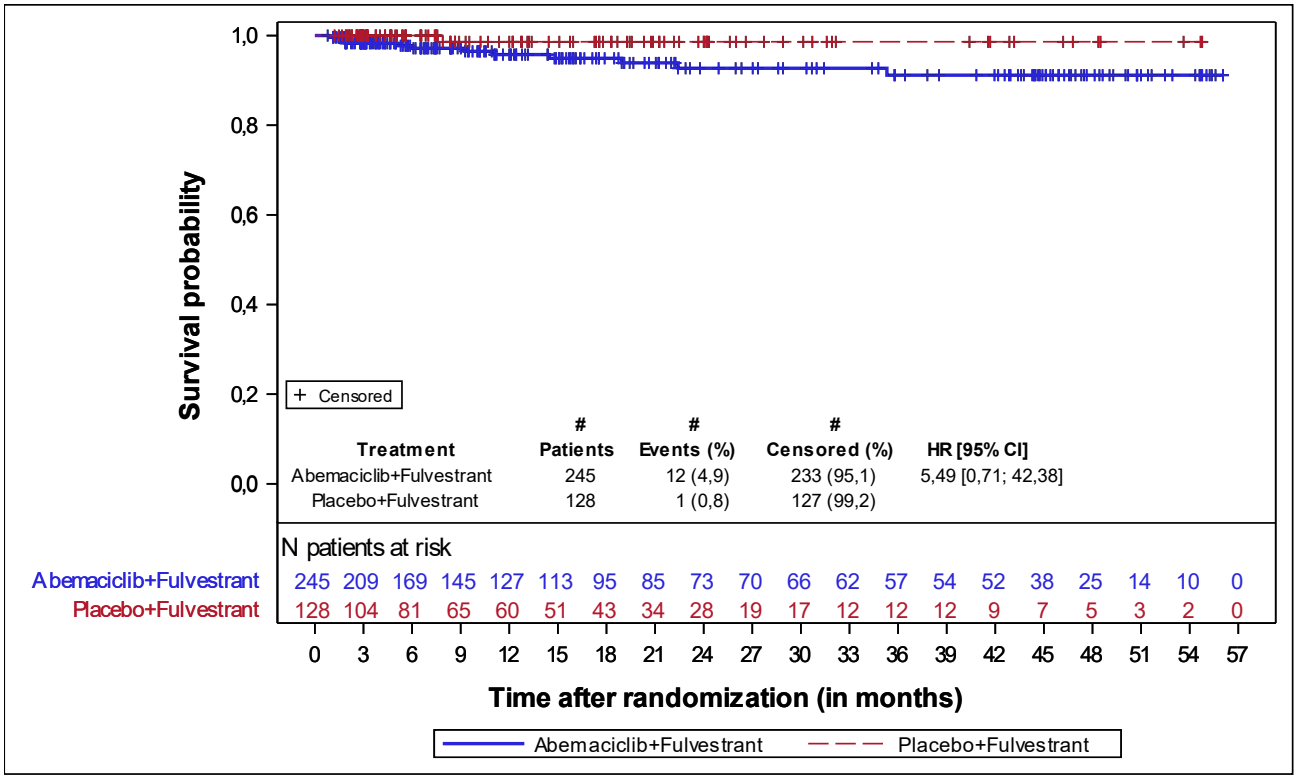
Figure 133: Kaplan-Meier curves for adverse events according PT - Infections and infestations / Lung infection
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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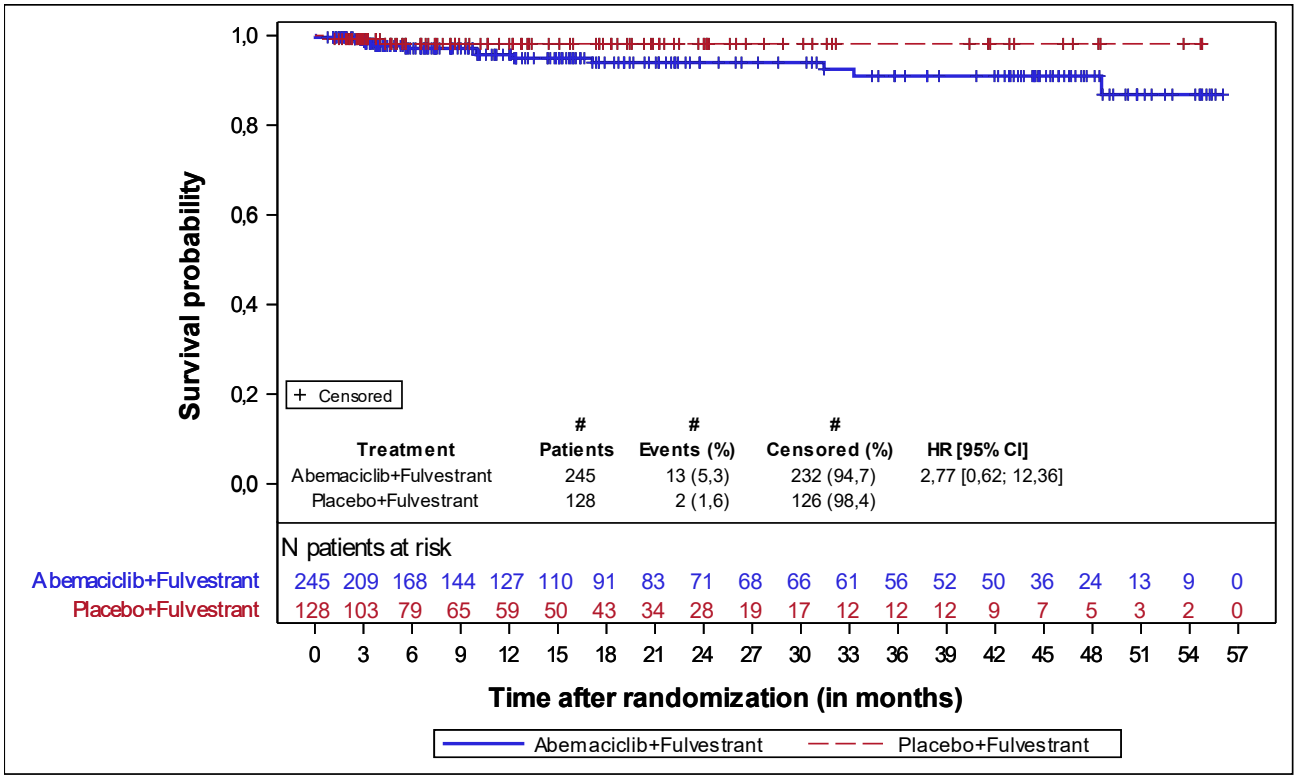
08JUL2021 / 02:43

Figure 134: Kaplan-Meier curves for adverse events according PT - Vascular disorders / Lymphoedema
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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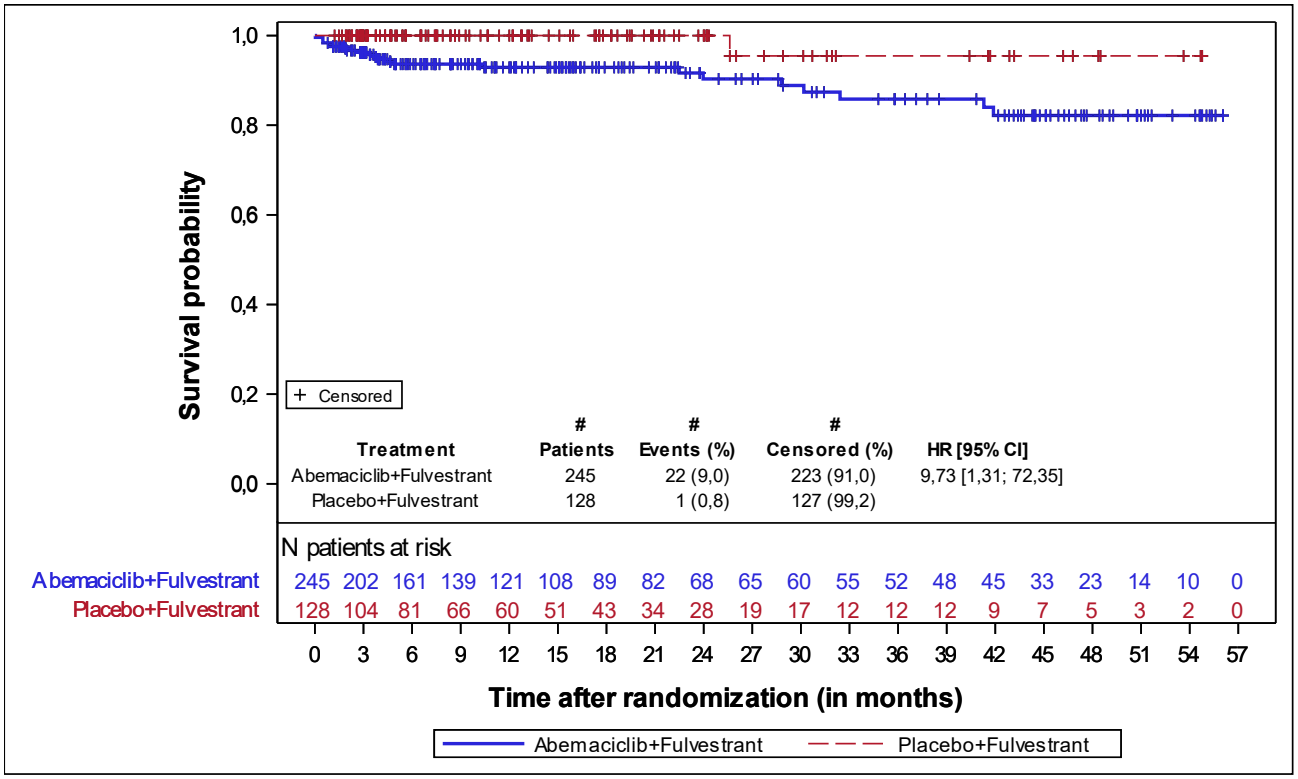
Figure 135: Kaplan-Meier curves for adverse events according PT - Blood and lymphatic system disorders / Lymphopenia Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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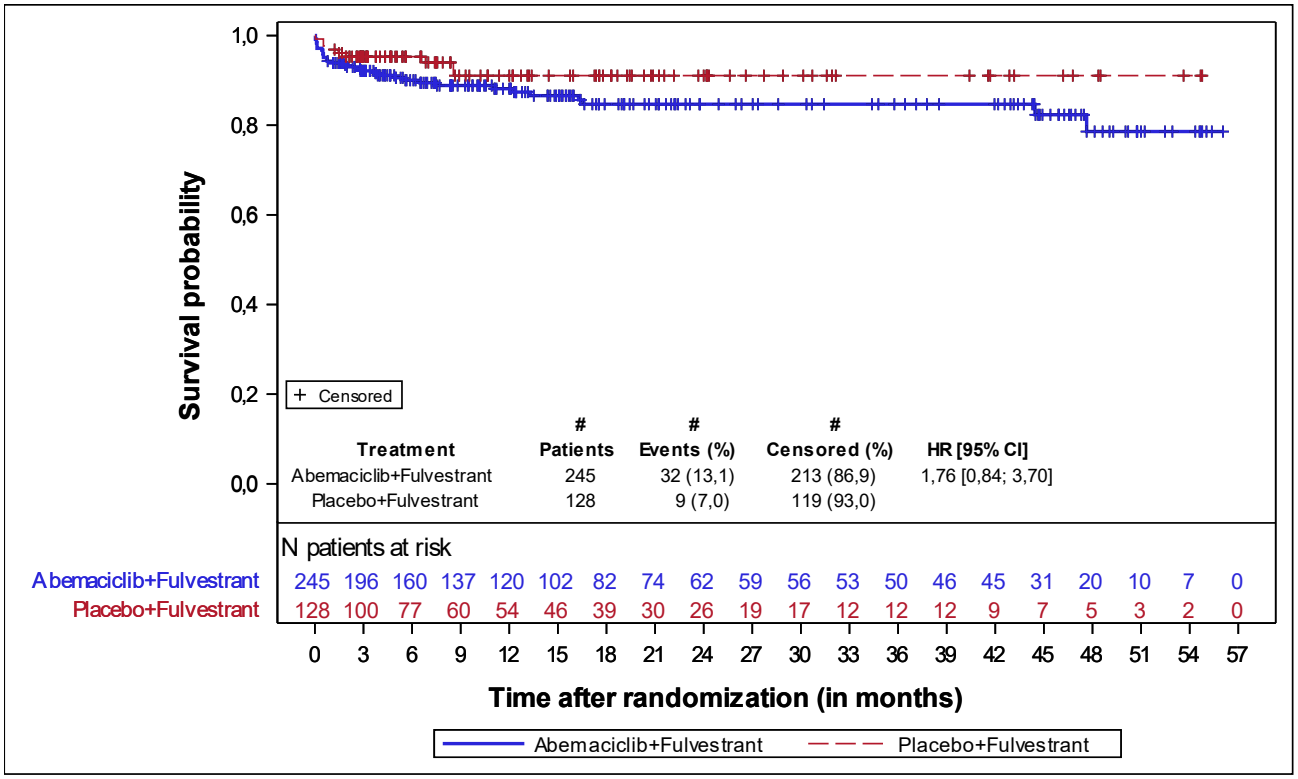
08JUL2021 / 02:43

Figure 136: Kaplan-Meier curves for adverse events according PT - Musculoskeletal and connective tissue disorders / Muscular weakness Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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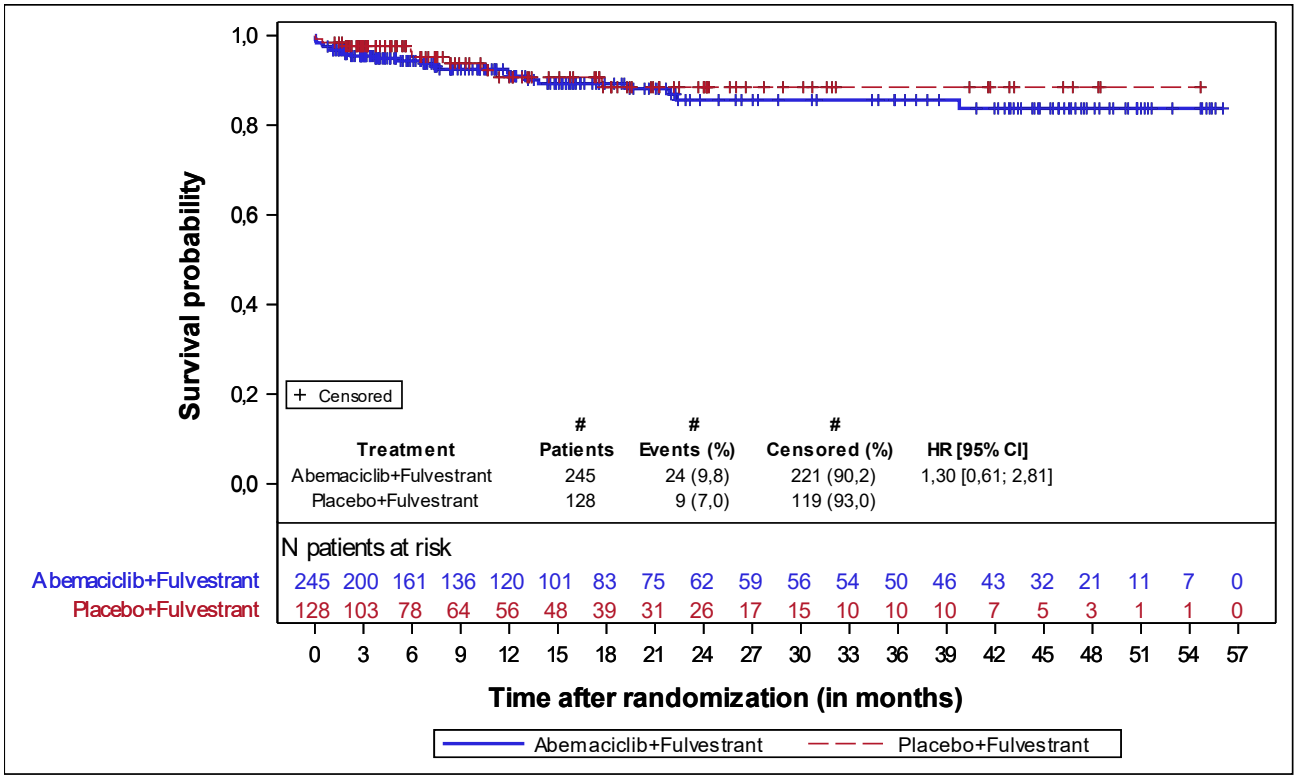
08JUL2021 / 02:43

Figure 137: Kaplan-Meier curves for adverse events according PT - Musculoskeletal and connective tissue disorders / Myalgia
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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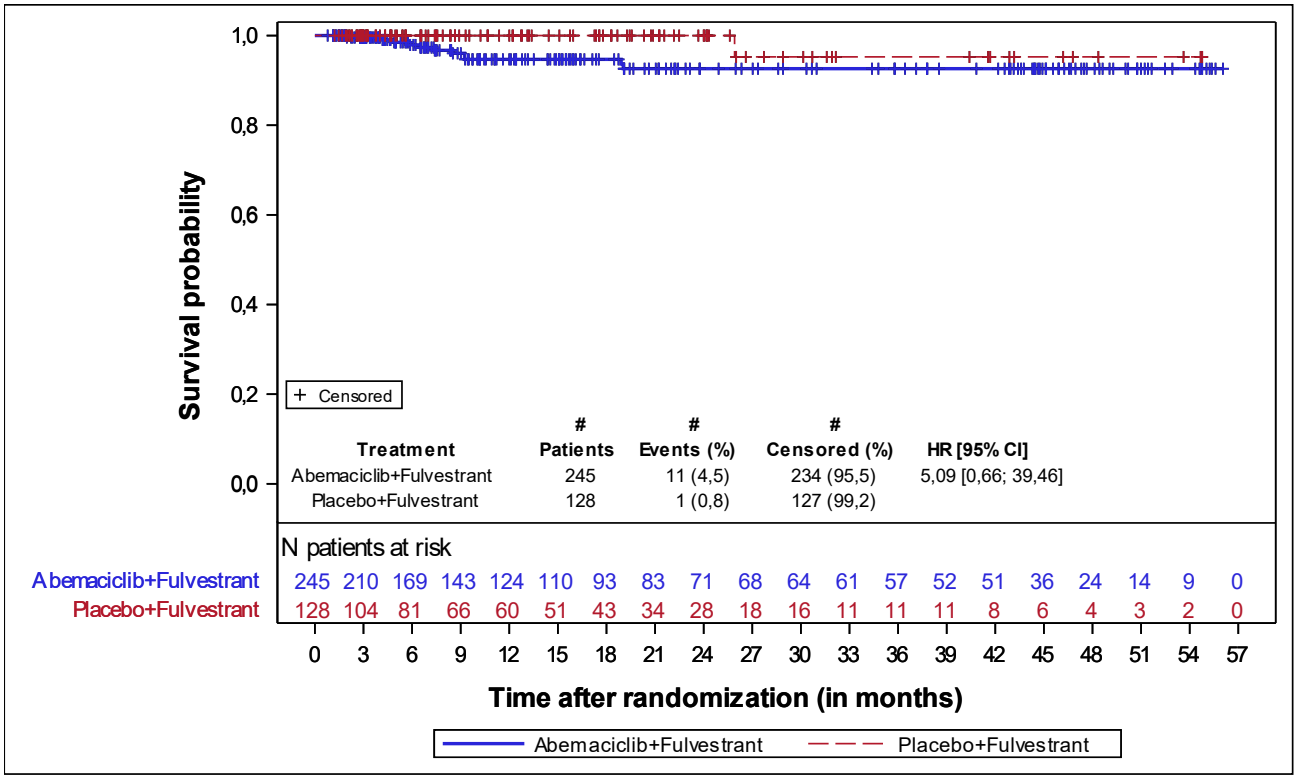
08JUL2021 / 02:43

Figure 138: Kaplan-Meier curves for adverse events according PT - Skin and subcutaneous tissue disorders / Nail ridging
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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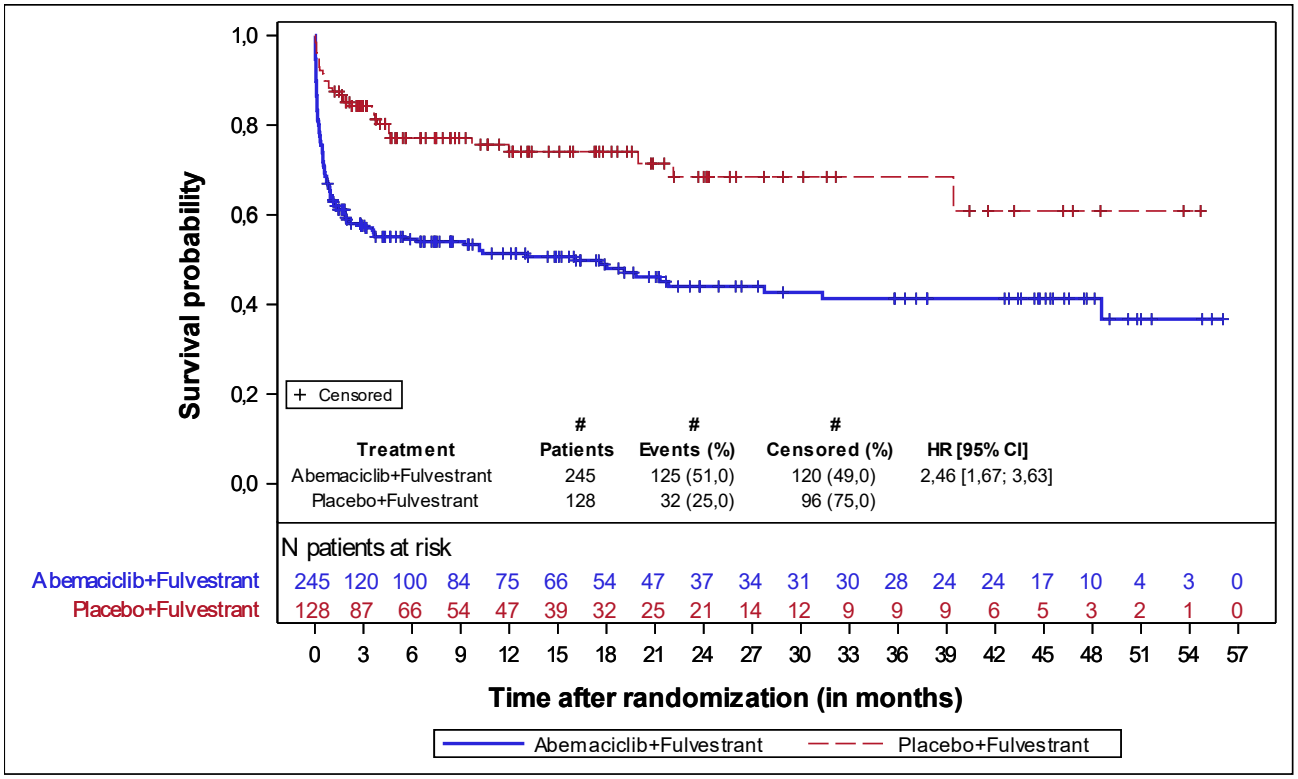
08JUL2021 / 02:43

Figure 139: Kaplan-Meier curves for adverse events according PT - Gastrointestinal disorders / Nausea
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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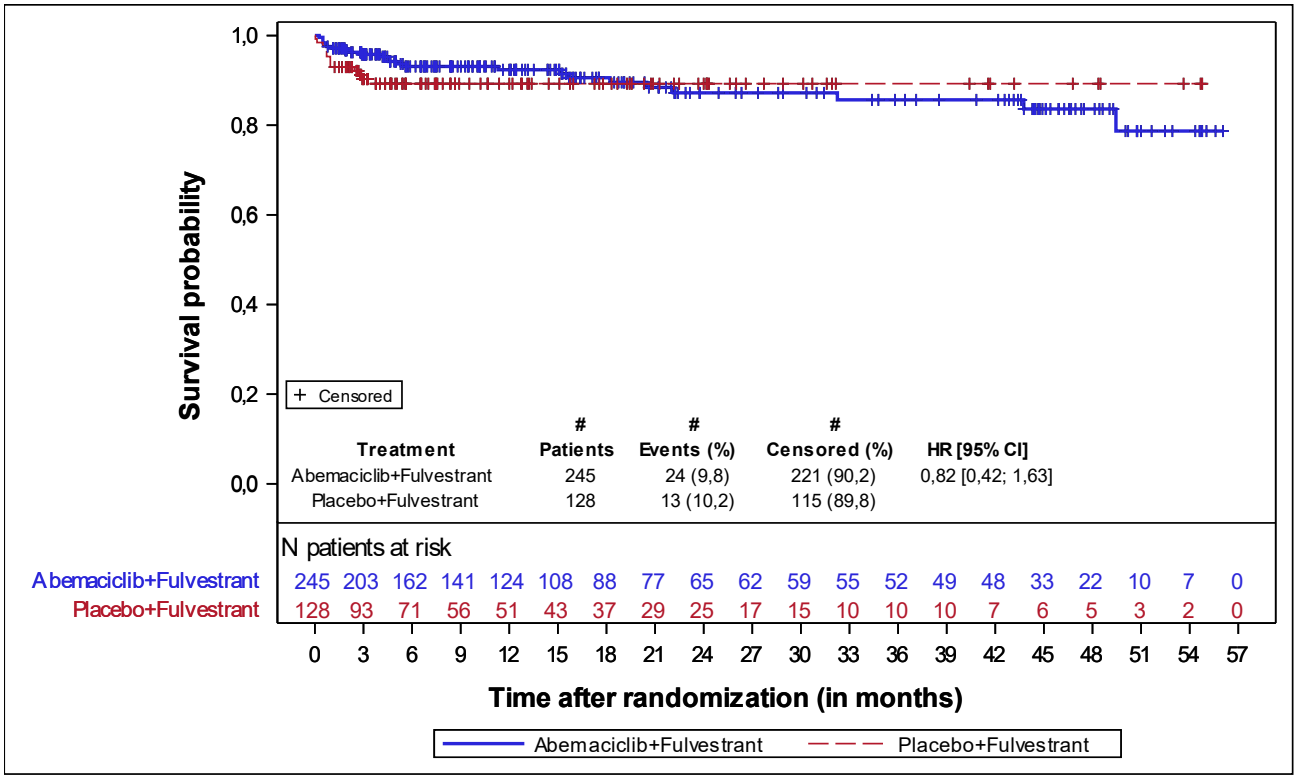
08JUL2021 / 02:43

Figure 140: Kaplan-Meier curves for adverse events according PT - Nervous system disorders / Neuropathy
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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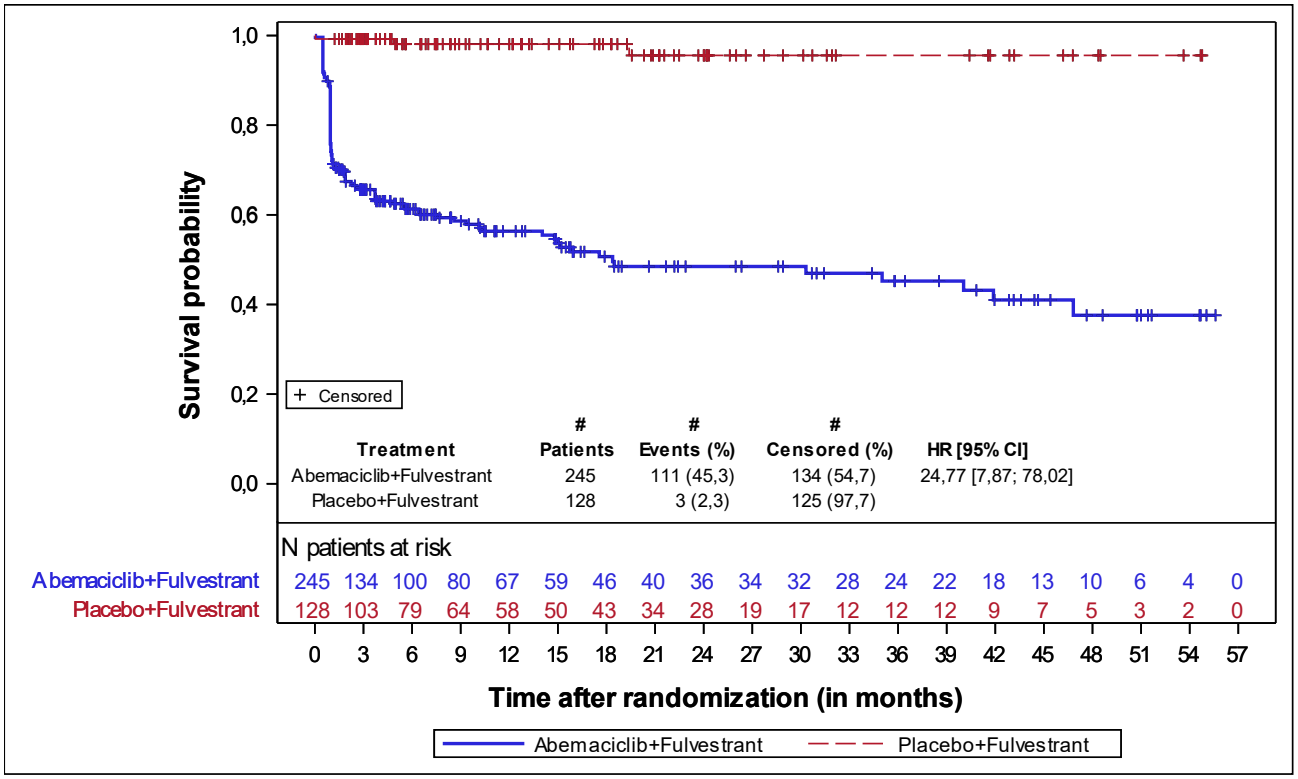
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 141: Kaplan-Meier curves for adverse events according PT - Blood and lymphatic system disorders / Neutropenia Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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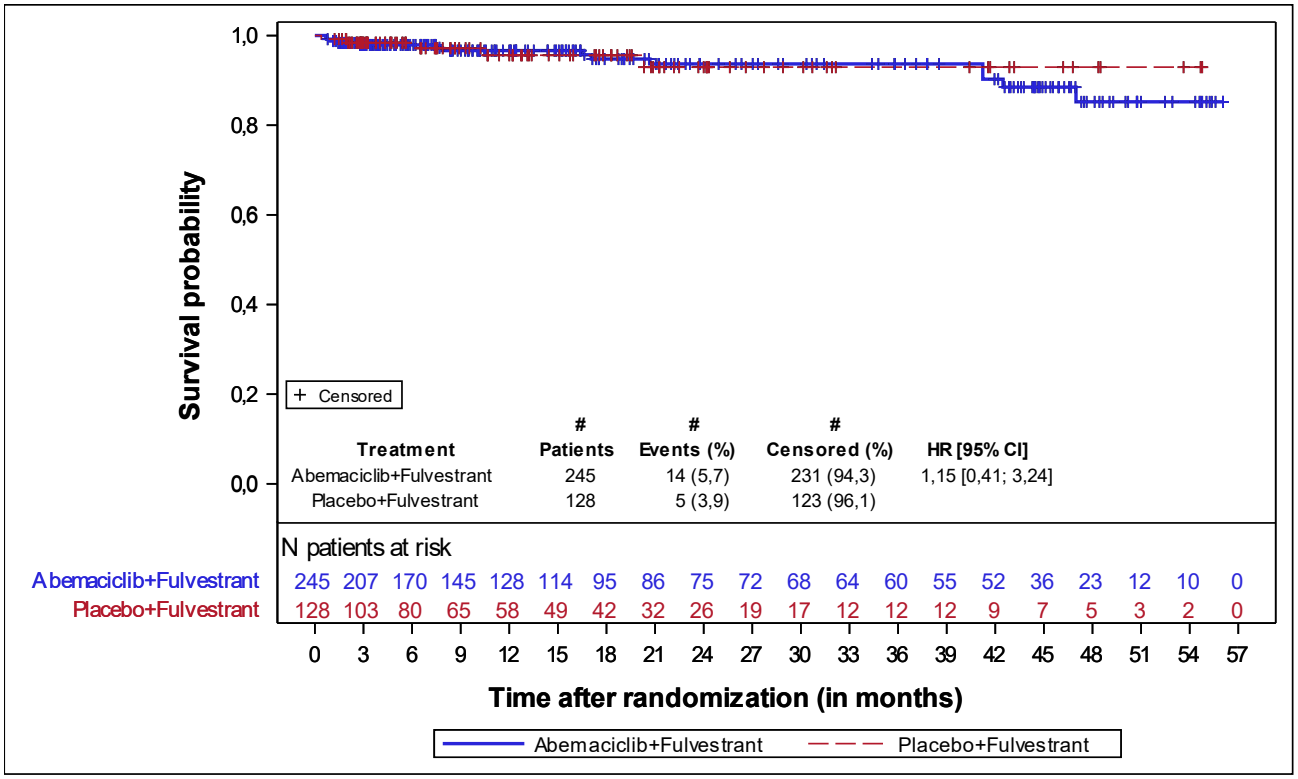
08JUL2021 / 02:43

Figure 142: Kaplan-Meier curves for adverse events according PT - General disorders and administration site conditions / Non-cardiac chest pain Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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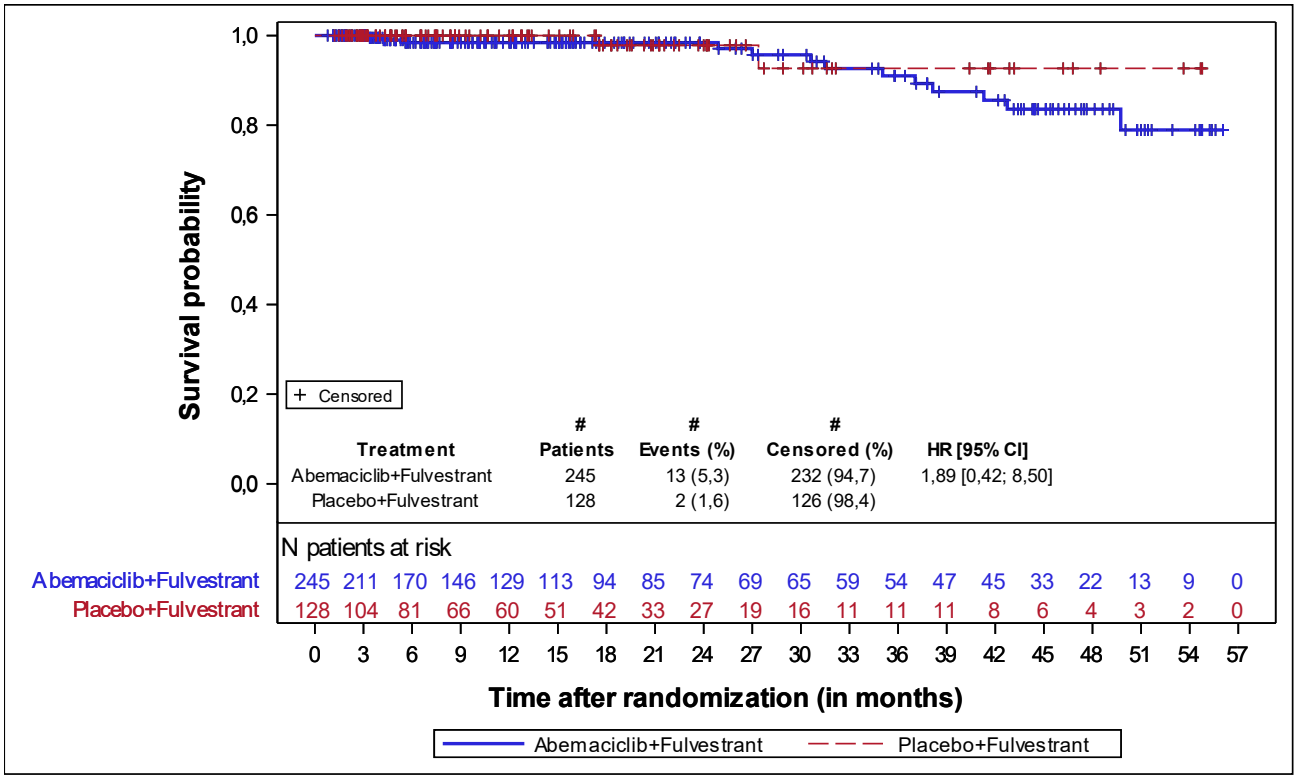
Figure 143: Kaplan-Meier curves for adverse events according PT - Not coded / Not coded
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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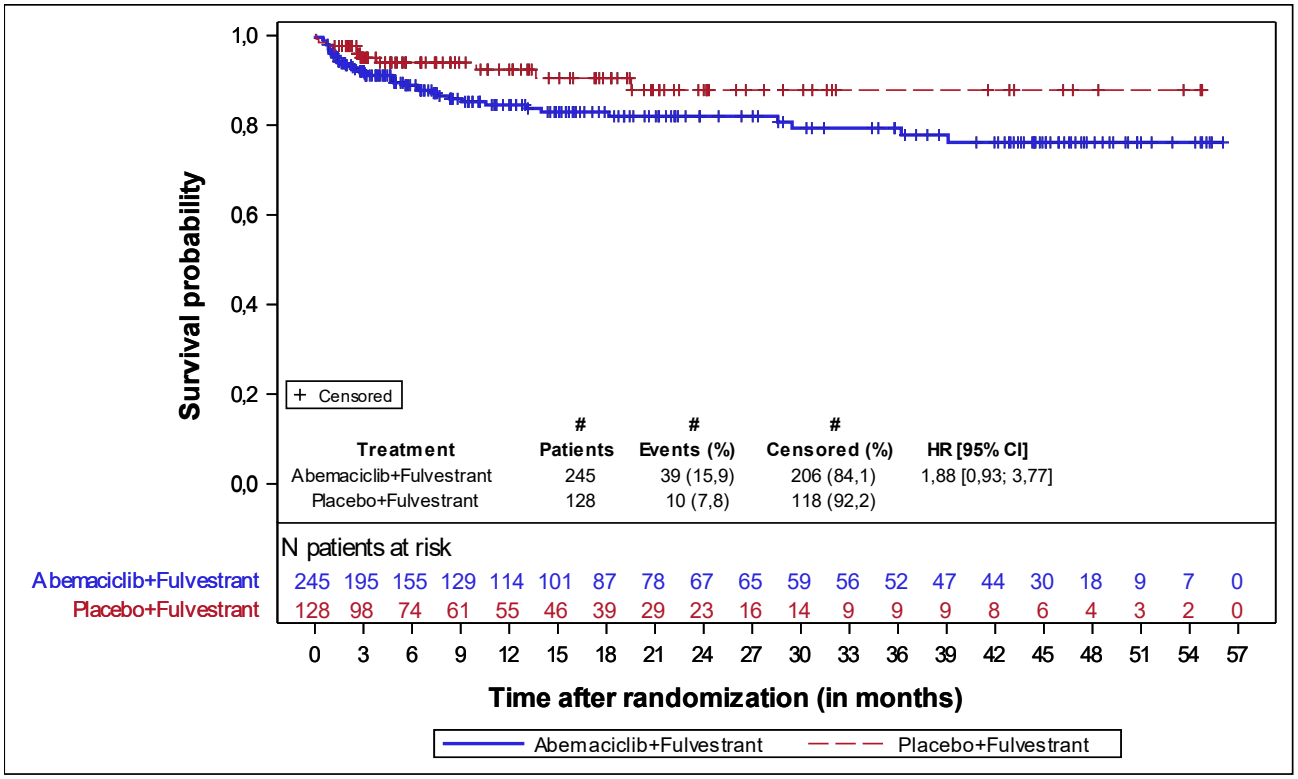
08JUL2021 / 02:43

Figure 144: Kaplan-Meier curves for adverse events according PT - General disorders and administration site conditions / Oedema peripheral Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraep056_popa1.rtf
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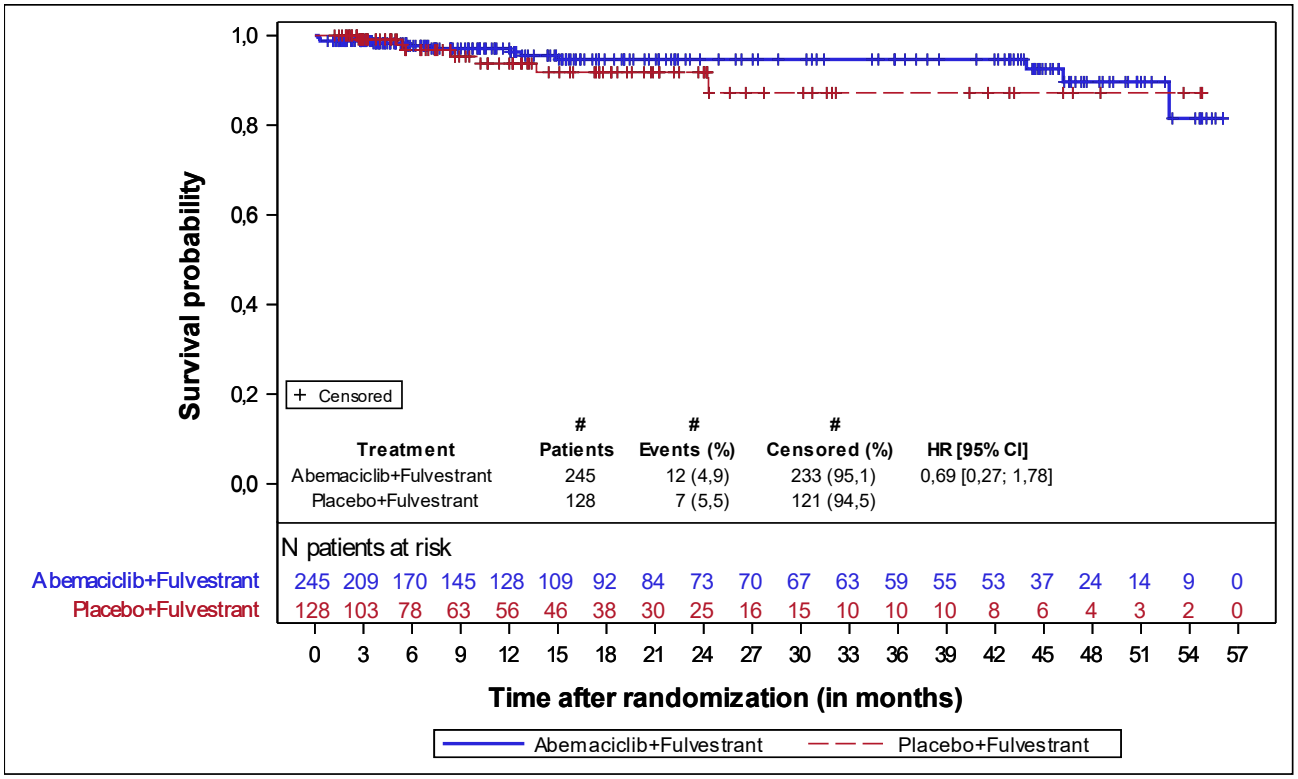
08JUL2021 / 02:43

Figure 145: Kaplan-Meier curves for adverse events according PT - Respiratory, thoracic and mediastinal disorders / Oropharyngeal pain Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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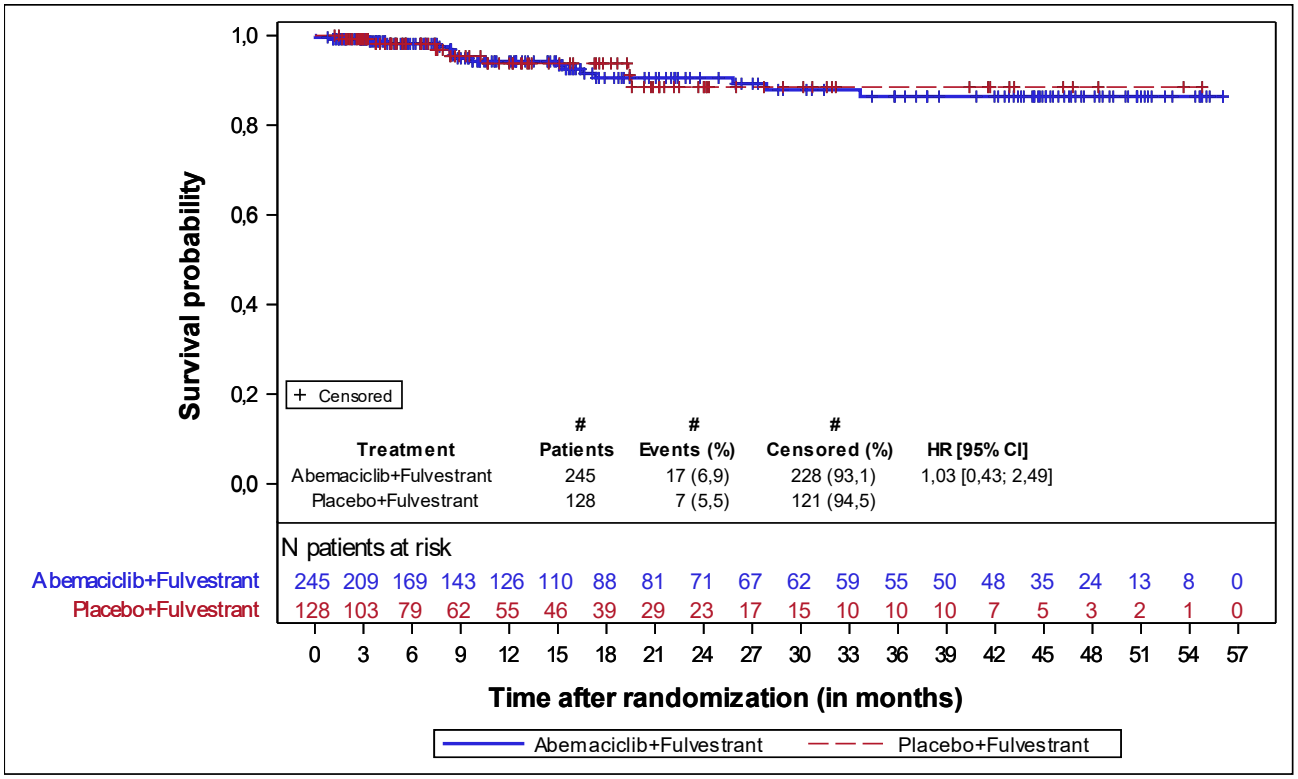
08JUL2021 / 02:43

Figure 146: Kaplan-Meier curves for adverse events according PT - General disorders and administration site conditions / Pain Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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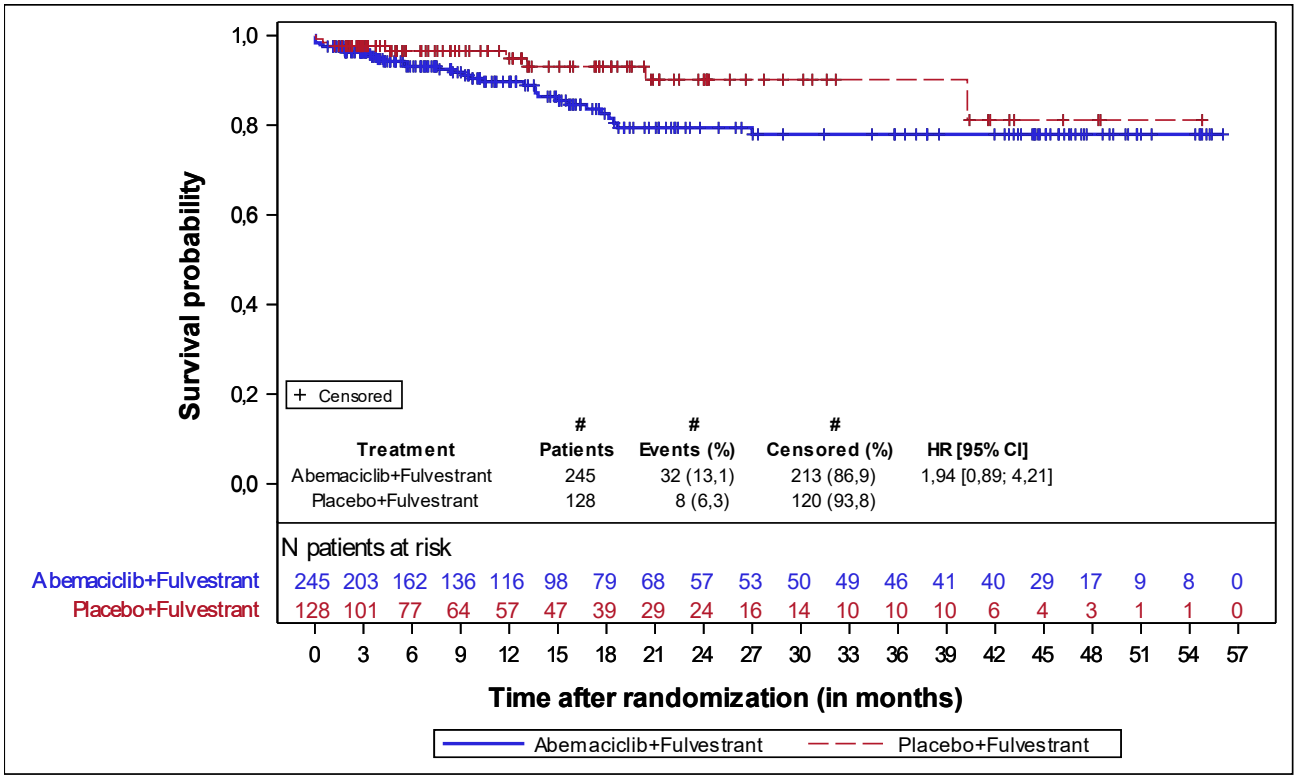
08JUL2021 / 02:43

Figure 147: Kaplan-Meier curves for adverse events according PT - Musculoskeletal and connective tissue disorders / Pain in extremity Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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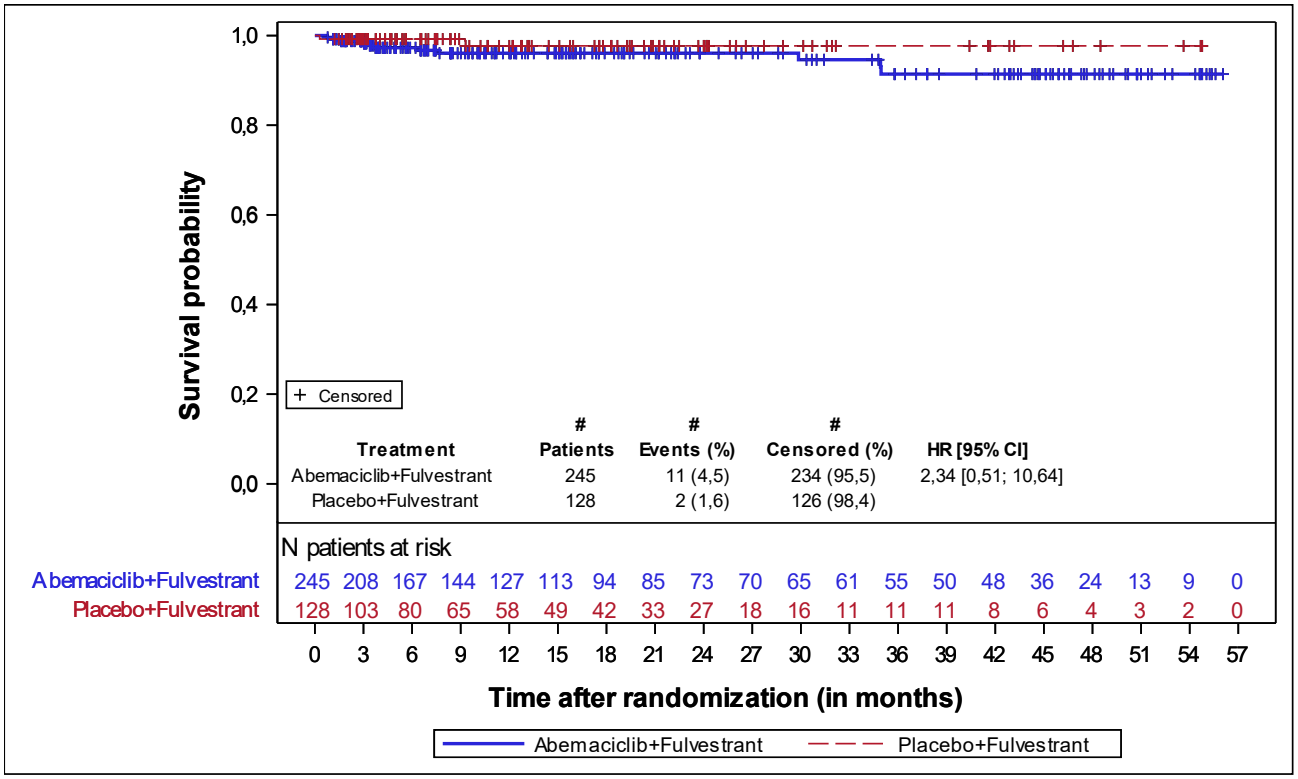
Figure 148: Kaplan-Meier curves for adverse events according PT - Infections and infestations / Pharyngitis
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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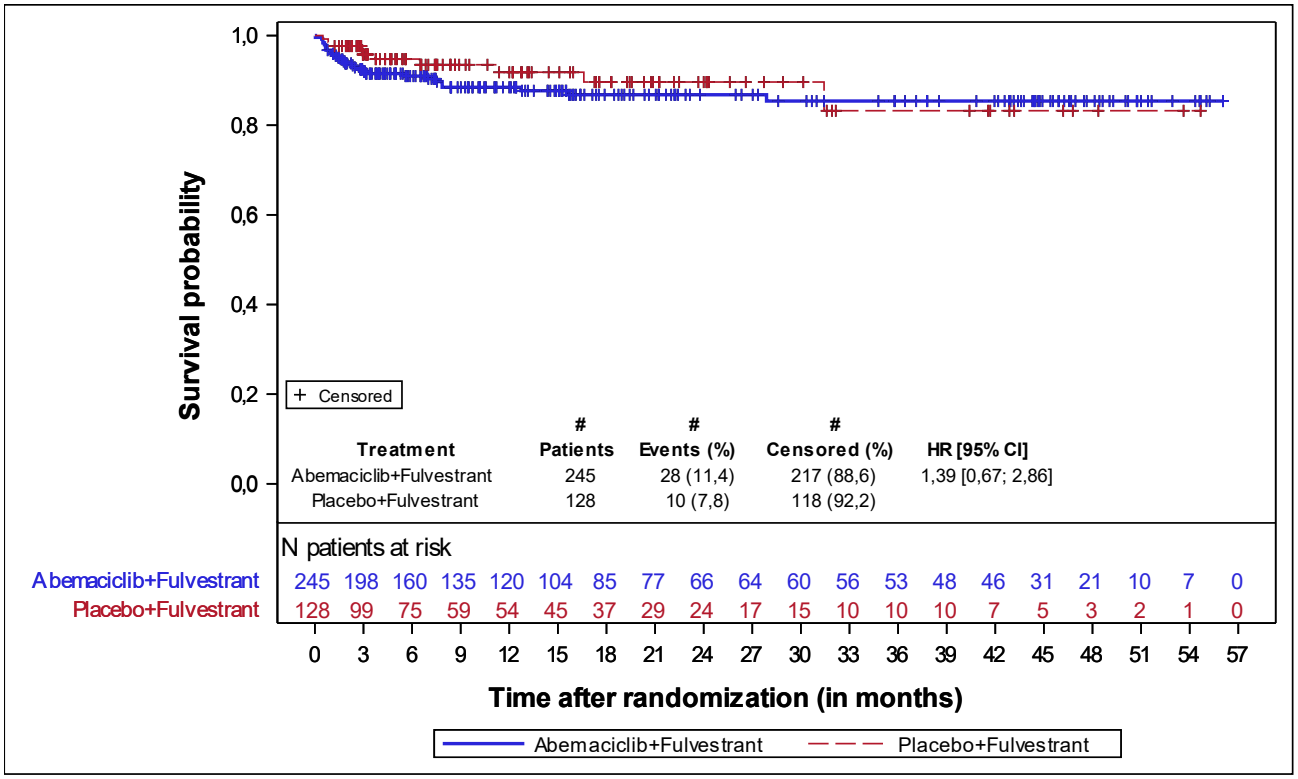
Figure 149: Kaplan-Meier curves for adverse events according PT - Skin and subcutaneous tissue disorders / Pruritus Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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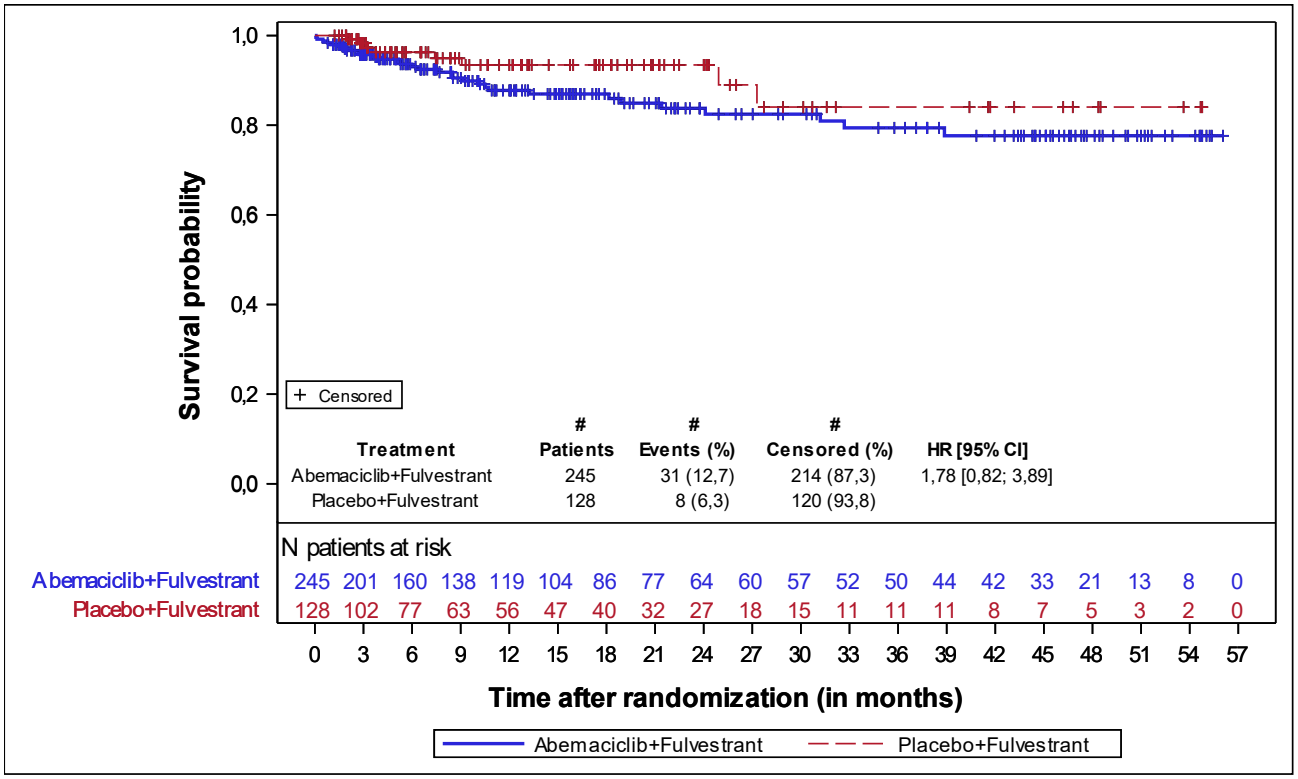
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 150: Kaplan-Meier curves for adverse events according PT - General disorders and administration site conditions / Pyrexia Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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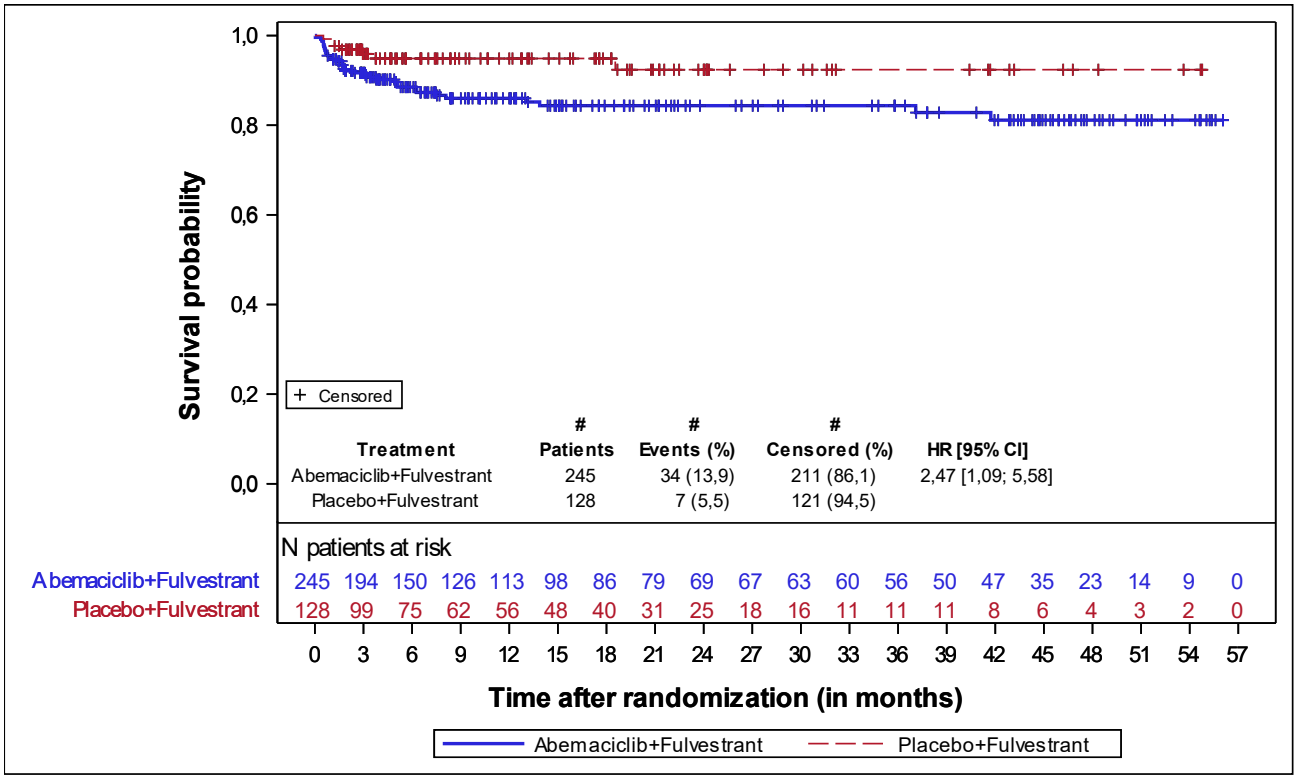
08JUL2021 / 02:43

Figure 151: Kaplan-Meier curves for adverse events according PT - Skin and subcutaneous tissue disorders / Rash Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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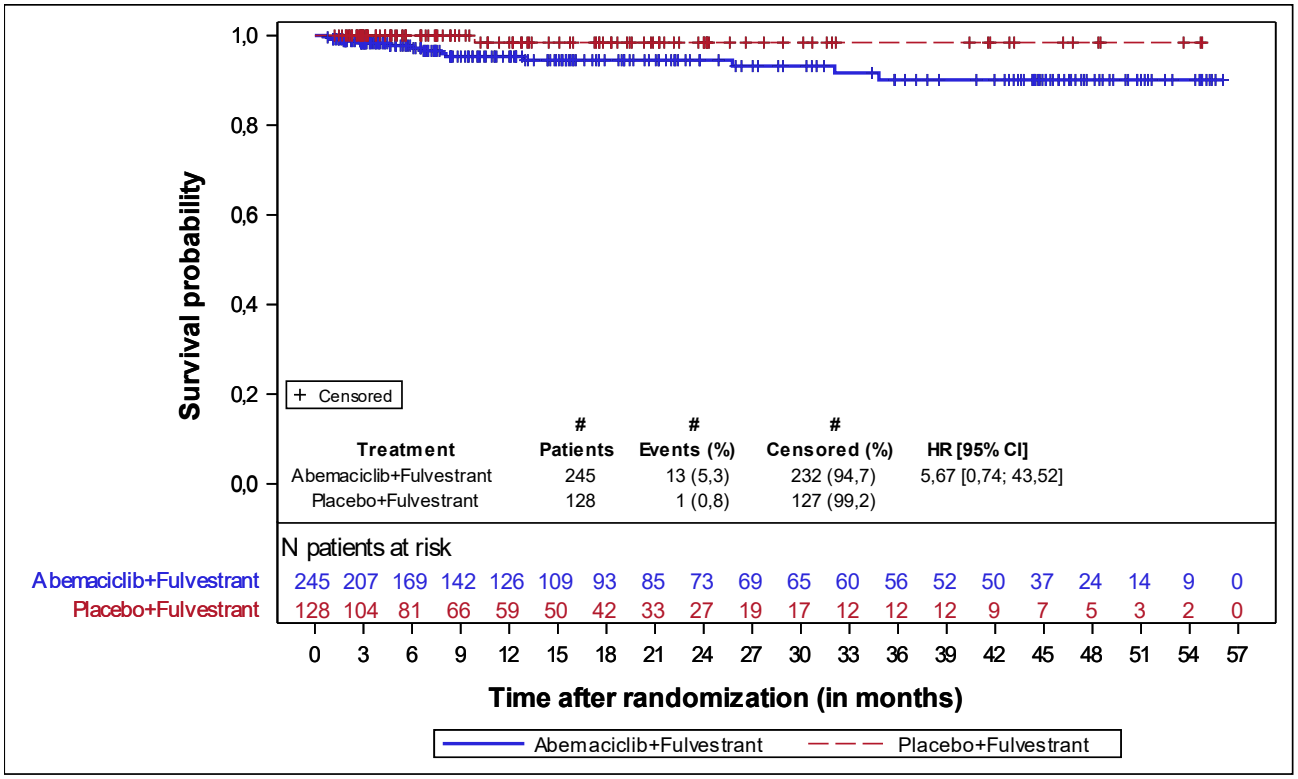
08JUL2021 / 02:43

Figure 152: Kaplan-Meier curves for adverse events according PT - Respiratory, thoracic and mediastinal disorders / Rhinitis allergic Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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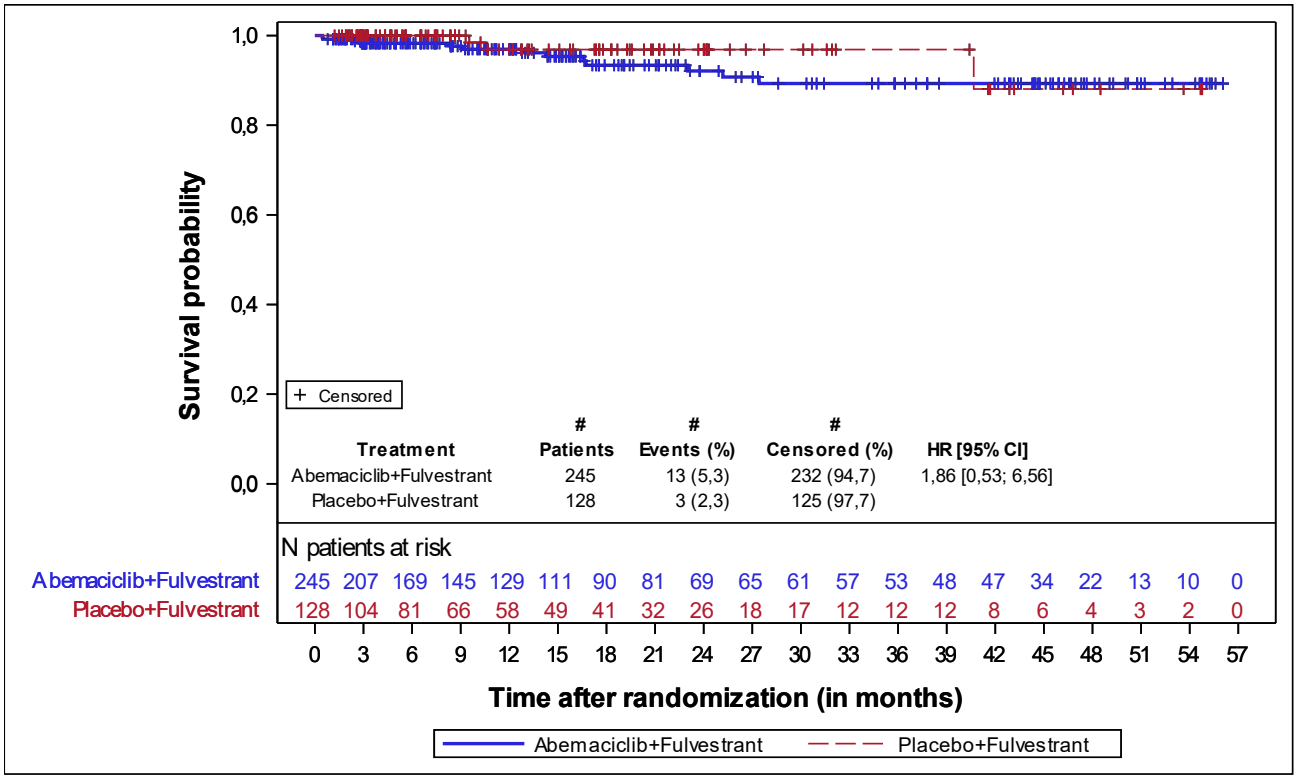
08JUL2021 / 02:43

Figure 153: Kaplan-Meier curves for adverse events according PT - Infections and infestations / Sinusitis
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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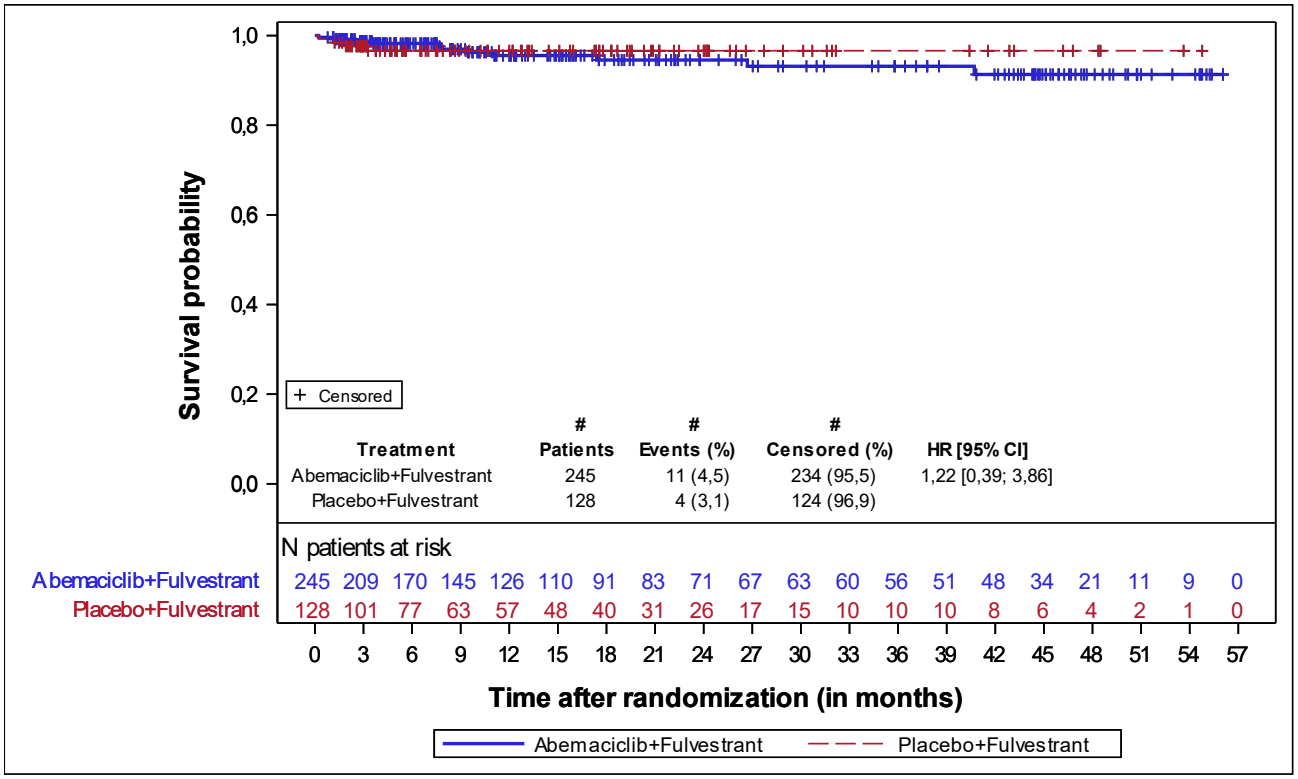
08JUL2021 / 02:43

Figure 154: Kaplan-Meier curves for adverse events according PT - Infections and infestations / Skin infection
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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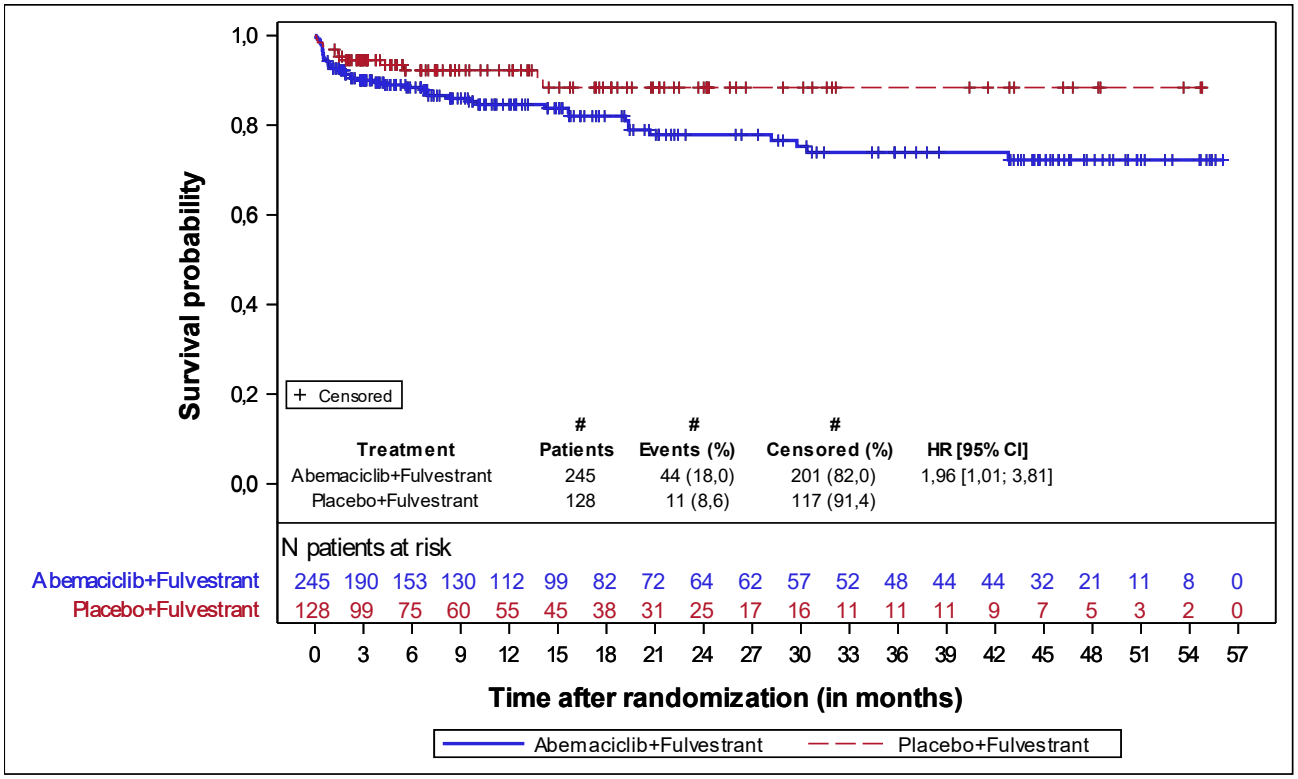
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 155: Kaplan-Meier curves for adverse events according PT - Gastrointestinal disorders / Stomatitis
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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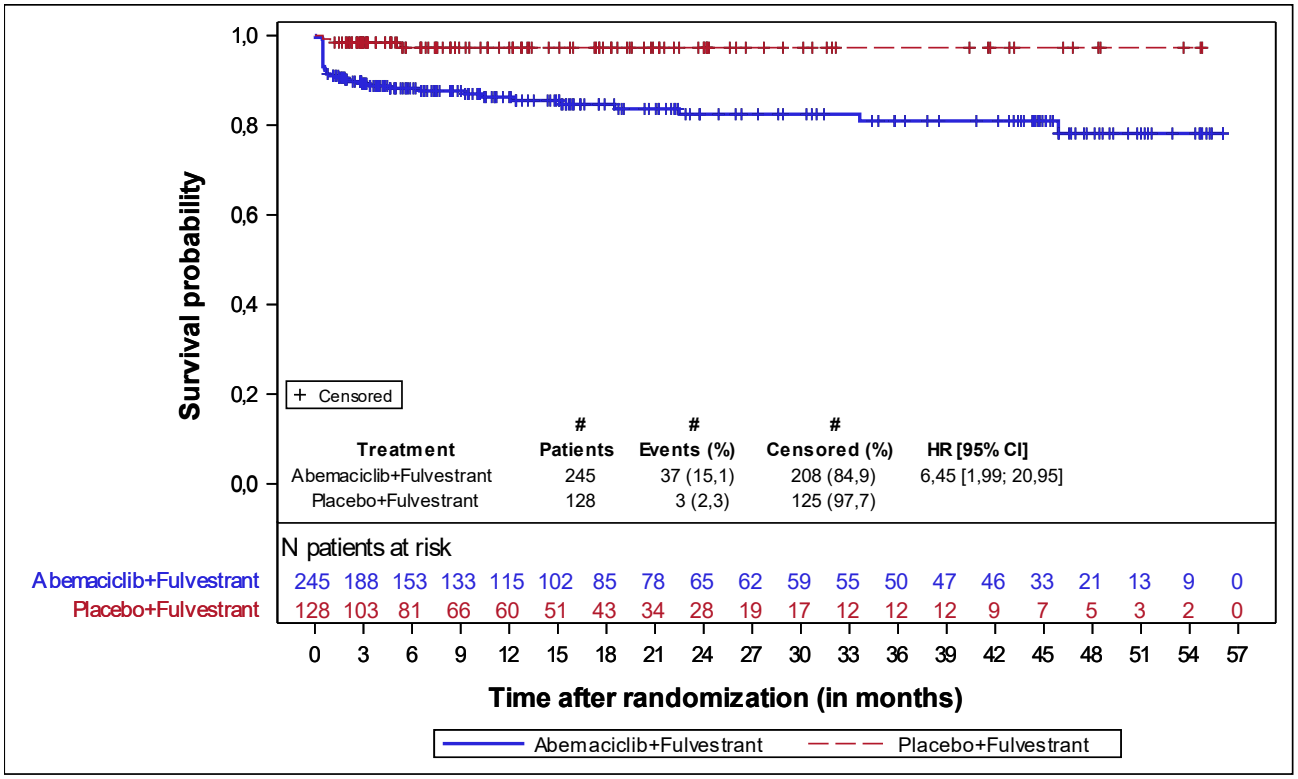
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 156: Kaplan-Meier curves for adverse events according PT - Blood and lymphatic system disorders / Thrombocytopenia Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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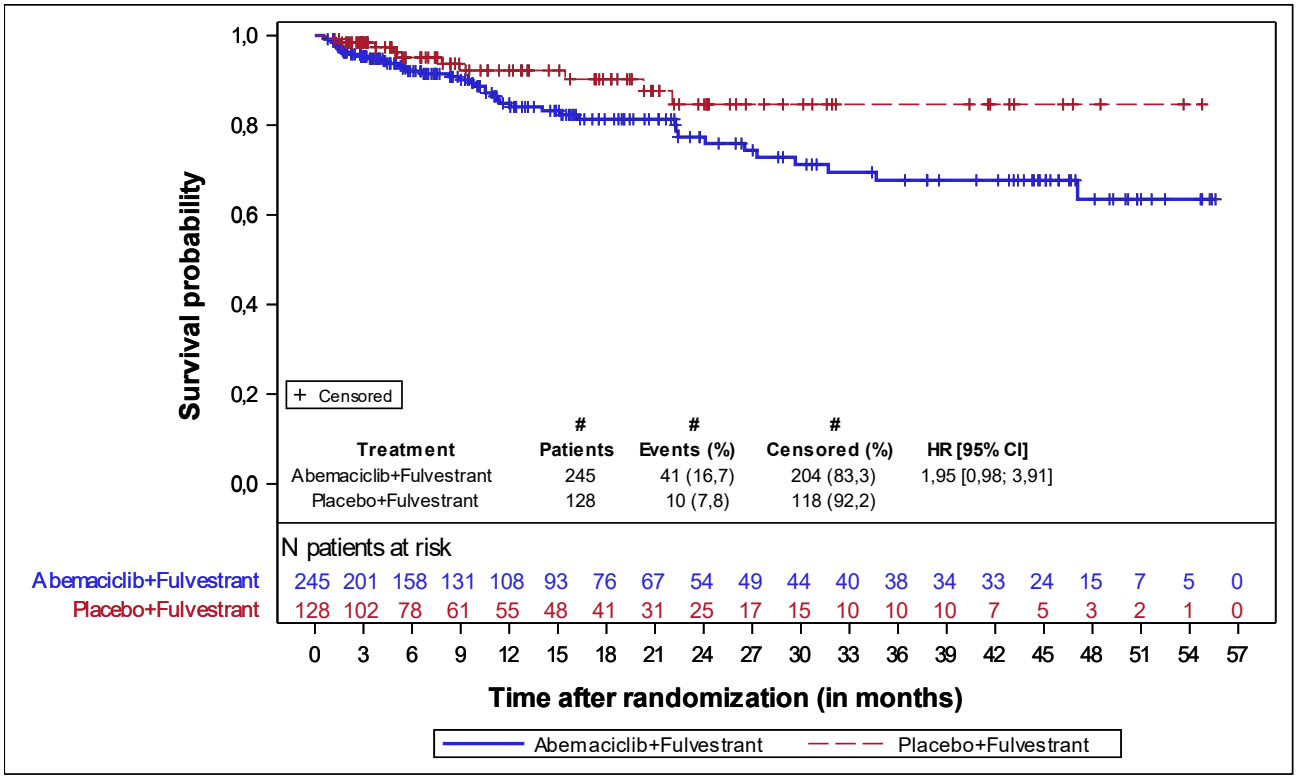
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 157: Kaplan-Meier curves for adverse events according PT - Infections and infestations / Upper respiratory tract infection Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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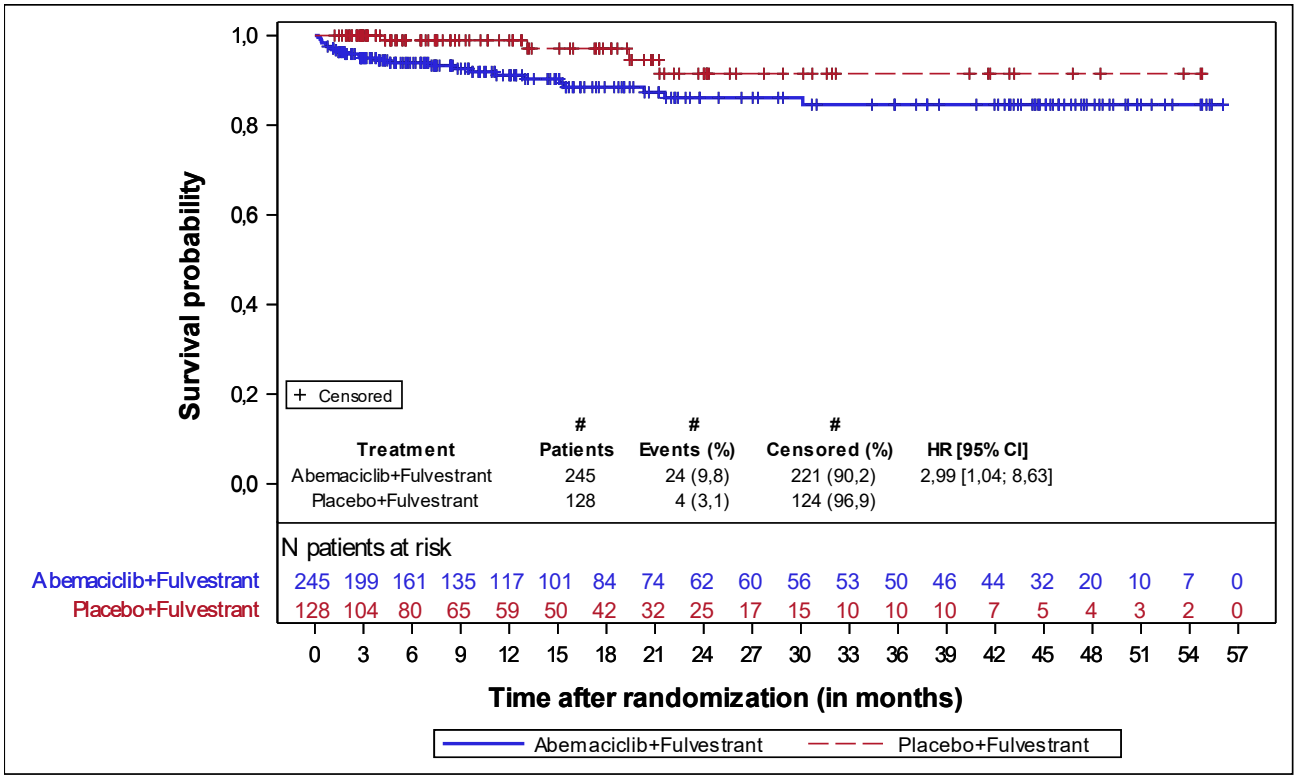
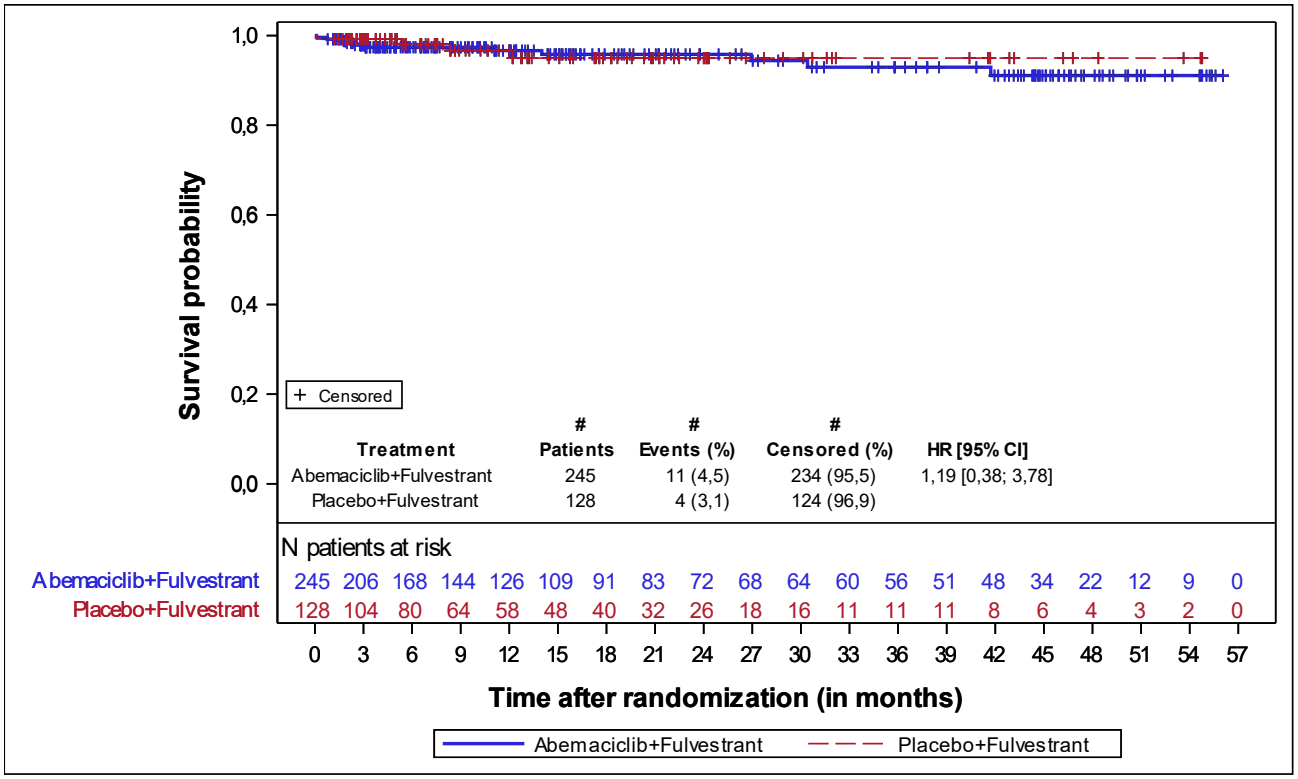
08JUL2021 / 02:43

Figure 158: Kaplan-Meier curves for adverse events according PT - Infections and infestations / Urinary tract infection
Safety Population - Postmenopausal (1st line)



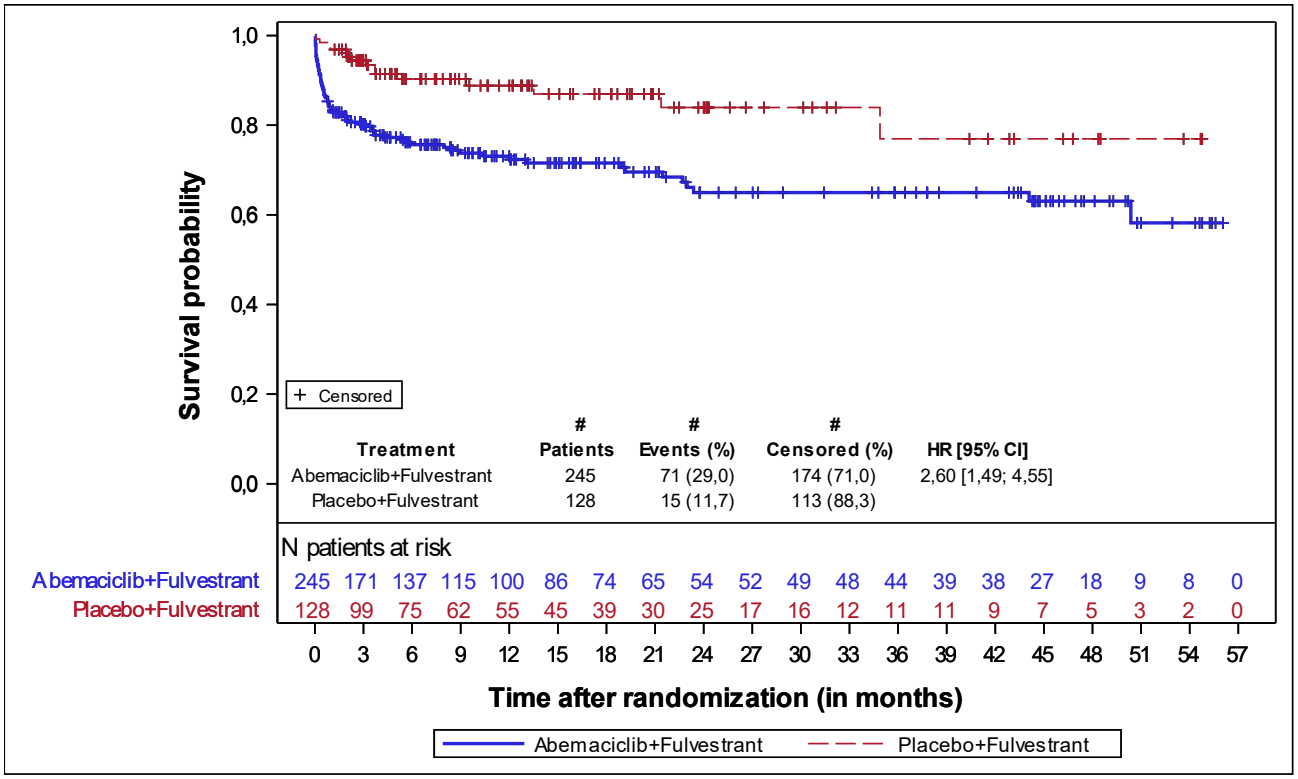
Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraep070_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 159: Kaplan-Meier curves for adverse events according PT - Eye disorders / Vision blurred
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraep071_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 160: Kaplan-Meier curves for adverse events according PT - Gastrointestinal disorders / Vomiting
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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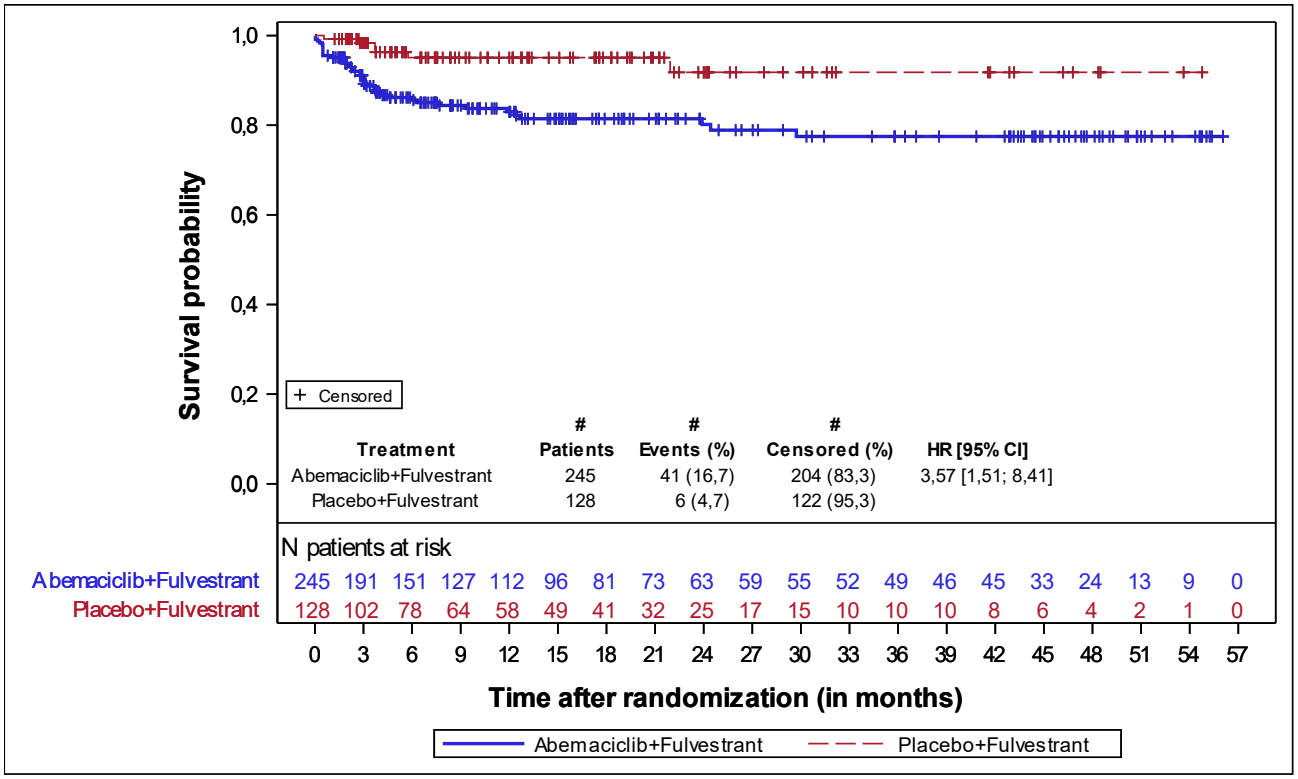
Figure 161: Kaplan-Meier curves for adverse events according PT - Investigations / Weight decreased
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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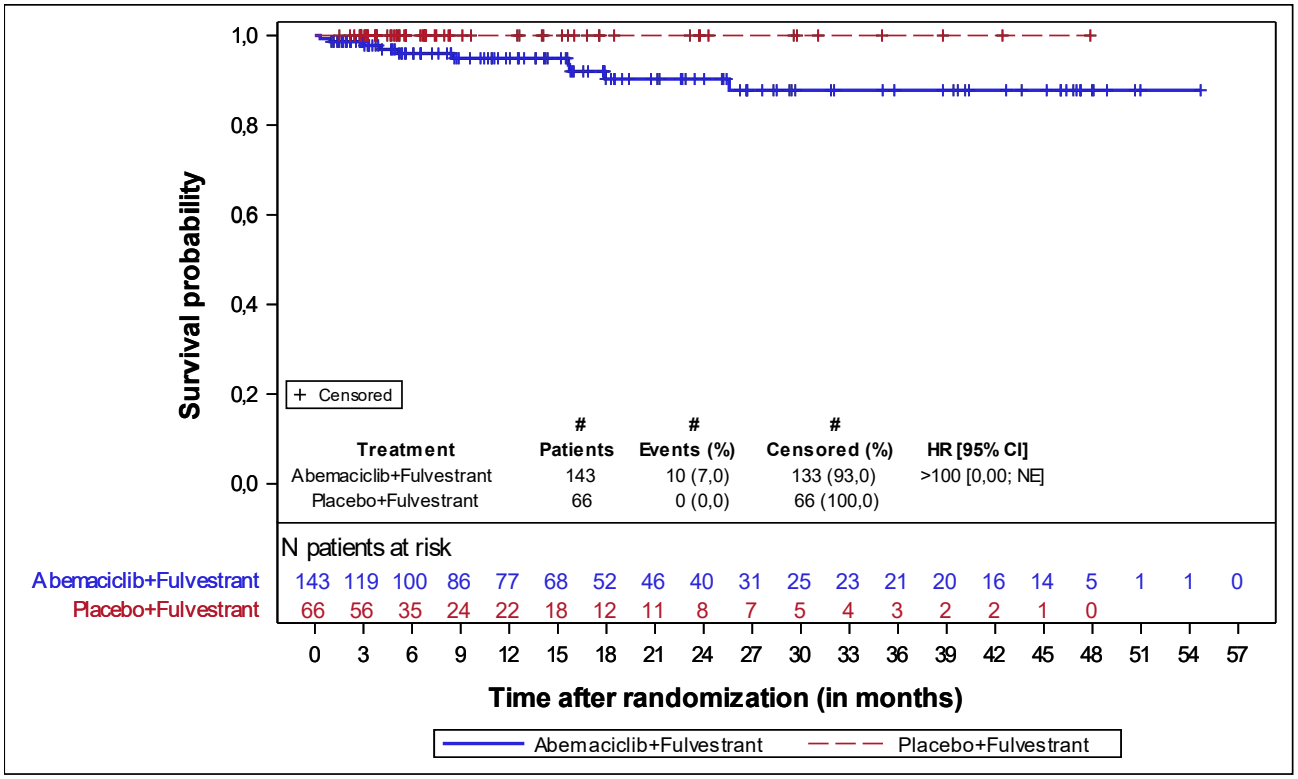
Figure 162: Kaplan-Meier curves for adverse events according PT - Gastrointestinal disorders / Abdominal distension
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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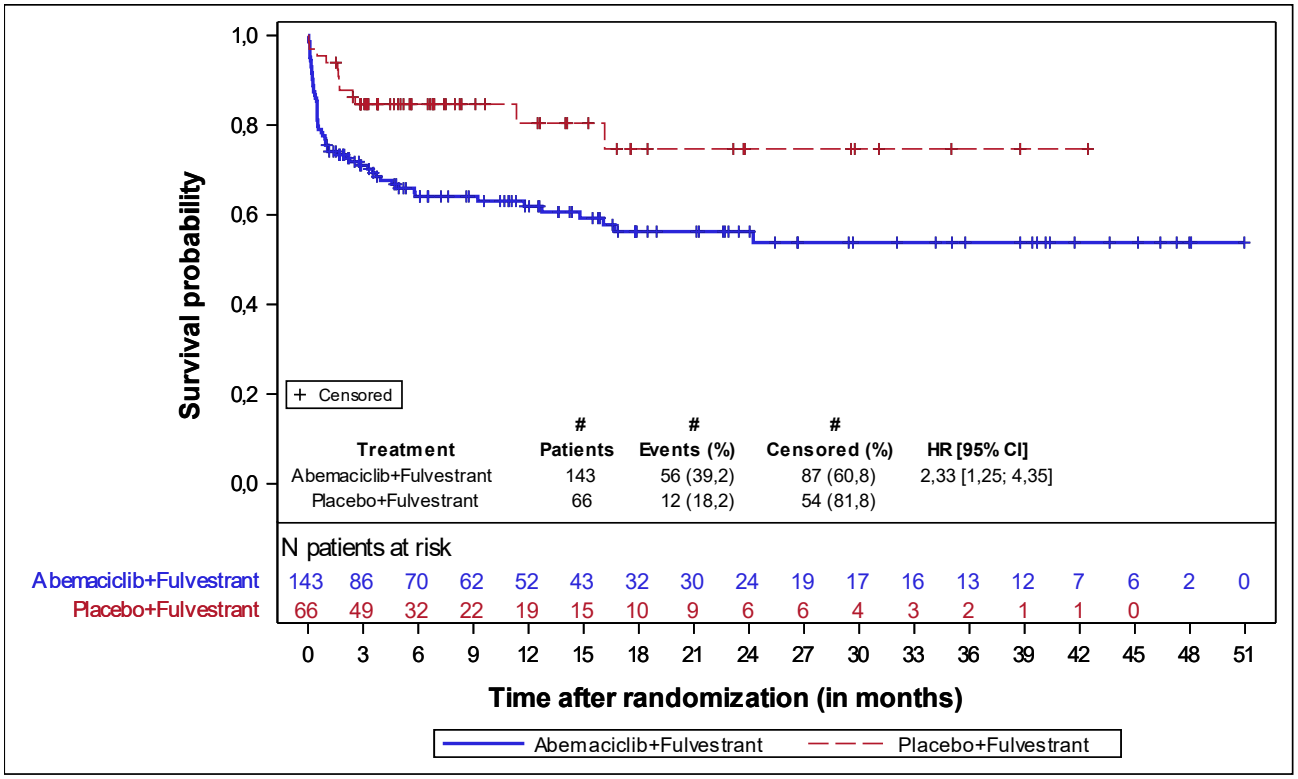
Figure 163: Kaplan-Meier curves for adverse events according PT - Gastrointestinal disorders / Abdominal pain
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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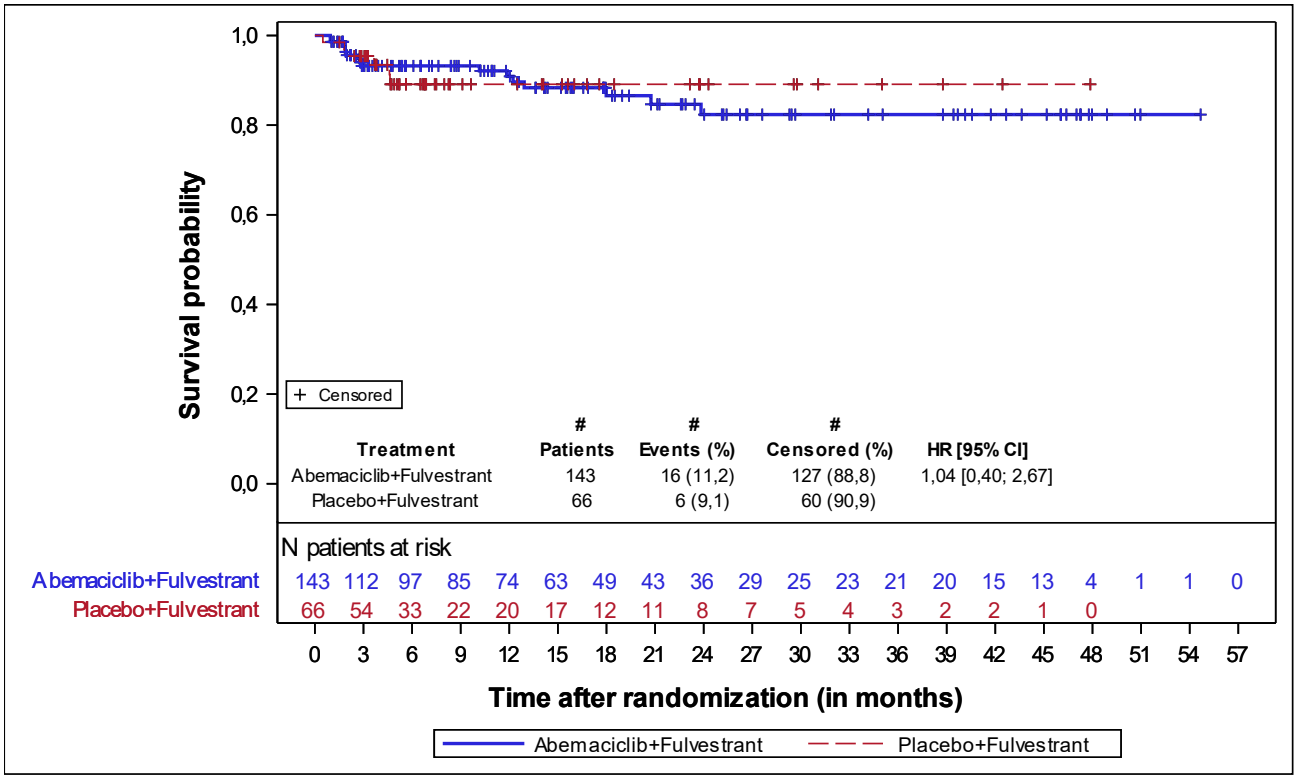
Figure 164: Kaplan-Meier curves for adverse events according PT - Investigations / Alanine aminotransferase increased
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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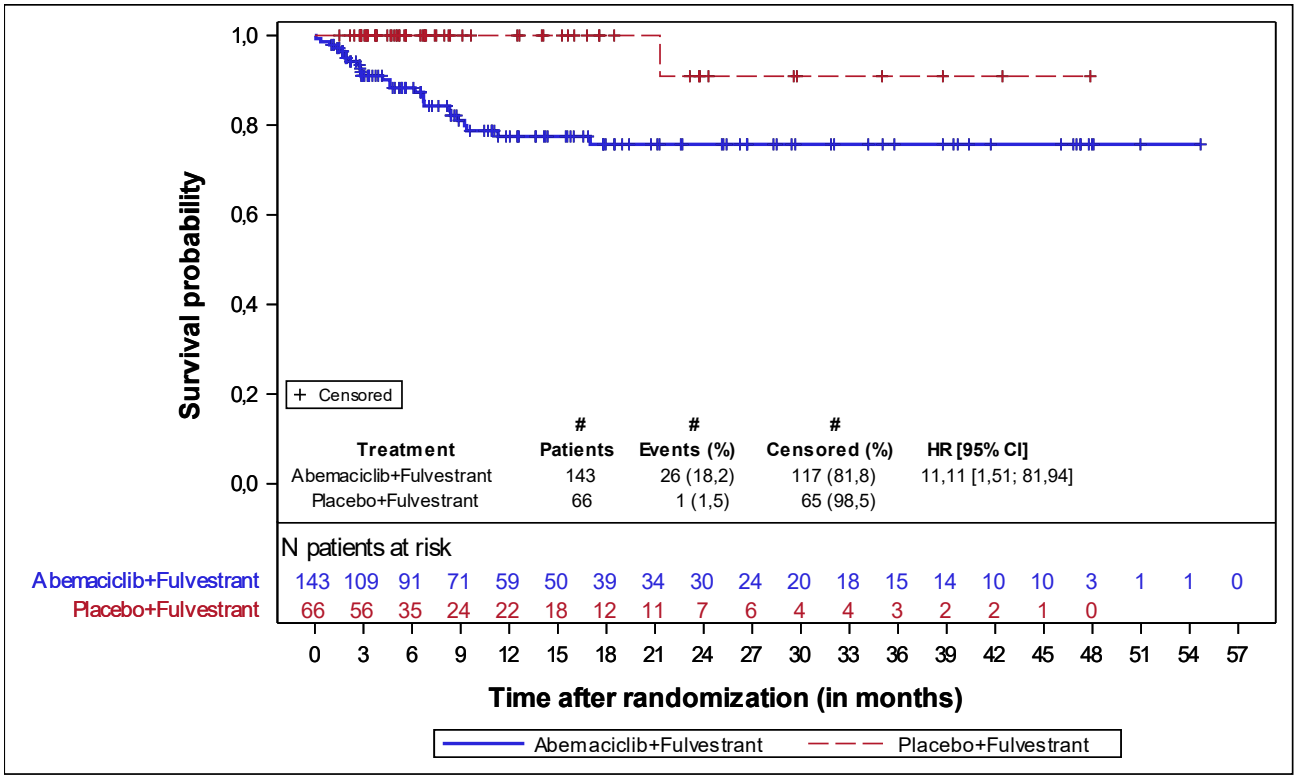
Figure 165: Kaplan-Meier curves for adverse events according PT - Skin and subcutaneous tissue disorders / Alopecia Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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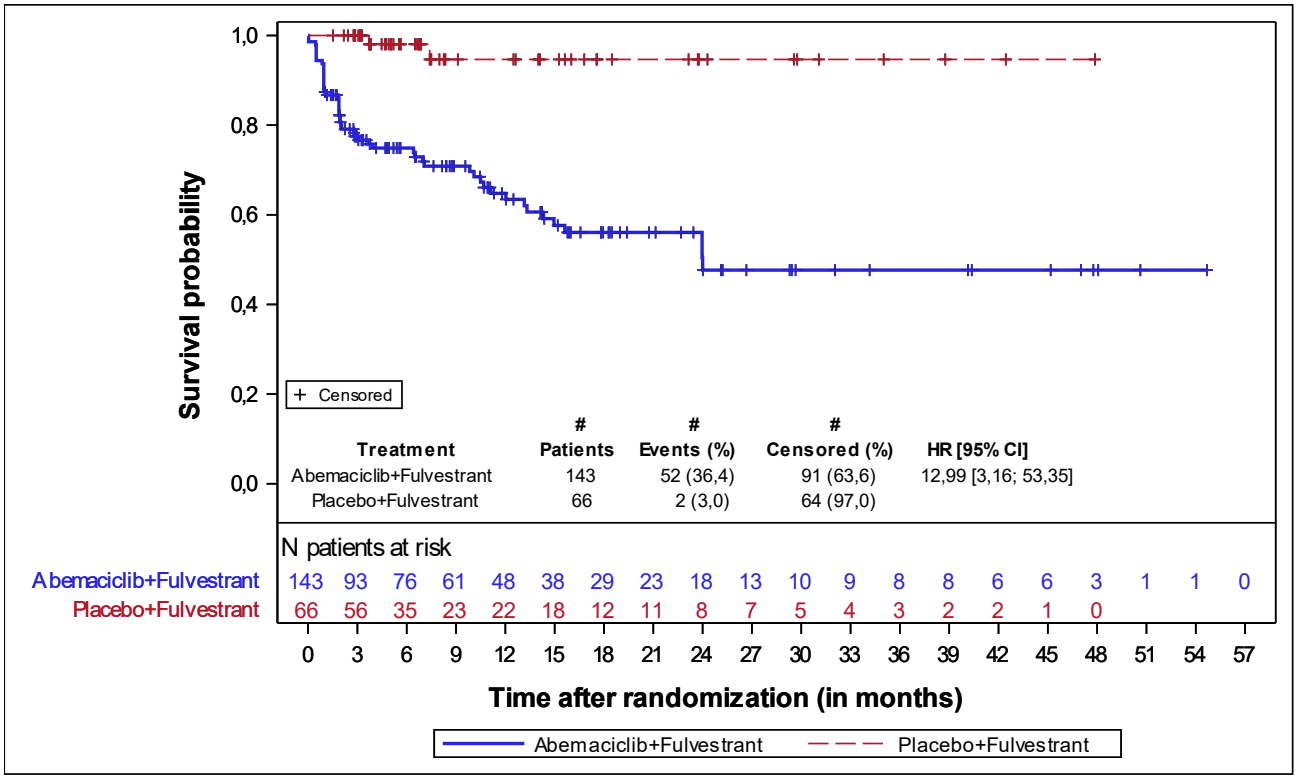
Figure 166: Kaplan-Meier curves for adverse events according PT - Blood and lymphatic system disorders / Anaemia Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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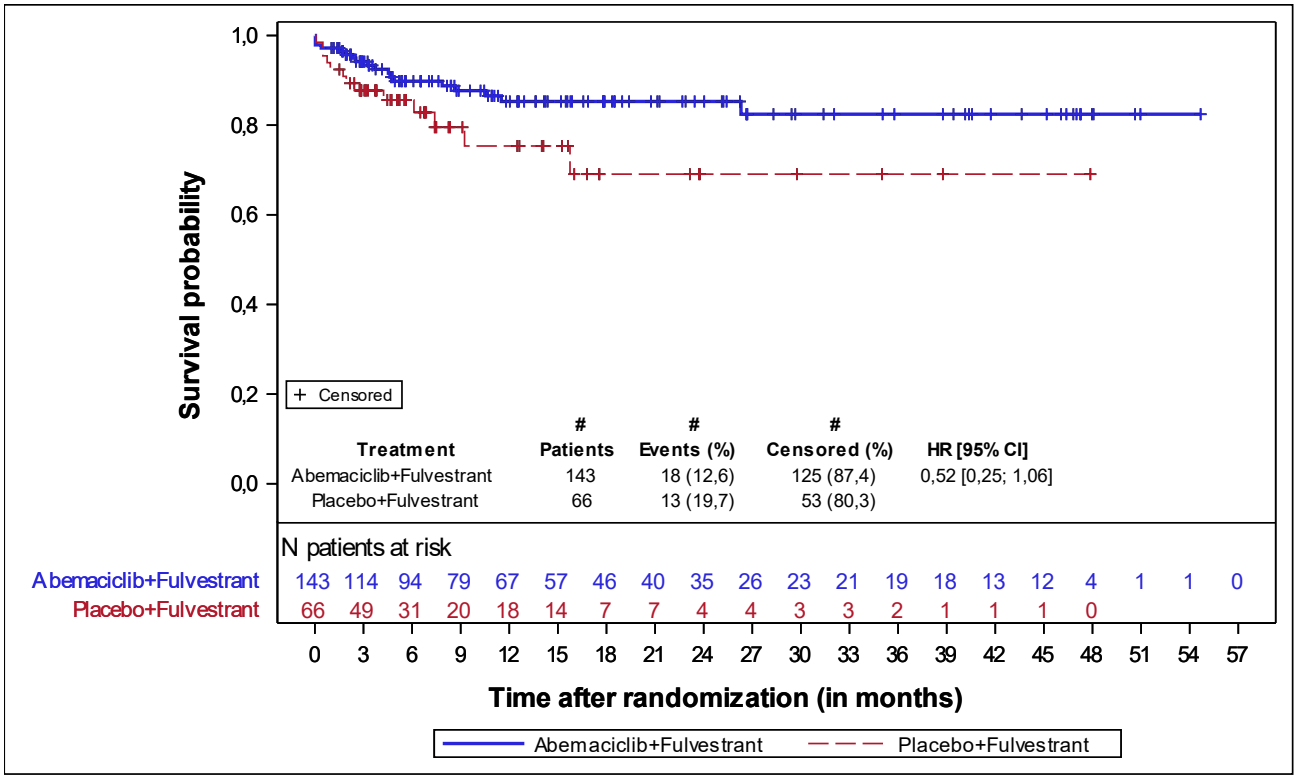
Figure 167: Kaplan-Meier curves for adverse events according PT - Musculoskeletal and connective tissue disorders / Arthralgia
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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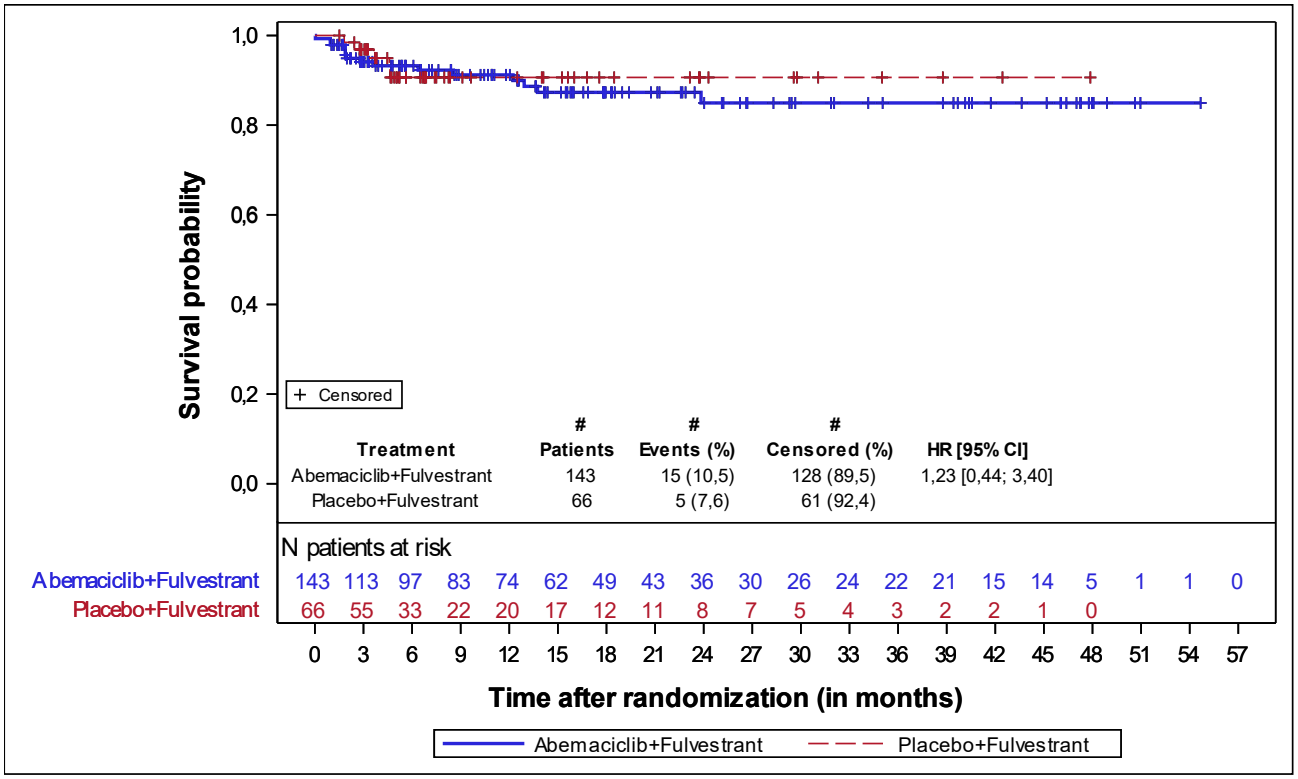
Figure 168: Kaplan-Meier curves for adverse events according PT - Investigations / Aspartate aminotransferase increased
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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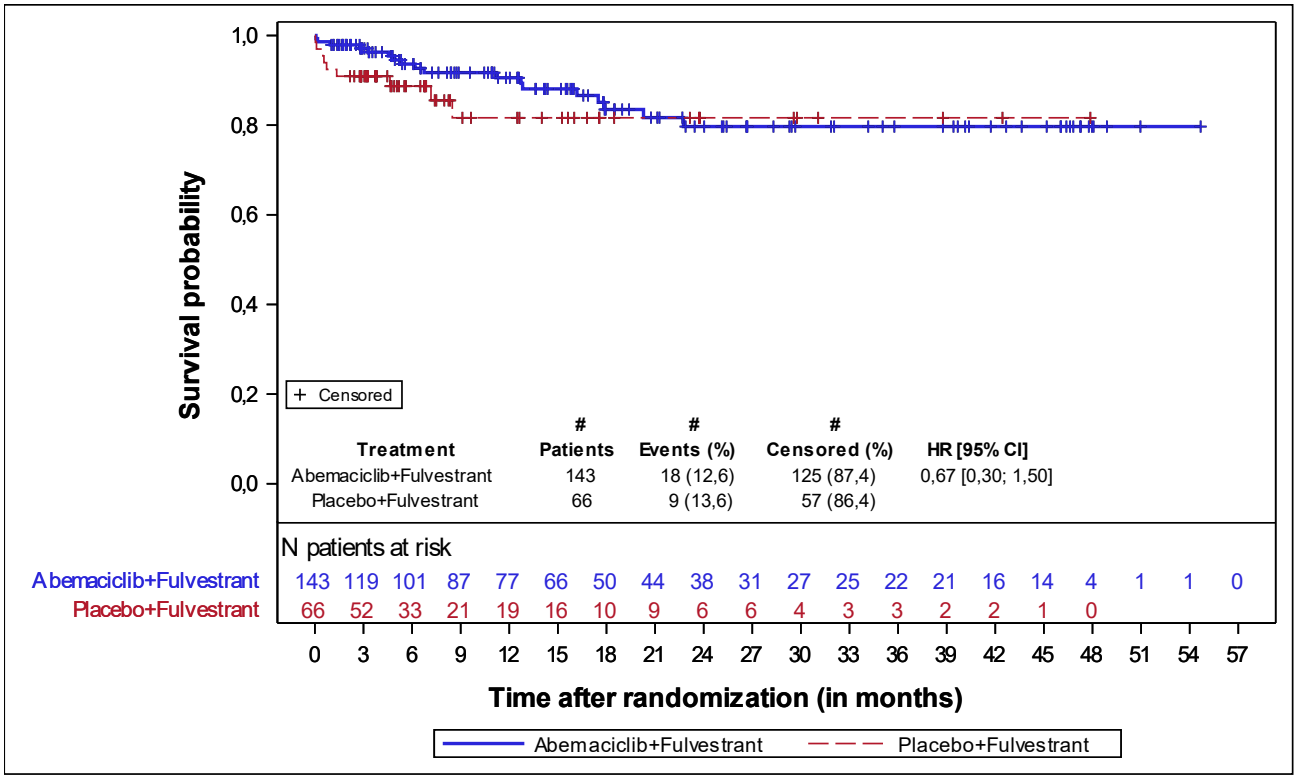
Figure 169: Kaplan-Meier curves for adverse events according PT - Musculoskeletal and connective tissue disorders / Back pain
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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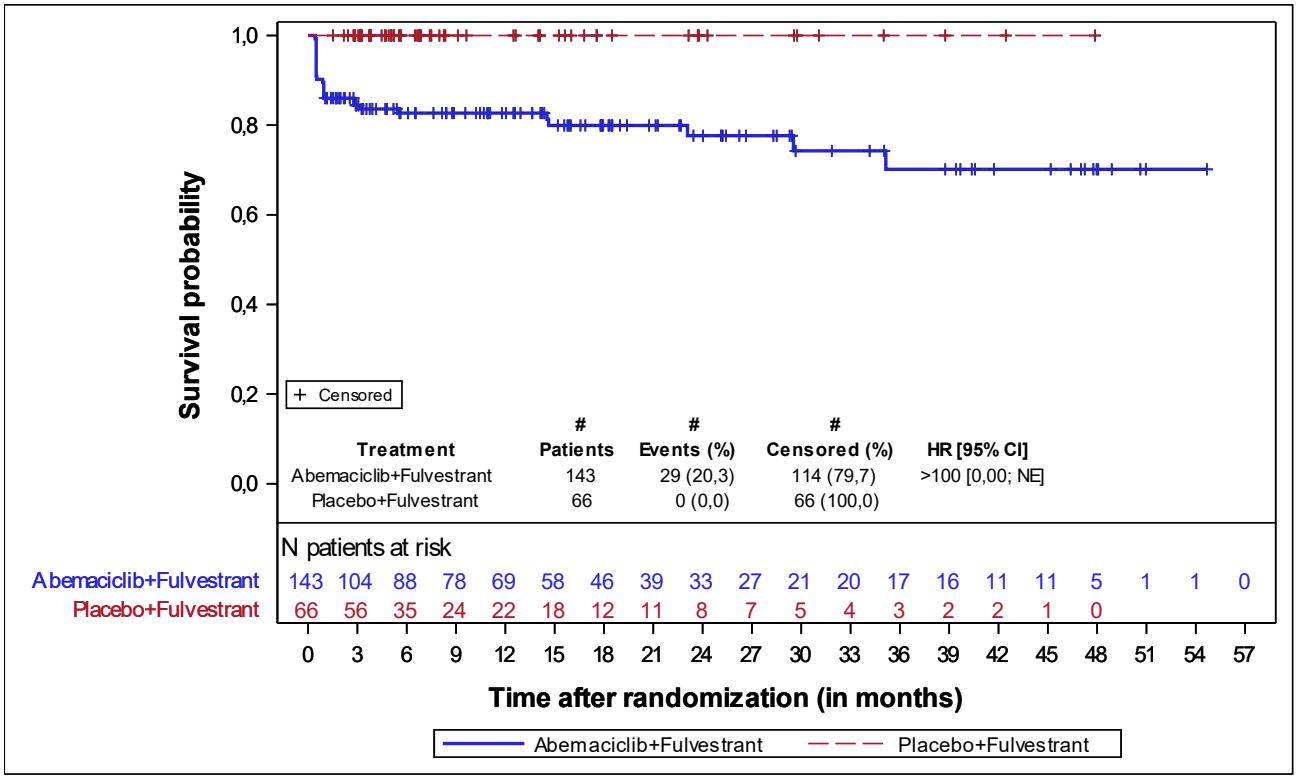
Figure 170: Kaplan-Meier curves for adverse events according PT - Investigations / Blood creatinine increased
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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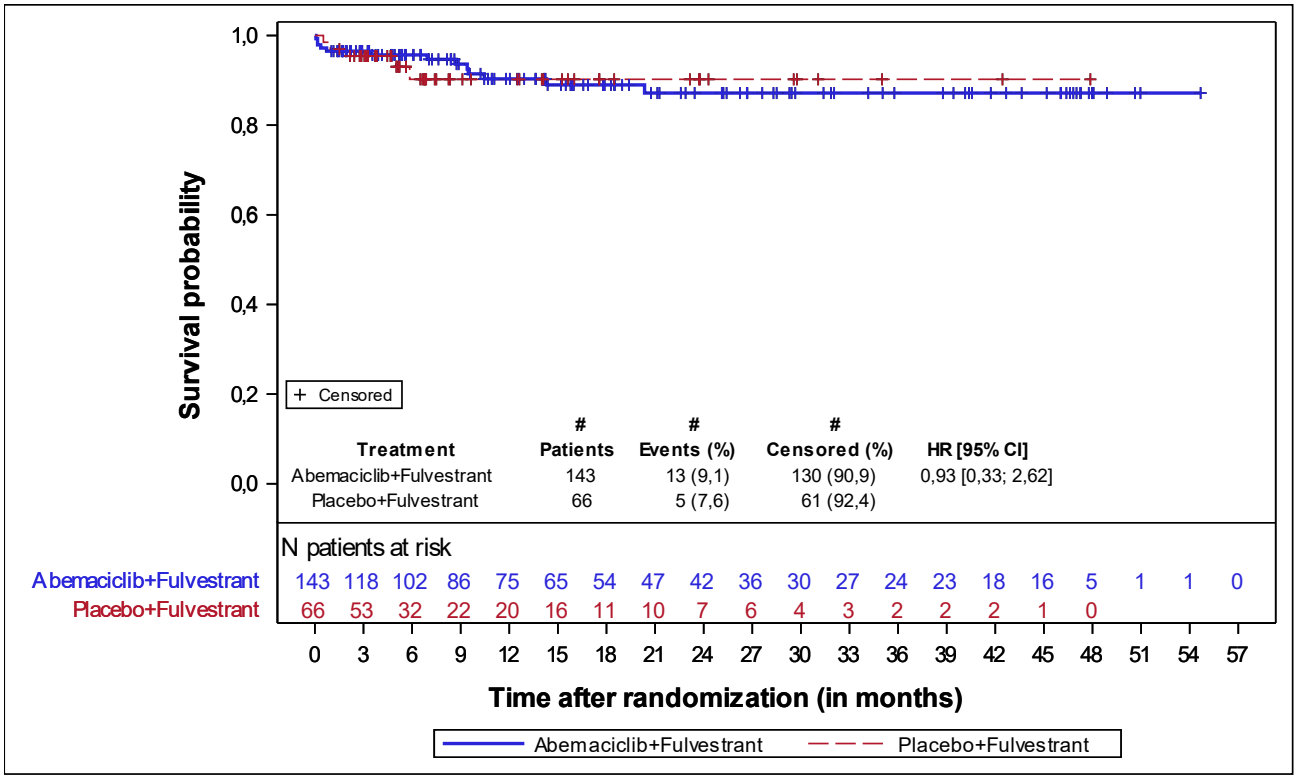
Figure 171: Kaplan-Meier curves for adverse events according PT - Musculoskeletal and connective tissue disorders / Bone pain
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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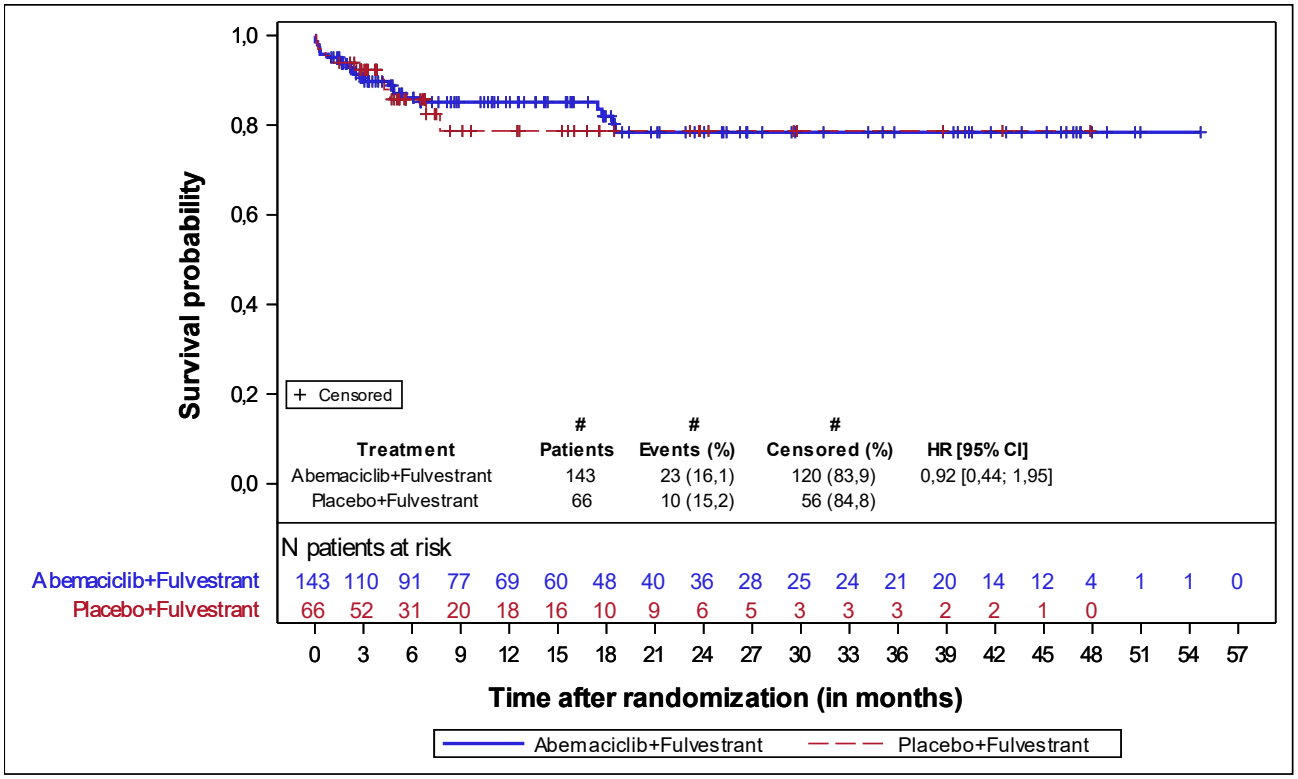
Figure 172: Kaplan-Meier curves for adverse events according PT - Gastrointestinal disorders / Constipation
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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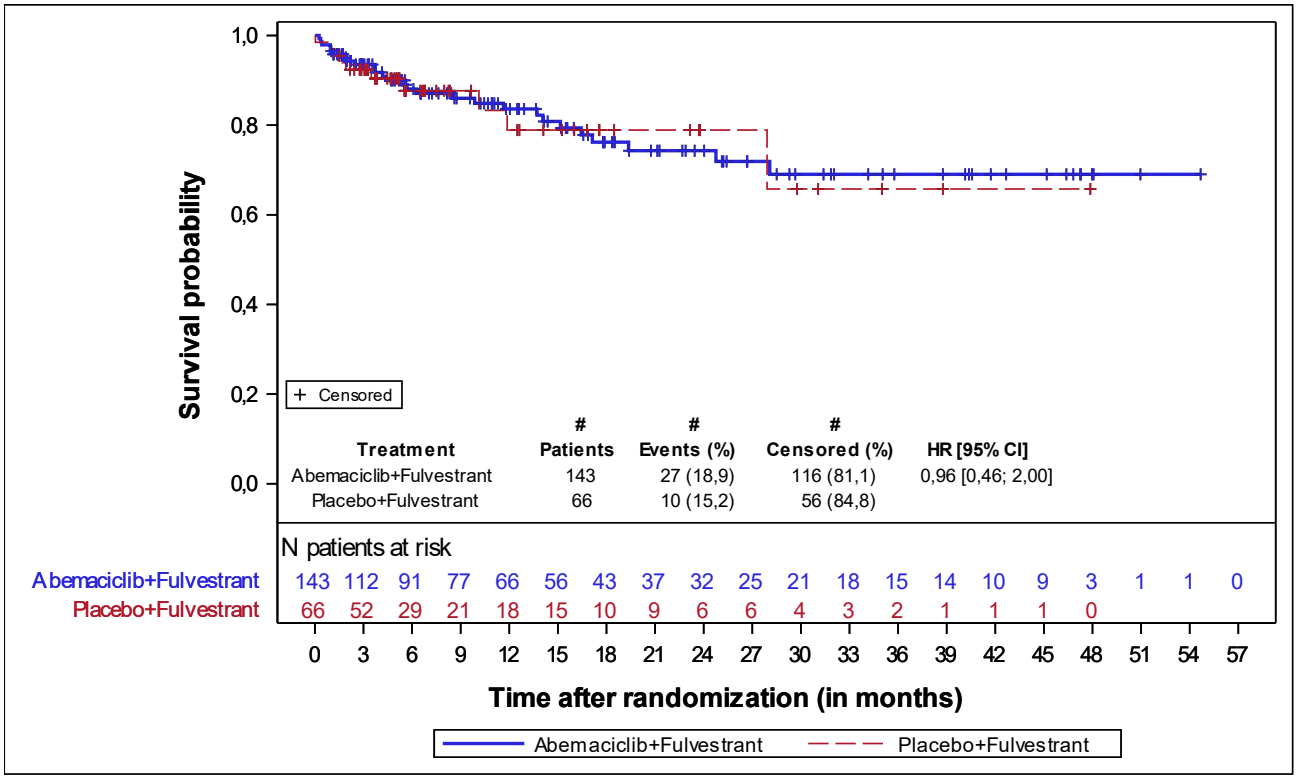
Figure 173: Kaplan-Meier curves for adverse events according PT - Respiratory, thoracic and mediastinal disorders / Cough
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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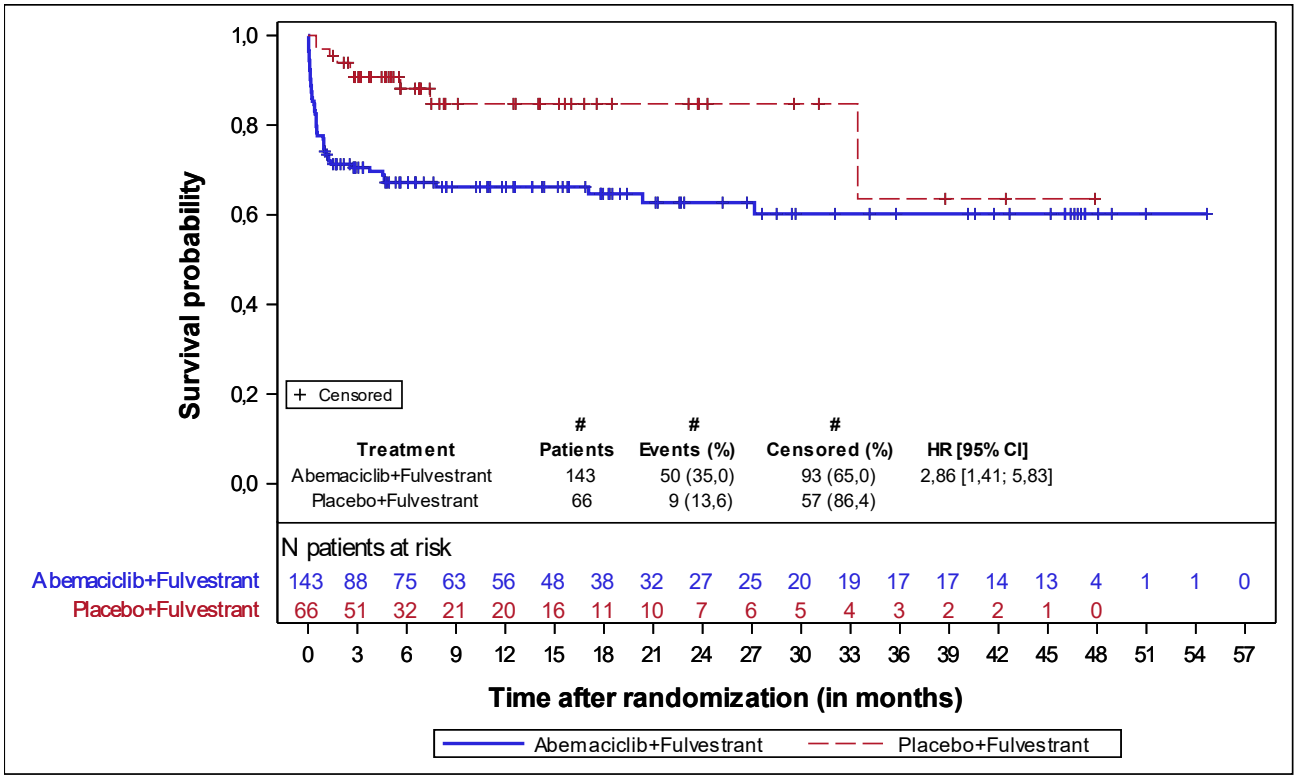
Figure 174: Kaplan-Meier curves for adverse events according PT - Metabolism and nutrition disorders / Decreased appetite Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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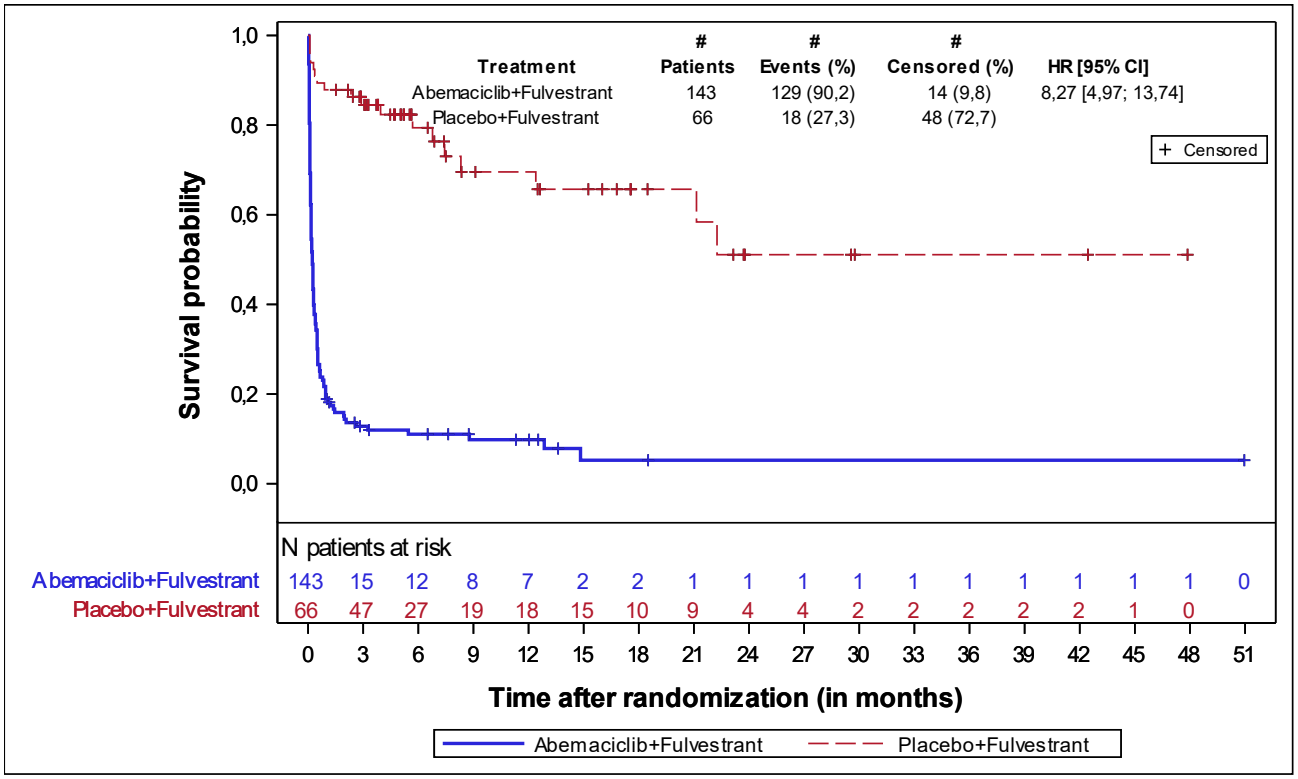
Figure 175: Kaplan-Meier curves for adverse events according PT - Gastrointestinal disorders / Diarrhoea
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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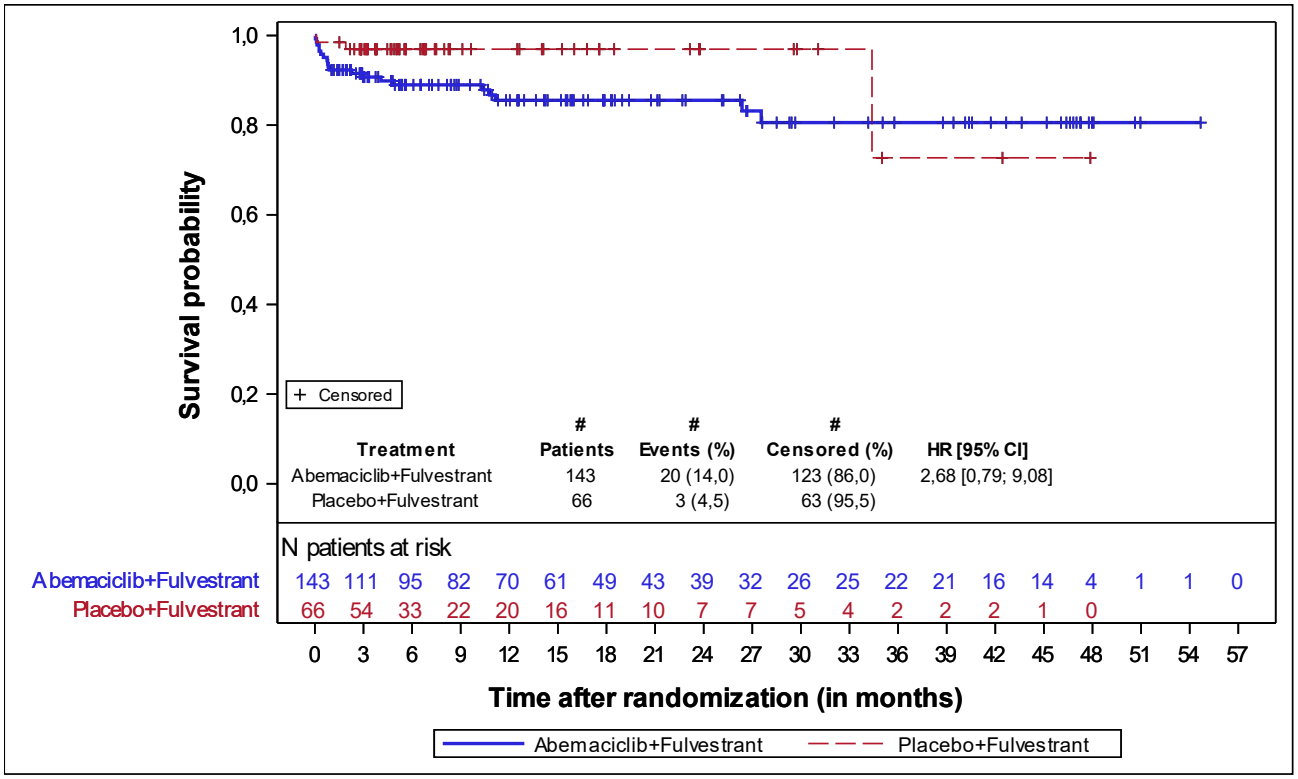
08JUL2021 / 02:43

Figure 176: Kaplan-Meier curves for adverse events according PT - Nervous system disorders / Dizziness
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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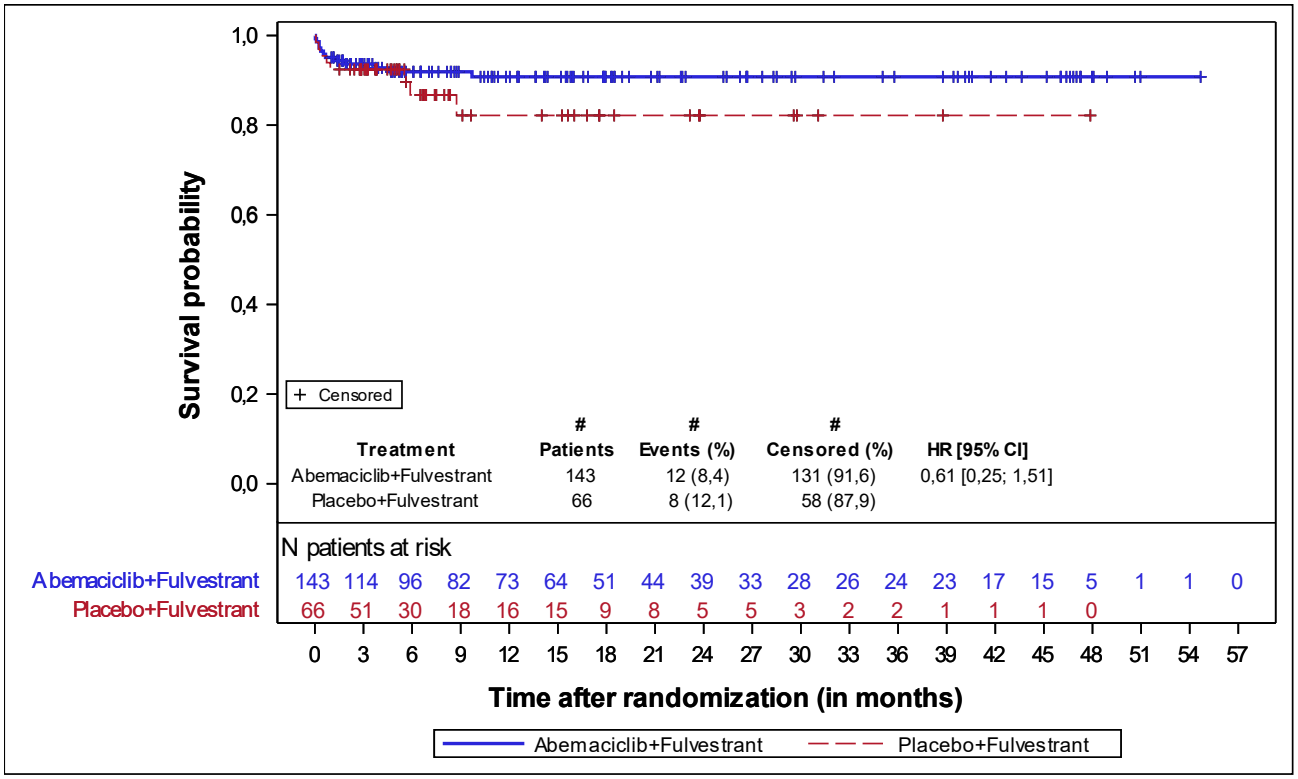
Figure 177: Kaplan-Meier curves for adverse events according PT - Gastrointestinal disorders / Dry mouth
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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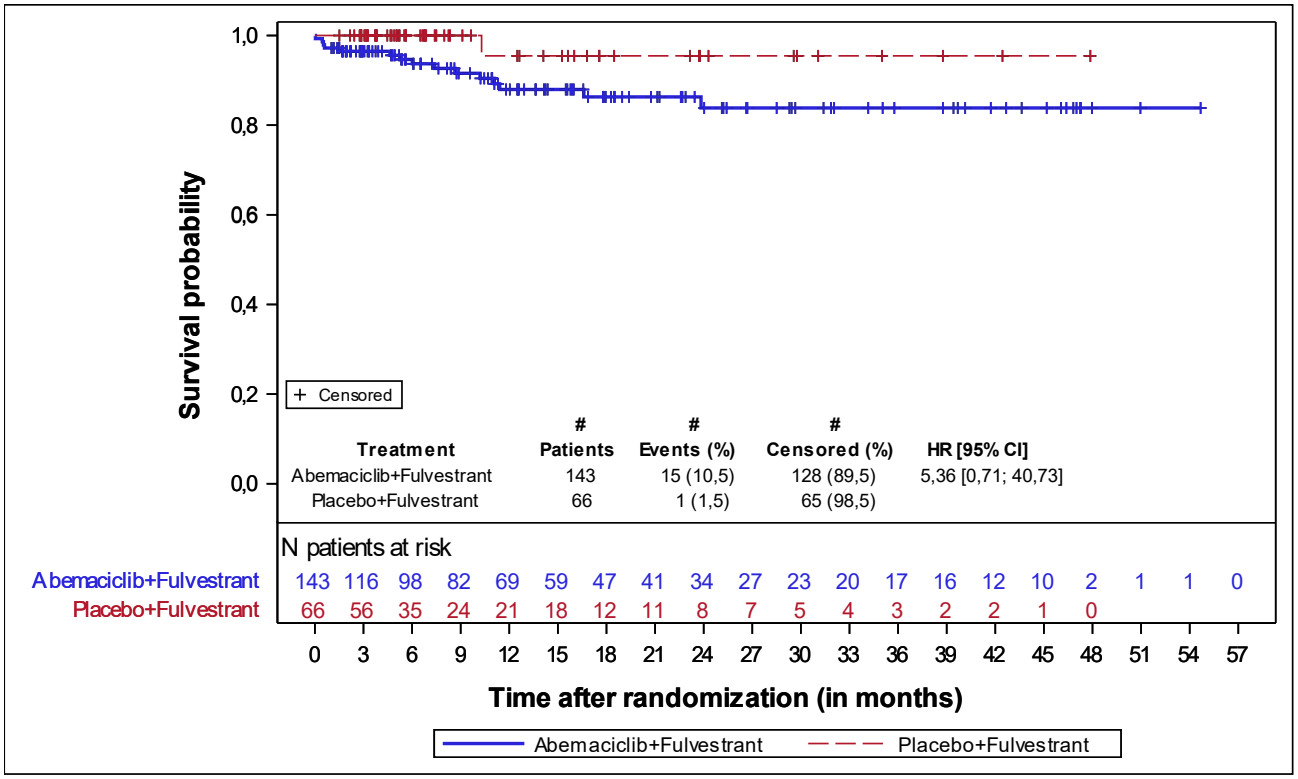
Figure 178: Kaplan-Meier curves for adverse events according PT - Skin and subcutaneous tissue disorders / Dry skin Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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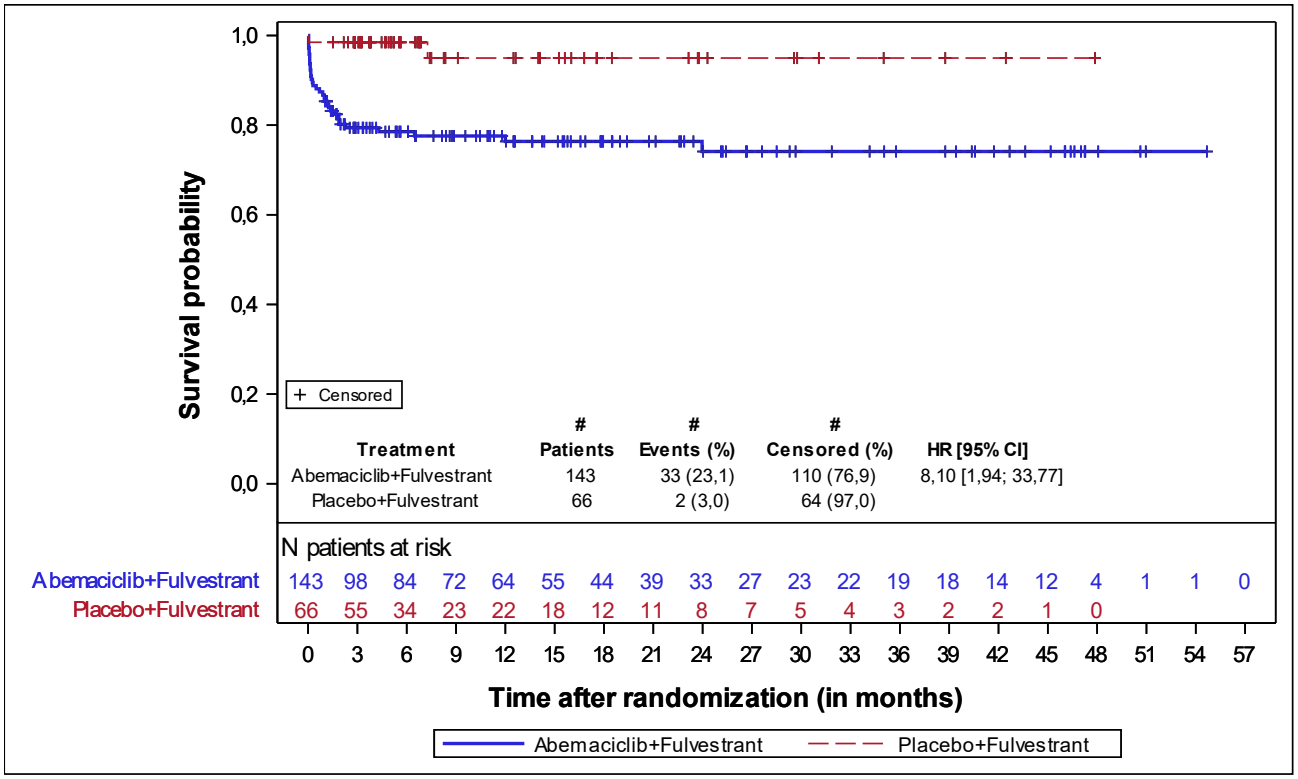
08JUL2021 / 02:43

Figure 179: Kaplan-Meier curves for adverse events according PT - Nervous system disorders / Dysgeusia
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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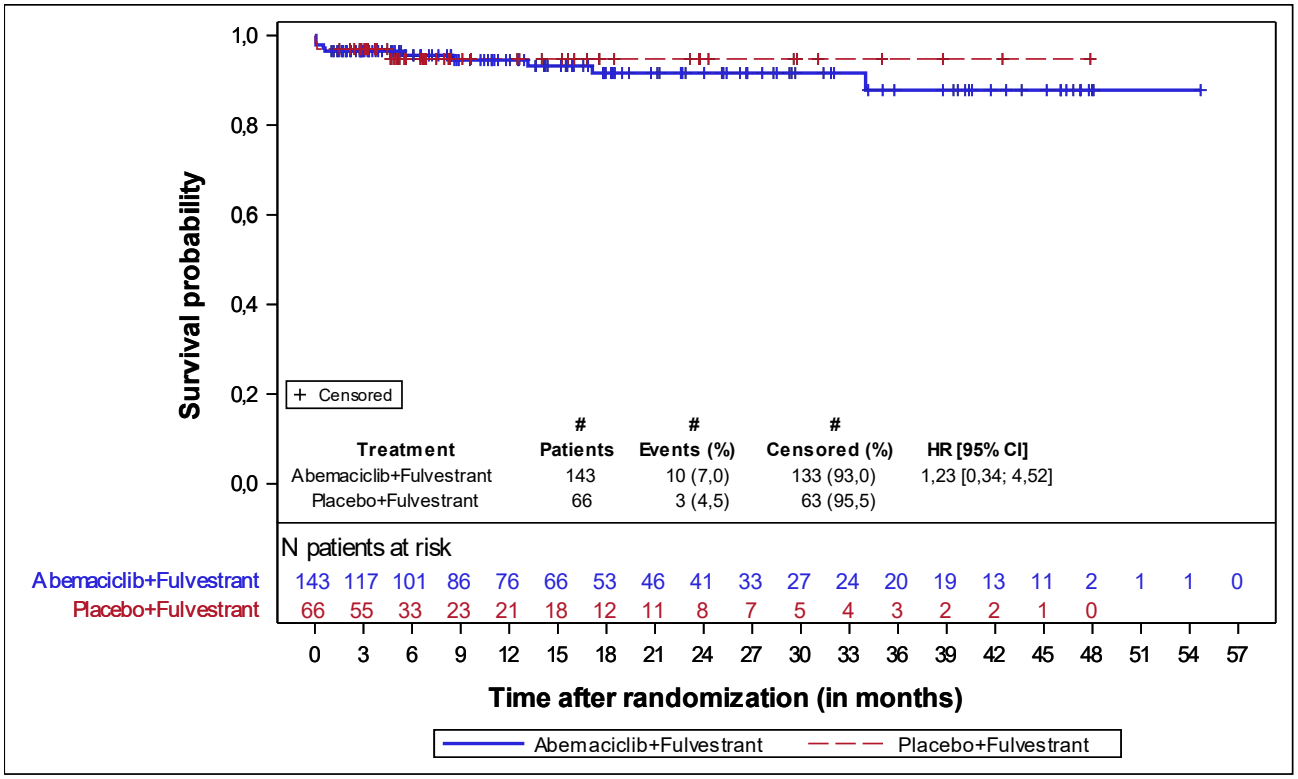
Figure 180: Kaplan-Meier curves for adverse events according PT - Gastrointestinal disorders / Dyspepsia
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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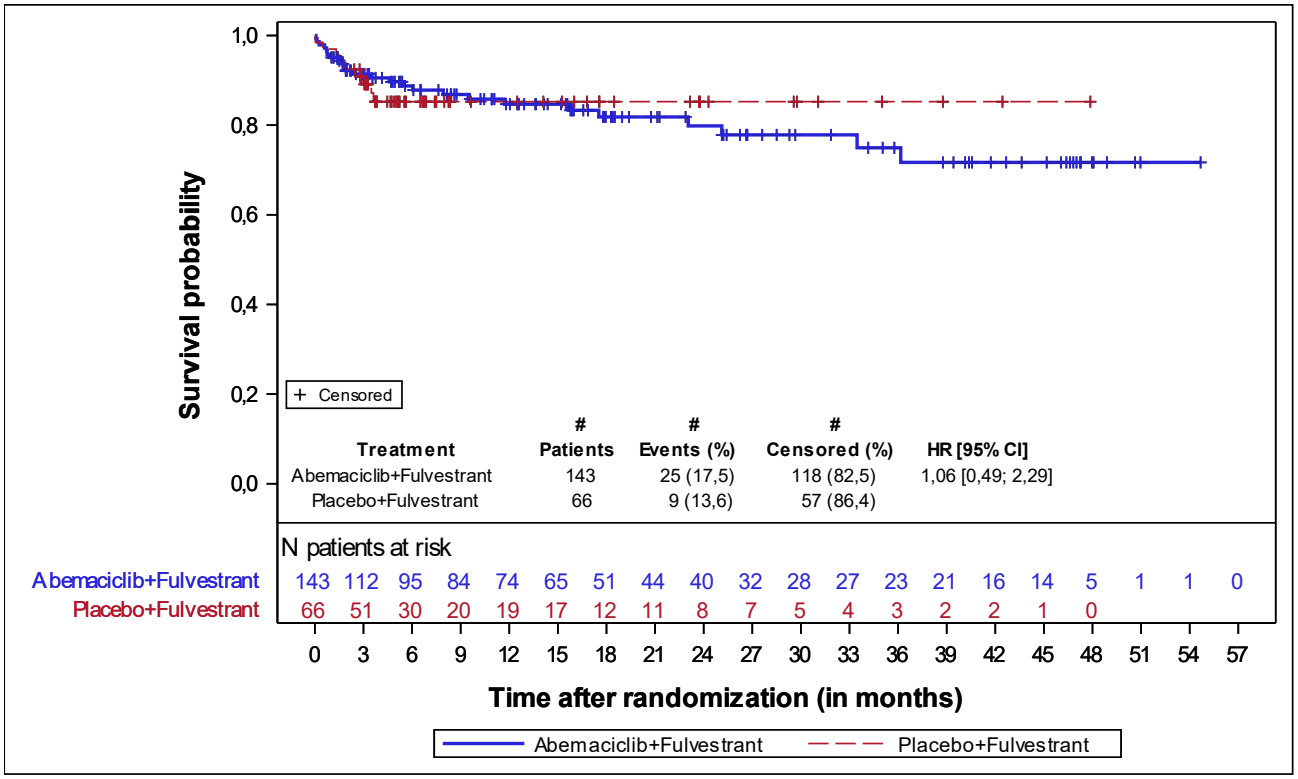
Figure 181: Kaplan-Meier curves for adverse events according PT - Respiratory, thoracic and mediastinal disorders / Dyspnoea
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraep020_popa2.rtf
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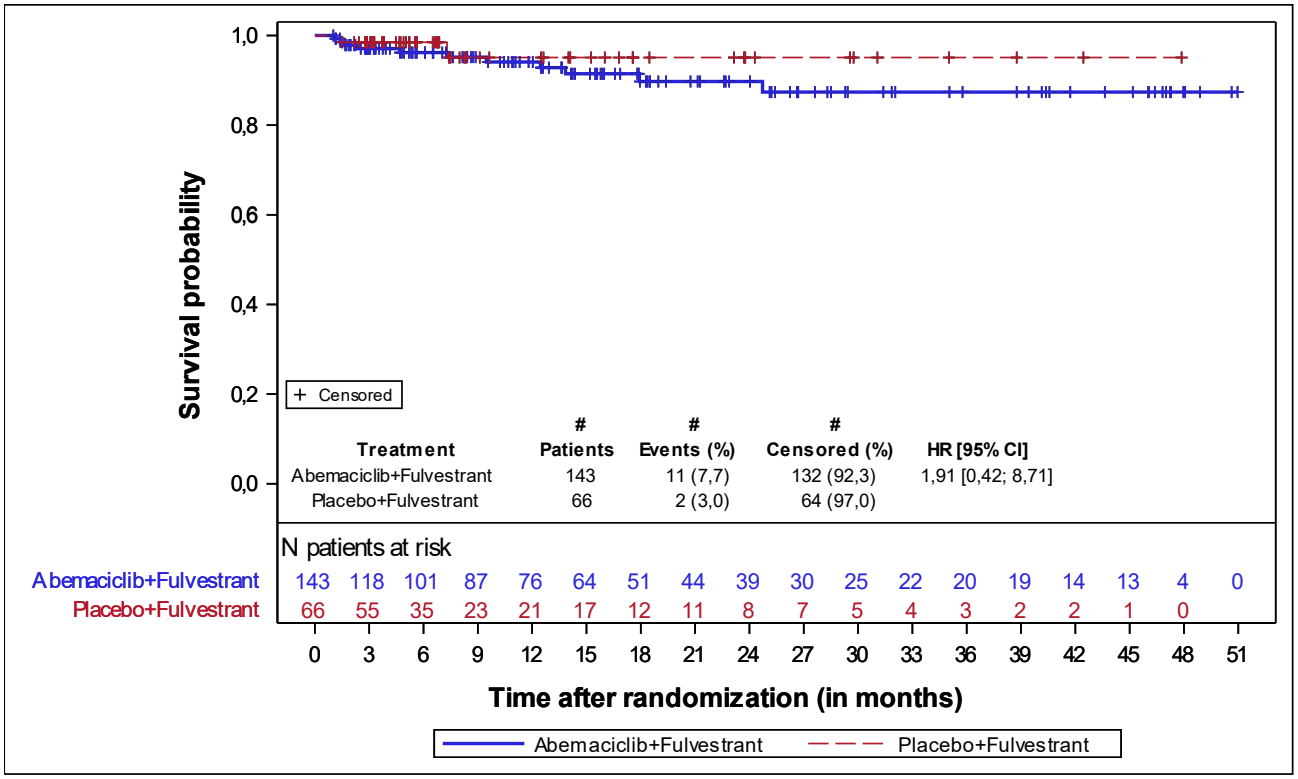
Figure 182: Kaplan-Meier curves for adverse events according PT - Vascular disorders / Embolism
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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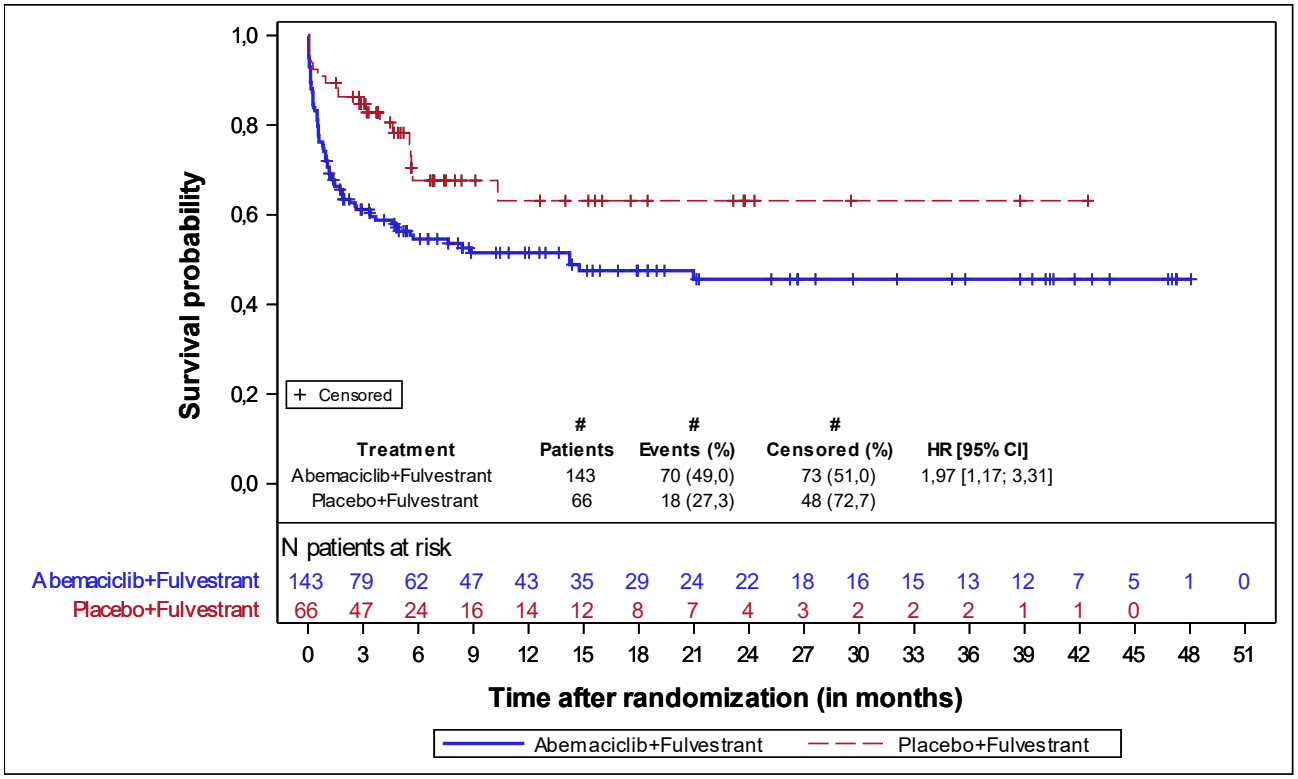
Figure 183: Kaplan-Meier curves for adverse events according PT - General disorders and administration site conditions / Fatigue Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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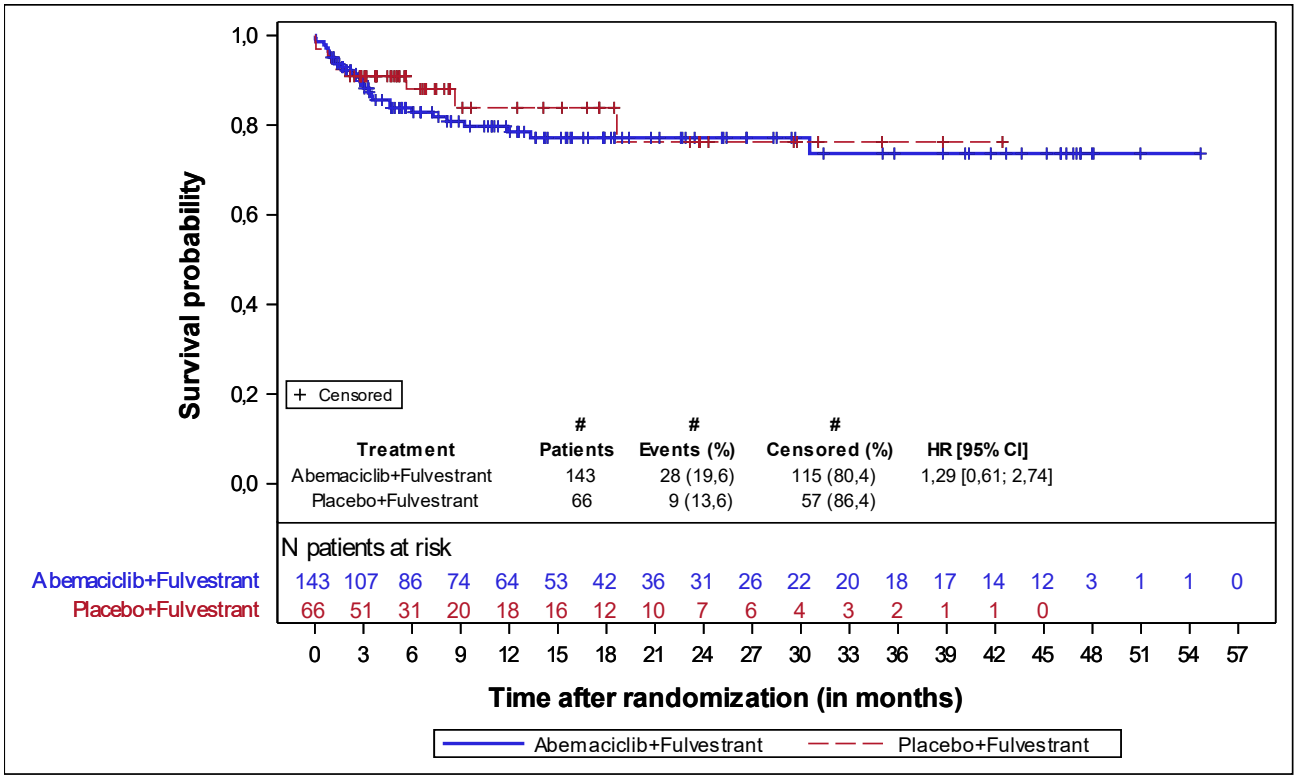
Figure 184: Kaplan-Meier curves for adverse events according PT - Nervous system disorders / Headache
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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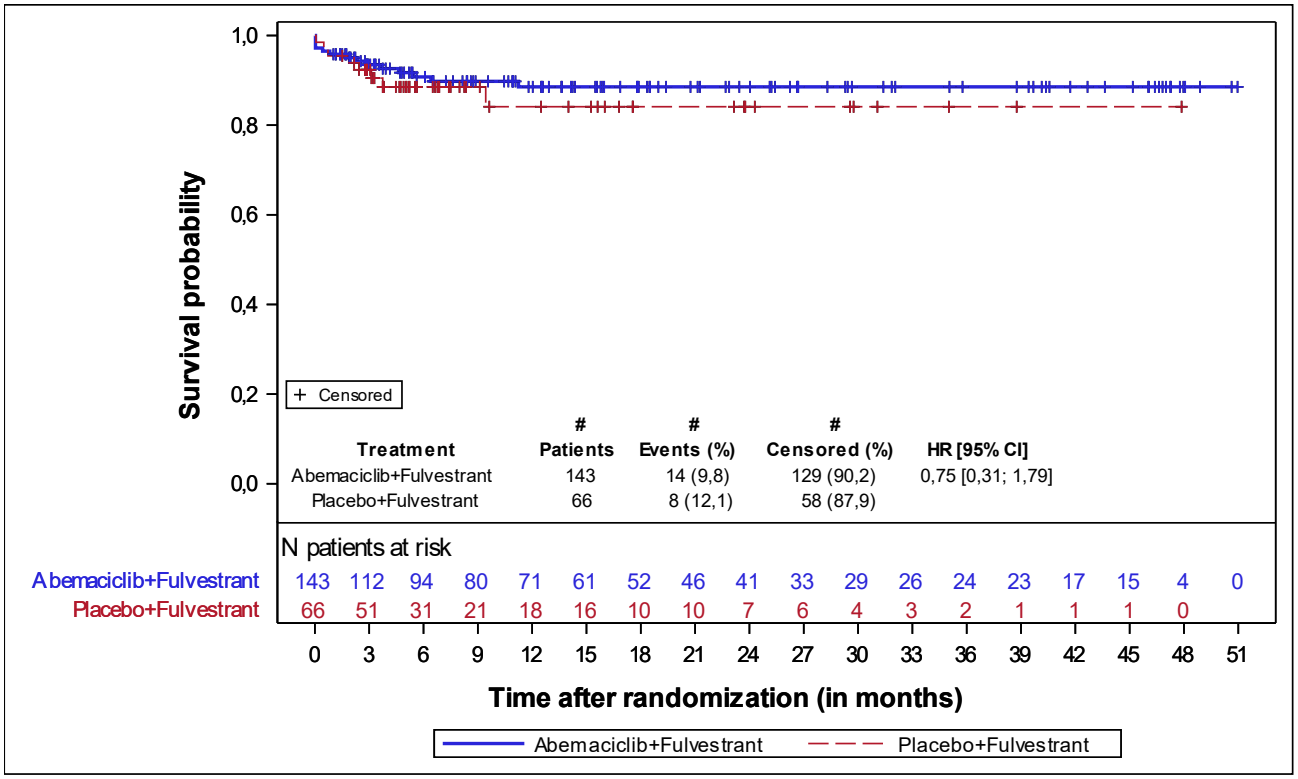
Figure 185: Kaplan-Meier curves for adverse events according PT - Vascular disorders / Hot flush
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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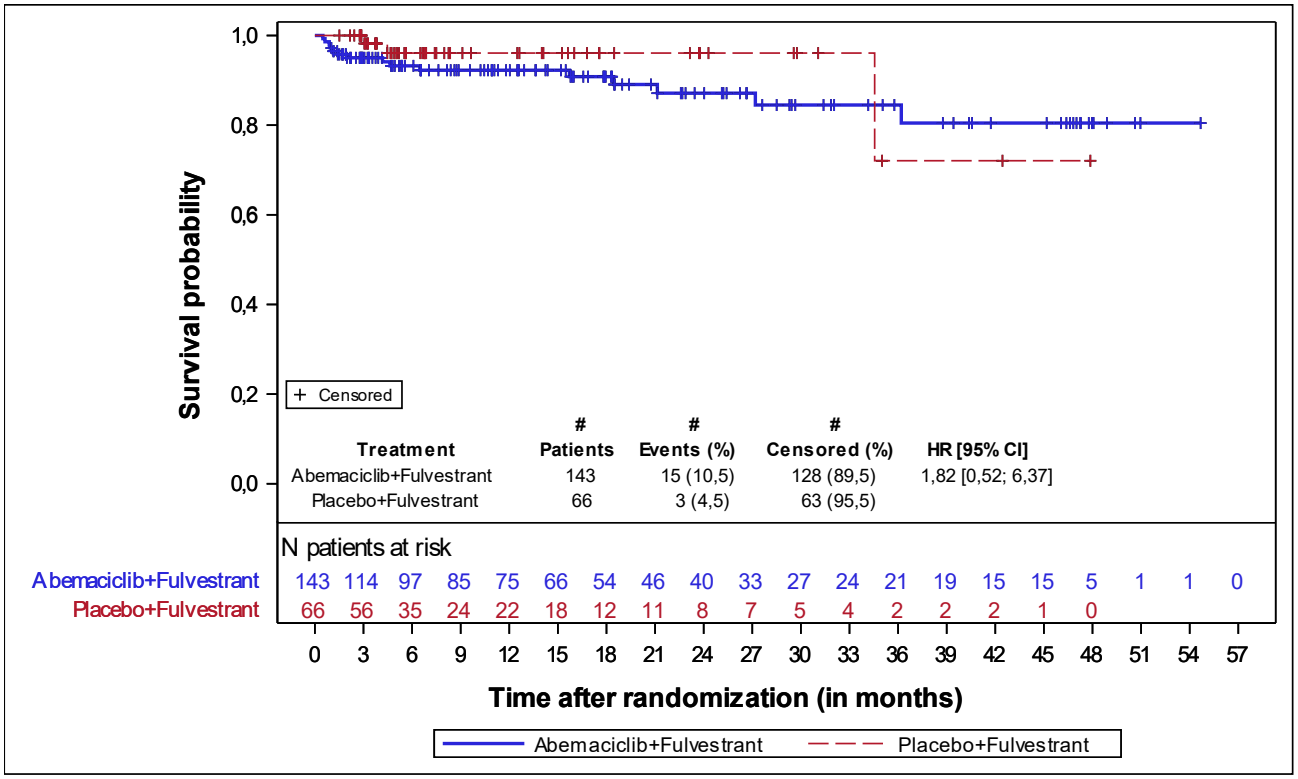
Figure 186: Kaplan-Meier curves for adverse events according PT - Metabolism and nutrition disorders / Hypokalaemia
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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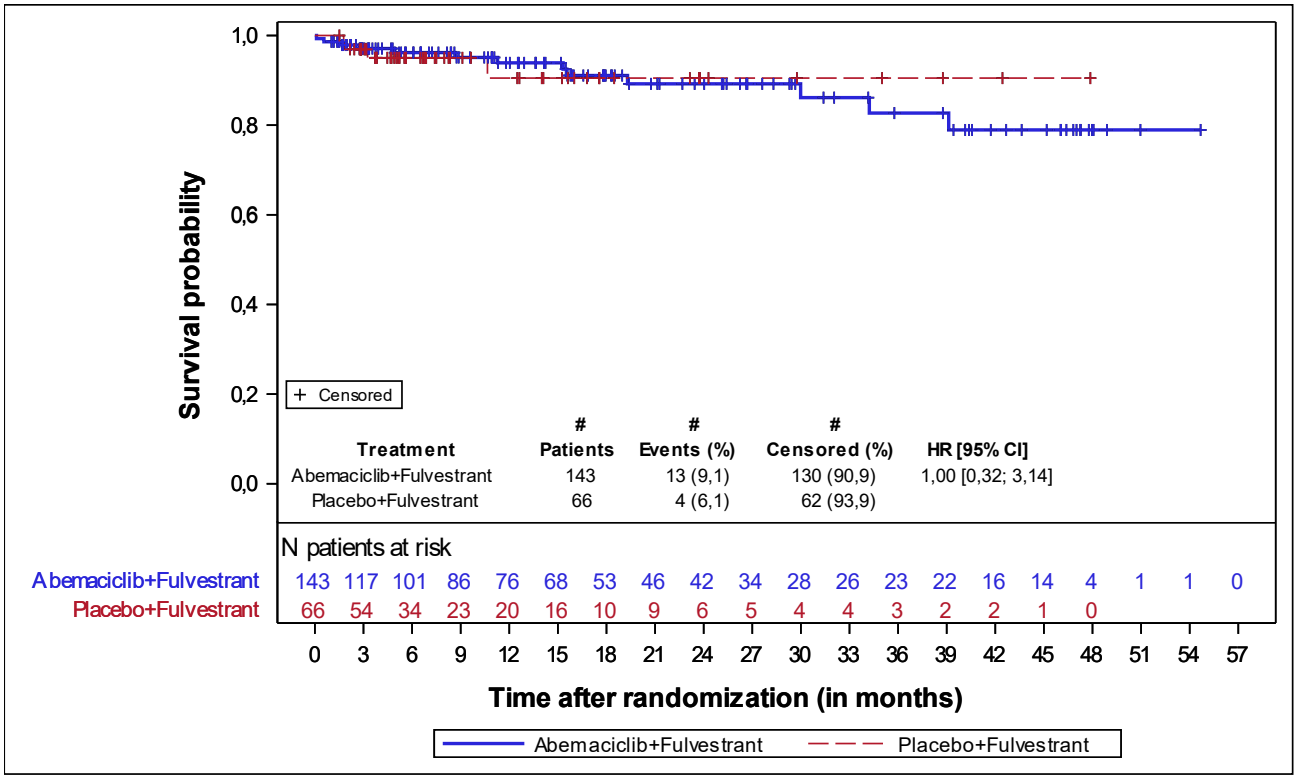
Figure 187: Kaplan-Meier curves for adverse events according PT - General disorders and administration site conditions / Influenza like illness Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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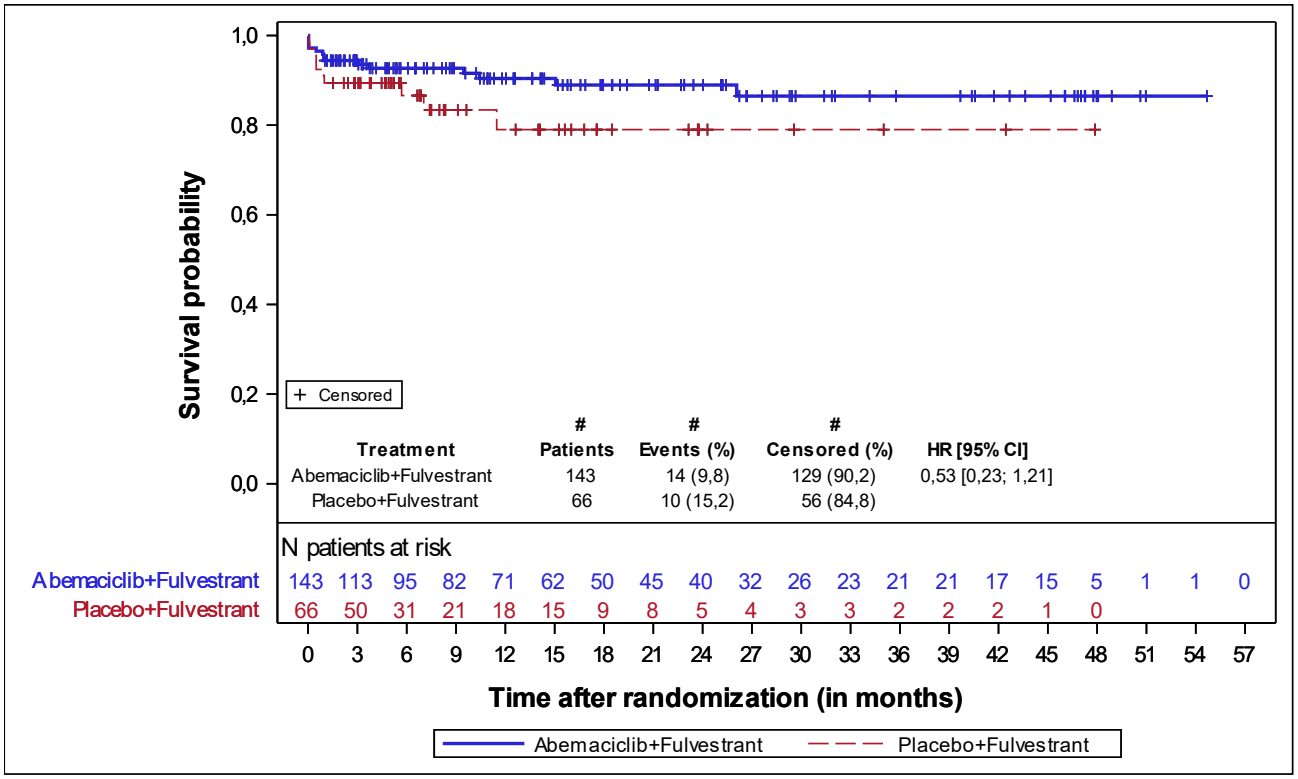
Figure 188: Kaplan-Meier curves for adverse events according PT - General disorders and administration site conditions / Injection site reaction Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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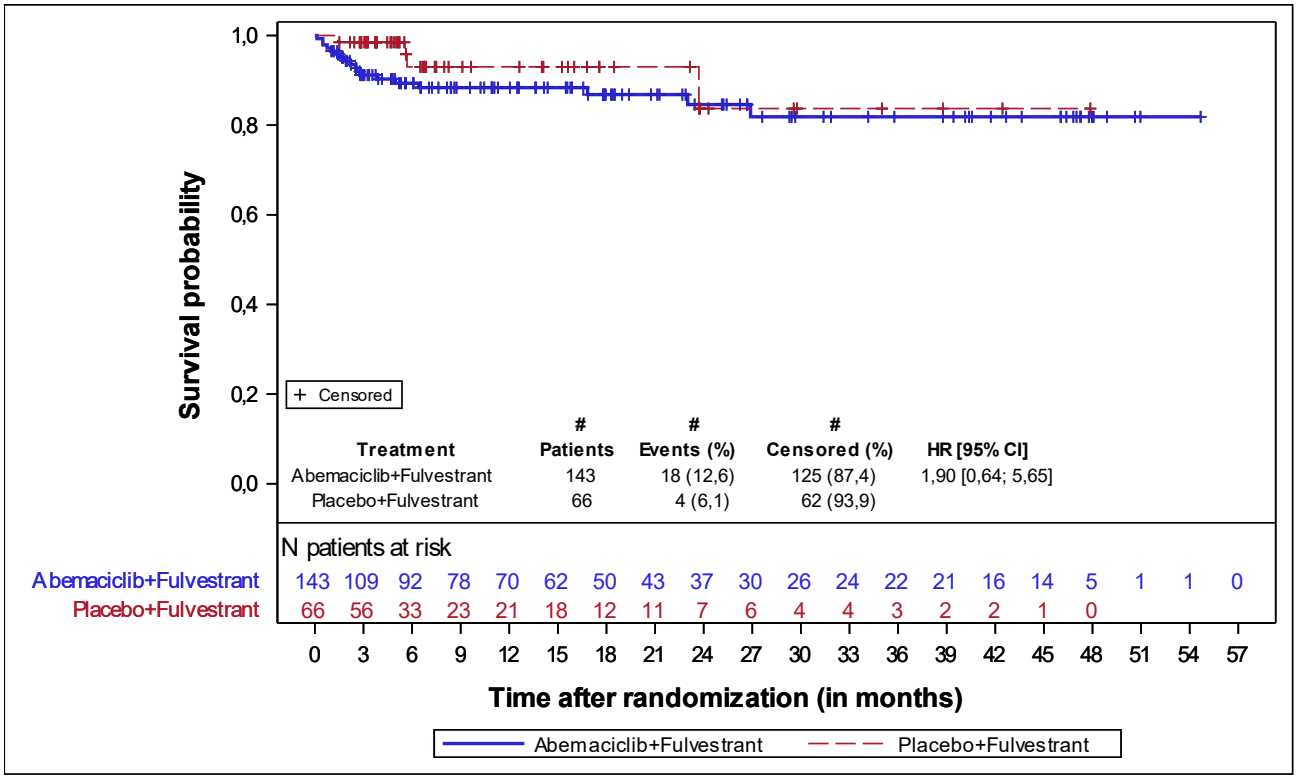
Figure 189: Kaplan-Meier curves for adverse events according PT - Psychiatric disorders / Insomnia
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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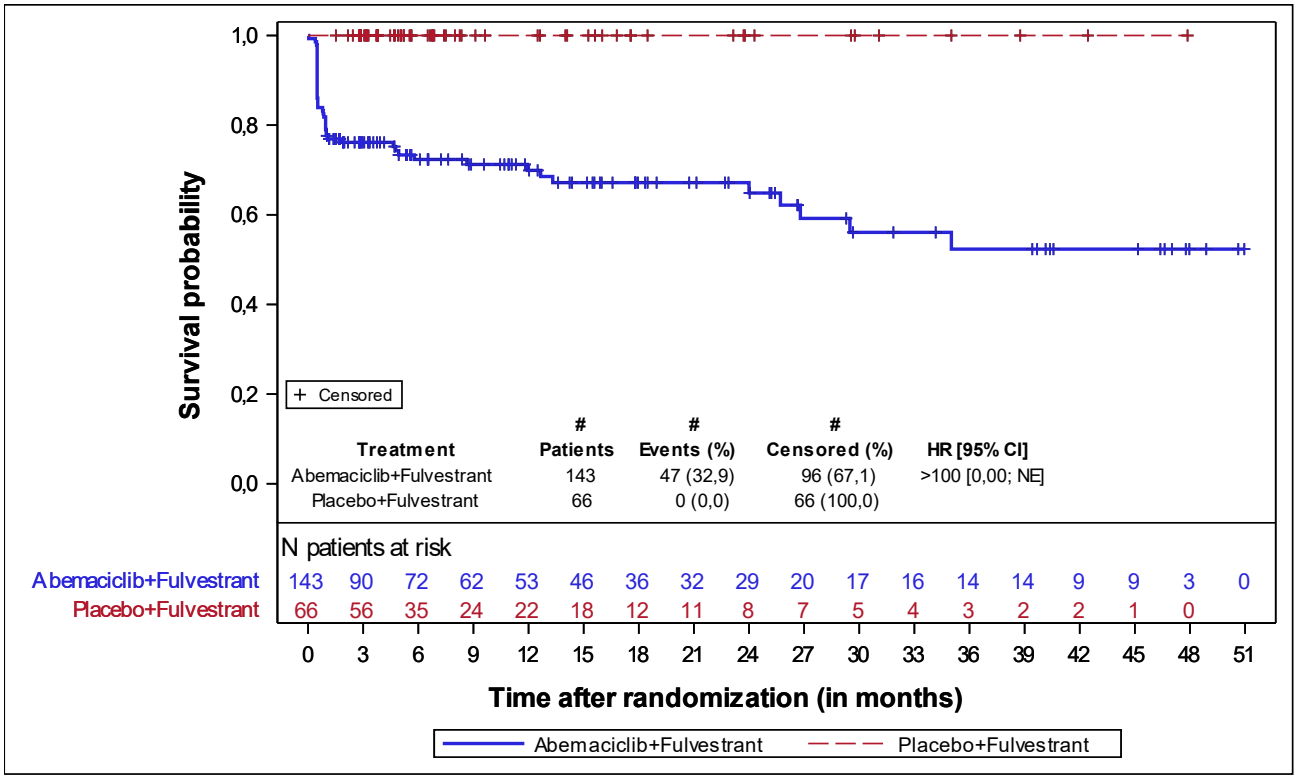
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 190: Kaplan-Meier curves for adverse events according PT - Blood and lymphatic system disorders / Leukopenia Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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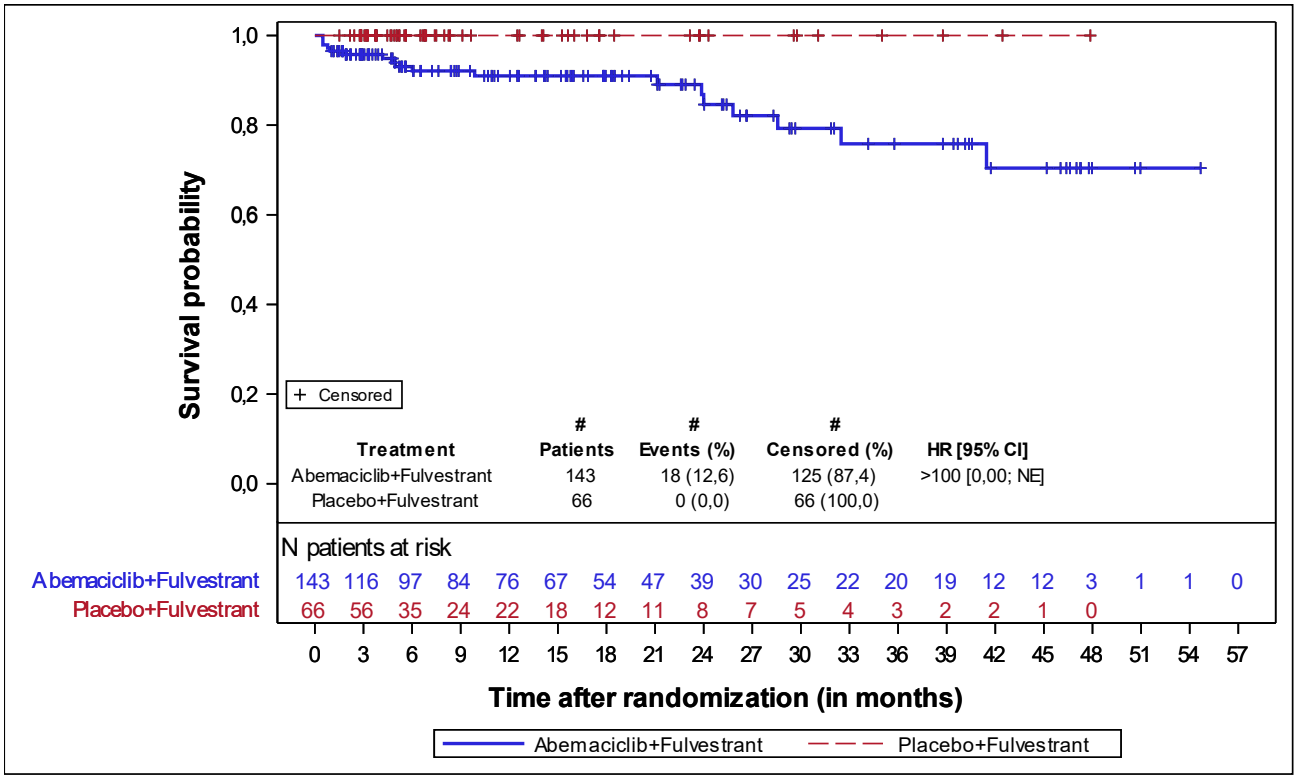
08JUL2021 / 02:43

Figure 191: Kaplan-Meier curves for adverse events according PT - Blood and lymphatic system disorders / Lymphopenia Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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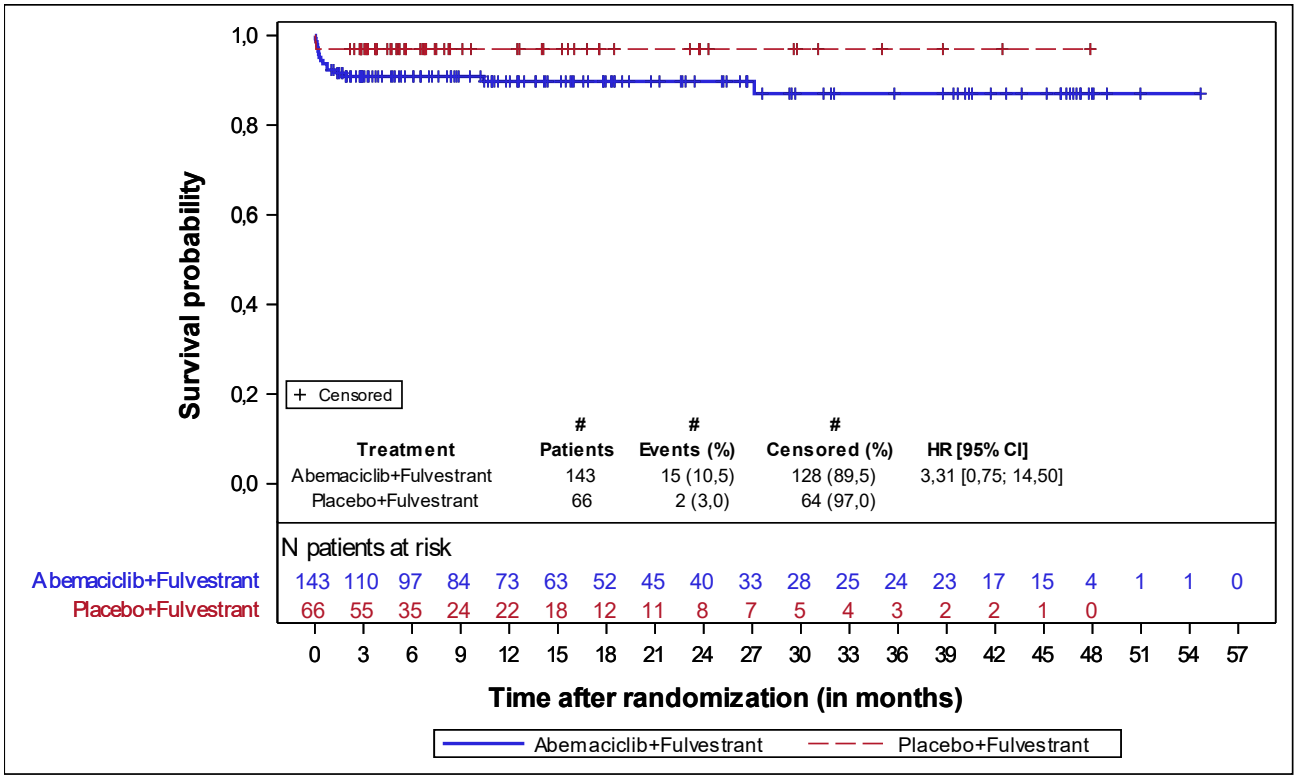
Figure 192: Kaplan-Meier curves for adverse events according PT - Musculoskeletal and connective tissue disorders / Muscular weakness Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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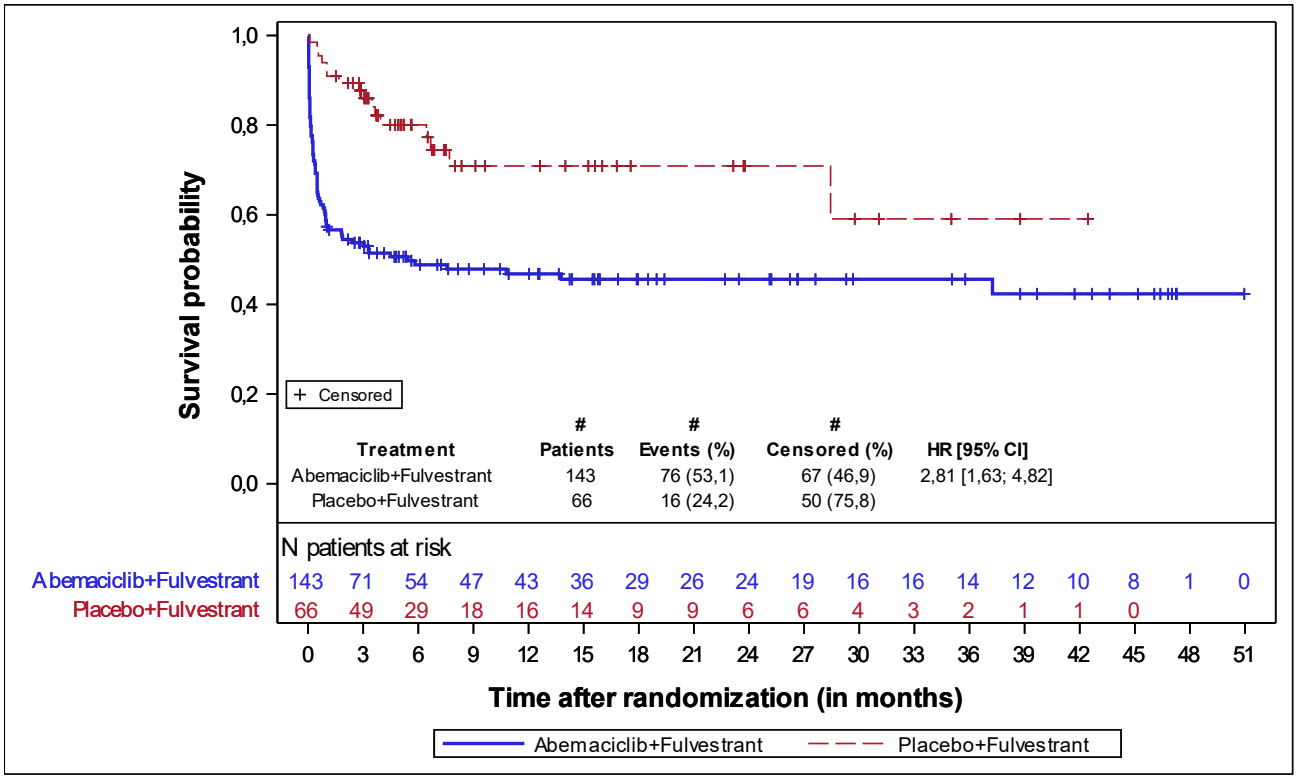
Figure 193: Kaplan-Meier curves for adverse events according PT - Gastrointestinal disorders / Nausea
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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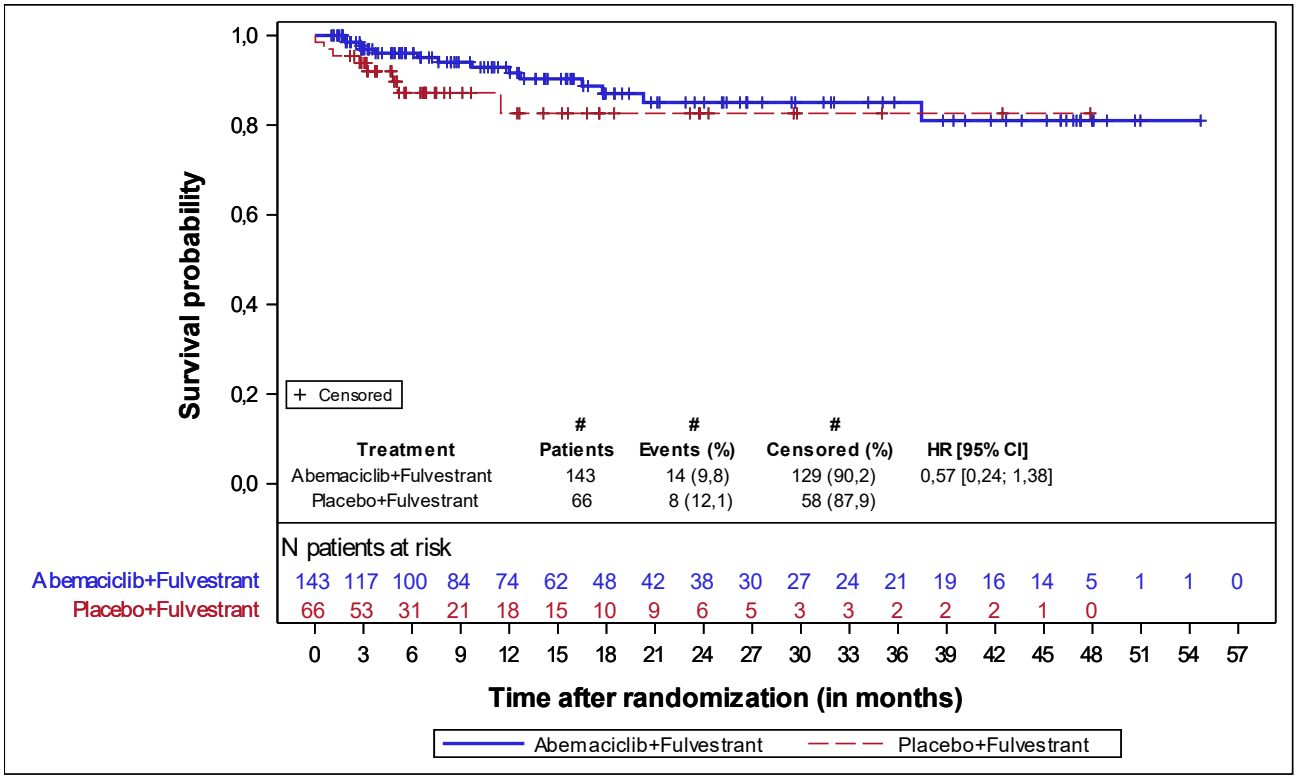
08JUL2021 / 02:43

Figure 194: Kaplan-Meier curves for adverse events according PT - Nervous system disorders / Neuropathy
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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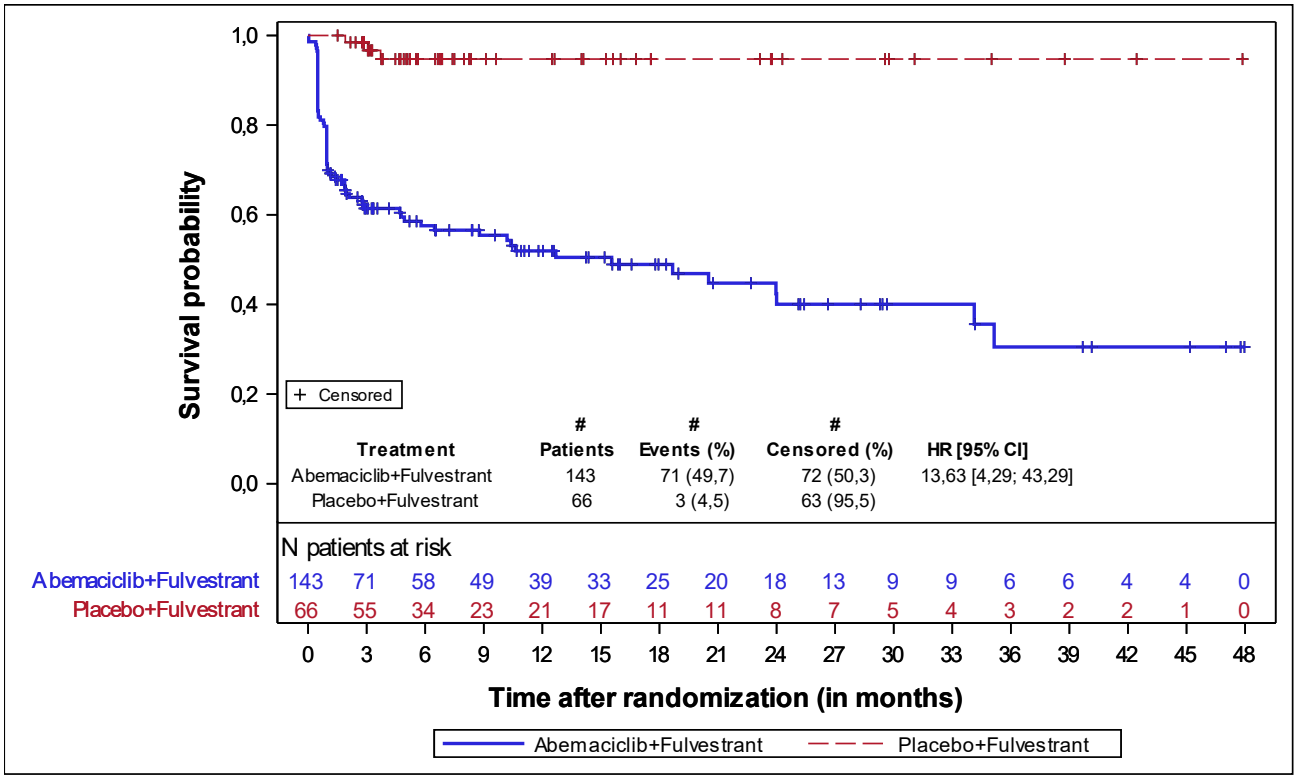
08JUL2021 / 02:43

Figure 195: Kaplan-Meier curves for adverse events according PT - Blood and lymphatic system disorders / Neutropenia Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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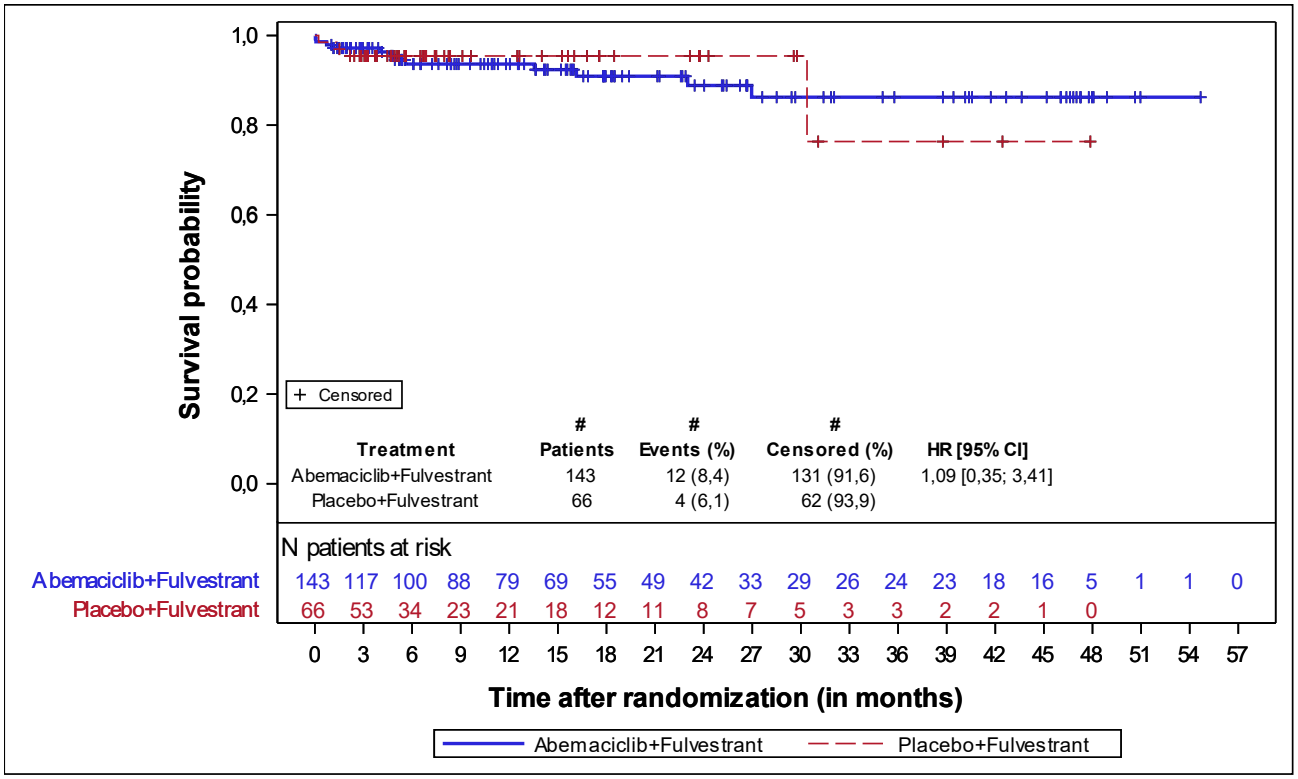
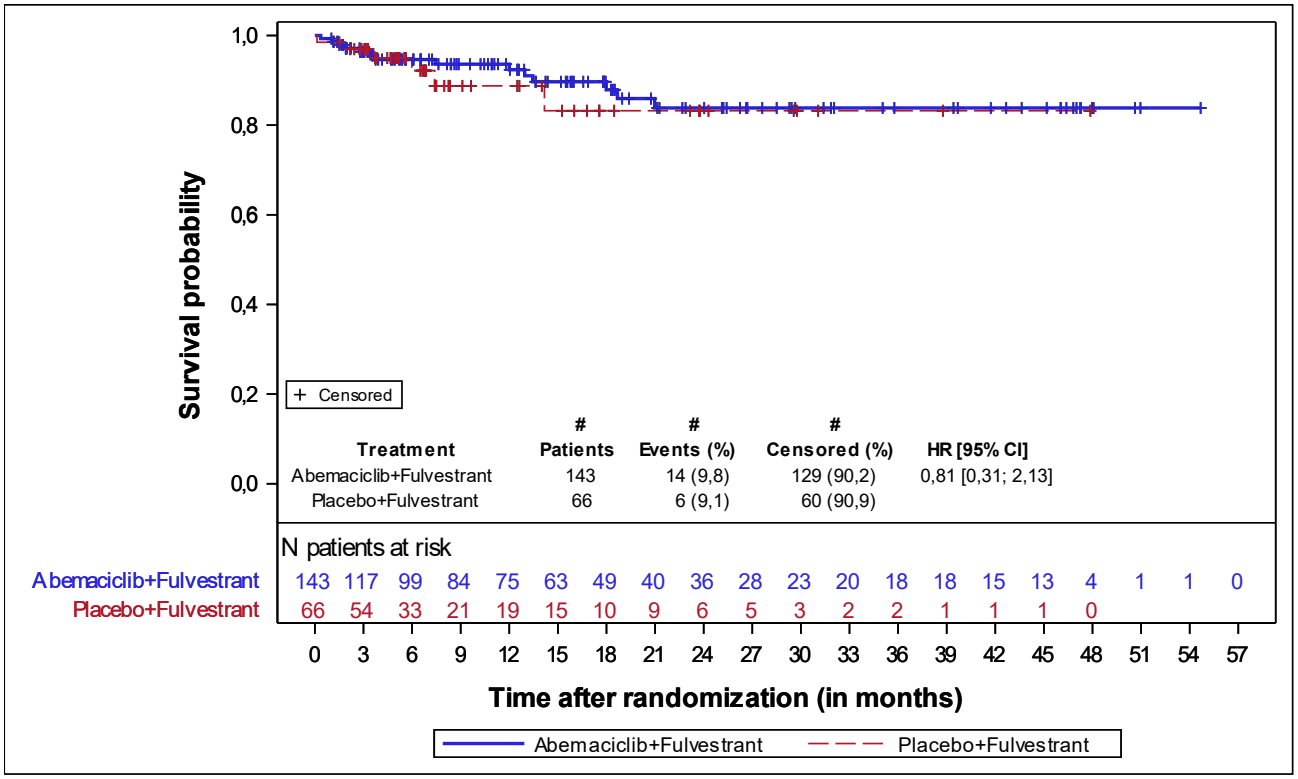
08JUL2021 / 02:43

Figure 196: Kaplan-Meier curves for adverse events according PT - General disorders and administration site conditions / Non-cardiac chest pain Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraep035_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 197: Kaplan-Meier curves for adverse events according PT - General disorders and administration site conditions / Oedema peripheral Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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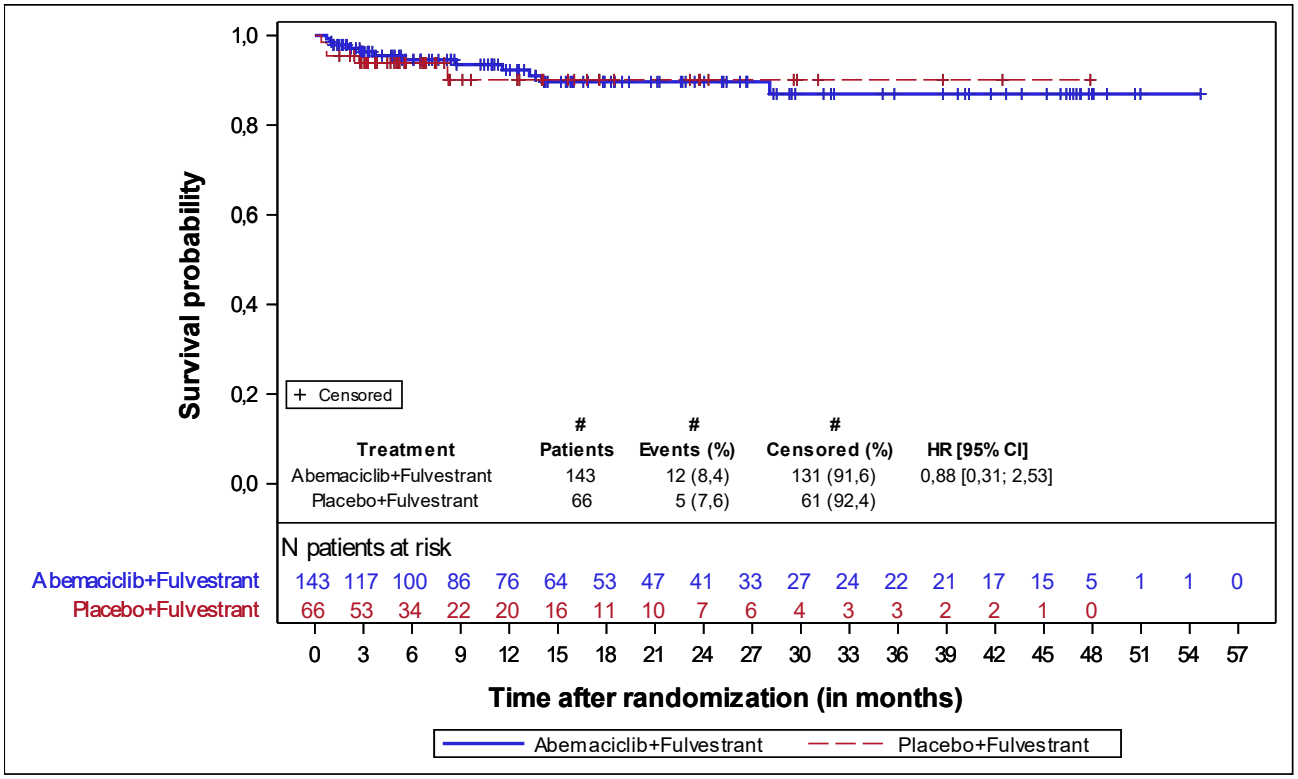
Figure 198: Kaplan-Meier curves for adverse events according PT - Respiratory, thoracic and mediastinal disorders / Oropharyngeal pain Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraep037_popa2.rtf
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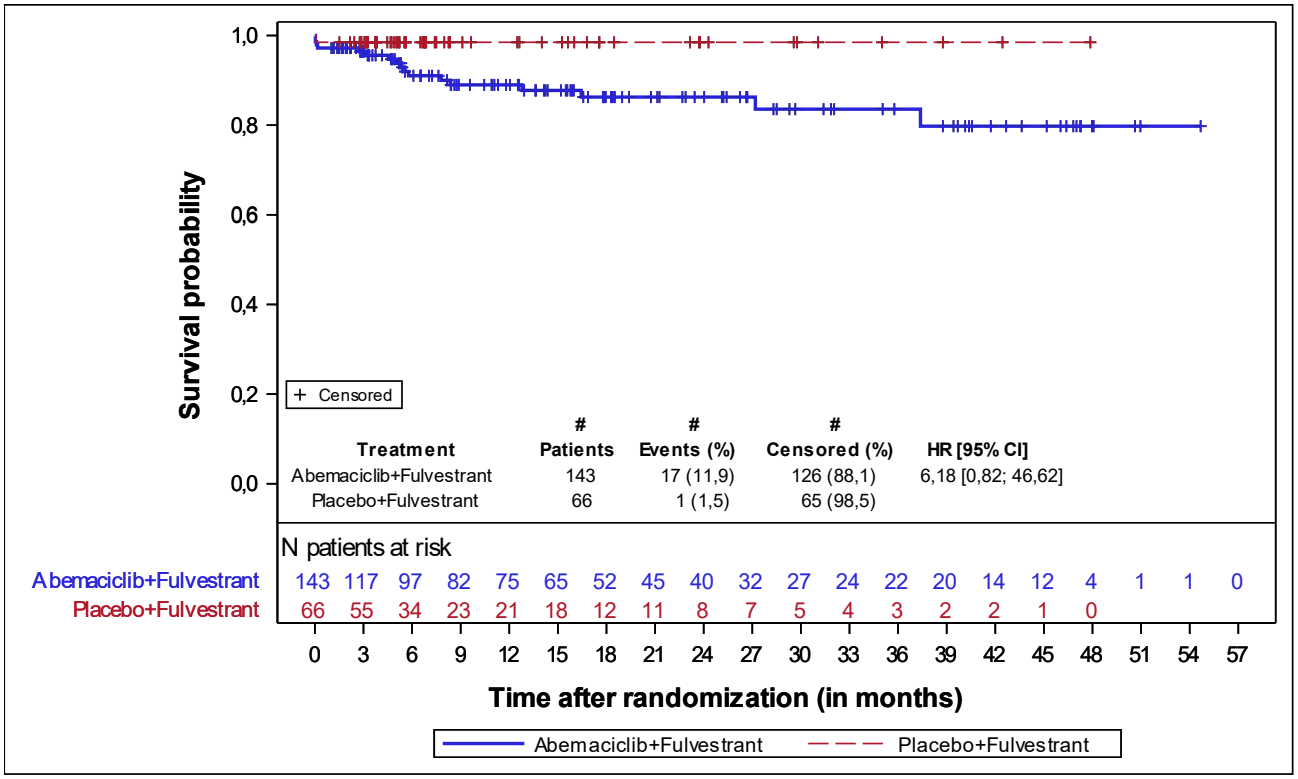
08JUL2021 / 02:43

Figure 199: Kaplan-Meier curves for adverse events according PT - Musculoskeletal and connective tissue disorders / Pain in extremity Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraep038_popa2.rtf
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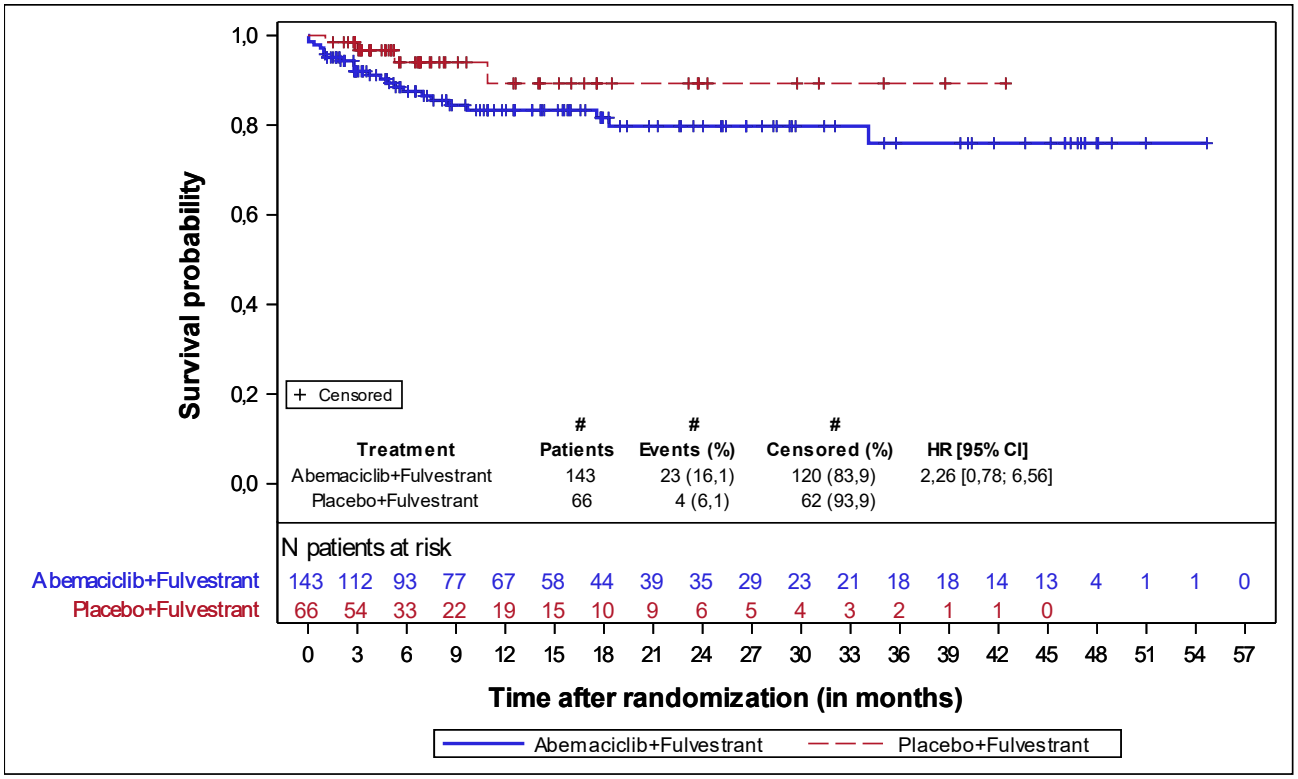
08JUL2021 / 02:43

Figure 200: Kaplan-Meier curves for adverse events according PT - Skin and subcutaneous tissue disorders / Pruritus Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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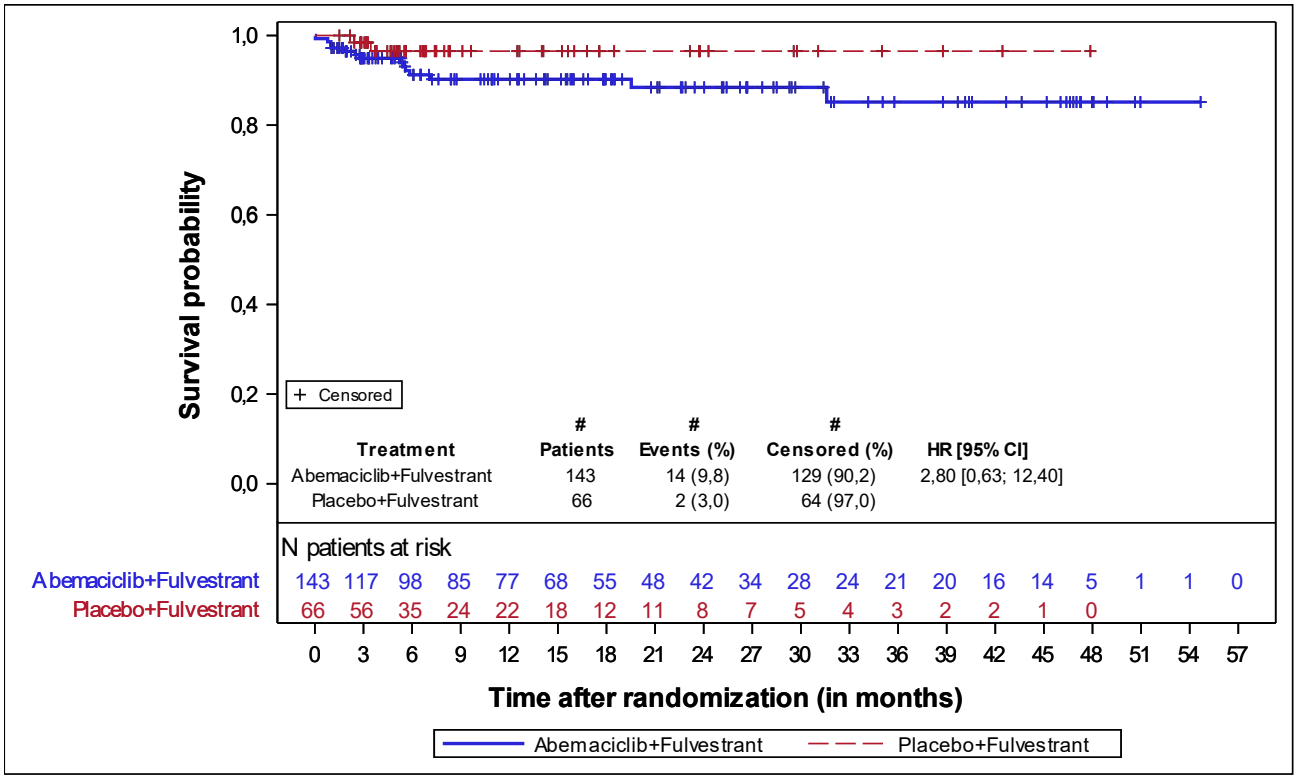
08JUL2021 / 02:43

Figure 201: Kaplan-Meier curves for adverse events according PT - General disorders and administration site conditions / Pyrexia Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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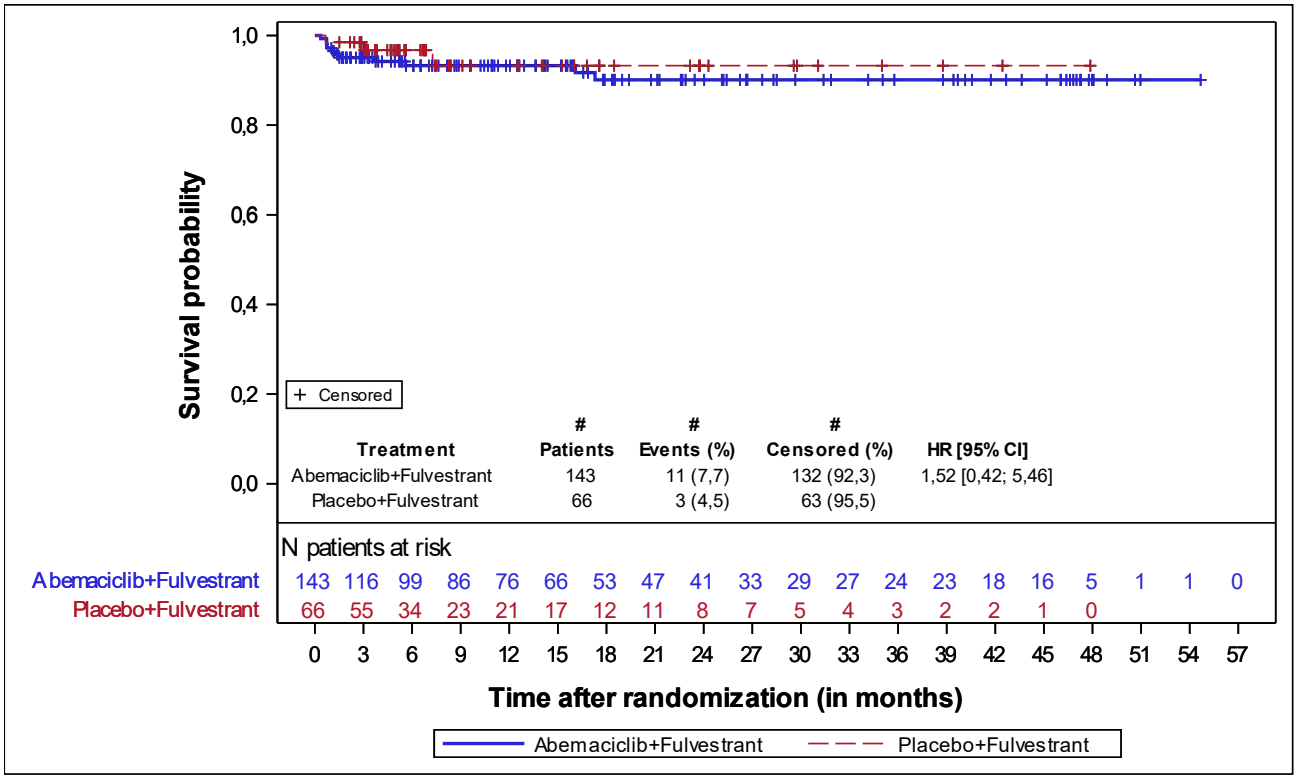
Figure 202: Kaplan-Meier curves for adverse events according PT - Skin and subcutaneous tissue disorders / Rash Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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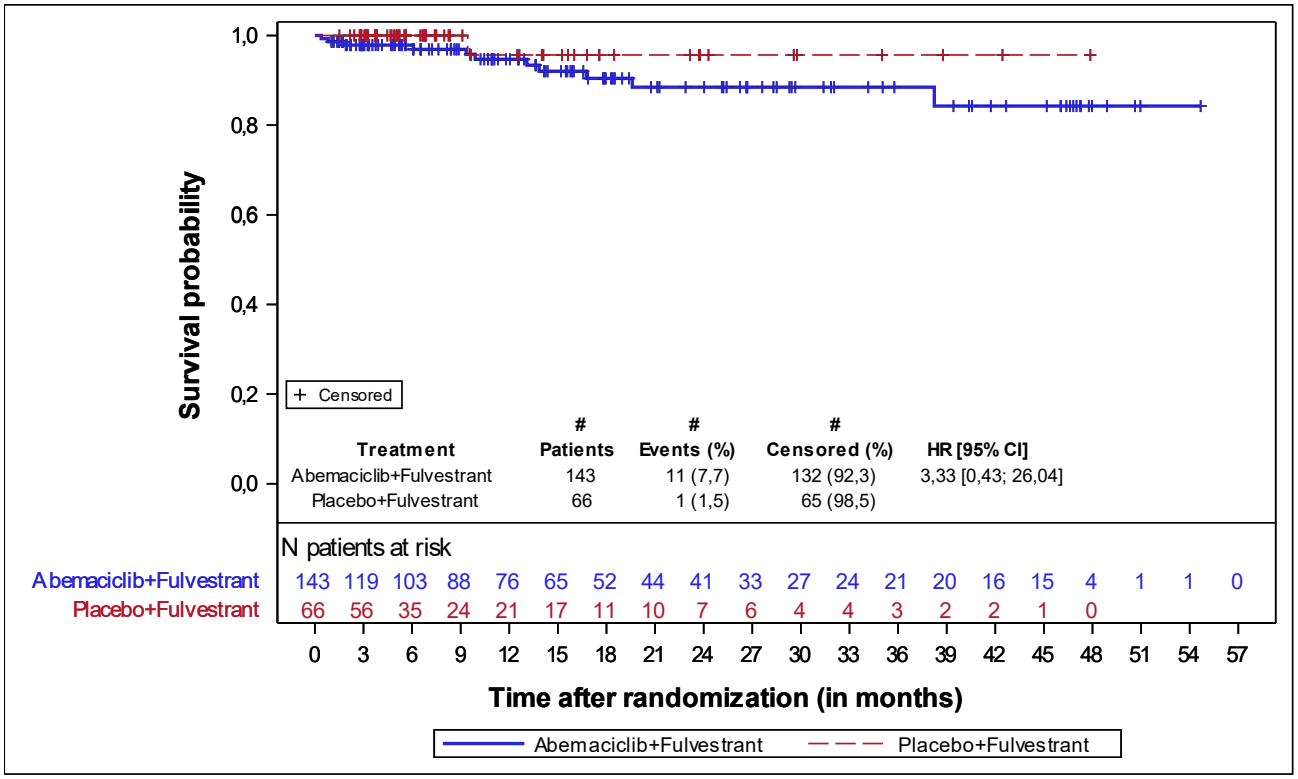
Figure 203: Kaplan-Meier curves for adverse events according PT - Infections and infestations / Skin infection
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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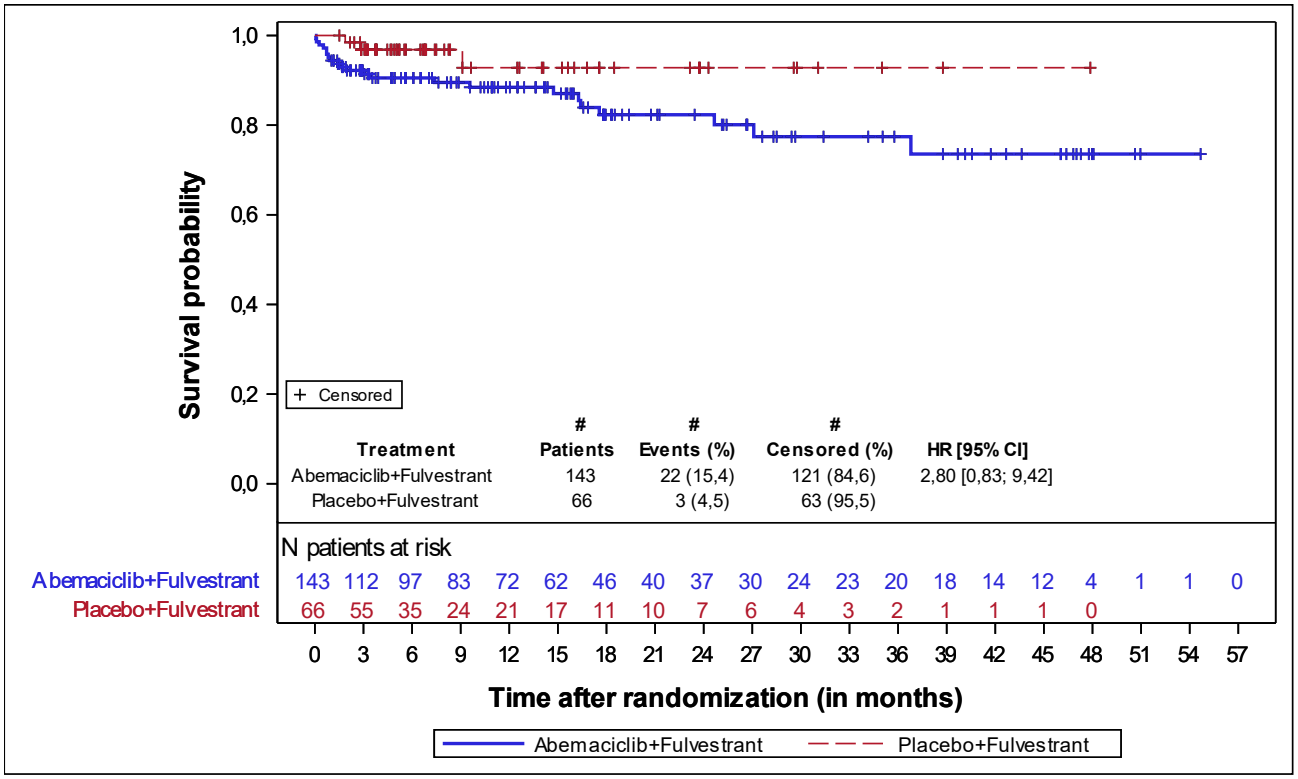
Figure 204: Kaplan-Meier curves for adverse events according PT - Gastrointestinal disorders / Stomatitis
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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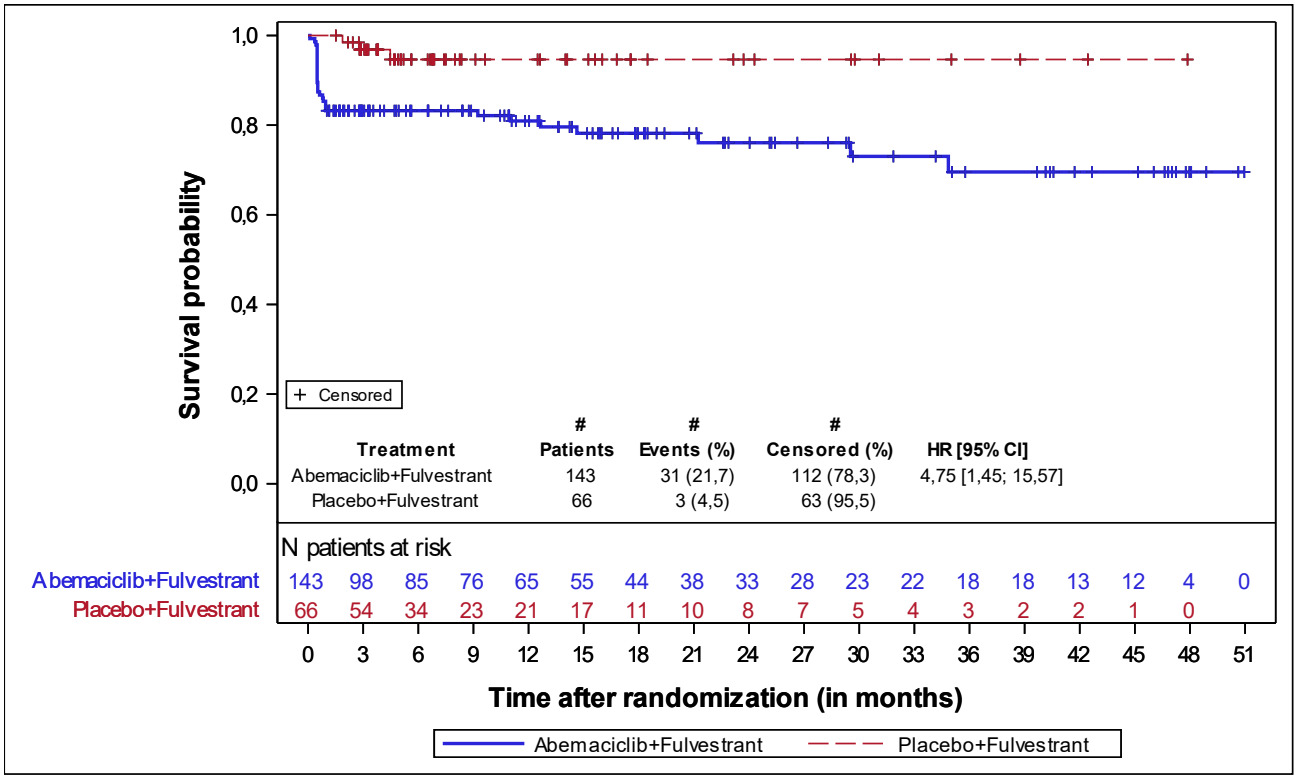
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 205: Kaplan-Meier curves for adverse events according PT - Blood and lymphatic system disorders / Thrombocytopenia Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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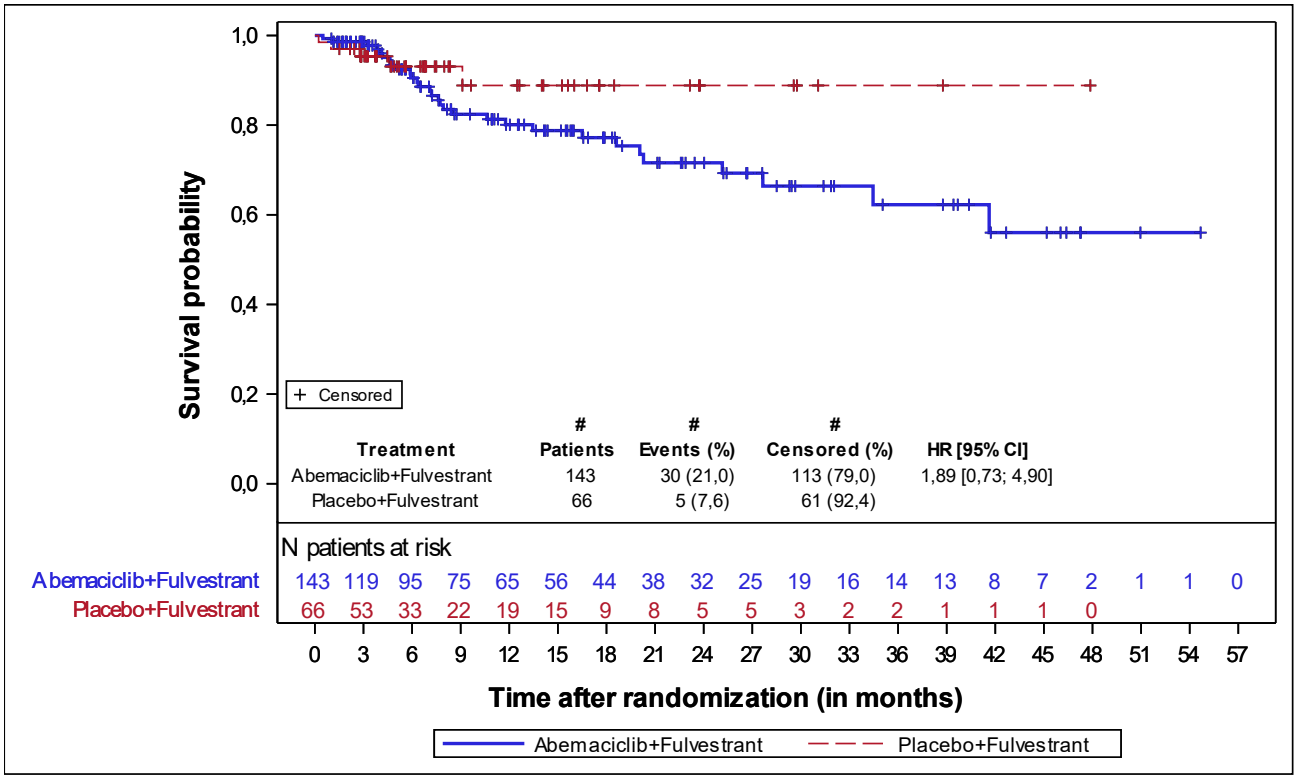
08JUL2021 / 02:43

Figure 206: Kaplan-Meier curves for adverse events according PT - Infections and infestations / Upper respiratory tract infection Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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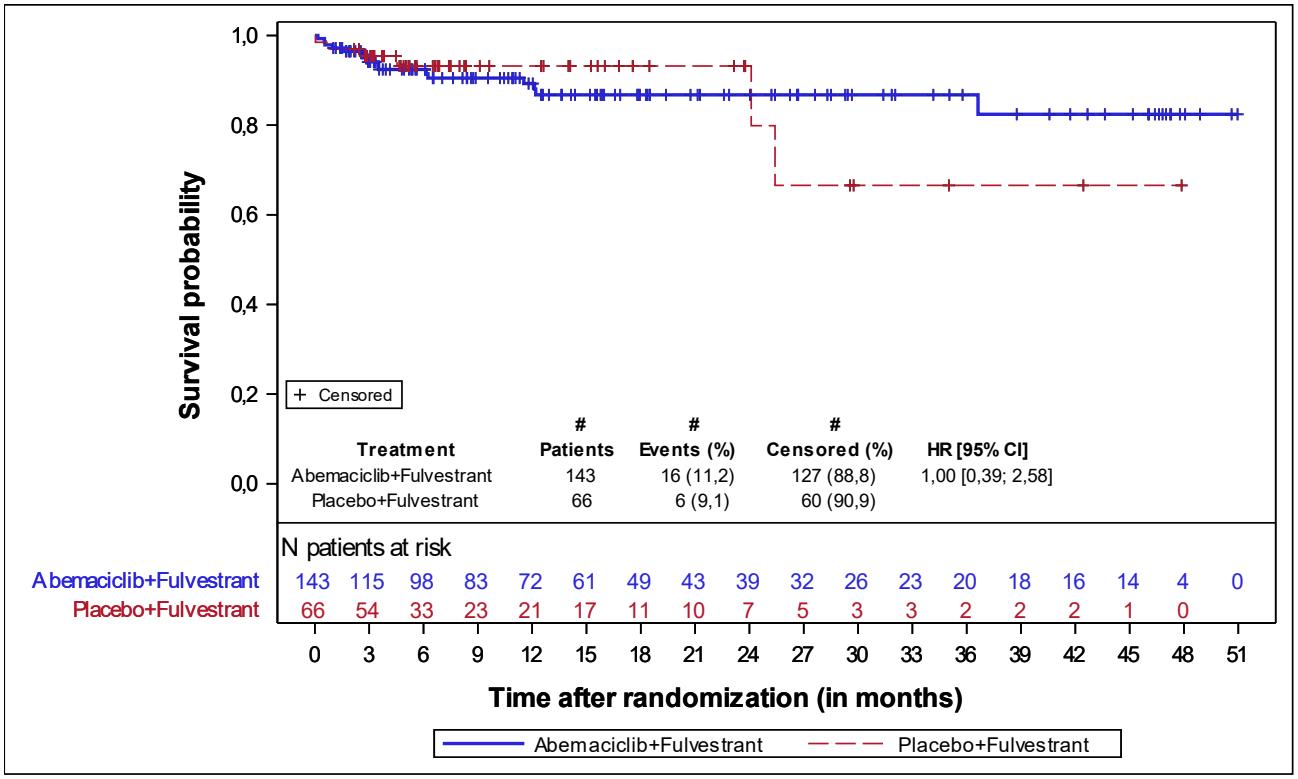
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 207: Kaplan-Meier curves for adverse events according PT - Infections and infestations / Urinary tract infection
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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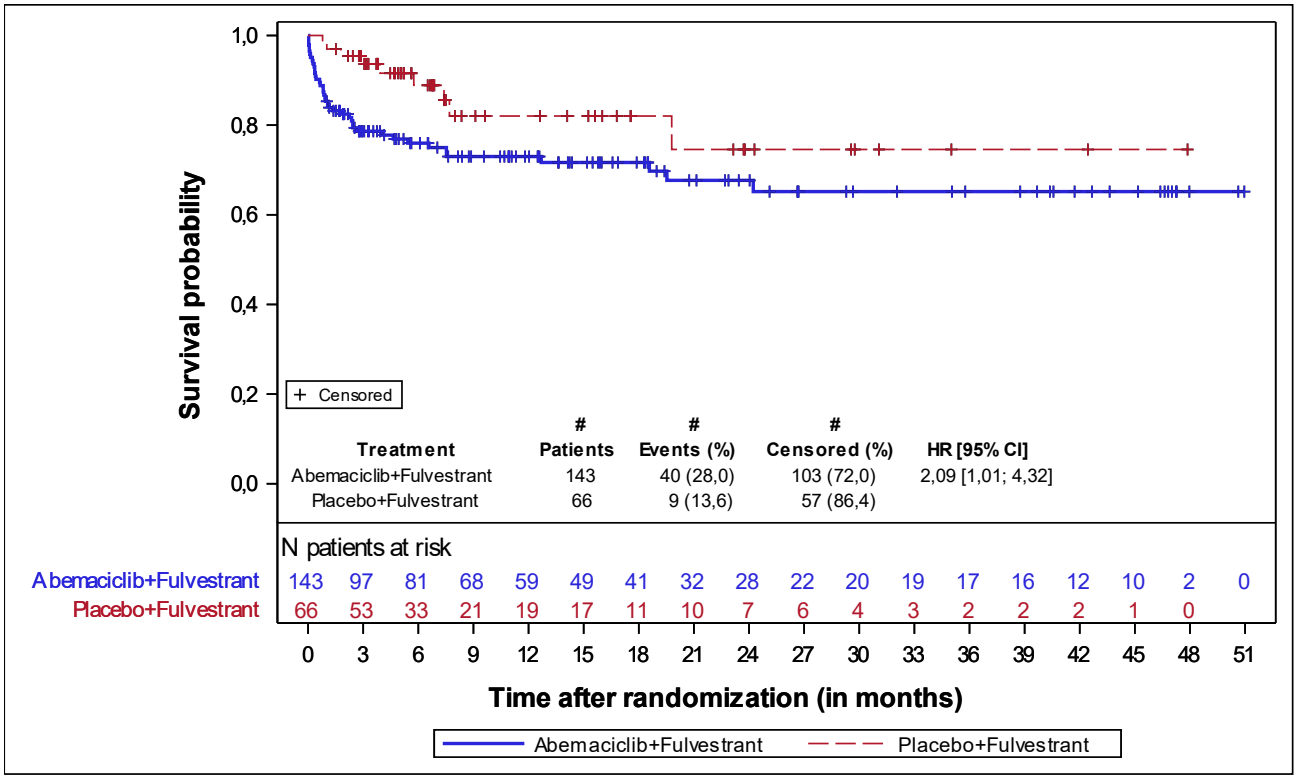
08JUL2021 / 02:43

Figure 208: Kaplan-Meier curves for adverse events according PT - Gastrointestinal disorders / Vomiting
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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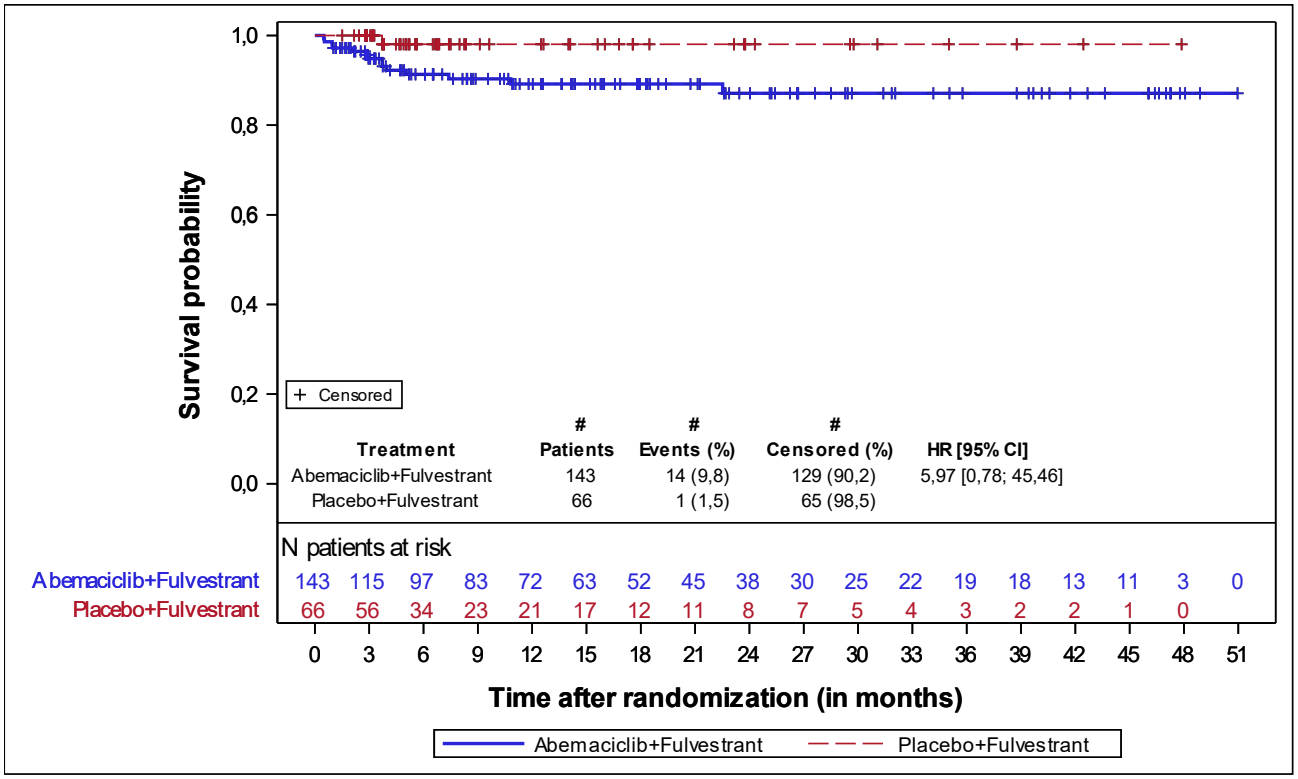
Figure 209: Kaplan-Meier curves for adverse events according PT - Investigations / Weight decreased
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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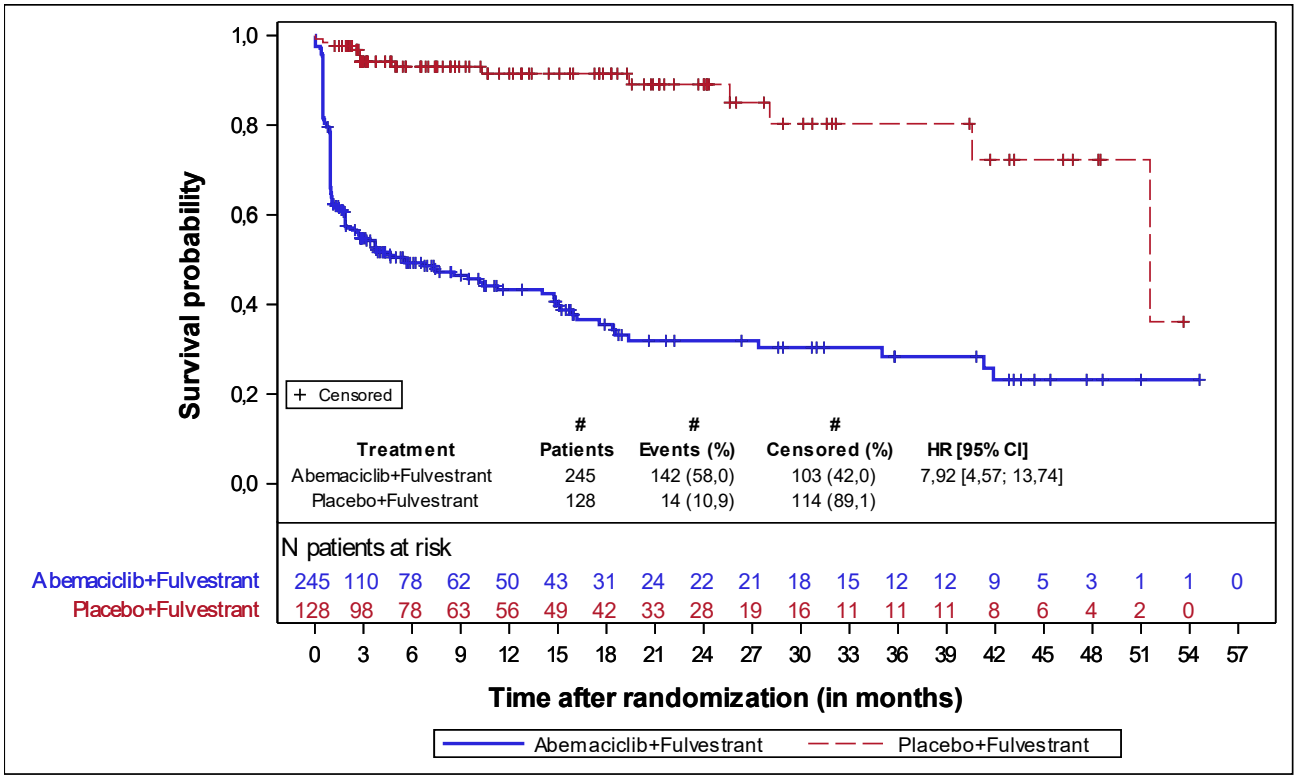
Figure 210: Kaplan-Meier curves for adverse events according SOC - Blood and lymphatic system disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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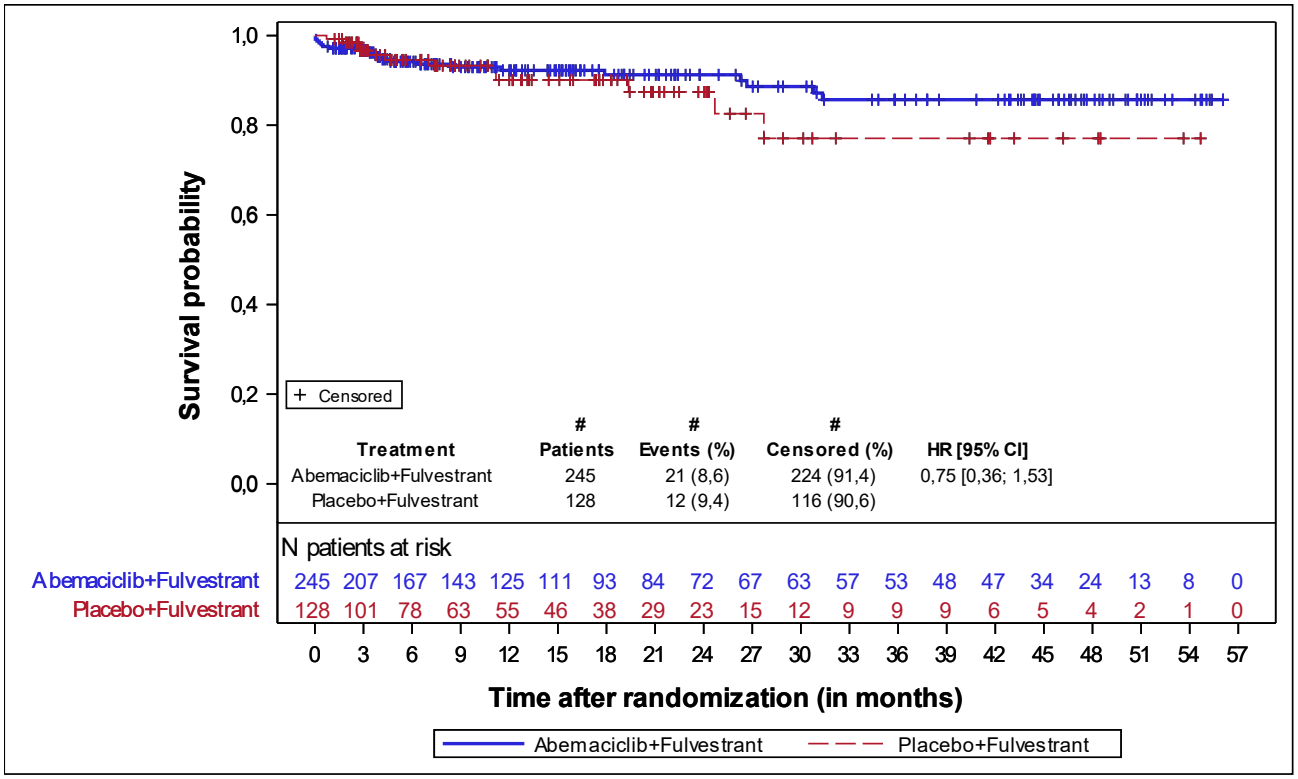
Figure 211: Kaplan-Meier curves for adverse events according SOC - Cardiac disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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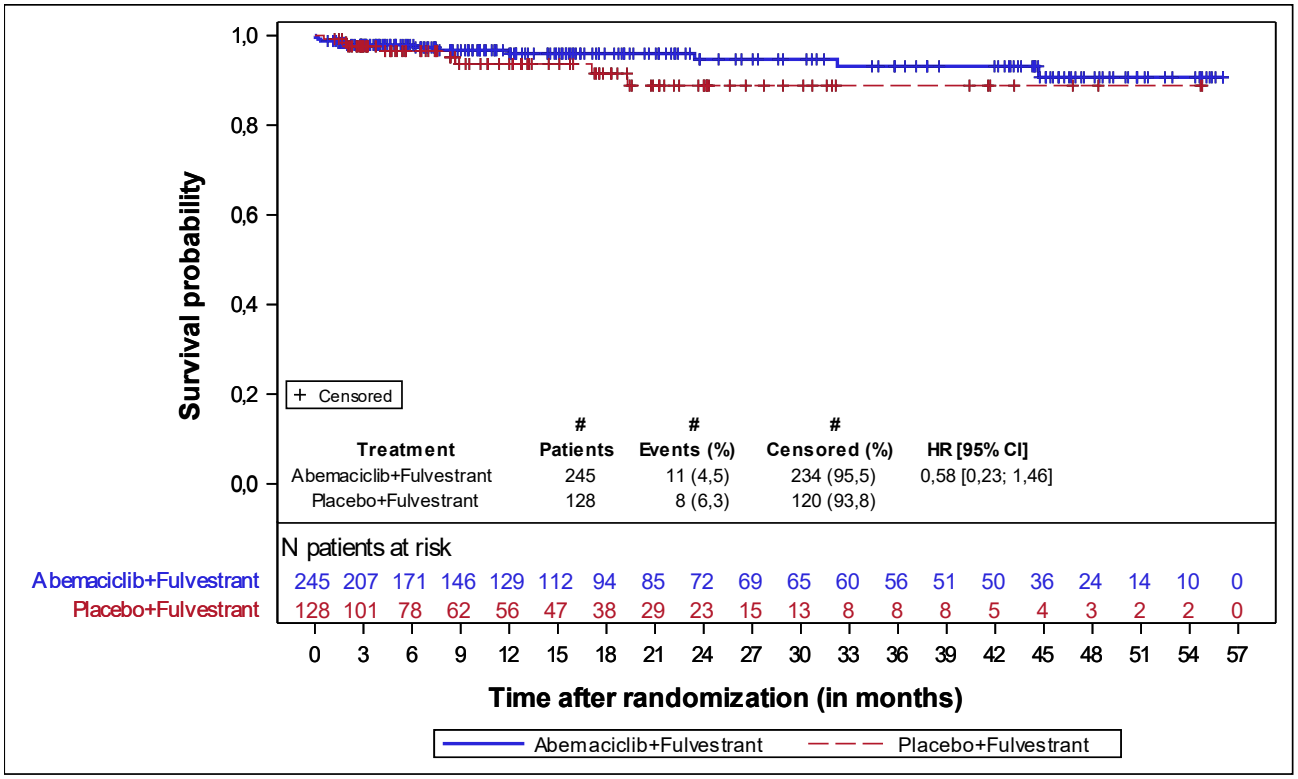
08JUL2021 / 02:43

Figure 212: Kaplan-Meier curves for adverse events according SOC - Ear and labyrinth disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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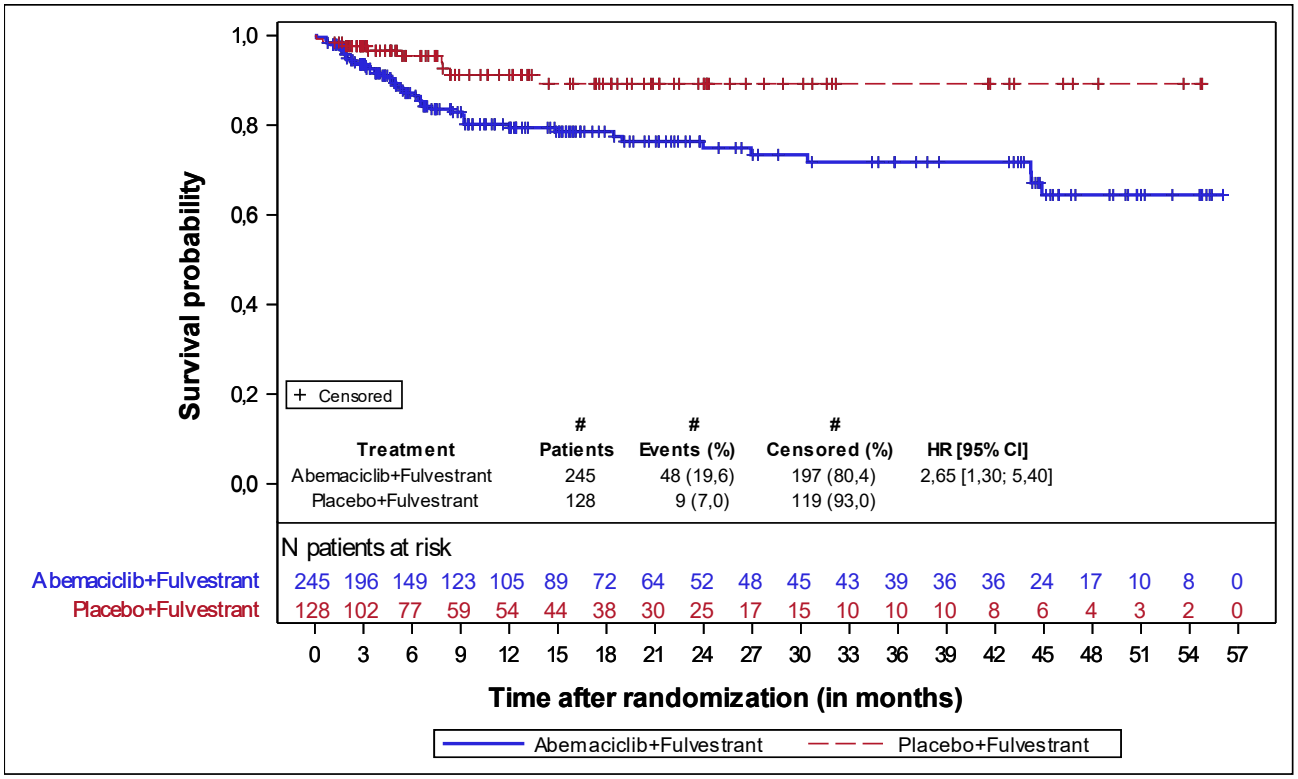
08JUL2021 / 02:43

Figure 213: Kaplan-Meier curves for adverse events according SOC - Eye disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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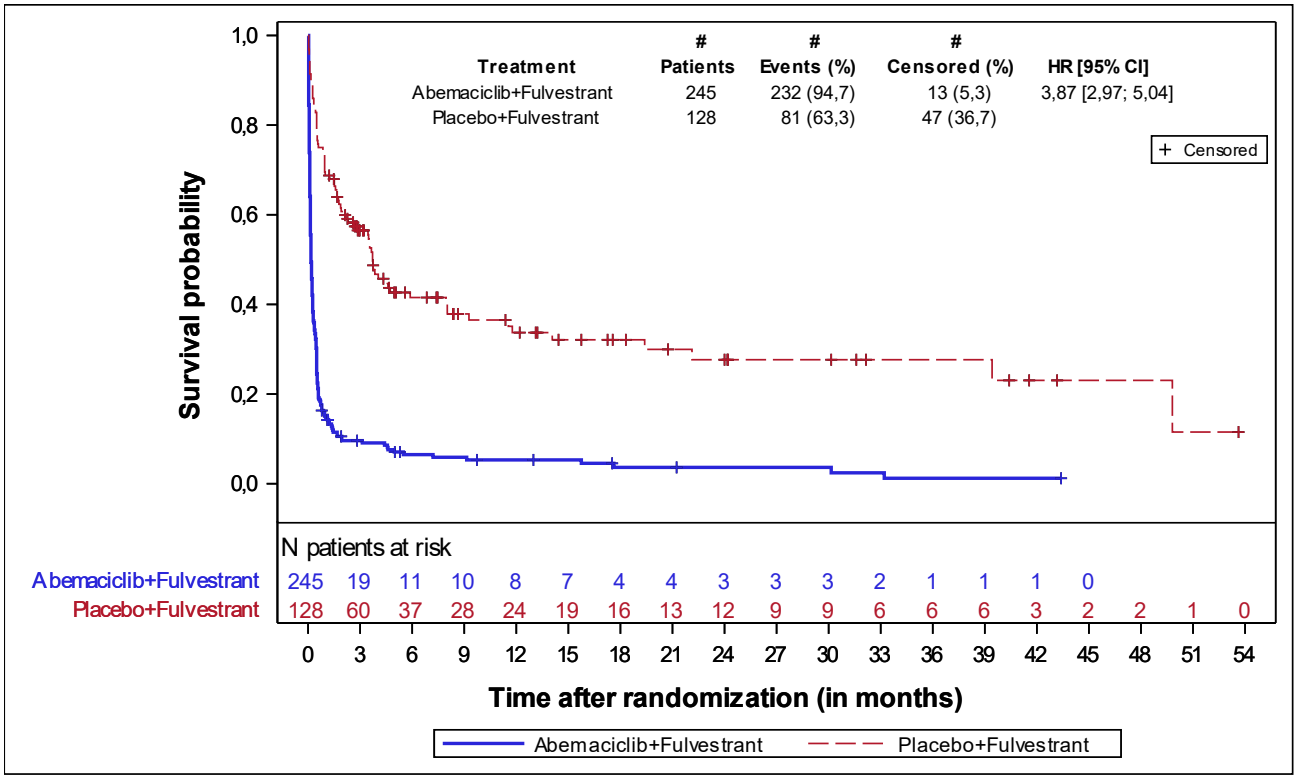
08JUL2021 / 02:43

Figure 214: Kaplan-Meier curves for adverse events according SOC - Gastrointestinal disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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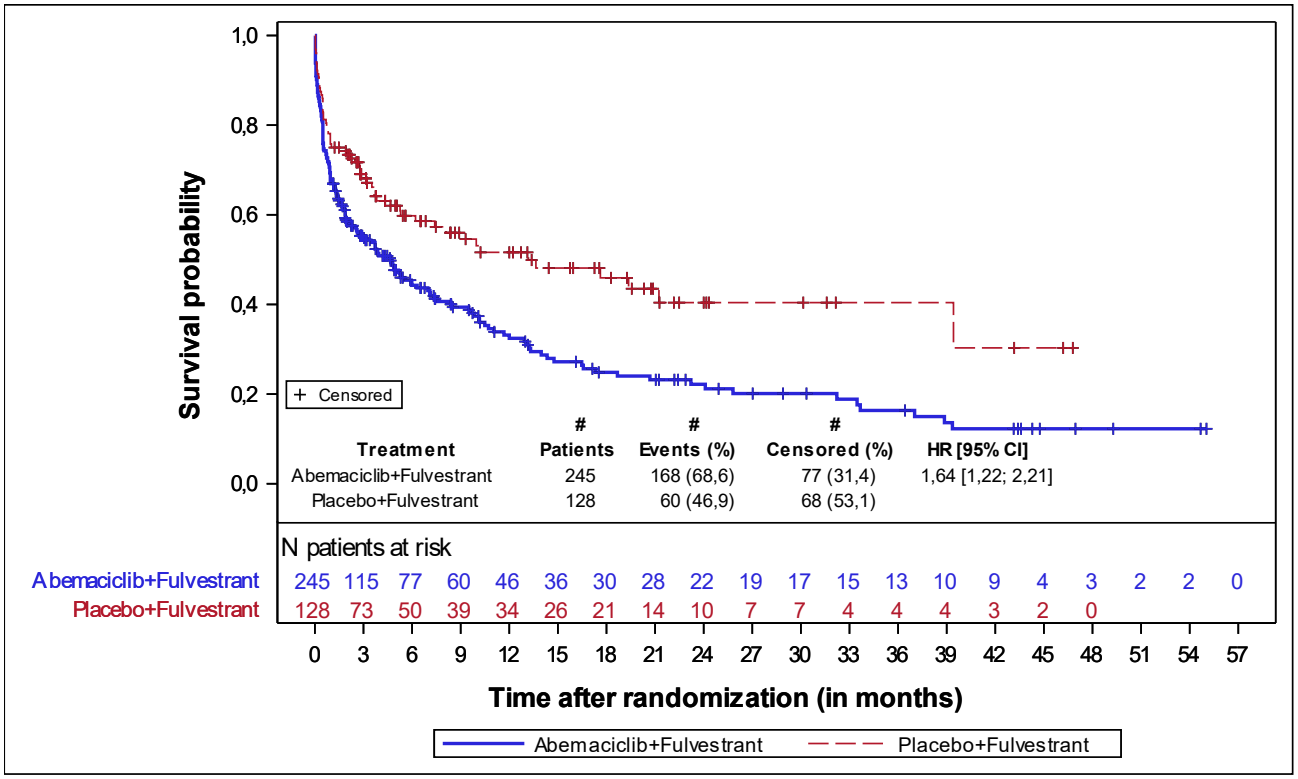
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraes005_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 215: Kaplan-Meier curves for adverse events according SOC - General disorders and administration site conditions Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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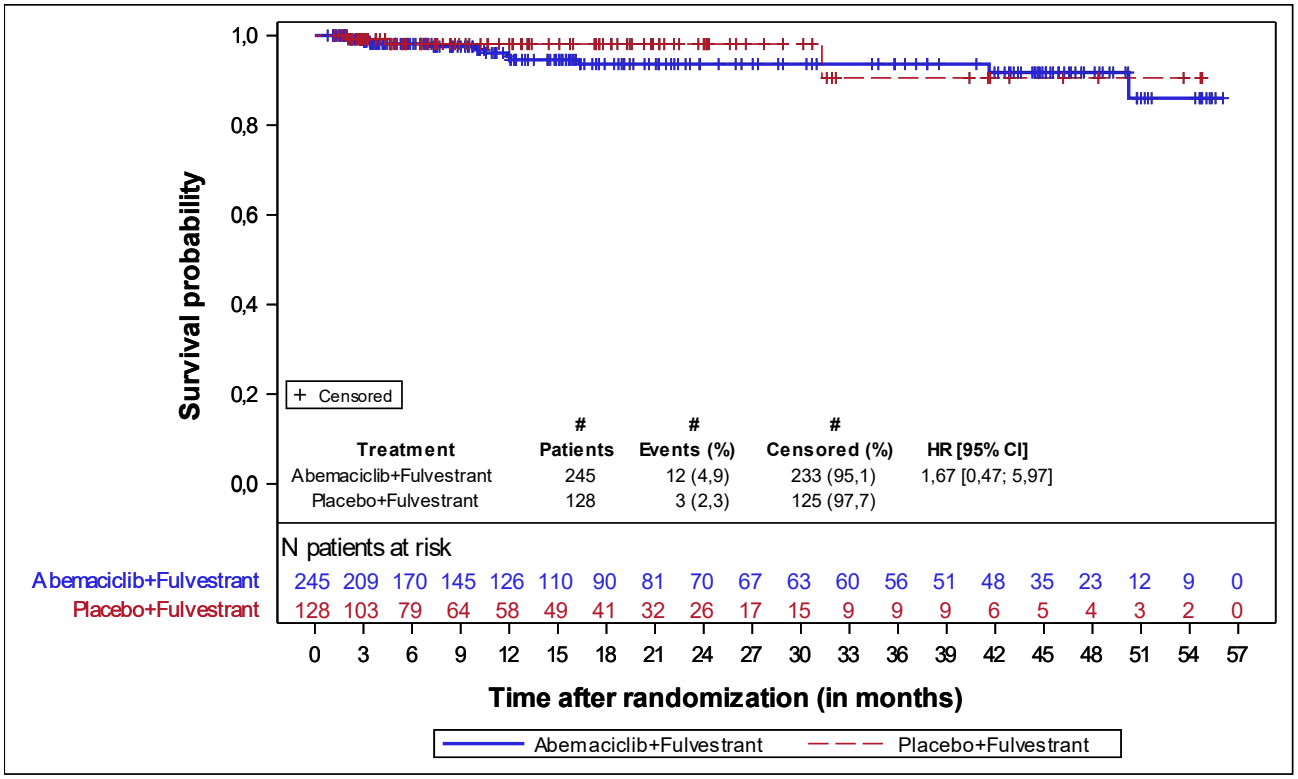
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraes006_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
08JUL2021 / 02:43

Figure 216: Kaplan-Meier curves for adverse events according SOC - Immune system disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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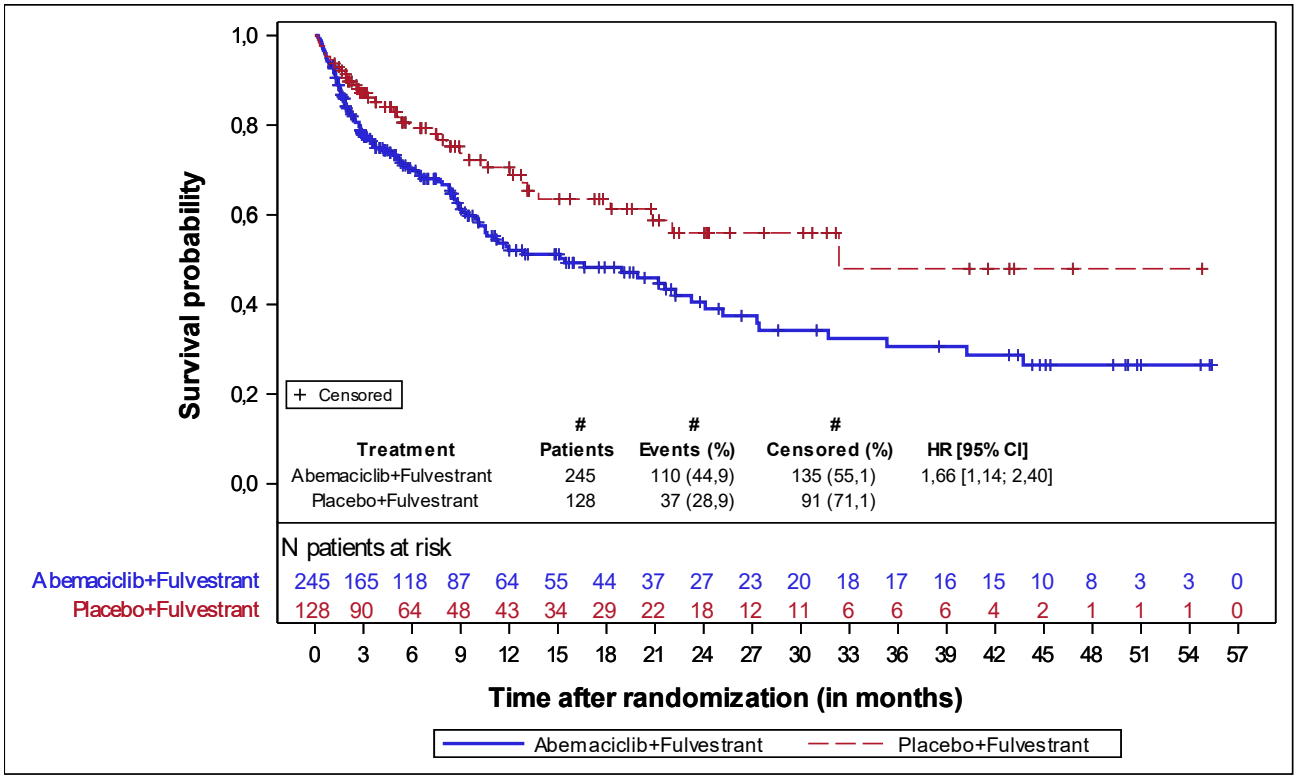
Figure 217: Kaplan-Meier curves for adverse events according SOC - Infections and infestations
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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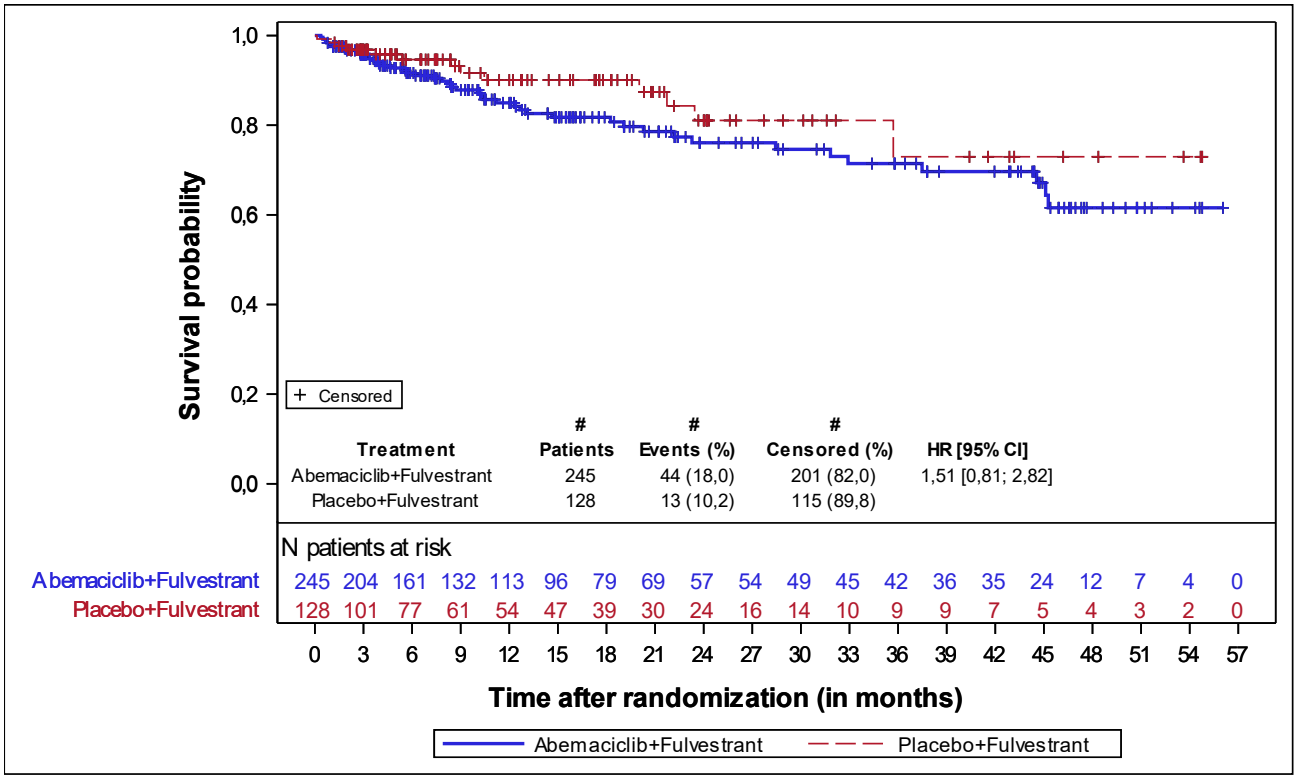
Figure 218: Kaplan-Meier curves for adverse events according SOC - Injury, poisoning and procedural complications
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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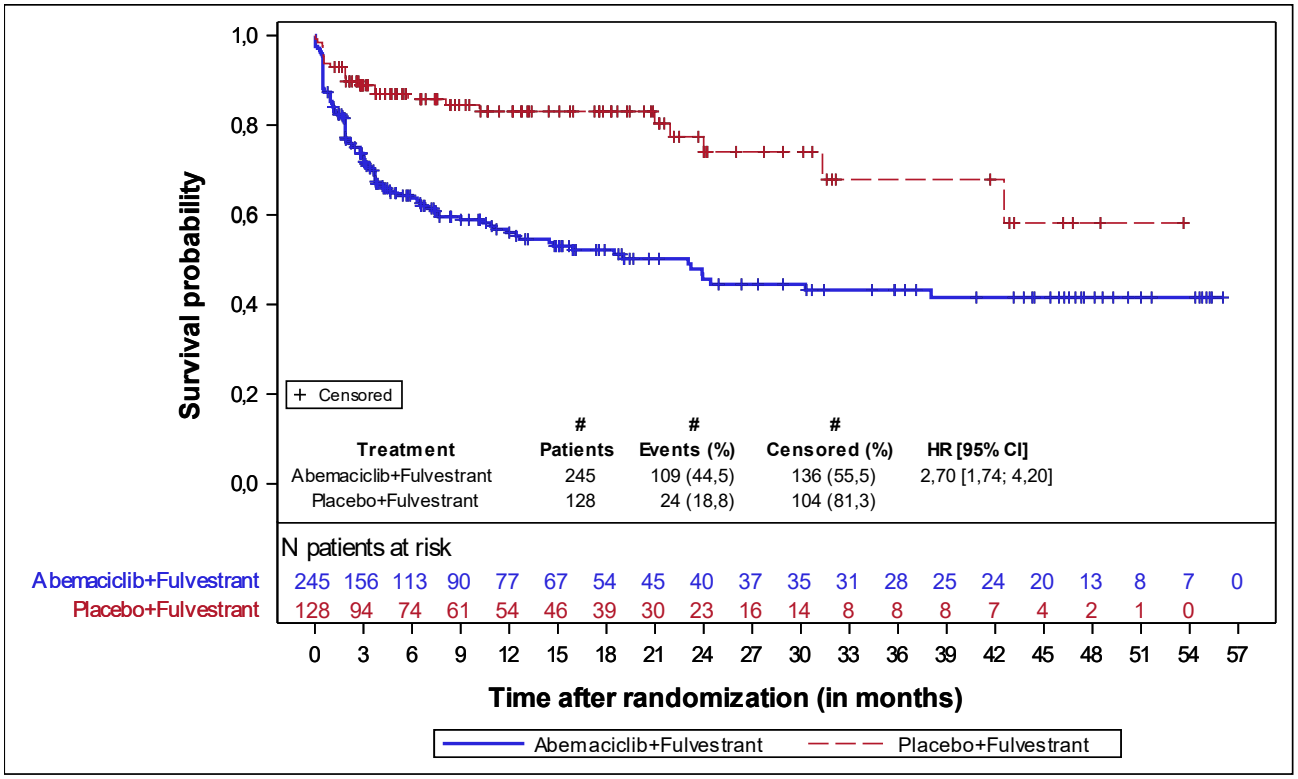
Figure 219: Kaplan-Meier curves for adverse events according SOC - Investigations
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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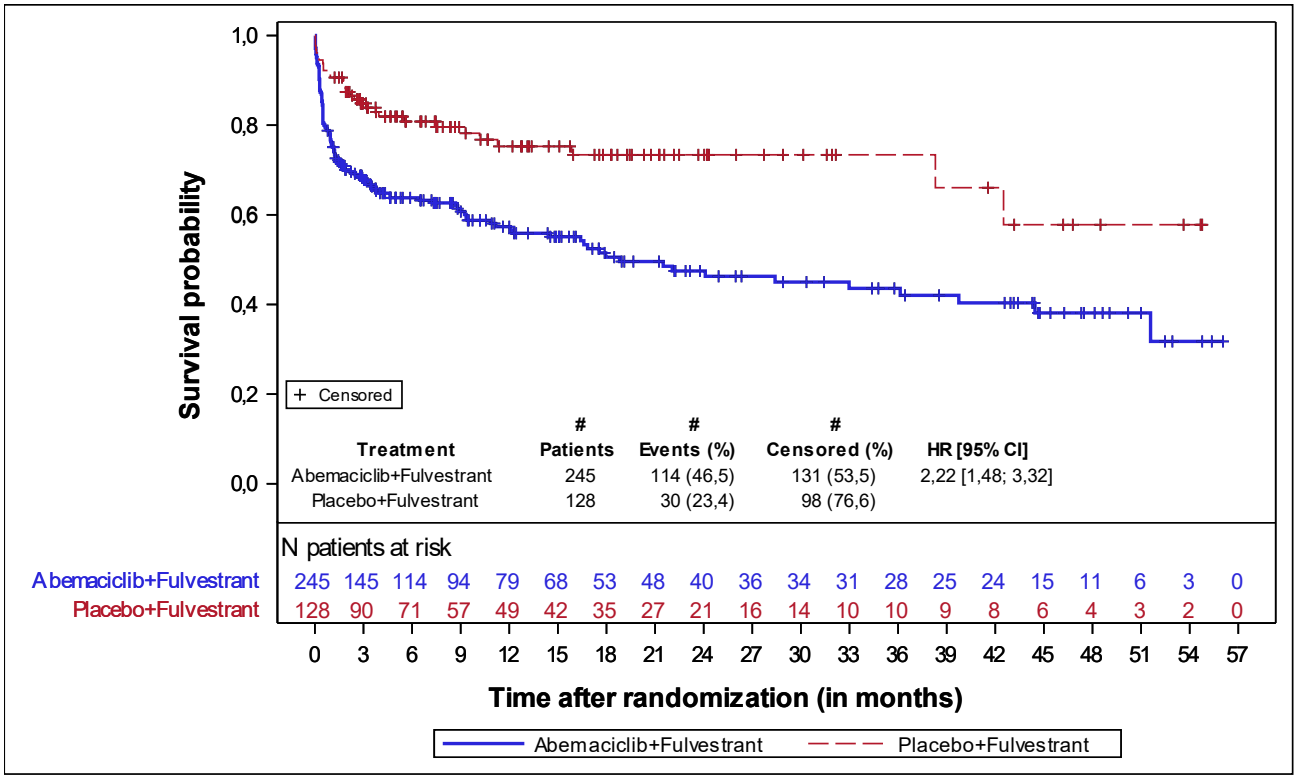
Figure 220: Kaplan-Meier curves for adverse events according SOC - Metabolism and nutrition disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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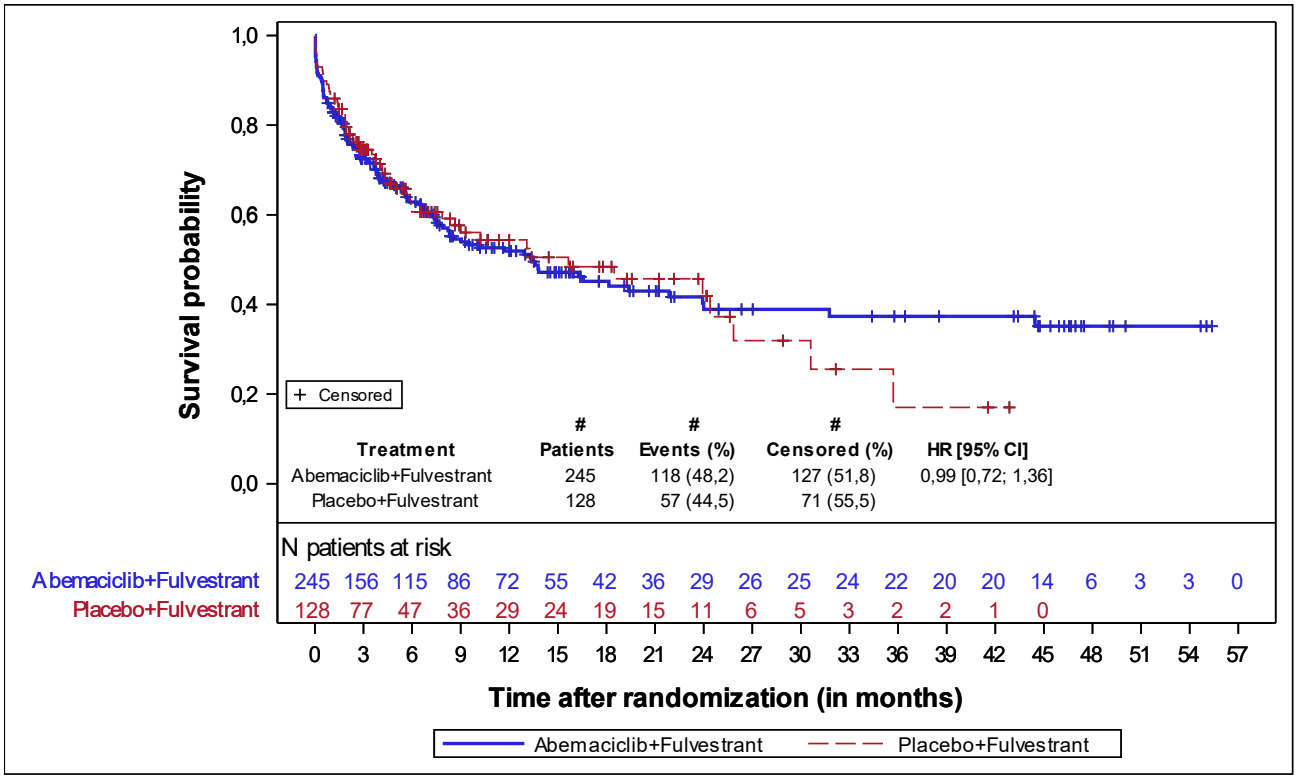
Figure 221: Kaplan-Meier curves for adverse events according SOC - Musculoskeletal and connective tissue disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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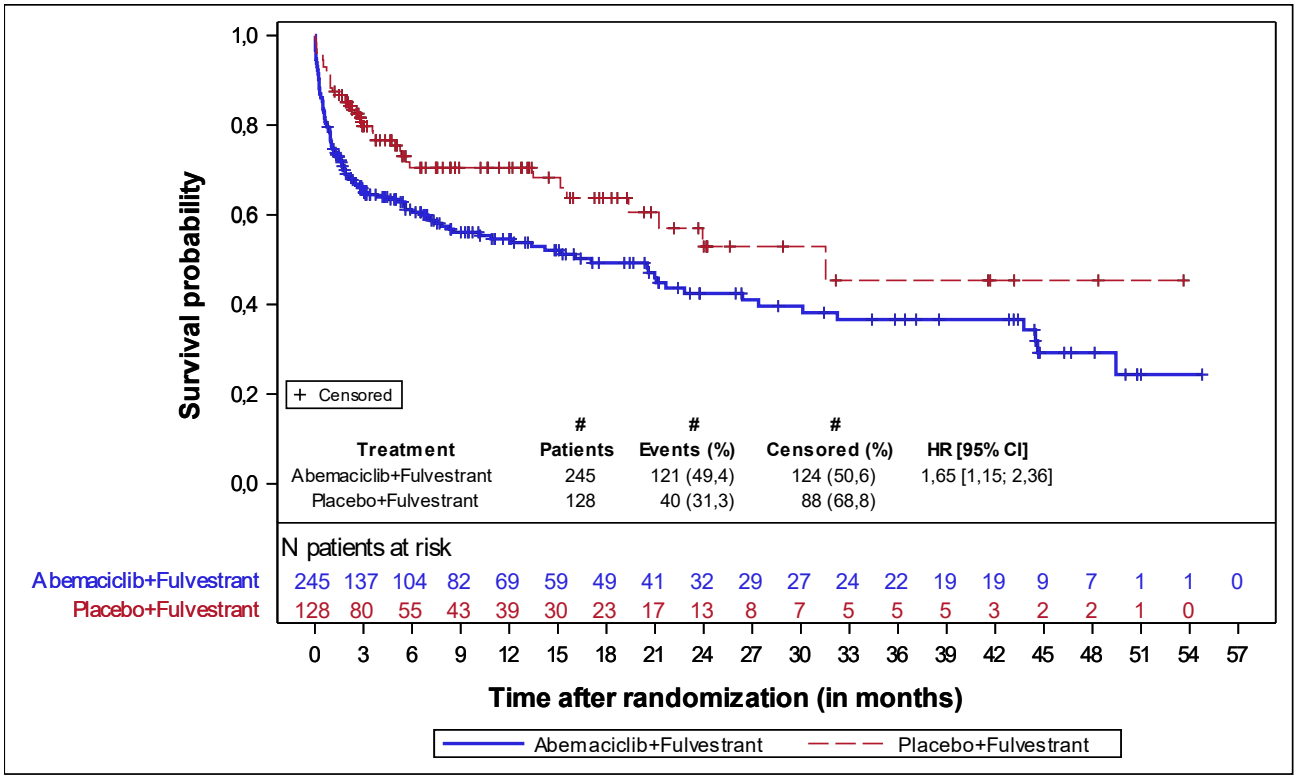
Figure 222: Kaplan-Meier curves for adverse events according SOC - Nervous system disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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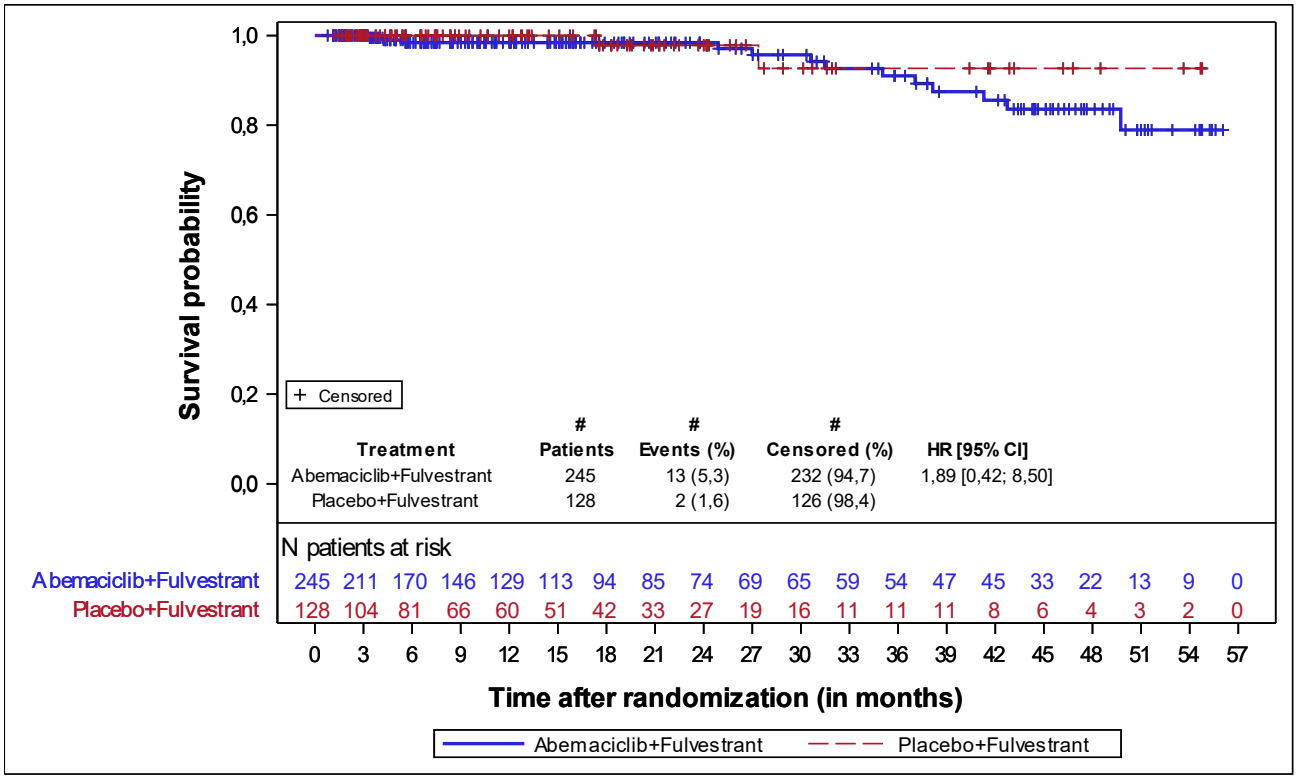
Figure 223: Kaplan-Meier curves for adverse events according SOC - Not coded
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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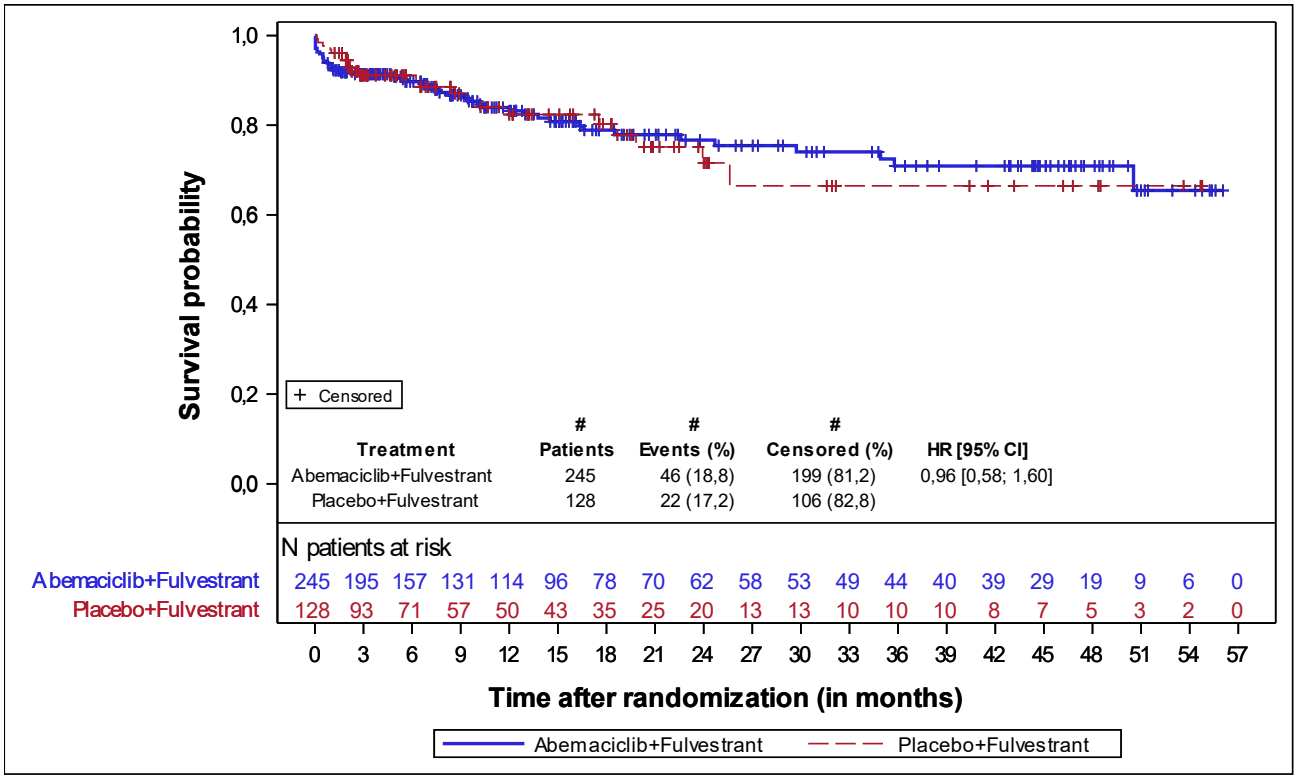
Figure 224: Kaplan-Meier curves for adverse events according SOC - Psychiatric disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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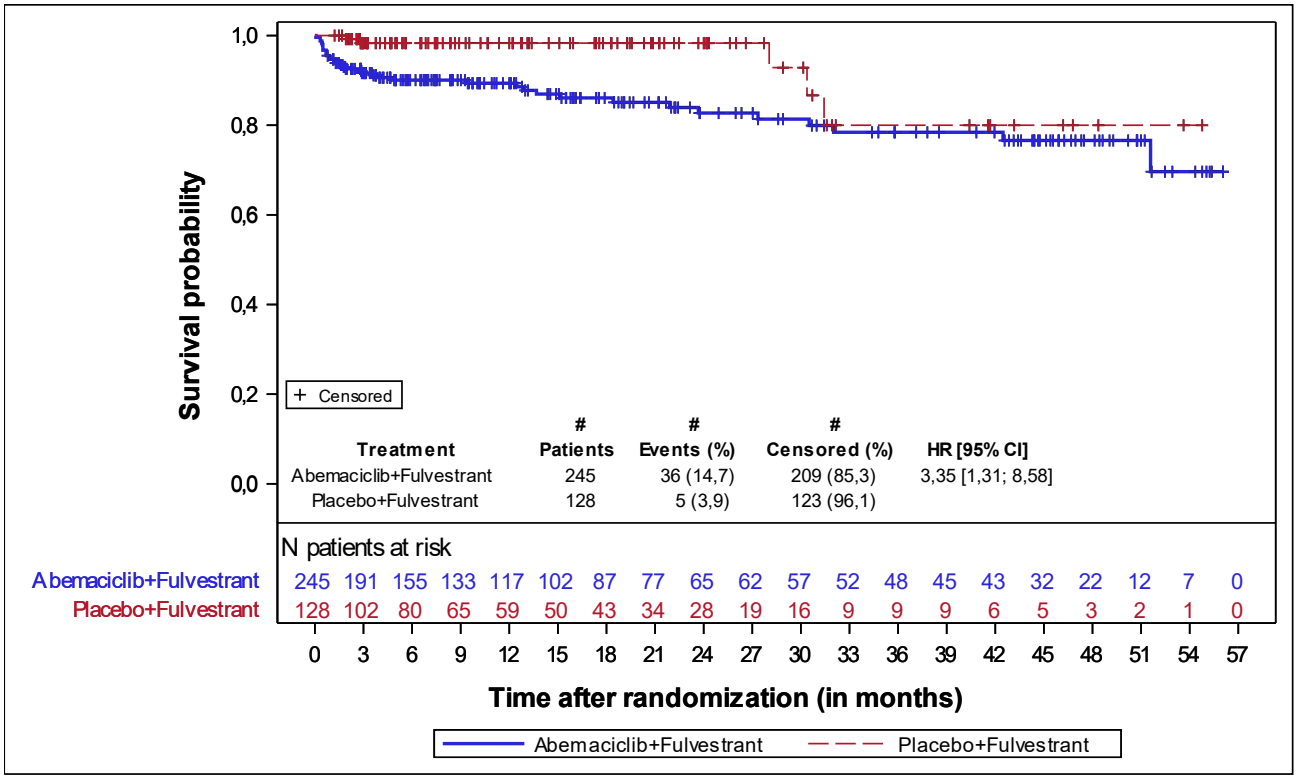
Figure 225: Kaplan-Meier curves for adverse events according SOC - Renal and urinary disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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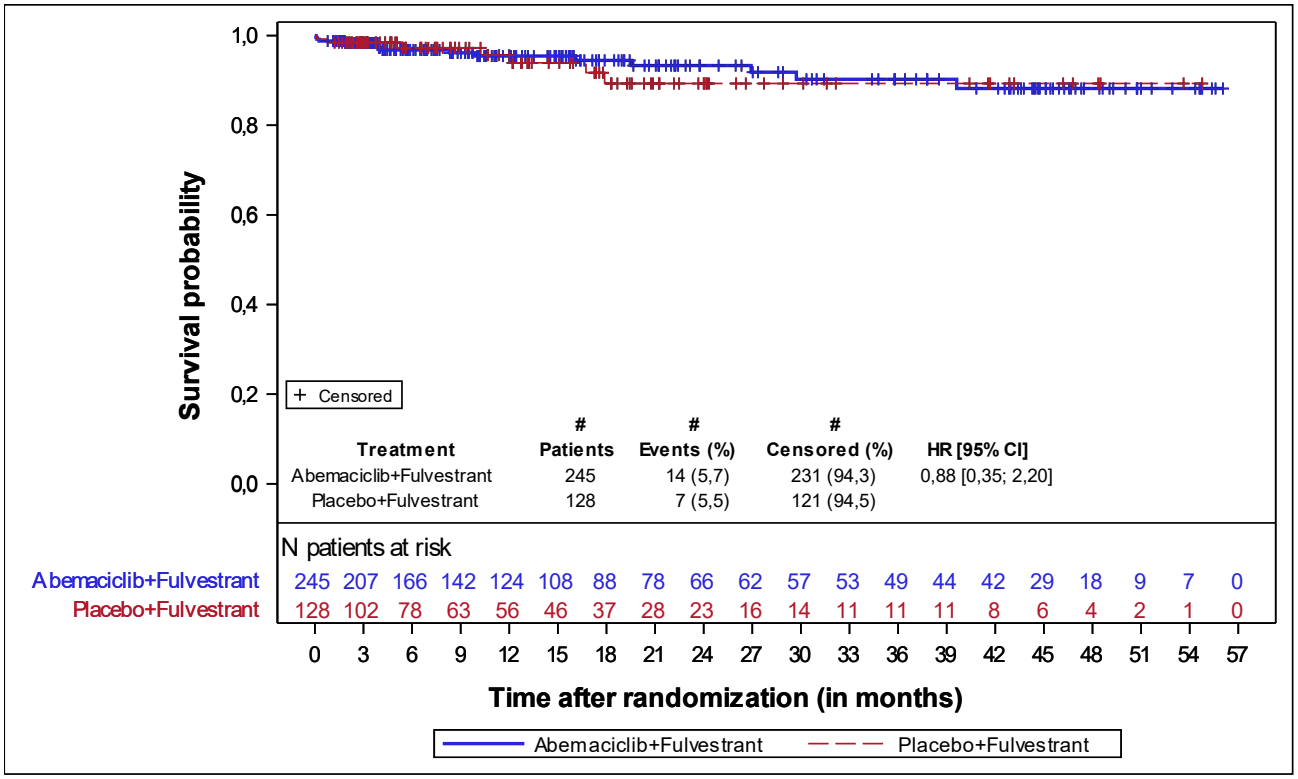
08JUL2021 / 02:43

Figure 226: Kaplan-Meier curves for adverse events according SOC - Reproductive system and breast disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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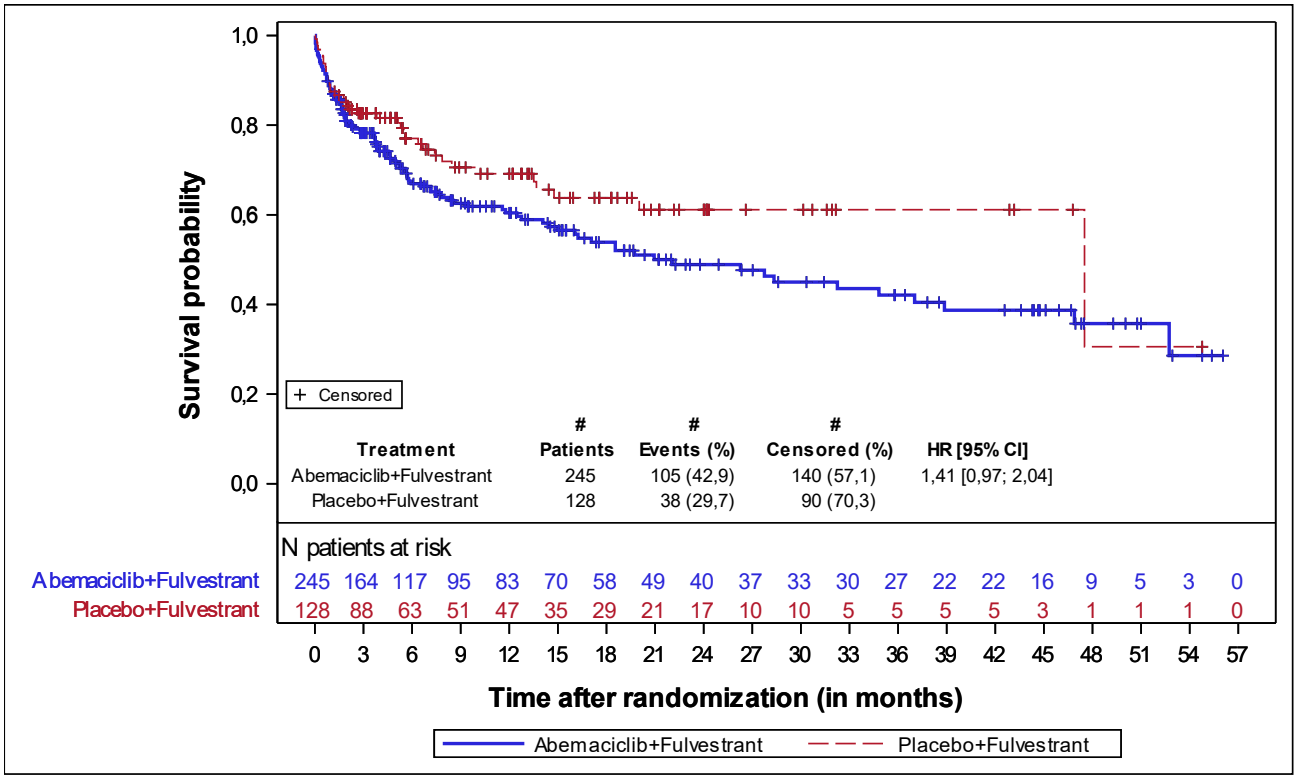
Figure 227: Kaplan-Meier curves for adverse events according SOC - Respiratory, thoracic and mediastinal disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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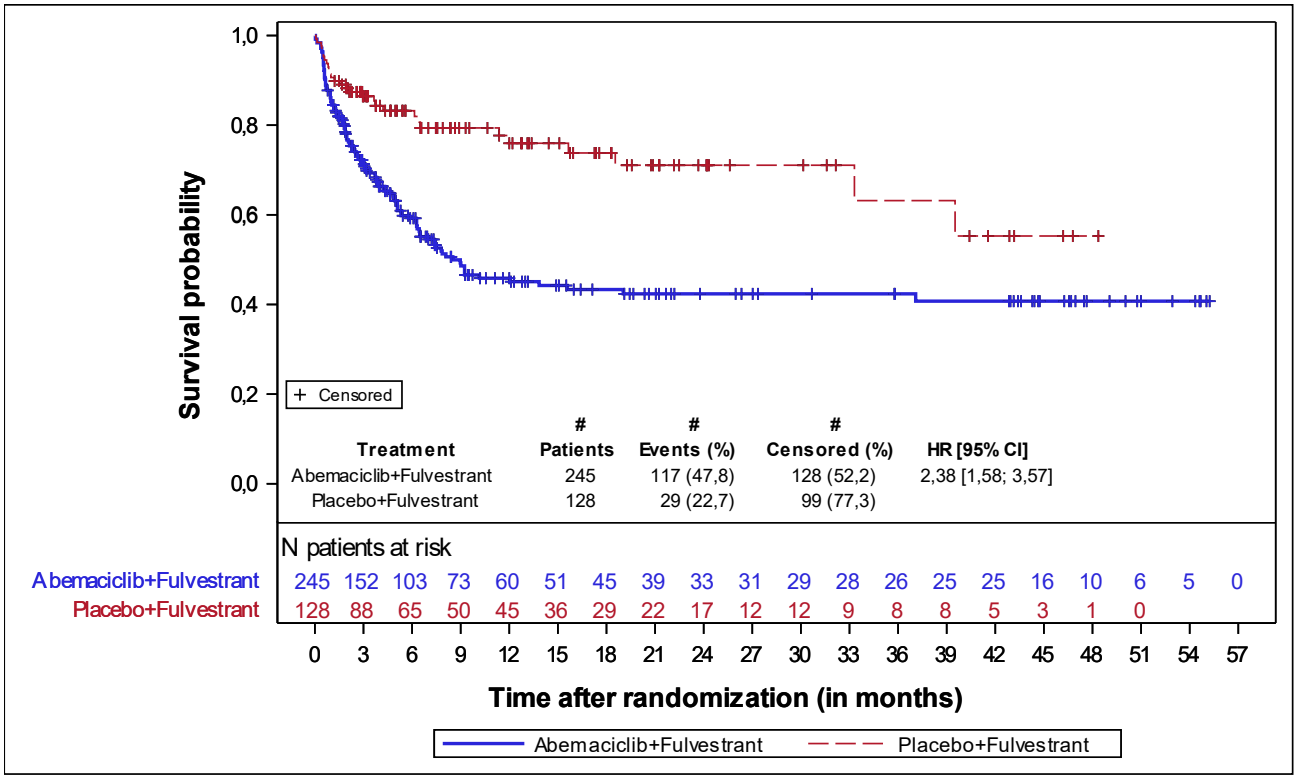
Figure 228: Kaplan-Meier curves for adverse events according SOC - Skin and subcutaneous tissue disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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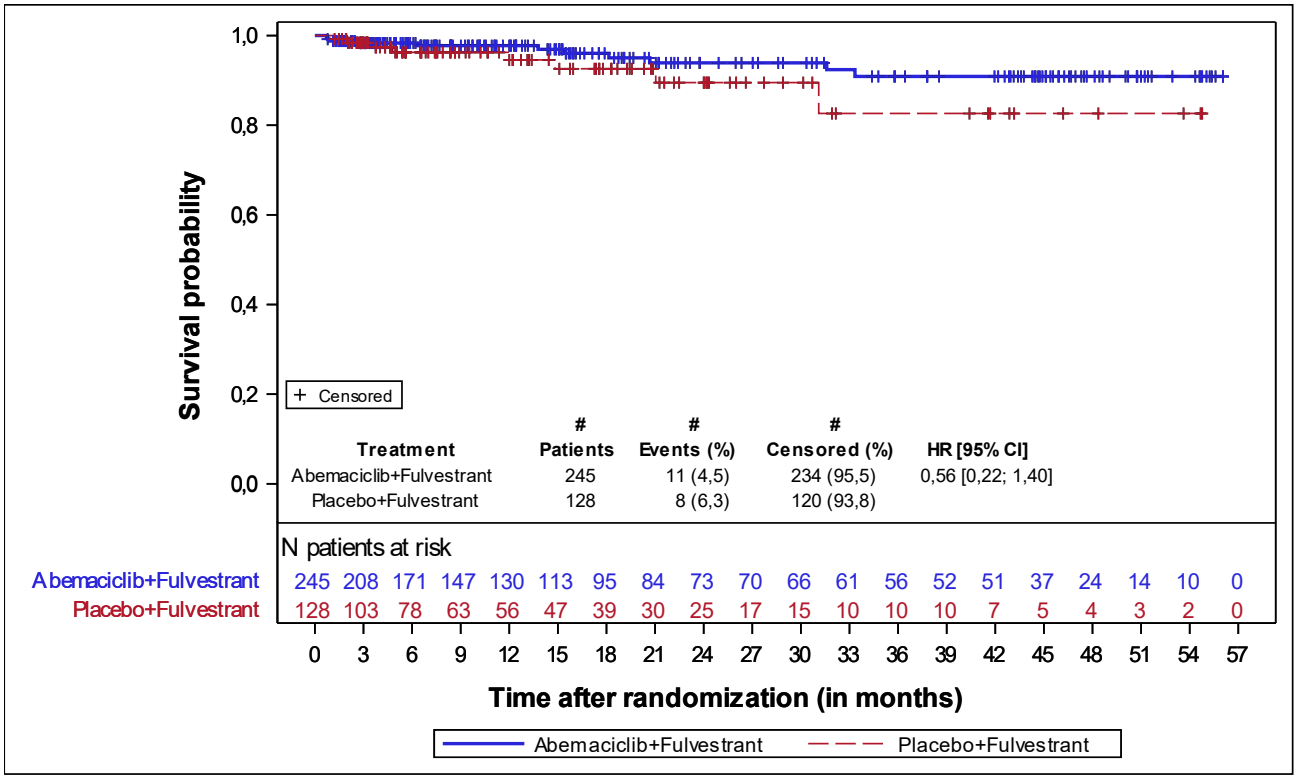
08JUL2021 / 02:43

Figure 229: Kaplan-Meier curves for adverse events according SOC - Surgical and medical procedures
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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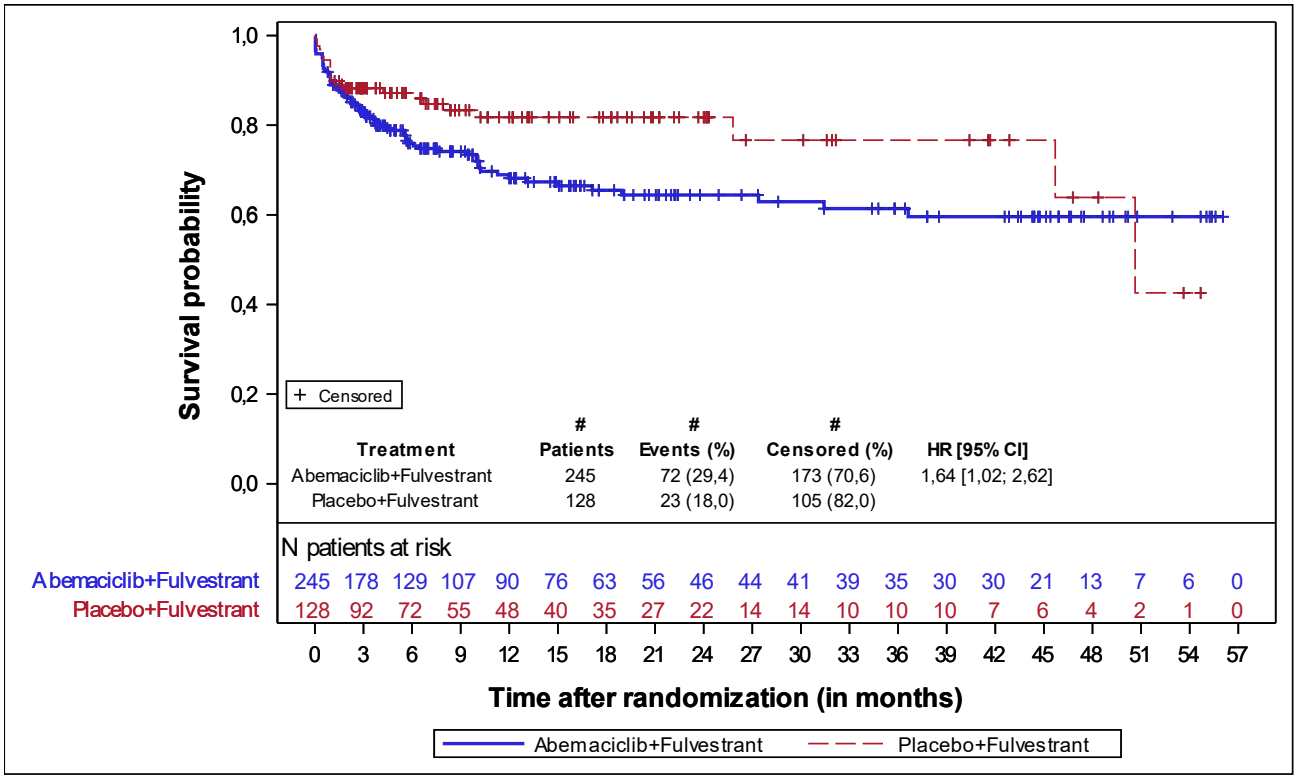
Figure 230: Kaplan-Meier curves for adverse events according SOC - Vascular disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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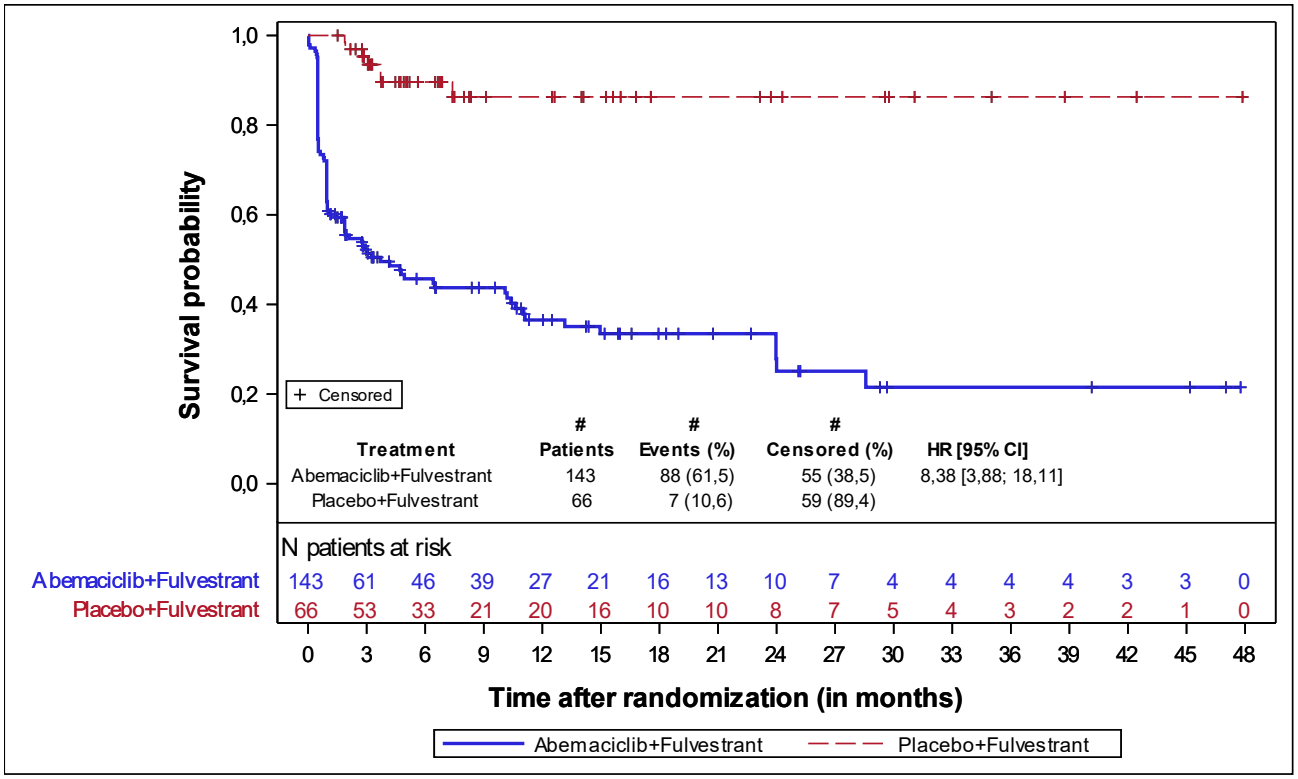
08JUL2021 / 02:43

Figure 231: Kaplan-Meier curves for adverse events according SOC - Blood and lymphatic system disorders Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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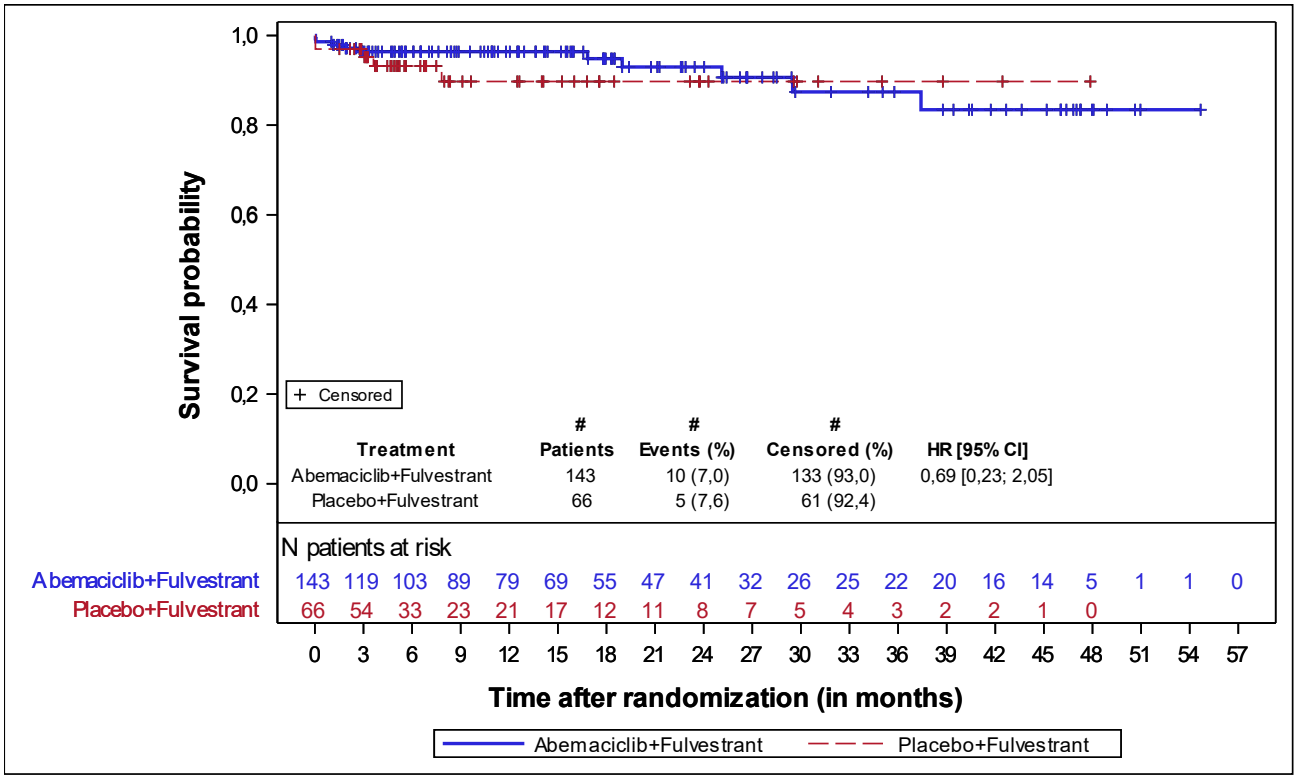
08JUL2021 / 02:43

Figure 232: Kaplan-Meier curves for adverse events according SOC - Cardiac disorders
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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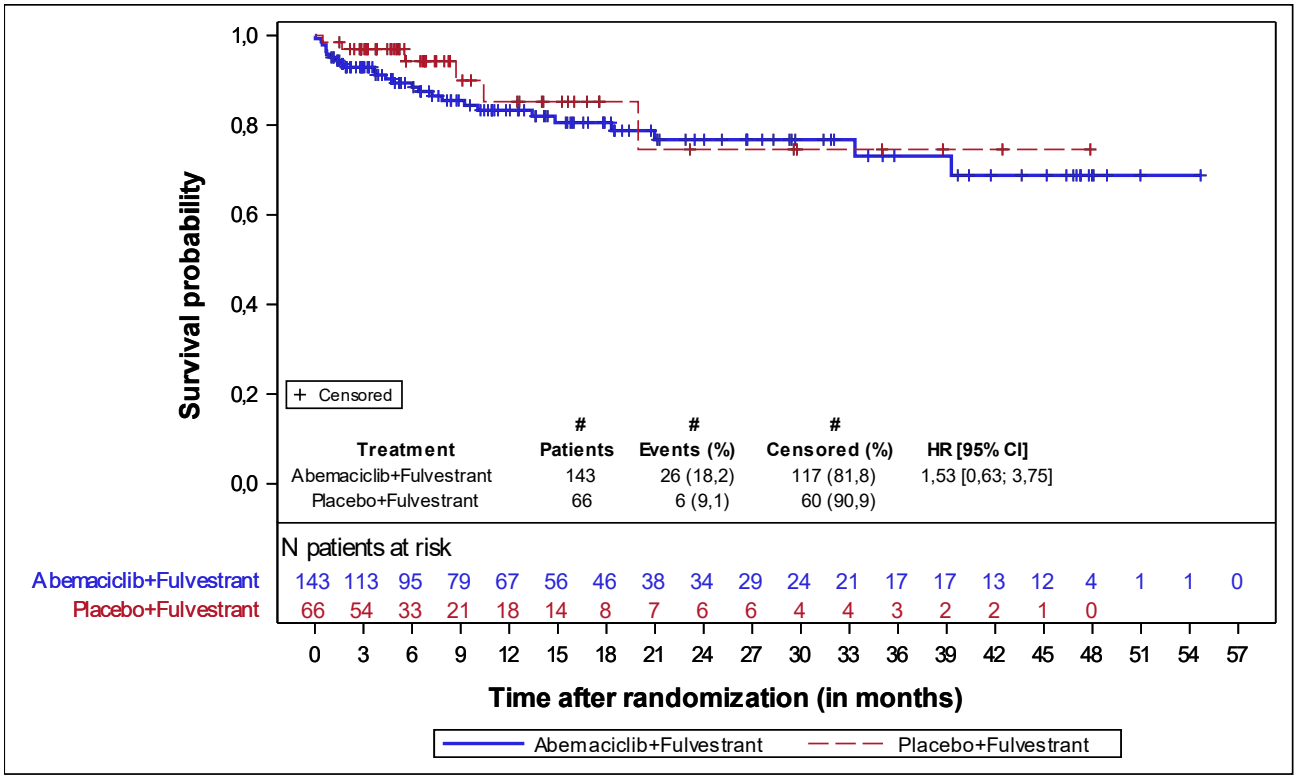
08JUL2021 / 02:43

Figure 233: Kaplan-Meier curves for adverse events according SOC - Eye disorders
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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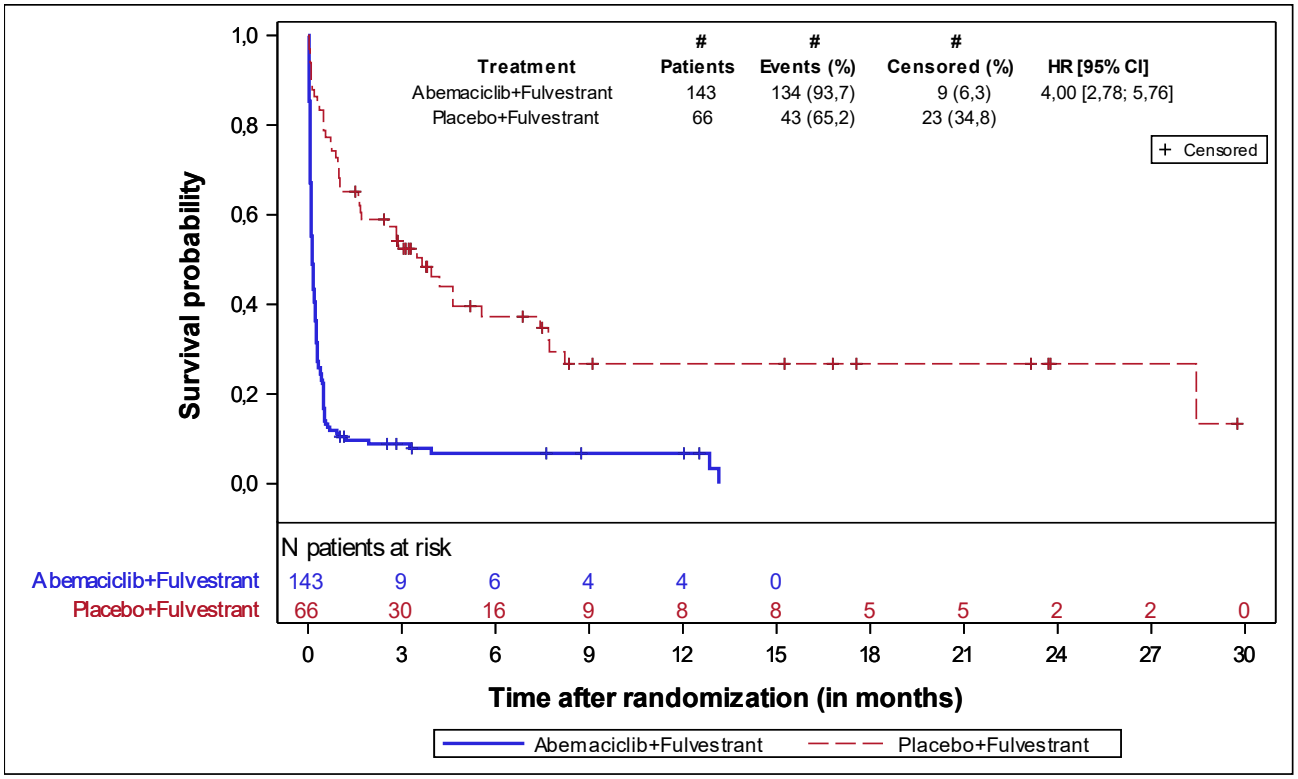
08JUL2021 / 02:43

Figure 234: Kaplan-Meier curves for adverse events according SOC - Gastrointestinal disorders
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraes004_popa2.rtf
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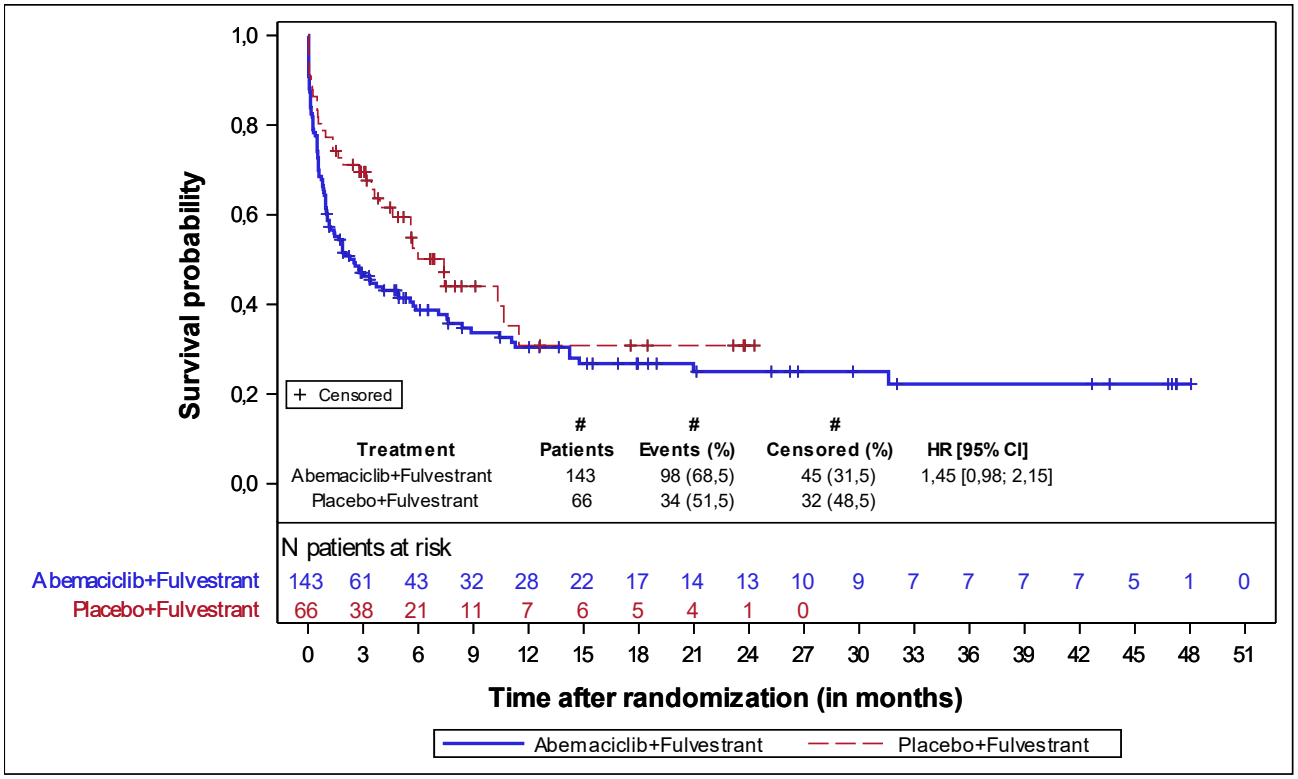
Figure 235: Kaplan-Meier curves for adverse events according SOC - General disorders and administration site conditions Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraes005_popa2.rtf
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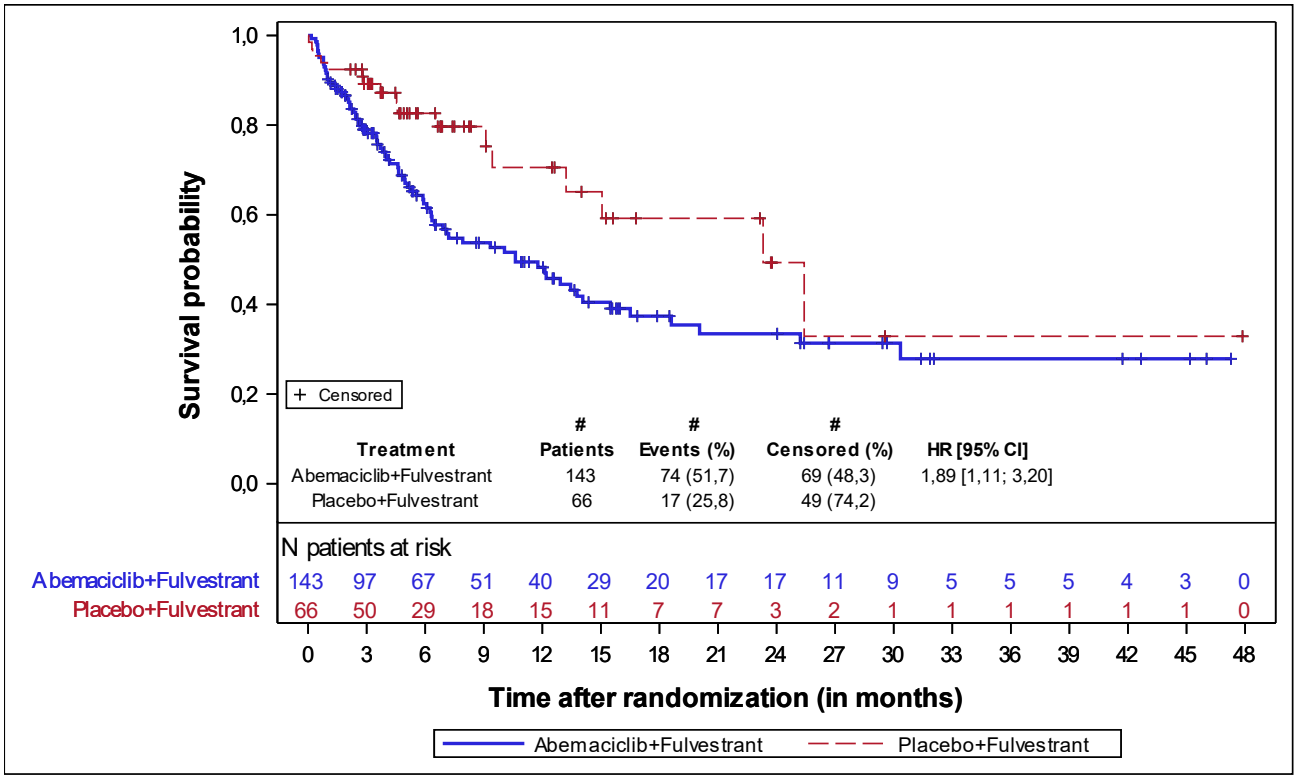
Figure 236: Kaplan-Meier curves for adverse events according SOC - Infections and infestations
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraes006_popa2.rtf
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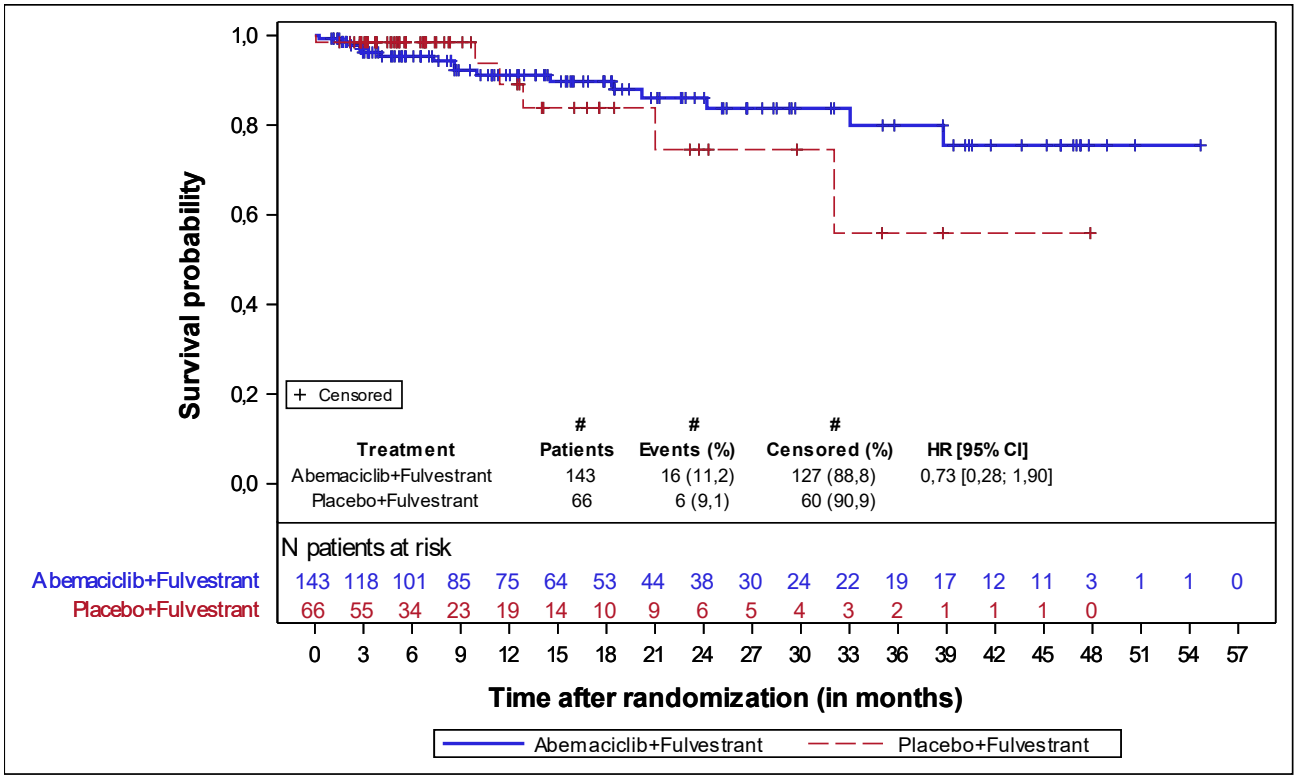
Figure 237: Kaplan-Meier curves for adverse events according SOC - Injury, poisoning and procedural complications
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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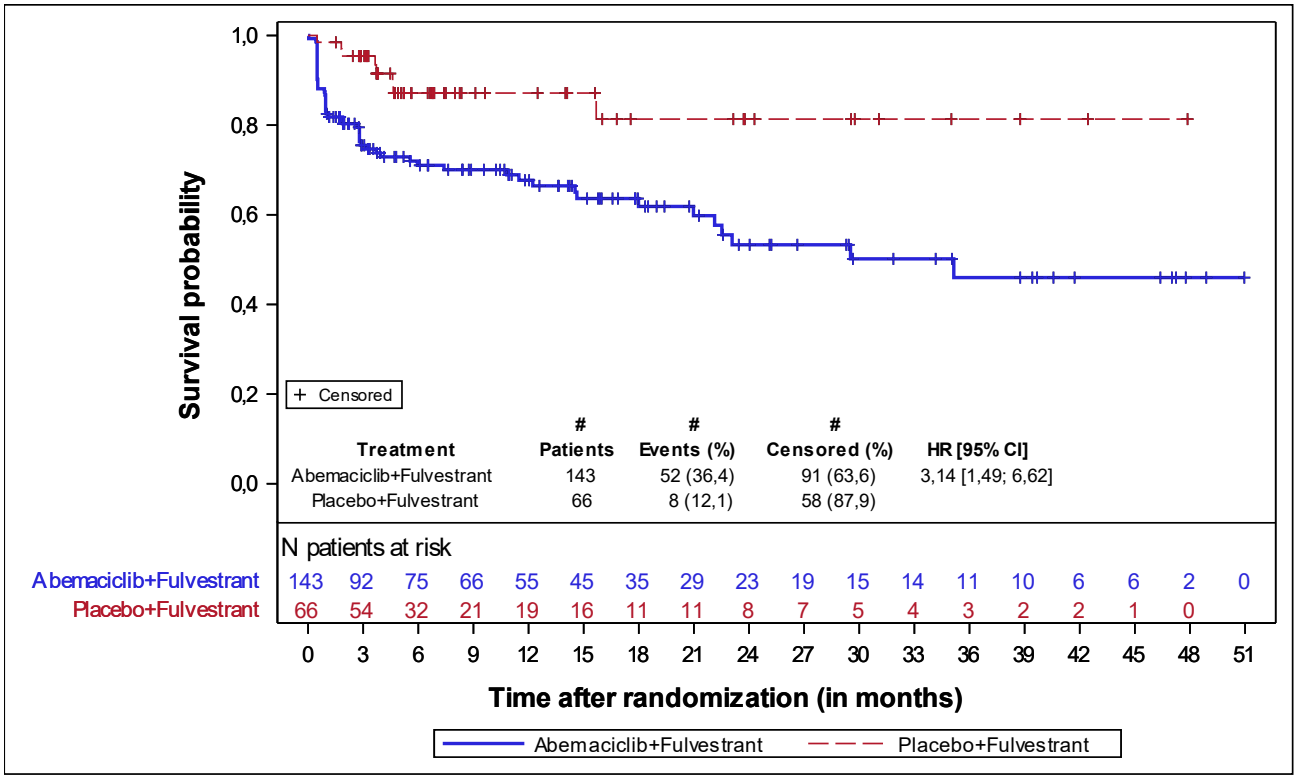
Figure 238: Kaplan-Meier curves for adverse events according SOC - Investigations
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraes008_popa2.rtf
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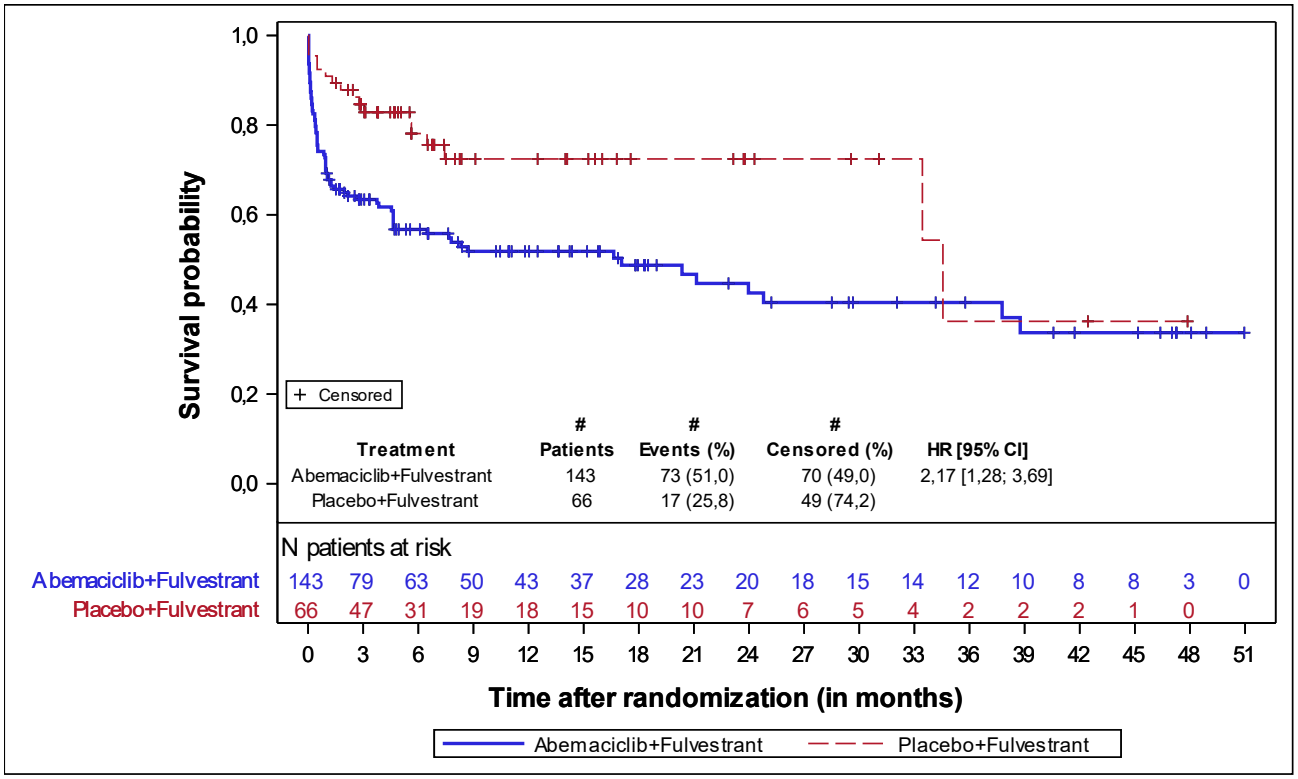
Figure 239: Kaplan-Meier curves for adverse events according SOC - Metabolism and nutrition disorders
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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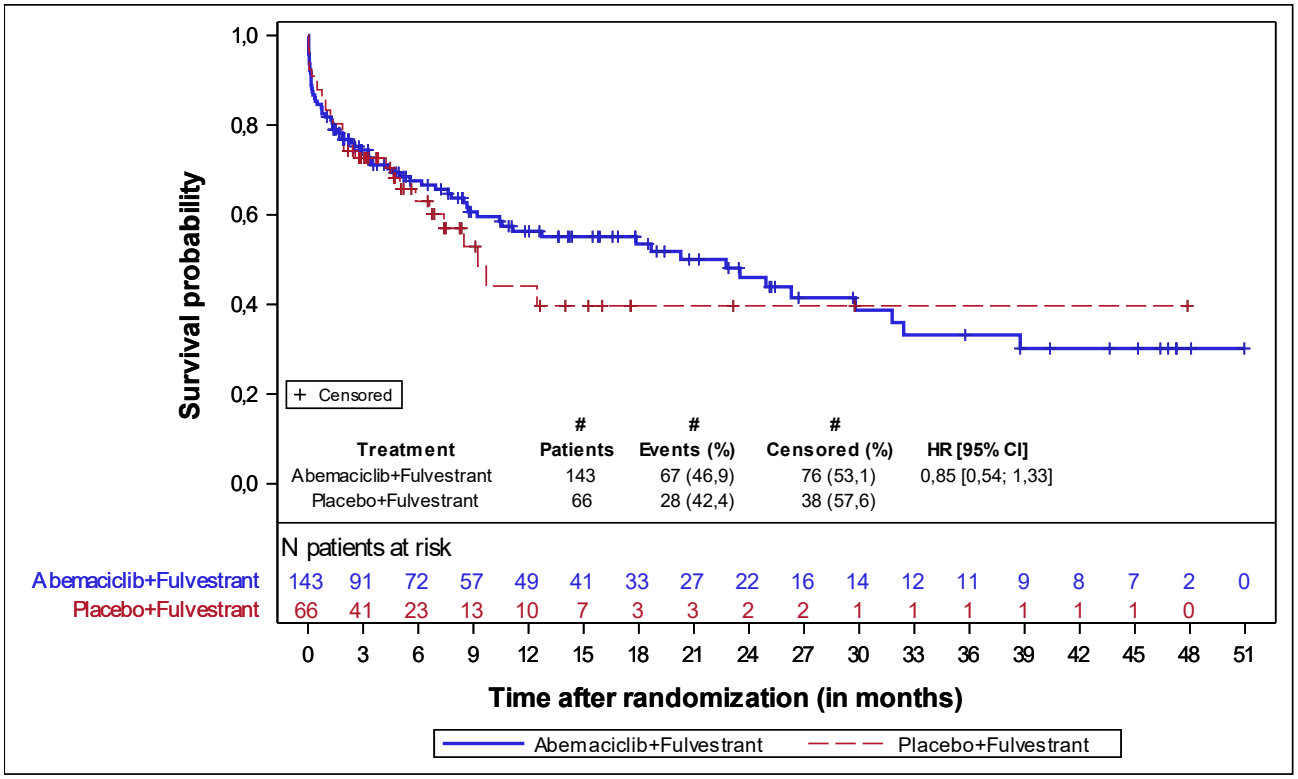
Figure 240: Kaplan-Meier curves for adverse events according SOC - Musculoskeletal and connective tissue disorders
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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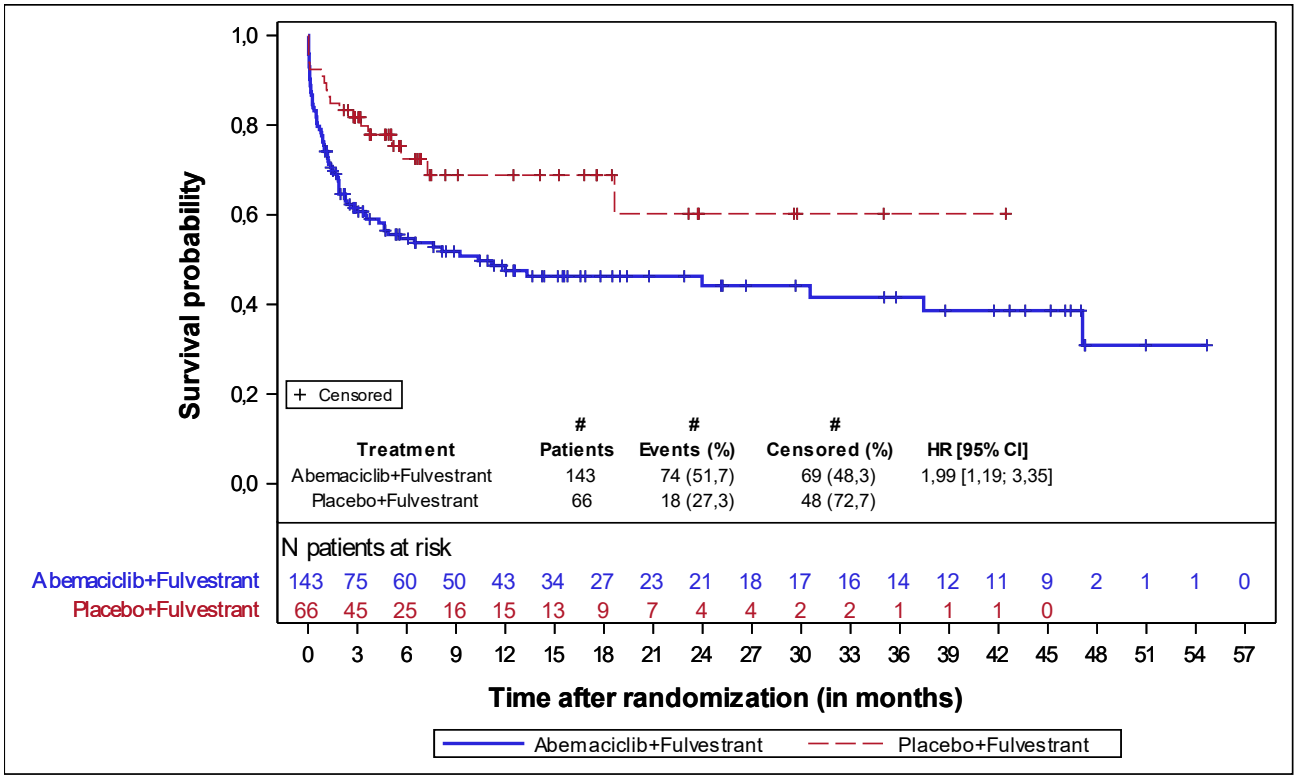
Figure 241: Kaplan-Meier curves for adverse events according SOC - Nervous system disorders
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraes011_popa2.rtf
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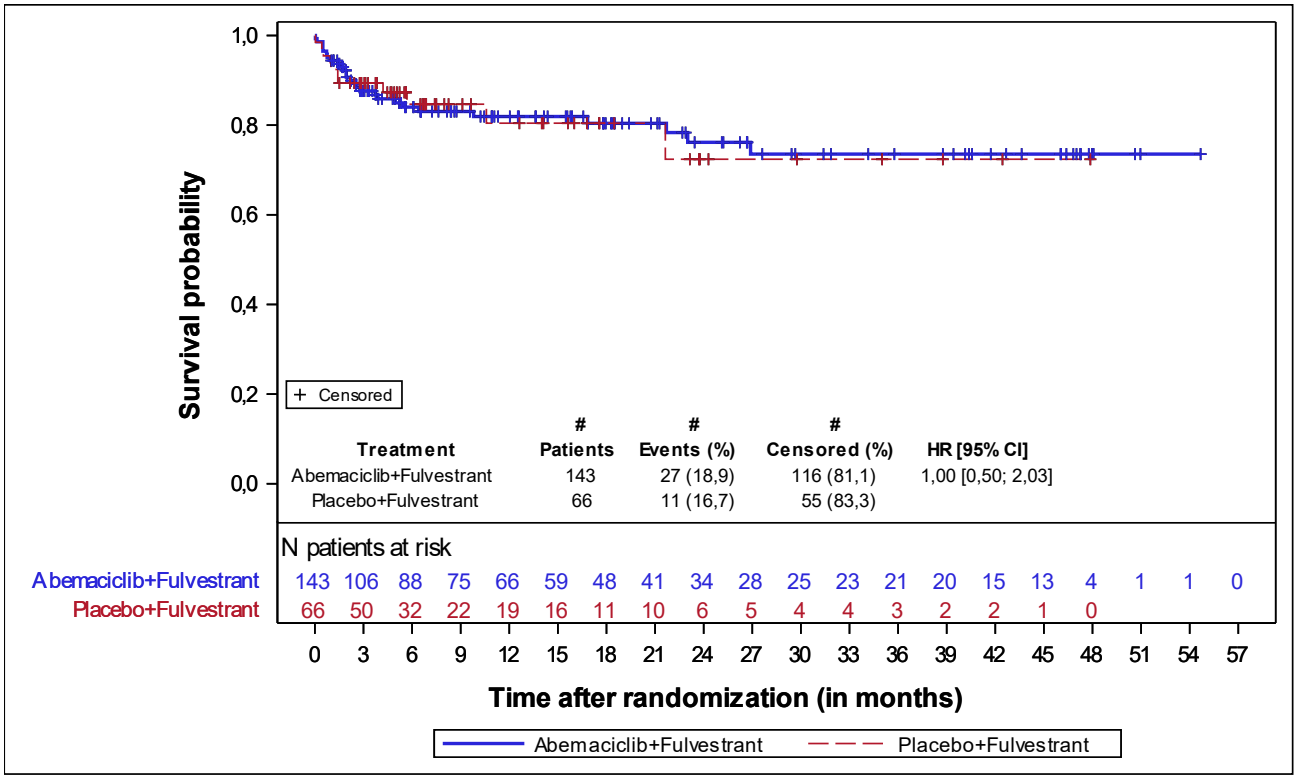
Figure 242: Kaplan-Meier curves for adverse events according SOC - Psychiatric disorders
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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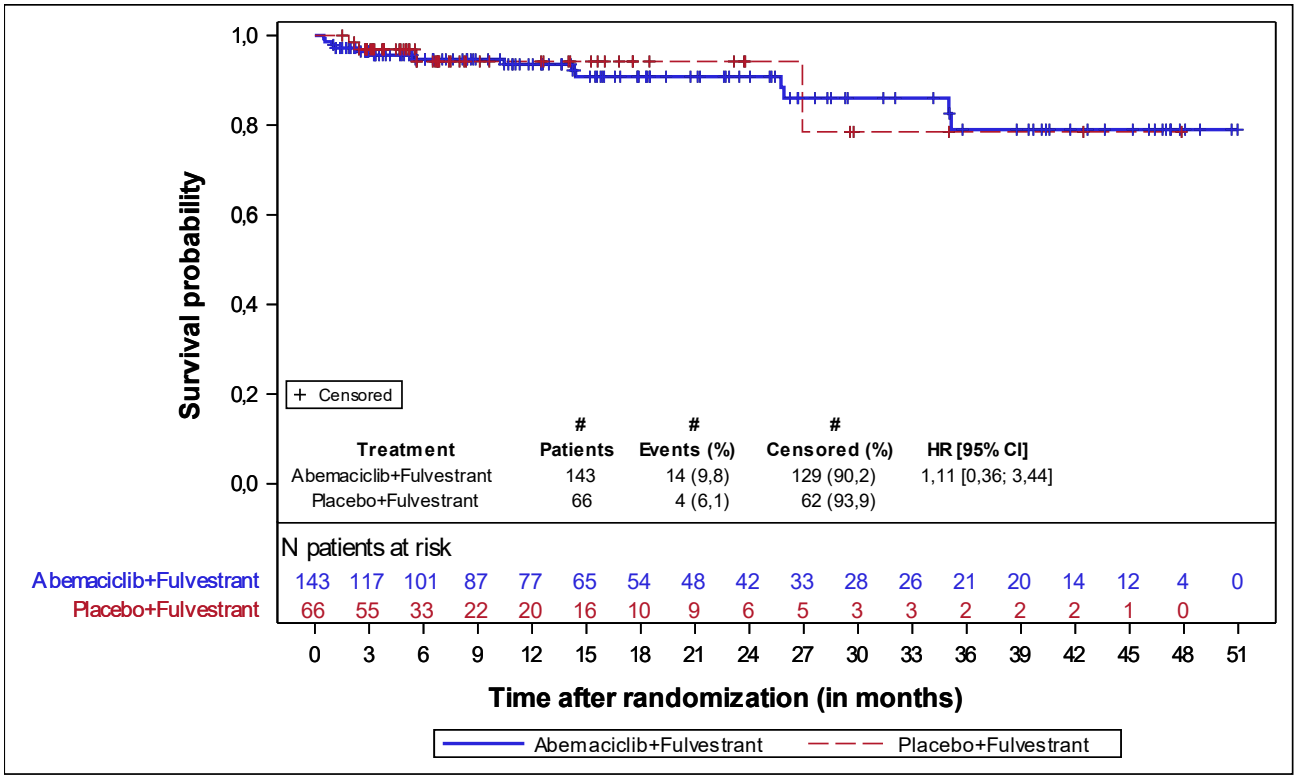
Figure 243: Kaplan-Meier curves for adverse events according SOC - Renal and urinary disorders
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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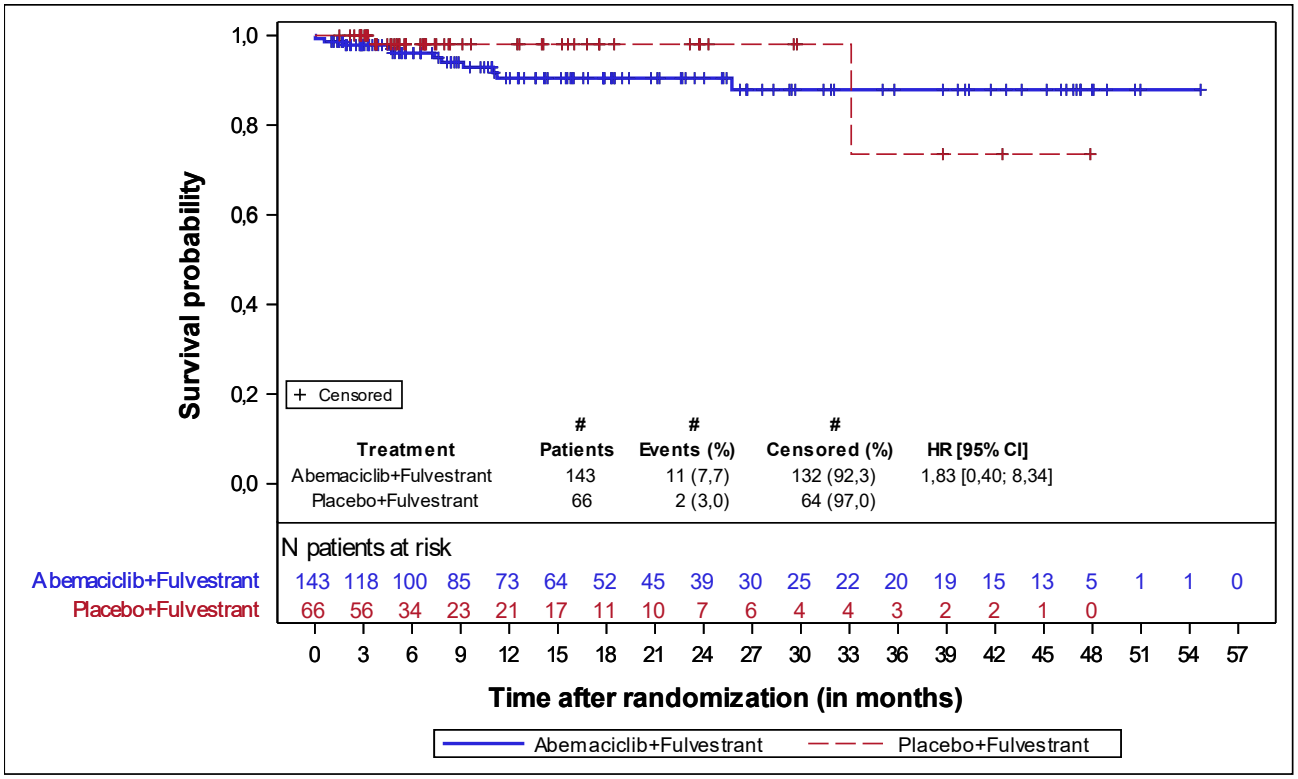
Figure 244: Kaplan-Meier curves for adverse events according SOC - Reproductive system and breast disorders
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttiraes014_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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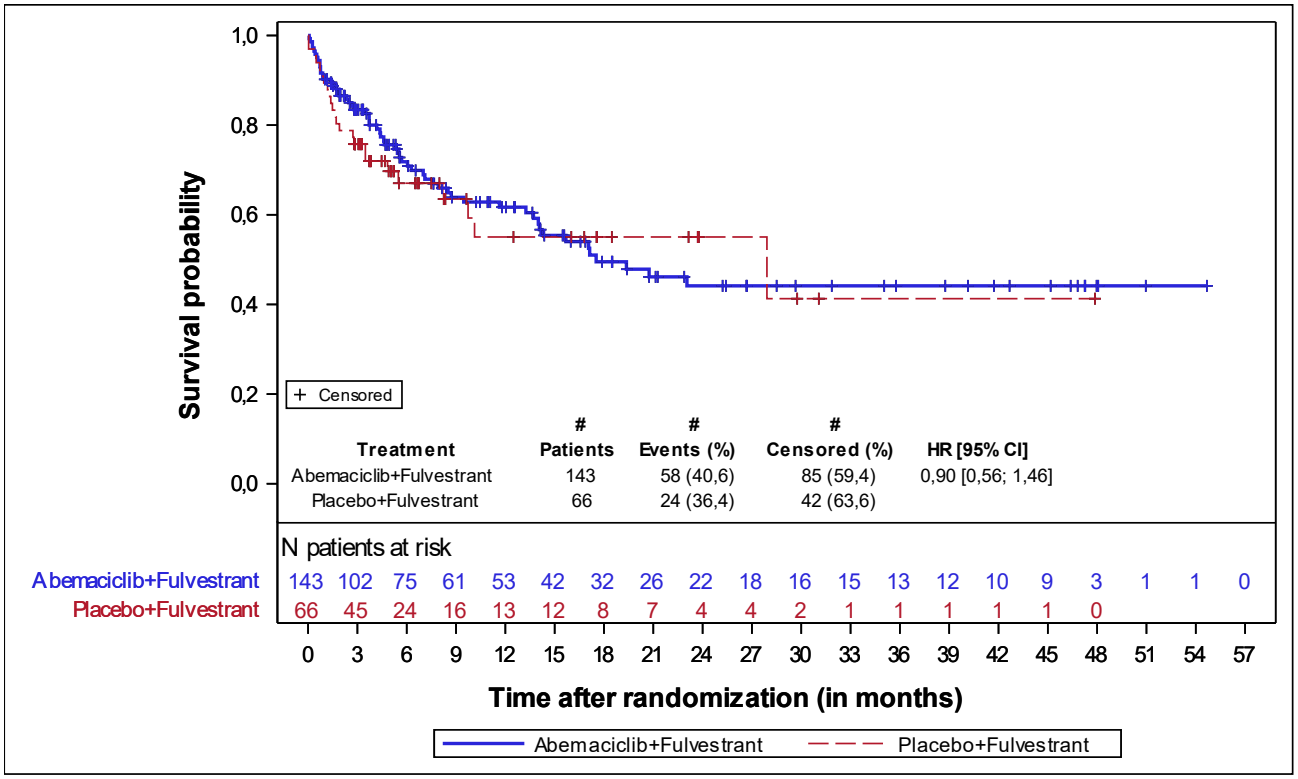
Figure 245: Kaplan-Meier curves for adverse events according SOC - Respiratory, thoracic and mediastinal disorders
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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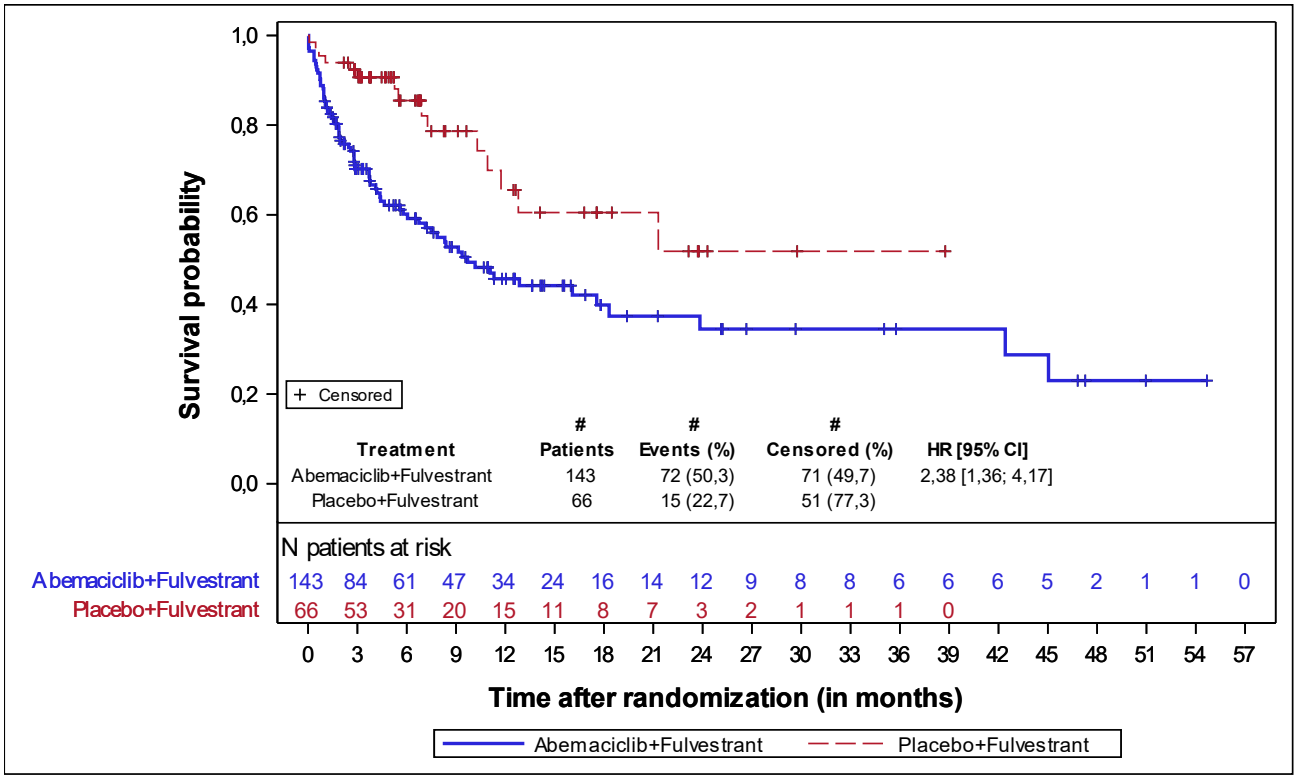
Figure 246: Kaplan-Meier curves for adverse events according SOC - Skin and subcutaneous tissue disorders
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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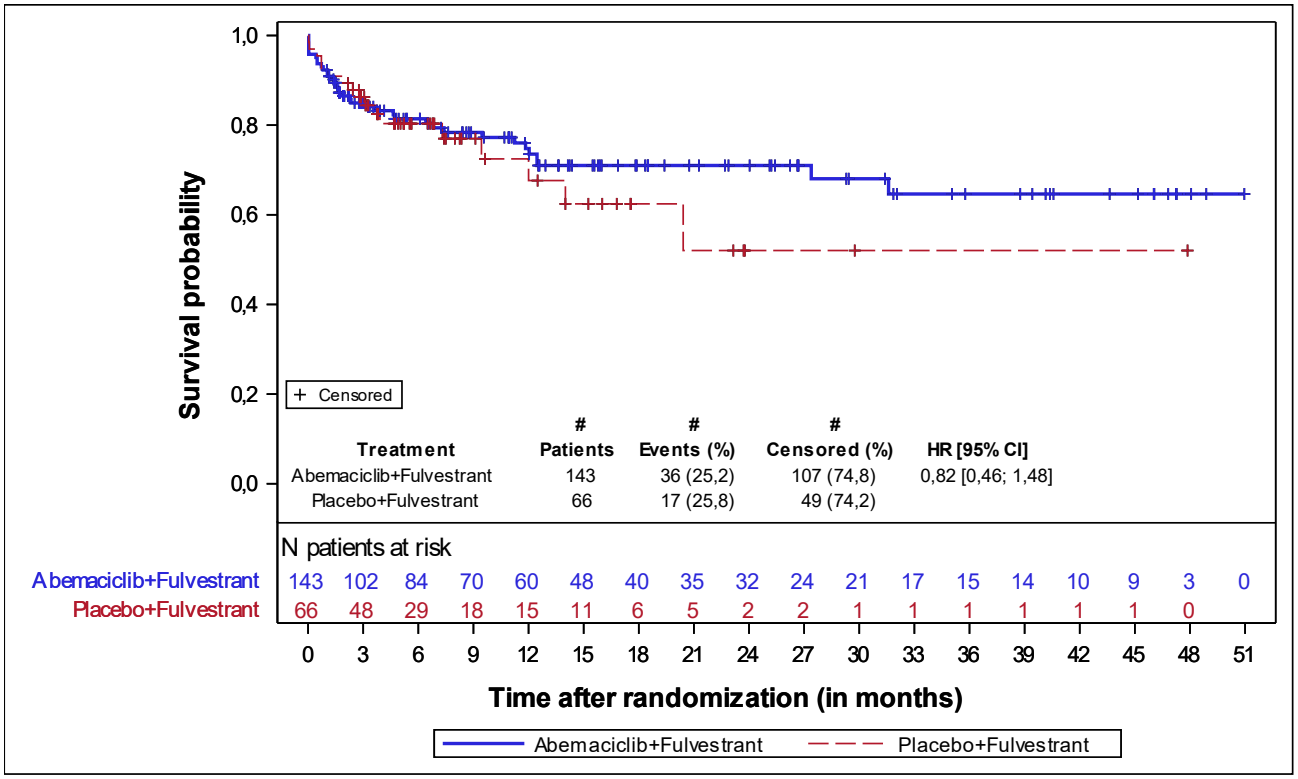
Figure 247: Kaplan-Meier curves for adverse events according SOC - Vascular disorders
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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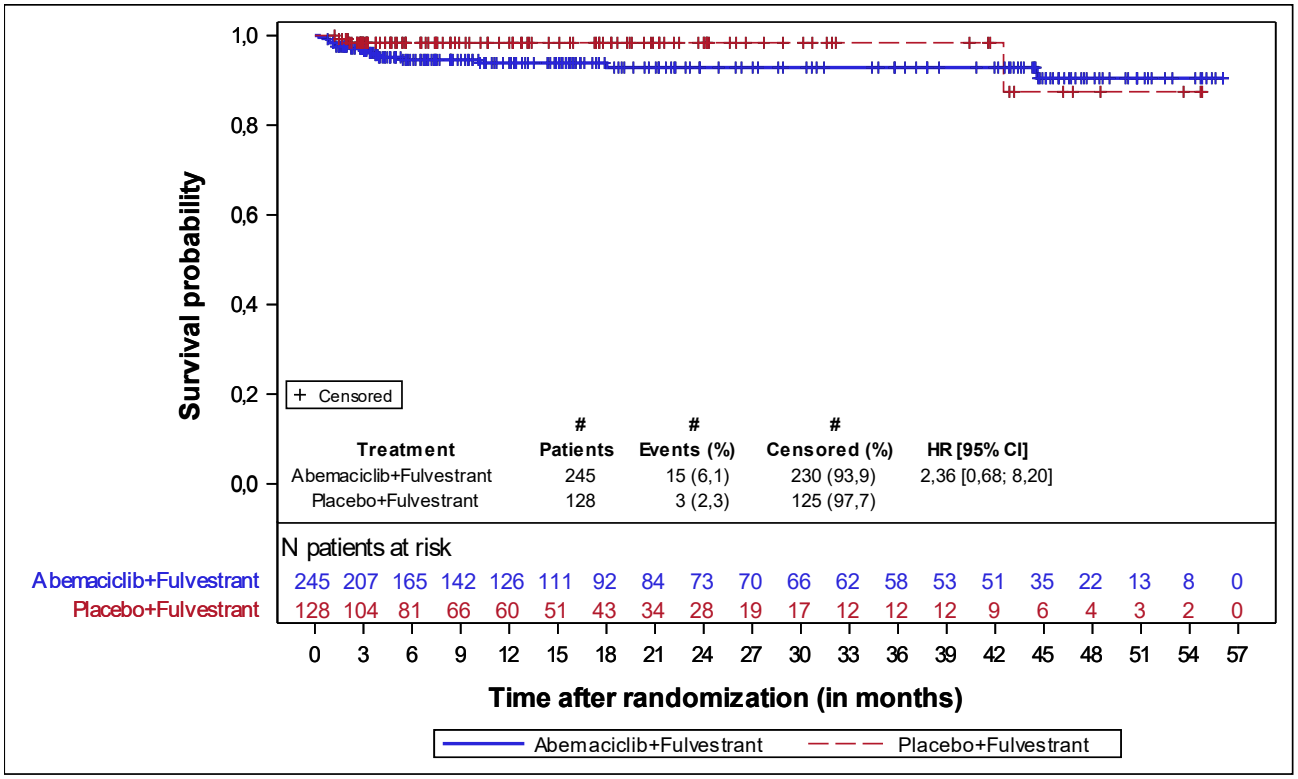
Figure 248: Kaplan-Meier curves for serious adverse events according SOC - Gastrointestinal disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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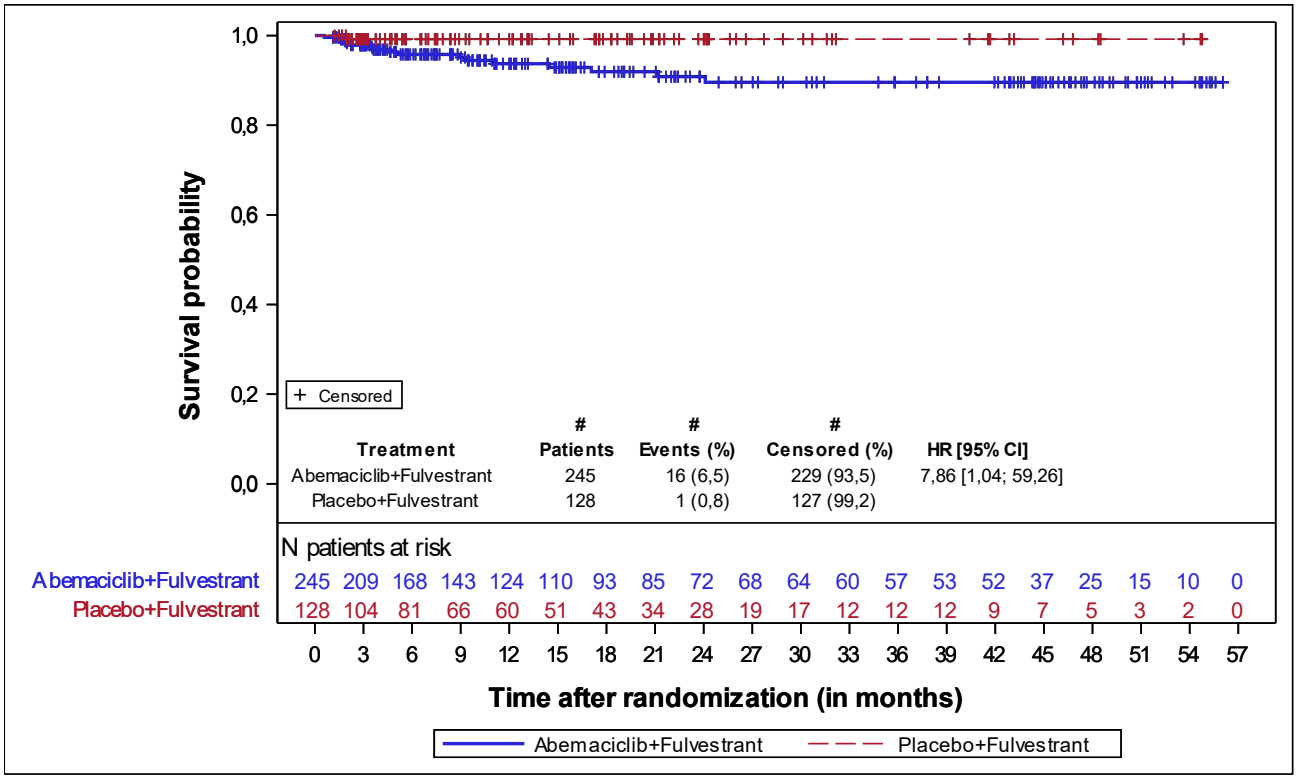
Figure 249: Kaplan-Meier curves for serious adverse events according SOC - Infections and infestations
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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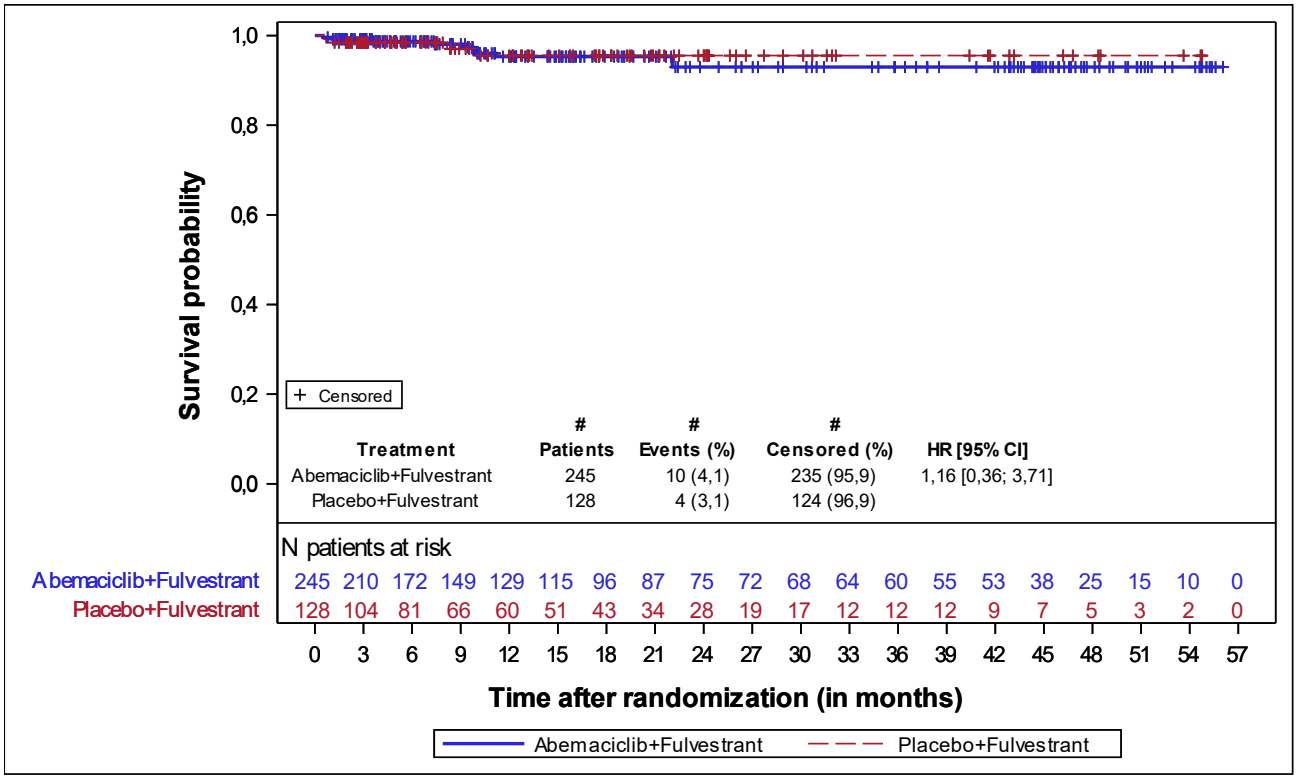
Figure 250: Kaplan-Meier curves for serious adverse events according SOC - Respiratory, thoracic and mediastinal disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttirsaes003_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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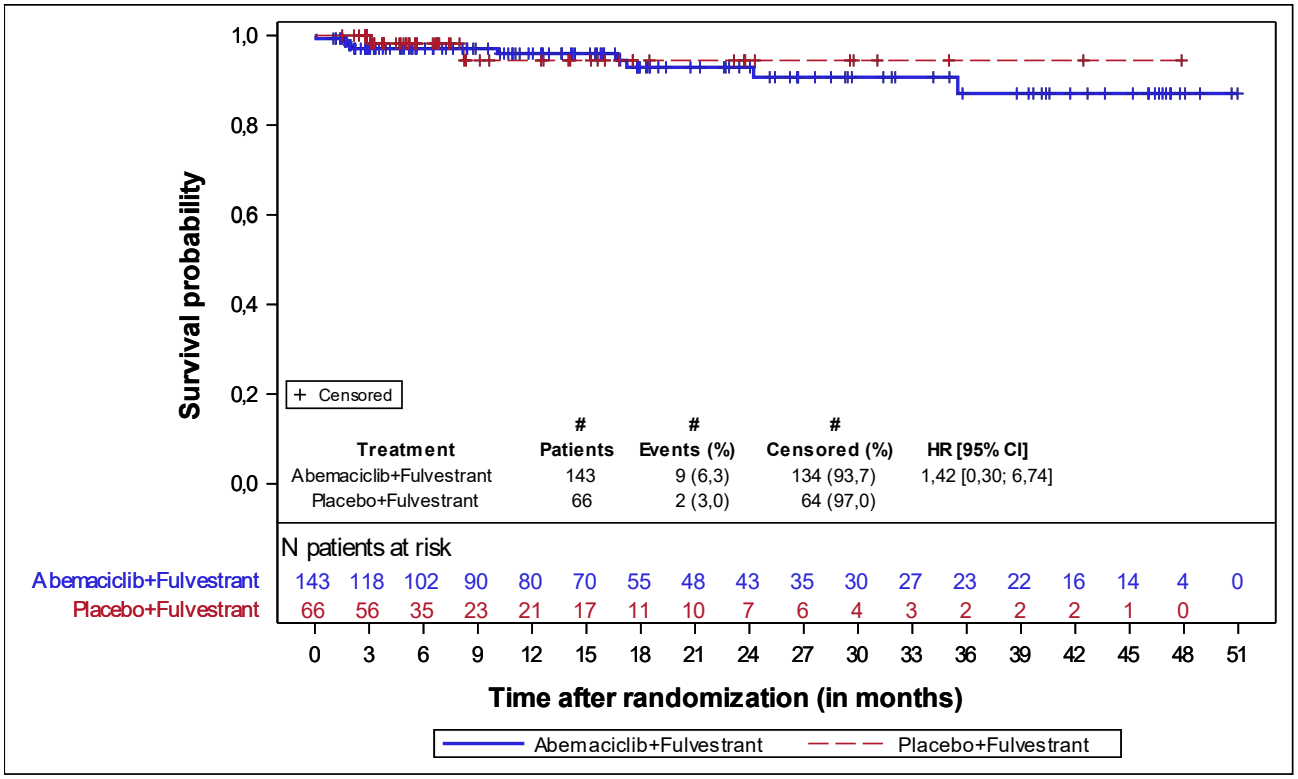
Figure 251: Kaplan-Meier curves for serious adverse events according SOC - Gastrointestinal disorders
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttirsaes001_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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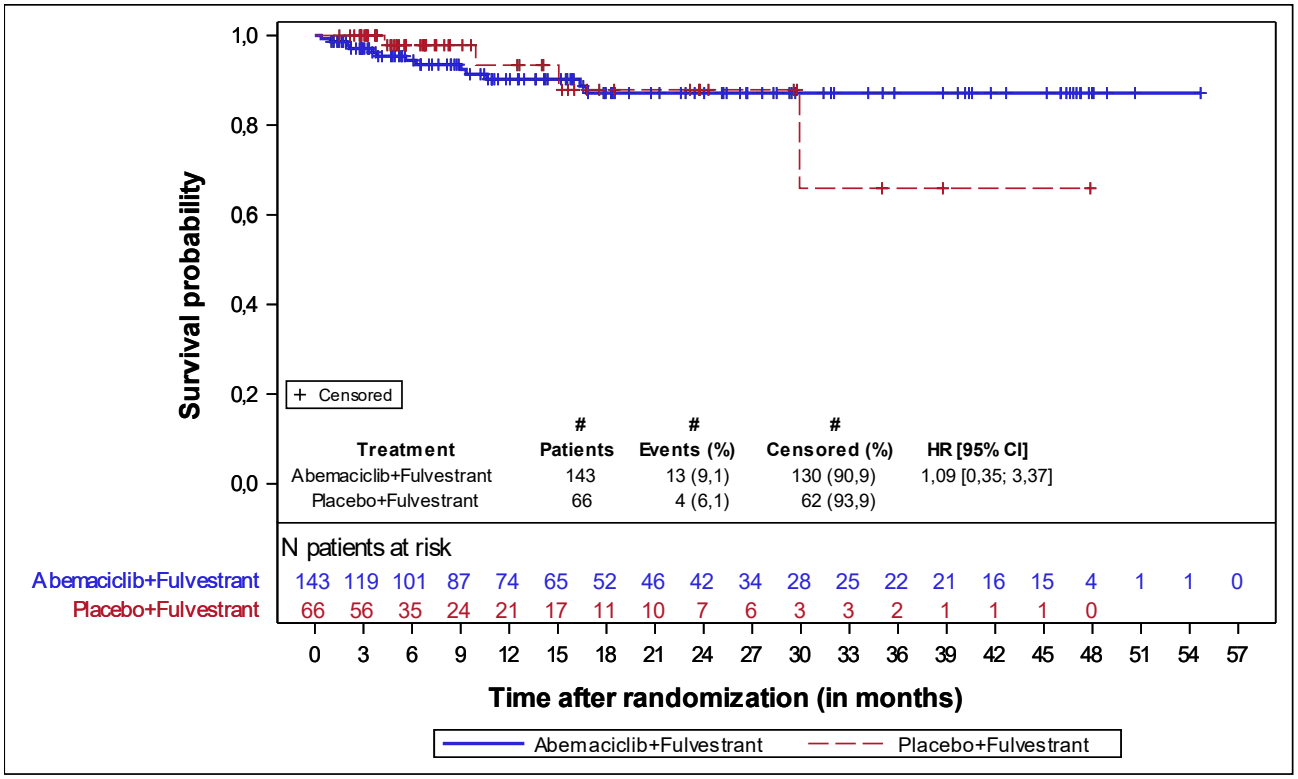
Figure 252: Kaplan-Meier curves for serious adverse events according SOC - Infections and infestations
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttirsaes002_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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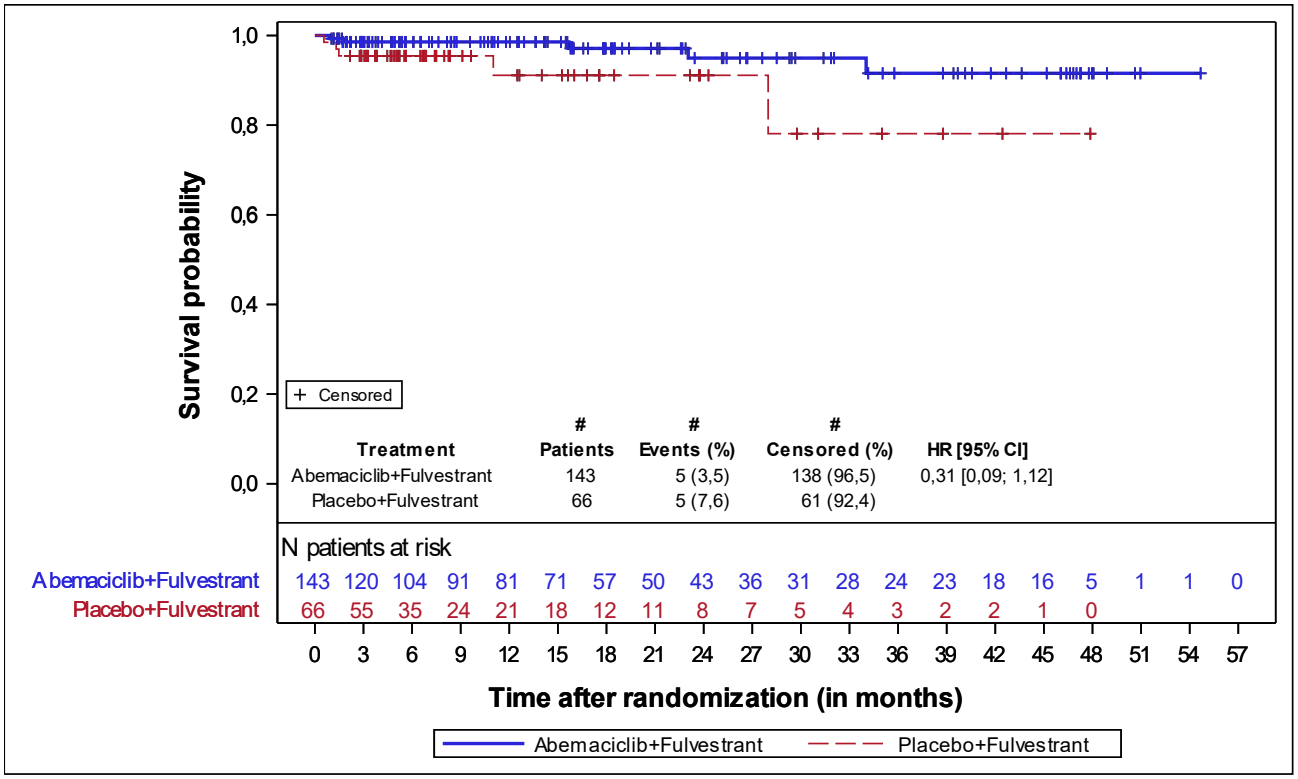
Figure 253: Kaplan-Meier curves for serious adverse events according SOC - Respiratory, thoracic and mediastinal disorders
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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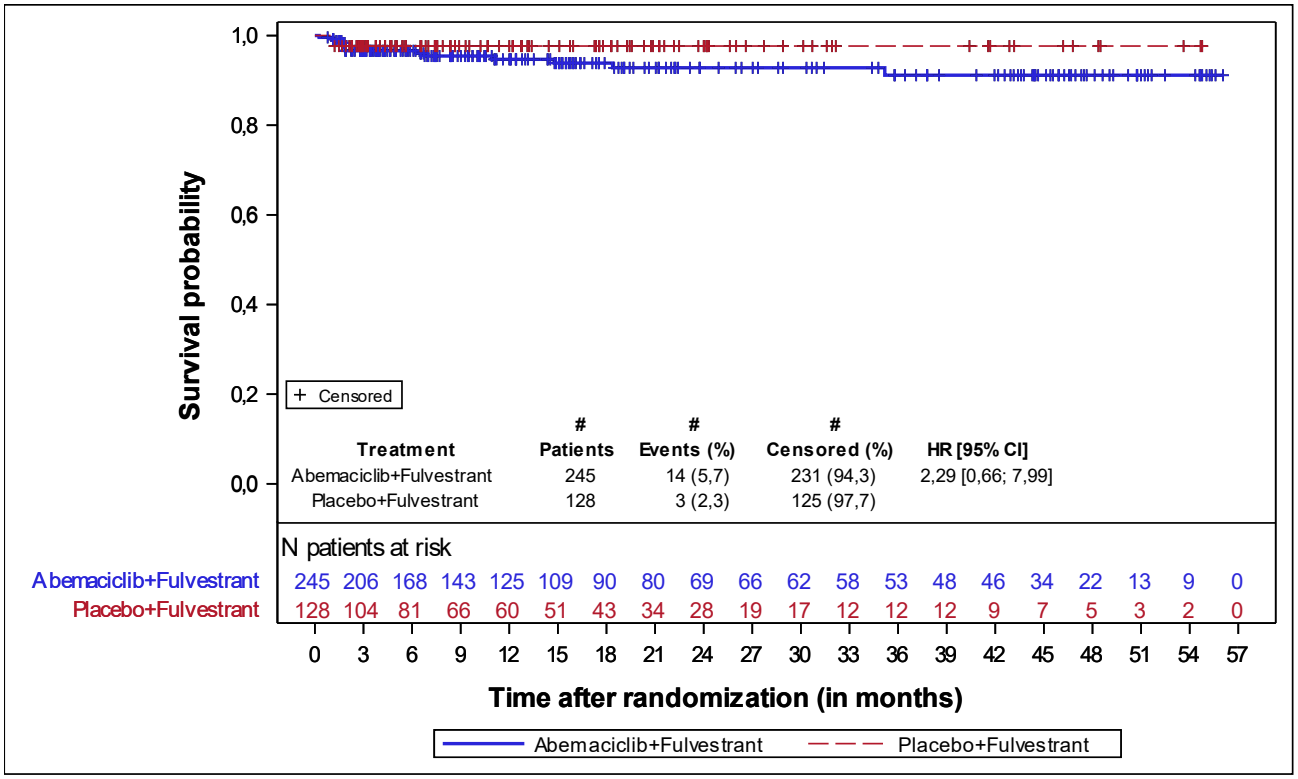
Figure 254: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according PT - Investigations / Alanine aminotransferase increased
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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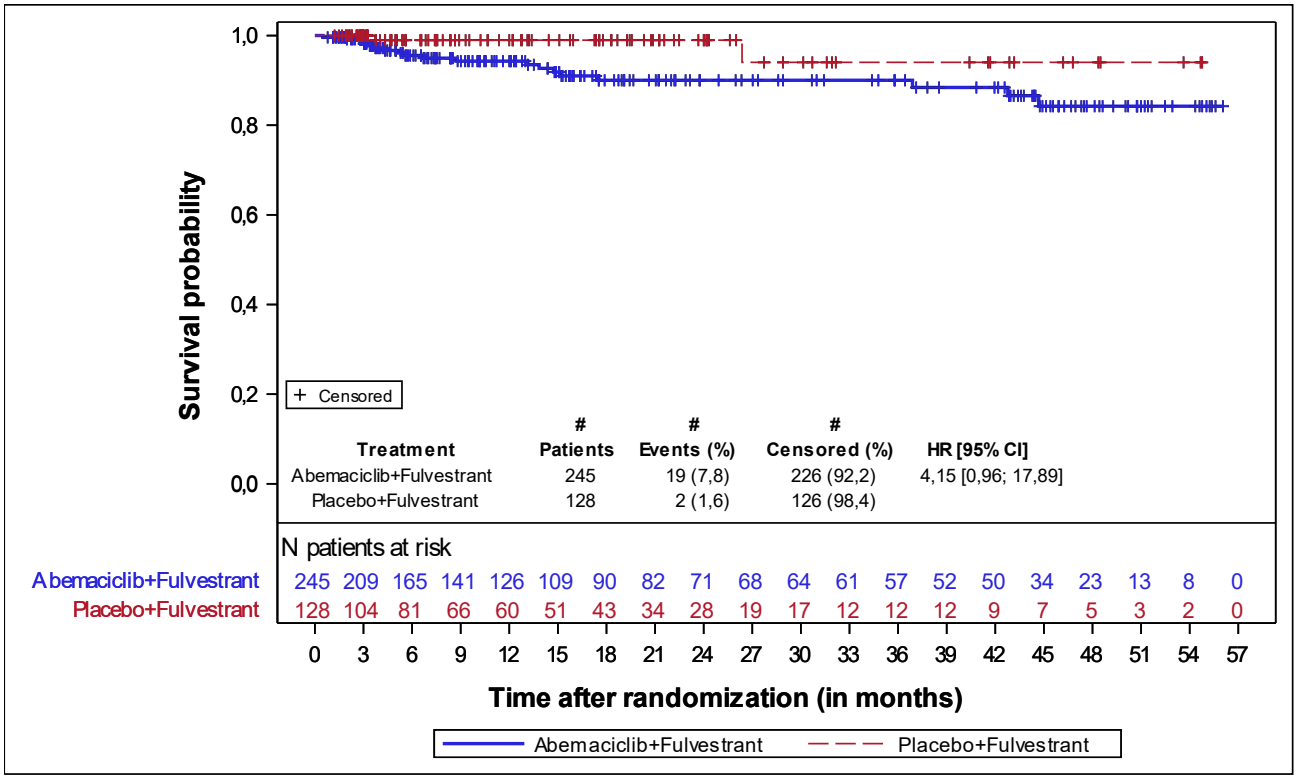
Figure 255: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according PT - Blood and lymphatic system disorders / Anaemia
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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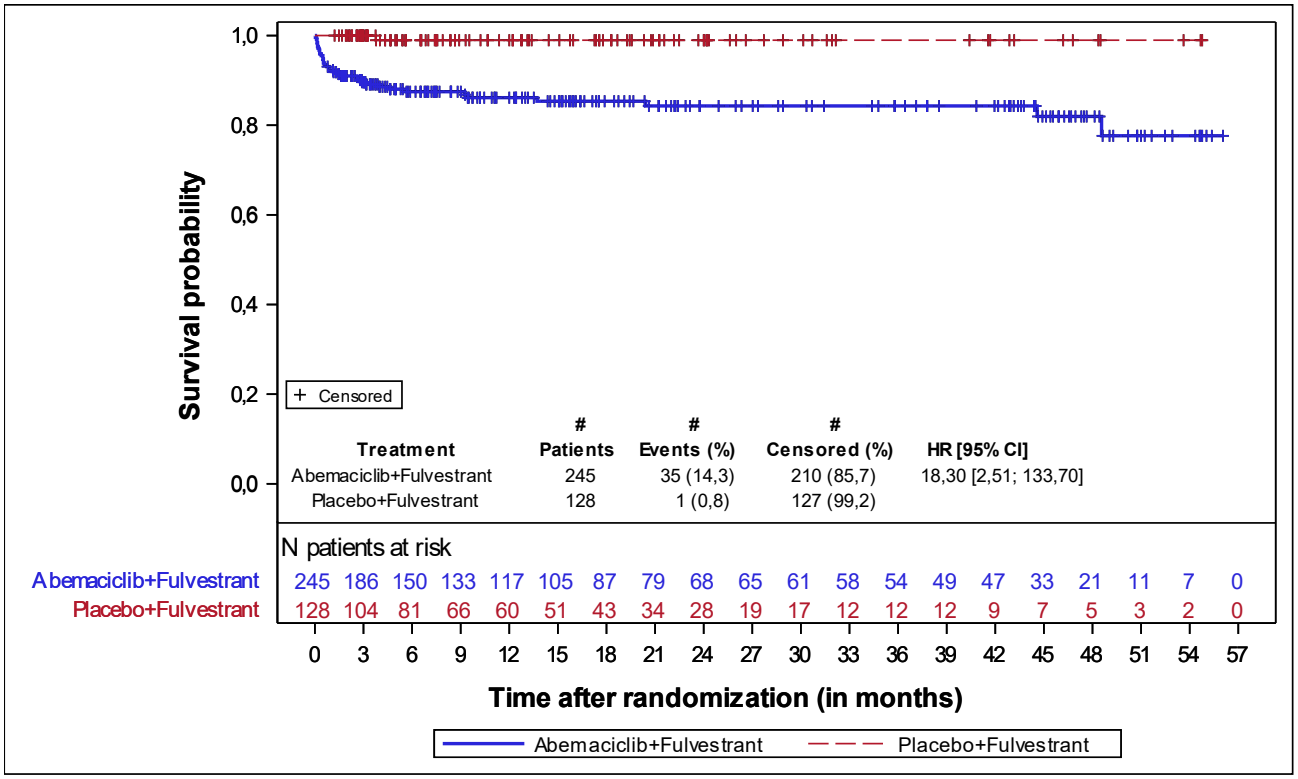
Figure 256: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according PT - Gastrointestinal disorders / Diarrhoea
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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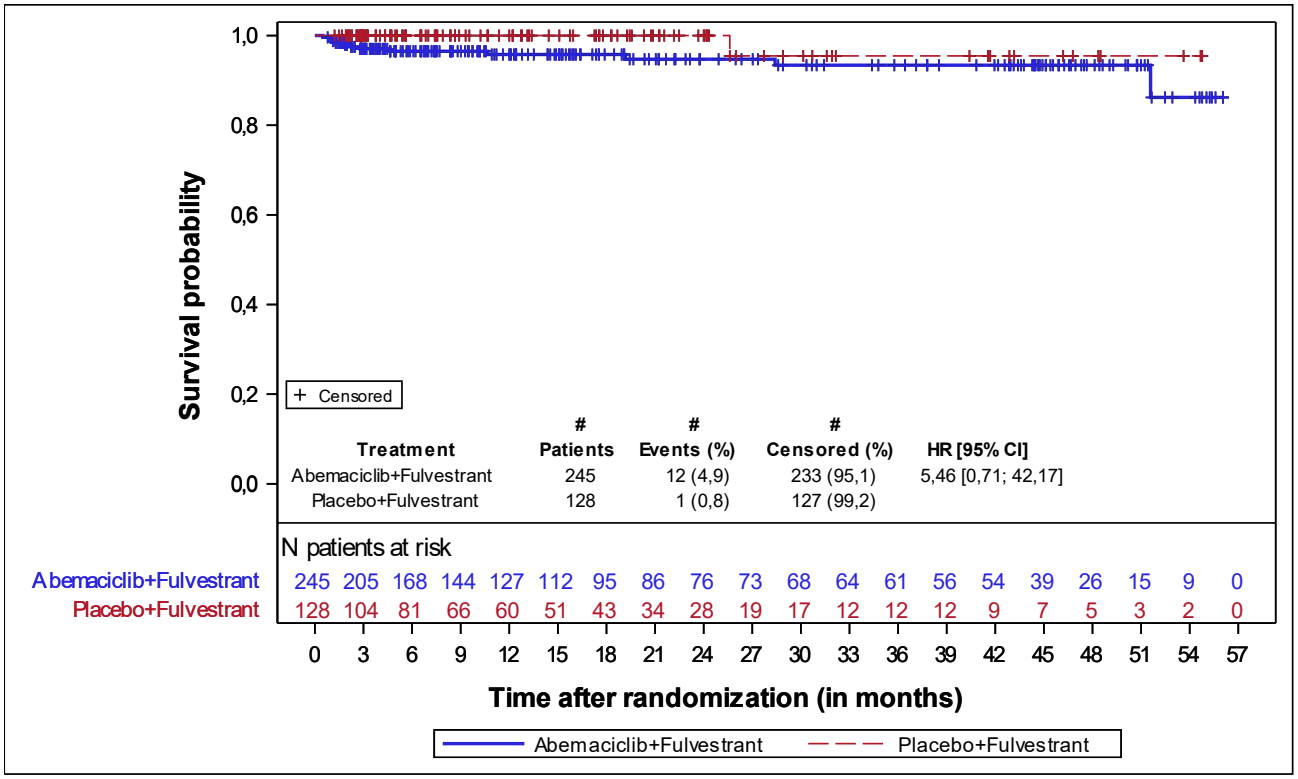
Figure 257: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according PT - Metabolism and nutrition disorders / Hypokalaemia
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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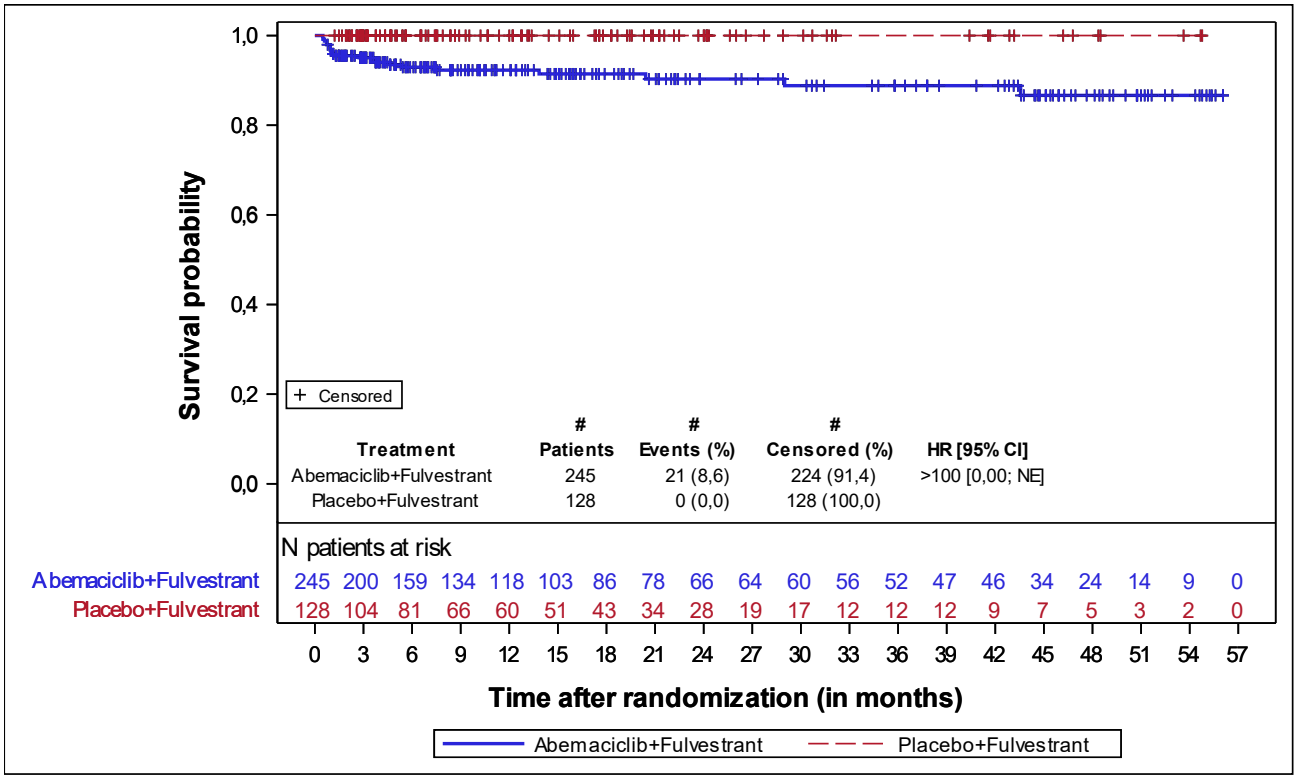
Figure 258: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according PT - Blood and lymphatic system disorders / Leukopenia
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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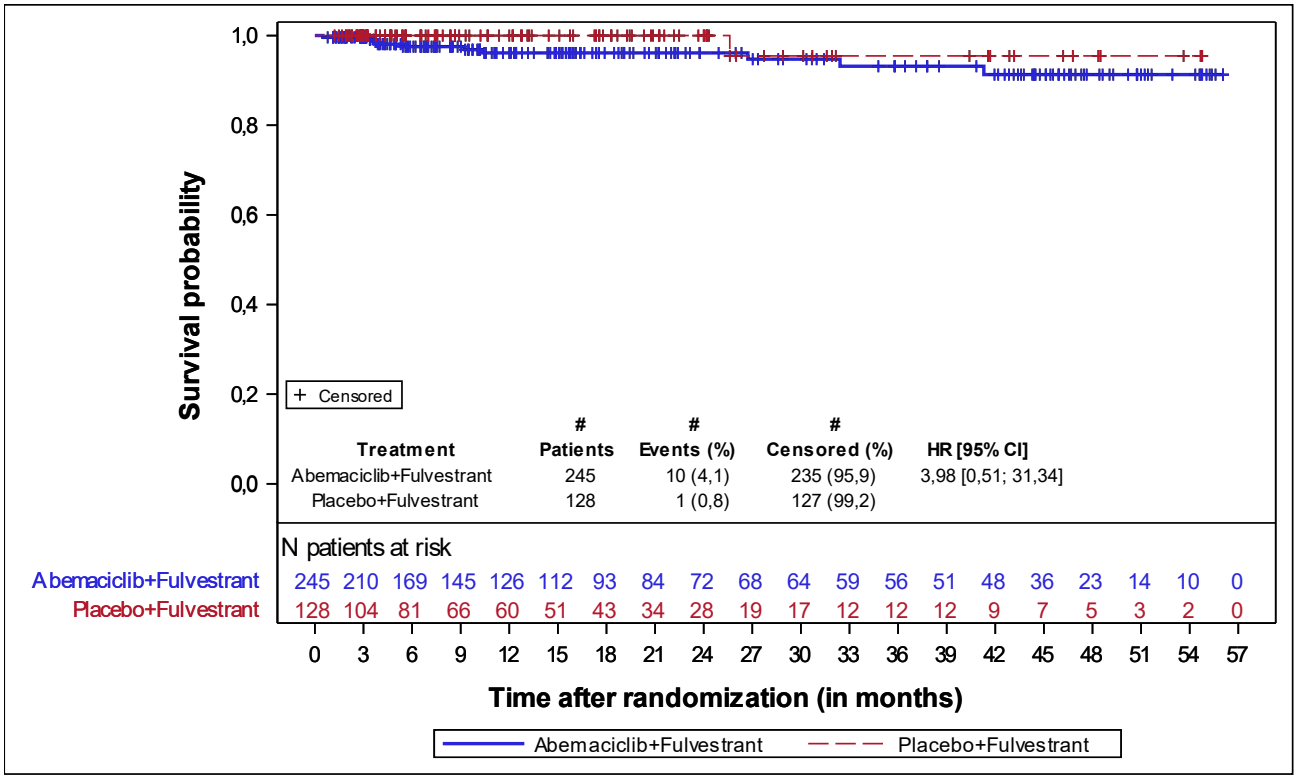
Figure 259: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according PT - Blood and lymphatic system disorders / Lymphopenia
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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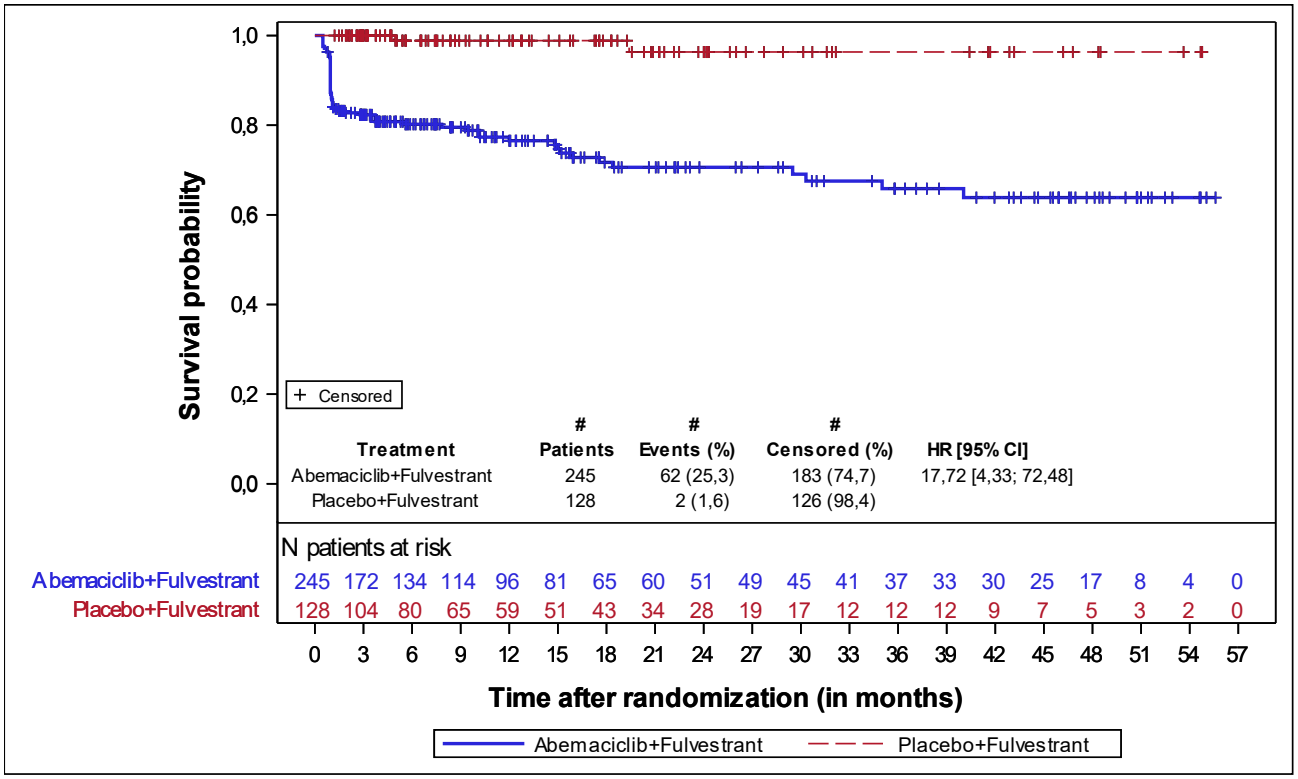
Figure 260: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according PT - Blood and lymphatic system disorders / Neutropenia
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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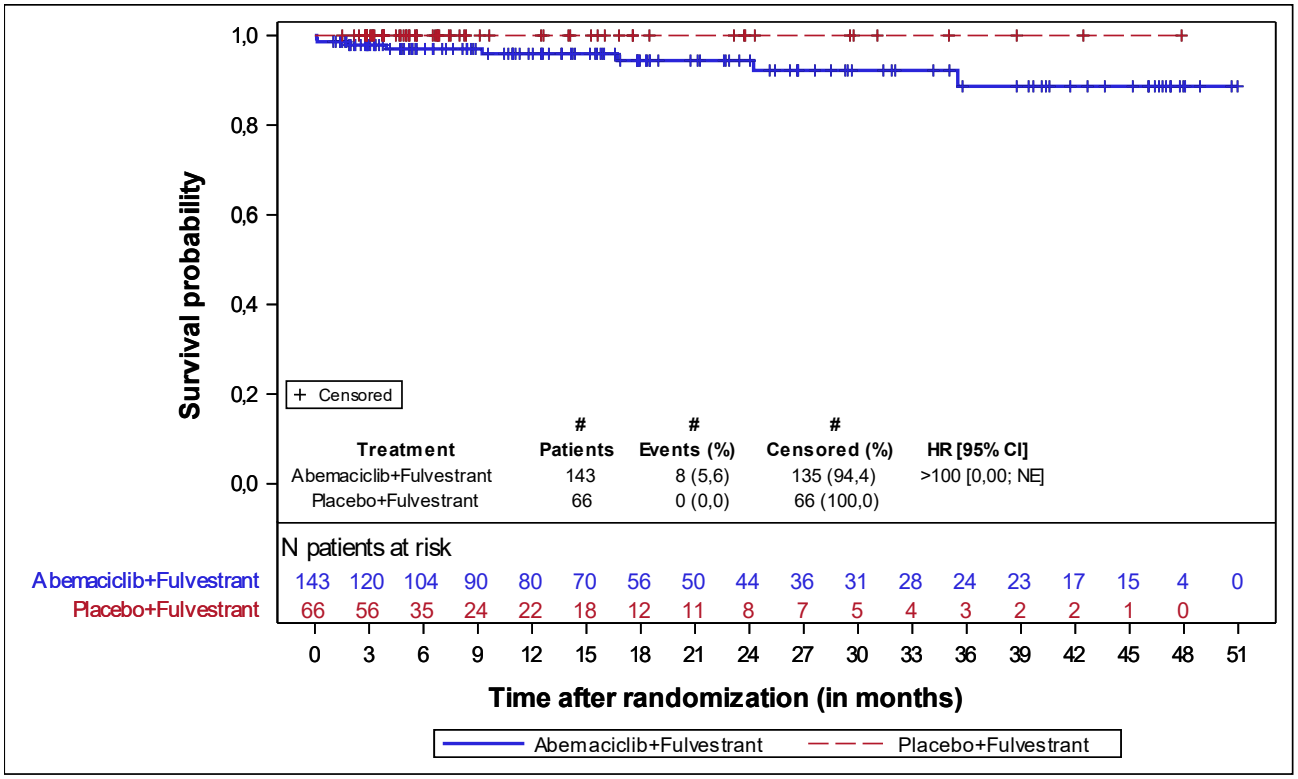
Figure 261: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according PT - Gastrointestinal disorders / Abdominal pain
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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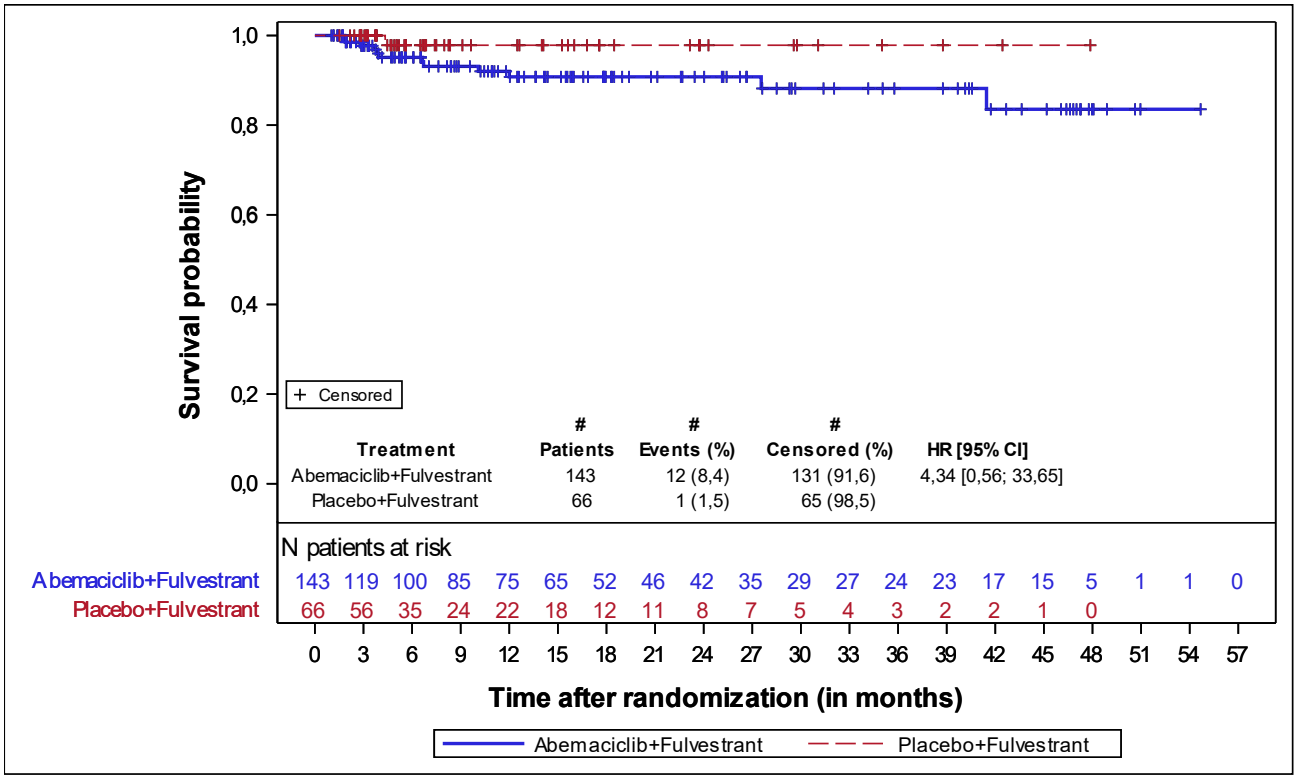
Figure 262: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according PT - Blood and lymphatic system disorders / Anaemia
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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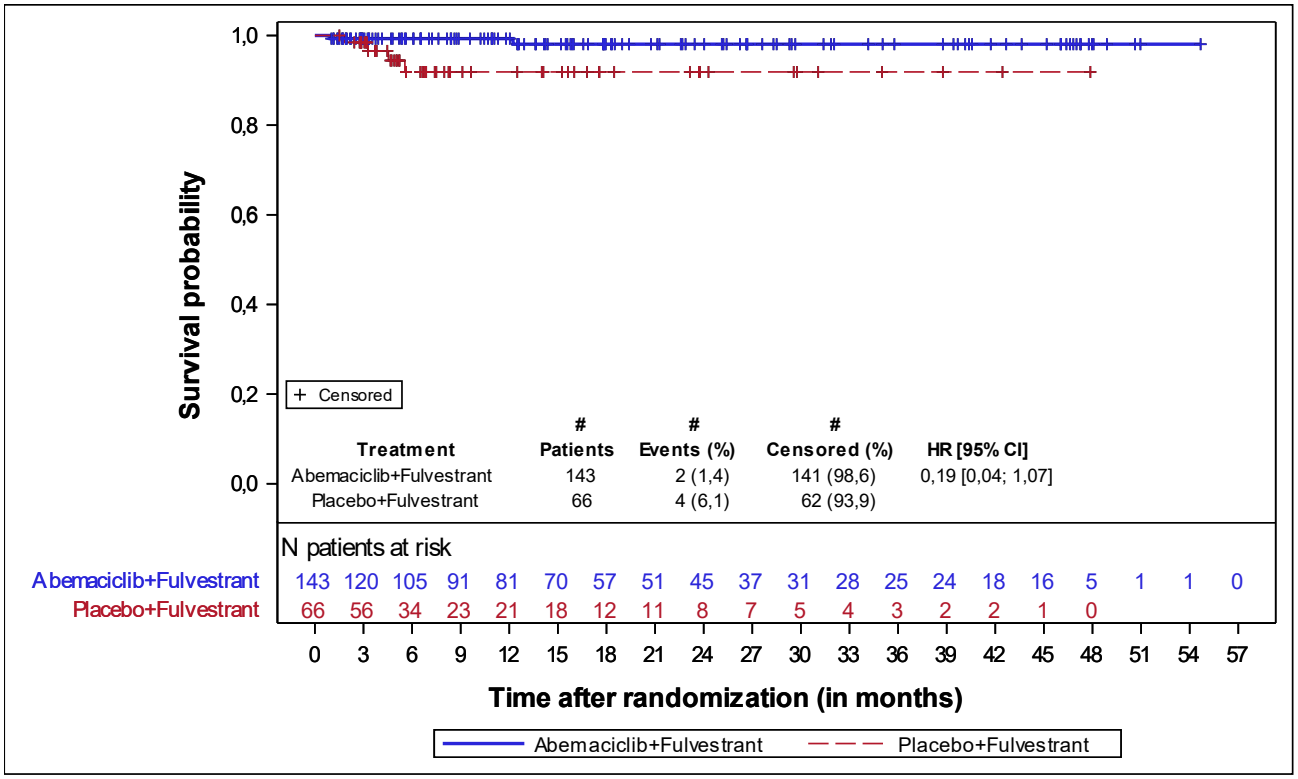
Figure 263: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according PT - Investigations / Aspartate aminotransferase increased
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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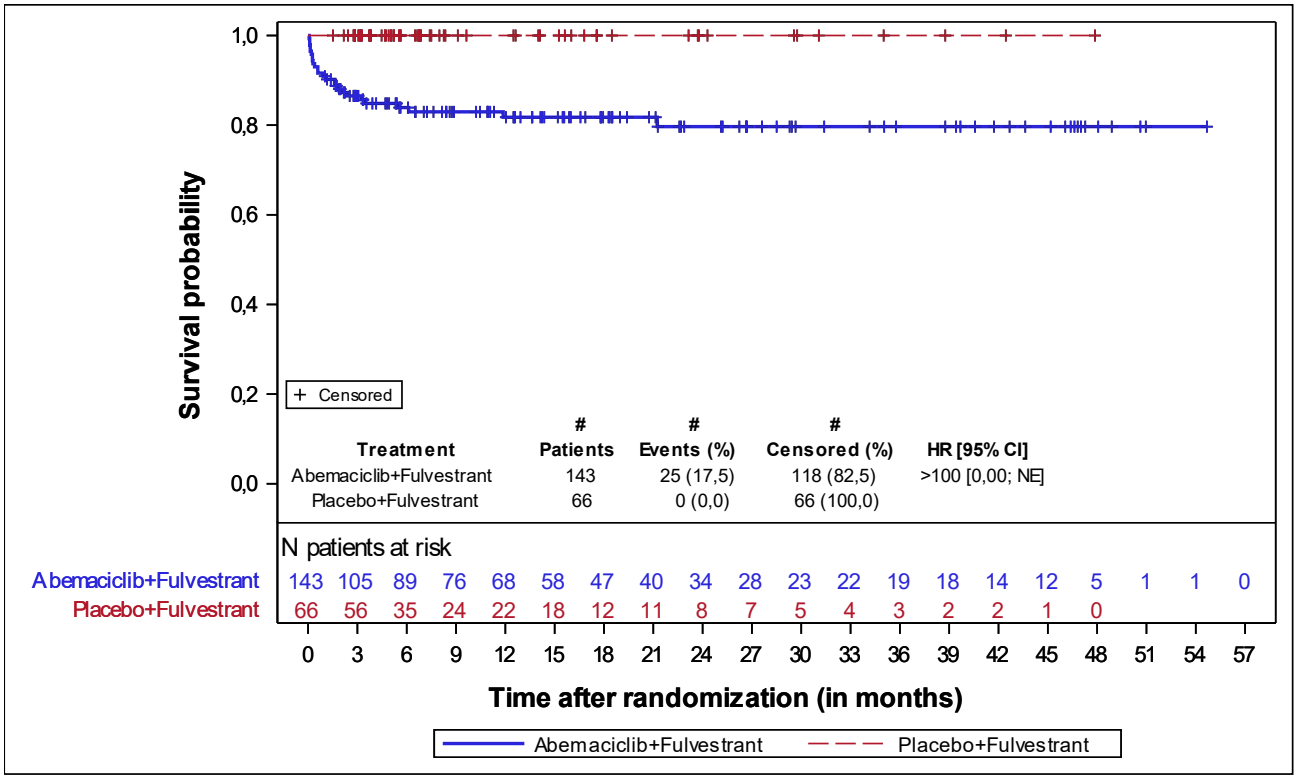
Figure 264: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according PT - Gastrointestinal disorders / Diarrhoea
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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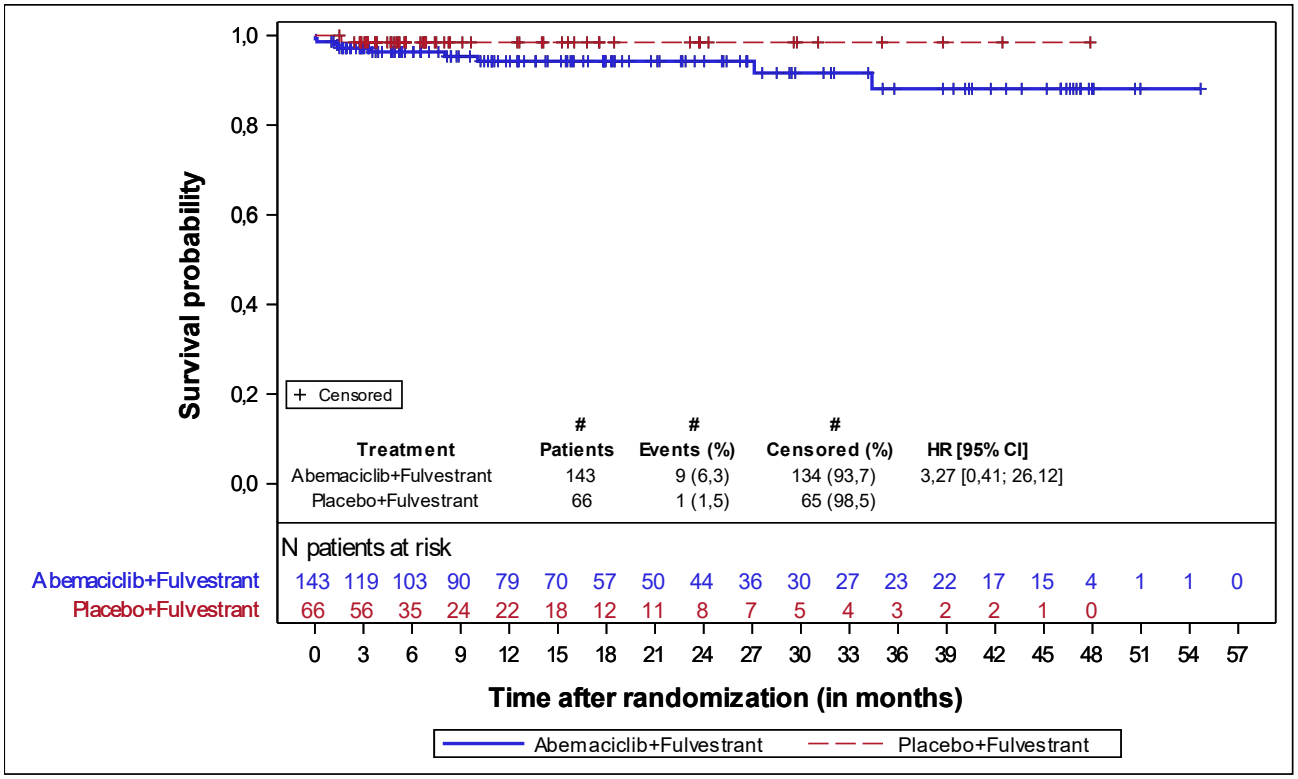
Figure 265: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according PT - General disorders and administration site conditions / Fatigue
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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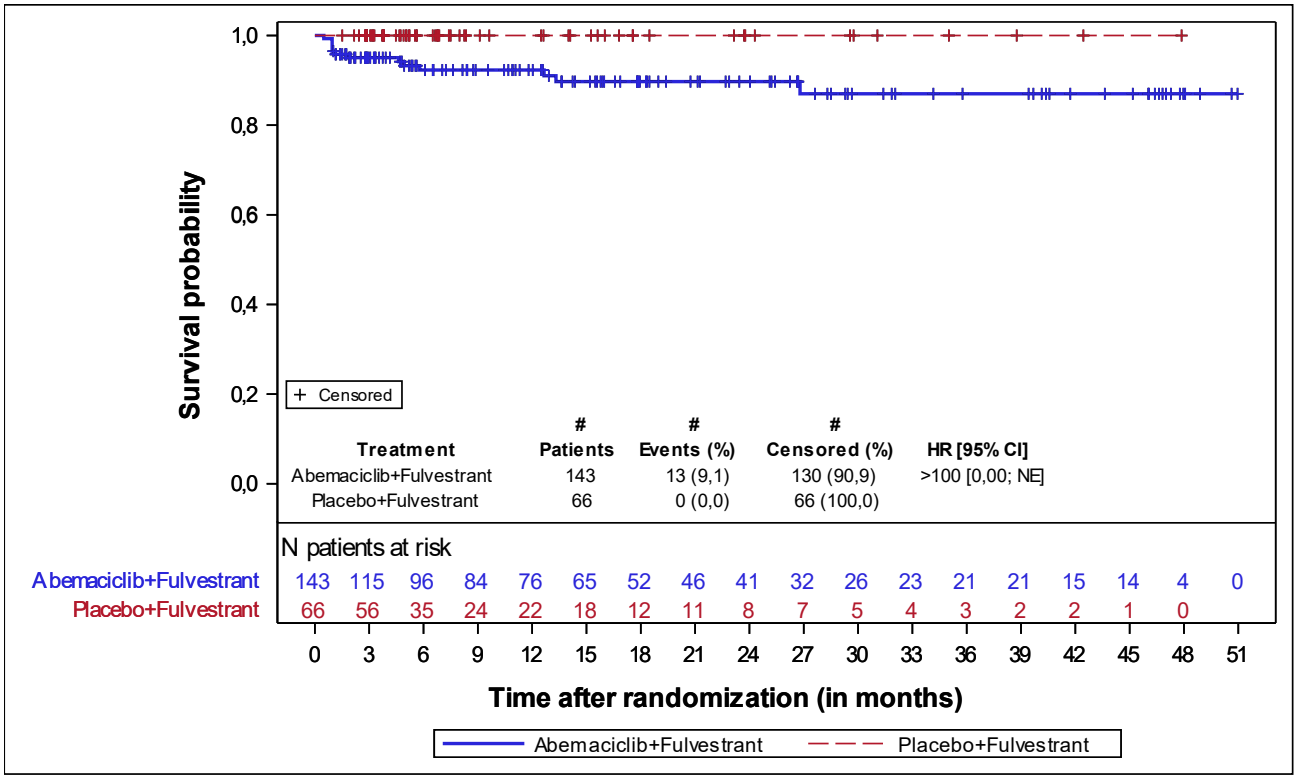
Figure 266: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according PT - Blood and lymphatic system disorders / Leukopenia
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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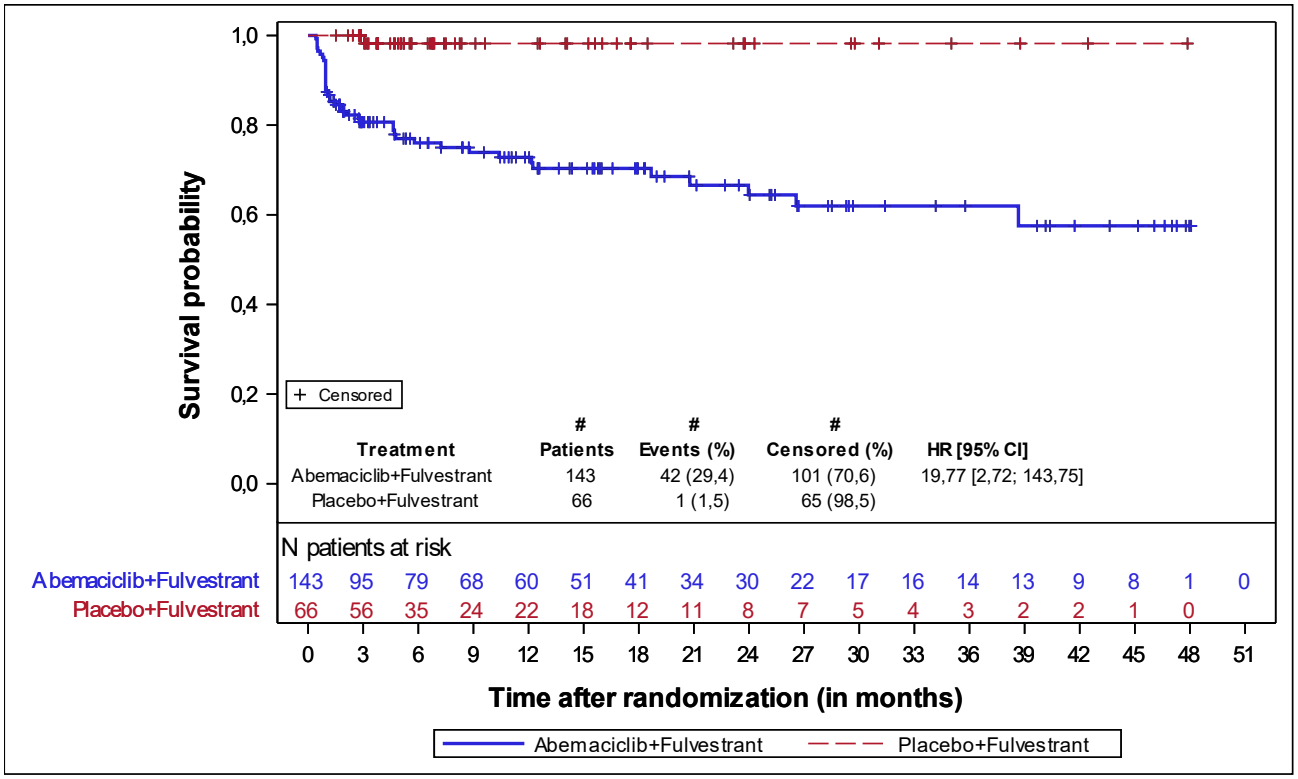
08JUL2021 / 02:43

Figure 267: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according PT - Blood and lymphatic system disorders / Neutropenia
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; N: Number; NE: Not evaluable/not reached; PT: Preferred Term
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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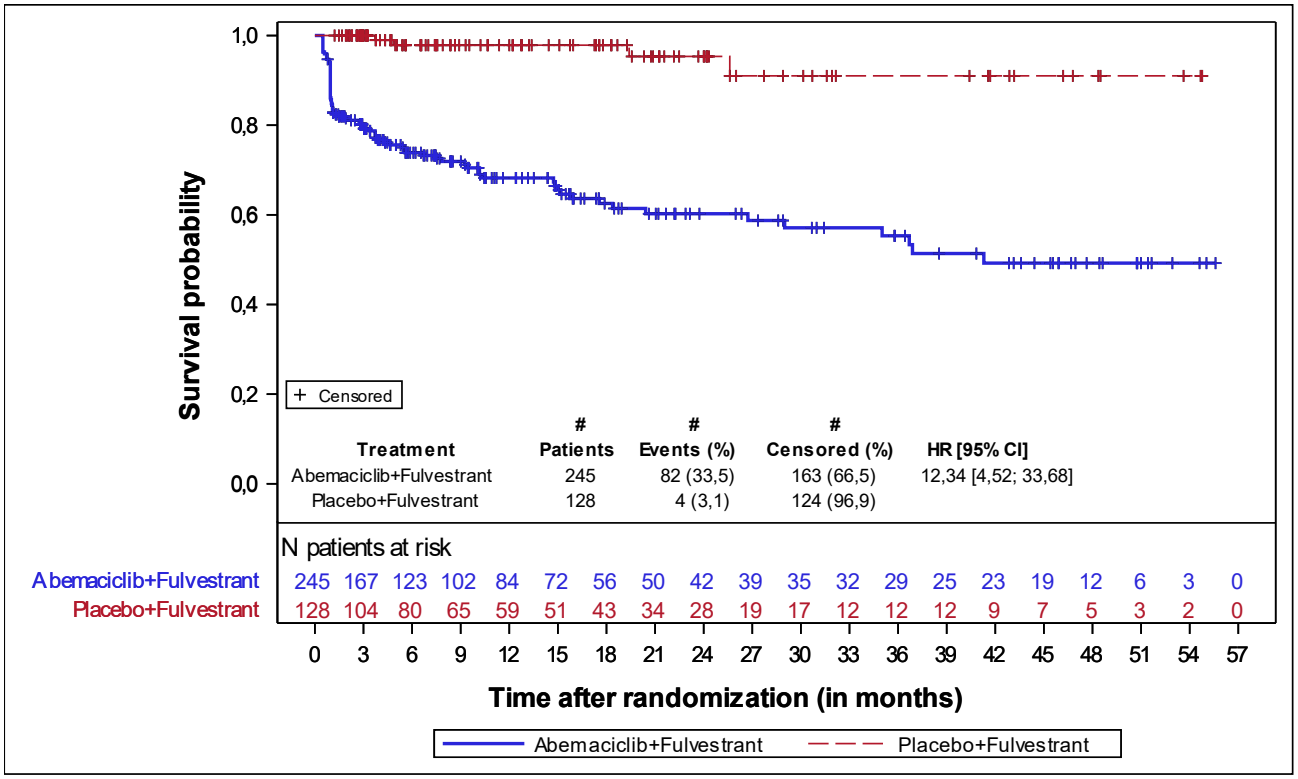
Figure 268: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according SOC - Blood and lymphatic system disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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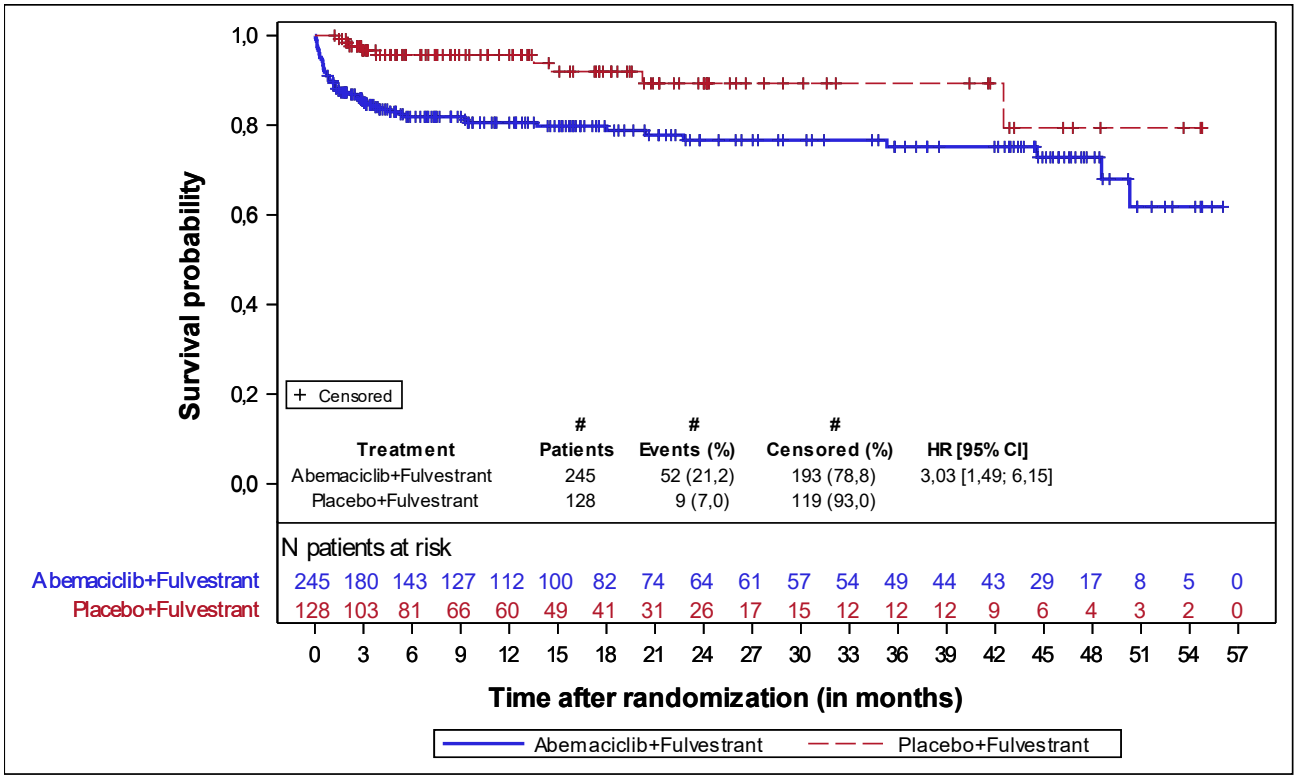
Figure 269: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according SOC - Gastrointestinal disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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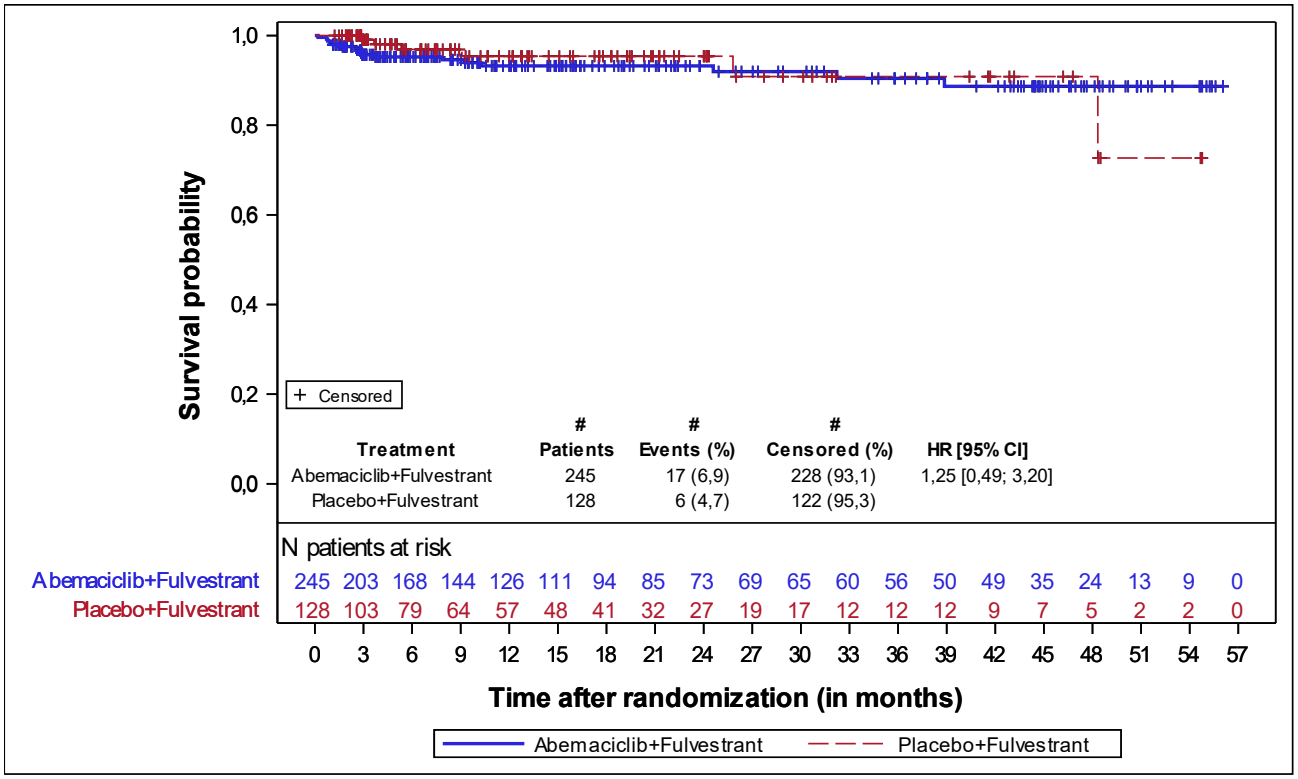
08JUL2021 / 02:43

Figure 270: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according SOC - General disorders and administration site conditions
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttirgr3s003_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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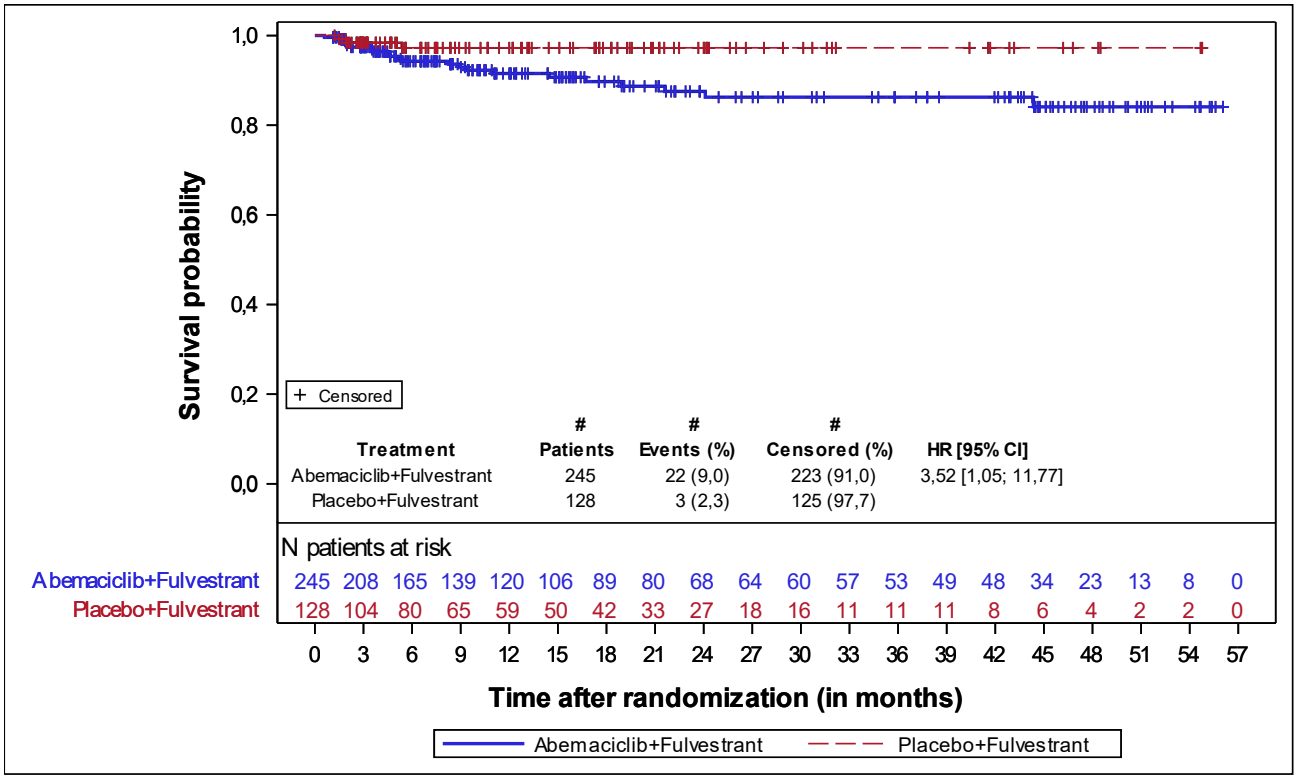
Figure 271: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according SOC - Infections and infestations
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttirgr3s004_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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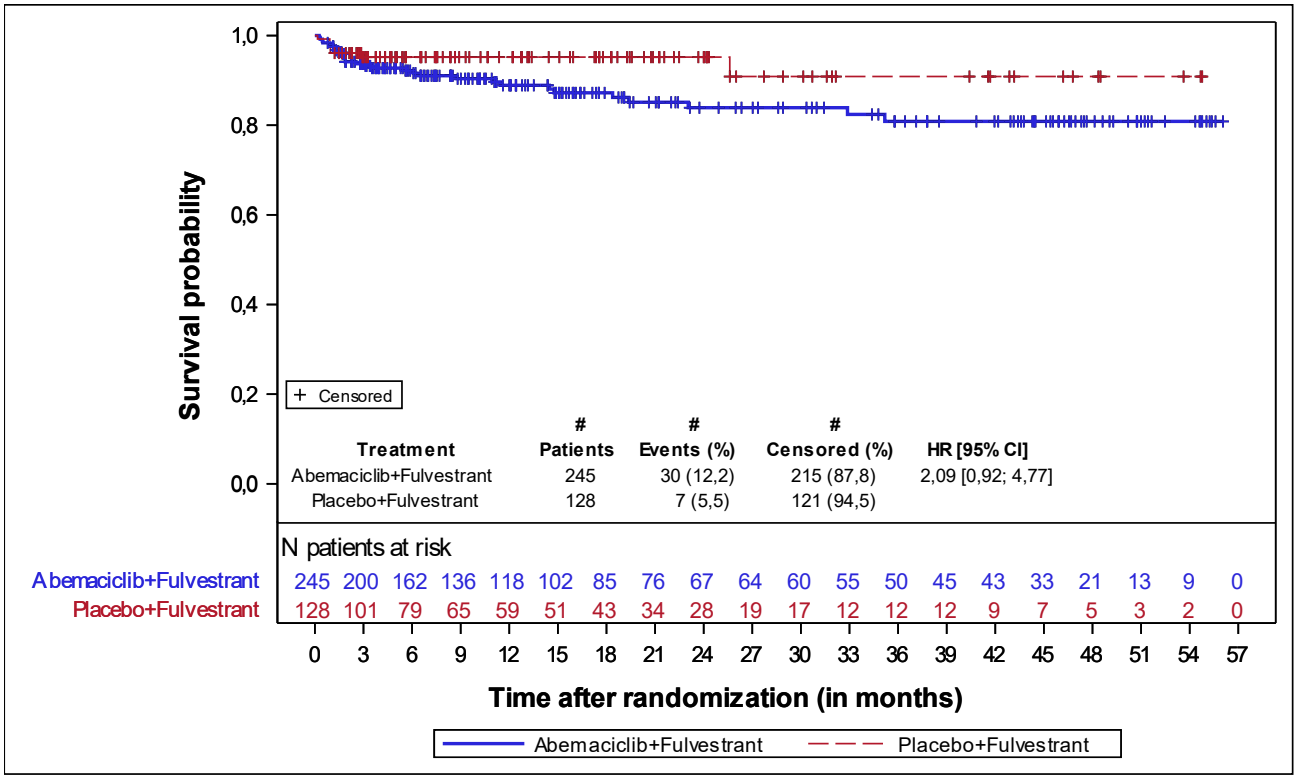
Figure 272: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according SOC - Investigations
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttirgr3s005_popa1.rtf
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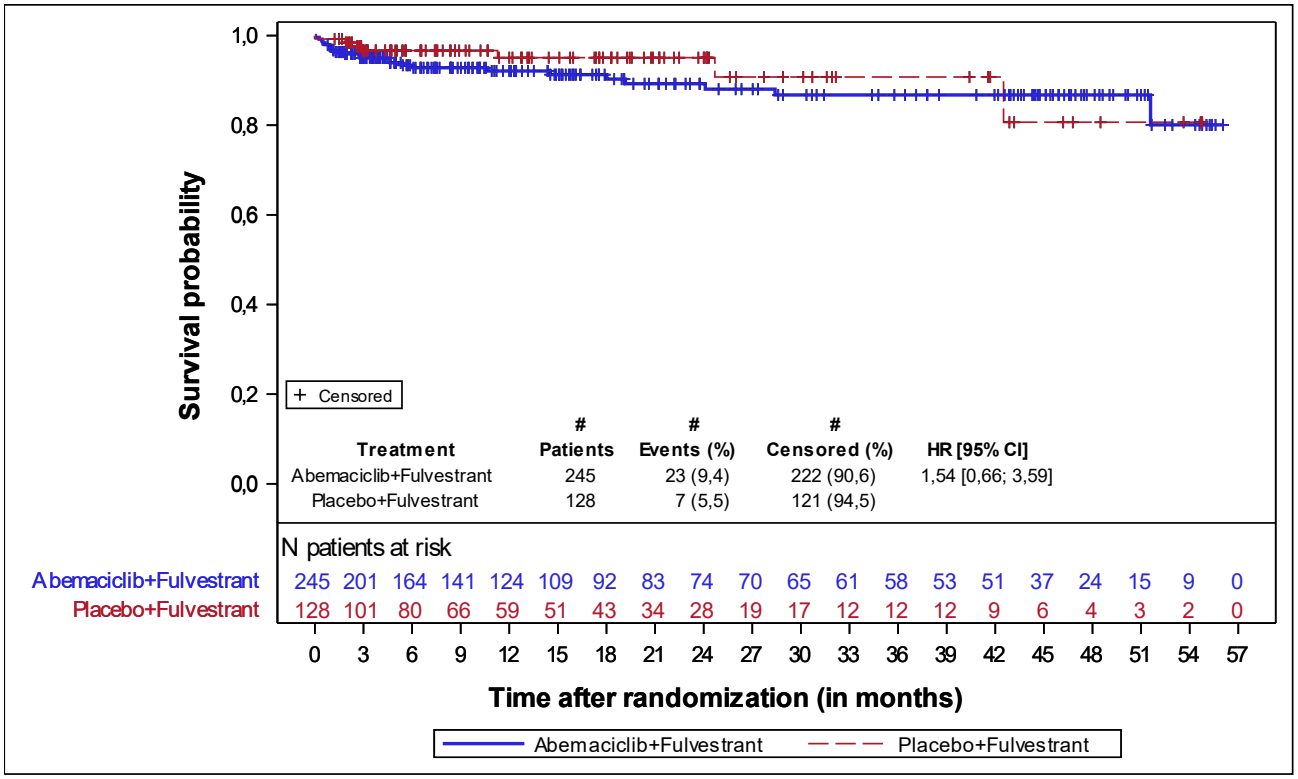
Figure 273: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according SOC - Metabolism and nutrition disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttirgr3s006_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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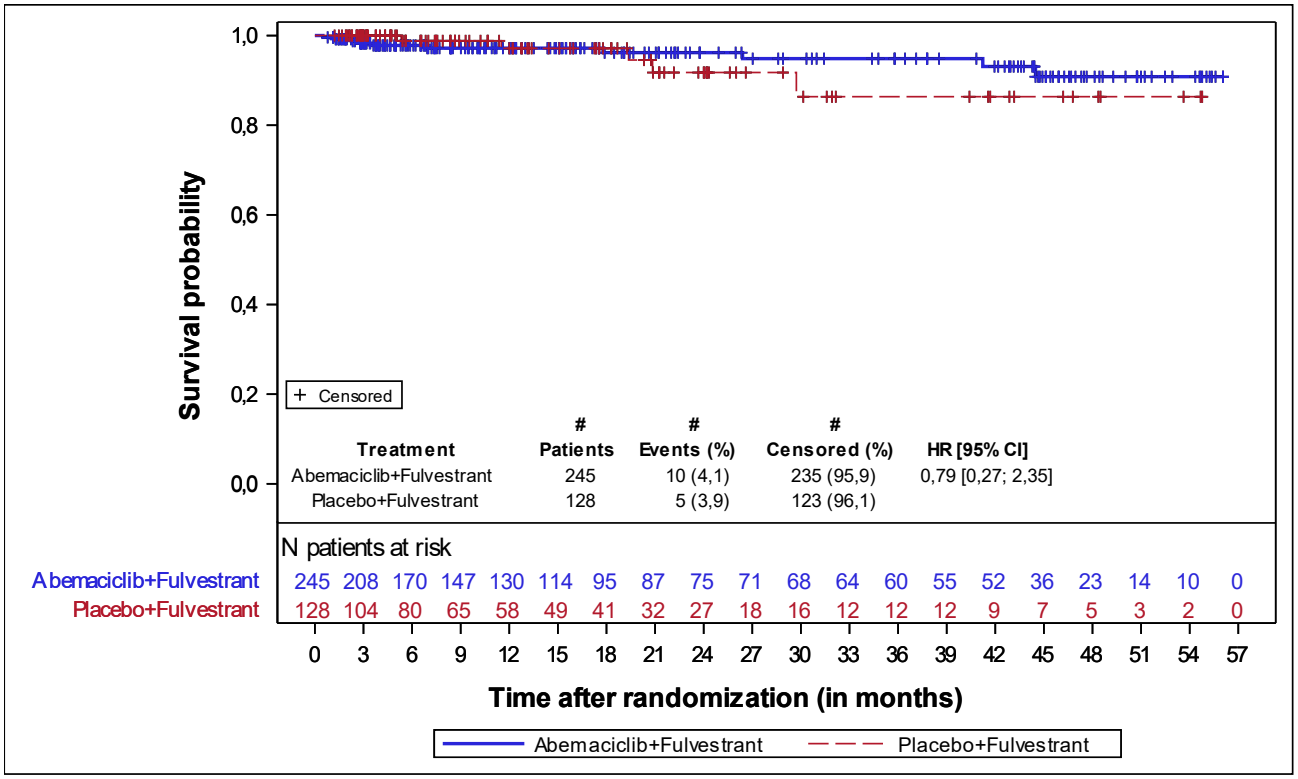
Figure 274: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according SOC - Nervous system disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttirgr3s007_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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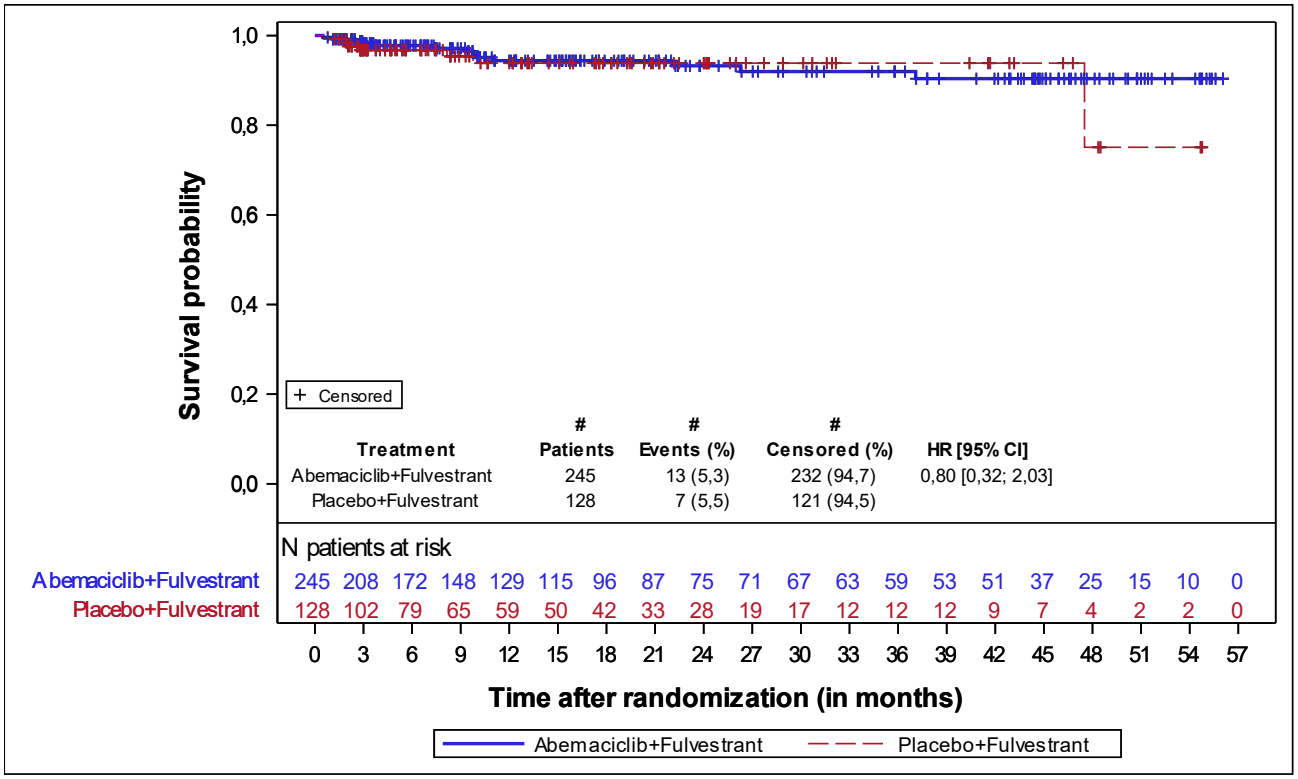
Figure 275: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according SOC - Respiratory, thoracic and mediastinal disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttirgr3s008_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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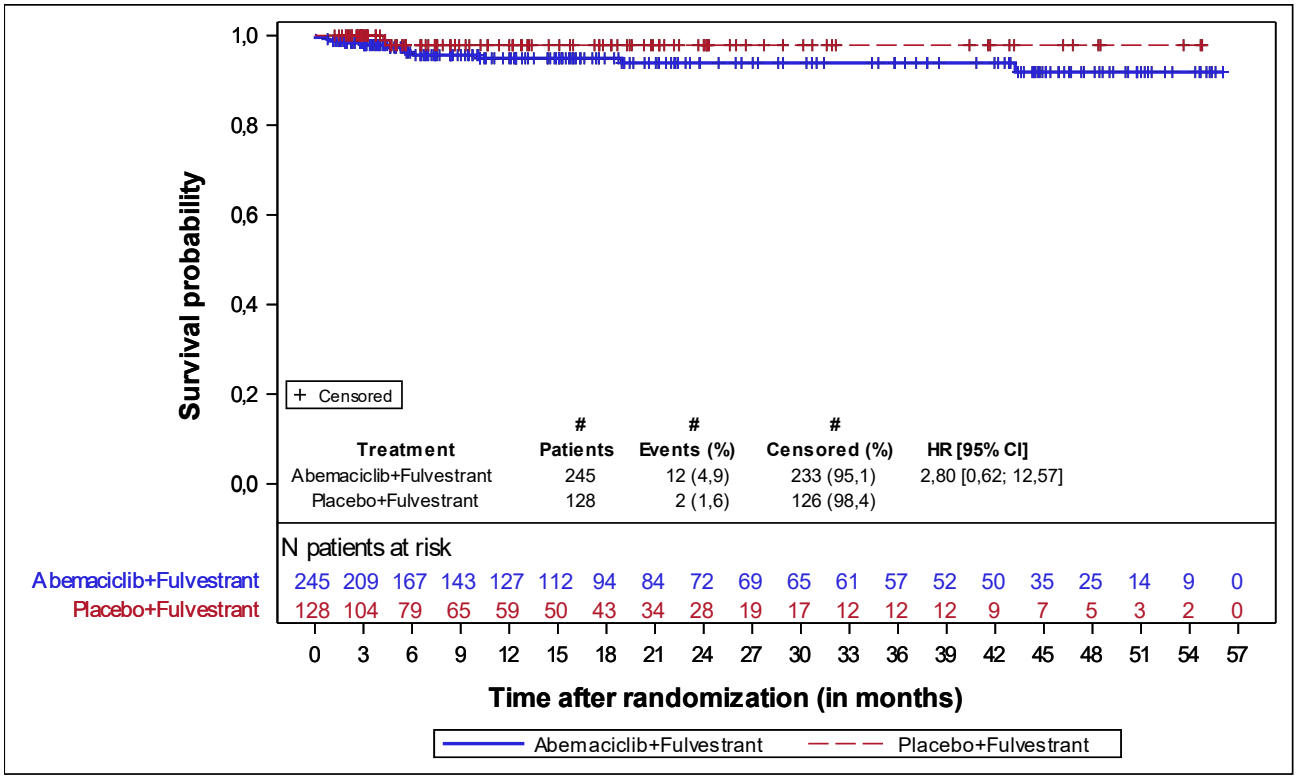
Figure 276: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according SOC - Vascular disorders
Safety Population - Postmenopausal (1st line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttirgr3s009_popa1.rtf
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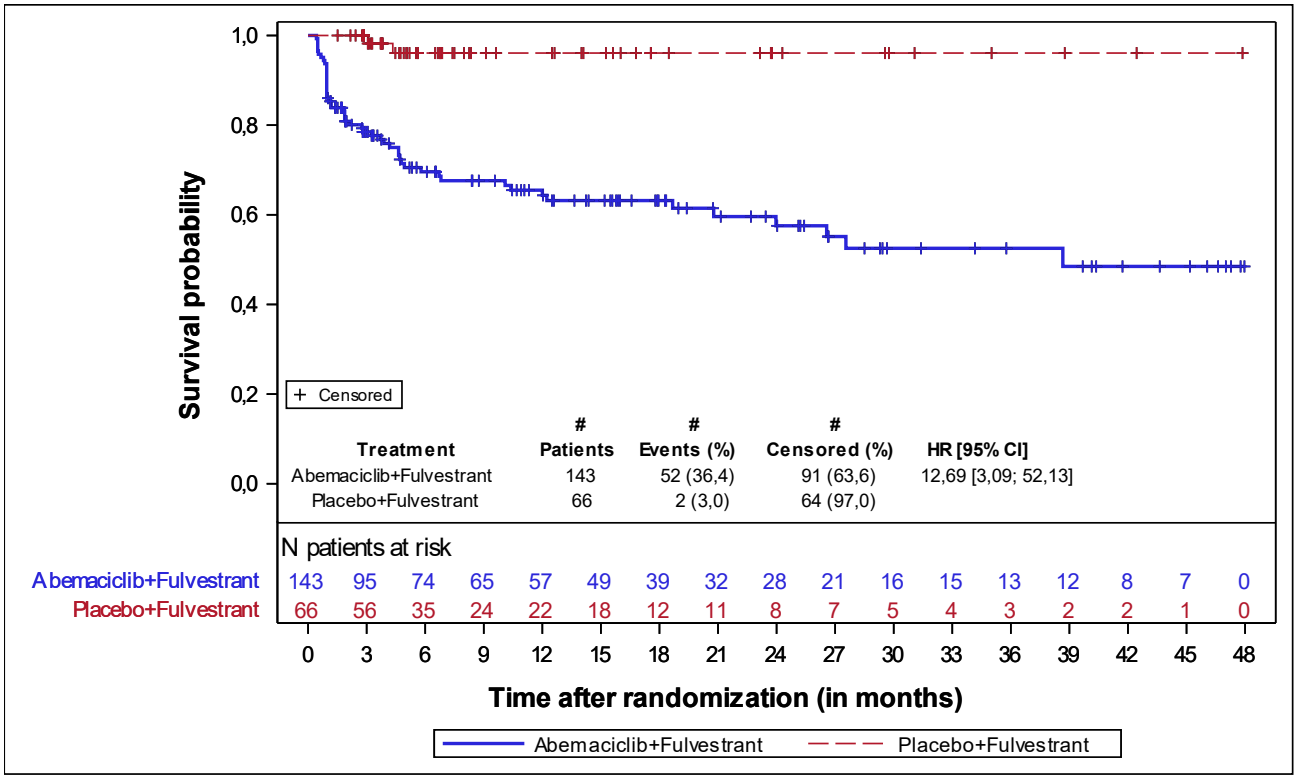
Figure 277: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according SOC - Blood and lymphatic system disorders
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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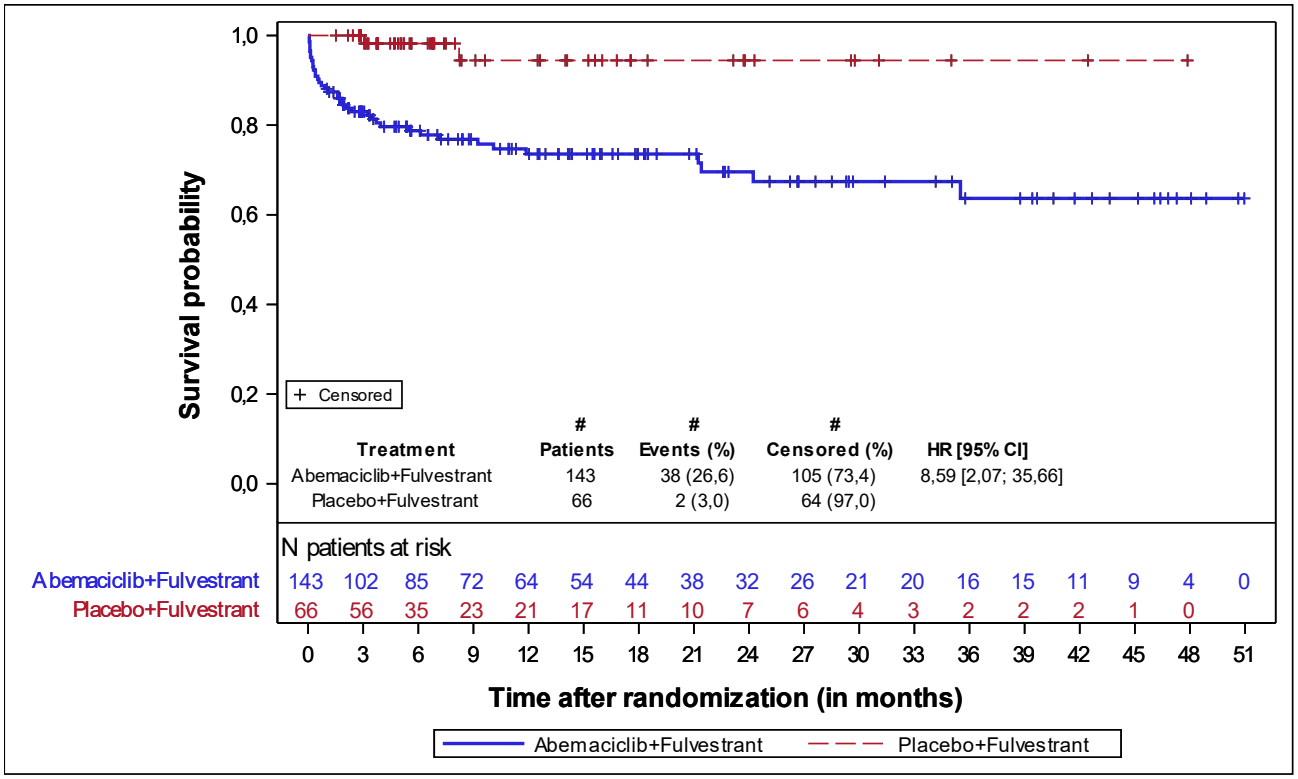
Figure 278: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according SOC - Gastrointestinal disorders
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttirgr3s002_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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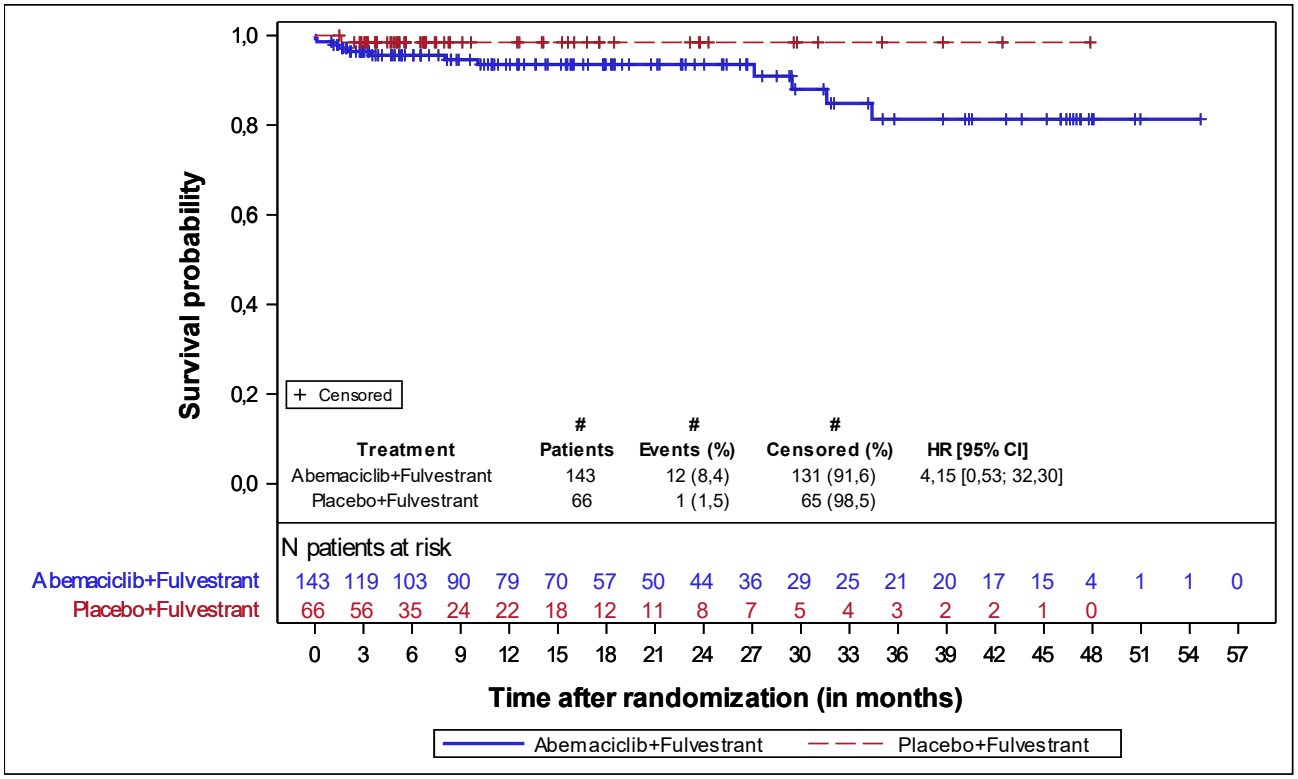
Figure 279: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according SOC - General disorders and administration site conditions
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttirgr3s003_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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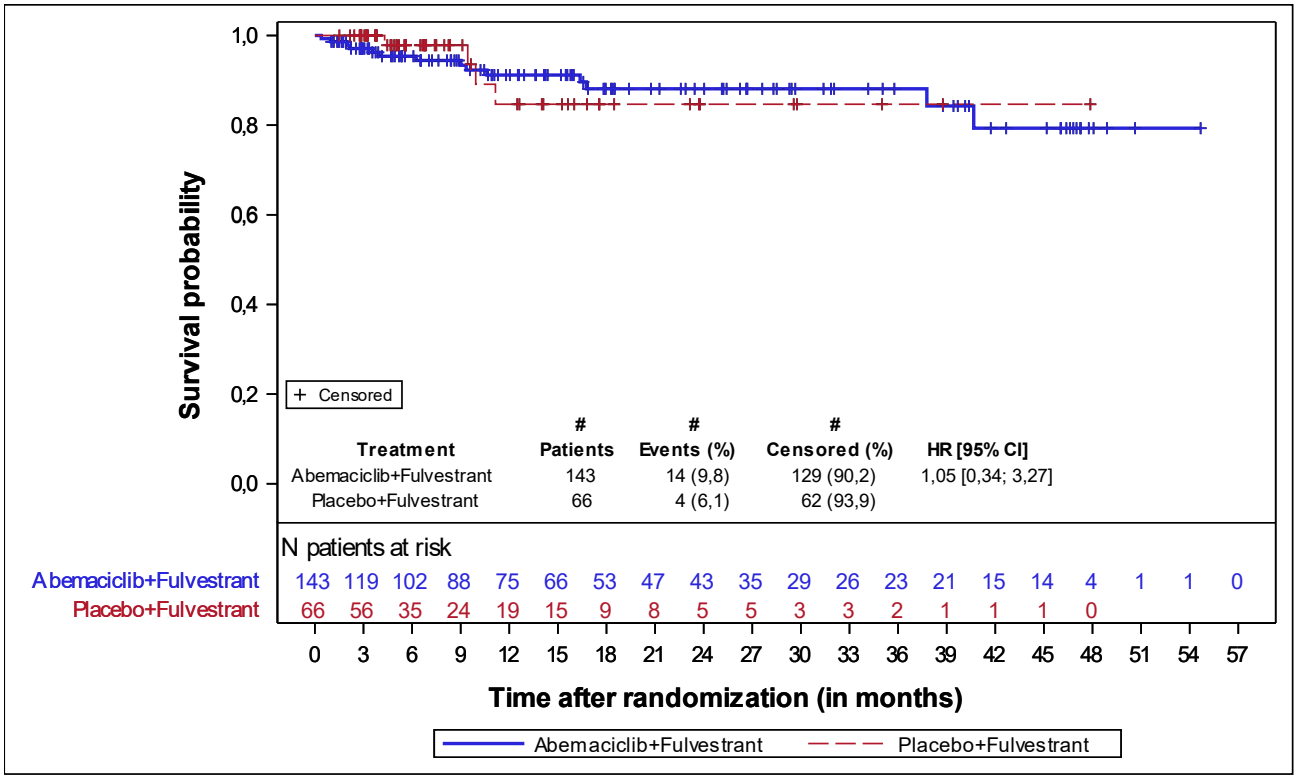
Figure 280: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according SOC - Infections and infestations
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttirgr3s004_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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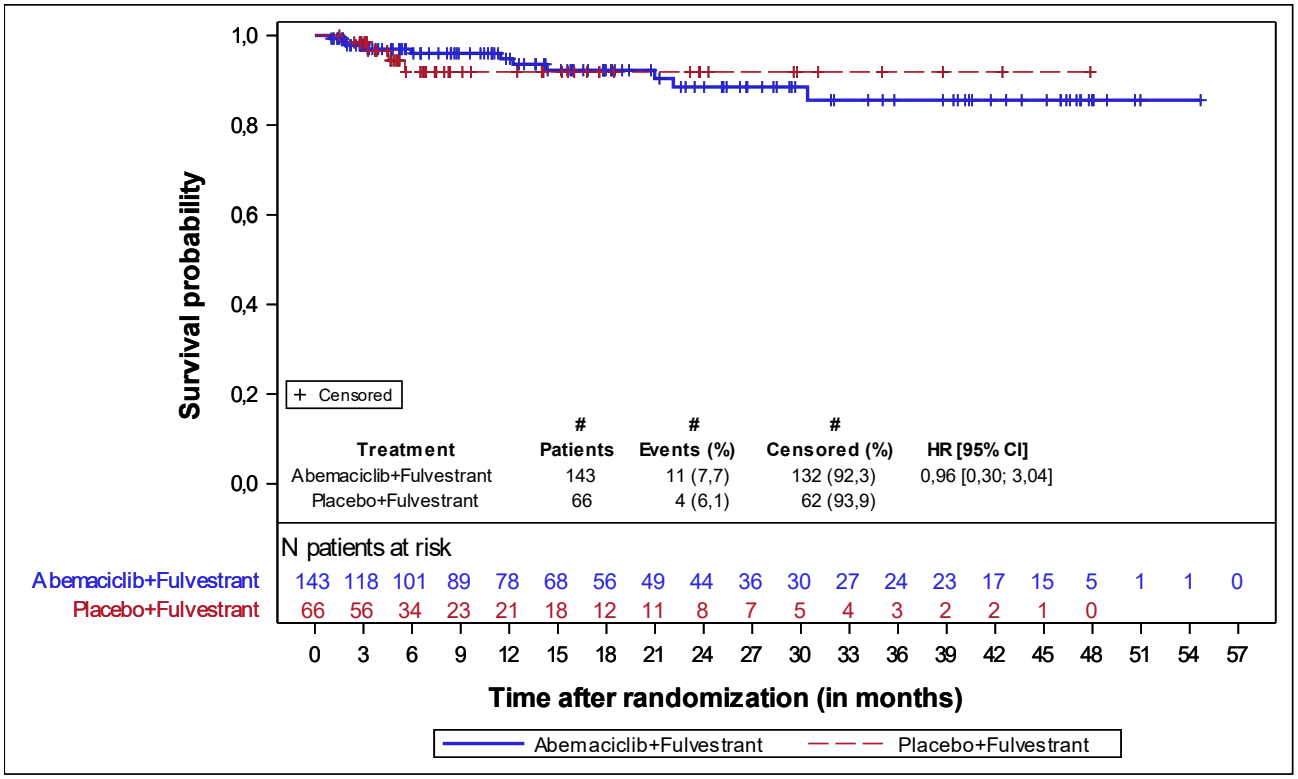
Figure 281: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according SOC - Investigations
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttirgr3s005_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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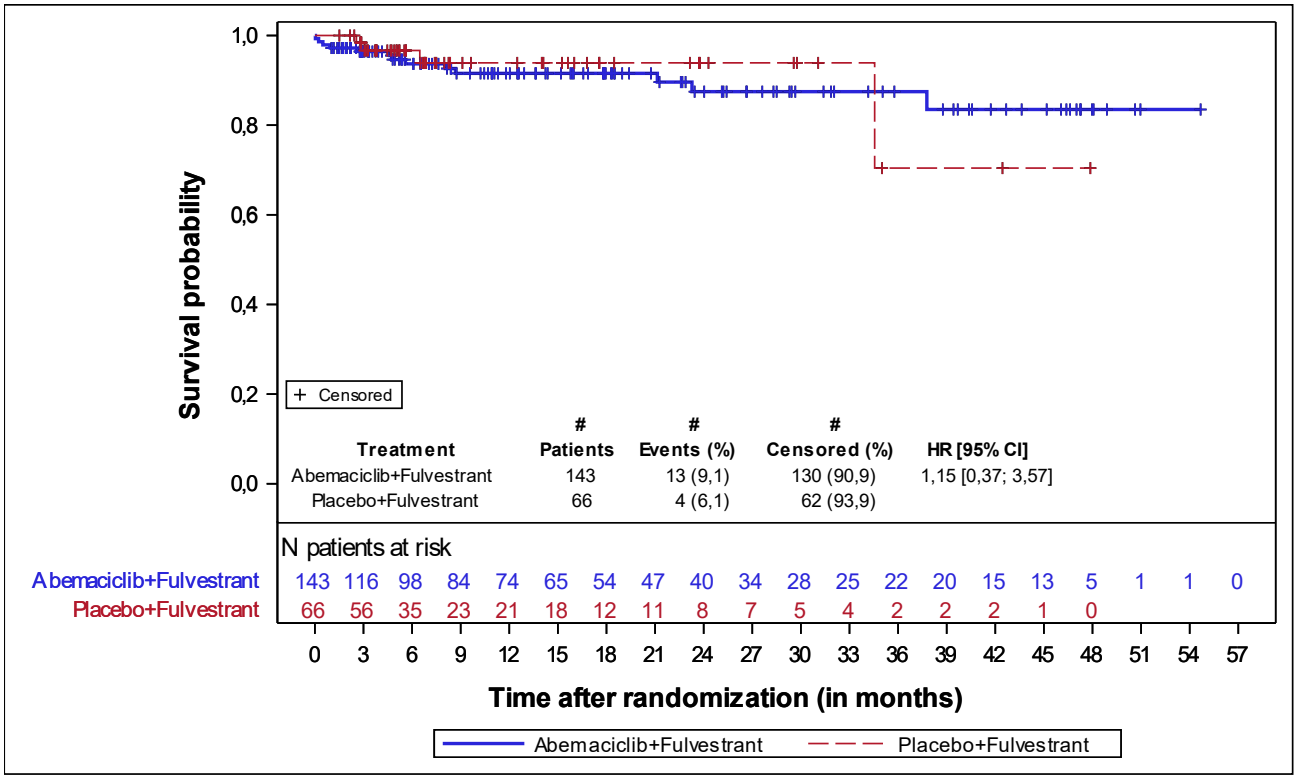
Figure 282: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according SOC - Metabolism and nutrition disorders
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttirgr3s006_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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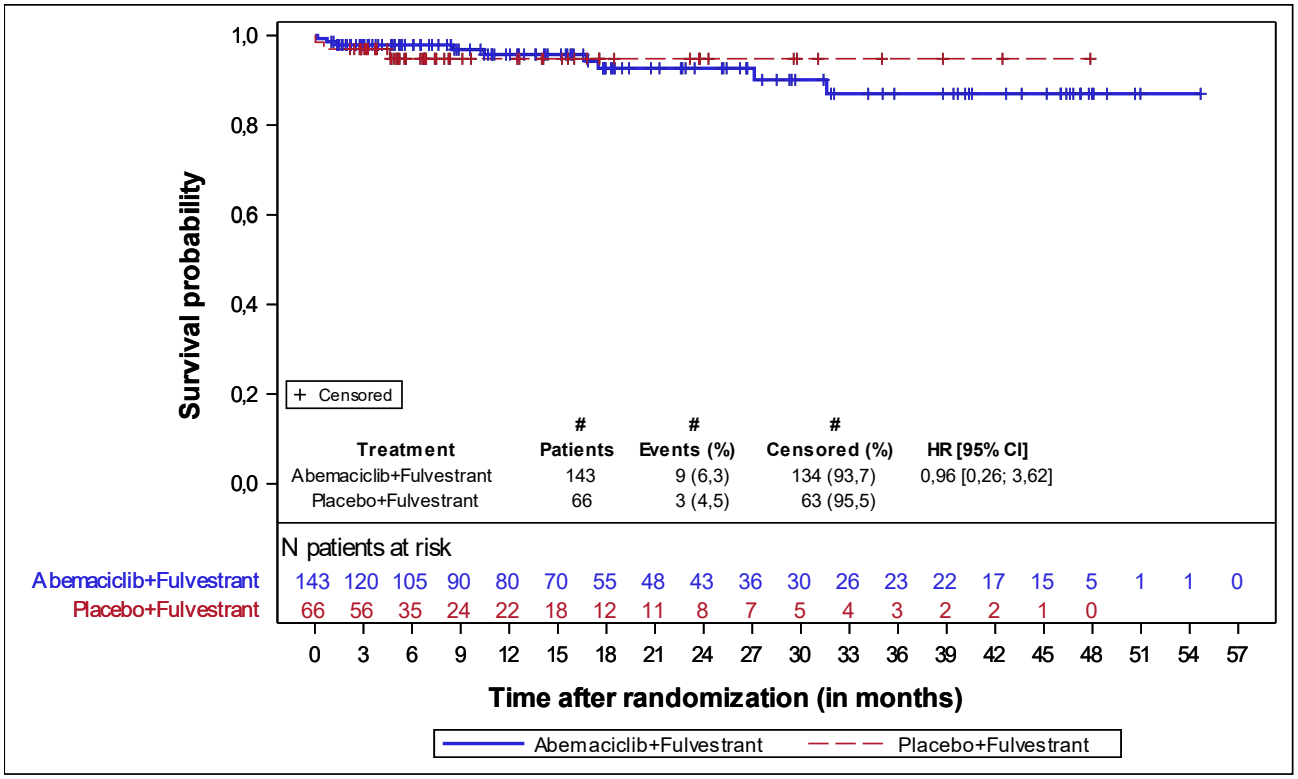
Figure 283: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according SOC - Musculoskeletal and connective tissue disorders
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttirgr3s007_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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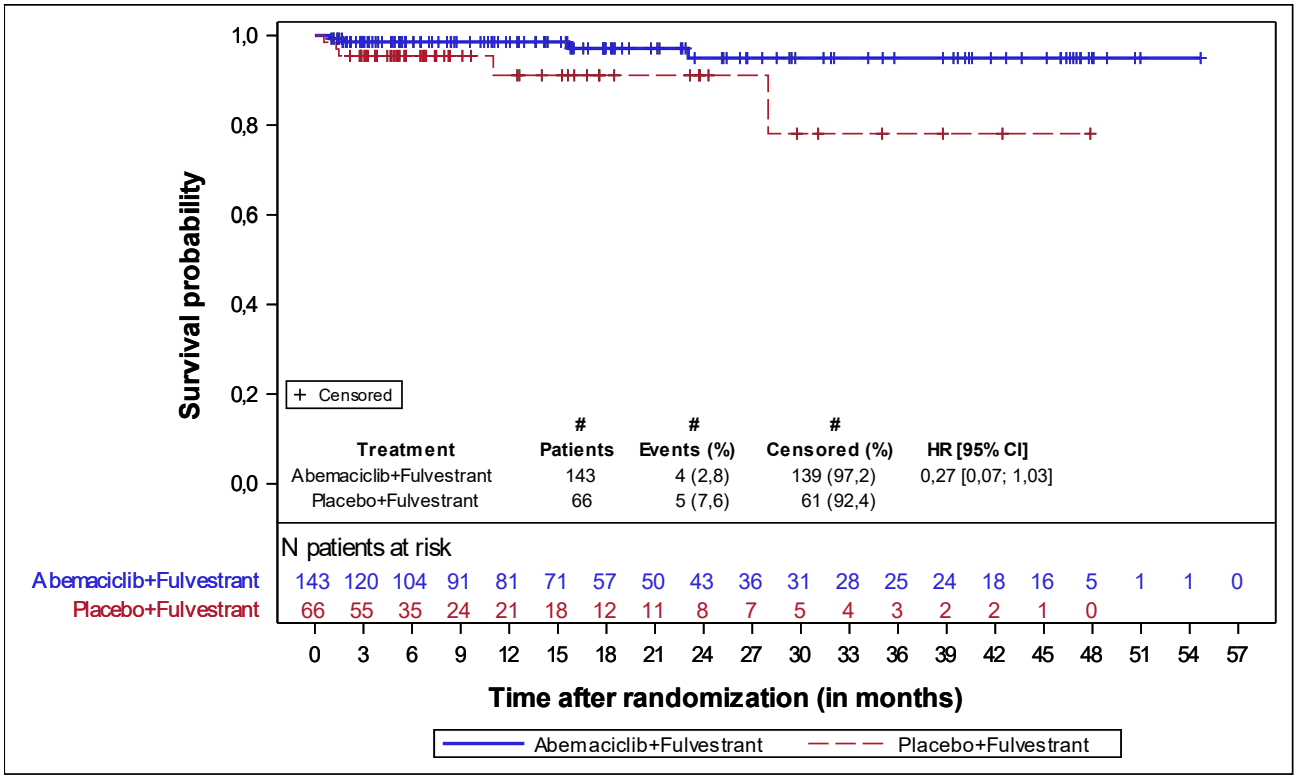
Figure 284: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according SOC - Respiratory, thoracic and mediastinal disorders
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttirgr3s008_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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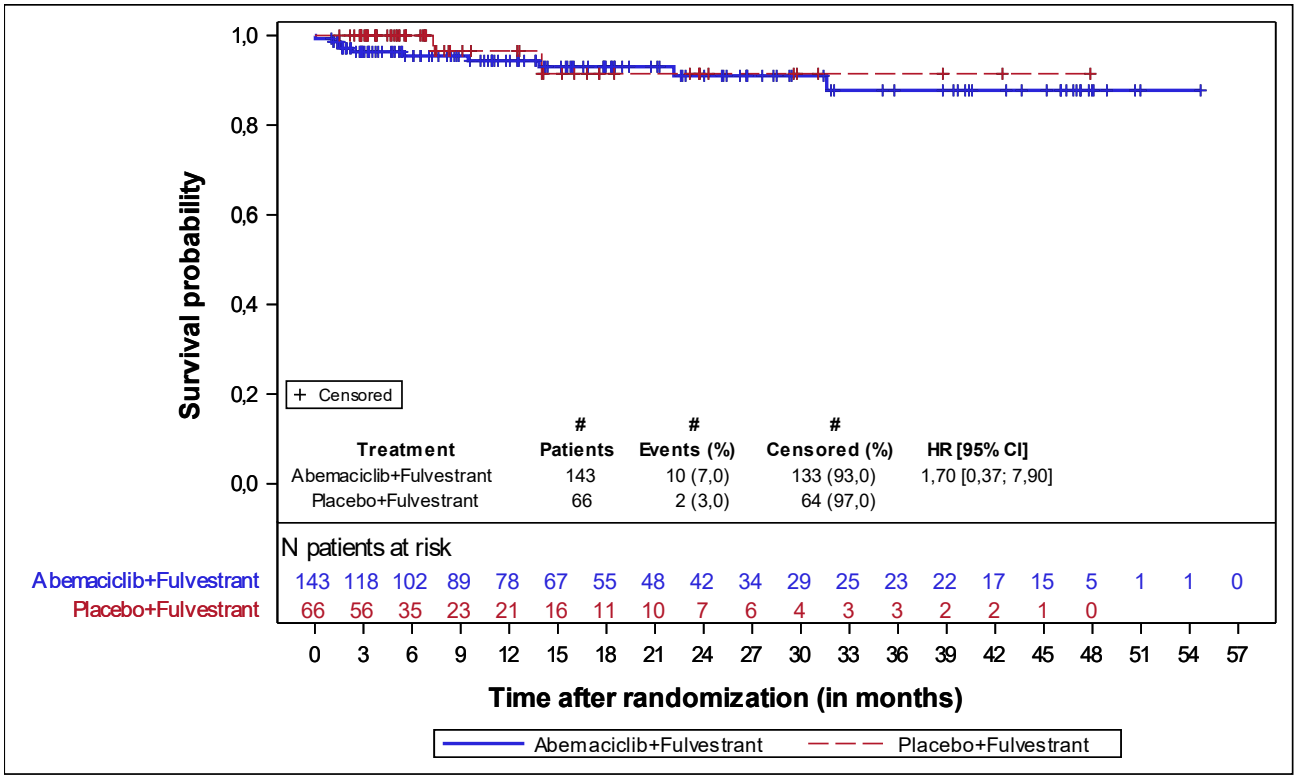
Figure 285: Kaplan-Meier curves for adverse events with CTCAE Grade ≥ 3 according SOC - Vascular disorders
Safety Population - Postmenopausal (2nd line)



Data cut-off: 20.06.2019
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; N: Number; NE: Not evaluable/not reached; SOC: System Organ Class
Censored patients are marked on the Kaplan-Meier curves with the symbols in the legend
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_aesocpt_km.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f_km_ttirgr3s009_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Anhang 4-G1.5: Subgruppenanalyse der Studie MONARCH-2

Tabelle 4-125 (Anhang): Ergebnisse der Interaktionstests aus dem vorangegangenen Dossier (MONARCH-2)

Tabelle 4-64: Ergebnis des Interaktionsterms der Subgruppenanalysen je Endpunkt für Studie MONARCH-2 – Postmenopausale Patientinnen *ohne vorangegangene endokrine Therapie (Erstlinie, A1)*

Endpunkt **Subgruppe**	**Alter**	**Anzahl betroffener Organe**	**Art der Erkrankung**	**ECOG-PS zu Baseline**	**Ethnische Zugehörigkeit**	**Geografische Region**	**Messbare Erkrankung zu Baseline**	**Progesteronrezeptorstatus**	**Sensitivität gegenüber endokriner Therapie**	**Startdosis**	**Vorangegangene antiöstrogene Therapie**
Gesamtüberleben	0,648	0,138	0,676	0,196	NB	0,422	0,730	0,847	0,342	0,564	0,915
Progressionsfreies Überleben	0,869	**0,004**	0,609	0,451	0,265	0,163	0,959	0,698	0,259	0,588	0,618
Zeit bis zum Ende der nächsten Therapielinie	0,722	**0,017**	0,538	0,691	0,054	0,253	0,526	0,642	0,755	0,599	0,640
Zeit bis zur ersten nachfolgenden Chemotherapie											
Zeit bis zur ersten nachfolgenden Chemotherapie	0,658	**0,043**	0,711	0,587	0,129	0,273	0,498	0,497	0,511	0,508	0,688
Zeit bis zur ersten nachfolgenden intravenösen Chemotherapie	0,616	0,077	0,893	0,557	0,186	0,414	0,806	0,363	0,285	0,535	0,518
Zeit bis zur ersten nachfolgenden endokrinen Therapie (Sensitivitätsanalyse)	0,282	**0,045**	0,658	0,345	0,266	0,425	0,256	0,724	0,288	0,622	0,264
Zeit bis zur ersten nachfolgenden systemischen Therapie (Sensitivitätsanalyse)	0,392	**0,027**	0,668	0,383	0,399	0,335	0,881	0,522	0,483	0,462	0,310
Symptomatik											
Appetitlosigkeit	0,706	0,426	0,401	0,450	NB	0,161	0,284	0,355	NB	0,537	0,553
Diarrhö	0,345	**0,016**	0,108	0,153	NB	0,089	0,316	0,772	NB	0,738	0,205

Endpunkt / **Subgruppe**	**Alter**	**Anzahl betroffener Organe**	**Art der Erkrankung**	**ECOG-PS zu Baseline**	**Ethnische Zugehörigkeit**	**Geografische Region**	**Messbare Erkrankung zu Baseline**	**Progesteronrezeptorstatus**	**Sensitivität gegenüber endokriner Therapie**	**Startdosis**	**Vorangegangene antiöstrogene Therapie**
Dyspnoe	0,291	**0,015**	0,108	0,611	NB	0,821	0,176	0,307	0,792	0,531	0,265
Fatigue	0,380	**0,039**	0,986	0,089	0,617	0,256	0,504	**0,025**	0,594	0,350	0,635
Finanzielle Schwierigkeiten	0,435	0,059	0,373	**0,018**	NB	0,522	0,812	0,892	0,064	0,306	**0,045**
Verstopfung	0,193	0,092	0,105	0,543	NB	0,767	0,097	0,607	NB	0,939	0,920
Schlaflosigkeit	0,295	0,053	NB	0,685	NB	0,557	**0,028**	0,167	NB	0,946	0,544
Übelkeit und Erbrechen	0,436	0,532	0,349	0,159	NB	0,068	0,238	0,977	NB	0,495	0,457
Schmerz	0,093	0,058	**0,049**	0,286	NB	0,109	0,285	0,680	0,850	0,984	0,444
Symptome im Armbereich	**0,033**	**0,015**	0,540	0,304	0,902	0,353	0,754	0,164	0,507	0,365	0,997
Symptome im Brustbereich	0,065	0,067	0,081	0,407	NB	0,078	0,064	NB	NB	0,658	0,114
Nebenwirkungen der systemischen Therapie	0,697	0,316	0,873	0,987	NB	0,440	0,511	0,621	0,749	0,918	0,771
Belastung durch Haarausfall	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
mBPI-sf: Schmerz	0,915	0,299	0,231	0,374	NB	0,257	0,467	0,968	0,334	0,089	**0,029**
Gesundheitszustand											
ECOG-PS	0,942	0,267	NB	0,089	NB	NB	0,635	0,236	NB	1,000	0,834
EQ-5D VAS (7 Punkte)	0,357	**<0,001**	0,792	0,570	NB	0,091	0,850	0,988	0,571	0,241	0,108
EQ-5D VAS (10 Punkte)	0,387	**0,003**	0,781	0,686	NB	0,097	0,670	0,993	0,385	0,245	0,179

Endpunkt / **Subgruppe**	**Alter**	**Anzahl betroffener Organe**	**Art der Erkrankung**	**ECOG-PS zu Baseline**	**Ethnische Zugehörigkeit**	**Geografische Region**	**Messbare Erkrankung zu Baseline**	**Progesteronrezeptorstatus**	**Sensitivität gegenüber endokriner Therapie**	**Startdosis**	**Vorangegangene antiöstrogene Therapie**
Gesundheitsbezogene Lebensqualität											
Globaler Gesundheitsstatus	0,080	**0,002**	0,595	0,809	0,646	0,623	0,819	0,574	0,461	0,114	0,350
Kognitive Funktion	0,474	0,146	0,452	0,835	0,189	0,965	0,803	0,338	0,983	0,135	0,857
Emotionale Funktion	0,464	0,147	0,240	0,275	NB	0,841	0,782	0,435	0,378	0,979	0,166
Körperliche Funktion	0,084	0,113	0,580	0,885	NB	0,105	0,673	0,304	0,604	0,979	0,790
Rollenfunktion	0,398	**0,031**	0,537	0,597	NB	0,333	0,958	0,945	0,887	0,633	0,565
Soziale Funktion	0,073	0,257	0,366	0,277	NB	0,313	0,262	0,913	NB	0,645	0,498
Körperbild	0,839	0,116	0,065	0,262	NB	0,658	0,194	0,893	0,514	0,760	0,375
Zukunftsperspektive	0,203	0,398	NB	0,946	NB	0,545	0,694	0,700	0,880	0,517	0,442
Freude an Sex	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Sexuelle Aktivität	0,881	0,316	NB	0,909	NB	NB	0,980	0,080	NB	0,653	0,841

Endpunkt Subgruppe	Alter	Anzahl betroffener Organe	Art der Erkrankung	ECOG-PS zu Baseline	Ethnische Zugehörigkeit	Geografische Region	Messbare Erkrankung zu Baseline	Progesteronrezeptorstatus	Sensitivität gegenüber endokriner Therapie	Startdosis	Vorangegangene antiöstrogene Therapie
Unerwünschte Ereignisse											
UE gesamt	0,912	0,895	0,739	0,903	0,494	0,555	0,915	0,206	**0,019**	0,672	**0,017**
SUE	0,643	0,787	0,675	0,789	NB	0,657	0,632	0,496	0,914	0,607	0,755
UE mit CTCAE-Grad ≥3	0,844	0,570	0,261	0,622	0,721	0,627	0,325	0,292	0,607	0,246	0,553
Kompletter Behandlungsabbruch aufgrund UE	0,421	0,689	NB	0,476	NB	NB	0,448	NB	NB	0,136	0,171
Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund UE	0,363	0,365	0,559	0,432	NB	0,543	0,316	0,601	NB	0,066	0,213

Datenschnitt: 20.06.2019

Diese Tabelle zeigt p-Werte der Interaktionsterme von Subgruppenfaktor und Behandlungsgruppe aus Cox-Proportional-Hazard-Modellen.

NB: nicht berechnet. Sollten weniger als zehn Ereignisse in einer Subgruppe auftreten, wurde auf einen Interaktionstest verzichtet.

Abkürzungen: A1: Postmenopausale Patientinnen ohne vorangegangene endokrine Therapie (Erstlinie); CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group Performance Status; EQ-5D: Fragebogen der EuroQol-Gruppe zur Lebensqualität auf 5 Dimensionen; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; SUE: Schwerwiegendes unerwünschtes Ereignis; UE: Unerwünschtes Ereignis; VAS: Visuelle Analogskala

Tabelle 4-65: Ergebnis des Interaktionsterms der Subgruppenanalysen je Endpunkt für Studie MONARCH-2 – Postmenopausale Patientinnen *mit vorangegangener endokriner Therapie (Zweitlinie, B1)*

Endpunkt / **Subgruppe**	**Alter**	**Anzahl betroffener Organe**	**Art der Erkrankung**	**ECOG-PS zu Baseline**	**Ethnische Zugehörigkeit**	**Geografische Region**	**Messbare Erkrankung zu Baseline**	**Progesteronrezeptorstatus**	**Sensitivität gegenüber endokriner Therapie**	**Startdosis**	**Vorangegangene antiöstrogene Therapie**
Gesamtüberleben	0,563	0,741	0,095	0,747	NB	0,856	0,116	0,804	0,332	0,206	0,223
Progressionsfreies Überleben	0,491	0,954	0,495	0,128	NB	0,339	0,100	0,345	0,180	0,962	0,992
Zeit bis zum Ende der nächsten Therapielinie	0,647	0,791	0,237	**0,007**	NB	0,750	0,087	0,256	0,353	0,568	0,453
Zeit bis zur ersten nachfolgenden Chemotherapie											
Zeit bis zur ersten nachfolgenden Chemotherapie	0,204	0,944	0,409	**0,029**	NB	0,324	0,068	0,598	**0,048**	0,778	0,840
Zeit bis zur ersten nachfolgenden intravenösen Chemotherapie	0,455	0,863	0,540	0,116	NB	0,339	0,157	0,297	0,132	0,873	0,771
Zeit bis zur ersten nachfolgenden endokrinen Therapie (Sensitivitätsanalyse)	0,548	0,656	0,275	0,213	NB	0,708	0,282	0,250	0,476	0,482	0,211
Zeit bis zur ersten nachfolgenden systemischen Therapie (Sensitivitätsanalyse)	0,464	0,690	0,521	**0,042**	NB	0,219	0,099	0,175	0,227	0,356	0,810
Symptomatik											
Appetitlosigkeit	0,616	0,677	0,239	0,067	NB	NB	0,635	NB	0,236	0,699	0,580
Diarrhö	0,706	0,145	0,495	0,162	NB	0,102	NB	NB	NB	0,474	0,593

Endpunkt / Subgruppe	Alter	Anzahl betroffener Organe	Art der Erkrankung	ECOG-PS zu Baseline	Ethnische Zugehörigkeit	Geografische Region	Messbare Erkrankung zu Baseline	Progesteronrezeptorstatus	Sensitivität gegenüber endokriner Therapie	Startdosis	Vorangegangene antiöstrogene Therapie
Dyspnoe	0,226	0,553	NB	0,536	NB	**0,029**	0,211	0,846	NB	0,605	0,207
Fatigue	0,931	0,504	0,350	0,056	NB	0,486	0,631	0,563	0,340	0,446	0,994
Finanzielle Schwierigkeiten	0,484	NB	NB	0,823	NB	NB	NB	NB	NB	NB	0,161
Verstopfung	0,445	0,481	NB	**0,012**	NB	NB	0,440	0,469	NB	0,714	0,969
Schlaflosigkeit	**0,006**	0,415	NB	0,513	NB	NB	0,761	**<0,001**	NB	0,106	0,770
Übelkeit und Erbrechen	0,065	0,516	NB	0,745	NB	0,147	0,974	NB	NB	0,316	0,720
Schmerz	0,535	0,378	0,663	0,788	NB	0,586	0,601	0,143	0,807	0,065	0,726
Symptome im Armbereich	0,337	0,801	0,785	0,835	NB	0,194	0,465	0,131	0,199	0,095	**0,031**
Symptome im Brustbereich	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Nebenwirkungen der systemischen Therapie	0,476	0,955	0,626	0,721	NB	NB	0,589	0,613	0,072	0,147	0,494
Belastung durch Haarausfall	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
mBPI-sf: Schmerz	0,062	0,972	0,854	0,200	NB	0,385	0,322	0,281	0,951	0,618	0,529
Gesundheitszustand											
ECOG-PS	NB	NB	NB	NB	NB	NB	NB	NB	NB	0,231	0,925
EQ-5D VAS (7 Punkte)	0,551	0,658	0,996	0,602	NB	0,085	0,393	0,633	0,069	0,815	**0,046**
EQ-5D VAS (10 Punkte)	0,593	0,703	1,000	0,655	NB	0,059	0,374	0,620	0,084	0,734	0,054

Endpunkt / **Subgruppe**	**Alter**	**Anzahl betroffener Organe**	**Art der Erkrankung**	**ECOG-PS zu Baseline**	**Ethnische Zugehörigkeit**	**Geografische Region**	**Messbare Erkrankung zu Baseline**	**Progesteronrezeptorstatus**	**Sensitivität gegenüber endokriner Therapie**	**Startdosis**	**Vorangegangene antiöstrogene Therapie**
Gesundheitsbezogene Lebensqualität											
Globaler Gesundheitsstatus	0,438	0,370	0,898	0,746	NB	0,089	0,137	0,386	**0,014**	0,908	0,493
Kognitive Funktion	0,089	0,409	0,836	0,553	NB	0,924	0,768	NB	0,416	0,570	0,432
Emotionale Funktion	0,217	0,599	0,462	0,462	NB	0,574	0,195	0,856	0,104	0,639	0,358
Körperliche Funktion	0,834	0,575	NB	0,347	NB	0,567	0,214	0,476	NB	0,536	0,356
Rollenfunktion	0,224	0,981	0,746	0,554	NB	**0,016**	0,739	0,880	0,191	0,217	0,589
Soziale Funktion	0,516	0,656	0,690	0,458	NB	0,665	0,266	0,851	NB	0,973	0,888
Körperbild	0,502	0,095	0,942	0,565	NB	0,098	0,271	NB	NB	0,943	0,599
Zukunftsperspektive	0,380	0,661	NB	0,894	NB	NB	0,311	NB	0,668	0,807	0,459
Freude an Sex	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Sexuelle Aktivität	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	0,434

Endpunkt / Subgruppe	Alter	Anzahl betroffener Organe	Art der Erkrankung	ECOG-PS zu Baseline	Ethnische Zugehörigkeit	Geografische Region	Messbare Erkrankung zu Baseline	Progesteronrezeptorstatus	Sensitivität gegenüber endokriner Therapie	Startdosis	Vorangegangene antiöstrogene Therapie
Unerwünschte Ereignisse											
UE gesamt	0,086	0,767	0,970	0,677	NB	0,889	0,657	0,249	0,773	0,974	0,202
SUE	0,535	0,290	NB	0,392	NB	0,885	0,378	0,901	0,408	0,968	**0,047**
UE mit CTCAE-Grad ≥3	0,745	0,169	0,464	0,484	NB	0,344	0,900	0,963	0,949	0,337	0,257
Kompletter Behandlungsabbruch aufgrund UE	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund UE	0,284	NB	NB	0,987	NB	NB	0,991	NB	NB	0,991	0,914

Datenschnitt: 20.06.2019

Diese Tabelle zeigt p-Werte der Interaktionsterme von Subgruppenfaktor und Behandlungsgruppe aus Cox-Proportional-Hazard-Modellen.

NB: nicht berechnet. Sollten weniger als zehn Ereignisse in einer Subgruppe auftreten, wurde auf einen Interaktionstest verzichtet.

Abkürzungen: B1: Postmenopausale Patientinnen mit vorangegangener endokriner Therapie (Zweitlinie); CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group Performance Status; EQ-5D: Fragebogen der EuroQol-Gruppe zur Lebensqualität auf 5 Dimensionen; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; SUE: Schwerwiegendes unerwünschtes Ereignis; UE: Unerwünschtes Ereignis; VAS: Visuelle Analogskala

Tabelle 4-126 (Anhang): Ergebnisse der Interaktionstests (MONARCH-2)

Tabelle 100.1: Ergebnis des Interaktionsterms der Subgruppenanalysen je Endpunkt für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

Endpunkt	Subgruppe										
	Alter	**Anzahl betroffener Organe**	**Art der Erkrankung**	**ECOG-PS zu Baseline**	**Ethnische Zugehörigkeit**	**Geografische Region**	**Messbare Erkrankung zu Baseline**	**Progesteron-rezeptor-status**	**Sensitivität gegenüber endokriner Therapie**	**Startdosis**	**Voran-gegangene antiöstrogene Therapie**
Symptomatik											
mBPI-sf: Schmerz (Anstieg des Scores um ≥2 Punkte gegenüber der Baseline oder ein Anstieg des Schmerzmittelgebrauchs um mindestens eine Größenordnung)	0,9145	0,2987	0,2312	0,3738	0,2284	0,2566	0,4674	0,9682	0,3336	0,0893	**0,0286**
mBPI-sf: Schmerz (Anstieg des Scores um ≥ 2 Punkte gegenüber der Baseline)	0,3313	0,6869	0,1587	0,9228	0,0778	0,0943	0,3125	0,9446	0,6081	0,7044	**0,0295**
mBPI-sf: Schmerz (Anstieg des Schmerzmittelgebrauchs um mindestens eine Größenordnung)	0,1140	0,8163	0,5952	**0,0236**	0,7314	0,9792	0,8048	0,3766	0,4163	**0,0188**	0,3816
Unerwünschte Ereignisse											
Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad)	0,9856	0,8811	0,7239	0,9784	0,7996	0,7638	0,9972	0,9841	0,9072	0,3211	0,9824
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie	0,9839	0,9567	0,8340	0,9838	0,9440	0,6598	0,9864	0,9883	0,7317	0,9866	0,9872
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie	0,9806	0,9882	0,8387	0,9820	0,9980	0,9976	0,6320	0,9863	0,6893	0,6751	0,9849
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: Neutropenie	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad)	0,0976	0,2273	0,1574	0,1841	0,2438	0,3330	0,6365	0,0961	0,4550	0,1480	0,6615
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen	0,8631	0,9580	0,8516	0,8644	0,9999	0,8985	0,9904	0,3309	0,7883	0,4189	0,7188
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen	0,0630	0,1692	0,1192	0,1656	0,1766	0,3470	0,8567	0,1685	0,3377	0,1909	0,7502

Endpunkt	Subgruppe										
	Alter	**Anzahl betroffener Organe**	**Art der Erkrankung**	**ECOG-PS zu Baseline**	**Ethnische Zugehörigkeit**	**Geografische Region**	**Messbare Erkrankung zu Baseline**	**Progesteron-rezeptor-status**	**Sensitivität gegenüber endokriner Therapie**	**Startdosis**	**Voran-gegangene antiöstrogene Therapie**
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen	0,9916	NB	0,9999	0,9901	1,0000	0,9999	0,9926	0,9920	1,0000	0,9922	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad)	0,8696	0,4752	0,9101	**0,0291**	0,0585	0,0540	0,8334	0,2547	0,8665	0,2061	0,8872
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe	0,9859	0,9999	0,9999	0,9884	0,9999	0,9999	0,9903	0,9918	0,9999	0,9859	0,9884
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe	0,8647	0,5082	0,8489	**0,0168**	**0,0435**	**0,0412**	0,9197	0,2125	0,9410	0,3223	0,8747
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Diarrhoe	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad)	0,9862	0,9987	0,9999	0,9322	0,9999	0,9998	0,9901	0,4076	0,9973	0,7115	0,9898
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Kreatinin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht	0,9862	0,9930	0,9999	0,8944	0,9999	0,9998	0,9901	0,4249	0,9969	0,7388	0,9899
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Kreatinin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad)	0,3812	0,8949	0,5576	0,8345	0,9998	0,7733	0,3918	0,9800	0,1356	0,8940	0,2840
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht	0,9905	NB	0,9999	0,6055	NB	NB	0,9921	0,6563	0,2716	0,8525	NB

Endpunkt	Subgruppe										
	Alter	Anzahl betroffener Organe	Art der Erkrankung	ECOG-PS zu Baseline	Ethnische Zugehörigkeit	Geografische Region	Messbare Erkrankung zu Baseline	Progesteron-rezeptor-status	Sensitivität gegenüber endokriner Therapie	Startdosis	Voran-gegangene antiöstrogene Therapie
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht	0,2547	0,9518	0,5768	0,6800	0,9363	0,9252	0,4415	0,7069	0,1758	0,8680	0,1507
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alaninaminotransferase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad)	0,7499	0,6951	0,9504	0,7044	0,3321	0,5312	0,8788	0,5700	0,3218	0,6026	0,8895
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht	NB	NB	NB	0,9926	NB	NB	NB	NB	0,7914	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht	0,5046	0,9365	0,9998	0,5336	0,2696	0,4528	0,8637	0,6410	0,2594	0,7581	0,5581
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Aspartataminotransferase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad)	0,9893	NB	1,0000	0,9918	1,0000	0,9999	NB	0,9937	0,9999	NB	0,9915
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alkalische Phosphatase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht	0,9896	NB	NB	0,9919	1,0000	0,9999	NB	0,9938	NB	NB	NB
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alkalische Phosphatase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Bilirubin im Blut erhöht (jeglicher Schweregrad)	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB

Endpunkt	Subgruppe										
	Alter	Anzahl betroffener Organe	Art der Erkrankung	ECOG-PS zu Baseline	Ethnische Zugehörigkeit	Geografische Region	Messbare Erkrankung zu Baseline	Progesteron-rezeptor-status	Sensitivität gegenüber endokriner Therapie	Startdosis	Voran-gegangene antiöstrogene Therapie
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Bilirubin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Bilirubin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Bilirubin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Pneumonitis (jeglicher Schweregrad)	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Pneumonitis	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Pneumonitis	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Pneumonitis	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad)	NB	NB	NB	1,0000	1,0000	NB	1,0000	0,9999	NB	0,9999	0,9999
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Venöse Thromboembolie	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Venöse Thromboembolie	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: Venöse Thromboembolie	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB

Endpunkt	Subgruppe										
	Alter	**Anzahl betroffener Organe**	**Art der Erkrankung**	**ECOG-PS zu Baseline**	**Ethnische Zugehörigkeit**	**Geografische Region**	**Messbare Erkrankung zu Baseline**	**Progesteron-rezeptor-status**	**Sensitivität gegenüber endokriner Therapie**	**Startdosis**	**Voran-gegangene antiöstrogene Therapie**
Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad)	0,7288	0,7586	0,8316	0,7872	0,4720	0,6889	0,5633	0,9870	0,1969	0,6422	0,6486
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber	0,5574	0,7430	0,9999	0,6573	0,9953	0,9772	0,9891	0,4830	0,7112	0,7082	0,6569
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber	0,9967	0,4513	0,9484	0,6445	0,4833	0,7089	0,7795	0,9458	0,1582	0,3564	0,4441
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB

Datenschnitt: 20.06.2019
Diese Tabelle zeigt p-Werte der Interaktionsterme von Subgruppenfaktor und Behandlungsgruppe aus Cox-Proportional-Hazard-Modellen.
NB: nicht berechnet. Ein Interaktionstest wird nur gerechnet, wenn jede Subgruppenkategorie mindestens 10 Patienten umfasst und mindestens 10 Ereignisse in einer der Subgruppenkategorien aufgetreten sind.
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EQ-5D: European Quality of Life Questionnaire 5 Dimensions; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; PT: Preferred Term; SMQ: Standardised MedDRA Queries; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_interact.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t100_interact_all_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 100.2: Ergebnis des Interaktionsterms der Subgruppenanalysen je Endpunkt für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

Endpunkt	Subgruppe										
	Alter	Anzahl betroffener Organe	Art der Erkrankung	ECOG-PS zu Baseline	Ethnische Zugehörigkeit	Geografische Region	Messbare Erkrankung zu Baseline	Progesteron-rezeptor-status	Sensitivität gegenüber endokriner Therapie	Startdosis	Voran-gegangene antiöstrogene Therapie
Symptomatik											
mBPI-sf: Schmerz (Anstieg des Scores um ≥2 Punkte gegenüber der Baseline oder ein Anstieg des Schmerzmittelgebrauchs um mindestens eine Größenordnung)	0,0623	0,9718	0,8541	0,2001	NB	0,3855	0,3221	0,2806	0,9511	0,6182	0,5293
mBPI-sf: Schmerz (Anstieg des Scores um ≥2 Punkte gegenüber der Baseline)	0,1154	0,9594	0,8553	0,1425	NB	0,4548	0,1631	0,1482	0,8445	0,4378	0,2597
mBPI-sf: Schmerz (Anstieg des Schmerzmittelgebrauchs um mindestens eine Größenordnung)	0,5091	0,7937	0,7665	0,7602	NB	0,5412	0,7276	0,9476	0,8756	0,6870	0,1720
Unerwünschte Ereignisse											
Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad)	0,4707	0,9444	0,9999	0,5321	NB	0,9978	0,9872	0,9883	0,3701	0,9860	0,9252
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie	0,9870	0,9999	0,9999	0,9861	NB	0,9999	0,9910	0,9883	0,9881	0,9903	0,9897
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie	0,9880	0,9386	0,9998	0,9892	NB	0,9998	0,9892	0,9898	0,2071	0,9881	0,9851
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: Neutropenie	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad)	0,3320	0,4804	0,8434	0,8916	NB	0,5613	0,5591	0,5582	0,1646	0,8587	0,1016
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen	0,2887	NB	NB	0,4700	NB	0,6535	0,5692	0,9220	0,1800	0,3258	0,9916

Endpunkt	Subgruppe										
	Alter	**Anzahl betroffener Organe**	**Art der Erkrankung**	**ECOG-PS zu Baseline**	**Ethnische Zugehörigkeit**	**Geografische Region**	**Messbare Erkrankung zu Baseline**	**Progesteron-rezeptor-status**	**Sensitivität gegenüber endokriner Therapie**	**Startdosis**	**Voran-gegangene antiöstrogene Therapie**
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen	0,3009	0,5064	0,7789	0,8677	NB	0,7013	0,4483	0,4964	0,1486	0,7466	0,1824
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen	0,9133	0,6632	NB	0,2908	NB	0,6167	0,8284	0,2240	**0,0443**	0,6422	0,9918
Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad)	0,3268	**0,0055**	0,3867	0,7269	NB	0,4929	0,1150	**0,0001**	0,1509	0,1397	0,6769
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe	0,9998	1,0000	1,0000	0,9999	NB	1,0000	0,9999	0,9999	0,9999	0,9998	1,0000
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe	0,2574	**0,0038**	0,2866	0,7801	NB	0,5186	0,0839	**0,0002**	0,1680	0,1629	0,7057
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Diarrhoe	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad)	0,9998	1,0000	1,0000	0,9999	NB	1,0000	0,9999	0,9999	0,9999	0,9999	0,9999
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Kreatinin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht	0,9998	1,0000	1,0000	0,9999	NB	1,0000	0,9999	0,9999	0,9999	0,9999	0,9999
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Kreatinin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad)	0,9416	NB	0,5801	0,4452	NB	0,9999	0,2962	0,9894	1,0000	0,9916	0,5025

Endpunkt	Subgruppe										
	Alter	Anzahl betroffener Organe	Art der Erkrankung	ECOG-PS zu Baseline	Ethnische Zugehörigkeit	Geografische Region	Messbare Erkrankung zu Baseline	Progesteron-rezeptor-status	Sensitivität gegenüber endokriner Therapie	Startdosis	Voran-gegangene antiöstrogene Therapie
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht	0,9583	NB	0,5884	0,5021	NB	0,9999	0,2927	0,9896	1,0000	0,9918	0,5482
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alaninaminotransferase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad)	0,6210	NB	NB	0,9815	NB	1,0000	0,7411	0,9901	1,0000	0,9922	0,3402
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht	0,8114	NB	NB	0,5703	NB	1,0000	0,9101	0,9906	0,9999	0,9925	0,1776
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Aspartataminotransferase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad)	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alkalische Phosphatase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alkalische Phosphatase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB

Endpunkt	Subgruppe										
	Alter	Anzahl betroffener Organe	Art der Erkrankung	ECOG-PS zu Baseline	Ethnische Zugehörigkeit	Geografische Region	Messbare Erkrankung zu Baseline	Progesteron-rezeptor-status	Sensitivität gegenüber endokriner Therapie	Startdosis	Voran-gegangene antiöstrogene Therapie
Zeit bis zum ersten unerwünschten Ereignis: PT Bilirubin im Blut erhöht (jeglicher Schweregrad)	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Bilirubin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Bilirubin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Bilirubin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Pneumonitis (jeglicher Schweregrad)	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Pneumonitis	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Pneumonitis	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Pneumonitis	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad)	NB	NB	NB	0,4866	NB	NB	0,9942	NB	0,9920	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Venöse Thromboembolie	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Venöse Thromboembolie	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: Venöse Thromboembolie	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB

Endpunkt	Subgruppe										
	Alter	**Anzahl betroffener Organe**	**Art der Erkrankung**	**ECOG-PS zu Baseline**	**Ethnische Zugehörigkeit**	**Geografische Region**	**Messbare Erkrankung zu Baseline**	**Progesteron-rezeptor-status**	**Sensitivität gegenüber endokriner Therapie**	**Startdosis**	**Voran-gegangene antiöstrogene Therapie**
Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad)	0,6257	0,2387	0,5913	0,9144	NB	0,9999	0,2862	0,9875	0,6004	0,9900	0,5905
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber	NB	NB	NB	NB	NB	NB	0,7148	0,9926	0,9922	0,9935	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber	0,6090	0,2613	0,6154	0,8200	NB	0,9999	0,3304	0,9876	0,6482	0,9902	0,7847
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB

Datenschnitt: 20.06.2019
Diese Tabelle zeigt p-Werte der Interaktionsterme von Subgruppenfaktor und Behandlungsgruppe aus Cox-Proportional-Hazard-Modellen.
NB: nicht berechnet. Ein Interaktionstest wird nur gerechnet, wenn jede Subgruppenkategorie mindestens 10 Patienten umfasst und mindestens 10 Ereignisse in einer der Subgruppenkategorien aufgetreten sind.
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EQ-5D: European Quality of Life Questionnaire 5 Dimensions; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; PT: Preferred Term; SMQ: Standardised MedDRA Queries; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_interact.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t100_interact_all_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 200.1: Interaction term results of the subgroup analysis for adverse events according SOC/PT - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Subgroup										
SOC/Preferred term	**Age**	**Organs involved**	**Nature of disease**	**ECOG-PS at Baseline**	**Race**	**Region**	**Measurable disease at baseline**	**Progesterone receptor**	**Sensitivity against endocrine therapy**	**Starting dose**	**Previous anti-estrogene therapy**
Time to first occurrence of adverse event											
Gastrointestinal disorders	0,6685	0,9907	0,4358	0,1327	0,4011	0,4852	0,9276	0,7633	0,6549	**0,0137**	0,2570
Diarrhoea	0,8696	0,4752	0,9101	**0,0291**	0,0585	0,0540	0,8334	0,2547	0,8665	0,2061	0,8872
Nausea	0,6116	0,7796	0,4650	0,9706	0,9579	0,9809	0,7336	0,1646	0,6511	**0,0126**	0,9904
Abdominal pain	0,4442	0,4036	0,9067	0,9785	0,5072	0,8140	0,9312	0,2188	0,8758	0,6839	0,6206
Vomiting	0,3585	0,3261	0,4052	0,2760	0,4213	0,2801	0,1569	0,4970	0,6366	0,1138	0,1738
Stomatitis	0,1365	0,1436	0,8553	0,2167	0,6248	0,7985	0,8842	0,7344	0,8737	0,7844	0,3252
General disorders and administration site conditions	0,9582	0,5507	0,8550	0,1391	0,6030	0,9644	0,5300	**0,0471**	0,6245	0,3889	0,6058
Fatigue	0,7150	0,1477	0,2739	0,5987	0,2103	0,4349	0,1152	0,1405	0,7748	0,8020	0,5112
Chills	0,9914	0,9999	NE	0,9910	1,0000	NE	0,9920	0,9896	0,9999	0,9917	0,9912
Blood and lymphatic system disorders	0,9196	0,8201	0,9712	0,8469	0,6772	0,6006	0,7610	0,5193	0,9688	0,9348	0,1192
Neutropenia	0,9856	0,8904	0,7250	0,9784	0,8292	0,7903	0,9711	0,9841	0,8815	0,3003	0,9825
Anaemia	0,7183	0,7946	0,6924	0,9660	0,4280	0,4550	0,6540	0,5772	0,9201	0,6420	0,2396
Leukopenia	0,9822	0,9752	0,8884	0,9832	0,9885	0,9520	0,6041	0,9877	0,9585	0,7275	0,9860
Thrombocytopenia	0,4299	0,5563	0,9996	0,9890	0,9200	0,9999	0,9705	0,9899	0,8314	0,9882	0,4040
Lymphopenia	0,9903	0,9999	0,9999	0,9908	0,9999	0,9998	0,9922	0,9907	1,0000	0,9919	0,9906
Nervous system disorders	0,5018	0,4575	0,6746	0,3688	0,7831	0,5127	0,9085	0,8383	0,2988	0,2898	0,4958
Headache	0,1709	0,8889	0,1335	0,3520	0,8227	0,9813	**0,0218**	0,5435	0,4687	0,5405	0,5607
Dysgeusia	0,7793	0,7897	0,1470	0,7275	0,9892	0,5858	**0,0276**	0,1985	0,9777	0,9858	0,5902
Skin and subcutaneous tissue disorders	0,1542	0,9022	**0,0340**	0,4531	0,9099	0,1977	0,4147	0,6421	0,6760	0,1682	**0,0025**
Alopecia	0,3670	0,5977	0,8087	0,5249	0,9910	0,9908	0,9103	0,9730	0,8776	0,6849	0,3509

SOC/Preferred term	Subgroup										
	Age	**Organs involved**	**Nature of disease**	**ECOG-PS at Baseline**	**Race**	**Region**	**Measurable disease at baseline**	**Progesterone receptor**	**Sensitivity against endocrine therapy**	**Starting dose**	**Previous anti-estrogene therapy**
Rash	0,7950	0,8621	0,2488	0,2826	0,5765	0,9616	0,8536	0,5373	0,8899	0,8348	0,3173
Metabolism and nutrition disorders	0,3000	0,7656	0,2079	0,7491	0,3485	0,8878	0,9000	0,2866	0,3161	**0,0256**	0,2274
Decreased appetite	0,6297	0,4620	0,2289	0,3641	0,2757	0,9477	0,6712	0,8705	0,8662	**0,0154**	0,9546
Hypokalaemia	0,4224	0,9998	0,9323	0,5733	0,6176	0,5086	0,9901	0,9916	0,9999	0,4888	0,8968
Dehydration	0,4303	0,9871	NE	0,9903	1,0000	0,7201	0,9211	0,9888	0,9772	0,9910	0,6282
Infections and infestations	0,0976	0,2273	0,1574	0,1841	0,2438	0,3330	0,6365	0,0961	0,4550	0,1480	0,6615
Urinary tract infection	0,9873	0,8644	0,7713	0,9880	0,1986	0,2904	0,9894	0,3305	0,9999	0,5193	0,8957
Investigations	0,6503	0,3085	0,1938	0,7463	0,7824	0,8879	0,2259	0,5079	0,6509	0,5052	0,2738
Aspartate aminotransferase increased	0,7499	0,6951	0,9504	0,7044	0,3321	0,5312	0,8788	0,5700	0,3218	0,6026	0,8895
Alanine aminotransferase increased	0,3812	0,8949	0,5576	0,8345	0,9998	0,7733	0,3918	0,9800	0,1356	0,8940	0,2840
Weight decreased	0,7853	0,9626	0,7991	0,4575	0,4521	0,2850	0,8421	0,7742	0,8976	0,2182	0,6270
Blood creatinine increased	0,9862	0,9987	0,9999	0,9322	0,9999	0,9998	0,9901	0,4076	0,9973	0,7115	0,9898
Blood alkaline phosphatase increased	0,9893	NE	1,0000	0,9918	1,0000	0,9999	NE	0,9937	0,9999	NE	0,9915
Vascular disorders	0,6039	0,6720	0,3078	0,6165	0,7551	0,7281	0,3060	0,9640	0,6660	0,2030	0,7227
Embolism	NE	NE	NE	1,0000	1,0000	NE	1,0000	0,9999	NE	0,9999	0,9999
Eye disorders	0,6646	0,2135	0,5787	0,5429	0,9646	0,9156	0,8877	0,3826	0,9252	0,2141	0,2666
Lacrimation increased	0,9886	0,9996	0,9982	0,3482	1,0000	1,0000	0,1745	0,5498	0,9752	0,9904	0,4471
Renal and urinary disorders	0,8667	0,5658	0,1549	0,3356	0,9943	0,8756	0,1149	0,4271	0,5964	0,4145	0,8472
Time to first occurrence of serious adverse event											
Infections and infestations	0,9916	NE	0,9999	0,9901	1,0000	0,9999	0,9926	0,9920	1,0000	0,9922	NE
Time to first occurrence of adverse event with CTCAE grade ≥ 3											

SOC/Preferred term	Subgroup										
	Age	**Organs involved**	**Nature of disease**	**ECOG-PS at Baseline**	**Race**	**Region**	**Measurable disease at baseline**	**Progesterone receptor**	**Sensitivity against endocrine therapy**	**Starting dose**	**Previous anti-estrogene therapy**
Blood and lymphatic system disorders	0,6516	0,8663	0,6365	0,9807	0,8034	0,9967	0,9838	0,7380	0,9954	0,2035	0,8735
Neutropenia	0,9839	0,9548	0,8357	0,9839	0,9586	0,6891	0,9865	0,9884	0,6808	0,9866	0,9874
Leukopenia	0,9999	1,0000	1,0000	0,9999	1,0000	NE	0,9998	0,9997	1,0000	1,0000	0,9999
Anaemia	0,5973	0,9993	0,3984	0,9909	0,9999	0,9999	0,9916	0,4078	0,9999	0,9761	0,9906
Gastrointestinal disorders	0,8971	0,3703	0,6046	0,6535	0,7053	0,7468	0,4933	0,7718	0,7538	0,1045	0,4062
Diarrhoea	0,9859	0,9999	0,9999	0,9884	0,9999	0,9999	0,9903	0,9918	0,9999	0,9859	0,9884
Infections and infestations	0,8631	0,9580	0,8516	0,8644	0,9999	0,8985	0,9904	0,3309	0,7883	0,4189	0,7188

Data cut-off: 20.06.2019, Safety-Population
The table shows p-values of the interaction term of subgroup factor and treatment group from Cox proportional hazard model.
NE: not evaluable/not calculated. The interaction test is only performed if each subgroup category comprises at least 10 patients and at least 10 events have occurred in one of the subgroup categories.
Abbreviations: CTCAE: common terminology criteria for adverse events; PT: Preferred Term; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_interact_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t200_interact_all_popa1.rtf
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Table 200.2: Interaction term results of the subgroup analysis for adverse events according SOC/PT - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Subgroup										
SOC/Preferred term	**Age**	**Organs involved**	**Nature of disease**	**ECOG-PS at Baseline**	**Race**	**Region**	**Measurable disease at baseline**	**Progesterone receptor**	**Sensitivity against endocrine therapy**	**Starting dose**	**Previous anti-estrogene therapy**
Time to first occurrence of adverse event											
Gastrointestinal disorders	0,3549	0,3040	0,8117	0,3216	NE	**0,0303**	0,3744	0,0727	0,2457	0,1392	0,8496
Diarrhoea	0,3268	**0,0055**	0,3867	0,7269	NE	0,4929	0,1150	**0,0001**	0,1509	0,1397	0,6769
Nausea	0,9999	0,4674	0,9127	0,6869	NE	0,4250	0,8297	0,8081	0,2917	0,0541	0,5625
Abdominal pain	0,3104	0,7078	0,3748	0,5702	NE	0,3219	0,4320	0,5209	0,9276	0,9600	0,4624
Vomiting	0,4159	0,5830	0,4870	0,2637	NE	0,1216	0,9311	0,9365	0,8166	0,9870	0,7988
General disorders and administration site conditions											
Fatigue	0,2394	0,6651	0,4475	0,3379	NE	**0,0310**	0,0655	0,2054	0,7529	0,8096	0,9926
Blood and lymphatic system disorders	0,3992	0,4916	0,7640	0,1308	NE	0,7612	0,9428	0,9853	**0,0417**	0,3803	0,5359
Neutropenia	0,4484	0,9254	0,9999	0,5443	NE	0,9815	0,9876	0,9885	0,3795	0,9861	0,9211
Anaemia	0,8541	0,9796	0,9998	0,9839	NE	0,9268	0,9898	0,9853	0,1718	0,9894	0,9861
Leukopenia	0,9999	1,0000	1,0000	0,9999	NE	1,0000	0,9997	0,9999	0,9998	0,9998	0,9998
Thrombocytopenia	0,3762	0,9634	0,8961	0,9864	NE	0,7520	0,2826	0,9924	0,0863	0,8244	0,9735
Lymphopenia	NE	NE	1,0000	1,0000	NE	1,0000	1,0000	1,0000	1,0000	0,9998	0,9999
Infections and infestations	0,3320	0,4804	0,8434	0,8916	NE	0,5613	0,5591	0,5582	0,1646	0,8587	0,1016
Nervous system disorders	**0,0004**	0,8403	0,9487	0,4411	NE	0,3551	0,5303	0,9647	0,3931	0,1114	0,4176
Dysgeusia	0,5329	0,9806	0,8749	0,9876	NE	0,8723	0,3044	0,9876	0,9891	0,9905	0,8396
Metabolism and nutrition disorders	**0,0384**	0,0988	0,2231	0,1466	NE	0,6285	0,2524	0,2839	0,9107	0,9814	0,9461
Decreased appetite	0,2824	0,7069	0,9346	0,1999	NE	0,6657	0,7832	0,9152	0,2172	0,9859	0,9325
Skin and subcutaneous tissue disorders	**0,0449**	0,1074	0,8502	0,3309	NE	0,7622	0,1606	0,8049	0,9353	0,6465	0,7137

SOC/Preferred term	Subgroup										
	Age	Organs involved	Nature of disease	ECOG-PS at Baseline	Race	Region	Measurable disease at baseline	Progesterone receptor	Sensitivity against endocrine therapy	Starting dose	Previous anti-estrogene therapy
Alopecia	0,9901	0,9999	0,9999	0,9891	NE	0,9999	0,9904	0,9899	0,9903	0,9922	0,9908
Musculoskeletal and connective tissue disorders											
Pain in extremity	0,9905	NE	NE	0,9903	NE	1,0000	0,9936	0,9995	0,9928	0,9923	NE
Investigations	0,3361	0,3807	0,8039	0,4492	NE	0,4712	0,3219	0,9886	0,8545	0,3302	0,6010
Blood creatinine increased	0,9998	1,0000	1,0000	0,9999	NE	1,0000	0,9999	0,9999	0,9999	0,9999	0,9999
Weight decreased	NE	NE	NE	0,9920	NE	NE	0,9911	0,9922	0,9928	NE	NE
Time to first occurrence of adverse event with CTCAE grade ≥ 3											
Blood and lymphatic system disorders	0,7435	0,9999	0,9998	0,8213	NE	0,9995	0,9891	0,9858	0,2965	0,9885	0,6183
Neutropenia	0,9871	0,9999	0,9999	0,9862	NE	0,9999	0,9912	0,9886	0,9882	0,9904	0,9898
Leukopenia	NE	NE	NE	NE	NE	NE	0,9974	1,0000	0,9998	1,0000	0,9996
Gastrointestinal disorders	0,9872	0,9999	0,8078	0,7504	NE	0,9768	0,9907	0,9873	0,9877	0,9903	0,7501
Diarrhoea	0,9998	1,0000	1,0000	0,9999	NE	1,0000	0,9999	0,9999	0,9999	0,9998	1,0000
Investigations											
Aspartate aminotransferase increased	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Respiratory, thoracic and mediastinal disorders	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Data cut-off: 20.06.2019, Safety-Population
The table shows p-values of the interaction term of subgroup factor and treatment group from Cox proportional hazard model.
NE: not evaluable/not calculated. The interaction test is only performed if each subgroup category comprises at least 10 patients and at least 10 events have occurred in one of the subgroup categories.
Abbreviations: CTCAE: common terminology criteria for adverse events; PT: Preferred Term; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_interact_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t200_interact_all_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 4-127 (Anhang): Ergebnisse der Subgruppenanalyse interagierender Subgruppen (MONARCH-2)

Tabelle 4-66: Interagierende Subgruppen für progressionsfreies Überleben – Postmenopausale Patientinnen *ohne vorangegangene endokrine Therapie (Erstlinie, A1)*

Subgruppe	**Ausprägung**	**Abemaciclib+Fulvestrant**		**Placebo+Fulvestrant**		**HR [95%-KI], p-Wert[1]**
		n/N (%)	**Mediane Ereigniszeit[2]**	**n/N (%)**	**Mediane Ereigniszeit[2]**	
Anzahl betroffener Organe	1	69/112 (61,6)	18,51 [14,14;25,12]	41/49 (83,7)	14,10 [7,86;19,17]	0,562 [0,381;0,830], 0,003
	2	45/73 (61,6)	19,73 [13,45;27,45]	33/36 (91,7)	4,21 [2,47;9,50]	0,354 [0,225;0,557], <0,001
	3 und mehr	49/61 (80,3)	13,18 [7,40;16,47]	35/43 (81,4)	16,60 [5,59;19,76]	1,033 [0,669;1,594], 0,891

Datenschnitt: 20.06.2019

1: Aus Log-rank-Test; 2: In Monaten

Abkürzungen: A1: Postmenopausale Patientinnen ohne vorangegangene endokrine Therapie (Erstlinie); HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse

Tabelle 4-71: Interagierende Subgruppen für Symptomatik – Postmenopausale Patientinnen *ohne vorangegangene endokrine Therapie (Erstlinie, A1)*

Subgruppe	Ausprägung	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		HR [95%-KI], p-Wert[1]
		n/N (%)	Mediane Ereigniszeit[2]	n/N (%)	Mediane Ereigniszeit[2]	
Diarrhö						
Anzahl betroffener Organe	1	29/112 (25,9)	49,91 [44,19;NE]	5/49 (10,2)	NE [24,23;NE]	2,457 [0,947;6,376], 0,050
	2	19/73 (26,0)	51,81 [44,48;NE]	9/36 (25,0)	21,63 [11,15;48,46]	0,766 [0,344;1,704], 0,498
	3 und mehr	17/60 (28,3)	40,37 [28,04;NE]	1/43 (2,3)	NE [NE;NE]	13,352 [1,777;100,35], 0,001
Dyspnoe						
Anzahl betroffener Organe	1	28/112 (25,0)	45,17 [42,84;55,43]	14/49 (28,6)	40,37 [19,92;NE]	0,654 [0,341;1,257], 0,096
	2	18/73 (24,7)	NE [41,33;NE]	6/36 (16,7)	NE [21,63;NE]	0,856 [0,337;2,176], 0,865
	3 und mehr	19/60 (31,7)	34,55 [18,08;NE]	3/43 (7,0)	NE [NE;NE]	4,973 [1,471;16,814], 0,004
Fatigue						
Anzahl betroffener Organe	1	36/112 (32,1)	44,19 [36,13;NE]	20/49 (40,8)	16,77 [9,47;NE]	0,659 [0,378;1,148], 0,190
	2	27/73 (37,0)	41,49 [24,92;55,13]	17/36 (47,2)	11,15 [3,78;48,46]	0,422 [0,226;0,789], 0,025
	3 und mehr	27/60 (45,0)	27,22 [12,07;43,30]	16/43 (37,2)	38,96 [12,95;NE]	1,313 [0,707;2,438], 0,404
Progesteron-rezeptor-status	Negativ	22/59 (37,3)	43,30 [14,10;NE]	17/31 (54,8)	9,21 [3,78;24,00]	0,385 [0,200;0,739], 0,007
	Positiv	67/183 (36,6)	41,33 [31,30;52,08]	34/93 (36,6)	38,96 [14,17;NE]	0,926 [0,611;1,403], 0,652

Subgruppe	Ausprägung	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		HR [95%-KI], p-Wert[1]
		n/N (%)	Mediane Ereigniszeit[2]	n/N (%)	Mediane Ereigniszeit[2]	
Finanzielle Schwierigkeiten						
ECOG-PS zu Baseline	1	25/110 (22,7)	NE [36,00;NE]	6/54 (11,1)	NE [NE;NE]	1,661 [0,680;4,060], 0,223
	0	20/135 (14,8)	NE [50,47;NE]	18/74 (24,3)	44,78 [20,84;51,91]	0,441 [0,231;0,842], 0,007
Vorangegangene antiöstrogene Therapie	Ja	20/109 (18,3)	NE [50,47;NE]	4/52 (7,7)	NE [25,35;NE]	1,866 [0,635;5,490], 0,257
	Nein	25/136 (18,3)	NE [46,06;NE]	20/76 (26,3)	44,78 [20,84;NE]	0,533 [0,295;0,965], 0,042
Schlaflosigkeit						
Messbare Erkrankung zu Baseline	Ja	35/169 (20,7)	47,67 [46,88;NE]	14/94 (14,9)	NE [32,48;NE]	1,024 [0,548;1,915], 0,779
	Nein	12/76 (15,8)	52,08 [44,68;55,13]	11/34 (32,4)	30,08 [17,49;42,08]	0,322 [0,139;0,746], 0,002
Schmerz						
Art der Erkrankung	Viszerale Metastasen	35/130 (26,9)	51,85 [39,45;NE]	21/80 (26,2)	25,12 [13,84;NE]	0,727 [0,420;1,259], 0,304
	Nur Knochenmetastasen	15/71 (21,1)	NE [38,93;NE]	14/29 (48,3)	17,79 [5,59;NE]	0,363 [0,174;0,757], 0,008
	Andere	14/44 (31,8)	53,03 [21,07;53,03]	3/19 (15,8)	48,46 [48,46;NE]	2,114 [0,606;7,375], 0,261
Symptome im Armbereich						
Anzahl betroffener Organe	1	24/112 (21,4)	51,52 [41,72;NE]	23/49 (46,9)	19,43 [7,63;38,86]	0,300 [0,167;0,537], <0,001
	2	19/73 (26,0)	NE [20,05;NE]	13/36 (36,1)	46,09 [8,88;48,46]	0,404 [0,198;0,824], 0,044
	3 und mehr	22/60 (36,7)	25,58 [16,80;51,85]	15/43 (34,9)	35,97 [7,43;NE]	1,069 [0,554;2,063], 0,883

Subgruppe	Ausprägung	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		HR [95%-KI], p-Wert[1]
		n/N (%)	Mediane Ereigniszeit[2]	n/N (%)	Mediane Ereigniszeit[2]	
Alter	<65 Jahre	32/147 (21,8)	NE [40,14;NE]	31/72 (43,1)	32,48 [11,57;38,86]	0,341 [0,207;0,563], <0,001
	≥65 Jahre	33/98 (33,7)	41,72 [22,19;51,52]	20/56 (35,7)	25,12 [9,40;48,46]	0,765 [0,438;1,338], 0,350
mBPI-sf: Schmerz						
Vorangegangene antiöstrogene Therapie	Ja	59/109 (54,1)	7,43 [3,72;24,95]	22/52 (42,3)	18,41 [9,34;25,12]	1,413 [0,865;2,309], 0,187
	Nein	65/136 (47,8)	12,43 [5,85;16,11]	42/76 (55,3)	3,72 [2,04;11,97]	0,703 [0,476;1,038], 0,092

Datenschnitt: 20.06.2019

1: Aus Log-rank-Test; 2: In Monaten

Abkürzungen: A1: Postmenopausale Patientinnen ohne vorangegangene endokrine Therapie (Erstlinie); ECOG-PS: Eastern Cooperative Oncology Group Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mBPI-sf; Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht

Tabelle 4-72: Interagierende Subgruppen für Symptomatik – Postmenopausale Patientinnen mit vorangegangener endokriner Therapie (Zweitlinie, B1)

Subgruppe	Ausprägung	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		HR [95%-KI], p-Wert[1]
		n/N (%)	Mediane Ereigniszeit[2]	n/N (%)	Mediane Ereigniszeit[2]	
Dyspnoe						
Geographische Region	Nordamerika	7/25 (28,0)	44,94 [15,25;NE]	7/16 (43,8)	9,63 [2,79;23,97]	0,265 [0,090;0,785], 0,014
	Europa	25/75 (33,3)	30,38 [13,97;NE]	6/37 (16,2)	NE [28,47;NE]	1,749 [0,716;4,274], 0,239
	Asien	12/43 (27,9)	49,02 [33,37;NE]	3/13 (23,1)	NE [5,06;NE]	1,001 [0,279;3,587], 0,958
Verstopfung						
ECOG-PS zu Baseline	1	15/57 (26,3)	38,70 [19,89;NE]	5/30 (16,7)	NE [12,69;NE]	1,411 [0,511;3,897], 0,552
	0	14/83 (16,9)	NE [40,34;NE]	10/36 (27,8)	15,68 [7,99;NE]	0,257 [0,110;0,603], <0,001
Schlaflosigkeit						
Alter	<65 Jahre	23/79 (29,1)	41,49 [33,04;NE]	1/28 (3,6)	NE [NE;NE]	5,427 [0,731;40,308], 0,065
	≥65 Jahre	13/64 (20,3)	41,95 [27,29;NE]	17/38 (44,7)	15,72 [5,98;34,95]	0,275 [0,132;0,575], <0,001
Progesteron-rezeptor-status	Negativ	2/23 (8,7)	NE [33,04;NE]	8/12 (66,7)	8,28 [0,95;27,91]	0,050 [0,011;0,242], <0,001
	Positiv	34/115 (29,6)	41,49 [27,29;44,22]	9/50 (18,0)	34,95 [19,89;NE]	1,119 [0,532;2,353], 0,759
Symptome im Armbereich						
Vorangegangene antiöstrogene Therapie	Ja	24/69 (34,8)	36,85 [20,12;50,63]	6/38 (15,8)	37,48 [16,57;NE]	1,579 [0,640;3,897], 0,356
	Nein	19/74 (25,7)	35,93 [29,95;NE]	10/28 (35,7)	NE [5,19;NE]	0,429 [0,198;0,931], 0,058

Subgruppe	Ausprägung	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		HR [95%-KI], p-Wert[1]
		n/N (%)	Mediane Ereigniszeit[2]	n/N (%)	Mediane Ereigniszeit[2]	
Datenschnitt: 20.06.2019 1: Aus Log-rank-Test; 2: In Monaten Abkürzungen: B1: Postmenopausale Patientinnen mit vorangegangener endokriner Therapie (Zweitlinie); ECOG-PS: Eastern Cooperative Oncology Group Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mBPI-sf; Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht						

Tabelle 4-75: Interagierende Subgruppen für Gesundheitsbezogene Lebensqualität – Postmenopausale Patientinnen *ohne vorangegangene endokrine Therapie (Erstlinie, A1)*

Subgruppe	Ausprägung	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		HR [95%-KI], p-Wert[1]
		n/N (%)	Mediane Ereigniszeit[2]	n/N (%)	Mediane Ereigniszeit[2]	
Globaler Gesundheitsstatus						
Anzahl betroffener Organe	1	30/112 (26,8)	NE [38,93;NE]	18/49 (36,7)	24,23 [17,49;48,89]	0,602 [0,333;1,089], 0,602
	2	22/73 (30,1)	47,21 [39,29;NE]	14/36 (38,9)	18,67 [6,74;NE]	0,403 [0,203;0,799], 0,017
	3 und mehr	19/60 (31,2)	40,31 [18,15;51,85]	4/43 (9,3)	NE [35,93;NE]	3,918 [1,333;11,517], 0,007
Rollenfunktion						
Anzahl betroffener Organe	1	25/112 (22,3)	NE [42,84;NE]	21/49 (42,9)	22,16 [11,15;NE]	0,415 [0,230;0,749], 0,005
	2	24/73 (32,9)	47,21 [21,67;55,59]	9/36 (25,0)	44,78 [9,07;NE]	0,803 [0,370;1,745], 0,677
	3 und mehr	22/60 (36,7)	30,61 [14,93;51,85]	12/43 (27,9)	49,74 [22,59;NE]	1,414 [0,699;2,860], 0,337

Datenschnitt: 20.06.2019

1: Aus Log-rank-Test; 2: In Monaten

Abkürzungen: A1: Postmenopausale Patientinnen ohne vorangegangene endokrine Therapie (Erstlinie); HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht

Tabelle 4-76: Interagierende Subgruppen für Gesundheitsbezogene Lebensqualität – Postmenopausale Patientinnen mit vorangegangener endokriner Therapie (Zweitlinie, B1)

Subgruppe	Ausprägung	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		HR [95%-KI], p-Wert[1]
		n/N (%)	Mediane Ereigniszeit[2]	n/N (%)	Mediane Ereigniszeit[2]	
Globaler Gesundheitsstatus						
Sensitivität gegenüber endokriner Therapie	Primäre Resistenz	14/26 (53,8)	13,84 [6,64;27,29]	1/10 (10,0)	42,41 [NE;NE]	6,220 [0,817;47,349], 0,033
	Sekundäre Resistenz	43/117 (36,8)	33,67 [22,13;41,95]	27/56 (48,2)	12,69 [5,98;23,97]	0,451 [0,276;0,737], <0,001
Rollenfunktion						
Geographi-sche Region	Nordamerika	7/25 (28,0)	44,94 [24,46;NE]	9/16 (56,3)	5,56 [2,07;NE]	0,226 [0,083;0,621], 0,020
	Europa	36/75 (48,0)	29,95 [9,21;38,73]	12/37 (32,4)	28,47 [7,46;NE]	1,286 [0,667;2,479], 0,435
	Asien	13/43 (30,2)	40,57 [22,75;NE]	5/13 (38,5)	19,89 [7,59;NE]	0,583 [0,206;1,653], 0,398

Datenschnitt: 20.06.2019

1: Aus Log-rank-Test; 2: In Monaten

Abkürzungen: B1: Postmenopausale Patientinnen mit vorangegangener endokriner Therapie (Zweitlinie); HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht

Tabelle 110.2.1: Interagierende Subgruppen - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,0443)					
Primäre Resistenz	2/26 (7,7)	NE [NE; NE]	3/10 (30,0)	NE [4,31; NE]	0,25 [0,04; 1,47] 0,0957
Sekundäre Resistenz	11/117 (9,4)	NE [NE; NE]	1/56 (1,8)	NE [29,92; NE]	3,83 [0,49; 29,97] 0,1694

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SOC: System Organ Class.

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Tabelle 111.1.1: Interagierende Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,0291)					
0	124/135 (91,9)	0,2 [0,20; 0,30]	17/74 (23,0)	NE [NE; NE]	11,10 [6,58; 18,72] <,0001
1	86/110 (78,2)	0,4 [0,23; 0,53]	18/54 (33,3)	24,9 [8,02; NE]	4,87 [2,90; 8,18] <,0001

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

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Tabelle 111.2.1: Interagierende Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,0055)					
1	40/47 (85,1)	0,3 [0,13; 0,66]	10/20 (50,0)	8,3 [0,49; NE]	3,29 [1,58; 6,84] 0,0007
2	47/49 (95,9)	0,2 [0,13; 0,39]	5/21 (23,8)	NE [12,39; NE]	18,50 [6,33; 54,13] <,0001
≥ 3	42/47 (89,4)	0,2 [0,10; 0,26]	3/25 (12,0)	NE [7,43; NE]	17,67 [5,39; 57,92] <,0001
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,0001)					
Positiv	110/115 (95,7)	0,2 [0,16; 0,30]	11/50 (22,0)	NE [12,39; NE]	14,84 [7,59; 29,03] <,0001
Negativ	15/23 (65,2)	0,4 [0,13; NE]	7/12 (58,3)	5,7 [0,30; NE]	1,52 [0,62; 3,73] 0,3660

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

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Tabelle 113.1.1: Interagierende Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,0168)					
0	124/135 (91,9)	0,3 [0,20; 0,36]	17/74 (23,0)	NE [NE; NE]	11,07 [6,56; 18,67] <,0001
1	84/110 (76,4)	0,5 [0,30; 0,59]	18/54 (33,3)	24,9 [8,02; NE]	4,54 [2,70; 7,62] <,0001
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 0,0435)					
Weiß/kaukasisch	129/155 (83,2)	0,5 [0,26; 0,49]	27/80 (33,8)	24,9 [11,77; NE]	5,38 [3,52; 8,21] <,0001
Asiatisch	53/58 (91,4)	0,2 [0,16; 0,36]	5/32 (15,6)	NE [NE; NE]	16,07 [6,30; 41,03] <,0001
Andere	15/17 (88,2)	0,2 [0,13; 0,72]	2/9 (22,2)	NE [2,04; NE]	9,38 [2,09; 42,08] 0,0005
Geografische Region (p-Wert des Interaktionsterms: 0,0412)					
Europa	77/97 (79,4)	0,4 [0,20; 0,53]	15/57 (26,3)	NE [14,93; NE]	5,97 [3,41; 10,46] <,0001
Nordamerika	80/92 (87,0)	0,5 [0,26; 0,56]	15/39 (38,5)	24,9 [5,36; NE]	5,15 [2,93; 9,05] <,0001
Asien	51/56 (91,1)	0,2 [0,16; 0,30]	5/32 (15,6)	NE [NE; NE]	16,78 [6,53; 43,14] <,0001

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

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Tabelle 113.2.1: Interagierende Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,0038)					
1	39/47 (83,0)	0,4 [0,16; 0,95]	10/20 (50,0)	8,3 [0,49; NE]	3,15 [1,51; 6,58] 0,0012
2	47/49 (95,9)	0,3 [0,16; 0,39]	5/21 (23,8)	NE [12,39; NE]	18,48 [6,32; 54,05] <,0001
≥ 3	42/47 (89,4)	0,2 [0,10; 0,30]	3/25 (12,0)	NE [7,43; NE]	17,60 [5,37; 57,70] <,0001
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,0002)					
Positiv	109/115 (94,8)	0,3 [0,16; 0,30]	11/50 (22,0)	NE [12,39; NE]	14,58 [7,44; 28,54] <,0001
Negativ	15/23 (65,2)	0,4 [0,13; NE]	7/12 (58,3)	5,7 [0,30; NE]	1,51 [0,61; 3,72] 0,3696

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

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Table 209.1.1: Interacting Subgroups: adverse events according PT - Metabolism and nutrition disorders/Decreased appetite - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Starting dose (p-value of the interaction term: 0,0154)					
150 mg	47/169 (27,8)	NE [NE; NE]	15/87 (17,2)	NE [38,30; NE]	1,57 [0,88; 2,82] 0,1258
200 mg	31/76 (40,8)	31,2 [9,34; NE]	2/41 (4,9)	NE [NE; NE]	10,66 [2,55; 44,58] <,0001

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

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Table 211.1.1: Interacting Subgroups: adverse events according PT - Gastrointestinal disorders/Diarrhoea - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
ECOG-PS at Baseline (p-value of the interaction term: 0,0291)					
0	124/135 (91,9)	0,2 [0,20; 0,30]	17/74 (23,0)	NE [NE; NE]	11,10 [6,58; 18,72] <,0001
1	86/110 (78,2)	0,4 [0,23; 0,53]	18/54 (33,3)	24,9 [8,02; NE]	4,87 [2,90; 8,18] <,0001

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

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Table 212.1.1: Interacting Subgroups: adverse events according PT - Nervous system disorders/Dysgeusia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Measurable disease at baseline (p-value of the interaction term: 0,0276)					
Yes	36/169 (21,3)	NE [NE; NE]	1/94 (1,1)	NE [NE; NE]	21,78 [2,99; 158,88] <,0001
No	10/76 (13,2)	NE [NE; NE]	3/34 (8,8)	NE [NE; NE]	1,57 [0,43; 5,70] 0,4889

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

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Table 215.1.1: Interacting Subgroups: adverse events according PT - Nervous system disorders/Headache - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Measurable disease at baseline (p-value of the interaction term: 0,0218)					
Yes	28/169 (16,6)	NE [NE; NE]	12/94 (12,8)	NE [31,53; NE]	1,13 [0,57; 2,22] 0,7327
No	26/76 (34,2)	30,1 [20,52; NE]	2/34 (5,9)	NE [NE; NE]	6,96 [1,65; 29,43] 0,0022

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

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Table 220.1.1: Interacting Subgroups: adverse events according PT - Gastrointestinal disorders/Nausea - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Starting dose (p-value of the interaction term: 0,0126)					
150 mg	78/169 (46,2)	21,3 [10,16; NE]	25/87 (28,7)	39,4 [19,96; NE]	1,73 [1,10; 2,73] 0,0159
200 mg	47/76 (61,8)	1,1 [0,36; 10,16]	7/41 (17,1)	NE [NE; NE]	5,27 [2,37; 11,69] <,0001

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

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Table 230.1.1: Interacting Subgroups: adverse events according SOC - Gastrointestinal disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Starting dose (p-value of the interaction term: 0,0137)					
150 mg	158/169 (93,5)	0,2 [0,16; 0,30]	55/87 (63,2)	3,6 [1,74; 9,27]	3,24 [2,37; 4,44] <,0001
200 mg	74/76 (97,4)	0,1 [0,10; 0,16]	26/41 (63,4)	3,8 [1,87; 22,13]	7,76 [4,46; 13,52] <,0001

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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Table 231.1.1: Interacting Subgroups: adverse events according SOC - General disorders and administration site conditions - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Progesterone receptor (p-value of the interaction term: 0,0471)					
Positive	122/183 (66,7)	5,3 [3,45; 9,50]	47/93 (50,5)	10,0 [4,57; 39,42]	1,39 [0,99; 1,95] 0,0547
Negative	43/59 (72,9)	1,9 [0,89; 6,97]	11/31 (35,5)	13,6 [3,52; NE]	3,01 [1,54; 5,87] 0,0007

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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Table 234.1.1: Interacting Subgroups: adverse events according SOC - Metabolism and nutrition disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Starting dose (p-value of the interaction term: 0,0256)					
150 mg	73/169 (43,2)	24,1 [14,53; NE]	24/87 (27,6)	42,5 [38,30; NE]	1,60 [1,01; 2,54] 0,0441
200 mg	41/76 (53,9)	10,8 [3,25; 28,41]	6/41 (14,6)	NE [NE; NE]	4,82 [2,04; 11,37] <,0001

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
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Table 237.1.1: Interacting Subgroups: adverse events according SOC - Skin and subcutaneous tissue disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Nature of disease (p-value of the interaction term: 0,0340)					
Visceral	68/130 (52,3)	6,5 [4,93; 10,16]	13/80 (16,3)	NE [39,52; NE]	3,67 [2,03; 6,64] <,0001
Bone only	31/71 (43,7)	13,8 [7,40; NE]	7/29 (24,1)	NE [33,30; NE]	2,07 [0,91; 4,71] 0,0768
Other	18/44 (40,9)	37,1 [5,10; NE]	9/19 (47,4)	15,6 [3,65; NE]	0,92 [0,41; 2,07] 0,8444
Previous anti-estrogene therapy (p-value of the interaction term: 0,0025)					
Yes	54/109 (49,5)	7,4 [5,10; NE]	4/52 (7,7)	NE [39,52; NE]	8,04 [2,91; 22,22] <,0001
No	63/136 (46,3)	9,0 [6,28; NE]	25/76 (32,9)	33,3 [12,00; NE]	1,46 [0,92; 2,32] 0,1109

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
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Table 252.2.1: Interacting Subgroups: adverse events according PT - Gastrointestinal disorders/Diarrhoea - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Organs involved (p-value of the interaction term: 0,0055)					
1	40/47 (85,1)	0,3 [0,13; 0,66]	10/20 (50,0)	8,3 [0,49; NE]	3,29 [1,58; 6,84] 0,0007
2	47/49 (95,9)	0,2 [0,13; 0,39]	5/21 (23,8)	NE [12,39; NE]	18,50 [6,33; 54,13] <,0001
≥ 3	42/47 (89,4)	0,2 [0,10; 0,26]	3/25 (12,0)	NE [7,43; NE]	17,67 [5,39; 57,92] <,0001
Progesterone receptor (p-value of the interaction term: 0,0001)					
Positive	110/115 (95,7)	0,2 [0,16; 0,30]	11/50 (22,0)	NE [12,39; NE]	14,84 [7,59; 29,03] <,0001
Negative	15/23 (65,2)	0,4 [0,13; NE]	7/12 (58,3)	5,7 [0,30; NE]	1,52 [0,62; 3,73] 0,3660

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

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Table 254.2.1: Interacting Subgroups: adverse events according PT - General disorders and administration site conditions/Fatigue - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Region (p-value of the interaction term: 0,0310)					
Europe	38/75 (50,7)	8,4 [3,39; NE]	11/37 (29,7)	NE [5,52; NE]	1,75 [0,89; 3,43] 0,0996
North America	21/25 (84,0)	0,6 [0,26; 1,45]	3/16 (18,8)	NE [5,59; NE]	8,48 [2,49; 28,84] <,0001
Asian	11/43 (25,6)	NE [20,98; NE]	4/13 (30,8)	NE [4,60; NE]	0,84 [0,27; 2,65] 0,7705

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

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Table 263.2.1: Interacting Subgroups: adverse events according SOC - Blood and lymphatic system disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Sensitivity against endocrine therapy (p-value of the interaction term: 0,0417)					
Primary resistance	15/26 (57,7)	4,7 [1,41; NE]	3/10 (30,0)	NE [2,79; NE]	2,45 [0,71; 8,50] 0,1377
Secondary resistance	73/117 (62,4)	3,3 [0,99; 10,39]	4/56 (7,1)	NE [NE; NE]	12,65 [4,62; 34,65] <,0001

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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Table 264.2.1: Interacting Subgroups: adverse events according SOC - Gastrointestinal disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Region (p-value of the interaction term: 0,0303)					
Europe	68/75 (90,7)	0,2 [0,13; 0,30]	25/37 (67,6)	2,6 [0,99; 5,56]	3,09 [1,92; 4,97] <,0001
North America	24/25 (96,0)	0,1 [0,03; 0,16]	11/16 (68,8)	3,9 [0,99; 7,43]	9,77 [3,19; 29,93] <,0001
Asian	42/43 (97,7)	0,1 [0,07; 0,16]	7/13 (53,8)	8,2 [0,13; NE]	7,62 [2,81; 20,68] <,0001

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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Table 267.2.1: Interacting Subgroups: adverse events according SOC - Metabolism and nutrition disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,0384)					
≥ 65 years	39/64 (60,9)	4,6 [1,25; 17,06]	8/38 (21,1)	33,4 [33,44; NE]	4,11 [1,91; 8,84] <,0001
< 65 years	34/79 (43,0)	37,8 [8,32; NE]	9/28 (32,1)	NE [5,56; NE]	1,33 [0,64; 2,78] 0,4443

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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Table 268.2.1: Interacting Subgroups: adverse events according SOC - Nervous system disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,0004)					
≥ 65 years	42/64 (65,6)	1,9 [0,89; 4,87]	6/38 (15,8)	NE [NE; NE]	5,74 [2,42; 13,59] <,0001
< 65 years	32/79 (40,5)	30,5 [10,36; NE]	12/28 (42,9)	18,6 [3,65; NE]	0,80 [0,41; 1,56] 0,5139

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
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Table 269.2.1: Interacting Subgroups: adverse events according SOC - Skin and subcutaneous tissue disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,0449)					
≥ 65 years	31/64 (48,4)	9,4 [4,41; 23,84]	5/38 (13,2)	NE [10,92; NE]	4,68 [1,81; 12,10] 0,0005
< 65 years	41/79 (51,9)	12,9 [4,64; 42,41]	10/28 (35,7)	11,7 [6,90; NE]	1,42 [0,71; 2,85] 0,3208

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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Tabelle 4-128 (Anhang): Ergebnisse der Subgruppenanalyse nicht interagierender Subgruppen (MONARCH-2)

Tabelle 101.1.2: Subgruppen für den stärksten Schmerz in den letzten 24 Stunden - Anstieg des Scores um ≥2 Punkte gegenüber der Baseline aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,3313)					
< 65 Jahre	61/147 (41,5)	18,1 [12,43; 38,93]	32/72 (44,4)	11,0 [5,59; 30,61]	0,82 [0,53; 1,26] 0,3529
≥ 65 Jahre	43/98 (43,9)	14,0 [3,72; 35,97]	22/56 (39,3)	19,6 [8,68; 35,93]	1,15 [0,69; 1,93] 0,5819
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,6869)					
1	49/112 (43,8)	16,6 [7,36; 35,97]	25/49 (51,0)	11,0 [3,72; 20,55]	0,83 [0,51; 1,35] 0,4542
2	28/73 (38,4)	39,8 [5,85; NE]	9/36 (25,0)	NE [5,79; NE]	1,46 [0,68; 3,13] 0,3324
≥ 3	27/60 (45,0)	14,5 [3,75; NE]	20/43 (46,5)	19,6 [3,68; 35,93]	0,97 [0,54; 1,73] 0,9062
Art der Erkrankung (p-Wert des Interaktionsterms: 0,1587)					
Viszerale Metastasen	53/130 (40,8)	18,1 [11,15; 39,81]	29/80 (36,3)	19,6 [7,40; 35,93]	0,95 [0,60; 1,50] 0,8138
Nur Knochenmetastasen	31/71 (43,7)	25,0 [7,43; NE]	19/29 (65,5)	11,0 [3,72; 20,55]	0,64 [0,36; 1,14] 0,1225
Andere	20/44 (45,5)	5,6 [2,04; 16,60]	6/19 (31,6)	NE [1,91; NE]	1,86 [0,75; 4,66] 0,1725
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9228)					
0	61/135 (45,2)	14,3 [6,28; 34,92]	33/74 (44,6)	10,8 [5,59; 35,93]	0,96 [0,63; 1,47] 0,8440
1	43/110 (39,1)	20,0 [11,15; NE]	21/54 (38,9)	18,4 [7,40; 30,61]	0,96 [0,57; 1,63] 0,8910
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 0,0778)					
Weiß/kaukasisch	64/155 (41,3)	14,3 [7,36; 39,81]	27/80 (33,8)	19,6 [10,85; 35,93]	1,23 [0,79; 1,93] 0,3694
Asiatisch	26/58 (44,8)	20,0 [12,43; NE]	20/32 (62,5)	3,7 [1,18; 24,69]	0,52 [0,29; 0,95] 0,0308

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Andere	10/17 (58,8)	7,4 [0,95; NE]	5/9 (55,6)	3,7 [0,95; NE]	0,93 [0,31; 2,80] 0,8627
Geografische Region (p-Wert des Interaktionsterms: 0,0943)					
Europa	40/97 (41,2)	16,6 [7,36; 38,93]	20/57 (35,1)	19,6 [11,05; 35,93]	1,28 [0,75; 2,19] 0,3781
Nordamerika	38/92 (41,3)	13,9 [4,08; NE]	14/39 (35,9)	20,5 [3,72; NE]	1,09 [0,59; 2,01] 0,7951
Asien	26/56 (46,4)	18,1 [5,59; NE]	20/32 (62,5)	3,7 [1,18; 24,69]	0,54 [0,30; 0,98] 0,0427
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,3125)					
Ja	72/169 (42,6)	14,3 [7,40; 24,95]	35/94 (37,2)	25,1 [7,40; 35,93]	1,06 [0,70; 1,58] 0,7946
Nein	32/76 (42,1)	36,0 [7,36; NE]	19/34 (55,9)	14,2 [3,75; 20,55]	0,73 [0,41; 1,30] 0,2774
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9446)					
Positiv	76/183 (41,5)	17,1 [12,43; 35,97]	41/93 (44,1)	16,7 [8,68; 25,12]	0,91 [0,62; 1,33] 0,5925
Negativ	27/59 (45,8)	8,1 [2,70; NE]	12/31 (38,7)	11,0 [1,91; NE]	1,00 [0,50; 1,98] 0,9918
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,6081)					
Primäre Resistenz	20/57 (35,1)	17,1 [8,09; NE]	12/35 (34,3)	14,2 [3,22; NE]	0,89 [0,43; 1,86] 0,7277
Sekundäre Resistenz	76/168 (45,2)	15,5 [7,36; 34,92]	33/79 (41,8)	16,7 [8,68; 30,61]	1,03 [0,68; 1,55] 0,8774
Nicht vortherapiert	8/20 (40,0)	20,0 [2,04; NE]	9/14 (64,3)	7,4 [0,99; 24,69]	0,68 [0,26; 1,78] 0,4288
Startdosis (p-Wert des Interaktionsterms: 0,7044)					
150 mg	72/169 (42,6)	14,5 [7,43; 38,53]	38/87 (43,7)	11,0 [6,38; 25,12]	0,91 [0,61; 1,35] 0,6219
200 mg	32/76 (42,1)	17,1 [6,02; 38,93]	16/41 (39,0)	20,5 [5,79; NE]	1,04 [0,57; 1,89] 0,9081

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Datenschnitt: 20.06.2019, Safety-Population 1: In Monaten; 2: Aus Log-rank-Test Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Brief Pain Inventory; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie.					

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/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
16JUL2021 / 08:04

Tabelle 101.2.2: Subgruppen für den stärksten Schmerz in den letzten 24 Stunden - Anstieg des Scores um ≥2 Punkte gegenüber der Baseline aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,1154)					
≥ 65 Jahre	26/64 (40,6)	16,5 [9,99; NE]	20/38 (52,6)	6,0 [1,87; 17,56]	0,48 [0,27; 0,88] 0,0158
< 65 Jahre	35/79 (44,3)	19,4 [7,46; NE]	9/28 (32,1)	NE [2,07; NE]	1,14 [0,55; 2,39] 0,7077
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,9594)					
1	17/47 (36,2)	25,3 [9,99; NE]	9/20 (45,0)	17,6 [3,75; NE]	0,71 [0,31; 1,59] 0,3971
2	26/49 (53,1)	11,3 [5,56; 22,16]	9/21 (42,9)	6,0 [1,08; NE]	0,72 [0,33; 1,55] 0,4027
≥ 3	18/47 (38,3)	31,7 [4,67; NE]	11/25 (44,0)	6,0 [1,91; NE]	0,65 [0,30; 1,41] 0,2695
Art der Erkrankung (p-Wert des Interaktionsterms: 0,8553)					
Viszerale Metastasen	34/78 (43,6)	19,4 [5,95; 44,19]	17/39 (43,6)	6,0 [1,87; NE]	0,67 [0,37; 1,22] 0,1928
Nur Knochenmetastasen	13/39 (33,3)	NE [11,11; NE]	7/15 (46,7)	17,6 [1,87; NE]	0,66 [0,26; 1,65] 0,3605
Andere	14/26 (53,8)	16,5 [4,21; 25,32]	5/12 (41,7)	6,0 [0,99; NE]	0,66 [0,22; 2,01] 0,4747
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,1425)					
0	35/83 (42,2)	22,2 [13,74; 44,19]	16/36 (44,4)	6,0 [2,07; NE]	0,52 [0,28; 0,98] 0,0401
1	26/57 (45,6)	11,1 [5,52; NE]	13/30 (43,3)	17,6 [1,87; NE]	1,01 [0,51; 1,98] 0,9764
Geografische Region (p-Wert des Interaktionsterms: 0,4548)					
Europa	29/75 (38,7)	22,2 [10,22; 44,19]	19/37 (51,4)	6,0 [1,87; 34,95]	0,60 [0,34; 1,08] 0,0895
Nordamerika	10/25 (40,0)	19,4 [5,52; NE]	3/16 (18,8)	NE [2,07; NE]	1,25 [0,31; 5,03] 0,7544

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Asien	22/43 (51,2)	16,5 [5,95; NE]	7/13 (53,8)	6,0 [0,99; NE]	0,74 [0,31; 1,75] 0,5082
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,1631)					
Ja	53/108 (49,1)	14,1 [9,99; 22,16]	22/53 (41,5)	6,0 [2,07; NE]	0,80 [0,48; 1,33] 0,4012
Nein	8/35 (22,9)	NE [18,48; NE]	7/13 (53,8)	16,8 [1,68; 34,95]	0,37 [0,13; 1,03] 0,0468
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,1482)					
Positiv	51/115 (44,3)	18,0 [11,11; 25,32]	18/50 (36,0)	34,9 [3,75; NE]	0,89 [0,52; 1,54] 0,7061
Negativ	9/23 (39,1)	38,7 [0,99; NE]	8/12 (66,7)	4,1 [1,74; NE]	0,44 [0,16; 1,22] 0,1031
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,8445)					
Primäre Resistenz	10/26 (38,5)	NE [1,91; NE]	5/10 (50,0)	17,6 [0,95; NE]	0,72 [0,24; 2,12] 0,5723
Sekundäre Resistenz	51/117 (43,6)	18,5 [11,01; 31,69]	24/56 (42,9)	16,8 [3,75; NE]	0,68 [0,42; 1,12] 0,1308
Startdosis (p-Wert des Interaktionsterms: 0,4378)					
150 mg	41/103 (39,8)	22,2 [11,31; NE]	21/49 (42,9)	16,8 [3,78; 34,95]	0,61 [0,36; 1,05] 0,0723
200 mg	20/40 (50,0)	11,1 [2,14; 31,69]	8/17 (47,1)	6,0 [0,99; NE]	0,95 [0,42; 2,19] 0,9282
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,2597)					
Ja	29/69 (42,0)	18,5 [11,15; NE]	20/38 (52,6)	6,0 [2,07; 34,95]	0,56 [0,31; 0,99] 0,0454
Nein	32/74 (43,2)	20,3 [5,95; 44,19]	9/28 (32,1)	NE [1,87; NE]	1,01 [0,48; 2,13] 0,9820

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Brief Pain Inventory; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie.

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/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 102.1.2: Subgruppen für den stärksten Schmerz in den letzten 24 Stunden - Anstieg des Schmerzmittelgebrauchs um mindestens eine Größenordnung aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,1140)					
< 65 Jahre	28/147 (19,0)	NE [NE; NE]	8/72 (11,1)	NE [NE; NE]	1,52 [0,69; 3,33] 0,2968
≥ 65 Jahre	18/98 (18,4)	NE [39,25; NE]	14/56 (25,0)	NE [15,45; NE]	0,59 [0,29; 1,21] 0,1454
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,8163)					
1	22/112 (19,6)	NE [NE; NE]	11/49 (22,4)	NE [19,63; NE]	0,79 [0,38; 1,63] 0,5168
2	16/73 (21,9)	NE [38,76; NE]	5/36 (13,9)	NE [9,04; NE]	1,23 [0,44; 3,39] 0,6950
≥ 3	8/60 (13,3)	NE [38,89; NE]	6/43 (14,0)	NE [NE; NE]	0,89 [0,31; 2,58] 0,8323
Art der Erkrankung (p-Wert des Interaktionsterms: 0,5952)					
Viszerale Metastasen	18/130 (13,8)	NE [NE; NE]	11/80 (13,8)	NE [NE; NE]	0,85 [0,40; 1,81] 0,6728
Nur Knochenmetastasen	17/71 (23,9)	NE [NE; NE]	8/29 (27,6)	NE [19,63; NE]	0,94 [0,41; 2,18] 0,8847
Andere	11/44 (25,0)	44,2 [36,20; NE]	3/19 (15,8)	NE [15,45; NE]	1,59 [0,44; 5,73] 0,4810
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 0,7314)					
Weiß/kaukasisch	28/155 (18,1)	NE [NE; NE]	12/80 (15,0)	NE [NE; NE]	1,05 [0,53; 2,07] 0,8871
Asiatisch	13/58 (22,4)	NE [39,25; NE]	7/32 (21,9)	NE [11,97; NE]	0,85 [0,33; 2,18] 0,7373
Andere	1/17 (5,9)	NE [NE; NE]	1/9 (11,1)	NE [15,45; NE]	0,22 [0,01; 3,59] 0,2467
Geografische Region (p-Wert des Interaktionsterms: 0,9792)					
Europa	20/97 (20,6)	NE [38,76; NE]	11/57 (19,3)	NE [22,49; NE]	1,00 [0,48; 2,10] 0,9897

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Nordamerika	13/92 (14,1)	NE [NE; NE]	4/39 (10,3)	NE [19,63; NE]	1,10 [0,35; 3,44] 0,8642
Asien	13/56 (23,2)	NE [39,25; NE]	7/32 (21,9)	NE [11,97; NE]	0,88 [0,34; 2,24] 0,7844
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,8048)					
Ja	28/169 (16,6)	NE [NE; NE]	13/94 (13,8)	NE [NE; NE]	0,98 [0,51; 1,90] 0,9515
Nein	18/76 (23,7)	NE [17,26; NE]	9/34 (26,5)	NE [19,63; NE]	0,98 [0,44; 2,18] 0,9560
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,3766)					
Positiv	38/183 (20,8)	NE [NE; NE]	16/93 (17,2)	NE [NE; NE]	1,04 [0,58; 1,87] 0,8902
Negativ	8/59 (13,6)	NE [NE; NE]	6/31 (19,4)	NE [19,63; NE]	0,67 [0,23; 1,94] 0,4571
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,4163)					
Primäre Resistenz	9/57 (15,8)	NE [38,89; NE]	7/35 (20,0)	NE [NE; NE]	0,52 [0,18; 1,45] 0,2024
Sekundäre Resistenz	32/168 (19,0)	NE [NE; NE]	12/79 (15,2)	NE [NE; NE]	1,20 [0,62; 2,33] 0,5965
Nicht vortherapiert	5/20 (25,0)	NE [14,07; NE]	3/14 (21,4)	NE [19,63; NE]	0,91 [0,22; 3,85] 0,9013
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,3816)					
Ja	17/109 (15,6)	NE [NE; NE]	5/52 (9,6)	NE [22,49; NE]	1,29 [0,47; 3,53] 0,6209
Nein	29/136 (21,3)	NE [44,15; NE]	17/76 (22,4)	NE [19,63; NE]	0,85 [0,47; 1,55] 0,5940

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Brief Pain Inventory; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_eff_tte_sub.sas
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Tabelle 102.2.2: Subgruppen für den stärksten Schmerz in den letzten 24 Stunden - Anstieg des Schmerzmittelgebrauchs um mindestens eine Größenordnung aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,5091)					
≥ 65 Jahre	10/64 (15,6)	NE [30,77; NE]	5/38 (13,2)	NE [20,28; NE]	0,94 [0,31; 2,82] 0,9137
< 65 Jahre	13/79 (16,5)	NE [NE; NE]	2/28 (7,1)	NE [NE; NE]	1,60 [0,36; 7,16] 0,5360
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,7937)					
1	6/47 (12,8)	NE [29,49; NE]	2/20 (10,0)	NE [20,28; NE]	0,92 [0,18; 4,67] 0,9208
2	8/49 (16,3)	NE [30,77; NE]	3/21 (14,3)	NE [NE; NE]	0,81 [0,21; 3,11] 0,7534
≥ 3	9/47 (19,1)	NE [25,22; NE]	2/25 (8,0)	NE [NE; NE]	1,68 [0,35; 8,04] 0,5150
Art der Erkrankung (p-Wert des Interaktionsterms: 0,7665)					
Viszerale Metastasen	15/78 (19,2)	NE [29,49; NE]	6/39 (15,4)	NE [NE; NE]	0,84 [0,32; 2,21] 0,7180
Nur Knochenmetastasen	6/39 (15,4)	NE [30,77; NE]	1/15 (6,7)	NE [20,28; NE]	1,97 [0,24; 16,42] 0,5247
Andere	2/26 (7,7)	NE [NE; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3805
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,7602)					
0	13/83 (15,7)	NE [NE; NE]	4/36 (11,1)	NE [NE; NE]	0,88 [0,28; 2,77] 0,8264
1	9/57 (15,8)	NE [29,49; NE]	3/30 (10,0)	NE [20,28; NE]	1,33 [0,36; 4,95] 0,6702
Geografische Region (p-Wert des Interaktionsterms: 0,5412)					
Europa	11/75 (14,7)	NE [30,77; NE]	6/37 (16,2)	NE [20,28; NE]	0,65 [0,24; 1,78] 0,3997
Nordamerika	3/25 (12,0)	NE [17,59; NE]	0/16 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,5885

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Asien	9/43 (20,9)	NE [29,49; NE]	1/13 (7,7)	NE [NE; NE]	2,64 [0,33; 20,97] 0,3395
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,7276)					
Ja	18/108 (16,7)	NE [NE; NE]	5/53 (9,4)	NE [NE; NE]	1,18 [0,43; 3,24] 0,7507
Nein	5/35 (14,3)	NE [NE; NE]	2/13 (15,4)	NE [20,28; NE]	0,85 [0,16; 4,41] 0,8448
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9476)					
Positiv	19/115 (16,5)	NE [NE; NE]	6/50 (12,0)	NE [NE; NE]	1,05 [0,41; 2,65] 0,9211
Negativ	3/23 (13,0)	NE [30,77; NE]	1/12 (8,3)	NE [NE; NE]	1,08 [0,11; 11,05] 0,9459
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,8756)					
Primäre Resistenz	6/26 (23,1)	NE [NE; NE]	2/10 (20,0)	NE [0,16; NE]	1,15 [0,23; 5,69] 0,8653
Sekundäre Resistenz	17/117 (14,5)	NE [NE; NE]	5/56 (8,9)	NE [20,28; NE]	0,92 [0,33; 2,56] 0,8694
Startdosis (p-Wert des Interaktionsterms: 0,6870)					
150 mg	18/103 (17,5)	NE [NE; NE]	6/49 (12,2)	NE [20,28; NE]	0,97 [0,38; 2,47] 0,9445
200 mg	5/40 (12,5)	NE [29,49; NE]	1/17 (5,9)	NE [NE; NE]	1,96 [0,22; 17,09] 0,5354
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,1720)					
Ja	14/69 (20,3)	NE [NE; NE]	3/38 (7,9)	NE [20,28; NE]	1,91 [0,54; 6,73] 0,3052
Nein	9/74 (12,2)	NE [29,49; NE]	4/28 (14,3)	NE [NE; NE]	0,58 [0,17; 1,95] 0,3733

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Brief Pain Inventory; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie.

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Summary of Time to Worsening by Subgroup: Pain at its Worst in Last 24 Hours (Def1) Page 1 of 4
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line) 05:05 13DEC2019
Safety Population TDTM
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019

	LY2835219 (N=245)				Placebo (N=128)				Arm Comparison		
Subgroup	n	events	Median (month)	95% CI	n	events	Median (month)	95% CI	Log Rank p value	Hazard Ratio *a(95% CI)	Interaction p-value*b
Overall	245	124	11.15	(6.02,14.76)	128	64	9.34	(5.79,18.41)	0.722	0.947 (0.700, 1.282)	
Starting dose											0.089
200 mg	76	42	7.69	(3.75,16.11)	41	17	14.17	(5.79, NE)	0.226	1.411 (0.803, 2.480)	
150 mg	169	82	12.43	(5.72,16.41)	87	47	9.30	(3.72,16.67)	0.208	0.790 (0.551, 1.133)	
Nature of Disease											0.231
VISCERAL	130	61	13.78	(6.02,20.02)	80	35	9.34	(5.79,25.12)	0.814	0.941 (0.621, 1.428)	
BONE ONLY	71	39	12.43	(5.46,17.10)	29	22	9.34	(2.04,16.67)	0.233	0.715 (0.423, 1.208)	
OTHER	44	24	5.56	(2.04,13.87)	19	7	NE	(0.99, NE)	0.302	1.696 (0.730, 3.944)	
Sensitivity to Endocrine Therapy											0.334
PRIMARY RESISTANCE	57	25	13.78	(5.56,38.89)	35	17	6.38	(2.04,14.17)	0.201	0.694 (0.374, 1.290)	
SECONDARY RESISTANCE	168	88	7.43	(5.59,15.45)	79	37	11.97	(7.43,21.24)	0.532	1.126 (0.766, 1.654)	
ENDOCRINE NAIVE	20	11	5.85	(0.99,44.15)	14	10	3.68	(0.95,24.69)	0.410	0.705 (0.298, 1.665)	

Abbreviations: CI = confidence interval; N = total population size; n = number of patients; NE = not estimable.
*a - LY2835219 v.s. Placebo.
*b - P-value for interaction term from a model with arm, the subgroup variable and arm*subgroup interaction term.
$ - IQWiG Definition: <10 patients in at least one sub-group category or <10 events within all sub-group categories; analyses not presented.
Nature of disease and sensitivity to endocrine therapy are based on CRF values.
The hazard ratio and logrank test p-value were calculated based on the unstratified analysis.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_ttw_subgrp_qs_all_pops.sas
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Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Summary of Time to Worsening by Subgroup: Pain at its Worst in Last 24 Hours (Def1) Page 2 of 4
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line) 05:05 13DEC2019
Safety Population TDTM
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019

	LY2835219 (N=245)				Placebo (N=128)				Arm Comparison		
Subgroup	n	events	Median (month)	95% CI	n	events	Median (month)	95% CI	Log Rank p value	Hazard Ratio *a(95% CI)	Interaction p-value*b
Measurable Disease at Baseline											0.467
Y	169	83	12.43	(5.65,15.45)	94	41	9.34	(3.72,25.12)	0.886	1.024 (0.704, 1.490)	
N	76	41	7.89	(4.01,16.41)	34	23	9.34	(3.72,18.41)	0.544	0.809 (0.485, 1.351)	
Number of Organs at Baseline											0.299
3+	60	30	14.53	(3.72,38.89)	43	23	9.34	(3.02,25.12)	0.496	0.851 (0.494, 1.466)	
2	73	36	7.30	(2.70,20.02)	36	11	NE	(5.79, NE)	0.153	1.500 (0.761, 2.955)	
1	112	58	12.43	(5.59,16.41)	49	30	9.30	(3.72,16.67)	0.383	0.806 (0.518, 1.253)	
Pooled Age Group 1											0.915
<65	147	74	13.78	(5.85,17.10)	72	35	9.34	(3.72,19.63)	0.769	0.942 (0.630, 1.410)	
>=65	98	50	7.40	(3.32,14.27)	56	29	9.34	(3.72,21.24)	0.906	0.974 (0.616, 1.542)	

Abbreviations: CI = confidence interval; N = total population size; n = number of patients; NE = not estimable.
*a - LY2835219 v.s. Placebo.
*b - P-value for interaction term from a model with arm, the subgroup variable and arm*subgroup interaction term.
$ - IQWiG Definition: <10 patients in at least one sub-group category or <10 events within all sub-group categories; analyses not presented.
Nature of disease and sensitivity to endocrine therapy are based on CRF values.
The hazard ratio and logrank test p-value were calculated based on the unstratified analysis.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_ttw_subgrp_qs_all_pops.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/t_ttwpadc_subgrp_popa1.rtf
Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Summary of Time to Worsening by Subgroup: Pain at its Worst in Last 24 Hours (Def1) Page 3 of 4
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line) 05:05 13DEC2019
Safety Population TDTM
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019

	LY2835219 (N=245)				Placebo (N=128)				Arm Comparison		
Subgroup	n	events	Median (month)	95% CI	n	events	Median (month)	95% CI	Log Rank p value	Hazard Ratio *a(95% CI)	Interaction p-value*b
Geographical Region											0.257
NORTH AMERICA	92	46	7.69	(3.75,14.76)	39	16	9.34	(3.19, NE)	0.838	1.001 (0.565, 1.773)	
EUROPE	97	48	7.46	(5.56,16.60)	57	27	14.17	(6.48,21.24)	0.462	1.169 (0.729, 1.874)	
ASIAN	56	30	16.11	(4.01,24.95)	32	21	3.72	(1.12,11.97)	0.097	0.637 (0.364, 1.115)	
Pooled Race Group 1											0.228
CAUCASIAN	155	76	11.15	(5.59,14.76)	80	34	16.67	(7.43,21.24)	0.567	1.119 (0.746, 1.678)	
ASIAN	58	30	16.11	(4.01,24.95)	32	21	3.72	(1.12,11.97)	0.070	0.613 (0.350, 1.074)	
OTHER	17	11	7.43	(0.95,34.92)	9	5	3.72	(0.95, NE)	0.982	1.019 (0.353, 2.939)	
Progesterone Receptor Status											0.968
NEGATIVE	59	31	7.43	(2.20,16.11)	31	15	6.48	(1.91,19.63)	0.929	0.927 (0.500, 1.719)	
POSITIVE	183	92	12.99	(6.28,16.41)	93	48	10.19	(5.79,19.56)	0.678	0.940 (0.662, 1.334)	

Abbreviations: CI = confidence interval; N = total population size; n = number of patients; NE = not estimable.
*a - LY2835219 v.s. Placebo.
*b - P-value for interaction term from a model with arm, the subgroup variable and arm*subgroup interaction term.
$ - IQWiG Definition: <10 patients in at least one sub-group category or <10 events within all sub-group categories; analyses not presented.
Nature of disease and sensitivity to endocrine therapy are based on CRF values.
The hazard ratio and logrank test p-value were calculated based on the unstratified analysis.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_ttw_subgrp_qs_all_pops.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/t_ttwpadc_subgrp_popa1.rtf
Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Summary of Time to Worsening by Subgroup: Pain at its Worst in Last 24 Hours (Def1) Page 4 of 4
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line) 05:05 13DEC2019
Safety Population TDTM
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019

	LY2835219 (N=245)				Placebo (N=128)				Arm Comparison		
Subgroup	n	events	Median (month)	95% CI	n	events	Median (month)	95% CI	Log Rank p value	Hazard Ratio *a(95% CI)	Interaction p-value*b
Baseline ECOG PS											0.374
1	110	51	12.99	(5.46,24.95)	54	23	18.41	(6.38,25.12)	0.674	1.122 (0.685, 1.837)	
0	135	73	7.43	(5.65,15.45)	74	41	7.43	(3.22,11.97)	0.455	0.845 (0.575, 1.242)	
Previous Anti-Estrogen Therapy											0.029
Y	109	59	7.43	(3.72,24.95)	52	22	18.41	(9.34,25.12)	0.187	1.413 (0.865, 2.309)	
N	136	65	12.43	(5.85,16.11)	76	42	3.72	(2.04,11.97)	0.092	0.703 (0.476, 1.038)	

Abbreviations: CI = confidence interval; N = total population size; n = number of patients; NE = not estimable.
*a - LY2835219 v.s. Placebo.
*b - P-value for interaction term from a model with arm, the subgroup variable and arm*subgroup interaction term.
$ - IQWiG Definition: <10 patients in at least one sub-group category or <10 events within all sub-group categories; analyses not presented.
Nature of disease and sensitivity to endocrine therapy are based on CRF values.
The hazard ratio and logrank test p-value were calculated based on the unstratified analysis.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_ttw_subgrp_qs_all_pops.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/t_ttwpadc_subgrp_popa1.rtf
Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Summary of Time to Worsening by Subgroup: Pain at its Worst in Last 24 Hours (Def1) Page 1 of 4
Pre-/perimenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line) 05:05 13DEC2019
Safety Population TDTM
B1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019

	LY2835219 (N=49)				Placebo (N=23)				Arm Comparison		
Subgroup	n	events	Median (month)	95% CI	n	events	Median (month)	95% CI	Log Rank p value	Hazard Ratio *a(95% CI)	Interaction p-value*b
Overall	49	28	11.24	(5.56,24.59)	23	11	8.09	(3.75, NE)	0.792	1.101 (0.545, 2.226)	
Starting dose											0.904
200 mg	19	12	21.07	(1.91,38.07)	6	4	7.43	(0.99, NE)	0.901	1.028 (0.330, 3.206)	
150 mg	30	16	11.24	(3.91,29.10)	17	7	11.41	(2.60, NE)	0.772	1.124 (0.460, 2.746)	
Nature of Disease $											
VISCERAL	26	17			7	3					
BONE ONLY	14	9			9	4					
OTHER	9	2			7	4					
Sensitivity to Endocrine Therapy $											
PRIMARY RESISTANCE	17	9			7	2					
SECONDARY RESISTANCE	27	16			14	8					
ENDOCRINE NAIVE	5	3			2	1					

Abbreviations: CI = confidence interval; N = total population size; n = number of patients; NE = not estimable.
*a - LY2835219 v.s. Placebo.
*b - P-value for interaction term from a model with arm, the subgroup variable and arm*subgroup interaction term.
$ - IQWiG Definition: <10 patients in at least one sub-group category or <10 events within all sub-group categories; analyses not presented.
Nature of disease and sensitivity to endocrine therapy are based on CRF values.
The hazard ratio and logrank test p-value were calculated based on the unstratified analysis.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_ttw_subgrp_qs_all_pops.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/t_ttwpadc_subgrp_popb1.rtf
Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Summary of Time to Worsening by Subgroup: Pain at its Worst in Last 24 Hours (Def1) Page 2 of 4
Pre-/perimenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line) 05:05 13DEC2019
Safety Population TDTM
B1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019

	LY2835219 (N=49)				Placebo (N=23)				Arm Comparison		
Subgroup	n	events	Median (month)	95% CI	n	events	Median (month)	95% CI	Log Rank p value	Hazard Ratio *a(95% CI)	Interaction p-value*b
Measurable Disease at Baseline											0.746
Y	33	17	16.87	(3.91,38.07)	14	6	8.09	(2.96, NE)	0.648	1.213 (0.477, 3.087)	
N	16	11	11.24	(1.97,24.59)	9	5	11.41	(0.99, NE)	0.773	0.961 (0.329, 2.802)	
Number of Organs at Baseline $											
3+	11	4			7	4					
2	14	8			4	1					
1	24	16			12	6					
Pooled Age Group 1											NE
<65	49	28	11.24	(5.56,24.59)	23	11	8.09	(3.75, NE)	0.792	1.101 (0.545, 2.226)	

Abbreviations: CI = confidence interval; N = total population size; n = number of patients; NE = not estimable.
*a - LY2835219 v.s. Placebo.
*b - P-value for interaction term from a model with arm, the subgroup variable and arm*subgroup interaction term.
$ - IQWiG Definition: <10 patients in at least one sub-group category or <10 events within all sub-group categories; analyses not presented.
Nature of disease and sensitivity to endocrine therapy are based on CRF values.
The hazard ratio and logrank test p-value were calculated based on the unstratified analysis.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_ttw_subgrp_qs_all_pops.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/t_ttwpadc_subgrp_popb1.rtf
Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Summary of Time to Worsening by Subgroup: Pain at its Worst in Last 24 Hours (Def1) Page 3 of 4
Pre-/perimenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line) 05:05 13DEC2019
Safety Population TDTM
B1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019

	LY2835219 (N=49)				Placebo (N=23)				Arm Comparison		
Subgroup	n	events	Median (month)	95% CI	n	events	Median (month)	95% CI	Log Rank p value	Hazard Ratio *a(95% CI)	Interaction p-value*b
Geographical Region $											
NORTH AMERICA	10	4			3	1					
EUROPE	6	4			5	2					
ASIAN	33	20			15	8					
Pooled Race Group 1 $											
CAUCASIAN	11	7			7	2					
ASIAN	33	20			15	8					
OTHER	5	1			1	1					
Progesterone Receptor Status $											
NEGATIVE	13	6			1	1					
POSITIVE	36	22			22	10					

Abbreviations: CI = confidence interval; N = total population size; n = number of patients; NE = not estimable.
*a - LY2835219 v.s. Placebo.
*b - P-value for interaction term from a model with arm, the subgroup variable and arm*subgroup interaction term.
$ - IQWiG Definition: <10 patients in at least one sub-group category or <10 events within all sub-group categories; analyses not presented.
Nature of disease and sensitivity to endocrine therapy are based on CRF values.
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Output Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/t_ttwpadc_subgrp_popb1.rtf
Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Summary of Time to Worsening by Subgroup: Pain at its Worst in Last 24 Hours (Def1) Page 4 of 4
Pre-/perimenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line) 05:05 13DEC2019
Safety Population TDTM
B1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019

	LY2835219 (N=49)				Placebo (N=23)				Arm Comparison		
Subgroup	n	events	Median (month)	95% CI	n	events	Median (month)	95% CI	Log Rank p value	Hazard Ratio *a(95% CI)	Interaction p-value*b
Baseline ECOG PS $											
1	13	6			4	1					
0	36	22			19	10					
Previous Anti-Estrogen Therapy $											
Y	40	23			21	10					
N	9	5			2	1					

Abbreviations: CI = confidence interval; N = total population size; n = number of patients; NE = not estimable.
*a - LY2835219 v.s. Placebo.
*b - P-value for interaction term from a model with arm, the subgroup variable and arm*subgroup interaction term.
$ - IQWiG Definition: <10 patients in at least one sub-group category or <10 events within all sub-group categories; analyses not presented.
Nature of disease and sensitivity to endocrine therapy are based on CRF values.
The hazard ratio and logrank test p-value were calculated based on the unstratified analysis.

Program Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_ttw_subgrp_qs_all_pops.sas
Output Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/t_ttwpadc_subgrp_popb1.rtf
Data Set Location: /lillyce/qa/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam

Tabelle 103.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9856)					
< 65 Jahre	72/147 (49,0)	15,9 [8,58; 35,01]	3/72 (4,2)	NE [NE; NE]	15,15 [4,77; 48,09] <,0001
≥ 65 Jahre	40/98 (40,8)	NE [6,41; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,8811)					
1	58/112 (51,8)	15,0 [3,78; 41,88]	1/49 (2,0)	NE [NE; NE]	32,71 [4,53; 236,33] <,0001
2	29/73 (39,7)	NE [6,41; NE]	1/36 (2,8)	NE [19,40; NE]	16,91 [2,30; 124,22] 0,0001
≥ 3	25/60 (41,7)	30,3 [4,80; NE]	1/43 (2,3)	NE [NE; NE]	24,53 [3,31; 181,71] <,0001
Art der Erkrankung (p-Wert des Interaktionsterms: 0,7239)					
Viszerale Metastasen	52/130 (40,0)	30,3 [10,36; NE]	1/80 (1,3)	NE [NE; NE]	38,33 [5,30; 277,00] <,0001
Nur Knochenmetastasen	41/71 (57,7)	7,5 [1,78; 40,04]	1/29 (3,4)	NE [NE; NE]	24,14 [3,32; 175,82] <,0001
Andere	19/44 (43,2)	14,8 [2,79; NE]	1/19 (5,3)	NE [NE; NE]	11,69 [1,56; 87,60] 0,0023
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9784)					
0	63/135 (46,7)	30,3 [7,50; NE]	3/74 (4,1)	NE [NE; NE]	14,52 [4,56; 46,27] <,0001
1	49/110 (44,5)	15,9 [6,48; 41,88]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 0,7996)					
Weiß/kaukasisch	59/155 (38,1)	NE [14,99; NE]	2/80 (2,5)	NE [NE; NE]	18,59 [4,54; 76,14] <,0001
Asiatisch	41/58 (70,7)	1,0 [0,95; 8,58]	1/32 (3,1)	NE [NE; NE]	41,72 [5,71; 304,69] <,0001

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Andere	8/17 (47,1)	41,9 [3,72; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0587
Geografische Region (p-Wert des Interaktionsterms: 0,7638)					
Europa	40/97 (41,2)	18,5 [14,99; NE]	1/57 (1,8)	NE [NE; NE]	30,05 [4,13; 218,76] <,0001
Nordamerika	33/92 (35,9)	41,9 [30,31; NE]	1/39 (2,6)	NE [19,40; NE]	14,27 [1,95; 104,50] 0,0006
Asien	39/56 (69,6)	1,0 [0,95; 9,34]	1/32 (3,1)	NE [NE; NE]	40,20 [5,50; 293,96] <,0001
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9972)					
Ja	72/169 (42,6)	18,5 [10,16; NE]	2/94 (2,1)	NE [NE; NE]	25,06 [6,15; 102,14] <,0001
Nein	40/76 (52,6)	15,0 [2,24; 40,04]	1/34 (2,9)	NE [NE; NE]	24,78 [3,40; 180,55] <,0001
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9841)					
Positiv	86/183 (47,0)	17,6 [8,58; 46,82]	3/93 (3,2)	NE [NE; NE]	19,13 [6,05; 60,52] <,0001
Negativ	25/59 (42,4)	41,9 [3,72; NE]	0/31 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9072)					
Primäre Resistenz	22/57 (38,6)	35,0 [6,48; NE]	1/35 (2,9)	NE [NE; NE]	14,81 [1,99; 110,15] 0,0005
Sekundäre Resistenz	82/168 (48,8)	15,0 [6,41; 40,04]	2/79 (2,5)	NE [NE; NE]	26,68 [6,56; 108,61] <,0001
Nicht vortherapiert	8/20 (40,0)	NE [0,95; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0099
Startdosis (p-Wert des Interaktionsterms: 0,3211)					
150 mg	77/169 (45,6)	18,4 [10,16; 41,88]	1/87 (1,1)	NE [NE; NE]	47,84 [6,65; 344,07] <,0001
200 mg	35/76 (46,1)	15,1 [1,78; NE]	2/41 (4,9)	NE [NE; NE]	13,26 [3,18; 55,22] <,0001
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9824)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	49/109 (45,0)	18,4 [8,58; NE]	3/52 (5,8)	NE [NE; NE]	9,86 [3,07; 31,68] <,0001
Nein	63/136 (46,3)	18,5 [6,48; NE]	0/76 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.
Neutropenie: PT Neutropenia, Febrile neutropenia and Neutrophil count decreased.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t103_ae_tte_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
14JUL2021 / 09:15

Tabelle 103.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,4707)					
≥ 65 Jahre	30/64 (46,9)	10,6 [4,70; NE]	1/38 (2,6)	NE [NE; NE]	23,52 [3,20; 172,65] <,0001
< 65 Jahre	43/79 (54,4)	18,7 [1,94; 28,57]	2/28 (7,1)	NE [NE; NE]	9,39 [2,28; 38,79] 0,0001
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,9444)					
1	21/47 (44,7)	15,6 [1,94; NE]	0/20 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0008
2	30/49 (61,2)	6,5 [1,87; 24,00]	2/21 (9,5)	NE [NE; NE]	8,25 [1,97; 34,59] 0,0006
≥ 3	22/47 (46,8)	20,5 [2,79; NE]	1/25 (4,0)	NE [NE; NE]	13,36 [1,80; 99,36] 0,0010
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9999)					
Viszerale Metastasen	43/78 (55,1)	10,4 [4,70; 24,00]	3/39 (7,7)	NE [NE; NE]	8,33 [2,58; 26,90] <,0001
Nur Knochenmetastasen	17/39 (43,6)	15,6 [0,99; NE]	0/15 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0034
Andere	13/26 (50,0)	18,7 [1,08; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0068
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,5321)					
0	43/83 (51,8)	18,7 [2,89; 34,13]	2/36 (5,6)	NE [NE; NE]	10,79 [2,61; 44,65] <,0001
1	30/57 (52,6)	10,2 [1,87; 24,00]	1/30 (3,3)	NE [NE; NE]	22,16 [3,02; 162,74] <,0001
Geografische Region (p-Wert des Interaktionsterms: 0,9978)					
Europa	30/75 (40,0)	24,0 [15,55; NE]	2/37 (5,4)	NE [NE; NE]	8,56 [2,04; 35,87] 0,0004
Nordamerika	12/25 (48,0)	12,7 [2,10; NE]	1/16 (6,3)	NE [NE; NE]	8,18 [1,05; 63,62] 0,0168

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Asien	31/43 (72,1)	1,0 [0,95; 6,48]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9872)					
Ja	59/108 (54,6)	10,4 [2,79; 24,00]	3/53 (5,7)	NE [NE; NE]	11,58 [3,62; 36,99] <,0001
Nein	14/35 (40,0)	NE [2,89; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0083
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9883)					
Positiv	57/115 (49,6)	18,7 [5,79; 34,13]	3/50 (6,0)	NE [NE; NE]	10,38 [3,25; 33,16] <,0001
Negativ	14/23 (60,9)	3,3 [0,95; 23,97]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0019
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,3701)					
Primäre Resistenz	12/26 (46,2)	15,6 [1,41; NE]	1/10 (10,0)	NE [3,72; NE]	6,23 [0,81; 48,07] 0,0447
Sekundäre Resistenz	61/117 (52,1)	12,7 [4,77; 24,00]	2/56 (3,6)	NE [NE; NE]	17,91 [4,37; 73,29] <,0001
Startdosis (p-Wert des Interaktionsterms: 0,9860)					
150 mg	52/103 (50,5)	18,7 [4,93; 34,13]	3/49 (6,1)	NE [NE; NE]	9,74 [3,04; 31,19] <,0001
200 mg	21/40 (52,5)	6,5 [0,99; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0004
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9252)					
Ja	37/69 (53,6)	10,4 [1,08; 28,57]	2/38 (5,3)	NE [NE; NE]	13,64 [3,28; 56,67] <,0001
Nein	36/74 (48,6)	15,6 [4,77; 35,15]	1/28 (3,6)	NE [NE; NE]	15,62 [2,14; 114,08] 0,0003

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.
Neutropenie: PT Neutropenia, Febrile neutropenia and Neutrophil count decreased.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
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Tabelle 104.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9839)					
< 65 Jahre	43/147 (29,3)	NE [35,01; NE]	2/72 (2,8)	NE [NE; NE]	11,61 [2,81; 47,92] <,0001
≥ 65 Jahre	20/98 (20,4)	NE [NE; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0003
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,9567)					
1	32/112 (28,6)	NE [40,04; NE]	0/49 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
2	17/73 (23,3)	NE [NE; NE]	1/36 (2,8)	NE [19,40; NE]	8,41 [1,12; 63,25] 0,0132
≥ 3	14/60 (23,3)	NE [30,31; NE]	1/43 (2,3)	NE [NE; NE]	12,15 [1,59; 92,67] 0,0021
Art der Erkrankung (p-Wert des Interaktionsterms: 0,8340)					
Viszerale Metastasen	27/130 (20,8)	NE [NE; NE]	1/80 (1,3)	NE [NE; NE]	17,19 [2,33; 126,55] 0,0001
Nur Knochenmetastasen	23/71 (32,4)	NE [17,56; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0007
Andere	13/44 (29,5)	NE [14,79; NE]	1/19 (5,3)	NE [NE; NE]	7,06 [0,92; 54,03] 0,0283
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9838)					
0	36/135 (26,7)	NE [NE; NE]	2/74 (2,7)	NE [NE; NE]	10,53 [2,53; 43,76] <,0001
1	27/110 (24,5)	NE [18,38; NE]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 0,9440)					
Weiß/kaukasisch	27/155 (17,4)	NE [NE; NE]	1/80 (1,3)	NE [NE; NE]	14,54 [1,98; 107,04] 0,0005
Asiatisch	29/58 (50,0)	14,8 [1,05; NE]	1/32 (3,1)	NE [NE; NE]	22,57 [3,07; 165,98] <,0001

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Andere	4/17 (23,5)	NE [30,31; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2954
Geografische Region (p-Wert des Interaktionsterms: 0,6598)					
Europa	19/97 (19,6)	NE [NE; NE]	0/57 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0004
Nordamerika	16/92 (17,4)	NE [NE; NE]	1/39 (2,6)	NE [19,40; NE]	5,86 [0,77; 44,49] 0,0525
Asien	28/56 (50,0)	14,8 [1,05; NE]	1/32 (3,1)	NE [NE; NE]	22,78 [3,09; 167,81] <,0001
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9864)					
Ja	40/169 (23,7)	NE [NE; NE]	2/94 (2,1)	NE [NE; NE]	12,07 [2,92; 49,97] <,0001
Nein	23/76 (30,3)	NE [17,56; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0004
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9883)					
Positiv	49/183 (26,8)	NE [NE; NE]	2/93 (2,2)	NE [NE; NE]	14,00 [3,40; 57,61] <,0001
Negativ	13/59 (22,0)	NE [NE; NE]	0/31 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0062
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,7317)					
Primäre Resistenz	13/57 (22,8)	NE [35,01; NE]	1/35 (2,9)	NE [NE; NE]	7,43 [0,97; 57,20] 0,0236
Sekundäre Resistenz	44/168 (26,2)	NE [NE; NE]	1/79 (1,3)	NE [NE; NE]	24,25 [3,34; 176,06] <,0001
Nicht vortherapiert	6/20 (30,0)	NE [1,08; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0314
Startdosis (p-Wert des Interaktionsterms: 0,9866)					
150 mg	40/169 (23,7)	NE [NE; NE]	0/87 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
200 mg	23/76 (30,3)	NE [15,12; NE]	2/41 (4,9)	NE [NE; NE]	7,64 [1,80; 32,42] 0,0012
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9872)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	31/109 (28,4)	NE [30,31; NE]	2/52 (3,8)	NE [NE; NE]	8,31 [1,99; 34,73] 0,0005
Nein	32/136 (23,5)	NE [NE; NE]	0/76 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.
Neutropenie: PT Neutropenia, Febrile neutropenia and Neutrophil count decreased.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t104_ae_tte_popa1_2.rtf
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Tabelle 104.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9870)					
≥ 65 Jahre	18/64 (28,1)	NE [NE; NE]	1/38 (2,6)	NE [NE; NE]	12,21 [1,63; 91,55] 0,0018
< 65 Jahre	25/79 (31,6)	NE [23,97; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0034
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,9999)					
1	15/47 (31,9)	NE [20,78; NE]	0/20 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0107
2	15/49 (30,6)	NE [18,67; NE]	1/21 (4,8)	NE [NE; NE]	6,56 [0,86; 49,73] 0,0359
≥ 3	13/47 (27,7)	NE [23,97; NE]	0/25 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0086
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9999)					
Viszerale Metastasen	23/78 (29,5)	NE [23,97; NE]	1/39 (2,6)	NE [NE; NE]	10,67 [1,44; 79,20] 0,0039
Nur Knochenmetastasen	10/39 (25,6)	NE [38,66; NE]	0/15 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0464
Andere	10/26 (38,5)	NE [3,25; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0232
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9861)					
0	23/83 (27,7)	NE [38,66; NE]	0/36 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0023
1	20/57 (35,1)	NE [8,78; NE]	1/30 (3,3)	NE [NE; NE]	12,07 [1,62; 89,99] 0,0019
Geografische Region (p-Wert des Interaktionsterms: 0,9999)					
Europa	14/75 (18,7)	NE [NE; NE]	0/37 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0101
Nordamerika	10/25 (40,0)	26,6 [3,25; NE]	1/16 (6,3)	NE [NE; NE]	6,40 [0,81; 50,60] 0,0432

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Asien	19/43 (44,2)	38,7 [5,79; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0076
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9910)					
Ja	34/108 (31,5)	NE [23,97; NE]	1/53 (1,9)	NE [NE; NE]	16,44 [2,25; 120,35] 0,0002
Nein	9/35 (25,7)	NE [20,78; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0586
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9883)					
Positiv	35/115 (30,4)	NE [26,56; NE]	1/50 (2,0)	NE [NE; NE]	15,68 [2,15; 114,54] 0,0003
Negativ	6/23 (26,1)	NE [23,97; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0812
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9881)					
Primäre Resistenz	8/26 (30,8)	NE [4,70; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0605
Sekundäre Resistenz	35/117 (29,9)	NE [38,66; NE]	1/56 (1,8)	NE [NE; NE]	16,56 [2,27; 121,09] 0,0002
Startdosis (p-Wert des Interaktionsterms: 0,9903)					
150 mg	32/103 (31,1)	NE [23,97; NE]	1/49 (2,0)	NE [NE; NE]	14,89 [2,03; 109,09] 0,0004
200 mg	11/40 (27,5)	NE [26,56; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0269
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9897)					
Ja	25/69 (36,2)	38,7 [18,67; NE]	0/38 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0002
Nein	18/74 (24,3)	NE [NE; NE]	1/28 (3,6)	NE [NE; NE]	6,89 [0,92; 51,77] 0,0294

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.
Neutropenie: PT Neutropenia, Febrile neutropenia and Neutrophil count decreased.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t104_ae_tte_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 105.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9806)					
< 65 Jahre	50/147 (34,0)	NE [30,58; NE]	2/72 (2,8)	NE [NE; NE]	13,71 [3,33; 56,35] <,0001
≥ 65 Jahre	36/98 (36,7)	41,9 [14,04; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,9882)					
1	43/112 (38,4)	NE [14,04; NE]	1/49 (2,0)	NE [NE; NE]	22,11 [3,04; 160,71] <,0001
2	23/73 (31,5)	NE [18,48; NE]	0/36 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0005
≥ 3	20/60 (33,3)	41,3 [16,37; NE]	1/43 (2,3)	NE [NE; NE]	18,88 [2,52; 141,32] <,0001
Art der Erkrankung (p-Wert des Interaktionsterms: 0,8387)					
Viszerale Metastasen	41/130 (31,5)	NE [30,58; NE]	0/80 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Nur Knochenmetastasen	32/71 (45,1)	41,9 [3,48; NE]	1/29 (3,4)	NE [NE; NE]	16,58 [2,26; 121,53] 0,0002
Andere	13/44 (29,5)	NE [41,26; NE]	1/19 (5,3)	NE [NE; NE]	6,74 [0,88; 51,63] 0,0332
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9820)					
0	51/135 (37,8)	NE [30,58; NE]	2/74 (2,7)	NE [NE; NE]	16,80 [4,09; 69,03] <,0001
1	35/110 (31,8)	NE [18,48; NE]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 0,9980)					
Weiß/kaukasisch	47/155 (30,3)	NE [NE; NE]	1/80 (1,3)	NE [NE; NE]	27,41 [3,78; 198,62] <,0001
Asiatisch	32/58 (55,2)	8,6 [1,58; 41,26]	1/32 (3,1)	NE [NE; NE]	24,31 [3,31; 178,39] <,0001

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Andere	6/17 (35,3)	46,8 [3,72; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0715
Geografische Region (p-Wert des Interaktionsterms: 0,9976)					
Europa	32/97 (33,0)	NE [18,48; NE]	1/57 (1,8)	NE [NE; NE]	21,77 [2,97; 159,39] <,0001
Nordamerika	24/92 (26,1)	NE [46,82; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0014
Asien	30/56 (53,6)	10,4 [1,48; NE]	1/32 (3,1)	NE [NE; NE]	23,06 [3,14; 169,61] <,0001
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,6320)					
Ja	55/169 (32,5)	NE [41,26; NE]	1/94 (1,1)	NE [NE; NE]	34,37 [4,76; 248,06] <,0001
Nein	31/76 (40,8)	NE [3,78; NE]	1/34 (2,9)	NE [NE; NE]	17,30 [2,36; 126,93] 0,0001
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9863)					
Positiv	66/183 (36,1)	NE [41,26; NE]	2/93 (2,2)	NE [NE; NE]	19,87 [4,87; 81,14] <,0001
Negativ	20/59 (33,9)	41,9 [16,37; NE]	0/31 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0005
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,6893)					
Primäre Resistenz	16/57 (28,1)	NE [30,58; NE]	1/35 (2,9)	NE [NE; NE]	10,25 [1,36; 77,48] 0,0052
Sekundäre Resistenz	64/168 (38,1)	46,8 [14,04; NE]	1/79 (1,3)	NE [NE; NE]	37,11 [5,15; 267,66] <,0001
Nicht vortherapiert	6/20 (30,0)	NE [16,37; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0379
Startdosis (p-Wert des Interaktionsterms: 0,6751)					
150 mg	59/169 (34,9)	NE [41,88; NE]	1/87 (1,1)	NE [NE; NE]	34,19 [4,74; 246,85] <,0001
200 mg	27/76 (35,5)	NE [30,58; NE]	1/41 (2,4)	NE [NE; NE]	18,53 [2,52; 136,50] <,0001
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9849)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	37/109 (33,9)	NE [30,58; NE]	2/52 (3,8)	NE [NE; NE]	9,87 [2,38; 40,96] 0,0001
Nein	49/136 (36,0)	NE [18,48; NE]	0/76 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.
Neutropenie: PT Neutropenia, Febrile neutropenia and Neutrophil count decreased.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
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Tabelle 105.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9880)					
≥ 65 Jahre	24/64 (37,5)	34,1 [6,48; NE]	0/38 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
< 65 Jahre	33/79 (41,8)	28,6 [12,69; NE]	2/28 (7,1)	NE [NE; NE]	6,70 [1,60; 27,95] 0,0025
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,9386)					
1	16/47 (34,0)	NE [10,62; NE]	0/20 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0044
2	26/49 (53,1)	14,2 [2,79; 34,13]	1/21 (4,8)	NE [NE; NE]	12,93 [1,75; 95,43] 0,0011
≥ 3	15/47 (31,9)	35,1 [20,52; NE]	1/25 (4,0)	NE [NE; NE]	8,48 [1,12; 64,42] 0,0132
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9998)					
Viszerale Metastasen	34/78 (43,6)	28,6 [10,19; NE]	2/39 (5,1)	NE [NE; NE]	9,06 [2,17; 37,80] 0,0002
Nur Knochenmetastasen	14/39 (35,9)	NE [10,62; NE]	0/15 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0097
Andere	9/26 (34,6)	NE [2,79; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0254
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9892)					
0	36/83 (43,4)	34,1 [12,69; NE]	2/36 (5,6)	NE [NE; NE]	8,67 [2,08; 36,11] 0,0004
1	21/57 (36,8)	24,0 [10,19; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0002
Geografische Region (p-Wert des Interaktionsterms: 0,9998)					
Europa	24/75 (32,0)	35,1 [24,00; NE]	2/37 (5,4)	NE [NE; NE]	6,42 [1,52; 27,21] 0,0037
Nordamerika	7/25 (28,0)	NE [12,69; NE]	0/16 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0940

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Asien	26/43 (60,5)	1,9 [0,95; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0005
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9892)					
Ja	47/108 (43,5)	28,6 [12,69; NE]	2/53 (3,8)	NE [NE; NE]	12,66 [3,07; 52,24] <,0001
Nein	10/35 (28,6)	NE [10,62; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0301
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9898)					
Positiv	46/115 (40,0)	34,1 [15,55; NE]	2/50 (4,0)	NE [NE; NE]	11,43 [2,77; 47,11] <,0001
Negativ	11/23 (47,8)	10,6 [1,41; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0067
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,2071)					
Primäre Resistenz	9/26 (34,6)	NE [5,13; NE]	1/10 (10,0)	NE [3,72; NE]	4,30 [0,54; 34,11] 0,1329
Sekundäre Resistenz	48/117 (41,0)	28,6 [12,69; NE]	1/56 (1,8)	NE [NE; NE]	25,66 [3,54; 186,03] <,0001
Startdosis (p-Wert des Interaktionsterms: 0,9881)					
150 mg	38/103 (36,9)	35,1 [24,00; NE]	2/49 (4,1)	NE [NE; NE]	9,56 [2,30; 39,67] 0,0001
200 mg	19/40 (47,5)	12,7 [1,87; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0008
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9851)					
Ja	30/69 (43,5)	28,6 [4,93; NE]	2/38 (5,3)	NE [NE; NE]	10,13 [2,42; 42,41] <,0001
Nein	27/74 (36,5)	34,1 [15,55; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0012

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.
Neutropenie: PT Neutropenia, Febrile neutropenia and Neutrophil count decreased.

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/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 107.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,0976)					
< 65 Jahre	69/147 (46,9)	15,1 [9,07; 27,29]	25/72 (34,7)	20,8 [12,03; NE]	1,28 [0,81; 2,03] 0,2859
≥ 65 Jahre	41/98 (41,8)	15,4 [10,13; 24,10]	12/56 (21,4)	32,4 [32,35; NE]	2,47 [1,29; 4,71] 0,0046
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,2273)					
1	55/112 (49,1)	12,0 [8,32; 24,10]	16/49 (32,7)	NE [13,81; NE]	1,63 [0,93; 2,84] 0,0847
2	29/73 (39,7)	13,0 [8,94; NE]	12/36 (33,3)	13,1 [8,94; NE]	1,00 [0,51; 1,99] 0,9889
≥ 3	26/60 (43,3)	16,6 [8,61; 27,42]	9/43 (20,9)	NE [NE; NE]	2,57 [1,20; 5,51] 0,0120
Art der Erkrankung (p-Wert des Interaktionsterms: 0,1574)					
Viszerale Metastasen	59/130 (45,4)	13,0 [8,78; 22,26]	19/80 (23,8)	NE [12,82; NE]	1,94 [1,16; 3,26] 0,0103
Nur Knochenmetastasen	34/71 (47,9)	19,9 [9,07; 31,69]	8/29 (27,6)	NE [13,81; NE]	1,97 [0,91; 4,26] 0,0808
Andere	17/44 (38,6)	18,9 [6,61; NE]	10/19 (52,6)	18,2 [8,94; 22,06]	0,84 [0,38; 1,85] 0,6683
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,1841)					
0	67/135 (49,6)	10,6 [8,55; 21,60]	28/74 (37,8)	22,1 [10,65; NE]	1,42 [0,91; 2,21] 0,1192
1	43/110 (39,1)	21,2 [11,15; 27,42]	9/54 (16,7)	NE [NE; NE]	2,49 [1,21; 5,11] 0,0100
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 0,2438)					
Weiß/kaukasisch	73/155 (47,1)	12,0 [9,07; 21,60]	19/80 (23,8)	NE [18,25; NE]	2,28 [1,37; 3,78] 0,0011
Asiatisch	22/58 (37,9)	22,3 [8,78; NE]	10/32 (31,3)	NE [13,12; NE]	1,24 [0,58; 2,63] 0,5749

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Andere	11/17 (64,7)	8,9 [1,58; 43,73]	5/9 (55,6)	32,4 [0,23; NE]	0,97 [0,33; 2,87] 0,9600
Geografische Region (p-Wert des Interaktionsterms: 0,3330)					
Europa	42/97 (43,3)	15,4 [9,90; 40,24]	12/57 (21,1)	NE [NE; NE]	2,27 [1,19; 4,32] 0,0103
Nordamerika	46/92 (50,0)	10,5 [7,63; 21,60]	15/39 (38,5)	12,0 [8,94; NE]	1,28 [0,71; 2,30] 0,4126
Asien	22/56 (39,3)	22,3 [8,78; NE]	10/32 (31,3)	NE [13,12; NE]	1,29 [0,61; 2,73] 0,5074
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,6365)					
Ja	76/169 (45,0)	15,1 [8,94; 24,10]	28/94 (29,8)	32,4 [12,82; NE]	1,58 [1,03; 2,44] 0,0362
Nein	34/76 (44,7)	19,9 [9,30; 31,69]	9/34 (26,5)	NE [13,81; NE]	1,92 [0,92; 4,02] 0,0790
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,0961)					
Positiv	83/183 (45,4)	12,0 [9,90; 24,10]	24/93 (25,8)	NE [22,06; NE]	2,01 [1,27; 3,17] 0,0022
Negativ	26/59 (44,1)	16,6 [9,07; 25,18]	12/31 (38,7)	9,5 [5,82; NE]	0,92 [0,46; 1,84] 0,8039
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,4550)					
Primäre Resistenz	22/57 (38,6)	18,9 [10,52; NE]	10/35 (28,6)	13,8 [7,59; NE]	1,03 [0,48; 2,21] 0,9346
Sekundäre Resistenz	74/168 (44,0)	16,6 [9,90; 24,10]	22/79 (27,8)	32,4 [20,84; NE]	1,86 [1,15; 3,00] 0,0096
Nicht vortherapiert	14/20 (70,0)	5,3 [2,01; 27,42]	5/14 (35,7)	NE [1,87; NE]	2,00 [0,72; 5,57] 0,1740
Startdosis (p-Wert des Interaktionsterms: 0,1480)					
150 mg	71/169 (42,0)	18,9 [10,13; 31,69]	26/87 (29,9)	32,4 [18,25; NE]	1,35 [0,86; 2,12] 0,1875
200 mg	39/76 (51,3)	11,3 [8,55; 22,26]	11/41 (26,8)	NE [13,12; NE]	2,48 [1,27; 4,84] 0,0061
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,6615)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	44/109 (40,4)	21,2 [9,30; NE]	12/52 (23,1)	NE [12,82; NE]	1,89 [1,00; 3,58] 0,0472
Nein	66/136 (48,5)	12,0 [9,07; 22,26]	25/76 (32,9)	22,1 [13,12; NE]	1,56 [0,98; 2,47] 0,0578

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SOC: System Organ Class.

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t107_ae_tte_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 107.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	n/N (%)	Mediane Ereigniszeit[1]	n/N (%)	Mediane Ereigniszeit[1]	HR [95% KI] p-Wert[2]
Alter (p-Wert des Interaktionsterms: 0,3320)					
≥ 65 Jahre	29/64 (45,3)	13,8 [5,56; NE]	7/38 (18,4)	25,4 [9,44; NE]	2,49 [1,09; 5,69] 0,0257
< 65 Jahre	45/79 (57,0)	10,1 [6,08; 15,48]	10/28 (35,7)	23,3 [9,11; NE]	1,42 [0,72; 2,83] 0,3108
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,4804)					
1	29/47 (61,7)	6,5 [4,96; 10,06]	5/20 (25,0)	15,1 [9,44; NE]	2,98 [1,15; 7,72] 0,0184
2	26/49 (53,1)	12,2 [4,18; 30,35]	8/21 (38,1)	23,3 [4,54; NE]	1,40 [0,63; 3,11] 0,4067
≥ 3	19/47 (40,4)	14,1 [7,92; NE]	4/25 (16,0)	NE [9,11; NE]	1,82 [0,61; 5,41] 0,2770
Art der Erkrankung (p-Wert des Interaktionsterms: 0,8434)					
Viszerale Metastasen	37/78 (47,4)	13,8 [10,62; NE]	9/39 (23,1)	23,3 [9,11; NE]	1,71 [0,82; 3,57] 0,1461
Nur Knochenmetastasen	23/39 (59,0)	6,9 [5,26; 12,92]	5/15 (33,3)	15,1 [4,57; NE]	1,99 [0,75; 5,24] 0,1562
Andere	14/26 (53,8)	6,3 [3,48; NE]	3/12 (25,0)	25,4 [4,54; NE]	2,47 [0,70; 8,70] 0,1453
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,8916)					
0	44/83 (53,0)	10,6 [6,08; 20,05]	9/36 (25,0)	23,3 [9,44; NE]	1,85 [0,90; 3,81] 0,0888
1	27/57 (47,4)	12,2 [5,56; 16,50]	8/30 (26,7)	15,1 [9,11; NE]	1,78 [0,81; 3,93] 0,1464
Geografische Region (p-Wert des Interaktionsterms: 0,5613)					
Europa	37/75 (49,3)	12,1 [6,08; 25,22]	7/37 (18,9)	NE [9,11; NE]	2,60 [1,16; 5,86] 0,0163
Nordamerika	18/25 (72,0)	5,9 [2,66; 10,62]	5/16 (31,3)	NE [2,86; NE]	1,47 [0,52; 4,15] 0,4637

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Asien	19/43 (44,2)	18,6 [5,88; NE]	5/13 (38,5)	25,4 [13,22; NE]	1,32 [0,49; 3,55] 0,5852
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,5591)					
Ja	54/108 (50,0)	12,2 [6,48; 18,61]	13/53 (24,5)	23,3 [13,22; NE]	1,74 [0,94; 3,21] 0,0723
Nein	20/35 (57,1)	6,9 [4,96; 12,92]	4/13 (30,8)	NE [4,57; NE]	2,54 [0,86; 7,48] 0,0804
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,5582)					
Positiv	64/115 (55,7)	10,6 [6,25; 13,78]	14/50 (28,0)	25,4 [13,22; NE]	1,88 [1,05; 3,35] 0,0306
Negativ	8/23 (34,8)	NE [4,96; NE]	3/12 (25,0)	15,1 [4,54; NE]	1,36 [0,36; 5,15] 0,6534
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,1646)					
Primäre Resistenz	12/26 (46,2)	9,3 [4,60; NE]	5/10 (50,0)	15,1 [0,23; NE]	1,03 [0,36; 2,96] 0,9556
Sekundäre Resistenz	62/117 (53,0)	10,6 [6,25; 15,48]	12/56 (21,4)	25,4 [13,22; NE]	2,28 [1,23; 4,24] 0,0074
Startdosis (p-Wert des Interaktionsterms: 0,8587)					
150 mg	51/103 (49,5)	10,6 [6,31; 25,22]	12/49 (24,5)	25,4 [15,06; NE]	1,85 [0,98; 3,47] 0,0530
200 mg	23/40 (57,5)	9,3 [4,18; 13,78]	5/17 (29,4)	13,2 [9,11; NE]	1,86 [0,70; 4,93] 0,2059
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,1016)					
Ja	36/69 (52,2)	12,9 [6,90; 18,61]	13/38 (34,2)	23,3 [9,44; NE]	1,27 [0,67; 2,42] 0,4559
Nein	38/74 (51,4)	7,2 [5,10; 14,07]	4/28 (14,3)	NE [NE; NE]	3,67 [1,31; 10,29] 0,0082

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t107_ae_tte_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 108.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,8631)					
< 65 Jahre	15/147 (10,2)	NE [NE; NE]	2/72 (2,8)	NE [NE; NE]	3,28 [0,75; 14,35] 0,0942
≥ 65 Jahre	7/98 (7,1)	NE [NE; NE]	1/56 (1,8)	NE [NE; NE]	3,64 [0,44; 29,97] 0,1986
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,9580)					
1	12/112 (10,7)	NE [NE; NE]	0/49 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0288
2	4/73 (5,5)	NE [NE; NE]	1/36 (2,8)	NE [NE; NE]	1,87 [0,21; 16,81] 0,5698
≥ 3	6/60 (10,0)	NE [NE; NE]	2/43 (4,7)	NE [NE; NE]	2,31 [0,46; 11,46] 0,2915
Art der Erkrankung (p-Wert des Interaktionsterms: 0,8516)					
Viszerale Metastasen	11/130 (8,5)	NE [NE; NE]	2/80 (2,5)	NE [NE; NE]	2,81 [0,62; 12,77] 0,1623
Nur Knochenmetastasen	8/71 (11,3)	NE [NE; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0543
Andere	3/44 (6,8)	NE [NE; NE]	1/19 (5,3)	NE [NE; NE]	1,31 [0,14; 12,65] 0,8126
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,8644)					
0	13/135 (9,6)	NE [NE; NE]	2/74 (2,7)	NE [NE; NE]	3,14 [0,71; 14,01] 0,1126
1	9/110 (8,2)	NE [NE; NE]	1/54 (1,9)	NE [NE; NE]	4,17 [0,53; 32,96] 0,1408
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 0,9999)					
Weiß/kaukasisch	14/155 (9,0)	NE [NE; NE]	2/80 (2,5)	NE [NE; NE]	3,19 [0,72; 14,10] 0,1052
Asiatisch	3/58 (5,2)	NE [NE; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1936

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Andere	4/17 (23,5)	NE [4,64; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1336
Geografische Region (p-Wert des Interaktionsterms: 0,8985)					
Europa	8/97 (8,2)	NE [NE; NE]	2/57 (3,5)	NE [NE; NE]	2,21 [0,47; 10,43] 0,3022
Nordamerika	11/92 (12,0)	NE [NE; NE]	1/39 (2,6)	NE [NE; NE]	3,86 [0,49; 30,15] 0,1647
Asien	3/56 (5,4)	NE [NE; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1874
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9904)					
Ja	15/169 (8,9)	NE [NE; NE]	3/94 (3,2)	NE [NE; NE]	2,41 [0,69; 8,35] 0,1522
Nein	7/76 (9,2)	NE [NE; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0626
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,3309)					
Positiv	18/183 (9,8)	NE [NE; NE]	1/93 (1,1)	NE [NE; NE]	8,43 [1,12; 63,26] 0,0129
Negativ	4/59 (6,8)	NE [NE; NE]	1/31 (3,2)	NE [NE; NE]	2,01 [0,22; 18,03] 0,5245
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,7883)					
Primäre Resistenz	7/57 (12,3)	NE [NE; NE]	0/35 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0985
Sekundäre Resistenz	13/168 (7,7)	NE [NE; NE]	2/79 (2,5)	NE [NE; NE]	2,97 [0,67; 13,22] 0,1328
Nicht vortherapiert	2/20 (10,0)	NE [NE; NE]	1/14 (7,1)	NE [5,33; NE]	1,25 [0,11; 13,88] 0,8494
Startdosis (p-Wert des Interaktionsterms: 0,4189)					
150 mg	14/169 (8,3)	NE [NE; NE]	1/87 (1,1)	NE [NE; NE]	6,30 [0,83; 47,98] 0,0414
200 mg	8/76 (10,5)	NE [NE; NE]	2/41 (4,9)	NE [NE; NE]	2,19 [0,46; 10,40] 0,3099
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,7188)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	11/109 (10,1)	NE [NE; NE]	1/52 (1,9)	NE [NE; NE]	4,46 [0,57; 34,74] 0,1178
Nein	11/136 (8,1)	NE [NE; NE]	2/76 (2,6)	NE [NE; NE]	2,97 [0,66; 13,42] 0,1365

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SOC: System Organ Class.

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Tabelle 108.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,2887)					
< 65 Jahre	8/79 (10,1)	NE [NE; NE]	3/28 (10,7)	NE [11,15; NE]	0,60 [0,16; 2,31] 0,4558
≥ 65 Jahre	6/64 (9,4)	NE [40,67; NE]	1/38 (2,6)	NE [NE; NE]	2,66 [0,31; 23,11] 0,3575
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,4700)					
0	6/83 (7,2)	NE [NE; NE]	2/36 (5,6)	NE [NE; NE]	0,68 [0,13; 3,66] 0,6509
1	8/57 (14,0)	NE [NE; NE]	2/30 (6,7)	NE [11,15; NE]	1,70 [0,36; 8,07] 0,4978
Geografische Region (p-Wert des Interaktionsterms: 0,6535)					
Europa	12/75 (16,0)	NE [37,78; NE]	2/37 (5,4)	NE [9,93; NE]	2,05 [0,45; 9,30] 0,3425
Nordamerika	2/25 (8,0)	NE [NE; NE]	1/16 (6,3)	NE [11,15; NE]	0,54 [0,04; 6,55] 0,6217
Asien	0/43 (0,0)	NE [NE; NE]	1/13 (7,7)	NE [NE; NE]	0,00 [0,00; NE] 0,0752
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,5692)					
Ja	9/108 (8,3)	NE [NE; NE]	3/53 (5,7)	NE [NE; NE]	0,83 [0,21; 3,23] 0,7831
Nein	5/35 (14,3)	NE [NE; NE]	1/13 (7,7)	NE [9,44; NE]	1,87 [0,22; 16,02] 0,5611
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9220)					
Positiv	10/115 (8,7)	NE [NE; NE]	3/50 (6,0)	NE [NE; NE]	1,08 [0,29; 3,98] 0,9074
Negativ	3/23 (13,0)	NE [40,67; NE]	1/12 (8,3)	NE [9,44; NE]	0,53 [0,04; 6,71] 0,6177
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,1800)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Primäre Resistenz	2/26 (7,7)	NE [NE; NE]	2/10 (20,0)	NE [4,31; NE]	0,35 [0,05; 2,50] 0,2743
Sekundäre Resistenz	12/117 (10,3)	NE [NE; NE]	2/56 (3,6)	NE [NE; NE]	1,75 [0,38; 8,04] 0,4639
Startdosis (p-Wert des Interaktionsterms: 0,3258)					
150 mg	13/103 (12,6)	NE [NE; NE]	3/49 (6,1)	NE [NE; NE]	1,38 [0,39; 4,93] 0,6178
200 mg	1/40 (2,5)	NE [NE; NE]	1/17 (5,9)	NE [9,93; NE]	0,26 [0,02; 4,10] 0,2993
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9916)					
Ja	3/69 (4,3)	NE [NE; NE]	4/38 (10,5)	NE [NE; NE]	0,23 [0,05; 1,09] 0,0455
Nein	11/74 (14,9)	NE [40,67; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0803

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SOC: System Organ Class.

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Tabelle 109.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,0630)					
< 65 Jahre	63/147 (42,9)	19,9 [10,52; 35,31]	24/72 (33,3)	20,8 [12,69; NE]	1,18 [0,74; 1,89] 0,4878
≥ 65 Jahre	39/98 (39,8)	21,6 [10,52; 27,42]	11/56 (19,6)	NE [32,35; NE]	2,51 [1,28; 4,92] 0,0053
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,1692)					
1	52/112 (46,4)	19,9 [9,07; 30,61]	16/49 (32,7)	NE [13,81; NE]	1,48 [0,85; 2,60] 0,1659
2	26/73 (35,6)	22,3 [9,90; NE]	11/36 (30,6)	13,1 [8,94; NE]	0,91 [0,44; 1,87] 0,7984
≥ 3	24/60 (40,0)	16,6 [10,52; 27,42]	8/43 (18,6)	NE [NE; NE]	2,77 [1,24; 6,20] 0,0097
Art der Erkrankung (p-Wert des Interaktionsterms: 0,1192)					
Viszerale Metastasen	55/130 (42,3)	15,4 [10,09; 27,29]	17/80 (21,3)	NE [12,82; NE]	1,96 [1,14; 3,38] 0,0136
Nur Knochenmetastasen	32/71 (45,1)	21,6 [11,15; 43,73]	8/29 (27,6)	NE [13,81; NE]	1,78 [0,82; 3,88] 0,1408
Andere	15/44 (34,1)	30,6 [8,61; NE]	10/19 (52,6)	18,2 [9,50; 22,06]	0,74 [0,33; 1,67] 0,4717
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,1656)					
0	63/135 (46,7)	12,0 [8,94; 30,61]	27/74 (36,5)	22,1 [12,03; NE]	1,34 [0,85; 2,11] 0,2026
1	39/110 (35,5)	22,3 [15,42; 40,24]	8/54 (14,8)	NE [NE; NE]	2,47 [1,15; 5,29] 0,0160
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 0,1766)					
Weiß/kaukasisch	67/155 (43,2)	15,4 [10,09; 27,42]	17/80 (21,3)	NE [18,25; NE]	2,26 [1,33; 3,85] 0,0021
Asiatisch	21/58 (36,2)	23,2 [10,13; NE]	10/32 (31,3)	NE [13,12; NE]	1,15 [0,54; 2,45] 0,7227

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Andere	10/17 (58,8)	8,9 [1,58; 43,73]	5/9 (55,6)	32,4 [0,23; NE]	0,84 [0,28; 2,53] 0,7606
Geografische Region (p-Wert des Interaktionsterms: 0,3470)					
Europa	38/97 (39,2)	27,3 [11,80; 40,24]	11/57 (19,3)	NE [NE; NE]	2,20 [1,12; 4,30] 0,0186
Nordamerika	43/92 (46,7)	11,3 [8,38; 24,10]	14/39 (35,9)	18,2 [8,94; NE]	1,24 [0,68; 2,28] 0,4793
Asien	21/56 (37,5)	23,2 [8,78; NE]	10/32 (31,3)	NE [13,12; NE]	1,19 [0,56; 2,54] 0,6503
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,8567)					
Ja	71/169 (42,0)	16,6 [10,09; 30,61]	26/94 (27,7)	32,4 [12,82; NE]	1,56 [1,00; 2,45] 0,0494
Nein	31/76 (40,8)	21,6 [11,80; 43,73]	9/34 (26,5)	NE [13,81; NE]	1,68 [0,79; 3,54] 0,1701
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,1685)					
Positiv	76/183 (41,5)	21,6 [10,62; 30,61]	24/93 (25,8)	NE [22,06; NE]	1,80 [1,14; 2,85] 0,0109
Negativ	25/59 (42,4)	21,2 [9,07; 40,24]	11/31 (35,5)	10,7 [5,82; NE]	0,92 [0,44; 1,89] 0,8115
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,3377)					
Primäre Resistenz	20/57 (35,1)	19,9 [10,52; NE]	10/35 (28,6)	13,8 [7,59; NE]	0,89 [0,41; 1,94] 0,7745
Sekundäre Resistenz	69/168 (41,1)	21,2 [11,97; 27,29]	20/79 (25,3)	32,4 [20,84; NE]	1,86 [1,13; 3,06] 0,0132
Nicht vortherapiert	13/20 (65,0)	9,1 [2,17; 40,24]	5/14 (35,7)	NE [1,87; NE]	1,84 [0,66; 5,18] 0,2383
Startdosis (p-Wert des Interaktionsterms: 0,1909)					
150 mg	67/169 (39,6)	25,2 [10,62; 40,24]	25/87 (28,7)	32,4 [18,25; NE]	1,30 [0,82; 2,05] 0,2675
200 mg	35/76 (46,1)	16,6 [9,07; 24,10]	10/41 (24,4)	NE [12,69; NE]	2,29 [1,13; 4,63] 0,0176
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,7502)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	39/109 (35,8)	24,1 [11,28; NE]	11/52 (21,2)	NE [12,82; NE]	1,78 [0,91; 3,48] 0,0869
Nein	63/136 (46,3)	15,1 [10,13; 25,18]	24/76 (31,6)	22,1 [13,12; NE]	1,51 [0,94; 2,42] 0,0837

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SOC: System Organ Class.

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Tabelle 109.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,3009)					
≥ 65 Jahre	27/64 (42,2)	13,8 [5,88; NE]	7/38 (18,4)	24,1 [15,06; NE]	2,34 [1,02; 5,38] 0,0396
< 65 Jahre	43/79 (54,4)	11,5 [6,48; 16,50]	10/28 (35,7)	23,3 [9,11; NE]	1,32 [0,66; 2,62] 0,4364
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,5064)					
1	27/47 (57,4)	6,9 [4,96; 12,92]	5/20 (25,0)	24,1 [13,22; NE]	2,87 [1,10; 7,48] 0,0236
2	26/49 (53,1)	12,2 [3,52; 30,35]	8/21 (38,1)	23,3 [4,54; NE]	1,39 [0,62; 3,08] 0,4193
≥ 3	17/47 (36,2)	25,2 [10,62; NE]	4/25 (16,0)	NE [9,11; NE]	1,52 [0,50; 4,59] 0,4566
Art der Erkrankung (p-Wert des Interaktionsterms: 0,7789)					
Viszerale Metastasen	35/78 (44,9)	14,1 [10,62; NE]	9/39 (23,1)	23,3 [9,11; NE]	1,56 [0,75; 3,27] 0,2311
Nur Knochenmetastasen	21/39 (53,8)	7,2 [5,88; 15,48]	5/15 (33,3)	24,1 [4,57; NE]	1,90 [0,71; 5,05] 0,1925
Andere	14/26 (53,8)	6,3 [3,48; NE]	3/12 (25,0)	25,4 [4,54; NE]	2,47 [0,70; 8,70] 0,1453
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,8677)					
0	42/83 (50,6)	12,1 [6,31; 25,22]	9/36 (25,0)	24,1 [23,31; NE]	1,74 [0,84; 3,59] 0,1288
1	25/57 (43,9)	12,9 [6,48; NE]	8/30 (26,7)	15,1 [9,11; NE]	1,64 [0,74; 3,65] 0,2170
Geografische Region (p-Wert des Interaktionsterms: 0,7013)					
Europa	33/75 (44,0)	14,1 [6,90; NE]	7/37 (18,9)	24,1 [9,11; NE]	2,24 [0,99; 5,08] 0,0475
Nordamerika	18/25 (72,0)	5,9 [2,66; 11,54]	5/16 (31,3)	NE [2,86; NE]	1,47 [0,52; 4,15] 0,4637

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Asien	19/43 (44,2)	18,6 [5,88; NE]	5/13 (38,5)	25,4 [13,22; NE]	1,32 [0,49; 3,55] 0,5852
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,4483)					
Ja	51/108 (47,2)	13,8 [10,62; 25,22]	13/53 (24,5)	23,3 [13,22; NE]	1,59 [0,86; 2,95] 0,1350
Nein	19/35 (54,3)	6,9 [5,26; 12,92]	4/13 (30,8)	24,1 [4,57; NE]	2,63 [0,88; 7,82] 0,0718
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,4964)					
Positiv	61/115 (53,0)	11,8 [6,48; 14,07]	14/50 (28,0)	25,4 [13,22; NE]	1,76 [0,98; 3,15] 0,0539
Negativ	7/23 (30,4)	NE [5,88; NE]	3/12 (25,0)	24,1 [4,54; NE]	1,09 [0,28; 4,26] 0,8984
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,1486)					
Primäre Resistenz	11/26 (42,3)	11,5 [5,92; NE]	5/10 (50,0)	15,1 [0,23; NE]	0,95 [0,33; 2,78] 0,9295
Sekundäre Resistenz	59/117 (50,4)	12,1 [6,90; 18,61]	12/56 (21,4)	25,4 [24,10; NE]	2,14 [1,15; 4,00] 0,0141
Startdosis (p-Wert des Interaktionsterms: 0,7466)					
150 mg	47/103 (45,6)	13,4 [6,90; NE]	12/49 (24,5)	24,1 [15,06; NE]	1,67 [0,89; 3,16] 0,1093
200 mg	23/40 (57,5)	11,5 [4,18; 13,78]	5/17 (29,4)	13,2 [9,11; NE]	1,86 [0,70; 4,93] 0,2059
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,1824)					
Ja	36/69 (52,2)	12,9 [6,90; 18,61]	13/38 (34,2)	23,3 [13,22; NE]	1,31 [0,69; 2,48] 0,4068
Nein	34/74 (45,9)	11,5 [5,56; NE]	4/28 (14,3)	NE [NE; NE]	3,15 [1,12; 8,90] 0,0222

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t109_ae_tte_popa2_2.rtf
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/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 110.1.2: Subgruppen - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9916)					
< 65 Jahre	12/147 (8,2)	NE [NE; NE]	1/72 (1,4)	NE [NE; NE]	5,07 [0,66; 39,02] 0,0826
≥ 65 Jahre	4/98 (4,1)	NE [NE; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1159
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9999)					
Viszerale Metastasen	9/130 (6,9)	NE [NE; NE]	1/80 (1,3)	NE [NE; NE]	4,54 [0,57; 35,96] 0,1164
Nur Knochenmetastasen	5/71 (7,0)	NE [NE; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1329
Andere	2/44 (4,5)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3477
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9901)					
0	7/135 (5,2)	NE [NE; NE]	0/74 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0564
1	9/110 (8,2)	NE [NE; NE]	1/54 (1,9)	NE [NE; NE]	4,10 [0,52; 32,39] 0,1467
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 1,0000)					
Weiß/kaukasisch	11/155 (7,1)	NE [NE; NE]	1/80 (1,3)	NE [NE; NE]	5,20 [0,67; 40,29] 0,0780
Asiatisch	1/58 (1,7)	NE [NE; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,5127
Andere	3/17 (17,6)	NE [8,88; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2172
Geografische Region (p-Wert des Interaktionsterms: 0,9999)					
Europa	6/97 (6,2)	NE [NE; NE]	0/57 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0677
Nordamerika	9/92 (9,8)	NE [NE; NE]	1/39 (2,6)	NE [NE; NE]	3,18 [0,40; 25,28] 0,2471

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Asien	1/56 (1,8)	NE [NE; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,5050
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9926)					
Ja	11/169 (6,5)	NE [NE; NE]	1/94 (1,1)	NE [NE; NE]	5,32 [0,69; 41,31] 0,0733
Nein	5/76 (6,6)	NE [NE; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1188
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9920)					
Positiv	12/183 (6,6)	NE [NE; NE]	0/93 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0154
Negativ	4/59 (6,8)	NE [NE; NE]	1/31 (3,2)	NE [NE; NE]	1,84 [0,20; 16,58] 0,5795
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 1,0000)					
Primäre Resistenz	5/57 (8,8)	NE [NE; NE]	0/35 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1532
Sekundäre Resistenz	10/168 (6,0)	NE [NE; NE]	1/79 (1,3)	NE [NE; NE]	4,79 [0,61; 37,42] 0,0987
Nicht vortherapiert	1/20 (5,0)	NE [NE; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3778
Startdosis (p-Wert des Interaktionsterms: 0,9922)					
150 mg	11/169 (6,5)	NE [NE; NE]	1/87 (1,1)	NE [NE; NE]	4,89 [0,63; 37,90] 0,0928
200 mg	5/76 (6,6)	NE [NE; NE]	0/41 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0853

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SOC: System Organ Class.

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Tabelle 110.2.2: Subgruppen - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9133)					
≥ 65 Jahre	5/64 (7,8)	NE [NE; NE]	2/38 (5,3)	NE [15,06; NE]	1,27 [0,24; 6,66] 0,7772
< 65 Jahre	8/79 (10,1)	NE [NE; NE]	2/28 (7,1)	NE [NE; NE]	1,03 [0,22; 4,88] 0,9686
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,6632)					
1	8/47 (17,0)	NE [NE; NE]	2/20 (10,0)	NE [15,06; NE]	1,30 [0,27; 6,17] 0,7395
2	1/49 (2,0)	NE [NE; NE]	1/21 (4,8)	NE [NE; NE]	0,42 [0,03; 6,71] 0,5260
≥ 3	4/47 (8,5)	NE [NE; NE]	1/25 (4,0)	NE [9,93; NE]	1,50 [0,16; 14,13] 0,7209
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,2908)					
0	4/83 (4,8)	NE [NE; NE]	2/36 (5,6)	29,9 [29,92; NE]	0,58 [0,10; 3,31] 0,5379
1	9/57 (15,8)	NE [NE; NE]	2/30 (6,7)	NE [15,06; NE]	1,92 [0,41; 8,91] 0,3991
Geografische Region (p-Wert des Interaktionsterms: 0,6167)					
Europa	10/75 (13,3)	NE [NE; NE]	3/37 (8,1)	NE [15,06; NE]	1,26 [0,34; 4,63] 0,7247
Nordamerika	2/25 (8,0)	NE [NE; NE]	0/16 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4370
Asien	1/43 (2,3)	NE [NE; NE]	1/13 (7,7)	NE [NE; NE]	0,32 [0,02; 5,12] 0,3954
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,8284)					
Ja	8/108 (7,4)	NE [NE; NE]	2/53 (3,8)	NE [NE; NE]	1,49 [0,31; 7,12] 0,6141
Nein	5/35 (14,3)	NE [NE; NE]	2/13 (15,4)	NE [15,06; NE]	0,99 [0,19; 5,11] 0,9921

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,2240)					
Positiv	10/115 (8,7)	NE [NE; NE]	2/50 (4,0)	NE [NE; NE]	1,78 [0,39; 8,18] 0,4503
Negativ	2/23 (8,7)	NE [NE; NE]	2/12 (16,7)	29,9 [15,06; NE]	0,23 [0,03; 1,80] 0,1329
Startdosis (p-Wert des Interaktionsterms: 0,6422)					
150 mg	11/103 (10,7)	NE [NE; NE]	3/49 (6,1)	NE [29,92; NE]	1,28 [0,35; 4,63] 0,7060
200 mg	2/40 (5,0)	NE [NE; NE]	1/17 (5,9)	NE [9,93; NE]	0,65 [0,06; 7,23] 0,7208
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9918)					
Ja	2/69 (2,9)	NE [NE; NE]	4/38 (10,5)	NE [29,92; NE]	0,16 [0,03; 0,93] 0,0212
Nein	11/74 (14,9)	NE [NE; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0762

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
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Tabelle 111.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,8696)					
< 65 Jahre	124/147 (84,4)	0,3 [0,23; 0,49]	18/72 (25,0)	NE [14,93; NE]	7,66 [4,63; 12,68] <,0001
≥ 65 Jahre	86/98 (87,8)	0,2 [0,16; 0,36]	17/56 (30,4)	NE [NE; NE]	7,20 [4,23; 12,27] <,0001
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,4752)					
1	96/112 (85,7)	0,3 [0,20; 0,46]	13/49 (26,5)	NE [24,92; NE]	7,31 [4,05; 13,18] <,0001
2	66/73 (90,4)	0,3 [0,20; 0,46]	8/36 (22,2)	NE [11,31; NE]	10,17 [4,82; 21,46] <,0001
≥ 3	48/60 (80,0)	0,3 [0,16; 0,59]	14/43 (32,6)	NE [5,46; NE]	5,28 [2,87; 9,70] <,0001
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9101)					
Viszerale Metastasen	110/130 (84,6)	0,3 [0,23; 0,49]	21/80 (26,3)	NE [NE; NE]	7,18 [4,47; 11,56] <,0001
Nur Knochenmetastasen	60/71 (84,5)	0,3 [0,16; 0,53]	7/29 (24,1)	NE [14,93; NE]	7,56 [3,41; 16,74] <,0001
Andere	40/44 (90,9)	0,2 [0,13; 0,30]	7/19 (36,8)	24,9 [3,81; NE]	7,69 [3,34; 17,73] <,0001
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 0,0585)					
Weiß/kaukasisch	130/155 (83,9)	0,4 [0,23; 0,49]	27/80 (33,8)	24,9 [11,77; NE]	5,57 [3,65; 8,51] <,0001
Asiatisch	53/58 (91,4)	0,2 [0,16; 0,36]	5/32 (15,6)	NE [NE; NE]	16,07 [6,30; 41,03] <,0001
Andere	15/17 (88,2)	0,2 [0,13; 0,72]	2/9 (22,2)	NE [2,04; NE]	9,38 [2,09; 42,08] 0,0005
Geografische Region (p-Wert des Interaktionsterms: 0,0540)					
Europa	79/97 (81,4)	0,3 [0,16; 0,49]	15/57 (26,3)	NE [14,93; NE]	6,42 [3,67; 11,24] <,0001

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Nordamerika	80/92 (87,0)	0,3 [0,23; 0,49]	15/39 (38,5)	24,9 [5,36; NE]	5,16 [2,94; 9,06] <,0001
Asien	51/56 (91,1)	0,2 [0,16; 0,30]	5/32 (15,6)	NE [NE; NE]	16,78 [6,53; 43,14] <,0001
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,8334)					
Ja	147/169 (87,0)	0,3 [0,20; 0,36]	26/94 (27,7)	NE [24,92; NE]	7,88 [5,13; 12,09] <,0001
Nein	63/76 (82,9)	0,3 [0,16; 0,56]	9/34 (26,5)	NE [14,93; NE]	6,63 [3,26; 13,48] <,0001
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,2547)					
Positiv	156/183 (85,2)	0,3 [0,23; 0,43]	29/93 (31,2)	NE [24,92; NE]	6,57 [4,38; 9,85] <,0001
Negativ	51/59 (86,4)	0,3 [0,20; 0,49]	5/31 (16,1)	NE [14,93; NE]	11,43 [4,50; 29,01] <,0001
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,8665)					
Primäre Resistenz	50/57 (87,7)	0,3 [0,16; 0,49]	11/35 (31,4)	NE [4,73; NE]	7,14 [3,65; 13,97] <,0001
Sekundäre Resistenz	142/168 (84,5)	0,3 [0,23; 0,46]	20/79 (25,3)	NE [24,92; NE]	7,39 [4,59; 11,89] <,0001
Nicht vortherapiert	18/20 (90,0)	0,2 [0,13; 0,49]	4/14 (28,6)	NE [5,36; NE]	9,81 [3,14; 30,60] <,0001
Startdosis (p-Wert des Interaktionsterms: 0,2061)					
150 mg	141/169 (83,4)	0,4 [0,26; 0,49]	23/87 (26,4)	NE [24,92; NE]	6,57 [4,20; 10,27] <,0001
200 mg	69/76 (90,8)	0,2 [0,13; 0,23]	12/41 (29,3)	NE [8,02; NE]	11,43 [5,89; 22,18] <,0001
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,8872)					
Ja	93/109 (85,3)	0,3 [0,23; 0,49]	14/52 (26,9)	NE [14,93; NE]	7,82 [4,40; 13,90] <,0001
Nein	117/136 (86,0)	0,2 [0,20; 0,43]	21/76 (27,6)	NE [24,92; NE]	7,03 [4,38; 11,28] <,0001

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Datenschnitt: 20.06.2019, Safety-Population 1: In Monaten; 2: Aus Log-rank-Test Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.					

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t111_ae_tte_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 111.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,3268)					
≥ 65 Jahre	56/64 (87,5)	0,2 [0,13; 0,33]	12/38 (31,6)	22,3 [7,43; NE]	7,03 [3,63; 13,62] <,0001
< 65 Jahre	73/79 (92,4)	0,2 [0,16; 0,33]	6/28 (21,4)	NE [21,14; NE]	10,57 [4,52; 24,73] <,0001
Art der Erkrankung (p-Wert des Interaktionsterms: 0,3867)					
Viszerale Metastasen	72/78 (92,3)	0,2 [0,16; 0,30]	9/39 (23,1)	NE [7,43; NE]	11,61 [5,69; 23,69] <,0001
Nur Knochenmetastasen	33/39 (84,6)	0,4 [0,13; 0,79]	5/15 (33,3)	22,3 [6,77; NE]	6,69 [2,30; 19,41] <,0001
Andere	24/26 (92,3)	0,2 [0,10; 0,30]	4/12 (33,3)	12,4 [0,10; NE]	5,34 [1,81; 15,75] 0,0007
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,7269)					
0	76/83 (91,6)	0,2 [0,16; 0,26]	11/36 (30,6)	22,3 [7,43; NE]	7,59 [3,97; 14,54] <,0001
1	51/57 (89,5)	0,3 [0,13; 0,49]	7/30 (23,3)	NE [8,32; NE]	10,34 [4,37; 24,49] <,0001
Geografische Region (p-Wert des Interaktionsterms: 0,4929)					
Europa	64/75 (85,3)	0,5 [0,26; 0,53]	9/37 (24,3)	NE [8,32; NE]	7,22 [3,55; 14,71] <,0001
Nordamerika	24/25 (96,0)	0,2 [0,13; 0,33]	5/16 (31,3)	21,1 [3,95; NE]	39,93 [5,25; 303,43] <,0001
Asien	41/43 (95,3)	0,1 [0,10; 0,16]	4/13 (30,8)	NE [0,89; NE]	9,20 [3,14; 26,98] <,0001
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,1150)					
Ja	101/108 (93,5)	0,2 [0,16; 0,26]	13/53 (24,5)	NE [12,39; NE]	10,61 [5,85; 19,27] <,0001
Nein	28/35 (80,0)	0,4 [0,13; 1,97]	5/13 (38,5)	22,3 [6,77; NE]	5,37 [1,82; 15,88] 0,0008

Subgruppe	Abemaciclib+Fulvestrant n/N (%)	Abemaciclib+Fulvestrant Mediane Ereigniszeit[1]	Placebo+Fulvestrant n/N (%)	Placebo+Fulvestrant Mediane Ereigniszeit[1]	HR [95% KI] p-Wert[2]
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,1509)					
Primäre Resistenz	23/26 (88,5)	0,2 [0,10; 0,23]	1/10 (10,0)	NE [2,33; NE]	22,07 [2,92; 166,83] <,0001
Sekundäre Resistenz	106/117 (90,6)	0,3 [0,16; 0,33]	17/56 (30,4)	22,3 [8,32; NE]	7,18 [4,24; 12,15] <,0001
Startdosis (p-Wert des Interaktionsterms: 0,1397)					
150 mg	90/103 (87,4)	0,3 [0,16; 0,39]	15/49 (30,6)	22,3 [8,32; NE]	6,61 [3,77; 11,58] <,0001
200 mg	39/40 (97,5)	0,2 [0,10; 0,26]	3/17 (17,6)	NE [3,95; NE]	16,85 [4,94; 57,42] <,0001
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,6769)					
Ja	64/69 (92,8)	0,2 [0,13; 0,33]	12/38 (31,6)	22,3 [8,32; NE]	9,02 [4,55; 17,89] <,0001
Nein	65/74 (87,8)	0,2 [0,16; 0,33]	6/28 (21,4)	NE [6,77; NE]	8,77 [3,76; 20,44] <,0001

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

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Tabelle 112.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9859)					
< 65 Jahre	22/147 (15,0)	NE [NE; NE]	0/72 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0013
≥ 65 Jahre	13/98 (13,3)	NE [NE; NE]	1/56 (1,8)	NE [NE; NE]	7,99 [1,04; 61,08] 0,0172
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,9999)					
1	18/112 (16,1)	NE [NE; NE]	0/49 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0043
2	8/73 (11,0)	NE [NE; NE]	1/36 (2,8)	NE [NE; NE]	3,41 [0,42; 27,61] 0,2210
≥ 3	9/60 (15,0)	NE [NE; NE]	0/43 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0086
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9999)					
Viszerale Metastasen	16/130 (12,3)	NE [48,56; NE]	1/80 (1,3)	NE [NE; NE]	8,65 [1,14; 65,59] 0,0120
Nur Knochenmetastasen	12/71 (16,9)	NE [NE; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0189
Andere	7/44 (15,9)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0651
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9884)					
0	20/135 (14,8)	NE [NE; NE]	1/74 (1,4)	NE [NE; NE]	10,59 [1,42; 79,04] 0,0041
1	15/110 (13,6)	NE [NE; NE]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0053
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 0,9999)					
Weiß/kaukasisch	21/155 (13,5)	NE [NE; NE]	0/80 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0008
Asiatisch	8/58 (13,8)	NE [NE; NE]	1/32 (3,1)	NE [NE; NE]	4,12 [0,51; 33,31] 0,1499

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Andere	3/17 (17,6)	48,6 [NE; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2745
Geografische Region (p-Wert des Interaktionsterms: 0,9999)					
Europa	12/97 (12,4)	NE [NE; NE]	0/57 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0081
Nordamerika	15/92 (16,3)	NE [48,56; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0108
Asien	8/56 (14,3)	NE [NE; NE]	1/32 (3,1)	NE [NE; NE]	4,25 [0,53; 34,37] 0,1397
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9903)					
Ja	21/169 (12,4)	NE [NE; NE]	1/94 (1,1)	NE [NE; NE]	10,86 [1,46; 80,87] 0,0035
Nein	14/76 (18,4)	NE [NE; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0077
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9918)					
Positiv	30/183 (16,4)	NE [NE; NE]	1/93 (1,1)	NE [NE; NE]	15,33 [2,09; 112,55] 0,0003
Negativ	5/59 (8,5)	NE [NE; NE]	0/31 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0982
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9999)					
Primäre Resistenz	8/57 (14,0)	NE [44,58; NE]	1/35 (2,9)	NE [NE; NE]	4,22 [0,52; 34,28] 0,1429
Sekundäre Resistenz	23/168 (13,7)	NE [NE; NE]	0/79 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0010
Nicht vortherapiert	4/20 (20,0)	NE [NE; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0822
Startdosis (p-Wert des Interaktionsterms: 0,9859)					
150 mg	20/169 (11,8)	NE [NE; NE]	0/87 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0019
200 mg	15/76 (19,7)	NE [NE; NE]	1/41 (2,4)	NE [NE; NE]	8,90 [1,17; 67,46] 0,0104
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9884)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	17/109 (15,6)	NE [48,56; NE]	0/52 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0079
Nein	18/136 (13,2)	NE [NE; NE]	1/76 (1,3)	NE [NE; NE]	10,87 [1,45; 81,37] 0,0036

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

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Tabelle 112.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9998)					
≥ 65 Jahre	15/64 (23,4)	NE [NE; NE]	0/38 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0021
< 65 Jahre	10/79 (12,7)	NE [NE; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0609
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 1,0000)					
1	8/47 (17,0)	NE [NE; NE]	0/20 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0734
2	10/49 (20,4)	NE [NE; NE]	0/21 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0309
≥ 3	7/47 (14,9)	NE [NE; NE]	0/25 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0439
Art der Erkrankung (p-Wert des Interaktionsterms: 1,0000)					
Viszerale Metastasen	11/78 (14,1)	NE [NE; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0172
Nur Knochenmetastasen	7/39 (17,9)	NE [NE; NE]	0/15 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0955
Andere	7/26 (26,9)	NE [5,42; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0558
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9999)					
0	17/83 (20,5)	NE [NE; NE]	0/36 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0066
1	8/57 (14,0)	NE [NE; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0372
Geografische Region (p-Wert des Interaktionsterms: 1,0000)					
Europa	10/75 (13,3)	NE [NE; NE]	0/37 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0262
Nordamerika	6/25 (24,0)	NE [11,87; NE]	0/16 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0912

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Asien	9/43 (20,9)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0802
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9999)					
Ja	20/108 (18,5)	NE [NE; NE]	0/53 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0013
Nein	5/35 (14,3)	NE [21,24; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1490
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9999)					
Positiv	18/115 (15,7)	NE [NE; NE]	0/50 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0049
Negativ	6/23 (26,1)	NE [11,87; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0711
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9999)					
Primäre Resistenz	7/26 (26,9)	NE [21,24; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0792
Sekundäre Resistenz	18/117 (15,4)	NE [NE; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0030
Startdosis (p-Wert des Interaktionsterms: 0,9998)					
150 mg	15/103 (14,6)	NE [NE; NE]	0/49 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0079
200 mg	10/40 (25,0)	NE [NE; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0276
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 1,0000)					
Ja	12/69 (17,4)	NE [NE; NE]	0/38 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0095
Nein	13/74 (17,6)	NE [NE; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0266

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

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Tabelle 113.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,8647)					
< 65 Jahre	122/147 (83,0)	0,4 [0,23; 0,49]	18/72 (25,0)	NE [14,93; NE]	7,25 [4,38; 11,99] <,0001
≥ 65 Jahre	86/98 (87,8)	0,3 [0,20; 0,46]	17/56 (30,4)	NE [NE; NE]	7,13 [4,19; 12,15] <,0001
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,5082)					
1	96/112 (85,7)	0,3 [0,20; 0,49]	13/49 (26,5)	NE [24,92; NE]	7,29 [4,04; 13,16] <,0001
2	64/73 (87,7)	0,4 [0,20; 0,49]	8/36 (22,2)	NE [11,31; NE]	8,99 [4,27; 18,93] <,0001
≥ 3	48/60 (80,0)	0,3 [0,20; 0,59]	14/43 (32,6)	NE [5,46; NE]	5,22 [2,84; 9,60] <,0001
Art der Erkrankung (p-Wert des Interaktionsterms: 0,8489)					
Viszerale Metastasen	108/130 (83,1)	0,4 [0,26; 0,49]	21/80 (26,3)	NE [NE; NE]	6,70 [4,17; 10,77] <,0001
Nur Knochenmetastasen	60/71 (84,5)	0,3 [0,16; 0,53]	7/29 (24,1)	NE [14,93; NE]	7,54 [3,41; 16,71] <,0001
Andere	40/44 (90,9)	0,2 [0,13; 0,36]	7/19 (36,8)	24,9 [3,81; NE]	7,69 [3,34; 17,73] <,0001
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9197)					
Ja	145/169 (85,8)	0,3 [0,23; 0,46]	26/94 (27,7)	NE [24,92; NE]	7,43 [4,85; 11,40] <,0001
Nein	63/76 (82,9)	0,4 [0,20; 0,56]	9/34 (26,5)	NE [14,93; NE]	6,62 [3,26; 13,46] <,0001
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,2125)					
Positiv	154/183 (84,2)	0,4 [0,23; 0,49]	29/93 (31,2)	NE [24,92; NE]	6,25 [4,17; 9,37] <,0001
Negativ	51/59 (86,4)	0,3 [0,20; 0,53]	5/31 (16,1)	NE [14,93; NE]	11,39 [4,49; 28,91] <,0001

Subgruppe	Abemaciclib+Fulvestrant n/N (%)	Abemaciclib+Fulvestrant Mediane Ereigniszeit[1]	Placebo+Fulvestrant n/N (%)	Placebo+Fulvestrant Mediane Ereigniszeit[1]	HR [95% KI] p-Wert[2]
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9410)					
Primäre Resistenz	50/57 (87,7)	0,3 [0,16; 0,49]	11/35 (31,4)	NE [4,73; NE]	7,14 [3,65; 13,97] <,0001
Sekundäre Resistenz	140/168 (83,3)	0,4 [0,23; 0,49]	20/79 (25,3)	NE [24,92; NE]	7,03 [4,37; 11,31] <,0001
Nicht vortherapiert	18/20 (90,0)	0,2 [0,13; 0,82]	4/14 (28,6)	NE [5,36; NE]	9,76 [3,13; 30,45] <,0001
Startdosis (p-Wert des Interaktionsterms: 0,3223)					
150 mg	140/169 (82,8)	0,4 [0,26; 0,49]	23/87 (26,4)	NE [24,92; NE]	6,41 [4,10; 10,02] <,0001
200 mg	68/76 (89,5)	0,2 [0,13; 0,36]	12/41 (29,3)	NE [8,02; NE]	10,08 [5,26; 19,31] <,0001
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,8747)					
Ja	92/109 (84,4)	0,4 [0,23; 0,49]	14/52 (26,9)	NE [14,93; NE]	7,53 [4,23; 13,38] <,0001
Nein	116/136 (85,3)	0,3 [0,20; 0,49]	21/76 (27,6)	NE [24,92; NE]	6,78 [4,23; 10,87] <,0001

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
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Tabelle 113.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,2574)					
≥ 65 Jahre	55/64 (85,9)	0,3 [0,16; 0,49]	12/38 (31,6)	22,3 [7,43; NE]	6,77 [3,49; 13,13] <,0001
< 65 Jahre	73/79 (92,4)	0,2 [0,16; 0,39]	6/28 (21,4)	NE [21,14; NE]	10,56 [4,51; 24,70] <,0001
Art der Erkrankung (p-Wert des Interaktionsterms: 0,2866)					
Viszerale Metastasen	72/78 (92,3)	0,2 [0,16; 0,30]	9/39 (23,1)	NE [7,43; NE]	11,61 [5,69; 23,69] <,0001
Nur Knochenmetastasen	32/39 (82,1)	0,5 [0,16; 1,97]	5/15 (33,3)	22,3 [6,77; NE]	6,42 [2,20; 18,71] 0,0001
Andere	24/26 (92,3)	0,3 [0,13; 0,49]	4/12 (33,3)	12,4 [0,10; NE]	5,23 [1,77; 15,44] 0,0009
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,7801)					
0	76/83 (91,6)	0,2 [0,16; 0,33]	11/36 (30,6)	22,3 [7,43; NE]	7,55 [3,94; 14,45] <,0001
1	50/57 (87,7)	0,3 [0,16; 0,49]	7/30 (23,3)	NE [8,32; NE]	9,99 [4,21; 23,68] <,0001
Geografische Region (p-Wert des Interaktionsterms: 0,5186)					
Europa	63/75 (84,0)	0,5 [0,30; 0,66]	9/37 (24,3)	NE [8,32; NE]	7,04 [3,45; 14,35] <,0001
Nordamerika	24/25 (96,0)	0,2 [0,13; 0,33]	5/16 (31,3)	21,1 [3,95; NE]	39,93 [5,25; 303,43] <,0001
Asien	41/43 (95,3)	0,1 [0,10; 0,20]	4/13 (30,8)	NE [0,89; NE]	9,08 [3,10; 26,63] <,0001
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,0839)					
Ja	101/108 (93,5)	0,2 [0,16; 0,30]	13/53 (24,5)	NE [12,39; NE]	10,58 [5,83; 19,21] <,0001
Nein	27/35 (77,1)	0,5 [0,16; 2,30]	5/13 (38,5)	22,3 [6,77; NE]	5,14 [1,73; 15,27] 0,0012

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,1680)					
Primäre Resistenz	22/26 (84,6)	0,2 [0,10; 0,30]	1/10 (10,0)	NE [2,33; NE]	20,12 [2,65; 152,60] <,0001
Sekundäre Resistenz	106/117 (90,6)	0,3 [0,20; 0,39]	17/56 (30,4)	22,3 [8,32; NE]	7,15 [4,22; 12,10] <,0001
Startdosis (p-Wert des Interaktionsterms: 0,1629)					
150 mg	90/103 (87,4)	0,3 [0,16; 0,43]	15/49 (30,6)	22,3 [8,32; NE]	6,58 [3,76; 11,53] <,0001
200 mg	38/40 (95,0)	0,2 [0,10; 0,33]	3/17 (17,6)	NE [3,95; NE]	15,61 [4,56; 53,39] <,0001
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,7057)					
Ja	64/69 (92,8)	0,3 [0,16; 0,43]	12/38 (31,6)	22,3 [8,32; NE]	8,99 [4,53; 17,83] <,0001
Nein	64/74 (86,5)	0,3 [0,16; 0,39]	6/28 (21,4)	NE [6,77; NE]	8,46 [3,63; 19,73] <,0001

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t113_ae_tte_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 115.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	n/N (%)	Mediane Ereigniszeit[1]	n/N (%)	Mediane Ereigniszeit[1]	HR [95% KI] p-Wert[2]
Alter (p-Wert des Interaktionsterms: 0,9862)					
< 65 Jahre	17/147 (11,6)	NE [NE; NE]	0/72 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0093
≥ 65 Jahre	16/98 (16,3)	NE [45,80; NE]	2/56 (3,6)	NE [NE; NE]	4,79 [1,10; 20,91] 0,0213
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,9987)					
1	14/112 (12,5)	NE [47,44; NE]	0/49 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0281
2	12/73 (16,4)	NE [41,69; NE]	1/36 (2,8)	NE [NE; NE]	5,05 [0,65; 39,21] 0,0852
≥ 3	7/60 (11,7)	NE [NE; NE]	1/43 (2,3)	NE [NE; NE]	5,21 [0,64; 42,40] 0,0845
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9999)					
Viszerale Metastasen	17/130 (13,1)	NE [NE; NE]	2/80 (2,5)	NE [NE; NE]	4,81 [1,11; 20,90] 0,0206
Nur Knochenmetastasen	10/71 (14,1)	NE [45,80; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0843
Andere	6/44 (13,6)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0926
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9322)					
0	17/135 (12,6)	NE [NE; NE]	1/74 (1,4)	NE [NE; NE]	9,08 [1,21; 68,28] 0,0093
1	16/110 (14,5)	NE [41,69; NE]	1/54 (1,9)	NE [NE; NE]	6,56 [0,87; 49,71] 0,0360
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 0,9999)					
Weiß/kaukasisch	19/155 (12,3)	NE [NE; NE]	2/80 (2,5)	NE [NE; NE]	4,49 [1,04; 19,30] 0,0271
Asiatisch	10/58 (17,2)	NE [47,44; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0374

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Andere	4/17 (23,5)	NE [1,97; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1186
Geografische Region (p-Wert des Interaktionsterms: 0,9998)					
Europa	9/97 (9,3)	NE [NE; NE]	2/57 (3,5)	NE [NE; NE]	2,55 [0,55; 11,79] 0,2161
Nordamerika	14/92 (15,2)	NE [45,80; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0226
Asien	10/56 (17,9)	NE [47,44; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0345
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9901)					
Ja	22/169 (13,0)	NE [NE; NE]	2/94 (2,1)	NE [NE; NE]	5,74 [1,35; 24,45] 0,0075
Nein	11/76 (14,5)	NE [45,80; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0542
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,4076)					
Positiv	26/183 (14,2)	NE [NE; NE]	1/93 (1,1)	NE [NE; NE]	12,34 [1,67; 91,11] 0,0016
Negativ	7/59 (11,9)	NE [36,00; NE]	1/31 (3,2)	NE [NE; NE]	3,17 [0,39; 25,93] 0,2560
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9973)					
Primäre Resistenz	5/57 (8,8)	NE [47,44; NE]	1/35 (2,9)	NE [NE; NE]	2,08 [0,23; 19,11] 0,5093
Sekundäre Resistenz	24/168 (14,3)	NE [NE; NE]	0/79 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0009
Nicht vortherapiert	4/20 (20,0)	NE [38,04; NE]	1/14 (7,1)	NE [NE; NE]	2,57 [0,29; 23,09] 0,3819
Startdosis (p-Wert des Interaktionsterms: 0,7115)					
150 mg	22/169 (13,0)	NE [NE; NE]	1/87 (1,1)	NE [NE; NE]	9,93 [1,33; 73,87] 0,0057
200 mg	11/76 (14,5)	NE [47,44; NE]	1/41 (2,4)	NE [NE; NE]	5,93 [0,76; 46,09] 0,0531
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9898)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	8/109 (7,3)	NE [NE; NE]	0/52 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0833
Nein	25/136 (18,4)	NE [45,80; NE]	2/76 (2,6)	NE [NE; NE]	6,92 [1,64; 29,24] 0,0022

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t115_ae_tte_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 115.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9998)					
≥ 65 Jahre	17/64 (26,6)	NE [23,08; NE]	0/38 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0009
< 65 Jahre	12/79 (15,2)	NE [NE; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0472
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 1,0000)					
1	10/47 (21,3)	NE [NE; NE]	0/20 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0323
2	10/49 (20,4)	NE [29,52; NE]	0/21 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0414
≥ 3	9/47 (19,1)	NE [35,15; NE]	0/25 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0378
Art der Erkrankung (p-Wert des Interaktionsterms: 1,0000)					
Viszerale Metastasen	19/78 (24,4)	NE [35,15; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0027
Nur Knochenmetastasen	9/39 (23,1)	NE [NE; NE]	0/15 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0495
Andere	1/26 (3,8)	NE [NE; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4969
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9999)					
0	16/83 (19,3)	NE [NE; NE]	0/36 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0088
1	13/57 (22,8)	NE [29,52; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0064
Geografische Region (p-Wert des Interaktionsterms: 1,0000)					
Europa	16/75 (21,3)	NE [29,52; NE]	0/37 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0046
Nordamerika	5/25 (20,0)	NE [NE; NE]	0/16 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0738

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Asien	8/43 (18,6)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1040
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9999)					
Ja	21/108 (19,4)	NE [NE; NE]	0/53 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0019
Nein	8/35 (22,9)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0635
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9999)					
Positiv	22/115 (19,1)	NE [NE; NE]	0/50 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0021
Negativ	6/23 (26,1)	NE [3,12; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0571
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9999)					
Primäre Resistenz	4/26 (15,4)	NE [14,63; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1765
Sekundäre Resistenz	25/117 (21,4)	NE [NE; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0006
Startdosis (p-Wert des Interaktionsterms: 0,9999)					
150 mg	23/103 (22,3)	NE [35,15; NE]	0/49 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0011
200 mg	6/40 (15,0)	NE [NE; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0929
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9999)					
Ja	16/69 (23,2)	NE [NE; NE]	0/38 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0021
Nein	13/74 (17,6)	NE [35,15; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0361

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t115_ae_tte_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 117.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9862)					
< 65 Jahre	17/147 (11,6)	NE [NE; NE]	0/72 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0093
≥ 65 Jahre	15/98 (15,3)	NE [NE; NE]	2/56 (3,6)	NE [NE; NE]	4,46 [1,02; 19,55] 0,0301
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,9930)					
1	14/112 (12,5)	NE [47,44; NE]	0/49 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0281
2	11/73 (15,1)	NE [41,69; NE]	1/36 (2,8)	NE [NE; NE]	4,51 [0,58; 35,27] 0,1163
≥ 3	7/60 (11,7)	NE [NE; NE]	1/43 (2,3)	NE [NE; NE]	5,21 [0,64; 42,40] 0,0845
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9999)					
Viszerale Metastasen	16/130 (12,3)	NE [NE; NE]	2/80 (2,5)	NE [NE; NE]	4,48 [1,03; 19,54] 0,0292
Nur Knochenmetastasen	10/71 (14,1)	NE [45,80; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0843
Andere	6/44 (13,6)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0926
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,8944)					
0	17/135 (12,6)	NE [NE; NE]	1/74 (1,4)	NE [NE; NE]	9,08 [1,21; 68,28] 0,0093
1	15/110 (13,6)	NE [41,69; NE]	1/54 (1,9)	NE [NE; NE]	6,03 [0,79; 45,91] 0,0483
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 0,9999)					
Weiß/kaukasisch	18/155 (11,6)	NE [NE; NE]	2/80 (2,5)	NE [NE; NE]	4,21 [0,97; 18,18] 0,0362
Asiatisch	10/58 (17,2)	NE [47,44; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0374

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Andere	4/17 (23,5)	NE [1,97; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1186
Geografische Region (p-Wert des Interaktionsterms: 0,9998)					
Europa	8/97 (8,2)	NE [NE; NE]	2/57 (3,5)	NE [NE; NE]	2,23 [0,47; 10,53] 0,2969
Nordamerika	14/92 (15,2)	NE [45,80; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0226
Asien	10/56 (17,9)	NE [47,44; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0345
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9901)					
Ja	21/169 (12,4)	NE [NE; NE]	2/94 (2,1)	NE [NE; NE]	5,43 [1,27; 23,22] 0,0103
Nein	11/76 (14,5)	NE [45,80; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0542
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,4249)					
Positiv	25/183 (13,7)	NE [NE; NE]	1/93 (1,1)	NE [NE; NE]	11,78 [1,59; 87,10] 0,0021
Negativ	7/59 (11,9)	NE [36,00; NE]	1/31 (3,2)	NE [NE; NE]	3,17 [0,39; 25,93] 0,2560
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9969)					
Primäre Resistenz	5/57 (8,8)	NE [47,44; NE]	1/35 (2,9)	NE [NE; NE]	2,08 [0,23; 19,11] 0,5093
Sekundäre Resistenz	23/168 (13,7)	NE [NE; NE]	0/79 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0012
Nicht vortherapiert	4/20 (20,0)	NE [38,04; NE]	1/14 (7,1)	NE [NE; NE]	2,57 [0,29; 23,09] 0,3819
Startdosis (p-Wert des Interaktionsterms: 0,7388)					
150 mg	21/169 (12,4)	NE [NE; NE]	1/87 (1,1)	NE [NE; NE]	9,37 [1,26; 69,92] 0,0078
200 mg	11/76 (14,5)	NE [47,44; NE]	1/41 (2,4)	NE [NE; NE]	5,93 [0,76; 46,09] 0,0531
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9899)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	8/109 (7,3)	NE [NE; NE]	0/52 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0833
Nein	24/136 (17,6)	NE [45,80; NE]	2/76 (2,6)	NE [NE; NE]	6,60 [1,56; 27,95] 0,0031

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t117_ae_tte_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 117.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9998)					
≥ 65 Jahre	17/64 (26,6)	NE [23,08; NE]	0/38 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0010
< 65 Jahre	12/79 (15,2)	NE [NE; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0472
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 1,0000)					
1	10/47 (21,3)	NE [NE; NE]	0/20 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0323
2	10/49 (20,4)	NE [29,52; NE]	0/21 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0414
≥ 3	9/47 (19,1)	NE [35,15; NE]	0/25 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0422
Art der Erkrankung (p-Wert des Interaktionsterms: 1,0000)					
Viszerale Metastasen	19/78 (24,4)	NE [29,52; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0030
Nur Knochenmetastasen	9/39 (23,1)	NE [NE; NE]	0/15 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0495
Andere	1/26 (3,8)	NE [NE; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4969
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9999)					
0	16/83 (19,3)	NE [NE; NE]	0/36 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0088
1	13/57 (22,8)	NE [29,52; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0067
Geografische Region (p-Wert des Interaktionsterms: 1,0000)					
Europa	16/75 (21,3)	NE [29,52; NE]	0/37 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0051
Nordamerika	5/25 (20,0)	NE [NE; NE]	0/16 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0738

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Asien	8/43 (18,6)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1040
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9999)					
Ja	21/108 (19,4)	NE [NE; NE]	0/53 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0021
Nein	8/35 (22,9)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0635
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9999)					
Positiv	22/115 (19,1)	NE [NE; NE]	0/50 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0021
Negativ	6/23 (26,1)	NE [5,13; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0657
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9999)					
Primäre Resistenz	4/26 (15,4)	NE [14,63; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1765
Sekundäre Resistenz	25/117 (21,4)	NE [NE; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0006
Startdosis (p-Wert des Interaktionsterms: 0,9999)					
150 mg	23/103 (22,3)	NE [35,15; NE]	0/49 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0012
200 mg	6/40 (15,0)	NE [NE; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0929
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9999)					
Ja	16/69 (23,2)	NE [NE; NE]	0/38 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0021
Nein	13/74 (17,6)	NE [35,15; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0394

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t117_ae_tte_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 119.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	n/N (%)	Mediane Ereigniszeit[1]	n/N (%)	Mediane Ereigniszeit[1]	HR [95% KI] p-Wert[2]
Alter (p-Wert des Interaktionsterms: 0,3812)					
< 65 Jahre	32/147 (21,8)	NE [NE; NE]	4/72 (5,6)	NE [NE; NE]	3,67 [1,30; 10,39] 0,0084
≥ 65 Jahre	9/98 (9,2)	NE [NE; NE]	3/56 (5,4)	NE [31,33; NE]	1,76 [0,47; 6,55] 0,3919
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,8949)					
1	20/112 (17,9)	NE [NE; NE]	3/49 (6,1)	NE [NE; NE]	3,09 [0,92; 10,40] 0,0548
2	11/73 (15,1)	NE [NE; NE]	1/36 (2,8)	NE [NE; NE]	4,41 [0,57; 34,48] 0,1220
≥ 3	10/60 (16,7)	NE [36,43; NE]	3/43 (7,0)	NE [31,33; NE]	2,50 [0,69; 9,10] 0,1498
Art der Erkrankung (p-Wert des Interaktionsterms: 0,5576)					
Viszerale Metastasen	22/130 (16,9)	NE [NE; NE]	6/80 (7,5)	NE [31,33; NE]	2,00 [0,81; 4,96] 0,1259
Nur Knochenmetastasen	15/71 (21,1)	NE [NE; NE]	1/29 (3,4)	NE [NE; NE]	7,05 [0,93; 53,41] 0,0274
Andere	4/44 (9,1)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1532
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,8345)					
0	24/135 (17,8)	NE [NE; NE]	4/74 (5,4)	NE [NE; NE]	3,31 [1,15; 9,54] 0,0188
1	17/110 (15,5)	NE [NE; NE]	3/54 (5,6)	NE [31,33; NE]	2,61 [0,76; 8,92] 0,1122
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 0,9998)					
Weiß/kaukasisch	18/155 (11,6)	NE [NE; NE]	3/80 (3,8)	NE [NE; NE]	2,91 [0,86; 9,88] 0,0728
Asiatisch	20/58 (34,5)	NE [11,08; NE]	4/32 (12,5)	31,3 [20,98; NE]	2,93 [0,99; 8,65] 0,0412

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Andere	2/17 (11,8)	NE [NE; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2627
Geografische Region (p-Wert des Interaktionsterms: 0,7733)					
Europa	10/97 (10,3)	NE [NE; NE]	1/57 (1,8)	NE [NE; NE]	5,65 [0,72; 44,16] 0,0622
Nordamerika	12/92 (13,0)	NE [NE; NE]	2/39 (5,1)	NE [NE; NE]	2,35 [0,52; 10,58] 0,2513
Asien	19/56 (33,9)	NE [11,08; NE]	4/32 (12,5)	31,3 [20,98; NE]	2,82 [0,95; 8,36] 0,0512
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,3918)					
Ja	28/169 (16,6)	NE [NE; NE]	6/94 (6,4)	NE [NE; NE]	2,41 [1,00; 5,84] 0,0435
Nein	13/76 (17,1)	NE [NE; NE]	1/34 (2,9)	NE [NE; NE]	6,58 [0,86; 50,35] 0,0361
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9800)					
Positiv	34/183 (18,6)	NE [NE; NE]	6/93 (6,5)	NE [NE; NE]	2,85 [1,20; 6,81] 0,0133
Negativ	6/59 (10,2)	NE [NE; NE]	1/31 (3,2)	NE [NE; NE]	3,07 [0,37; 25,54] 0,2735
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,1356)					
Primäre Resistenz	8/57 (14,0)	NE [NE; NE]	2/35 (5,7)	NE [NE; NE]	2,00 [0,42; 9,66] 0,3764
Sekundäre Resistenz	29/168 (17,3)	NE [NE; NE]	2/79 (2,5)	NE [NE; NE]	7,19 [1,71; 30,13] 0,0016
Nicht vortherapiert	4/20 (20,0)	NE [NE; NE]	3/14 (21,4)	NE [20,98; NE]	0,89 [0,20; 4,00] 0,8817
Startdosis (p-Wert des Interaktionsterms: 0,8940)					
150 mg	25/169 (14,8)	NE [NE; NE]	4/87 (4,6)	NE [NE; NE]	2,94 [1,02; 8,46] 0,0361
200 mg	16/76 (21,1)	NE [NE; NE]	3/41 (7,3)	NE [31,33; NE]	3,37 [0,98; 11,58] 0,0406
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,2840)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	23/109 (21,1)	NE [NE; NE]	2/52 (3,8)	NE [NE; NE]	5,15 [1,21; 21,86] 0,0133
Nein	18/136 (13,2)	NE [NE; NE]	5/76 (6,6)	NE [31,33; NE]	2,03 [0,75; 5,48] 0,1529

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t119_ae_tte_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 119.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9416)					
≥ 65 Jahre	8/64 (12,5)	NE [NE; NE]	4/38 (10,5)	NE [NE; NE]	1,17 [0,35; 3,92] 0,8010
< 65 Jahre	8/79 (10,1)	NE [NE; NE]	2/28 (7,1)	NE [NE; NE]	1,08 [0,23; 5,14] 0,9206
Art der Erkrankung (p-Wert des Interaktionsterms: 0,5801)					
Viszerale Metastasen	6/78 (7,7)	NE [NE; NE]	4/39 (10,3)	NE [NE; NE]	0,48 [0,13; 1,76] 0,2597
Nur Knochenmetastasen	8/39 (20,5)	NE [NE; NE]	2/15 (13,3)	NE [4,60; NE]	1,67 [0,35; 7,88] 0,5122
Andere	2/26 (7,7)	NE [NE; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3204
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,4452)					
0	12/83 (14,5)	NE [NE; NE]	3/36 (8,3)	NE [NE; NE]	1,39 [0,39; 5,01] 0,6142
1	4/57 (7,0)	NE [NE; NE]	3/30 (10,0)	NE [NE; NE]	0,65 [0,15; 2,92] 0,5737
Geografische Region (p-Wert des Interaktionsterms: 0,9999)					
Europa	4/75 (5,3)	NE [NE; NE]	6/37 (16,2)	NE [NE; NE]	0,30 [0,08; 1,06] 0,0472
Nordamerika	2/25 (8,0)	NE [17,98; NE]	0/16 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,6143
Asien	10/43 (23,3)	NE [20,75; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0724
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,2962)					
Ja	10/108 (9,3)	NE [NE; NE]	5/53 (9,4)	NE [NE; NE]	0,72 [0,24; 2,16] 0,5525
Nein	6/35 (17,1)	NE [NE; NE]	1/13 (7,7)	NE [NE; NE]	2,63 [0,32; 21,87] 0,3526

Subgruppe	Abemaciclib+Fulvestrant n/N (%)	Abemaciclib+Fulvestrant Mediane Ereigniszeit[1]	Placebo+Fulvestrant n/N (%)	Placebo+Fulvestrant Mediane Ereigniszeit[1]	HR [95% KI] p-Wert[2]
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9894)					
Positiv	13/115 (11,3)	NE [NE; NE]	5/50 (10,0)	NE [NE; NE]	0,95 [0,34; 2,68] 0,9205
Negativ	3/23 (13,0)	NE [NE; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2284
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 1,0000)					
Primäre Resistenz	0/26 (0,0)	NE [NE; NE]	0/10 (0,0)	NE [NE; NE]	NE
Sekundäre Resistenz	16/117 (13,7)	NE [NE; NE]	6/56 (10,7)	NE [NE; NE]	1,04 [0,40; 2,69] 0,9359
Startdosis (p-Wert des Interaktionsterms: 0,9916)					
150 mg	10/103 (9,7)	NE [NE; NE]	6/49 (12,2)	NE [NE; NE]	0,66 [0,24; 1,83] 0,4186
200 mg	6/40 (15,0)	NE [20,75; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1525
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,5025)					
Ja	6/69 (8,7)	NE [NE; NE]	2/38 (5,3)	NE [NE; NE]	1,56 [0,31; 7,77] 0,5819
Nein	10/74 (13,5)	NE [NE; NE]	4/28 (14,3)	NE [NE; NE]	0,68 [0,21; 2,23] 0,5225

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t119_ae_tte_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 120.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9905)					
≥ 65 Jahre	4/98 (4,1)	NE [NE; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1157
< 65 Jahre	10/147 (6,8)	NE [NE; NE]	3/72 (4,2)	NE [NE; NE]	1,45 [0,40; 5,28] 0,5723
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9999)					
Viszerale Metastasen	8/130 (6,2)	NE [NE; NE]	3/80 (3,8)	NE [NE; NE]	1,51 [0,40; 5,74] 0,5424
Nur Knochenmetastasen	4/71 (5,6)	NE [NE; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1913
Andere	2/44 (4,5)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3259
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,6055)					
0	11/135 (8,1)	NE [NE; NE]	2/74 (2,7)	NE [NE; NE]	2,95 [0,65; 13,29] 0,1407
1	3/110 (2,7)	NE [NE; NE]	1/54 (1,9)	NE [NE; NE]	1,19 [0,12; 11,68] 0,8834
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9921)					
Ja	10/169 (5,9)	NE [NE; NE]	3/94 (3,2)	NE [NE; NE]	1,73 [0,47; 6,29] 0,4038
Nein	4/76 (5,3)	NE [NE; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1713
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,6563)					
Positiv	11/183 (6,0)	NE [NE; NE]	2/93 (2,2)	NE [NE; NE]	2,66 [0,59; 12,02] 0,1874
Negativ	3/59 (5,1)	NE [NE; NE]	1/31 (3,2)	NE [NE; NE]	1,51 [0,16; 14,49] 0,7206
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,2716)					

Subgruppe	Abemaciclib+Fulvestrant n/N (%)	Abemaciclib+Fulvestrant Mediane Ereigniszeit[1]	Placebo+Fulvestrant n/N (%)	Placebo+Fulvestrant Mediane Ereigniszeit[1]	HR [95% KI] p-Wert[2]
Primäre Resistenz	1/57 (1,8)	NE [NE; NE]	1/35 (2,9)	NE [NE; NE]	0,45 [0,03; 7,47] 0,5700
Sekundäre Resistenz	12/168 (7,1)	NE [NE; NE]	1/79 (1,3)	NE [NE; NE]	5,62 [0,73; 43,26] 0,0617
Nicht vortherapiert	1/20 (5,0)	NE [NE; NE]	1/14 (7,1)	NE [NE; NE]	0,69 [0,04; 11,06] 0,7935
Startdosis (p-Wert des Interaktionsterms: 0,8525)					
150 mg	9/169 (5,3)	NE [NE; NE]	2/87 (2,3)	NE [NE; NE]	2,10 [0,45; 9,76] 0,3352
200 mg	5/76 (6,6)	NE [NE; NE]	1/41 (2,4)	NE [NE; NE]	2,90 [0,34; 24,81] 0,3094

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t120_ae_tte_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 121.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,2547)					
< 65 Jahre	28/147 (19,0)	NE [NE; NE]	3/72 (4,2)	NE [NE; NE]	4,21 [1,28; 13,86] 0,0099
≥ 65 Jahre	8/98 (8,2)	NE [NE; NE]	3/56 (5,4)	NE [31,33; NE]	1,52 [0,40; 5,76] 0,5383
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,9518)					
1	18/112 (16,1)	NE [NE; NE]	3/49 (6,1)	NE [NE; NE]	2,72 [0,80; 9,25] 0,0940
2	9/73 (12,3)	NE [NE; NE]	1/36 (2,8)	NE [NE; NE]	3,29 [0,41; 26,27] 0,2338
≥ 3	9/60 (15,0)	NE [36,43; NE]	2/43 (4,7)	NE [31,33; NE]	3,44 [0,74; 15,94] 0,0927
Art der Erkrankung (p-Wert des Interaktionsterms: 0,5768)					
Viszerale Metastasen	18/130 (13,8)	NE [NE; NE]	5/80 (6,3)	NE [31,33; NE]	1,86 [0,69; 5,05] 0,2128
Nur Knochenmetastasen	14/71 (19,7)	NE [NE; NE]	1/29 (3,4)	NE [NE; NE]	6,57 [0,86; 49,99] 0,0359
Andere	4/44 (9,1)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1522
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,6800)					
0	20/135 (14,8)	NE [NE; NE]	4/74 (5,4)	NE [NE; NE]	2,67 [0,91; 7,83] 0,0616
1	16/110 (14,5)	NE [NE; NE]	2/54 (3,7)	NE [31,33; NE]	3,64 [0,84; 15,86] 0,0654
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 0,9363)					
Weiß/kaukasisch	16/155 (10,3)	NE [NE; NE]	2/80 (2,5)	NE [NE; NE]	3,83 [0,88; 16,69] 0,0538
Asiatisch	19/58 (32,8)	NE [12,16; NE]	4/32 (12,5)	31,3 [20,98; NE]	2,74 [0,92; 8,11] 0,0587

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Andere	1/17 (5,9)	NE [NE; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4386
Geografische Region (p-Wert des Interaktionsterms: 0,9252)					
Europa	8/97 (8,2)	NE [NE; NE]	0/57 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0358
Nordamerika	10/92 (10,9)	NE [NE; NE]	2/39 (5,1)	NE [NE; NE]	1,87 [0,41; 8,65] 0,4126
Asien	18/56 (32,1)	NE [12,16; NE]	4/32 (12,5)	31,3 [20,98; NE]	2,62 [0,88; 7,81] 0,0733
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,4415)					
Ja	24/169 (14,2)	NE [NE; NE]	5/94 (5,3)	NE [NE; NE]	2,40 [0,91; 6,31] 0,0665
Nein	12/76 (15,8)	NE [NE; NE]	1/34 (2,9)	NE [NE; NE]	6,09 [0,79; 46,87] 0,0476
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,7069)					
Positiv	31/183 (16,9)	NE [NE; NE]	5/93 (5,4)	NE [NE; NE]	3,05 [1,19; 7,86] 0,0149
Negativ	4/59 (6,8)	NE [NE; NE]	1/31 (3,2)	NE [NE; NE]	2,04 [0,23; 18,26] 0,5152
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,1758)					
Primäre Resistenz	8/57 (14,0)	NE [NE; NE]	1/35 (2,9)	NE [NE; NE]	4,00 [0,49; 32,55] 0,1610
Sekundäre Resistenz	24/168 (14,3)	NE [NE; NE]	2/79 (2,5)	NE [NE; NE]	5,83 [1,38; 24,67] 0,0066
Nicht vortherapiert	4/20 (20,0)	NE [NE; NE]	3/14 (21,4)	NE [20,98; NE]	0,89 [0,20; 4,00] 0,8817
Startdosis (p-Wert des Interaktionsterms: 0,8680)					
150 mg	22/169 (13,0)	NE [NE; NE]	3/87 (3,4)	NE [NE; NE]	3,31 [0,99; 11,09] 0,0395
200 mg	14/76 (18,4)	NE [NE; NE]	3/41 (7,3)	NE [31,33; NE]	2,93 [0,84; 10,21] 0,0771
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,1507)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	20/109 (18,3)	NE [NE; NE]	1/52 (1,9)	NE [NE; NE]	8,79 [1,18; 65,53] 0,0105
Nein	16/136 (11,8)	NE [NE; NE]	5/76 (6,6)	NE [31,33; NE]	1,76 [0,64; 4,80] 0,2654

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

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Tabelle 121.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9583)					
≥ 65 Jahre	8/64 (12,5)	NE [NE; NE]	4/38 (10,5)	NE [NE; NE]	1,18 [0,35; 3,94] 0,7924
< 65 Jahre	8/79 (10,1)	NE [NE; NE]	2/28 (7,1)	NE [NE; NE]	0,95 [0,20; 4,54] 0,9486
Art der Erkrankung (p-Wert des Interaktionsterms: 0,5884)					
Viszerale Metastasen	6/78 (7,7)	NE [NE; NE]	4/39 (10,3)	NE [NE; NE]	0,49 [0,13; 1,77] 0,2658
Nur Knochenmetastasen	8/39 (20,5)	NE [38,93; NE]	2/15 (13,3)	NE [4,60; NE]	1,53 [0,32; 7,27] 0,5867
Andere	2/26 (7,7)	NE [NE; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3204
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,5021)					
0	12/83 (14,5)	NE [NE; NE]	3/36 (8,3)	NE [NE; NE]	1,23 [0,34; 4,49] 0,7557
1	4/57 (7,0)	NE [NE; NE]	3/30 (10,0)	NE [NE; NE]	0,65 [0,15; 2,91] 0,5695
Geografische Region (p-Wert des Interaktionsterms: 0,9999)					
Europa	4/75 (5,3)	NE [NE; NE]	6/37 (16,2)	NE [NE; NE]	0,30 [0,08; 1,06] 0,0472
Nordamerika	2/25 (8,0)	NE [17,98; NE]	0/16 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,6143
Asien	10/43 (23,3)	NE [38,93; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0997
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,2927)					
Ja	10/108 (9,3)	NE [NE; NE]	5/53 (9,4)	NE [NE; NE]	0,72 [0,24; 2,14] 0,5440
Nein	6/35 (17,1)	NE [38,93; NE]	1/13 (7,7)	NE [NE; NE]	2,42 [0,29; 20,19] 0,3988

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9896)					
Positiv	13/115 (11,3)	NE [NE; NE]	5/50 (10,0)	NE [NE; NE]	0,88 [0,31; 2,50] 0,8132
Negativ	3/23 (13,0)	NE [NE; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2284
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 1,0000)					
Primäre Resistenz	0/26 (0,0)	NE [NE; NE]	0/10 (0,0)	NE [NE; NE]	NE
Sekundäre Resistenz	16/117 (13,7)	NE [NE; NE]	6/56 (10,7)	NE [NE; NE]	0,96 [0,37; 2,49] 0,9287
Startdosis (p-Wert des Interaktionsterms: 0,9918)					
150 mg	10/103 (9,7)	NE [NE; NE]	6/49 (12,2)	NE [NE; NE]	0,59 [0,21; 1,67] 0,3170
200 mg	6/40 (15,0)	NE [20,75; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1525
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,5482)					
Ja	6/69 (8,7)	NE [NE; NE]	2/38 (5,3)	NE [NE; NE]	1,29 [0,25; 6,59] 0,7589
Nein	10/74 (13,5)	NE [NE; NE]	4/28 (14,3)	NE [NE; NE]	0,68 [0,21; 2,23] 0,5247

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

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Tabelle 123.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	n/N (%)	Mediane Ereigniszeit[1]	n/N (%)	Mediane Ereigniszeit[1]	HR [95% KI] p-Wert[2]
Alter (p-Wert des Interaktionsterms: 0,7499)					
< 65 Jahre	32/147 (21,8)	NE [NE; NE]	6/72 (8,3)	NE [NE; NE]	2,40 [1,00; 5,74] 0,0425
≥ 65 Jahre	10/98 (10,2)	NE [NE; NE]	3/56 (5,4)	NE [31,33; NE]	1,78 [0,49; 6,54] 0,3765
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,6951)					
1	21/112 (18,8)	NE [NE; NE]	5/49 (10,2)	NE [NE; NE]	1,84 [0,69; 4,90] 0,2131
2	12/73 (16,4)	NE [44,38; NE]	1/36 (2,8)	NE [NE; NE]	4,28 [0,55; 33,30] 0,1303
≥ 3	9/60 (15,0)	NE [36,43; NE]	3/43 (7,0)	NE [31,33; NE]	2,26 [0,61; 8,37] 0,2075
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9504)					
Viszerale Metastasen	21/130 (16,2)	NE [NE; NE]	6/80 (7,5)	NE [31,33; NE]	1,83 [0,73; 4,56] 0,1898
Nur Knochenmetastasen	17/71 (23,9)	NE [NE; NE]	3/29 (10,3)	NE [NE; NE]	2,51 [0,73; 8,59] 0,1290
Andere	4/44 (9,1)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1532
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,7044)					
0	25/135 (18,5)	NE [NE; NE]	5/74 (6,8)	NE [NE; NE]	2,63 [1,00; 6,87] 0,0409
1	17/110 (15,5)	NE [NE; NE]	4/54 (7,4)	NE [31,33; NE]	1,85 [0,62; 5,53] 0,2650
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 0,3321)					
Weiß/kaukasisch	19/155 (12,3)	NE [NE; NE]	3/80 (3,8)	NE [NE; NE]	2,96 [0,88; 10,02] 0,0669
Asiatisch	19/58 (32,8)	NE [11,08; NE]	4/32 (12,5)	31,3 [20,98; NE]	2,72 [0,92; 8,07] 0,0602

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Andere	3/17 (17,6)	NE [30,18; NE]	2/9 (22,2)	NE [0,56; NE]	0,64 [0,10; 4,02] 0,6193
Geografische Region (p-Wert des Interaktionsterms: 0,5312)					
Europa	9/97 (9,3)	NE [NE; NE]	1/57 (1,8)	NE [NE; NE]	4,79 [0,61; 37,79] 0,1008
Nordamerika	15/92 (16,3)	NE [NE; NE]	4/39 (10,3)	NE [NE; NE]	1,43 [0,47; 4,33] 0,5279
Asien	18/56 (32,1)	NE [12,16; NE]	4/32 (12,5)	31,3 [20,98; NE]	2,60 [0,87; 7,76] 0,0751
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,8788)					
Ja	26/169 (15,4)	NE [NE; NE]	6/94 (6,4)	NE [NE; NE]	2,21 [0,91; 5,38] 0,0732
Nein	16/76 (21,1)	NE [35,15; NE]	3/34 (8,8)	NE [NE; NE]	2,45 [0,71; 8,45] 0,1418
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,5700)					
Positiv	33/183 (18,0)	NE [NE; NE]	8/93 (8,6)	NE [NE; NE]	2,00 [0,92; 4,35] 0,0729
Negativ	8/59 (13,6)	NE [NE; NE]	1/31 (3,2)	NE [NE; NE]	3,60 [0,45; 29,02] 0,1977
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,3218)					
Primäre Resistenz	9/57 (15,8)	NE [36,43; NE]	1/35 (2,9)	NE [NE; NE]	4,53 [0,56; 36,28] 0,1187
Sekundäre Resistenz	29/168 (17,3)	NE [NE; NE]	5/79 (6,3)	NE [NE; NE]	2,71 [1,05; 7,01] 0,0323
Nicht vortherapiert	4/20 (20,0)	NE [NE; NE]	3/14 (21,4)	NE [20,98; NE]	0,87 [0,19; 3,89] 0,8538
Startdosis (p-Wert des Interaktionsterms: 0,6026)					
150 mg	27/169 (16,0)	NE [NE; NE]	6/87 (6,9)	NE [NE; NE]	2,01 [0,83; 4,89] 0,1163
200 mg	15/76 (19,7)	NE [30,18; NE]	3/41 (7,3)	NE [31,33; NE]	3,04 [0,88; 10,51] 0,0652
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,8895)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	22/109 (20,2)	NE [NE; NE]	4/52 (7,7)	NE [NE; NE]	2,39 [0,82; 6,96] 0,0992
Nein	20/136 (14,7)	NE [NE; NE]	5/76 (6,6)	NE [31,33; NE]	2,18 [0,82; 5,82] 0,1108

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

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Tabelle 123.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	n/N (%)	Mediane Ereigniszeit[1]	n/N (%)	Mediane Ereigniszeit[1]	HR [95% KI] p-Wert[2]
Alter (p-Wert des Interaktionsterms: 0,6210)					
< 65 Jahre	7/79 (8,9)	NE [NE; NE]	1/28 (3,6)	NE [NE; NE]	1,81 [0,22; 14,79] 0,5761
≥ 65 Jahre	8/64 (12,5)	NE [NE; NE]	4/38 (10,5)	NE [NE; NE]	1,29 [0,39; 4,28] 0,6822
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9815)					
0	10/83 (12,0)	NE [NE; NE]	3/36 (8,3)	NE [NE; NE]	1,33 [0,36; 4,86] 0,6696
1	5/57 (8,8)	NE [NE; NE]	2/30 (6,7)	NE [NE; NE]	1,22 [0,24; 6,31] 0,8110
Geografische Region (p-Wert des Interaktionsterms: 1,0000)					
Europa	7/75 (9,3)	NE [NE; NE]	5/37 (13,5)	NE [NE; NE]	0,62 [0,19; 1,95] 0,4056
Nordamerika	0/25 (0,0)	NE [NE; NE]	0/16 (0,0)	NE [NE; NE]	NE
Asien	8/43 (18,6)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1098
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,7411)					
Ja	11/108 (10,2)	NE [NE; NE]	4/53 (7,5)	NE [NE; NE]	1,07 [0,34; 3,43] 0,9061
Nein	4/35 (11,4)	NE [NE; NE]	1/13 (7,7)	NE [NE; NE]	1,70 [0,19; 15,21] 0,6326
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9901)					
Positiv	13/115 (11,3)	NE [NE; NE]	4/50 (8,0)	NE [NE; NE]	1,22 [0,40; 3,77] 0,7273
Negativ	2/23 (8,7)	NE [NE; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2751
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 1,0000)					
Primäre Resistenz	0/26 (0,0)	NE [NE; NE]	0/10 (0,0)	NE [NE; NE]	NE

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Sekundäre Resistenz	15/117 (12,8)	NE [NE; NE]	5/56 (8,9)	NE [NE; NE]	1,25 [0,45; 3,48] 0,6677
Startdosis (p-Wert des Interaktionsterms: 0,9922)					
150 mg	12/103 (11,7)	NE [NE; NE]	5/49 (10,2)	NE [NE; NE]	1,01 [0,35; 2,89] 0,9833
200 mg	3/40 (7,5)	NE [NE; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3021
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,3402)					
Ja	8/69 (11,6)	NE [NE; NE]	2/38 (5,3)	NE [NE; NE]	2,01 [0,42; 9,47] 0,3697
Nein	7/74 (9,5)	NE [NE; NE]	3/28 (10,7)	NE [NE; NE]	0,77 [0,20; 3,05] 0,7106

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

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Tabelle 124.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9926)					
0	7/135 (5,2)	NE [NE; NE]	3/74 (4,1)	NE [NE; NE]	1,16 [0,30; 4,50] 0,8289
1	2/110 (1,8)	NE [NE; NE]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3794
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,7914)					
Primäre Resistenz	0/57 (0,0)	NE [NE; NE]	0/35 (0,0)	NE [NE; NE]	NE
Sekundäre Resistenz	8/168 (4,8)	NE [NE; NE]	2/79 (2,5)	NE [NE; NE]	1,81 [0,38; 8,52] 0,4460
Nicht vortherapiert	1/20 (5,0)	NE [NE; NE]	1/14 (7,1)	NE [NE; NE]	0,69 [0,04; 11,06] 0,7935

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t124_ae_tte_popa1_2.rtf
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Tabelle 125.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,5046)					
< 65 Jahre	32/147 (21,8)	NE [NE; NE]	5/72 (6,9)	NE [NE; NE]	2,90 [1,13; 7,46] 0,0202
≥ 65 Jahre	9/98 (9,2)	NE [NE; NE]	3/56 (5,4)	NE [31,33; NE]	1,63 [0,44; 6,07] 0,4643
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,9365)					
1	20/112 (17,9)	NE [NE; NE]	5/49 (10,2)	NE [NE; NE]	1,77 [0,66; 4,72] 0,2485
2	12/73 (16,4)	NE [44,38; NE]	0/36 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0387
≥ 3	9/60 (15,0)	NE [36,43; NE]	3/43 (7,0)	NE [31,33; NE]	2,27 [0,61; 8,40] 0,2058
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9998)					
Viszerale Metastasen	21/130 (16,2)	NE [NE; NE]	5/80 (6,3)	NE [31,33; NE]	2,21 [0,83; 5,89] 0,1047
Nur Knochenmetastasen	16/71 (22,5)	NE [NE; NE]	3/29 (10,3)	NE [NE; NE]	2,38 [0,69; 8,18] 0,1570
Andere	4/44 (9,1)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1522
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,5336)					
0	24/135 (17,8)	NE [NE; NE]	4/74 (5,4)	NE [NE; NE]	3,21 [1,11; 9,28] 0,0225
1	17/110 (15,5)	NE [NE; NE]	4/54 (7,4)	NE [31,33; NE]	1,85 [0,62; 5,53] 0,2650
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 0,2696)					
Weiß/kaukasisch	18/155 (11,6)	NE [NE; NE]	3/80 (3,8)	NE [NE; NE]	2,80 [0,82; 9,51] 0,0855
Asiatisch	19/58 (32,8)	NE [11,08; NE]	3/32 (9,4)	31,3 [20,98; NE]	3,75 [1,10; 12,79] 0,0233

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Andere	3/17 (17,6)	NE [30,18; NE]	2/9 (22,2)	NE [0,56; NE]	0,64 [0,10; 4,02] 0,6193
Geografische Region (p-Wert des Interaktionsterms: 0,4528)					
Europa	8/97 (8,2)	NE [NE; NE]	1/57 (1,8)	NE [NE; NE]	4,25 [0,53; 33,98] 0,1376
Nordamerika	15/92 (16,3)	NE [NE; NE]	4/39 (10,3)	NE [NE; NE]	1,43 [0,47; 4,33] 0,5279
Asien	18/56 (32,1)	NE [11,08; NE]	3/32 (9,4)	31,3 [20,98; NE]	3,58 [1,05; 12,27] 0,0302
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,8637)					
Ja	26/169 (15,4)	NE [NE; NE]	5/94 (5,3)	NE [NE; NE]	2,66 [1,02; 6,94] 0,0374
Nein	15/76 (19,7)	NE [NE; NE]	3/34 (8,8)	NE [NE; NE]	2,29 [0,66; 7,96] 0,1784
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,6410)					
Positiv	32/183 (17,5)	NE [NE; NE]	7/93 (7,5)	NE [NE; NE]	2,24 [0,99; 5,09] 0,0476
Negativ	8/59 (13,6)	NE [NE; NE]	1/31 (3,2)	NE [NE; NE]	3,60 [0,45; 29,02] 0,1977
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,2594)					
Primäre Resistenz	9/57 (15,8)	NE [36,43; NE]	1/35 (2,9)	NE [NE; NE]	4,53 [0,56; 36,28] 0,1187
Sekundäre Resistenz	28/168 (16,7)	NE [NE; NE]	4/79 (5,1)	NE [NE; NE]	3,31 [1,16; 9,45] 0,0178
Nicht vortherapiert	4/20 (20,0)	NE [NE; NE]	3/14 (21,4)	NE [20,98; NE]	0,87 [0,19; 3,89] 0,8538
Startdosis (p-Wert des Interaktionsterms: 0,7581)					
150 mg	26/169 (15,4)	NE [NE; NE]	5/87 (5,7)	NE [NE; NE]	2,36 [0,90; 6,16] 0,0715
200 mg	15/76 (19,7)	NE [30,18; NE]	3/41 (7,3)	NE [31,33; NE]	3,04 [0,88; 10,51] 0,0652
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,5581)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	22/109 (20,2)	NE [NE; NE]	3/52 (5,8)	NE [NE; NE]	3,24 [0,97; 10,87] 0,0435
Nein	19/136 (14,0)	NE [NE; NE]	5/76 (6,6)	NE [31,33; NE]	2,07 [0,77; 5,56] 0,1394

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 125.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,8114)					
< 65 Jahre	7/79 (8,9)	NE [NE; NE]	1/28 (3,6)	NE [NE; NE]	1,76 [0,21; 14,44] 0,5932
≥ 65 Jahre	8/64 (12,5)	NE [NE; NE]	3/38 (7,9)	NE [NE; NE]	1,72 [0,45; 6,49] 0,4201
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,5703)					
0	10/83 (12,0)	NE [NE; NE]	3/36 (8,3)	NE [NE; NE]	1,33 [0,36; 4,87] 0,6676
1	5/57 (8,8)	NE [NE; NE]	1/30 (3,3)	NE [NE; NE]	2,37 [0,28; 20,34] 0,4170
Geografische Region (p-Wert des Interaktionsterms: 1,0000)					
Europa	7/75 (9,3)	NE [NE; NE]	4/37 (10,8)	NE [NE; NE]	0,76 [0,22; 2,61] 0,6596
Nordamerika	0/25 (0,0)	NE [NE; NE]	0/16 (0,0)	NE [NE; NE]	NE
Asien	8/43 (18,6)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1140
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9101)					
Ja	11/108 (10,2)	NE [NE; NE]	3/53 (5,7)	NE [NE; NE]	1,41 [0,39; 5,13] 0,6014
Nein	4/35 (11,4)	NE [NE; NE]	1/13 (7,7)	NE [NE; NE]	1,72 [0,19; 15,37] 0,6252
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9906)					
Positiv	13/115 (11,3)	NE [NE; NE]	3/50 (6,0)	NE [NE; NE]	1,62 [0,46; 5,70] 0,4510
Negativ	2/23 (8,7)	NE [NE; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2751
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9999)					
Primäre Resistenz	0/26 (0,0)	NE [NE; NE]	0/10 (0,0)	NE [NE; NE]	NE

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Sekundäre Resistenz	15/117 (12,8)	NE [NE; NE]	4/56 (7,1)	NE [NE; NE]	1,55 [0,51; 4,71] 0,4366
Startdosis (p-Wert des Interaktionsterms: 0,9925)					
150 mg	12/103 (11,7)	NE [NE; NE]	4/49 (8,2)	NE [NE; NE]	1,26 [0,40; 3,93] 0,6922
200 mg	3/40 (7,5)	NE [NE; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3021
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,1776)					
Ja	8/69 (11,6)	NE [NE; NE]	1/38 (2,6)	NE [NE; NE]	3,95 [0,49; 31,69] 0,1621
Nein	7/74 (9,5)	NE [NE; NE]	3/28 (10,7)	NE [NE; NE]	0,78 [0,20; 3,06] 0,7139

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
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/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 127.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	n/N (%)	Mediane Ereigniszeit[1]	n/N (%)	Mediane Ereigniszeit[1]	HR [95% KI] p-Wert[2]
Alter (p-Wert des Interaktionsterms: 0,9893)					
< 65 Jahre	12/147 (8,2)	NE [51,81; NE]	0/72 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0210
≥ 65 Jahre	5/98 (5,1)	NE [NE; NE]	1/56 (1,8)	NE [NE; NE]	3,00 [0,35; 25,71] 0,2918
Art der Erkrankung (p-Wert des Interaktionsterms: 1,0000)					
Viszerale Metastasen	9/130 (6,9)	NE [NE; NE]	1/80 (1,3)	NE [NE; NE]	4,57 [0,57; 36,29] 0,1152
Nur Knochenmetastasen	8/71 (11,3)	NE [51,81; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0624
Andere	0/44 (0,0)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	NE
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9918)					
0	11/135 (8,1)	NE [51,81; NE]	1/74 (1,4)	NE [NE; NE]	5,42 [0,70; 42,11] 0,0699
1	6/110 (5,5)	NE [NE; NE]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0943
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 1,0000)					
Weiß/kaukasisch	10/155 (6,5)	NE [NE; NE]	1/80 (1,3)	NE [NE; NE]	4,94 [0,63; 38,62] 0,0912
Asiatisch	4/58 (6,9)	NE [51,81; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1929
Andere	2/17 (11,8)	NE [45,90; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4452
Geografische Region (p-Wert des Interaktionsterms: 0,9999)					
Europa	3/97 (3,1)	NE [NE; NE]	0/57 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1981
Nordamerika	10/92 (10,9)	NE [NE; NE]	1/39 (2,6)	NE [NE; NE]	3,72 [0,47; 29,28] 0,1814

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Asien	4/56 (7,1)	NE [51,81; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1865
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9937)					
Positiv	14/183 (7,7)	NE [51,81; NE]	1/93 (1,1)	NE [NE; NE]	6,60 [0,87; 50,36] 0,0356
Negativ	3/59 (5,1)	NE [NE; NE]	0/31 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2490
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9999)					
Primäre Resistenz	5/57 (8,8)	NE [51,81; NE]	1/35 (2,9)	NE [NE; NE]	2,13 [0,24; 19,16] 0,4886
Sekundäre Resistenz	10/168 (6,0)	NE [NE; NE]	0/79 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0336
Nicht vortherapiert	2/20 (10,0)	NE [NE; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2544
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9915)					
Ja	8/109 (7,3)	NE [NE; NE]	0/52 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0655
Nein	9/136 (6,6)	NE [51,81; NE]	1/76 (1,3)	NE [NE; NE]	5,32 [0,67; 42,21] 0,0767

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t127_ae_tte_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 129.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9896)					
≥ 65 Jahre	5/98 (5,1)	NE [NE; NE]	1/56 (1,8)	NE [NE; NE]	2,89 [0,34; 24,77] 0,3098
< 65 Jahre	11/147 (7,5)	NE [51,81; NE]	0/72 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0279
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9919)					
0	10/135 (7,4)	NE [51,81; NE]	1/74 (1,4)	NE [NE; NE]	4,81 [0,61; 37,74] 0,0985
1	6/110 (5,5)	NE [NE; NE]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0961
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 1,0000)					
Weiß/kaukasisch	9/155 (5,8)	NE [NE; NE]	1/80 (1,3)	NE [NE; NE]	4,36 [0,55; 34,45] 0,1271
Asiatisch	4/58 (6,9)	NE [51,81; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1929
Andere	2/17 (11,8)	NE [45,90; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4452
Geografische Region (p-Wert des Interaktionsterms: 0,9999)					
Europa	3/97 (3,1)	NE [NE; NE]	0/57 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2115
Nordamerika	9/92 (9,8)	NE [NE; NE]	1/39 (2,6)	NE [NE; NE]	3,29 [0,41; 26,21] 0,2338
Asien	4/56 (7,1)	NE [51,81; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1865
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9938)					
Positiv	13/183 (7,1)	NE [51,81; NE]	1/93 (1,1)	NE [NE; NE]	6,02 [0,79; 46,17] 0,0492
Negativ	3/59 (5,1)	NE [NE; NE]	0/31 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2490

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Datenschnitt: 20.06.2019, Safety-Population 1: In Monaten; 2: Aus Log-rank-Test Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.					

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
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Tabelle 139.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	n/N (%)	Mediane Ereigniszeit[1]	n/N (%)	Mediane Ereigniszeit[1]	HR [95% KI] p-Wert[2]
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 1,0000)					
0	10/135 (7,4)	NE [NE; NE]	0/74 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0358
1	7/110 (6,4)	NE [NE; NE]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0713
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 1,0000)					
Weiß/kaukasisch	10/155 (6,5)	NE [NE; NE]	0/80 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0357
Asiatisch	4/58 (6,9)	NE [NE; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1240
Andere	2/17 (11,8)	NE [19,43; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3753
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 1,0000)					
Ja	12/169 (7,1)	NE [NE; NE]	0/94 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0197
Nein	5/76 (6,6)	NE [NE; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1234
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9999)					
Positiv	12/183 (6,6)	NE [NE; NE]	0/93 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0232
Negativ	5/59 (8,5)	NE [NE; NE]	0/31 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1063
Startdosis (p-Wert des Interaktionsterms: 0,9999)					
150 mg	13/169 (7,7)	NE [NE; NE]	0/87 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0170
200 mg	4/76 (5,3)	NE [NE; NE]	0/41 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1511
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9999)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	7/109 (6,4)	NE [NE; NE]	0/52 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1174
Nein	10/136 (7,4)	NE [NE; NE]	0/76 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0203

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.
Venöse Thromboembolie: PT Embolism

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t139_ae_tte_popa1_2.rtf
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Tabelle 139.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,4866)					
0	9/83 (10,8)	NE [NE; NE]	1/36 (2,8)	NE [NE; NE]	2,59 [0,32; 20,77] 0,3540
1	2/57 (3,5)	NE [NE; NE]	1/30 (3,3)	NE [NE; NE]	0,97 [0,09; 10,76] 0,9825
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9942)					
Ja	9/108 (8,3)	NE [NE; NE]	2/53 (3,8)	NE [NE; NE]	1,44 [0,30; 6,82] 0,6417
Nein	2/35 (5,7)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3631
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9920)					
Primäre Resistenz	2/26 (7,7)	NE [24,72; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3856
Sekundäre Resistenz	9/117 (7,7)	NE [NE; NE]	2/56 (3,6)	NE [NE; NE]	1,62 [0,35; 7,63] 0,5340

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.
Venöse Thromboembolie: PT Embolism

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
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Tabelle 143.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,7288)					
< 65 Jahre	43/147 (29,3)	NE [35,18; NE]	8/72 (11,1)	NE [NE; NE]	2,54 [1,19; 5,40] 0,0121
≥ 65 Jahre	17/98 (17,3)	NE [NE; NE]	5/56 (8,9)	NE [31,33; NE]	2,05 [0,76; 5,58] 0,1503
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,7586)					
1	31/112 (27,7)	NE [NE; NE]	6/49 (12,2)	NE [NE; NE]	2,46 [1,03; 5,90] 0,0369
2	17/73 (23,3)	NE [32,88; NE]	2/36 (5,6)	NE [NE; NE]	3,48 [0,80; 15,17] 0,0768
≥ 3	12/60 (20,0)	NE [36,43; NE]	5/43 (11,6)	NE [31,33; NE]	1,78 [0,63; 5,07] 0,2710
Art der Erkrankung (p-Wert des Interaktionsterms: 0,8316)					
Viszerale Metastasen	30/130 (23,1)	NE [36,43; NE]	9/80 (11,3)	NE [31,33; NE]	1,85 [0,88; 3,92] 0,1004
Nur Knochenmetastasen	24/71 (33,8)	NE [17,79; NE]	4/29 (13,8)	NE [NE; NE]	2,94 [1,02; 8,49] 0,0363
Andere	6/44 (13,6)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0806
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,7872)					
0	33/135 (24,4)	NE [NE; NE]	7/74 (9,5)	NE [NE; NE]	2,61 [1,15; 5,91] 0,0166
1	27/110 (24,5)	NE [35,18; NE]	6/54 (11,1)	NE [31,33; NE]	2,18 [0,90; 5,28] 0,0770
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 0,4720)					
Weiß/kaukasisch	29/155 (18,7)	NE [NE; NE]	7/80 (8,8)	NE [NE; NE]	2,06 [0,90; 4,71] 0,0788
Asiatisch	23/58 (39,7)	32,9 [10,85; NE]	4/32 (12,5)	31,3 [20,98; NE]	3,40 [1,16; 9,92] 0,0175

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Andere	5/17 (29,4)	NE [8,88; NE]	2/9 (22,2)	NE [0,56; NE]	1,17 [0,23; 6,11] 0,8478
Geografische Region (p-Wert des Interaktionsterms: 0,6889)					
Europa	17/97 (17,5)	NE [NE; NE]	5/57 (8,8)	NE [NE; NE]	1,95 [0,72; 5,27] 0,1838
Nordamerika	21/92 (22,8)	NE [NE; NE]	4/39 (10,3)	NE [NE; NE]	2,06 [0,70; 6,02] 0,1771
Asien	22/56 (39,3)	32,9 [10,85; NE]	4/32 (12,5)	31,3 [20,98; NE]	3,29 [1,12; 9,65] 0,0215
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,5633)					
Ja	36/169 (21,3)	NE [NE; NE]	9/94 (9,6)	NE [NE; NE]	2,10 [1,01; 4,37] 0,0419
Nein	24/76 (31,6)	NE [17,79; NE]	4/34 (11,8)	NE [NE; NE]	3,25 [1,13; 9,39] 0,0209
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9870)					
Positiv	49/183 (26,8)	NE [NE; NE]	10/93 (10,8)	NE [NE; NE]	2,54 [1,29; 5,03] 0,0053
Negativ	10/59 (16,9)	NE [NE; NE]	2/31 (6,5)	NE [16,41; NE]	2,59 [0,57; 11,85] 0,2009
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,1969)					
Primäre Resistenz	16/57 (28,1)	NE [17,56; NE]	3/35 (8,6)	NE [16,41; NE]	2,87 [0,83; 9,95] 0,0810
Sekundäre Resistenz	39/168 (23,2)	NE [NE; NE]	6/79 (7,6)	NE [NE; NE]	3,26 [1,38; 7,71] 0,0043
Nicht vortherapiert	5/20 (25,0)	NE [6,94; NE]	4/14 (28,6)	NE [20,98; NE]	0,85 [0,23; 3,17] 0,8055
Startdosis (p-Wert des Interaktionsterms: 0,6422)					
150 mg	37/169 (21,9)	NE [NE; NE]	8/87 (9,2)	NE [NE; NE]	2,19 [1,02; 4,70] 0,0401
200 mg	23/76 (30,3)	NE [17,79; NE]	5/41 (12,2)	NE [31,33; NE]	2,95 [1,12; 7,77] 0,0217
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,6486)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	27/109 (24,8)	NE [36,43; NE]	6/52 (11,5)	NE [NE; NE]	2,07 [0,85; 5,03] 0,0989
Nein	33/136 (24,3)	NE [NE; NE]	7/76 (9,2)	NE [31,33; NE]	2,74 [1,21; 6,19] 0,0118

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SMQ: Standardised MedDRA Queries.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
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Tabelle 143.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,6257)					
≥ 65 Jahre	13/64 (20,3)	NE [22,03; NE]	4/38 (10,5)	NE [NE; NE]	1,87 [0,61; 5,78] 0,2686
< 65 Jahre	13/79 (16,5)	NE [NE; NE]	3/28 (10,7)	NE [15,68; NE]	1,11 [0,31; 3,92] 0,8724
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,2387)					
1	13/47 (27,7)	30,4 [15,68; NE]	1/20 (5,0)	NE [NE; NE]	5,28 [0,69; 40,48] 0,0730
2	8/49 (16,3)	NE [NE; NE]	3/21 (14,3)	NE [15,68; NE]	0,89 [0,24; 3,40] 0,8688
≥ 3	5/47 (10,6)	NE [NE; NE]	3/25 (12,0)	NE [NE; NE]	0,88 [0,21; 3,69] 0,8545
Art der Erkrankung (p-Wert des Interaktionsterms: 0,5913)					
Viszerale Metastasen	12/78 (15,4)	NE [NE; NE]	5/39 (12,8)	NE [15,68; NE]	0,79 [0,27; 2,28] 0,6611
Nur Knochenmetastasen	11/39 (28,2)	NE [12,92; NE]	2/15 (13,3)	NE [4,60; NE]	2,37 [0,52; 10,70] 0,2488
Andere	3/26 (11,5)	NE [NE; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2222
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9144)					
0	17/83 (20,5)	NE [NE; NE]	4/36 (11,1)	NE [15,68; NE]	1,41 [0,47; 4,25] 0,5423
1	9/57 (15,8)	NE [22,13; NE]	3/30 (10,0)	NE [NE; NE]	1,60 [0,43; 5,93] 0,4760
Geografische Region (p-Wert des Interaktionsterms: 0,9999)					
Europa	10/75 (13,3)	NE [NE; NE]	7/37 (18,9)	NE [15,68; NE]	0,62 [0,24; 1,64] 0,3334
Nordamerika	4/25 (16,0)	NE [17,98; NE]	0/16 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4778

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Asien	12/43 (27,9)	NE [20,75; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0555
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,2862)					
Ja	18/108 (16,7)	NE [NE; NE]	6/53 (11,3)	NE [15,68; NE]	1,07 [0,42; 2,73] 0,8936
Nein	8/35 (22,9)	NE [12,92; NE]	1/13 (7,7)	NE [NE; NE]	3,73 [0,46; 29,88] 0,1840
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9875)					
Positiv	22/115 (19,1)	NE [NE; NE]	6/50 (12,0)	NE [NE; NE]	1,31 [0,53; 3,25] 0,5568
Negativ	4/23 (17,4)	NE [11,87; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1414
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,6004)					
Primäre Resistenz	2/26 (7,7)	NE [22,03; NE]	1/10 (10,0)	NE [15,68; NE]	1,03 [0,09; 11,40] 0,9825
Sekundäre Resistenz	24/117 (20,5)	NE [NE; NE]	6/56 (10,7)	NE [NE; NE]	1,58 [0,64; 3,91] 0,3148
Startdosis (p-Wert des Interaktionsterms: 0,9900)					
150 mg	17/103 (16,5)	NE [NE; NE]	7/49 (14,3)	NE [NE; NE]	0,94 [0,39; 2,28] 0,8931
200 mg	9/40 (22,5)	NE [20,75; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0884
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,5905)					
Ja	11/69 (15,9)	NE [NE; NE]	3/38 (7,9)	NE [NE; NE]	1,82 [0,51; 6,54] 0,3532
Nein	15/74 (20,3)	NE [22,03; NE]	4/28 (14,3)	NE [NE; NE]	1,06 [0,35; 3,23] 0,9260

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SMQ: Standardised MedDRA Queries.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t143_ae_tte_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Tabelle 144.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,5574)					
< 65 Jahre	18/147 (12,2)	NE [NE; NE]	4/72 (5,6)	NE [NE; NE]	1,93 [0,65; 5,72] 0,2249
≥ 65 Jahre	7/98 (7,1)	NE [NE; NE]	1/56 (1,8)	NE [NE; NE]	4,21 [0,52; 34,24] 0,1433
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,7430)					
1	11/112 (9,8)	NE [NE; NE]	1/49 (2,0)	NE [NE; NE]	4,67 [0,60; 36,20] 0,1040
2	9/73 (12,3)	NE [NE; NE]	2/36 (5,6)	NE [NE; NE]	1,87 [0,40; 8,80] 0,4212
≥ 3	5/60 (8,3)	NE [NE; NE]	2/43 (4,7)	NE [NE; NE]	1,85 [0,36; 9,55] 0,4546
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9999)					
Viszerale Metastasen	14/130 (10,8)	NE [NE; NE]	5/80 (6,3)	NE [NE; NE]	1,48 [0,53; 4,13] 0,4516
Nur Knochenmetastasen	8/71 (11,3)	NE [NE; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0635
Andere	3/44 (6,8)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2324
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,6573)					
0	17/135 (12,6)	NE [NE; NE]	4/74 (5,4)	NE [NE; NE]	2,17 [0,73; 6,45] 0,1544
1	8/110 (7,3)	NE [NE; NE]	1/54 (1,9)	NE [NE; NE]	3,50 [0,44; 28,16] 0,2084
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 0,9953)					
Weiß/kaukasisch	13/155 (8,4)	NE [NE; NE]	3/80 (3,8)	NE [NE; NE]	2,19 [0,62; 7,68] 0,2096
Asiatisch	9/58 (15,5)	NE [NE; NE]	2/32 (6,3)	NE [NE; NE]	2,18 [0,46; 10,30] 0,3132

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Andere	2/17 (11,8)	NE [NE; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2627
Geografische Region (p-Wert des Interaktionsterms: 0,9772)					
Europa	8/97 (8,2)	NE [NE; NE]	2/57 (3,5)	NE [NE; NE]	2,31 [0,49; 10,86] 0,2773
Nordamerika	8/92 (8,7)	NE [NE; NE]	1/39 (2,6)	NE [NE; NE]	3,22 [0,40; 25,82] 0,2445
Asien	9/56 (16,1)	NE [NE; NE]	2/32 (6,3)	NE [NE; NE]	2,25 [0,48; 10,62] 0,2941
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9891)					
Ja	16/169 (9,5)	NE [NE; NE]	5/94 (5,3)	NE [NE; NE]	1,58 [0,58; 4,32] 0,3690
Nein	9/76 (11,8)	NE [NE; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0362
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,4830)					
Positiv	22/183 (12,0)	NE [NE; NE]	3/93 (3,2)	NE [NE; NE]	3,53 [1,05; 11,80] 0,0290
Negativ	3/59 (5,1)	NE [NE; NE]	1/31 (3,2)	NE [NE; NE]	1,50 [0,16; 14,40] 0,7250
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,7112)					
Primäre Resistenz	3/57 (5,3)	NE [NE; NE]	1/35 (2,9)	NE [NE; NE]	1,41 [0,14; 13,79] 0,7679
Sekundäre Resistenz	20/168 (11,9)	NE [NE; NE]	3/79 (3,8)	NE [NE; NE]	3,07 [0,91; 10,36] 0,0565
Nicht vortherapiert	2/20 (10,0)	NE [NE; NE]	1/14 (7,1)	NE [NE; NE]	1,22 [0,11; 13,59] 0,8707
Startdosis (p-Wert des Interaktionsterms: 0,7082)					
150 mg	18/169 (10,7)	NE [NE; NE]	3/87 (3,4)	NE [NE; NE]	2,72 [0,80; 9,28] 0,0951
200 mg	7/76 (9,2)	NE [NE; NE]	2/41 (4,9)	NE [NE; NE]	2,00 [0,41; 9,61] 0,3798
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,6569)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	14/109 (12,8)	NE [NE; NE]	2/52 (3,8)	NE [NE; NE]	3,04 [0,69; 13,41] 0,1215
Nein	11/136 (8,1)	NE [NE; NE]	3/76 (3,9)	NE [NE; NE]	1,95 [0,54; 7,00] 0,2995

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SMQ: Standardised MedDRA Queries.

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Tabelle 144.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,7148)					
Ja	7/108 (6,5)	NE [NE; NE]	3/53 (5,7)	NE [NE; NE]	0,72 [0,18; 2,87] 0,6373
Nein	3/35 (8,6)	NE [NE; NE]	1/13 (7,7)	NE [4,54; NE]	1,22 [0,13; 11,71] 0,8647
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9926)					
Positiv	9/115 (7,8)	NE [NE; NE]	3/50 (6,0)	NE [NE; NE]	1,06 [0,29; 3,95] 0,9294
Negativ	1/23 (4,3)	NE [30,41; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,7055
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9922)					
Primäre Resistenz	1/26 (3,8)	NE [22,13; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,5127
Sekundäre Resistenz	9/117 (7,7)	NE [NE; NE]	4/56 (7,1)	NE [NE; NE]	0,83 [0,25; 2,73] 0,7563
Startdosis (p-Wert des Interaktionsterms: 0,9935)					
150 mg	7/103 (6,8)	NE [NE; NE]	4/49 (8,2)	NE [NE; NE]	0,62 [0,18; 2,15] 0,4456
200 mg	3/40 (7,5)	NE [NE; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3101

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SMQ: Standardised MedDRA Queries.

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Tabelle 145.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9967)					
< 65 Jahre	41/147 (27,9)	NE [35,41; NE]	8/72 (11,1)	NE [NE; NE]	2,39 [1,12; 5,10] 0,0198
≥ 65 Jahre	16/98 (16,3)	NE [NE; NE]	4/56 (7,1)	NE [31,33; NE]	2,42 [0,81; 7,25] 0,1035
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,4513)					
1	29/112 (25,9)	NE [NE; NE]	6/49 (12,2)	NE [NE; NE]	2,29 [0,95; 5,52] 0,0573
2	17/73 (23,3)	NE [33,57; NE]	1/36 (2,8)	NE [NE; NE]	6,74 [0,89; 50,92] 0,0324
≥ 3	11/60 (18,3)	NE [36,43; NE]	5/43 (11,6)	NE [31,33; NE]	1,61 [0,56; 4,63] 0,3754
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9484)					
Viszerale Metastasen	29/130 (22,3)	NE [36,43; NE]	8/80 (10,0)	NE [31,33; NE]	2,00 [0,91; 4,40] 0,0766
Nur Knochenmetastasen	22/71 (31,0)	NE [23,93; NE]	4/29 (13,8)	NE [NE; NE]	2,67 [0,92; 7,77] 0,0601
Andere	6/44 (13,6)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0801
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,6445)					
0	31/135 (23,0)	NE [NE; NE]	6/74 (8,1)	NE [NE; NE]	2,85 [1,19; 6,83] 0,0141
1	26/110 (23,6)	NE [35,41; NE]	6/54 (11,1)	NE [31,33; NE]	2,09 [0,86; 5,09] 0,0958
Ethnische Zugehörigkeit (p-Wert des Interaktionsterms: 0,4833)					
Weiß/kaukasisch	26/155 (16,8)	NE [NE; NE]	6/80 (7,5)	NE [NE; NE]	2,14 [0,88; 5,21] 0,0851
Asiatisch	23/58 (39,7)	33,6 [10,85; NE]	4/32 (12,5)	31,3 [20,98; NE]	3,41 [1,17; 9,97] 0,0170

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Andere	5/17 (29,4)	NE [8,88; NE]	2/9 (22,2)	NE [0,56; NE]	1,17 [0,23; 6,11] 0,8478
Geografische Region (p-Wert des Interaktionsterms: 0,7089)					
Europa	15/97 (15,5)	NE [NE; NE]	4/57 (7,0)	NE [NE; NE]	2,10 [0,70; 6,33] 0,1785
Nordamerika	20/92 (21,7)	NE [NE; NE]	4/39 (10,3)	NE [NE; NE]	1,98 [0,67; 5,82] 0,2049
Asien	22/56 (39,3)	33,6 [10,85; NE]	4/32 (12,5)	31,3 [20,98; NE]	3,30 [1,13; 9,69] 0,0210
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,7795)					
Ja	35/169 (20,7)	NE [NE; NE]	8/94 (8,5)	NE [NE; NE]	2,29 [1,06; 4,94] 0,0300
Nein	22/76 (28,9)	NE [17,82; NE]	4/34 (11,8)	NE [NE; NE]	2,94 [1,01; 8,54] 0,0377
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9458)					
Positiv	46/183 (25,1)	NE [NE; NE]	10/93 (10,8)	NE [NE; NE]	2,37 [1,19; 4,69] 0,0110
Negativ	10/59 (16,9)	NE [NE; NE]	2/31 (6,5)	NE [16,41; NE]	2,59 [0,57; 11,85] 0,2009
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,1582)					
Primäre Resistenz	14/57 (24,6)	NE [36,43; NE]	3/35 (8,6)	NE [16,41; NE]	2,47 [0,70; 8,68] 0,1456
Sekundäre Resistenz	38/168 (22,6)	NE [NE; NE]	5/79 (6,3)	NE [NE; NE]	3,81 [1,50; 9,69] 0,0024
Nicht vortherapiert	5/20 (25,0)	NE [6,94; NE]	4/14 (28,6)	NE [20,98; NE]	0,85 [0,23; 3,17] 0,8055
Startdosis (p-Wert des Interaktionsterms: 0,3564)					
150 mg	34/169 (20,1)	NE [NE; NE]	8/87 (9,2)	NE [NE; NE]	1,98 [0,92; 4,30] 0,0759
200 mg	23/76 (30,3)	NE [17,82; NE]	4/41 (9,8)	NE [31,33; NE]	3,70 [1,28; 10,71] 0,0097
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,4441)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	25/109 (22,9)	NE [NE; NE]	6/52 (11,5)	NE [NE; NE]	1,89 [0,77; 4,61] 0,1548
Nein	32/136 (23,5)	NE [NE; NE]	6/76 (7,9)	NE [31,33; NE]	3,08 [1,29; 7,38] 0,0078

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SMQ: Standardised MedDRA Queries.

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Tabelle 145.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-2 - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,6090)					
≥ 65 Jahre	12/64 (18,8)	NE [22,03; NE]	4/38 (10,5)	NE [NE; NE]	1,79 [0,57; 5,57] 0,3102
< 65 Jahre	12/79 (15,2)	NE [NE; NE]	3/28 (10,7)	NE [15,68; NE]	1,01 [0,28; 3,62] 0,9827
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,2613)					
1	12/47 (25,5)	NE [22,03; NE]	1/20 (5,0)	NE [NE; NE]	4,92 [0,64; 37,92] 0,0902
2	7/49 (14,3)	NE [NE; NE]	3/21 (14,3)	NE [15,68; NE]	0,81 [0,21; 3,15] 0,7579
≥ 3	5/47 (10,6)	NE [NE; NE]	3/25 (12,0)	NE [NE; NE]	0,88 [0,21; 3,69] 0,8545
Art der Erkrankung (p-Wert des Interaktionsterms: 0,6154)					
Viszerale Metastasen	11/78 (14,1)	NE [NE; NE]	5/39 (12,8)	NE [15,68; NE]	0,74 [0,25; 2,18] 0,5885
Nur Knochenmetastasen	10/39 (25,6)	NE [22,03; NE]	2/15 (13,3)	NE [4,60; NE]	2,19 [0,48; 10,03] 0,2992
Andere	3/26 (11,5)	NE [NE; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2222
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,8200)					
0	15/83 (18,1)	NE [NE; NE]	4/36 (11,1)	NE [15,68; NE]	1,30 [0,43; 3,98] 0,6419
1	9/57 (15,8)	NE [22,32; NE]	3/30 (10,0)	NE [NE; NE]	1,59 [0,43; 5,88] 0,4844
Geografische Region (p-Wert des Interaktionsterms: 0,9999)					
Europa	9/75 (12,0)	NE [NE; NE]	7/37 (18,9)	NE [15,68; NE]	0,57 [0,21; 1,55] 0,2660
Nordamerika	3/25 (12,0)	NE [17,98; NE]	0/16 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,5382

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Asien	12/43 (27,9)	NE [20,75; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0576
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,3304)					
Ja	17/108 (15,7)	NE [NE; NE]	6/53 (11,3)	NE [15,68; NE]	1,02 [0,40; 2,64] 0,9605
Nein	7/35 (20,0)	NE [22,03; NE]	1/13 (7,7)	NE [NE; NE]	3,28 [0,40; 26,72] 0,2402
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9876)					
Positiv	20/115 (17,4)	NE [NE; NE]	6/50 (12,0)	NE [NE; NE]	1,22 [0,49; 3,05] 0,6709
Negativ	4/23 (17,4)	NE [11,87; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1414
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,6482)					
Primäre Resistenz	2/26 (7,7)	NE [22,03; NE]	1/10 (10,0)	NE [15,68; NE]	1,03 [0,09; 11,40] 0,9825
Sekundäre Resistenz	22/117 (18,8)	NE [NE; NE]	6/56 (10,7)	NE [NE; NE]	1,49 [0,60; 3,70] 0,3905
Startdosis (p-Wert des Interaktionsterms: 0,9902)					
150 mg	15/103 (14,6)	NE [NE; NE]	7/49 (14,3)	NE [NE; NE]	0,86 [0,35; 2,12] 0,7397
200 mg	9/40 (22,5)	NE [20,75; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0884
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,7847)					
Ja	9/69 (13,0)	NE [NE; NE]	3/38 (7,9)	NE [NE; NE]	1,54 [0,42; 5,71] 0,5132
Nein	15/74 (20,3)	NE [22,03; NE]	4/28 (14,3)	NE [NE; NE]	1,06 [0,35; 3,23] 0,9224

Datenschnitt: 20.06.2019, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mg: Milligramm; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SMQ: Standardised MedDRA Queries.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_ae_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t145_ae_tte_popa2_2.rtf
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/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 201.1.2: Subgroups: adverse events according PT - Gastrointestinal disorders/Abdominal pain - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,4442)					
< 65 years	55/147 (37,4)	NE [28,80; NE]	15/72 (20,8)	49,8 [49,81; NE]	1,97 [1,11; 3,49] 0,0181
≥ 65 years	34/98 (34,7)	NE [34,22; NE]	8/56 (14,3)	NE [25,38; NE]	2,80 [1,29; 6,06] 0,0064
Organs involved (p-value of the interaction term: 0,4036)					
1	37/112 (33,0)	NE [NE; NE]	10/49 (20,4)	49,8 [NE; NE]	1,89 [0,94; 3,81] 0,0702
2	29/73 (39,7)	28,8 [12,36; NE]	8/36 (22,2)	23,0 [11,54; NE]	1,69 [0,77; 3,73] 0,1860
≥ 3	23/60 (38,3)	NE [18,15; NE]	5/43 (11,6)	NE [NE; NE]	3,94 [1,50; 10,38] 0,0027
Nature of disease (p-value of the interaction term: 0,9067)					
Visceral	51/130 (39,2)	34,2 [18,15; NE]	14/80 (17,5)	NE [25,38; NE]	2,48 [1,37; 4,48] 0,0019
Bone only	20/71 (28,2)	NE [NE; NE]	5/29 (17,2)	49,8 [NE; NE]	1,89 [0,71; 5,05] 0,1960
Other	18/44 (40,9)	NE [1,94; NE]	4/19 (21,1)	NE [23,01; NE]	2,25 [0,76; 6,65] 0,1315
ECOG-PS at Baseline (p-value of the interaction term: 0,9785)					
0	55/135 (40,7)	NE [13,08; NE]	15/74 (20,3)	49,8 [25,38; NE]	2,27 [1,28; 4,02] 0,0039
1	34/110 (30,9)	NE [NE; NE]	8/54 (14,8)	NE [NE; NE]	2,32 [1,07; 5,01] 0,0281
Race (p-value of the interaction term: 0,5072)					
Caucasian	55/155 (35,5)	NE [28,80; NE]	15/80 (18,8)	49,8 [NE; NE]	2,14 [1,21; 3,79] 0,0076
Asian	21/58 (36,2)	NE [5,59; NE]	5/32 (15,6)	NE [NE; NE]	2,58 [0,97; 6,88] 0,0496

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	10/17 (58,8)	3,9 [0,16; NE]	1/9 (11,1)	NE [23,01; NE]	6,78 [0,86; 53,21] 0,0353
Region (p-value of the interaction term: 0,8140)					
Europe	35/97 (36,1)	NE [18,51; NE]	9/57 (15,8)	NE [NE; NE]	2,67 [1,28; 5,57] 0,0062
North America	35/92 (38,0)	NE [12,36; NE]	9/39 (23,1)	49,8 [23,01; NE]	1,89 [0,90; 3,93] 0,0860
Asian	19/56 (33,9)	NE [34,22; NE]	5/32 (15,6)	NE [NE; NE]	2,37 [0,88; 6,39] 0,0789
Measurable disease at baseline (p-value of the interaction term: 0,9312)					
Yes	64/169 (37,9)	NE [28,80; NE]	17/94 (18,1)	NE [25,38; NE]	2,32 [1,36; 3,96] 0,0015
No	25/76 (32,9)	NE [NE; NE]	6/34 (17,6)	49,8 [NE; NE]	2,21 [0,91; 5,39] 0,0744
Progesterone receptor (p-value of the interaction term: 0,2188)					
Positive	64/183 (35,0)	NE [NE; NE]	14/93 (15,1)	NE [NE; NE]	2,66 [1,49; 4,74] 0,0006
Negative	23/59 (39,0)	34,2 [5,59; NE]	9/31 (29,0)	49,8 [NE; NE]	1,37 [0,63; 2,98] 0,4225
Sensitivity against endocrine therapy (p-value of the interaction term: 0,8758)					
Primary resistance	21/57 (36,8)	NE [10,16; NE]	6/35 (17,1)	NE [NE; NE]	2,61 [1,05; 6,47] 0,0323
Secondary resistance	61/168 (36,3)	NE [28,80; NE]	14/79 (17,7)	NE [NE; NE]	2,31 [1,29; 4,14] 0,0037
Endocrine naive	7/20 (35,0)	NE [2,60; NE]	3/14 (21,4)	NE [49,81; NE]	1,67 [0,43; 6,47] 0,4523
Starting dose (p-value of the interaction term: 0,6839)					
150 mg	56/169 (33,1)	NE [34,22; NE]	13/87 (14,9)	NE [NE; NE]	2,48 [1,35; 4,53] 0,0023
200 mg	33/76 (43,4)	NE [5,56; NE]	10/41 (24,4)	49,8 [25,38; NE]	2,03 [1,00; 4,12] 0,0465
Previous anti-estrogene therapy (p-value of the interaction term: 0,6206)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	39/109 (35,8)	NE [18,51; NE]	8/52 (15,4)	NE [NE; NE]	2,71 [1,26; 5,80] 0,0076
No	50/136 (36,8)	NE [28,80; NE]	15/76 (19,7)	49,8 [25,38; NE]	2,04 [1,15; 3,64] 0,0135

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t201_aesocpt_tte_sub_popa1_2.rtf
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Table 202.1.2: Subgroups: adverse events according PT - Investigations/Alanine aminotransferase increased - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,3812)					
< 65 years	32/147 (21,8)	NE [NE; NE]	4/72 (5,6)	NE [NE; NE]	3,67 [1,30; 10,39] 0,0084
≥ 65 years	9/98 (9,2)	NE [NE; NE]	3/56 (5,4)	NE [31,33; NE]	1,76 [0,47; 6,55] 0,3919
Organs involved (p-value of the interaction term: 0,8949)					
1	20/112 (17,9)	NE [NE; NE]	3/49 (6,1)	NE [NE; NE]	3,09 [0,92; 10,40] 0,0548
2	11/73 (15,1)	NE [NE; NE]	1/36 (2,8)	NE [NE; NE]	4,41 [0,57; 34,48] 0,1220
≥ 3	10/60 (16,7)	NE [36,43; NE]	3/43 (7,0)	NE [31,33; NE]	2,50 [0,69; 9,10] 0,1498
Nature of disease (p-value of the interaction term: 0,5576)					
Visceral	22/130 (16,9)	NE [NE; NE]	6/80 (7,5)	NE [31,33; NE]	2,00 [0,81; 4,96] 0,1259
Bone only	15/71 (21,1)	NE [NE; NE]	1/29 (3,4)	NE [NE; NE]	7,05 [0,93; 53,41] 0,0274
Other	4/44 (9,1)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1532
ECOG-PS at Baseline (p-value of the interaction term: 0,8345)					
0	24/135 (17,8)	NE [NE; NE]	4/74 (5,4)	NE [NE; NE]	3,31 [1,15; 9,54] 0,0188
1	17/110 (15,5)	NE [NE; NE]	3/54 (5,6)	NE [31,33; NE]	2,61 [0,76; 8,92] 0,1122
Race (p-value of the interaction term: 0,9998)					
Caucasian	18/155 (11,6)	NE [NE; NE]	3/80 (3,8)	NE [NE; NE]	2,91 [0,86; 9,88] 0,0728
Asian	20/58 (34,5)	NE [11,08; NE]	4/32 (12,5)	31,3 [20,98; NE]	2,93 [0,99; 8,65] 0,0412

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	2/17 (11,8)	NE [NE; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2627
Region (p-value of the interaction term: 0,7733)					
Europe	10/97 (10,3)	NE [NE; NE]	1/57 (1,8)	NE [NE; NE]	5,65 [0,72; 44,16] 0,0622
North America	12/92 (13,0)	NE [NE; NE]	2/39 (5,1)	NE [NE; NE]	2,35 [0,52; 10,58] 0,2513
Asian	19/56 (33,9)	NE [11,08; NE]	4/32 (12,5)	31,3 [20,98; NE]	2,82 [0,95; 8,36] 0,0512
Measurable disease at baseline (p-value of the interaction term: 0,3918)					
Yes	28/169 (16,6)	NE [NE; NE]	6/94 (6,4)	NE [NE; NE]	2,41 [1,00; 5,84] 0,0435
No	13/76 (17,1)	NE [NE; NE]	1/34 (2,9)	NE [NE; NE]	6,58 [0,86; 50,35] 0,0361
Progesterone receptor (p-value of the interaction term: 0,9800)					
Positive	34/183 (18,6)	NE [NE; NE]	6/93 (6,5)	NE [NE; NE]	2,85 [1,20; 6,81] 0,0133
Negative	6/59 (10,2)	NE [NE; NE]	1/31 (3,2)	NE [NE; NE]	3,07 [0,37; 25,54] 0,2735
Sensitivity against endocrine therapy (p-value of the interaction term: 0,1356)					
Primary resistance	8/57 (14,0)	NE [NE; NE]	2/35 (5,7)	NE [NE; NE]	2,00 [0,42; 9,66] 0,3764
Secondary resistance	29/168 (17,3)	NE [NE; NE]	2/79 (2,5)	NE [NE; NE]	7,19 [1,71; 30,13] 0,0016
Endocrine naive	4/20 (20,0)	NE [NE; NE]	3/14 (21,4)	NE [20,98; NE]	0,89 [0,20; 4,00] 0,8817
Starting dose (p-value of the interaction term: 0,8940)					
150 mg	25/169 (14,8)	NE [NE; NE]	4/87 (4,6)	NE [NE; NE]	2,94 [1,02; 8,46] 0,0361
200 mg	16/76 (21,1)	NE [NE; NE]	3/41 (7,3)	NE [31,33; NE]	3,37 [0,98; 11,58] 0,0406
Previous anti-estrogene therapy (p-value of the interaction term: 0,2840)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	23/109 (21,1)	NE [NE; NE]	2/52 (3,8)	NE [NE; NE]	5,15 [1,21; 21,86] 0,0133
No	18/136 (13,2)	NE [NE; NE]	5/76 (6,6)	NE [31,33; NE]	2,03 [0,75; 5,48] 0,1529

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t202_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 203.1.2: Subgroups: adverse events according PT - Skin and subcutaneous tissue disorders/Alopecia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,3670)					
< 65 years	35/147 (23,8)	NE [NE; NE]	2/72 (2,8)	NE [NE; NE]	8,61 [2,07; 35,78] 0,0004
≥ 65 years	11/98 (11,2)	NE [NE; NE]	2/56 (3,6)	NE [NE; NE]	3,31 [0,73; 14,94] 0,0985
Organs involved (p-value of the interaction term: 0,5977)					
1	20/112 (17,9)	NE [NE; NE]	1/49 (2,0)	NE [NE; NE]	9,39 [1,26; 69,94] 0,0075
2	15/73 (20,5)	NE [NE; NE]	2/36 (5,6)	NE [NE; NE]	3,20 [0,73; 14,03] 0,1037
≥ 3	11/60 (18,3)	NE [NE; NE]	1/43 (2,3)	NE [NE; NE]	8,81 [1,14; 68,37] 0,0119
Nature of disease (p-value of the interaction term: 0,8087)					
Visceral	28/130 (21,5)	NE [NE; NE]	2/80 (2,5)	NE [NE; NE]	8,20 [1,95; 34,44] 0,0006
Bone only	11/71 (15,5)	NE [NE; NE]	1/29 (3,4)	NE [NE; NE]	5,03 [0,65; 38,99] 0,0856
Other	7/44 (15,9)	NE [NE; NE]	1/19 (5,3)	NE [NE; NE]	3,75 [0,46; 30,52] 0,1841
ECOG-PS at Baseline (p-value of the interaction term: 0,5249)					
0	28/135 (20,7)	NE [NE; NE]	2/74 (2,7)	NE [NE; NE]	8,17 [1,95; 34,29] 0,0006
1	18/110 (16,4)	NE [NE; NE]	2/54 (3,7)	NE [NE; NE]	4,23 [0,98; 18,25] 0,0352
Race (p-value of the interaction term: 0,9910)					
Caucasian	36/155 (23,2)	NE [NE; NE]	3/80 (3,8)	NE [NE; NE]	6,24 [1,92; 20,27] 0,0005
Asian	9/58 (15,5)	NE [NE; NE]	1/32 (3,1)	NE [NE; NE]	5,07 [0,64; 40,12] 0,0868

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	0/17 (0,0)	NE [NE; NE]	0/9 (0,0)	NE [NE; NE]	NE
Region (p-value of the interaction term: 0,9908)					
Europe	20/97 (20,6)	NE [NE; NE]	2/57 (3,5)	NE [NE; NE]	6,07 [1,42; 25,97] 0,0055
North America	17/92 (18,5)	NE [NE; NE]	1/39 (2,6)	NE [NE; NE]	6,50 [0,86; 48,89] 0,0362
Asian	9/56 (16,1)	NE [NE; NE]	1/32 (3,1)	NE [NE; NE]	5,22 [0,66; 41,26] 0,0804
Measurable disease at baseline (p-value of the interaction term: 0,9103)					
Yes	35/169 (20,7)	NE [NE; NE]	3/94 (3,2)	NE [NE; NE]	6,37 [1,96; 20,71] 0,0004
No	11/76 (14,5)	NE [NE; NE]	1/34 (2,9)	NE [NE; NE]	5,47 [0,71; 42,43] 0,0673
Progesterone receptor (p-value of the interaction term: 0,9730)					
Positive	33/183 (18,0)	NE [NE; NE]	3/93 (3,2)	NE [NE; NE]	5,78 [1,77; 18,85] 0,0010
Negative	11/59 (18,6)	NE [21,24; NE]	1/31 (3,2)	NE [NE; NE]	5,87 [0,76; 45,46] 0,0546
Sensitivity against endocrine therapy (p-value of the interaction term: 0,8776)					
Primary resistance	14/57 (24,6)	NE [12,03; NE]	1/35 (2,9)	NE [NE; NE]	8,18 [1,08; 62,25] 0,0153
Secondary resistance	26/168 (15,5)	NE [NE; NE]	2/79 (2,5)	NE [NE; NE]	6,42 [1,52; 27,03] 0,0036
Endocrine naive	6/20 (30,0)	NE [6,54; NE]	1/14 (7,1)	NE [5,59; NE]	3,84 [0,46; 31,90] 0,1805
Starting dose (p-value of the interaction term: 0,6849)					
150 mg	30/169 (17,8)	NE [NE; NE]	2/87 (2,3)	NE [NE; NE]	7,52 [1,80; 31,48] 0,0011
200 mg	16/76 (21,1)	NE [NE; NE]	2/41 (4,9)	NE [NE; NE]	4,83 [1,11; 21,01] 0,0202
Previous anti-estrogene therapy (p-value of the interaction term: 0,3509)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	25/109 (22,9)	NE [NE; NE]	1/52 (1,9)	NE [NE; NE]	12,30 [1,67; 90,78] 0,0016
No	21/136 (15,4)	NE [NE; NE]	3/76 (3,9)	NE [NE; NE]	3,98 [1,19; 13,34] 0,0155

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t203_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 204.1.2: Subgroups: adverse events according PT - Blood and lymphatic system disorders/Anaemia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,7183)					
< 65 years	44/147 (29,9)	42,8 [39,09; NE]	4/72 (5,6)	NE [NE; NE]	5,39 [1,94; 15,03] 0,0003
≥ 65 years	33/98 (33,7)	41,9 [18,54; NE]	3/56 (5,4)	51,6 [NE; NE]	7,27 [2,22; 23,77] 0,0001
Organs involved (p-value of the interaction term: 0,7946)					
1	43/112 (38,4)	40,8 [23,01; NE]	3/49 (6,1)	NE [26,37; NE]	6,67 [2,06; 21,55] 0,0002
2	18/73 (24,7)	NE [36,82; NE]	0/36 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0058
≥ 3	16/60 (26,7)	42,2 [17,92; NE]	4/43 (9,3)	51,6 [51,55; NE]	5,19 [1,50; 17,94] 0,0038
Nature of disease (p-value of the interaction term: 0,6924)					
Visceral	36/130 (27,7)	NE [26,07; NE]	3/80 (3,8)	51,6 [NE; NE]	7,51 [2,31; 24,42] <,0001
Bone only	29/71 (40,8)	39,8 [18,54; NE]	2/29 (6,9)	NE [NE; NE]	6,44 [1,53; 27,06] 0,0035
Other	12/44 (27,3)	42,2 [12,46; NE]	2/19 (10,5)	NE [26,37; NE]	3,63 [0,81; 16,25] 0,0719
ECOG-PS at Baseline (p-value of the interaction term: 0,9660)					
0	43/135 (31,9)	44,7 [39,09; NE]	4/74 (5,4)	NE [NE; NE]	6,19 [2,22; 17,27] <,0001
1	34/110 (30,9)	41,9 [22,49; NE]	3/54 (5,6)	51,6 [NE; NE]	5,89 [1,81; 19,22] 0,0008
Race (p-value of the interaction term: 0,4280)					
Caucasian	43/155 (27,7)	44,7 [27,19; NE]	2/80 (2,5)	NE [NE; NE]	11,45 [2,77; 47,29] <,0001
Asian	24/58 (41,4)	39,1 [10,36; NE]	4/32 (12,5)	51,6 [26,37; NE]	3,79 [1,31; 10,99] 0,0086

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	8/17 (47,1)	39,8 [6,02; NE]	1/9 (11,1)	NE [2,79; NE]	3,87 [0,48; 31,25] 0,1714
Region (p-value of the interaction term: 0,4550)					
Europe	21/97 (21,6)	NE [36,82; NE]	2/57 (3,5)	NE [NE; NE]	6,21 [1,46; 26,50] 0,0047
North America	33/92 (35,9)	39,1 [18,54; 44,68]	1/39 (2,6)	NE [NE; NE]	13,92 [1,90; 101,92] 0,0007
Asian	23/56 (41,1)	39,1 [10,36; NE]	4/32 (12,5)	51,6 [26,37; NE]	3,75 [1,29; 10,94] 0,0094
Measurable disease at baseline (p-value of the interaction term: 0,6540)					
Yes	48/169 (28,4)	NE [36,82; NE]	4/94 (4,3)	51,6 [51,55; NE]	6,98 [2,51; 19,37] <,0001
No	29/76 (38,2)	39,8 [18,54; NE]	3/34 (8,8)	NE [NE; NE]	4,67 [1,42; 15,40] 0,0053
Progesterone receptor (p-value of the interaction term: 0,5772)					
Positive	58/183 (31,7)	42,2 [27,19; NE]	6/93 (6,5)	51,6 [51,55; NE]	5,29 [2,28; 12,26] <,0001
Negative	17/59 (28,8)	NE [16,60; NE]	1/31 (3,2)	NE [NE; NE]	9,71 [1,29; 72,98] 0,0066
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9201)					
Primary resistance	19/57 (33,3)	39,1 [19,36; NE]	2/35 (5,7)	NE [NE; NE]	4,90 [1,12; 21,37] 0,0193
Secondary resistance	52/168 (31,0)	42,8 [26,07; NE]	4/79 (5,1)	NE [NE; NE]	6,86 [2,48; 18,98] <,0001
Endocrine naive	6/20 (30,0)	NE [14,76; NE]	1/14 (7,1)	NE [51,55; NE]	5,30 [0,59; 47,36] 0,1029
Starting dose (p-value of the interaction term: 0,6420)					
150 mg	45/169 (26,6)	44,7 [39,85; NE]	4/87 (4,6)	NE [NE; NE]	5,33 [1,91; 14,86] 0,0003
200 mg	32/76 (42,1)	17,9 [9,40; NE]	3/41 (7,3)	NE [51,55; NE]	7,69 [2,35; 25,16] <,0001
Previous anti-estrogene therapy (p-value of the interaction term: 0,2396)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	33/109 (30,3)	NE [26,07; NE]	4/52 (7,7)	NE [NE; NE]	3,89 [1,38; 11,02] 0,0058
No	44/136 (32,4)	39,8 [27,19; NE]	3/76 (3,9)	NE [51,55; NE]	9,79 [3,02; 31,75] <,0001

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t204_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 205.1.2: Subgroups: adverse events according PT - Investigations/Aspartate aminotransferase increased - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,7499)					
< 65 years	32/147 (21,8)	NE [NE; NE]	6/72 (8,3)	NE [NE; NE]	2,40 [1,00; 5,74] 0,0425
≥ 65 years	10/98 (10,2)	NE [NE; NE]	3/56 (5,4)	NE [31,33; NE]	1,78 [0,49; 6,54] 0,3765
Organs involved (p-value of the interaction term: 0,6951)					
1	21/112 (18,8)	NE [NE; NE]	5/49 (10,2)	NE [NE; NE]	1,84 [0,69; 4,90] 0,2131
2	12/73 (16,4)	NE [44,38; NE]	1/36 (2,8)	NE [NE; NE]	4,28 [0,55; 33,30] 0,1303
≥ 3	9/60 (15,0)	NE [36,43; NE]	3/43 (7,0)	NE [31,33; NE]	2,26 [0,61; 8,37] 0,2075
Nature of disease (p-value of the interaction term: 0,9504)					
Visceral	21/130 (16,2)	NE [NE; NE]	6/80 (7,5)	NE [31,33; NE]	1,83 [0,73; 4,56] 0,1898
Bone only	17/71 (23,9)	NE [NE; NE]	3/29 (10,3)	NE [NE; NE]	2,51 [0,73; 8,59] 0,1290
Other	4/44 (9,1)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1532
ECOG-PS at Baseline (p-value of the interaction term: 0,7044)					
0	25/135 (18,5)	NE [NE; NE]	5/74 (6,8)	NE [NE; NE]	2,63 [1,00; 6,87] 0,0409
1	17/110 (15,5)	NE [NE; NE]	4/54 (7,4)	NE [31,33; NE]	1,85 [0,62; 5,53] 0,2650
Race (p-value of the interaction term: 0,3321)					
Caucasian	19/155 (12,3)	NE [NE; NE]	3/80 (3,8)	NE [NE; NE]	2,96 [0,88; 10,02] 0,0669
Asian	19/58 (32,8)	NE [11,08; NE]	4/32 (12,5)	31,3 [20,98; NE]	2,72 [0,92; 8,07] 0,0602

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	3/17 (17,6)	NE [30,18; NE]	2/9 (22,2)	NE [0,56; NE]	0,64 [0,10; 4,02] 0,6193
Region (p-value of the interaction term: 0,5312)					
Europe	9/97 (9,3)	NE [NE; NE]	1/57 (1,8)	NE [NE; NE]	4,79 [0,61; 37,79] 0,1008
North America	15/92 (16,3)	NE [NE; NE]	4/39 (10,3)	NE [NE; NE]	1,43 [0,47; 4,33] 0,5279
Asian	18/56 (32,1)	NE [12,16; NE]	4/32 (12,5)	31,3 [20,98; NE]	2,60 [0,87; 7,76] 0,0751
Measurable disease at baseline (p-value of the interaction term: 0,8788)					
Yes	26/169 (15,4)	NE [NE; NE]	6/94 (6,4)	NE [NE; NE]	2,21 [0,91; 5,38] 0,0732
No	16/76 (21,1)	NE [35,15; NE]	3/34 (8,8)	NE [NE; NE]	2,45 [0,71; 8,45] 0,1418
Progesterone receptor (p-value of the interaction term: 0,5700)					
Positive	33/183 (18,0)	NE [NE; NE]	8/93 (8,6)	NE [NE; NE]	2,00 [0,92; 4,35] 0,0729
Negative	8/59 (13,6)	NE [NE; NE]	1/31 (3,2)	NE [NE; NE]	3,60 [0,45; 29,02] 0,1977
Sensitivity against endocrine therapy (p-value of the interaction term: 0,3218)					
Primary resistance	9/57 (15,8)	NE [36,43; NE]	1/35 (2,9)	NE [NE; NE]	4,53 [0,56; 36,28] 0,1187
Secondary resistance	29/168 (17,3)	NE [NE; NE]	5/79 (6,3)	NE [NE; NE]	2,71 [1,05; 7,01] 0,0323
Endocrine naive	4/20 (20,0)	NE [NE; NE]	3/14 (21,4)	NE [20,98; NE]	0,87 [0,19; 3,89] 0,8538
Starting dose (p-value of the interaction term: 0,6026)					
150 mg	27/169 (16,0)	NE [NE; NE]	6/87 (6,9)	NE [NE; NE]	2,01 [0,83; 4,89] 0,1163
200 mg	15/76 (19,7)	NE [30,18; NE]	3/41 (7,3)	NE [31,33; NE]	3,04 [0,88; 10,51] 0,0652
Previous anti-estrogene therapy (p-value of the interaction term: 0,8895)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	22/109 (20,2)	NE [NE; NE]	4/52 (7,7)	NE [NE; NE]	2,39 [0,82; 6,96] 0,0992
No	20/136 (14,7)	NE [NE; NE]	5/76 (6,6)	NE [31,33; NE]	2,18 [0,82; 5,82] 0,1108

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 206.1.2: Subgroups: adverse events according PT - Investigations/Blood alkaline phosphatase increased - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,9893)					
< 65 years	12/147 (8,2)	NE [51,81; NE]	0/72 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0210
≥ 65 years	5/98 (5,1)	NE [NE; NE]	1/56 (1,8)	NE [NE; NE]	3,00 [0,35; 25,71] 0,2918
Nature of disease (p-value of the interaction term: 1,0000)					
Visceral	9/130 (6,9)	NE [NE; NE]	1/80 (1,3)	NE [NE; NE]	4,57 [0,57; 36,29] 0,1152
Bone only	8/71 (11,3)	NE [51,81; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0624
Other	0/44 (0,0)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	NE
ECOG-PS at Baseline (p-value of the interaction term: 0,9918)					
0	11/135 (8,1)	NE [51,81; NE]	1/74 (1,4)	NE [NE; NE]	5,42 [0,70; 42,11] 0,0699
1	6/110 (5,5)	NE [NE; NE]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0943
Race (p-value of the interaction term: 1,0000)					
Caucasian	10/155 (6,5)	NE [NE; NE]	1/80 (1,3)	NE [NE; NE]	4,94 [0,63; 38,62] 0,0912
Asian	4/58 (6,9)	NE [51,81; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1929
Other	2/17 (11,8)	NE [45,90; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4452
Region (p-value of the interaction term: 0,9999)					
Europe	3/97 (3,1)	NE [NE; NE]	0/57 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1981
North America	10/92 (10,9)	NE [NE; NE]	1/39 (2,6)	NE [NE; NE]	3,72 [0,47; 29,28] 0,1814

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	4/56 (7,1)	NE [51,81; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1865
Progesterone receptor (p-value of the interaction term: 0,9937)					
Positive	14/183 (7,7)	NE [51,81; NE]	1/93 (1,1)	NE [NE; NE]	6,60 [0,87; 50,36] 0,0356
Negative	3/59 (5,1)	NE [NE; NE]	0/31 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2490
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9999)					
Primary resistance	5/57 (8,8)	NE [51,81; NE]	1/35 (2,9)	NE [NE; NE]	2,13 [0,24; 19,16] 0,4886
Secondary resistance	10/168 (6,0)	NE [NE; NE]	0/79 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0336
Endocrine naive	2/20 (10,0)	NE [NE; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2544
Previous anti-estrogene therapy (p-value of the interaction term: 0,9915)					
Yes	8/109 (7,3)	NE [NE; NE]	0/52 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0655
No	9/136 (6,6)	NE [51,81; NE]	1/76 (1,3)	NE [NE; NE]	5,32 [0,67; 42,21] 0,0767

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

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Table 207.1.2: Subgroups: adverse events according PT - Investigations/Blood creatinine increased - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,9862)					
< 65 years	17/147 (11,6)	NE [NE; NE]	0/72 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0093
≥ 65 years	16/98 (16,3)	NE [45,80; NE]	2/56 (3,6)	NE [NE; NE]	4,79 [1,10; 20,91] 0,0213
Organs involved (p-value of the interaction term: 0,9987)					
1	14/112 (12,5)	NE [47,44; NE]	0/49 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0281
2	12/73 (16,4)	NE [41,69; NE]	1/36 (2,8)	NE [NE; NE]	5,05 [0,65; 39,21] 0,0852
≥ 3	7/60 (11,7)	NE [NE; NE]	1/43 (2,3)	NE [NE; NE]	5,21 [0,64; 42,40] 0,0845
Nature of disease (p-value of the interaction term: 0,9999)					
Visceral	17/130 (13,1)	NE [NE; NE]	2/80 (2,5)	NE [NE; NE]	4,81 [1,11; 20,90] 0,0206
Bone only	10/71 (14,1)	NE [45,80; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0843
Other	6/44 (13,6)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0926
ECOG-PS at Baseline (p-value of the interaction term: 0,9322)					
0	17/135 (12,6)	NE [NE; NE]	1/74 (1,4)	NE [NE; NE]	9,08 [1,21; 68,28] 0,0093
1	16/110 (14,5)	NE [41,69; NE]	1/54 (1,9)	NE [NE; NE]	6,56 [0,87; 49,71] 0,0360
Race (p-value of the interaction term: 0,9999)					
Caucasian	19/155 (12,3)	NE [NE; NE]	2/80 (2,5)	NE [NE; NE]	4,49 [1,04; 19,30] 0,0271
Asian	10/58 (17,2)	NE [47,44; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0374

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	4/17 (23,5)	NE [1,97; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1186
Region (p-value of the interaction term: 0,9998)					
Europe	9/97 (9,3)	NE [NE; NE]	2/57 (3,5)	NE [NE; NE]	2,55 [0,55; 11,79] 0,2161
North America	14/92 (15,2)	NE [45,80; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0226
Asian	10/56 (17,9)	NE [47,44; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0345
Measurable disease at baseline (p-value of the interaction term: 0,9901)					
Yes	22/169 (13,0)	NE [NE; NE]	2/94 (2,1)	NE [NE; NE]	5,74 [1,35; 24,45] 0,0075
No	11/76 (14,5)	NE [45,80; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0542
Progesterone receptor (p-value of the interaction term: 0,4076)					
Positive	26/183 (14,2)	NE [NE; NE]	1/93 (1,1)	NE [NE; NE]	12,34 [1,67; 91,11] 0,0016
Negative	7/59 (11,9)	NE [36,00; NE]	1/31 (3,2)	NE [NE; NE]	3,17 [0,39; 25,93] 0,2560
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9973)					
Primary resistance	5/57 (8,8)	NE [47,44; NE]	1/35 (2,9)	NE [NE; NE]	2,08 [0,23; 19,11] 0,5093
Secondary resistance	24/168 (14,3)	NE [NE; NE]	0/79 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0009
Endocrine naive	4/20 (20,0)	NE [38,04; NE]	1/14 (7,1)	NE [NE; NE]	2,57 [0,29; 23,09] 0,3819
Starting dose (p-value of the interaction term: 0,7115)					
150 mg	22/169 (13,0)	NE [NE; NE]	1/87 (1,1)	NE [NE; NE]	9,93 [1,33; 73,87] 0,0057
200 mg	11/76 (14,5)	NE [47,44; NE]	1/41 (2,4)	NE [NE; NE]	5,93 [0,76; 46,09] 0,0531
Previous anti-estrogene therapy (p-value of the interaction term: 0,9898)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	8/109 (7,3)	NE [NE; NE]	0/52 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0833
No	25/136 (18,4)	NE [45,80; NE]	2/76 (2,6)	NE [NE; NE]	6,92 [1,64; 29,24] 0,0022

Data cut-off: 20.06.2019, Safety-Population
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Table 208.1.2: Subgroups: adverse events according PT - General disorders and administration site conditions/Chills - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,9914)					
< 65 years	15/147 (10,2)	NE [NE; NE]	1/72 (1,4)	NE [NE; NE]	6,82 [0,90; 51,64] 0,0311
≥ 65 years	4/98 (4,1)	NE [NE; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1204
Organs involved (p-value of the interaction term: 0,9999)					
1	11/112 (9,8)	NE [NE; NE]	0/49 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0247
2	4/73 (5,5)	NE [NE; NE]	1/36 (2,8)	NE [12,95; NE]	1,12 [0,12; 10,22] 0,9195
≥ 3	4/60 (6,7)	NE [NE; NE]	0/43 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0875
ECOG-PS at Baseline (p-value of the interaction term: 0,9910)					
0	11/135 (8,1)	NE [NE; NE]	1/74 (1,4)	NE [NE; NE]	5,77 [0,74; 44,68] 0,0575
1	8/110 (7,3)	NE [NE; NE]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0472
Race (p-value of the interaction term: 1,0000)					
Caucasian	15/155 (9,7)	NE [NE; NE]	1/80 (1,3)	NE [NE; NE]	7,53 [0,99; 56,98] 0,0213
Asian	3/58 (5,2)	NE [NE; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2192
Other	1/17 (5,9)	NE [NE; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,6171
Measurable disease at baseline (p-value of the interaction term: 0,9920)					
Yes	11/169 (6,5)	NE [NE; NE]	1/94 (1,1)	NE [NE; NE]	5,60 [0,72; 43,45] 0,0632
No	8/76 (10,5)	NE [NE; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0471

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Progesterone receptor (p-value of the interaction term: 0,9896)					
Positive	13/183 (7,1)	NE [NE; NE]	1/93 (1,1)	NE [NE; NE]	6,45 [0,84; 49,28] 0,0388
Negative	6/59 (10,2)	NE [NE; NE]	0/31 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0727
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9999)					
Primary resistance	6/57 (10,5)	NE [NE; NE]	0/35 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0896
Secondary resistance	11/168 (6,5)	NE [NE; NE]	0/79 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0213
Endocrine naive	2/20 (10,0)	NE [23,97; NE]	1/14 (7,1)	NE [12,95; NE]	1,26 [0,11; 14,00] 0,8477
Starting dose (p-value of the interaction term: 0,9917)					
150 mg	13/169 (7,7)	NE [NE; NE]	1/87 (1,1)	NE [NE; NE]	6,24 [0,82; 47,70] 0,0435
200 mg	6/76 (7,9)	NE [NE; NE]	0/41 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0719
Previous anti-estrogene therapy (p-value of the interaction term: 0,9912)					
Yes	7/109 (6,4)	NE [NE; NE]	0/52 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0862
No	12/136 (8,8)	NE [NE; NE]	1/76 (1,3)	NE [NE; NE]	6,75 [0,88; 51,95] 0,0335

Data cut-off: 20.06.2019, Safety-Population
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Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 209.1.2: Subgroups: adverse events according PT - Metabolism and nutrition disorders/Decreased appetite - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,6297)					
< 65 years	39/147 (26,5)	NE [44,45; NE]	8/72 (11,1)	NE [NE; NE]	2,30 [1,07; 4,93] 0,0275
≥ 65 years	39/98 (39,8)	NE [9,34; NE]	9/56 (16,1)	NE [38,30; NE]	3,01 [1,45; 6,22] 0,0018
Organs involved (p-value of the interaction term: 0,4620)					
1	41/112 (36,6)	NE [31,20; NE]	5/49 (10,2)	NE [NE; NE]	3,77 [1,49; 9,56] 0,0027
2	23/73 (31,5)	NE [23,64; NE]	5/36 (13,9)	NE [NE; NE]	2,21 [0,84; 5,84] 0,1011
≥ 3	14/60 (23,3)	NE [NE; NE]	7/43 (16,3)	NE [38,30; NE]	1,62 [0,65; 4,01] 0,2948
Nature of disease (p-value of the interaction term: 0,2289)					
Visceral	41/130 (31,5)	NE [31,63; NE]	14/80 (17,5)	NE [38,30; NE]	1,88 [1,02; 3,46] 0,0389
Bone only	18/71 (25,4)	NE [NE; NE]	2/29 (6,9)	NE [NE; NE]	4,05 [0,94; 17,44] 0,0421
Other	19/44 (43,2)	36,1 [3,72; NE]	1/19 (5,3)	NE [15,85; NE]	10,40 [1,39; 77,73] 0,0046
ECOG-PS at Baseline (p-value of the interaction term: 0,3641)					
0	48/135 (35,6)	NE [23,64; NE]	9/74 (12,2)	NE [38,30; NE]	3,13 [1,53; 6,39] 0,0010
1	30/110 (27,3)	NE [36,13; NE]	8/54 (14,8)	NE [NE; NE]	1,93 [0,88; 4,22] 0,0921
Race (p-value of the interaction term: 0,2757)					
Caucasian	54/155 (34,8)	NE [31,20; NE]	9/80 (11,3)	NE [38,30; NE]	3,36 [1,66; 6,81] 0,0004
Asian	19/58 (32,8)	NE [36,13; NE]	5/32 (15,6)	NE [NE; NE]	2,20 [0,82; 5,95] 0,1109

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	3/17 (17,6)	NE [12,43; NE]	2/9 (22,2)	NE [1,78; NE]	0,54 [0,09; 3,41] 0,5069
Region (p-value of the interaction term: 0,9477)					
Europe	27/97 (27,8)	NE [NE; NE]	6/57 (10,5)	NE [38,30; NE]	2,81 [1,16; 6,80] 0,0170
North America	32/92 (34,8)	NE [16,41; NE]	6/39 (15,4)	NE [NE; NE]	2,35 [0,98; 5,64] 0,0475
Asian	19/56 (33,9)	NE [22,06; NE]	5/32 (15,6)	NE [NE; NE]	2,29 [0,85; 6,18] 0,0935
Measurable disease at baseline (p-value of the interaction term: 0,6712)					
Yes	57/169 (33,7)	NE [34,92; NE]	14/94 (14,9)	NE [38,30; NE]	2,42 [1,35; 4,34] 0,0023
No	21/76 (27,6)	NE [NE; NE]	3/34 (8,8)	NE [NE; NE]	3,55 [1,06; 11,91] 0,0284
Progesterone receptor (p-value of the interaction term: 0,8705)					
Positive	56/183 (30,6)	NE [36,13; NE]	12/93 (12,9)	NE [38,30; NE]	2,47 [1,32; 4,62] 0,0033
Negative	20/59 (33,9)	NE [6,58; NE]	5/31 (16,1)	NE [NE; NE]	2,37 [0,89; 6,32] 0,0745
Sensitivity against endocrine therapy (p-value of the interaction term: 0,8662)					
Primary resistance	18/57 (31,6)	NE [18,02; NE]	6/35 (17,1)	NE [NE; NE]	1,78 [0,70; 4,53] 0,2199
Secondary resistance	51/168 (30,4)	NE [36,13; NE]	11/79 (13,9)	NE [38,30; NE]	2,36 [1,23; 4,53] 0,0079
Endocrine naive	9/20 (45,0)	31,2 [0,89; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0080
Previous anti-estrogene therapy (p-value of the interaction term: 0,9546)					
Yes	32/109 (29,4)	NE [36,13; NE]	6/52 (11,5)	NE [38,30; NE]	2,52 [1,05; 6,04] 0,0322
No	46/136 (33,8)	NE [23,64; NE]	11/76 (14,5)	NE [NE; NE]	2,61 [1,35; 5,04] 0,0031

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 20.06.2019, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.					

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t209_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 210.1.2: Subgroups: adverse events according PT - Metabolism and nutrition disorders/Dehydration - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,4303)					
< 65 years	5/147 (3,4)	NE [NE; NE]	1/72 (1,4)	NE [42,51; NE]	1,82 [0,21; 15,88] 0,5814
≥ 65 years	13/98 (13,3)	NE [NE; NE]	1/56 (1,8)	NE [NE; NE]	7,65 [1,00; 58,48] 0,0206
Organs involved (p-value of the interaction term: 0,9871)					
1	9/112 (8,0)	NE [NE; NE]	1/49 (2,0)	NE [NE; NE]	3,64 [0,46; 28,89] 0,1914
2	3/73 (4,1)	NE [NE; NE]	0/36 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2696
≥ 3	6/60 (10,0)	NE [NE; NE]	1/43 (2,3)	NE [42,51; NE]	4,36 [0,52; 36,22] 0,1368
ECOG-PS at Baseline (p-value of the interaction term: 0,9903)					
0	10/135 (7,4)	NE [NE; NE]	2/74 (2,7)	NE [42,51; NE]	2,17 [0,47; 10,02] 0,3081
1	8/110 (7,3)	NE [NE; NE]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0456
Race (p-value of the interaction term: 1,0000)					
Caucasian	15/155 (9,7)	NE [NE; NE]	2/80 (2,5)	NE [42,51; NE]	3,57 [0,81; 15,66] 0,0716
Asian	0/58 (0,0)	NE [NE; NE]	0/32 (0,0)	NE [NE; NE]	NE
Other	3/17 (17,6)	NE [17,85; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3253
Region (p-value of the interaction term: 0,7201)					
Europe	3/97 (3,1)	NE [NE; NE]	1/57 (1,8)	NE [42,51; NE]	1,42 [0,15; 13,86] 0,7600
North America	15/92 (16,3)	NE [NE; NE]	1/39 (2,6)	NE [NE; NE]	6,03 [0,80; 45,73] 0,0477

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	0/56 (0,0)	NE [NE; NE]	0/32 (0,0)	NE [NE; NE]	NE
Measurable disease at baseline (p-value of the interaction term: 0,9211)					
Yes	9/169 (5,3)	NE [NE; NE]	1/94 (1,1)	NE [42,51; NE]	4,22 [0,53; 33,54] 0,1384
No	9/76 (11,8)	NE [NE; NE]	1/34 (2,9)	NE [NE; NE]	3,93 [0,49; 31,15] 0,1627
Progesterone receptor (p-value of the interaction term: 0,9888)					
Positive	12/183 (6,6)	NE [NE; NE]	2/93 (2,2)	NE [42,51; NE]	2,66 [0,59; 11,99] 0,1844
Negative	6/59 (10,2)	NE [NE; NE]	0/31 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0843
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9772)					
Primary resistance	6/57 (10,5)	NE [NE; NE]	1/35 (2,9)	NE [NE; NE]	2,62 [0,30; 22,76] 0,3660
Secondary resistance	9/168 (5,4)	NE [NE; NE]	1/79 (1,3)	NE [42,51; NE]	3,73 [0,47; 29,68] 0,1825
Endocrine naive	3/20 (15,0)	NE [NE; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1368
Starting dose (p-value of the interaction term: 0,9910)					
150 mg	11/169 (6,5)	NE [NE; NE]	2/87 (2,3)	NE [42,51; NE]	2,23 [0,49; 10,22] 0,2882
200 mg	7/76 (9,2)	NE [NE; NE]	0/41 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0480
Previous anti-estrogene therapy (p-value of the interaction term: 0,6282)					
Yes	7/109 (6,4)	NE [NE; NE]	1/52 (1,9)	NE [42,51; NE]	2,26 [0,27; 18,85] 0,4378
No	11/136 (8,1)	NE [NE; NE]	1/76 (1,3)	NE [NE; NE]	6,28 [0,81; 48,62] 0,0438

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t210_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 211.1.2: Subgroups: adverse events according PT - Gastrointestinal disorders/Diarrhoea - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,8696)					
< 65 years	124/147 (84,4)	0,3 [0,23; 0,49]	18/72 (25,0)	NE [14,93; NE]	7,66 [4,63; 12,68] <,0001
≥ 65 years	86/98 (87,8)	0,2 [0,16; 0,36]	17/56 (30,4)	NE [NE; NE]	7,20 [4,23; 12,27] <,0001
Organs involved (p-value of the interaction term: 0,4752)					
1	96/112 (85,7)	0,3 [0,20; 0,46]	13/49 (26,5)	NE [24,92; NE]	7,31 [4,05; 13,18] <,0001
2	66/73 (90,4)	0,3 [0,20; 0,46]	8/36 (22,2)	NE [11,31; NE]	10,17 [4,82; 21,46] <,0001
≥ 3	48/60 (80,0)	0,3 [0,16; 0,59]	14/43 (32,6)	NE [5,46; NE]	5,28 [2,87; 9,70] <,0001
Nature of disease (p-value of the interaction term: 0,9101)					
Visceral	110/130 (84,6)	0,3 [0,23; 0,49]	21/80 (26,3)	NE [NE; NE]	7,18 [4,47; 11,56] <,0001
Bone only	60/71 (84,5)	0,3 [0,16; 0,53]	7/29 (24,1)	NE [14,93; NE]	7,56 [3,41; 16,74] <,0001
Other	40/44 (90,9)	0,2 [0,13; 0,30]	7/19 (36,8)	24,9 [3,81; NE]	7,69 [3,34; 17,73] <,0001
Race (p-value of the interaction term: 0,0585)					
Caucasian	130/155 (83,9)	0,4 [0,23; 0,49]	27/80 (33,8)	24,9 [11,77; NE]	5,57 [3,65; 8,51] <,0001
Asian	53/58 (91,4)	0,2 [0,16; 0,36]	5/32 (15,6)	NE [NE; NE]	16,07 [6,30; 41,03] <,0001
Other	15/17 (88,2)	0,2 [0,13; 0,72]	2/9 (22,2)	NE [2,04; NE]	9,38 [2,09; 42,08] 0,0005
Region (p-value of the interaction term: 0,0540)					
Europe	79/97 (81,4)	0,3 [0,16; 0,49]	15/57 (26,3)	NE [14,93; NE]	6,42 [3,67; 11,24] <,0001

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
North America	80/92 (87,0)	0,3 [0,23; 0,49]	15/39 (38,5)	24,9 [5,36; NE]	5,16 [2,94; 9,06] <,0001
Asian	51/56 (91,1)	0,2 [0,16; 0,30]	5/32 (15,6)	NE [NE; NE]	16,78 [6,53; 43,14] <,0001
Measurable disease at baseline (p-value of the interaction term: 0,8334)					
Yes	147/169 (87,0)	0,3 [0,20; 0,36]	26/94 (27,7)	NE [24,92; NE]	7,88 [5,13; 12,09] <,0001
No	63/76 (82,9)	0,3 [0,16; 0,56]	9/34 (26,5)	NE [14,93; NE]	6,63 [3,26; 13,48] <,0001
Progesterone receptor (p-value of the interaction term: 0,2547)					
Positive	156/183 (85,2)	0,3 [0,23; 0,43]	29/93 (31,2)	NE [24,92; NE]	6,57 [4,38; 9,85] <,0001
Negative	51/59 (86,4)	0,3 [0,20; 0,49]	5/31 (16,1)	NE [14,93; NE]	11,43 [4,50; 29,01] <,0001
Sensitivity against endocrine therapy (p-value of the interaction term: 0,8665)					
Primary resistance	50/57 (87,7)	0,3 [0,16; 0,49]	11/35 (31,4)	NE [4,73; NE]	7,14 [3,65; 13,97] <,0001
Secondary resistance	142/168 (84,5)	0,3 [0,23; 0,46]	20/79 (25,3)	NE [24,92; NE]	7,39 [4,59; 11,89] <,0001
Endocrine naive	18/20 (90,0)	0,2 [0,13; 0,49]	4/14 (28,6)	NE [5,36; NE]	9,81 [3,14; 30,60] <,0001
Starting dose (p-value of the interaction term: 0,2061)					
150 mg	141/169 (83,4)	0,4 [0,26; 0,49]	23/87 (26,4)	NE [24,92; NE]	6,57 [4,20; 10,27] <,0001
200 mg	69/76 (90,8)	0,2 [0,13; 0,23]	12/41 (29,3)	NE [8,02; NE]	11,43 [5,89; 22,18] <,0001
Previous anti-estrogene therapy (p-value of the interaction term: 0,8872)					
Yes	93/109 (85,3)	0,3 [0,23; 0,49]	14/52 (26,9)	NE [14,93; NE]	7,82 [4,40; 13,90] <,0001
No	117/136 (86,0)	0,2 [0,20; 0,43]	21/76 (27,6)	NE [24,92; NE]	7,03 [4,38; 11,28] <,0001

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 20.06.2019, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.					

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t211_aesocpt_tte_sub_popa1_2.rtf
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/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 212.1.2: Subgroups: adverse events according PT - Nervous system disorders/Dysgeusia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,7793)					
< 65 years	23/147 (15,6)	NE [NE; NE]	2/72 (2,8)	NE [NE; NE]	5,70 [1,34; 24,19] 0,0076
≥ 65 years	23/98 (23,5)	NE [NE; NE]	2/56 (3,6)	NE [NE; NE]	7,56 [1,78; 32,08] 0,0012
Organs involved (p-value of the interaction term: 0,7897)					
1	19/112 (17,0)	NE [NE; NE]	3/49 (6,1)	NE [NE; NE]	2,94 [0,87; 9,95] 0,0683
2	13/73 (17,8)	NE [NE; NE]	1/36 (2,8)	NE [NE; NE]	6,39 [0,83; 48,97] 0,0402
≥ 3	14/60 (23,3)	NE [NE; NE]	0/43 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0008
Nature of disease (p-value of the interaction term: 0,1470)					
Visceral	25/130 (19,2)	NE [NE; NE]	1/80 (1,3)	NE [NE; NE]	16,58 [2,25; 122,38] 0,0002
Bone only	11/71 (15,5)	NE [NE; NE]	3/29 (10,3)	NE [NE; NE]	1,57 [0,44; 5,63] 0,4842
Other	10/44 (22,7)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0265
ECOG-PS at Baseline (p-value of the interaction term: 0,7275)					
0	26/135 (19,3)	NE [NE; NE]	2/74 (2,7)	NE [NE; NE]	7,75 [1,84; 32,64] 0,0010
1	20/110 (18,2)	NE [NE; NE]	2/54 (3,7)	NE [NE; NE]	5,28 [1,23; 22,59] 0,0120
Race (p-value of the interaction term: 0,9892)					
Caucasian	34/155 (21,9)	NE [NE; NE]	3/80 (3,8)	NE [NE; NE]	6,34 [1,95; 20,65] 0,0004
Asian	9/58 (15,5)	NE [NE; NE]	1/32 (3,1)	NE [NE; NE]	5,31 [0,67; 41,91] 0,0761

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	2/17 (11,8)	NE [NE; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3724
Region (p-value of the interaction term: 0,5858)					
Europe	11/97 (11,3)	NE [NE; NE]	2/57 (3,5)	NE [NE; NE]	3,32 [0,74; 14,98] 0,0978
North America	26/92 (28,3)	NE [NE; NE]	1/39 (2,6)	NE [NE; NE]	12,38 [1,68; 91,33] 0,0015
Asian	9/56 (16,1)	NE [NE; NE]	1/32 (3,1)	NE [NE; NE]	5,51 [0,70; 43,47] 0,0685
Progesterone receptor (p-value of the interaction term: 0,1985)					
Positive	36/183 (19,7)	NE [NE; NE]	2/93 (2,2)	NE [NE; NE]	9,85 [2,37; 40,91] 0,0001
Negative	9/59 (15,3)	NE [NE; NE]	2/31 (6,5)	NE [NE; NE]	2,60 [0,56; 12,03] 0,2046
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9777)					
Primary resistance	12/57 (21,1)	NE [NE; NE]	0/35 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0057
Secondary resistance	29/168 (17,3)	NE [NE; NE]	3/79 (3,8)	NE [NE; NE]	4,93 [1,50; 16,18] 0,0035
Endocrine naive	5/20 (25,0)	NE [21,67; NE]	1/14 (7,1)	NE [NE; NE]	3,47 [0,40; 29,87] 0,2271
Starting dose (p-value of the interaction term: 0,9858)					
150 mg	35/169 (20,7)	NE [NE; NE]	3/87 (3,4)	NE [NE; NE]	6,37 [1,96; 20,72] 0,0004
200 mg	11/76 (14,5)	NE [NE; NE]	1/41 (2,4)	NE [NE; NE]	6,54 [0,84; 50,69] 0,0381
Previous anti-estrogene therapy (p-value of the interaction term: 0,5902)					
Yes	19/109 (17,4)	NE [NE; NE]	2/52 (3,8)	NE [NE; NE]	4,79 [1,12; 20,56] 0,0198
No	27/136 (19,9)	NE [NE; NE]	2/76 (2,6)	NE [NE; NE]	8,16 [1,94; 34,33] 0,0006

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 20.06.2019, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.					

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
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/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 213.1.2: Subgroups: adverse events according PT - Vascular disorders/Embolism - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
ECOG-PS at Baseline (p-value of the interaction term: 1,0000)					
0	10/135 (7,4)	NE [NE; NE]	0/74 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0358
1	7/110 (6,4)	NE [NE; NE]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0713
Race (p-value of the interaction term: 1,0000)					
Caucasian	10/155 (6,5)	NE [NE; NE]	0/80 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0357
Asian	4/58 (6,9)	NE [NE; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1240
Other	2/17 (11,8)	NE [19,43; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3753
Measurable disease at baseline (p-value of the interaction term: 1,0000)					
Yes	12/169 (7,1)	NE [NE; NE]	0/94 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0197
No	5/76 (6,6)	NE [NE; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1234
Progesterone receptor (p-value of the interaction term: 0,9999)					
Positive	12/183 (6,6)	NE [NE; NE]	0/93 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0232
Negative	5/59 (8,5)	NE [NE; NE]	0/31 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1063
Starting dose (p-value of the interaction term: 0,9999)					
150 mg	13/169 (7,7)	NE [NE; NE]	0/87 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0170
200 mg	4/76 (5,3)	NE [NE; NE]	0/41 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1511
Previous anti-estrogene therapy (p-value of the interaction term: 0,9999)					
Yes	7/109 (6,4)	NE [NE; NE]	0/52 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1174

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
No	10/136 (7,4)	NE [NE; NE]	0/76 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0203

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

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Table 214.1.2: Subgroups: adverse events according PT - General disorders and administration site conditions/Fatigue - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,7150)					
< 65 years	69/147 (46,9)	23,2 [9,83; 46,19]	22/72 (30,6)	46,5 [21,24; NE]	1,66 [1,02; 2,68] 0,0380
≥ 65 years	51/98 (52,0)	7,6 [3,02; 37,02]	17/56 (30,4)	NE [NE; NE]	1,93 [1,11; 3,36] 0,0172
Organs involved (p-value of the interaction term: 0,1477)					
1	56/112 (50,0)	18,7 [3,72; 46,19]	13/49 (26,5)	NE [NE; NE]	2,20 [1,20; 4,03] 0,0088
2	35/73 (47,9)	11,0 [7,10; NE]	14/36 (38,9)	18,8 [2,79; NE]	1,01 [0,54; 1,89] 0,9716
≥ 3	29/60 (48,3)	9,5 [7,36; NE]	12/43 (27,9)	42,2 [42,18; NE]	2,10 [1,06; 4,14] 0,0293
Nature of disease (p-value of the interaction term: 0,2739)					
Visceral	62/130 (47,7)	11,0 [7,50; 40,08]	23/80 (28,8)	42,2 [21,24; NE]	1,70 [1,05; 2,75] 0,0284
Bone only	34/71 (47,9)	23,2 [3,12; 46,19]	6/29 (20,7)	NE [NE; NE]	2,84 [1,19; 6,78] 0,0139
Other	24/44 (54,5)	7,6 [2,10; NE]	10/19 (52,6)	17,6 [0,46; NE]	1,11 [0,52; 2,34] 0,7905
ECOG-PS at Baseline (p-value of the interaction term: 0,5987)					
0	62/135 (45,9)	33,5 [7,56; NE]	23/74 (31,1)	46,5 [42,18; NE]	1,58 [0,98; 2,56] 0,0582
1	58/110 (52,7)	9,6 [3,12; 32,22]	16/54 (29,6)	NE [17,62; NE]	1,92 [1,10; 3,34] 0,0198
Race (p-value of the interaction term: 0,2103)					
Caucasian	89/155 (57,4)	7,4 [3,02; 14,76]	26/80 (32,5)	42,2 [18,84; NE]	2,07 [1,33; 3,20] 0,0009
Asian	17/58 (29,3)	52,4 [16,27; NE]	8/32 (25,0)	NE [NE; NE]	1,04 [0,44; 2,43] 0,9276

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	8/17 (47,1)	18,7 [0,30; NE]	4/9 (44,4)	NE [0,10; NE]	1,05 [0,31; 3,54] 0,9390
Region (p-value of the interaction term: 0,4349)					
Europe	48/97 (49,5)	14,8 [4,90; 36,85]	16/57 (28,1)	46,5 [42,18; NE]	2,05 [1,16; 3,61] 0,0114
North America	55/92 (59,8)	3,7 [2,10; 10,16]	15/39 (38,5)	18,8 [6,21; NE]	1,84 [1,04; 3,27] 0,0340
Asian	17/56 (30,4)	52,4 [16,27; NE]	8/32 (25,0)	NE [NE; NE]	1,08 [0,46; 2,52] 0,8621
Measurable disease at baseline (p-value of the interaction term: 0,1152)					
Yes	82/169 (48,5)	10,2 [7,50; 40,08]	32/94 (34,0)	42,2 [18,84; NE]	1,45 [0,96; 2,18] 0,0747
No	38/76 (50,0)	18,7 [2,56; 46,19]	7/34 (20,6)	NE [NE; NE]	3,01 [1,34; 6,75] 0,0051
Progesterone receptor (p-value of the interaction term: 0,1405)					
Positive	88/183 (48,1)	18,7 [8,32; 40,08]	31/93 (33,3)	42,2 [21,24; NE]	1,49 [0,99; 2,25] 0,0570
Negative	29/59 (49,2)	8,3 [2,76; NE]	6/31 (19,4)	NE [NE; NE]	3,14 [1,30; 7,57] 0,0072
Sensitivity against endocrine therapy (p-value of the interaction term: 0,7748)					
Primary resistance	30/57 (52,6)	9,5 [3,88; 46,19]	10/35 (28,6)	NE [7,82; NE]	1,80 [0,87; 3,71] 0,1057
Secondary resistance	78/168 (46,4)	18,7 [7,50; NE]	25/79 (31,6)	42,2 [21,24; NE]	1,63 [1,04; 2,57] 0,0315
Endocrine naive	12/20 (60,0)	7,5 [0,49; NE]	4/14 (28,6)	46,5 [3,62; NE]	2,52 [0,81; 7,84] 0,0978
Starting dose (p-value of the interaction term: 0,8020)					
150 mg	80/169 (47,3)	18,7 [7,36; 37,02]	25/87 (28,7)	42,2 [42,18; NE]	1,68 [1,07; 2,64] 0,0225
200 mg	40/76 (52,6)	9,8 [2,10; 52,41]	14/41 (34,1)	46,5 [18,84; NE]	1,84 [1,00; 3,40] 0,0464
Previous anti-estrogene therapy (p-value of the interaction term: 0,5112)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	54/109 (49,5)	16,5 [5,56; 36,85]	14/52 (26,9)	42,2 [21,24; NE]	2,02 [1,12; 3,65] 0,0168
No	66/136 (48,5)	14,8 [4,90; NE]	25/76 (32,9)	46,5 [17,62; NE]	1,59 [1,00; 2,52] 0,0467

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

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Table 215.1.2: Subgroups: adverse events according PT - Nervous system disorders/Headache - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,1709)					
< 65 years	42/147 (28,6)	NE [29,72; NE]	13/72 (18,1)	NE [31,53; NE]	1,47 [0,79; 2,74] 0,2218
≥ 65 years	12/98 (12,2)	NE [44,61; NE]	1/56 (1,8)	NE [NE; NE]	5,47 [0,70; 42,67] 0,0689
Organs involved (p-value of the interaction term: 0,8889)					
1	29/112 (25,9)	NE [26,93; NE]	6/49 (12,2)	NE [NE; NE]	2,05 [0,85; 4,96] 0,1021
2	12/73 (16,4)	NE [NE; NE]	3/36 (8,3)	NE [13,97; NE]	1,73 [0,48; 6,21] 0,3957
≥ 3	13/60 (21,7)	NE [40,70; NE]	5/43 (11,6)	NE [31,53; NE]	1,93 [0,69; 5,43] 0,2027
Nature of disease (p-value of the interaction term: 0,1335)					
Visceral	23/130 (17,7)	NE [NE; NE]	9/80 (11,3)	NE [31,53; NE]	1,38 [0,63; 2,99] 0,4160
Bone only	24/71 (33,8)	42,7 [20,52; NE]	2/29 (6,9)	NE [NE; NE]	5,86 [1,38; 24,86] 0,0066
Other	7/44 (15,9)	NE [40,70; NE]	3/19 (15,8)	NE [13,97; NE]	0,92 [0,24; 3,58] 0,9044
ECOG-PS at Baseline (p-value of the interaction term: 0,3520)					
0	36/135 (26,7)	NE [40,70; NE]	8/74 (10,8)	NE [NE; NE]	2,37 [1,10; 5,11] 0,0231
1	18/110 (16,4)	NE [NE; NE]	6/54 (11,1)	NE [31,53; NE]	1,31 [0,51; 3,32] 0,5730
Race (p-value of the interaction term: 0,8227)					
Caucasian	33/155 (21,3)	NE [40,70; NE]	9/80 (11,3)	NE [31,53; NE]	1,65 [0,79; 3,46] 0,1787
Asian	13/58 (22,4)	NE [NE; NE]	3/32 (9,4)	NE [22,13; NE]	2,47 [0,70; 8,71] 0,1470

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	6/17 (35,3)	NE [0,46; NE]	1/9 (11,1)	NE [1,32; NE]	3,72 [0,45; 30,94] 0,1931
Region (p-value of the interaction term: 0,9813)					
Europe	18/97 (18,6)	NE [NE; NE]	6/57 (10,5)	NE [31,53; NE]	1,71 [0,68; 4,30] 0,2521
North America	24/92 (26,1)	44,6 [26,93; NE]	5/39 (12,8)	NE [NE; NE]	1,74 [0,66; 4,59] 0,2566
Asian	12/56 (21,4)	NE [NE; NE]	3/32 (9,4)	NE [22,13; NE]	2,29 [0,64; 8,16] 0,1897
Progesterone receptor (p-value of the interaction term: 0,5435)					
Positive	45/183 (24,6)	NE [42,74; NE]	11/93 (11,8)	NE [NE; NE]	1,97 [1,01; 3,81] 0,0414
Negative	8/59 (13,6)	NE [NE; NE]	3/31 (9,7)	NE [13,97; NE]	1,41 [0,37; 5,32] 0,6126
Sensitivity against endocrine therapy (p-value of the interaction term: 0,4687)					
Primary resistance	18/57 (31,6)	40,7 [17,06; NE]	3/35 (8,6)	NE [16,27; NE]	3,00 [0,87; 10,33] 0,0680
Secondary resistance	31/168 (18,5)	NE [NE; NE]	10/79 (12,7)	NE [31,53; NE]	1,37 [0,67; 2,81] 0,3872
Endocrine naive	5/20 (25,0)	NE [13,61; NE]	1/14 (7,1)	NE [22,13; NE]	3,29 [0,38; 28,37] 0,2503
Starting dose (p-value of the interaction term: 0,5405)					
150 mg	41/169 (24,3)	NE [44,61; NE]	9/87 (10,3)	NE [31,53; NE]	2,11 [1,02; 4,36] 0,0389
200 mg	13/76 (17,1)	NE [40,70; NE]	5/41 (12,2)	NE [NE; NE]	1,40 [0,50; 3,95] 0,5177
Previous anti-estrogene therapy (p-value of the interaction term: 0,5607)					
Yes	29/109 (26,6)	NE [30,12; NE]	8/52 (15,4)	NE [31,53; NE]	1,60 [0,73; 3,51] 0,2371
No	25/136 (18,4)	NE [44,61; NE]	6/76 (7,9)	NE [NE; NE]	2,19 [0,90; 5,36] 0,0775

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 20.06.2019, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.					

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 216.1.2: Subgroups: adverse events according PT - Metabolism and nutrition disorders/Hypokalaemia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,4224)					
< 65 years	12/147 (8,2)	NE [51,58; NE]	2/72 (2,8)	NE [NE; NE]	2,53 [0,56; 11,36] 0,2090
≥ 65 years	13/98 (13,3)	NE [NE; NE]	1/56 (1,8)	NE [NE; NE]	7,57 [0,99; 57,93] 0,0213
Organs involved (p-value of the interaction term: 0,9998)					
1	11/112 (9,8)	NE [51,58; NE]	2/49 (4,1)	NE [25,61; NE]	2,15 [0,47; 9,78] 0,3085
2	6/73 (8,2)	NE [NE; NE]	1/36 (2,8)	NE [NE; NE]	2,74 [0,33; 22,87] 0,3304
≥ 3	8/60 (13,3)	NE [NE; NE]	0/43 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0138
Nature of disease (p-value of the interaction term: 0,9323)					
Visceral	12/130 (9,2)	NE [NE; NE]	2/80 (2,5)	NE [NE; NE]	3,11 [0,69; 13,98] 0,1185
Bone only	9/71 (12,7)	NE [51,58; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0512
Other	4/44 (9,1)	NE [NE; NE]	1/19 (5,3)	NE [25,61; NE]	1,86 [0,21; 16,70] 0,5727
ECOG-PS at Baseline (p-value of the interaction term: 0,5733)					
0	12/135 (8,9)	NE [51,58; NE]	2/74 (2,7)	NE [NE; NE]	2,68 [0,59; 12,06] 0,1820
1	13/110 (11,8)	NE [NE; NE]	1/54 (1,9)	NE [NE; NE]	6,35 [0,83; 48,59] 0,0402
Race (p-value of the interaction term: 0,6176)					
Caucasian	22/155 (14,2)	NE [NE; NE]	2/80 (2,5)	NE [NE; NE]	5,55 [1,31; 23,63] 0,0088
Asian	3/58 (5,2)	NE [51,58; NE]	1/32 (3,1)	NE [25,61; NE]	1,07 [0,10; 11,03] 0,9569

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	0/17 (0,0)	NE [NE; NE]	0/9 (0,0)	NE [NE; NE]	NE
Region (p-value of the interaction term: 0,5086)					
Europe	7/97 (7,2)	NE [NE; NE]	1/57 (1,8)	NE [NE; NE]	3,89 [0,48; 31,63] 0,1701
North America	16/92 (17,4)	NE [NE; NE]	1/39 (2,6)	NE [NE; NE]	6,18 [0,82; 46,74] 0,0430
Asian	2/56 (3,6)	NE [51,58; NE]	1/32 (3,1)	NE [25,61; NE]	0,57 [0,05; 7,05] 0,6611
Measurable disease at baseline (p-value of the interaction term: 0,9901)					
Yes	15/169 (8,9)	NE [NE; NE]	3/94 (3,2)	NE [NE; NE]	2,44 [0,70; 8,46] 0,1453
No	10/76 (13,2)	NE [51,58; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0333
Progesterone receptor (p-value of the interaction term: 0,9916)					
Positive	19/183 (10,4)	NE [51,58; NE]	3/93 (3,2)	NE [NE; NE]	2,98 [0,88; 10,09] 0,0654
Negative	5/59 (8,5)	NE [NE; NE]	0/31 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1219
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9999)					
Primary resistance	11/57 (19,3)	NE [51,58; NE]	0/35 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0216
Secondary resistance	11/168 (6,5)	NE [NE; NE]	3/79 (3,8)	NE [NE; NE]	1,73 [0,48; 6,22] 0,3915
Endocrine naive	3/20 (15,0)	NE [14,47; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1982
Starting dose (p-value of the interaction term: 0,4888)					
150 mg	12/169 (7,1)	NE [NE; NE]	2/87 (2,3)	NE [NE; NE]	2,73 [0,61; 12,24] 0,1716
200 mg	13/76 (17,1)	NE [51,58; NE]	1/41 (2,4)	NE [NE; NE]	6,83 [0,89; 52,30] 0,0319
Previous anti-estrogene therapy (p-value of the interaction term: 0,8968)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	9/109 (8,3)	NE [NE; NE]	1/52 (1,9)	NE [NE; NE]	3,98 [0,50; 31,49] 0,1576
No	16/136 (11,8)	NE [51,58; NE]	2/76 (2,6)	NE [NE; NE]	4,33 [0,99; 18,84] 0,0332

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 217.1.2: Subgroups: adverse events according PT - Eye disorders/Lacrimation increased - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,9886)					
< 65 years	13/147 (8,8)	NE [NE; NE]	3/72 (4,2)	NE [NE; NE]	1,88 [0,54; 6,61] 0,3153
≥ 65 years	9/98 (9,2)	NE [NE; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0343
Organs involved (p-value of the interaction term: 0,9996)					
1	10/112 (8,9)	NE [NE; NE]	2/49 (4,1)	NE [NE; NE]	2,05 [0,45; 9,40] 0,3475
2	6/73 (8,2)	NE [NE; NE]	1/36 (2,8)	NE [13,87; NE]	2,03 [0,24; 17,05] 0,5066
≥ 3	6/60 (10,0)	NE [NE; NE]	0/43 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0338
Nature of disease (p-value of the interaction term: 0,9982)					
Visceral	11/130 (8,5)	NE [NE; NE]	0/80 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0169
Bone only	8/71 (11,3)	NE [NE; NE]	2/29 (6,9)	NE [NE; NE]	1,66 [0,35; 7,90] 0,5182
Other	3/44 (6,8)	NE [NE; NE]	1/19 (5,3)	NE [13,87; NE]	1,54 [0,16; 14,85] 0,7055
ECOG-PS at Baseline (p-value of the interaction term: 0,3482)					
0	13/135 (9,6)	NE [NE; NE]	1/74 (1,4)	NE [NE; NE]	6,47 [0,84; 49,57] 0,0385
1	9/110 (8,2)	NE [NE; NE]	2/54 (3,7)	NE [NE; NE]	1,86 [0,40; 8,67] 0,4246
Race (p-value of the interaction term: 1,0000)					
Caucasian	18/155 (11,6)	NE [NE; NE]	3/80 (3,8)	NE [NE; NE]	2,70 [0,79; 9,19] 0,0983
Asian	0/58 (0,0)	NE [NE; NE]	0/32 (0,0)	NE [NE; NE]	NE

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	3/17 (17,6)	NE [12,00; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2911
Region (p-value of the interaction term: 1,0000)					
Europe	12/97 (12,4)	NE [44,88; NE]	3/57 (5,3)	NE [NE; NE]	2,18 [0,61; 7,72] 0,2170
North America	10/92 (10,9)	NE [NE; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0674
Asian	0/56 (0,0)	NE [NE; NE]	0/32 (0,0)	NE [NE; NE]	NE
Measurable disease at baseline (p-value of the interaction term: 0,1745)					
Yes	16/169 (9,5)	NE [NE; NE]	1/94 (1,1)	NE [NE; NE]	8,09 [1,07; 61,07] 0,0157
No	6/76 (7,9)	NE [NE; NE]	2/34 (5,9)	NE [NE; NE]	1,27 [0,25; 6,40] 0,7702
Progesterone receptor (p-value of the interaction term: 0,5498)					
Positive	18/183 (9,8)	NE [NE; NE]	2/93 (2,2)	NE [NE; NE]	4,24 [0,98; 18,32] 0,0353
Negative	4/59 (6,8)	NE [NE; NE]	1/31 (3,2)	NE [NE; NE]	2,10 [0,23; 18,75] 0,4987
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9752)					
Primary resistance	8/57 (14,0)	NE [NE; NE]	2/35 (5,7)	NE [NE; NE]	1,98 [0,42; 9,42] 0,3806
Secondary resistance	10/168 (6,0)	NE [NE; NE]	0/79 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0349
Endocrine naive	4/20 (20,0)	NE [42,12; NE]	1/14 (7,1)	NE [13,87; NE]	2,49 [0,28; 22,38] 0,3981
Starting dose (p-value of the interaction term: 0,9904)					
150 mg	18/169 (10,7)	NE [NE; NE]	3/87 (3,4)	NE [NE; NE]	2,52 [0,74; 8,59] 0,1266
200 mg	4/76 (5,3)	NE [NE; NE]	0/41 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1223
Previous anti-estrogene therapy (p-value of the interaction term: 0,4471)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	11/109 (10,1)	NE [NE; NE]	2/52 (3,8)	NE [NE; NE]	2,20 [0,48; 9,97] 0,2960
No	11/136 (8,1)	NE [NE; NE]	1/76 (1,3)	NE [NE; NE]	5,91 [0,76; 45,87] 0,0535

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 218.1.2: Subgroups: adverse events according PT - Blood and lymphatic system disorders/Leukopenia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,9822)					
< 65 years	42/147 (28,6)	NE [35,93; NE]	2/72 (2,8)	NE [NE; NE]	10,83 [2,62; 44,75] <,0001
≥ 65 years	31/98 (31,6)	NE [27,39; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Organs involved (p-value of the interaction term: 0,9752)					
1	41/112 (36,6)	46,8 [22,13; NE]	1/49 (2,0)	NE [NE; NE]	19,88 [2,73; 144,63] <,0001
2	16/73 (21,9)	NE [NE; NE]	0/36 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0068
≥ 3	16/60 (26,7)	41,3 [24,10; NE]	1/43 (2,3)	NE [NE; NE]	14,16 [1,87; 107,00] 0,0007
Nature of disease (p-value of the interaction term: 0,8884)					
Visceral	33/130 (25,4)	NE [46,82; NE]	0/80 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Bone only	28/71 (39,4)	41,9 [16,18; NE]	1/29 (3,4)	NE [NE; NE]	13,41 [1,82; 98,71] 0,0009
Other	12/44 (27,3)	41,3 [22,13; NE]	1/19 (5,3)	NE [NE; NE]	6,53 [0,85; 50,32] 0,0381
ECOG-PS at Baseline (p-value of the interaction term: 0,9832)					
0	44/135 (32,6)	46,8 [27,39; NE]	2/74 (2,7)	NE [NE; NE]	12,73 [3,09; 52,57] <,0001
1	29/110 (26,4)	NE [41,26; NE]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Race (p-value of the interaction term: 0,9885)					
Caucasian	37/155 (23,9)	NE [NE; NE]	1/80 (1,3)	NE [NE; NE]	20,73 [2,84; 151,11] <,0001
Asian	26/58 (44,8)	41,3 [3,95; NE]	1/32 (3,1)	NE [NE; NE]	17,16 [2,32; 126,81] 0,0001

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	9/17 (52,9)	27,4 [20,42; 46,82]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0682
Region (p-value of the interaction term: 0,9520)					
Europe	17/97 (17,5)	NE [NE; NE]	1/57 (1,8)	NE [NE; NE]	10,38 [1,38; 77,94] 0,0047
North America	31/92 (33,7)	35,9 [24,10; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0002
Asian	25/56 (44,6)	41,3 [3,95; NE]	1/32 (3,1)	NE [NE; NE]	17,03 [2,30; 126,07] 0,0001
Measurable disease at baseline (p-value of the interaction term: 0,6041)					
Yes	47/169 (27,8)	NE [41,26; NE]	1/94 (1,1)	NE [NE; NE]	27,33 [3,77; 198,04] <,0001
No	26/76 (34,2)	NE [16,18; NE]	1/34 (2,9)	NE [NE; NE]	13,26 [1,80; 97,90] 0,0010
Progesterone receptor (p-value of the interaction term: 0,9877)					
Positive	57/183 (31,1)	46,8 [30,58; NE]	2/93 (2,2)	NE [NE; NE]	15,71 [3,83; 64,36] <,0001
Negative	14/59 (23,7)	NE [41,88; NE]	0/31 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0058
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9585)					
Primary resistance	22/57 (38,6)	30,6 [20,42; NE]	1/35 (2,9)	NE [NE; NE]	13,53 [1,81; 100,99] 0,0009
Secondary resistance	44/168 (26,2)	NE [46,82; NE]	1/79 (1,3)	NE [NE; NE]	22,26 [3,07; 161,63] <,0001
Endocrine naive	7/20 (35,0)	NE [5,79; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0231
Starting dose (p-value of the interaction term: 0,7275)					
150 mg	49/169 (29,0)	46,8 [27,39; NE]	1/87 (1,1)	NE [NE; NE]	25,46 [3,51; 184,36] <,0001
200 mg	24/76 (31,6)	NE [30,58; NE]	1/41 (2,4)	NE [NE; NE]	15,17 [2,05; 112,25] 0,0004
Previous anti-estrogene therapy (p-value of the interaction term: 0,9860)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	29/109 (26,6)	NE [46,82; NE]	2/52 (3,8)	NE [NE; NE]	6,72 [1,60; 28,20] 0,0026
No	44/136 (32,4)	NE [27,39; NE]	0/76 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t218_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 219.1.2: Subgroups: adverse events according PT - Blood and lymphatic system disorders/Lymphopenia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,9903)					
< 65 years	13/147 (8,8)	NE [NE; NE]	1/72 (1,4)	NE [NE; NE]	4,98 [0,65; 38,21] 0,0870
≥ 65 years	9/98 (9,2)	NE [NE; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0294
Organs involved (p-value of the interaction term: 0,9999)					
1	9/112 (8,0)	NE [NE; NE]	1/49 (2,0)	NE [25,61; NE]	3,18 [0,40; 25,43] 0,2507
2	5/73 (6,8)	NE [NE; NE]	0/36 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3206
≥ 3	8/60 (13,3)	NE [NE; NE]	0/43 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0135
Nature of disease (p-value of the interaction term: 0,9999)					
Visceral	11/130 (8,5)	NE [NE; NE]	0/80 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0266
Bone only	7/71 (9,9)	NE [NE; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0953
Other	4/44 (9,1)	NE [NE; NE]	1/19 (5,3)	NE [25,61; NE]	1,83 [0,20; 16,39] 0,5825
ECOG-PS at Baseline (p-value of the interaction term: 0,9908)					
0	13/135 (9,6)	NE [NE; NE]	1/74 (1,4)	NE [NE; NE]	5,51 [0,72; 42,43] 0,0657
1	9/110 (8,2)	NE [NE; NE]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0470
Race (p-value of the interaction term: 0,9999)					
Caucasian	17/155 (11,0)	NE [NE; NE]	0/80 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0040
Asian	1/58 (1,7)	NE [NE; NE]	1/32 (3,1)	NE [25,61; NE]	0,14 [0,01; 2,29] 0,1079

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	4/17 (23,5)	41,9 [22,49; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2635
Region (p-value of the interaction term: 0,9998)					
Europe	13/97 (13,4)	NE [NE; NE]	0/57 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0066
North America	8/92 (8,7)	NE [NE; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1083
Asian	1/56 (1,8)	NE [NE; NE]	1/32 (3,1)	NE [25,61; NE]	0,14 [0,01; 2,29] 0,1079
Measurable disease at baseline (p-value of the interaction term: 0,9922)					
Yes	14/169 (8,3)	NE [NE; NE]	1/94 (1,1)	NE [NE; NE]	6,04 [0,79; 46,15] 0,0484
No	8/76 (10,5)	NE [NE; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0618
Progesterone receptor (p-value of the interaction term: 0,9907)					
Positive	20/183 (10,9)	NE [NE; NE]	1/93 (1,1)	NE [NE; NE]	8,96 [1,20; 66,88] 0,0096
Negative	2/59 (3,4)	NE [NE; NE]	0/31 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4013
Sensitivity against endocrine therapy (p-value of the interaction term: 1,0000)					
Primary resistance	6/57 (10,5)	NE [NE; NE]	0/35 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1153
Secondary resistance	16/168 (9,5)	NE [NE; NE]	1/79 (1,3)	NE [NE; NE]	6,66 [0,88; 50,41] 0,0340
Endocrine naive	0/20 (0,0)	NE [NE; NE]	0/14 (0,0)	NE [NE; NE]	NE
Starting dose (p-value of the interaction term: 0,9919)					
150 mg	18/169 (10,7)	NE [NE; NE]	1/87 (1,1)	NE [NE; NE]	7,36 [0,98; 55,44] 0,0233
200 mg	4/76 (5,3)	NE [NE; NE]	0/41 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1623
Previous anti-estrogene therapy (p-value of the interaction term: 0,9906)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	13/109 (11,9)	NE [NE; NE]	0/52 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0185
No	9/136 (6,6)	NE [NE; NE]	1/76 (1,3)	NE [NE; NE]	3,84 [0,48; 30,62] 0,1722

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t219_aesocpt_tte_sub_popa1_2.rtf
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Table 220.1.2: Subgroups: adverse events according PT - Gastrointestinal disorders/Nausea - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,6116)					
< 65 years	70/147 (47,6)	21,3 [6,31; NE]	17/72 (23,6)	NE [39,42; NE]	2,30 [1,36; 3,92] 0,0015
≥ 65 years	55/98 (56,1)	3,6 [0,72; 19,10]	15/56 (26,8)	NE [22,13; NE]	2,79 [1,58; 4,95] 0,0002
Organs involved (p-value of the interaction term: 0,7796)					
1	63/112 (56,3)	10,2 [1,22; 19,10]	14/49 (28,6)	NE [19,96; NE]	2,41 [1,35; 4,31] 0,0021
2	31/73 (42,5)	NE [3,65; NE]	5/36 (13,9)	NE [NE; NE]	3,37 [1,31; 8,68] 0,0075
≥ 3	31/60 (51,7)	9,2 [0,95; NE]	13/43 (30,2)	39,4 [22,13; NE]	2,25 [1,17; 4,30] 0,0124
Nature of disease (p-value of the interaction term: 0,4650)					
Visceral	60/130 (46,2)	21,8 [5,56; NE]	20/80 (25,0)	NE [39,42; NE]	2,03 [1,22; 3,38] 0,0053
Bone only	38/71 (53,5)	10,2 [0,95; NE]	8/29 (27,6)	NE [19,96; NE]	2,50 [1,16; 5,36] 0,0152
Other	27/44 (61,4)	1,9 [0,33; 19,10]	4/19 (21,1)	NE [3,85; NE]	4,19 [1,46; 12,00] 0,0038
ECOG-PS at Baseline (p-value of the interaction term: 0,9706)					
0	73/135 (54,1)	10,4 [1,94; 31,33]	19/74 (25,7)	NE [39,42; NE]	2,49 [1,50; 4,12] 0,0003
1	52/110 (47,3)	17,7 [1,87; NE]	13/54 (24,1)	NE [22,13; NE]	2,48 [1,35; 4,55] 0,0026
Race (p-value of the interaction term: 0,9579)					
Caucasian	85/155 (54,8)	5,6 [1,22; 21,30]	22/80 (27,5)	NE [39,42; NE]	2,41 [1,51; 3,85] 0,0001
Asian	25/58 (43,1)	NE [3,65; NE]	6/32 (18,8)	NE [19,96; NE]	2,89 [1,18; 7,06] 0,0151

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	12/17 (70,6)	1,9 [0,36; NE]	3/9 (33,3)	NE [0,30; NE]	2,64 [0,73; 9,57] 0,1266
Region (p-value of the interaction term: 0,9809)					
Europe	42/97 (43,3)	21,8 [17,65; NE]	12/57 (21,1)	NE [39,42; NE]	2,32 [1,22; 4,41] 0,0081
North America	60/92 (65,2)	1,1 [0,56; 3,55]	14/39 (35,9)	NE [3,85; NE]	2,36 [1,32; 4,24] 0,0028
Asian	23/56 (41,1)	NE [6,31; NE]	6/32 (18,8)	NE [19,96; NE]	2,70 [1,10; 6,64] 0,0249
Measurable disease at baseline (p-value of the interaction term: 0,7336)					
Yes	83/169 (49,1)	19,8 [3,55; NE]	23/94 (24,5)	NE [39,42; NE]	2,35 [1,48; 3,73] 0,0002
No	42/76 (55,3)	10,2 [0,95; 27,75]	9/34 (26,5)	NE [19,96; NE]	2,76 [1,34; 5,69] 0,0040
Progesterone receptor (p-value of the interaction term: 0,1646)					
Positive	91/183 (49,7)	17,7 [3,12; NE]	27/93 (29,0)	NE [22,13; NE]	2,03 [1,32; 3,11] 0,0011
Negative	31/59 (52,5)	10,2 [0,59; NE]	5/31 (16,1)	NE [NE; NE]	4,08 [1,59; 10,51] 0,0016
Sensitivity against endocrine therapy (p-value of the interaction term: 0,6511)					
Primary resistance	28/57 (49,1)	18,0 [0,79; NE]	10/35 (28,6)	NE [4,57; NE]	1,76 [0,85; 3,66] 0,1193
Secondary resistance	87/168 (51,8)	13,0 [2,10; 48,56]	19/79 (24,1)	NE [39,42; NE]	2,67 [1,62; 4,39] <,0001
Endocrine naive	10/20 (50,0)	19,8 [0,16; NE]	3/14 (21,4)	NE [3,85; NE]	3,03 [0,83; 11,06] 0,0773
Previous anti-estrogene therapy (p-value of the interaction term: 0,9904)					
Yes	57/109 (52,3)	16,1 [1,87; 48,56]	13/52 (25,0)	NE [39,42; NE]	2,42 [1,32; 4,42] 0,0031
No	68/136 (50,0)	18,0 [1,94; NE]	19/76 (25,0)	NE [22,13; NE]	2,46 [1,48; 4,09] 0,0004

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 20.06.2019, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.					

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t220_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 221.1.2: Subgroups: adverse events according PT - Blood and lymphatic system disorders/Neutropenia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,9856)					
< 65 years	71/147 (48,3)	17,6 [9,34; 40,04]	3/72 (4,2)	NE [NE; NE]	14,72 [4,63; 46,75] <,0001
≥ 65 years	40/98 (40,8)	NE [6,41; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Organs involved (p-value of the interaction term: 0,8904)					
1	57/112 (50,9)	15,0 [5,49; 41,88]	1/49 (2,0)	NE [NE; NE]	31,63 [4,38; 228,33] <,0001
2	29/73 (39,7)	NE [6,41; NE]	1/36 (2,8)	NE [19,40; NE]	16,91 [2,30; 124,22] 0,0001
≥ 3	25/60 (41,7)	30,3 [4,80; NE]	1/43 (2,3)	NE [NE; NE]	24,53 [3,31; 181,71] <,0001
Nature of disease (p-value of the interaction term: 0,7250)					
Visceral	52/130 (40,0)	30,3 [10,36; NE]	1/80 (1,3)	NE [NE; NE]	38,33 [5,30; 277,00] <,0001
Bone only	40/71 (56,3)	15,0 [1,87; 40,04]	1/29 (3,4)	NE [NE; NE]	22,69 [3,12; 165,32] <,0001
Other	19/44 (43,2)	14,8 [2,79; NE]	1/19 (5,3)	NE [NE; NE]	11,69 [1,56; 87,60] 0,0023
ECOG-PS at Baseline (p-value of the interaction term: 0,9784)					
0	62/135 (45,9)	35,0 [9,34; NE]	3/74 (4,1)	NE [NE; NE]	14,13 [4,43; 45,05] <,0001
1	49/110 (44,5)	15,9 [6,48; 41,88]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Race (p-value of the interaction term: 0,8292)					
Caucasian	59/155 (38,1)	NE [14,99; NE]	2/80 (2,5)	NE [NE; NE]	18,59 [4,54; 76,14] <,0001
Asian	40/58 (69,0)	1,0 [0,95; 9,34]	1/32 (3,1)	NE [NE; NE]	38,91 [5,33; 284,06] <,0001

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	8/17 (47,1)	41,9 [3,72; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0587
Region (p-value of the interaction term: 0,7903)					
Europe	40/97 (41,2)	18,5 [14,99; NE]	1/57 (1,8)	NE [NE; NE]	30,05 [4,13; 218,76] <,0001
North America	33/92 (35,9)	41,9 [30,31; NE]	1/39 (2,6)	NE [19,40; NE]	14,27 [1,95; 104,50] 0,0006
Asian	38/56 (67,9)	1,0 [0,95; 10,36]	1/32 (3,1)	NE [NE; NE]	37,48 [5,13; 273,94] <,0001
Measurable disease at baseline (p-value of the interaction term: 0,9711)					
Yes	72/169 (42,6)	18,5 [10,16; NE]	2/94 (2,1)	NE [NE; NE]	25,06 [6,15; 102,14] <,0001
No	39/76 (51,3)	15,1 [2,56; 41,88]	1/34 (2,9)	NE [NE; NE]	23,49 [3,22; 171,24] <,0001
Progesterone receptor (p-value of the interaction term: 0,9841)					
Positive	85/183 (46,4)	17,6 [8,58; 46,82]	3/93 (3,2)	NE [NE; NE]	18,73 [5,92; 59,28] <,0001
Negative	25/59 (42,4)	41,9 [3,72; NE]	0/31 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Sensitivity against endocrine therapy (p-value of the interaction term: 0,8815)					
Primary resistance	21/57 (36,8)	NE [10,16; NE]	1/35 (2,9)	NE [NE; NE]	13,81 [1,85; 102,95] 0,0008
Secondary resistance	82/168 (48,8)	15,0 [6,41; 40,04]	2/79 (2,5)	NE [NE; NE]	26,68 [6,56; 108,61] <,0001
Endocrine naive	8/20 (40,0)	NE [0,95; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0099
Starting dose (p-value of the interaction term: 0,3003)					
150 mg	77/169 (45,6)	18,4 [10,16; 41,88]	1/87 (1,1)	NE [NE; NE]	47,84 [6,65; 344,07] <,0001
200 mg	34/76 (44,7)	NE [1,87; NE]	2/41 (4,9)	NE [NE; NE]	12,67 [3,04; 52,83] <,0001
Previous anti-estrogene therapy (p-value of the interaction term: 0,9825)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	49/109 (45,0)	18,4 [8,58; NE]	3/52 (5,8)	NE [NE; NE]	9,86 [3,07; 31,68] <,0001
No	62/136 (45,6)	18,5 [6,48; NE]	0/76 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t221_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 222.1.2: Subgroups: adverse events according PT - Skin and subcutaneous tissue disorders/Rash - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,7950)					
< 65 years	23/147 (15,6)	NE [NE; NE]	4/72 (5,6)	NE [NE; NE]	2,70 [0,93; 7,80] 0,0568
≥ 65 years	11/98 (11,2)	NE [NE; NE]	3/56 (5,4)	NE [NE; NE]	2,10 [0,58; 7,56] 0,2479
Organs involved (p-value of the interaction term: 0,8621)					
1	17/112 (15,2)	NE [NE; NE]	3/49 (6,1)	NE [NE; NE]	2,45 [0,72; 8,39] 0,1393
2	9/73 (12,3)	NE [NE; NE]	1/36 (2,8)	NE [18,54; NE]	3,54 [0,44; 28,33] 0,2031
≥ 3	8/60 (13,3)	NE [NE; NE]	3/43 (7,0)	NE [NE; NE]	2,00 [0,53; 7,53] 0,2979
Nature of disease (p-value of the interaction term: 0,2488)					
Visceral	16/130 (12,3)	NE [NE; NE]	2/80 (2,5)	NE [NE; NE]	4,90 [1,13; 21,30] 0,0189
Bone only	12/71 (16,9)	NE [NE; NE]	2/29 (6,9)	NE [NE; NE]	2,53 [0,56; 11,36] 0,2097
Other	6/44 (13,6)	NE [37,08; NE]	3/19 (15,8)	NE [18,54; NE]	0,83 [0,21; 3,36] 0,7959
ECOG-PS at Baseline (p-value of the interaction term: 0,2826)					
0	16/135 (11,9)	NE [NE; NE]	5/74 (6,8)	NE [NE; NE]	1,66 [0,61; 4,54] 0,3201
1	18/110 (16,4)	NE [NE; NE]	2/54 (3,7)	NE [NE; NE]	4,38 [1,01; 18,91] 0,0307
Race (p-value of the interaction term: 0,5765)					
Caucasian	18/155 (11,6)	NE [NE; NE]	2/80 (2,5)	NE [NE; NE]	4,39 [1,02; 18,95] 0,0304
Asian	13/58 (22,4)	NE [NE; NE]	4/32 (12,5)	NE [NE; NE]	1,79 [0,58; 5,52] 0,3048

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	3/17 (17,6)	NE [8,09; NE]	1/9 (11,1)	NE [18,54; NE]	1,21 [0,12; 12,12] 0,8723
Region (p-value of the interaction term: 0,9616)					
Europe	6/97 (6,2)	NE [NE; NE]	0/57 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0649
North America	16/92 (17,4)	NE [NE; NE]	3/39 (7,7)	NE [NE; NE]	2,08 [0,60; 7,19] 0,2376
Asian	12/56 (21,4)	NE [NE; NE]	4/32 (12,5)	NE [NE; NE]	1,69 [0,54; 5,28] 0,3592
Measurable disease at baseline (p-value of the interaction term: 0,8536)					
Yes	22/169 (13,0)	NE [NE; NE]	5/94 (5,3)	NE [NE; NE]	2,36 [0,89; 6,23] 0,0750
No	12/76 (15,8)	NE [NE; NE]	2/34 (5,9)	NE [NE; NE]	2,74 [0,61; 12,30] 0,1709
Progesterone receptor (p-value of the interaction term: 0,5373)					
Positive	25/183 (13,7)	NE [NE; NE]	6/93 (6,5)	NE [NE; NE]	2,10 [0,86; 5,13] 0,0946
Negative	8/59 (13,6)	NE [41,72; NE]	1/31 (3,2)	NE [NE; NE]	4,08 [0,51; 32,72] 0,1519
Sensitivity against endocrine therapy (p-value of the interaction term: 0,8899)					
Primary resistance	6/57 (10,5)	NE [NE; NE]	1/35 (2,9)	NE [NE; NE]	3,44 [0,41; 28,60] 0,2233
Secondary resistance	24/168 (14,3)	NE [NE; NE]	6/79 (7,6)	NE [NE; NE]	1,91 [0,78; 4,67] 0,1508
Endocrine naive	4/20 (20,0)	NE [41,72; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0950
Starting dose (p-value of the interaction term: 0,8348)					
150 mg	24/169 (14,2)	NE [NE; NE]	5/87 (5,7)	NE [NE; NE]	2,28 [0,87; 6,01] 0,0859
200 mg	10/76 (13,2)	NE [NE; NE]	2/41 (4,9)	NE [NE; NE]	2,90 [0,63; 13,23] 0,1501
Previous anti-estrogene therapy (p-value of the interaction term: 0,3173)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	13/109 (11,9)	NE [NE; NE]	1/52 (1,9)	NE [NE; NE]	6,32 [0,83; 48,30] 0,0415
No	21/136 (15,4)	NE [NE; NE]	6/76 (7,9)	NE [NE; NE]	1,88 [0,76; 4,67] 0,1663

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 223.1.2: Subgroups: adverse events according PT - Gastrointestinal disorders/Stomatitis - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,1365)					
< 65 years	29/147 (19,7)	NE [NE; NE]	4/72 (5,6)	NE [NE; NE]	3,40 [1,20; 9,69] 0,0147
≥ 65 years	15/98 (15,3)	NE [NE; NE]	7/56 (12,5)	NE [NE; NE]	1,12 [0,46; 2,77] 0,8000
Organs involved (p-value of the interaction term: 0,1436)					
1	27/112 (24,1)	NE [NE; NE]	5/49 (10,2)	NE [NE; NE]	2,31 [0,89; 6,00] 0,0773
2	7/73 (9,6)	NE [NE; NE]	4/36 (11,1)	NE [NE; NE]	0,75 [0,22; 2,61] 0,6498
≥ 3	10/60 (16,7)	NE [42,81; NE]	2/43 (4,7)	NE [NE; NE]	3,84 [0,84; 17,56] 0,0620
Nature of disease (p-value of the interaction term: 0,8553)					
Visceral	20/130 (15,4)	NE [NE; NE]	7/80 (8,8)	NE [NE; NE]	1,56 [0,66; 3,70] 0,3113
Bone only	21/71 (29,6)	NE [28,18; NE]	4/29 (13,8)	NE [NE; NE]	2,27 [0,78; 6,62] 0,1236
Other	3/44 (6,8)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2476
ECOG-PS at Baseline (p-value of the interaction term: 0,2167)					
0	27/135 (20,0)	NE [NE; NE]	9/74 (12,2)	NE [NE; NE]	1,47 [0,69; 3,14] 0,3155
1	17/110 (15,5)	NE [NE; NE]	2/54 (3,7)	NE [NE; NE]	4,19 [0,97; 18,15] 0,0371
Race (p-value of the interaction term: 0,6248)					
Caucasian	25/155 (16,1)	NE [NE; NE]	7/80 (8,8)	NE [NE; NE]	1,73 [0,75; 4,01] 0,1938
Asian	16/58 (27,6)	NE [30,38; NE]	3/32 (9,4)	NE [NE; NE]	2,85 [0,82; 9,87] 0,0841

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	2/17 (11,8)	NE [NE; NE]	1/9 (11,1)	NE [0,10; NE]	0,83 [0,07; 9,33] 0,8786
Region (p-value of the interaction term: 0,7985)					
Europe	16/97 (16,5)	NE [NE; NE]	5/57 (8,8)	NE [NE; NE]	1,84 [0,67; 5,02] 0,2285
North America	13/92 (14,1)	NE [NE; NE]	3/39 (7,7)	NE [NE; NE]	1,55 [0,44; 5,48] 0,4907
Asian	15/56 (26,8)	NE [42,81; NE]	3/32 (9,4)	NE [NE; NE]	2,80 [0,80; 9,76] 0,0920
Measurable disease at baseline (p-value of the interaction term: 0,8842)					
Yes	26/169 (15,4)	NE [NE; NE]	7/94 (7,4)	NE [NE; NE]	1,96 [0,85; 4,52] 0,1095
No	18/76 (23,7)	NE [28,18; NE]	4/34 (11,8)	NE [NE; NE]	2,07 [0,70; 6,13] 0,1791
Progesterone receptor (p-value of the interaction term: 0,7344)					
Positive	33/183 (18,0)	NE [NE; NE]	7/93 (7,5)	NE [NE; NE]	2,27 [1,00; 5,14] 0,0432
Negative	11/59 (18,6)	NE [NE; NE]	3/31 (9,7)	NE [13,74; NE]	1,81 [0,50; 6,49] 0,3546
Sensitivity against endocrine therapy (p-value of the interaction term: 0,8737)					
Primary resistance	9/57 (15,8)	NE [NE; NE]	2/35 (5,7)	NE [13,74; NE]	2,55 [0,55; 11,88] 0,2177
Secondary resistance	30/168 (17,9)	NE [NE; NE]	9/79 (11,4)	NE [NE; NE]	1,53 [0,73; 3,23] 0,2595
Endocrine naive	5/20 (25,0)	NE [28,18; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0750
Starting dose (p-value of the interaction term: 0,7844)					
150 mg	28/169 (16,6)	NE [NE; NE]	7/87 (8,0)	NE [NE; NE]	1,82 [0,79; 4,18] 0,1523
200 mg	16/76 (21,1)	NE [42,81; NE]	4/41 (9,8)	NE [NE; NE]	2,27 [0,76; 6,79] 0,1330
Previous anti-estrogene therapy (p-value of the interaction term: 0,3252)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	21/109 (19,3)	NE [NE; NE]	3/52 (5,8)	NE [NE; NE]	3,13 [0,93; 10,53] 0,0515
No	23/136 (16,9)	NE [NE; NE]	8/76 (10,5)	NE [NE; NE]	1,52 [0,68; 3,41] 0,3008

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
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Table 224.1.2: Subgroups: adverse events according PT - Blood and lymphatic system disorders/Thrombocytopenia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,4299)					
< 65 years	23/147 (15,6)	NE [NE; NE]	1/72 (1,4)	NE [NE; NE]	10,95 [1,48; 81,12] 0,0033
≥ 65 years	14/98 (14,3)	NE [NE; NE]	2/56 (3,6)	NE [NE; NE]	4,22 [0,96; 18,58] 0,0379
Organs involved (p-value of the interaction term: 0,5563)					
1	20/112 (17,9)	NE [NE; NE]	1/49 (2,0)	NE [NE; NE]	8,54 [1,14; 63,79] 0,0120
2	5/73 (6,8)	NE [NE; NE]	1/36 (2,8)	NE [NE; NE]	2,29 [0,27; 19,76] 0,4408
≥ 3	12/60 (20,0)	NE [NE; NE]	1/43 (2,3)	NE [NE; NE]	9,43 [1,23; 72,55] 0,0082
Nature of disease (p-value of the interaction term: 0,9996)					
Visceral	18/130 (13,8)	NE [NE; NE]	2/80 (2,5)	NE [NE; NE]	5,34 [1,24; 23,07] 0,0119
Bone only	13/71 (18,3)	NE [NE; NE]	1/29 (3,4)	NE [NE; NE]	5,53 [0,72; 42,38] 0,0640
Other	6/44 (13,6)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0905
ECOG-PS at Baseline (p-value of the interaction term: 0,9890)					
0	22/135 (16,3)	NE [NE; NE]	0/74 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0005
1	15/110 (13,6)	NE [NE; NE]	3/54 (5,6)	NE [NE; NE]	2,41 [0,70; 8,35] 0,1510
Race (p-value of the interaction term: 0,9200)					
Caucasian	19/155 (12,3)	NE [NE; NE]	2/80 (2,5)	NE [NE; NE]	4,72 [1,10; 20,29] 0,0212
Asian	11/58 (19,0)	NE [NE; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0094

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	5/17 (29,4)	45,9 [12,23; NE]	1/9 (11,1)	NE [5,26; NE]	2,81 [0,32; 24,31] 0,3305
Region (p-value of the interaction term: 0,9999)					
Europe	10/97 (10,3)	NE [NE; NE]	0/57 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0159
North America	16/92 (17,4)	NE [45,90; NE]	3/39 (7,7)	NE [NE; NE]	2,07 [0,60; 7,14] 0,2401
Asian	11/56 (19,6)	NE [NE; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0081
Measurable disease at baseline (p-value of the interaction term: 0,9705)					
Yes	23/169 (13,6)	NE [NE; NE]	2/94 (2,1)	NE [NE; NE]	6,40 [1,51; 27,17] 0,0038
No	14/76 (18,4)	NE [NE; NE]	1/34 (2,9)	NE [NE; NE]	6,68 [0,88; 50,95] 0,0340
Progesterone receptor (p-value of the interaction term: 0,9899)					
Positive	29/183 (15,8)	NE [NE; NE]	3/93 (3,2)	NE [NE; NE]	4,92 [1,50; 16,16] 0,0036
Negative	8/59 (13,6)	NE [NE; NE]	0/31 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0371
Sensitivity against endocrine therapy (p-value of the interaction term: 0,8314)					
Primary resistance	15/57 (26,3)	NE [NE; NE]	1/35 (2,9)	NE [NE; NE]	9,71 [1,28; 73,61] 0,0069
Secondary resistance	18/168 (10,7)	NE [NE; NE]	2/79 (2,5)	NE [NE; NE]	4,06 [0,94; 17,54] 0,0418
Endocrine naive	4/20 (20,0)	NE [NE; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0897
Starting dose (p-value of the interaction term: 0,9882)					
150 mg	19/169 (11,2)	NE [NE; NE]	3/87 (3,4)	NE [NE; NE]	2,95 [0,87; 10,01] 0,0688
200 mg	18/76 (23,7)	NE [NE; NE]	0/41 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0009
Previous anti-estrogene therapy (p-value of the interaction term: 0,4040)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	17/109 (15,6)	NE [NE; NE]	2/52 (3,8)	NE [NE; NE]	3,88 [0,89; 16,86] 0,0504
No	20/136 (14,7)	NE [NE; NE]	1/76 (1,3)	NE [NE; NE]	11,55 [1,55; 86,15] 0,0025

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t224_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 225.1.2: Subgroups: adverse events according PT - Infections and infestations/Urinary tract infection - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,9873)					
< 65 years	13/147 (8,8)	NE [NE; NE]	4/72 (5,6)	NE [NE; NE]	1,41 [0,46; 4,32] 0,5508
≥ 65 years	11/98 (11,2)	NE [NE; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0088
Organs involved (p-value of the interaction term: 0,8644)					
1	16/112 (14,3)	NE [NE; NE]	2/49 (4,1)	NE [NE; NE]	3,63 [0,84; 15,80] 0,0655
2	5/73 (6,8)	NE [NE; NE]	1/36 (2,8)	NE [13,12; NE]	1,38 [0,15; 12,38] 0,7754
≥ 3	3/60 (5,0)	NE [NE; NE]	1/43 (2,3)	NE [NE; NE]	2,77 [0,28; 26,99] 0,3598
Nature of disease (p-value of the interaction term: 0,7713)					
Visceral	11/130 (8,5)	NE [NE; NE]	2/80 (2,5)	NE [NE; NE]	2,88 [0,63; 13,06] 0,1514
Bone only	8/71 (11,3)	NE [NE; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0538
Other	5/44 (11,4)	NE [NE; NE]	2/19 (10,5)	NE [21,27; NE]	1,29 [0,25; 6,68] 0,7601
ECOG-PS at Baseline (p-value of the interaction term: 0,9880)					
0	13/135 (9,6)	NE [NE; NE]	4/74 (5,4)	NE [NE; NE]	1,58 [0,51; 4,86] 0,4239
1	11/110 (10,0)	NE [NE; NE]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0211
Race (p-value of the interaction term: 0,1986)					
Caucasian	17/155 (11,0)	NE [NE; NE]	1/80 (1,3)	NE [NE; NE]	8,70 [1,16; 65,38] 0,0112
Asian	3/58 (5,2)	NE [NE; NE]	2/32 (6,3)	NE [21,27; NE]	0,72 [0,12; 4,46] 0,7251

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	4/17 (23,5)	NE [11,15; NE]	1/9 (11,1)	NE [4,31; NE]	1,73 [0,19; 16,09] 0,6273
Region (p-value of the interaction term: 0,2904)					
Europe	8/97 (8,2)	NE [NE; NE]	1/57 (1,8)	NE [NE; NE]	4,66 [0,58; 37,28] 0,1106
North America	13/92 (14,1)	NE [NE; NE]	1/39 (2,6)	NE [NE; NE]	5,11 [0,67; 39,14] 0,0801
Asian	3/56 (5,4)	NE [NE; NE]	2/32 (6,3)	NE [21,27; NE]	0,75 [0,12; 4,62] 0,7544
Measurable disease at baseline (p-value of the interaction term: 0,9894)					
Yes	16/169 (9,5)	NE [NE; NE]	4/94 (4,3)	NE [NE; NE]	2,02 [0,67; 6,07] 0,1992
No	8/76 (10,5)	NE [NE; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0392
Progesterone receptor (p-value of the interaction term: 0,3305)					
Positive	17/183 (9,3)	NE [NE; NE]	2/93 (2,2)	NE [NE; NE]	4,21 [0,97; 18,22] 0,0368
Negative	6/59 (10,2)	NE [NE; NE]	2/31 (6,5)	NE [NE; NE]	1,48 [0,30; 7,33] 0,6309
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9999)					
Primary resistance	1/57 (1,8)	NE [NE; NE]	0/35 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,5050
Secondary resistance	19/168 (11,3)	NE [NE; NE]	4/79 (5,1)	NE [NE; NE]	2,27 [0,77; 6,68] 0,1255
Endocrine naive	4/20 (20,0)	NE [NE; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0912
Starting dose (p-value of the interaction term: 0,5193)					
150 mg	15/169 (8,9)	NE [NE; NE]	3/87 (3,4)	NE [NE; NE]	2,26 [0,65; 7,81] 0,1873
200 mg	9/76 (11,8)	NE [NE; NE]	1/41 (2,4)	NE [NE; NE]	5,25 [0,67; 41,46] 0,0785
Previous anti-estrogene therapy (p-value of the interaction term: 0,8957)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	8/109 (7,3)	NE [NE; NE]	1/52 (1,9)	NE [NE; NE]	3,34 [0,42; 26,86] 0,2283
No	16/136 (11,8)	NE [NE; NE]	3/76 (3,9)	NE [NE; NE]	2,95 [0,86; 10,13] 0,0711

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t225_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 226.1.2: Subgroups: adverse events according PT - Gastrointestinal disorders/Vomiting - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,3585)					
< 65 years	43/147 (29,3)	NE [50,37; NE]	10/72 (13,9)	NE [NE; NE]	2,16 [1,08; 4,29] 0,0251
≥ 65 years	28/98 (28,6)	NE [23,38; NE]	5/56 (8,9)	NE [34,88; NE]	3,45 [1,33; 8,96] 0,0067
Organs involved (p-value of the interaction term: 0,3261)					
1	34/112 (30,4)	NE [44,09; NE]	3/49 (6,1)	NE [NE; NE]	5,39 [1,65; 17,59] 0,0017
2	16/73 (21,9)	NE [NE; NE]	4/36 (11,1)	NE [13,51; NE]	1,88 [0,63; 5,63] 0,2536
≥ 3	21/60 (35,0)	23,4 [18,90; NE]	8/43 (18,6)	NE [34,88; NE]	2,12 [0,94; 4,78] 0,0653
Nature of disease (p-value of the interaction term: 0,4052)					
Visceral	37/130 (28,5)	NE [NE; NE]	10/80 (12,5)	NE [34,88; NE]	2,29 [1,14; 4,62] 0,0170
Bone only	19/71 (26,8)	NE [50,37; NE]	1/29 (3,4)	NE [NE; NE]	8,33 [1,11; 62,41] 0,0135
Other	15/44 (34,1)	NE [19,17; NE]	4/19 (21,1)	NE [13,51; NE]	1,97 [0,65; 5,93] 0,2217
ECOG-PS at Baseline (p-value of the interaction term: 0,2760)					
0	46/135 (34,1)	50,4 [23,38; NE]	8/74 (10,8)	NE [34,88; NE]	3,32 [1,56; 7,04] 0,0009
1	25/110 (22,7)	NE [NE; NE]	7/54 (13,0)	NE [NE; NE]	1,86 [0,80; 4,29] 0,1419
Race (p-value of the interaction term: 0,4213)					
Caucasian	48/155 (31,0)	NE [23,38; NE]	11/80 (13,8)	NE [34,88; NE]	2,42 [1,26; 4,66] 0,0064
Asian	15/58 (25,9)	NE [50,37; NE]	1/32 (3,1)	NE [NE; NE]	8,18 [1,08; 62,20] 0,0155

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	6/17 (35,3)	NE [0,56; NE]	2/9 (22,2)	NE [0,07; NE]	1,44 [0,29; 7,23] 0,6522
Region (p-value of the interaction term: 0,2801)					
Europe	21/97 (21,6)	NE [NE; NE]	4/57 (7,0)	NE [34,88; NE]	3,20 [1,10; 9,34] 0,0241
North America	37/92 (40,2)	23,4 [18,90; NE]	10/39 (25,6)	NE [21,37; NE]	1,66 [0,82; 3,35] 0,1511
Asian	13/56 (23,2)	NE [50,37; NE]	1/32 (3,1)	NE [NE; NE]	7,38 [0,96; 56,71] 0,0243
Measurable disease at baseline (p-value of the interaction term: 0,1569)					
Yes	52/169 (30,8)	NE [NE; NE]	14/94 (14,9)	NE [34,88; NE]	2,11 [1,17; 3,82] 0,0111
No	19/76 (25,0)	NE [50,37; NE]	1/34 (2,9)	NE [NE; NE]	8,98 [1,20; 67,32] 0,0096
Progesterone receptor (p-value of the interaction term: 0,4970)					
Positive	50/183 (27,3)	NE [50,37; NE]	12/93 (12,9)	NE [NE; NE]	2,21 [1,18; 4,15] 0,0115
Negative	19/59 (32,2)	NE [8,94; NE]	3/31 (9,7)	NE [21,37; NE]	3,71 [1,10; 12,54] 0,0237
Sensitivity against endocrine therapy (p-value of the interaction term: 0,6366)					
Primary resistance	19/57 (33,3)	50,4 [22,98; NE]	3/35 (8,6)	NE [NE; NE]	3,26 [0,95; 11,14] 0,0463
Secondary resistance	43/168 (25,6)	NE [NE; NE]	10/79 (12,7)	NE [34,88; NE]	2,17 [1,09; 4,33] 0,0240
Endocrine naive	9/20 (45,0)	10,5 [0,39; NE]	2/14 (14,3)	NE [5,39; NE]	4,06 [0,87; 18,87] 0,0531
Starting dose (p-value of the interaction term: 0,1138)					
150 mg	40/169 (23,7)	NE [NE; NE]	11/87 (12,6)	NE [34,88; NE]	1,82 [0,93; 3,55] 0,0764
200 mg	31/76 (40,8)	NE [8,94; NE]	4/41 (9,8)	NE [NE; NE]	5,11 [1,80; 14,51] 0,0006
Previous anti-estrogene therapy (p-value of the interaction term: 0,1738)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	29/109 (26,6)	NE [NE; NE]	8/52 (15,4)	NE [34,88; NE]	1,72 [0,78; 3,76] 0,1716
No	42/136 (30,9)	NE [44,09; NE]	7/76 (9,2)	NE [NE; NE]	3,71 [1,66; 8,26] 0,0006

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t226_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 227.1.2: Subgroups: adverse events according PT - Investigations/Weight decreased - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,7853)					
< 65 years	21/147 (14,3)	NE [NE; NE]	3/72 (4,2)	NE [NE; NE]	3,16 [0,94; 10,60] 0,0497
≥ 65 years	20/98 (20,4)	NE [NE; NE]	3/56 (5,4)	NE [NE; NE]	4,29 [1,27; 14,42] 0,0101
Organs involved (p-value of the interaction term: 0,9626)					
1	21/112 (18,8)	NE [NE; NE]	4/49 (8,2)	NE [NE; NE]	2,34 [0,80; 6,84] 0,1083
2	12/73 (16,4)	NE [NE; NE]	0/36 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0219
≥ 3	8/60 (13,3)	NE [NE; NE]	2/43 (4,7)	NE [NE; NE]	2,99 [0,64; 14,10] 0,1450
Nature of disease (p-value of the interaction term: 0,7991)					
Visceral	17/130 (13,1)	NE [NE; NE]	2/80 (2,5)	NE [NE; NE]	4,83 [1,11; 20,95] 0,0200
Bone only	11/71 (15,5)	NE [NE; NE]	2/29 (6,9)	NE [NE; NE]	2,30 [0,51; 10,42] 0,2661
Other	13/44 (29,5)	NE [7,63; NE]	2/19 (10,5)	NE [21,93; NE]	3,39 [0,76; 15,04] 0,0888
ECOG-PS at Baseline (p-value of the interaction term: 0,4575)					
0	20/135 (14,8)	NE [NE; NE]	4/74 (5,4)	NE [NE; NE]	2,57 [0,88; 7,55] 0,0741
1	21/110 (19,1)	NE [NE; NE]	2/54 (3,7)	NE [NE; NE]	5,42 [1,27; 23,14] 0,0103
Race (p-value of the interaction term: 0,4521)					
Caucasian	27/155 (17,4)	NE [NE; NE]	3/80 (3,8)	NE [NE; NE]	4,60 [1,39; 15,16] 0,0058
Asian	8/58 (13,8)	NE [NE; NE]	3/32 (9,4)	NE [21,93; NE]	1,36 [0,36; 5,19] 0,6525

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	4/17 (23,5)	NE [9,34; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2191
Region (p-value of the interaction term: 0,2850)					
Europe	13/97 (13,4)	NE [NE; NE]	1/57 (1,8)	NE [NE; NE]	7,21 [0,94; 55,10] 0,0260
North America	21/92 (22,8)	NE [NE; NE]	2/39 (5,1)	NE [NE; NE]	4,71 [1,10; 20,12] 0,0210
Asian	7/56 (12,5)	NE [NE; NE]	3/32 (9,4)	NE [21,93; NE]	1,21 [0,31; 4,74] 0,7892
Measurable disease at baseline (p-value of the interaction term: 0,8421)					
Yes	28/169 (16,6)	NE [NE; NE]	4/94 (4,3)	NE [NE; NE]	3,77 [1,32; 10,76] 0,0076
No	13/76 (17,1)	NE [NE; NE]	2/34 (5,9)	NE [NE; NE]	3,01 [0,68; 13,37] 0,1284
Progesterone receptor (p-value of the interaction term: 0,7742)					
Positive	25/183 (13,7)	NE [NE; NE]	4/93 (4,3)	NE [NE; NE]	3,17 [1,10; 9,11] 0,0239
Negative	15/59 (25,4)	NE [24,43; NE]	2/31 (6,5)	NE [NE; NE]	4,13 [0,94; 18,08] 0,0403
Sensitivity against endocrine therapy (p-value of the interaction term: 0,8976)					
Primary resistance	7/57 (12,3)	NE [NE; NE]	0/35 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0619
Secondary resistance	28/168 (16,7)	NE [NE; NE]	5/79 (6,3)	NE [NE; NE]	2,70 [1,04; 7,01] 0,0327
Endocrine naive	6/20 (30,0)	NE [2,96; NE]	1/14 (7,1)	NE [5,75; NE]	4,87 [0,59; 40,49] 0,1045
Starting dose (p-value of the interaction term: 0,2182)					
150 mg	19/169 (11,2)	NE [NE; NE]	4/87 (4,6)	NE [NE; NE]	2,18 [0,74; 6,41] 0,1485
200 mg	22/76 (28,9)	NE [NE; NE]	2/41 (4,9)	NE [NE; NE]	7,36 [1,73; 31,33] 0,0015
Previous anti-estrogene therapy (p-value of the interaction term: 0,6270)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	13/109 (11,9)	NE [NE; NE]	1/52 (1,9)	NE [NE; NE]	5,89 [0,77; 45,06] 0,0525
No	28/136 (20,6)	NE [NE; NE]	5/76 (6,6)	NE [NE; NE]	3,30 [1,27; 8,54] 0,0092

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

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Table 228.1.2: Subgroups: adverse events according SOC - Blood and lymphatic system disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,9196)					
< 65 years	88/147 (59,9)	4,6 [1,87; 14,79]	8/72 (11,1)	NE [28,08; NE]	8,13 [3,94; 16,81] <,0001
≥ 65 years	54/98 (55,1)	7,5 [1,87; 18,54]	6/56 (10,7)	51,6 [NE; NE]	7,34 [3,15; 17,10] <,0001
Organs involved (p-value of the interaction term: 0,8201)					
1	74/112 (66,1)	3,8 [0,95; 11,28]	5/49 (10,2)	NE [25,61; NE]	9,84 [3,97; 24,38] <,0001
2	36/73 (49,3)	6,7 [2,33; NE]	3/36 (8,3)	NE [19,40; NE]	7,81 [2,40; 25,41] <,0001
≥ 3	32/60 (53,3)	10,2 [0,99; 19,36]	6/43 (14,0)	51,6 [40,57; NE]	9,08 [3,16; 26,04] <,0001
Nature of disease (p-value of the interaction term: 0,9712)					
Visceral	70/130 (53,8)	6,7 [2,56; 18,38]	8/80 (10,0)	51,6 [40,57; NE]	8,48 [3,89; 18,46] <,0001
Bone only	49/71 (69,0)	4,6 [0,95; 14,99]	4/29 (13,8)	NE [28,08; NE]	8,27 [2,97; 23,01] <,0001
Other	23/44 (52,3)	14,0 [0,95; NE]	2/19 (10,5)	NE [25,61; NE]	8,04 [1,88; 34,39] 0,0009
ECOG-PS at Baseline (p-value of the interaction term: 0,8469)					
0	77/135 (57,0)	6,7 [1,87; 17,56]	8/74 (10,8)	NE [28,08; NE]	7,52 [3,62; 15,59] <,0001
1	65/110 (59,1)	5,5 [1,51; 14,76]	6/54 (11,1)	51,6 [40,57; NE]	10,07 [4,03; 25,14] <,0001
Race (p-value of the interaction term: 0,6772)					
Caucasian	78/155 (50,3)	10,2 [3,78; 16,18]	8/80 (10,0)	NE [40,57; NE]	6,89 [3,32; 14,30] <,0001
Asian	46/58 (79,3)	1,0 [0,95; 1,08]	5/32 (15,6)	51,6 [25,61; NE]	14,69 [5,20; 41,47] <,0001

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	14/17 (82,4)	3,7 [0,49; 27,39]	1/9 (11,1)	NE [2,79; NE]	9,25 [1,21; 70,89] 0,0095
Region (p-value of the interaction term: 0,6006)					
Europe	46/97 (47,4)	15,1 [3,72; NE]	4/57 (7,0)	NE [40,57; NE]	8,89 [3,20; 24,74] <,0001
North America	52/92 (56,5)	8,6 [3,72; 18,54]	5/39 (12,8)	NE [28,08; NE]	5,79 [2,31; 14,51] <,0001
Asian	44/56 (78,6)	1,0 [0,95; 1,05]	5/32 (15,6)	51,6 [25,61; NE]	14,35 [5,07; 40,62] <,0001
Measurable disease at baseline (p-value of the interaction term: 0,7610)					
Yes	93/169 (55,0)	5,6 [1,94; 14,79]	9/94 (9,6)	51,6 [40,57; NE]	8,28 [4,17; 16,44] <,0001
No	49/76 (64,5)	4,7 [1,05; 14,99]	5/34 (14,7)	NE [28,08; NE]	7,25 [2,87; 18,30] <,0001
Progesterone receptor (p-value of the interaction term: 0,5193)					
Positive	108/183 (59,0)	5,6 [1,87; 14,76]	12/93 (12,9)	51,6 [40,57; NE]	7,59 [4,07; 14,15] <,0001
Negative	32/59 (54,2)	6,7 [0,99; 41,88]	2/31 (6,5)	NE [28,08; NE]	11,63 [2,78; 48,63] <,0001
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9688)					
Primary resistance	30/57 (52,6)	10,2 [0,95; NE]	3/35 (8,6)	NE [NE; NE]	7,60 [2,31; 25,00] <,0001
Secondary resistance	100/168 (59,5)	3,8 [1,87; 10,36]	9/79 (11,4)	NE [40,57; NE]	8,42 [4,24; 16,72] <,0001
Endocrine naive	12/20 (60,0)	11,3 [0,95; NE]	2/14 (14,3)	51,6 [28,08; NE]	6,48 [1,43; 29,27] 0,0057
Starting dose (p-value of the interaction term: 0,9348)					
150 mg	94/169 (55,6)	9,5 [3,72; 16,18]	8/87 (9,2)	NE [NE; NE]	8,16 [3,96; 16,81] <,0001
200 mg	48/76 (63,2)	1,4 [0,95; 6,71]	6/41 (14,6)	51,6 [28,08; NE]	7,92 [3,36; 18,68] <,0001
Previous anti-estrogene therapy (p-value of the interaction term: 0,1192)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	60/109 (55,0)	8,6 [2,33; 15,12]	8/52 (15,4)	NE [40,57; NE]	5,08 [2,42; 10,66] <,0001
No	82/136 (60,3)	3,7 [0,99; 14,04]	6/76 (7,9)	51,6 [51,55; NE]	11,74 [5,11; 26,94] <,0001

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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Table 229.1.2: Subgroups: adverse events according SOC - Eye disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,6646)					
< 65 years	31/147 (21,1)	NE [NE; NE]	6/72 (8,3)	NE [NE; NE]	2,34 [0,97; 5,61] 0,0502
≥ 65 years	17/98 (17,3)	NE [44,88; NE]	3/56 (5,4)	NE [NE; NE]	3,21 [0,94; 11,00] 0,0497
Organs involved (p-value of the interaction term: 0,2135)					
1	21/112 (18,8)	NE [NE; NE]	4/49 (8,2)	NE [NE; NE]	2,23 [0,76; 6,52] 0,1332
2	11/73 (15,1)	NE [44,19; NE]	3/36 (8,3)	NE [13,87; NE]	0,99 [0,27; 3,67] 0,9930
≥ 3	16/60 (26,7)	NE [9,07; NE]	2/43 (4,7)	NE [NE; NE]	6,47 [1,49; 28,19] 0,0042
Nature of disease (p-value of the interaction term: 0,5787)					
Visceral	25/130 (19,2)	NE [44,19; NE]	4/80 (5,0)	NE [NE; NE]	3,38 [1,17; 9,73] 0,0166
Bone only	18/71 (25,4)	NE [26,93; NE]	3/29 (10,3)	NE [NE; NE]	2,58 [0,76; 8,78] 0,1166
Other	5/44 (11,4)	NE [NE; NE]	2/19 (10,5)	NE [13,87; NE]	1,31 [0,25; 6,76] 0,7482
ECOG-PS at Baseline (p-value of the interaction term: 0,5429)					
0	26/135 (19,3)	NE [44,88; NE]	6/74 (8,1)	NE [NE; NE]	2,17 [0,89; 5,29] 0,0802
1	22/110 (20,0)	NE [44,19; NE]	3/54 (5,6)	NE [NE; NE]	3,49 [1,04; 11,67] 0,0305
Race (p-value of the interaction term: 0,9646)					
Caucasian	34/155 (21,9)	NE [44,22; NE]	8/80 (10,0)	NE [NE; NE]	2,00 [0,93; 4,33] 0,0716
Asian	6/58 (10,3)	NE [NE; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0804

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	6/17 (35,3)	NE [5,00; NE]	1/9 (11,1)	NE [8,35; NE]	2,29 [0,26; 20,00] 0,4411
Region (p-value of the interaction term: 0,9156)					
Europe	22/97 (22,7)	NE [44,88; NE]	5/57 (8,8)	NE [NE; NE]	2,57 [0,97; 6,79] 0,0482
North America	21/92 (22,8)	NE [26,93; NE]	4/39 (10,3)	NE [NE; NE]	1,87 [0,64; 5,47] 0,2463
Asian	5/56 (8,9)	NE [NE; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1119
Measurable disease at baseline (p-value of the interaction term: 0,8877)					
Yes	32/169 (18,9)	NE [NE; NE]	6/94 (6,4)	NE [NE; NE]	2,76 [1,15; 6,60] 0,0176
No	16/76 (21,1)	NE [26,93; NE]	3/34 (8,8)	NE [NE; NE]	2,49 [0,72; 8,60] 0,1349
Progesterone receptor (p-value of the interaction term: 0,3826)					
Positive	38/183 (20,8)	NE [44,88; NE]	6/93 (6,5)	NE [NE; NE]	3,12 [1,32; 7,40] 0,0063
Negative	10/59 (16,9)	NE [NE; NE]	3/31 (9,7)	NE [NE; NE]	1,66 [0,46; 6,04] 0,4372
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9252)					
Primary resistance	12/57 (21,1)	NE [23,97; NE]	2/35 (5,7)	NE [NE; NE]	3,42 [0,76; 15,35] 0,0880
Secondary resistance	30/168 (17,9)	NE [NE; NE]	5/79 (6,3)	NE [NE; NE]	2,73 [1,05; 7,05] 0,0310
Endocrine naive	6/20 (30,0)	NE [8,42; NE]	2/14 (14,3)	NE [13,87; NE]	1,98 [0,40; 9,84] 0,3935
Starting dose (p-value of the interaction term: 0,2141)					
150 mg	35/169 (20,7)	NE [44,22; NE]	8/87 (9,2)	NE [NE; NE]	1,91 [0,88; 4,13] 0,0958
200 mg	13/76 (17,1)	NE [NE; NE]	1/41 (2,4)	NE [NE; NE]	8,12 [1,06; 62,09] 0,0161
Previous anti-estrogene therapy (p-value of the interaction term: 0,2666)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	21/109 (19,3)	NE [44,88; NE]	5/52 (9,6)	NE [NE; NE]	1,71 [0,64; 4,56] 0,2763
No	27/136 (19,9)	NE [44,22; NE]	4/76 (5,3)	NE [NE; NE]	3,88 [1,35; 11,09] 0,0065

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t229_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 230.1.2: Subgroups: adverse events according SOC - Gastrointestinal disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,6685)					
< 65 years	139/147 (94,6)	0,2 [0,16; 0,26]	43/72 (59,7)	3,8 [2,17; 11,77]	4,06 [2,83; 5,81] <,0001
≥ 65 years	93/98 (94,9)	0,1 [0,10; 0,23]	38/56 (67,9)	3,6 [1,58; 7,96]	3,65 [2,47; 5,41] <,0001
Organs involved (p-value of the interaction term: 0,9907)					
1	107/112 (95,5)	0,2 [0,13; 0,20]	32/49 (65,3)	3,8 [1,51; 11,77]	3,70 [2,45; 5,58] <,0001
2	72/73 (98,6)	0,3 [0,16; 0,43]	22/36 (61,1)	3,7 [0,95; 9,27]	4,44 [2,67; 7,37] <,0001
≥ 3	53/60 (88,3)	0,2 [0,10; 0,23]	27/43 (62,8)	3,6 [1,74; 22,13]	3,79 [2,30; 6,25] <,0001
Nature of disease (p-value of the interaction term: 0,4358)					
Visceral	122/130 (93,8)	0,2 [0,16; 0,30]	51/80 (63,8)	3,6 [1,64; 4,73]	3,68 [2,61; 5,19] <,0001
Bone only	67/71 (94,4)	0,1 [0,10; 0,20]	19/29 (65,5)	8,0 [0,95; NE]	3,73 [2,18; 6,37] <,0001
Other	43/44 (97,7)	0,2 [0,10; 0,30]	11/19 (57,9)	3,8 [2,86; NE]	5,40 [2,67; 10,93] <,0001
ECOG-PS at Baseline (p-value of the interaction term: 0,1327)					
0	134/135 (99,3)	0,2 [0,13; 0,23]	47/74 (63,5)	3,7 [1,87; 9,27]	5,06 [3,53; 7,26] <,0001
1	98/110 (89,1)	0,2 [0,13; 0,33]	34/54 (63,0)	3,8 [1,74; 8,02]	3,07 [2,05; 4,57] <,0001
Race (p-value of the interaction term: 0,4011)					
Caucasian	142/155 (91,6)	0,2 [0,13; 0,26]	50/80 (62,5)	2,7 [1,51; 4,60]	3,32 [2,37; 4,63] <,0001
Asian	58/58 (100,0)	0,2 [0,13; 0,23]	22/32 (68,8)	5,9 [1,58; 11,54]	10,15 [4,95; 20,81] <,0001

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	17/17 (100,0)	0,2 [0,03; 0,56]	5/9 (55,6)	9,3 [0,07; NE]	4,00 [1,43; 11,23] 0,0049
Region (p-value of the interaction term: 0,4852)					
Europe	87/97 (89,7)	0,2 [0,13; 0,36]	32/57 (56,1)	3,5 [1,74; 39,42]	3,51 [2,32; 5,32] <,0001
North America	89/92 (96,7)	0,2 [0,13; 0,26]	27/39 (69,2)	2,7 [0,56; 4,57]	3,30 [2,09; 5,19] <,0001
Asian	56/56 (100,0)	0,2 [0,13; 0,23]	22/32 (68,8)	5,9 [1,58; 11,54]	10,02 [4,88; 20,57] <,0001
Measurable disease at baseline (p-value of the interaction term: 0,9276)					
Yes	161/169 (95,3)	0,2 [0,13; 0,26]	60/94 (63,8)	3,7 [1,74; 4,73]	4,18 [3,05; 5,74] <,0001
No	71/76 (93,4)	0,2 [0,10; 0,23]	21/34 (61,8)	8,0 [1,78; NE]	3,63 [2,18; 6,02] <,0001
Progesterone receptor (p-value of the interaction term: 0,7633)					
Positive	173/183 (94,5)	0,2 [0,13; 0,26]	60/93 (64,5)	3,8 [2,30; 8,02]	3,90 [2,87; 5,30] <,0001
Negative	56/59 (94,9)	0,2 [0,13; 0,26]	19/31 (61,3)	3,5 [0,53; NE]	3,38 [1,96; 5,80] <,0001
Sensitivity against endocrine therapy (p-value of the interaction term: 0,6549)					
Primary resistance	54/57 (94,7)	0,2 [0,10; 0,26]	22/35 (62,9)	3,7 [2,10; 4,73]	4,05 [2,40; 6,85] <,0001
Secondary resistance	160/168 (95,2)	0,2 [0,13; 0,23]	51/79 (64,6)	3,5 [1,68; 8,02]	3,57 [2,58; 4,94] <,0001
Endocrine naive	18/20 (90,0)	0,2 [0,10; 0,49]	8/14 (57,1)	15,0 [0,85; NE]	5,93 [2,15; 16,39] 0,0001
Previous anti-estrogene therapy (p-value of the interaction term: 0,2570)					
Yes	101/109 (92,7)	0,2 [0,13; 0,26]	29/52 (55,8)	8,0 [1,78; 39,42]	4,52 [2,93; 6,97] <,0001
No	131/136 (96,3)	0,2 [0,13; 0,23]	52/76 (68,4)	3,5 [1,68; 4,57]	3,41 [2,44; 4,76] <,0001

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 20.06.2019, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.					

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/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 231.1.2: Subgroups: adverse events according SOC - General disorders and administration site conditions - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,9582)					
< 65 years	97/147 (66,0)	5,3 [3,72; 10,16]	31/72 (43,1)	21,2 [5,29; NE]	1,69 [1,12; 2,53] 0,0105
≥ 65 years	71/98 (72,4)	1,9 [0,95; 5,95]	29/56 (51,8)	10,0 [3,52; NE]	1,67 [1,08; 2,58] 0,0200
Organs involved (p-value of the interaction term: 0,5507)					
1	77/112 (68,8)	3,7 [1,84; 6,31]	24/49 (49,0)	13,6 [3,19; NE]	1,64 [1,03; 2,59] 0,0339
2	50/73 (68,5)	6,0 [1,61; 10,16]	17/36 (47,2)	8,1 [0,95; NE]	1,31 [0,75; 2,28] 0,3367
≥ 3	41/60 (68,3)	5,6 [1,84; 9,50]	19/43 (44,2)	21,2 [4,57; NE]	2,16 [1,24; 3,77] 0,0056
Nature of disease (p-value of the interaction term: 0,8550)					
Visceral	91/130 (70,0)	5,2 [2,47; 8,48]	35/80 (43,8)	13,2 [5,26; NE]	1,78 [1,20; 2,63] 0,0033
Bone only	46/71 (64,8)	4,9 [1,94; 12,92]	14/29 (48,3)	13,6 [3,19; NE]	1,60 [0,88; 2,92] 0,1201
Other	31/44 (70,5)	1,4 [0,36; 7,10]	11/19 (57,9)	3,5 [0,30; NE]	1,39 [0,70; 2,78] 0,3503
ECOG-PS at Baseline (p-value of the interaction term: 0,1391)					
0	90/135 (66,7)	6,0 [3,72; 9,83]	38/74 (51,4)	10,0 [4,57; NE]	1,37 [0,94; 2,01] 0,1011
1	78/110 (70,9)	2,7 [1,35; 4,87]	22/54 (40,7)	19,4 [3,62; NE]	2,13 [1,32; 3,43] 0,0014
Race (p-value of the interaction term: 0,6030)					
Caucasian	116/155 (74,8)	2,6 [1,48; 3,95]	39/80 (48,8)	13,2 [3,65; 39,42]	1,82 [1,26; 2,62] 0,0011
Asian	33/58 (56,9)	9,8 [4,90; 17,33]	13/32 (40,6)	19,4 [8,09; NE]	1,61 [0,85; 3,07] 0,1420

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	10/17 (58,8)	6,3 [0,30; NE]	5/9 (55,6)	7,4 [0,10; NE]	1,09 [0,37; 3,22] 0,8773
Region (p-value of the interaction term: 0,9644)					
Europe	67/97 (69,1)	4,6 [1,87; 9,63]	26/57 (45,6)	21,2 [3,19; NE]	1,68 [1,06; 2,64] 0,0237
North America	69/92 (75,0)	2,1 [1,28; 4,67]	21/39 (53,8)	6,2 [2,17; 17,62]	1,56 [0,95; 2,55] 0,0756
Asian	32/56 (57,1)	9,8 [4,87; 14,33]	13/32 (40,6)	19,4 [8,09; NE]	1,65 [0,86; 3,15] 0,1243
Measurable disease at baseline (p-value of the interaction term: 0,5300)					
Yes	115/169 (68,0)	4,8 [2,73; 7,56]	45/94 (47,9)	10,2 [3,81; 39,42]	1,54 [1,09; 2,18] 0,0133
No	53/76 (69,7)	3,1 [1,68; 7,13]	15/34 (44,1)	19,4 [5,29; NE]	2,05 [1,15; 3,65] 0,0126
Sensitivity against endocrine therapy (p-value of the interaction term: 0,6245)					
Primary resistance	38/57 (66,7)	4,9 [1,94; 9,83]	16/35 (45,7)	8,1 [3,02; NE]	1,35 [0,75; 2,42] 0,3237
Secondary resistance	116/168 (69,0)	3,7 [1,87; 7,10]	37/79 (46,8)	19,4 [5,26; NE]	1,81 [1,25; 2,63] 0,0014
Endocrine naive	14/20 (70,0)	4,8 [0,49; 25,81]	7/14 (50,0)	5,3 [0,95; NE]	1,36 [0,55; 3,39] 0,5145
Starting dose (p-value of the interaction term: 0,3889)					
150 mg	116/169 (68,6)	4,8 [2,73; 7,36]	36/87 (41,4)	39,4 [9,96; NE]	1,82 [1,25; 2,64] 0,0016
200 mg	52/76 (68,4)	2,1 [0,92; 9,83]	24/41 (58,5)	5,3 [3,62; 19,36]	1,36 [0,84; 2,21] 0,2101
Previous anti-estrogene therapy (p-value of the interaction term: 0,6058)					
Yes	70/109 (64,2)	5,3 [3,72; 9,83]	20/52 (38,5)	39,4 [19,36; NE]	1,84 [1,11; 3,02] 0,0151
No	98/136 (72,1)	3,1 [1,41; 6,31]	40/76 (52,6)	8,1 [3,81; 13,64]	1,58 [1,09; 2,28] 0,0147

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 20.06.2019, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.					

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Table 232.1.2: Subgroups: adverse events according SOC - Infections and infestations - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,0976)					
< 65 years	69/147 (46,9)	15,1 [9,07; 27,29]	25/72 (34,7)	20,8 [12,03; NE]	1,28 [0,81; 2,03] 0,2859
≥ 65 years	41/98 (41,8)	15,4 [10,13; 24,10]	12/56 (21,4)	32,4 [32,35; NE]	2,47 [1,29; 4,71] 0,0046
Organs involved (p-value of the interaction term: 0,2273)					
1	55/112 (49,1)	12,0 [8,32; 24,10]	16/49 (32,7)	NE [13,81; NE]	1,63 [0,93; 2,84] 0,0847
2	29/73 (39,7)	13,0 [8,94; NE]	12/36 (33,3)	13,1 [8,94; NE]	1,00 [0,51; 1,99] 0,9889
≥ 3	26/60 (43,3)	16,6 [8,61; 27,42]	9/43 (20,9)	NE [NE; NE]	2,57 [1,20; 5,51] 0,0120
Nature of disease (p-value of the interaction term: 0,1574)					
Visceral	59/130 (45,4)	13,0 [8,78; 22,26]	19/80 (23,8)	NE [12,82; NE]	1,94 [1,16; 3,26] 0,0103
Bone only	34/71 (47,9)	19,9 [9,07; 31,69]	8/29 (27,6)	NE [13,81; NE]	1,97 [0,91; 4,26] 0,0808
Other	17/44 (38,6)	18,9 [6,61; NE]	10/19 (52,6)	18,2 [8,94; 22,06]	0,84 [0,38; 1,85] 0,6683
ECOG-PS at Baseline (p-value of the interaction term: 0,1841)					
0	67/135 (49,6)	10,6 [8,55; 21,60]	28/74 (37,8)	22,1 [10,65; NE]	1,42 [0,91; 2,21] 0,1192
1	43/110 (39,1)	21,2 [11,15; 27,42]	9/54 (16,7)	NE [NE; NE]	2,49 [1,21; 5,11] 0,0100
Race (p-value of the interaction term: 0,2438)					
Caucasian	73/155 (47,1)	12,0 [9,07; 21,60]	19/80 (23,8)	NE [18,25; NE]	2,28 [1,37; 3,78] 0,0011
Asian	22/58 (37,9)	22,3 [8,78; NE]	10/32 (31,3)	NE [13,12; NE]	1,24 [0,58; 2,63] 0,5749

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	11/17 (64,7)	8,9 [1,58; 43,73]	5/9 (55,6)	32,4 [0,23; NE]	0,97 [0,33; 2,87] 0,9600
Region (p-value of the interaction term: 0,3330)					
Europe	42/97 (43,3)	15,4 [9,90; 40,24]	12/57 (21,1)	NE [NE; NE]	2,27 [1,19; 4,32] 0,0103
North America	46/92 (50,0)	10,5 [7,63; 21,60]	15/39 (38,5)	12,0 [8,94; NE]	1,28 [0,71; 2,30] 0,4126
Asian	22/56 (39,3)	22,3 [8,78; NE]	10/32 (31,3)	NE [13,12; NE]	1,29 [0,61; 2,73] 0,5074
Measurable disease at baseline (p-value of the interaction term: 0,6365)					
Yes	76/169 (45,0)	15,1 [8,94; 24,10]	28/94 (29,8)	32,4 [12,82; NE]	1,58 [1,03; 2,44] 0,0362
No	34/76 (44,7)	19,9 [9,30; 31,69]	9/34 (26,5)	NE [13,81; NE]	1,92 [0,92; 4,02] 0,0790
Progesterone receptor (p-value of the interaction term: 0,0961)					
Positive	83/183 (45,4)	12,0 [9,90; 24,10]	24/93 (25,8)	NE [22,06; NE]	2,01 [1,27; 3,17] 0,0022
Negative	26/59 (44,1)	16,6 [9,07; 25,18]	12/31 (38,7)	9,5 [5,82; NE]	0,92 [0,46; 1,84] 0,8039
Sensitivity against endocrine therapy (p-value of the interaction term: 0,4550)					
Primary resistance	22/57 (38,6)	18,9 [10,52; NE]	10/35 (28,6)	13,8 [7,59; NE]	1,03 [0,48; 2,21] 0,9346
Secondary resistance	74/168 (44,0)	16,6 [9,90; 24,10]	22/79 (27,8)	32,4 [20,84; NE]	1,86 [1,15; 3,00] 0,0096
Endocrine naive	14/20 (70,0)	5,3 [2,01; 27,42]	5/14 (35,7)	NE [1,87; NE]	2,00 [0,72; 5,57] 0,1740
Starting dose (p-value of the interaction term: 0,1480)					
150 mg	71/169 (42,0)	18,9 [10,13; 31,69]	26/87 (29,9)	32,4 [18,25; NE]	1,35 [0,86; 2,12] 0,1875
200 mg	39/76 (51,3)	11,3 [8,55; 22,26]	11/41 (26,8)	NE [13,12; NE]	2,48 [1,27; 4,84] 0,0061
Previous anti-estrogene therapy (p-value of the interaction term: 0,6615)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	44/109 (40,4)	21,2 [9,30; NE]	12/52 (23,1)	NE [12,82; NE]	1,89 [1,00; 3,58] 0,0472
No	66/136 (48,5)	12,0 [9,07; 22,26]	25/76 (32,9)	22,1 [13,12; NE]	1,56 [0,98; 2,47] 0,0578

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 233.1.2: Subgroups: adverse events according SOC - Investigations - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,6503)					
< 65 years	66/147 (44,9)	19,0 [10,85; NE]	12/72 (16,7)	NE [42,54; NE]	2,99 [1,62; 5,54] 0,0002
≥ 65 years	43/98 (43,9)	23,0 [4,64; NE]	12/56 (21,4)	NE [31,33; NE]	2,46 [1,29; 4,66] 0,0046
Organs involved (p-value of the interaction term: 0,3085)					
1	54/112 (48,2)	23,0 [6,48; NE]	11/49 (22,4)	NE [21,93; NE]	2,51 [1,31; 4,81] 0,0040
2	33/73 (45,2)	15,9 [6,31; NE]	3/36 (8,3)	NE [NE; NE]	5,70 [1,75; 18,58] 0,0011
≥ 3	22/60 (36,7)	23,9 [14,47; NE]	10/43 (23,3)	42,5 [31,33; NE]	1,91 [0,90; 4,05] 0,0877
Nature of disease (p-value of the interaction term: 0,1938)					
Visceral	51/130 (39,2)	19,0 [12,62; NE]	17/80 (21,3)	42,5 [31,33; NE]	1,92 [1,11; 3,32] 0,0182
Bone only	37/71 (52,1)	23,0 [4,64; 38,04]	5/29 (17,2)	NE [20,98; NE]	3,75 [1,47; 9,57] 0,0030
Other	21/44 (47,7)	10,8 [3,16; NE]	2/19 (10,5)	NE [21,93; NE]	6,24 [1,46; 26,71] 0,0048
ECOG-PS at Baseline (p-value of the interaction term: 0,7463)					
0	60/135 (44,4)	23,0 [10,39; NE]	13/74 (17,6)	NE [42,54; NE]	2,90 [1,59; 5,28] 0,0003
1	49/110 (44,5)	18,5 [6,54; NE]	11/54 (20,4)	NE [24,00; NE]	2,44 [1,27; 4,71] 0,0058
Race (p-value of the interaction term: 0,7824)					
Caucasian	66/155 (42,6)	23,9 [9,01; NE]	14/80 (17,5)	NE [42,54; NE]	2,67 [1,50; 4,76] 0,0005
Asian	30/58 (51,7)	11,8 [4,24; NE]	7/32 (21,9)	31,3 [20,98; NE]	2,88 [1,26; 6,58] 0,0089

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	9/17 (52,9)	12,4 [0,49; NE]	3/9 (33,3)	NE [0,16; NE]	1,70 [0,46; 6,29] 0,4196
Region (p-value of the interaction term: 0,8879)					
Europe	33/97 (34,0)	NE [23,05; NE]	9/57 (15,8)	NE [42,54; NE]	2,28 [1,09; 4,77] 0,0248
North America	48/92 (52,2)	10,4 [3,72; 23,90]	8/39 (20,5)	NE [NE; NE]	2,96 [1,40; 6,26] 0,0029
Asian	28/56 (50,0)	12,6 [6,02; NE]	7/32 (21,9)	31,3 [20,98; NE]	2,72 [1,18; 6,26] 0,0143
Measurable disease at baseline (p-value of the interaction term: 0,2259)					
Yes	71/169 (42,0)	19,0 [11,84; NE]	19/94 (20,2)	NE [31,33; NE]	2,27 [1,37; 3,77] 0,0011
No	38/76 (50,0)	23,0 [6,02; 38,04]	5/34 (14,7)	NE [NE; NE]	4,16 [1,63; 10,61] 0,0012
Progesterone receptor (p-value of the interaction term: 0,5079)					
Positive	79/183 (43,2)	23,9 [12,43; NE]	19/93 (20,4)	NE [31,33; NE]	2,40 [1,45; 3,97] 0,0004
Negative	28/59 (47,5)	11,8 [3,72; 38,04]	5/31 (16,1)	NE [NE; NE]	3,44 [1,33; 8,93] 0,0066
Sensitivity against endocrine therapy (p-value of the interaction term: 0,6509)					
Primary resistance	21/57 (36,8)	23,9 [12,43; NE]	4/35 (11,4)	NE [NE; NE]	3,12 [1,07; 9,12] 0,0284
Secondary resistance	75/168 (44,6)	19,0 [10,39; NE]	14/79 (17,7)	NE [42,54; NE]	3,06 [1,73; 5,41] <,0001
Endocrine naive	13/20 (65,0)	3,8 [0,95; 38,04]	6/14 (42,9)	31,3 [1,87; NE]	1,80 [0,68; 4,76] 0,2264
Starting dose (p-value of the interaction term: 0,5052)					
150 mg	68/169 (40,2)	24,4 [14,73; NE]	15/87 (17,2)	NE [42,54; NE]	2,45 [1,40; 4,29] 0,0012
200 mg	41/76 (53,9)	6,0 [3,02; 23,21]	9/41 (22,0)	NE [24,00; NE]	3,37 [1,63; 6,95] 0,0005
Previous anti-estrogene therapy (p-value of the interaction term: 0,2738)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	42/109 (38,5)	NE [12,43; NE]	10/52 (19,2)	42,5 [24,00; NE]	2,06 [1,03; 4,12] 0,0356
No	67/136 (49,3)	14,7 [4,18; 30,28]	14/76 (18,4)	NE [31,33; NE]	3,33 [1,87; 5,93] <,0001

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t233_aesocpt_tte_sub_popa1_2.rtf
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Table 234.1.2: Subgroups: adverse events according SOC - Metabolism and nutrition disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,3000)					
< 65 years	58/147 (39,5)	36,1 [17,95; NE]	15/72 (20,8)	NE [42,51; NE]	1,87 [1,06; 3,30] 0,0284
≥ 65 years	56/98 (57,1)	3,7 [1,18; 16,60]	15/56 (26,8)	38,3 [38,30; NE]	2,84 [1,60; 5,03] 0,0002
Organs involved (p-value of the interaction term: 0,7656)					
1	57/112 (50,9)	16,4 [6,48; 39,75]	11/49 (22,4)	NE [NE; NE]	2,48 [1,30; 4,73] 0,0046
2	35/73 (47,9)	18,0 [9,34; 44,45]	8/36 (22,2)	NE [NE; NE]	2,18 [1,01; 4,72] 0,0417
≥ 3	22/60 (36,7)	28,4 [16,83; NE]	11/43 (25,6)	42,5 [38,30; NE]	1,71 [0,83; 3,53] 0,1443
Nature of disease (p-value of the interaction term: 0,2079)					
Visceral	58/130 (44,6)	21,5 [12,16; 44,45]	22/80 (27,5)	42,5 [38,30; NE]	1,72 [1,05; 2,82] 0,0281
Bone only	34/71 (47,9)	17,6 [8,88; NE]	6/29 (20,7)	NE [NE; NE]	2,60 [1,09; 6,20] 0,0257
Other	22/44 (50,0)	36,1 [1,28; NE]	2/19 (10,5)	NE [15,85; NE]	6,61 [1,55; 28,17] 0,0032
ECOG-PS at Baseline (p-value of the interaction term: 0,7491)					
0	66/135 (48,9)	18,8 [9,40; 39,75]	17/74 (23,0)	NE [38,30; NE]	2,33 [1,37; 3,98] 0,0014
1	48/110 (43,6)	21,5 [8,88; NE]	13/54 (24,1)	NE [NE; NE]	2,06 [1,12; 3,81] 0,0182
Race (p-value of the interaction term: 0,3485)					
Caucasian	78/155 (50,3)	14,5 [4,64; 24,10]	18/80 (22,5)	42,5 [38,30; NE]	2,54 [1,52; 4,24] 0,0002
Asian	24/58 (41,4)	44,4 [21,50; NE]	7/32 (21,9)	NE [15,85; NE]	2,02 [0,86; 4,73] 0,0982

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	8/17 (47,1)	33,0 [1,28; NE]	4/9 (44,4)	9,3 [1,78; NE]	0,90 [0,27; 3,07] 0,8795
Region (p-value of the interaction term: 0,8878)					
Europe	40/97 (41,2)	17,6 [12,16; NE]	11/57 (19,3)	NE [38,30; NE]	2,43 [1,24; 4,74] 0,0072
North America	51/92 (55,4)	9,3 [3,72; 24,10]	12/39 (30,8)	NE [9,30; NE]	1,92 [1,02; 3,60] 0,0398
Asian	23/56 (41,1)	44,4 [21,50; NE]	7/32 (21,9)	NE [15,85; NE]	1,99 [0,85; 4,68] 0,1075
Measurable disease at baseline (p-value of the interaction term: 0,9000)					
Yes	77/169 (45,6)	21,5 [12,16; 44,45]	22/94 (23,4)	NE [38,30; NE]	2,17 [1,35; 3,49] 0,0010
No	37/76 (48,7)	16,4 [8,68; NE]	8/34 (23,5)	NE [NE; NE]	2,35 [1,09; 5,05] 0,0248
Progesterone receptor (p-value of the interaction term: 0,2866)					
Positive	78/183 (42,6)	33,0 [16,41; NE]	23/93 (24,7)	NE [38,30; NE]	1,87 [1,17; 2,98] 0,0073
Negative	34/59 (57,6)	9,2 [3,02; 18,81]	7/31 (22,6)	NE [NE; NE]	3,15 [1,39; 7,11] 0,0035
Sensitivity against endocrine therapy (p-value of the interaction term: 0,3161)					
Primary resistance	31/57 (54,4)	17,6 [3,25; 44,45]	9/35 (25,7)	NE [10,16; NE]	2,04 [0,96; 4,34] 0,0597
Secondary resistance	70/168 (41,7)	33,0 [14,53; NE]	19/79 (24,1)	42,5 [38,30; NE]	1,92 [1,16; 3,19] 0,0104
Endocrine naive	13/20 (65,0)	4,6 [0,30; NE]	2/14 (14,3)	NE [NE; NE]	5,65 [1,27; 25,07] 0,0103
Previous anti-estrogene therapy (p-value of the interaction term: 0,2274)					
Yes	44/109 (40,4)	36,1 [18,81; NE]	13/52 (25,0)	42,5 [38,30; NE]	1,64 [0,88; 3,05] 0,1150
No	70/136 (51,5)	16,4 [8,68; 22,06]	17/76 (22,4)	NE [NE; NE]	2,75 [1,62; 4,68] <,0001

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 20.06.2019, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.					

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/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 235.1.2: Subgroups: adverse events according SOC - Nervous system disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,5018)					
< 65 years	77/147 (52,4)	14,2 [6,97; 20,98]	25/72 (34,7)	31,5 [15,16; NE]	1,50 [0,96; 2,36] 0,0749
≥ 65 years	44/98 (44,9)	27,4 [6,64; 44,48]	15/56 (26,8)	23,9 [19,36; NE]	1,74 [0,96; 3,15] 0,0652
Organs involved (p-value of the interaction term: 0,4575)					
1	60/112 (53,6)	12,3 [6,64; 22,82]	19/49 (38,8)	23,9 [13,48; NE]	1,36 [0,81; 2,30] 0,2405
2	31/73 (42,5)	21,7 [13,38; NE]	9/36 (25,0)	NE [5,62; NE]	1,54 [0,72; 3,28] 0,2572
≥ 3	30/60 (50,0)	43,8 [1,87; NE]	12/43 (27,9)	NE [19,36; NE]	2,23 [1,14; 4,37] 0,0163
Nature of disease (p-value of the interaction term: 0,6746)					
Visceral	62/130 (47,7)	21,0 [6,64; 44,48]	23/80 (28,8)	31,5 [19,36; NE]	1,69 [1,05; 2,74] 0,0296
Bone only	37/71 (52,1)	12,3 [6,97; 44,61]	12/29 (41,4)	23,9 [5,26; NE]	1,34 [0,70; 2,59] 0,3800
Other	22/44 (50,0)	21,7 [2,14; NE]	5/19 (26,3)	NE [5,62; NE]	2,11 [0,80; 5,59] 0,1242
ECOG-PS at Baseline (p-value of the interaction term: 0,3688)					
0	77/135 (57,0)	10,2 [5,56; 20,98]	24/74 (32,4)	NE [15,16; NE]	1,91 [1,20; 3,02] 0,0051
1	44/110 (40,0)	26,4 [15,12; NE]	16/54 (29,6)	31,5 [19,36; NE]	1,36 [0,76; 2,42] 0,2962
Race (p-value of the interaction term: 0,7831)					
Caucasian	78/155 (50,3)	15,1 [5,95; 26,40]	24/80 (30,0)	31,5 [15,16; NE]	1,78 [1,12; 2,81] 0,0126
Asian	31/58 (53,4)	17,1 [3,85; 44,48]	11/32 (34,4)	21,2 [15,55; NE]	1,45 [0,72; 2,93] 0,2955

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	9/17 (52,9)	7,1 [0,26; NE]	4/9 (44,4)	5,6 [0,10; NE]	1,29 [0,40; 4,23] 0,6763
Region (p-value of the interaction term: 0,5127)					
Europe	37/97 (38,1)	30,1 [15,12; NE]	17/57 (29,8)	NE [15,16; NE]	1,26 [0,71; 2,23] 0,4373
North America	54/92 (58,7)	4,5 [1,58; 14,20]	12/39 (30,8)	NE [5,62; NE]	2,21 [1,18; 4,15] 0,0110
Asian	30/56 (53,6)	17,1 [3,85; 44,48]	11/32 (34,4)	21,2 [15,55; NE]	1,43 [0,70; 2,89] 0,3201
Measurable disease at baseline (p-value of the interaction term: 0,9085)					
Yes	82/169 (48,5)	21,0 [6,64; 32,25]	28/94 (29,8)	31,5 [19,36; NE]	1,68 [1,09; 2,58] 0,0170
No	39/76 (51,3)	12,3 [6,97; 30,12]	12/34 (35,3)	23,9 [13,48; NE]	1,60 [0,84; 3,08] 0,1508
Progesterone receptor (p-value of the interaction term: 0,8383)					
Positive	95/183 (51,9)	16,1 [8,32; 21,67]	32/93 (34,4)	31,5 [15,55; NE]	1,61 [1,08; 2,41] 0,0179
Negative	24/59 (40,7)	44,5 [6,97; NE]	8/31 (25,8)	23,9 [23,93; NE]	1,61 [0,72; 3,62] 0,2444
Sensitivity against endocrine therapy (p-value of the interaction term: 0,2988)					
Primary resistance	29/57 (50,9)	17,1 [2,50; 32,25]	7/35 (20,0)	NE [13,48; NE]	2,68 [1,17; 6,16] 0,0156
Secondary resistance	79/168 (47,0)	21,1 [7,82; 44,48]	28/79 (35,4)	31,5 [15,55; NE]	1,36 [0,88; 2,09] 0,1652
Endocrine naive	13/20 (65,0)	7,0 [0,85; 43,76]	5/14 (35,7)	NE [1,87; NE]	2,03 [0,72; 5,71] 0,1735
Starting dose (p-value of the interaction term: 0,2898)					
150 mg	82/169 (48,5)	16,1 [7,82; 26,40]	29/87 (33,3)	23,9 [15,16; NE]	1,47 [0,96; 2,25] 0,0762
200 mg	39/76 (51,3)	17,1 [6,64; 32,25]	11/41 (26,8)	NE [21,24; NE]	2,17 [1,11; 4,24] 0,0202
Previous anti-estrogene therapy (p-value of the interaction term: 0,4958)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	54/109 (49,5)	16,1 [5,13; 30,12]	15/52 (28,8)	31,5 [15,16; NE]	1,98 [1,11; 3,50] 0,0176
No	67/136 (49,3)	17,1 [7,82; 32,25]	25/76 (32,9)	23,9 [15,55; NE]	1,47 [0,92; 2,33] 0,1015

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 236.1.2: Subgroups: adverse events according SOC - Renal and urinary disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,8667)					
< 65 years	25/147 (17,0)	NE [51,58; NE]	3/72 (4,2)	NE [30,38; NE]	3,48 [1,05; 11,58] 0,0304
≥ 65 years	11/98 (11,2)	NE [NE; NE]	2/56 (3,6)	NE [31,43; NE]	3,00 [0,66; 13,64] 0,1347
Organs involved (p-value of the interaction term: 0,5658)					
1	15/112 (13,4)	NE [51,58; NE]	4/49 (8,2)	NE [28,04; NE]	1,28 [0,42; 3,94] 0,6672
2	13/73 (17,8)	NE [NE; NE]	1/36 (2,8)	NE [31,43; NE]	5,34 [0,69; 41,31] 0,0726
≥ 3	8/60 (13,3)	NE [NE; NE]	0/43 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0127
Nature of disease (p-value of the interaction term: 0,1549)					
Visceral	21/130 (16,2)	NE [NE; NE]	1/80 (1,3)	NE [NE; NE]	12,03 [1,61; 89,64] 0,0019
Bone only	9/71 (12,7)	NE [51,58; NE]	3/29 (10,3)	NE [28,04; NE]	0,80 [0,21; 3,14] 0,7520
Other	6/44 (13,6)	NE [NE; NE]	1/19 (5,3)	NE [31,43; NE]	2,74 [0,33; 22,76] 0,3314
ECOG-PS at Baseline (p-value of the interaction term: 0,3356)					
0	20/135 (14,8)	NE [51,58; NE]	4/74 (5,4)	NE [30,38; NE]	2,34 [0,79; 6,89] 0,1129
1	16/110 (14,5)	NE [NE; NE]	1/54 (1,9)	NE [NE; NE]	7,20 [0,95; 54,45] 0,0255
Race (p-value of the interaction term: 0,9943)					
Caucasian	26/155 (16,8)	NE [NE; NE]	4/80 (5,0)	NE [NE; NE]	3,34 [1,16; 9,56] 0,0174
Asian	4/58 (6,9)	NE [51,58; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3411

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	6/17 (35,3)	27,4 [4,80; NE]	1/9 (11,1)	31,4 [NE; NE]	2,46 [0,29; 21,01] 0,3967
Region (p-value of the interaction term: 0,8756)					
Europe	13/97 (13,4)	NE [NE; NE]	2/57 (3,5)	NE [NE; NE]	3,92 [0,88; 17,37] 0,0522
North America	19/92 (20,7)	NE [NE; NE]	3/39 (7,7)	31,4 [28,04; NE]	2,42 [0,71; 8,23] 0,1448
Asian	4/56 (7,1)	NE [51,58; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3365
Measurable disease at baseline (p-value of the interaction term: 0,1149)					
Yes	26/169 (15,4)	NE [NE; NE]	2/94 (2,1)	NE [NE; NE]	6,81 [1,61; 28,73] 0,0025
No	10/76 (13,2)	NE [51,58; NE]	3/34 (8,8)	NE [28,04; NE]	1,04 [0,27; 3,96] 0,9571
Progesterone receptor (p-value of the interaction term: 0,4271)					
Positive	27/183 (14,8)	NE [51,58; NE]	3/93 (3,2)	NE [NE; NE]	4,02 [1,22; 13,32] 0,0137
Negative	8/59 (13,6)	NE [NE; NE]	2/31 (6,5)	NE [28,04; NE]	2,12 [0,45; 10,02] 0,3297
Sensitivity against endocrine therapy (p-value of the interaction term: 0,5964)					
Primary resistance	8/57 (14,0)	NE [51,58; NE]	2/35 (5,7)	NE [NE; NE]	1,90 [0,39; 9,31] 0,4189
Secondary resistance	24/168 (14,3)	NE [NE; NE]	2/79 (2,5)	NE [31,43; NE]	5,20 [1,22; 22,09] 0,0126
Endocrine naive	4/20 (20,0)	NE [NE; NE]	1/14 (7,1)	NE [28,04; NE]	2,73 [0,30; 24,47] 0,3501
Starting dose (p-value of the interaction term: 0,4145)					
150 mg	23/169 (13,6)	NE [NE; NE]	4/87 (4,6)	NE [31,43; NE]	2,49 [0,85; 7,24] 0,0839
200 mg	13/76 (17,1)	NE [51,58; NE]	1/41 (2,4)	NE [28,04; NE]	6,82 [0,89; 52,36] 0,0325
Previous anti-estrogene therapy (p-value of the interaction term: 0,8472)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	11/109 (10,1)	NE [NE; NE]	1/52 (1,9)	NE [NE; NE]	4,27 [0,55; 33,40] 0,1318
No	25/136 (18,4)	NE [51,58; NE]	4/76 (5,3)	NE [30,38; NE]	3,32 [1,15; 9,57] 0,0187

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t236_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 237.1.2: Subgroups: adverse events according SOC - Skin and subcutaneous tissue disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,1542)					
< 65 years	76/147 (51,7)	7,8 [6,25; 12,03]	14/72 (19,4)	NE [33,30; NE]	3,16 [1,79; 5,60] <,0001
≥ 65 years	41/98 (41,8)	37,1 [5,10; NE]	15/56 (26,8)	39,5 [18,54; NE]	1,66 [0,92; 3,01] 0,0911
Organs involved (p-value of the interaction term: 0,9022)					
1	53/112 (47,3)	8,1 [6,25; NE]	10/49 (20,4)	NE [33,30; NE]	2,63 [1,34; 5,18] 0,0036
2	34/73 (46,6)	9,0 [5,33; NE]	7/36 (19,4)	18,5 [11,38; NE]	2,36 [1,04; 5,36] 0,0334
≥ 3	30/60 (50,0)	8,5 [3,72; NE]	12/43 (27,9)	NE [15,65; NE]	2,16 [1,10; 4,24] 0,0216
ECOG-PS at Baseline (p-value of the interaction term: 0,4531)					
0	67/135 (49,6)	7,9 [6,25; NE]	20/74 (27,0)	39,5 [18,54; NE]	2,10 [1,28; 3,47] 0,0029
1	50/110 (45,5)	9,2 [5,10; NE]	9/54 (16,7)	NE [NE; NE]	3,00 [1,47; 6,10] 0,0015
Race (p-value of the interaction term: 0,9099)					
Caucasian	70/155 (45,2)	9,0 [5,79; NE]	15/80 (18,8)	NE [33,30; NE]	2,62 [1,50; 4,57] 0,0005
Asian	34/58 (58,6)	7,0 [2,43; 19,04]	9/32 (28,1)	NE [11,38; NE]	2,50 [1,20; 5,24] 0,0117
Other	9/17 (52,9)	8,1 [0,95; NE]	3/9 (33,3)	18,5 [0,72; NE]	1,89 [0,51; 7,03] 0,3357
Region (p-value of the interaction term: 0,1977)					
Europe	42/97 (43,3)	10,2 [6,44; NE]	8/57 (14,0)	NE [39,52; NE]	3,57 [1,67; 7,61] 0,0004
North America	42/92 (45,7)	7,4 [4,93; NE]	12/39 (30,8)	33,3 [12,00; NE]	1,45 [0,76; 2,77] 0,2531

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	33/56 (58,9)	7,0 [2,43; 19,04]	9/32 (28,1)	NE [11,38; NE]	2,48 [1,18; 5,19] 0,0131
Measurable disease at baseline (p-value of the interaction term: 0,4147)					
Yes	85/169 (50,3)	7,5 [5,33; 13,84]	20/94 (21,3)	NE [39,52; NE]	2,67 [1,64; 4,35] <,0001
No	32/76 (42,1)	15,6 [6,28; NE]	9/34 (26,5)	NE [33,30; NE]	1,79 [0,85; 3,76] 0,1183
Progesterone receptor (p-value of the interaction term: 0,6421)					
Positive	86/183 (47,0)	9,0 [6,31; NE]	21/93 (22,6)	NE [39,52; NE]	2,44 [1,52; 3,94] 0,0002
Negative	29/59 (49,2)	9,2 [3,72; NE]	8/31 (25,8)	33,3 [6,44; NE]	1,91 [0,87; 4,19] 0,0979
Sensitivity against endocrine therapy (p-value of the interaction term: 0,6760)					
Primary resistance	25/57 (43,9)	12,0 [5,33; NE]	7/35 (20,0)	NE [11,38; NE]	2,25 [0,97; 5,20] 0,0519
Secondary resistance	79/168 (47,0)	7,9 [6,28; NE]	16/79 (20,3)	NE [39,52; NE]	2,73 [1,59; 4,68] 0,0001
Endocrine naive	13/20 (65,0)	5,8 [1,87; NE]	6/14 (42,9)	33,3 [4,21; NE]	1,75 [0,66; 4,62] 0,2527
Starting dose (p-value of the interaction term: 0,1682)					
150 mg	83/169 (49,1)	8,1 [6,25; NE]	16/87 (18,4)	NE [39,52; NE]	2,94 [1,72; 5,02] <,0001
200 mg	34/76 (44,7)	9,2 [5,33; NE]	13/41 (31,7)	33,3 [11,38; NE]	1,68 [0,88; 3,18] 0,1094

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 238.1.2: Subgroups: adverse events according SOC - Vascular disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,6039)					
< 65 years	46/147 (31,3)	NE [31,43; NE]	12/72 (16,7)	NE [NE; NE]	1,84 [0,97; 3,47] 0,0563
≥ 65 years	26/98 (26,5)	NE [18,94; NE]	11/56 (19,6)	45,7 [25,81; NE]	1,36 [0,67; 2,75] 0,3954
Organs involved (p-value of the interaction term: 0,6720)					
1	34/112 (30,4)	NE [36,62; NE]	8/49 (16,3)	NE [25,81; NE]	1,98 [0,91; 4,27] 0,0779
2	22/73 (30,1)	NE [11,28; NE]	8/36 (22,2)	45,7 [NE; NE]	1,21 [0,53; 2,72] 0,6494
≥ 3	16/60 (26,7)	NE [17,13; NE]	7/43 (16,3)	50,6 [50,63; NE]	1,74 [0,72; 4,24] 0,2128
Nature of disease (p-value of the interaction term: 0,3078)					
Visceral	34/130 (26,2)	NE [31,43; NE]	11/80 (13,8)	50,6 [NE; NE]	1,79 [0,91; 3,54] 0,0883
Bone only	27/71 (38,0)	NE [10,16; NE]	6/29 (20,7)	NE [25,81; NE]	2,19 [0,90; 5,31] 0,0760
Other	11/44 (25,0)	NE [36,62; NE]	6/19 (31,6)	45,7 [7,92; NE]	0,76 [0,28; 2,05] 0,5877
ECOG-PS at Baseline (p-value of the interaction term: 0,6165)					
0	42/135 (31,1)	NE [27,39; NE]	15/74 (20,3)	NE [25,81; NE]	1,49 [0,82; 2,68] 0,1831
1	30/110 (27,3)	NE [31,43; NE]	8/54 (14,8)	50,6 [NE; NE]	1,90 [0,87; 4,15] 0,1011
Race (p-value of the interaction term: 0,7551)					
Caucasian	49/155 (31,6)	NE [NE; NE]	18/80 (22,5)	NE [25,81; NE]	1,38 [0,80; 2,37] 0,2402
Asian	12/58 (20,7)	NE [31,43; NE]	4/32 (12,5)	50,6 [NE; NE]	1,65 [0,53; 5,21] 0,3839

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	6/17 (35,3)	NE [2,24; NE]	1/9 (11,1)	45,7 [NE; NE]	2,48 [0,29; 21,51] 0,3939
Region (p-value of the interaction term: 0,7281)					
Europe	30/97 (30,9)	NE [18,94; NE]	13/57 (22,8)	NE [NE; NE]	1,32 [0,69; 2,53] 0,3955
North America	30/92 (32,6)	NE [14,99; NE]	6/39 (15,4)	45,7 [25,81; NE]	2,03 [0,84; 4,91] 0,1067
Asian	12/56 (21,4)	NE [31,43; NE]	4/32 (12,5)	50,6 [NE; NE]	1,70 [0,54; 5,36] 0,3562
Measurable disease at baseline (p-value of the interaction term: 0,3060)					
Yes	47/169 (27,8)	NE [36,62; NE]	18/94 (19,1)	50,6 [45,70; NE]	1,40 [0,81; 2,41] 0,2246
No	25/76 (32,9)	NE [13,08; NE]	5/34 (14,7)	NE [25,81; NE]	2,58 [0,99; 6,76] 0,0448
Progesterone receptor (p-value of the interaction term: 0,9640)					
Positive	55/183 (30,1)	NE [NE; NE]	17/93 (18,3)	50,6 [45,70; NE]	1,68 [0,98; 2,90] 0,0567
Negative	16/59 (27,1)	NE [10,16; NE]	5/31 (16,1)	NE [NE; NE]	1,62 [0,59; 4,44] 0,3446
Sensitivity against endocrine therapy (p-value of the interaction term: 0,6660)					
Primary resistance	18/57 (31,6)	NE [17,13; NE]	4/35 (11,4)	25,8 [NE; NE]	2,38 [0,80; 7,13] 0,1096
Secondary resistance	45/168 (26,8)	NE [NE; NE]	14/79 (17,7)	NE [45,70; NE]	1,56 [0,85; 2,83] 0,1443
Endocrine naive	9/20 (45,0)	10,2 [3,72; NE]	5/14 (35,7)	50,6 [0,95; NE]	1,36 [0,45; 4,16] 0,5827
Starting dose (p-value of the interaction term: 0,2030)					
150 mg	52/169 (30,8)	NE [31,43; NE]	13/87 (14,9)	NE [45,70; NE]	2,03 [1,10; 3,72] 0,0203
200 mg	20/76 (26,3)	NE [17,13; NE]	10/41 (24,4)	50,6 [50,63; NE]	1,11 [0,52; 2,37] 0,7835
Previous anti-estrogene therapy (p-value of the interaction term: 0,7227)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	32/109 (29,4)	NE [36,62; NE]	8/52 (15,4)	NE [NE; NE]	1,88 [0,86; 4,07] 0,1057
No	40/136 (29,4)	NE [31,43; NE]	15/76 (19,7)	50,6 [25,81; NE]	1,55 [0,85; 2,81] 0,1448

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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Table 239.1.2: Subgroups: serious adverse events according SOC - Infections and infestations - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,9916)					
< 65 years	12/147 (8,2)	NE [NE; NE]	1/72 (1,4)	NE [NE; NE]	5,07 [0,66; 39,02] 0,0826
≥ 65 years	4/98 (4,1)	NE [NE; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1159
Nature of disease (p-value of the interaction term: 0,9999)					
Visceral	9/130 (6,9)	NE [NE; NE]	1/80 (1,3)	NE [NE; NE]	4,54 [0,57; 35,96] 0,1164
Bone only	5/71 (7,0)	NE [NE; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1329
Other	2/44 (4,5)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3477
ECOG-PS at Baseline (p-value of the interaction term: 0,9901)					
0	7/135 (5,2)	NE [NE; NE]	0/74 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0564
1	9/110 (8,2)	NE [NE; NE]	1/54 (1,9)	NE [NE; NE]	4,10 [0,52; 32,39] 0,1467
Race (p-value of the interaction term: 1,0000)					
Caucasian	11/155 (7,1)	NE [NE; NE]	1/80 (1,3)	NE [NE; NE]	5,20 [0,67; 40,29] 0,0780
Asian	1/58 (1,7)	NE [NE; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,5127
Other	3/17 (17,6)	NE [8,88; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2172
Region (p-value of the interaction term: 0,9999)					
Europe	6/97 (6,2)	NE [NE; NE]	0/57 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0677
North America	9/92 (9,8)	NE [NE; NE]	1/39 (2,6)	NE [NE; NE]	3,18 [0,40; 25,28] 0,2471

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	1/56 (1,8)	NE [NE; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,5050
Measurable disease at baseline (p-value of the interaction term: 0,9926)					
Yes	11/169 (6,5)	NE [NE; NE]	1/94 (1,1)	NE [NE; NE]	5,32 [0,69; 41,31] 0,0733
No	5/76 (6,6)	NE [NE; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1188
Progesterone receptor (p-value of the interaction term: 0,9920)					
Positive	12/183 (6,6)	NE [NE; NE]	0/93 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0154
Negative	4/59 (6,8)	NE [NE; NE]	1/31 (3,2)	NE [NE; NE]	1,84 [0,20; 16,58] 0,5795
Sensitivity against endocrine therapy (p-value of the interaction term: 1,0000)					
Primary resistance	5/57 (8,8)	NE [NE; NE]	0/35 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1532
Secondary resistance	10/168 (6,0)	NE [NE; NE]	1/79 (1,3)	NE [NE; NE]	4,79 [0,61; 37,42] 0,0987
Endocrine naive	1/20 (5,0)	NE [NE; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3778
Starting dose (p-value of the interaction term: 0,9922)					
150 mg	11/169 (6,5)	NE [NE; NE]	1/87 (1,1)	NE [NE; NE]	4,89 [0,63; 37,90] 0,0928
200 mg	5/76 (6,6)	NE [NE; NE]	0/41 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0853

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 240.1.2: Subgroups: adverse events with CTCAE grade >= 3 according PT - Blood and lymphatic system disorders/Anaemia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,5973)					
< 65 years	14/147 (9,5)	NE [NE; NE]	1/72 (1,4)	NE [NE; NE]	5,61 [0,74; 42,78] 0,0607
≥ 65 years	5/98 (5,1)	NE [NE; NE]	1/56 (1,8)	NE [NE; NE]	2,56 [0,29; 22,42] 0,3773
Organs involved (p-value of the interaction term: 0,9993)					
1	9/112 (8,0)	NE [NE; NE]	1/49 (2,0)	NE [26,37; NE]	3,24 [0,41; 25,90] 0,2403
2	6/73 (8,2)	NE [NE; NE]	0/36 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1811
≥ 3	4/60 (6,7)	NE [NE; NE]	1/43 (2,3)	NE [NE; NE]	3,09 [0,34; 27,66] 0,2882
Nature of disease (p-value of the interaction term: 0,3984)					
Visceral	10/130 (7,7)	NE [NE; NE]	1/80 (1,3)	NE [NE; NE]	4,81 [0,61; 37,85] 0,0996
Bone only	8/71 (11,3)	NE [NE; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0704
Other	1/44 (2,3)	NE [NE; NE]	1/19 (5,3)	NE [26,37; NE]	0,46 [0,03; 7,29] 0,5684
ECOG-PS at Baseline (p-value of the interaction term: 0,9909)					
0	12/135 (8,9)	NE [NE; NE]	2/74 (2,7)	NE [NE; NE]	2,72 [0,60; 12,26] 0,1739
1	7/110 (6,4)	NE [NE; NE]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0897
Race (p-value of the interaction term: 0,9999)					
Caucasian	9/155 (5,8)	NE [NE; NE]	0/80 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0561
Asian	9/58 (15,5)	NE [NE; NE]	2/32 (6,3)	NE [26,37; NE]	2,30 [0,49; 10,81] 0,2767

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	1/17 (5,9)	NE [NE; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4386
Region (p-value of the interaction term: 0,9999)					
Europe	5/97 (5,2)	NE [NE; NE]	0/57 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1034
North America	5/92 (5,4)	NE [NE; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1859
Asian	9/56 (16,1)	NE [NE; NE]	2/32 (6,3)	NE [26,37; NE]	2,36 [0,50; 11,09] 0,2618
Measurable disease at baseline (p-value of the interaction term: 0,9916)					
Yes	13/169 (7,7)	NE [NE; NE]	2/94 (2,1)	NE [NE; NE]	2,93 [0,66; 13,06] 0,1387
No	6/76 (7,9)	NE [NE; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1086
Progesterone receptor (p-value of the interaction term: 0,4078)					
Positive	15/183 (8,2)	NE [NE; NE]	1/93 (1,1)	NE [NE; NE]	6,27 [0,82; 47,70] 0,0425
Negative	4/59 (6,8)	NE [NE; NE]	1/31 (3,2)	NE [NE; NE]	1,91 [0,21; 17,11] 0,5531
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9999)					
Primary resistance	5/57 (8,8)	NE [NE; NE]	0/35 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1876
Secondary resistance	13/168 (7,7)	NE [NE; NE]	2/79 (2,5)	NE [NE; NE]	2,75 [0,62; 12,26] 0,1671
Endocrine naive	1/20 (5,0)	NE [NE; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4533
Starting dose (p-value of the interaction term: 0,9761)					
150 mg	11/169 (6,5)	NE [NE; NE]	1/87 (1,1)	NE [NE; NE]	4,24 [0,54; 33,23] 0,1343
200 mg	8/76 (10,5)	NE [NE; NE]	1/41 (2,4)	NE [NE; NE]	4,38 [0,55; 35,07] 0,1288
Previous anti-estrogene therapy (p-value of the interaction term: 0,9906)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	8/109 (7,3)	NE [NE; NE]	0/52 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0757
No	11/136 (8,1)	NE [NE; NE]	2/76 (2,6)	NE [NE; NE]	2,67 [0,59; 12,10] 0,1845

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

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Table 241.1.2: Subgroups: adverse events with CTCAE grade >= 3 according PT - Gastrointestinal disorders/Diarrhoea - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,9859)					
< 65 years	22/147 (15,0)	NE [NE; NE]	0/72 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0013
≥ 65 years	13/98 (13,3)	NE [NE; NE]	1/56 (1,8)	NE [NE; NE]	7,99 [1,04; 61,08] 0,0172
Organs involved (p-value of the interaction term: 0,9999)					
1	18/112 (16,1)	NE [NE; NE]	0/49 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0043
2	8/73 (11,0)	NE [NE; NE]	1/36 (2,8)	NE [NE; NE]	3,41 [0,42; 27,61] 0,2210
≥ 3	9/60 (15,0)	NE [NE; NE]	0/43 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0086
Nature of disease (p-value of the interaction term: 0,9999)					
Visceral	16/130 (12,3)	NE [48,56; NE]	1/80 (1,3)	NE [NE; NE]	8,65 [1,14; 65,59] 0,0120
Bone only	12/71 (16,9)	NE [NE; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0189
Other	7/44 (15,9)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0651
ECOG-PS at Baseline (p-value of the interaction term: 0,9884)					
0	20/135 (14,8)	NE [NE; NE]	1/74 (1,4)	NE [NE; NE]	10,59 [1,42; 79,04] 0,0041
1	15/110 (13,6)	NE [NE; NE]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0053
Race (p-value of the interaction term: 0,9999)					
Caucasian	21/155 (13,5)	NE [NE; NE]	0/80 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0008
Asian	8/58 (13,8)	NE [NE; NE]	1/32 (3,1)	NE [NE; NE]	4,12 [0,51; 33,31] 0,1499

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	3/17 (17,6)	48,6 [NE; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2745
Region (p-value of the interaction term: 0,9999)					
Europe	12/97 (12,4)	NE [NE; NE]	0/57 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0081
North America	15/92 (16,3)	NE [48,56; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0108
Asian	8/56 (14,3)	NE [NE; NE]	1/32 (3,1)	NE [NE; NE]	4,25 [0,53; 34,37] 0,1397
Measurable disease at baseline (p-value of the interaction term: 0,9903)					
Yes	21/169 (12,4)	NE [NE; NE]	1/94 (1,1)	NE [NE; NE]	10,86 [1,46; 80,87] 0,0035
No	14/76 (18,4)	NE [NE; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0077
Progesterone receptor (p-value of the interaction term: 0,9918)					
Positive	30/183 (16,4)	NE [NE; NE]	1/93 (1,1)	NE [NE; NE]	15,33 [2,09; 112,55] 0,0003
Negative	5/59 (8,5)	NE [NE; NE]	0/31 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0982
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9999)					
Primary resistance	8/57 (14,0)	NE [44,58; NE]	1/35 (2,9)	NE [NE; NE]	4,22 [0,52; 34,28] 0,1429
Secondary resistance	23/168 (13,7)	NE [NE; NE]	0/79 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0010
Endocrine naive	4/20 (20,0)	NE [NE; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0822
Starting dose (p-value of the interaction term: 0,9859)					
150 mg	20/169 (11,8)	NE [NE; NE]	0/87 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0019
200 mg	15/76 (19,7)	NE [NE; NE]	1/41 (2,4)	NE [NE; NE]	8,90 [1,17; 67,46] 0,0104
Previous anti-estrogene therapy (p-value of the interaction term: 0,9884)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	17/109 (15,6)	NE [48,56; NE]	0/52 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0079
No	18/136 (13,2)	NE [NE; NE]	1/76 (1,3)	NE [NE; NE]	10,87 [1,45; 81,37] 0,0036

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t241_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 242.1.2: Subgroups: adverse events with CTCAE grade >= 3 according PT - Blood and lymphatic system disorders/Leukopenia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,9999)					
< 65 years	11/147 (7,5)	NE [NE; NE]	0/72 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0306
≥ 65 years	10/98 (10,2)	NE [NE; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0144
Organs involved (p-value of the interaction term: 1,0000)					
1	13/112 (11,6)	NE [NE; NE]	0/49 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0217
2	5/73 (6,8)	NE [NE; NE]	0/36 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1174
≥ 3	3/60 (5,0)	NE [NE; NE]	0/43 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1390
Nature of disease (p-value of the interaction term: 1,0000)					
Visceral	6/130 (4,6)	NE [NE; NE]	0/80 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0559
Bone only	12/71 (16,9)	NE [NE; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0256
Other	3/44 (6,8)	NE [NE; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2323
ECOG-PS at Baseline (p-value of the interaction term: 0,9999)					
0	13/135 (9,6)	NE [NE; NE]	0/74 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0117
1	8/110 (7,3)	NE [NE; NE]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0468
Race (p-value of the interaction term: 1,0000)					
Caucasian	10/155 (6,5)	NE [NE; NE]	0/80 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0311
Asian	8/58 (13,8)	NE [NE; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0311

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	3/17 (17,6)	NE [20,42; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3196
Measurable disease at baseline (p-value of the interaction term: 0,9998)					
Yes	9/169 (5,3)	NE [NE; NE]	0/94 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0263
No	12/76 (15,8)	NE [NE; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0204
Progesterone receptor (p-value of the interaction term: 0,9997)					
Positive	19/183 (10,4)	NE [NE; NE]	0/93 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0024
Negative	2/59 (3,4)	NE [NE; NE]	0/31 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3011
Sensitivity against endocrine therapy (p-value of the interaction term: 1,0000)					
Primary resistance	8/57 (14,0)	NE [43,56; NE]	0/35 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0578
Secondary resistance	13/168 (7,7)	NE [NE; NE]	0/79 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0131
Endocrine naive	0/20 (0,0)	NE [NE; NE]	0/14 (0,0)	NE [NE; NE]	NE
Starting dose (p-value of the interaction term: 1,0000)					
150 mg	15/169 (8,9)	NE [NE; NE]	0/87 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0089
200 mg	6/76 (7,9)	NE [NE; NE]	0/41 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0661
Previous anti-estrogene therapy (p-value of the interaction term: 0,9999)					
Yes	8/109 (7,3)	NE [NE; NE]	0/52 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0551
No	13/136 (9,6)	NE [NE; NE]	0/76 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0088

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 20.06.2019, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.					

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t242_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 243.1.2: Subgroups: adverse events with CTCAE grade >= 3 according PT - Blood and lymphatic system disorders/Neutropenia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,9839)					
< 65 years	42/147 (28,6)	NE [30,31; NE]	2/72 (2,8)	NE [NE; NE]	11,07 [2,68; 45,74] <,0001
≥ 65 years	20/98 (20,4)	NE [NE; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0003
Organs involved (p-value of the interaction term: 0,9548)					
1	31/112 (27,7)	NE [35,01; NE]	0/49 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0001
2	17/73 (23,3)	NE [NE; NE]	1/36 (2,8)	NE [19,40; NE]	8,41 [1,12; 63,25] 0,0132
≥ 3	14/60 (23,3)	NE [30,31; NE]	1/43 (2,3)	NE [NE; NE]	12,15 [1,59; 92,67] 0,0021
Nature of disease (p-value of the interaction term: 0,8357)					
Visceral	27/130 (20,8)	NE [NE; NE]	1/80 (1,3)	NE [NE; NE]	17,19 [2,33; 126,55] 0,0001
Bone only	22/71 (31,0)	NE [29,49; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0013
Other	13/44 (29,5)	NE [14,79; NE]	1/19 (5,3)	NE [NE; NE]	7,06 [0,92; 54,03] 0,0283
ECOG-PS at Baseline (p-value of the interaction term: 0,9839)					
0	35/135 (25,9)	NE [NE; NE]	2/74 (2,7)	NE [NE; NE]	9,95 [2,39; 41,40] <,0001
1	27/110 (24,5)	NE [18,38; NE]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Race (p-value of the interaction term: 0,9586)					
Caucasian	27/155 (17,4)	NE [NE; NE]	1/80 (1,3)	NE [NE; NE]	14,36 [1,95; 105,70] 0,0005
Asian	28/58 (48,3)	14,8 [1,08; NE]	1/32 (3,1)	NE [NE; NE]	21,31 [2,90; 156,88] <,0001

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	4/17 (23,5)	NE [30,31; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2954
Region (p-value of the interaction term: 0,6891)					
Europe	19/97 (19,6)	NE [NE; NE]	0/57 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0004
North America	16/92 (17,4)	NE [NE; NE]	1/39 (2,6)	NE [19,40; NE]	5,86 [0,77; 44,49] 0,0525
Asian	27/56 (48,2)	14,8 [1,08; NE]	1/32 (3,1)	NE [NE; NE]	21,44 [2,91; 158,09] <,0001
Measurable disease at baseline (p-value of the interaction term: 0,9865)					
Yes	40/169 (23,7)	NE [NE; NE]	2/94 (2,1)	NE [NE; NE]	12,07 [2,92; 49,97] <,0001
No	22/76 (28,9)	NE [29,49; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0008
Progesterone receptor (p-value of the interaction term: 0,9884)					
Positive	48/183 (26,2)	NE [NE; NE]	2/93 (2,2)	NE [NE; NE]	13,45 [3,27; 55,38] <,0001
Negative	13/59 (22,0)	NE [NE; NE]	0/31 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0062
Sensitivity against endocrine therapy (p-value of the interaction term: 0,6808)					
Primary resistance	12/57 (21,1)	NE [35,01; NE]	1/35 (2,9)	NE [NE; NE]	6,08 [0,78; 47,47] 0,0499
Secondary resistance	44/168 (26,2)	NE [NE; NE]	1/79 (1,3)	NE [NE; NE]	24,25 [3,34; 176,06] <,0001
Endocrine naive	6/20 (30,0)	NE [1,08; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0314
Starting dose (p-value of the interaction term: 0,9866)					
150 mg	40/169 (23,7)	NE [NE; NE]	0/87 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
200 mg	22/76 (28,9)	NE [NE; NE]	2/41 (4,9)	NE [NE; NE]	7,20 [1,69; 30,66] 0,0018
Previous anti-estrogene therapy (p-value of the interaction term: 0,9874)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	31/109 (28,4)	NE [29,49; NE]	2/52 (3,8)	NE [NE; NE]	8,13 [1,94; 33,98] 0,0006
No	31/136 (22,8)	NE [NE; NE]	0/76 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t243_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 244.1.2: Subgroups: time to adverse events with CTCAE grade >= 3 according SOC - Blood and lymphatic system disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,6516)					
< 65 years	55/147 (37,4)	35,0 [17,56; NE]	3/72 (4,2)	NE [NE; NE]	10,35 [3,24; 33,09] <,0001
≥ 65 years	27/98 (27,6)	NE [NE; NE]	1/56 (1,8)	NE [NE; NE]	18,27 [2,48; 134,48] <,0001
Organs involved (p-value of the interaction term: 0,8663)					
1	39/112 (34,8)	41,3 [20,42; NE]	1/49 (2,0)	NE [25,61; NE]	19,20 [2,64; 139,88] <,0001
2	23/73 (31,5)	NE [26,73; NE]	1/36 (2,8)	NE [19,40; NE]	11,02 [1,48; 81,79] 0,0032
≥ 3	20/60 (33,3)	NE [10,32; NE]	2/43 (4,7)	NE [NE; NE]	9,62 [2,23; 41,43] 0,0002
Nature of disease (p-value of the interaction term: 0,6365)					
Visceral	39/130 (30,0)	NE [26,73; NE]	2/80 (2,5)	NE [NE; NE]	12,81 [3,09; 53,08] <,0001
Bone only	27/71 (38,0)	35,0 [15,12; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0002
Other	16/44 (36,4)	NE [9,34; NE]	2/19 (10,5)	NE [25,61; NE]	4,75 [1,09; 20,74] 0,0223
ECOG-PS at Baseline (p-value of the interaction term: 0,9807)					
0	47/135 (34,8)	41,3 [26,73; NE]	4/74 (5,4)	NE [NE; NE]	7,16 [2,58; 19,88] <,0001
1	35/110 (31,8)	NE [15,91; NE]	0/54 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Race (p-value of the interaction term: 0,8034)					
Caucasian	40/155 (25,8)	NE [36,69; NE]	1/80 (1,3)	NE [NE; NE]	21,73 [2,99; 158,08] <,0001
Asian	33/58 (56,9)	6,7 [1,05; 18,38]	3/32 (9,4)	NE [25,61; NE]	9,61 [2,93; 31,47] <,0001

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	6/17 (35,3)	41,3 [10,16; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1357
Region (p-value of the interaction term: 0,9967)					
Europe	27/97 (27,8)	NE [26,73; NE]	0/57 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
North America	23/92 (25,0)	NE [35,01; NE]	1/39 (2,6)	NE [19,40; NE]	8,82 [1,19; 65,48] 0,0101
Asian	32/56 (57,1)	6,7 [1,05; 18,38]	3/32 (9,4)	NE [25,61; NE]	9,83 [2,99; 32,29] <,0001
Measurable disease at baseline (p-value of the interaction term: 0,9838)					
Yes	57/169 (33,7)	41,3 [20,42; NE]	4/94 (4,3)	NE [NE; NE]	8,91 [3,23; 24,55] <,0001
No	25/76 (32,9)	35,0 [17,56; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0002
Progesterone receptor (p-value of the interaction term: 0,7380)					
Positive	66/183 (36,1)	36,9 [20,42; NE]	3/93 (3,2)	NE [NE; NE]	13,09 [4,11; 41,64] <,0001
Negative	15/59 (25,4)	NE [15,91; NE]	1/31 (3,2)	NE [NE; NE]	8,79 [1,16; 66,56] 0,0108
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9954)					
Primary resistance	20/57 (35,1)	36,7 [17,56; NE]	1/35 (2,9)	NE [NE; NE]	10,53 [1,40; 79,23] 0,0044
Secondary resistance	55/168 (32,7)	NE [26,73; NE]	3/79 (3,8)	NE [NE; NE]	10,63 [3,33; 34,00] <,0001
Endocrine naive	7/20 (35,0)	NE [1,08; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0195
Starting dose (p-value of the interaction term: 0,2035)					
150 mg	54/169 (32,0)	41,3 [26,73; NE]	1/87 (1,1)	NE [NE; NE]	29,65 [4,10; 214,20] <,0001
200 mg	28/76 (36,8)	36,9 [7,82; NE]	3/41 (7,3)	NE [NE; NE]	6,61 [2,01; 21,80] 0,0003
Previous anti-estrogene therapy (p-value of the interaction term: 0,8735)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	41/109 (37,6)	36,7 [14,99; NE]	2/52 (3,8)	NE [NE; NE]	11,38 [2,75; 47,06] <,0001
No	41/136 (30,1)	NE [35,01; NE]	2/76 (2,6)	NE [NE; NE]	13,02 [3,15; 53,88] <,0001

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t244_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 245.1.2: Subgroups: time to adverse events with CTCAE grade >= 3 according SOC - Gastrointestinal disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,8971)					
< 65 years	33/147 (22,4)	NE [48,56; NE]	5/72 (6,9)	NE [42,51; NE]	3,04 [1,19; 7,81] 0,0150
≥ 65 years	19/98 (19,4)	NE [NE; NE]	4/56 (7,1)	NE [NE; NE]	3,07 [1,04; 9,02] 0,0321
Organs involved (p-value of the interaction term: 0,3703)					
1	27/112 (24,1)	50,3 [48,56; NE]	2/49 (4,1)	NE [NE; NE]	5,95 [1,41; 25,09] 0,0058
2	15/73 (20,5)	NE [44,58; NE]	4/36 (11,1)	NE [13,51; NE]	1,73 [0,57; 5,26] 0,3279
≥ 3	10/60 (16,7)	NE [NE; NE]	3/43 (7,0)	NE [42,51; NE]	2,50 [0,69; 9,11] 0,1497
Nature of disease (p-value of the interaction term: 0,6046)					
Visceral	26/130 (20,0)	NE [48,56; NE]	6/80 (7,5)	NE [42,51; NE]	2,54 [1,04; 6,21] 0,0342
Bone only	17/71 (23,9)	NE [50,30; NE]	1/29 (3,4)	NE [NE; NE]	7,71 [1,02; 58,04] 0,0190
Other	9/44 (20,5)	NE [35,31; NE]	2/19 (10,5)	NE [13,51; NE]	2,18 [0,47; 10,13] 0,3058
ECOG-PS at Baseline (p-value of the interaction term: 0,6535)					
0	30/135 (22,2)	NE [48,56; NE]	6/74 (8,1)	NE [42,51; NE]	2,63 [1,09; 6,35] 0,0252
1	22/110 (20,0)	NE [NE; NE]	3/54 (5,6)	NE [NE; NE]	3,84 [1,15; 12,85] 0,0185
Race (p-value of the interaction term: 0,7053)					
Caucasian	31/155 (20,0)	NE [50,30; NE]	7/80 (8,8)	NE [42,51; NE]	2,34 [1,03; 5,33] 0,0369
Asian	11/58 (19,0)	NE [44,58; NE]	1/32 (3,1)	NE [NE; NE]	5,64 [0,72; 44,11] 0,0636

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	4/17 (23,5)	48,6 [NE; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1851
Region (p-value of the interaction term: 0,7468)					
Europe	18/97 (18,6)	NE [NE; NE]	4/57 (7,0)	NE [42,51; NE]	2,62 [0,88; 7,74] 0,0708
North America	23/92 (25,0)	NE [48,56; NE]	4/39 (10,3)	NE [20,22; NE]	2,58 [0,89; 7,48] 0,0715
Asian	11/56 (19,6)	NE [44,58; NE]	1/32 (3,1)	NE [NE; NE]	5,82 [0,74; 45,53] 0,0579
Measurable disease at baseline (p-value of the interaction term: 0,4933)					
Yes	33/169 (19,5)	NE [48,56; NE]	7/94 (7,4)	NE [42,51; NE]	2,51 [1,11; 5,69] 0,0225
No	19/76 (25,0)	NE [50,30; NE]	2/34 (5,9)	NE [NE; NE]	4,79 [1,11; 20,58] 0,0202
Progesterone receptor (p-value of the interaction term: 0,7718)					
Positive	41/183 (22,4)	NE [48,56; NE]	6/93 (6,5)	NE [42,51; NE]	3,45 [1,46; 8,13] 0,0027
Negative	10/59 (16,9)	NE [NE; NE]	2/31 (6,5)	NE [NE; NE]	2,90 [0,64; 13,25] 0,1498
Sensitivity against endocrine therapy (p-value of the interaction term: 0,7538)					
Primary resistance	13/57 (22,8)	NE [44,58; NE]	3/35 (8,6)	NE [14,47; NE]	2,31 [0,65; 8,25] 0,1827
Secondary resistance	32/168 (19,0)	NE [48,56; NE]	5/79 (6,3)	NE [42,51; NE]	2,91 [1,13; 7,51] 0,0207
Endocrine naive	7/20 (35,0)	NE [0,89; NE]	1/14 (7,1)	NE [13,51; NE]	5,71 [0,70; 46,43] 0,0657
Starting dose (p-value of the interaction term: 0,1045)					
150 mg	28/169 (16,6)	50,3 [48,56; NE]	7/87 (8,0)	NE [42,51; NE]	1,78 [0,77; 4,12] 0,1704
200 mg	24/76 (31,6)	NE [44,58; NE]	2/41 (4,9)	NE [NE; NE]	7,71 [1,82; 32,64] 0,0010
Previous anti-estrogene therapy (p-value of the interaction term: 0,4062)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	23/109 (21,1)	NE [48,56; NE]	2/52 (3,8)	42,5 [42,51; NE]	4,51 [1,05; 19,35] 0,0263
No	29/136 (21,3)	NE [NE; NE]	7/76 (9,2)	NE [NE; NE]	2,56 [1,12; 5,84] 0,0209

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t245_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 246.1.2: Subgroups: time to adverse events with CTCAE grade >= 3 according SOC - Infections and infestations - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,8631)					
< 65 years	15/147 (10,2)	NE [NE; NE]	2/72 (2,8)	NE [NE; NE]	3,28 [0,75; 14,35] 0,0942
≥ 65 years	7/98 (7,1)	NE [NE; NE]	1/56 (1,8)	NE [NE; NE]	3,64 [0,44; 29,97] 0,1986
Organs involved (p-value of the interaction term: 0,9580)					
1	12/112 (10,7)	NE [NE; NE]	0/49 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0288
2	4/73 (5,5)	NE [NE; NE]	1/36 (2,8)	NE [NE; NE]	1,87 [0,21; 16,81] 0,5698
≥ 3	6/60 (10,0)	NE [NE; NE]	2/43 (4,7)	NE [NE; NE]	2,31 [0,46; 11,46] 0,2915
Nature of disease (p-value of the interaction term: 0,8516)					
Visceral	11/130 (8,5)	NE [NE; NE]	2/80 (2,5)	NE [NE; NE]	2,81 [0,62; 12,77] 0,1623
Bone only	8/71 (11,3)	NE [NE; NE]	0/29 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0543
Other	3/44 (6,8)	NE [NE; NE]	1/19 (5,3)	NE [NE; NE]	1,31 [0,14; 12,65] 0,8126
ECOG-PS at Baseline (p-value of the interaction term: 0,8644)					
0	13/135 (9,6)	NE [NE; NE]	2/74 (2,7)	NE [NE; NE]	3,14 [0,71; 14,01] 0,1126
1	9/110 (8,2)	NE [NE; NE]	1/54 (1,9)	NE [NE; NE]	4,17 [0,53; 32,96] 0,1408
Race (p-value of the interaction term: 0,9999)					
Caucasian	14/155 (9,0)	NE [NE; NE]	2/80 (2,5)	NE [NE; NE]	3,19 [0,72; 14,10] 0,1052
Asian	3/58 (5,2)	NE [NE; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1936

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Other	4/17 (23,5)	NE [4,64; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1336
Region (p-value of the interaction term: 0,8985)					
Europe	8/97 (8,2)	NE [NE; NE]	2/57 (3,5)	NE [NE; NE]	2,21 [0,47; 10,43] 0,3022
North America	11/92 (12,0)	NE [NE; NE]	1/39 (2,6)	NE [NE; NE]	3,86 [0,49; 30,15] 0,1647
Asian	3/56 (5,4)	NE [NE; NE]	0/32 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1874
Measurable disease at baseline (p-value of the interaction term: 0,9904)					
Yes	15/169 (8,9)	NE [NE; NE]	3/94 (3,2)	NE [NE; NE]	2,41 [0,69; 8,35] 0,1522
No	7/76 (9,2)	NE [NE; NE]	0/34 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0626
Progesterone receptor (p-value of the interaction term: 0,3309)					
Positive	18/183 (9,8)	NE [NE; NE]	1/93 (1,1)	NE [NE; NE]	8,43 [1,12; 63,26] 0,0129
Negative	4/59 (6,8)	NE [NE; NE]	1/31 (3,2)	NE [NE; NE]	2,01 [0,22; 18,03] 0,5245
Sensitivity against endocrine therapy (p-value of the interaction term: 0,7883)					
Primary resistance	7/57 (12,3)	NE [NE; NE]	0/35 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0985
Secondary resistance	13/168 (7,7)	NE [NE; NE]	2/79 (2,5)	NE [NE; NE]	2,97 [0,67; 13,22] 0,1328
Endocrine naive	2/20 (10,0)	NE [NE; NE]	1/14 (7,1)	NE [5,33; NE]	1,25 [0,11; 13,88] 0,8494
Starting dose (p-value of the interaction term: 0,4189)					
150 mg	14/169 (8,3)	NE [NE; NE]	1/87 (1,1)	NE [NE; NE]	6,30 [0,83; 47,98] 0,0414
200 mg	8/76 (10,5)	NE [NE; NE]	2/41 (4,9)	NE [NE; NE]	2,19 [0,46; 10,40] 0,3099
Previous anti-estrogene therapy (p-value of the interaction term: 0,7188)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	11/109 (10,1)	NE [NE; NE]	1/52 (1,9)	NE [NE; NE]	4,46 [0,57; 34,74] 0,1178
No	11/136 (8,1)	NE [NE; NE]	2/76 (2,6)	NE [NE; NE]	2,97 [0,66; 13,42] 0,1365

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t246_aesocpt_tte_sub_popa1_2.rtf
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Table 247.2.2: Subgroups: adverse events according PT - Gastrointestinal disorders/Abdominal pain - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,3104)					
≥ 65 years	20/64 (31,3)	NE [NE; NE]	4/38 (10,5)	NE [NE; NE]	3,35 [1,14; 9,82] 0,0194
< 65 years	36/79 (45,6)	16,1 [4,93; NE]	8/28 (28,6)	NE [16,14; NE]	1,64 [0,76; 3,53] 0,2053
Organs involved (p-value of the interaction term: 0,7078)					
1	24/47 (51,1)	9,2 [2,27; NE]	5/20 (25,0)	NE [11,34; NE]	2,36 [0,90; 6,19] 0,0734
2	20/49 (40,8)	NE [5,82; NE]	3/21 (14,3)	NE [16,14; NE]	3,20 [0,95; 10,81] 0,0476
≥ 3	12/47 (25,5)	NE [16,08; NE]	4/25 (16,0)	NE [NE; NE]	1,61 [0,52; 5,04] 0,4062
Nature of disease (p-value of the interaction term: 0,3748)					
Visceral	27/78 (34,6)	NE [16,08; NE]	10/39 (25,6)	NE [11,34; NE]	1,35 [0,65; 2,81] 0,4177
Bone only	19/39 (48,7)	4,6 [2,27; NE]	2/15 (13,3)	NE [NE; NE]	4,30 [1,00; 18,47] 0,0326
Other	10/26 (38,5)	NE [4,93; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0252
ECOG-PS at Baseline (p-value of the interaction term: 0,5702)					
0	31/83 (37,3)	NE [16,08; NE]	7/36 (19,4)	NE [11,34; NE]	1,98 [0,87; 4,52] 0,0977
1	24/57 (42,1)	NE [3,72; NE]	5/30 (16,7)	NE [16,14; NE]	2,86 [1,09; 7,50] 0,0252
Region (p-value of the interaction term: 0,3219)					
Europe	32/75 (42,7)	24,2 [3,95; NE]	7/37 (18,9)	NE [NE; NE]	2,72 [1,20; 6,18] 0,0127
North America	13/25 (52,0)	16,1 [2,79; NE]	2/16 (12,5)	16,1 [NE; NE]	3,83 [0,85; 17,35] 0,0618

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	11/43 (25,6)	NE [NE; NE]	3/13 (23,1)	NE [1,71; NE]	1,07 [0,30; 3,83] 0,9185
Measurable disease at baseline (p-value of the interaction term: 0,4320)					
Yes	39/108 (36,1)	NE [16,08; NE]	10/53 (18,9)	NE [16,14; NE]	2,01 [1,00; 4,04] 0,0455
No	17/35 (48,6)	16,7 [3,25; NE]	2/13 (15,4)	NE [NE; NE]	3,96 [0,91; 17,20] 0,0475
Progesterone receptor (p-value of the interaction term: 0,5209)					
Positive	47/115 (40,9)	NE [11,77; NE]	11/50 (22,0)	NE [NE; NE]	2,02 [1,04; 3,89] 0,0331
Negative	7/23 (30,4)	NE [16,70; NE]	1/12 (8,3)	NE [11,34; NE]	3,61 [0,44; 29,52] 0,2024
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9276)					
Primary resistance	10/26 (38,5)	NE [2,79; NE]	2/10 (20,0)	NE [1,71; NE]	2,23 [0,49; 10,20] 0,2874
Secondary resistance	46/117 (39,3)	NE [14,79; NE]	10/56 (17,9)	NE [16,14; NE]	2,25 [1,13; 4,47] 0,0178
Starting dose (p-value of the interaction term: 0,9600)					
150 mg	40/103 (38,8)	NE [14,79; NE]	9/49 (18,4)	NE [NE; NE]	2,34 [1,13; 4,84] 0,0179
200 mg	16/40 (40,0)	NE [3,72; NE]	3/17 (17,6)	NE [NE; NE]	2,32 [0,68; 7,97] 0,1678
Previous anti-estrogene therapy (p-value of the interaction term: 0,4624)					
Yes	36/69 (52,2)	9,2 [2,10; NE]	8/38 (21,1)	NE [16,14; NE]	3,02 [1,40; 6,50] 0,0031
No	20/74 (27,0)	NE [24,23; NE]	4/28 (14,3)	NE [NE; NE]	1,75 [0,60; 5,17] 0,3021

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas

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/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 248.2.2: Subgroups: adverse events according PT - Skin and subcutaneous tissue disorders/Alopecia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,9901)					
≥ 65 years	14/64 (21,9)	NE [NE; NE]	1/38 (2,6)	NE [21,30; NE]	7,84 [1,03; 59,85] 0,0187
< 65 years	12/79 (15,2)	NE [NE; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0475
Organs involved (p-value of the interaction term: 0,9999)					
1	6/47 (12,8)	NE [NE; NE]	1/20 (5,0)	NE [21,30; NE]	2,55 [0,30; 21,26] 0,3710
2	13/49 (26,5)	NE [NE; NE]	0/21 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0180
≥ 3	7/47 (14,9)	NE [NE; NE]	0/25 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0941
Nature of disease (p-value of the interaction term: 0,9999)					
Visceral	20/78 (25,6)	NE [NE; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0022
Bone only	3/39 (7,7)	NE [NE; NE]	1/15 (6,7)	NE [21,30; NE]	1,06 [0,11; 10,20] 0,9597
Other	3/26 (11,5)	NE [NE; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2689
ECOG-PS at Baseline (p-value of the interaction term: 0,9891)					
0	14/83 (16,9)	NE [NE; NE]	1/36 (2,8)	NE [21,30; NE]	4,84 [0,63; 37,04] 0,0936
1	11/57 (19,3)	NE [NE; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0158
Region (p-value of the interaction term: 0,9999)					
Europe	15/75 (20,0)	NE [NE; NE]	1/37 (2,7)	NE [21,30; NE]	6,52 [0,86; 49,43] 0,0368
North America	4/25 (16,0)	NE [NE; NE]	0/16 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0923

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	7/43 (16,3)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1376
Measurable disease at baseline (p-value of the interaction term: 0,9904)					
Yes	23/108 (21,3)	NE [NE; NE]	0/53 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0017
No	3/35 (8,6)	NE [NE; NE]	1/13 (7,7)	NE [21,30; NE]	1,31 [0,14; 12,65] 0,8122
Progesterone receptor (p-value of the interaction term: 0,9899)					
Positive	23/115 (20,0)	NE [NE; NE]	0/50 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0019
Negative	3/23 (13,0)	NE [NE; NE]	1/12 (8,3)	21,3 [NE; NE]	0,84 [0,08; 8,50] 0,8860
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9903)					
Primary resistance	4/26 (15,4)	NE [NE; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1972
Secondary resistance	22/117 (18,8)	NE [NE; NE]	1/56 (1,8)	NE [21,30; NE]	8,97 [1,21; 66,68] 0,0094
Starting dose (p-value of the interaction term: 0,9922)					
150 mg	20/103 (19,4)	NE [NE; NE]	1/49 (2,0)	NE [21,30; NE]	8,68 [1,16; 64,78] 0,0111
200 mg	6/40 (15,0)	NE [NE; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1046
Previous anti-estrogene therapy (p-value of the interaction term: 0,9908)					
Yes	15/69 (21,7)	NE [NE; NE]	1/38 (2,6)	NE [21,30; NE]	7,90 [1,04; 59,84] 0,0176
No	11/74 (14,9)	NE [NE; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0618

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas

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/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 249.2.2: Subgroups: adverse events according PT - Blood and lymphatic system disorders/Anaemia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,8541)					
≥ 65 years	22/64 (34,4)	24,0 [10,68; NE]	1/38 (2,6)	NE [NE; NE]	14,21 [1,91; 105,56] 0,0006
< 65 years	30/79 (38,0)	24,0 [14,27; NE]	1/28 (3,6)	NE [NE; NE]	11,33 [1,54; 83,08] 0,0025
Organs involved (p-value of the interaction term: 0,9796)					
1	16/47 (34,0)	NE [6,97; NE]	0/20 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0044
2	21/49 (42,9)	24,0 [10,68; NE]	1/21 (4,8)	NE [NE; NE]	9,93 [1,34; 73,92] 0,0056
≥ 3	15/47 (31,9)	NE [13,15; NE]	1/25 (4,0)	NE [7,40; NE]	7,32 [0,96; 55,79] 0,0247
Nature of disease (p-value of the interaction term: 0,9998)					
Visceral	30/78 (38,5)	24,0 [11,11; NE]	2/39 (5,1)	NE [NE; NE]	7,63 [1,82; 32,00] 0,0011
Bone only	13/39 (33,3)	NE [10,09; NE]	0/15 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0137
Other	9/26 (34,6)	24,0 [10,68; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0417
ECOG-PS at Baseline (p-value of the interaction term: 0,9839)					
0	30/83 (36,1)	24,0 [13,32; NE]	2/36 (5,6)	NE [NE; NE]	6,06 [1,44; 25,43] 0,0050
1	22/57 (38,6)	24,0 [7,07; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0001
Region (p-value of the interaction term: 0,9268)					
Europe	28/75 (37,3)	24,0 [12,03; NE]	0/37 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
North America	7/25 (28,0)	NE [9,83; NE]	1/16 (6,3)	NE [7,40; NE]	3,36 [0,40; 27,95] 0,2370

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	17/43 (39,5)	NE [3,72; NE]	1/13 (7,7)	NE [NE; NE]	6,65 [0,88; 50,05] 0,0328
Measurable disease at baseline (p-value of the interaction term: 0,9898)					
Yes	45/108 (41,7)	24,0 [11,11; NE]	2/53 (3,8)	NE [NE; NE]	11,45 [2,77; 47,29] <,0001
No	7/35 (20,0)	NE [12,03; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0794
Progesterone receptor (p-value of the interaction term: 0,9853)					
Positive	41/115 (35,7)	NE [13,32; NE]	2/50 (4,0)	NE [NE; NE]	9,70 [2,35; 40,08] 0,0001
Negative	10/23 (43,5)	24,0 [2,83; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0170
Sensitivity against endocrine therapy (p-value of the interaction term: 0,1718)					
Primary resistance	7/26 (26,9)	NE [10,68; NE]	1/10 (10,0)	NE [3,72; NE]	3,35 [0,41; 27,48] 0,2335
Secondary resistance	45/117 (38,5)	24,0 [13,32; NE]	1/56 (1,8)	NE [NE; NE]	23,36 [3,22; 169,54] <,0001
Starting dose (p-value of the interaction term: 0,9894)					
150 mg	43/103 (41,7)	24,0 [12,03; NE]	2/49 (4,1)	NE [NE; NE]	10,75 [2,60; 44,41] <,0001
200 mg	9/40 (22,5)	NE [NE; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0304
Previous anti-estrogene therapy (p-value of the interaction term: 0,9861)					
Yes	27/69 (39,1)	24,0 [13,15; NE]	2/38 (5,3)	NE [NE; NE]	8,23 [1,95; 34,61] 0,0006
No	25/74 (33,8)	24,0 [11,11; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0020

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t249_aesocpt_tte_sub_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 250.2.2: Subgroups: adverse events according PT - Investigations/Blood creatinine increased - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,9998)					
≥ 65 years	17/64 (26,6)	NE [23,08; NE]	0/38 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0009
< 65 years	12/79 (15,2)	NE [NE; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0472
Organs involved (p-value of the interaction term: 1,0000)					
1	10/47 (21,3)	NE [NE; NE]	0/20 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0323
2	10/49 (20,4)	NE [29,52; NE]	0/21 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0414
≥ 3	9/47 (19,1)	NE [35,15; NE]	0/25 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0378
Nature of disease (p-value of the interaction term: 1,0000)					
Visceral	19/78 (24,4)	NE [35,15; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0027
Bone only	9/39 (23,1)	NE [NE; NE]	0/15 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0495
Other	1/26 (3,8)	NE [NE; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4969
ECOG-PS at Baseline (p-value of the interaction term: 0,9999)					
0	16/83 (19,3)	NE [NE; NE]	0/36 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0088
1	13/57 (22,8)	NE [29,52; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0064
Region (p-value of the interaction term: 1,0000)					
Europe	16/75 (21,3)	NE [29,52; NE]	0/37 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0046
North America	5/25 (20,0)	NE [NE; NE]	0/16 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0738

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	8/43 (18,6)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1040
Measurable disease at baseline (p-value of the interaction term: 0,9999)					
Yes	21/108 (19,4)	NE [NE; NE]	0/53 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0019
No	8/35 (22,9)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0635
Progesterone receptor (p-value of the interaction term: 0,9999)					
Positive	22/115 (19,1)	NE [NE; NE]	0/50 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0021
Negative	6/23 (26,1)	NE [3,12; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0571
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9999)					
Primary resistance	4/26 (15,4)	NE [14,63; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1765
Secondary resistance	25/117 (21,4)	NE [NE; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0006
Starting dose (p-value of the interaction term: 0,9999)					
150 mg	23/103 (22,3)	NE [35,15; NE]	0/49 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0011
200 mg	6/40 (15,0)	NE [NE; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0929
Previous anti-estrogene therapy (p-value of the interaction term: 0,9999)					
Yes	16/69 (23,2)	NE [NE; NE]	0/38 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0021
No	13/74 (17,6)	NE [35,15; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0361

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t250_aesocpt_tte_sub_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 251.2.2: Subgroups: adverse events according PT - Metabolism and nutrition disorders/Decreased appetite - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,2824)					
≥ 65 years	29/64 (45,3)	20,4 [3,75; NE]	5/38 (13,2)	33,4 [33,44; NE]	4,15 [1,60; 10,73] 0,0015
< 65 years	21/79 (26,6)	NE [NE; NE]	4/28 (14,3)	NE [NE; NE]	2,07 [0,71; 6,02] 0,1750
Organs involved (p-value of the interaction term: 0,7069)					
1	16/47 (34,0)	NE [7,79; NE]	2/20 (10,0)	33,4 [33,44; NE]	3,84 [0,88; 16,73] 0,0538
2	17/49 (34,7)	NE [20,35; NE]	4/21 (19,0)	NE [5,62; NE]	2,04 [0,69; 6,08] 0,1884
≥ 3	17/47 (36,2)	NE [17,06; NE]	3/25 (12,0)	NE [7,43; NE]	3,53 [1,03; 12,08] 0,0331
Nature of disease (p-value of the interaction term: 0,9346)					
Visceral	25/78 (32,1)	NE [NE; NE]	7/39 (17,9)	NE [NE; NE]	1,98 [0,85; 4,59] 0,1052
Bone only	12/39 (30,8)	NE [27,16; NE]	2/15 (13,3)	33,4 [5,62; NE]	2,60 [0,58; 11,60] 0,1947
Other	13/26 (50,0)	20,4 [0,95; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0065
ECOG-PS at Baseline (p-value of the interaction term: 0,1999)					
0	30/83 (36,1)	NE [27,16; NE]	7/36 (19,4)	NE [NE; NE]	2,06 [0,90; 4,72] 0,0798
1	20/57 (35,1)	NE [17,06; NE]	2/30 (6,7)	NE [33,44; NE]	6,08 [1,42; 26,01] 0,0055
Region (p-value of the interaction term: 0,6657)					
Europe	23/75 (30,7)	NE [20,35; NE]	6/37 (16,2)	NE [33,44; NE]	2,03 [0,82; 4,98] 0,1169
North America	7/25 (28,0)	NE [27,16; NE]	1/16 (6,3)	NE [7,43; NE]	3,96 [0,47; 33,07] 0,1702

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	20/43 (46,5)	NE [0,92; NE]	2/13 (15,4)	NE [2,79; NE]	3,85 [0,90; 16,47] 0,0499
Measurable disease at baseline (p-value of the interaction term: 0,7832)					
Yes	41/108 (38,0)	NE [20,35; NE]	8/53 (15,1)	NE [NE; NE]	2,88 [1,35; 6,16] 0,0043
No	9/35 (25,7)	NE [27,16; NE]	1/13 (7,7)	NE [33,44; NE]	3,96 [0,50; 31,38] 0,1588
Progesterone receptor (p-value of the interaction term: 0,9152)					
Positive	38/115 (33,0)	NE [NE; NE]	7/50 (14,0)	NE [33,44; NE]	2,64 [1,18; 5,92] 0,0144
Negative	10/23 (43,5)	27,2 [0,92; NE]	2/12 (16,7)	NE [1,32; NE]	2,74 [0,59; 12,65] 0,1778
Sensitivity against endocrine therapy (p-value of the interaction term: 0,2172)					
Primary resistance	9/26 (34,6)	NE [0,99; NE]	3/10 (30,0)	NE [0,49; NE]	1,34 [0,36; 4,95] 0,6652
Secondary resistance	41/117 (35,0)	NE [27,16; NE]	6/56 (10,7)	NE [33,44; NE]	3,56 [1,51; 8,41] 0,0020
Starting dose (p-value of the interaction term: 0,9859)					
150 mg	31/103 (30,1)	NE [NE; NE]	9/49 (18,4)	NE [33,44; NE]	1,72 [0,82; 3,62] 0,1493
200 mg	19/40 (47,5)	17,1 [0,26; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0017
Previous anti-estrogene therapy (p-value of the interaction term: 0,9325)					
Yes	27/69 (39,1)	NE [2,73; NE]	6/38 (15,8)	NE [33,44; NE]	2,96 [1,22; 7,20] 0,0120
No	23/74 (31,1)	NE [27,16; NE]	3/28 (10,7)	NE [NE; NE]	2,97 [0,89; 9,90] 0,0633

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t251_aesocpt_tte_sub_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 252.2.2: Subgroups: adverse events according PT - Gastrointestinal disorders/Diarrhoea - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,3268)					
≥ 65 years	56/64 (87,5)	0,2 [0,13; 0,33]	12/38 (31,6)	22,3 [7,43; NE]	7,03 [3,63; 13,62] <,0001
< 65 years	73/79 (92,4)	0,2 [0,16; 0,33]	6/28 (21,4)	NE [21,14; NE]	10,57 [4,52; 24,73] <,0001
Nature of disease (p-value of the interaction term: 0,3867)					
Visceral	72/78 (92,3)	0,2 [0,16; 0,30]	9/39 (23,1)	NE [7,43; NE]	11,61 [5,69; 23,69] <,0001
Bone only	33/39 (84,6)	0,4 [0,13; 0,79]	5/15 (33,3)	22,3 [6,77; NE]	6,69 [2,30; 19,41] <,0001
Other	24/26 (92,3)	0,2 [0,10; 0,30]	4/12 (33,3)	12,4 [0,10; NE]	5,34 [1,81; 15,75] 0,0007
ECOG-PS at Baseline (p-value of the interaction term: 0,7269)					
0	76/83 (91,6)	0,2 [0,16; 0,26]	11/36 (30,6)	22,3 [7,43; NE]	7,59 [3,97; 14,54] <,0001
1	51/57 (89,5)	0,3 [0,13; 0,49]	7/30 (23,3)	NE [8,32; NE]	10,34 [4,37; 24,49] <,0001
Region (p-value of the interaction term: 0,4929)					
Europe	64/75 (85,3)	0,5 [0,26; 0,53]	9/37 (24,3)	NE [8,32; NE]	7,22 [3,55; 14,71] <,0001
North America	24/25 (96,0)	0,2 [0,13; 0,33]	5/16 (31,3)	21,1 [3,95; NE]	39,93 [5,25; 303,43] <,0001
Asian	41/43 (95,3)	0,1 [0,10; 0,16]	4/13 (30,8)	NE [0,89; NE]	9,20 [3,14; 26,98] <,0001
Measurable disease at baseline (p-value of the interaction term: 0,1150)					
Yes	101/108 (93,5)	0,2 [0,16; 0,26]	13/53 (24,5)	NE [12,39; NE]	10,61 [5,85; 19,27] <,0001
No	28/35 (80,0)	0,4 [0,13; 1,97]	5/13 (38,5)	22,3 [6,77; NE]	5,37 [1,82; 15,88] 0,0008
Sensitivity against endocrine therapy (p-value of the interaction term: 0,1509)					

Subgroup	Abemaciclib+Fulvestrant n/N (%)	Abemaciclib+Fulvestrant Median time to event[1]	Placebo+Fulvestrant n/N (%)	Placebo+Fulvestrant Median time to event[1]	HR [95% CI] p-value[2]
Primary resistance	23/26 (88,5)	0,2 [0,10; 0,23]	1/10 (10,0)	NE [2,33; NE]	22,07 [2,92; 166,83] <,0001
Secondary resistance	106/117 (90,6)	0,3 [0,16; 0,33]	17/56 (30,4)	22,3 [8,32; NE]	7,18 [4,24; 12,15] <,0001
Starting dose (p-value of the interaction term: 0,1397)					
150 mg	90/103 (87,4)	0,3 [0,16; 0,39]	15/49 (30,6)	22,3 [8,32; NE]	6,61 [3,77; 11,58] <,0001
200 mg	39/40 (97,5)	0,2 [0,10; 0,26]	3/17 (17,6)	NE [3,95; NE]	16,85 [4,94; 57,42] <,0001
Previous anti-estrogene therapy (p-value of the interaction term: 0,6769)					
Yes	64/69 (92,8)	0,2 [0,13; 0,33]	12/38 (31,6)	22,3 [8,32; NE]	9,02 [4,55; 17,89] <,0001
No	65/74 (87,8)	0,2 [0,16; 0,33]	6/28 (21,4)	NE [6,77; NE]	8,77 [3,76; 20,44] <,0001

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t252_aesocpt_tte_sub_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 253.2.2: Subgroups: adverse events according PT - Nervous system disorders/Dysgeusia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,5329)					
≥ 65 years	19/64 (29,7)	NE [NE; NE]	1/38 (2,6)	NE [NE; NE]	12,80 [1,71; 95,69] 0,0013
< 65 years	14/79 (17,7)	NE [NE; NE]	1/28 (3,6)	NE [NE; NE]	5,05 [0,66; 38,49] 0,0818
Organs involved (p-value of the interaction term: 0,9806)					
1	9/47 (19,1)	NE [NE; NE]	1/20 (5,0)	NE [NE; NE]	3,96 [0,50; 31,35] 0,1600
2	14/49 (28,6)	NE [NE; NE]	0/21 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0093
≥ 3	10/47 (21,3)	NE [NE; NE]	1/25 (4,0)	NE [NE; NE]	5,67 [0,73; 44,30] 0,0617
Nature of disease (p-value of the interaction term: 0,8749)					
Visceral	16/78 (20,5)	NE [NE; NE]	1/39 (2,6)	NE [NE; NE]	8,68 [1,15; 65,43] 0,0114
Bone only	9/39 (23,1)	NE [23,97; NE]	1/15 (6,7)	NE [7,27; NE]	3,83 [0,48; 30,23] 0,1712
Other	8/26 (30,8)	NE [4,31; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0372
ECOG-PS at Baseline (p-value of the interaction term: 0,9876)					
0	22/83 (26,5)	NE [NE; NE]	2/36 (5,6)	NE [NE; NE]	5,04 [1,18; 21,47] 0,0149
1	10/57 (17,5)	NE [NE; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0196
Region (p-value of the interaction term: 0,8723)					
Europe	9/75 (12,0)	NE [NE; NE]	1/37 (2,7)	NE [NE; NE]	4,44 [0,56; 35,16] 0,1226
North America	12/25 (48,0)	6,5 [0,20; NE]	1/16 (6,3)	NE [NE; NE]	9,10 [1,18; 70,12] 0,0095

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	12/43 (27,9)	NE [23,97; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0455
Measurable disease at baseline (p-value of the interaction term: 0,3044)					
Yes	26/108 (24,1)	NE [NE; NE]	1/53 (1,9)	NE [NE; NE]	13,62 [1,85; 100,43] 0,0008
No	7/35 (20,0)	NE [23,97; NE]	1/13 (7,7)	NE [7,27; NE]	3,07 [0,38; 24,96] 0,2709
Progesterone receptor (p-value of the interaction term: 0,9876)					
Positive	28/115 (24,3)	NE [NE; NE]	2/50 (4,0)	NE [NE; NE]	6,52 [1,55; 27,39] 0,0031
Negative	5/23 (21,7)	NE [12,00; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1097
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9891)					
Primary resistance	4/26 (15,4)	NE [NE; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1982
Secondary resistance	29/117 (24,8)	NE [NE; NE]	2/56 (3,6)	NE [NE; NE]	7,31 [1,74; 30,65] 0,0014
Starting dose (p-value of the interaction term: 0,9905)					
150 mg	20/103 (19,4)	NE [NE; NE]	2/49 (4,1)	NE [NE; NE]	4,74 [1,11; 20,31] 0,0208
200 mg	13/40 (32,5)	NE [4,31; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0092
Previous anti-estrogene therapy (p-value of the interaction term: 0,8396)					
Yes	16/69 (23,2)	NE [NE; NE]	1/38 (2,6)	NE [NE; NE]	9,14 [1,21; 69,02] 0,0090
No	17/74 (23,0)	NE [NE; NE]	1/28 (3,6)	NE [7,27; NE]	6,96 [0,92; 52,31] 0,0283

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t253_aesocpt_tte_sub_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 254.2.2: Subgroups: adverse events according PT - General disorders and administration site conditions/Fatigue - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,2394)					
≥ 65 years	35/64 (54,7)	5,7 [1,87; NE]	9/38 (23,7)	NE [5,62; NE]	2,62 [1,26; 5,47] 0,0076
< 65 years	35/79 (44,3)	NE [2,56; NE]	9/28 (32,1)	NE [5,69; NE]	1,47 [0,70; 3,06] 0,2981
Organs involved (p-value of the interaction term: 0,6651)					
1	26/47 (55,3)	8,4 [1,87; NE]	6/20 (30,0)	NE [3,91; NE]	1,89 [0,77; 4,61] 0,1583
2	22/49 (44,9)	NE [2,63; NE]	7/21 (33,3)	NE [4,60; NE]	1,51 [0,64; 3,53] 0,3434
≥ 3	22/47 (46,8)	14,2 [1,22; NE]	5/25 (20,0)	NE [5,59; NE]	2,70 [1,02; 7,16] 0,0374
Nature of disease (p-value of the interaction term: 0,4475)					
Visceral	34/78 (43,6)	NE [4,80; NE]	8/39 (20,5)	NE [NE; NE]	2,38 [1,10; 5,16] 0,0233
Bone only	24/39 (61,5)	4,6 [0,95; 14,24]	8/15 (53,3)	5,7 [0,16; NE]	1,26 [0,56; 2,80] 0,5742
Other	12/26 (46,2)	14,8 [2,63; NE]	2/12 (16,7)	NE [0,95; NE]	2,95 [0,66; 13,22] 0,1357
ECOG-PS at Baseline (p-value of the interaction term: 0,3379)					
0	37/83 (44,6)	NE [3,68; NE]	11/36 (30,6)	NE [5,59; NE]	1,54 [0,78; 3,02] 0,2094
1	30/57 (52,6)	8,4 [2,27; NE]	7/30 (23,3)	NE [5,69; NE]	2,62 [1,15; 5,97] 0,0175
Measurable disease at baseline (p-value of the interaction term: 0,0655)					
Yes	52/108 (48,1)	14,8 [3,35; NE]	11/53 (20,8)	NE [NE; NE]	2,63 [1,37; 5,05] 0,0025
No	18/35 (51,4)	5,7 [1,41; NE]	7/13 (53,8)	5,7 [0,26; NE]	0,91 [0,38; 2,18] 0,8253

Subgroup	Abemaciclib+Fulvestrant n/N (%)	Abemaciclib+Fulvestrant Median time to event[1]	Placebo+Fulvestrant n/N (%)	Placebo+Fulvestrant Median time to event[1]	HR [95% CI] p-value[2]
Progesterone receptor (p-value of the interaction term: 0,2054)					
Positive	53/115 (46,1)	21,0 [5,56; NE]	15/50 (30,0)	NE [5,62; NE]	1,61 [0,91; 2,87] 0,0993
Negative	14/23 (60,9)	3,4 [0,56; NE]	2/12 (16,7)	NE [5,52; NE]	4,74 [1,07; 20,99] 0,0239
Sensitivity against endocrine therapy (p-value of the interaction term: 0,7529)					
Primary resistance	11/26 (42,3)	NE [2,27; NE]	2/10 (20,0)	NE [1,64; NE]	2,45 [0,54; 11,07] 0,2289
Secondary resistance	59/117 (50,4)	14,2 [3,35; NE]	16/56 (28,6)	NE [5,69; NE]	1,89 [1,08; 3,29] 0,0226
Starting dose (p-value of the interaction term: 0,8096)					
150 mg	56/103 (54,4)	8,4 [2,63; NE]	15/49 (30,6)	NE [5,62; NE]	1,91 [1,08; 3,38] 0,0246
200 mg	14/40 (35,0)	NE [2,56; NE]	3/17 (17,6)	NE [NE; NE]	2,19 [0,63; 7,63] 0,2035
Previous anti-estrogene therapy (p-value of the interaction term: 0,9926)					
Yes	32/69 (46,4)	21,0 [3,68; NE]	10/38 (26,3)	NE [5,69; NE]	1,91 [0,94; 3,90] 0,0701
No	38/74 (51,4)	7,6 [1,45; NE]	8/28 (28,6)	10,3 [5,62; NE]	1,93 [0,90; 4,16] 0,0865

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t254_aesocpt_tte_sub_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 255.2.2: Subgroups: adverse events according PT - Blood and lymphatic system disorders/Leukopenia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,9999)					
≥ 65 years	22/64 (34,4)	26,8 [11,93; NE]	0/38 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0001
< 65 years	25/79 (31,6)	NE [29,49; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0022
Organs involved (p-value of the interaction term: 1,0000)					
1	12/47 (25,5)	NE [25,71; NE]	0/20 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0269
2	20/49 (40,8)	26,8 [5,79; NE]	0/21 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0018
≥ 3	15/47 (31,9)	NE [29,49; NE]	0/25 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0029
Nature of disease (p-value of the interaction term: 1,0000)					
Visceral	28/78 (35,9)	NE [24,00; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0001
Bone only	10/39 (25,6)	35,0 [13,32; NE]	0/15 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0436
Other	9/26 (34,6)	NE [1,08; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0265
ECOG-PS at Baseline (p-value of the interaction term: 0,9999)					
0	31/83 (37,3)	35,0 [25,71; NE]	0/36 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0002
1	16/57 (28,1)	NE [24,00; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0021
Region (p-value of the interaction term: 1,0000)					
Europe	18/75 (24,0)	NE [26,79; NE]	0/37 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0022
North America	9/25 (36,0)	25,7 [4,93; NE]	0/16 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0250

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	20/43 (46,5)	35,0 [0,95; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0049
Measurable disease at baseline (p-value of the interaction term: 0,9997)					
Yes	40/108 (37,0)	NE [24,00; NE]	0/53 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
No	7/35 (20,0)	NE [25,71; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0746
Progesterone receptor (p-value of the interaction term: 0,9999)					
Positive	40/115 (34,8)	NE [26,79; NE]	0/50 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Negative	7/23 (30,4)	NE [8,65; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0821
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9998)					
Primary resistance	6/26 (23,1)	NE [11,93; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1137
Secondary resistance	41/117 (35,0)	35,0 [25,71; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Starting dose (p-value of the interaction term: 0,9998)					
150 mg	31/103 (30,1)	NE [26,79; NE]	0/49 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0001
200 mg	16/40 (40,0)	NE [1,87; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0029
Previous anti-estrogene therapy (p-value of the interaction term: 0,9998)					
Yes	27/69 (39,1)	NE [12,66; NE]	0/38 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
No	20/74 (27,0)	NE [25,71; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0065

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t255_aesocpt_tte_sub_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 256.2.2: Subgroups: adverse events according PT - Blood and lymphatic system disorders/Lymphopenia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Nature of disease (p-value of the interaction term: 1,0000)					
Visceral	10/78 (12,8)	NE [NE; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0779
Bone only	6/39 (15,4)	NE [41,46; NE]	0/15 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1412
Other	2/26 (7,7)	NE [25,81; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4733
ECOG-PS at Baseline (p-value of the interaction term: 1,0000)					
0	12/83 (14,5)	NE [41,46; NE]	0/36 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1099
1	6/57 (10,5)	NE [NE; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0716
Region (p-value of the interaction term: 1,0000)					
Europe	11/75 (14,7)	NE [25,81; NE]	0/37 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0272
North America	2/25 (8,0)	NE [32,48; NE]	0/16 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4913
Asian	5/43 (11,6)	NE [41,46; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2525
Measurable disease at baseline (p-value of the interaction term: 1,0000)					
Yes	14/108 (13,0)	NE [NE; NE]	0/53 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0346
No	4/35 (11,4)	NE [41,46; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2250
Progesterone receptor (p-value of the interaction term: 1,0000)					
Positive	15/115 (13,0)	NE [41,46; NE]	0/50 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0315
Negative	3/23 (13,0)	NE [NE; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2156

Subgroup	Abemaciclib+Fulvestrant n/N (%)	Abemaciclib+Fulvestrant Median time to event[1]	Placebo+Fulvestrant n/N (%)	Placebo+Fulvestrant Median time to event[1]	HR [95% CI] p-value[2]
Sensitivity against endocrine therapy (p-value of the interaction term: 1,0000)					
Primary resistance	3/26 (11,5)	NE [21,14; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2809
Secondary resistance	15/117 (12,8)	NE [41,46; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0287
Starting dose (p-value of the interaction term: 0,9998)					
150 mg	11/103 (10,7)	NE [41,46; NE]	0/49 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0622
200 mg	7/40 (17,5)	NE [25,81; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0901
Previous anti-estrogene therapy (p-value of the interaction term: 0,9999)					
Yes	12/69 (17,4)	NE [41,46; NE]	0/38 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0230
No	6/74 (8,1)	NE [28,57; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2780

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 257.2.2: Subgroups: adverse events according PT - Gastrointestinal disorders/Nausea - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,9999)					
≥ 65 years	35/64 (54,7)	4,5 [0,39; NE]	10/38 (26,3)	NE [28,44; NE]	2,82 [1,39; 5,70] 0,0028
< 65 years	41/79 (51,9)	5,8 [0,99; NE]	6/28 (21,4)	NE [7,69; NE]	2,98 [1,26; 7,03] 0,0088
Organs involved (p-value of the interaction term: 0,4674)					
1	29/47 (61,7)	1,8 [0,49; 37,25]	4/20 (20,0)	NE [7,69; NE]	4,46 [1,56; 12,76] 0,0023
2	29/49 (59,2)	1,8 [0,49; NE]	8/21 (38,1)	NE [2,89; NE]	2,01 [0,92; 4,41] 0,0774
≥ 3	18/47 (38,3)	NE [3,32; NE]	4/25 (16,0)	28,4 [28,44; NE]	2,68 [0,90; 7,94] 0,0662
Nature of disease (p-value of the interaction term: 0,9127)					
Visceral	39/78 (50,0)	10,8 [1,81; NE]	9/39 (23,1)	28,4 [28,44; NE]	2,50 [1,21; 5,17] 0,0110
Bone only	25/39 (64,1)	0,8 [0,16; 13,78]	5/15 (33,3)	NE [3,48; NE]	2,97 [1,13; 7,79] 0,0206
Other	12/26 (46,2)	NE [0,49; NE]	2/12 (16,7)	NE [6,67; NE]	3,56 [0,79; 15,92] 0,0769
ECOG-PS at Baseline (p-value of the interaction term: 0,6869)					
0	41/83 (49,4)	13,8 [0,62; NE]	7/36 (19,4)	NE [NE; NE]	3,23 [1,45; 7,20] 0,0026
1	34/57 (59,6)	1,9 [0,69; NE]	9/30 (30,0)	28,4 [6,44; NE]	2,69 [1,29; 5,63] 0,0063
Region (p-value of the interaction term: 0,4250)					
Europe	37/75 (49,3)	NE [0,82; NE]	10/37 (27,0)	NE [6,44; NE]	2,37 [1,18; 4,77] 0,0131
North America	19/25 (76,0)	0,5 [0,26; 4,47]	5/16 (31,3)	NE [2,89; NE]	3,45 [1,27; 9,37] 0,0101

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	20/43 (46,5)	37,2 [0,99; NE]	1/13 (7,7)	NE [7,69; NE]	7,58 [1,02; 56,56] 0,0197
Measurable disease at baseline (p-value of the interaction term: 0,8297)					
Yes	58/108 (53,7)	5,8 [0,99; NE]	12/53 (22,6)	NE [NE; NE]	2,93 [1,57; 5,46] 0,0004
No	18/35 (51,4)	3,0 [0,30; NE]	4/13 (30,8)	28,4 [3,65; NE]	2,46 [0,83; 7,31] 0,0955
Progesterone receptor (p-value of the interaction term: 0,8081)					
Positive	61/115 (53,0)	5,4 [0,99; NE]	11/50 (22,0)	NE [28,44; NE]	3,06 [1,61; 5,83] 0,0003
Negative	11/23 (47,8)	10,8 [0,36; NE]	2/12 (16,7)	NE [6,44; NE]	3,52 [0,78; 15,92] 0,0805
Sensitivity against endocrine therapy (p-value of the interaction term: 0,2917)					
Primary resistance	14/26 (53,8)	3,3 [0,26; NE]	1/10 (10,0)	NE [1,02; NE]	7,17 [0,94; 54,67] 0,0262
Secondary resistance	62/117 (53,0)	5,4 [0,95; NE]	15/56 (26,8)	NE [7,69; NE]	2,48 [1,41; 4,36] 0,0012
Starting dose (p-value of the interaction term: 0,0541)					
150 mg	50/103 (48,5)	13,8 [2,40; NE]	14/49 (28,6)	NE [7,69; NE]	2,03 [1,12; 3,68] 0,0172
200 mg	26/40 (65,0)	0,5 [0,13; 37,25]	2/17 (11,8)	NE [6,67; NE]	8,45 [2,00; 35,72] 0,0005
Previous anti-estrogene therapy (p-value of the interaction term: 0,5625)					
Yes	34/69 (49,3)	13,8 [0,95; NE]	7/38 (18,4)	NE [NE; NE]	3,26 [1,44; 7,37] 0,0026
No	42/74 (56,8)	1,8 [0,53; NE]	9/28 (32,1)	28,4 [3,65; NE]	2,28 [1,11; 4,71] 0,0226

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t257_aesocpt_tte_sub_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 258.2.2: Subgroups: adverse events according PT - Blood and lymphatic system disorders/Neutropenia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,4484)					
≥ 65 years	30/64 (46,9)	10,6 [4,70; NE]	1/38 (2,6)	NE [NE; NE]	23,52 [3,20; 172,65] <,0001
< 65 years	41/79 (51,9)	18,7 [1,94; 35,15]	2/28 (7,1)	NE [NE; NE]	8,94 [2,16; 36,97] 0,0002
Organs involved (p-value of the interaction term: 0,9254)					
1	21/47 (44,7)	15,6 [1,94; NE]	0/20 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0008
2	28/49 (57,1)	10,2 [1,87; 34,13]	2/21 (9,5)	NE [NE; NE]	7,72 [1,84; 32,47] 0,0010
≥ 3	22/47 (46,8)	20,5 [2,79; NE]	1/25 (4,0)	NE [NE; NE]	13,36 [1,80; 99,36] 0,0010
Nature of disease (p-value of the interaction term: 0,9999)					
Visceral	42/78 (53,8)	10,4 [4,70; 24,00]	3/39 (7,7)	NE [NE; NE]	8,18 [2,53; 26,46] <,0001
Bone only	17/39 (43,6)	15,6 [0,99; NE]	0/15 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0034
Other	12/26 (46,2)	18,7 [1,08; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0102
ECOG-PS at Baseline (p-value of the interaction term: 0,5443)					
0	42/83 (50,6)	18,7 [2,89; 35,15]	2/36 (5,6)	NE [NE; NE]	10,62 [2,56; 44,01] <,0001
1	29/57 (50,9)	10,2 [1,87; NE]	1/30 (3,3)	NE [NE; NE]	21,41 [2,91; 157,40] <,0001
Region (p-value of the interaction term: 0,9815)					
Europe	30/75 (40,0)	24,0 [15,55; NE]	2/37 (5,4)	NE [NE; NE]	8,56 [2,04; 35,87] 0,0004
North America	10/25 (40,0)	NE [2,10; NE]	1/16 (6,3)	NE [NE; NE]	7,41 [0,94; 58,21] 0,0257

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	31/43 (72,1)	1,0 [0,95; 6,48]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Measurable disease at baseline (p-value of the interaction term: 0,9876)					
Yes	58/108 (53,7)	10,4 [2,79; 24,00]	3/53 (5,7)	NE [NE; NE]	11,46 [3,58; 36,63] <,0001
No	13/35 (37,1)	NE [2,89; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0115
Progesterone receptor (p-value of the interaction term: 0,9885)					
Positive	56/115 (48,7)	18,7 [5,79; 35,15]	3/50 (6,0)	NE [NE; NE]	10,15 [3,18; 32,45] <,0001
Negative	13/23 (56,5)	4,7 [0,95; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0032
Sensitivity against endocrine therapy (p-value of the interaction term: 0,3795)					
Primary resistance	12/26 (46,2)	15,6 [1,41; NE]	1/10 (10,0)	NE [3,72; NE]	6,23 [0,81; 48,07] 0,0447
Secondary resistance	59/117 (50,4)	12,7 [4,93; 34,13]	2/56 (3,6)	NE [NE; NE]	17,26 [4,21; 70,68] <,0001
Starting dose (p-value of the interaction term: 0,9861)					
150 mg	50/103 (48,5)	18,7 [5,79; 35,15]	3/49 (6,1)	NE [NE; NE]	9,31 [2,90; 29,86] <,0001
200 mg	21/40 (52,5)	6,5 [0,99; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0004
Previous anti-estrogene therapy (p-value of the interaction term: 0,9211)					
Yes	36/69 (52,2)	10,4 [1,08; NE]	2/38 (5,3)	NE [NE; NE]	13,23 [3,18; 55,00] <,0001
No	35/74 (47,3)	15,6 [4,77; 35,15]	1/28 (3,6)	NE [NE; NE]	15,10 [2,07; 110,36] 0,0004

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t258_aesocpt_tte_sub_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 259.2.2: Subgroups: adverse events according PT - Musculoskeletal and connective tissue disorders/Pain in extremity - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,9905)					
≥ 65 years	6/64 (9,4)	NE [NE; NE]	0/38 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0792
< 65 years	11/79 (13,9)	NE [NE; NE]	1/28 (3,6)	NE [NE; NE]	2,94 [0,38; 22,89] 0,2800
ECOG-PS at Baseline (p-value of the interaction term: 0,9903)					
0	13/83 (15,7)	NE [NE; NE]	0/36 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0439
1	4/57 (7,0)	NE [NE; NE]	1/30 (3,3)	NE [NE; NE]	1,71 [0,19; 15,40] 0,6283
Region (p-value of the interaction term: 1,0000)					
Europe	6/75 (8,0)	NE [NE; NE]	0/37 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1603
North America	9/25 (36,0)	NE [5,36; NE]	1/16 (6,3)	NE [NE; NE]	4,25 [0,53; 34,43] 0,1413
Asian	2/43 (4,7)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4219
Measurable disease at baseline (p-value of the interaction term: 0,9936)					
Yes	13/108 (12,0)	NE [NE; NE]	1/53 (1,9)	NE [NE; NE]	4,67 [0,60; 36,04] 0,1045
No	4/35 (11,4)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2057
Progesterone receptor (p-value of the interaction term: 0,9995)					
Positive	17/115 (14,8)	NE [NE; NE]	1/50 (2,0)	NE [NE; NE]	5,99 [0,80; 45,15] 0,0479
Negative	0/23 (0,0)	NE [NE; NE]	0/12 (0,0)	NE [NE; NE]	NE
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9928)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Primary resistance	1/26 (3,8)	NE [NE; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,5186
Secondary resistance	16/117 (13,7)	NE [NE; NE]	1/56 (1,8)	NE [NE; NE]	5,94 [0,78; 45,09] 0,0504
Starting dose (p-value of the interaction term: 0,9923)					
150 mg	15/103 (14,6)	NE [NE; NE]	0/49 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0229
200 mg	2/40 (5,0)	NE [NE; NE]	1/17 (5,9)	NE [NE; NE]	0,85 [0,08; 9,35] 0,8922

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t259_aesocpt_tte_sub_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 260.2.2: Subgroups: adverse events according PT - Blood and lymphatic system disorders/Thrombocytopenia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,3762)					
≥ 65 years	14/64 (21,9)	NE [NE; NE]	1/38 (2,6)	NE [NE; NE]	8,91 [1,17; 67,88] 0,0106
< 65 years	17/79 (21,5)	NE [NE; NE]	2/28 (7,1)	NE [NE; NE]	2,82 [0,65; 12,28] 0,1497
Organs involved (p-value of the interaction term: 0,9634)					
1	9/47 (19,1)	NE [34,85; NE]	1/20 (5,0)	NE [NE; NE]	3,51 [0,44; 27,82] 0,2054
2	12/49 (24,5)	NE [29,52; NE]	2/21 (9,5)	NE [NE; NE]	2,70 [0,60; 12,12] 0,1805
≥ 3	10/47 (21,3)	NE [NE; NE]	0/25 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0191
Nature of disease (p-value of the interaction term: 0,8961)					
Visceral	18/78 (23,1)	NE [29,52; NE]	2/39 (5,1)	NE [NE; NE]	4,22 [0,97; 18,29] 0,0366
Bone only	6/39 (15,4)	NE [34,85; NE]	1/15 (6,7)	NE [NE; NE]	2,30 [0,28; 19,14] 0,4315
Other	7/26 (26,9)	NE [NE; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0537
ECOG-PS at Baseline (p-value of the interaction term: 0,9864)					
0	18/83 (21,7)	NE [NE; NE]	3/36 (8,3)	NE [NE; NE]	2,70 [0,79; 9,22] 0,1006
1	13/57 (22,8)	34,8 [29,52; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0070
Region (p-value of the interaction term: 0,7520)					
Europe	14/75 (18,7)	NE [29,52; NE]	1/37 (2,7)	NE [NE; NE]	6,47 [0,85; 49,35] 0,0381
North America	2/25 (8,0)	NE [NE; NE]	0/16 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2519

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	15/43 (34,9)	NE [12,66; NE]	2/13 (15,4)	NE [4,47; NE]	2,74 [0,63; 12,01] 0,1694
Measurable disease at baseline (p-value of the interaction term: 0,2826)					
Yes	27/108 (25,0)	NE [NE; NE]	2/53 (3,8)	NE [NE; NE]	6,67 [1,58; 28,13] 0,0029
No	4/35 (11,4)	NE [34,85; NE]	1/13 (7,7)	NE [NE; NE]	1,52 [0,17; 13,64] 0,7046
Progesterone receptor (p-value of the interaction term: 0,9924)					
Positive	28/115 (24,3)	NE [34,85; NE]	3/50 (6,0)	NE [NE; NE]	4,19 [1,27; 13,80] 0,0107
Negative	3/23 (13,0)	NE [NE; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2475
Sensitivity against endocrine therapy (p-value of the interaction term: 0,0863)					
Primary resistance	6/26 (23,1)	NE [14,63; NE]	2/10 (20,0)	NE [2,79; NE]	1,29 [0,26; 6,39] 0,7605
Secondary resistance	25/117 (21,4)	NE [NE; NE]	1/56 (1,8)	NE [NE; NE]	11,51 [1,56; 85,20] 0,0024
Starting dose (p-value of the interaction term: 0,8244)					
150 mg	19/103 (18,4)	NE [NE; NE]	2/49 (4,1)	NE [NE; NE]	4,04 [0,94; 17,44] 0,0428
200 mg	12/40 (30,0)	NE [NE; NE]	1/17 (5,9)	NE [NE; NE]	6,19 [0,80; 47,72] 0,0453
Previous anti-estrogene therapy (p-value of the interaction term: 0,9735)					
Yes	18/69 (26,1)	NE [34,85; NE]	2/38 (5,3)	NE [NE; NE]	5,00 [1,16; 21,64] 0,0172
No	13/74 (17,6)	NE [NE; NE]	1/28 (3,6)	NE [NE; NE]	4,65 [0,61; 35,75] 0,1041

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas

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/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 261.2.2: Subgroups: adverse events according PT - Gastrointestinal disorders/Vomiting - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,4159)					
≥ 65 years	15/64 (23,4)	NE [NE; NE]	6/38 (15,8)	NE [19,79; NE]	1,59 [0,62; 4,11] 0,3344
< 65 years	25/79 (31,6)	NE [19,53; NE]	3/28 (10,7)	NE [NE; NE]	2,91 [0,88; 9,64] 0,0679
Organs involved (p-value of the interaction term: 0,5830)					
1	15/47 (31,9)	NE [7,53; NE]	3/20 (15,0)	NE [7,69; NE]	2,36 [0,68; 8,15] 0,1623
2	16/49 (32,7)	NE [18,58; NE]	5/21 (23,8)	NE [7,40; NE]	1,39 [0,51; 3,82] 0,5175
≥ 3	9/47 (19,1)	NE [NE; NE]	1/25 (4,0)	NE [NE; NE]	4,92 [0,62; 38,95] 0,0946
Nature of disease (p-value of the interaction term: 0,4870)					
Visceral	23/78 (29,5)	NE [24,23; NE]	5/39 (12,8)	NE [NE; NE]	2,31 [0,88; 6,11] 0,0814
Bone only	13/39 (33,3)	NE [6,58; NE]	2/15 (13,3)	NE [3,91; NE]	3,06 [0,69; 13,56] 0,1218
Other	4/26 (15,4)	NE [18,58; NE]	2/12 (16,7)	19,8 [NE; NE]	0,67 [0,12; 3,84] 0,6388
ECOG-PS at Baseline (p-value of the interaction term: 0,2637)					
0	22/83 (26,5)	NE [NE; NE]	6/36 (16,7)	NE [19,79; NE]	1,49 [0,60; 3,69] 0,3901
1	18/57 (31,6)	NE [18,58; NE]	3/30 (10,0)	NE [NE; NE]	3,51 [1,03; 11,93] 0,0319
Region (p-value of the interaction term: 0,1216)					
Europe	15/75 (20,0)	NE [NE; NE]	5/37 (13,5)	NE [NE; NE]	1,37 [0,50; 3,78] 0,5431
North America	14/25 (56,0)	4,6 [0,62; NE]	1/16 (6,3)	NE [NE; NE]	12,05 [1,58; 91,93] 0,0022

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	11/43 (25,6)	NE [NE; NE]	3/13 (23,1)	NE [7,69; NE]	1,15 [0,32; 4,14] 0,8267
Measurable disease at baseline (p-value of the interaction term: 0,9311)					
Yes	30/108 (27,8)	NE [NE; NE]	7/53 (13,2)	NE [19,79; NE]	2,10 [0,92; 4,79] 0,0727
No	10/35 (28,6)	NE [7,53; NE]	2/13 (15,4)	NE [3,91; NE]	2,37 [0,52; 10,86] 0,2511
Progesterone receptor (p-value of the interaction term: 0,9365)					
Positive	32/115 (27,8)	NE [NE; NE]	6/50 (12,0)	NE [NE; NE]	2,43 [1,01; 5,81] 0,0397
Negative	5/23 (21,7)	NE [NE; NE]	1/12 (8,3)	NE [5,75; NE]	2,88 [0,34; 24,71] 0,3119
Sensitivity against endocrine therapy (p-value of the interaction term: 0,8166)					
Primary resistance	6/26 (23,1)	NE [NE; NE]	1/10 (10,0)	NE [7,40; NE]	2,55 [0,31; 21,17] 0,3697
Secondary resistance	34/117 (29,1)	NE [NE; NE]	8/56 (14,3)	NE [19,79; NE]	2,02 [0,93; 4,39] 0,0688
Starting dose (p-value of the interaction term: 0,9870)					
150 mg	26/103 (25,2)	NE [NE; NE]	9/49 (18,4)	NE [19,79; NE]	1,27 [0,60; 2,73] 0,5331
200 mg	14/40 (35,0)	NE [2,43; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0073
Previous anti-estrogene therapy (p-value of the interaction term: 0,7988)					
Yes	20/69 (29,0)	NE [NE; NE]	5/38 (13,2)	NE [19,79; NE]	2,25 [0,84; 6,02] 0,0954
No	20/74 (27,0)	NE [24,23; NE]	4/28 (14,3)	NE [NE; NE]	1,88 [0,64; 5,54] 0,2417

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

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/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 262.2.2: Subgroups: adverse events according PT - Investigations/Weight decreased - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
ECOG-PS at Baseline (p-value of the interaction term: 0,9920)					
0	10/83 (12,0)	NE [NE; NE]	1/36 (2,8)	NE [NE; NE]	3,99 [0,51; 31,40] 0,1548
1	4/57 (7,0)	NE [NE; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1711
Measurable disease at baseline (p-value of the interaction term: 0,9911)					
Yes	9/108 (8,3)	NE [NE; NE]	1/53 (1,9)	NE [NE; NE]	3,83 [0,48; 30,42] 0,1725
No	5/35 (14,3)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1315
Progesterone receptor (p-value of the interaction term: 0,9922)					
Positive	10/115 (8,7)	NE [NE; NE]	1/50 (2,0)	NE [NE; NE]	3,93 [0,50; 30,78] 0,1588
Negative	2/23 (8,7)	NE [NE; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2800
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9928)					
Primary resistance	2/26 (7,7)	NE [NE; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3893
Secondary resistance	12/117 (10,3)	NE [NE; NE]	1/56 (1,8)	NE [NE; NE]	5,18 [0,67; 39,98] 0,0783

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/t262_aesocpt_tte_sub_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 263.2.2: Subgroups: adverse events according SOC - Blood and lymphatic system disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,3992)					
≥ 65 years	38/64 (59,4)	4,8 [0,99; 10,62]	3/38 (7,9)	NE [NE; NE]	12,05 [3,70; 39,26] <,0001
< 65 years	50/79 (63,3)	3,0 [0,95; 14,96]	4/28 (14,3)	NE [NE; NE]	6,14 [2,21; 17,01] <,0001
Organs involved (p-value of the interaction term: 0,4916)					
1	26/47 (55,3)	6,4 [0,95; NE]	1/20 (5,0)	NE [NE; NE]	15,48 [2,10; 114,23] 0,0003
2	33/49 (67,3)	3,7 [0,99; 14,96]	4/21 (19,0)	NE [NE; NE]	5,23 [1,85; 14,81] 0,0005
≥ 3	29/47 (61,7)	3,0 [0,95; 13,15]	2/25 (8,0)	NE [7,40; NE]	10,53 [2,51; 44,23] <,0001
Nature of disease (p-value of the interaction term: 0,7640)					
Visceral	50/78 (64,1)	4,2 [0,99; 11,01]	6/39 (15,4)	NE [NE; NE]	5,69 [2,44; 13,29] <,0001
Bone only	21/39 (53,8)	6,4 [0,95; NE]	1/15 (6,7)	NE [NE; NE]	11,66 [1,56; 86,87] 0,0023
Other	17/26 (65,4)	2,8 [0,49; 23,97]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0008
ECOG-PS at Baseline (p-value of the interaction term: 0,1308)					
0	54/83 (65,1)	2,9 [0,99; 11,01]	6/36 (16,7)	NE [NE; NE]	5,42 [2,33; 12,62] <,0001
1	34/57 (59,6)	3,3 [0,95; 10,62]	1/30 (3,3)	NE [NE; NE]	27,22 [3,72; 199,27] <,0001
Region (p-value of the interaction term: 0,7612)					
Europe	35/75 (46,7)	15,0 [6,41; 24,00]	3/37 (8,1)	NE [NE; NE]	7,16 [2,20; 23,31] 0,0001
North America	16/25 (64,0)	2,1 [0,95; 28,57]	2/16 (12,5)	NE [7,40; NE]	7,28 [1,66; 32,00] 0,0022

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	37/43 (86,0)	0,6 [0,49; 1,87]	2/13 (15,4)	NE [3,72; NE]	11,80 [2,82; 49,33] <,0001
Measurable disease at baseline (p-value of the interaction term: 0,9428)					
Yes	72/108 (66,7)	2,8 [0,99; 6,48]	6/53 (11,3)	NE [NE; NE]	8,41 [3,65; 19,37] <,0001
No	16/35 (45,7)	10,6 [1,84; NE]	1/13 (7,7)	NE [NE; NE]	7,99 [1,06; 60,37] 0,0163
Progesterone receptor (p-value of the interaction term: 0,9853)					
Positive	69/115 (60,0)	4,2 [1,84; 11,01]	7/50 (14,0)	NE [NE; NE]	6,04 [2,77; 13,16] <,0001
Negative	17/23 (73,9)	2,9 [0,95; 10,62]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0002
Starting dose (p-value of the interaction term: 0,3803)					
150 mg	63/103 (61,2)	4,9 [1,87; 11,11]	6/49 (12,2)	NE [NE; NE]	6,83 [2,95; 15,79] <,0001
200 mg	25/40 (62,5)	1,9 [0,79; 6,48]	1/17 (5,9)	NE [NE; NE]	18,43 [2,48; 136,88] <,0001
Previous anti-estrogene therapy (p-value of the interaction term: 0,5359)					
Yes	43/69 (62,3)	3,7 [0,95; 14,96]	5/38 (13,2)	NE [NE; NE]	6,82 [2,70; 17,26] <,0001
No	45/74 (60,8)	3,3 [1,41; 10,62]	2/28 (7,1)	NE [NE; NE]	11,90 [2,88; 49,10] <,0001

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 264.2.2: Subgroups: adverse events according SOC - Gastrointestinal disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,3549)					
≥ 65 years	58/64 (90,6)	0,1 [0,10; 0,23]	23/38 (60,5)	4,6 [2,89; 8,22]	4,40 [2,64; 7,34] <,0001
< 65 years	76/79 (96,2)	0,2 [0,10; 0,23]	20/28 (71,4)	1,3 [0,72; 4,64]	3,29 [1,97; 5,50] <,0001
Organs involved (p-value of the interaction term: 0,3040)					
1	43/47 (91,5)	0,1 [0,10; 0,26]	15/20 (75,0)	3,6 [0,20; 7,69]	2,57 [1,40; 4,72] 0,0018
2	48/49 (98,0)	0,2 [0,10; 0,23]	14/21 (66,7)	3,5 [1,71; 8,22]	8,37 [3,95; 17,75] <,0001
≥ 3	43/47 (91,5)	0,1 [0,07; 0,23]	14/25 (56,0)	7,4 [0,95; NE]	4,46 [2,33; 8,51] <,0001
Nature of disease (p-value of the interaction term: 0,8117)					
Visceral	74/78 (94,9)	0,2 [0,10; 0,23]	25/39 (64,1)	2,9 [1,02; 7,43]	4,34 [2,68; 7,06] <,0001
Bone only	35/39 (89,7)	0,1 [0,10; 0,30]	10/15 (66,7)	3,6 [0,76; 7,73]	3,29 [1,59; 6,80] 0,0008
Other	25/26 (96,2)	0,1 [0,07; 0,26]	8/12 (66,7)	2,8 [0,10; NE]	5,45 [2,01; 14,73] 0,0003
ECOG-PS at Baseline (p-value of the interaction term: 0,3216)					
0	80/83 (96,4)	0,1 [0,07; 0,16]	24/36 (66,7)	2,8 [0,99; 7,73]	4,82 [2,96; 7,85] <,0001
1	52/57 (91,2)	0,2 [0,10; 0,30]	19/30 (63,3)	4,2 [1,64; 7,69]	3,38 [1,94; 5,89] <,0001
Measurable disease at baseline (p-value of the interaction term: 0,3744)					
Yes	104/108 (96,3)	0,1 [0,10; 0,20]	34/53 (64,2)	2,9 [1,02; 4,64]	4,73 [3,12; 7,16] <,0001
No	30/35 (85,7)	0,2 [0,10; 0,43]	9/13 (69,2)	5,6 [0,76; NE]	3,25 [1,45; 7,31] 0,0029
Progesterone receptor (p-value of the interaction term: 0,0727)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Positive	111/115 (96,5)	0,1 [0,10; 0,16]	31/50 (62,0)	3,6 [1,68; 7,43]	5,16 [3,35; 7,94] <,0001
Negative	18/23 (78,3)	0,2 [0,07; 0,46]	8/12 (66,7)	3,7 [0,30; 7,73]	1,99 [0,86; 4,62] 0,1055
Sensitivity against endocrine therapy (p-value of the interaction term: 0,2457)					
Primary resistance	24/26 (92,3)	0,1 [0,07; 0,16]	5/10 (50,0)	4,6 [0,20; NE]	5,36 [1,97; 14,61] 0,0003
Secondary resistance	110/117 (94,0)	0,2 [0,10; 0,23]	38/56 (67,9)	3,5 [1,61; 5,56]	3,82 [2,58; 5,65] <,0001
Starting dose (p-value of the interaction term: 0,1392)					
150 mg	95/103 (92,2)	0,2 [0,10; 0,23]	35/49 (71,4)	2,9 [1,61; 5,56]	3,53 [2,35; 5,31] <,0001
200 mg	39/40 (97,5)	0,1 [0,07; 0,16]	8/17 (47,1)	4,6 [0,10; NE]	6,42 [2,64; 15,60] <,0001
Previous anti-estrogene therapy (p-value of the interaction term: 0,8496)					
Yes	65/69 (94,2)	0,1 [0,10; 0,23]	25/38 (65,8)	4,6 [1,61; 7,69]	3,95 [2,42; 6,42] <,0001
No	69/74 (93,2)	0,2 [0,10; 0,23]	18/28 (64,3)	2,9 [0,99; NE]	4,04 [2,33; 7,00] <,0001

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 265.2.2: Subgroups: adverse events according SOC - Infections and infestations - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,3320)					
≥ 65 years	29/64 (45,3)	13,8 [5,56; NE]	7/38 (18,4)	25,4 [9,44; NE]	2,49 [1,09; 5,69] 0,0257
< 65 years	45/79 (57,0)	10,1 [6,08; 15,48]	10/28 (35,7)	23,3 [9,11; NE]	1,42 [0,72; 2,83] 0,3108
Organs involved (p-value of the interaction term: 0,4804)					
1	29/47 (61,7)	6,5 [4,96; 10,06]	5/20 (25,0)	15,1 [9,44; NE]	2,98 [1,15; 7,72] 0,0184
2	26/49 (53,1)	12,2 [4,18; 30,35]	8/21 (38,1)	23,3 [4,54; NE]	1,40 [0,63; 3,11] 0,4067
≥ 3	19/47 (40,4)	14,1 [7,92; NE]	4/25 (16,0)	NE [9,11; NE]	1,82 [0,61; 5,41] 0,2770
Nature of disease (p-value of the interaction term: 0,8434)					
Visceral	37/78 (47,4)	13,8 [10,62; NE]	9/39 (23,1)	23,3 [9,11; NE]	1,71 [0,82; 3,57] 0,1461
Bone only	23/39 (59,0)	6,9 [5,26; 12,92]	5/15 (33,3)	15,1 [4,57; NE]	1,99 [0,75; 5,24] 0,1562
Other	14/26 (53,8)	6,3 [3,48; NE]	3/12 (25,0)	25,4 [4,54; NE]	2,47 [0,70; 8,70] 0,1453
ECOG-PS at Baseline (p-value of the interaction term: 0,8916)					
0	44/83 (53,0)	10,6 [6,08; 20,05]	9/36 (25,0)	23,3 [9,44; NE]	1,85 [0,90; 3,81] 0,0888
1	27/57 (47,4)	12,2 [5,56; 16,50]	8/30 (26,7)	15,1 [9,11; NE]	1,78 [0,81; 3,93] 0,1464
Region (p-value of the interaction term: 0,5613)					
Europe	37/75 (49,3)	12,1 [6,08; 25,22]	7/37 (18,9)	NE [9,11; NE]	2,60 [1,16; 5,86] 0,0163
North America	18/25 (72,0)	5,9 [2,66; 10,62]	5/16 (31,3)	NE [2,86; NE]	1,47 [0,52; 4,15] 0,4637

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	19/43 (44,2)	18,6 [5,88; NE]	5/13 (38,5)	25,4 [13,22; NE]	1,32 [0,49; 3,55] 0,5852
Measurable disease at baseline (p-value of the interaction term: 0,5591)					
Yes	54/108 (50,0)	12,2 [6,48; 18,61]	13/53 (24,5)	23,3 [13,22; NE]	1,74 [0,94; 3,21] 0,0723
No	20/35 (57,1)	6,9 [4,96; 12,92]	4/13 (30,8)	NE [4,57; NE]	2,54 [0,86; 7,48] 0,0804
Progesterone receptor (p-value of the interaction term: 0,5582)					
Positive	64/115 (55,7)	10,6 [6,25; 13,78]	14/50 (28,0)	25,4 [13,22; NE]	1,88 [1,05; 3,35] 0,0306
Negative	8/23 (34,8)	NE [4,96; NE]	3/12 (25,0)	15,1 [4,54; NE]	1,36 [0,36; 5,15] 0,6534
Sensitivity against endocrine therapy (p-value of the interaction term: 0,1646)					
Primary resistance	12/26 (46,2)	9,3 [4,60; NE]	5/10 (50,0)	15,1 [0,23; NE]	1,03 [0,36; 2,96] 0,9556
Secondary resistance	62/117 (53,0)	10,6 [6,25; 15,48]	12/56 (21,4)	25,4 [13,22; NE]	2,28 [1,23; 4,24] 0,0074
Starting dose (p-value of the interaction term: 0,8587)					
150 mg	51/103 (49,5)	10,6 [6,31; 25,22]	12/49 (24,5)	25,4 [15,06; NE]	1,85 [0,98; 3,47] 0,0530
200 mg	23/40 (57,5)	9,3 [4,18; 13,78]	5/17 (29,4)	13,2 [9,11; NE]	1,86 [0,70; 4,93] 0,2059
Previous anti-estrogene therapy (p-value of the interaction term: 0,1016)					
Yes	36/69 (52,2)	12,9 [6,90; 18,61]	13/38 (34,2)	23,3 [9,44; NE]	1,27 [0,67; 2,42] 0,4559
No	38/74 (51,4)	7,2 [5,10; 14,07]	4/28 (14,3)	NE [NE; NE]	3,67 [1,31; 10,29] 0,0082

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 266.2.2: Subgroups: adverse events according SOC - Investigations - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,3361)					
≥ 65 years	26/64 (40,6)	23,1 [5,95; NE]	4/38 (10,5)	NE [NE; NE]	4,61 [1,61; 13,22] 0,0018
< 65 years	26/79 (32,9)	NE [22,13; NE]	4/28 (14,3)	NE [15,68; NE]	2,15 [0,75; 6,19] 0,1447
Organs involved (p-value of the interaction term: 0,3807)					
1	20/47 (42,6)	21,0 [7,40; NE]	1/20 (5,0)	NE [NE; NE]	9,60 [1,29; 71,54] 0,0068
2	20/49 (40,8)	29,5 [5,95; NE]	4/21 (19,0)	NE [15,68; NE]	2,33 [0,80; 6,84] 0,1132
≥ 3	12/47 (25,5)	NE [22,52; NE]	3/25 (12,0)	NE [NE; NE]	2,00 [0,56; 7,13] 0,2810
Nature of disease (p-value of the interaction term: 0,8039)					
Visceral	28/78 (35,9)	29,5 [17,98; NE]	5/39 (12,8)	NE [15,68; NE]	2,66 [1,02; 6,92] 0,0374
Bone only	19/39 (48,7)	14,6 [3,72; NE]	2/15 (13,3)	NE [4,60; NE]	4,65 [1,08; 19,99] 0,0231
Other	5/26 (19,2)	NE [NE; NE]	1/12 (8,3)	NE [NE; NE]	2,69 [0,31; 23,07] 0,3490
ECOG-PS at Baseline (p-value of the interaction term: 0,4492)					
0	30/83 (36,1)	NE [22,52; NE]	5/36 (13,9)	NE [15,68; NE]	2,60 [1,00; 6,73] 0,0428
1	22/57 (38,6)	21,0 [12,23; NE]	3/30 (10,0)	NE [NE; NE]	4,64 [1,38; 15,55] 0,0062
Region (p-value of the interaction term: 0,4712)					
Europe	24/75 (32,0)	35,1 [20,98; NE]	7/37 (18,9)	NE [15,68; NE]	1,73 [0,74; 4,01] 0,2010
North America	10/25 (40,0)	22,1 [3,72; NE]	0/16 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0145

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	18/43 (41,9)	22,5 [3,95; NE]	1/13 (7,7)	NE [NE; NE]	6,68 [0,89; 50,07] 0,0322
Measurable disease at baseline (p-value of the interaction term: 0,3219)					
Yes	37/108 (34,3)	35,1 [22,13; NE]	7/53 (13,2)	NE [15,68; NE]	2,51 [1,12; 5,66] 0,0217
No	15/35 (42,9)	21,0 [3,72; NE]	1/13 (7,7)	NE [NE; NE]	7,43 [0,98; 56,39] 0,0223
Progesterone receptor (p-value of the interaction term: 0,9886)					
Positive	40/115 (34,8)	35,1 [22,13; NE]	7/50 (14,0)	NE [NE; NE]	2,57 [1,15; 5,73] 0,0176
Negative	10/23 (43,5)	21,0 [2,89; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0126
Sensitivity against endocrine therapy (p-value of the interaction term: 0,8545)					
Primary resistance	8/26 (30,8)	22,1 [5,95; NE]	1/10 (10,0)	NE [15,68; NE]	4,62 [0,57; 37,74] 0,1184
Secondary resistance	44/117 (37,6)	35,1 [20,98; NE]	7/56 (12,5)	NE [NE; NE]	3,11 [1,40; 6,93] 0,0035
Starting dose (p-value of the interaction term: 0,3302)					
150 mg	37/103 (35,9)	35,1 [20,98; NE]	7/49 (14,3)	NE [NE; NE]	2,47 [1,10; 5,56] 0,0238
200 mg	15/40 (37,5)	22,1 [2,89; NE]	1/17 (5,9)	NE [NE; NE]	7,81 [1,03; 59,37] 0,0187
Previous anti-estrogene therapy (p-value of the interaction term: 0,6010)					
Yes	25/69 (36,2)	NE [12,23; NE]	4/38 (10,5)	NE [NE; NE]	3,74 [1,30; 10,76] 0,0089
No	27/74 (36,5)	23,1 [14,63; NE]	4/28 (14,3)	NE [NE; NE]	2,45 [0,85; 7,03] 0,0850

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 267.2.2: Subgroups: adverse events according SOC - Metabolism and nutrition disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Organs involved (p-value of the interaction term: 0,0988)					
1	27/47 (57,4)	8,3 [4,54; 24,79]	2/20 (10,0)	33,4 [33,44; NE]	7,01 [1,66; 29,52] 0,0020
2	24/49 (49,0)	20,4 [0,95; NE]	9/21 (42,9)	34,6 [3,06; NE]	1,17 [0,54; 2,54] 0,6727
≥ 3	22/47 (46,8)	24,0 [1,25; NE]	6/25 (24,0)	NE [6,48; NE]	2,17 [0,88; 5,39] 0,0876
Nature of disease (p-value of the interaction term: 0,2231)					
Visceral	38/78 (48,7)	24,0 [3,75; NE]	13/39 (33,3)	NE [6,48; NE]	1,55 [0,82; 2,92] 0,1720
Bone only	21/39 (53,8)	16,6 [3,85; 37,78]	3/15 (20,0)	33,4 [5,62; NE]	3,13 [0,93; 10,52] 0,0515
Other	14/26 (53,8)	6,5 [0,95; NE]	1/12 (8,3)	34,6 [NE; NE]	7,97 [1,05; 60,83] 0,0174
ECOG-PS at Baseline (p-value of the interaction term: 0,1466)					
0	40/83 (48,2)	24,8 [3,75; NE]	11/36 (30,6)	34,6 [7,43; NE]	1,62 [0,82; 3,19] 0,1579
1	33/57 (57,9)	7,7 [2,73; 17,06]	6/30 (20,0)	NE [33,44; NE]	3,69 [1,54; 8,83] 0,0017
Region (p-value of the interaction term: 0,6285)					
Europe	36/75 (48,0)	17,1 [4,64; NE]	11/37 (29,7)	33,4 [6,48; NE]	1,73 [0,88; 3,40] 0,1065
North America	14/25 (56,0)	6,5 [1,05; 38,76]	3/16 (18,8)	NE [7,43; NE]	2,99 [0,84; 10,60] 0,0759
Asian	23/43 (53,5)	7,8 [0,53; NE]	3/13 (23,1)	34,6 [2,79; NE]	2,84 [0,85; 9,49] 0,0769
Measurable disease at baseline (p-value of the interaction term: 0,2524)					
Yes	58/108 (53,7)	7,8 [2,73; 38,76]	16/53 (30,2)	34,6 [7,43; NE]	1,97 [1,13; 3,44] 0,0148

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
No	15/35 (42,9)	24,8 [4,64; NE]	1/13 (7,7)	NE [33,44; NE]	6,67 [0,88; 50,60] 0,0338
Progesterone receptor (p-value of the interaction term: 0,2839)					
Positive	57/115 (49,6)	17,1 [4,64; 38,76]	15/50 (30,0)	34,6 [33,44; NE]	1,81 [1,03; 3,21] 0,0382
Negative	14/23 (60,9)	7,7 [0,36; 24,79]	2/12 (16,7)	NE [1,32; NE]	4,05 [0,92; 17,96] 0,0447
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9107)					
Primary resistance	16/26 (61,5)	4,6 [0,43; NE]	4/10 (40,0)	NE [0,49; NE]	2,14 [0,71; 6,45] 0,1672
Secondary resistance	57/117 (48,7)	20,4 [4,64; NE]	13/56 (23,2)	34,6 [33,44; NE]	2,20 [1,20; 4,03] 0,0087
Starting dose (p-value of the interaction term: 0,9814)					
150 mg	47/103 (45,6)	24,0 [7,66; NE]	17/49 (34,7)	33,4 [6,48; NE]	1,31 [0,75; 2,28] 0,3440
200 mg	26/40 (65,0)	2,2 [0,26; 17,06]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0001
Previous anti-estrogene therapy (p-value of the interaction term: 0,9461)					
Yes	39/69 (56,5)	4,6 [0,95; 38,76]	11/38 (28,9)	33,4 [33,44; NE]	2,31 [1,18; 4,54] 0,0126
No	34/74 (45,9)	17,1 [6,48; NE]	6/28 (21,4)	NE [5,62; NE]	2,10 [0,88; 5,01] 0,0864

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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Table 268.2.2: Subgroups: adverse events according SOC - Nervous system disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Organs involved (p-value of the interaction term: 0,8403)					
1	25/47 (53,2)	8,2 [4,64; NE]	7/20 (35,0)	18,6 [3,22; NE]	1,47 [0,63; 3,44] 0,3709
2	28/49 (57,1)	9,2 [1,84; 37,45]	6/21 (28,6)	NE [5,10; NE]	2,13 [0,88; 5,17] 0,0875
≥ 3	21/47 (44,7)	NE [1,87; NE]	5/25 (20,0)	NE [5,65; NE]	2,47 [0,93; 6,56] 0,0600
Nature of disease (p-value of the interaction term: 0,9487)					
Visceral	42/78 (53,8)	10,4 [1,87; NE]	10/39 (25,6)	NE [NE; NE]	2,28 [1,14; 4,56] 0,0165
Bone only	20/39 (51,3)	8,2 [2,96; NE]	5/15 (33,3)	18,6 [3,22; NE]	1,69 [0,63; 4,53] 0,2926
Other	12/26 (46,2)	11,1 [1,45; NE]	3/12 (25,0)	NE [0,79; NE]	1,89 [0,53; 6,73] 0,3171
ECOG-PS at Baseline (p-value of the interaction term: 0,4411)					
0	43/83 (51,8)	24,0 [2,37; NE]	11/36 (30,6)	NE [7,27; NE]	1,71 [0,88; 3,35] 0,1128
1	30/57 (52,6)	7,6 [2,27; NE]	7/30 (23,3)	NE [18,64; NE]	2,57 [1,13; 5,87] 0,0194
Region (p-value of the interaction term: 0,3551)					
Europe	31/75 (41,3)	NE [4,64; NE]	9/37 (24,3)	NE [7,27; NE]	1,89 [0,90; 3,98] 0,0899
North America	20/25 (80,0)	1,4 [0,16; 5,59]	4/16 (25,0)	NE [0,10; NE]	3,53 [1,20; 10,44] 0,0126
Asian	23/43 (53,5)	13,3 [2,27; 47,11]	5/13 (38,5)	NE [1,12; NE]	1,35 [0,51; 3,60] 0,5427
Measurable disease at baseline (p-value of the interaction term: 0,5303)					
Yes	60/108 (55,6)	6,5 [1,87; 37,45]	14/53 (26,4)	NE [NE; NE]	2,26 [1,26; 4,07] 0,0048

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
No	14/35 (40,0)	24,0 [5,59; NE]	4/13 (30,8)	18,6 [3,22; NE]	1,39 [0,45; 4,28] 0,5635
Progesterone receptor (p-value of the interaction term: 0,9647)					
Positive	61/115 (53,0)	7,6 [2,73; 37,45]	15/50 (30,0)	NE [7,27; NE]	1,87 [1,06; 3,30] 0,0271
Negative	10/23 (43,5)	47,1 [1,87; NE]	3/12 (25,0)	NE [2,76; NE]	1,88 [0,50; 7,02] 0,3429
Sensitivity against endocrine therapy (p-value of the interaction term: 0,3931)					
Primary resistance	10/26 (38,5)	NE [2,27; NE]	1/10 (10,0)	NE [1,12; NE]	4,53 [0,58; 35,45] 0,1139
Secondary resistance	64/117 (54,7)	8,2 [2,96; 37,45]	17/56 (30,4)	NE [7,27; NE]	1,84 [1,07; 3,16] 0,0244
Starting dose (p-value of the interaction term: 0,1114)					
150 mg	49/103 (47,6)	24,0 [4,87; NE]	15/49 (30,6)	NE [7,27; NE]	1,53 [0,86; 2,74] 0,1473
200 mg	25/40 (62,5)	2,4 [0,99; 37,45]	3/17 (17,6)	NE [NE; NE]	4,36 [1,31; 14,52] 0,0087
Previous anti-estrogene therapy (p-value of the interaction term: 0,4176)					
Yes	39/69 (56,5)	4,6 [1,87; NE]	13/38 (34,2)	NE [5,10; NE]	1,86 [0,99; 3,49] 0,0519
No	35/74 (47,3)	12,0 [5,59; NE]	5/28 (17,9)	NE [7,27; NE]	2,60 [1,01; 6,66] 0,0386

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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Table 269.2.2: Subgroups: adverse events according SOC - Skin and subcutaneous tissue disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Organs involved (p-value of the interaction term: 0,1074)					
1	24/47 (51,1)	9,7 [4,41; 23,84]	9/20 (45,0)	10,3 [5,49; NE]	1,21 [0,56; 2,63] 0,6357
2	26/49 (53,1)	9,1 [3,72; 45,04]	2/21 (9,5)	NE [NE; NE]	6,36 [1,50; 26,91] 0,0039
≥ 3	22/47 (46,8)	11,1 [5,59; NE]	4/25 (16,0)	NE [10,92; NE]	2,70 [0,92; 7,90] 0,0599
Nature of disease (p-value of the interaction term: 0,8502)					
Visceral	41/78 (52,6)	8,4 [3,72; 42,41]	8/39 (20,5)	NE [10,92; NE]	2,86 [1,34; 6,13] 0,0047
Bone only	18/39 (46,2)	9,1 [5,79; 23,84]	4/15 (26,7)	21,3 [5,26; NE]	2,05 [0,69; 6,10] 0,1890
Other	13/26 (50,0)	11,1 [3,78; NE]	3/12 (25,0)	NE [1,05; NE]	1,69 [0,47; 6,03] 0,4113
ECOG-PS at Baseline (p-value of the interaction term: 0,3309)					
0	41/83 (49,4)	12,9 [6,05; 45,04]	9/36 (25,0)	21,3 [10,29; NE]	1,94 [0,94; 4,02] 0,0694
1	30/57 (52,6)	7,5 [4,64; 17,56]	6/30 (20,0)	NE [10,92; NE]	3,43 [1,43; 8,27] 0,0034
Region (p-value of the interaction term: 0,7622)					
Europe	32/75 (42,7)	11,3 [7,13; NE]	8/37 (21,6)	21,3 [10,92; NE]	1,92 [0,88; 4,19] 0,0944
North America	14/25 (56,0)	2,8 [1,81; NE]	4/16 (25,0)	NE [5,49; NE]	2,62 [0,86; 8,02] 0,0785
Asian	26/43 (60,5)	7,9 [2,83; 23,84]	3/13 (23,1)	NE [6,90; NE]	3,18 [0,96; 10,56] 0,0457
Measurable disease at baseline (p-value of the interaction term: 0,1606)					
Yes	58/108 (53,7)	9,1 [4,41; 16,08]	10/53 (18,9)	NE [11,74; NE]	3,02 [1,54; 5,92] 0,0007

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
No	14/35 (40,0)	18,3 [6,74; NE]	5/13 (38,5)	12,8 [5,26; NE]	1,12 [0,40; 3,18] 0,8262
Progesterone receptor (p-value of the interaction term: 0,8049)					
Positive	60/115 (52,2)	9,4 [5,79; 16,08]	12/50 (24,0)	NE [10,92; NE]	2,38 [1,28; 4,44] 0,0048
Negative	11/23 (47,8)	18,3 [2,79; NE]	3/12 (25,0)	21,3 [2,99; NE]	1,91 [0,52; 7,01] 0,3194
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9353)					
Primary resistance	12/26 (46,2)	18,3 [2,83; NE]	3/10 (30,0)	NE [2,56; NE]	2,20 [0,61; 7,90] 0,2173
Secondary resistance	60/117 (51,3)	9,7 [6,74; 17,56]	12/56 (21,4)	21,3 [10,92; NE]	2,37 [1,27; 4,43] 0,0051
Starting dose (p-value of the interaction term: 0,6465)					
150 mg	52/103 (50,5)	11,1 [6,74; 18,31]	10/49 (20,4)	NE [10,92; NE]	2,63 [1,33; 5,19] 0,0038
200 mg	20/40 (50,0)	8,4 [3,72; NE]	5/17 (29,4)	11,7 [5,49; NE]	1,82 [0,68; 4,89] 0,2300
Previous anti-estrogene therapy (p-value of the interaction term: 0,7137)					
Yes	37/69 (53,6)	9,7 [4,37; 18,31]	10/38 (26,3)	NE [11,74; NE]	2,24 [1,11; 4,52] 0,0208
No	35/74 (47,3)	10,2 [5,59; 42,41]	5/28 (17,9)	NE [7,27; NE]	2,63 [1,02; 6,74] 0,0372

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 270.2.2: Subgroups: adverse events with CTCAE grade >= 3 according PT - Gastrointestinal disorders/Diarrhoea - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,9998)					
≥ 65 years	15/64 (23,4)	NE [NE; NE]	0/38 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0021
< 65 years	10/79 (12,7)	NE [NE; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0609
Organs involved (p-value of the interaction term: 1,0000)					
1	8/47 (17,0)	NE [NE; NE]	0/20 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0734
2	10/49 (20,4)	NE [NE; NE]	0/21 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0309
≥ 3	7/47 (14,9)	NE [NE; NE]	0/25 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0439
Nature of disease (p-value of the interaction term: 1,0000)					
Visceral	11/78 (14,1)	NE [NE; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0172
Bone only	7/39 (17,9)	NE [NE; NE]	0/15 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0955
Other	7/26 (26,9)	NE [5,42; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0558
ECOG-PS at Baseline (p-value of the interaction term: 0,9999)					
0	17/83 (20,5)	NE [NE; NE]	0/36 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0066
1	8/57 (14,0)	NE [NE; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0372
Region (p-value of the interaction term: 1,0000)					
Europe	10/75 (13,3)	NE [NE; NE]	0/37 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0262
North America	6/25 (24,0)	NE [11,87; NE]	0/16 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0912

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	9/43 (20,9)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0802
Measurable disease at baseline (p-value of the interaction term: 0,9999)					
Yes	20/108 (18,5)	NE [NE; NE]	0/53 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0013
No	5/35 (14,3)	NE [21,24; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1490
Progesterone receptor (p-value of the interaction term: 0,9999)					
Positive	18/115 (15,7)	NE [NE; NE]	0/50 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0049
Negative	6/23 (26,1)	NE [11,87; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0711
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9999)					
Primary resistance	7/26 (26,9)	NE [21,24; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0792
Secondary resistance	18/117 (15,4)	NE [NE; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0030
Starting dose (p-value of the interaction term: 0,9998)					
150 mg	15/103 (14,6)	NE [NE; NE]	0/49 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0079
200 mg	10/40 (25,0)	NE [NE; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0276
Previous anti-estrogene therapy (p-value of the interaction term: 1,0000)					
Yes	12/69 (17,4)	NE [NE; NE]	0/38 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0095
No	13/74 (17,6)	NE [NE; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0266

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas
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/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 271.2.2: Subgroups: adverse events with CTCAE grade >= 3 according PT - Blood and lymphatic system disorders/Leukopenia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Measurable disease at baseline (p-value of the interaction term: 0,9974)					
Yes	13/108 (12,0)	NE [NE; NE]	0/53 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0208
No	0/35 (0,0)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	NE
Progesterone receptor (p-value of the interaction term: 1,0000)					
Positive	11/115 (9,6)	NE [NE; NE]	0/50 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0373
Negative	2/23 (8,7)	NE [NE; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3746
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9998)					
Primary resistance	1/26 (3,8)	NE [26,79; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4795
Secondary resistance	12/117 (10,3)	NE [NE; NE]	0/56 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0226
Starting dose (p-value of the interaction term: 1,0000)					
150 mg	10/103 (9,7)	NE [NE; NE]	0/49 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0439
200 mg	3/40 (7,5)	NE [26,79; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3119
Previous anti-estrogene therapy (p-value of the interaction term: 0,9996)					
Yes	12/69 (17,4)	NE [NE; NE]	0/38 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0143
No	1/74 (1,4)	NE [NE; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,5385

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/t_gba_aesocpt_tte_sub.sas

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
15JUL2021 / 03:20

Table 272.2.2: Subgroups: adverse events with CTCAE grade >= 3 according PT - Blood and lymphatic system disorders/Neutropenia - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,9871)					
≥ 65 years	18/64 (28,1)	NE [NE; NE]	1/38 (2,6)	NE [NE; NE]	12,21 [1,63; 91,55] 0,0018
< 65 years	24/79 (30,4)	NE [23,97; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0042
Organs involved (p-value of the interaction term: 0,9999)					
1	15/47 (31,9)	NE [20,78; NE]	0/20 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0107
2	14/49 (28,6)	NE [18,67; NE]	1/21 (4,8)	NE [NE; NE]	6,10 [0,80; 46,51] 0,0464
≥ 3	13/47 (27,7)	NE [23,97; NE]	0/25 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0086
Nature of disease (p-value of the interaction term: 0,9999)					
Visceral	23/78 (29,5)	NE [23,97; NE]	1/39 (2,6)	NE [NE; NE]	10,67 [1,44; 79,20] 0,0039
Bone only	10/39 (25,6)	NE [38,66; NE]	0/15 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0464
Other	9/26 (34,6)	NE [5,79; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0338
ECOG-PS at Baseline (p-value of the interaction term: 0,9862)					
0	23/83 (27,7)	NE [38,66; NE]	0/36 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0023
1	19/57 (33,3)	NE [12,16; NE]	1/30 (3,3)	NE [NE; NE]	11,51 [1,54; 86,01] 0,0025
Region (p-value of the interaction term: 0,9999)					
Europe	14/75 (18,7)	NE [NE; NE]	0/37 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0101
North America	9/25 (36,0)	26,6 [4,64; NE]	1/16 (6,3)	NE [NE; NE]	5,72 [0,71; 45,85] 0,0634

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	19/43 (44,2)	38,7 [5,79; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0076
Measurable disease at baseline (p-value of the interaction term: 0,9912)					
Yes	34/108 (31,5)	NE [23,97; NE]	1/53 (1,9)	NE [NE; NE]	16,44 [2,25; 120,35] 0,0002
No	8/35 (22,9)	NE [20,78; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0784
Progesterone receptor (p-value of the interaction term: 0,9886)					
Positive	35/115 (30,4)	NE [26,56; NE]	1/50 (2,0)	NE [NE; NE]	15,68 [2,15; 114,54] 0,0003
Negative	5/23 (21,7)	NE [23,97; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1248
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9882)					
Primary resistance	8/26 (30,8)	NE [4,70; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0605
Secondary resistance	34/117 (29,1)	NE [38,66; NE]	1/56 (1,8)	NE [NE; NE]	16,00 [2,19; 117,05] 0,0002
Starting dose (p-value of the interaction term: 0,9904)					
150 mg	31/103 (30,1)	NE [23,97; NE]	1/49 (2,0)	NE [NE; NE]	14,38 [1,96; 105,46] 0,0005
200 mg	11/40 (27,5)	NE [26,56; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0269
Previous anti-estrogene therapy (p-value of the interaction term: 0,9898)					
Yes	25/69 (36,2)	38,7 [18,67; NE]	0/38 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0002
No	17/74 (23,0)	NE [NE; NE]	1/28 (3,6)	NE [NE; NE]	6,47 [0,86; 48,81] 0,0371

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

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/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 273.2.2: Subgroups: time to adverse events with CTCAE grade >= 3 according SOC - Blood and lymphatic system disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,7435)					
≥ 65 years	24/64 (37,5)	27,6 [4,93; NE]	1/38 (2,6)	NE [NE; NE]	16,75 [2,26; 123,92] 0,0002
< 65 years	28/79 (35,4)	38,7 [20,78; NE]	1/28 (3,6)	NE [NE; NE]	9,90 [1,35; 72,88] 0,0055
Organs involved (p-value of the interaction term: 0,9999)					
1	19/47 (40,4)	27,6 [10,39; NE]	0/20 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0034
2	16/49 (32,7)	NE [18,67; NE]	2/21 (9,5)	NE [NE; NE]	3,59 [0,82; 15,65] 0,0688
≥ 3	17/47 (36,2)	NE [4,77; NE]	0/25 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0019
Nature of disease (p-value of the interaction term: 0,9998)					
Visceral	28/78 (35,9)	NE [12,23; NE]	2/39 (5,1)	NE [NE; NE]	6,92 [1,65; 29,13] 0,0022
Bone only	14/39 (35,9)	38,7 [20,78; NE]	0/15 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0165
Other	10/26 (38,5)	NE [3,25; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0233
ECOG-PS at Baseline (p-value of the interaction term: 0,8213)					
0	27/83 (32,5)	NE [26,56; NE]	1/36 (2,8)	NE [NE; NE]	11,09 [1,50; 81,96] 0,0030
1	25/57 (43,9)	12,2 [4,70; NE]	1/30 (3,3)	NE [NE; NE]	15,90 [2,15; 117,37] 0,0002
Region (p-value of the interaction term: 0,9995)					
Europe	18/75 (24,0)	NE [23,97; NE]	0/37 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0030
North America	13/25 (52,0)	4,9 [3,25; NE]	1/16 (6,3)	NE [NE; NE]	8,38 [1,08; 64,94] 0,0147

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	21/43 (48,8)	12,2 [5,79; NE]	1/13 (7,7)	NE [NE; NE]	8,45 [1,13; 62,87] 0,0123
Measurable disease at baseline (p-value of the interaction term: 0,9891)					
Yes	39/108 (36,1)	NE [18,67; NE]	2/53 (3,8)	NE [NE; NE]	9,87 [2,38; 40,93] 0,0001
No	13/35 (37,1)	27,6 [10,09; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0150
Progesterone receptor (p-value of the interaction term: 0,9858)					
Positive	41/115 (35,7)	NE [20,78; NE]	2/50 (4,0)	NE [NE; NE]	9,49 [2,29; 39,24] 0,0001
Negative	9/23 (39,1)	27,6 [4,70; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0346
Sensitivity against endocrine therapy (p-value of the interaction term: 0,2965)					
Primary resistance	10/26 (38,5)	26,6 [4,18; NE]	1/10 (10,0)	NE [4,34; NE]	4,49 [0,57; 35,14] 0,1165
Secondary resistance	42/117 (35,9)	38,7 [20,78; NE]	1/56 (1,8)	NE [NE; NE]	20,70 [2,85; 150,57] <,0001
Starting dose (p-value of the interaction term: 0,9885)					
150 mg	37/103 (35,9)	38,7 [20,78; NE]	2/49 (4,1)	NE [NE; NE]	8,78 [2,11; 36,47] 0,0003
200 mg	15/40 (37,5)	26,6 [4,18; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0058
Previous anti-estrogene therapy (p-value of the interaction term: 0,6183)					
Yes	29/69 (42,0)	26,6 [10,39; NE]	1/38 (2,6)	NE [NE; NE]	17,29 [2,35; 127,03] 0,0001
No	23/74 (31,1)	NE [23,97; NE]	1/28 (3,6)	NE [NE; NE]	8,60 [1,16; 63,83] 0,0113

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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/lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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Table 274.2.2: Subgroups: time to adverse events with CTCAE grade >= 3 according SOC - Gastrointestinal disorders - from RCT with medical drug to be assessed - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,9872)					
≥ 65 years	19/64 (29,7)	NE [NE; NE]	2/38 (5,3)	NE [NE; NE]	6,04 [1,40; 25,99] 0,0060
< 65 years	19/79 (24,1)	NE [35,51; NE]	0/28 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0127
Organs involved (p-value of the interaction term: 0,9999)					
1	15/47 (31,9)	NE [21,24; NE]	0/20 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0126
2	14/49 (28,6)	NE [24,23; NE]	2/21 (9,5)	NE [NE; NE]	2,86 [0,64; 12,74] 0,1488
≥ 3	9/47 (19,1)	NE [NE; NE]	0/25 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0213
Nature of disease (p-value of the interaction term: 0,8078)					
Visceral	19/78 (24,4)	NE [35,51; NE]	1/39 (2,6)	NE [NE; NE]	8,89 [1,19; 66,68] 0,0102
Bone only	12/39 (30,8)	NE [21,24; NE]	0/15 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0265
Other	7/26 (26,9)	NE [5,42; NE]	1/12 (8,3)	NE [8,22; NE]	3,53 [0,43; 28,71] 0,2088
ECOG-PS at Baseline (p-value of the interaction term: 0,7504)					
0	26/83 (31,3)	NE [24,23; NE]	1/36 (2,8)	NE [NE; NE]	10,03 [1,35; 74,41] 0,0054
1	12/57 (21,1)	NE [NE; NE]	1/30 (3,3)	NE [NE; NE]	6,58 [0,86; 50,65] 0,0366
Region (p-value of the interaction term: 0,9768)					
Europe	18/75 (24,0)	NE [NE; NE]	0/37 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0038
North America	9/25 (36,0)	35,5 [10,09; NE]	1/16 (6,3)	NE [NE; NE]	3,85 [0,47; 31,63] 0,1778

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Asian	11/43 (25,6)	NE [NE; NE]	1/13 (7,7)	NE [8,22; NE]	3,85 [0,50; 29,85] 0,1648
Measurable disease at baseline (p-value of the interaction term: 0,9907)					
Yes	29/108 (26,9)	NE [NE; NE]	2/53 (3,8)	NE [NE; NE]	7,06 [1,68; 29,68] 0,0019
No	9/35 (25,7)	24,2 [21,24; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0412
Progesterone receptor (p-value of the interaction term: 0,9873)					
Positive	29/115 (25,2)	NE [35,51; NE]	2/50 (4,0)	NE [NE; NE]	6,10 [1,45; 25,59] 0,0048
Negative	7/23 (30,4)	NE [2,37; NE]	0/12 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0465
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9877)					
Primary resistance	8/26 (30,8)	35,5 [21,24; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0450
Secondary resistance	30/117 (25,6)	NE [NE; NE]	2/56 (3,6)	NE [NE; NE]	6,96 [1,66; 29,21] 0,0020
Starting dose (p-value of the interaction term: 0,9903)					
150 mg	23/103 (22,3)	NE [NE; NE]	2/49 (4,1)	NE [NE; NE]	4,98 [1,17; 21,21] 0,0159
200 mg	15/40 (37,5)	35,5 [3,95; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0063
Previous anti-estrogene therapy (p-value of the interaction term: 0,7501)					
Yes	20/69 (29,0)	NE [35,51; NE]	1/38 (2,6)	NE [NE; NE]	10,29 [1,38; 76,95] 0,0049
No	18/74 (24,3)	NE [24,23; NE]	1/28 (3,6)	NE [NE; NE]	6,76 [0,90; 50,71] 0,0315

Data cut-off: 20.06.2019, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; mg: milligram; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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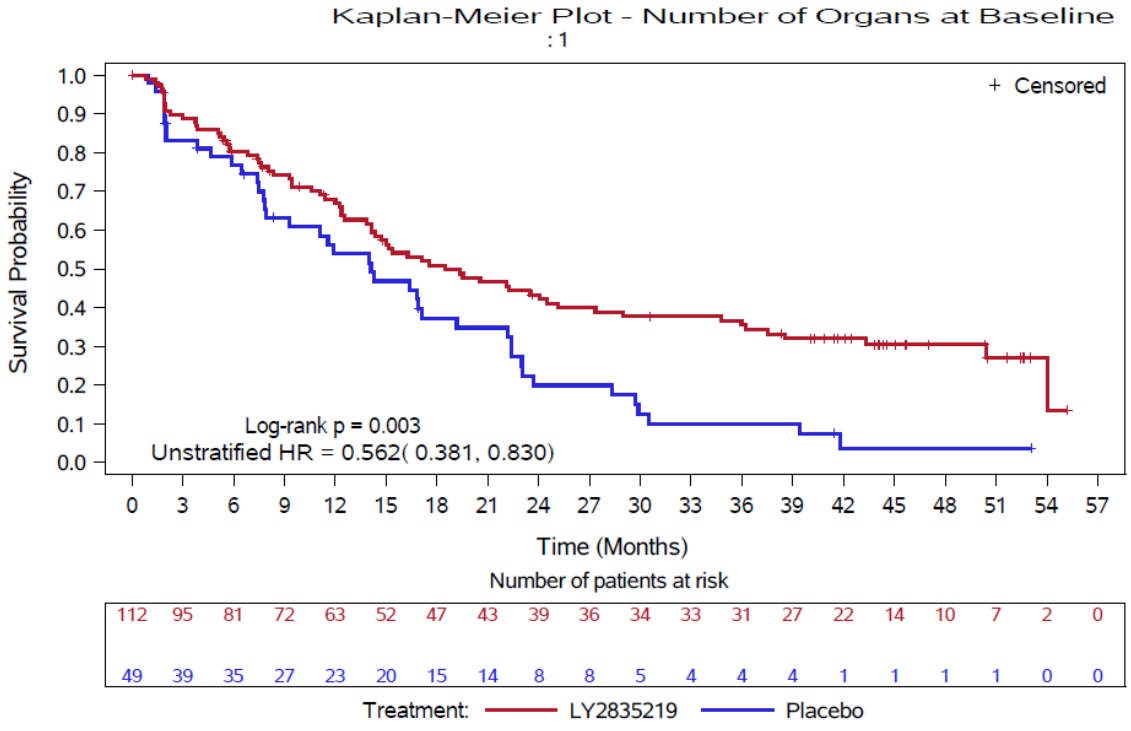
Abbildung 152 (Anhang): Kaplan-Meier-Kurven der Subgruppenanalysen (MONARCH-2)

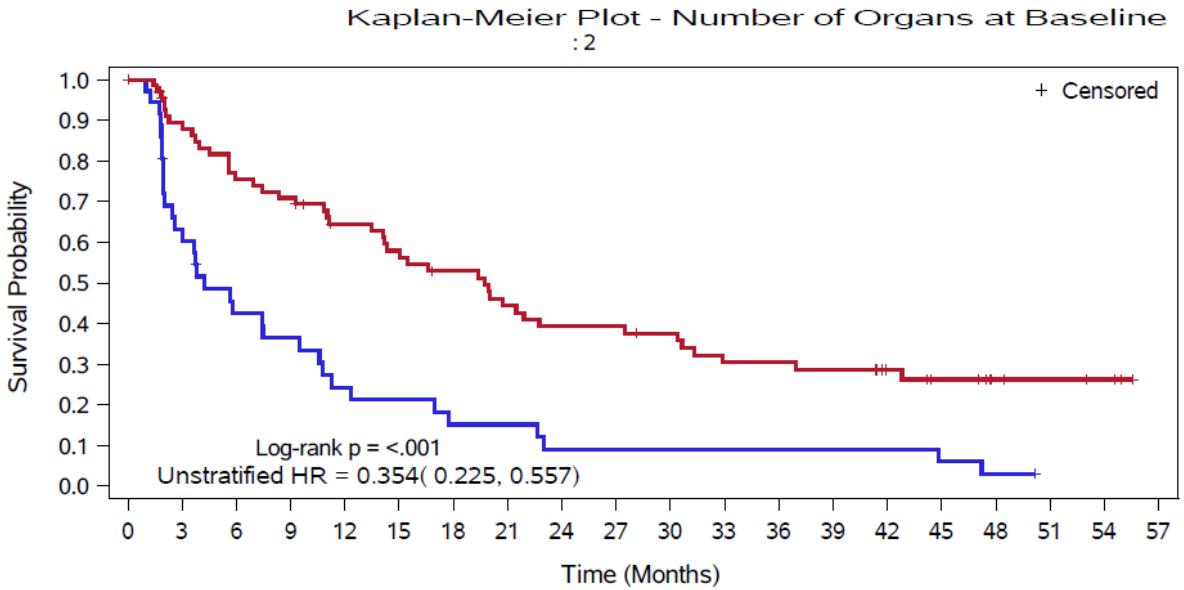
Signifikant interagierende Subgruppen – RCT

Kaplan-Meier Plot of PFS by Subgroup
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



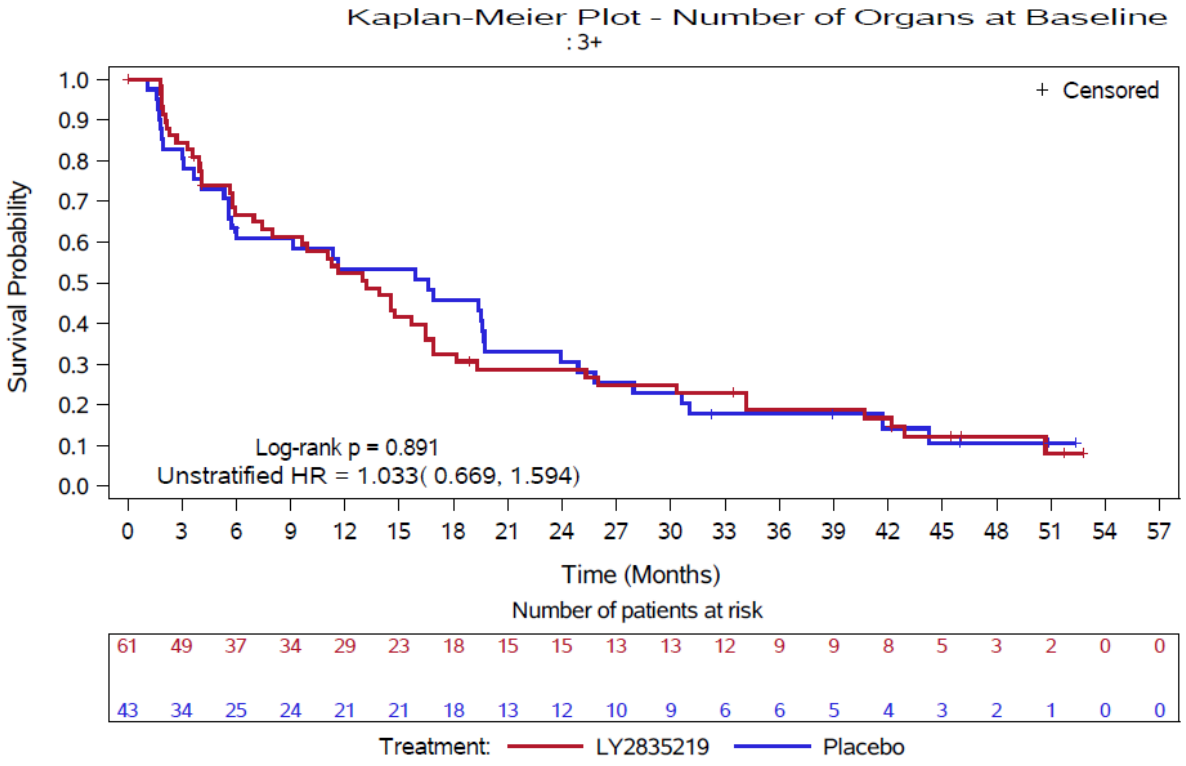
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	112	69 (61.6%)	43 (38.4%)	18.5 (14.1 - 25.1)
Placebo	49	41 (83.7%)	8 (16.3%)	14.1 (7.9 - 19.2)

Kaplan-Meier Plot of PFS by Subgroup
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



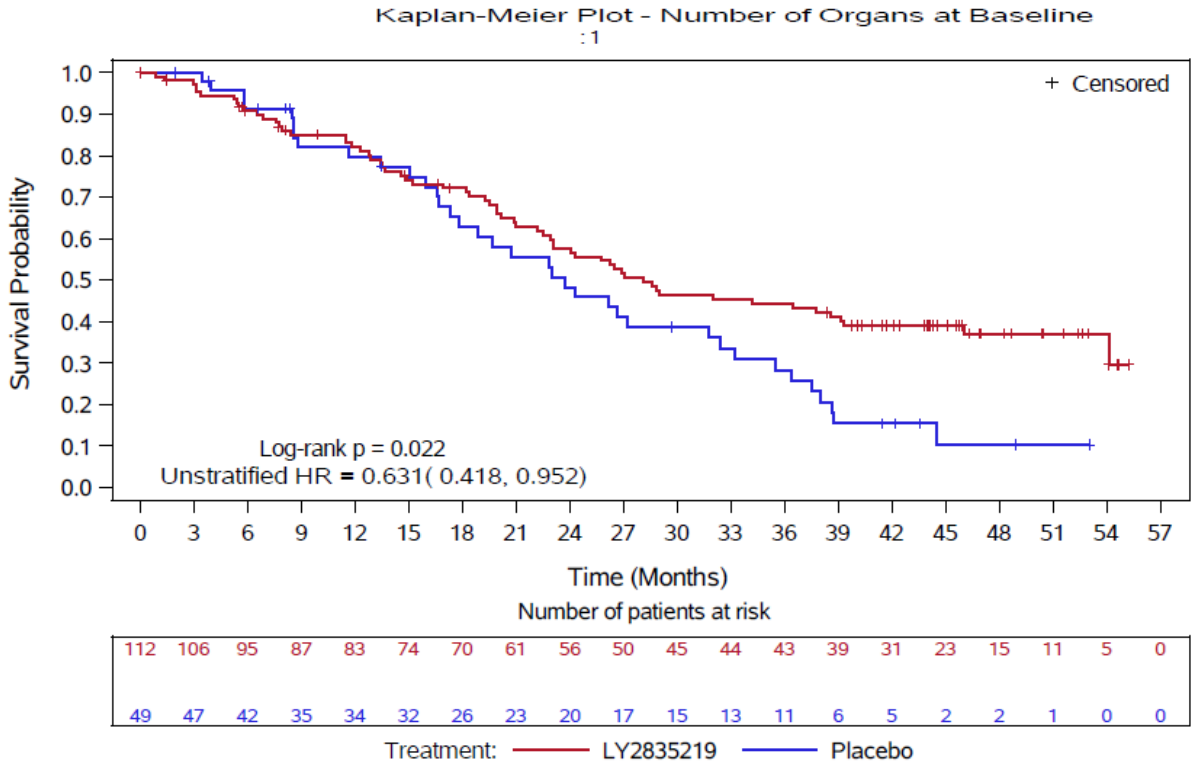
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	73	45 (61.6%)	28 (38.4%)	19.7 (13.4 - 27.5)
Placebo	36	33 (91.7%)	3 (8.3%)	4.2 (2.5 - 9.5)

Kaplan-Meier Plot of PFS by Subgroup
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



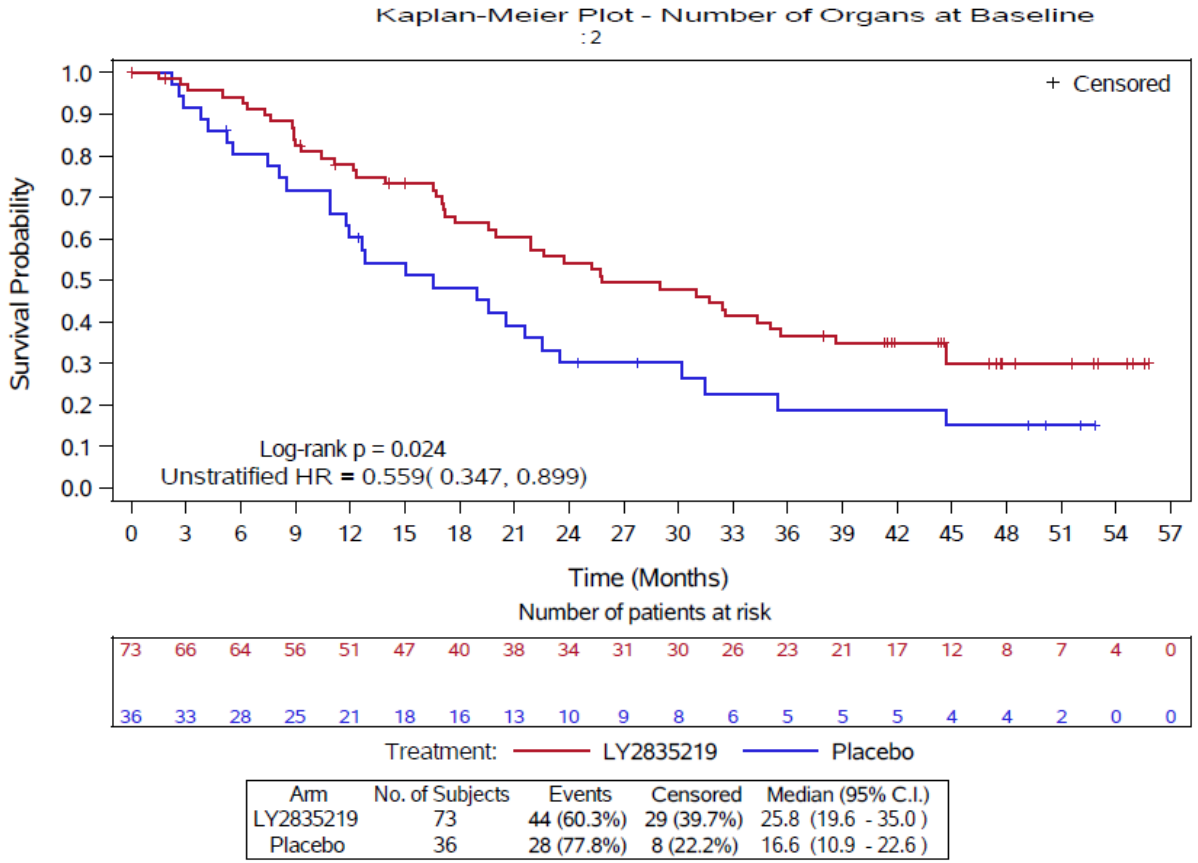
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	61	49 (80.3%)	12 (19.7%)	13.2 (7.4 - 16.5)
Placebo	43	35 (81.4%)	8 (18.6%)	16.6 (5.6 - 19.8)

Kaplan-Meier Plot of PFS2: time to discontinuation date of next line or death by Subgroup
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



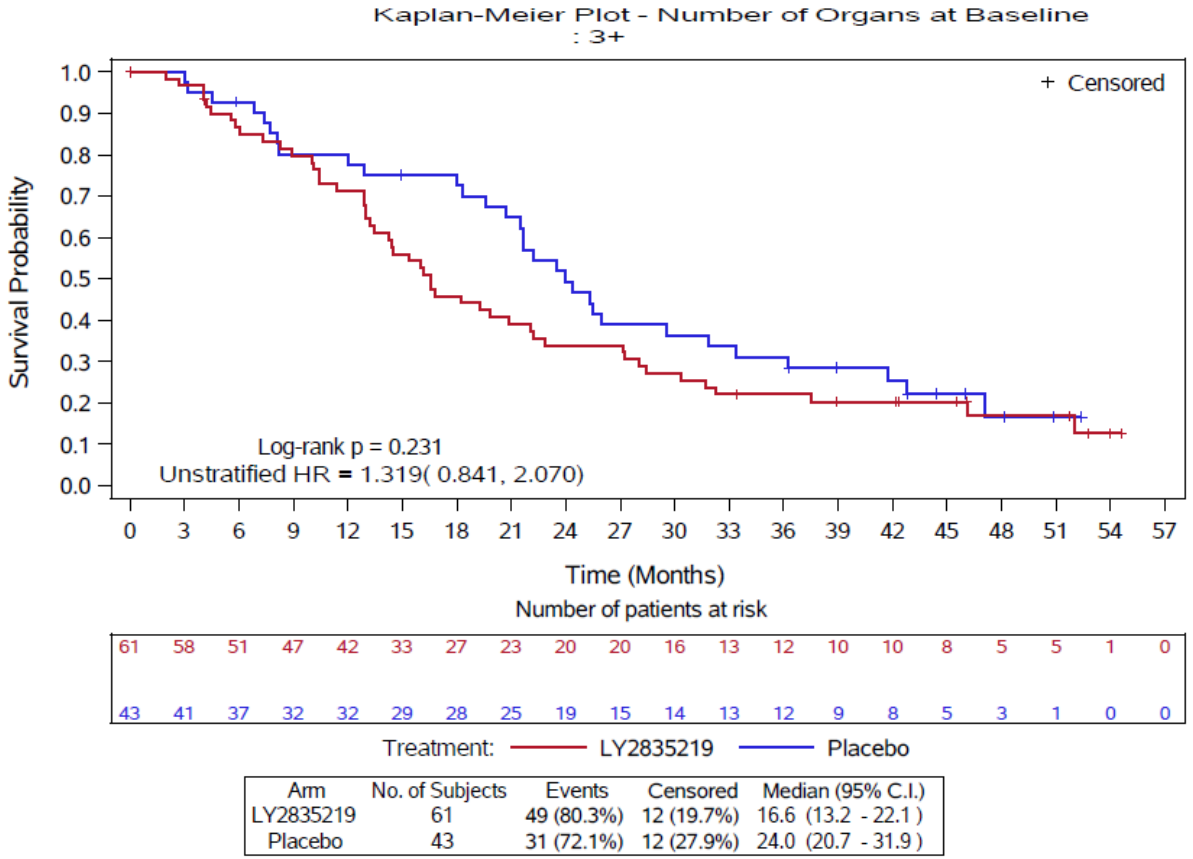
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	112	63 (56.3%)	49 (43.8%)	28.1 (22.9 - 39.1)
Placebo	49	36 (73.5%)	13 (26.5%)	23.7 (17.3 - 32.4)

Kaplan-Meier Plot of PFS2: time to discontinuation date of next line or death by Subgroup
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



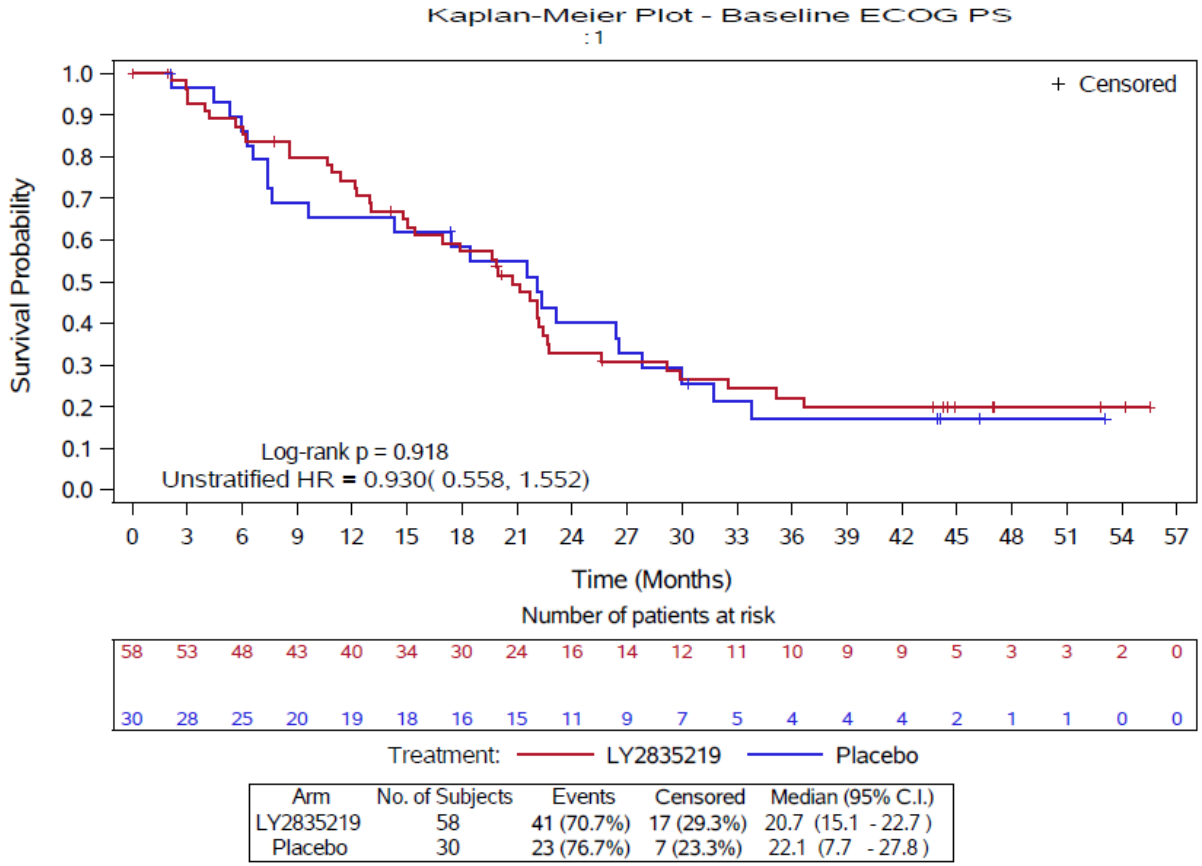
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	73	44 (60.3%)	29 (39.7%)	25.8 (19.6 - 35.0)
Placebo	36	28 (77.8%)	8 (22.2%)	16.6 (10.9 - 22.6)

Kaplan-Meier Plot of PFS2: time to discontinuation date of next line or death by Subgroup
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



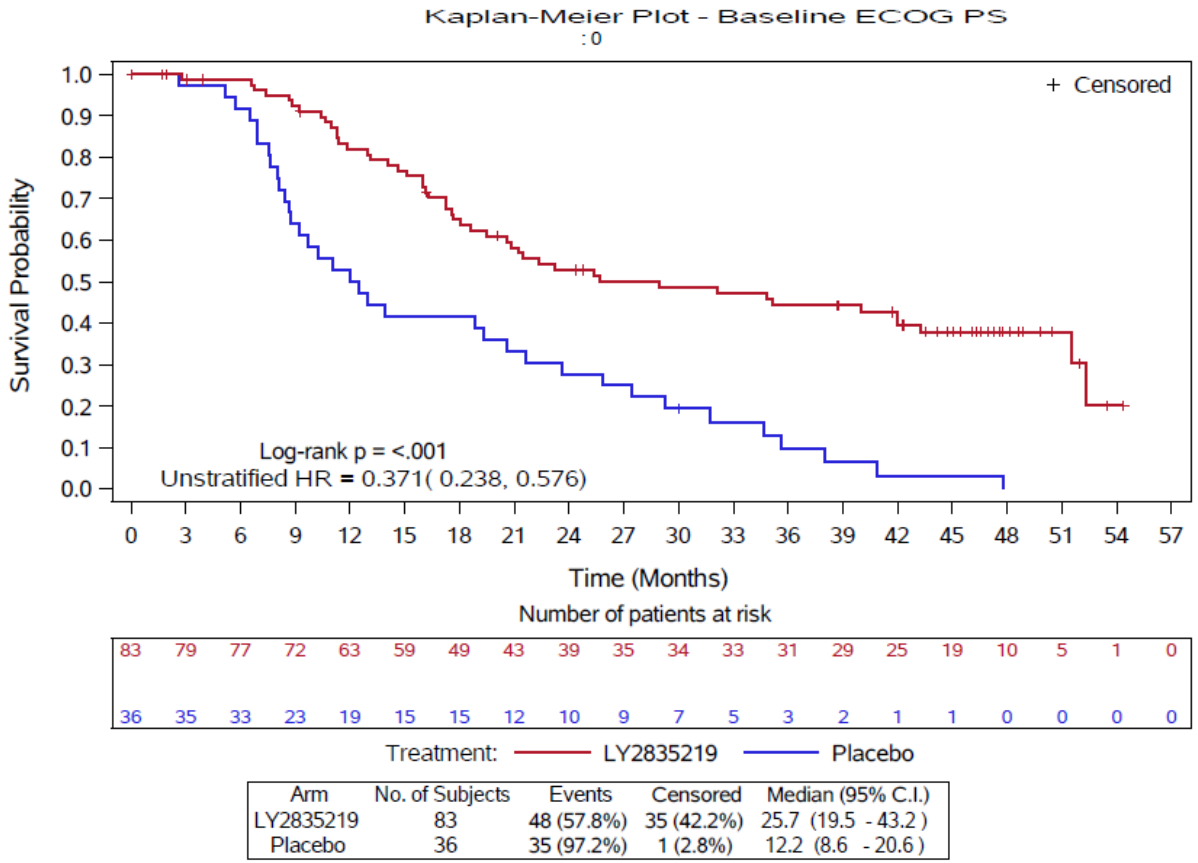
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	61	49 (80.3%)	12 (19.7%)	16.6 (13.2 - 22.1)
Placebo	43	31 (72.1%)	12 (27.9%)	24.0 (20.7 - 31.9)

Kaplan-Meier Plot of PFS2: time to discontinuation date of next line or death by Subgroup
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



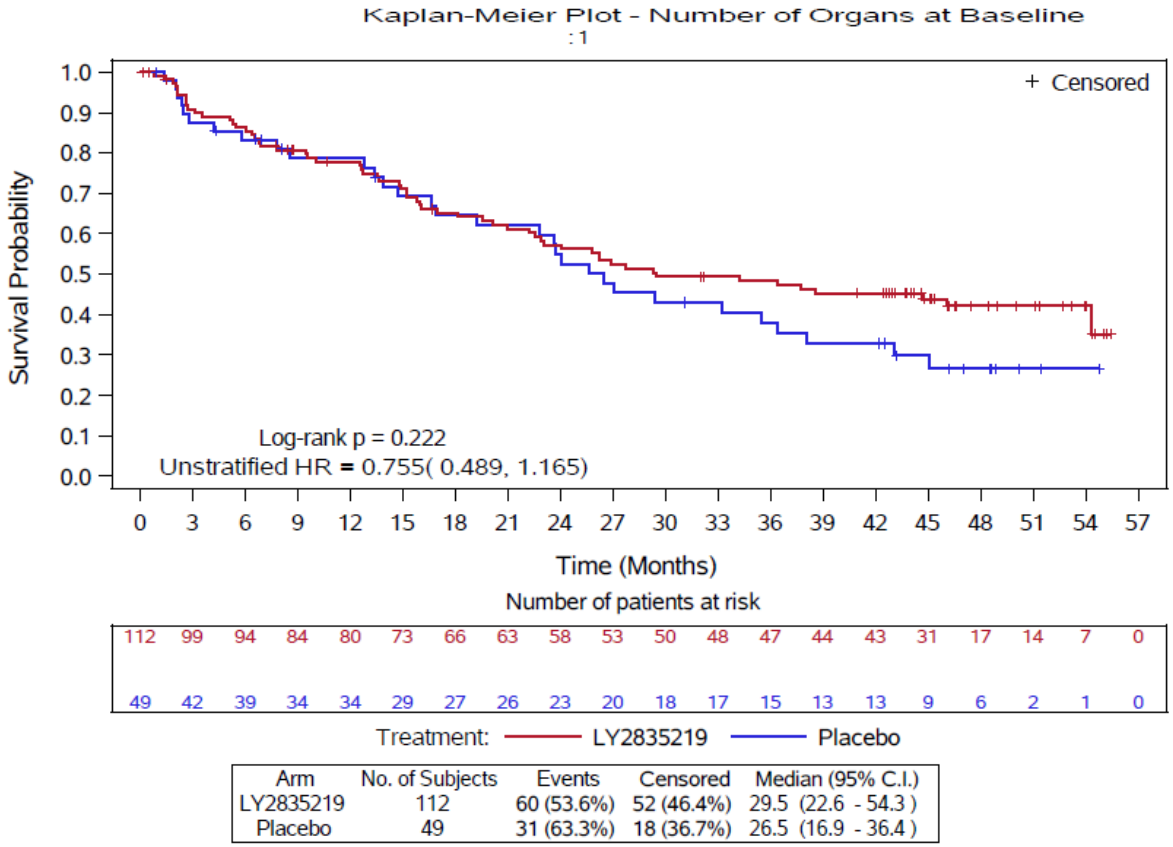
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	58	41 (70.7%)	17 (29.3%)	20.7 (15.1 - 22.7)
Placebo	30	23 (76.7%)	7 (23.3%)	22.1 (7.7 - 27.8)

Kaplan-Meier Plot of PFS2: time to discontinuation date of next line or death by Subgroup
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



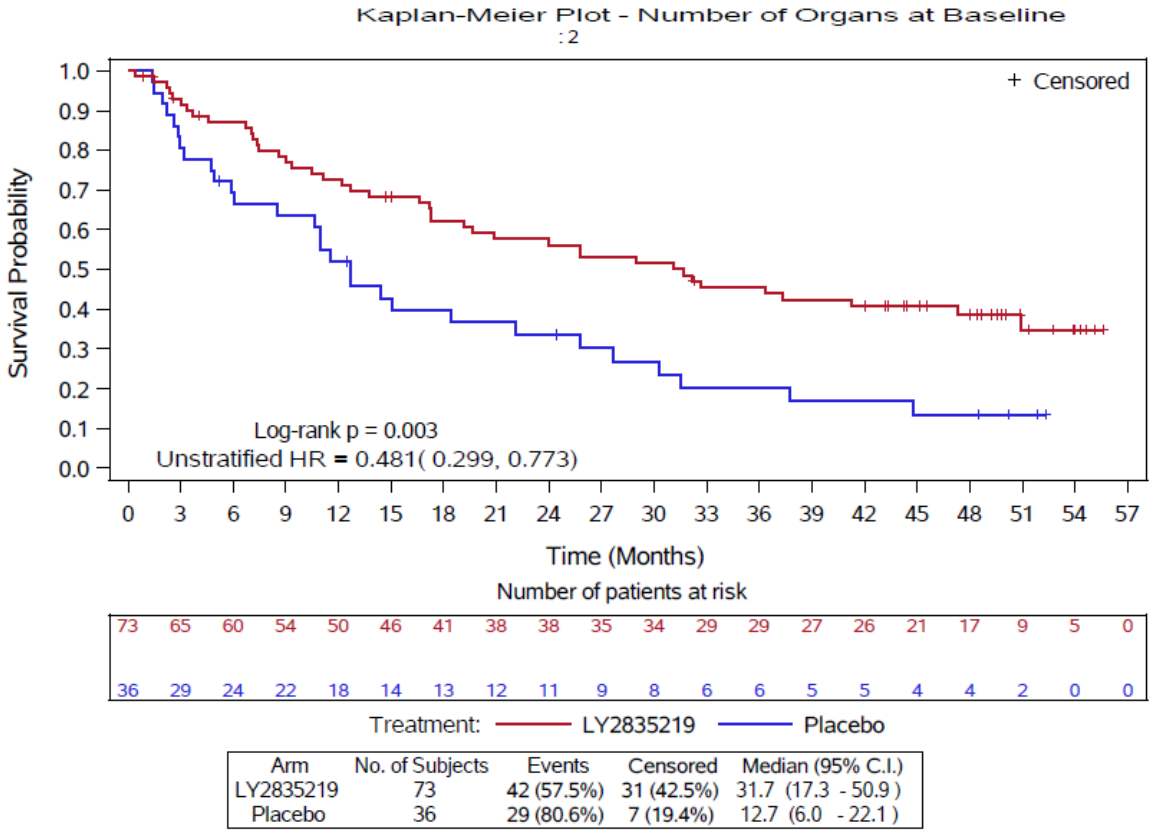
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	83	48 (57.8%)	35 (42.2%)	25.7 (19.5 - 43.2)
Placebo	36	35 (97.2%)	1 (2.8%)	12.2 (8.6 - 20.6)

Kaplan-Meier Plot of Time to First Post-discontinuation Chemotherapy or Death by Subgroup
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



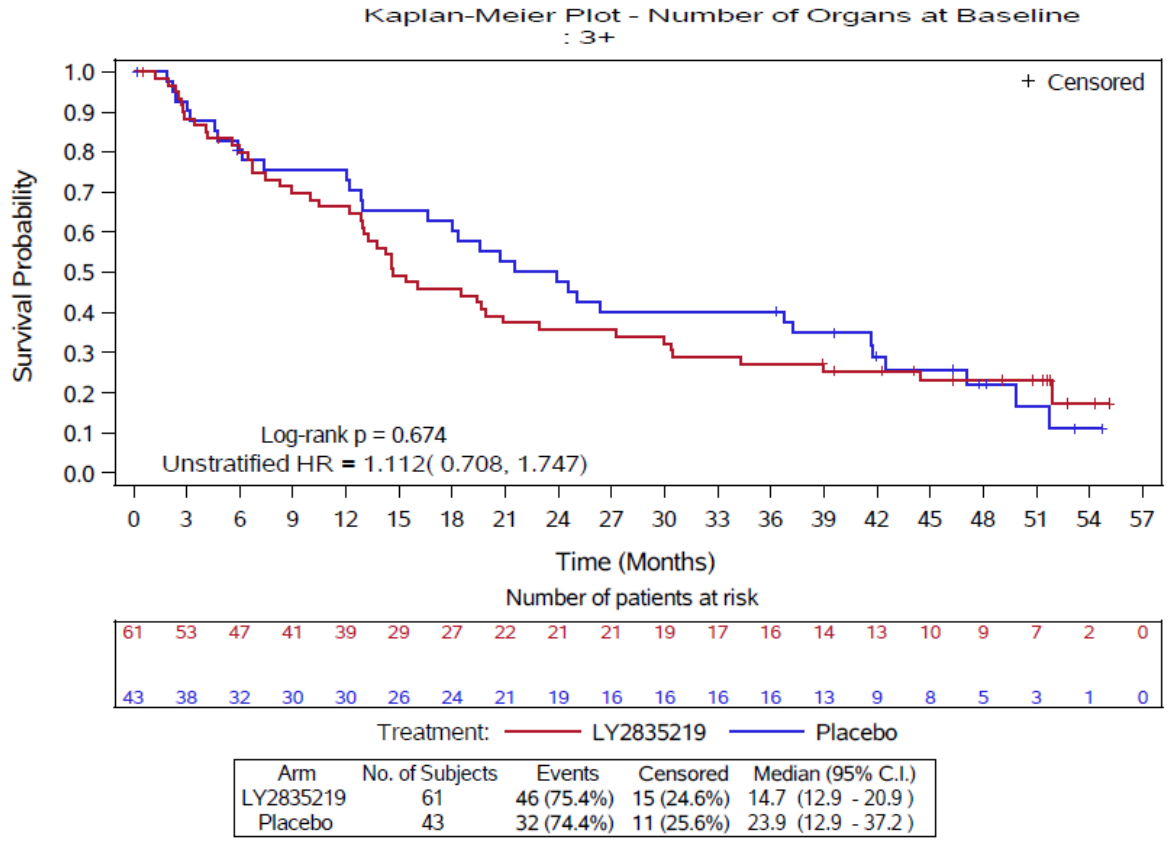
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	112	60 (53.6%)	52 (46.4%)	29.5 (22.6 - 54.3)
Placebo	49	31 (63.3%)	18 (36.7%)	26.5 (16.9 - 36.4)

Kaplan-Meier Plot of Time to First Post-discontinuation Chemotherapy or Death by Subgroup
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



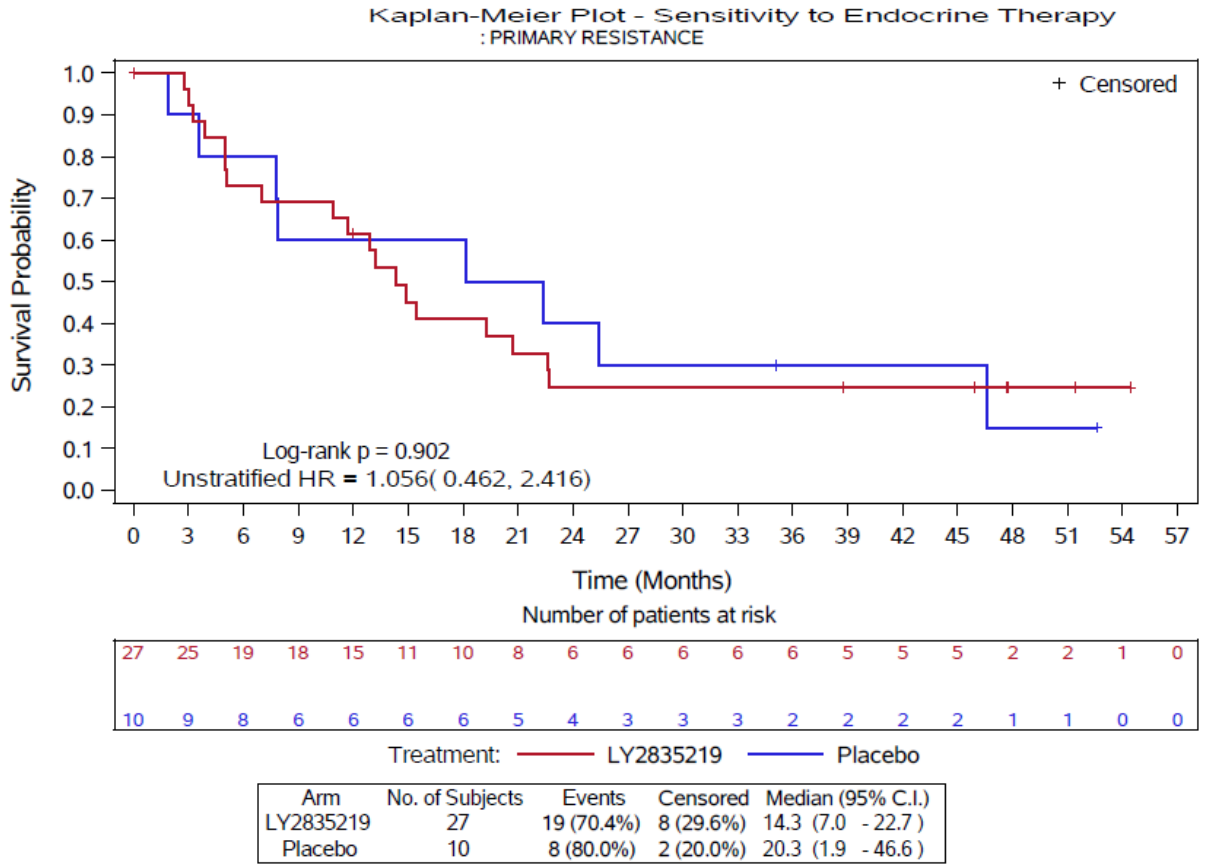
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	73	42 (57.5%)	31 (42.5%)	31.7 (17.3 - 50.9)
Placebo	36	29 (80.6%)	7 (19.4%)	12.7 (6.0 - 22.1)

Kaplan-Meier Plot of Time to First Post-discontinuation Chemotherapy or Death by Subgroup
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



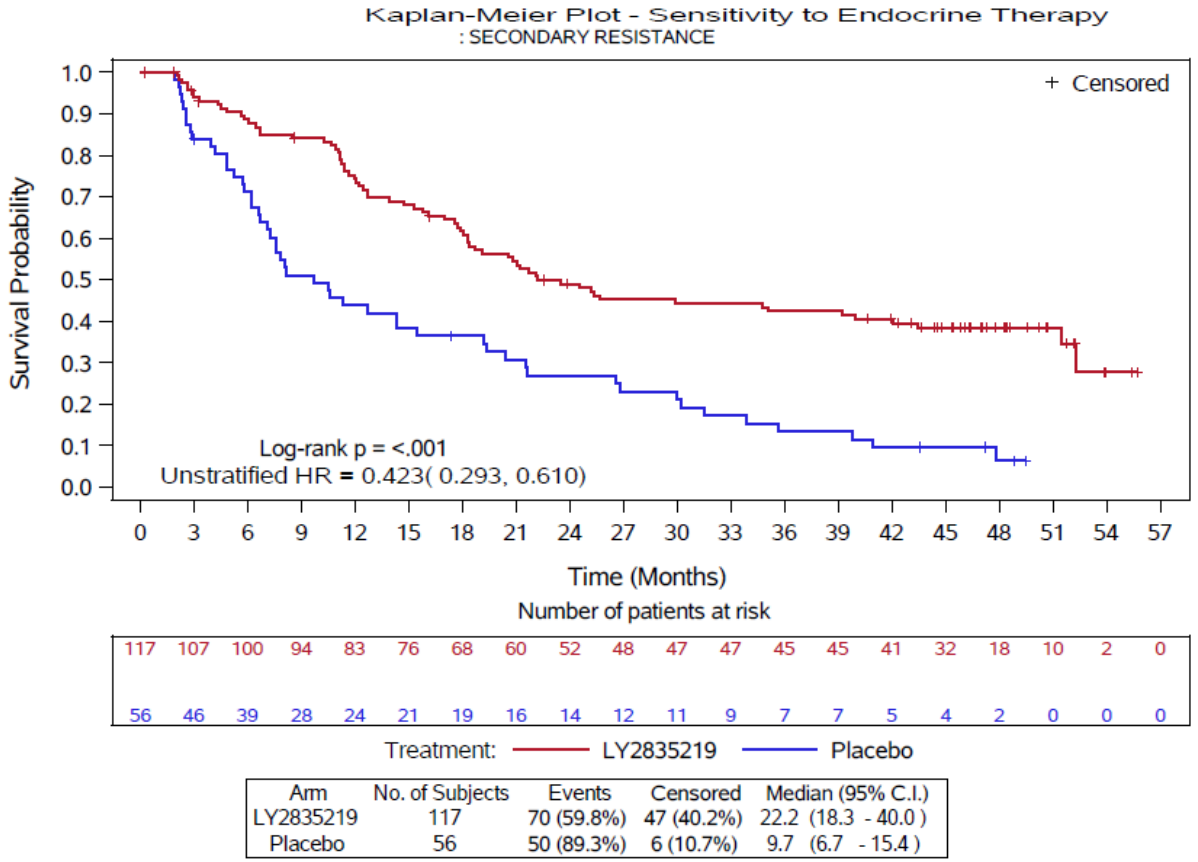
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	61	46 (75.4%)	15 (24.6%)	14.7 (12.9 - 20.9)
Placebo	43	32 (74.4%)	11 (25.6%)	23.9 (12.9 - 37.2)

Kaplan-Meier Plot of Time to First Post-discontinuation Chemotherapy or Death by Subgroup
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



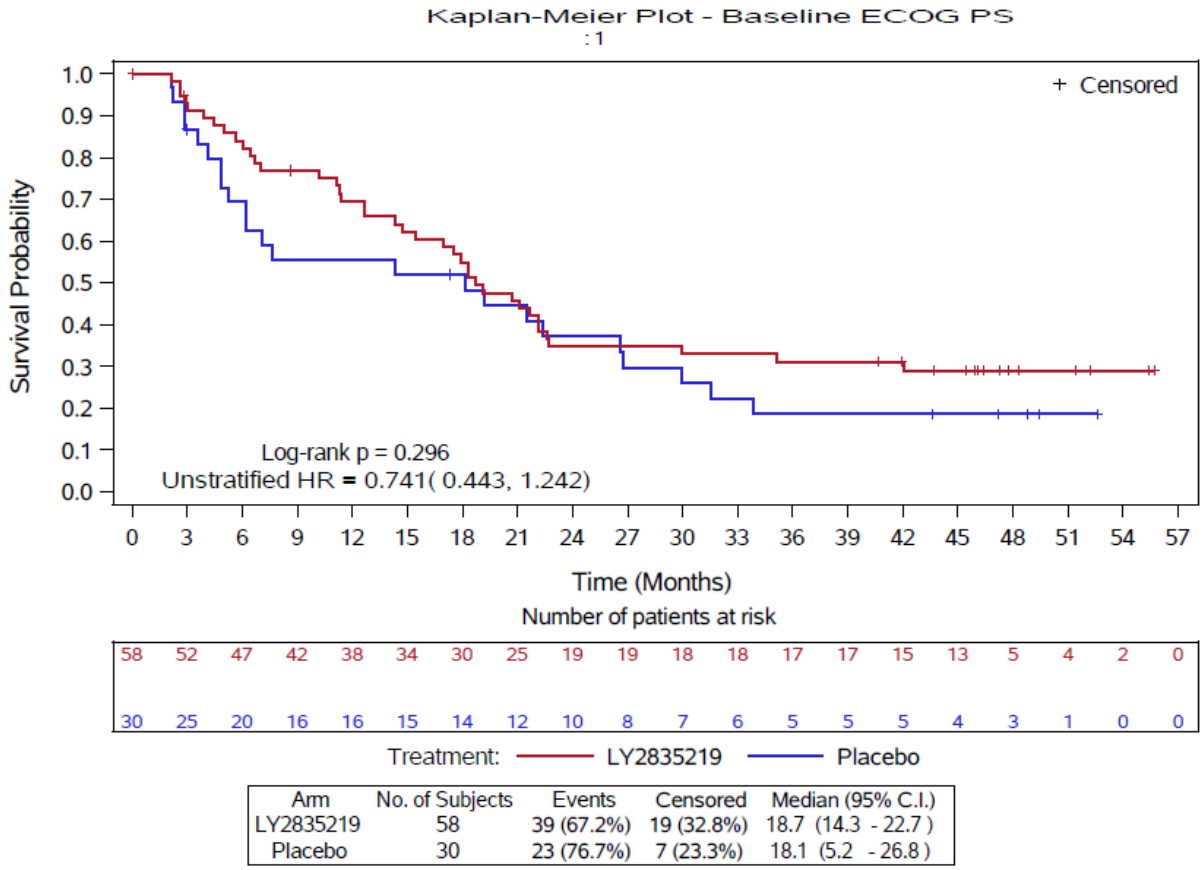
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	27	19 (70.4%)	8 (29.6%)	14.3 (7.0 - 22.7)
Placebo	10	8 (80.0%)	2 (20.0%)	20.3 (1.9 - 46.6)

Kaplan-Meier Plot of Time to First Post-discontinuation Chemotherapy or Death by Subgroup
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



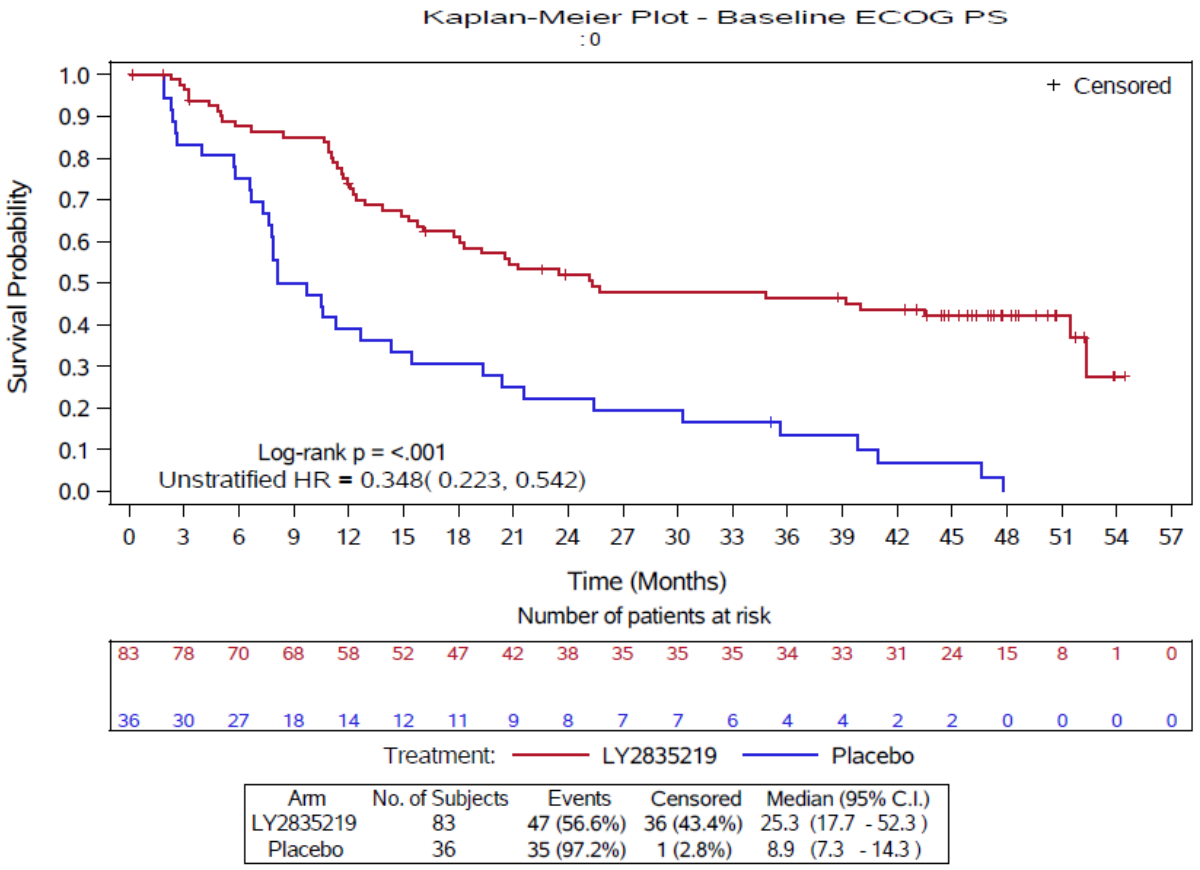
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	117	70 (59.8%)	47 (40.2%)	22.2 (18.3 - 40.0)
Placebo	56	50 (89.3%)	6 (10.7%)	9.7 (6.7 - 15.4)

Kaplan-Meier Plot of Time to First Post-discontinuation Chemotherapy or Death by Subgroup
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



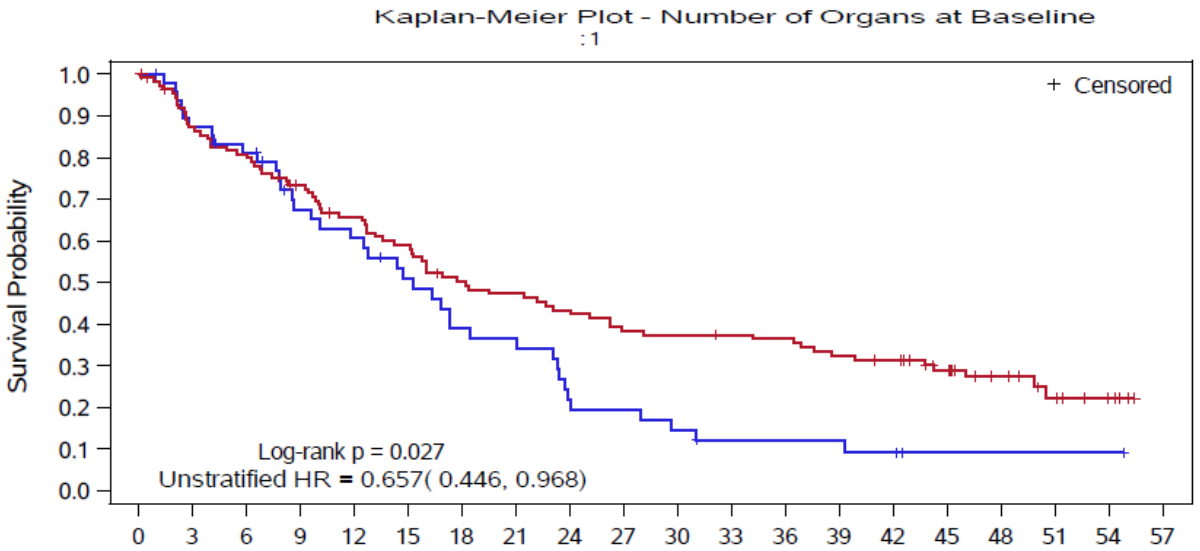
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	58	39 (67.2%)	19 (32.8%)	18.7 (14.3 - 22.7)
Placebo	30	23 (76.7%)	7 (23.3%)	18.1 (5.2 - 26.8)

Kaplan-Meier Plot of Time to First Post-discontinuation Chemotherapy or Death by Subgroup
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



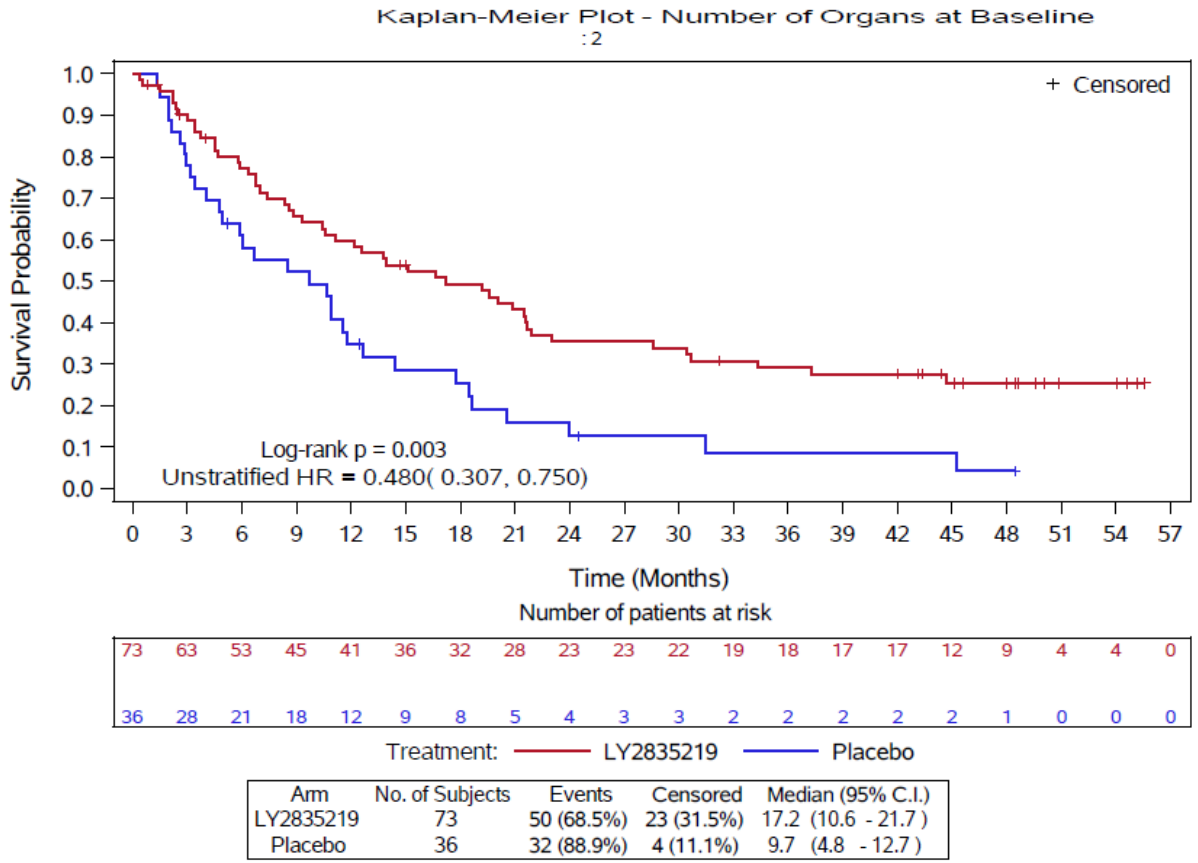
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	83	47 (56.6%)	36 (43.4%)	25.3 (17.7 - 52.3)
Placebo	36	35 (97.2%)	1 (2.8%)	8.9 (7.3 - 14.3)

Kaplan-Meier Plot of Time to First Post-discontinuation Therapy or Death by Subgroup
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



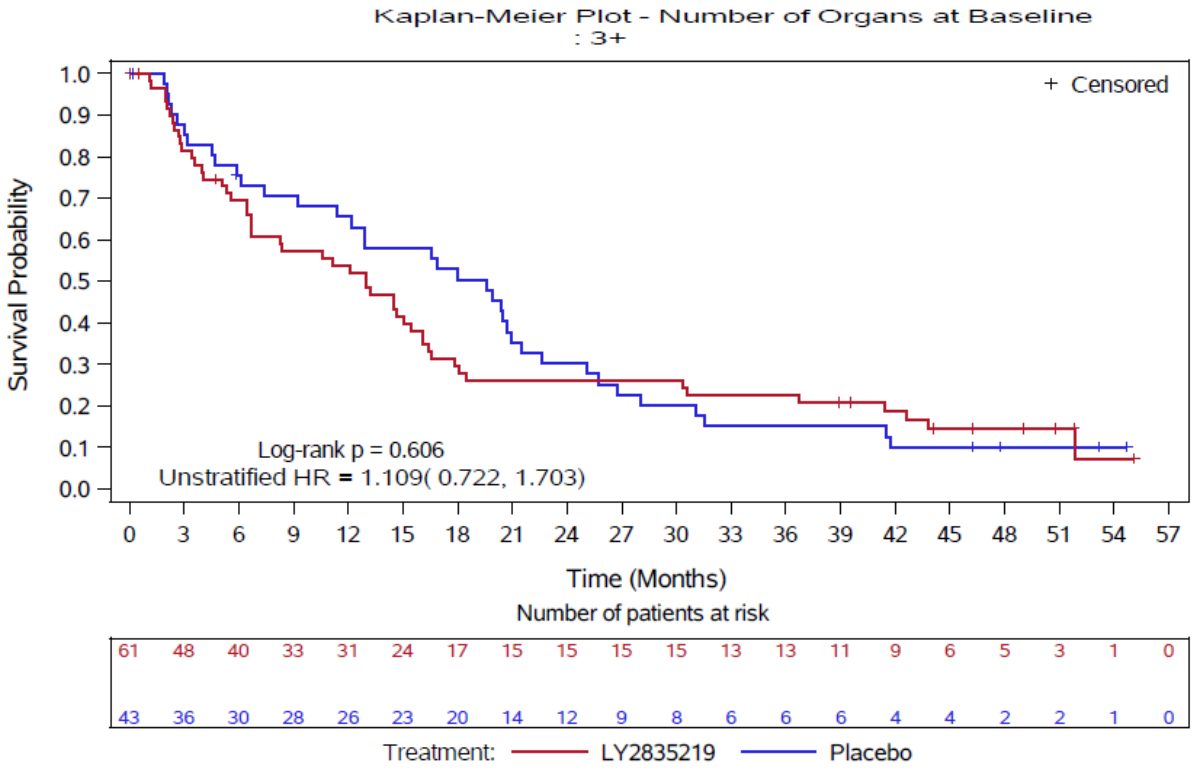
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	112	77 (68.8%)	35 (31.3%)	18.2 (14.3 - 26.3)
Placebo	49	39 (79.6%)	10 (20.4%)	15.3 (9.6 - 21.0)

Kaplan-Meier Plot of Time to First Post-discontinuation Therapy or Death by Subgroup
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



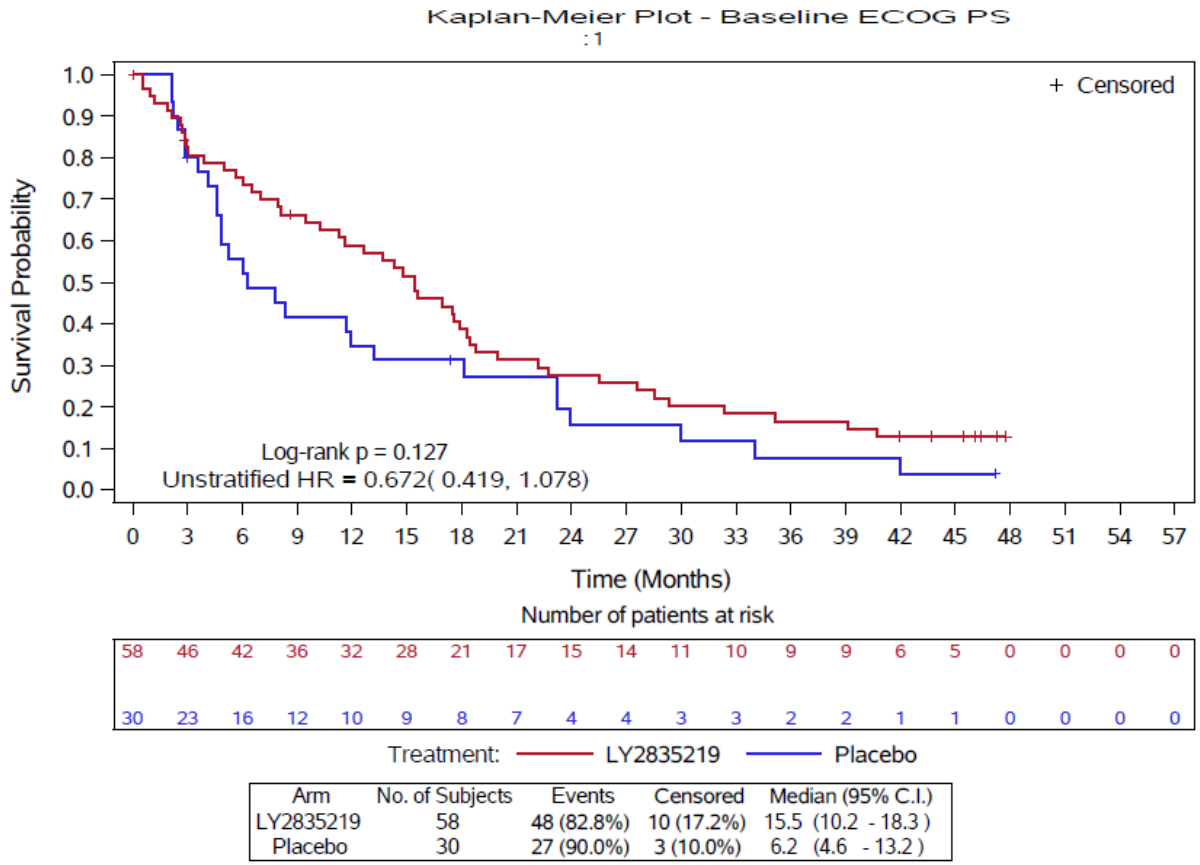
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	73	50 (68.5%)	23 (31.5%)	17.2 (10.6 - 21.7)
Placebo	36	32 (88.9%)	4 (11.1%)	9.7 (4.8 - 12.7)

Kaplan-Meier Plot of Time to First Post-discontinuation Therapy or Death by Subgroup
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



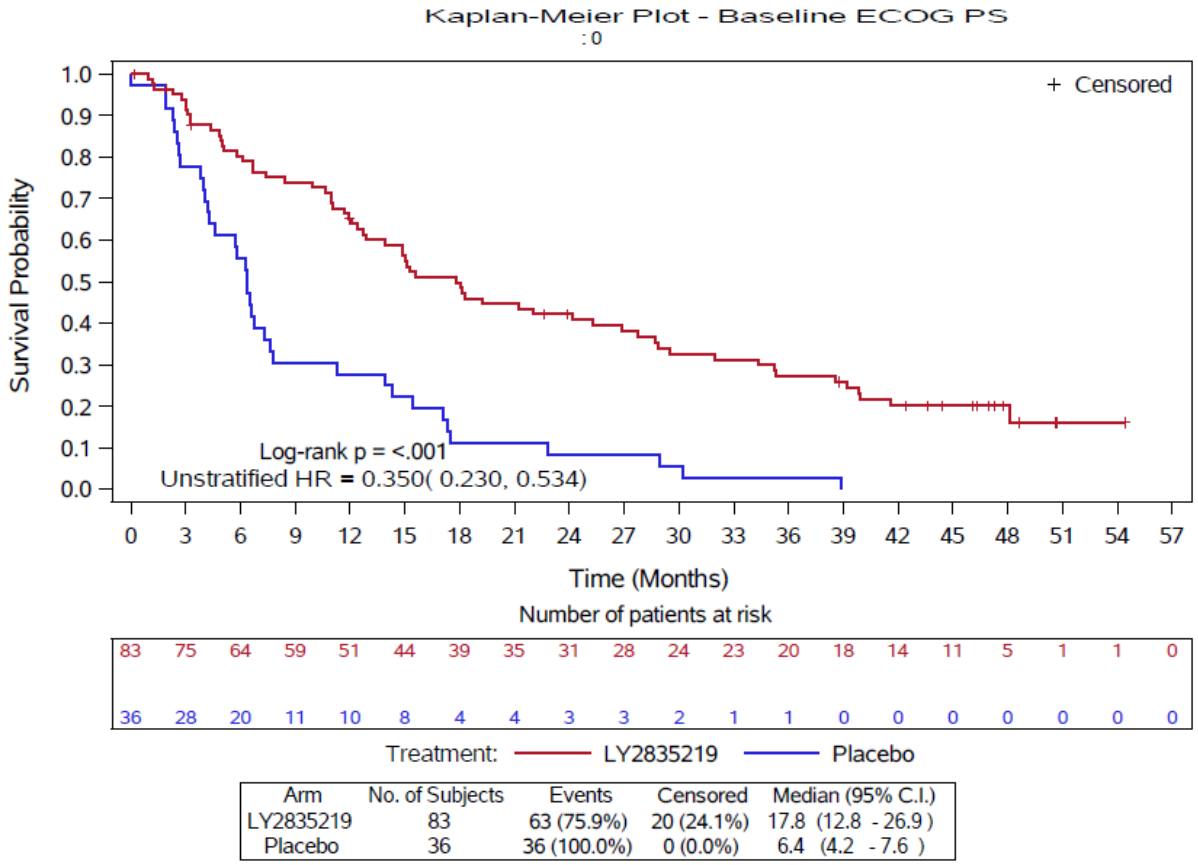
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	61	50 (82.0%)	11 (18.0%)	13.0 (6.7 - 16.1)
Placebo	43	36 (83.7%)	7 (16.3%)	19.6 (11.4 - 20.9)

Kaplan-Meier Plot of Time to First Post-discontinuation Therapy or Death by Subgroup
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



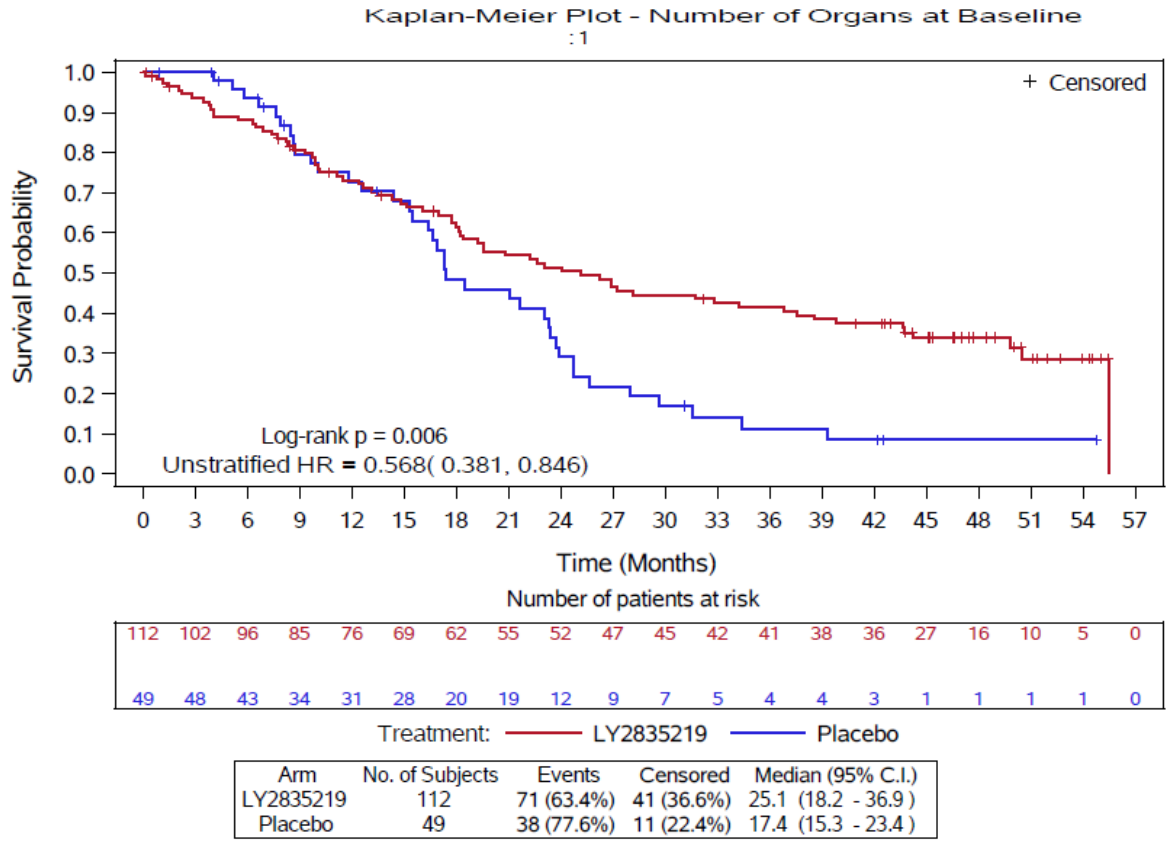
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	58	48 (82.8%)	10 (17.2%)	15.5 (10.2 - 18.3)
Placebo	30	27 (90.0%)	3 (10.0%)	6.2 (4.6 - 13.2)

Kaplan-Meier Plot of Time to First Post-discontinuation Therapy or Death by Subgroup
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



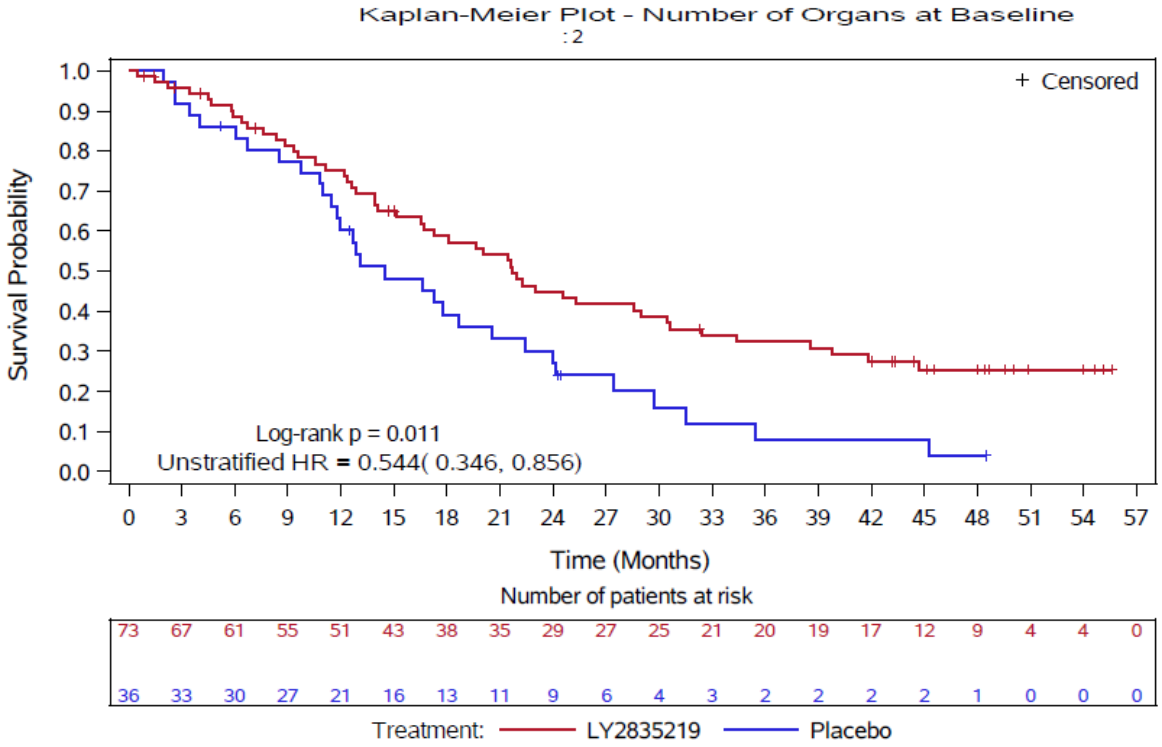
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	83	63 (75.9%)	20 (24.1%)	17.8 (12.8 - 26.9)
Placebo	36	36 (100.0%)	0 (0.0%)	6.4 (4.2 - 7.6)

Kaplan-Meier Plot of Time to First Post-discontinuation Endocrine Therapy or Death by Subgroup
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



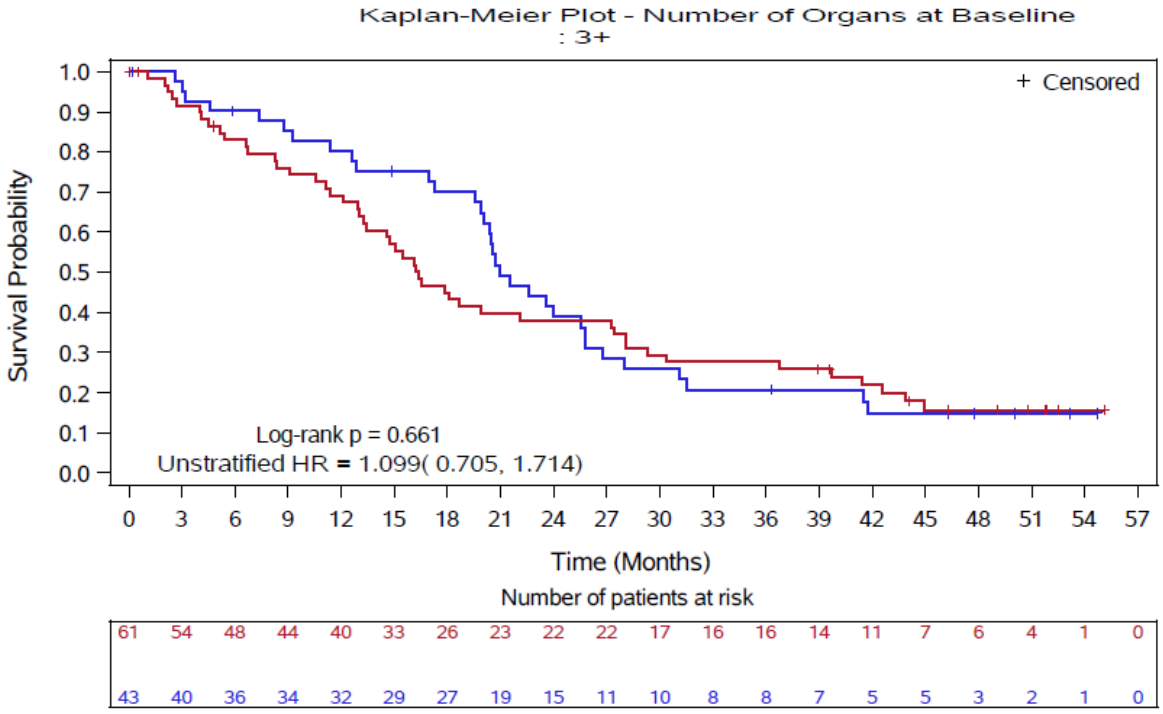
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	112	71 (63.4%)	41 (36.6%)	25.1 (18.2 - 36.9)
Placebo	49	38 (77.6%)	11 (22.4%)	17.4 (15.3 - 23.4)

Kaplan-Meier Plot of Time to First Post-discontinuation Endocrine Therapy or Death by Subgroup
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



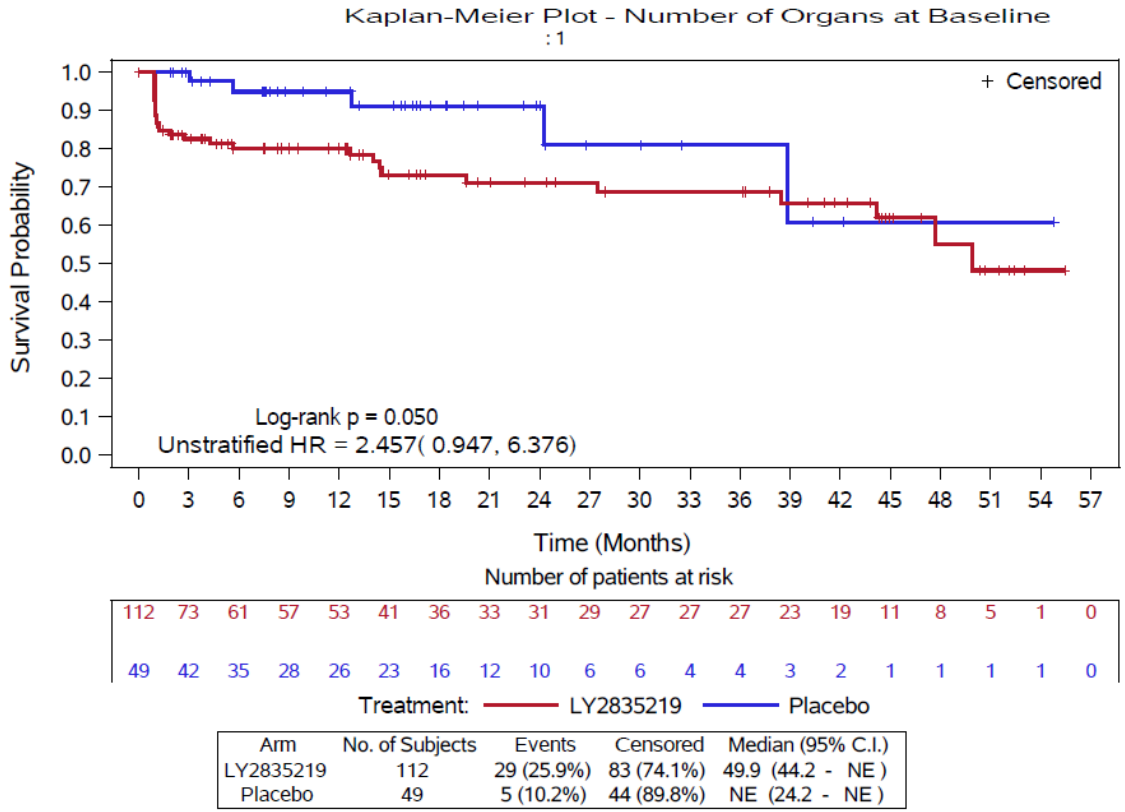
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	73	49 (67.1%)	24 (32.9%)	21.7 (16.6 - 30.4)
Placebo	36	31 (86.1%)	5 (13.9%)	14.5 (11.5 - 20.6)

Kaplan-Meier Plot of Time to First Post-discontinuation Endocrine Therapy or Death by Subgroup
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



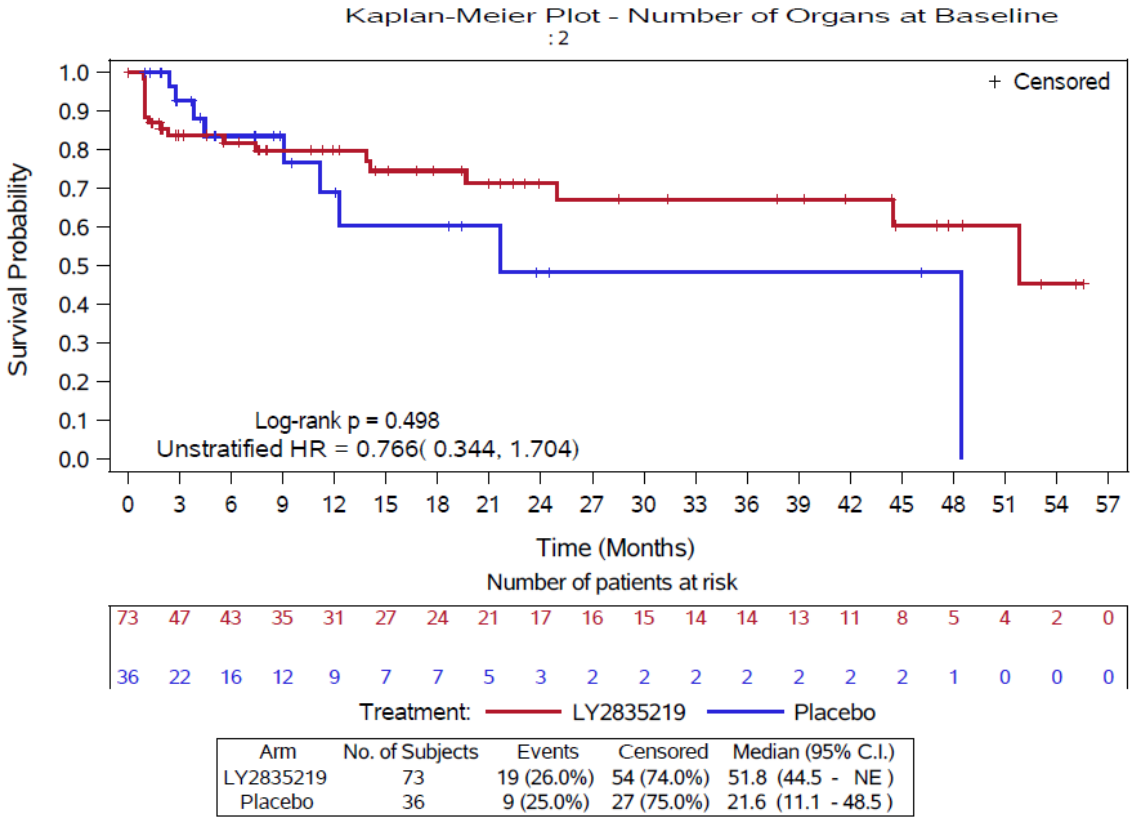
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	61	48 (78.7%)	13 (21.3%)	16.4 (13.2 - 27.3)
Placebo	43	33 (76.7%)	10 (23.3%)	20.9 (19.9 - 25.7)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items: Diarrhoea (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



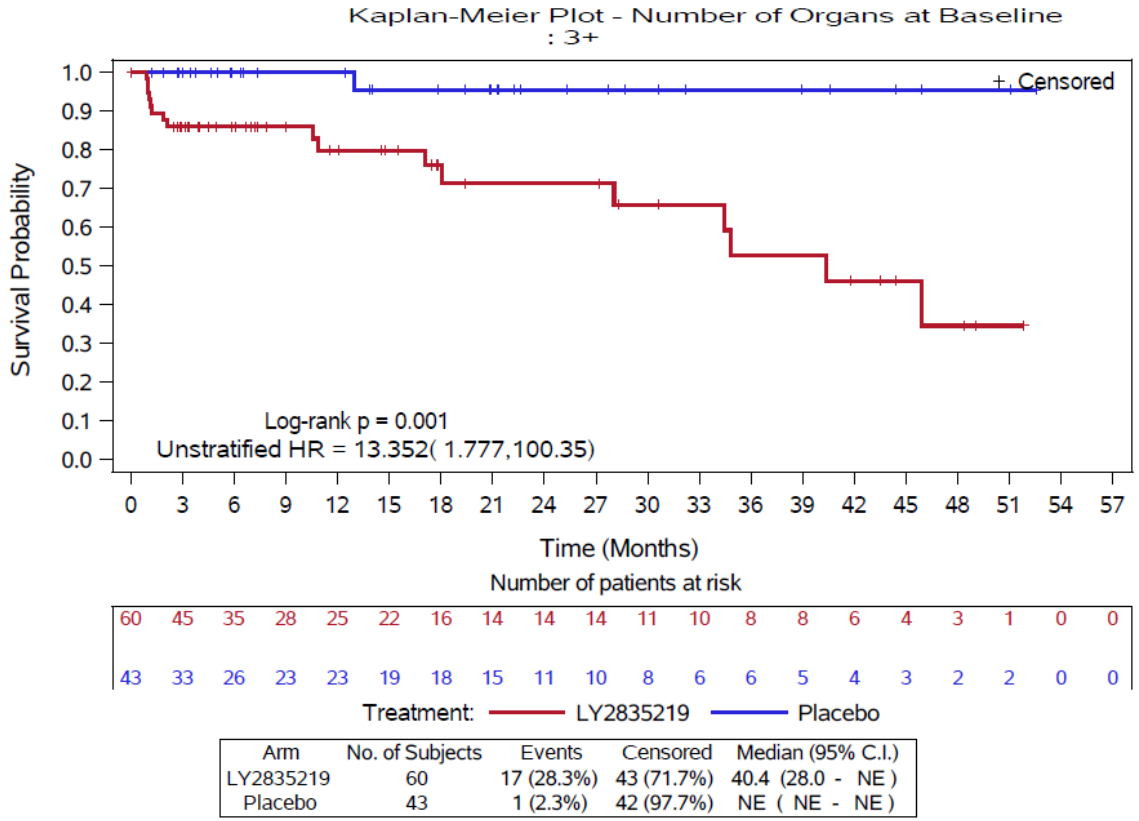
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	112	29 (25.9%)	83 (74.1%)	49.9 (44.2 - NE)
Placebo	49	5 (10.2%)	44 (89.8%)	NE (24.2 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Diarrhoea (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



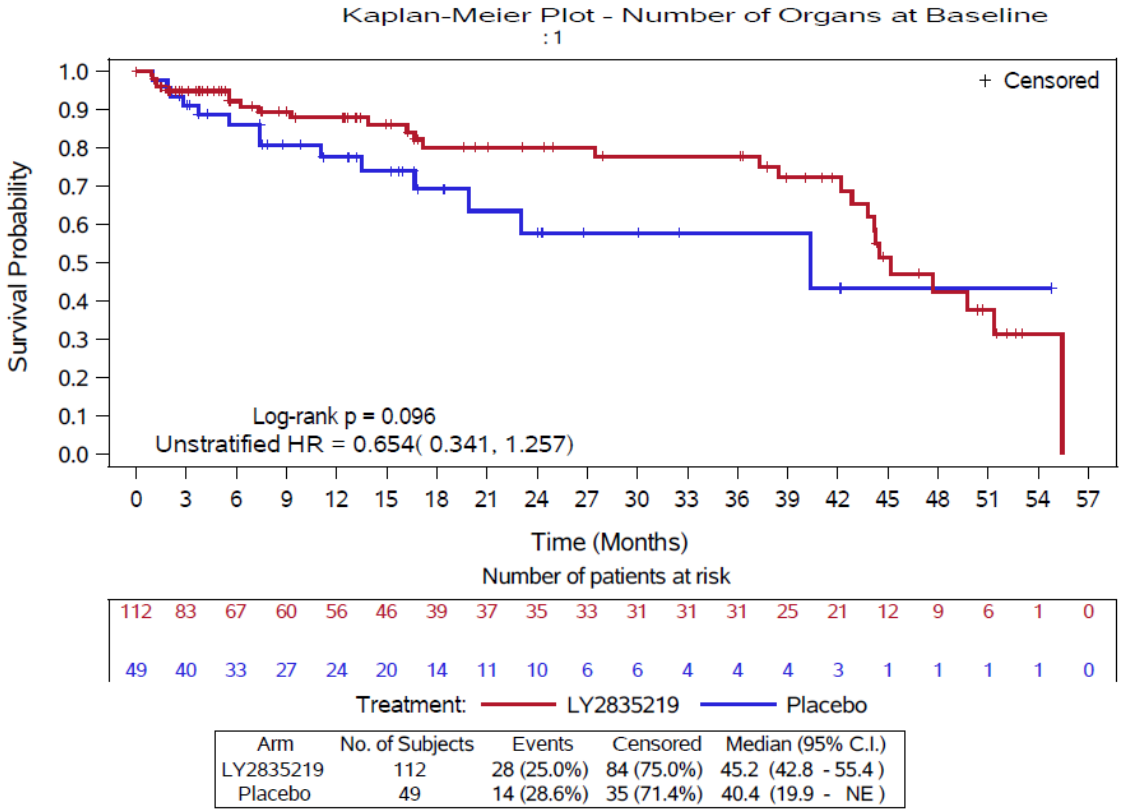
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	73	19 (26.0%)	54 (74.0%)	51.8 (44.5 - NE)
Placebo	36	9 (25.0%)	27 (75.0%)	21.6 (11.1 - 48.5)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Diarrhoea (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



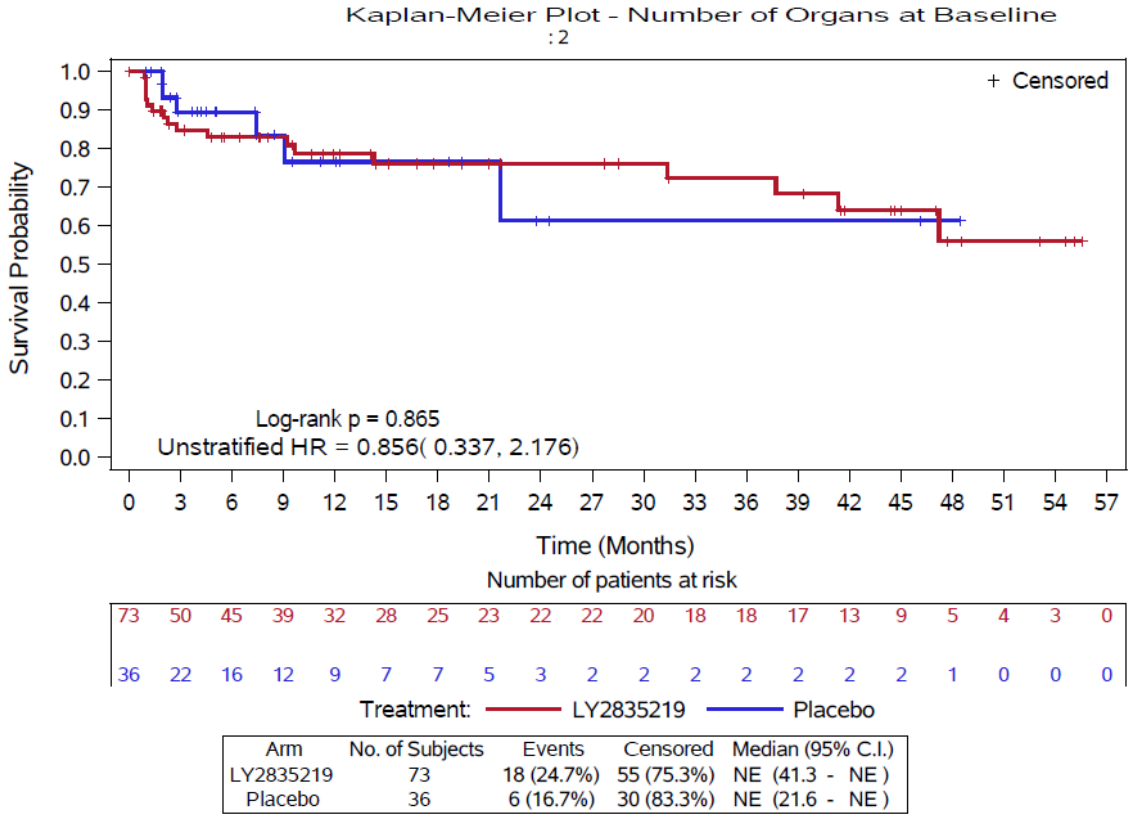
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	60	17 (28.3%)	43 (71.7%)	40.4 (28.0 - NE)
Placebo	43	1 (2.3%)	42 (97.7%)	NE (NE - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items: Dyspnoea (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



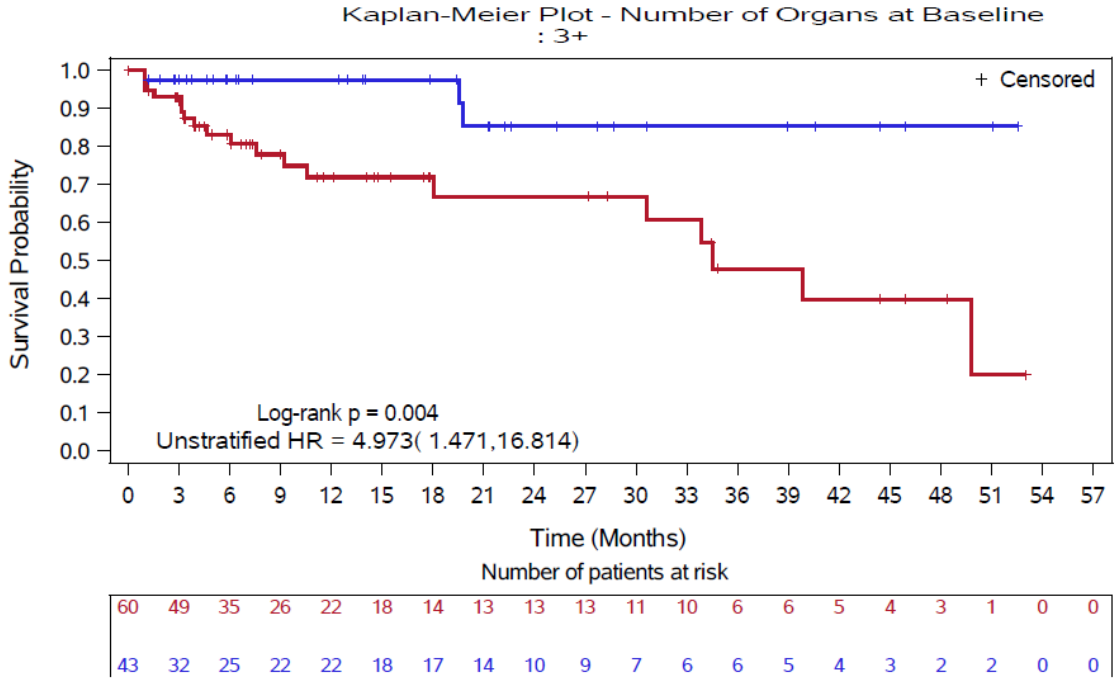
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	112	28 (25.0%)	84 (75.0%)	45.2 (42.8 - 55.4)
Placebo	49	14 (28.6%)	35 (71.4%)	40.4 (19.9 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items: Dyspnoea (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



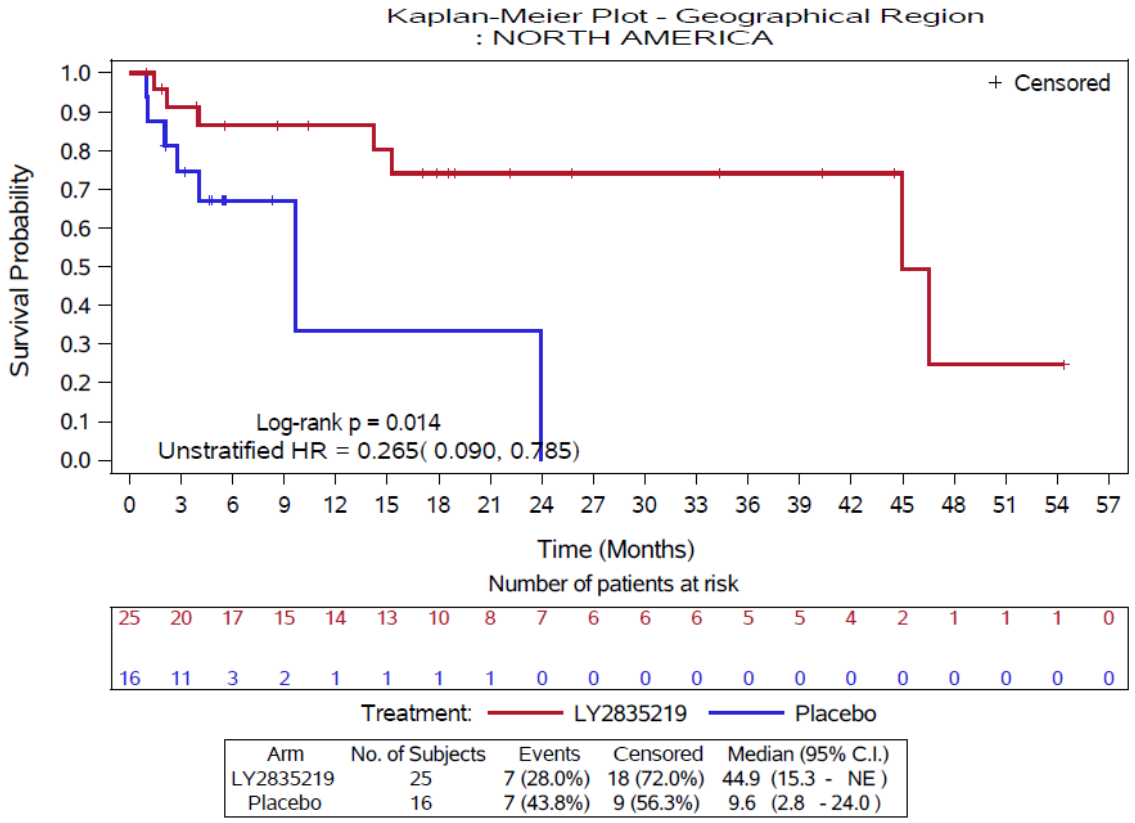
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	73	18 (24.7%)	55 (75.3%)	NE (41.3 - NE)
Placebo	36	6 (16.7%)	30 (83.3%)	NE (21.6 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Dyspnoea (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



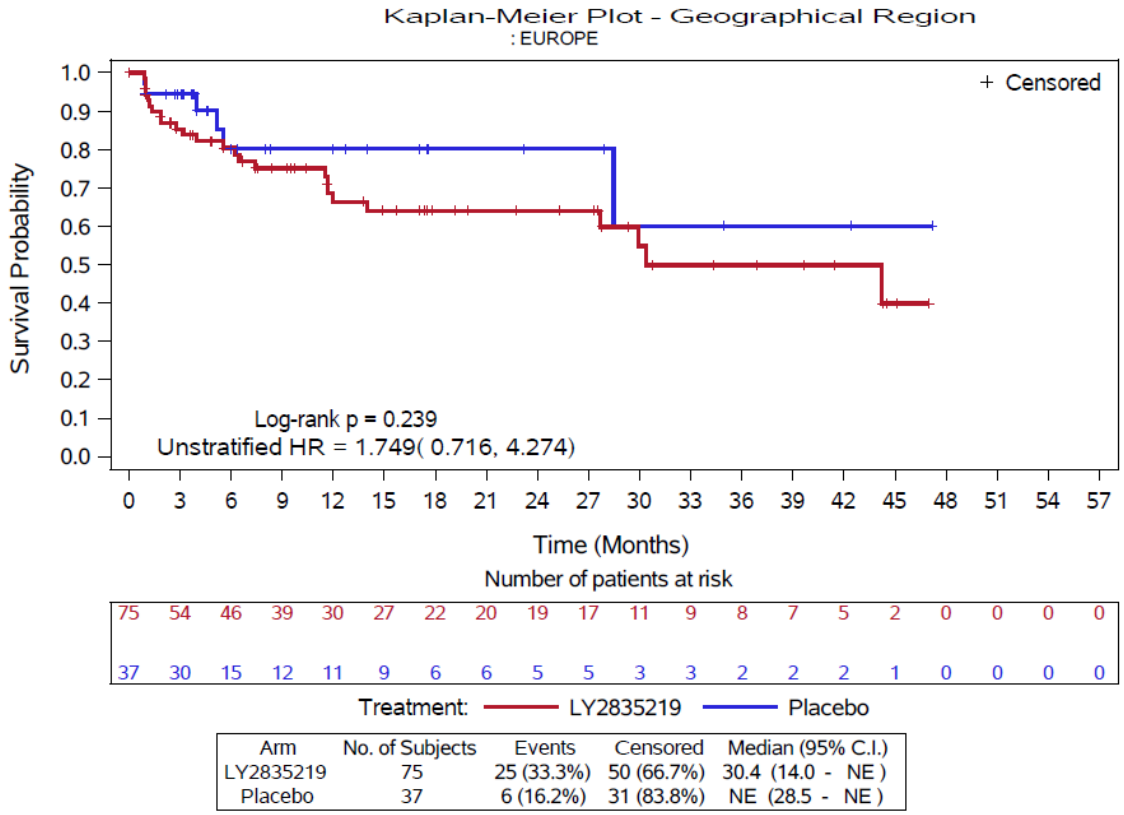
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	60	19 (31.7%)	41 (68.3%)	34.6 (18.1 - NE)
Placebo	43	3 (7.0%)	40 (93.0%)	NE (NE - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Dyspnoea (Def4)
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



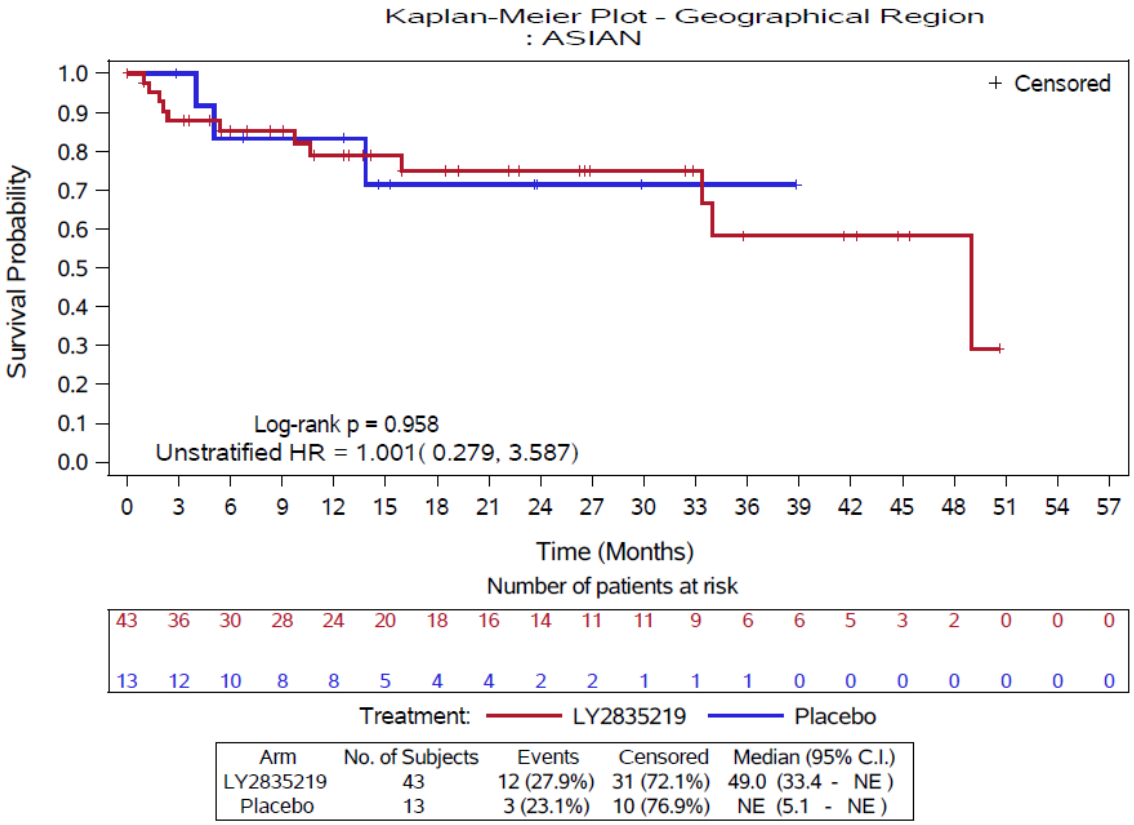
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	25	7 (28.0%)	18 (72.0%)	44.9 (15.3 - NE)
Placebo	16	7 (43.8%)	9 (56.3%)	9.6 (2.8 - 24.0)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Dyspnoea (Def4)
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



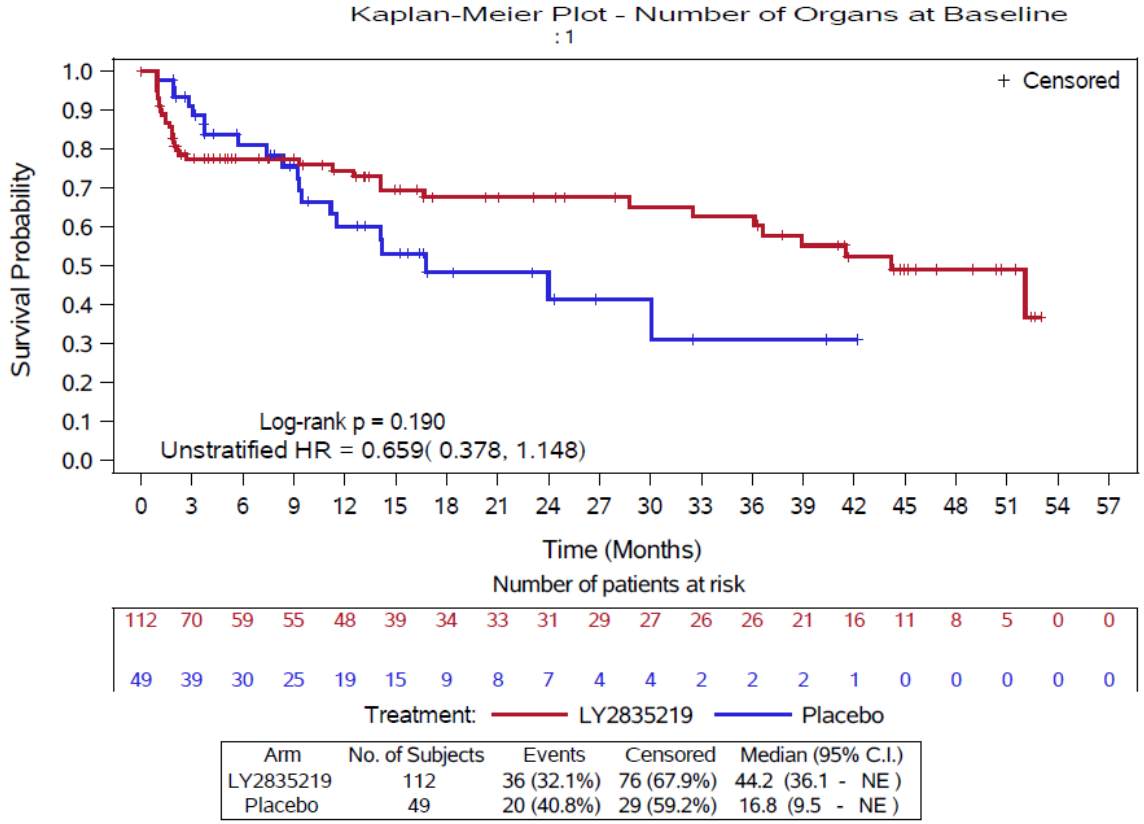
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	75	25 (33.3%)	50 (66.7%)	30.4 (14.0 - NE)
Placebo	37	6 (16.2%)	31 (83.8%)	NE (28.5 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Dyspnoea (Def4)
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



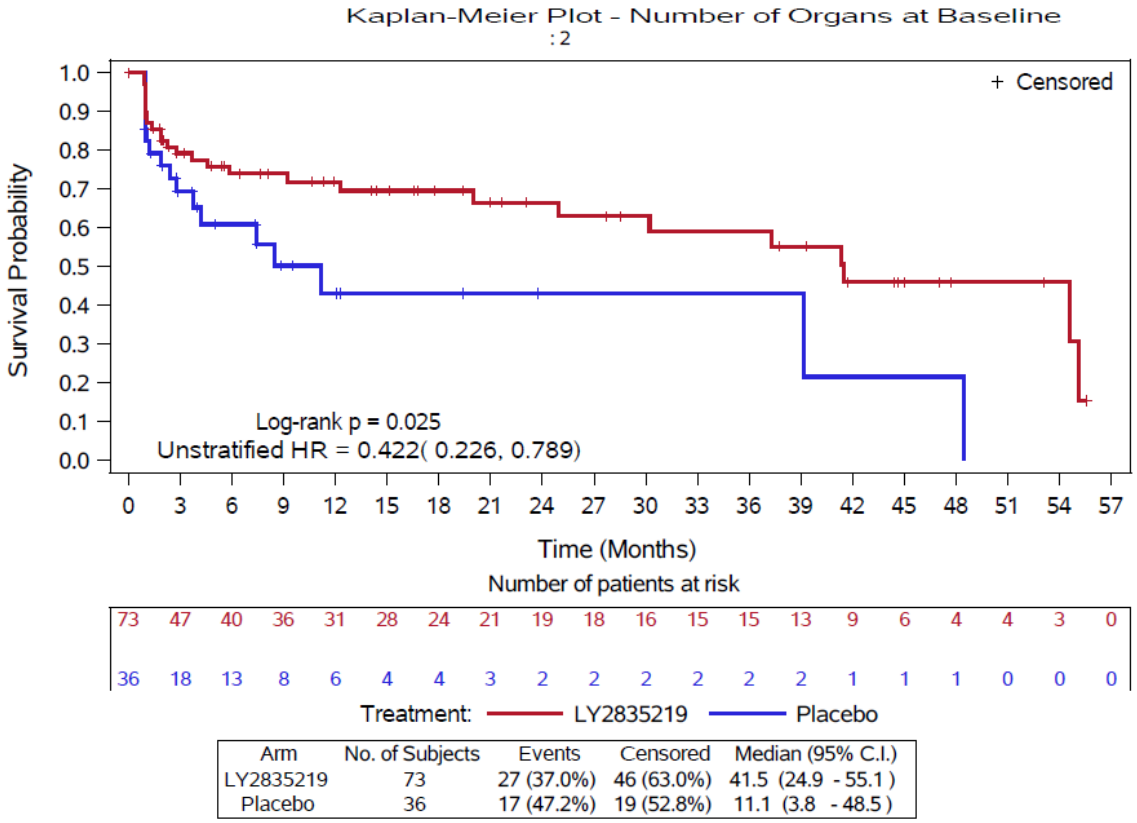
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	43	12 (27.9%)	31 (72.1%)	49.0 (33.4 - NE)
Placebo	13	3 (23.1%)	10 (76.9%)	NE (5.1 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items: Fatigue (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



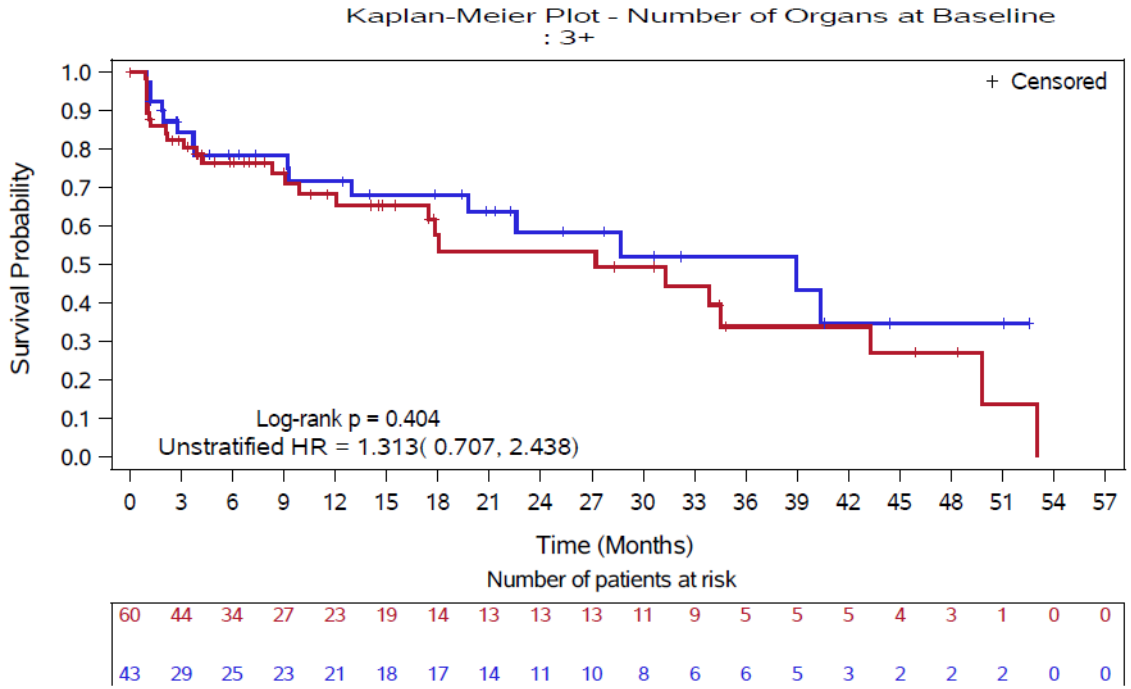
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	112	36 (32.1%)	76 (67.9%)	44.2 (36.1 - NE)
Placebo	49	20 (40.8%)	29 (59.2%)	16.8 (9.5 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items: Fatigue (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



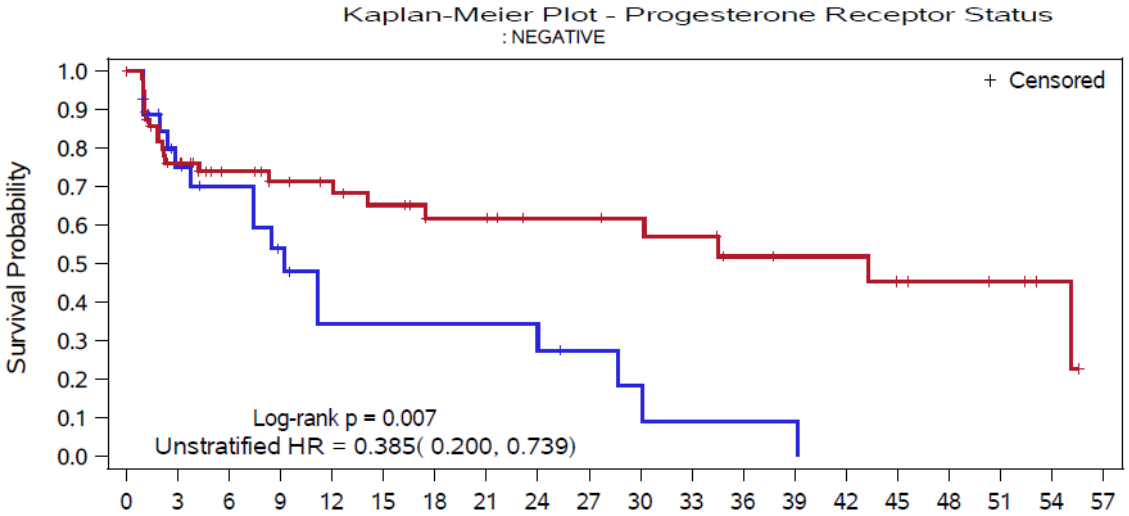
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	73	27 (37.0%)	46 (63.0%)	41.5 (24.9 - 55.1)
Placebo	36	17 (47.2%)	19 (52.8%)	11.1 (3.8 - 48.5)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items: Fatigue (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



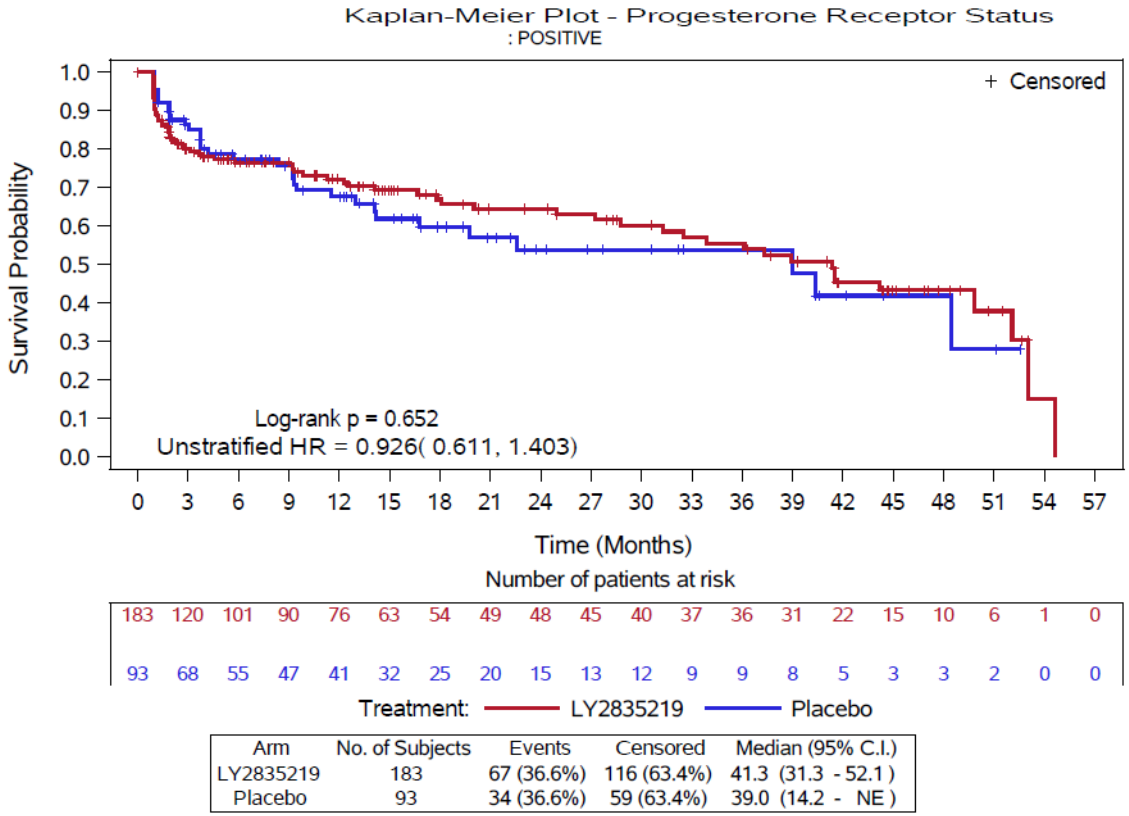
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	60	27 (45.0%)	33 (55.0%)	27.2 (12.1 - 43.3)
Placebo	43	16 (37.2%)	27 (62.8%)	39.0 (13.0 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items: Fatigue (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



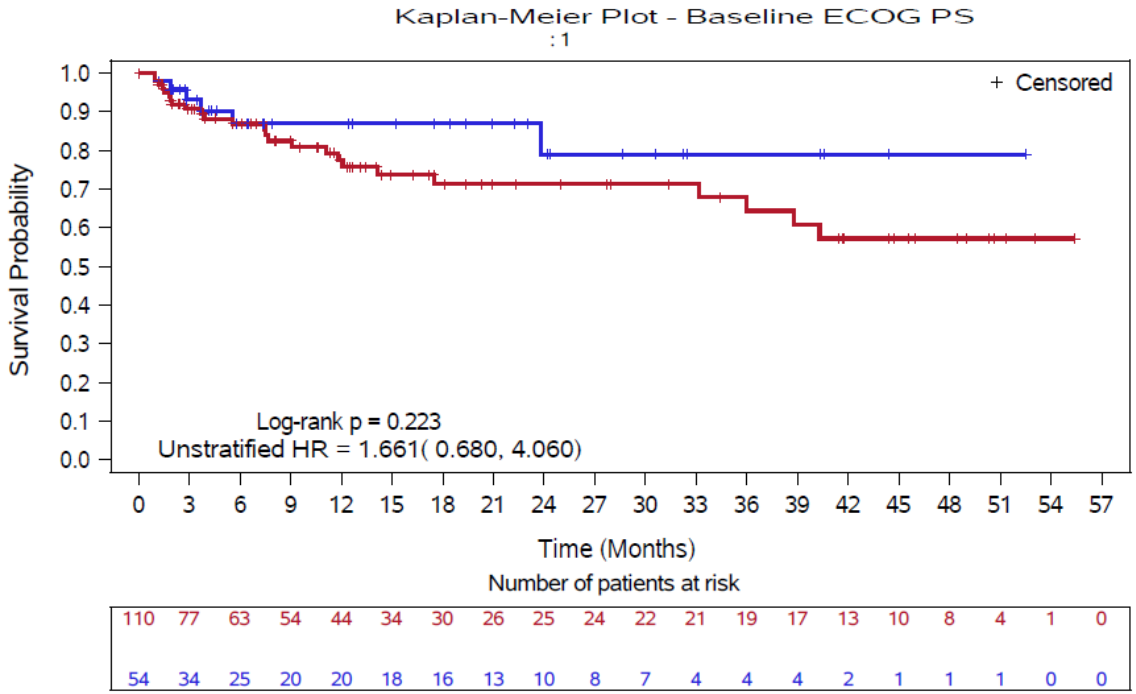
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	59	22 (37.3%)	37 (62.7%)	43.3 (14.1 - NE)
Placebo	31	17 (54.8%)	14 (45.2%)	9.2 (3.8 - 24.0)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items: Fatigue (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



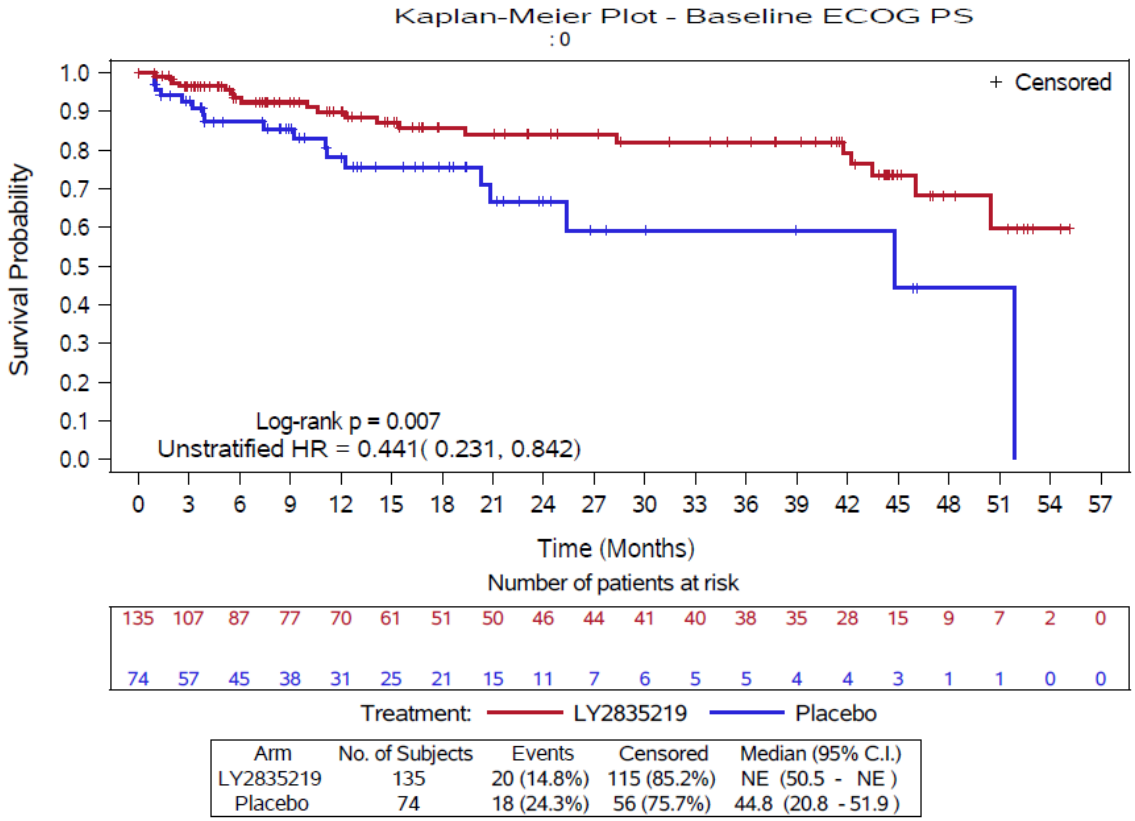
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	183	67 (36.6%)	116 (63.4%)	41.3 (31.3 - 52.1)
Placebo	93	34 (36.6%)	59 (63.4%)	39.0 (14.2 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items: Financial Difficulties (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



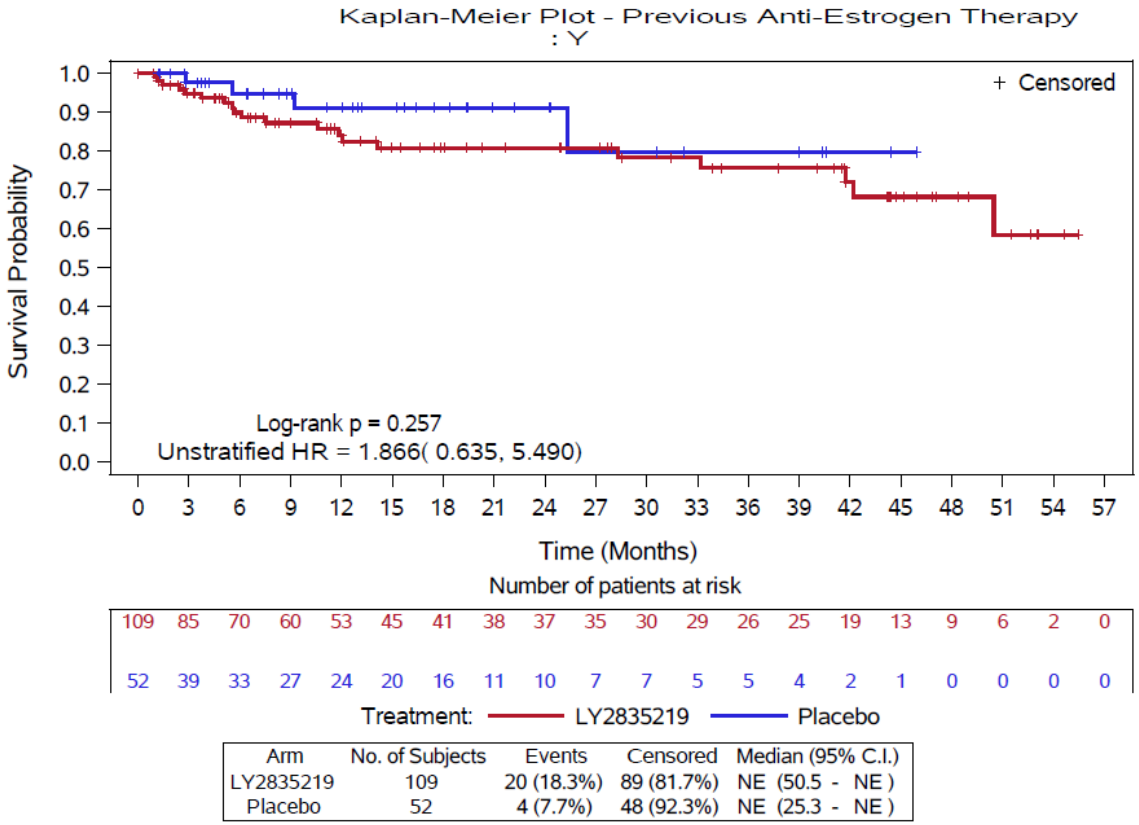
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	110	25 (22.7%)	85 (77.3%)	NE (36.0 - NE)
Placebo	54	6 (11.1%)	48 (88.9%)	NE (NE - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Financial Difficulties (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



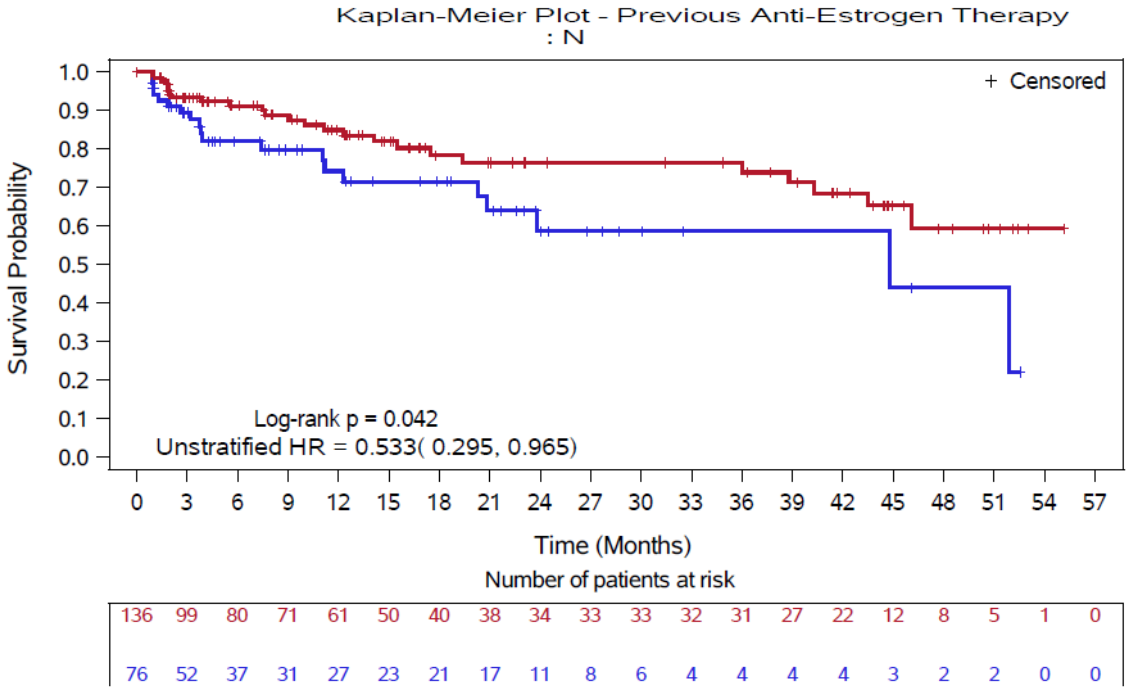
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	135	20 (14.8%)	115 (85.2%)	NE (50.5 - NE)
Placebo	74	18 (24.3%)	56 (75.7%)	44.8 (20.8 - 51.9)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items: Financial Difficulties (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



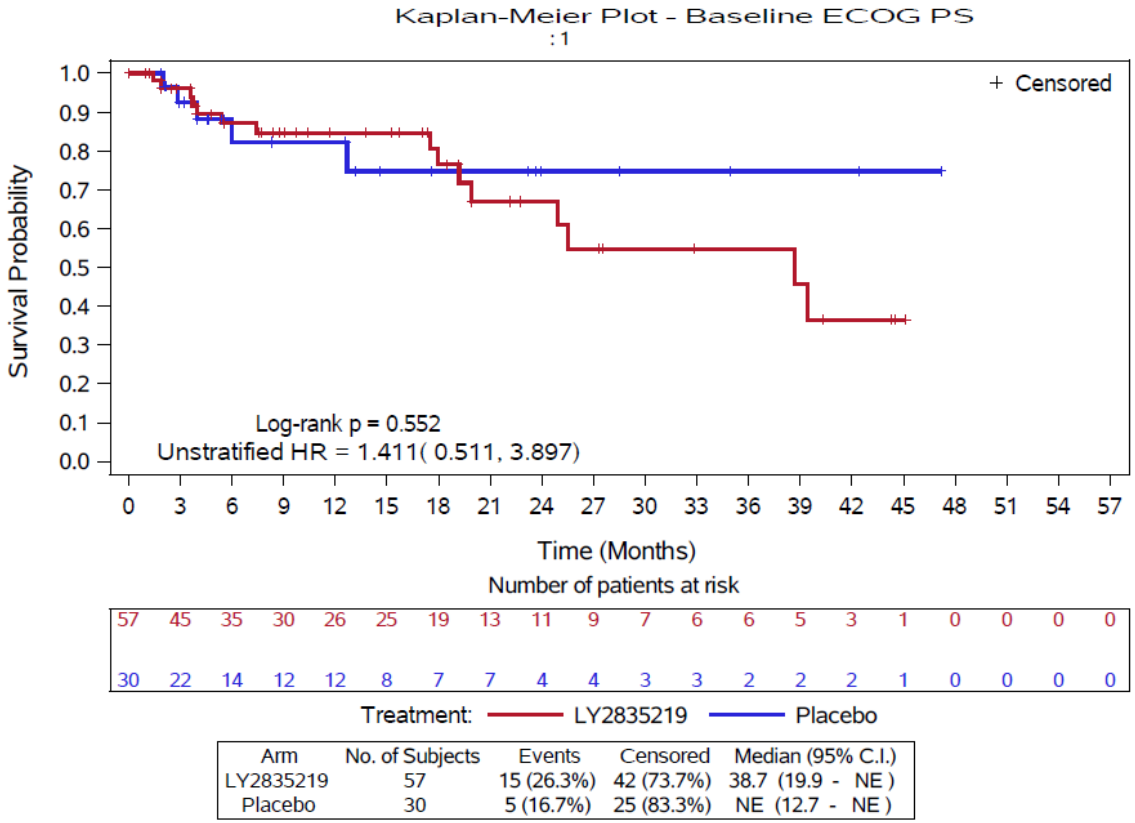
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	109	20 (18.3%)	89 (81.7%)	NE (50.5 - NE)
Placebo	52	4 (7.7%)	48 (92.3%)	NE (25.3 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items: Financial Difficulties (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



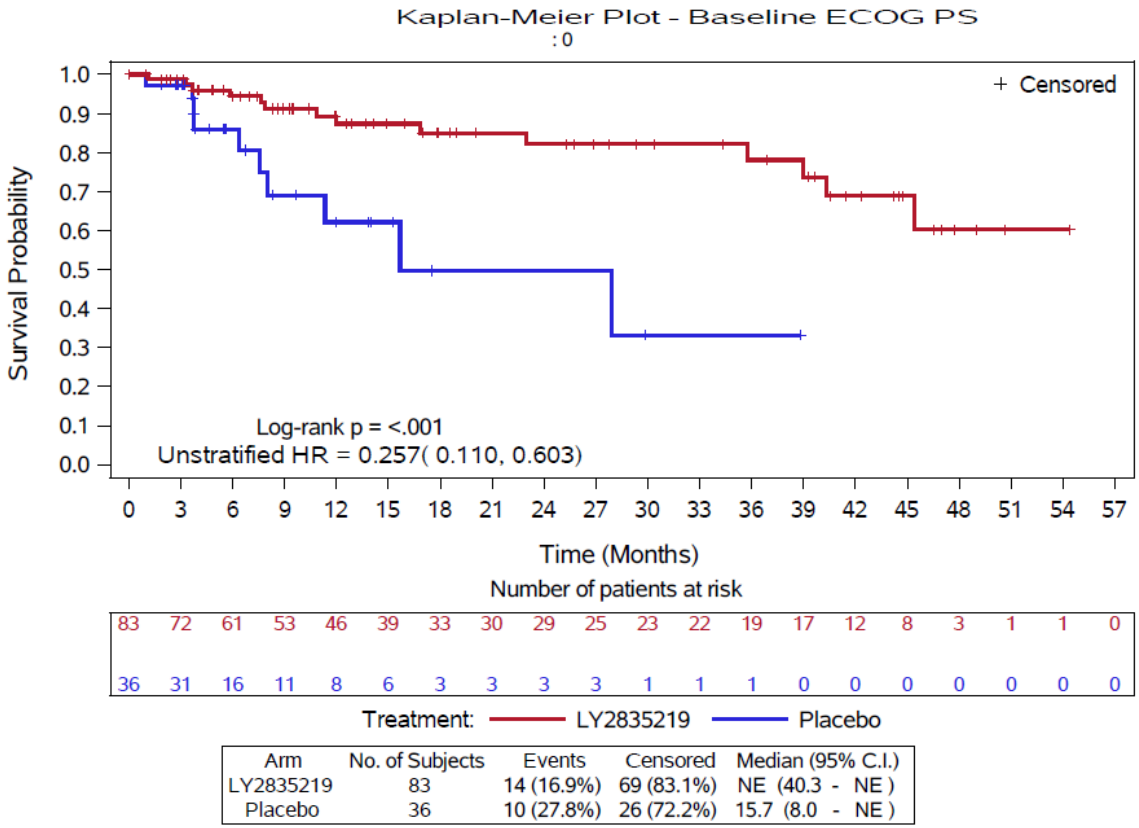
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	136	25 (18.4%)	111 (81.6%)	NE (46.1 - NE)
Placebo	76	20 (26.3%)	56 (73.7%)	44.8 (20.8 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items: Constipation (Def4)
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



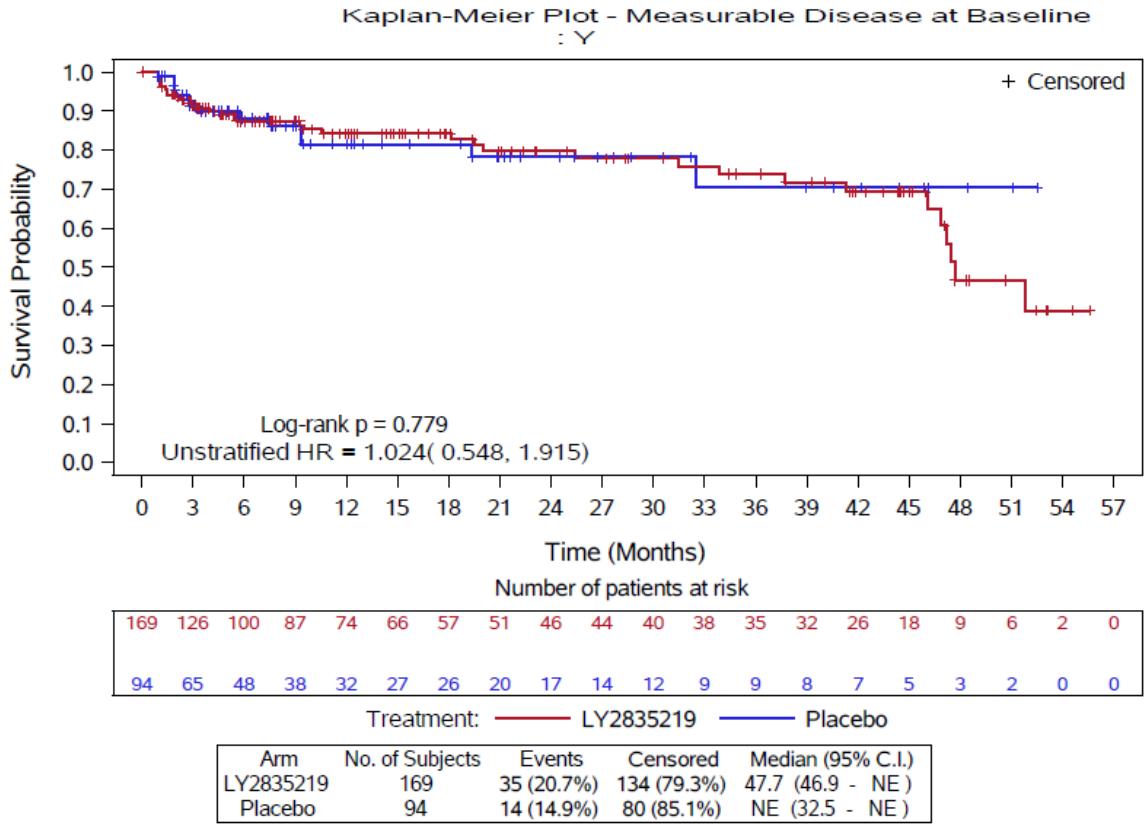
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	57	15 (26.3%)	42 (73.7%)	38.7 (19.9 - NE)
Placebo	30	5 (16.7%)	25 (83.3%)	NE (12.7 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Constipation (Def4)
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



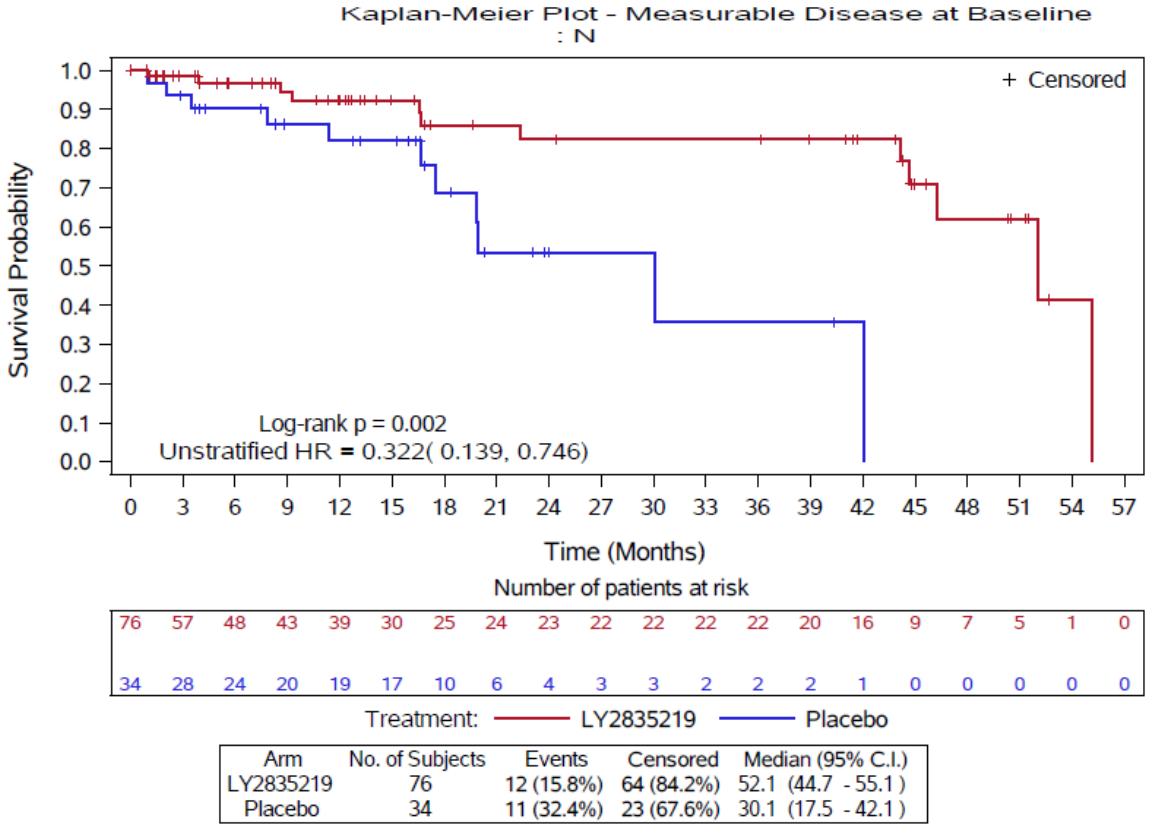
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	83	14 (16.9%)	69 (83.1%)	NE (40.3 - NE)
Placebo	36	10 (27.8%)	26 (72.2%)	15.7 (8.0 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items: Insomnia (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



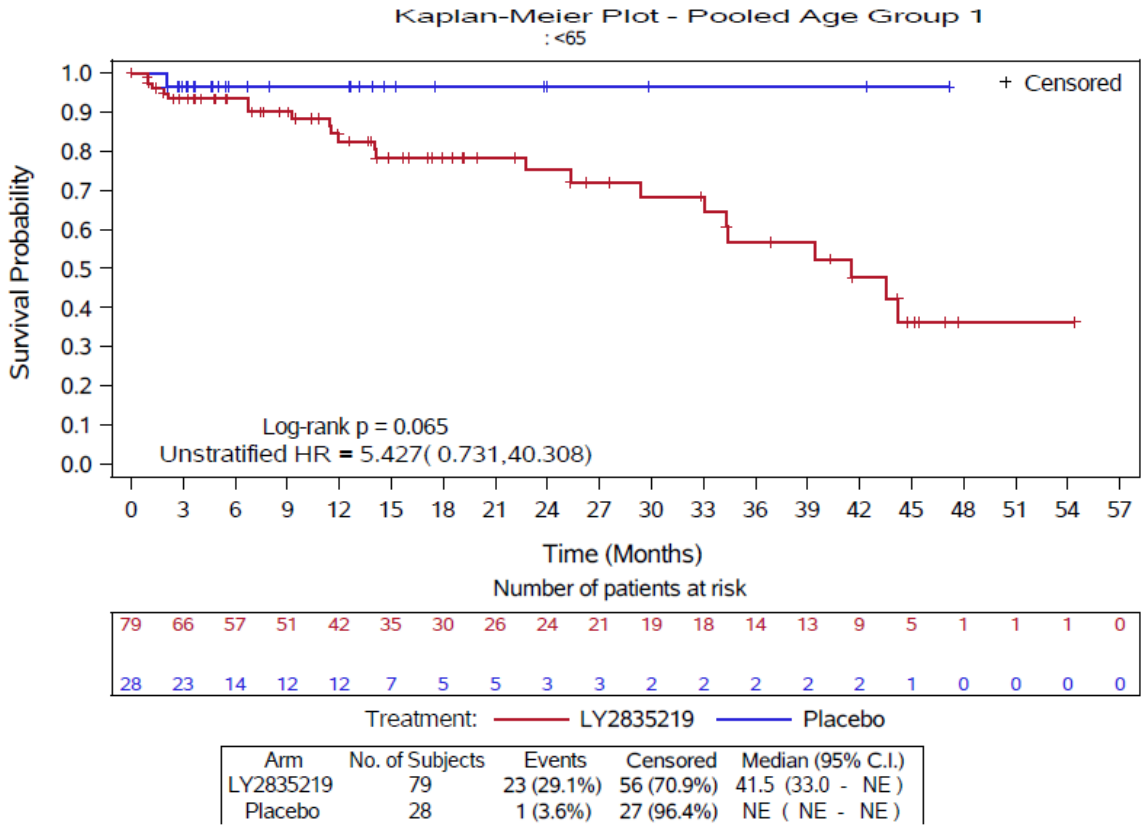
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	169	35 (20.7%)	134 (79.3%)	47.7 (46.9 - NE)
Placebo	94	14 (14.9%)	80 (85.1%)	NE (32.5 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items: Insomnia (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



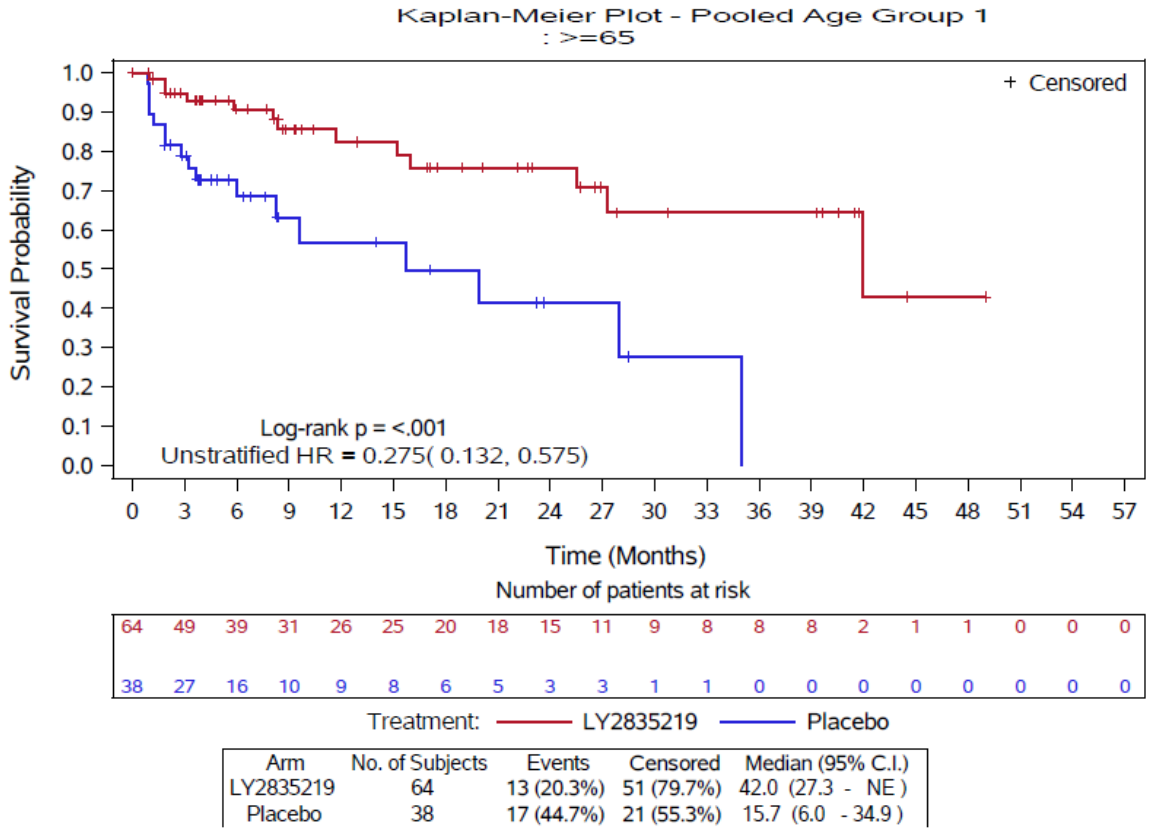
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	76	12 (15.8%)	64 (84.2%)	52.1 (44.7 - 55.1)
Placebo	34	11 (32.4%)	23 (67.6%)	30.1 (17.5 - 42.1)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Insomnia (Def4)
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



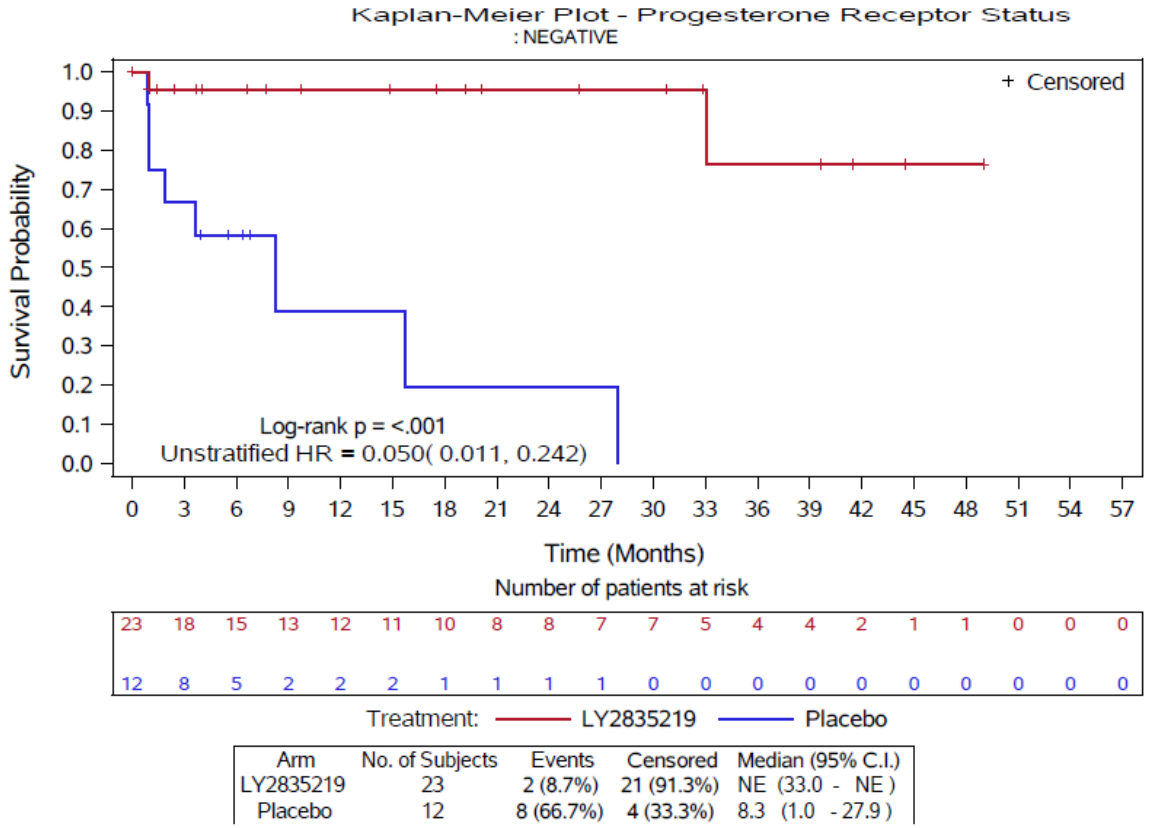
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	79	23 (29.1%)	56 (70.9%)	41.5 (33.0 - NE)
Placebo	28	1 (3.6%)	27 (96.4%)	NE (NE - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Insomnia (Def4)
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



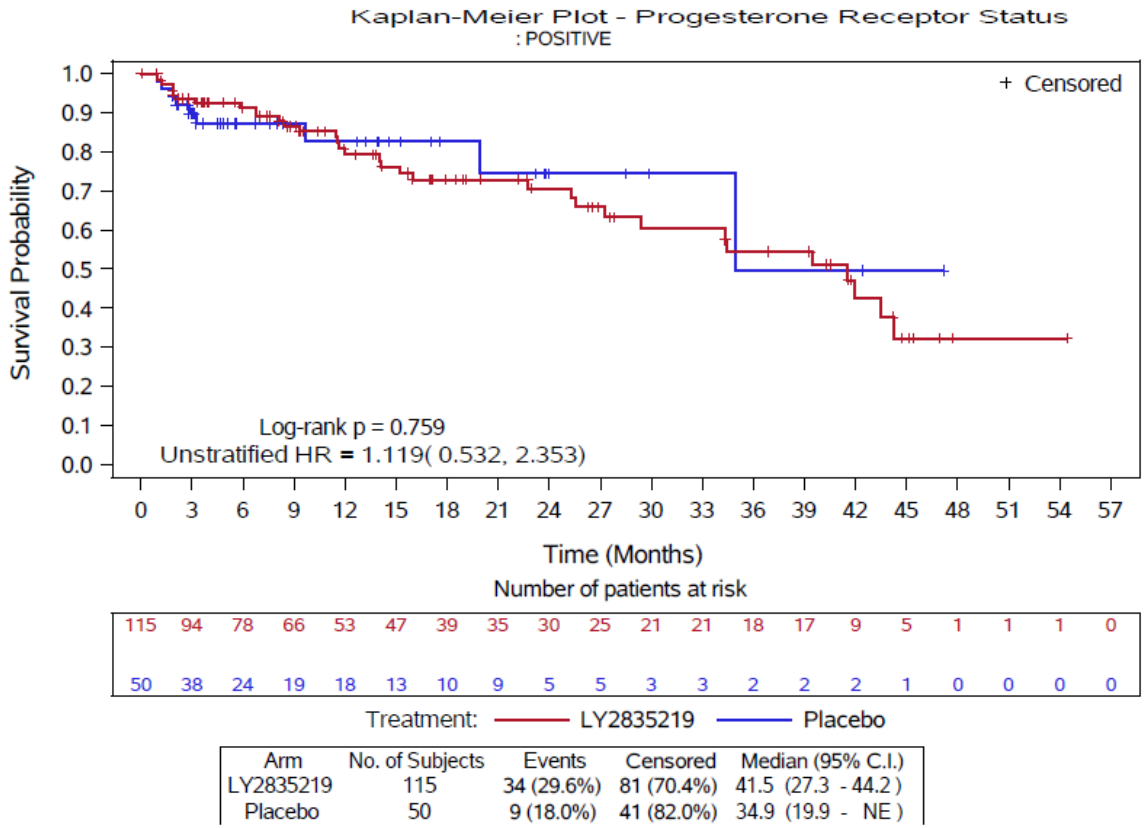
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	64	13 (20.3%)	51 (79.7%)	42.0 (27.3 - NE)
Placebo	38	17 (44.7%)	21 (55.3%)	15.7 (6.0 - 34.9)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Insomnia (Def4)
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



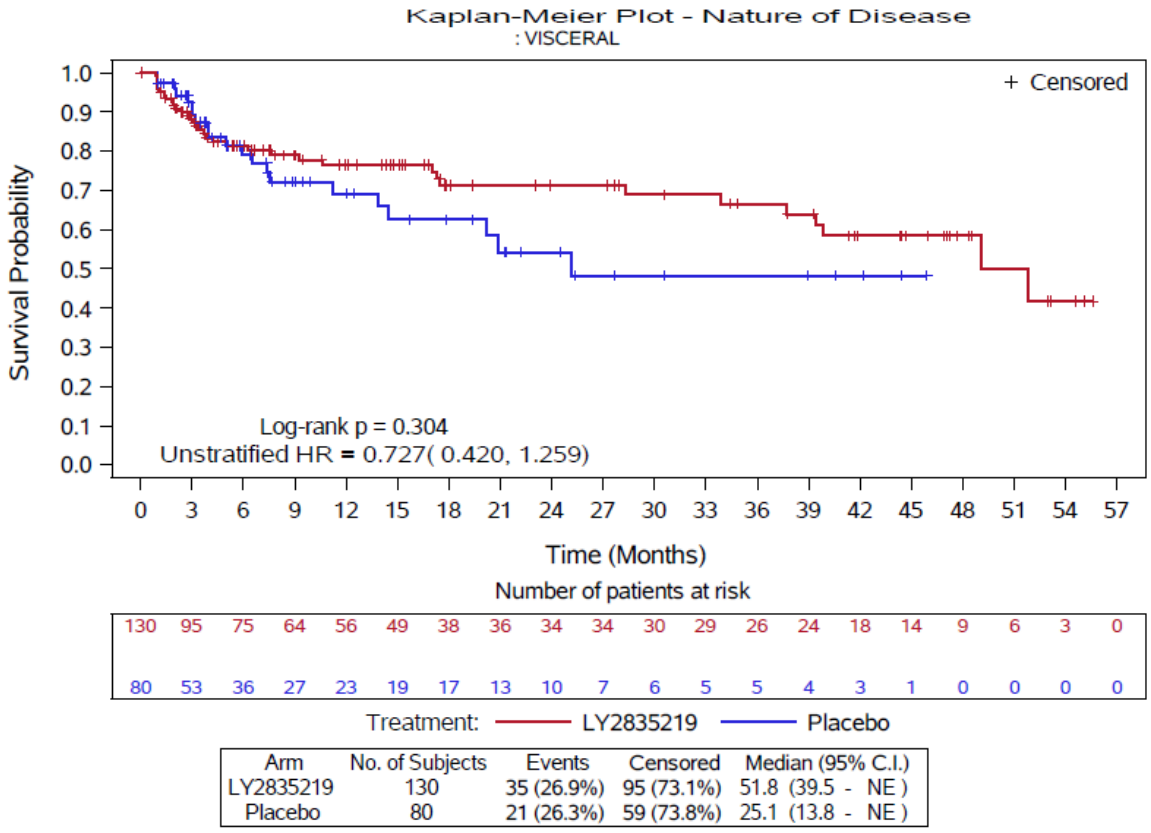
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	23	2 (8.7%)	21 (91.3%)	NE (33.0 - NE)
Placebo	12	8 (66.7%)	4 (33.3%)	8.3 (1.0 - 27.9)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Insomnia (Def4)
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



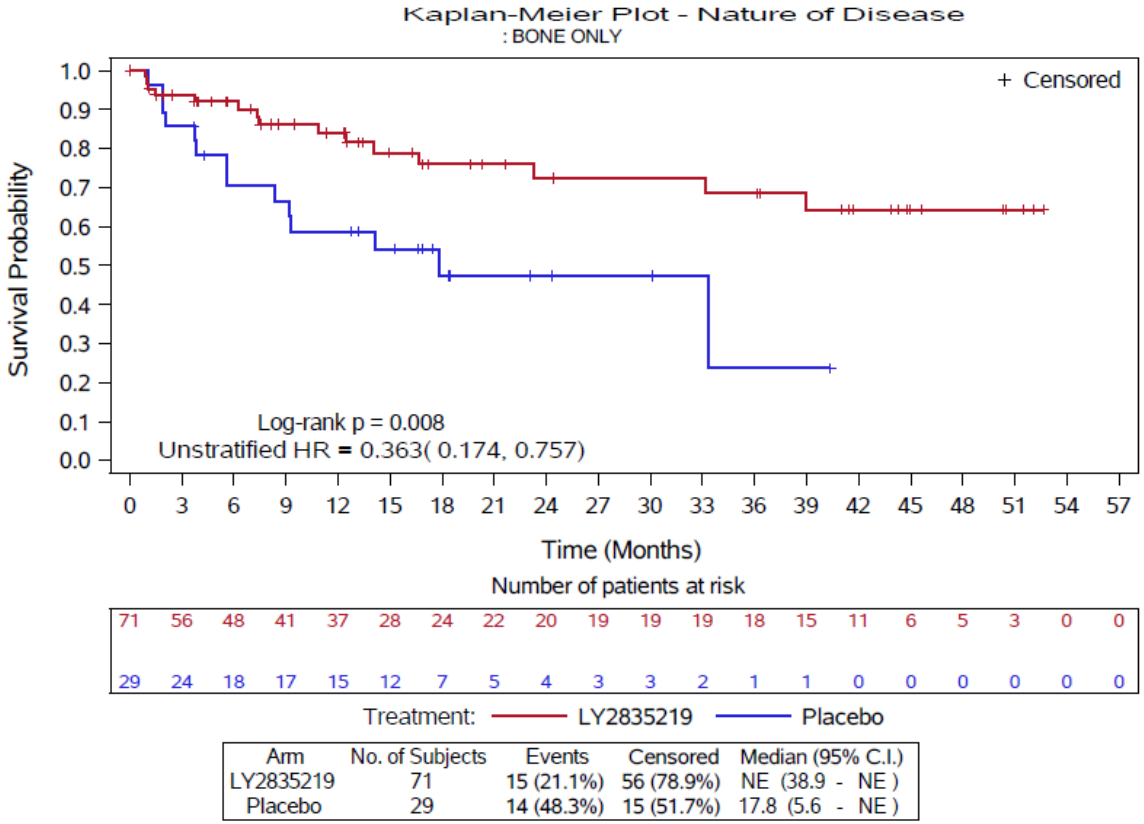
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	115	34 (29.6%)	81 (70.4%)	41.5 (27.3 - 44.2)
Placebo	50	9 (18.0%)	41 (82.0%)	34.9 (19.9 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Pain (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



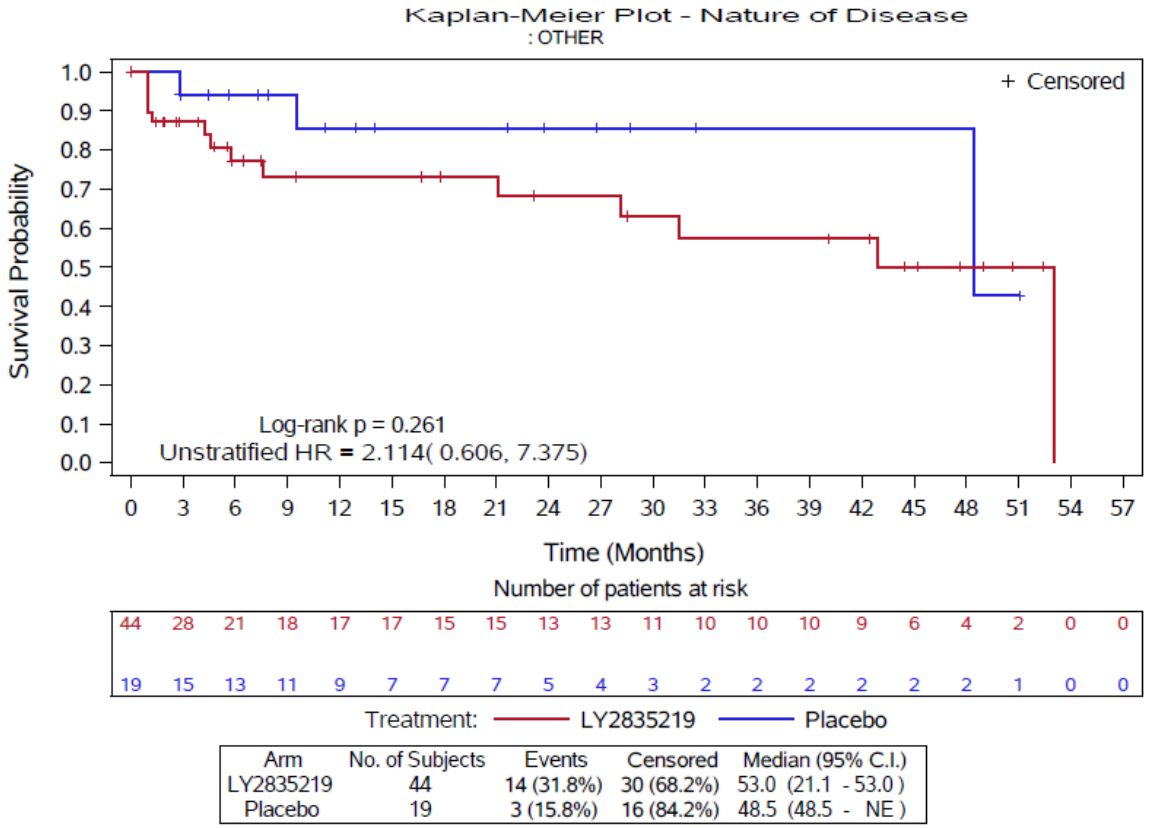
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	130	35 (26.9%)	95 (73.1%)	51.8 (39.5 - NE)
Placebo	80	21 (26.3%)	59 (73.8%)	25.1 (13.8 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Pain (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



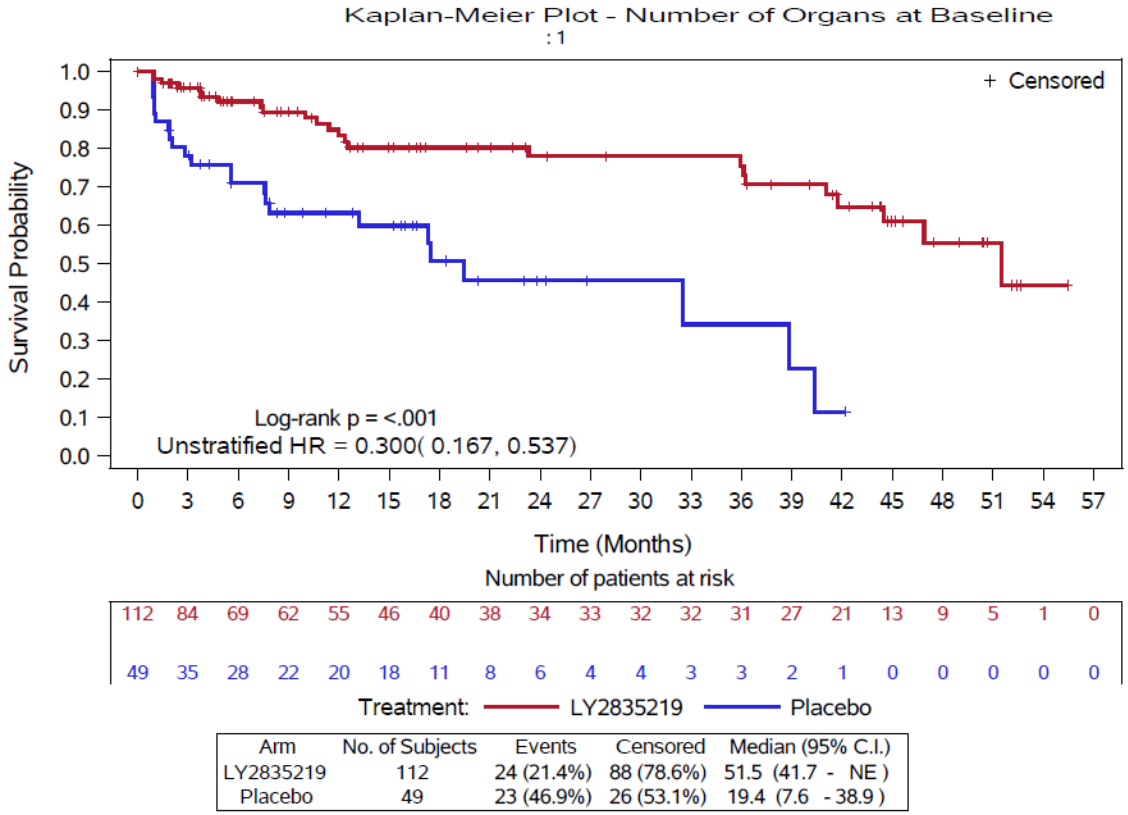
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	71	15 (21.1%)	56 (78.9%)	NE (38.9 - NE)
Placebo	29	14 (48.3%)	15 (51.7%)	17.8 (5.6 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items: Pain (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



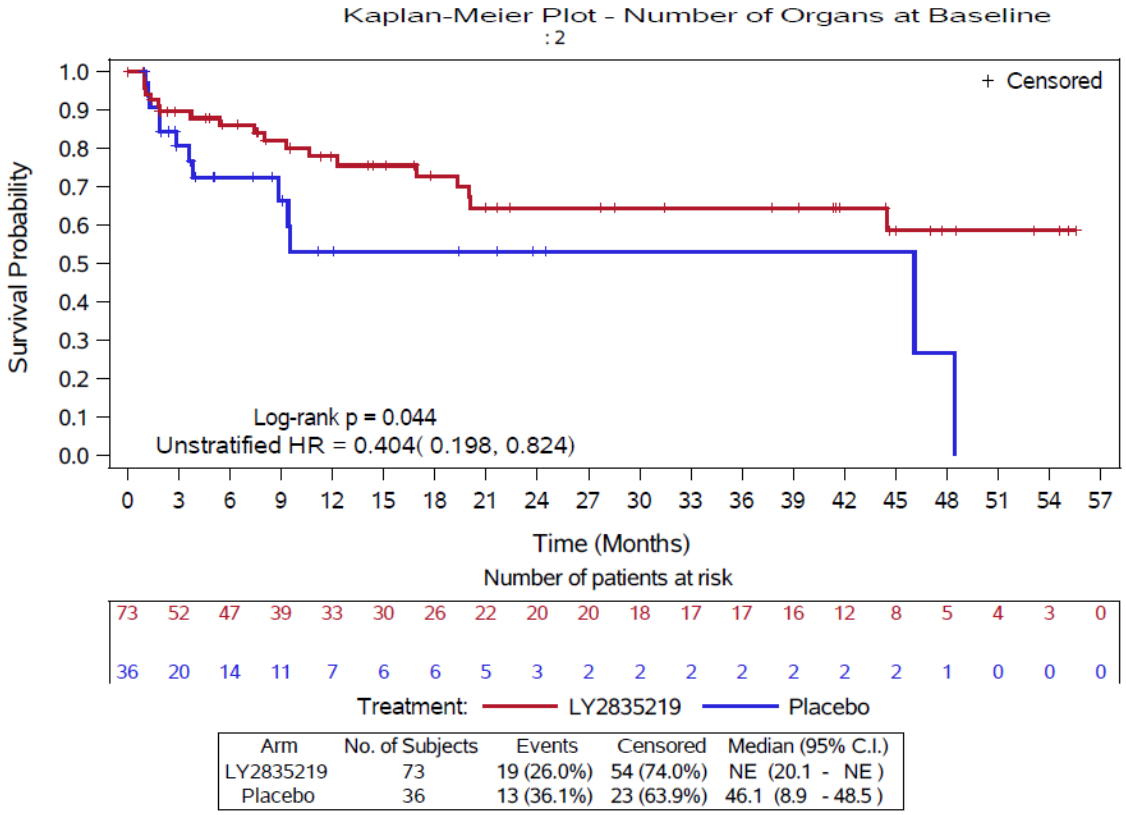
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	44	14 (31.8%)	30 (68.2%)	53.0 (21.1 - 53.0)
Placebo	19	3 (15.8%)	16 (84.2%)	48.5 (48.5 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Arm Symptoms (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



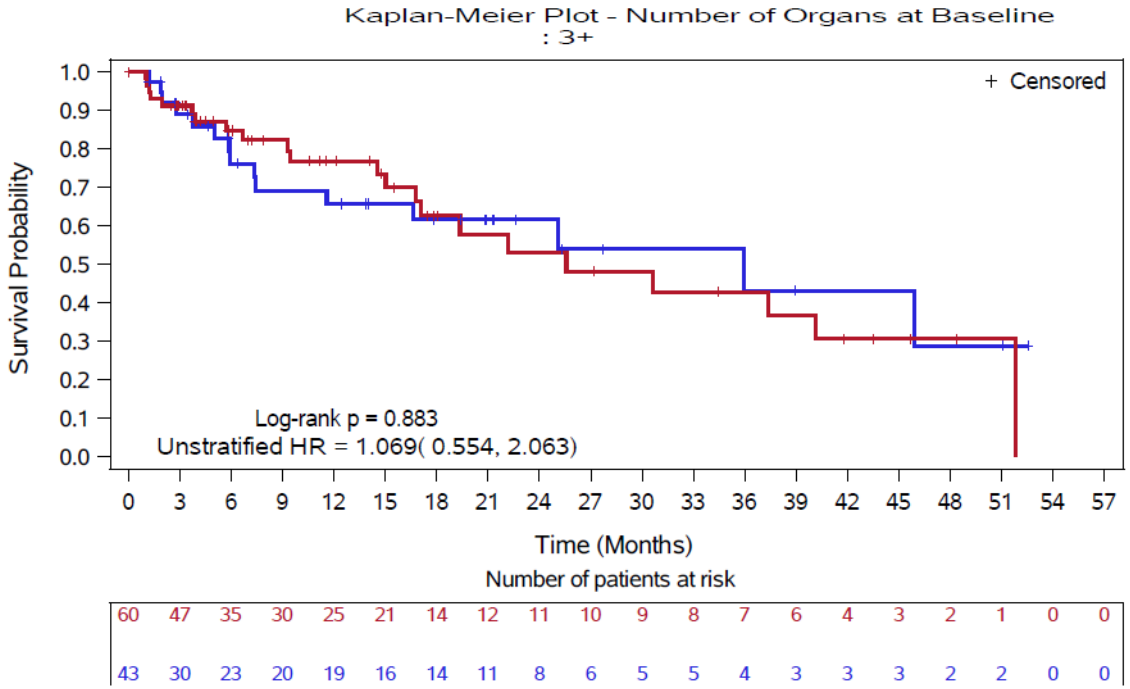
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	112	24 (21.4%)	88 (78.6%)	51.5 (41.7 - NE)
Placebo	49	23 (46.9%)	26 (53.1%)	19.4 (7.6 - 38.9)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Arm Symptoms (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



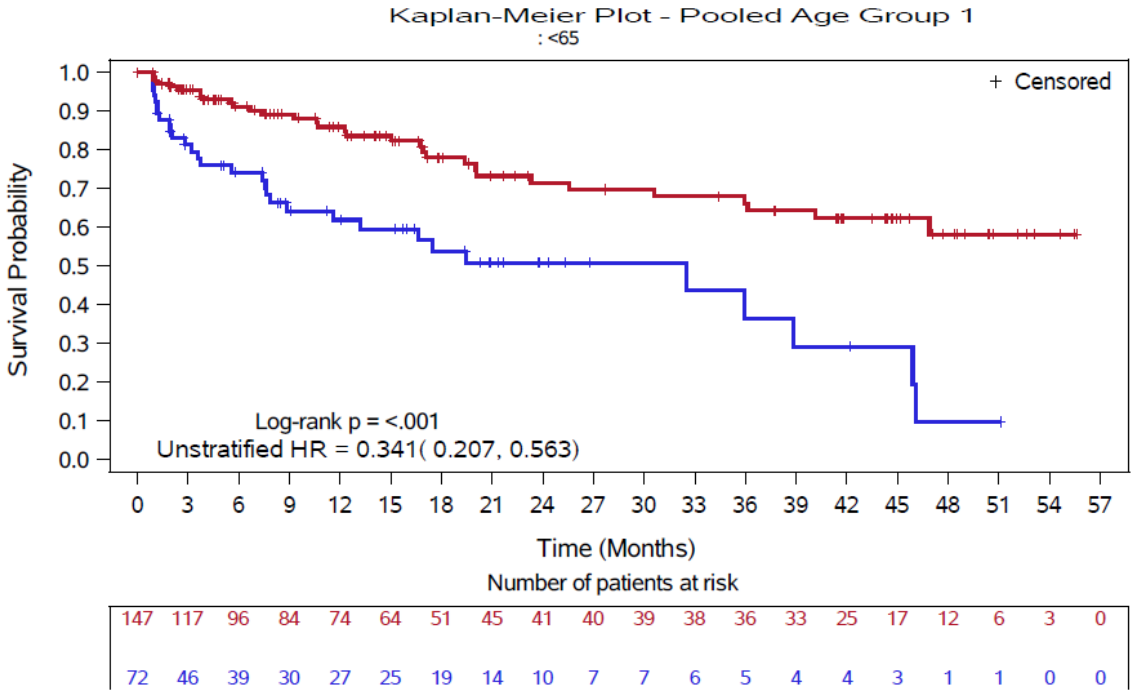
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	73	19 (26.0%)	54 (74.0%)	NE (20.1 - NE)
Placebo	36	13 (36.1%)	23 (63.9%)	46.1 (8.9 - 48.5)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Arm Symptoms (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



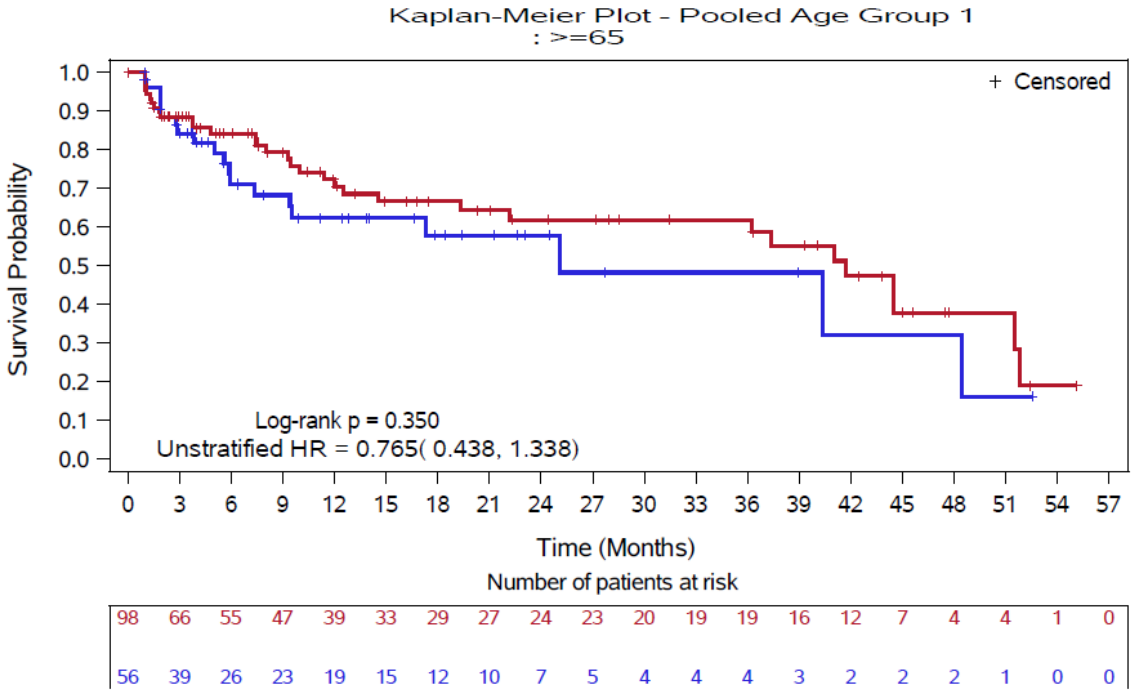
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	60	22 (36.7%)	38 (63.3%)	25.6 (16.8 - 51.8)
Placebo	43	15 (34.9%)	28 (65.1%)	36.0 (7.4 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Arm Symptoms (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



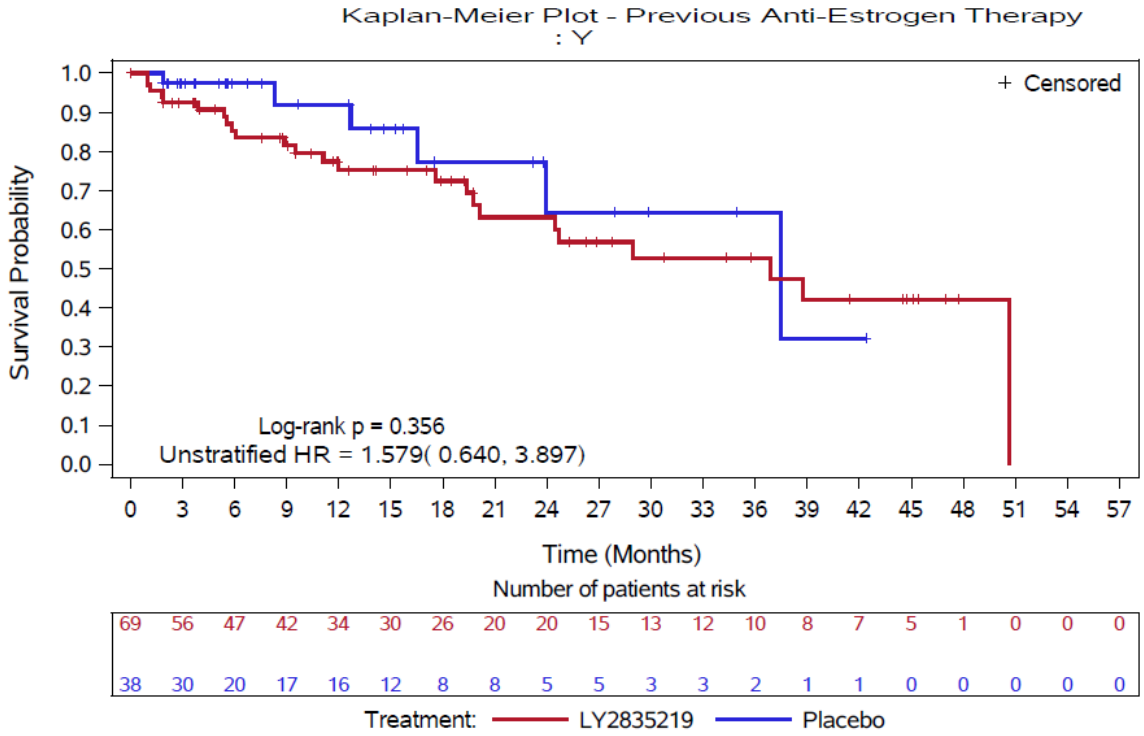
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	147	32 (21.8%)	115 (78.2%)	NE (40.1 - NE)
Placebo	72	31 (43.1%)	41 (56.9%)	32.5 (11.6 - 38.9)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Arm Symptoms (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



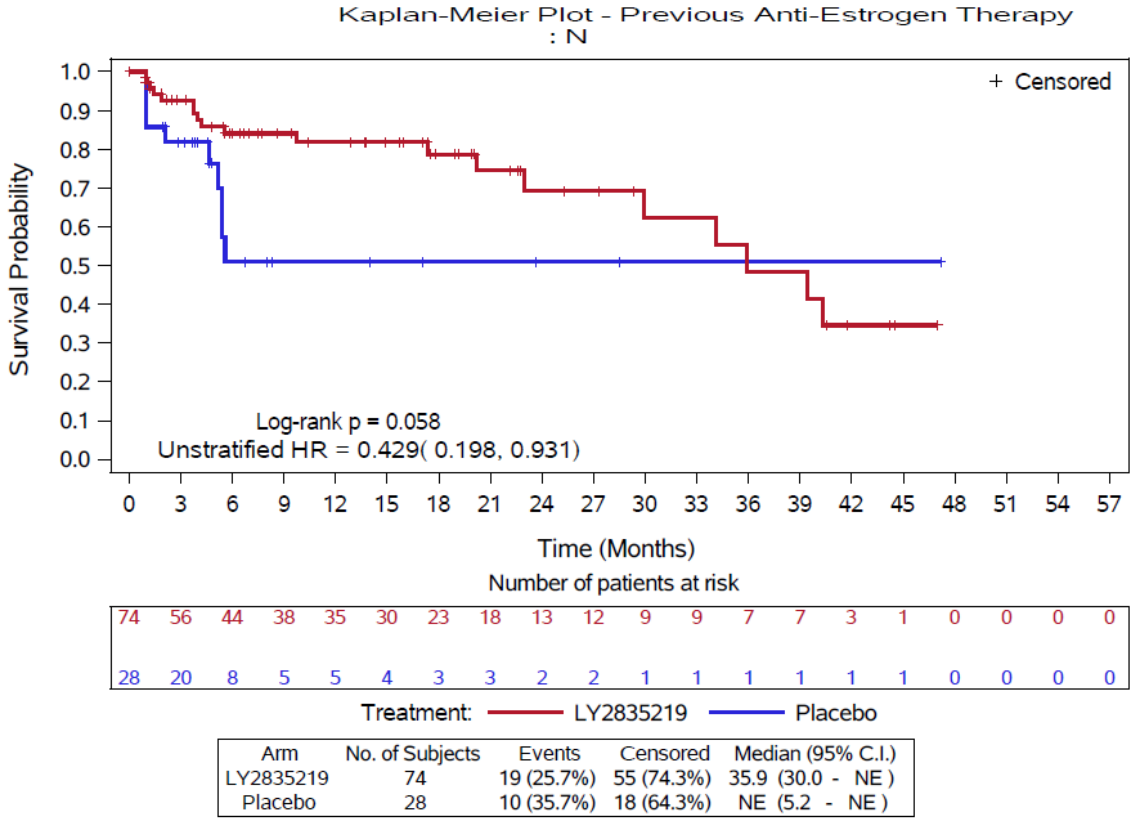
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	98	33 (33.7%)	65 (66.3%)	41.7 (22.2 - 51.5)
Placebo	56	20 (35.7%)	36 (64.3%)	25.1 (9.4 - 48.5)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Arm Symptoms (Def4)
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



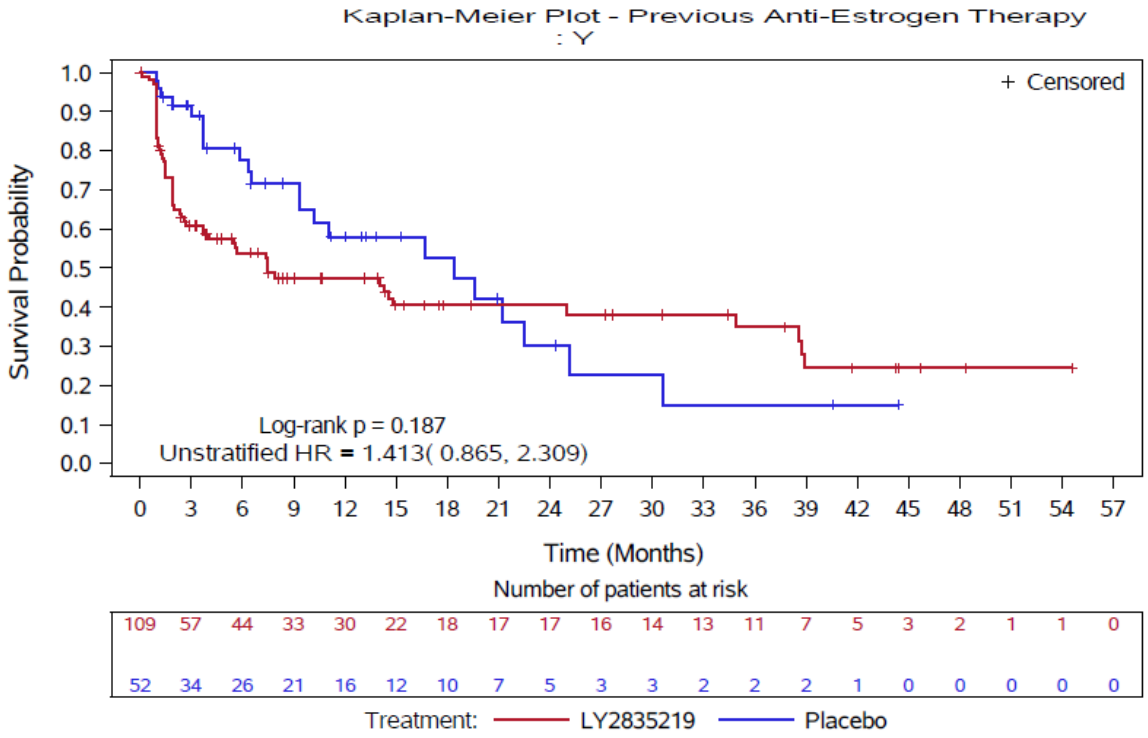
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	69	24 (34.8%)	45 (65.2%)	36.9 (20.1 - 50.6)
Placebo	38	6 (15.8%)	32 (84.2%)	37.5 (16.6 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Symptom Scales / Items:
Arm Symptoms (Def4)
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



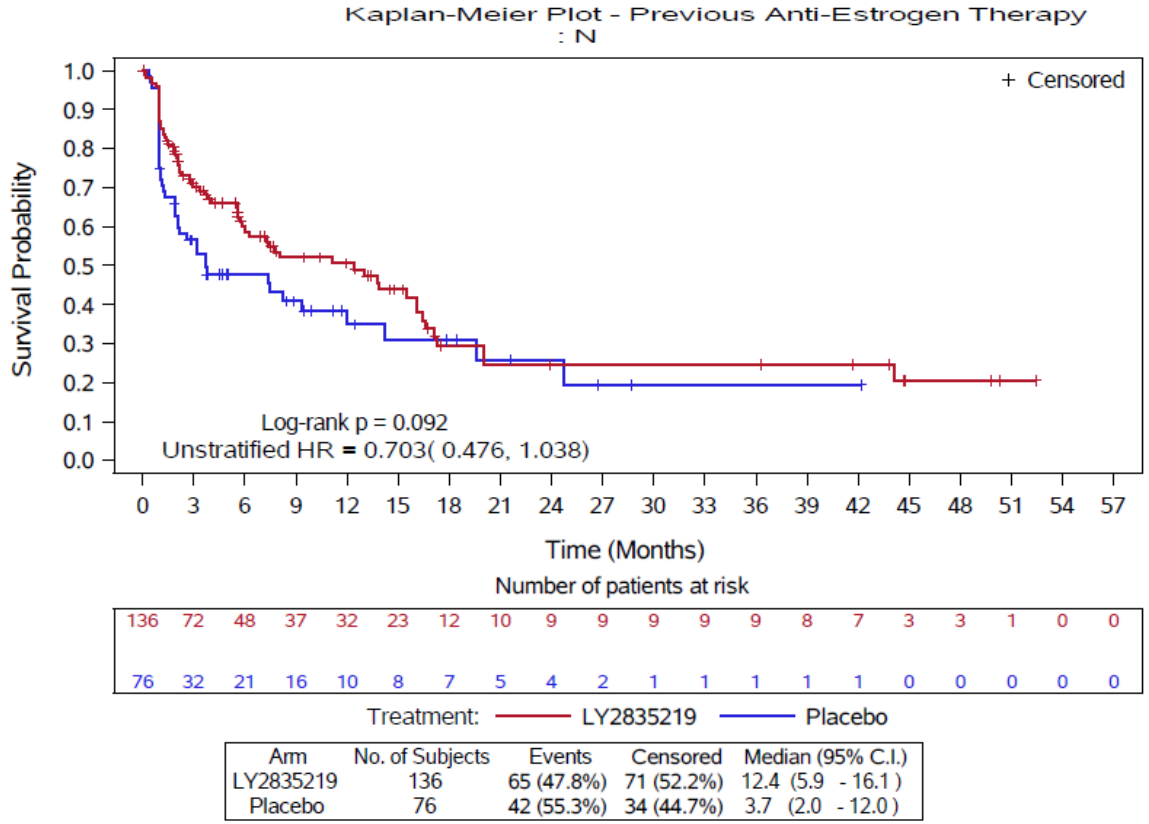
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	74	19 (25.7%)	55 (74.3%)	35.9 (30.0 - NE)
Placebo	28	10 (35.7%)	18 (64.3%)	NE (5.2 - NE)

Kaplan-Meier Plot of Time to Worsening by Subgroup: Pain at its Worst in Last 24 Hours
(Def1)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive
(1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



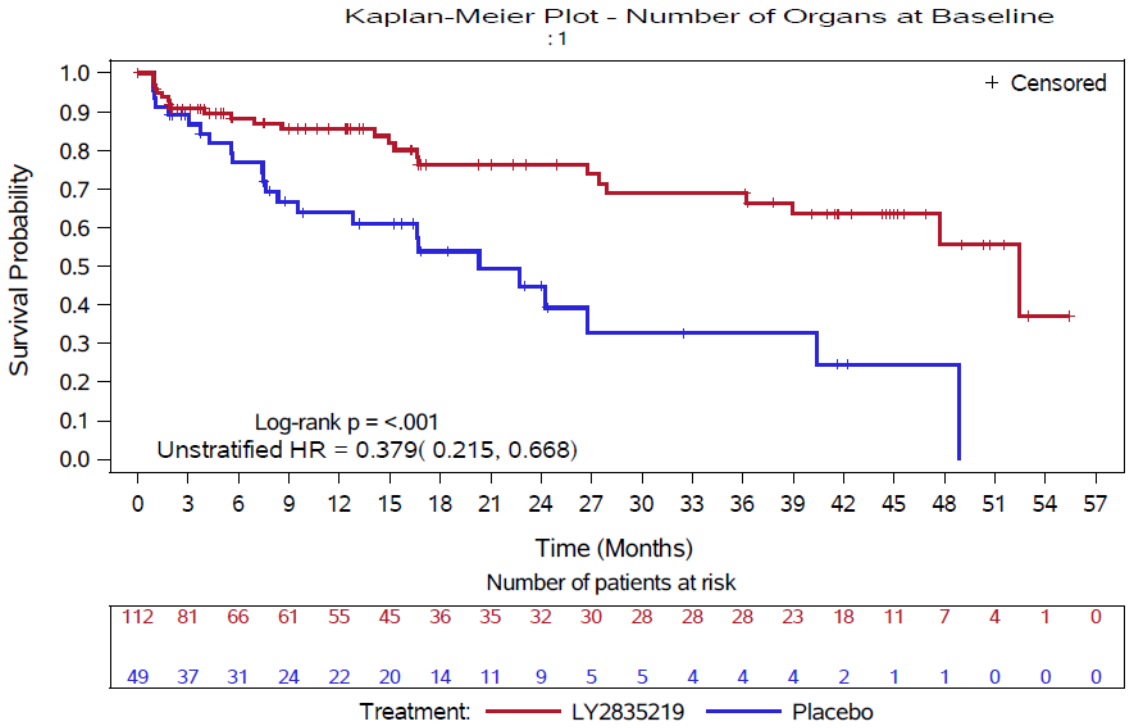
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	109	59 (54.1%)	50 (45.9%)	7.4 (3.7 - 25.0)
Placebo	52	22 (42.3%)	30 (57.7%)	18.4 (9.3 - 25.1)

Kaplan-Meier Plot of Time to Worsening by Subgroup: Pain at its Worst in Last 24 Hours
(Def1)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive
(1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



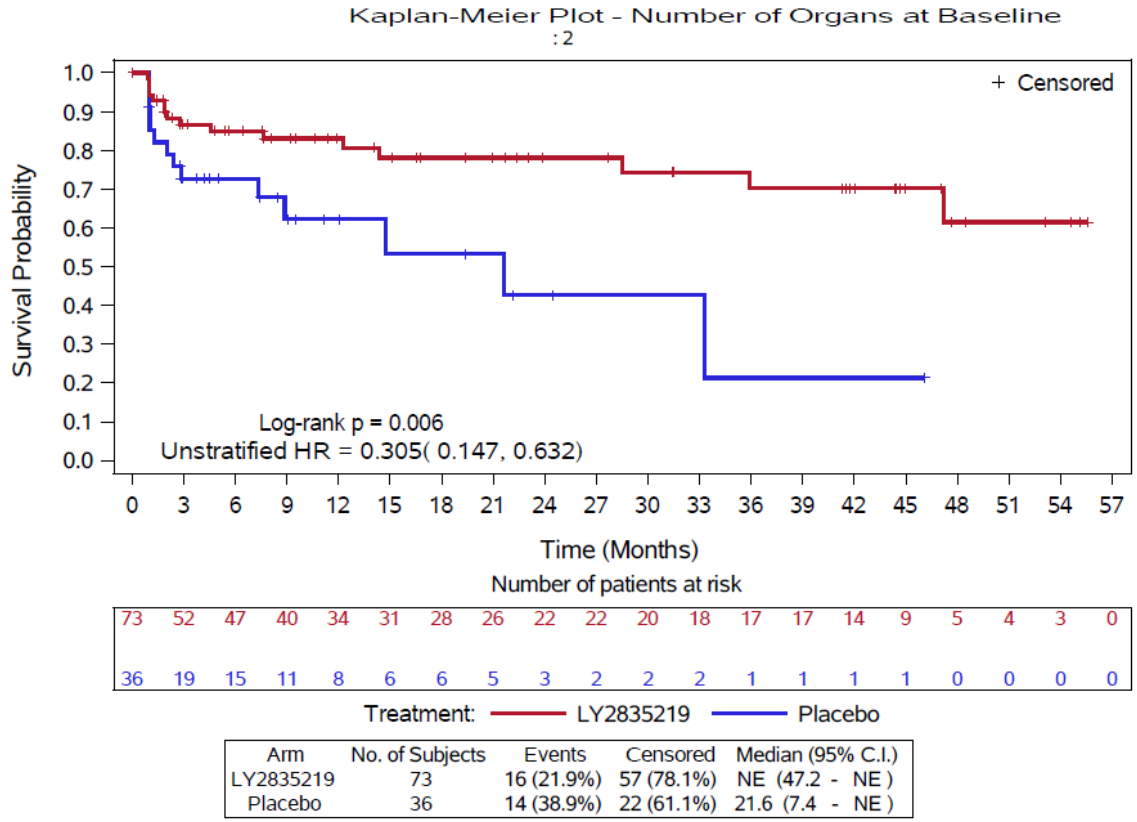
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	136	65 (47.8%)	71 (52.2%)	12.4 (5.9 - 16.1)
Placebo	76	42 (55.3%)	34 (44.7%)	3.7 (2.0 - 12.0)

Kaplan-Meier Plot of Time to Sustained Worsening in EQ-5DL VAS Score (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



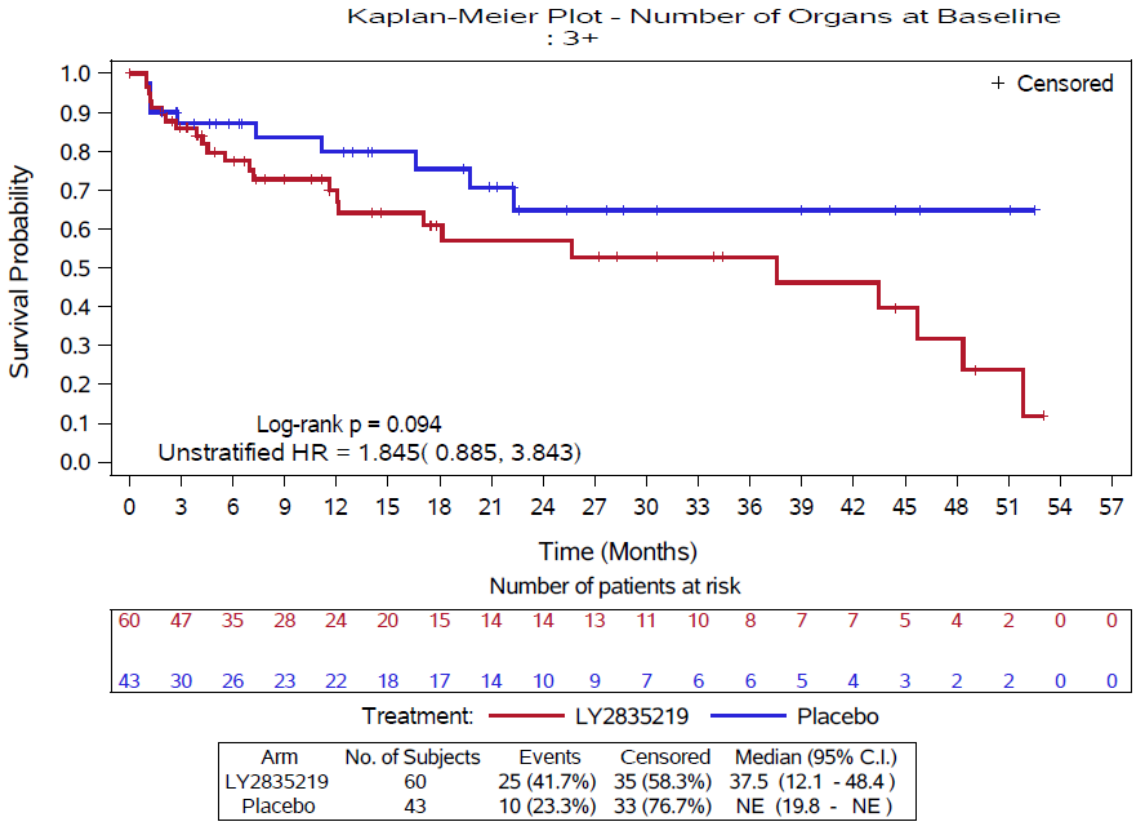
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	112	25 (22.3%)	87 (77.7%)	52.4 (38.9 - NE)
Placebo	49	24 (49.0%)	25 (51.0%)	20.3 (9.5 - 40.4)

Kaplan-Meier Plot of Time to Sustained Worsening in EQ-5DL VAS Score (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



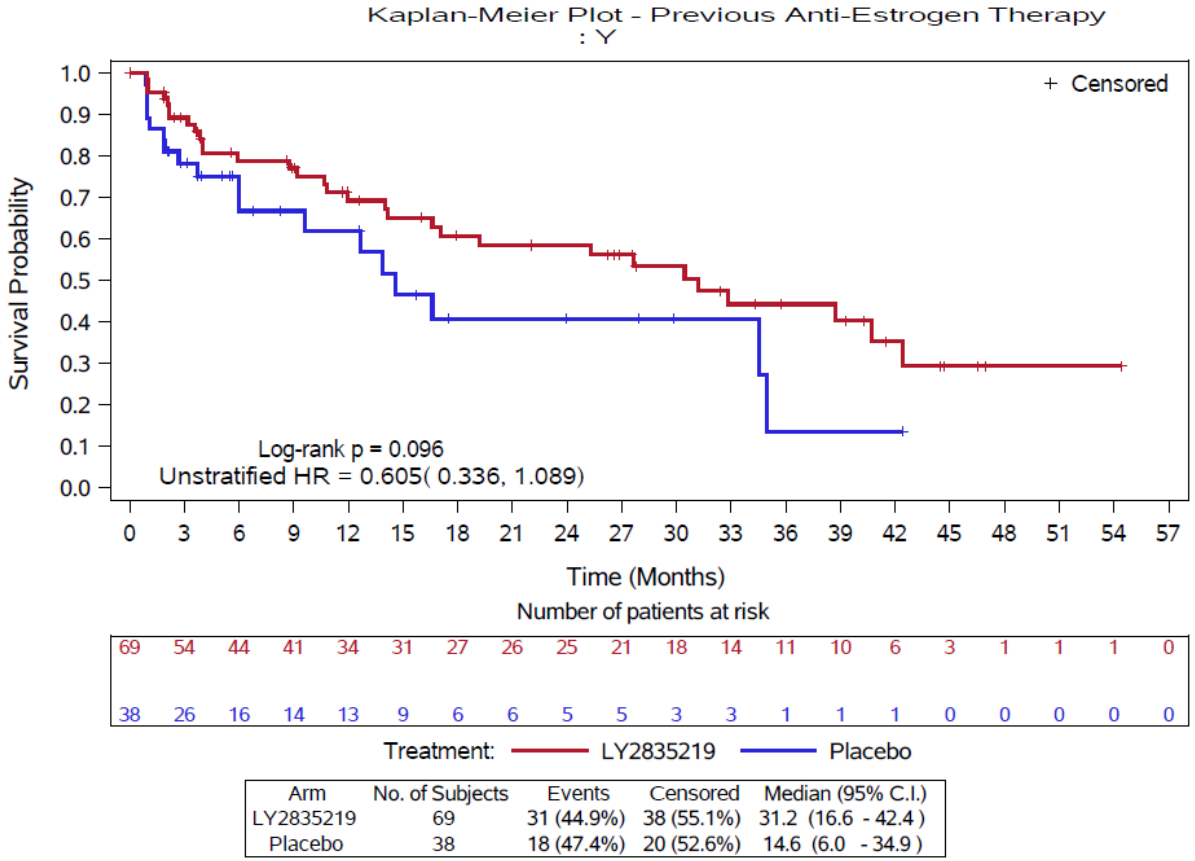
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	73	16 (21.9%)	57 (78.1%)	NE (47.2 - NE)
Placebo	36	14 (38.9%)	22 (61.1%)	21.6 (7.4 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening in EQ-5DL VAS Score (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



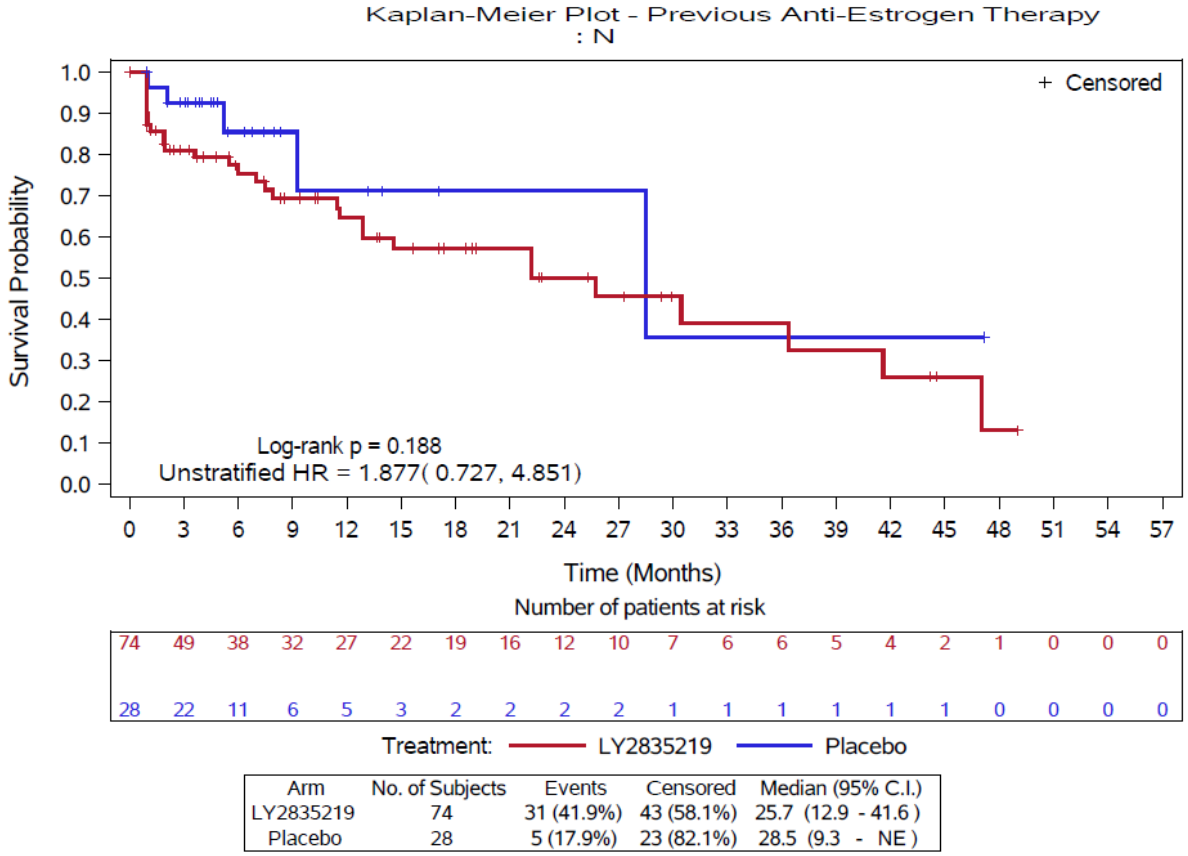
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	60	25 (41.7%)	35 (58.3%)	37.5 (12.1 - 48.4)
Placebo	43	10 (23.3%)	33 (76.7%)	NE (19.8 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening in EQ-5DL VAS Score (Def4)
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



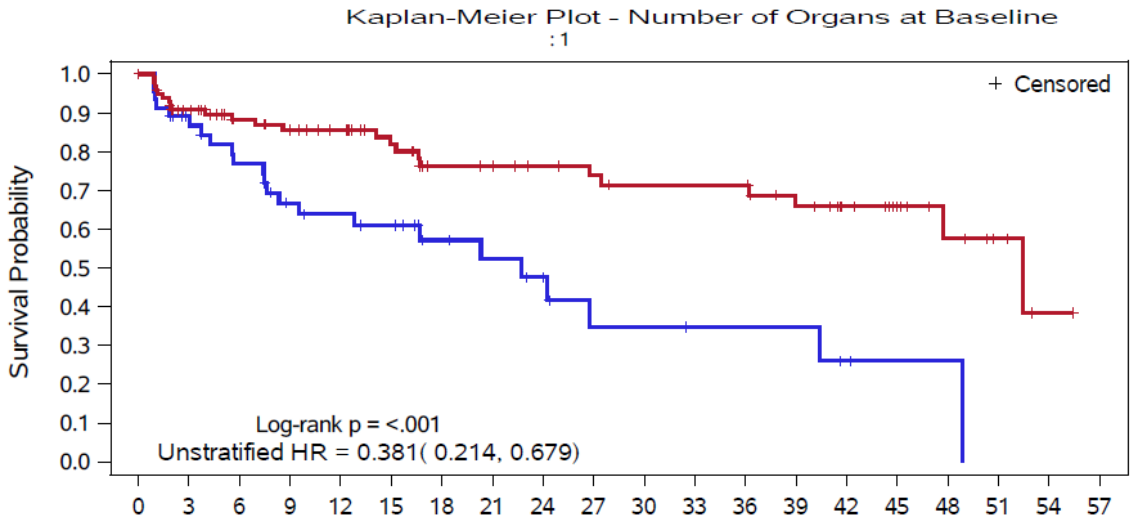
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	69	31 (44.9%)	38 (55.1%)	31.2 (16.6 - 42.4)
Placebo	38	18 (47.4%)	20 (52.6%)	14.6 (6.0 - 34.9)

Kaplan-Meier Plot of Time to Sustained Worsening in EQ-5DL VAS Score (Def4)
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



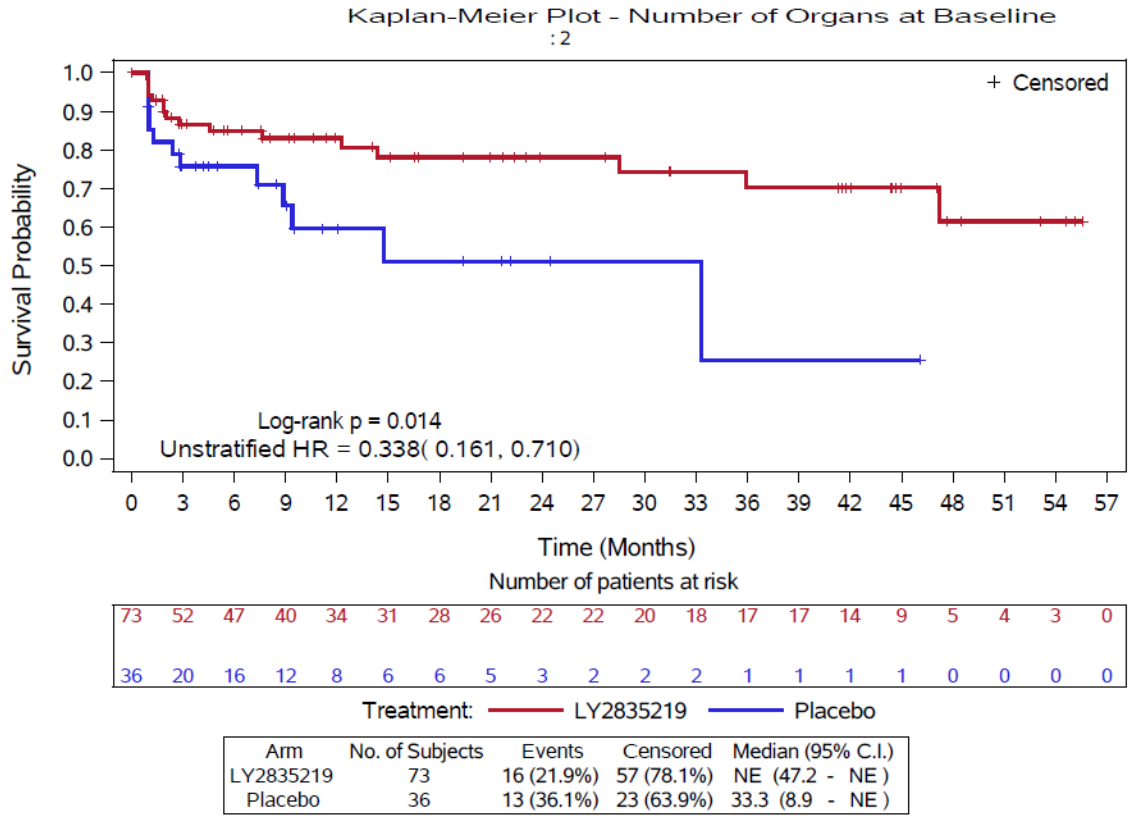
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	74	31 (41.9%)	43 (58.1%)	25.7 (12.9 - 41.6)
Placebo	28	5 (17.9%)	23 (82.1%)	28.5 (9.3 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening in EQ-5DL VAS Score (MID 10) (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



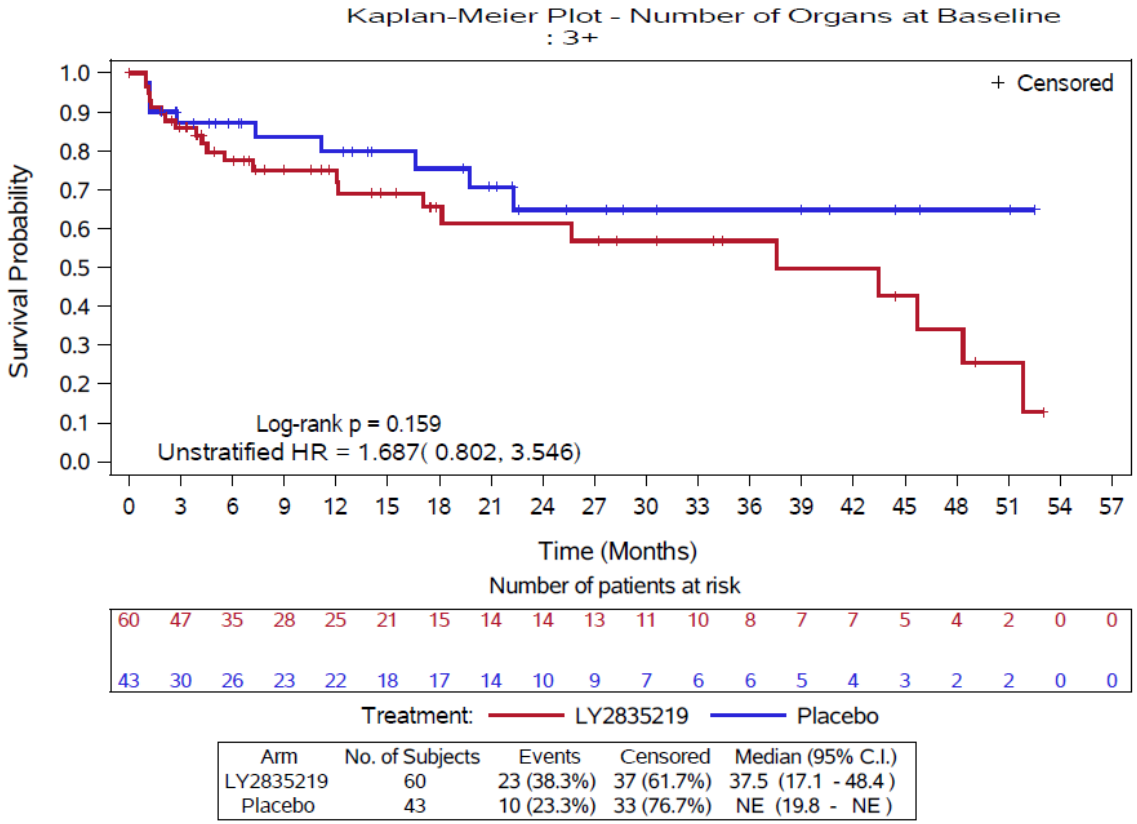
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	112	24 (21.4%)	88 (78.6%)	52.4 (47.7 - NE)
Placebo	49	23 (46.9%)	26 (53.1%)	22.7 (9.5 - 40.4)

Kaplan-Meier Plot of Time to Sustained Worsening in EQ-5DL VAS Score (MID 10) (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



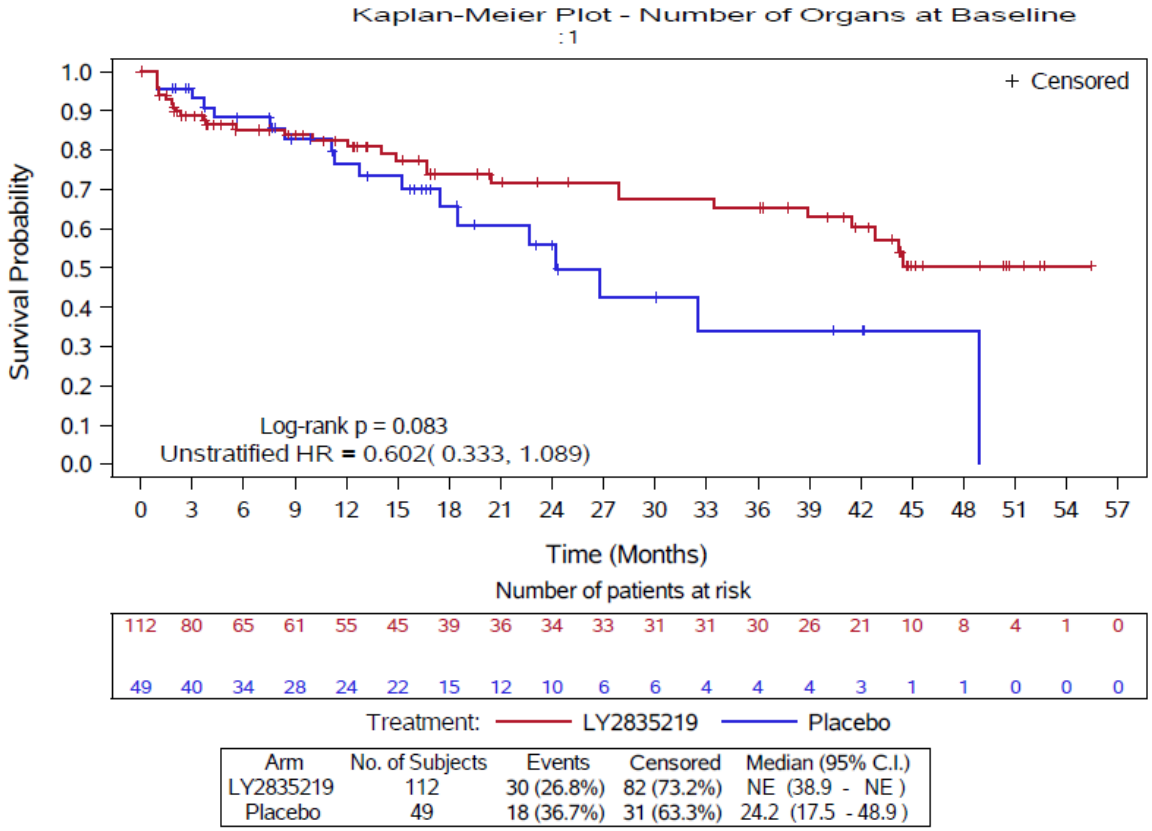
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	73	16 (21.9%)	57 (78.1%)	NE (47.2 - NE)
Placebo	36	13 (36.1%)	23 (63.9%)	33.3 (8.9 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening in EQ-5DL VAS Score (MID 10) (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



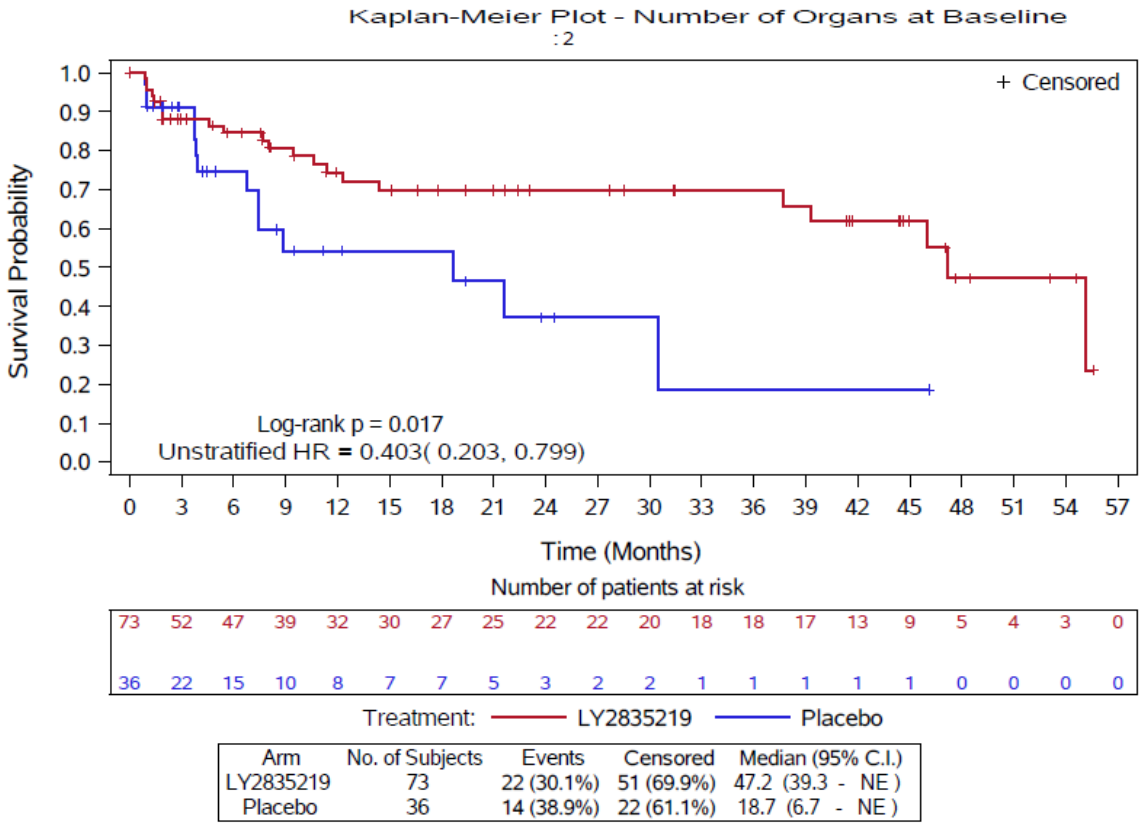
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	60	23 (38.3%)	37 (61.7%)	37.5 (17.1 - 48.4)
Placebo	43	10 (23.3%)	33 (76.7%)	NE (19.8 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Global Health Status / QoI (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



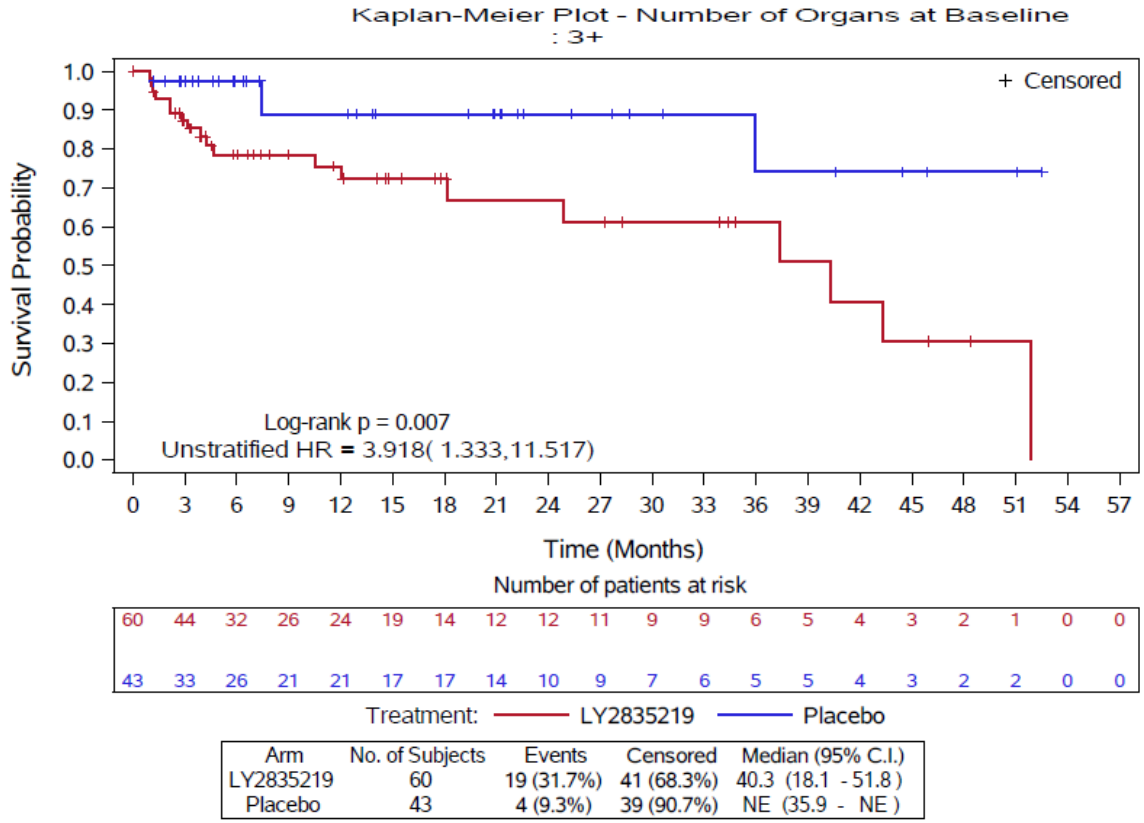
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	112	30 (26.8%)	82 (73.2%)	NE (38.9 - NE)
Placebo	49	18 (36.7%)	31 (63.3%)	24.2 (17.5 - 48.9)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Global Health Status / QoI (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



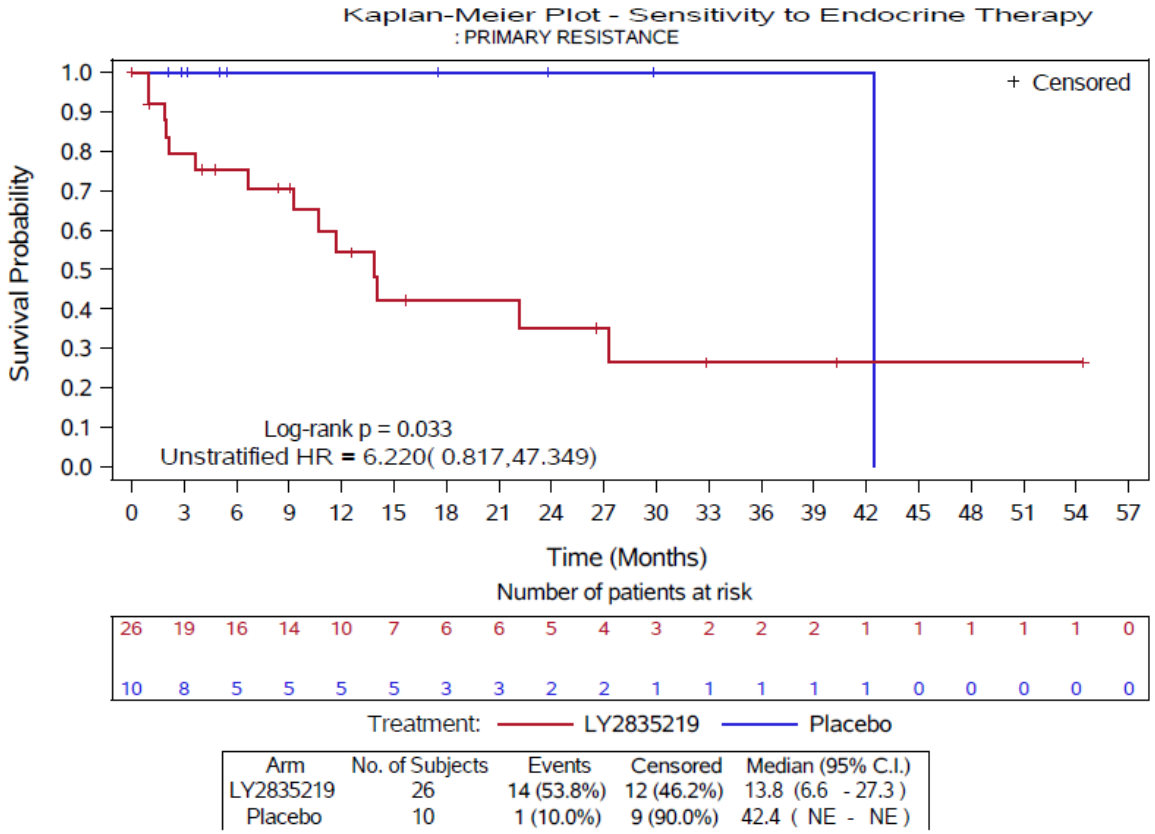
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	73	22 (30.1%)	51 (69.9%)	47.2 (39.3 - NE)
Placebo	36	14 (38.9%)	22 (61.1%)	18.7 (6.7 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Global Health Status / QoI (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



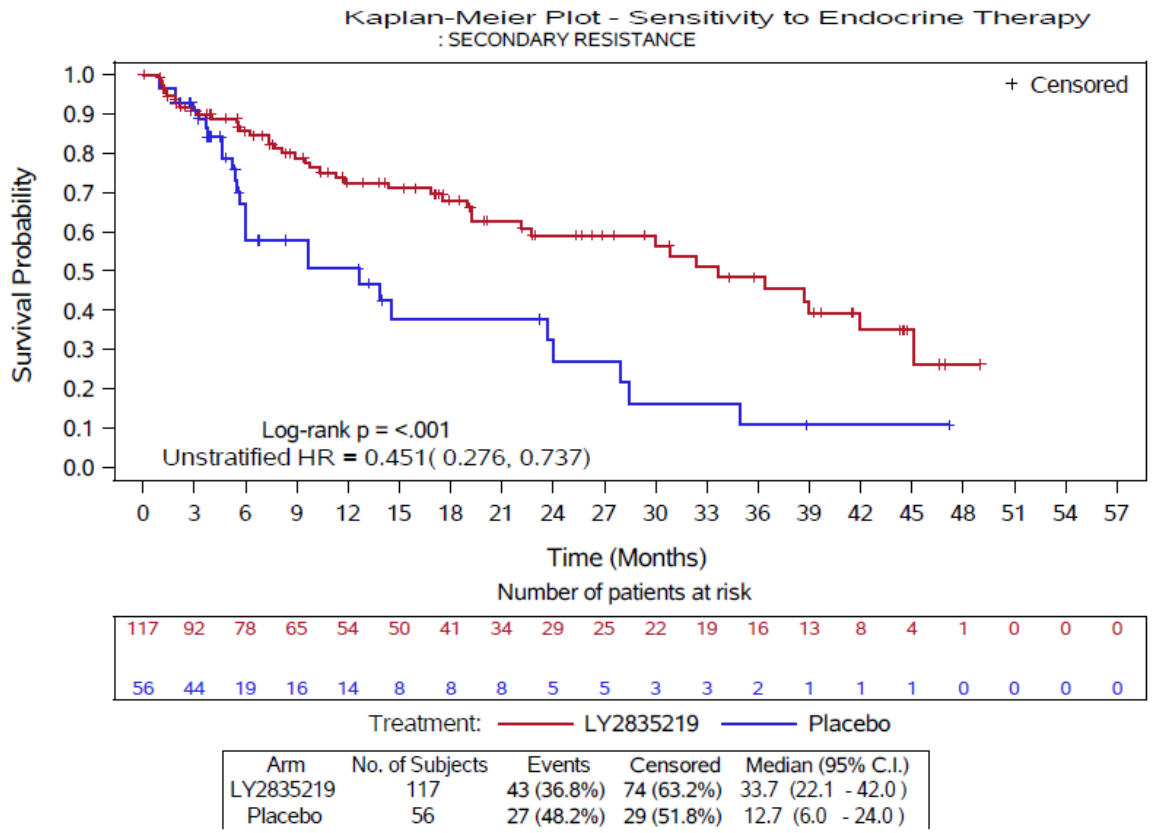
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	60	19 (31.7%)	41 (68.3%)	40.3 (18.1 - 51.8)
Placebo	43	4 (9.3%)	39 (90.7%)	NE (35.9 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Global Health Status / QoI (Def4)
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



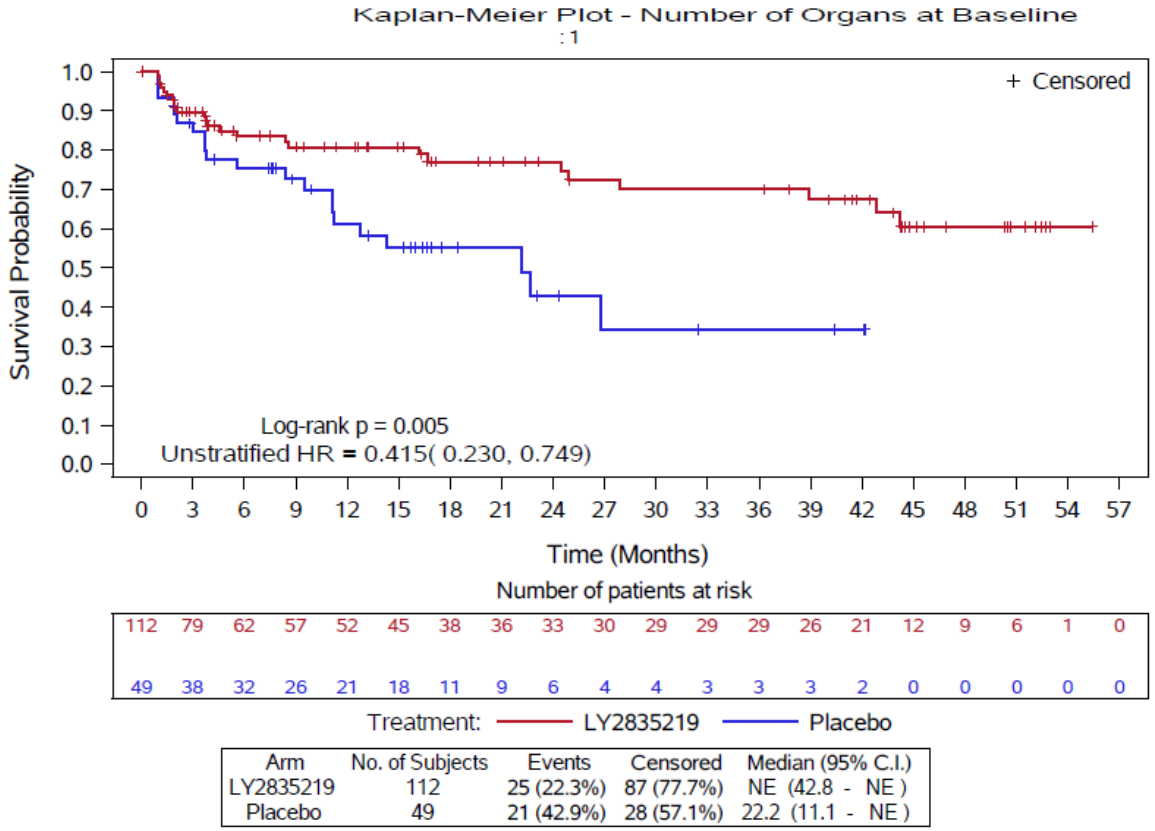
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	26	14 (53.8%)	12 (46.2%)	13.8 (6.6 - 27.3)
Placebo	10	1 (10.0%)	9 (90.0%)	42.4 (NE - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Global Health Status / QoI (Def4)
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



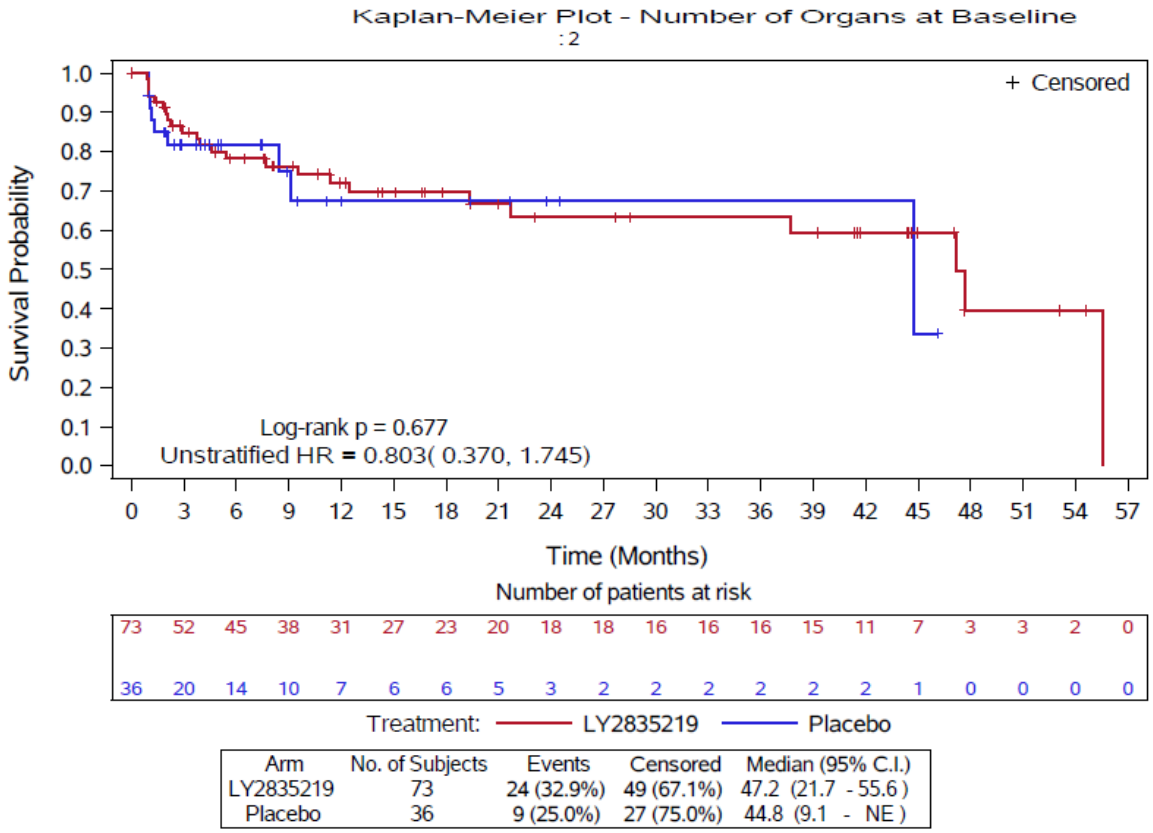
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	117	43 (36.8%)	74 (63.2%)	33.7 (22.1 - 42.0)
Placebo	56	27 (48.2%)	29 (51.8%)	12.7 (6.0 - 24.0)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Functional Scale: Role Functioning (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



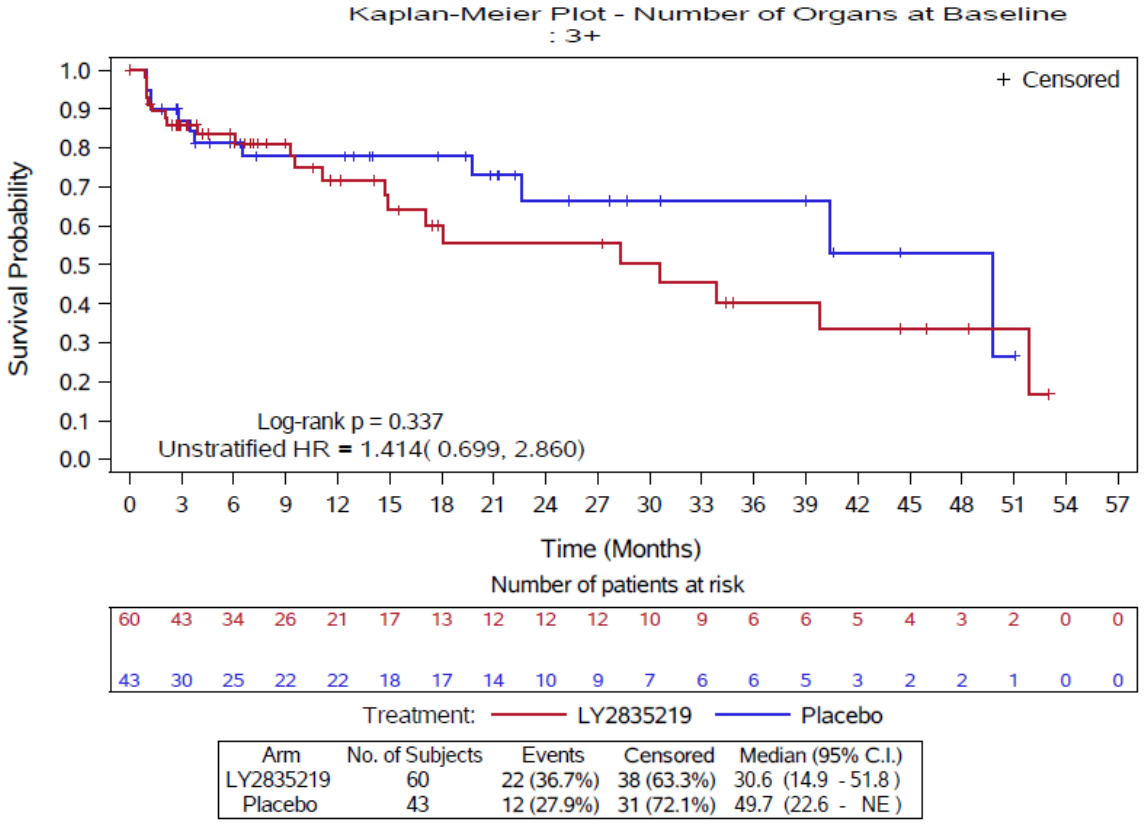
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	112	25 (22.3%)	87 (77.7%)	NE (42.8 - NE)
Placebo	49	21 (42.9%)	28 (57.1%)	22.2 (11.1 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Functional Scale: Role Functioning (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



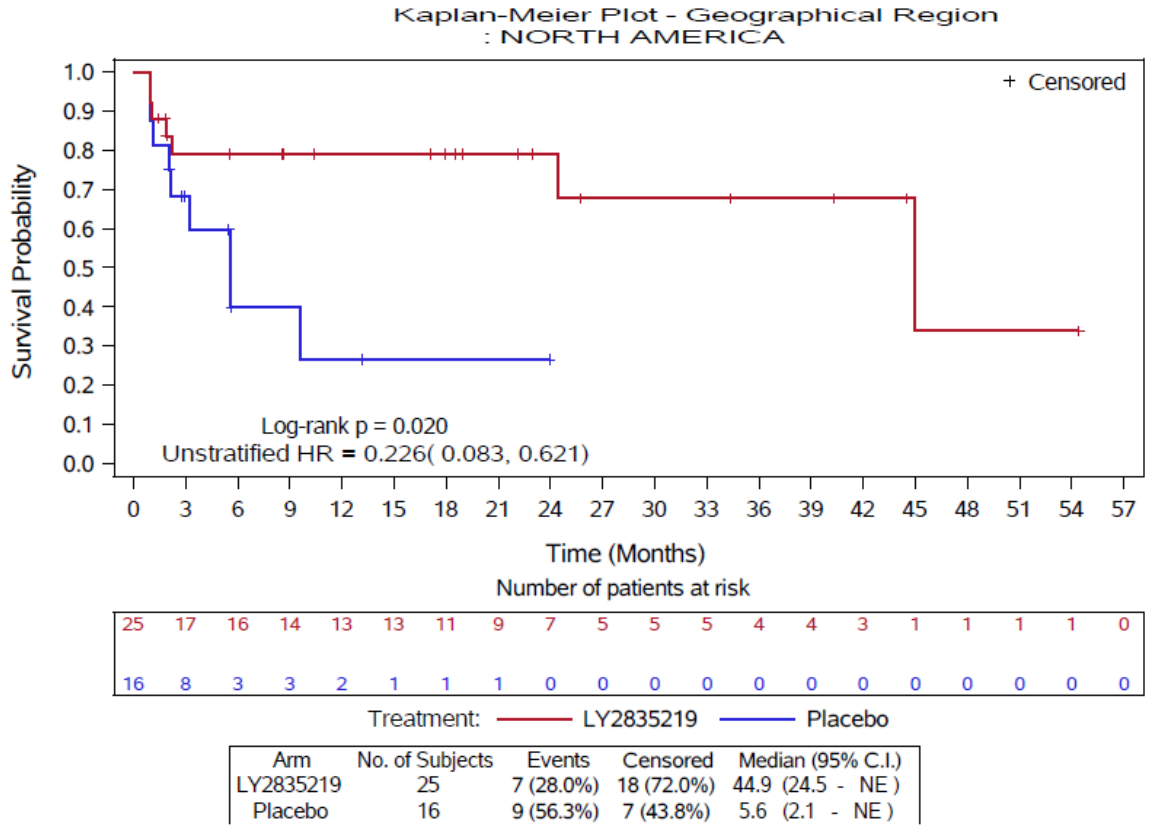
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	73	24 (32.9%)	49 (67.1%)	47.2 (21.7 - 55.6)
Placebo	36	9 (25.0%)	27 (75.0%)	44.8 (9.1 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Functional Scale: Role Functioning (Def4)
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



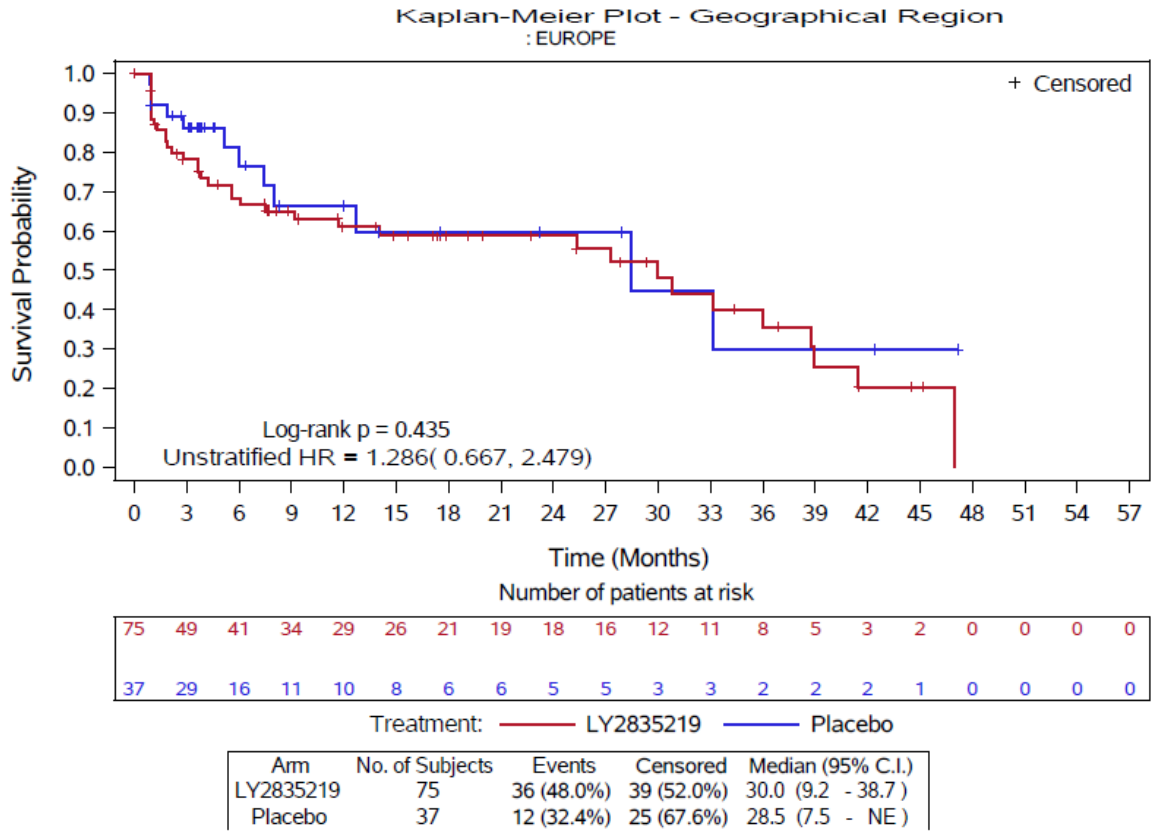
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	60	22 (36.7%)	38 (63.3%)	30.6 (14.9 - 51.8)
Placebo	43	12 (27.9%)	31 (72.1%)	49.7 (22.6 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Functional Scale: Role Functioning (Def4)
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



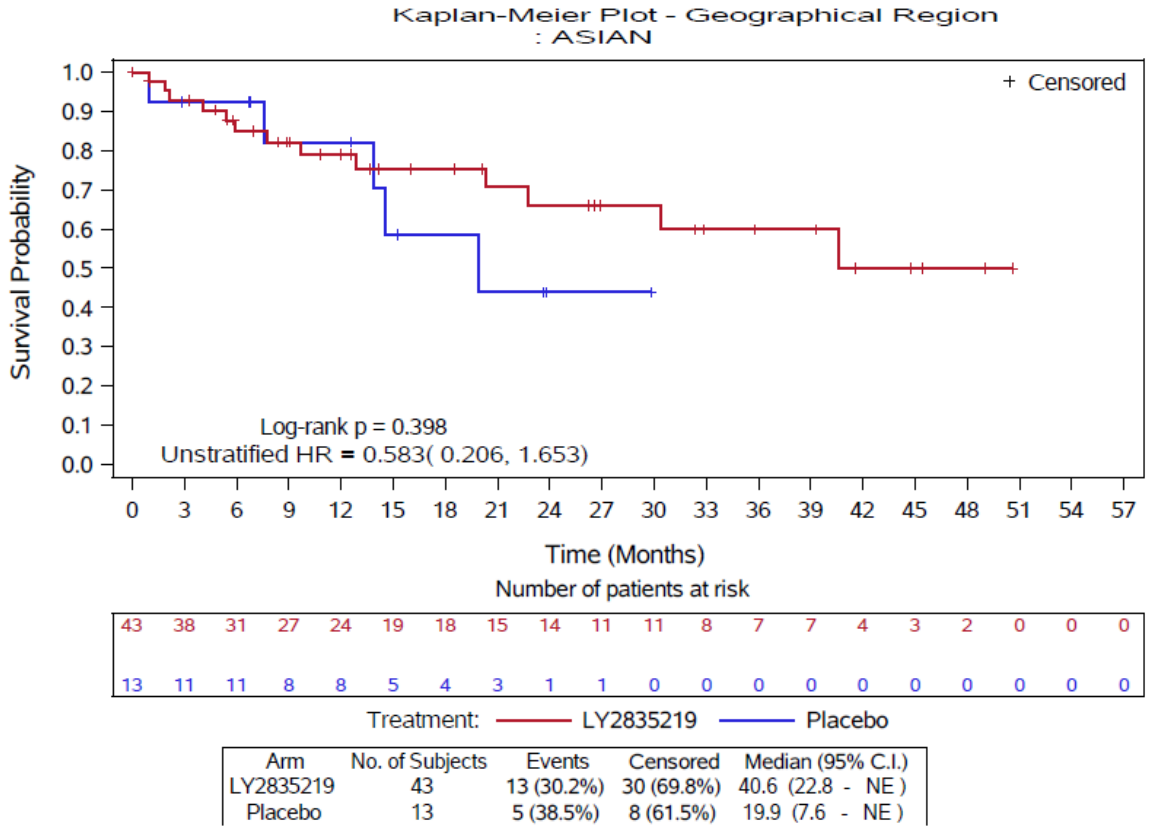
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	25	7 (28.0%)	18 (72.0%)	44.9 (24.5 - NE)
Placebo	16	9 (56.3%)	7 (43.8%)	5.6 (2.1 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Functional Scale: Role Functioning (Def4)
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



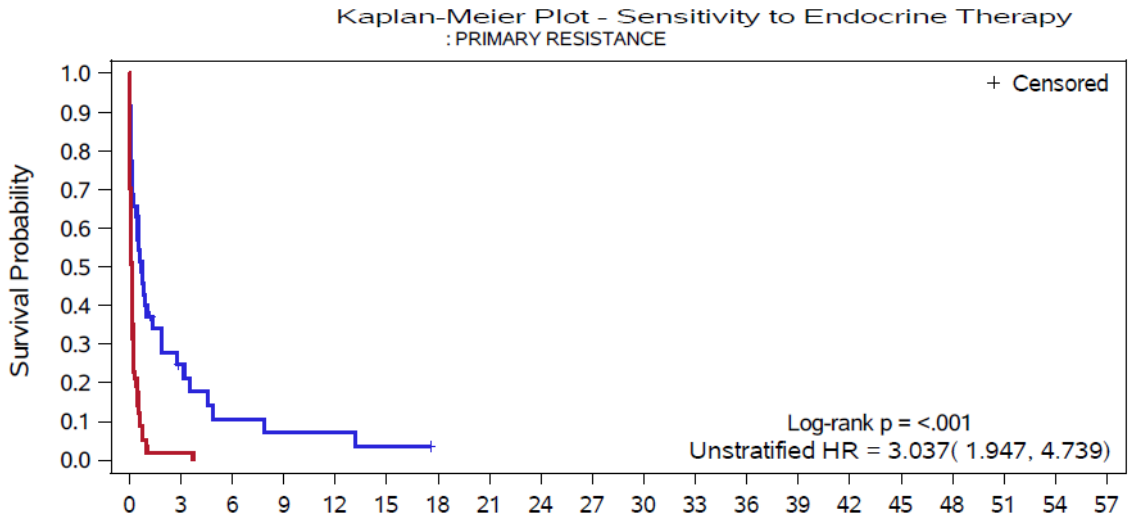
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	75	36 (48.0%)	39 (52.0%)	30.0 (9.2 - 38.7)
Placebo	37	12 (32.4%)	25 (67.6%)	28.5 (7.5 - NE)

Kaplan-Meier Plot of Time to Sustained Worsening by Subgroup: Functional Scale: Role Functioning (Def4)
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



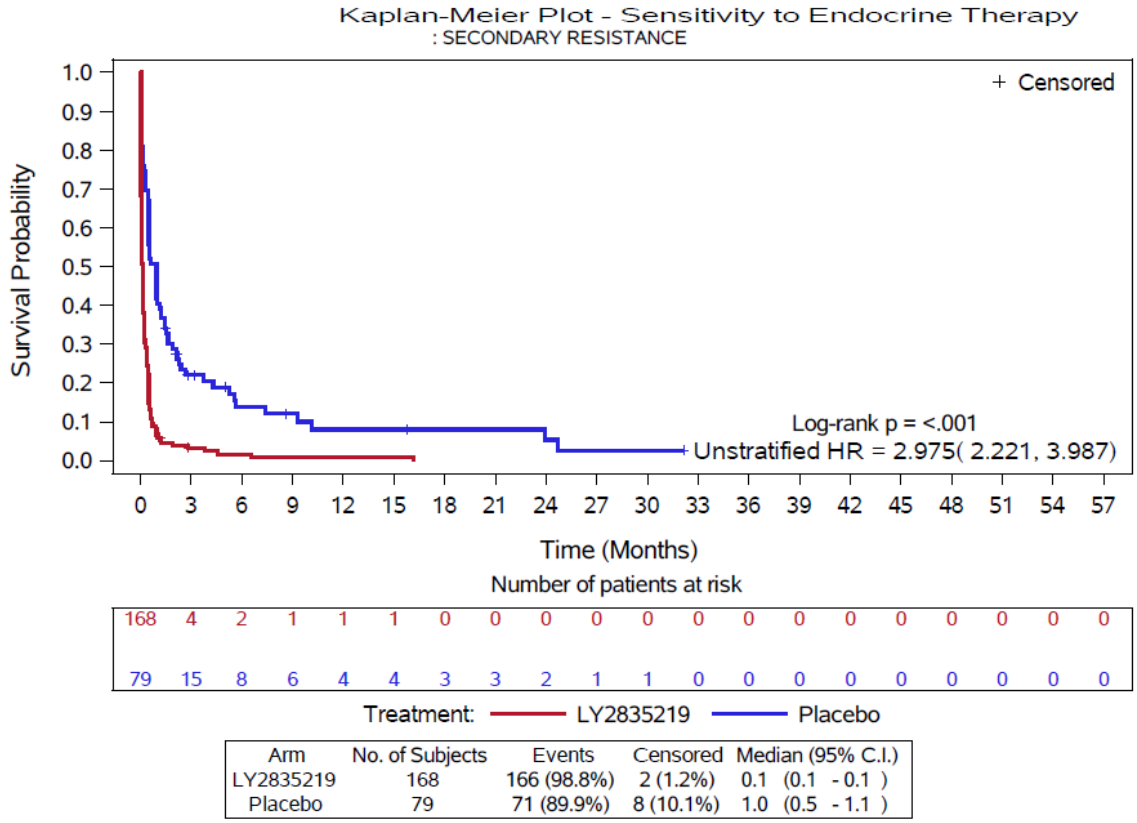
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	43	13 (30.2%)	30 (69.8%)	40.6 (22.8 - NE)
Placebo	13	5 (38.5%)	8 (61.5%)	19.9 (7.6 - NE)

Kaplan-Meier Plot of Time to any Treatment Emergent Adverse Event
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



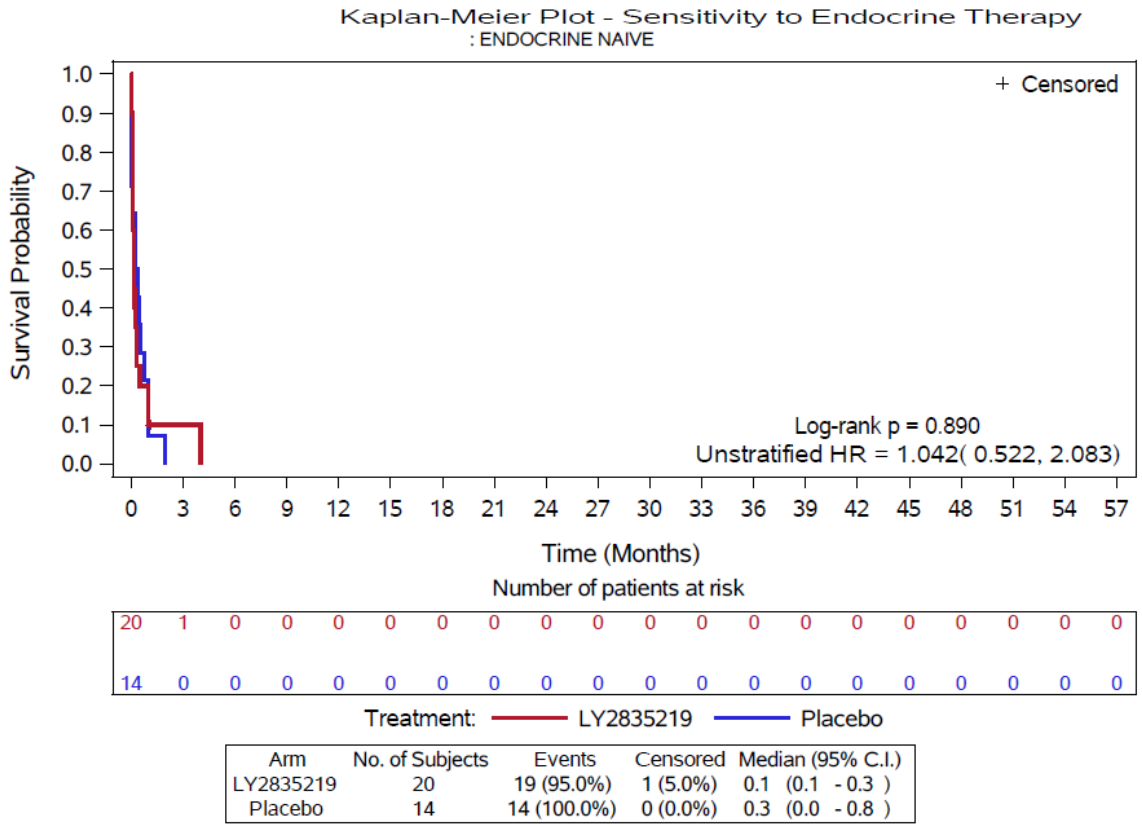
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	57	57 (100.0%)	0 (0.0%)	0.1 (0.1 - 0.2)
Placebo	35	32 (91.4%)	3 (8.6%)	0.7 (0.2 - 1.4)

Kaplan-Meier Plot of Time to any Treatment Emergent Adverse Event
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



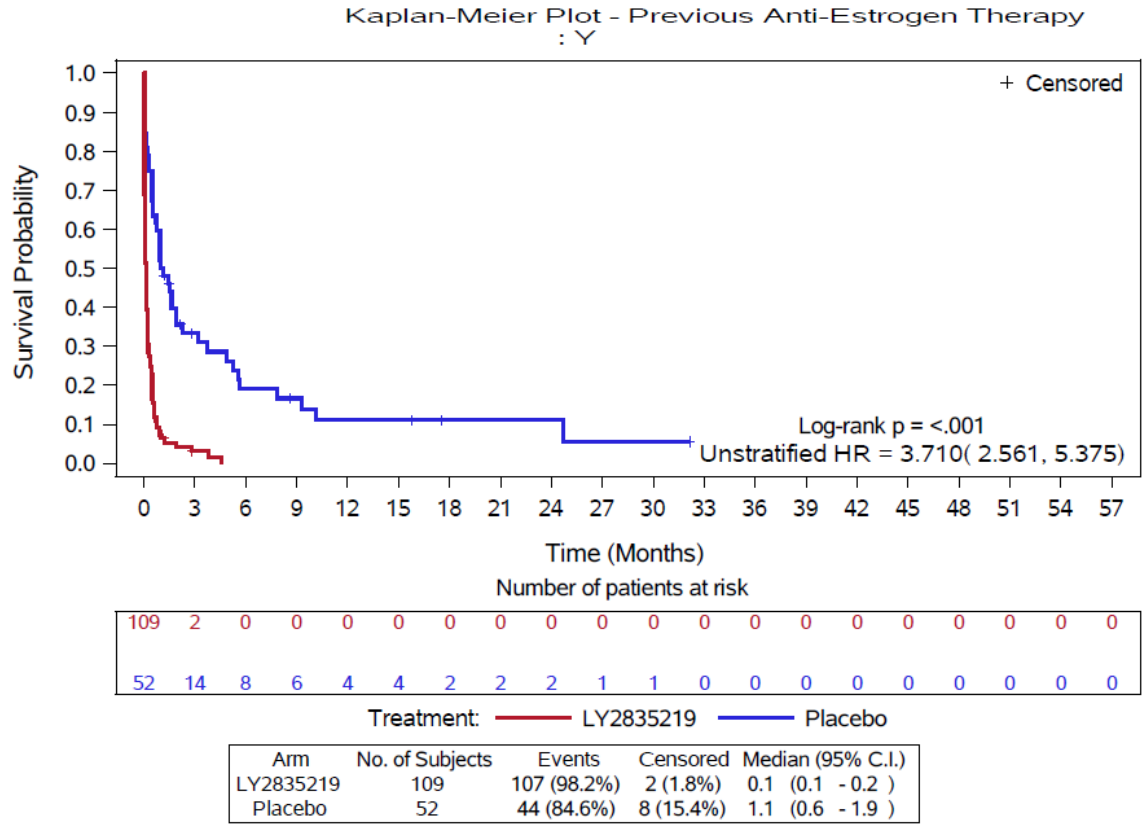
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	168	166 (98.8%)	2 (1.2%)	0.1 (0.1 - 0.1)
Placebo	79	71 (89.9%)	8 (10.1%)	1.0 (0.5 - 1.1)

Kaplan-Meier Plot of Time to any Treatment Emergent Adverse Event
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



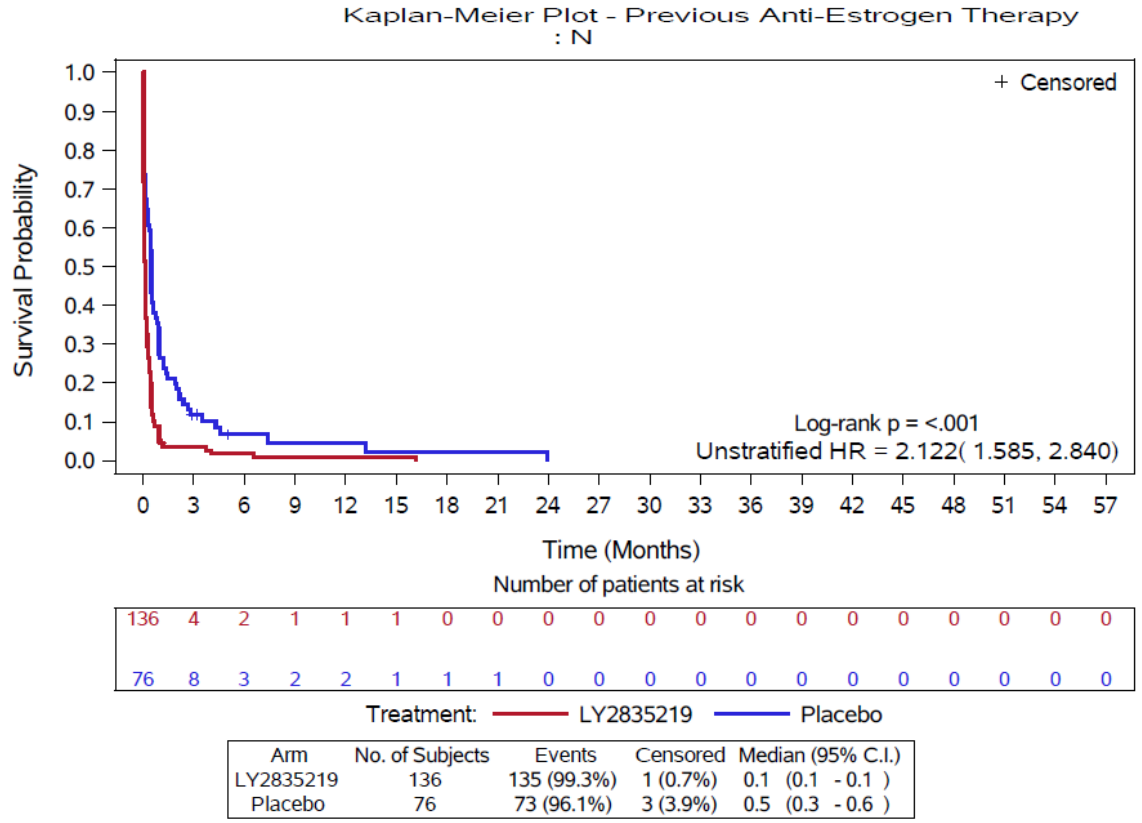
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	20	19 (95.0%)	1 (5.0%)	0.1 (0.1 - 0.3)
Placebo	14	14 (100.0%)	0 (0.0%)	0.3 (0.0 - 0.8)

Kaplan-Meier Plot of Time to any Treatment Emergent Adverse Event
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



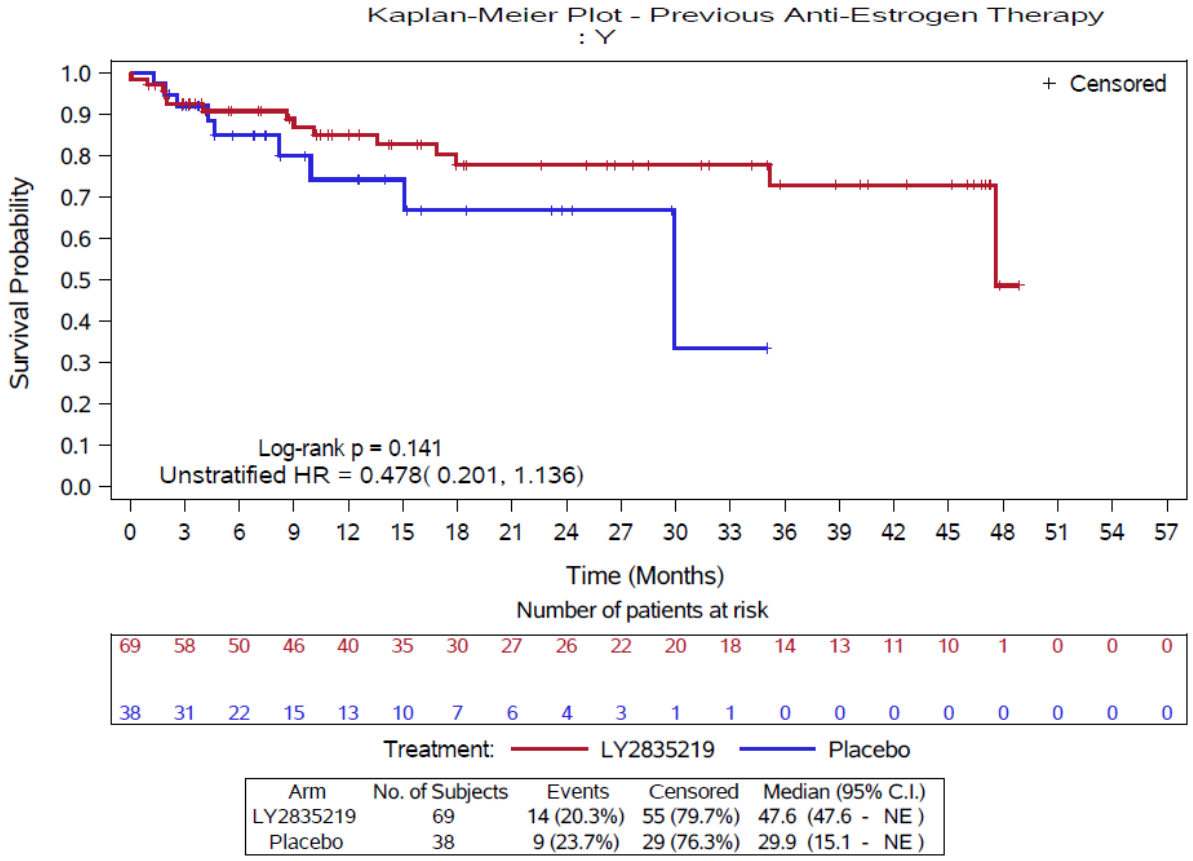
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	109	107 (98.2%)	2 (1.8%)	0.1 (0.1 - 0.2)
Placebo	52	44 (84.6%)	8 (15.4%)	1.1 (0.6 - 1.9)

Kaplan-Meier Plot of Time to any Treatment Emergent Adverse Event
Postmenopausal, not treated with endocrine ther. in the metast. setting + endocrine naive (1st line)
Safety Population
A1 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



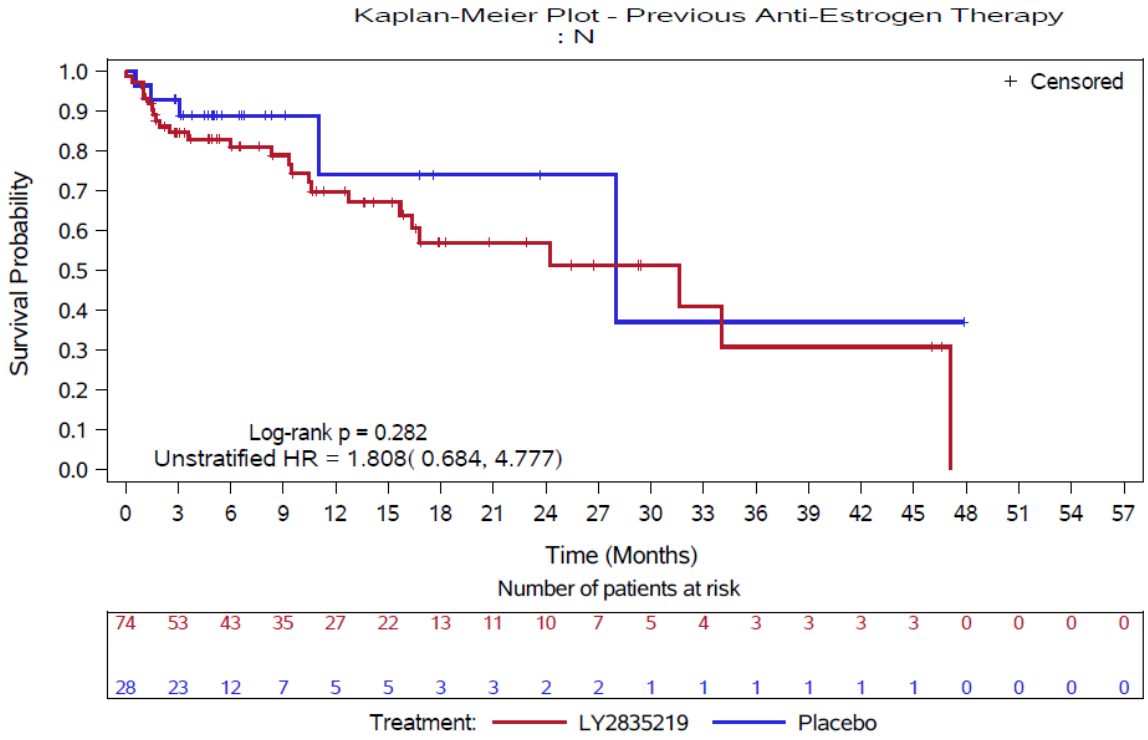
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	136	135 (99.3%)	1 (0.7%)	0.1 (0.1 - 0.1)
Placebo	76	73 (96.1%)	3 (3.9%)	0.5 (0.3 - 0.6)

Kaplan-Meier Plot of Time to any Serious Adverse Event
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



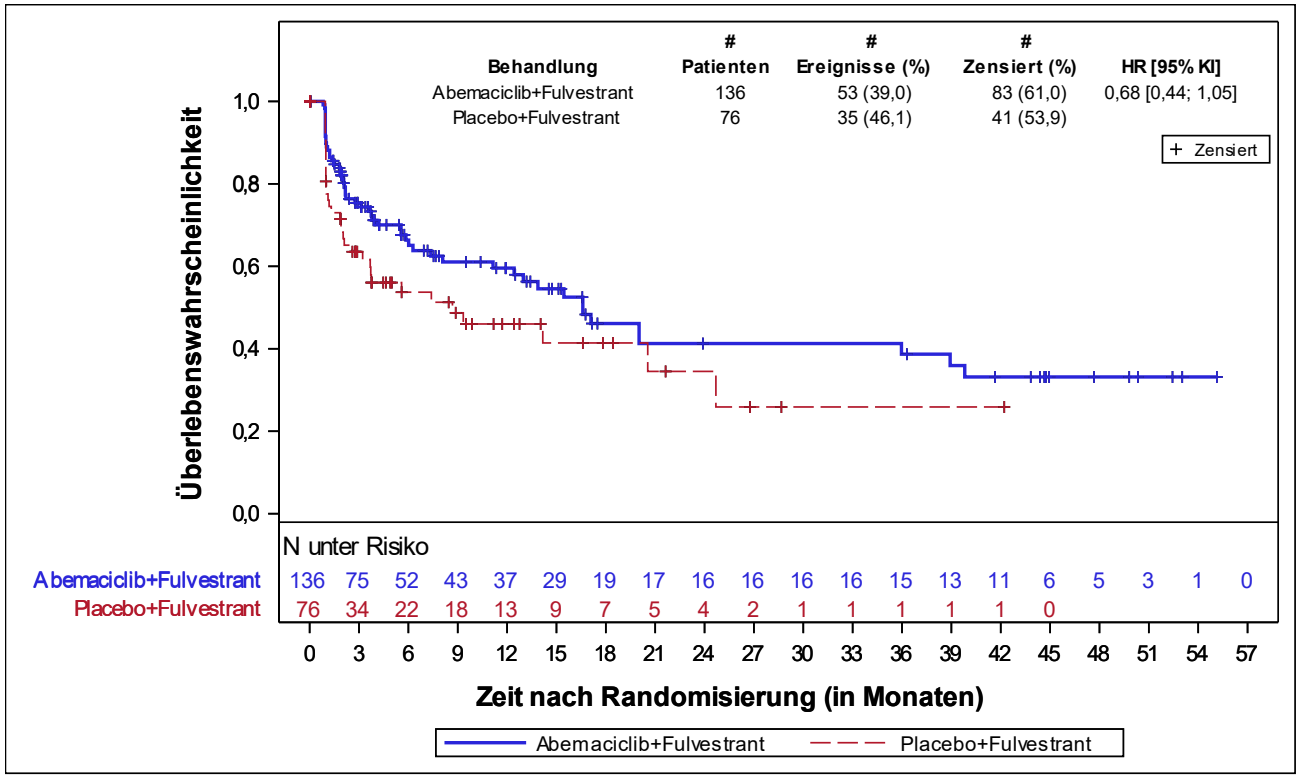
Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	69	14 (20.3%)	55 (79.7%)	47.6 (47.6 - NE)
Placebo	38	9 (23.7%)	29 (76.3%)	29.9 (15.1 - NE)

Kaplan-Meier Plot of Time to any Serious Adverse Event
Postmenopausal patients treated with endocrine therapy in the metastatic setting (2nd line)
Safety Population
A2 population
I3Y-MC-JPBL
Data cutoff: 20 JUN2019



Arm	No. of Subjects	Events	Censored	Median (95% C.I.)
LY2835219	74	26 (35.1%)	48 (64.9%)	31.6 (15.7 - 47.1)
Placebo	28	5 (17.9%)	23 (82.1%)	28.0 (11.0 - NE)

Abbildung 316: Kaplan-Meier-Kurven - Stärkster Schmerz in den letzten 24 Stunden - Anstieg des Scores um ≥2 Punkte gegenüber der Baseline, Subgruppenanalyse für Vorangegangene antiöstrogene Therapie = Nein
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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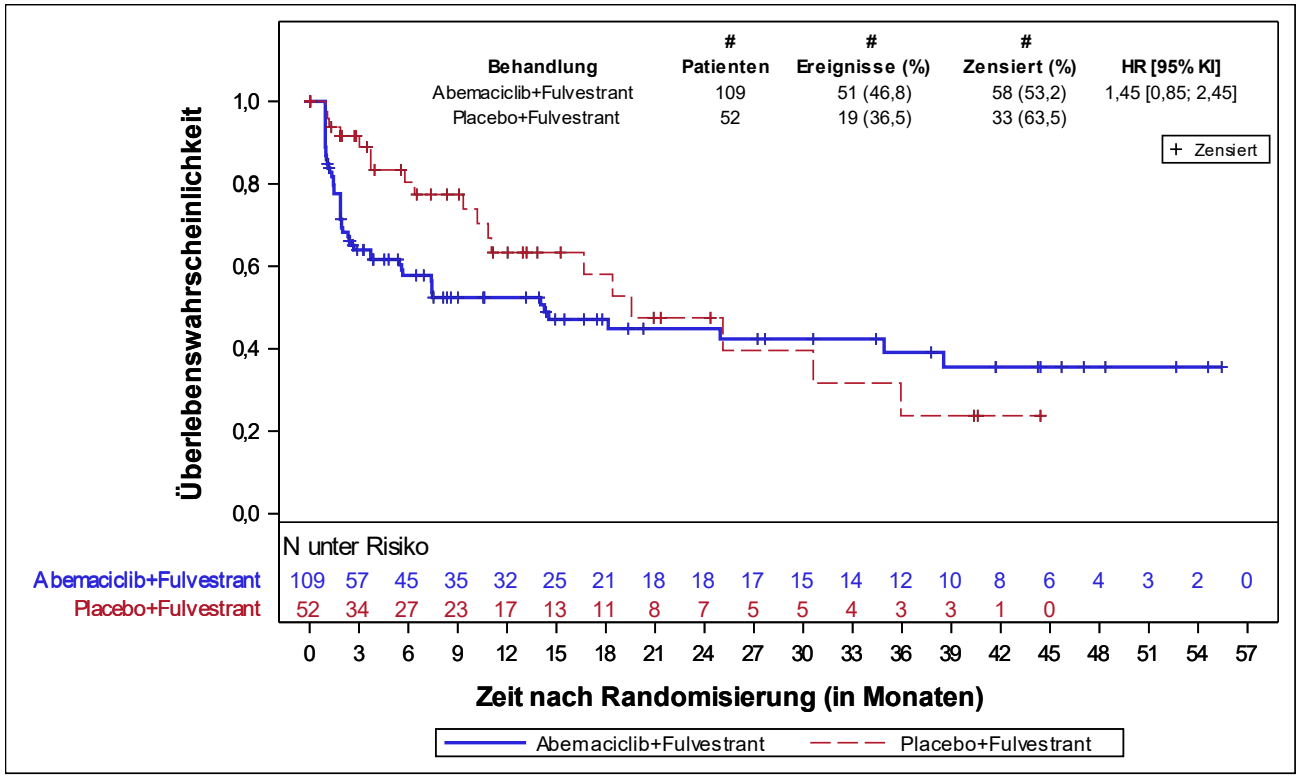
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f316_km_sub_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
20JUL2021 / 05:03

Abbildung 317: Kaplan-Meier-Kurven - Stärkster Schmerz in den letzten 24 Stunden - Anstieg des Scores um ≥2 Punkte gegenüber der Baseline, Subgruppenanalyse für Vorangegangene antiöstrogene Therapie = Ja
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f317_km_sub_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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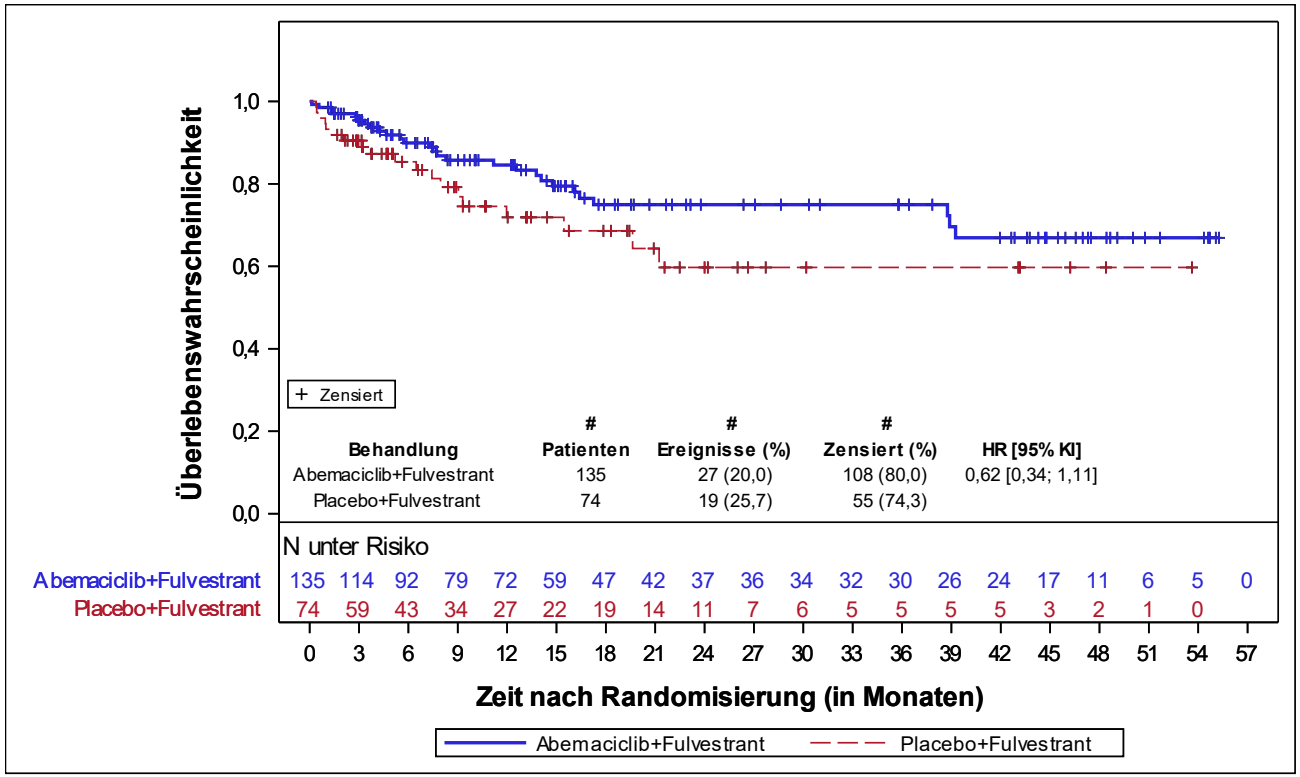
Abbildung 318: Kaplan-Meier-Kurven - Stärkster Schmerz in den letzten 24 Stunden - Anstieg des Schmerzmittelgebrauchs um mindestens eine Größenordnung, Subgruppenanalyse für ECOG-PS zu Baseline = 0
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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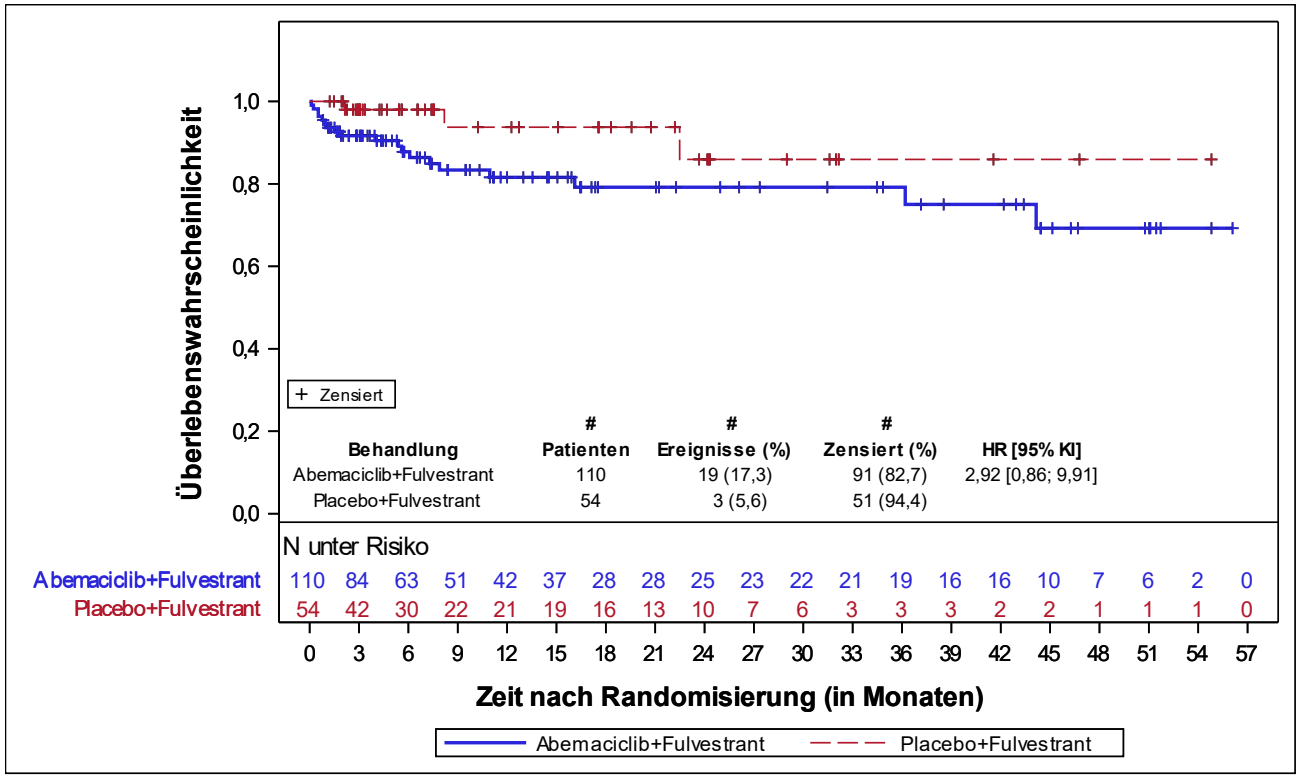
Abbildung 319: Kaplan-Meier-Kurven - Stärkster Schmerz in den letzten 24 Stunden - Anstieg des Schmerzmittelgebrauchs um mindestens eine Größenordnung, Subgruppenanalyse für ECOG-PS zu Baseline = 1
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f319_km_sub_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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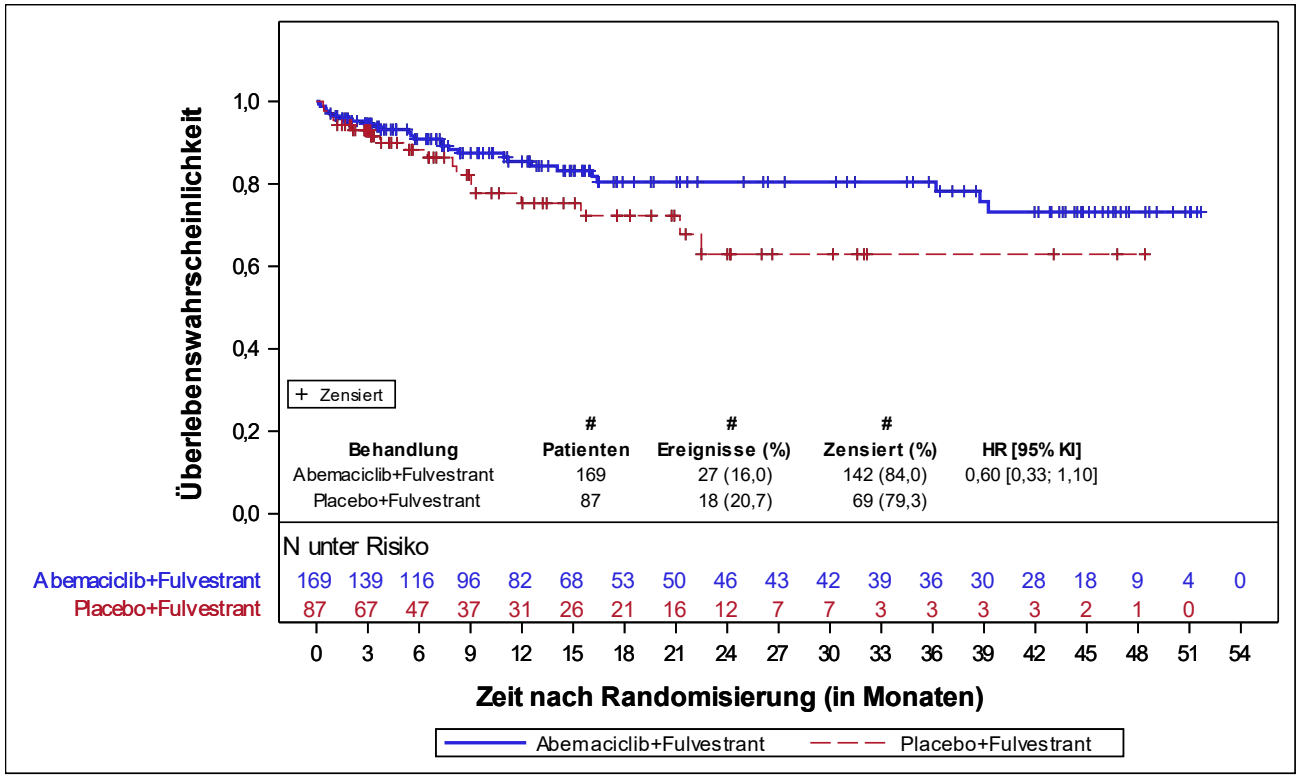
Abbildung 320: Kaplan-Meier-Kurven - Stärkster Schmerz in den letzten 24 Stunden - Anstieg des Schmerzmittelgebrauchs um mindestens eine Größenordnung, Subgruppenanalyse für Startdosis = 150 mg
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f320_km_sub_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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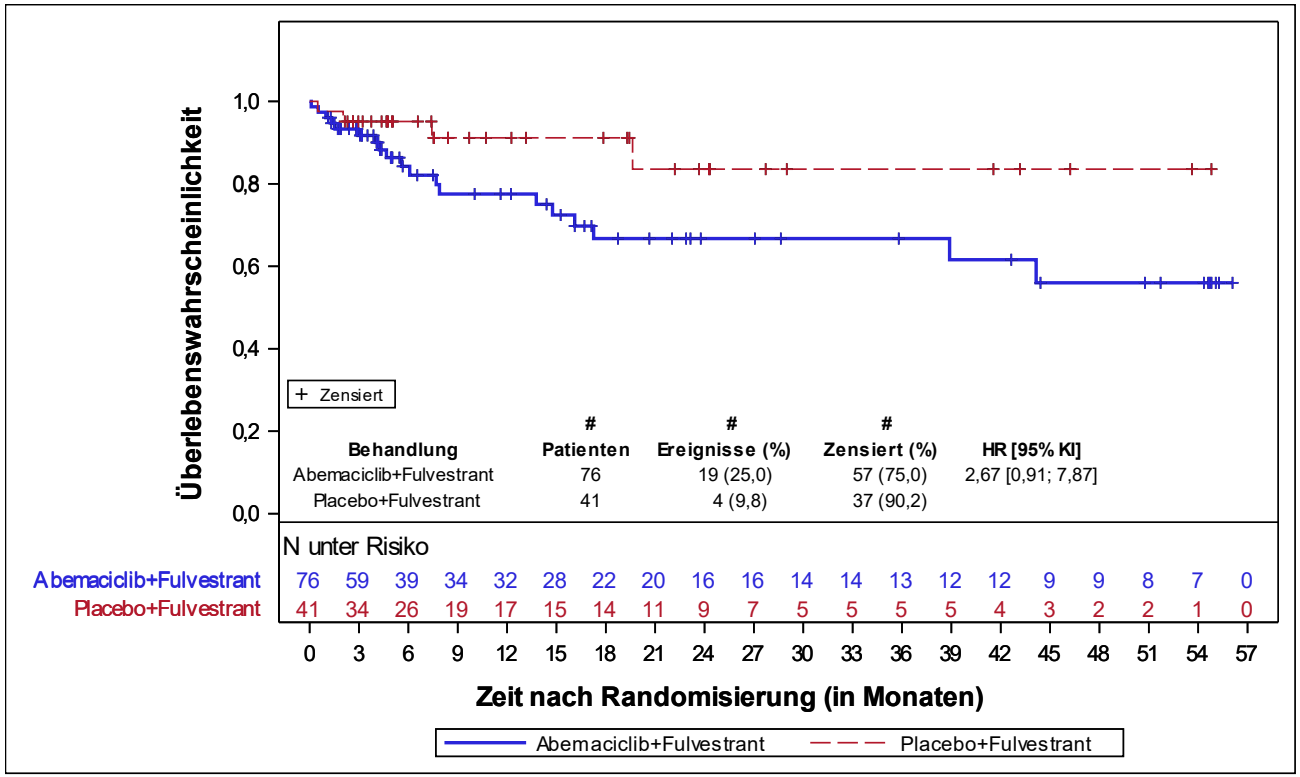
Abbildung 321: Kaplan-Meier-Kurven - Stärkster Schmerz in den letzten 24 Stunden - Anstieg des Schmerzmittelgebrauchs um mindestens eine Größenordnung, Subgruppenanalyse für Startdosis = 200 mg
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_mbpi_km_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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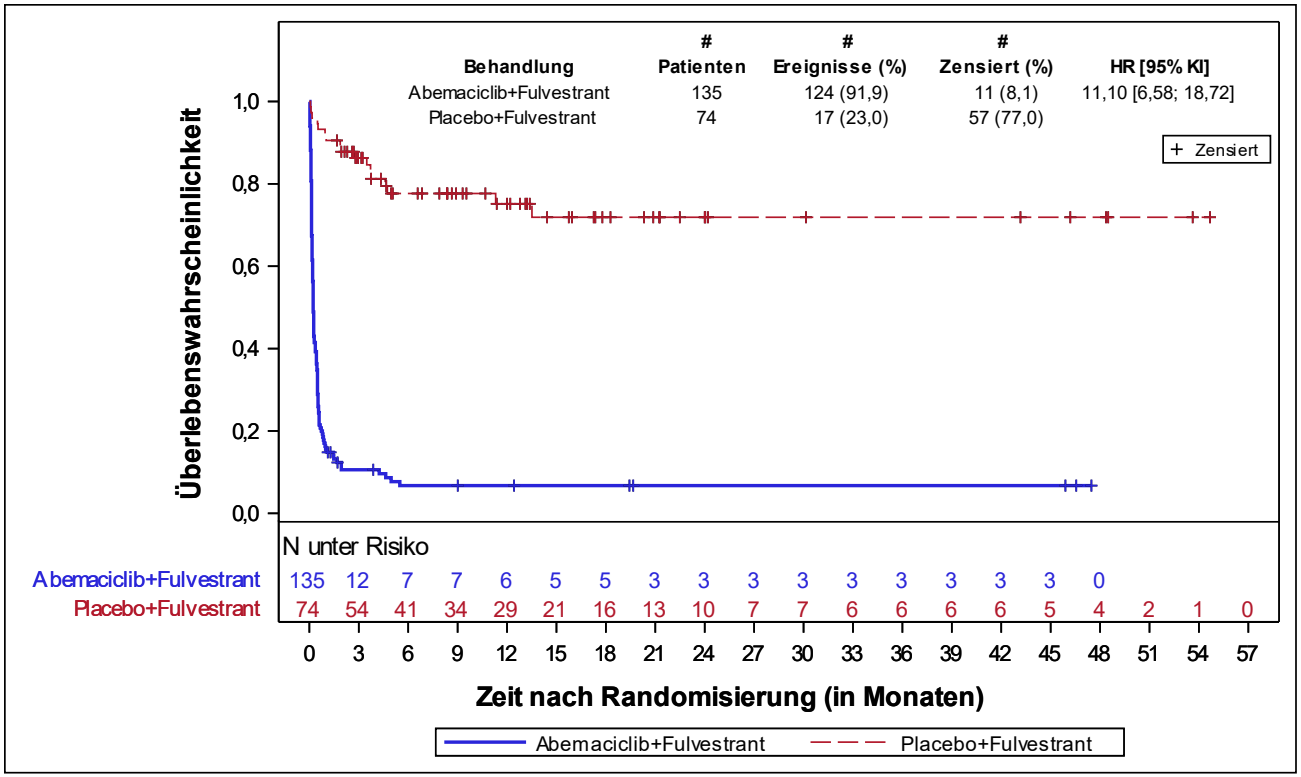
Abbildung 294: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad)
Subgruppenanalyse für ECOG-PS zu Baseline = 0
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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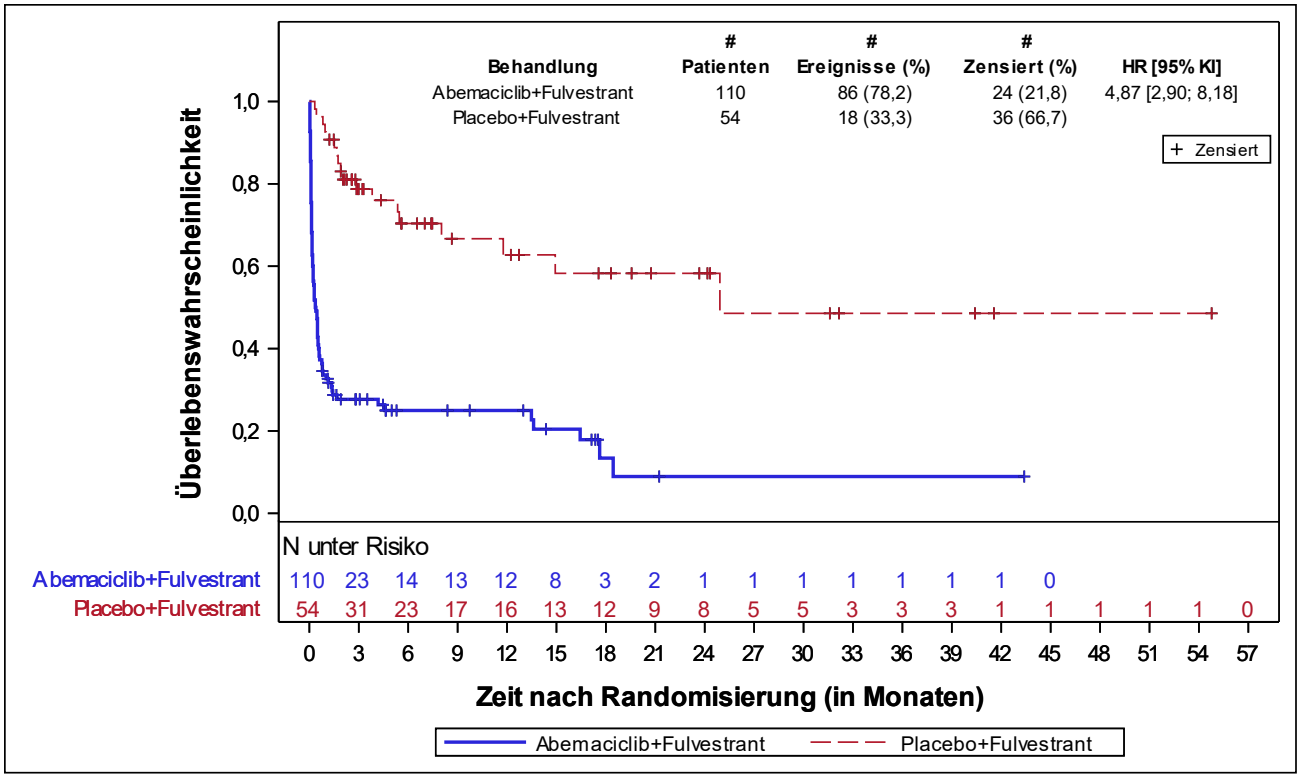
Abbildung 295: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad)
Subgruppenanalyse für ECOG-PS zu Baseline = 1
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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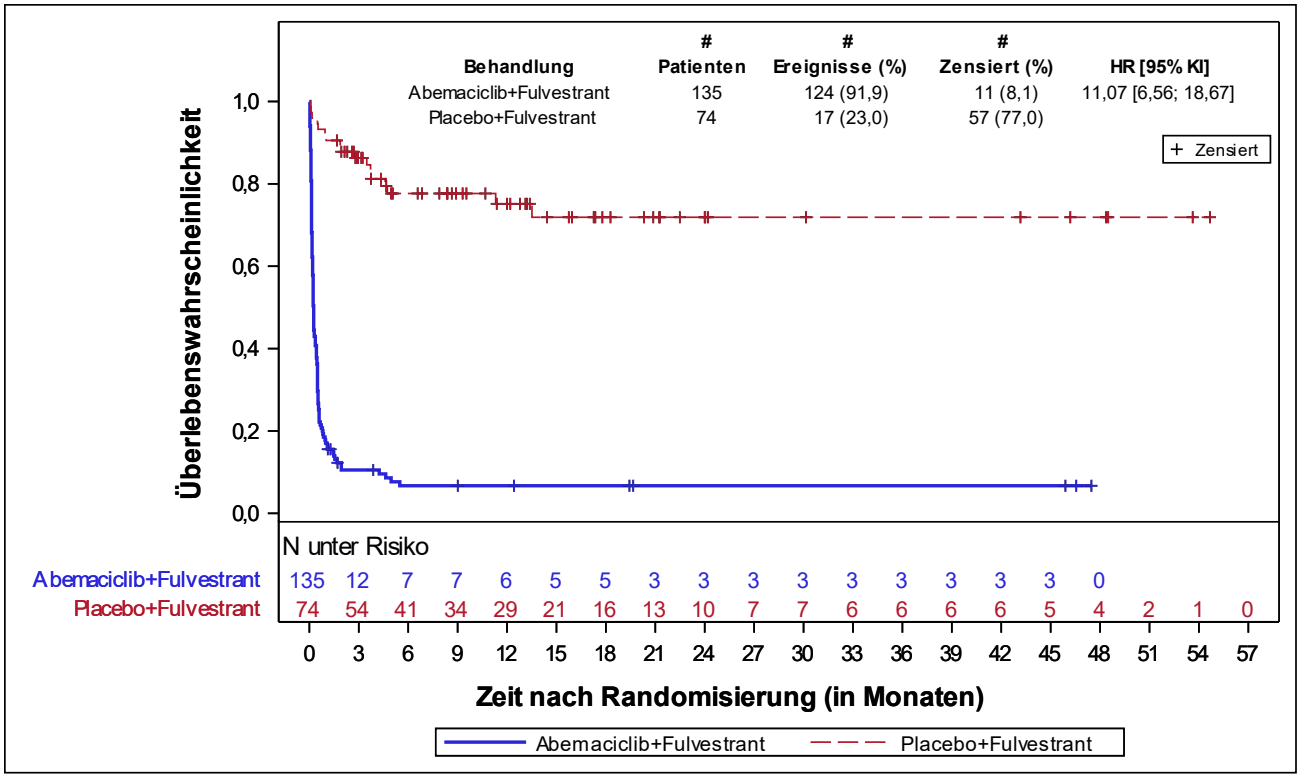
Abbildung 296: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe
Subgruppenanalyse für ECOG-PS zu Baseline = 0
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f296_km_sub_popa1.rtf
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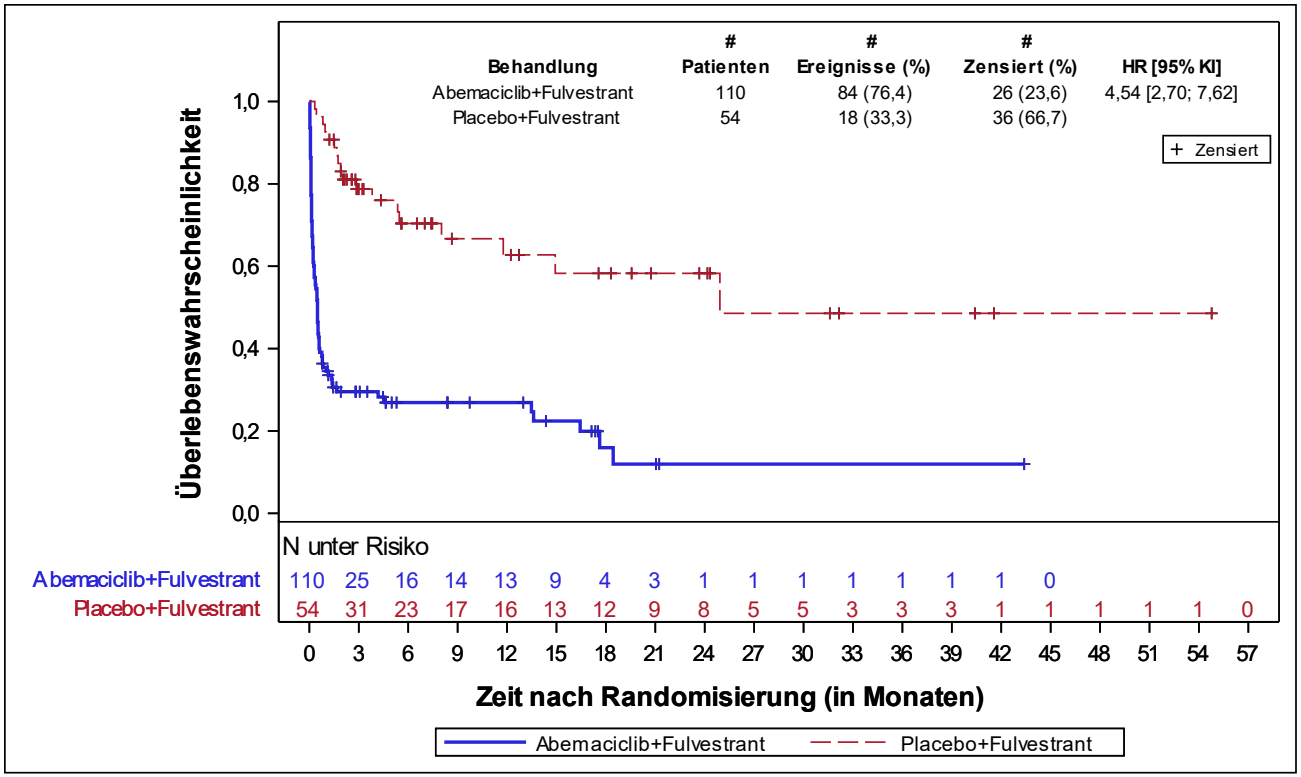
Abbildung 297: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe
Subgruppenanalyse für ECOG-PS zu Baseline = 1
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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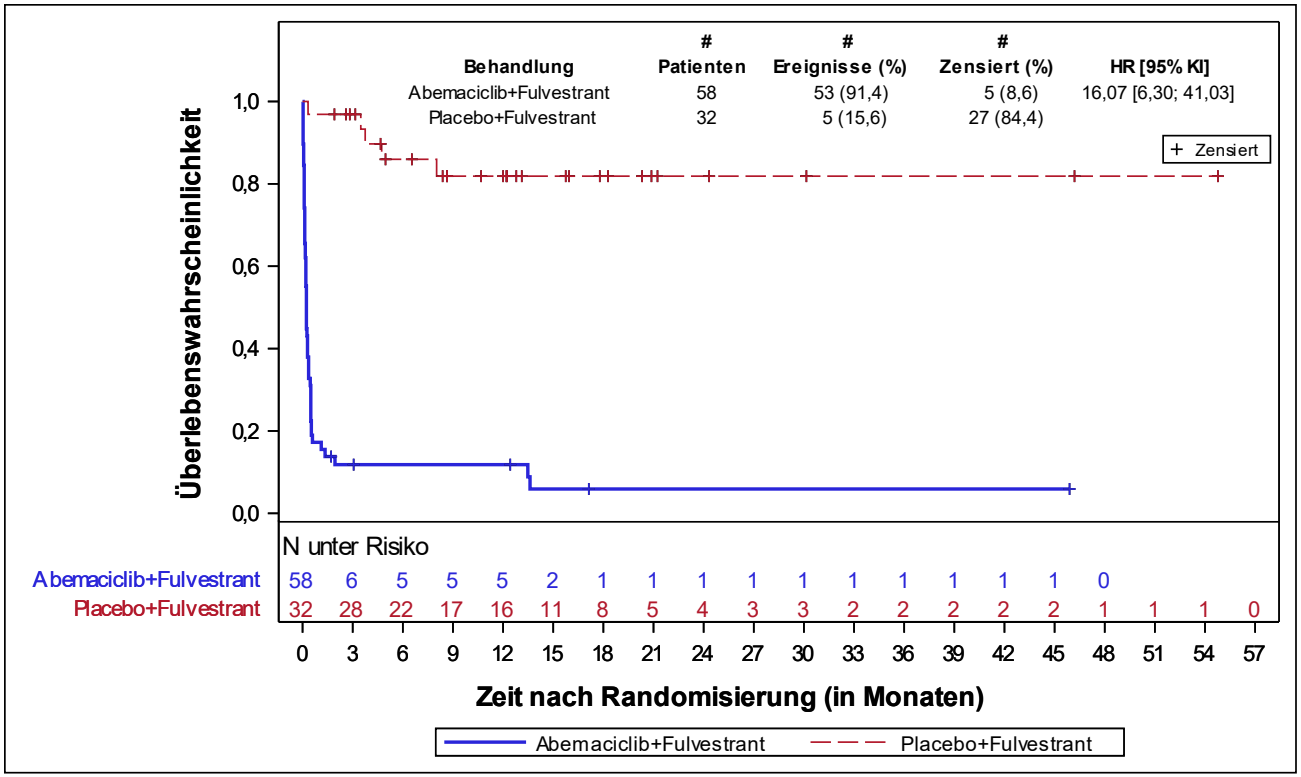
Abbildung 298: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe
Subgruppenanalyse für Ethnische Zugehörigkeit = Asiatisch
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f298_km_sub_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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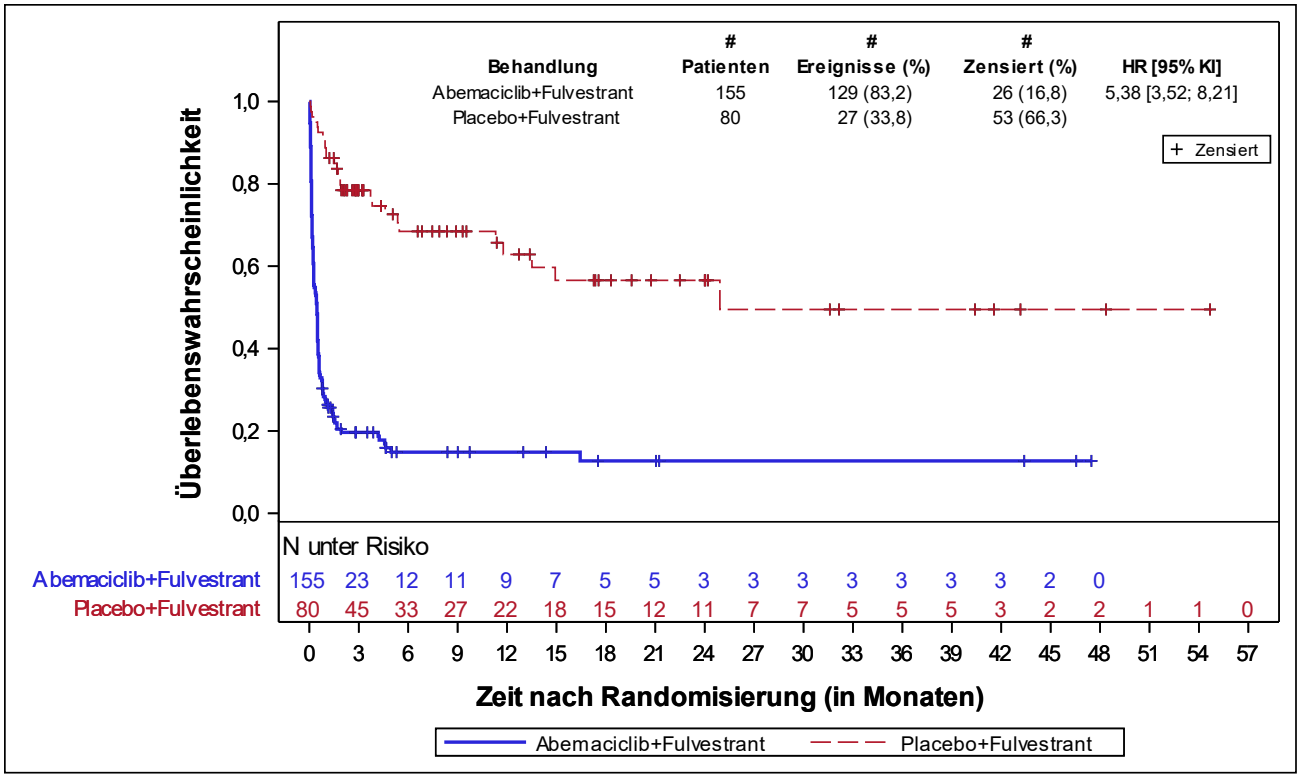
Abbildung 299: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe
Subgruppenanalyse für Ethnische Zugehörigkeit = Weiß/kaukasisch
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f299_km_sub_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_mc_jpbl/csr2/data/analysis/shared/adam
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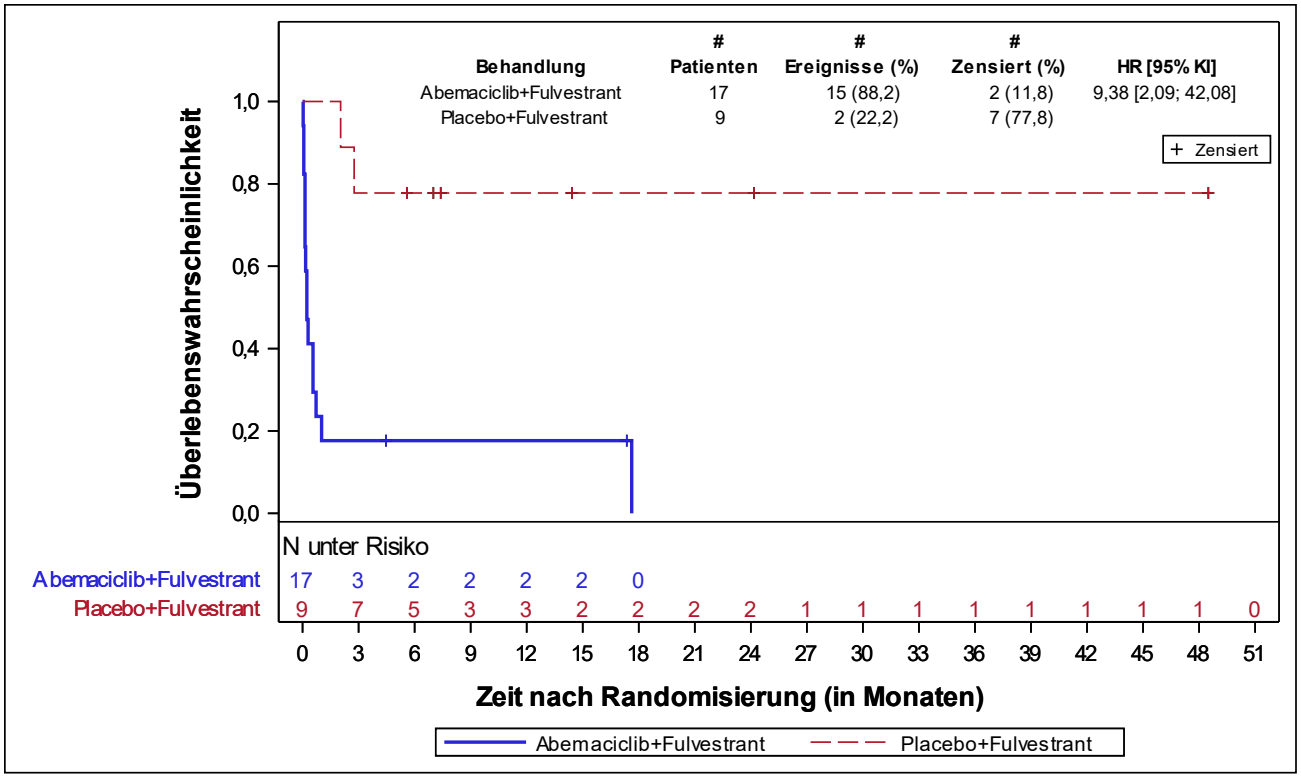
Abbildung 300: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe
Subgruppenanalyse für Ethnische Zugehörigkeit = Andere
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km_sub.sas
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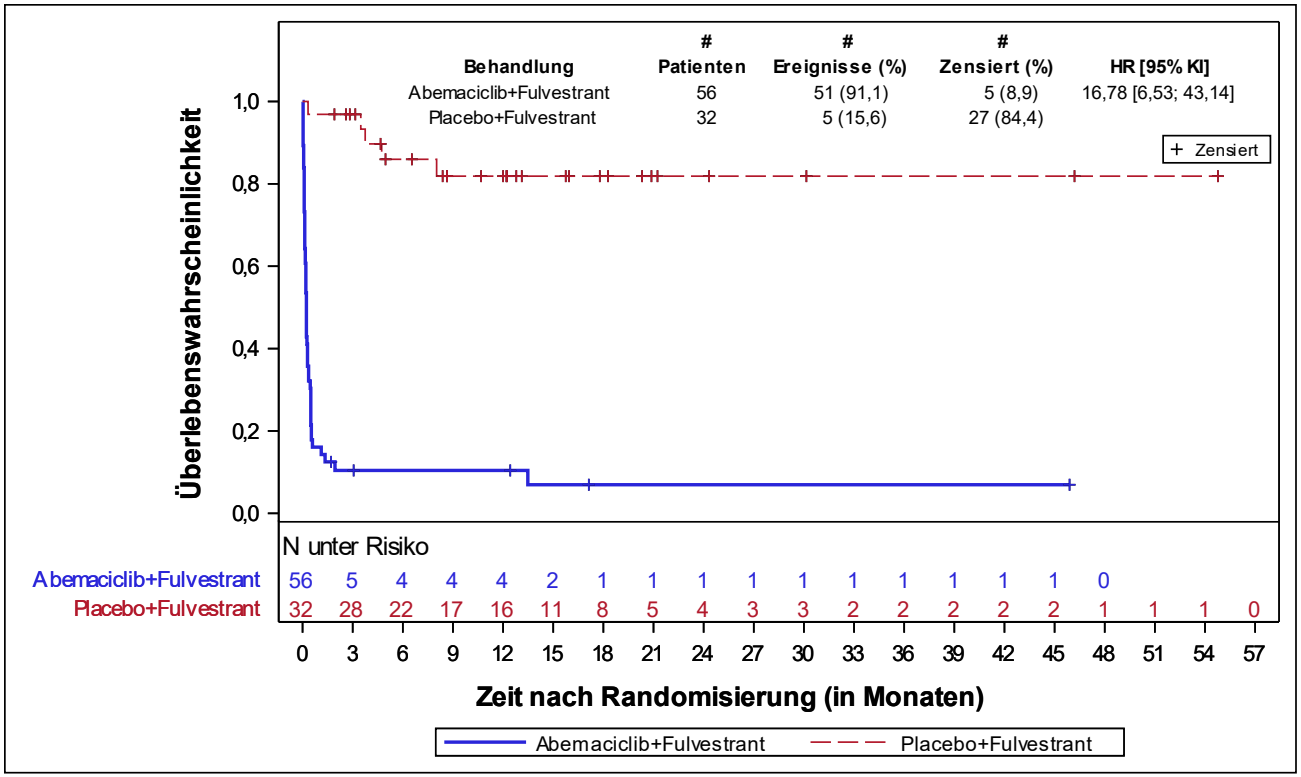
Abbildung 301: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe
Subgruppenanalyse für Geografische Region = Asien
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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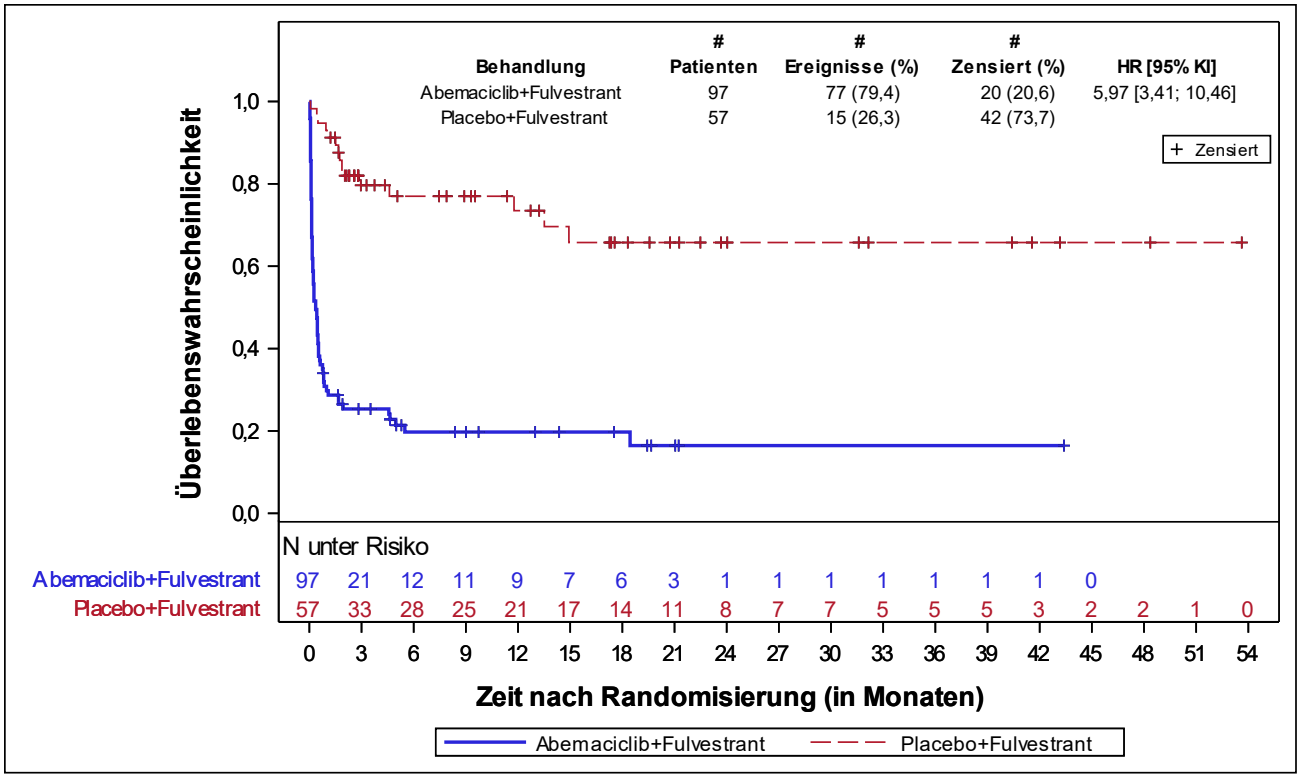
Abbildung 302: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe
Subgruppenanalyse für Geografische Region = Europa
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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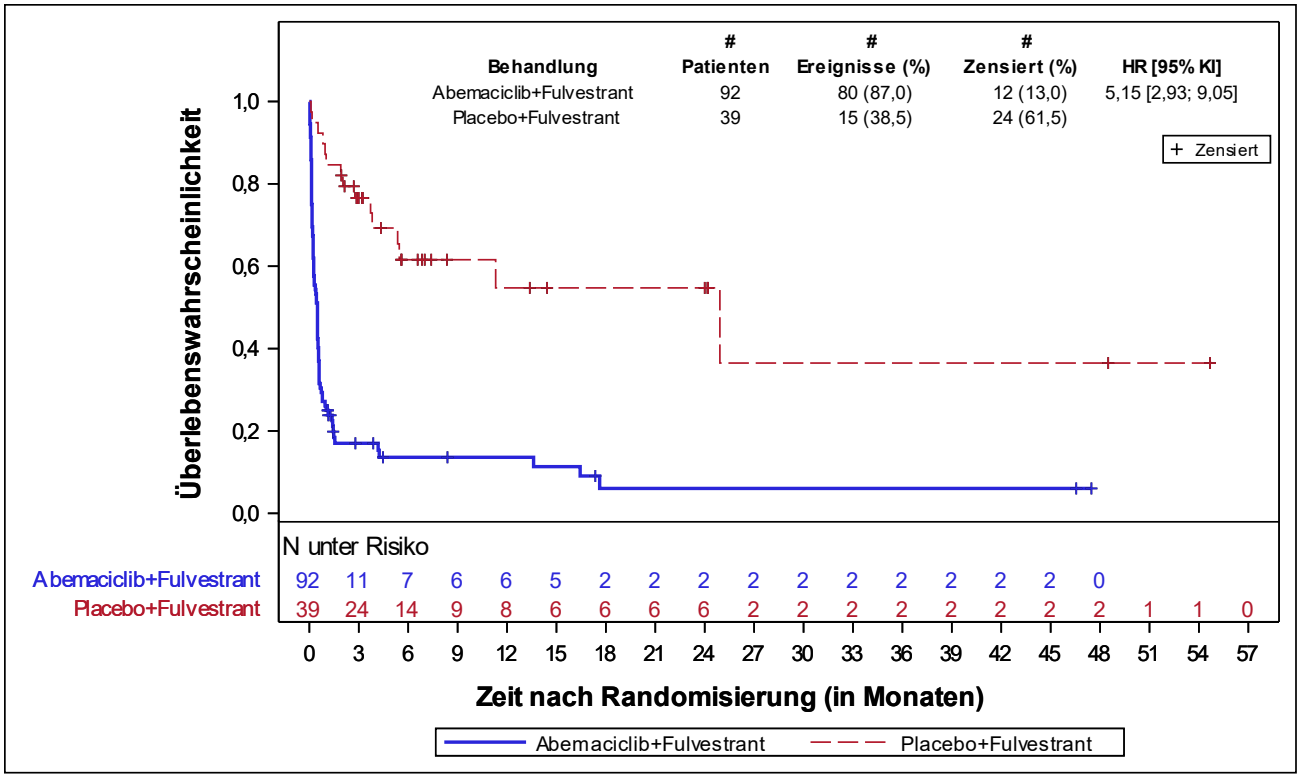
Abbildung 303: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe
Subgruppenanalyse für Geografische Region = Nordamerika
Safety Population - Postmenopausal A1 (Erstlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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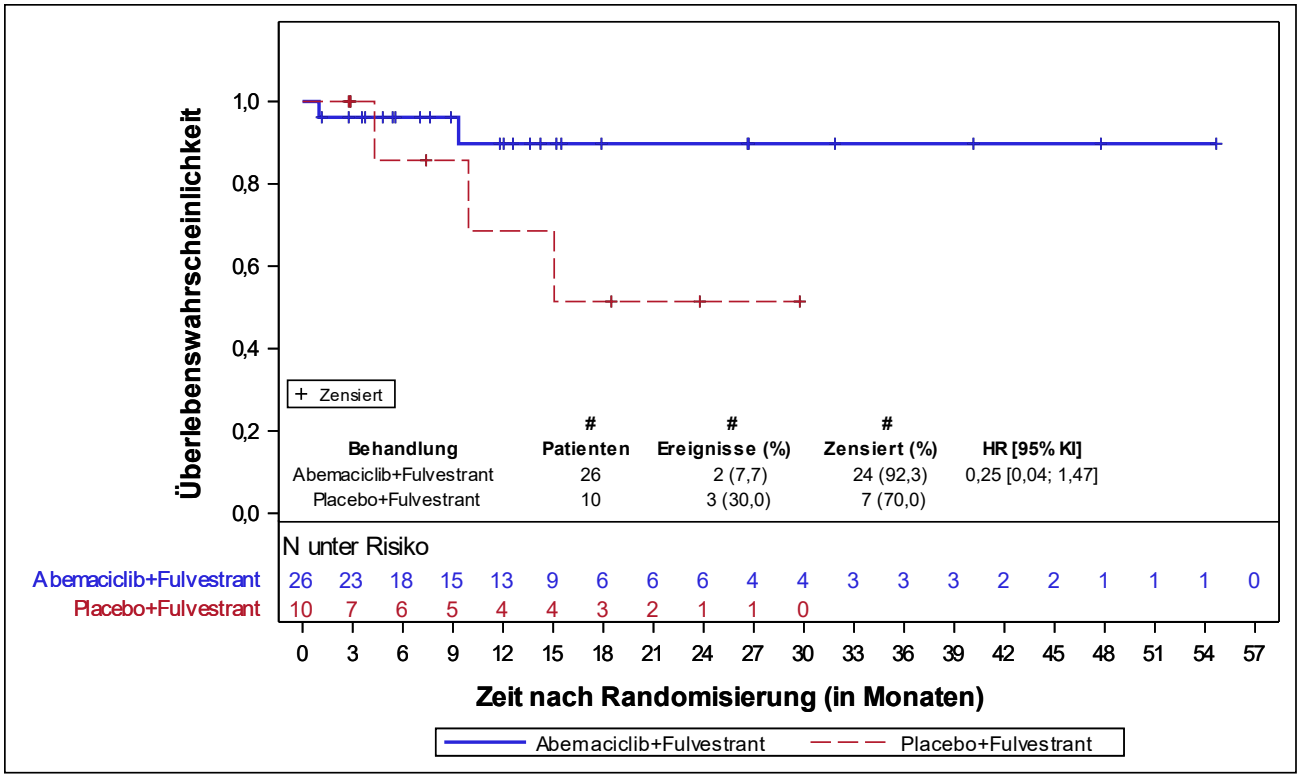
Abbildung 304: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie = Primäre Resistenz
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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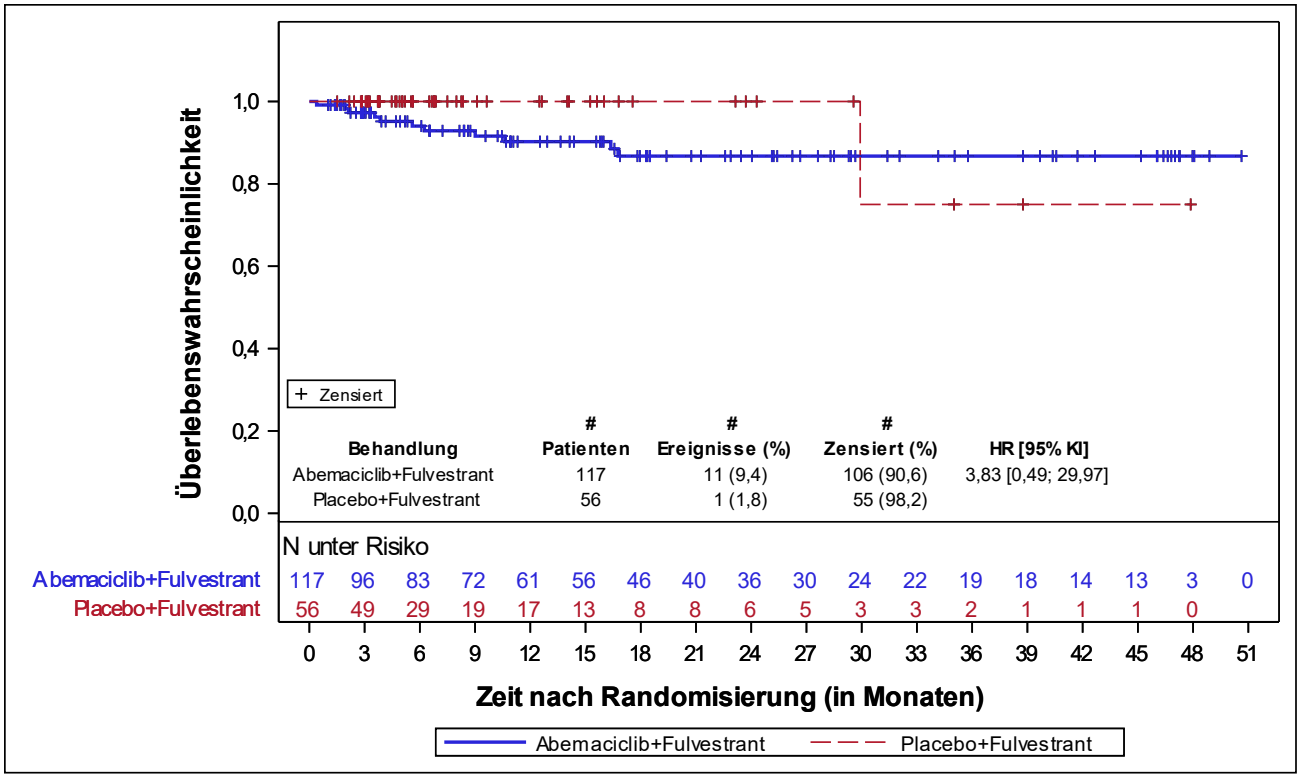
Abbildung 305: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie = Sekundäre Resistenz
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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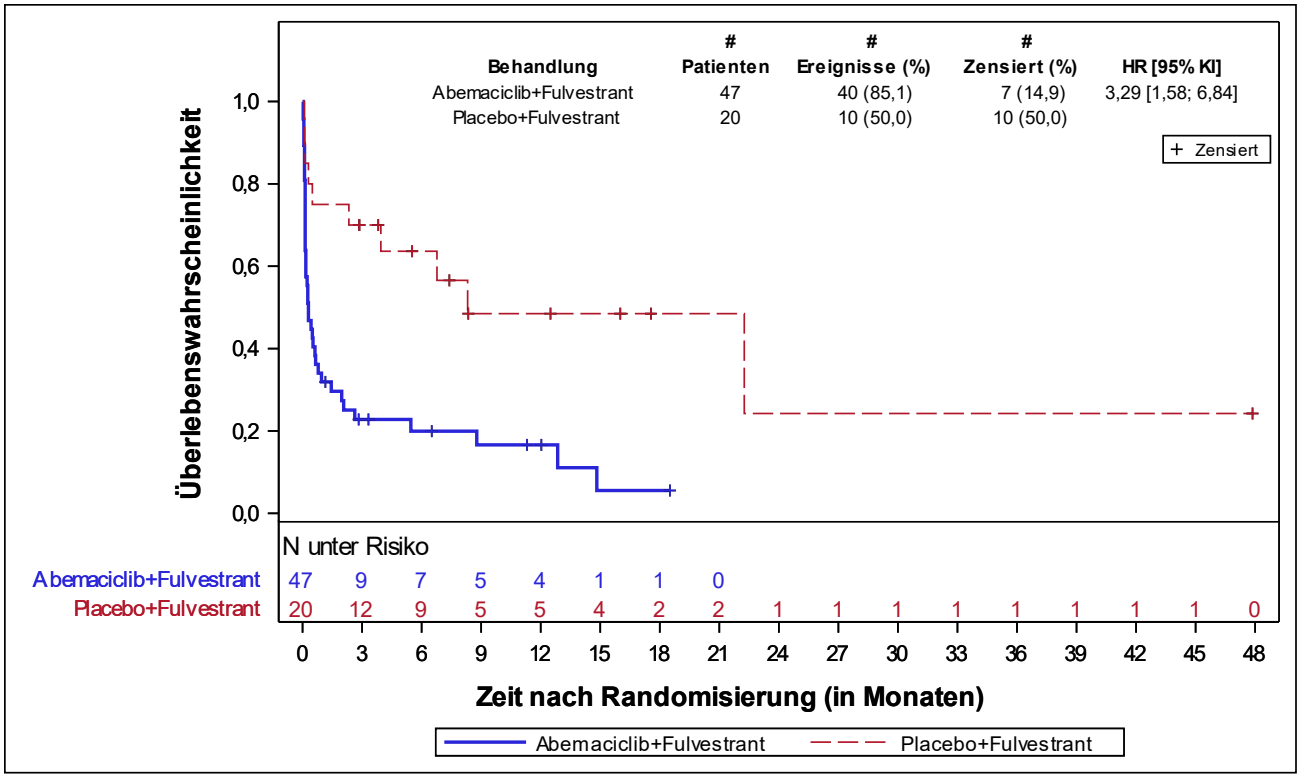
Abbildung 306: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad)
Subgruppenanalyse für Anzahl betroffener Organe = 1
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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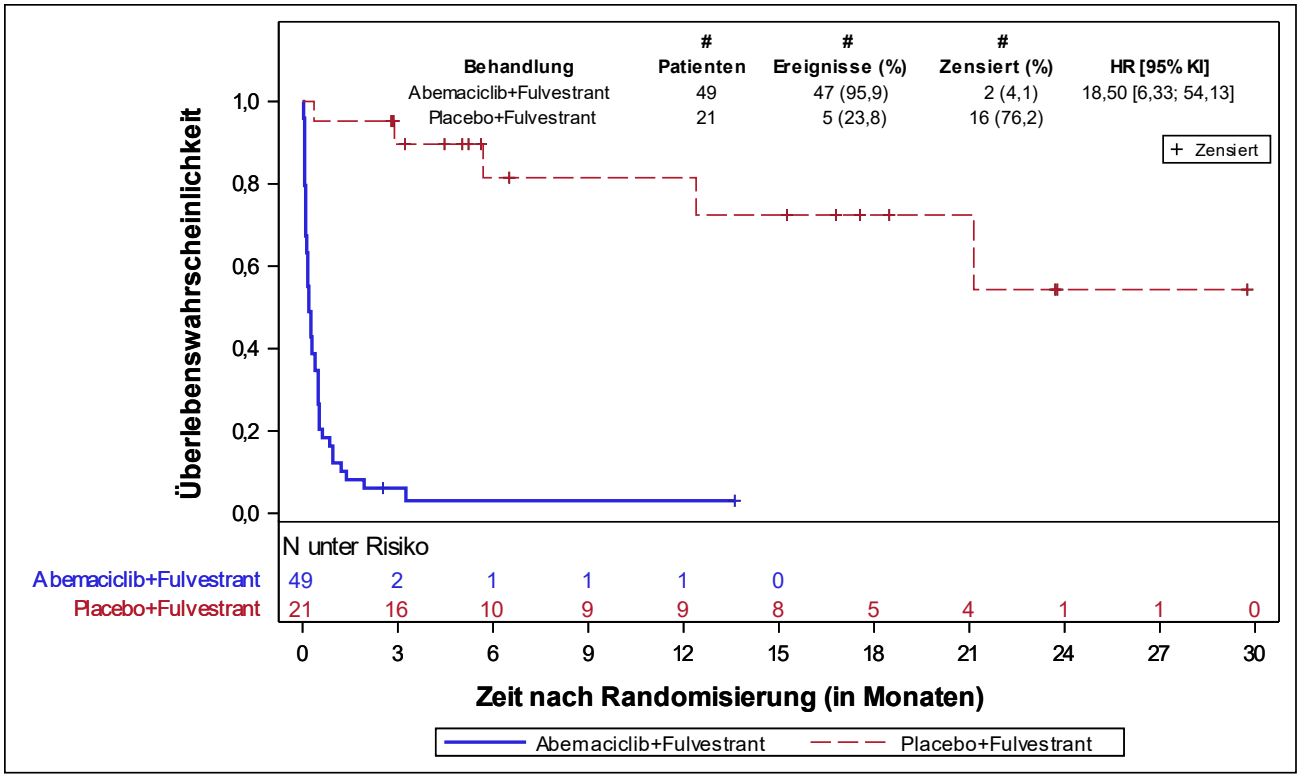
Abbildung 307: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad)
Subgruppenanalyse für Anzahl betroffener Organe = 2
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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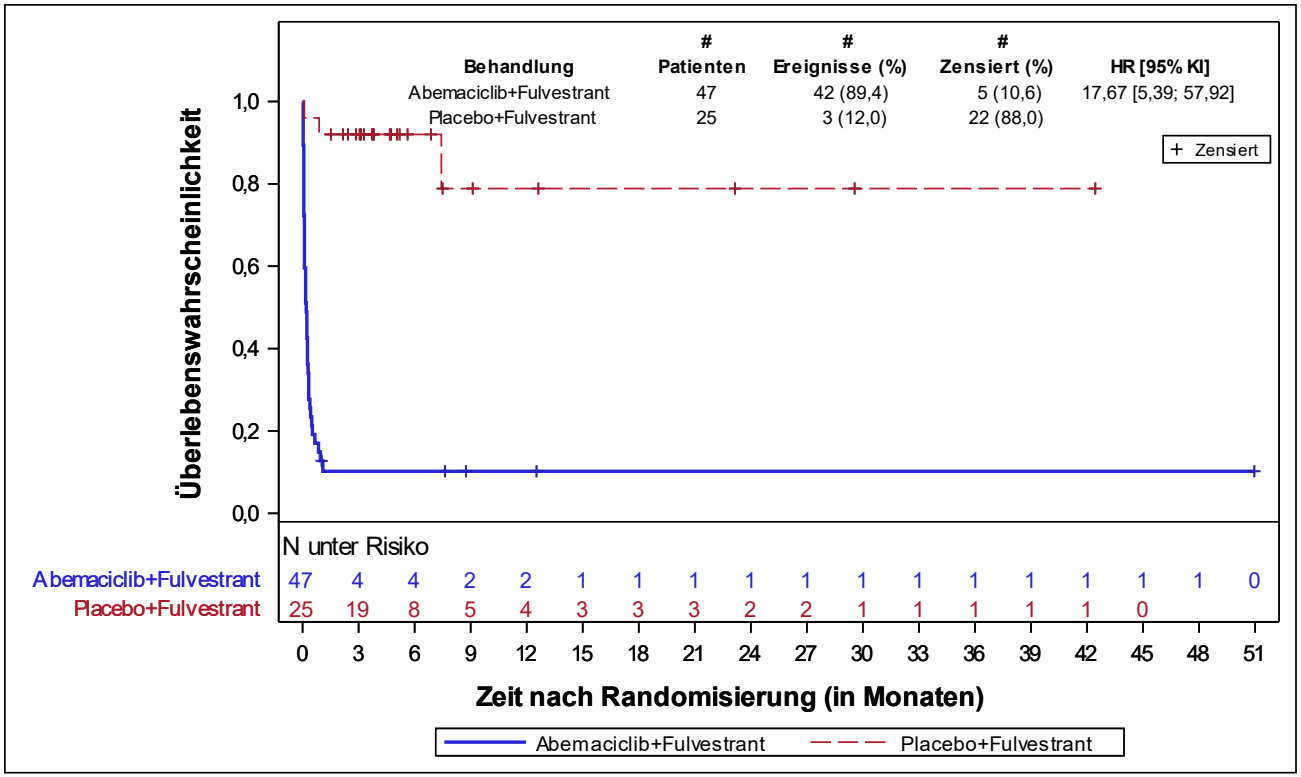
Abbildung 308: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad)
Subgruppenanalyse für Anzahl betroffener Organe = ≥ 3
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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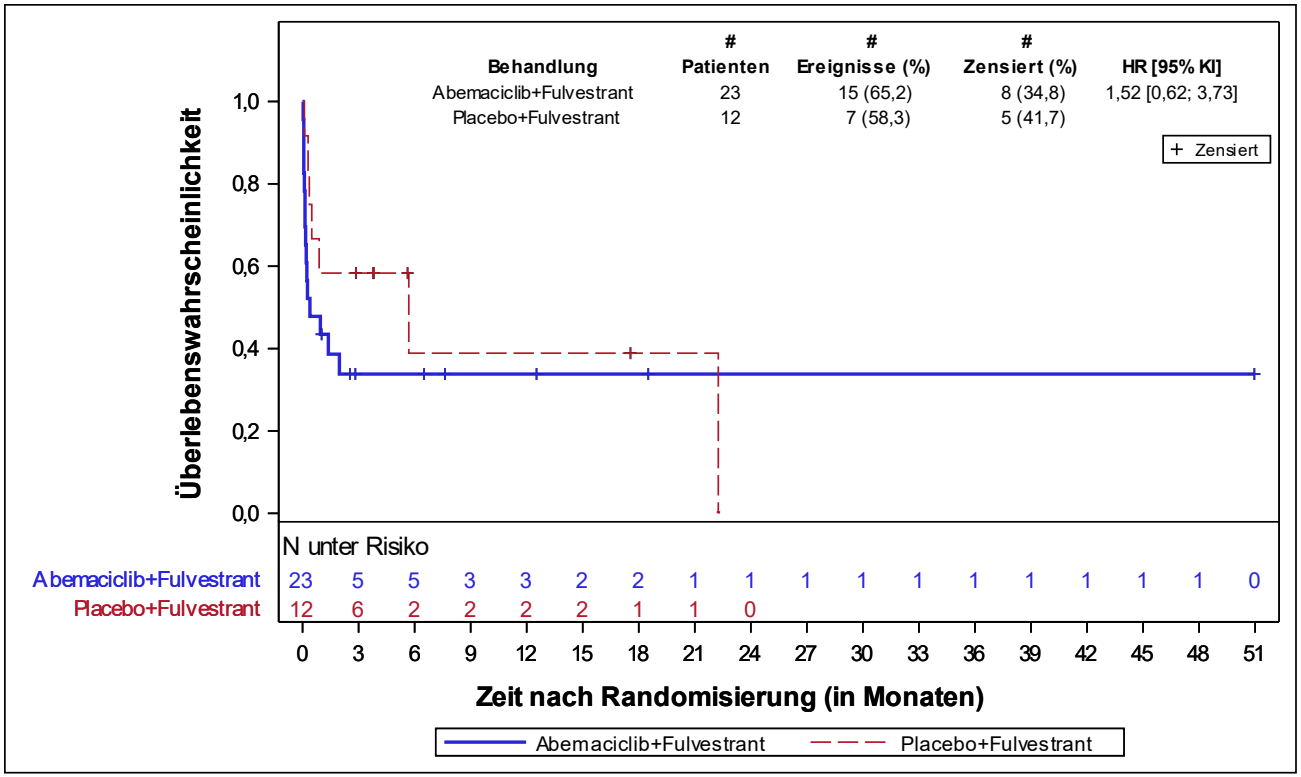
Abbildung 309: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad)
Subgruppenanalyse für Progesteronrezeptorstatus = Negativ
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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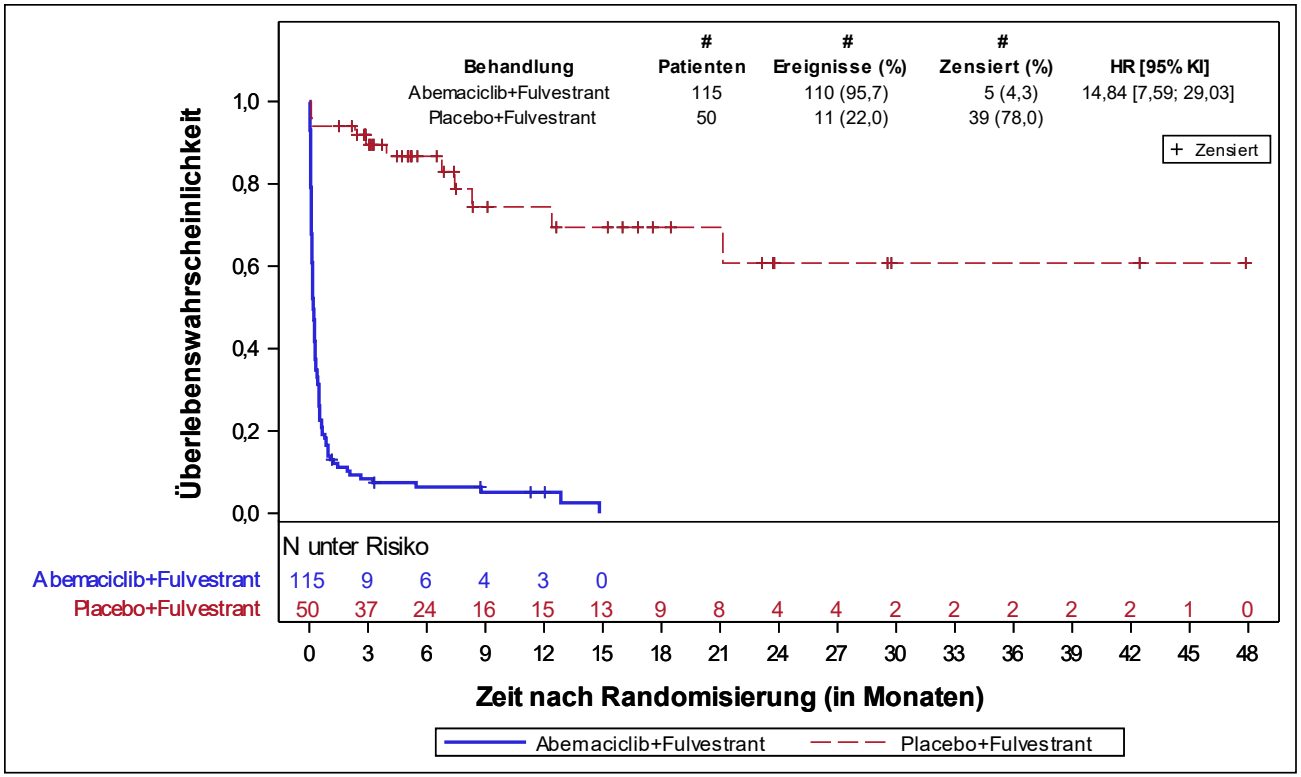
Abbildung 310: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad)
Subgruppenanalyse für Progesteronrezeptorstatus = Positiv
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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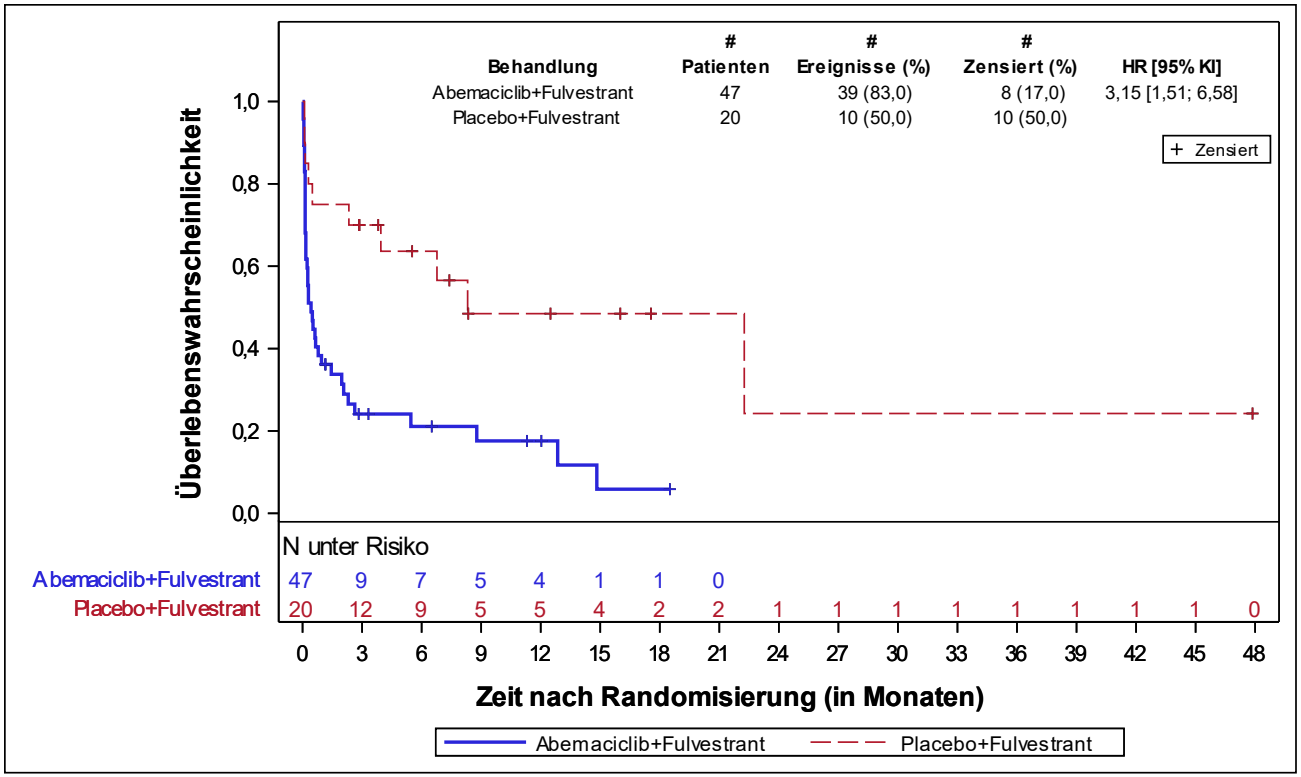
Abbildung 311: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe
Subgruppenanalyse für Anzahl betroffener Organe = 1
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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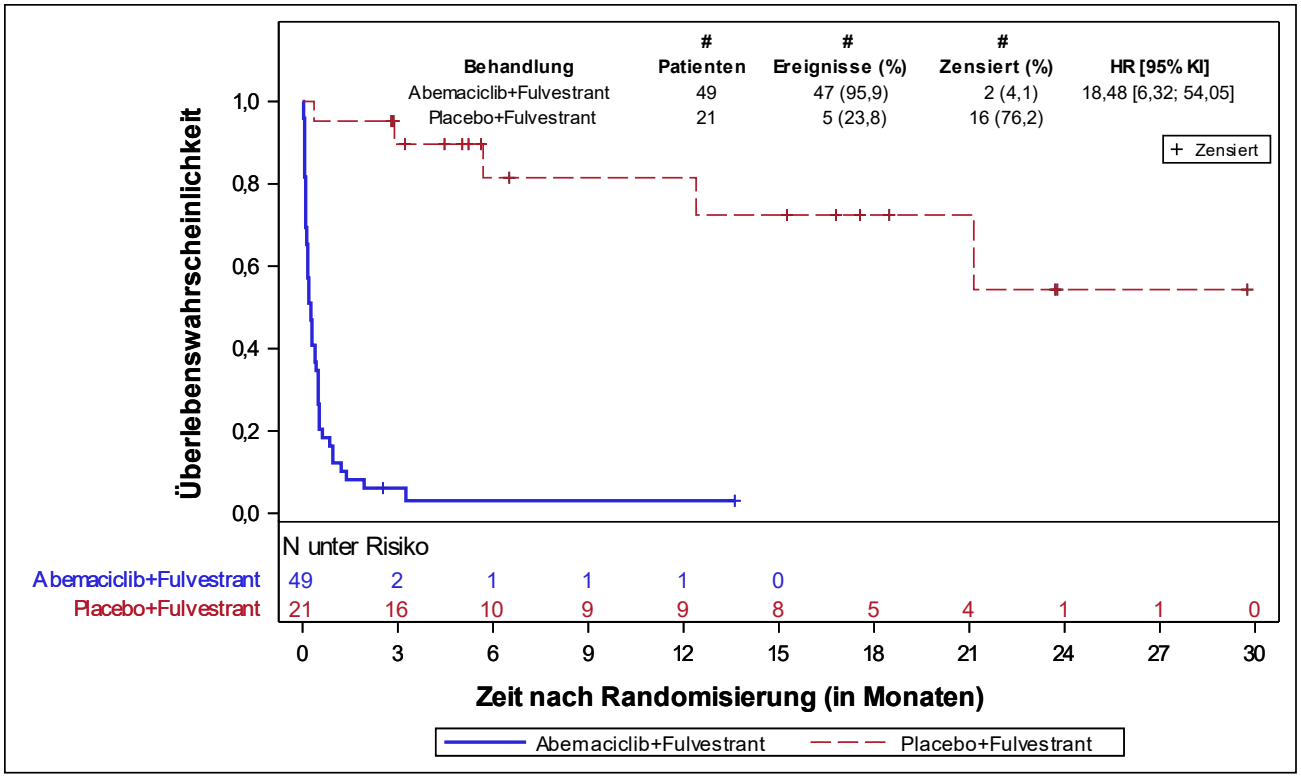
Abbildung 312: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe
Subgruppenanalyse für Anzahl betroffener Organe = 2
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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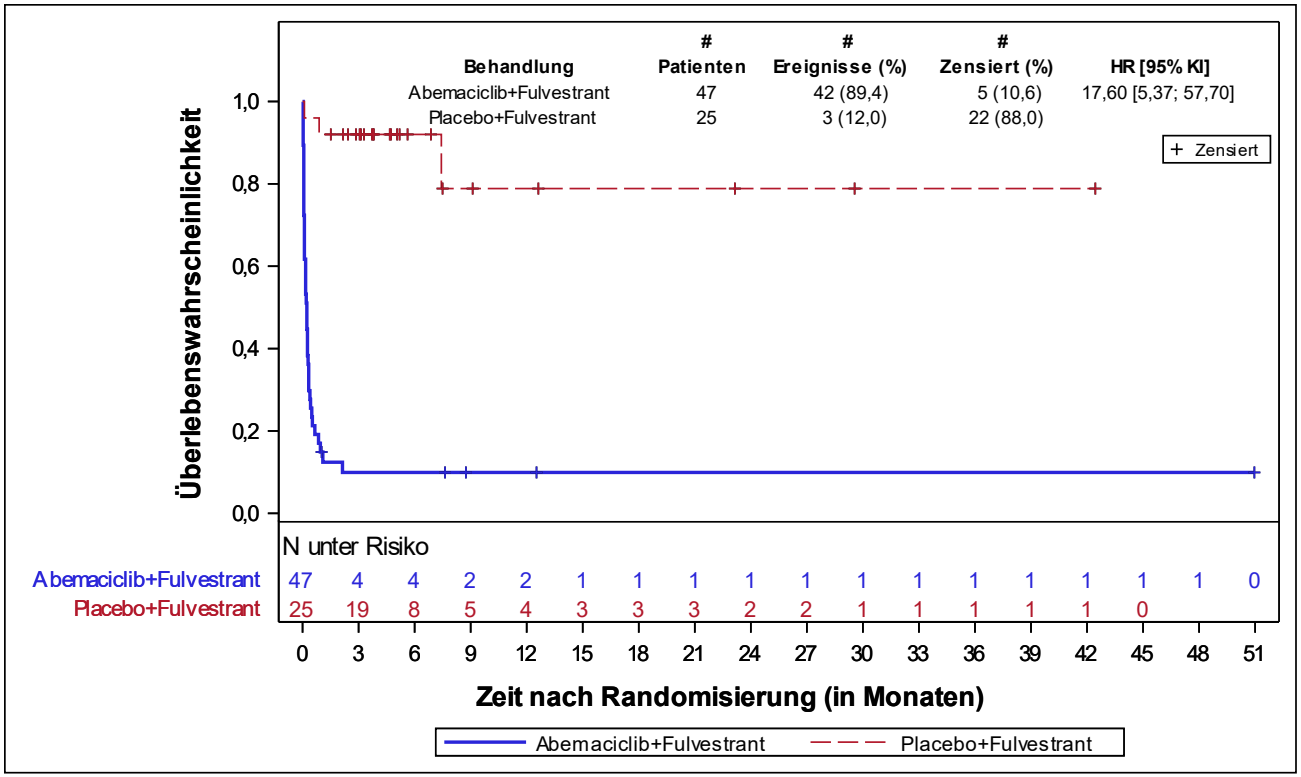
Abbildung 313: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe
Subgruppenanalyse für Anzahl betroffener Organe = ≥ 3
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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Output Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5//output/shared/tfl/german_dossier/f313_km_sub_popa2.rtf
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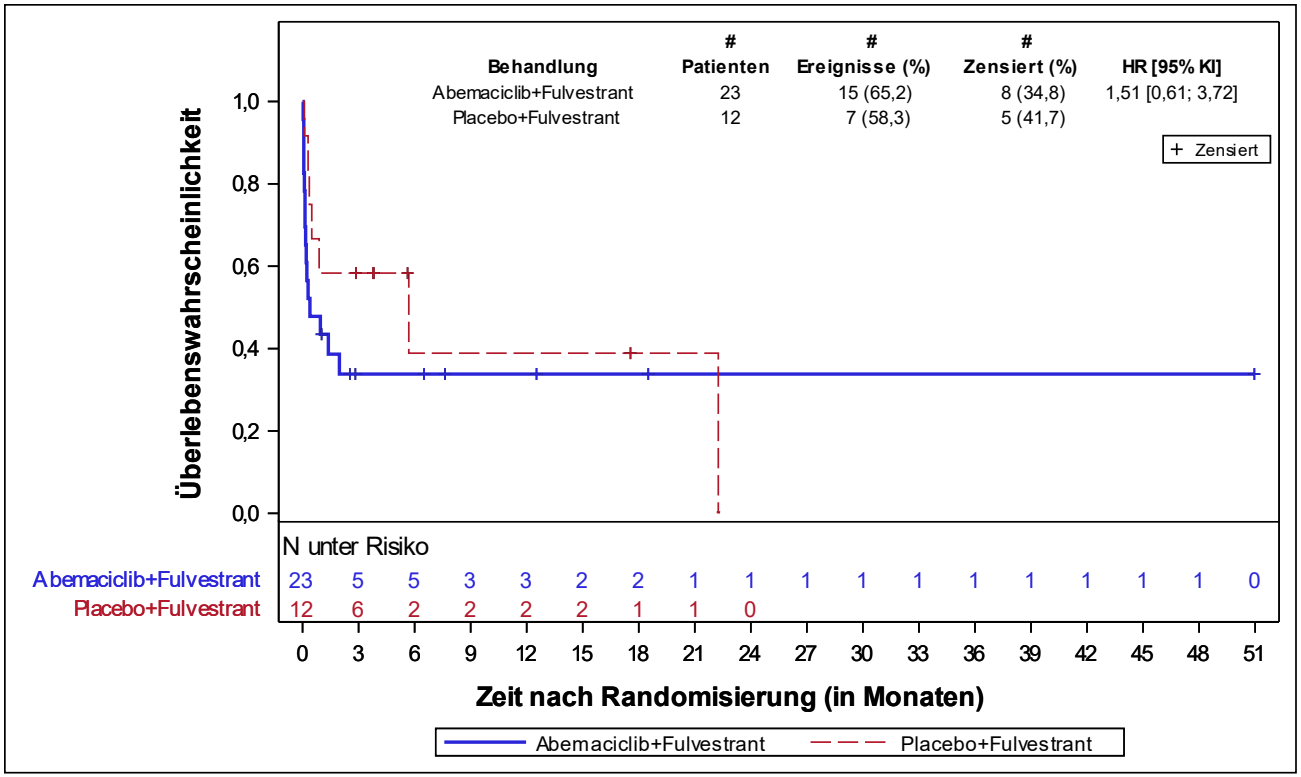
Abbildung 314: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe
Subgruppenanalyse für Progesteronrezeptorstatus = Negativ
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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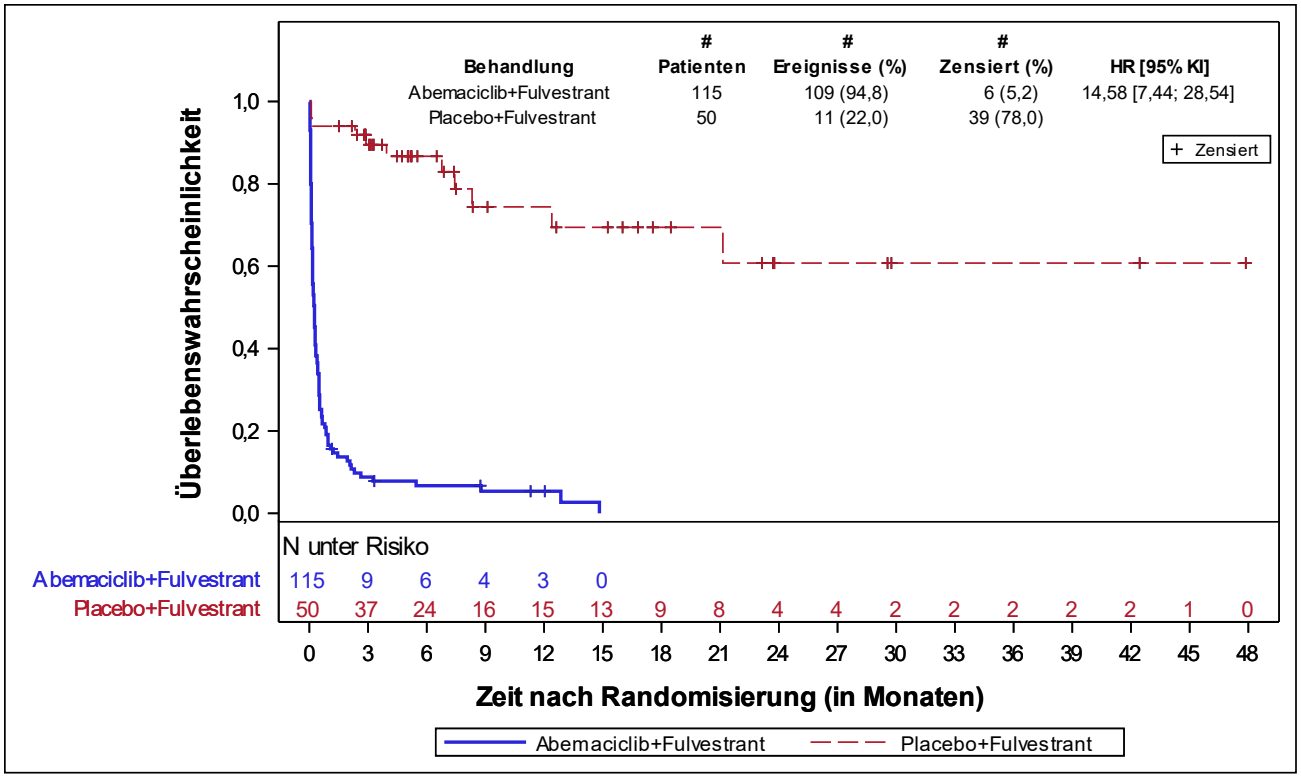
14JUL2021 / 10:33

Abbildung 315: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe
Subgruppenanalyse für Progesteronrezeptorstatus = Positiv
Safety Population - Postmenopausal B1 (Zweitlinie)



Datenschnitt: 20.06.2019, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/programs/tfl/primary/f_gba_ae_km_sub.sas
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14JUL2021 / 10:33

Anhang 4-G2: Weitere Analysen der Studie MONARCH-plus

Anhang 4-G2.1: Postprogressionstherapien

Tabelle 4-129 (Anhang): Liste der Postprogressionstherapien (MONARCH-plus)

Tabelle 2: Übersicht der Postprogressionstherapien - Monarch-plus

	Ohne vorangegangene endokrine Therapie (Erstlinie) (A1)			Mit vorangegangener endokriner Therapie (Zweitlinie) (B1)		
	Abemaciclib+ Fulvestrant (N=81)	**Placebo+ Fulvestrant (N=40)**	**Gesamt (N=121)**	**Abemaciclib+ Fulvestrant (N=23)**	**Placebo+ Fulvestrant (N=13)**	**Gesamt (N=36)**
Patientinnen, die einen Progress hatten, n (%)	65 (80,2)	33 (82,5)	98 (81,0)	18 (78,3)	12 (92,3)	30 (83,3)
Systemische Therapie, n (%) [1]						
Insgesamt	46 (70,8)	25 (75,8)	71 (72,4)	10 (55,6)	4 (33,3)	14 (46,7)
Chemotherapie	33 (50,8)	20 (60,6)	53 (54,1)	8 (44,4)	2 (16,7)	10 (33,3)
Endokrine Therapie	20 (30,8)	11 (33,3)	31 (31,6)	6 (33,3)	0	6 (20,0)
Andere systemische Therapie	9 (13,8)	6 (18,2)	15 (15,3)	2 (11,1)	1 (8,3)	3 (10,0)
Zielgerichtete Therapie	4 (6,2)	5 (15,2)	9 (9,2)	1 (5,6)	1 (8,3)	2 (6,7)
Erste Folgetherapie	46 (70,8)	25 (75,8)	71 (72,4)	10 (55,6)	4 (33,3)	14 (46,7)
Chemotherapie	30 (46,2)	19 (57,6)	49 (50,0)	6 (33,3)	2 (16,7)	8 (26,7)
Endokrine Therapie	15 (23,1)	5 (15,2)	20 (20,4)	4 (22,2)	0	4 (13,3)
Andere systemische Therapie	4 (6,2)	3 (9,1)	7 (7,1)	1 (5,6)	1 (8,3)	2 (6,7)
Zielgerichtete Therapie	1 (1,5)	3 (9,1)	4 (4,1)	0	1 (8,3)	1 (3,3)
Operativer Eingriff, n (%) [1]	1 (1,5)	2 (6,1)	3 (3,1)	0	0	0
Strahlentherapie, n (%) [1]	4 (6,2)	4 (12,1)	8 (8,2)	2 (11,1)	0	2 (6,7)

Datenschnitt: 18.05.2020, ITT-Population
[1] Prozentzahlen basieren auf der Gesamtzahl der Patientinnen mit Progress.
Abkürzungen: A1: Postmenopausale Patientinnen ohne vorangegangene endokrine Therapie (Erstlinie); B1: Postmenopausale Patientinnen mit vorangegangener endokriner Therapie (Zweitlinie); RCT: Randomisierte kontrollierte Studie; ITT: Intention to treat; N: Gesamtzahl der Patientinnen in der Analyse; n: Anzahl der Patientinnen

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/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
23JUL2021 / 04:17

Anhang 4-G2.2: Ergebnisse des Gesamtüberlebens - Postmenopausale Patientinnen

Tabelle 4-130 (Anhang): Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel - unstratifizierte Analyse (Studie MONARCH-plus, ITT-Population)

Tabelle 020: Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel - unstratifizierte Analyse (Studie MONARCH-plus)

Population	Abemaciclib+Fulvestrant n/N (%)	Abemaciclib+Fulvestrant Mediane Ereigniszeit[1]	Placebo+Fulvestrant n/N (%)	Placebo+Fulvestrant Mediane Ereigniszeit[1]	HR [95% KI] p-Wert
Gesamtüberlebenszeit					
ITT Population[2]	26/104 (25,0)	NE [NE; NE]	19/53 (35,8)	NE [19,79; NE]	0,529 [0,293; 0,957] 0,0325[3] 0,5768[4]

Datenschnitt: 18.05.2020
ITT-Population
1: In Monaten; 2: ITT-Population; 3: Aus Log-rank-Test; 4: p-Wert aus dem Modell mit Interaktion zwischen Behandlungsgruppe und Subpopulation (A1 vs. B1).
Abkürzungen: ET: Endokrine Therapie; HR: Hazard Ratio; ITT: Intention to Treat; KI: Konfidenzintervall; n: Anzahl verstorbener Patienten; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar/nicht erreicht.

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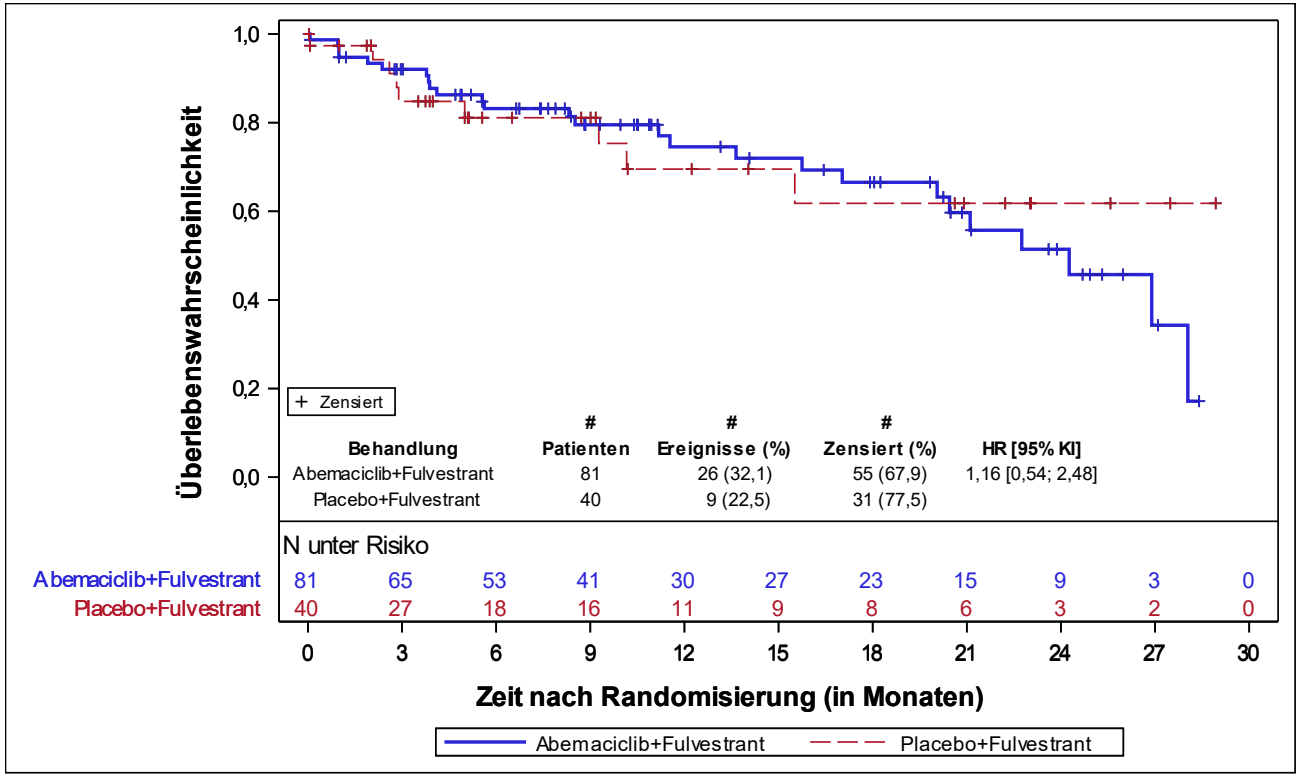
16AUG2021 / 03:47

Anhang 4-G2.3: Kaplan-Meier-Kurven für die Ergebnisse der Endpunkte Symptomatik, gesundheitsbezogene Lebensqualität und unerwünschte Ereignisse

Abbildung 153 (Anhang): Kaplan-Meier-Kurven für Symptomatik und gesundheitsbezogene Lebensqualität (MONARCH-plus)

Abbildung 005.1: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte) - Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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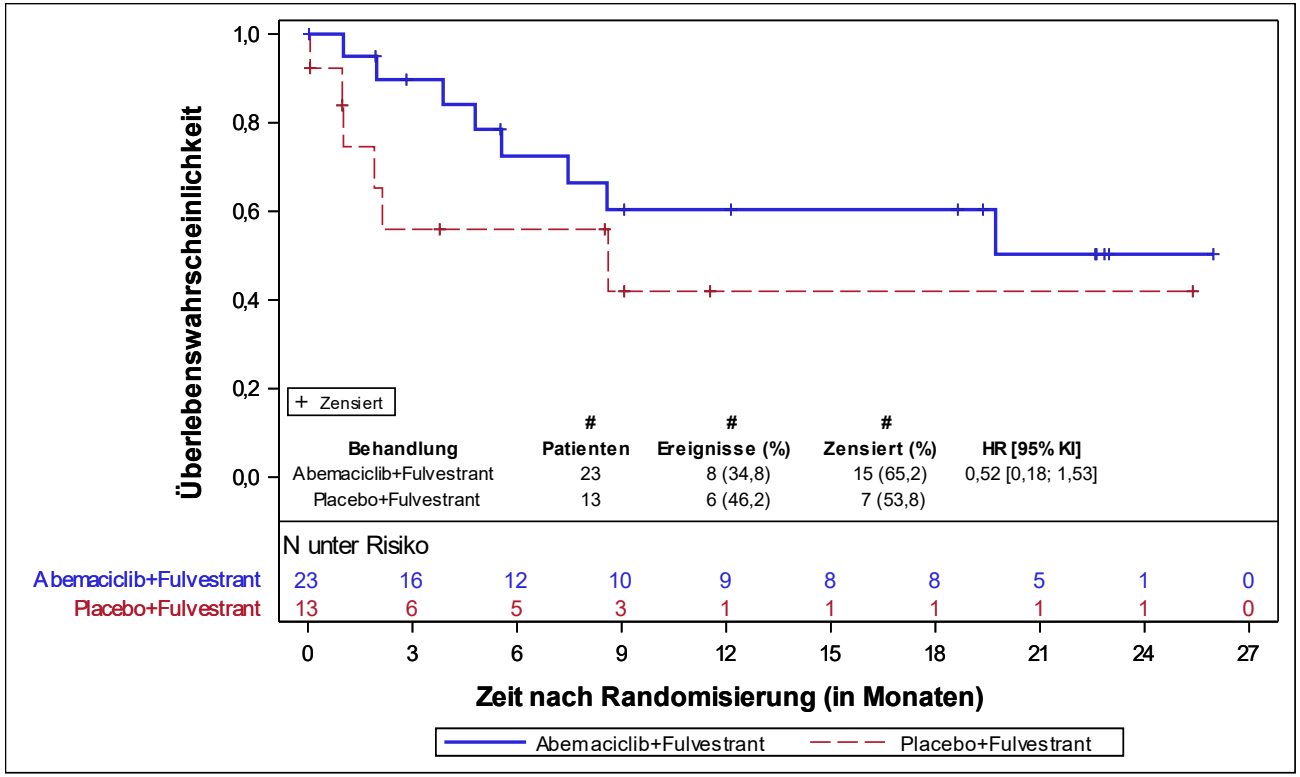
Abbildung 005.2: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte) - Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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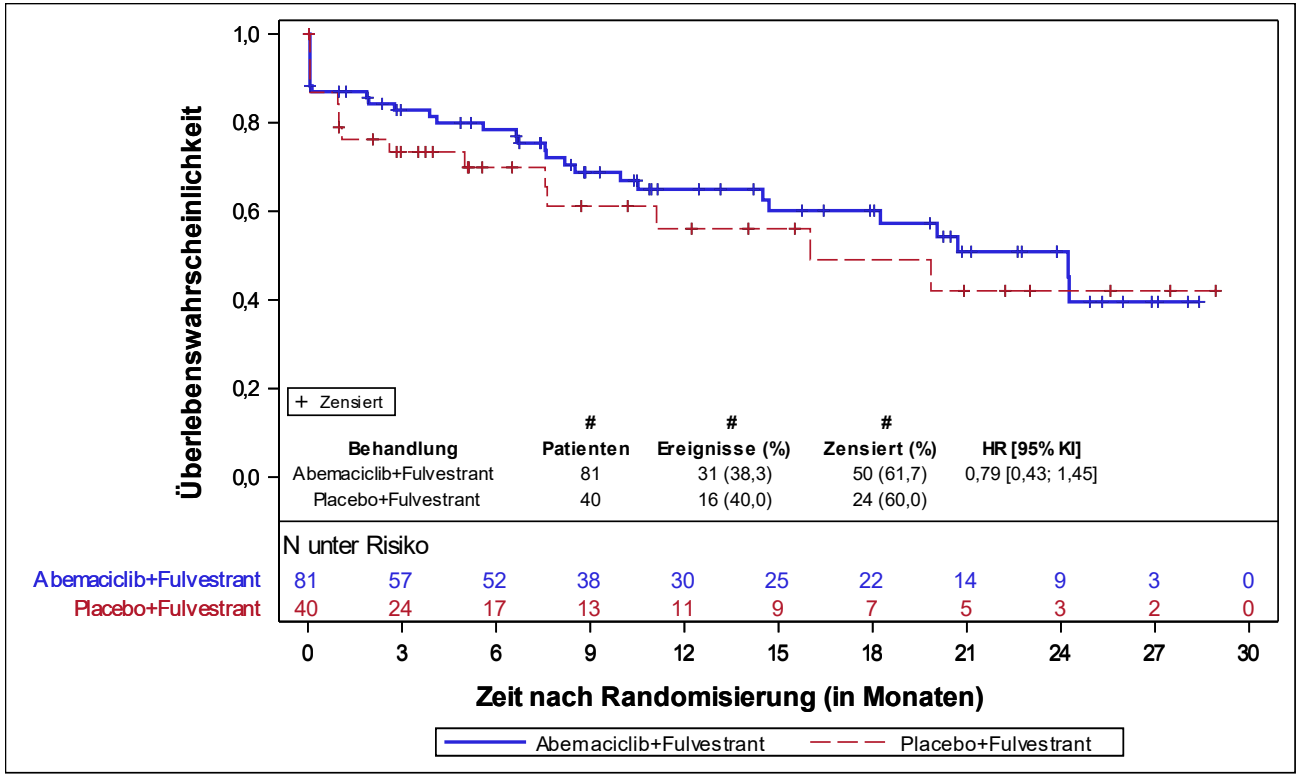
Abbildung 006.1: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte) - Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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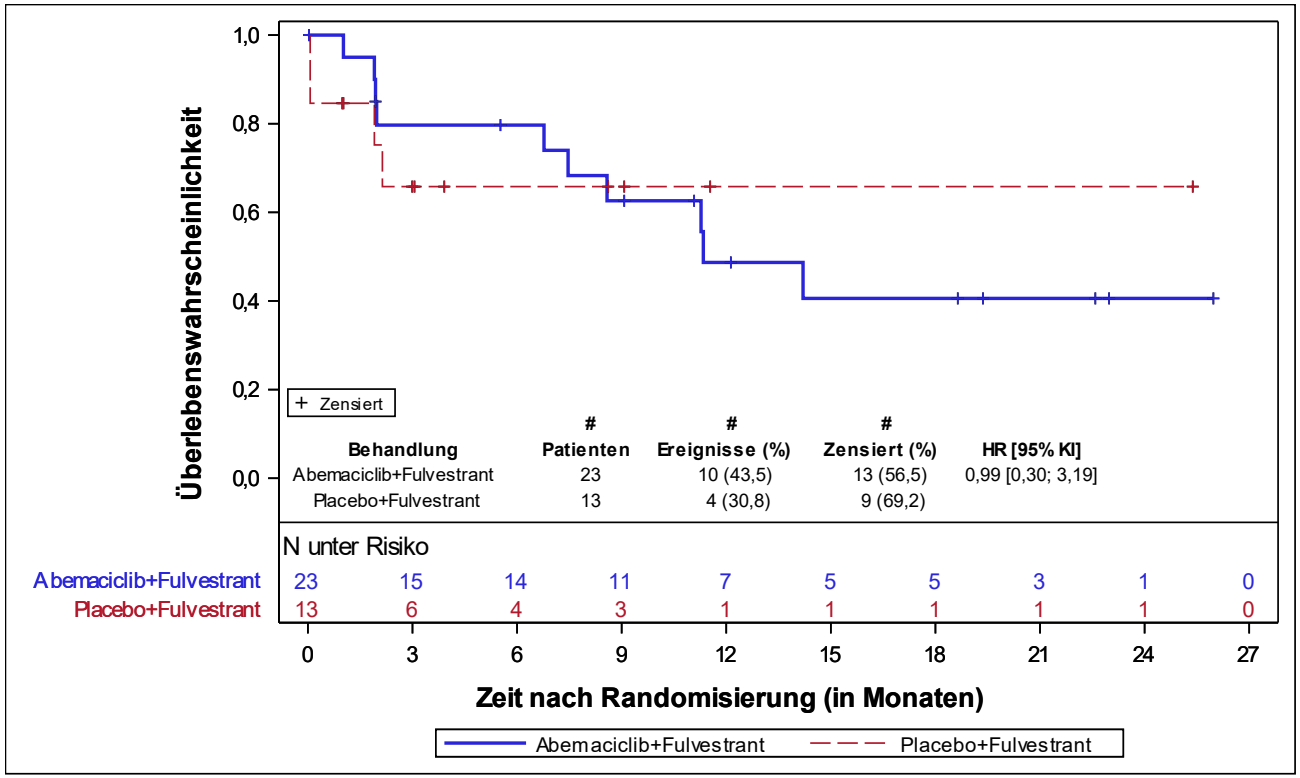
07SEP2021 / 03:44

Abbildung 006.2: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte) - Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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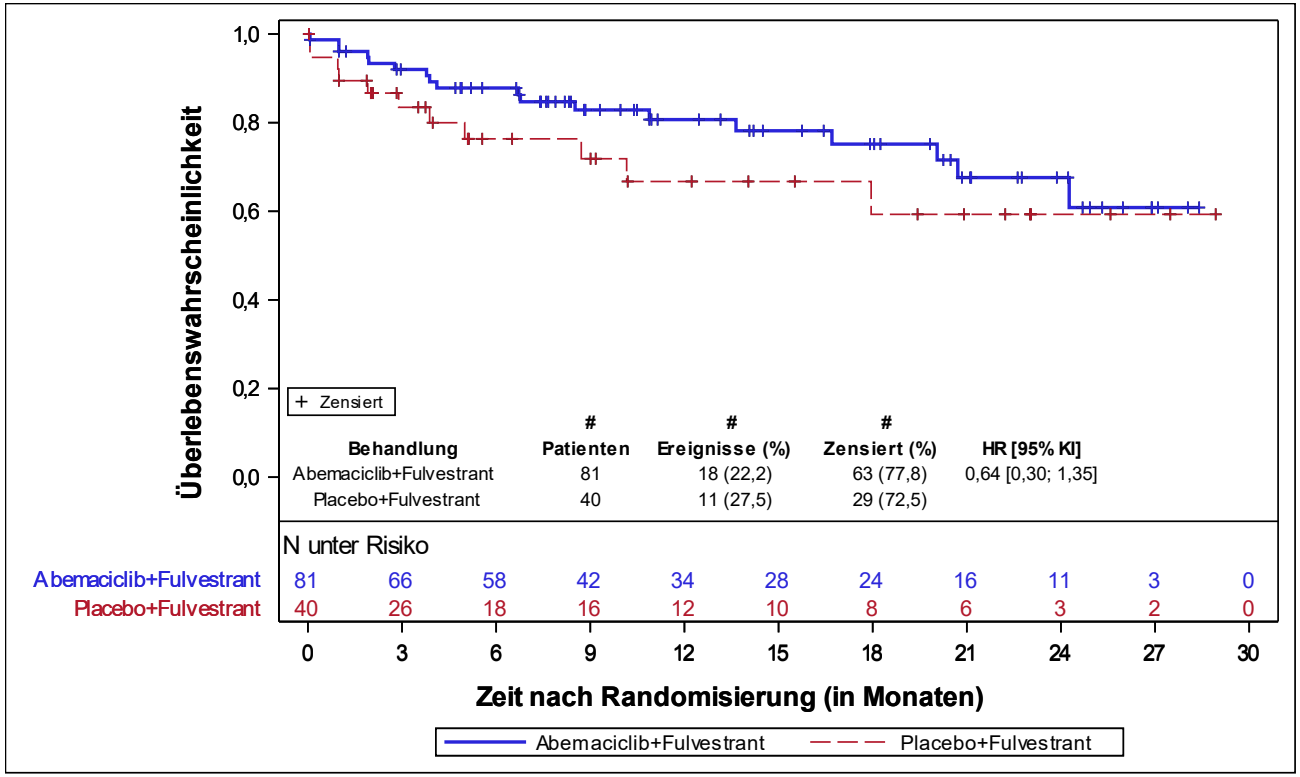
Abbildung 007.1: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte) - Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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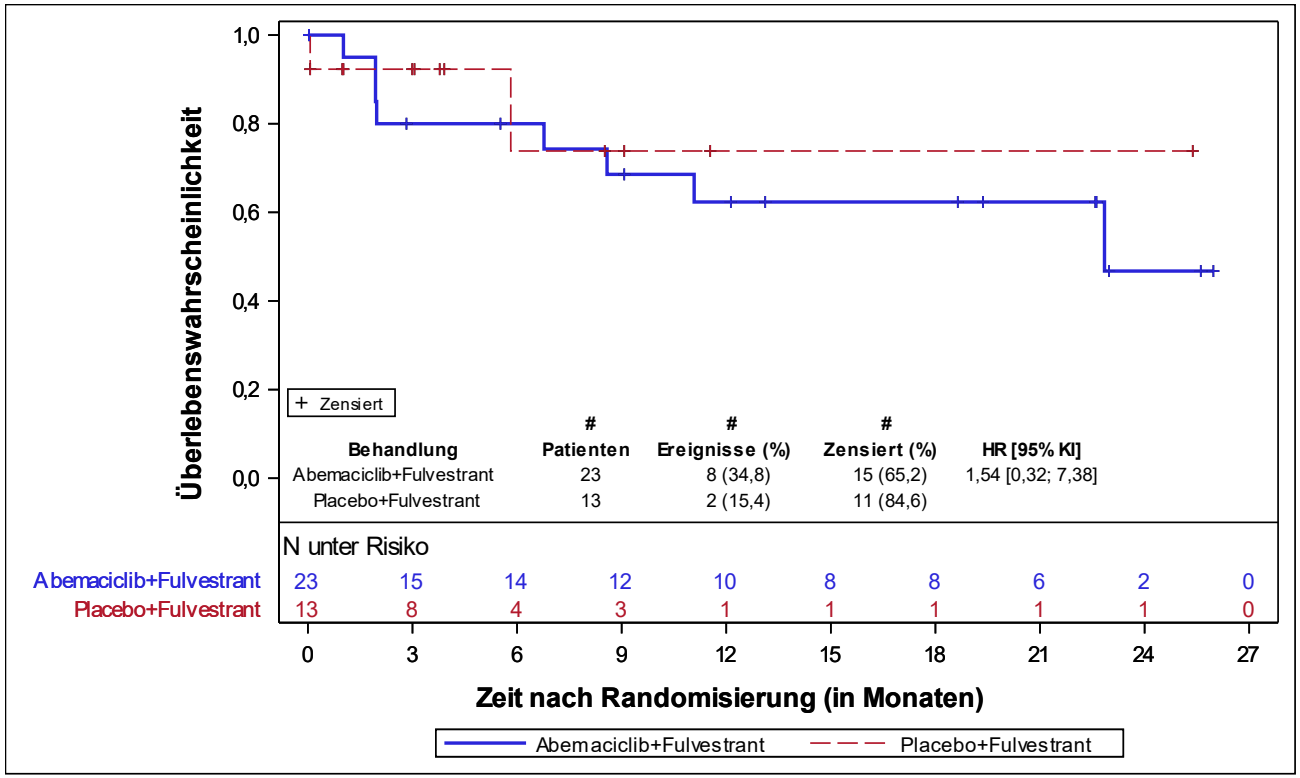
Abbildung 007.2: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte) - Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
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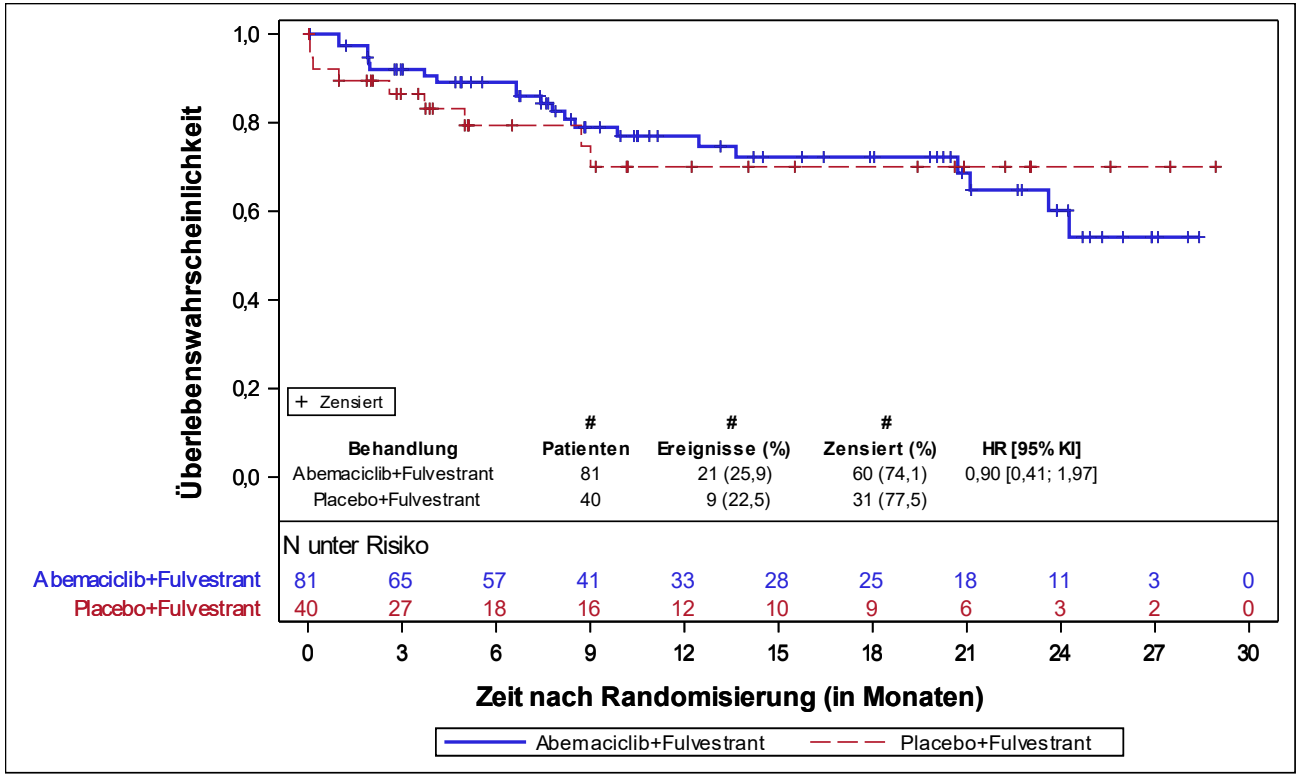
Abbildung 008.1: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte) - Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
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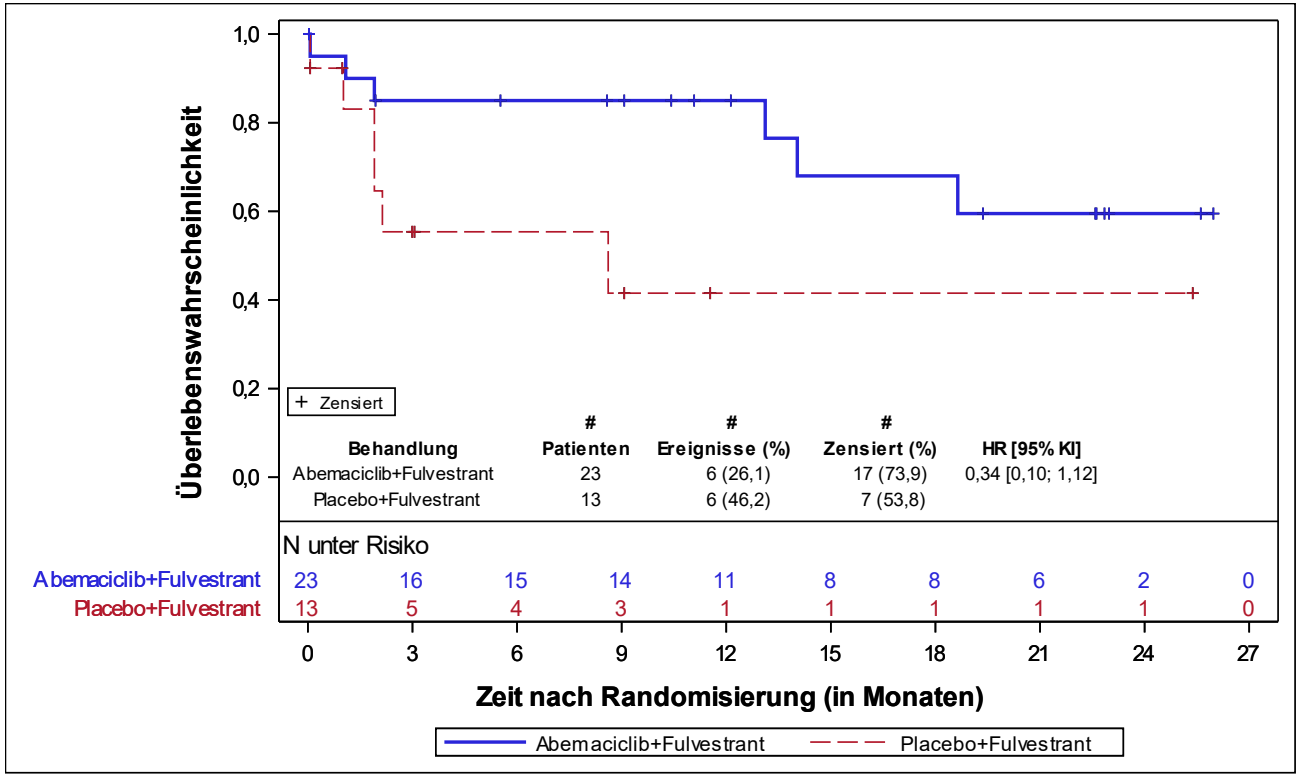
Abbildung 008.2: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte) - Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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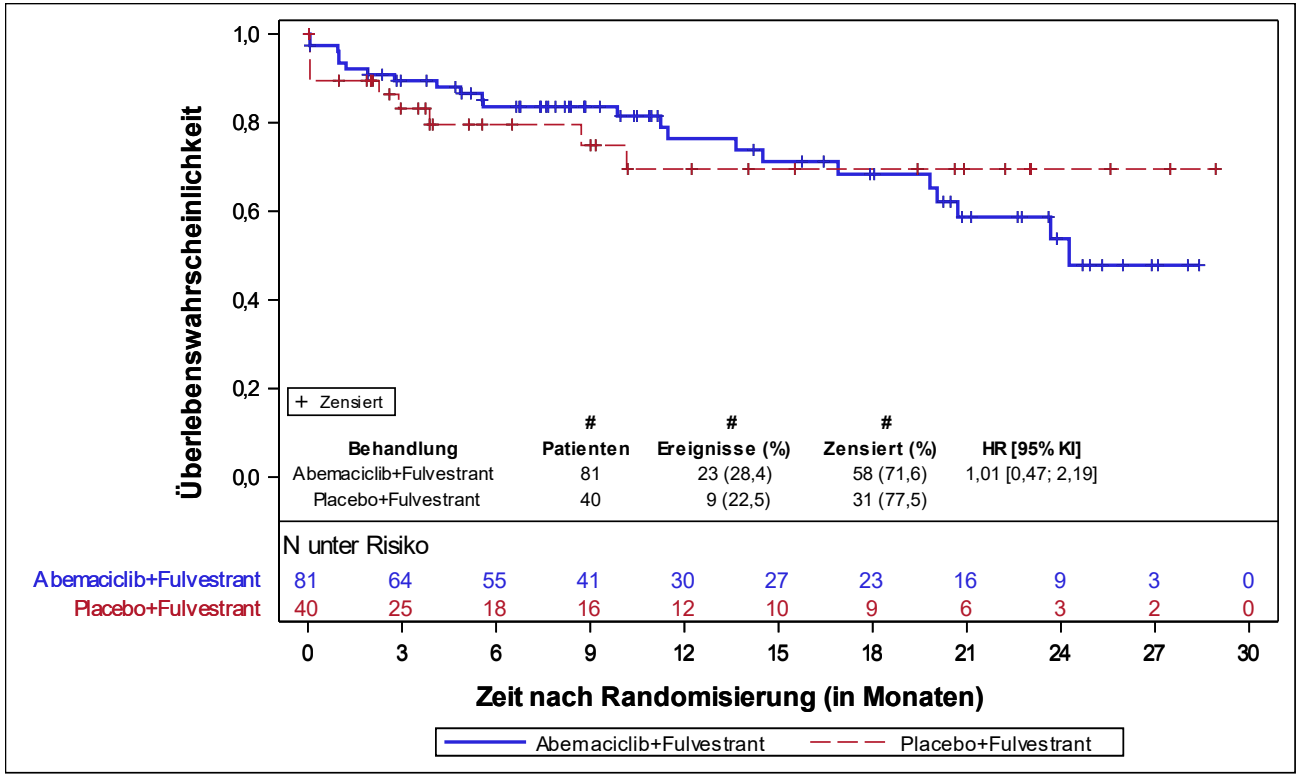
Abbildung 009.1: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte) - Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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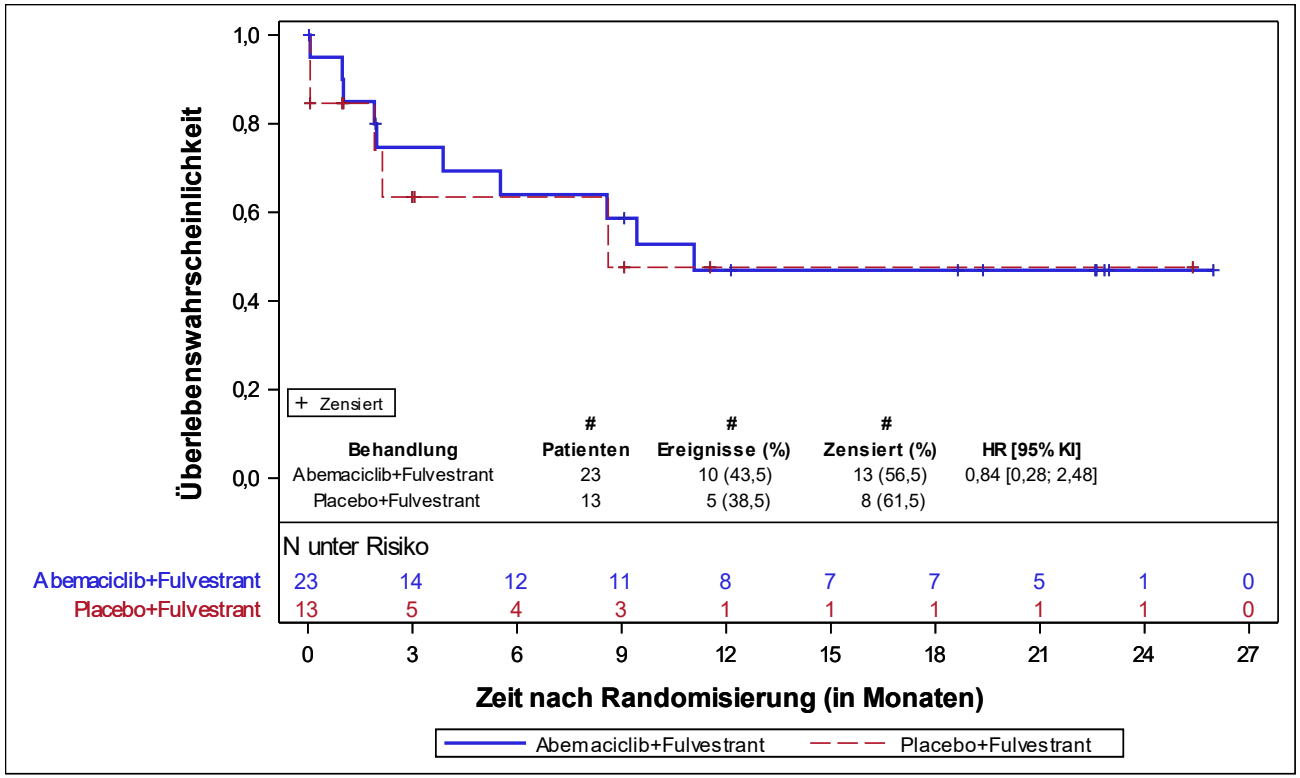
Abbildung 009.2: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte) - Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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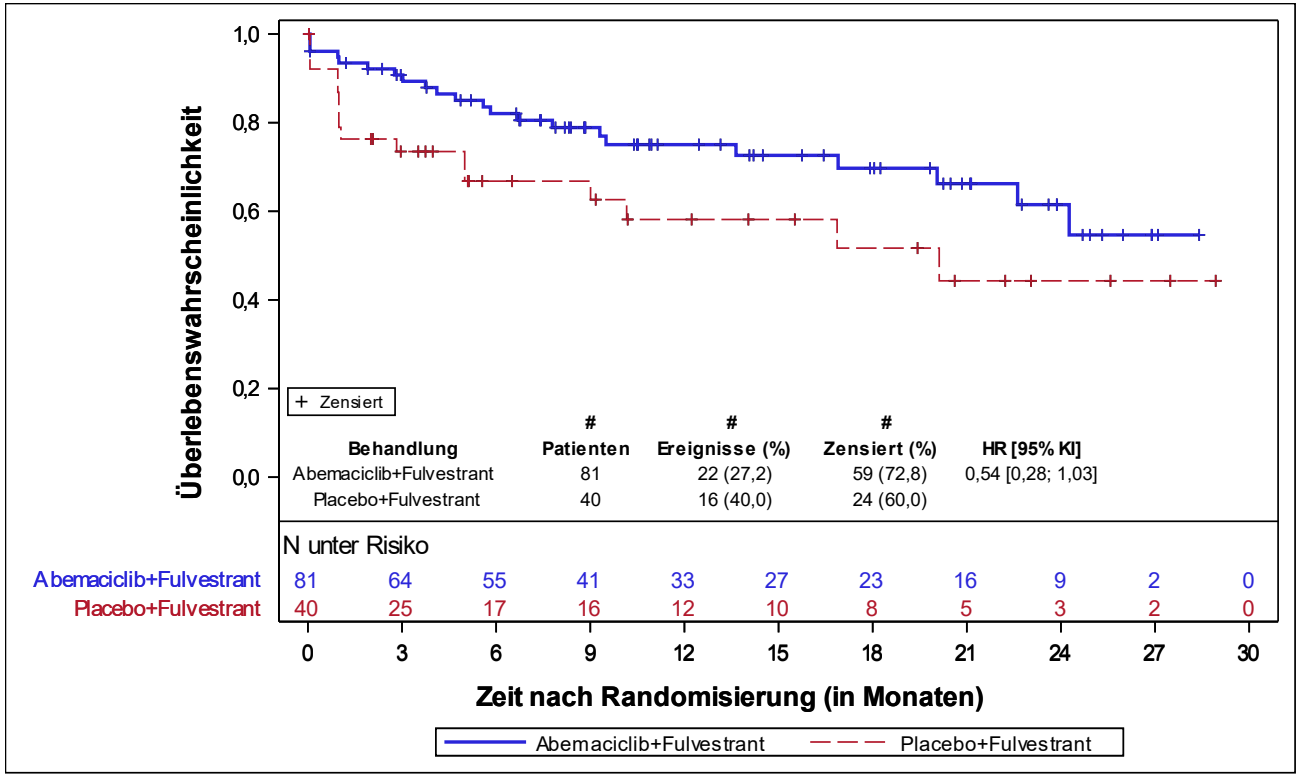
Abbildung 010.1: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte) - Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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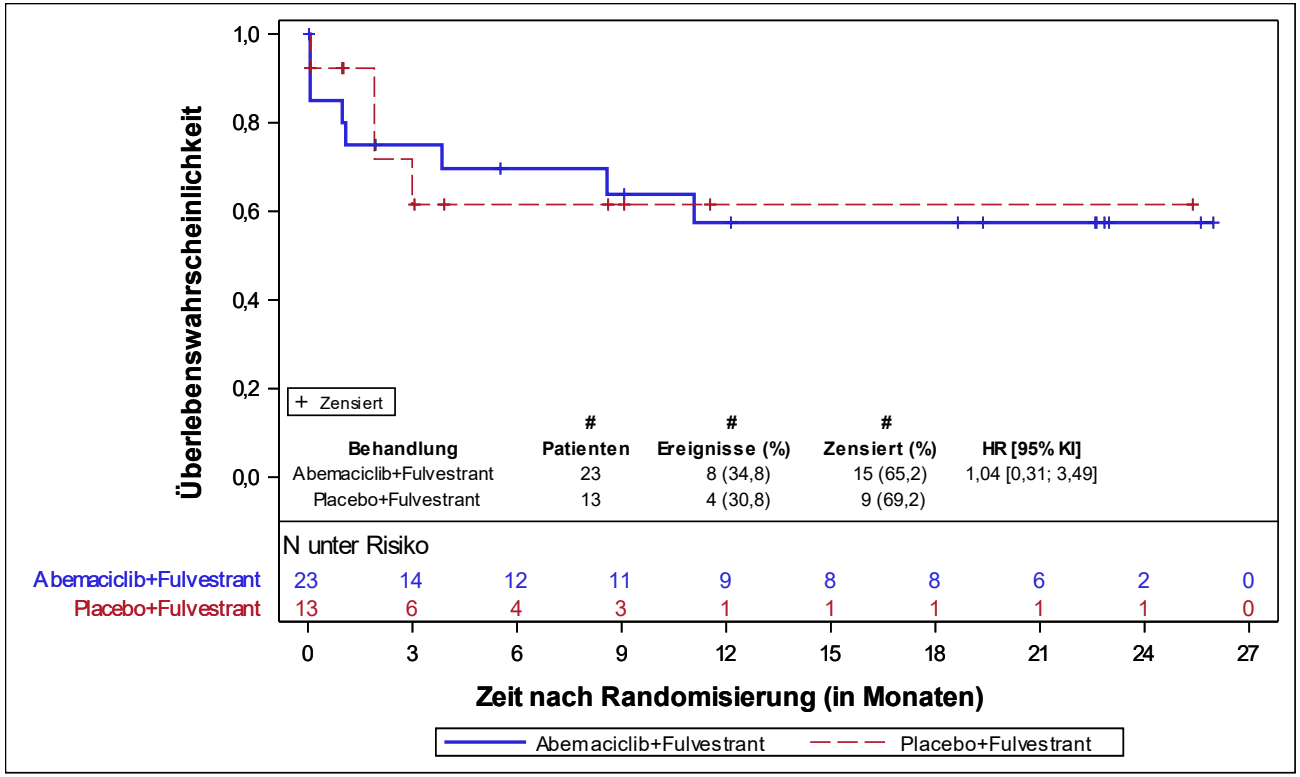
Abbildung 010.2: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte) - Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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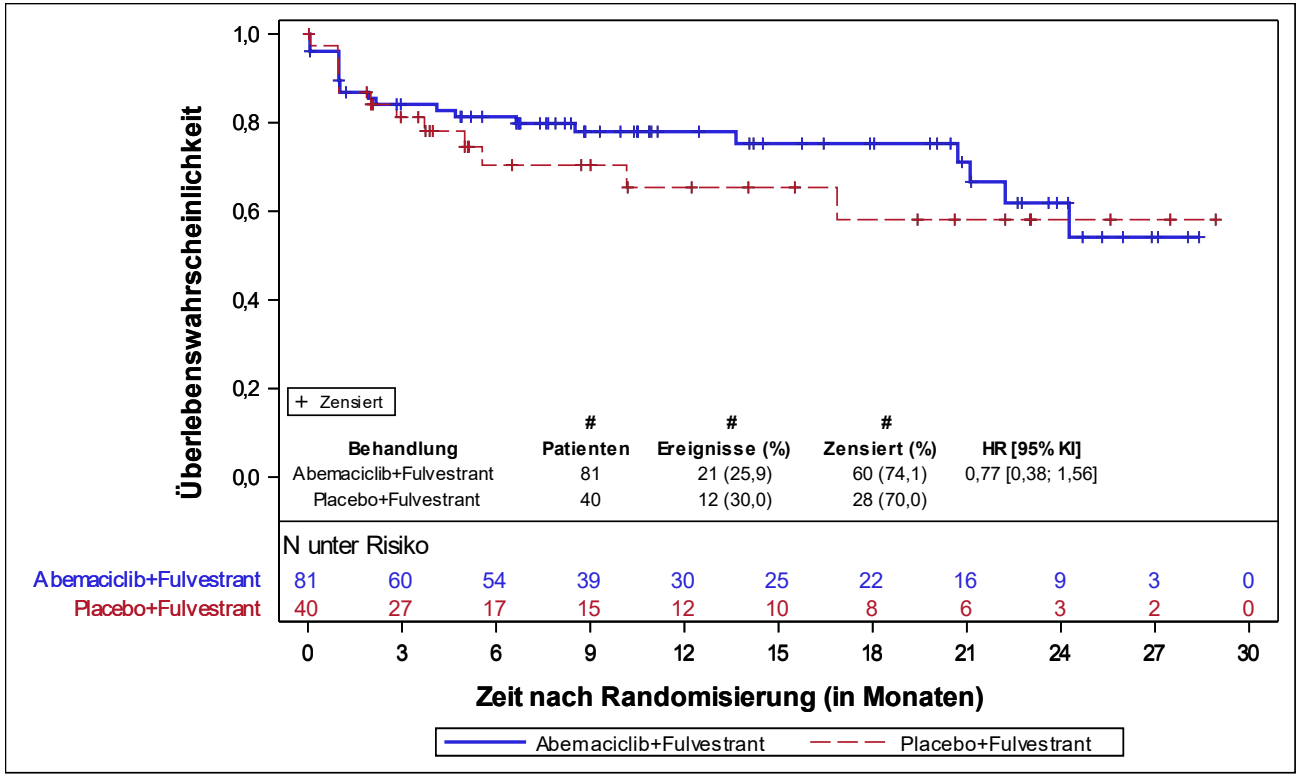
Abbildung 011.1: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte) - Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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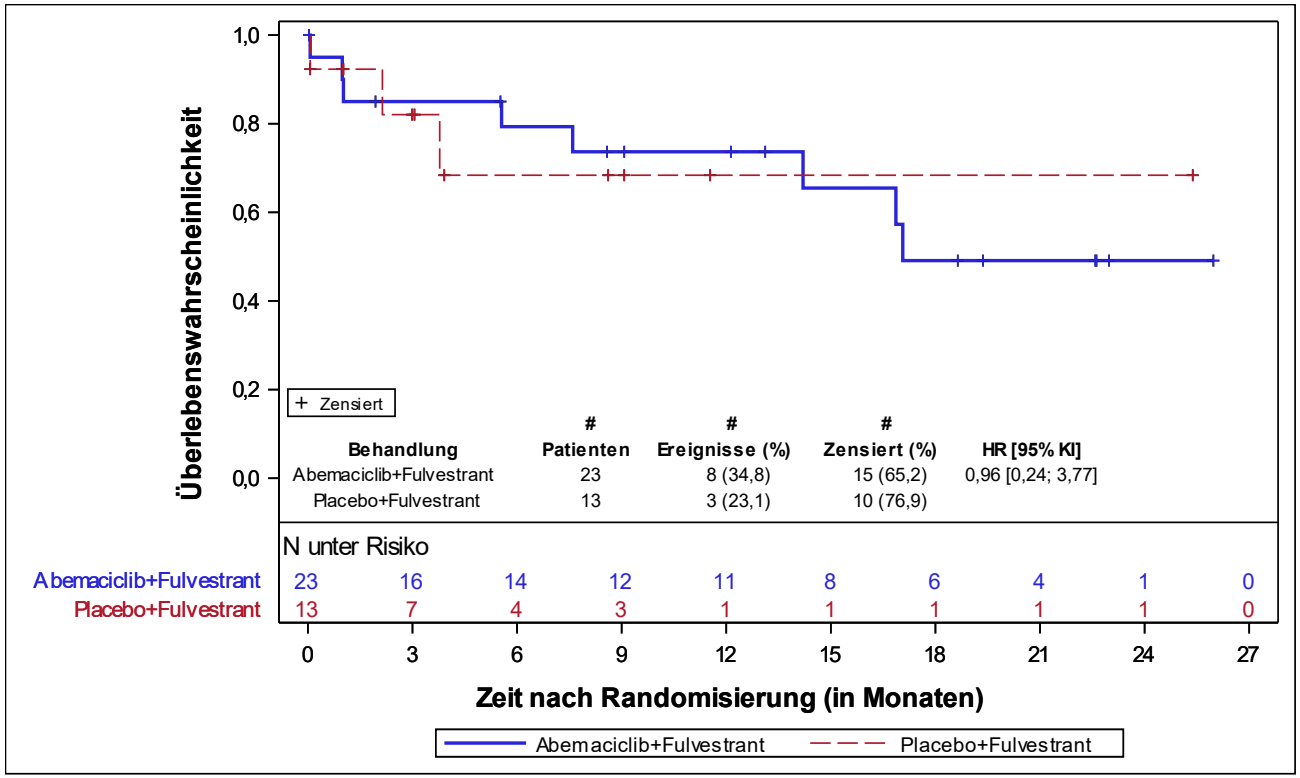
Abbildung 011.2: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte) - Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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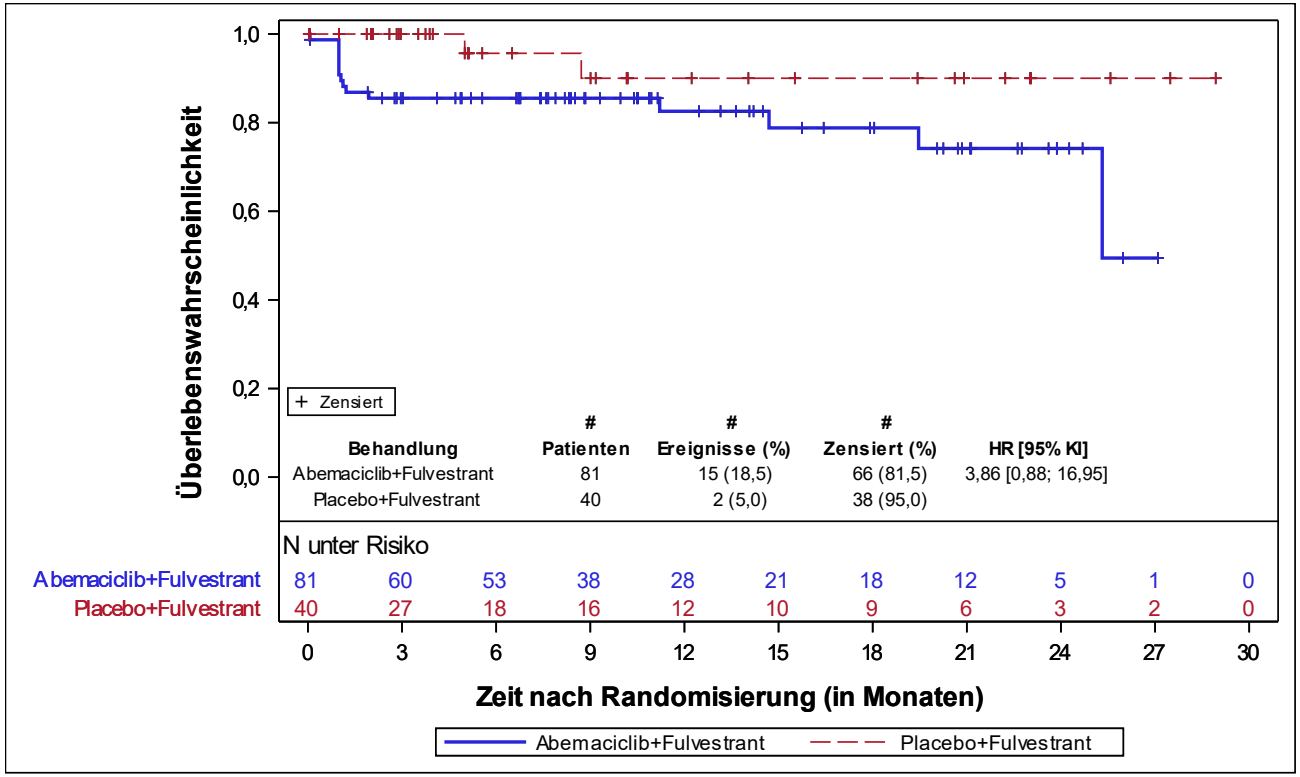
Abbildung 012.1: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte) - Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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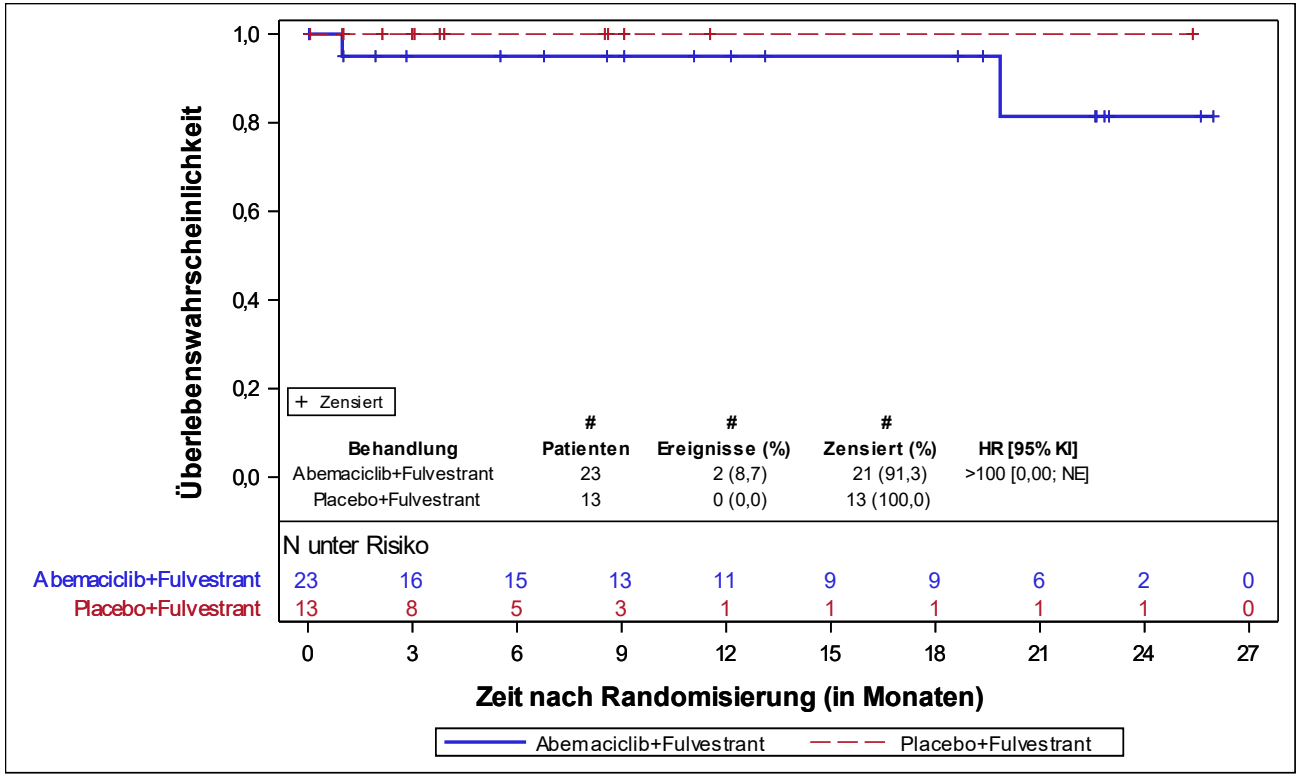
Abbildung 012.2: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte) - Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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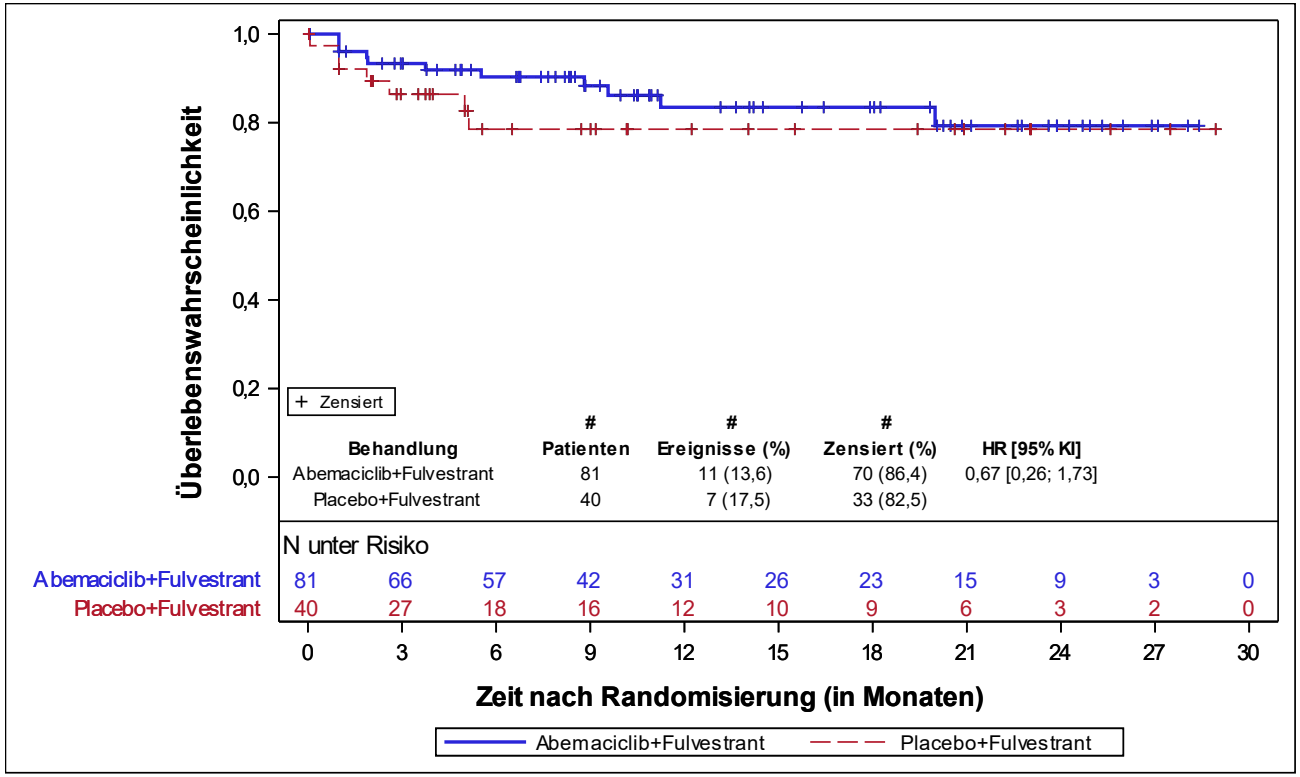
Abbildung 013.1: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte) - Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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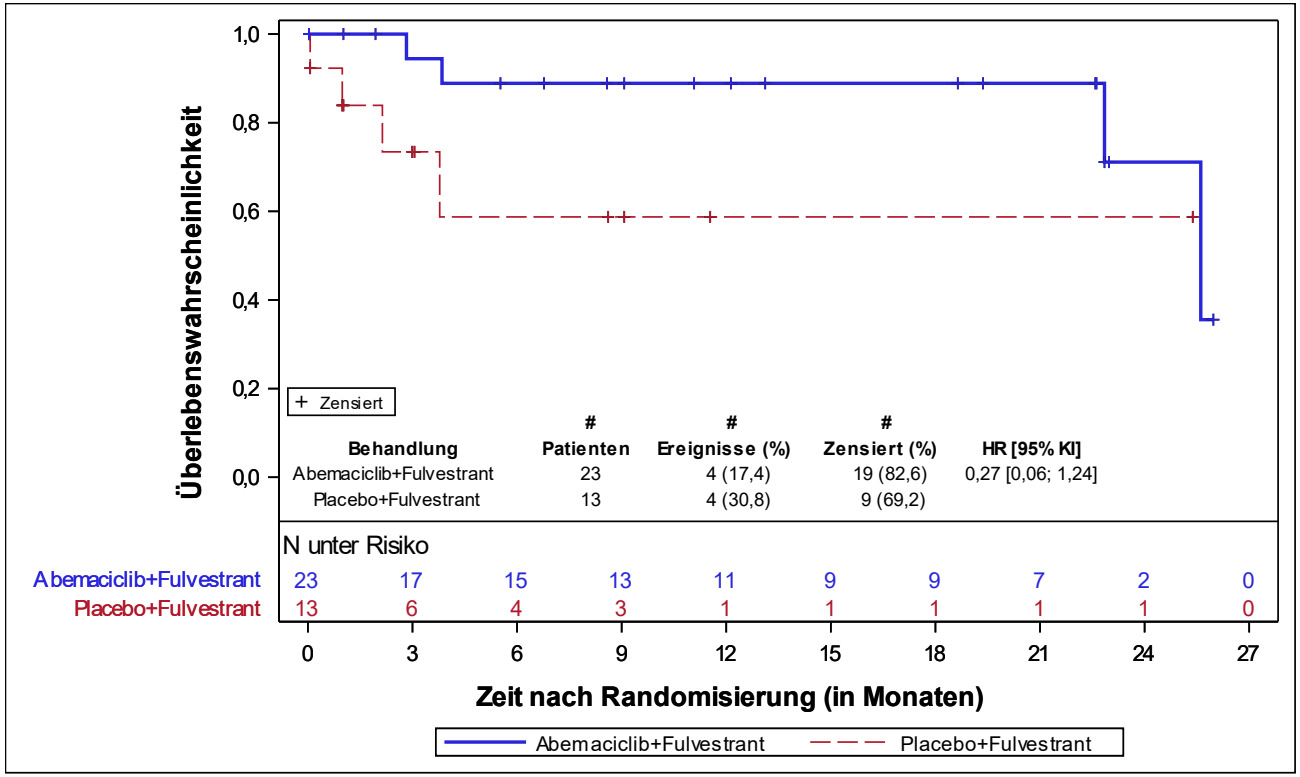
Abbildung 013.2: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte) - Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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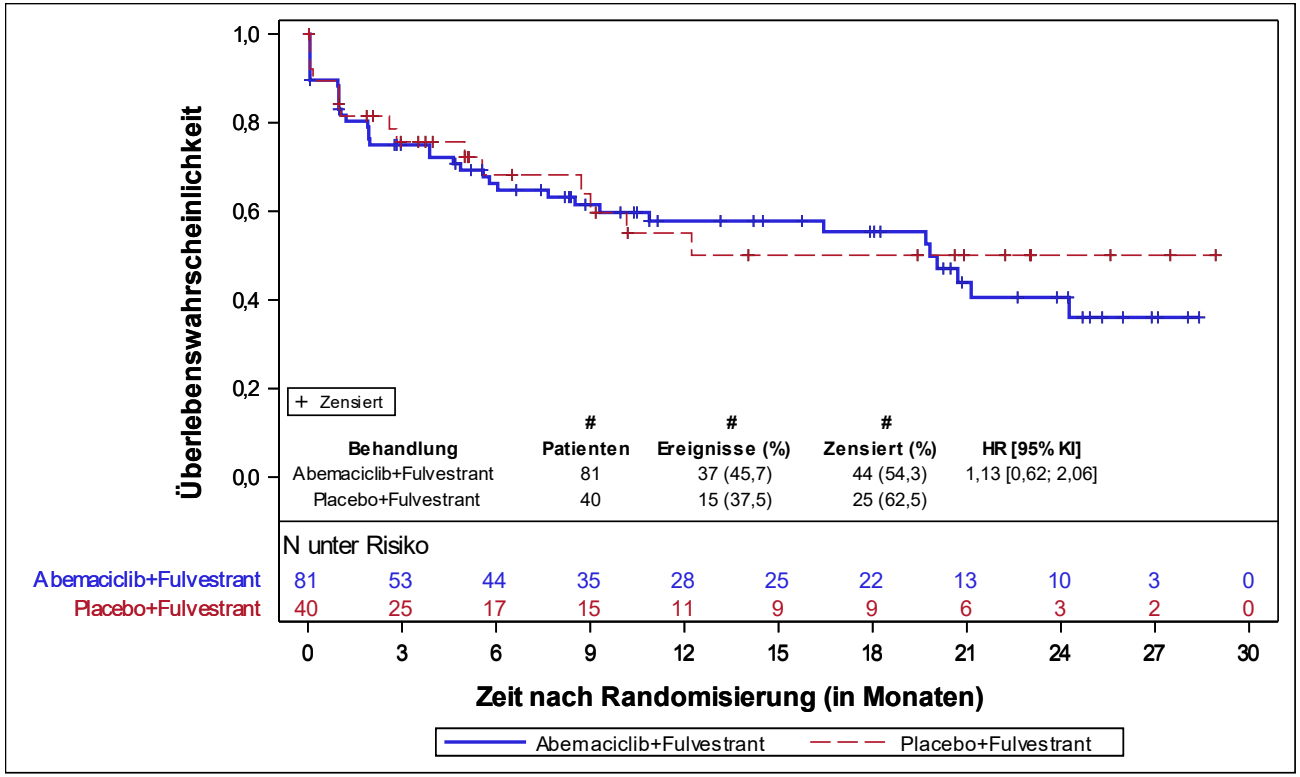
Abbildung 014.1: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte) - Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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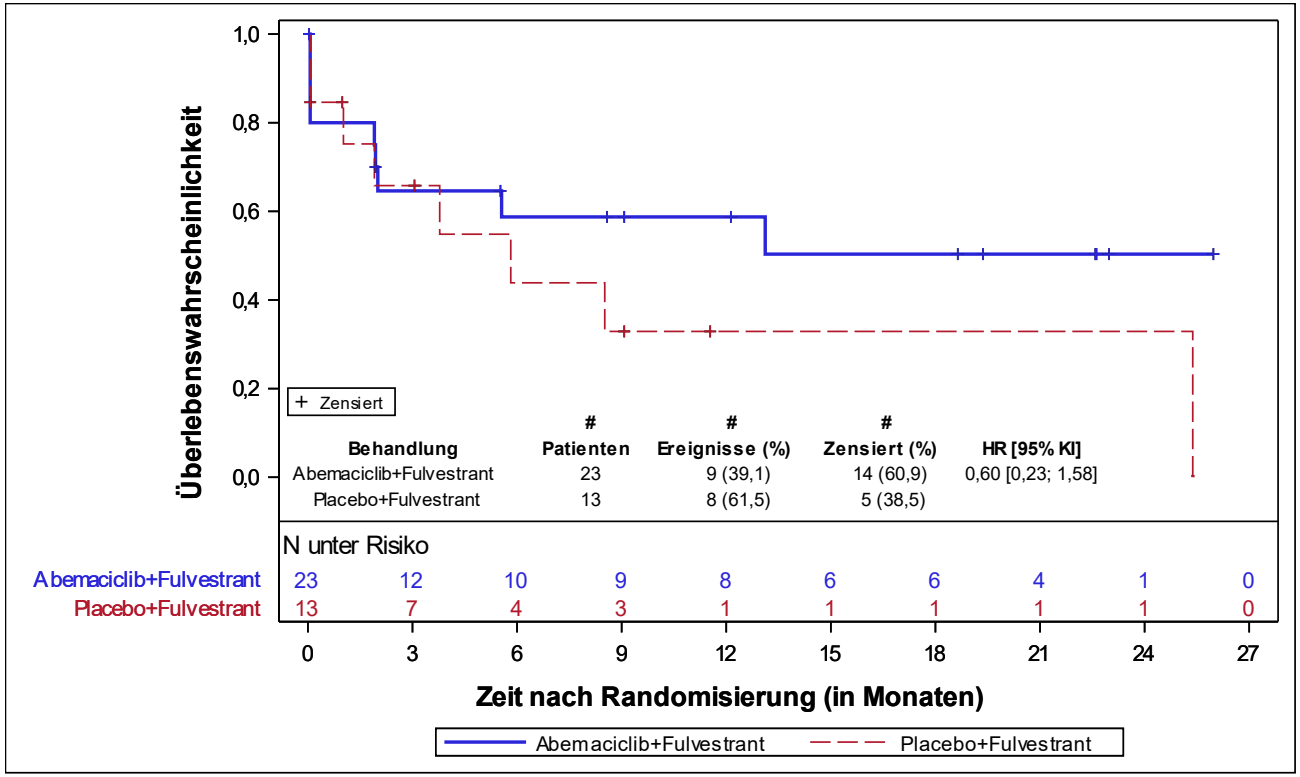
Abbildung 014.2: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte) - Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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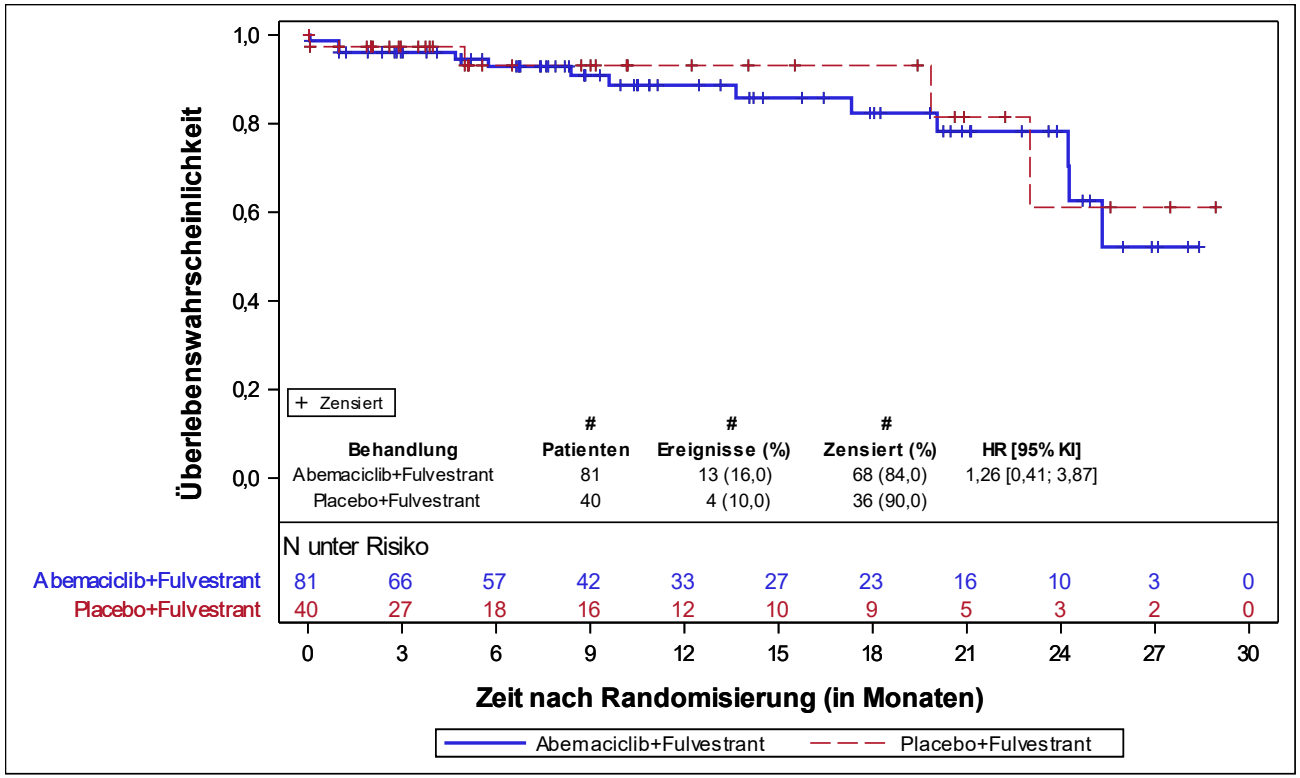
Abbildung 015.1: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte) - Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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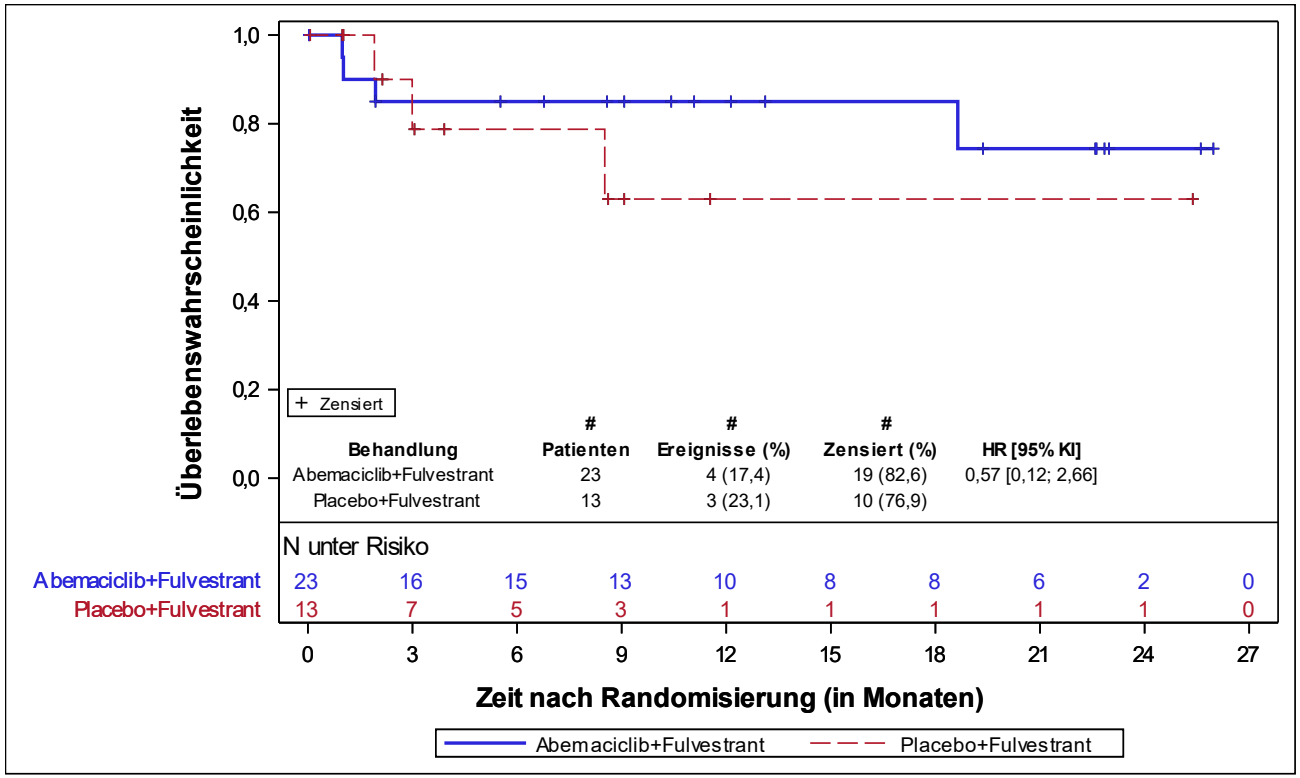
Abbildung 015.2: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte) - Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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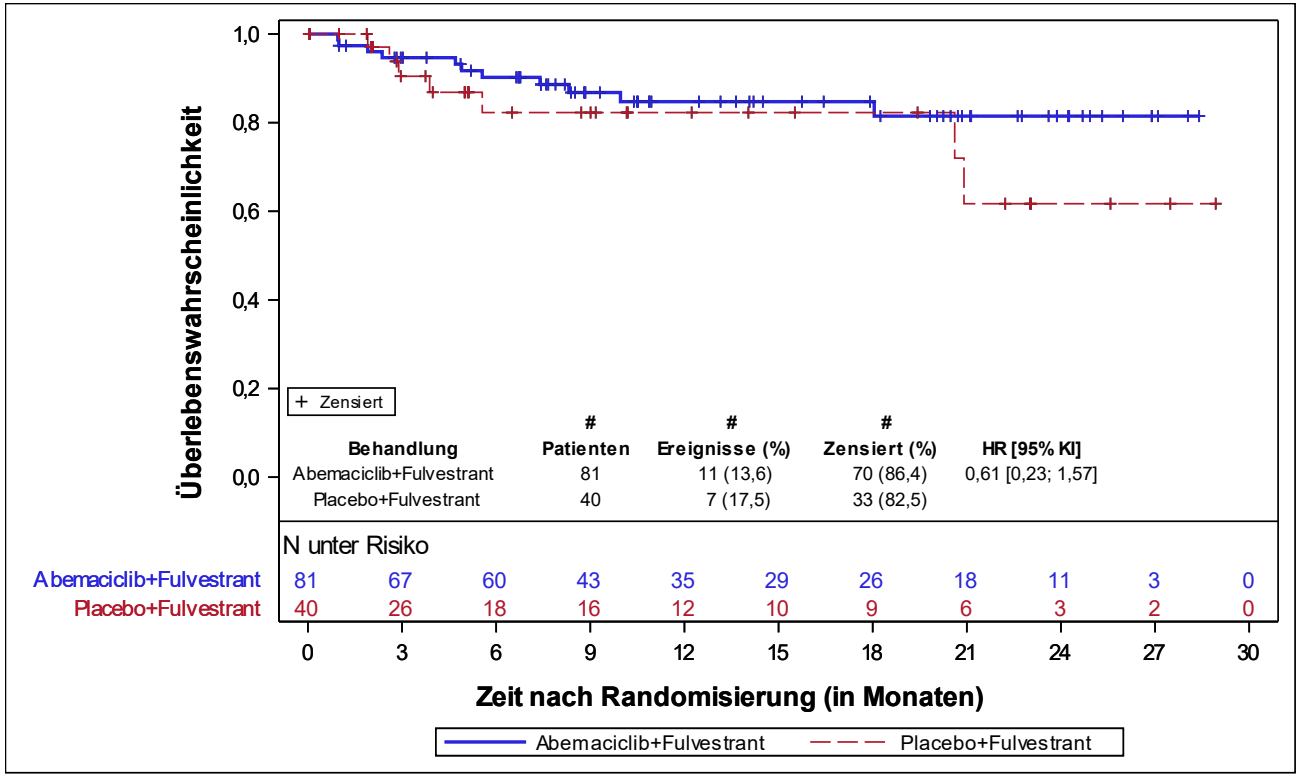
Abbildung 016.1: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte) - Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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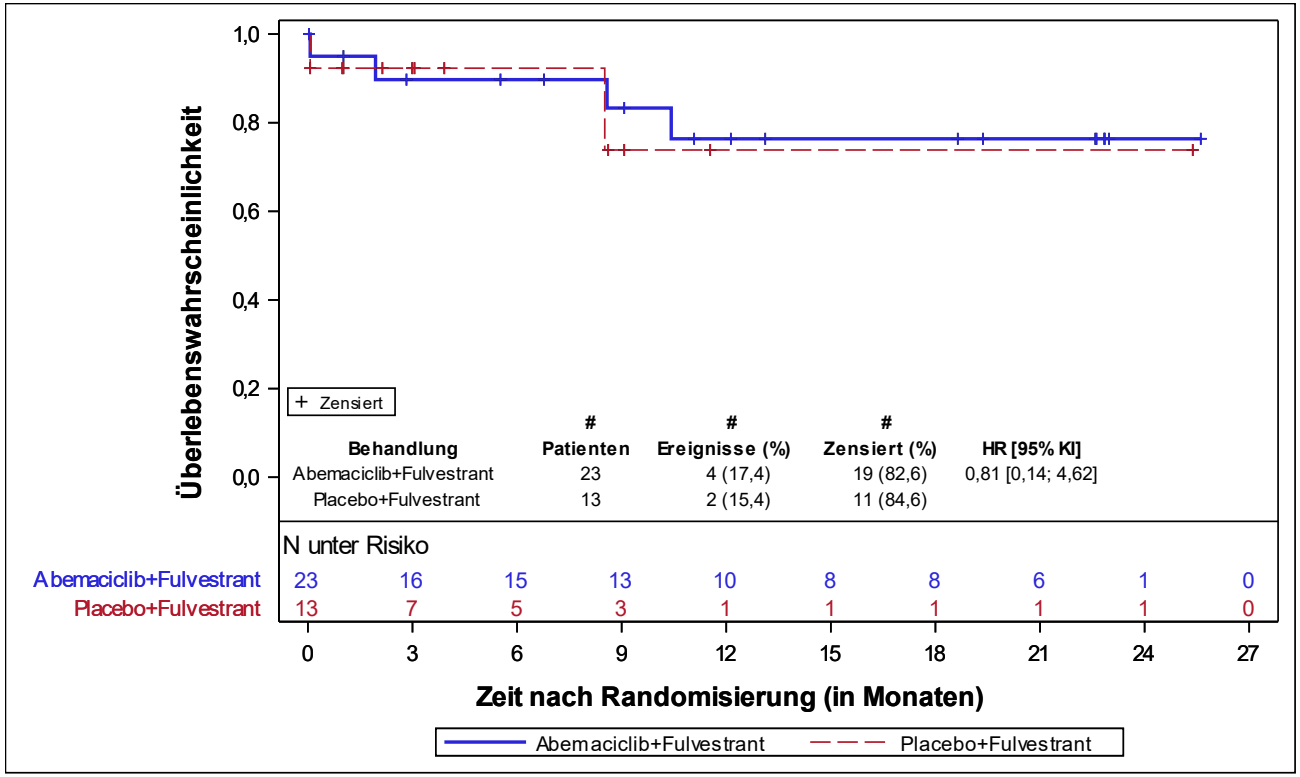
Abbildung 016.2: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte) - Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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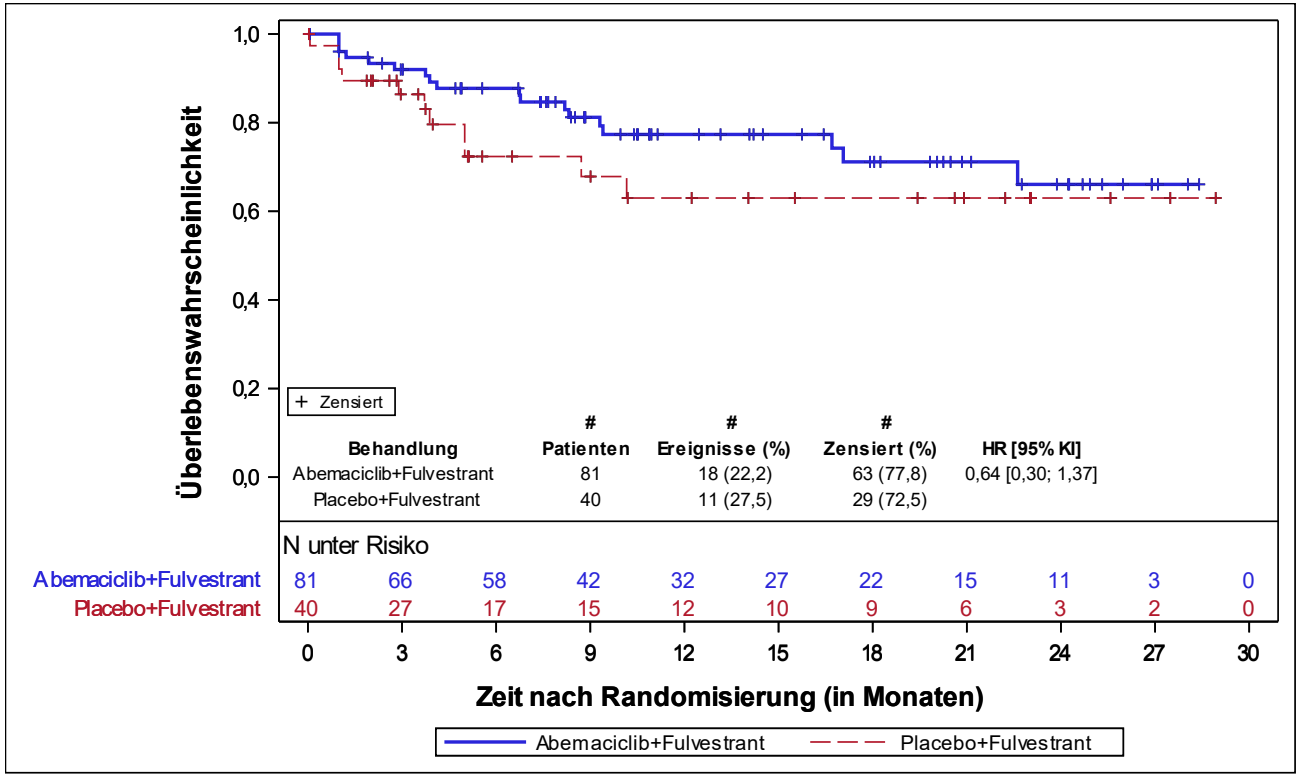
Abbildung 017.1: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte) - Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
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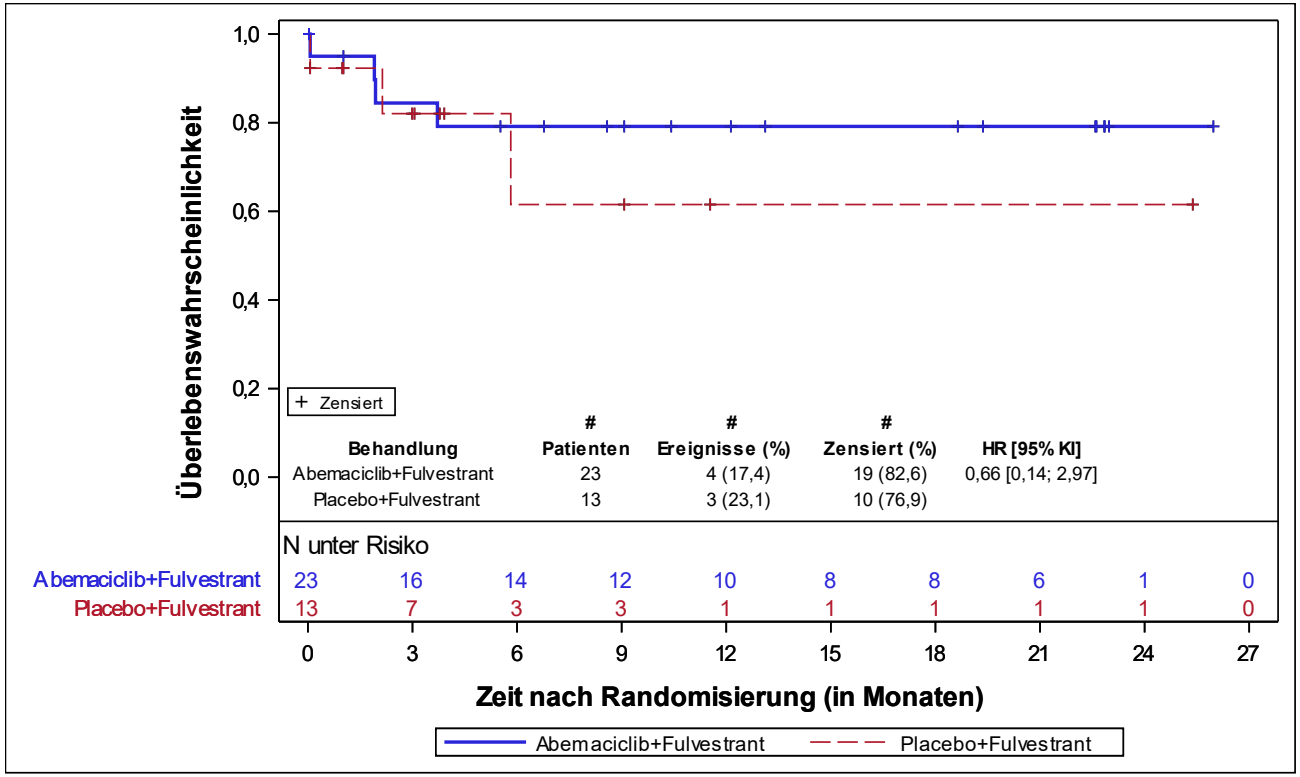
Abbildung 017.2: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte) - Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
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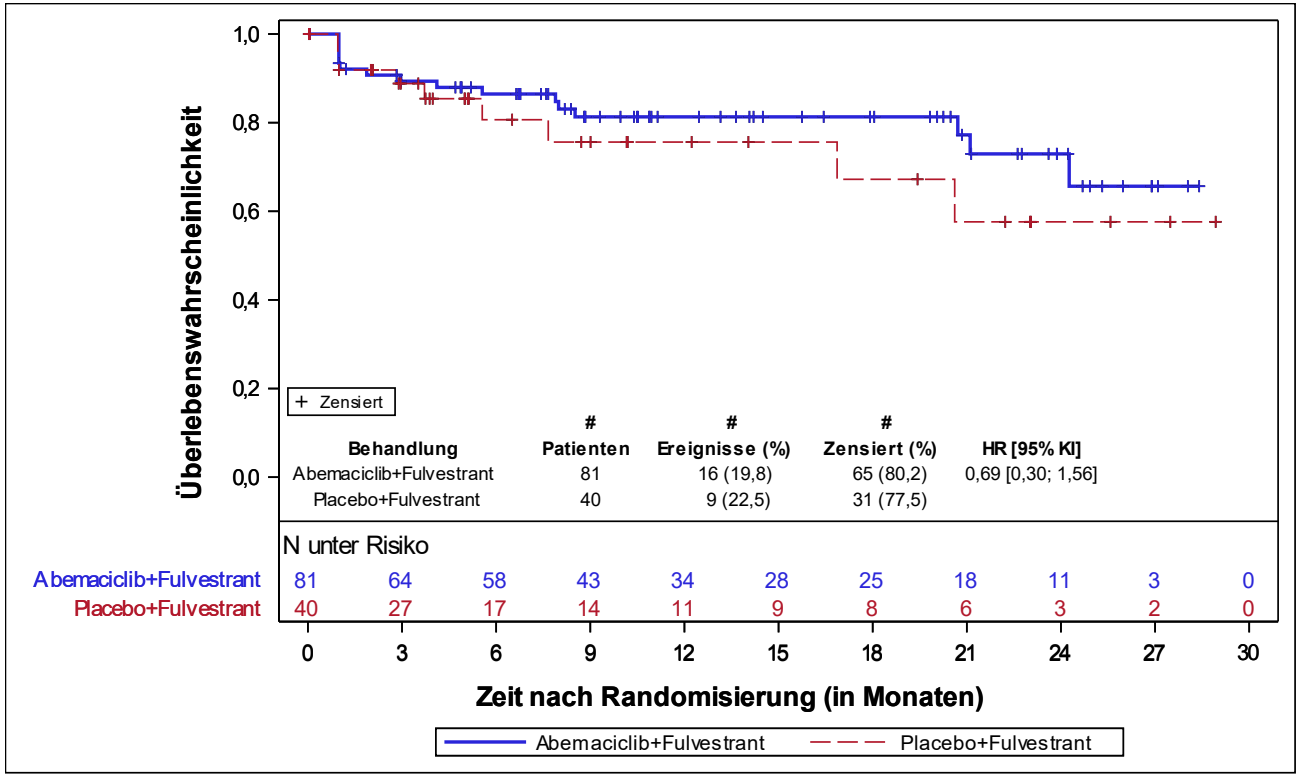
Abbildung 018.1: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte) - Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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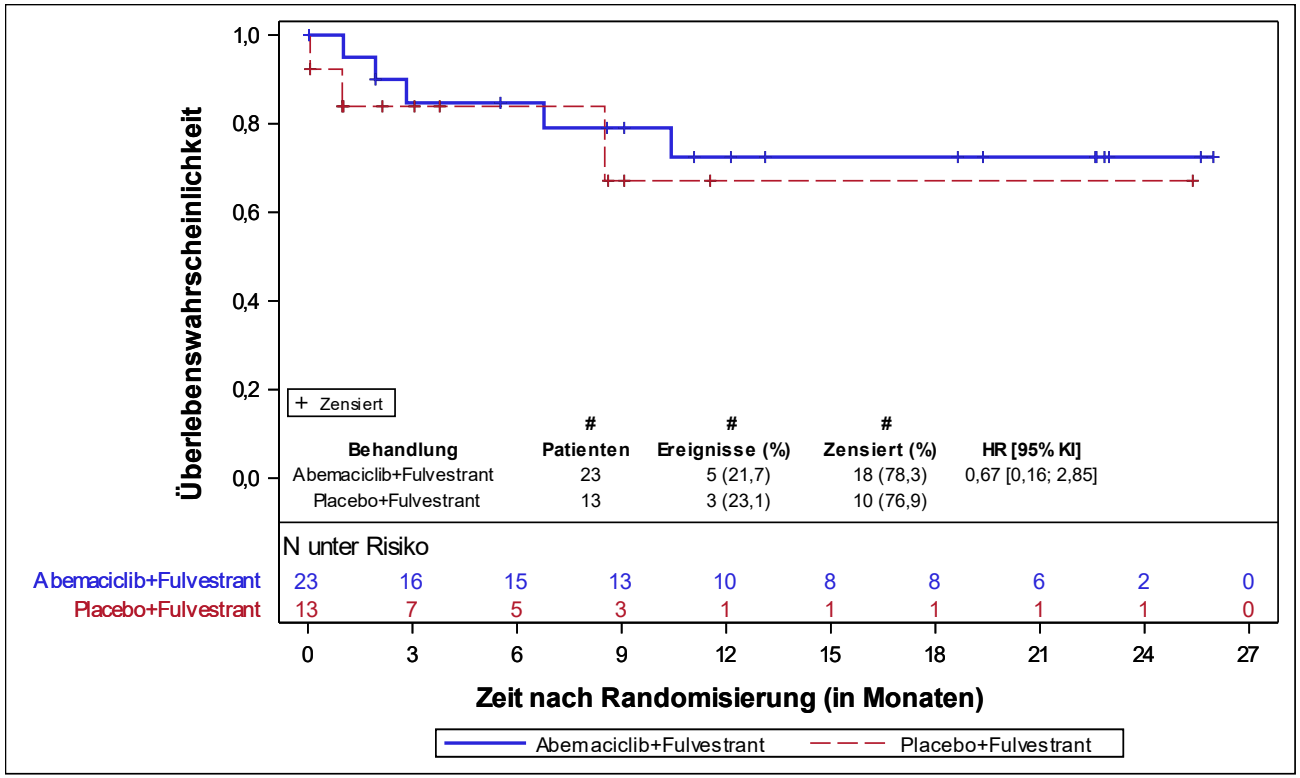
Abbildung 018.2: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte) - Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
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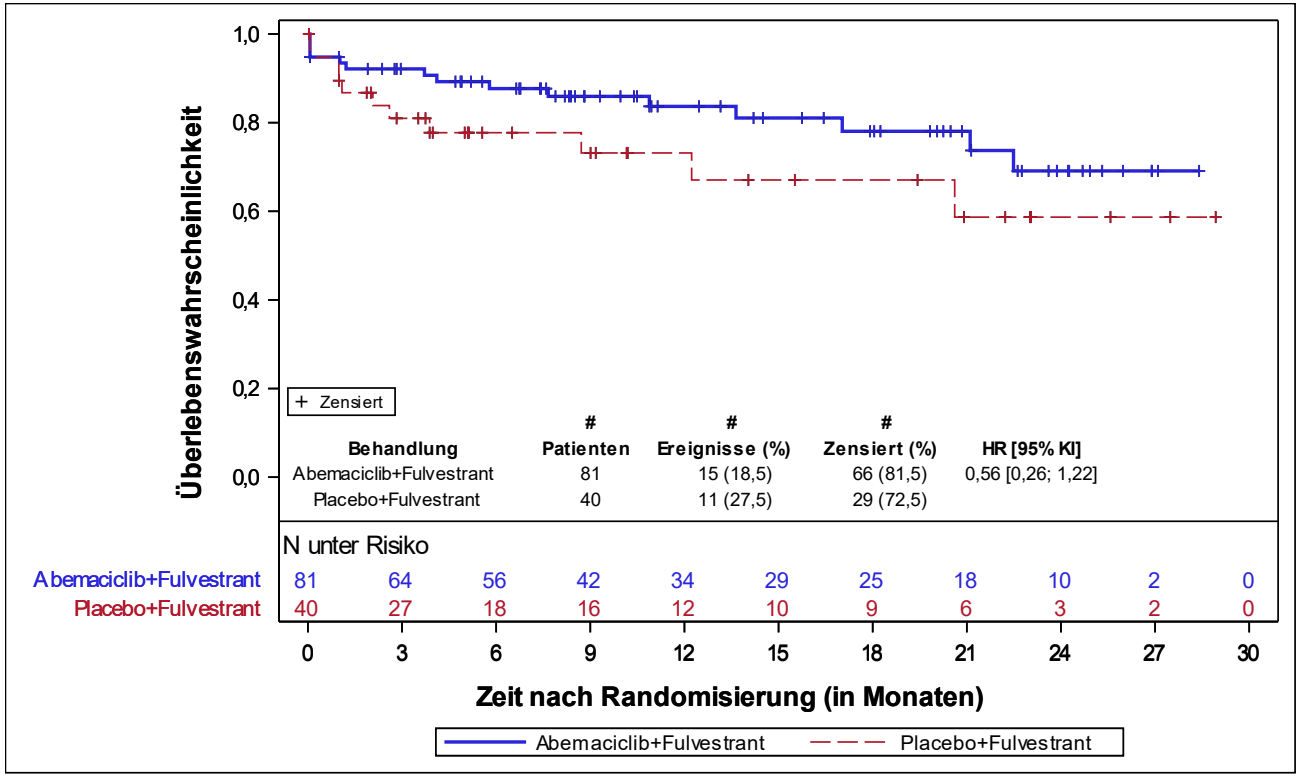
Abbildung 019.1: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte) - Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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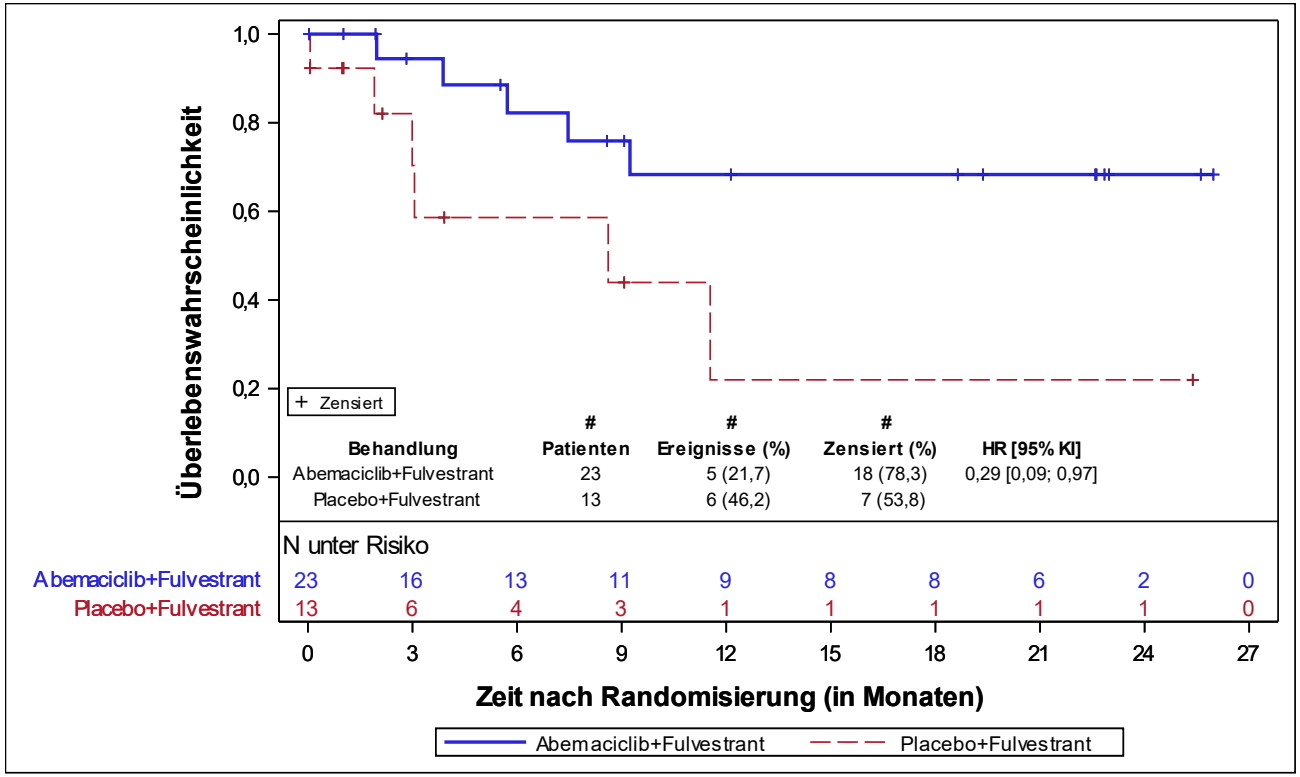
Abbildung 019.2: Kaplan-Meier-Kurven - Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte) - Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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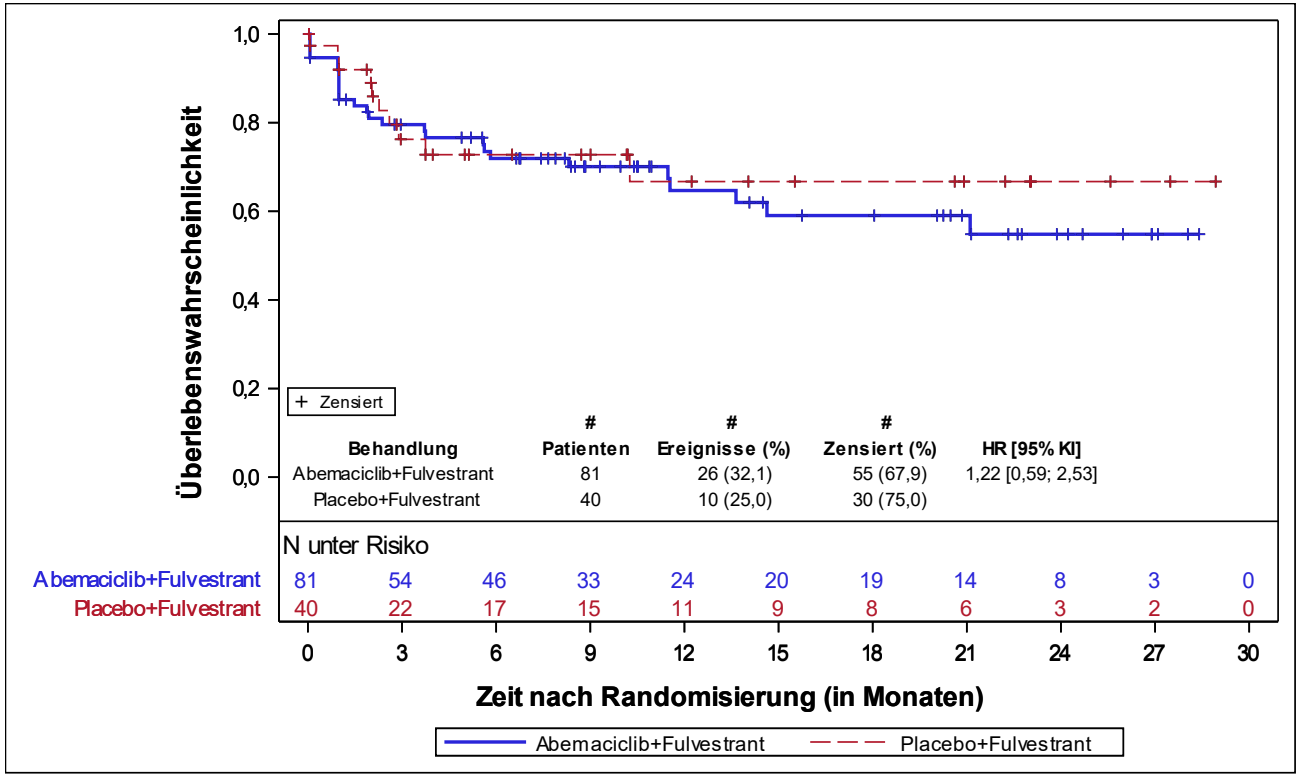
Abbildung 020.1: Kaplan-Meier-Kurven - Stärkster Schmerz in den letzten 24 Stunden - Anstieg des Scores um ≥2 Punkte gegenüber der Baseline Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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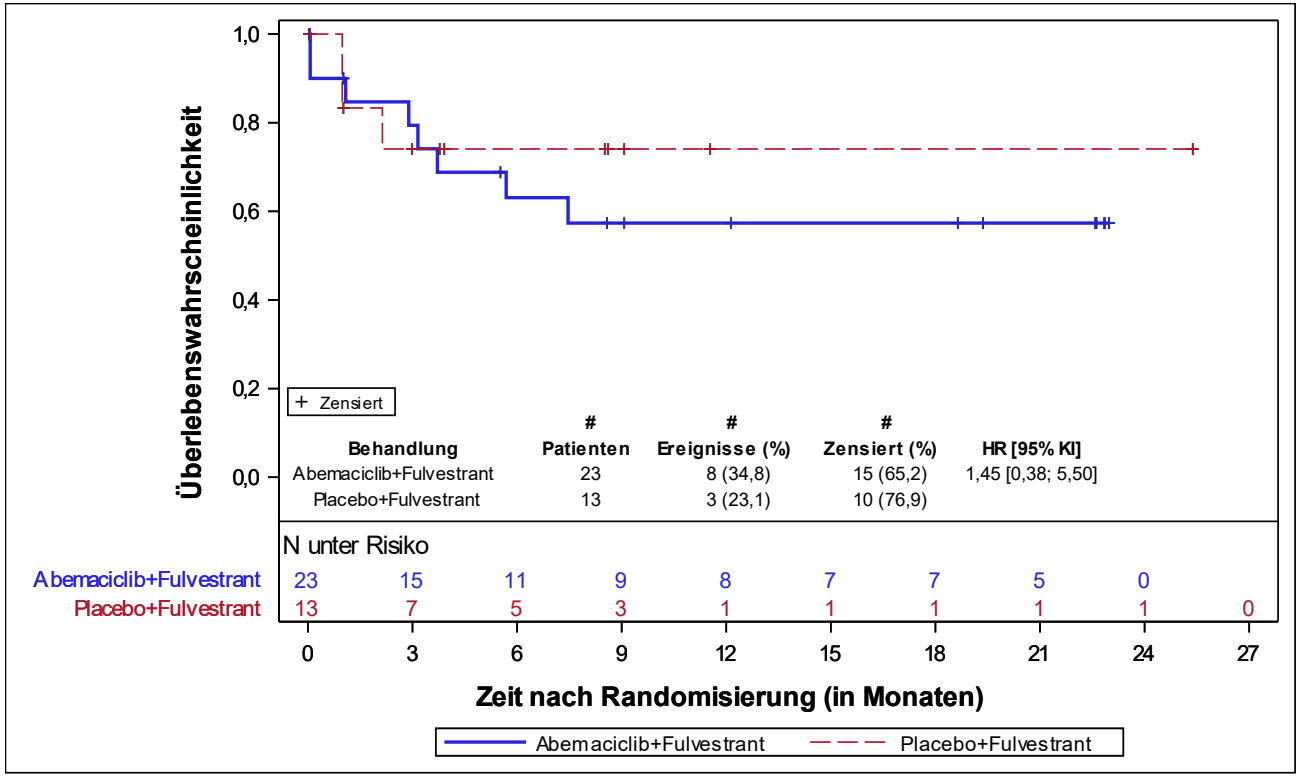
Abbildung 020.2: Kaplan-Meier-Kurven - Stärkster Schmerz in den letzten 24 Stunden - Anstieg des Scores um ≥2 Punkte gegenüber der Baseline Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; N: Anzahl der Patienten; #: Anzahl.
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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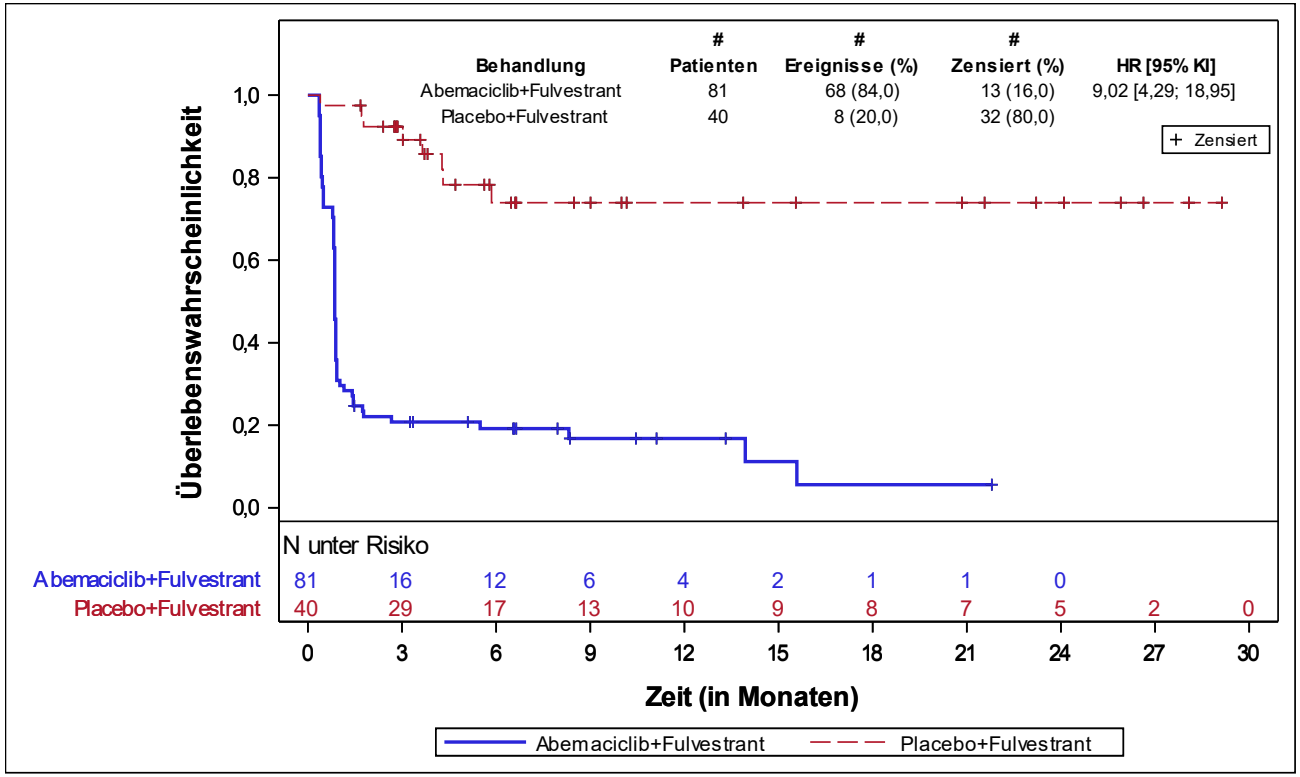
Abbildung 154 (Anhang): Kaplan-Meier-Kurven für UESI (MONARCH-plus)

Abbildung 026.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad)
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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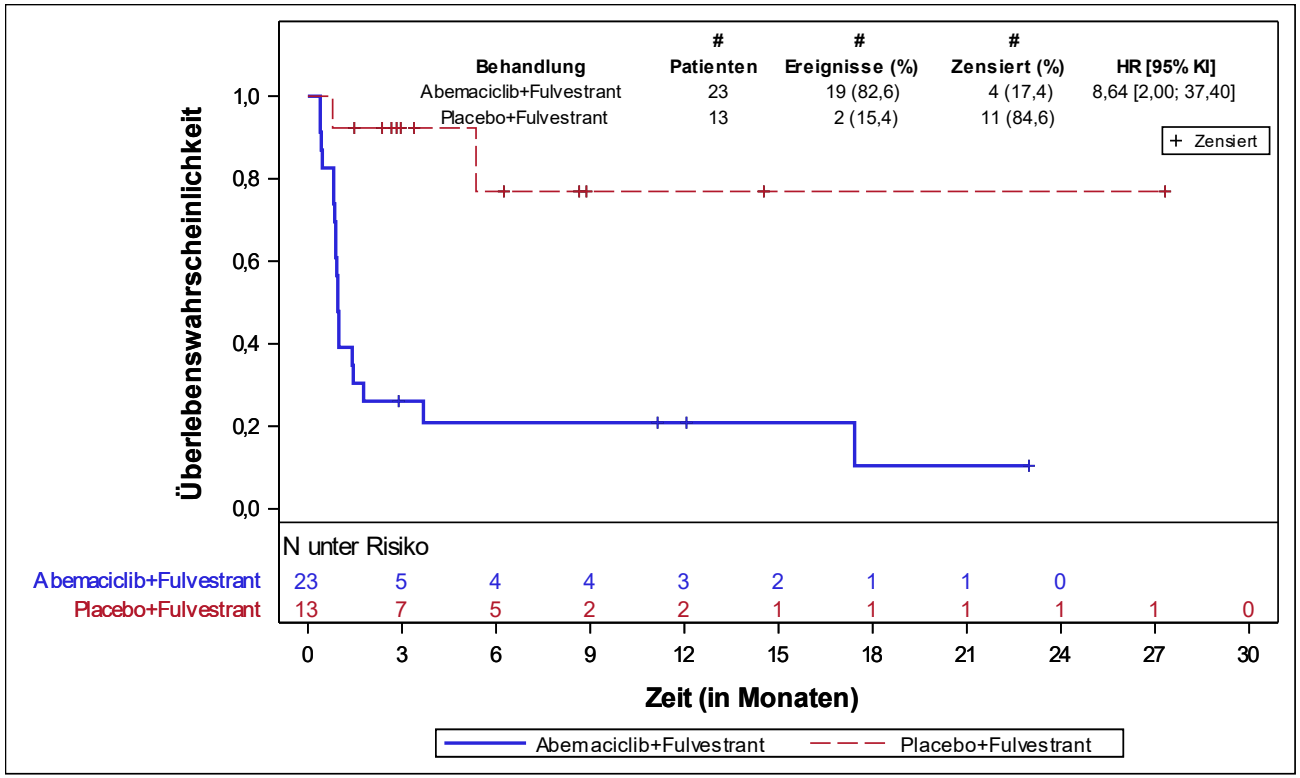
Abbildung 026.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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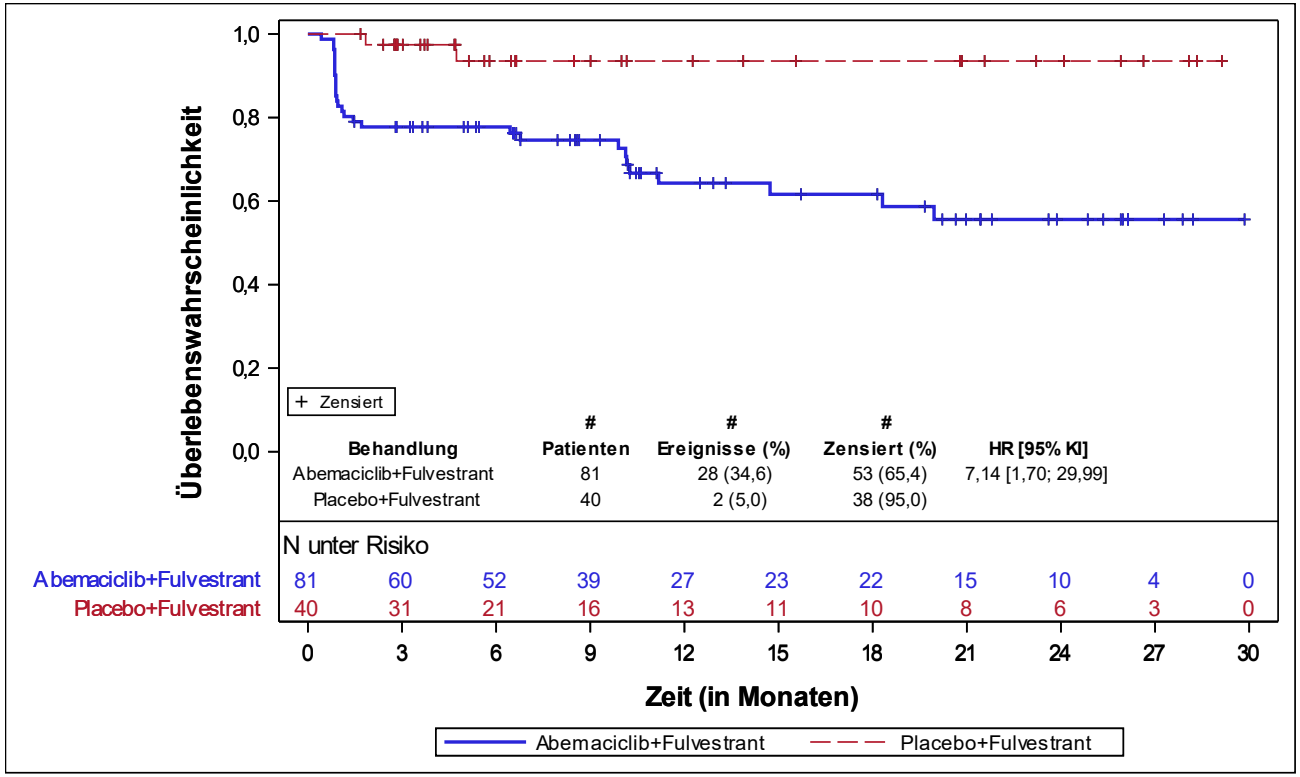
Abbildung 027.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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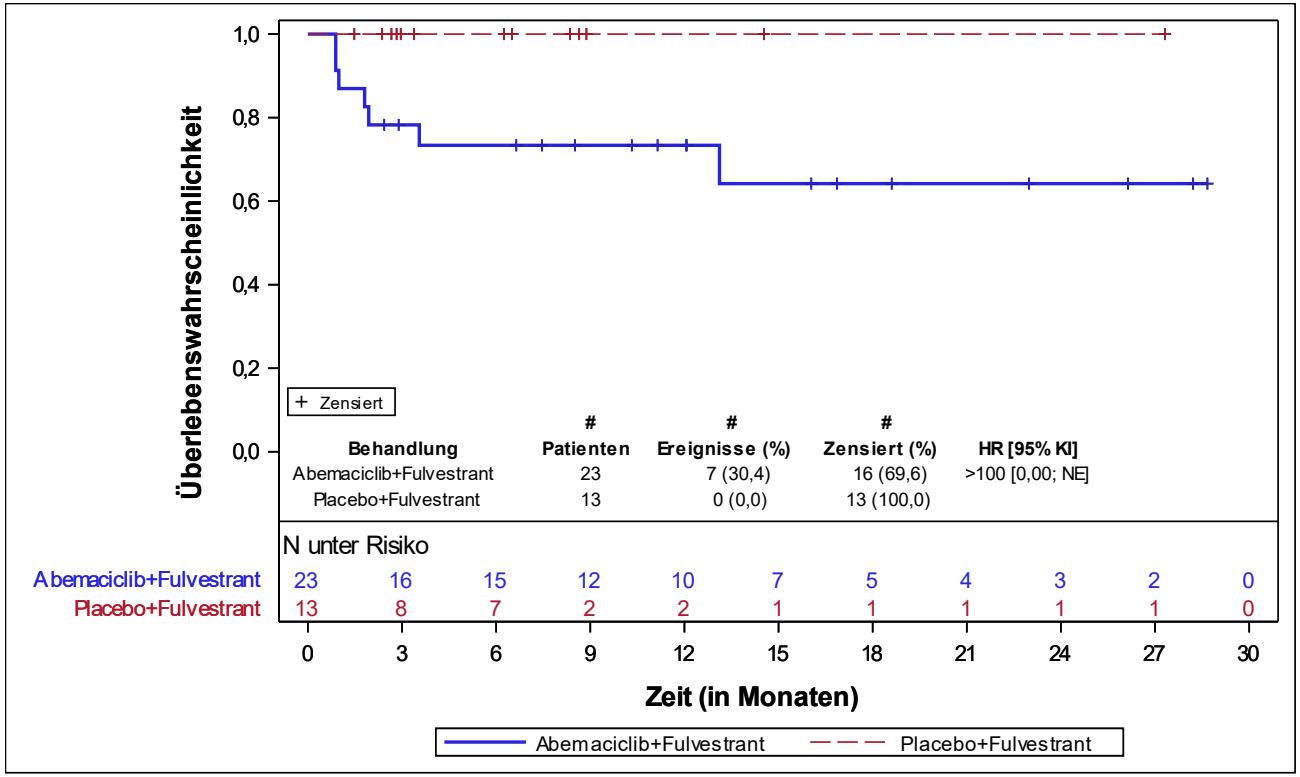
Abbildung 027.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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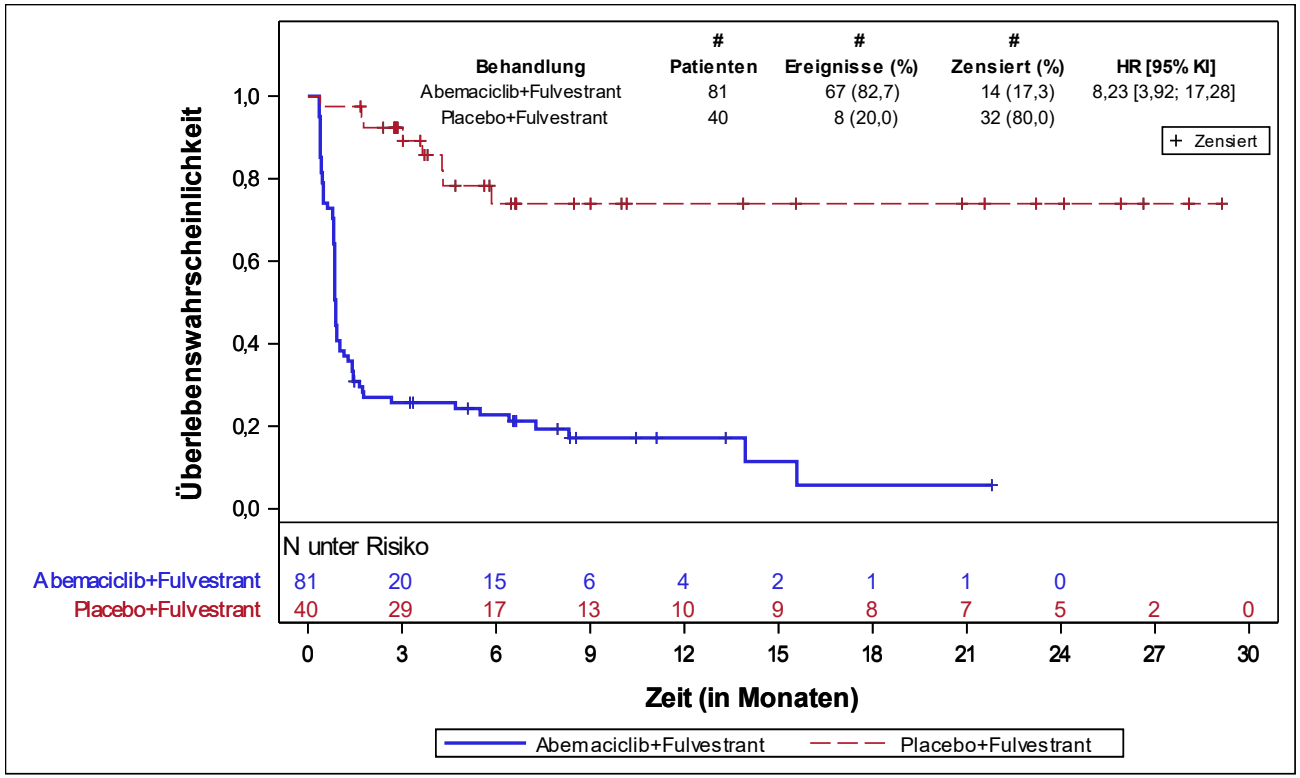
Abbildung 028.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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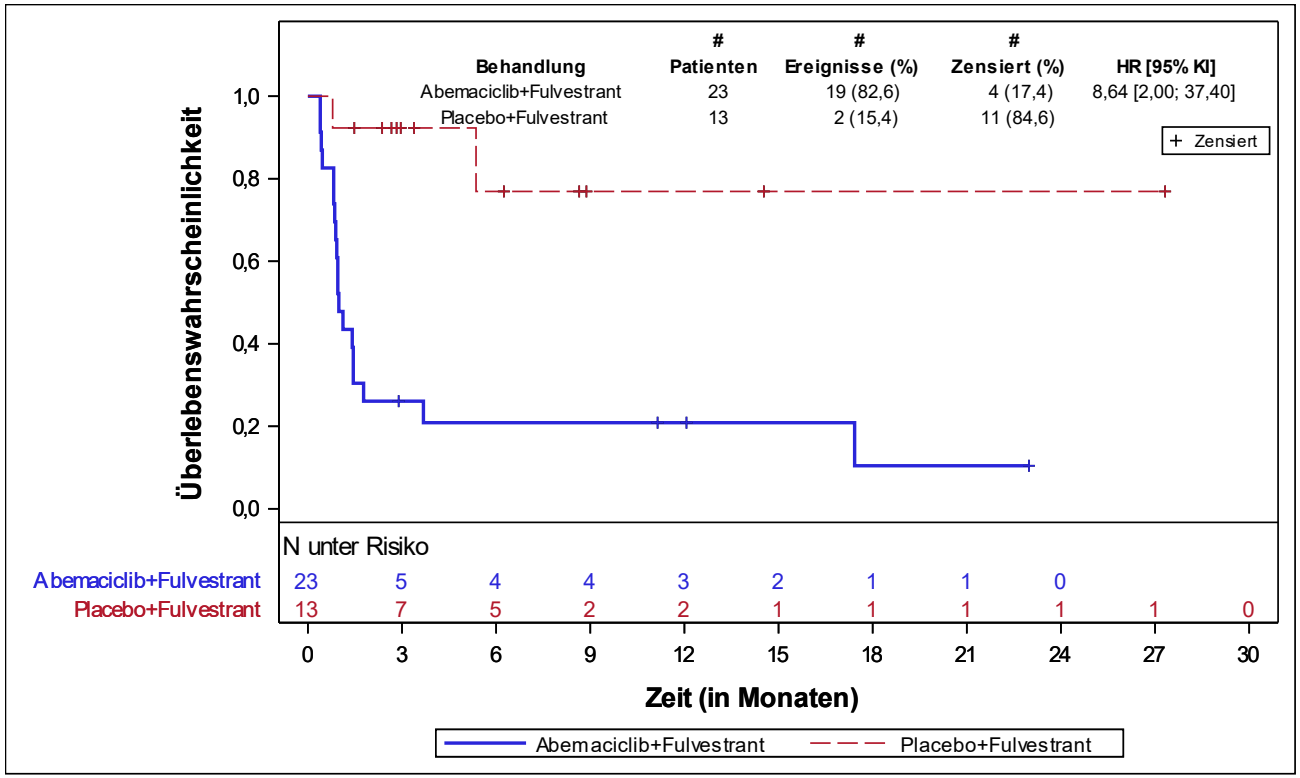
Abbildung 028.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/f_gba_ae_km.sas
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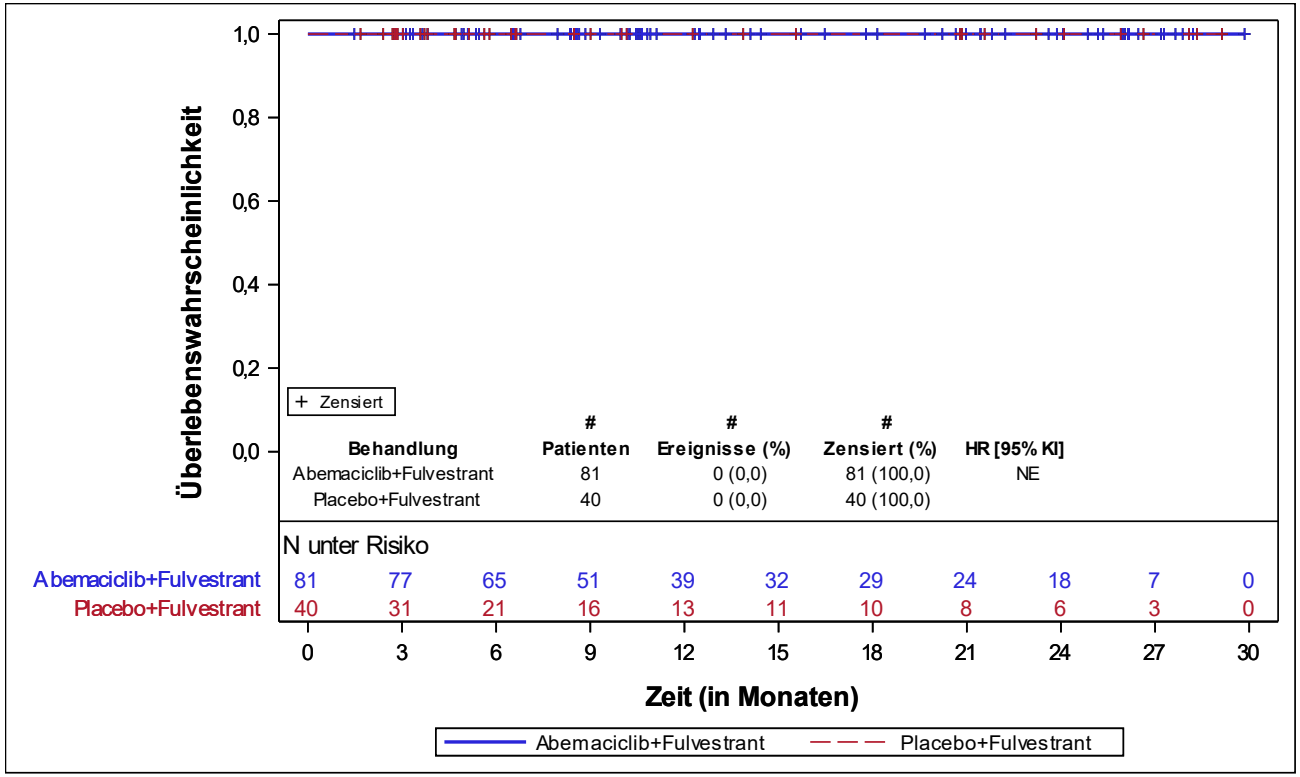
Abbildung 029.1: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: Neutropenie Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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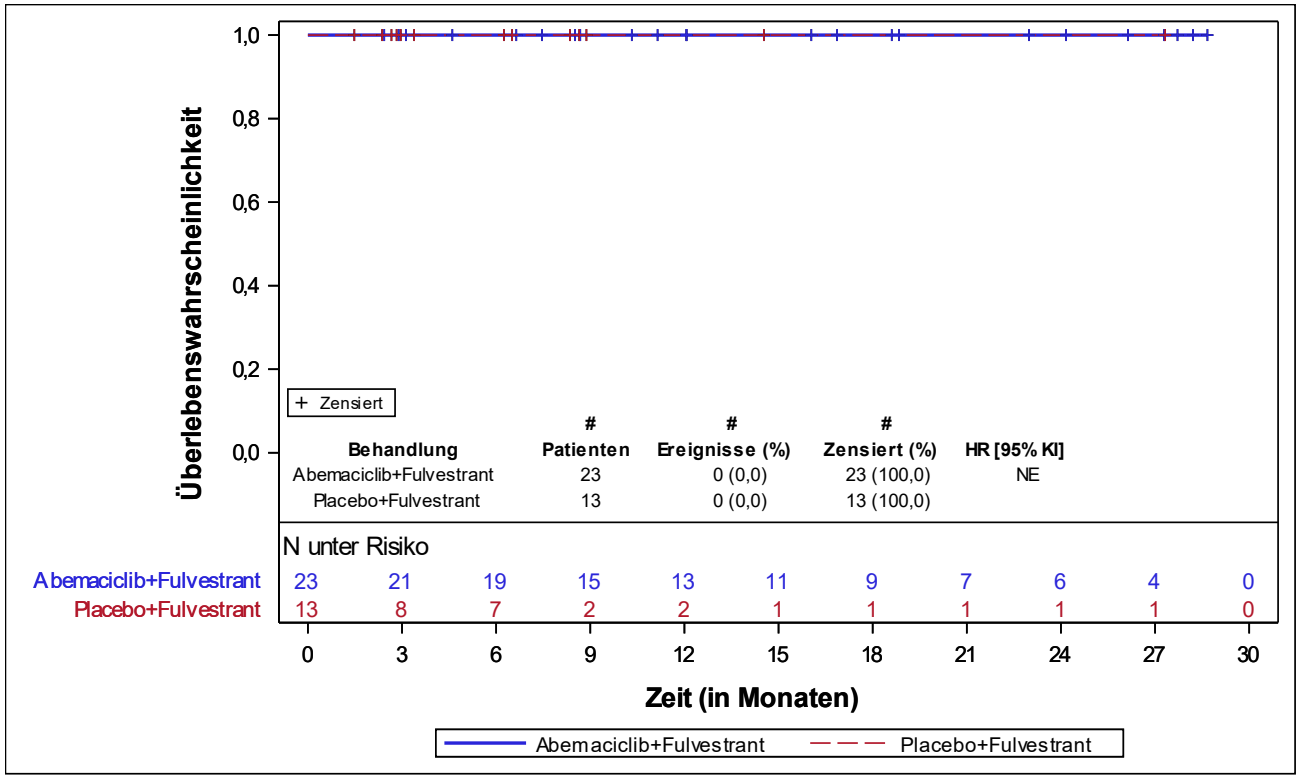
Abbildung 029.2: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: Neutropenie Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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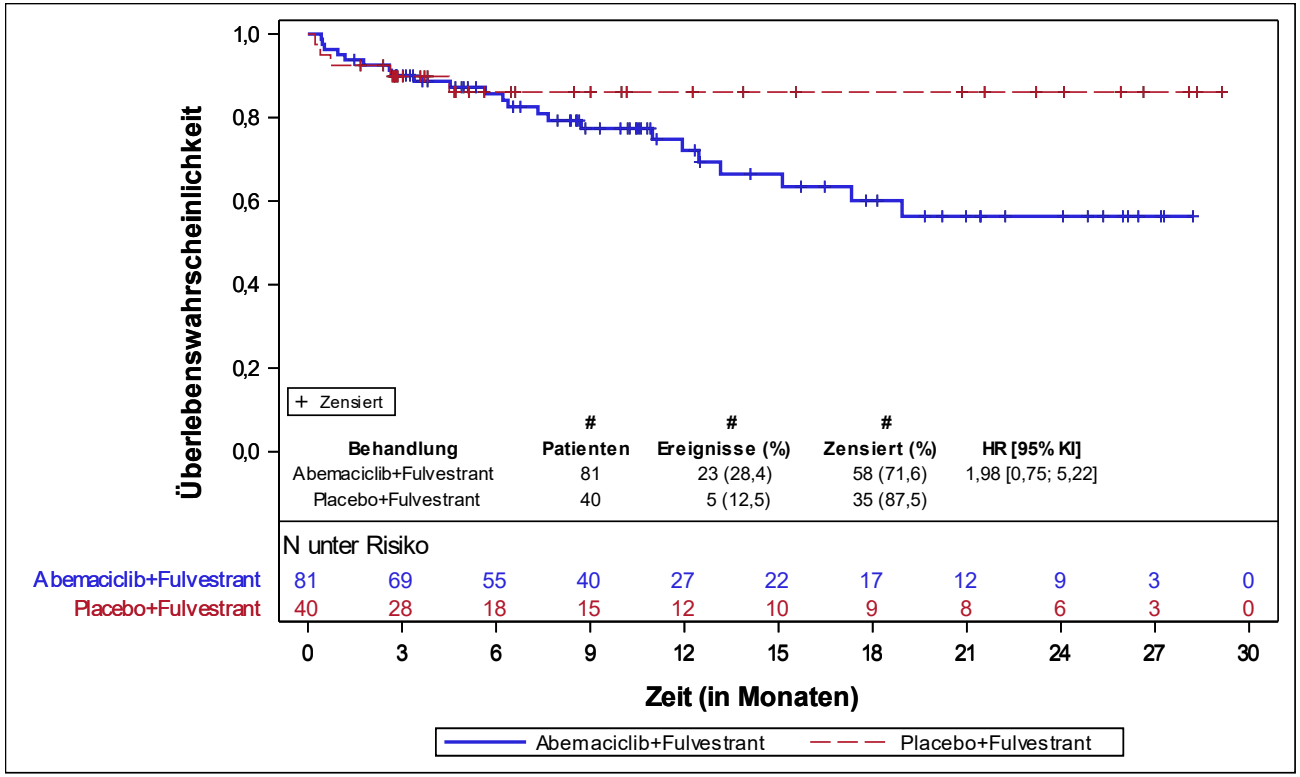
Abbildung 030.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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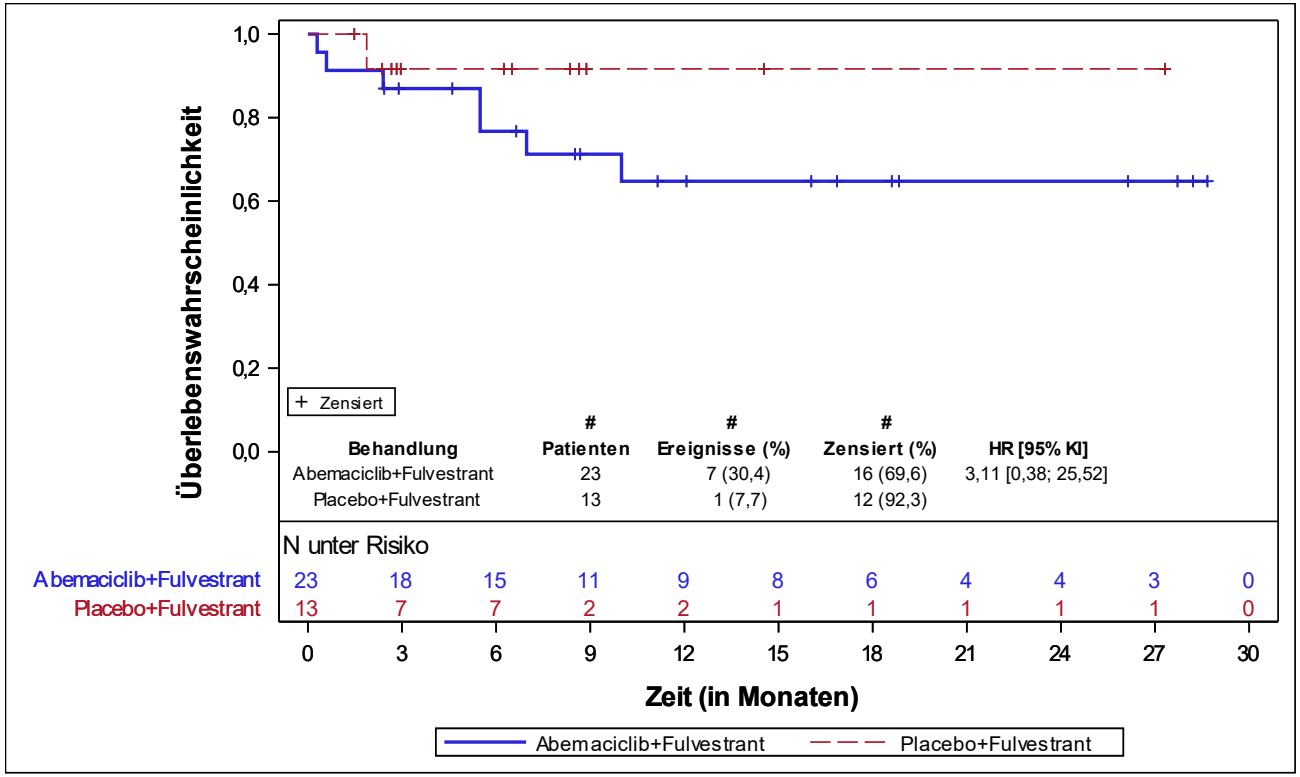
Abbildung 030.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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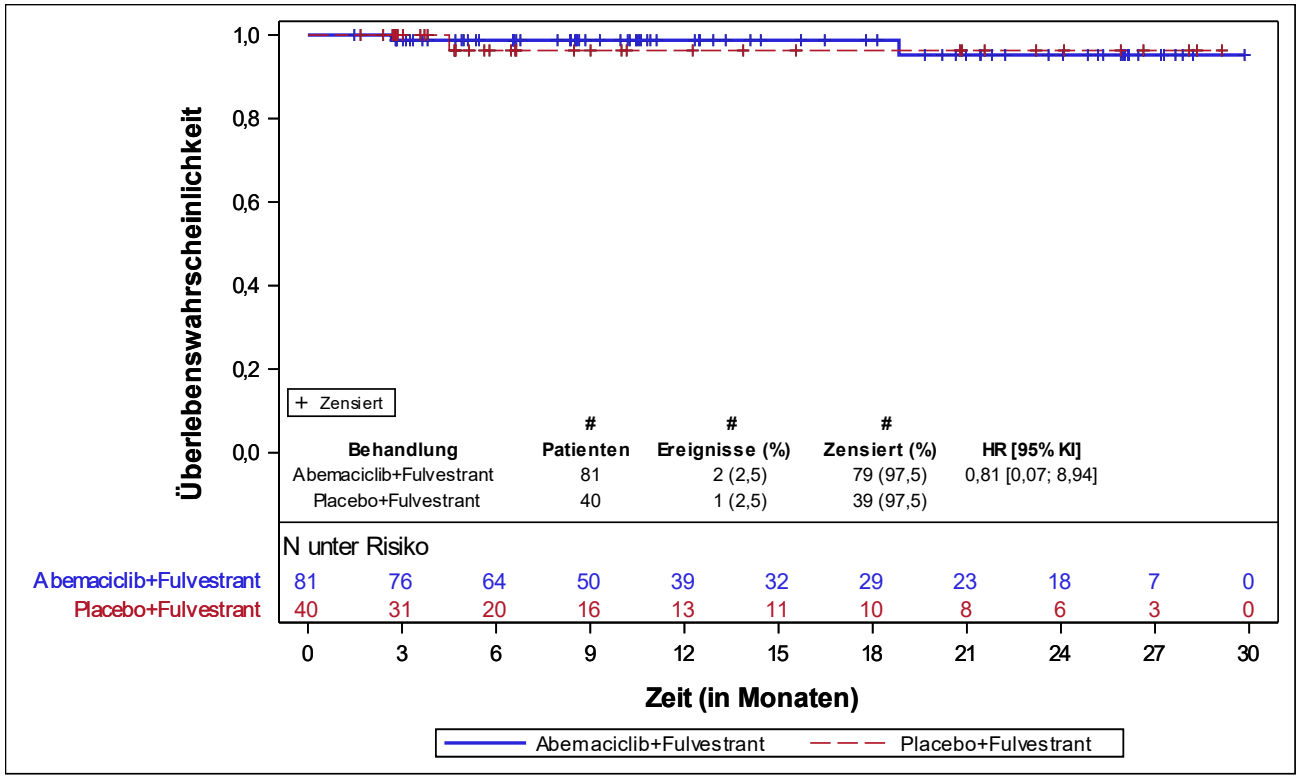
Abbildung 031.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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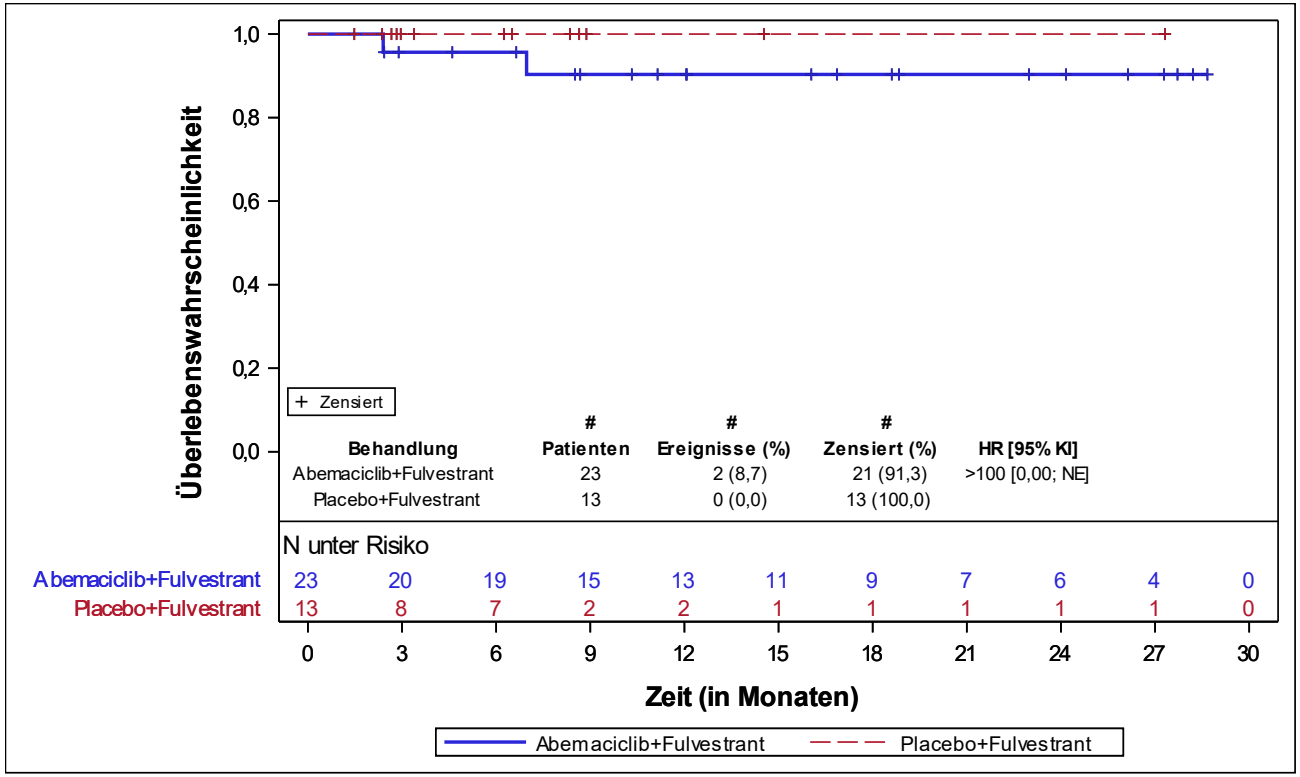
Abbildung 031.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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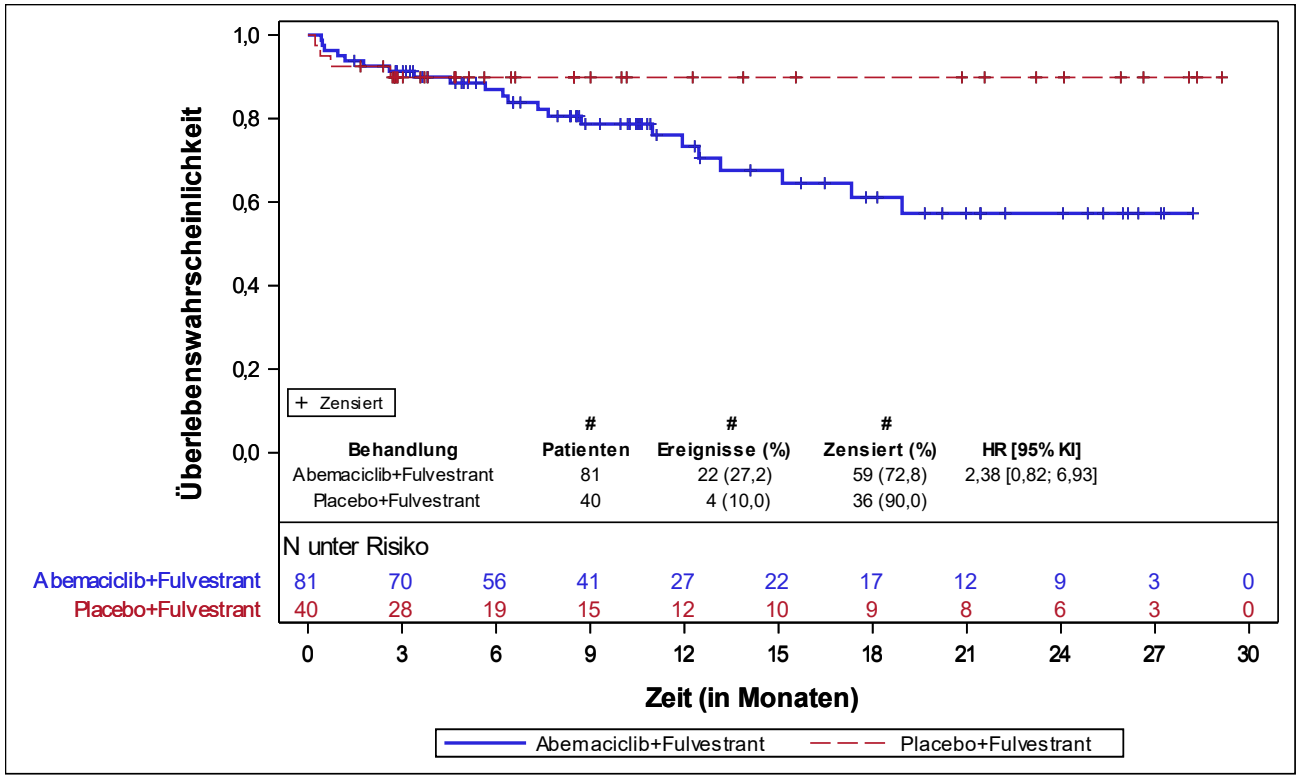
Abbildung 032.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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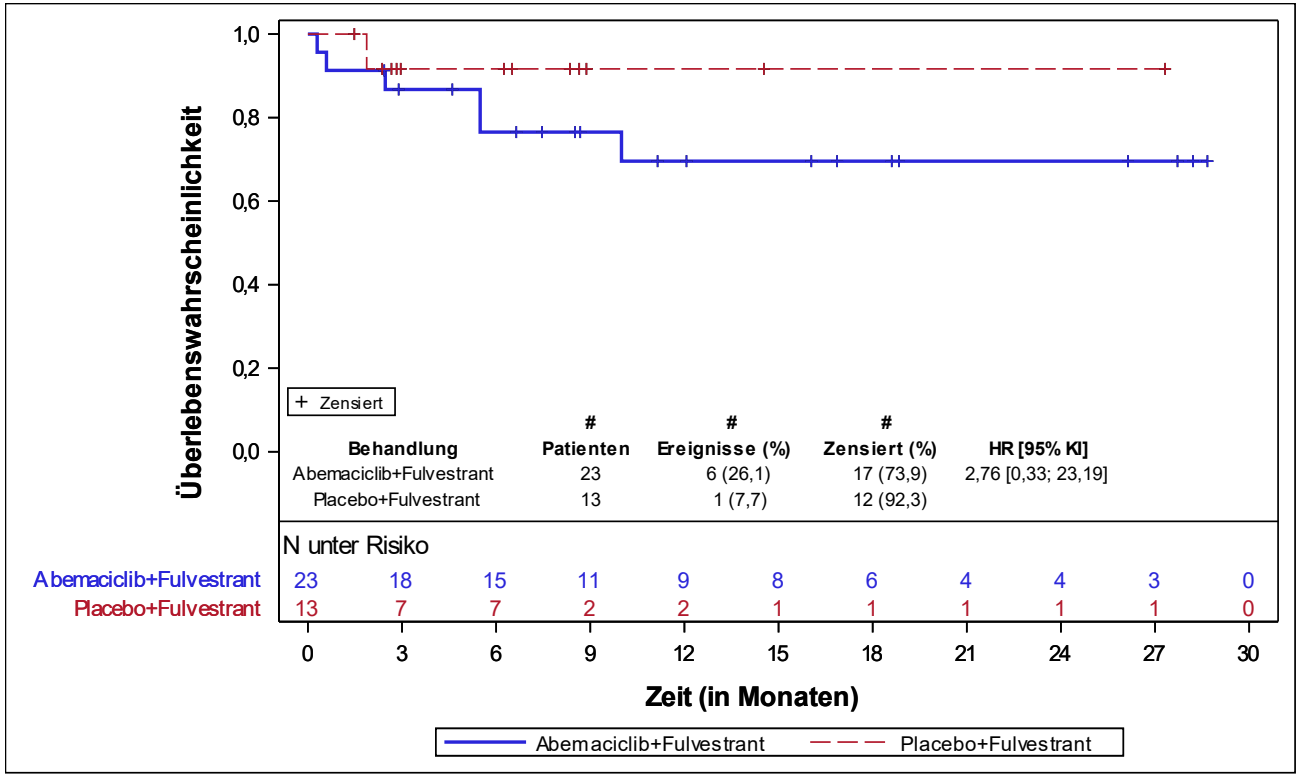
Abbildung 032.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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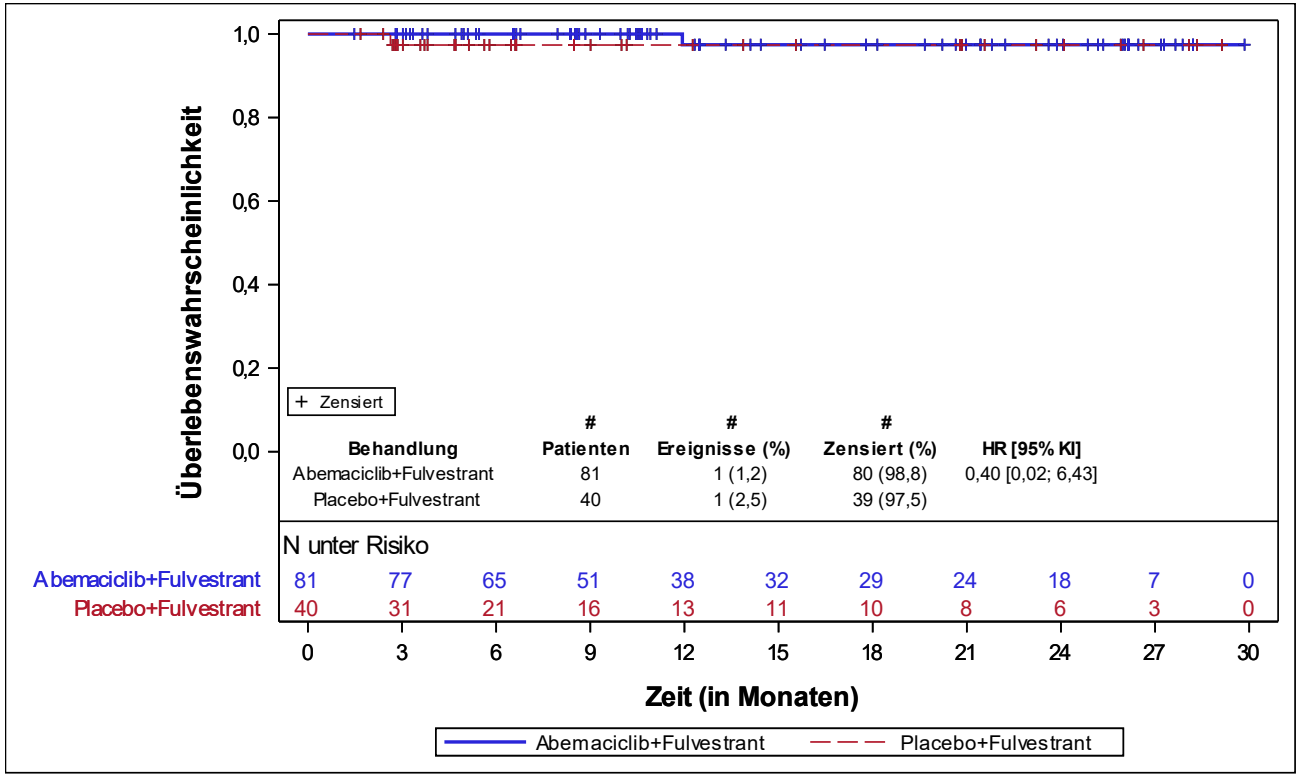
Abbildung 033.1: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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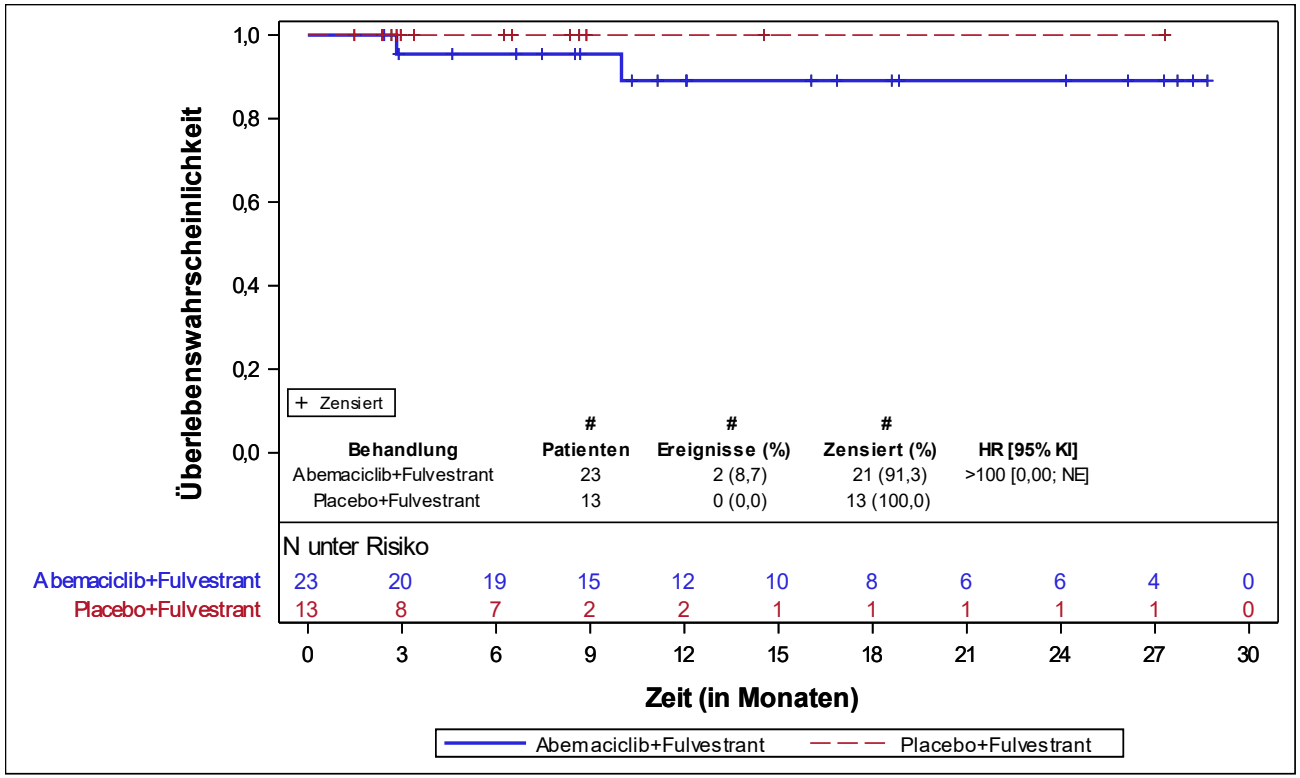
Abbildung 033.2: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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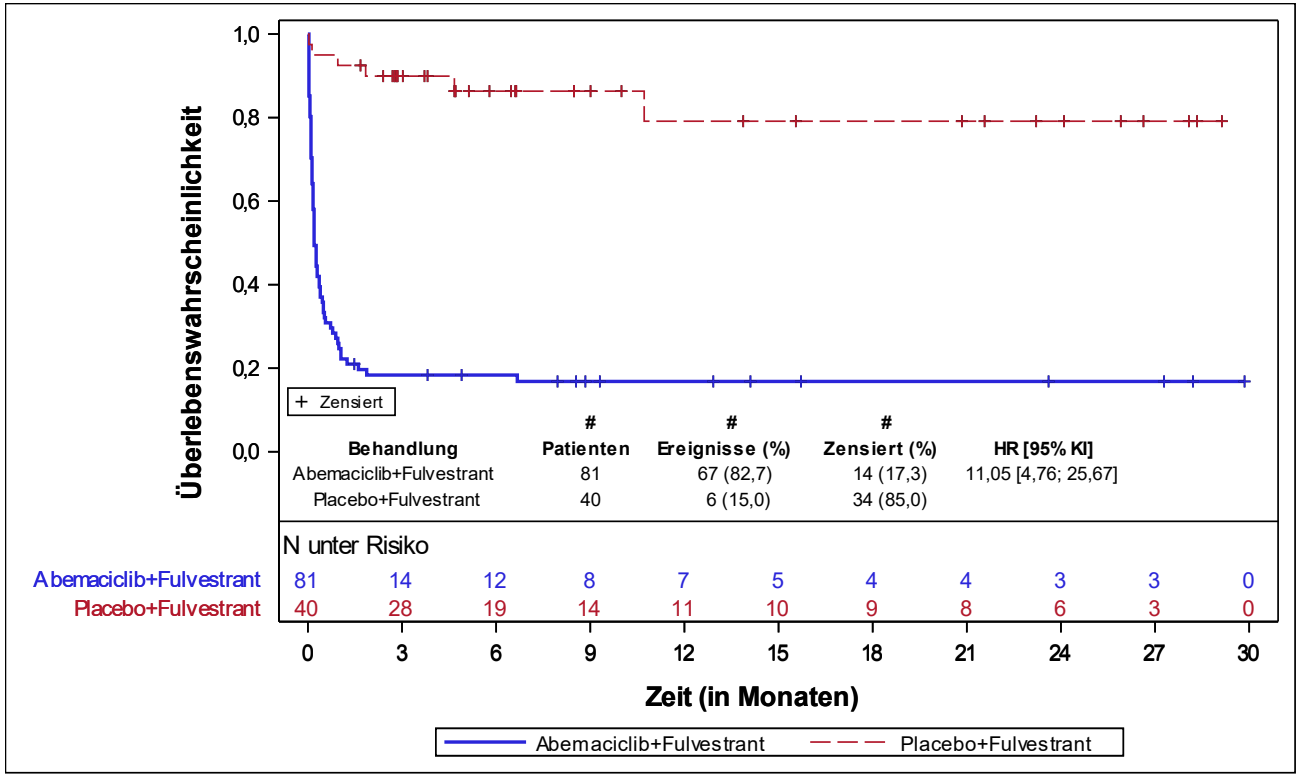
Abbildung 034.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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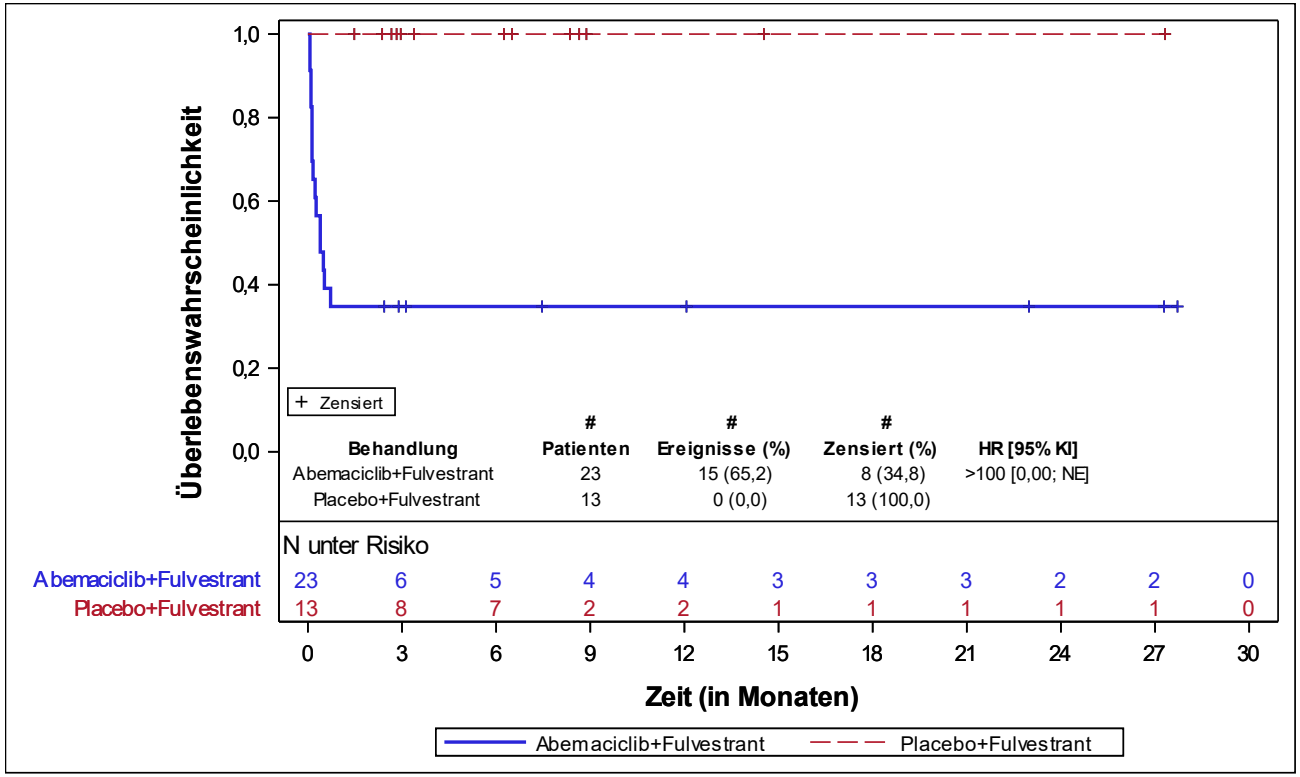
Abbildung 034.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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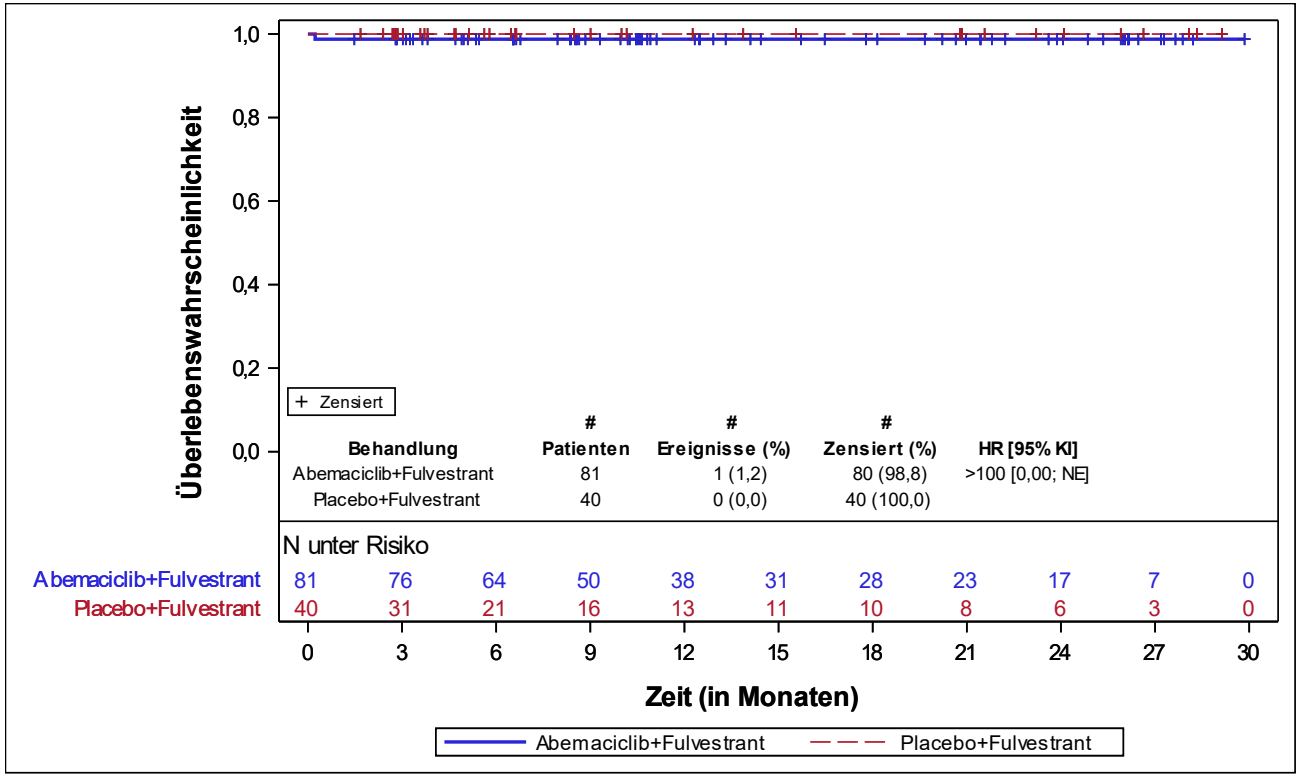
Abbildung 035.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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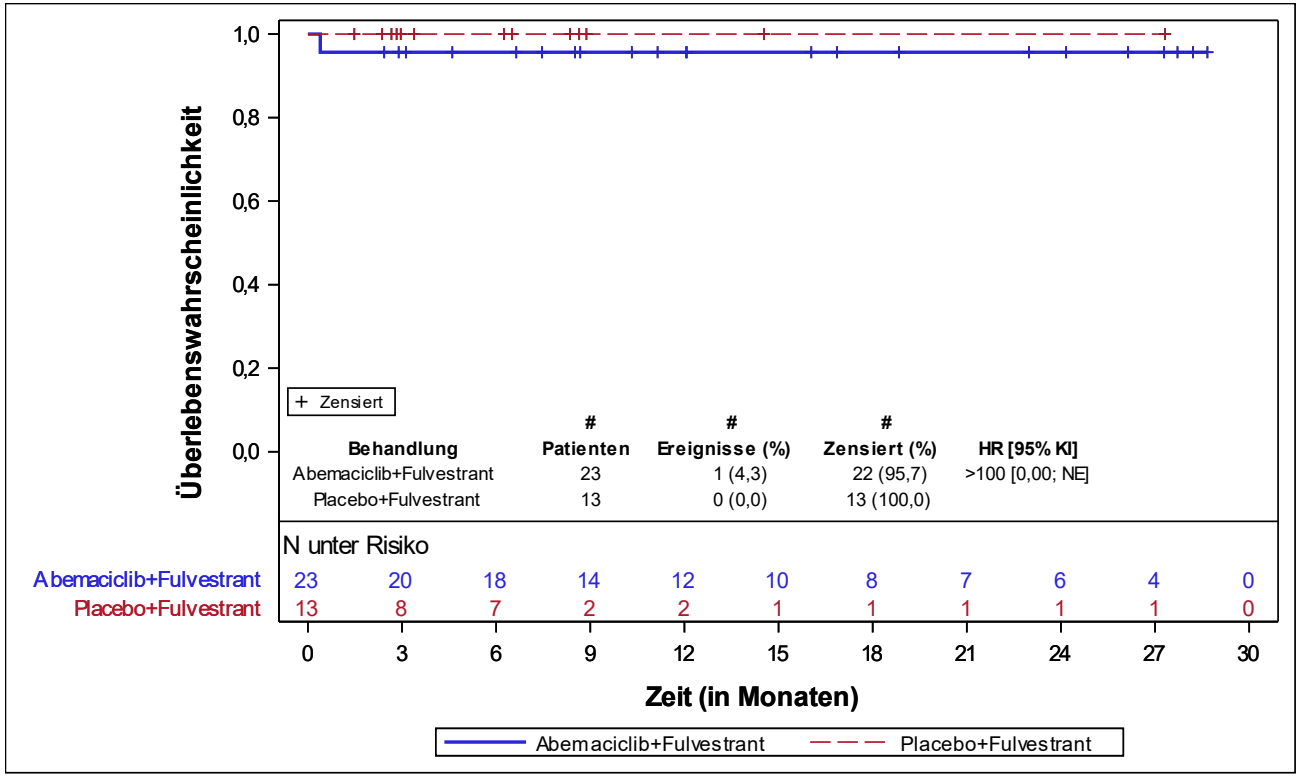
Abbildung 035.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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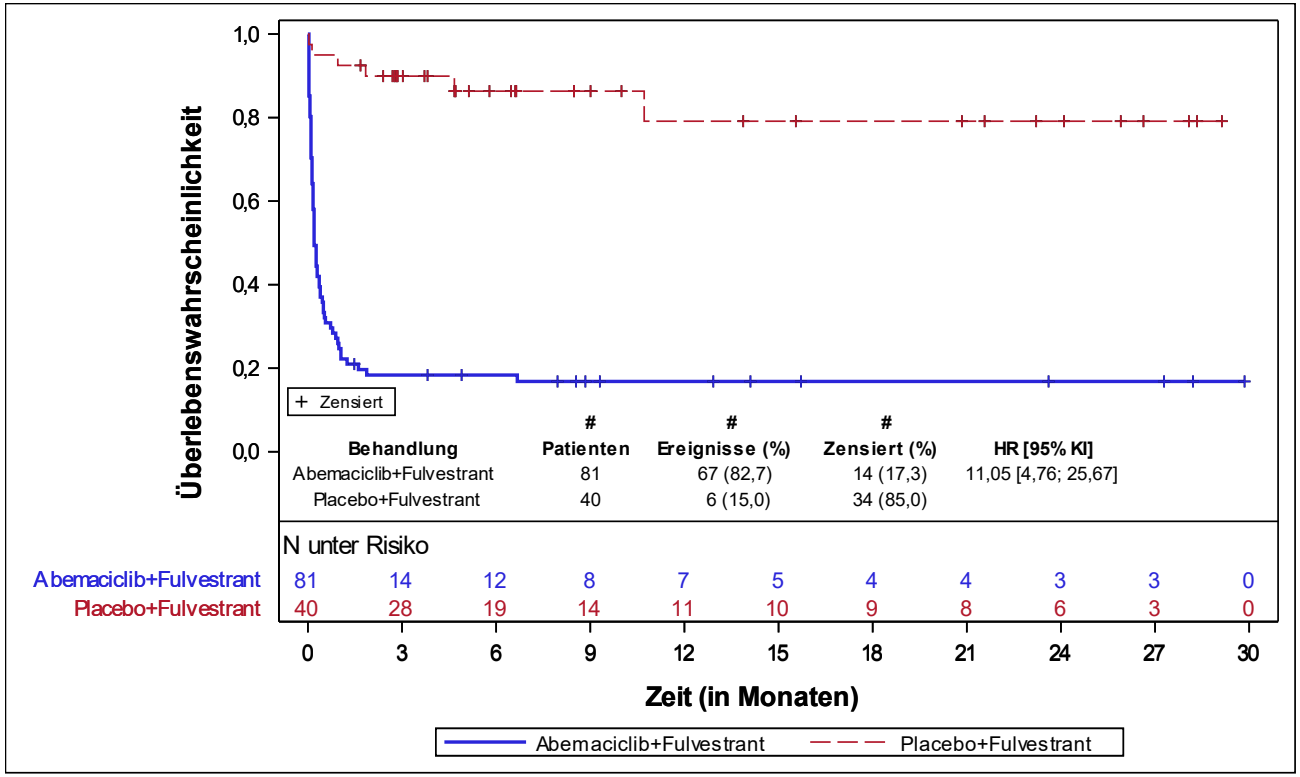
Abbildung 036.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/f_gba_ae_km.sas
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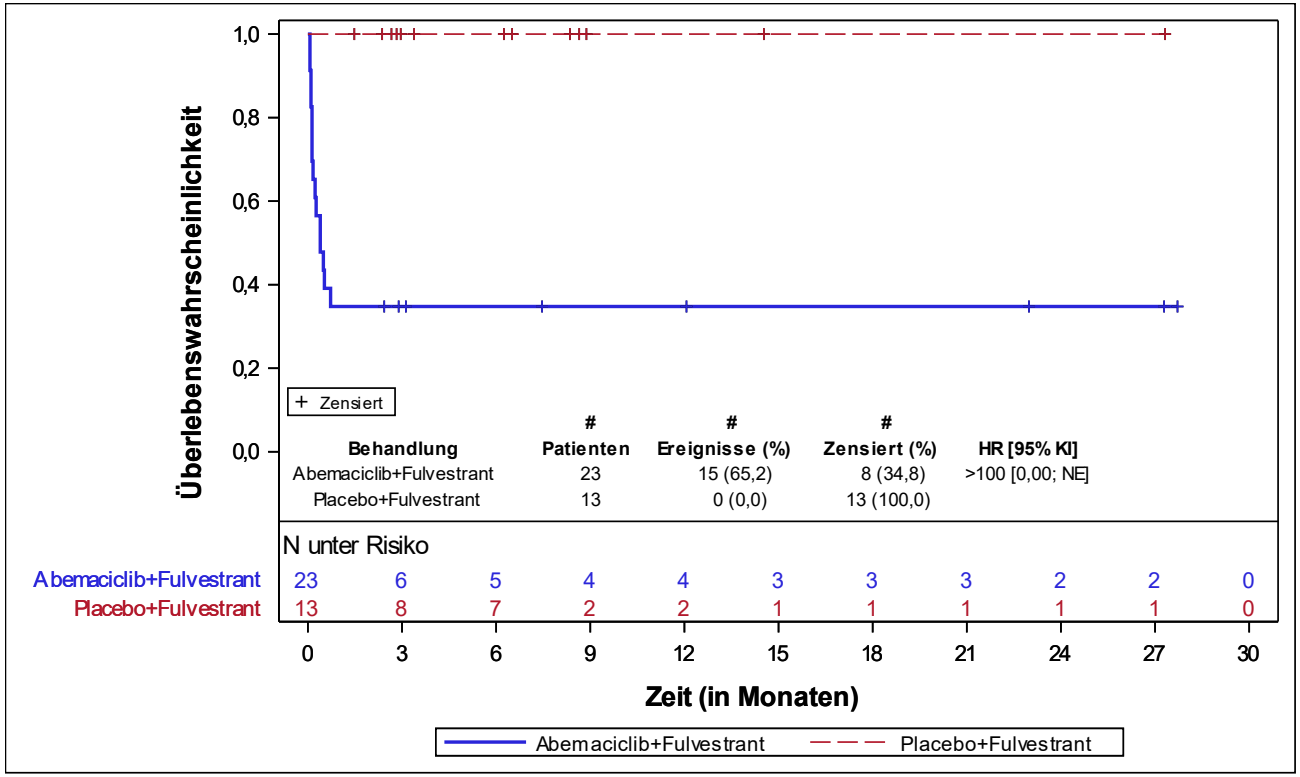
Abbildung 036.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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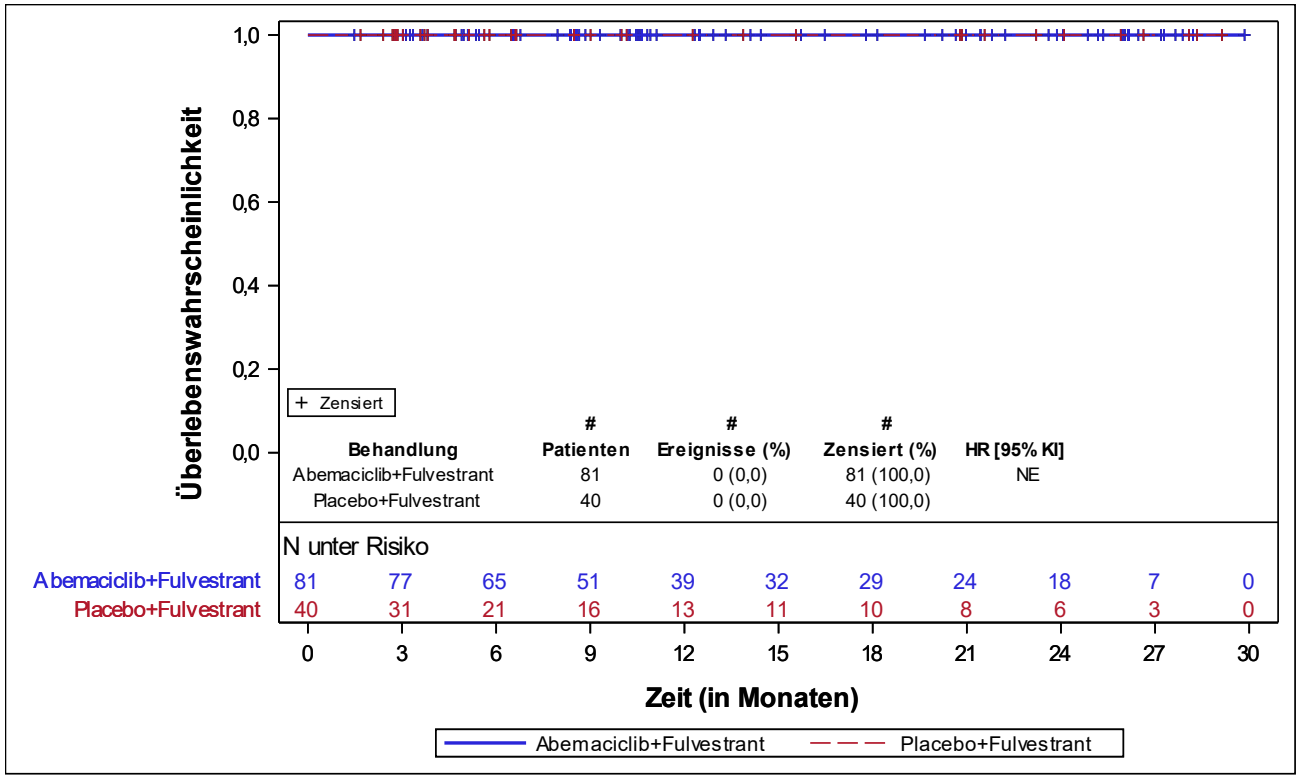
Abbildung 037.1: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Diarrhoe Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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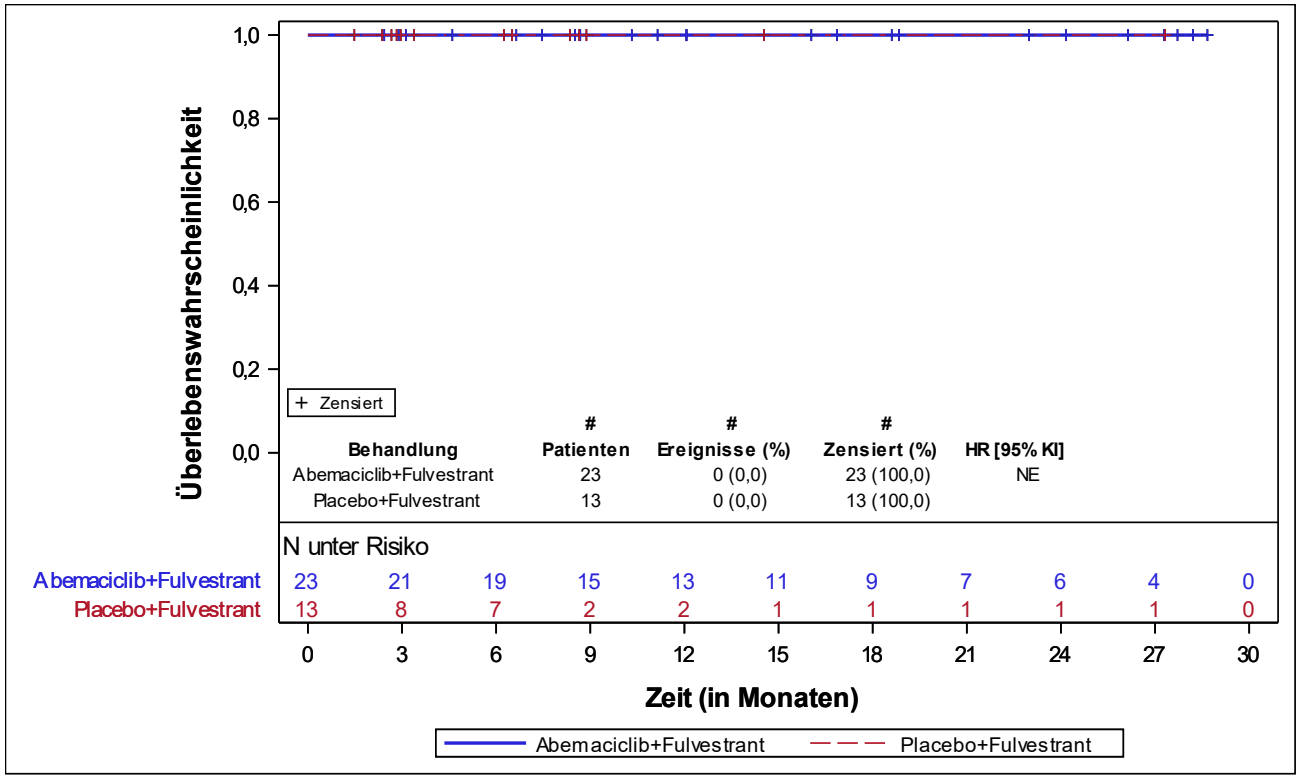
Abbildung 037.2: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Diarrhoe Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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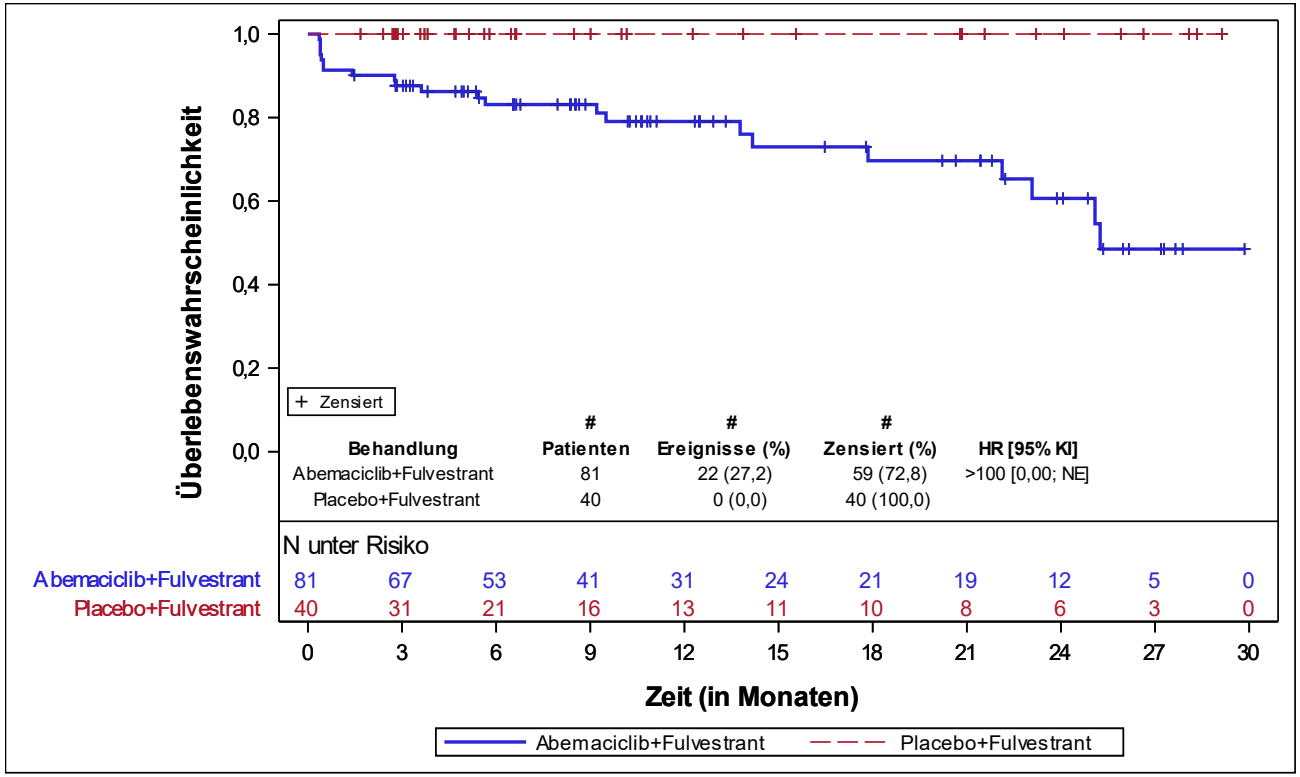
Abbildung 038.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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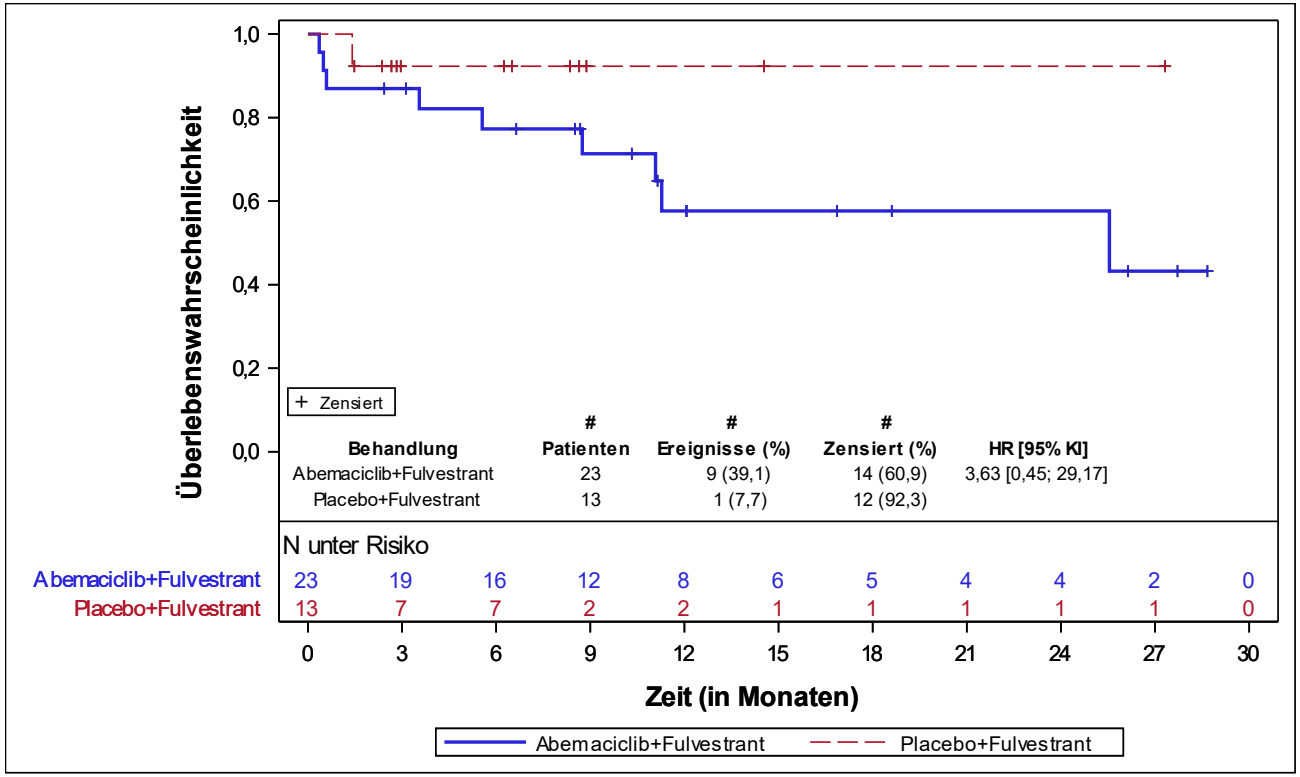
Abbildung 038.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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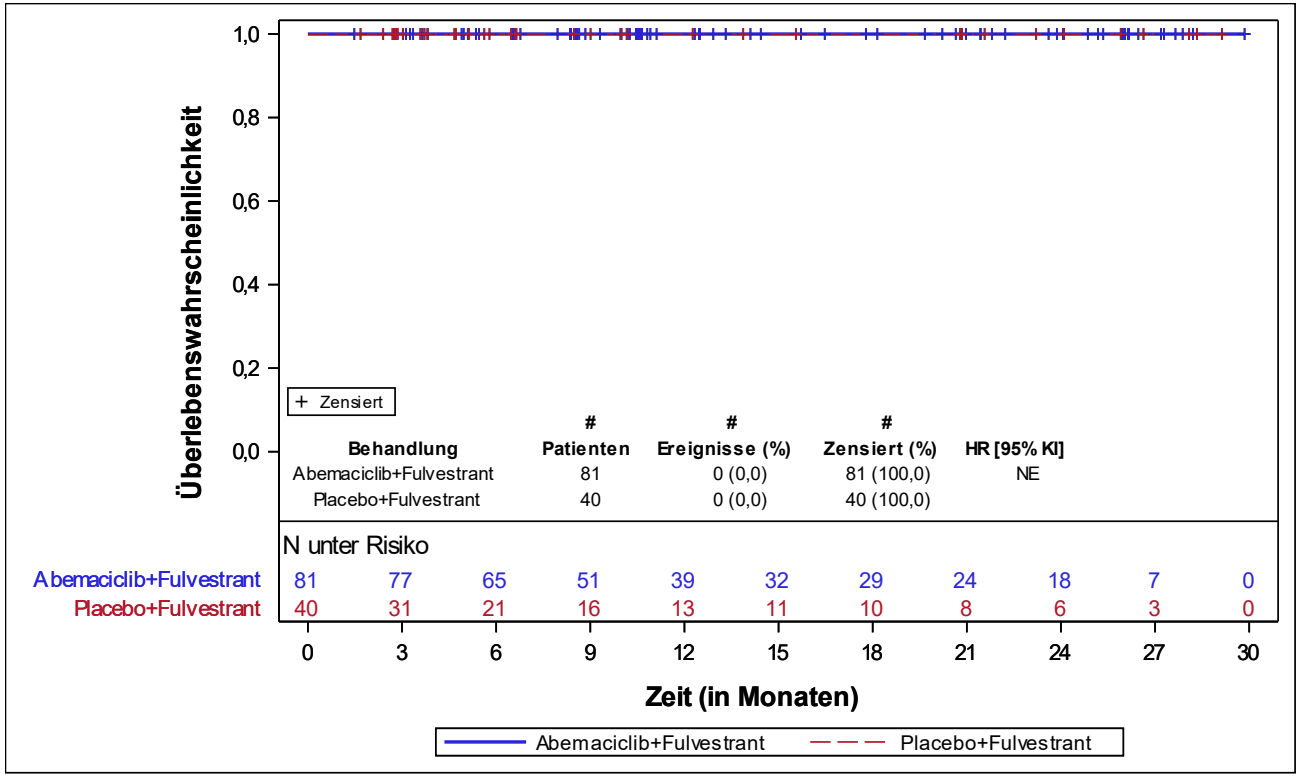
Abbildung 039.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Kreatinin im Blut erhöht Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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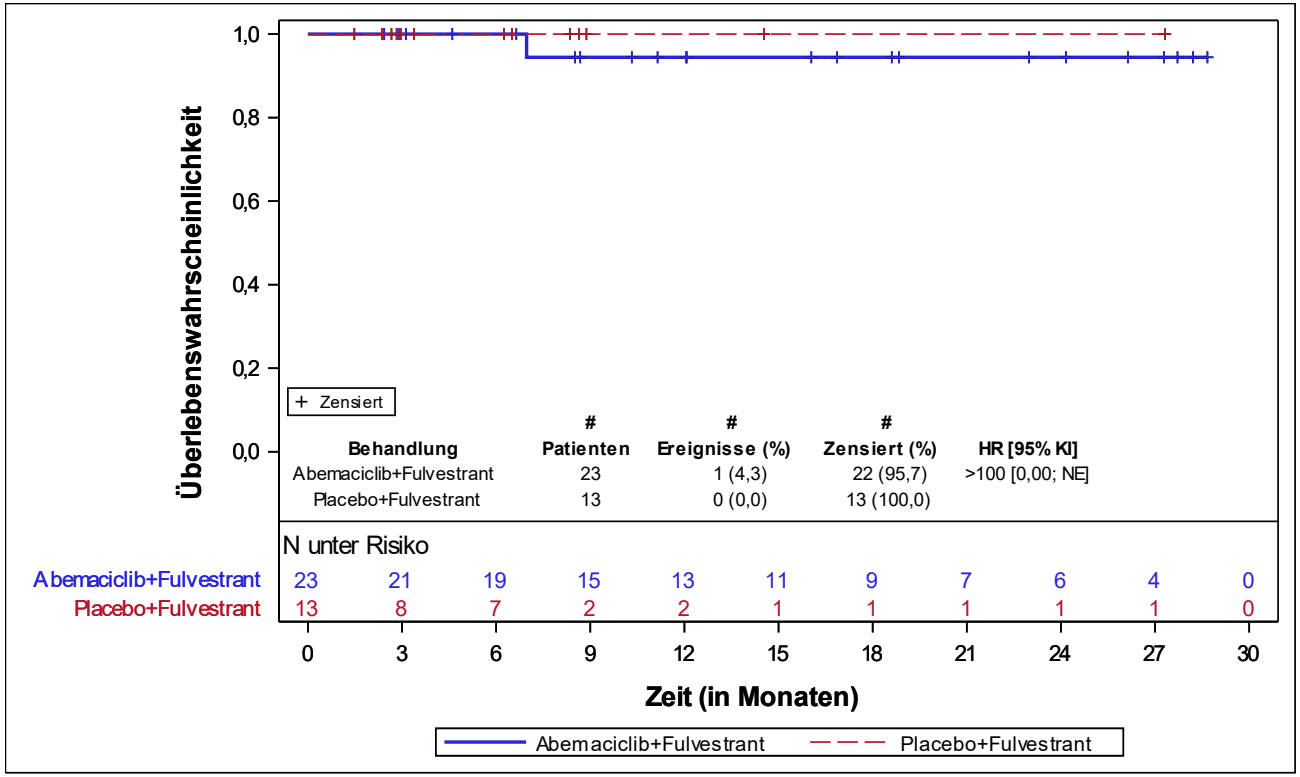
Abbildung 039.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Kreatinin im Blut erhöht Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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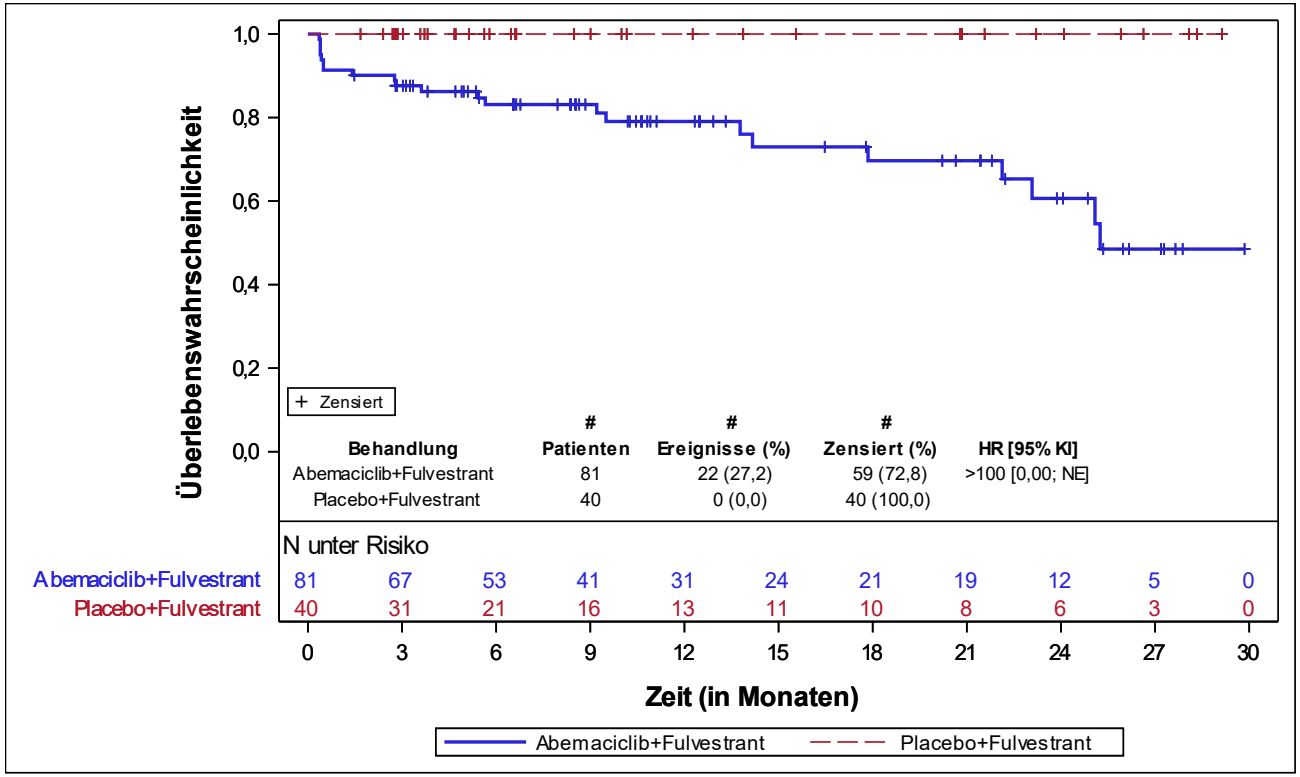
Abbildung 040.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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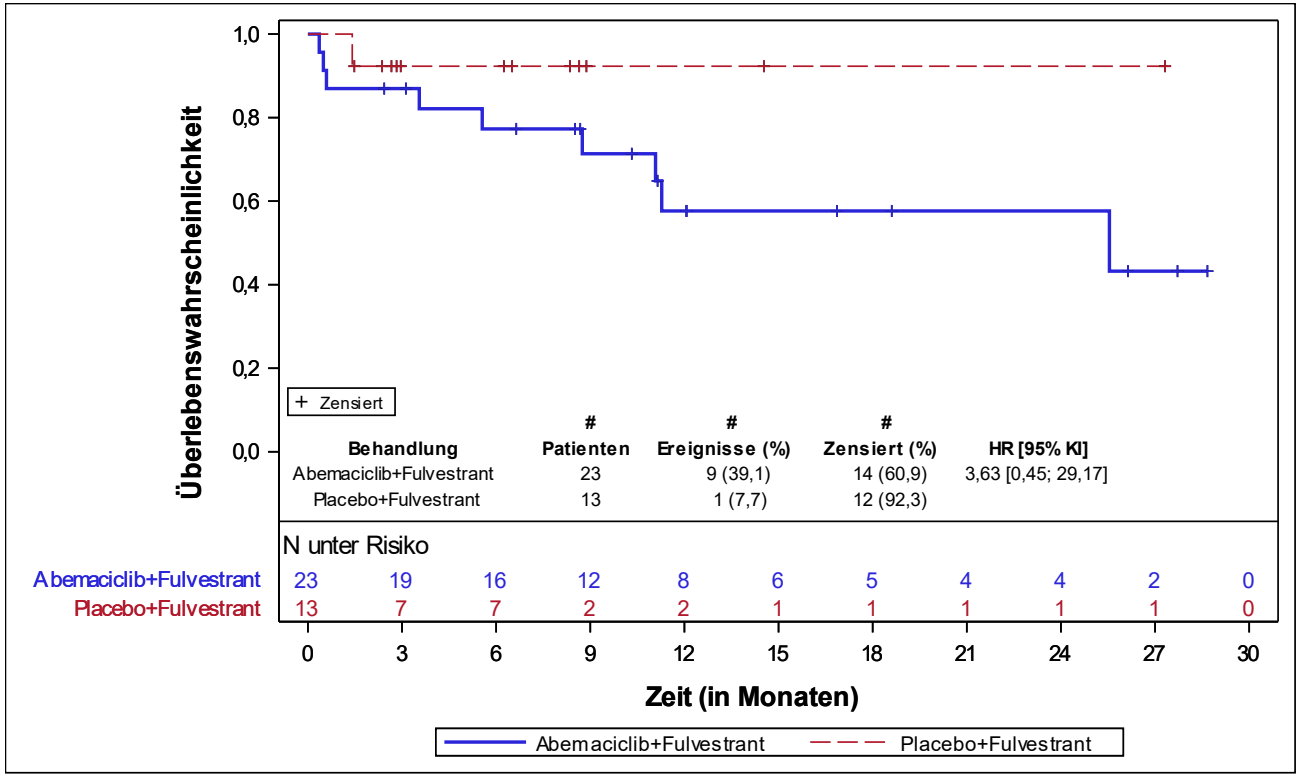
Abbildung 040.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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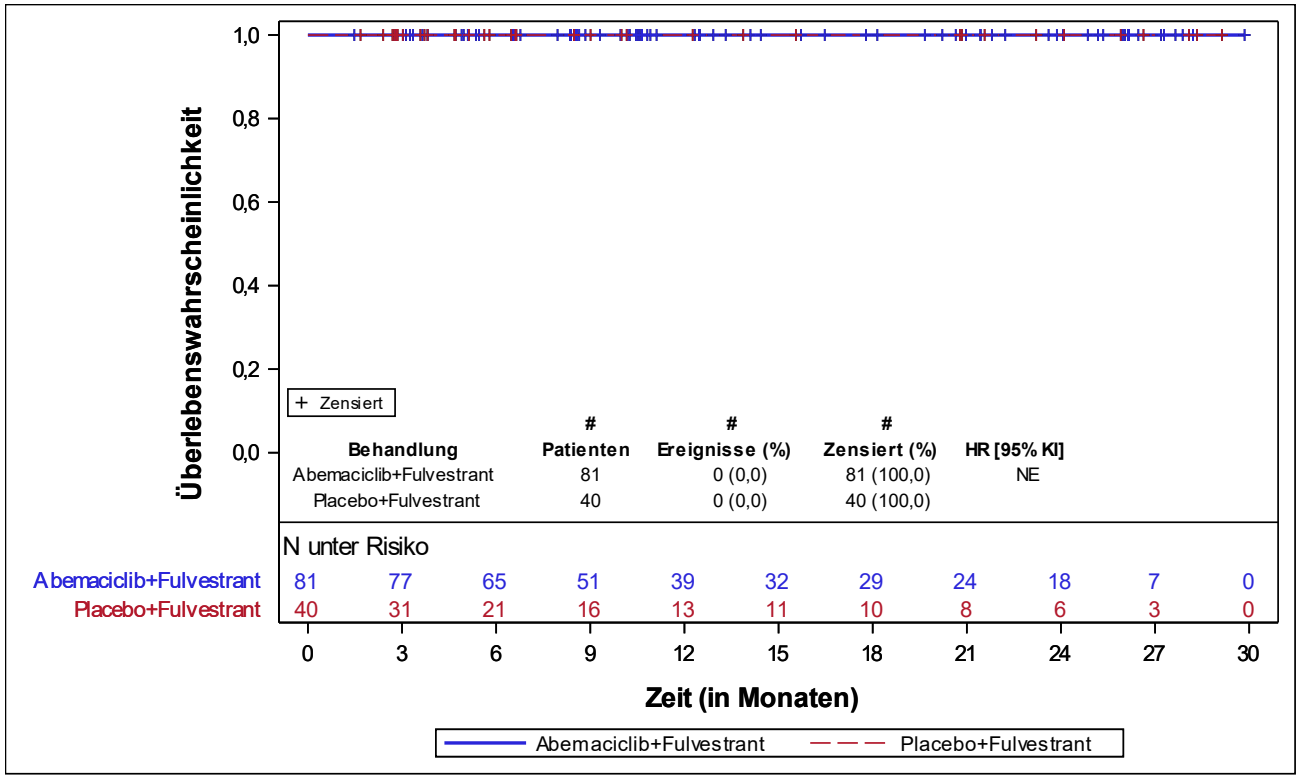
Abbildung 041.1: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Kreatinin im Blut erhöht Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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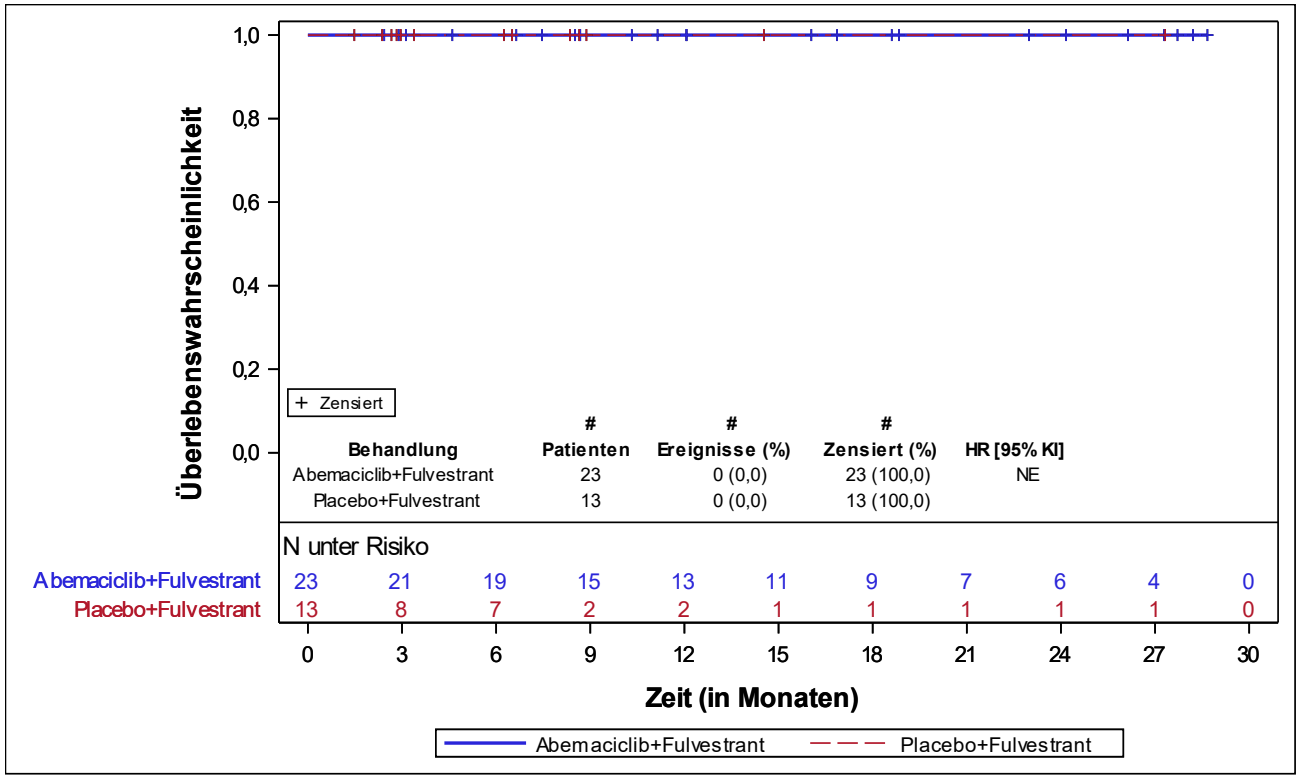
Abbildung 041.2: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Kreatinin im Blut erhöht Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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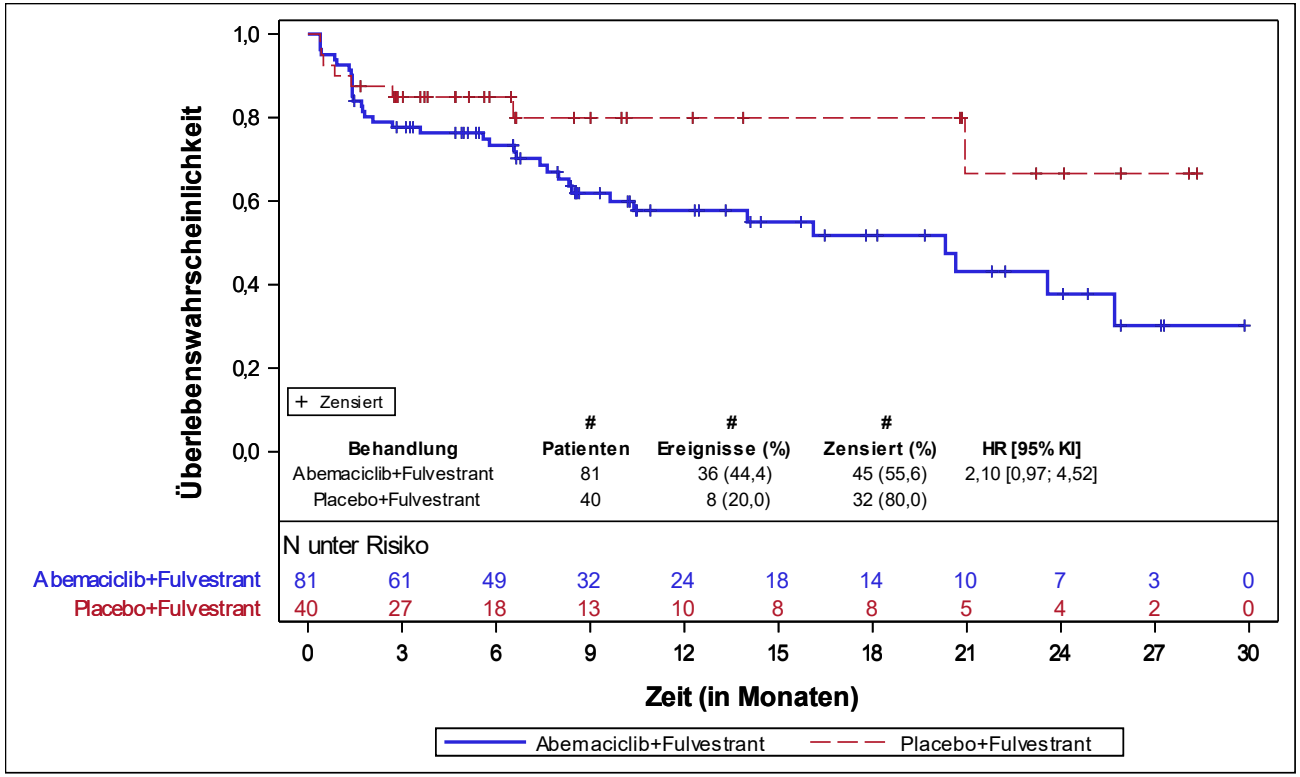
Abbildung 042.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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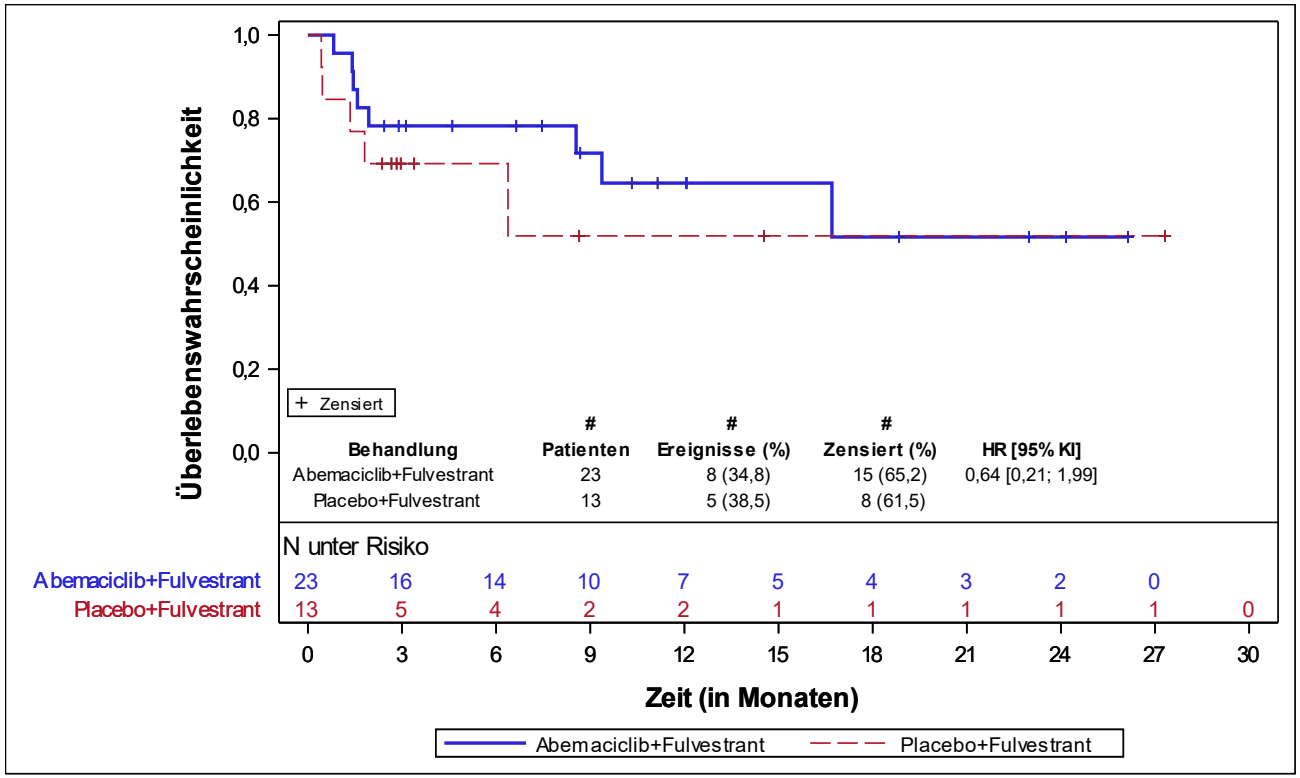
Abbildung 042.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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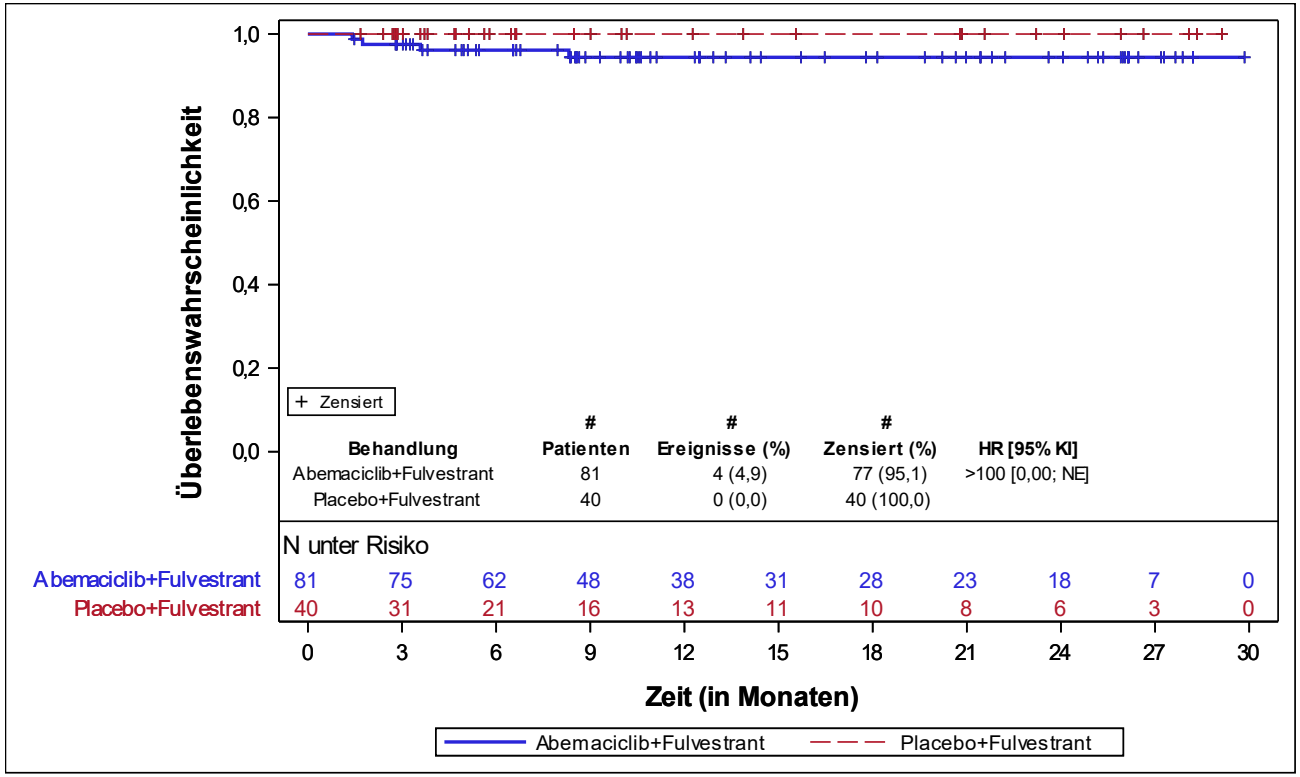
Abbildung 043.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/f_gba_ae_km.sas
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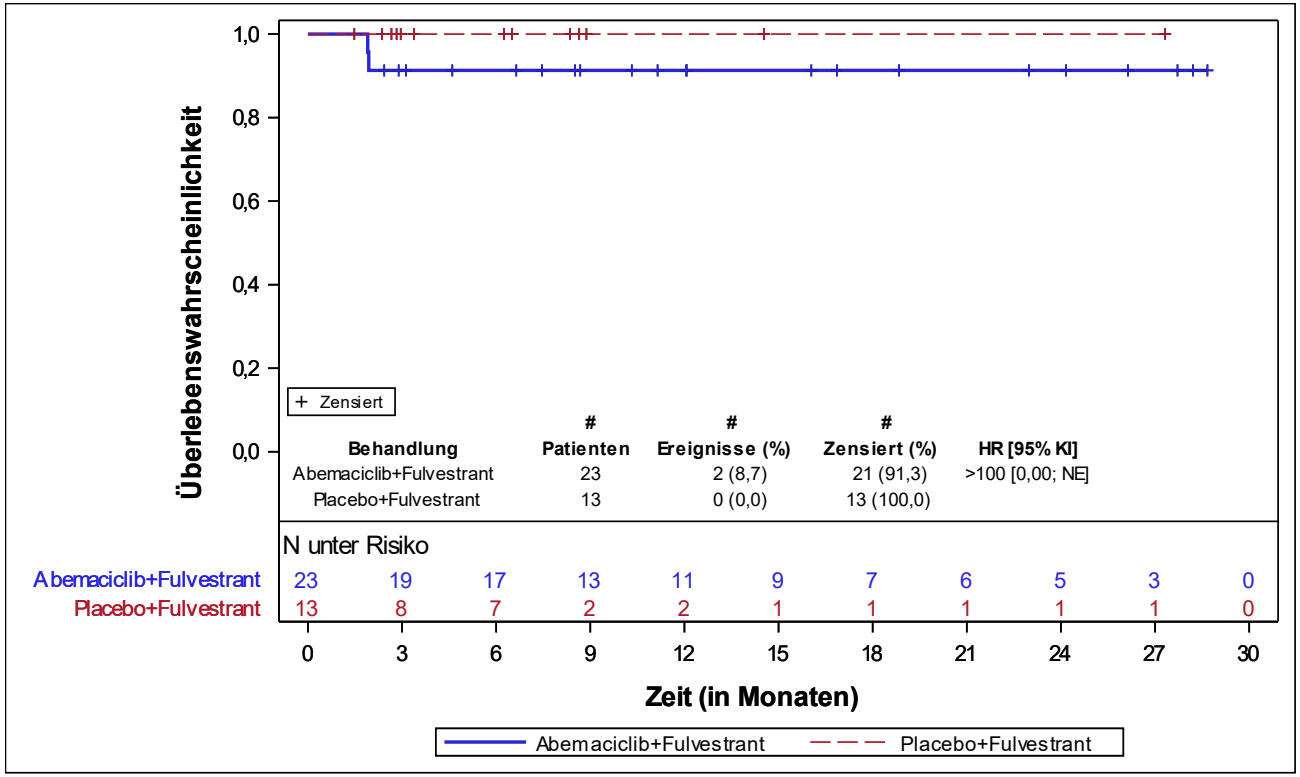
Abbildung 043.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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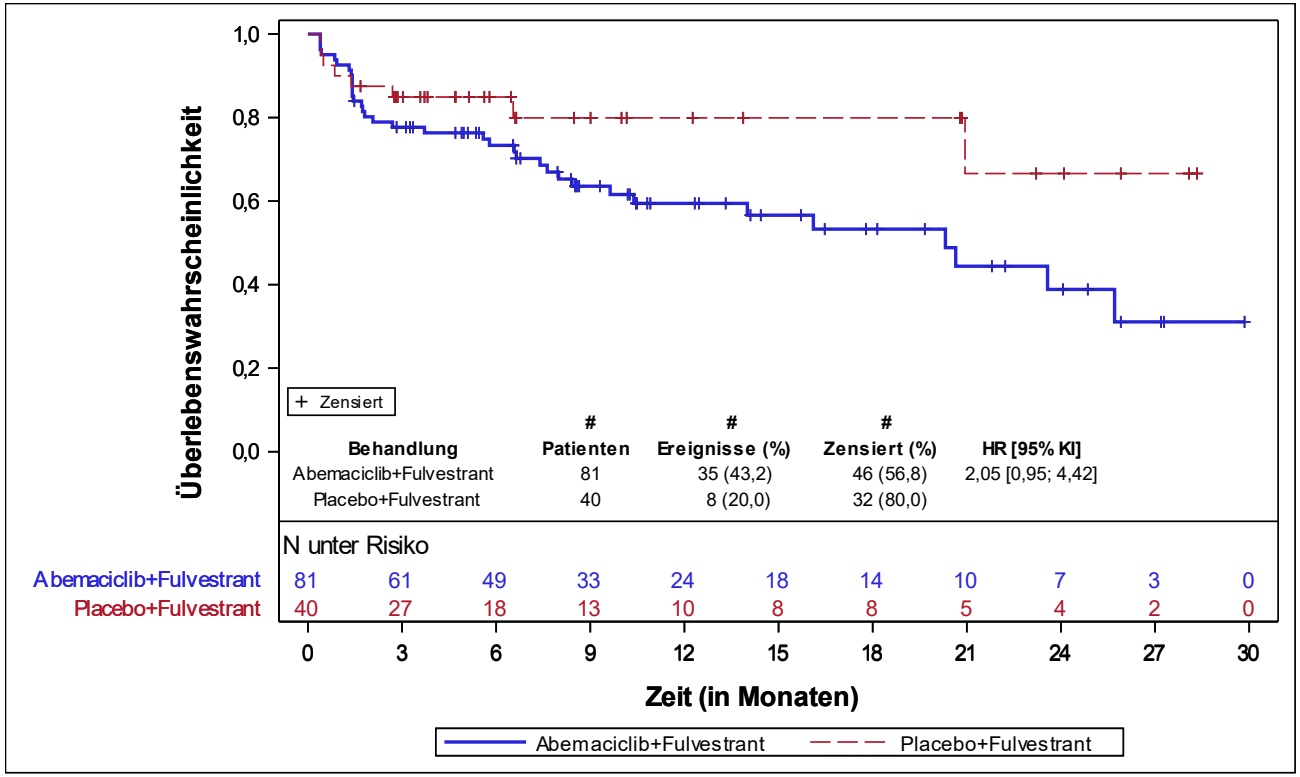
Abbildung 044.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/f_gba_ae_km.sas
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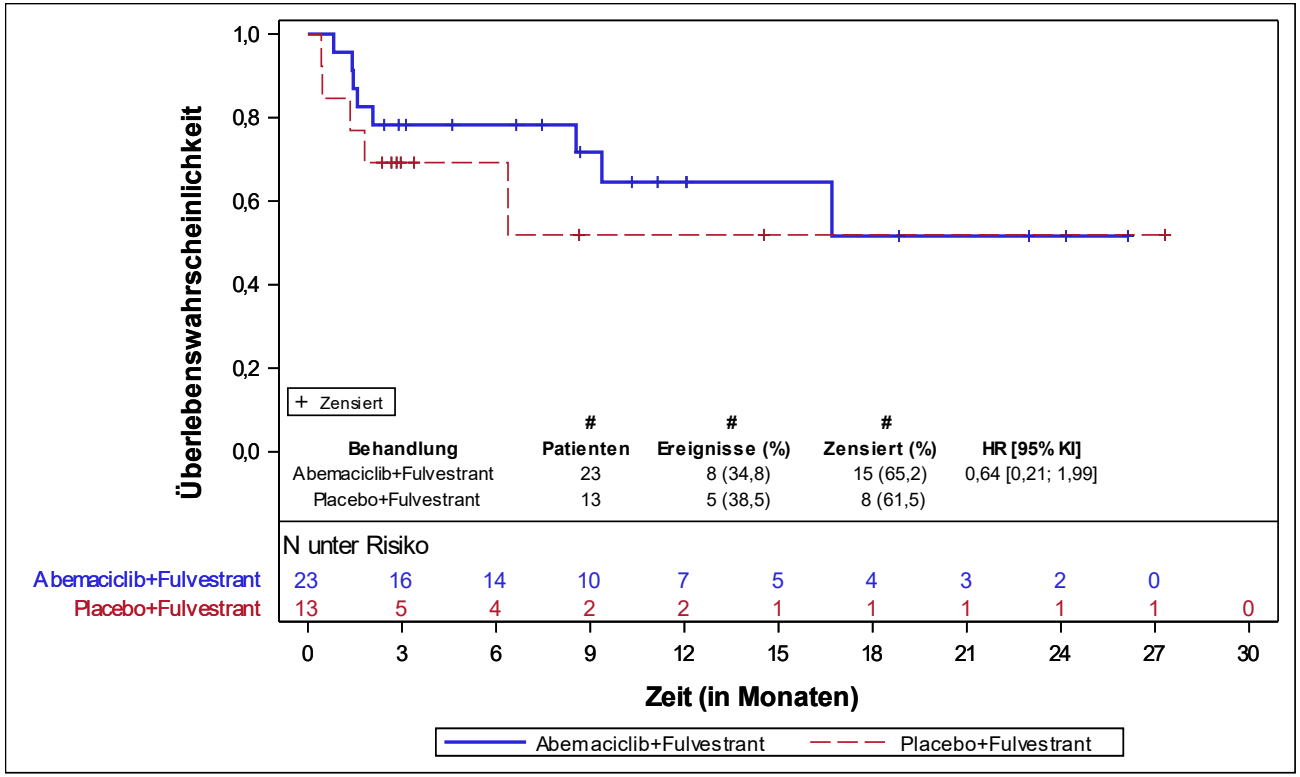
Abbildung 044.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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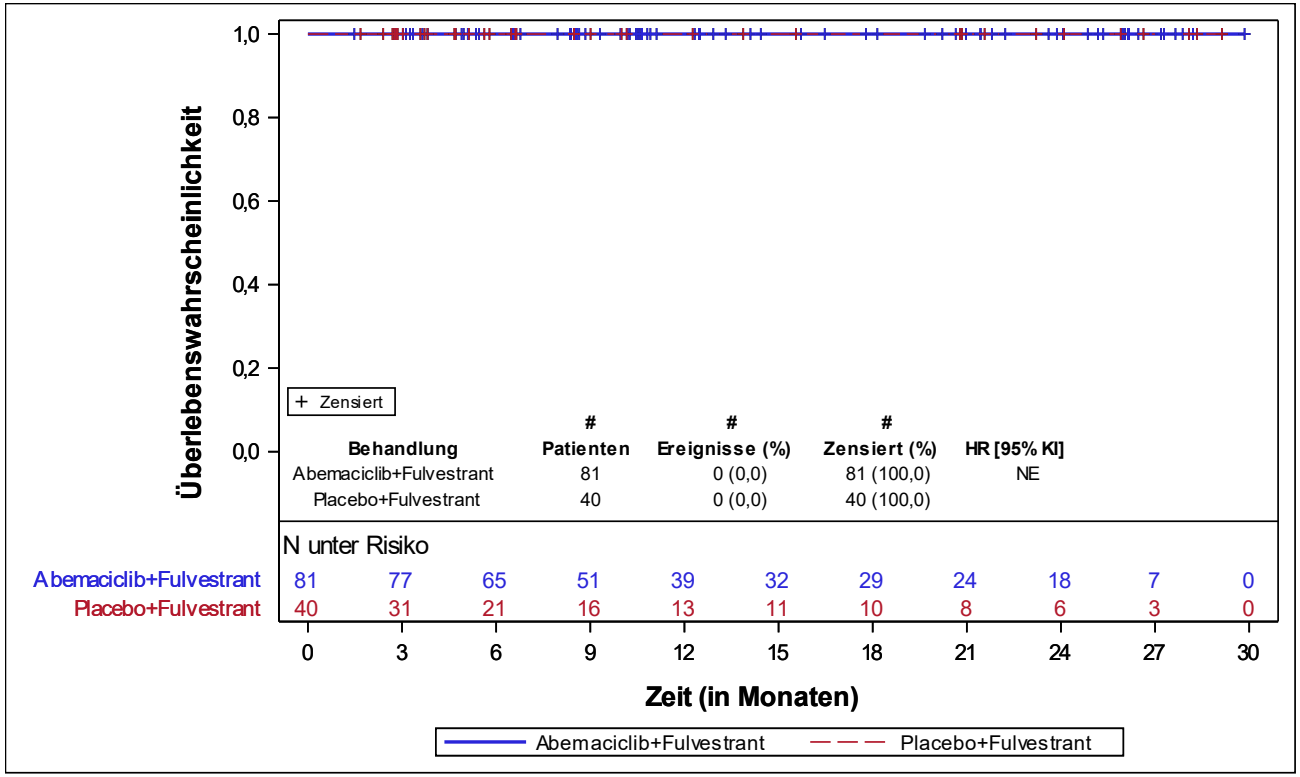
Abbildung 045.1: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alaninaminotransferase erhöht Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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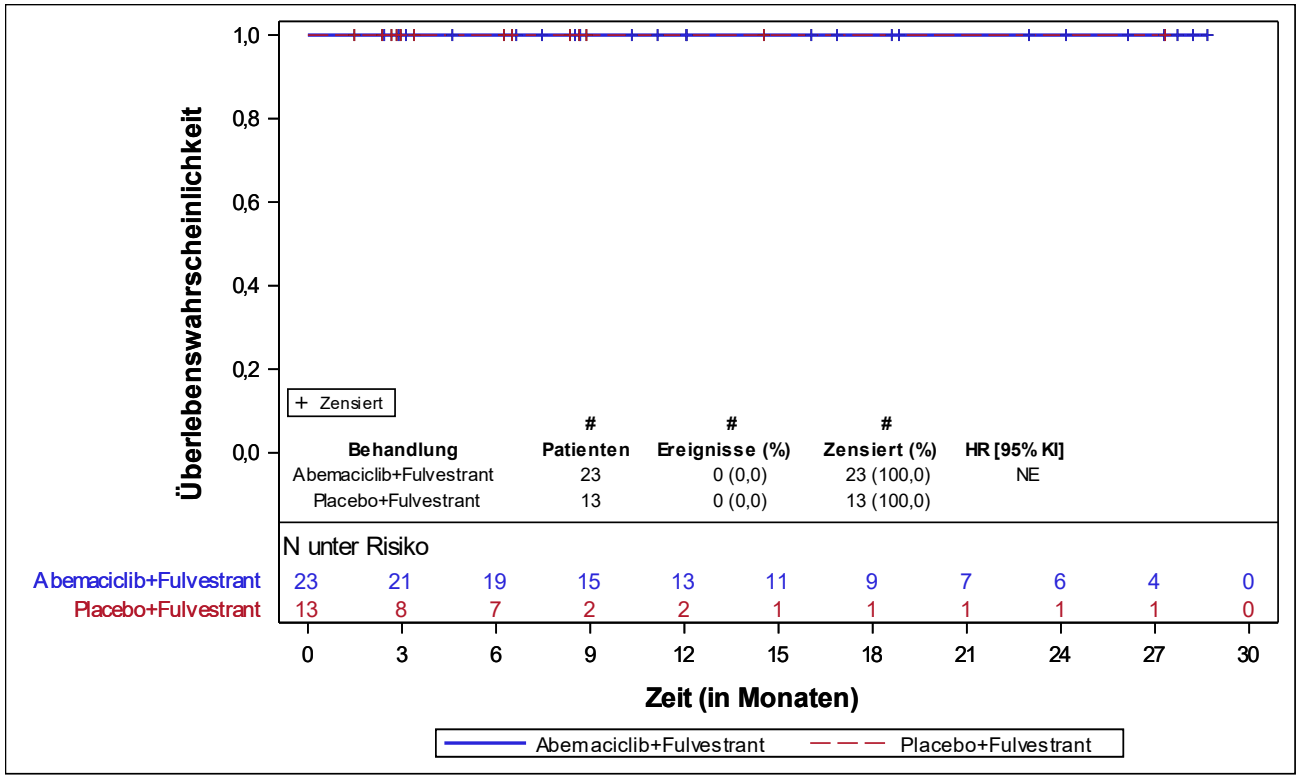
Abbildung 045.2: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alaninaminotransferase erhöht Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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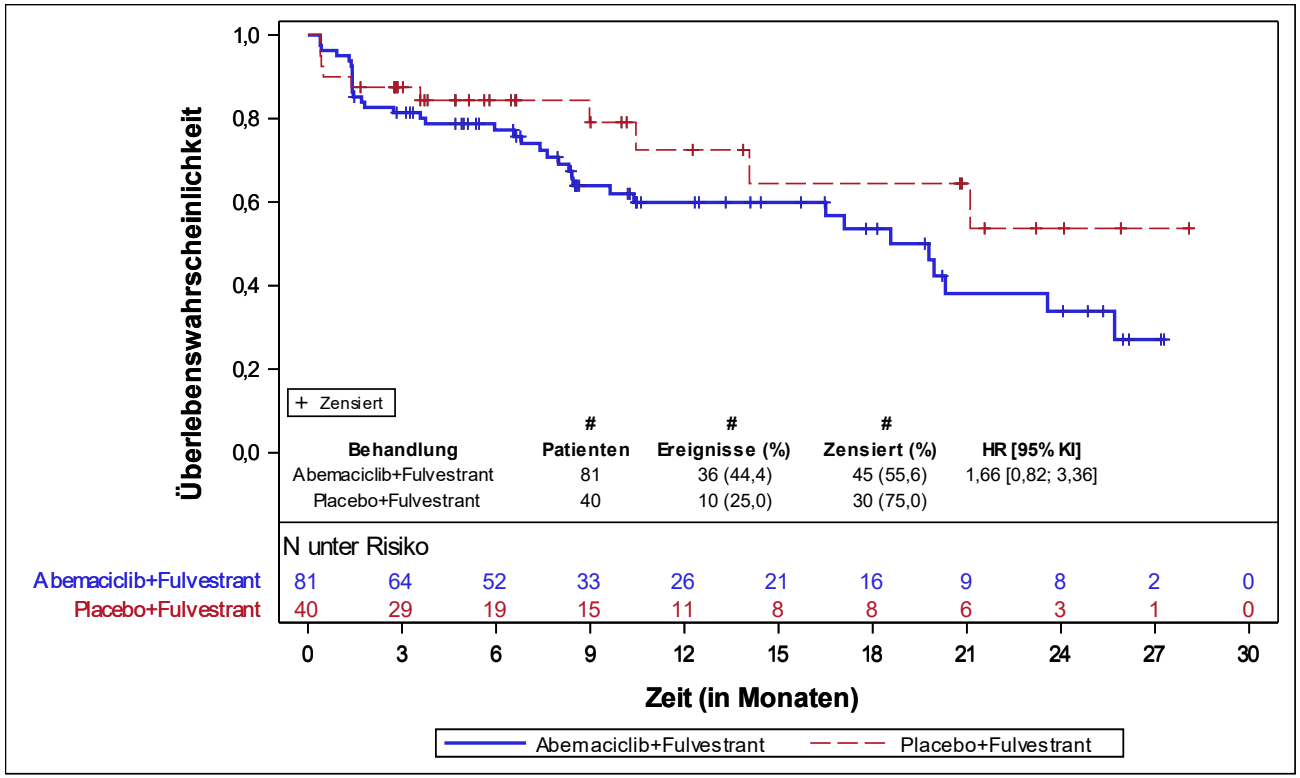
Abbildung 046.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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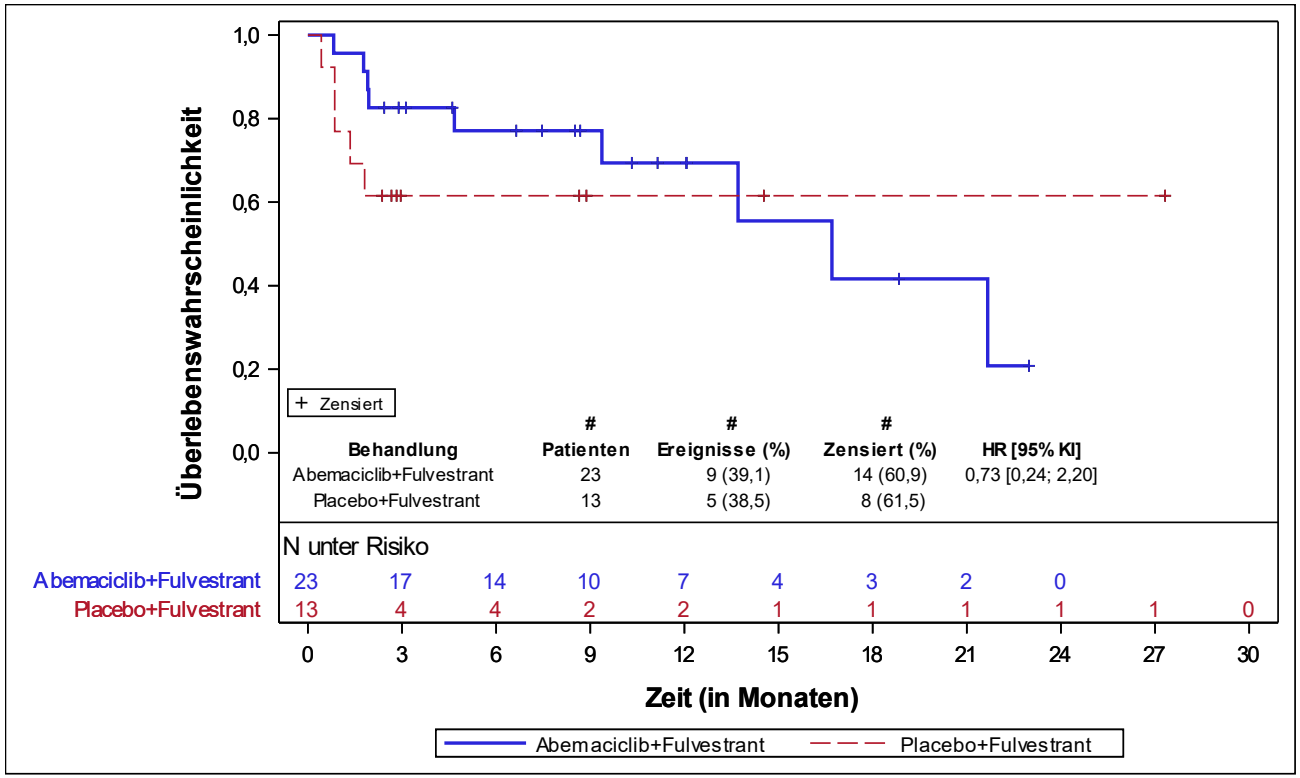
Abbildung 046.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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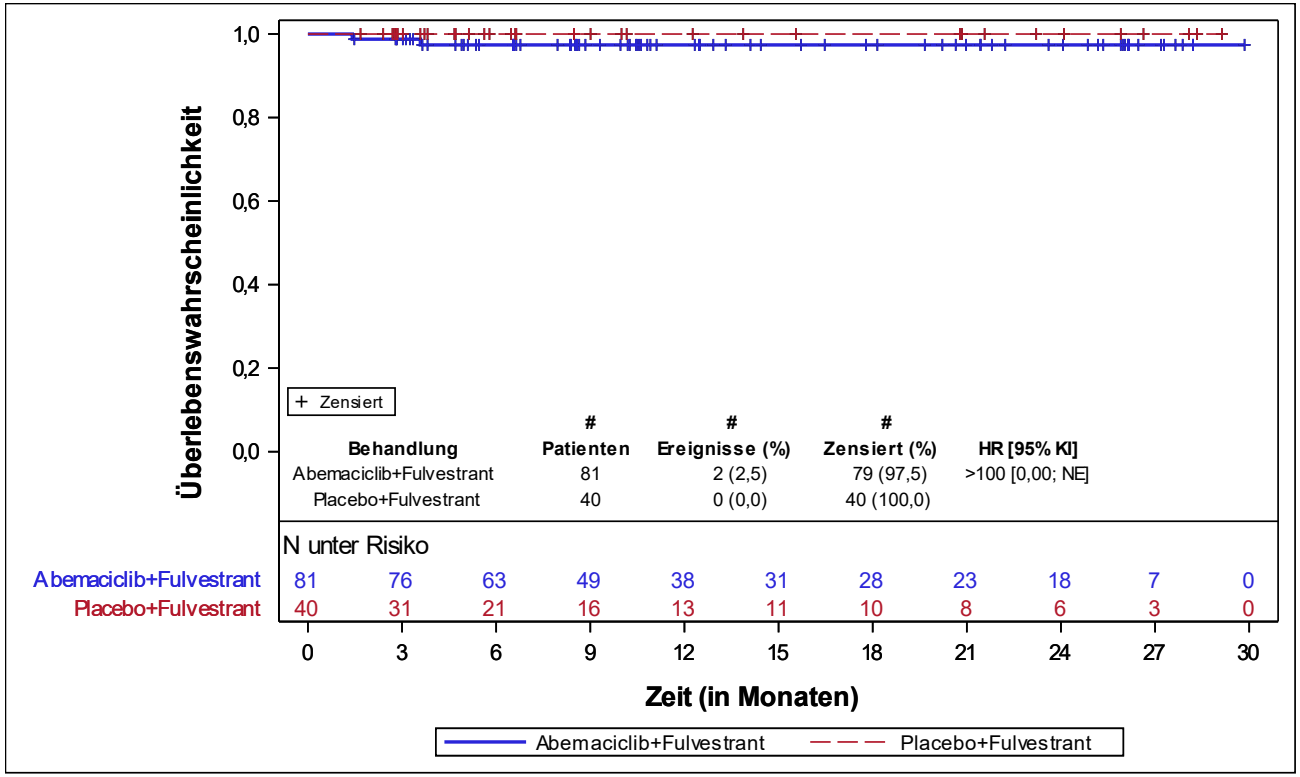
Abbildung 047.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/f_km_ttas3aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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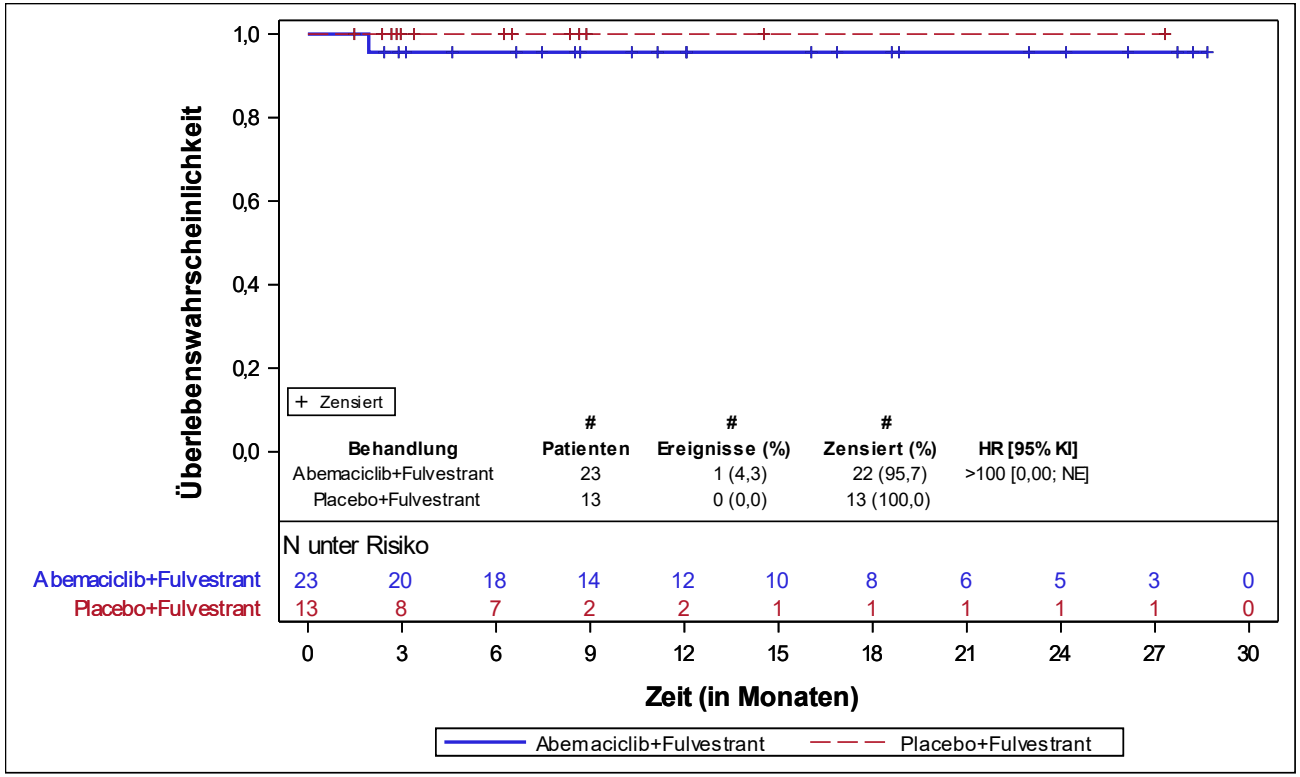
Abbildung 047.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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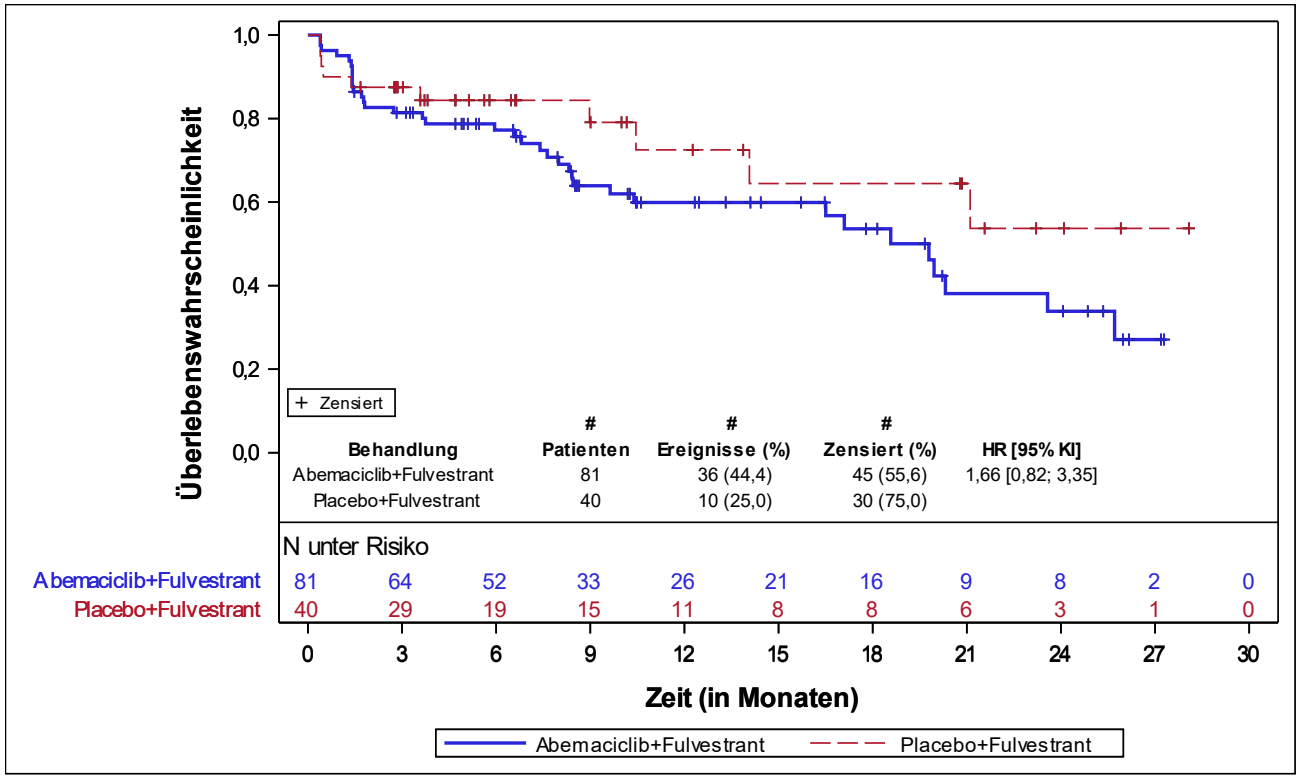
Abbildung 048.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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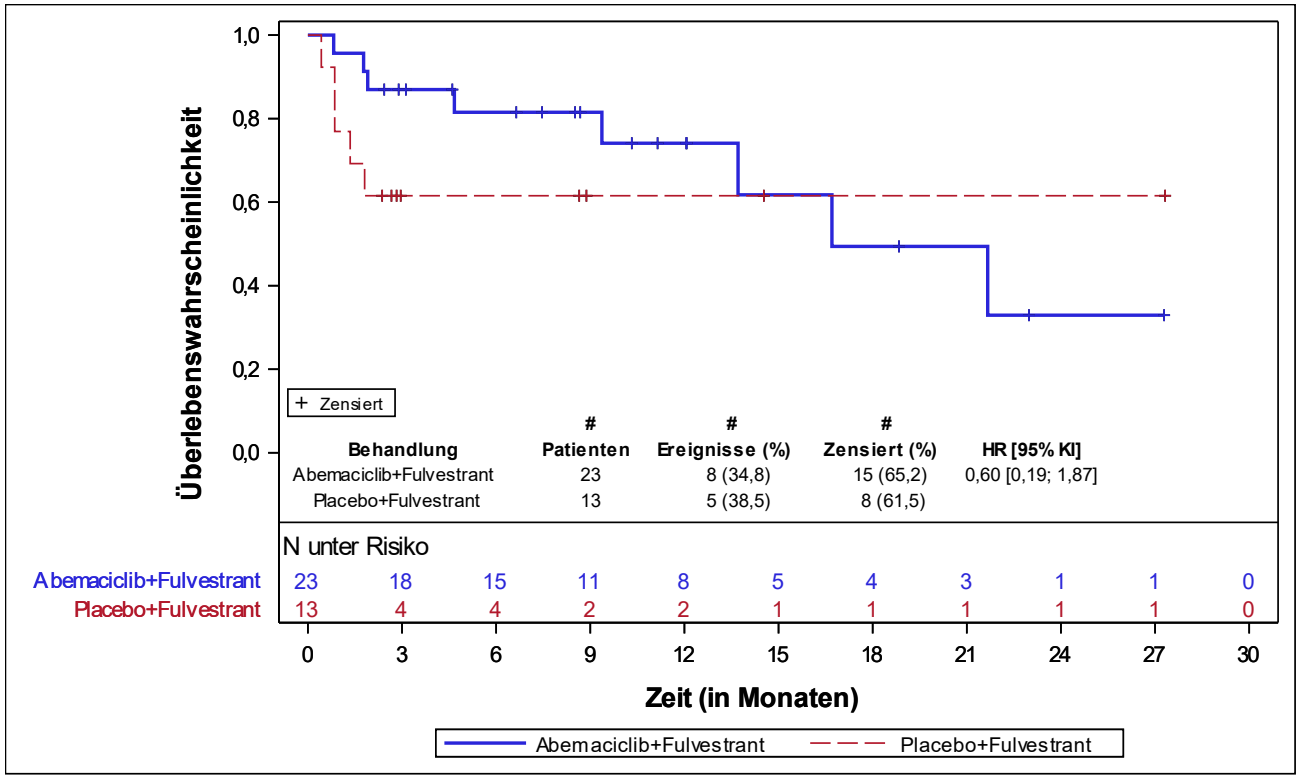
Abbildung 048.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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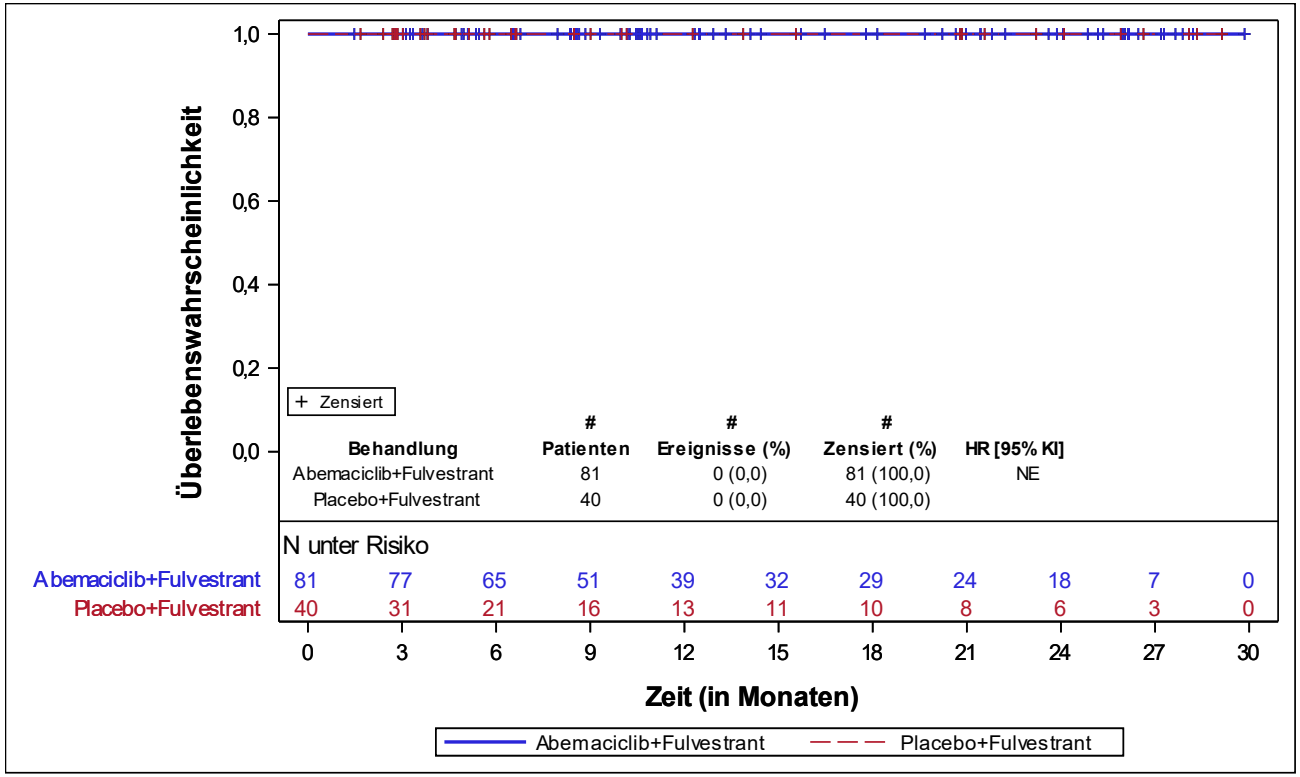
Abbildung 049.1: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Aspartataminotransferase erhöht Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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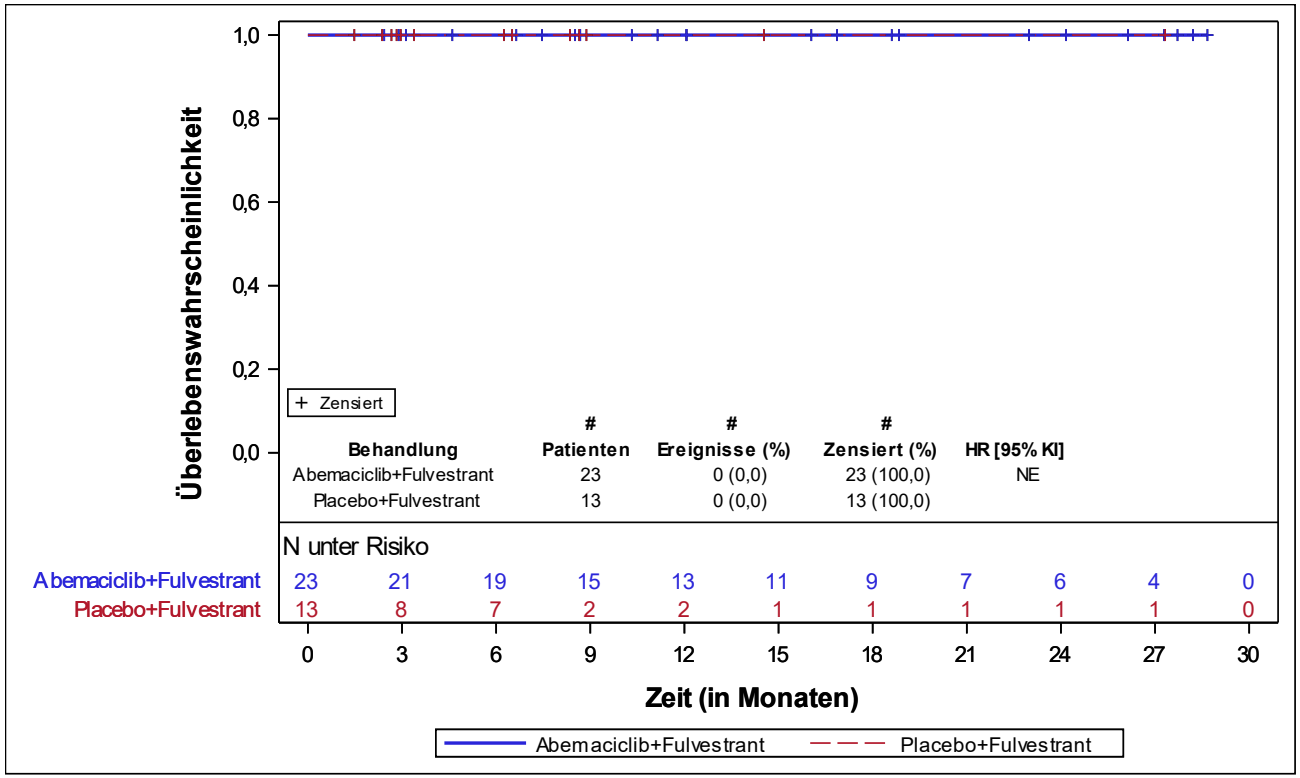
Abbildung 049.2: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Aspartataminotransferase erhöht Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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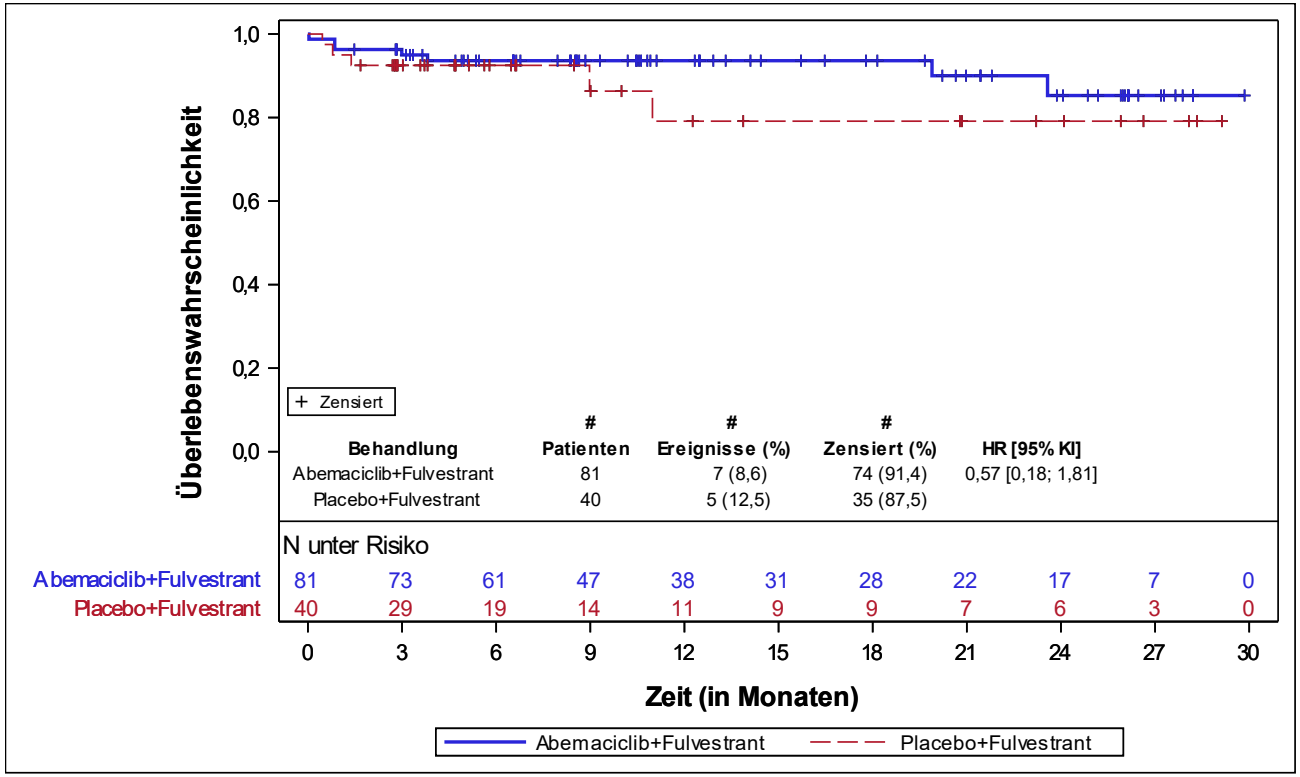
Abbildung 050.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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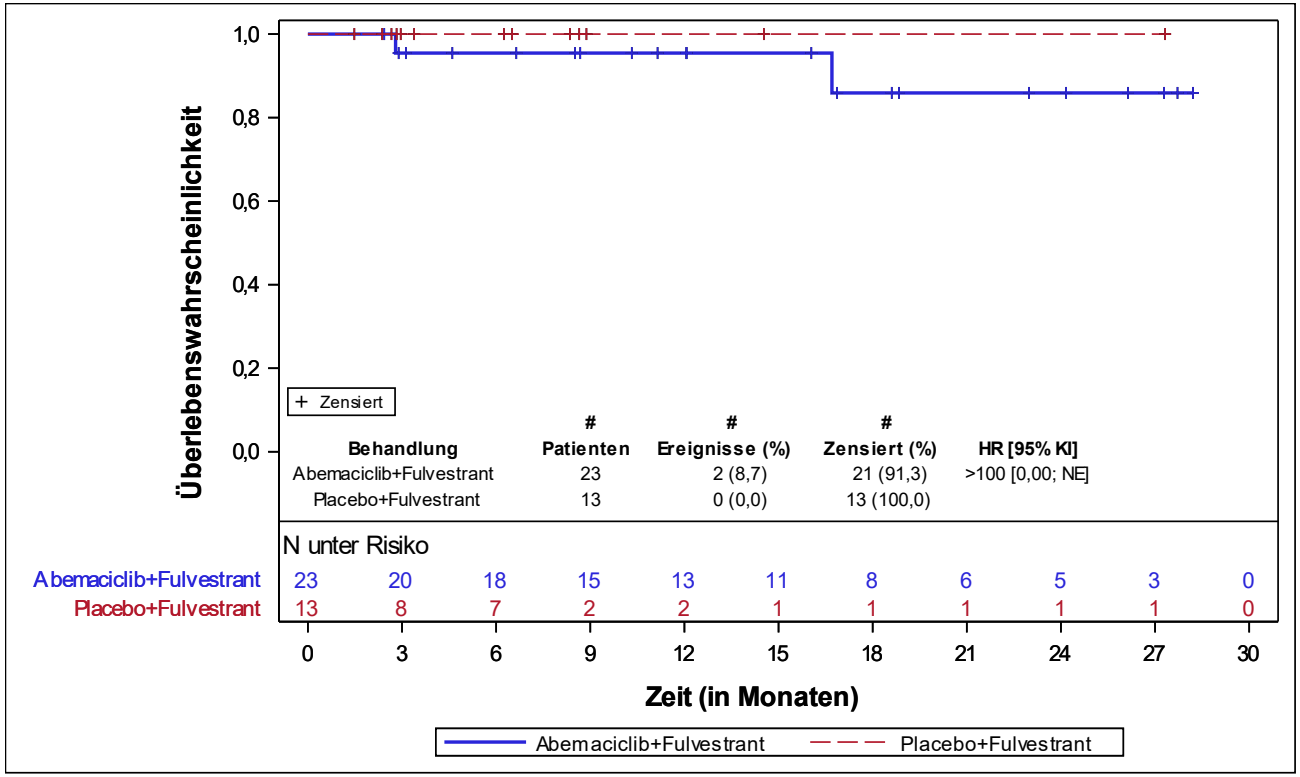
Abbildung 050.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/f_gba_ae_km.sas
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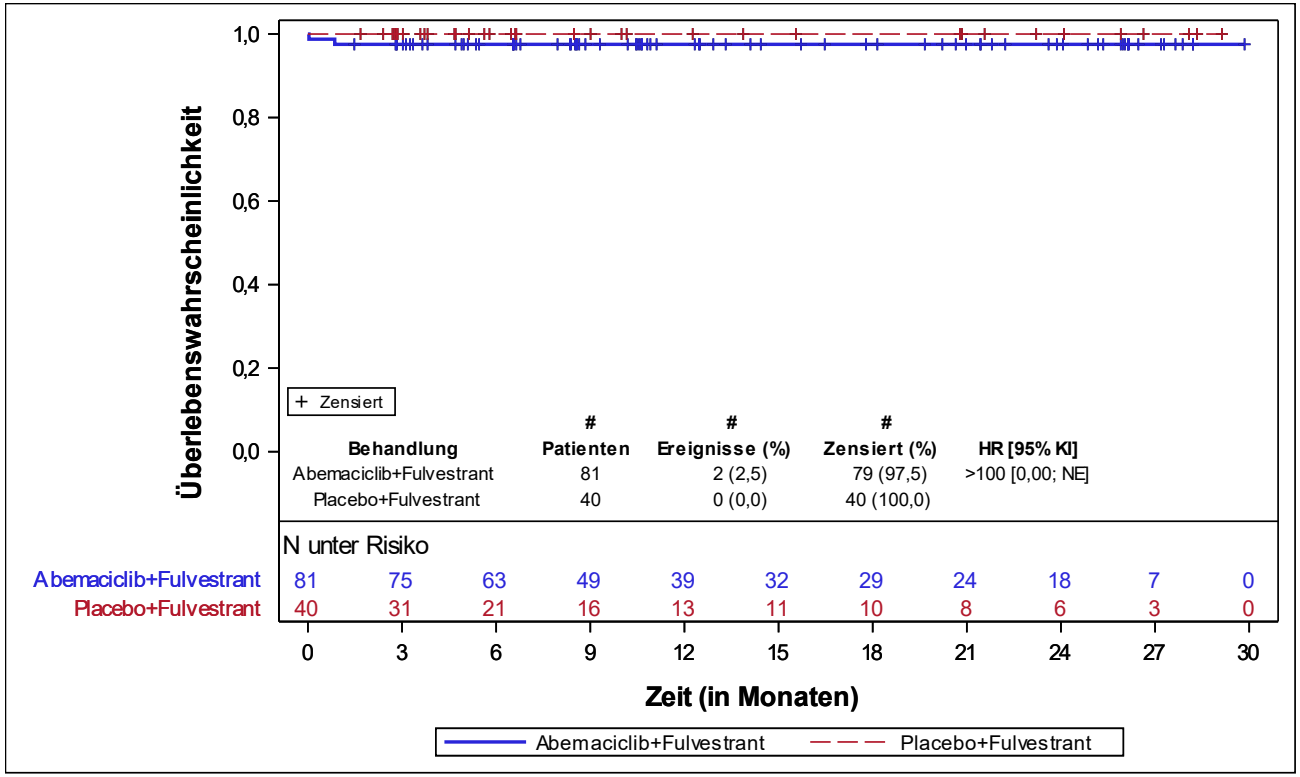
Abbildung 051.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alkalische Phosphatase erhöht Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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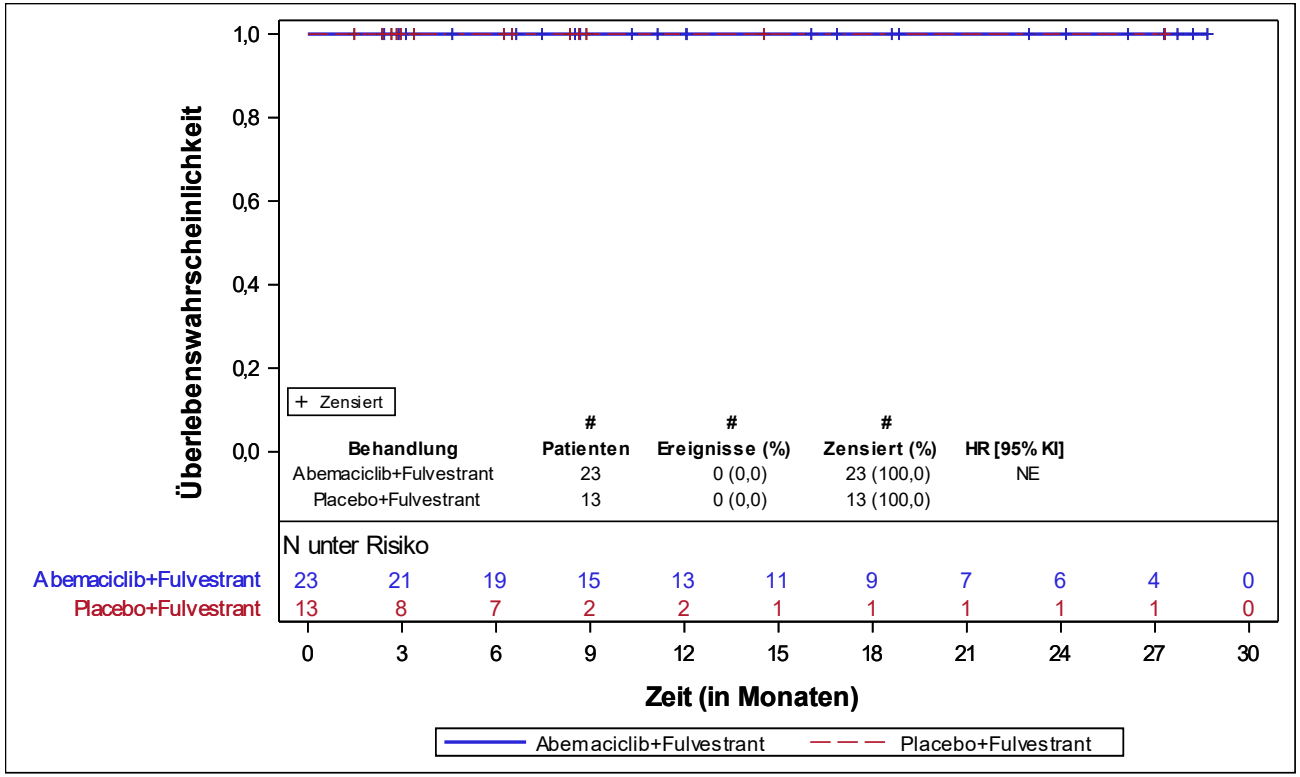
Abbildung 051.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alkalische Phosphatase erhöht Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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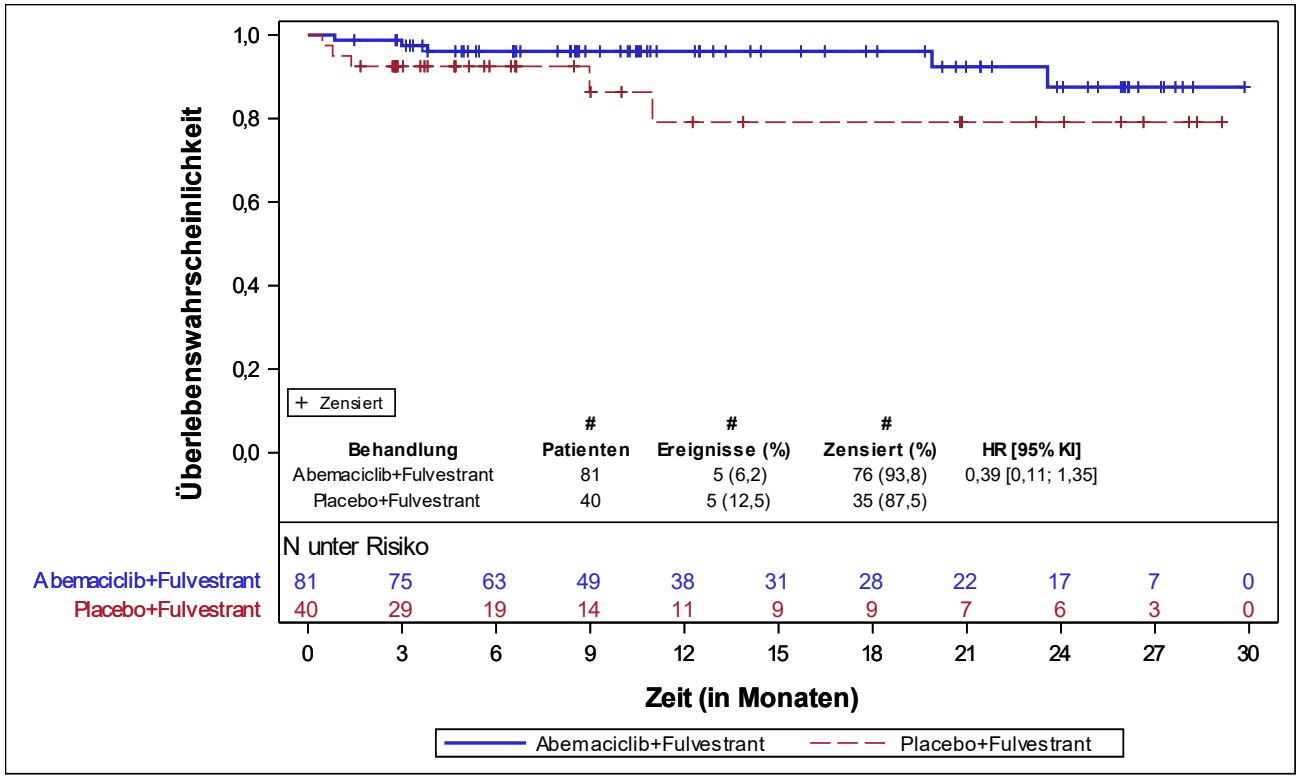
Abbildung 052.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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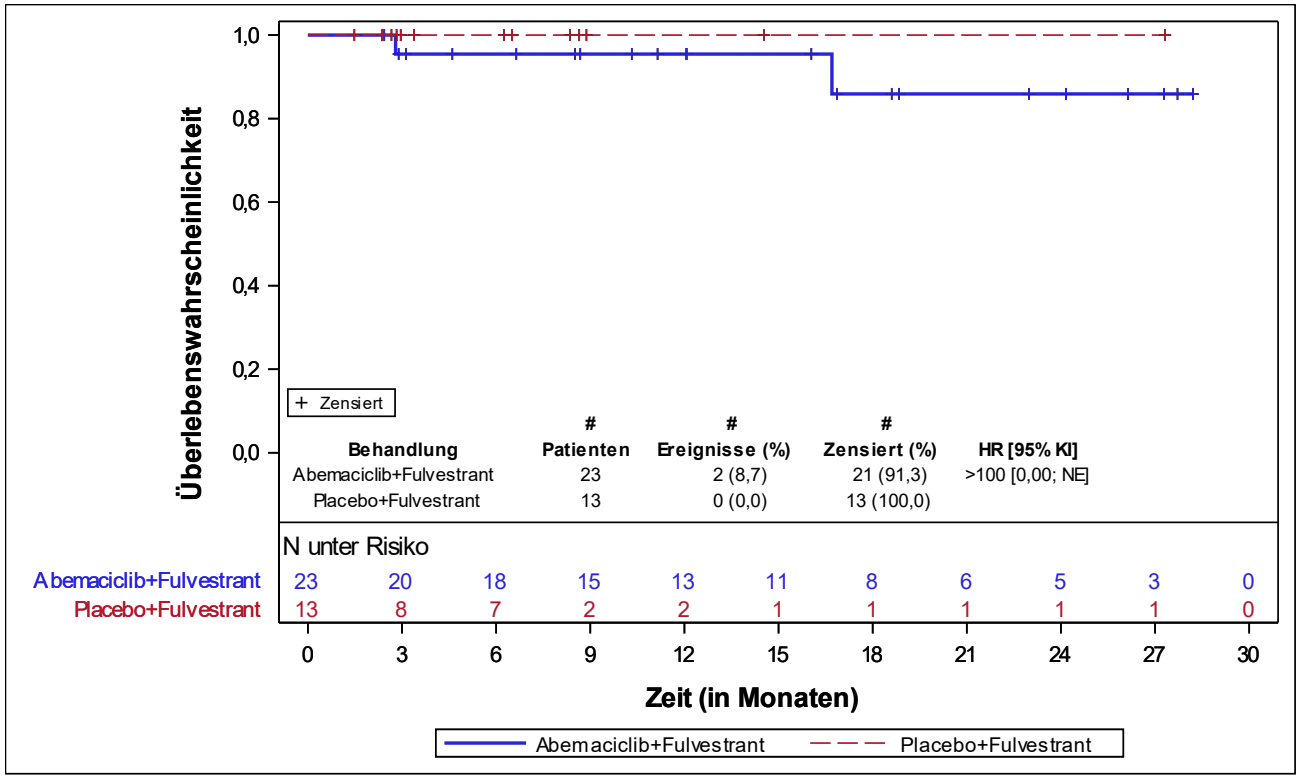
Abbildung 052.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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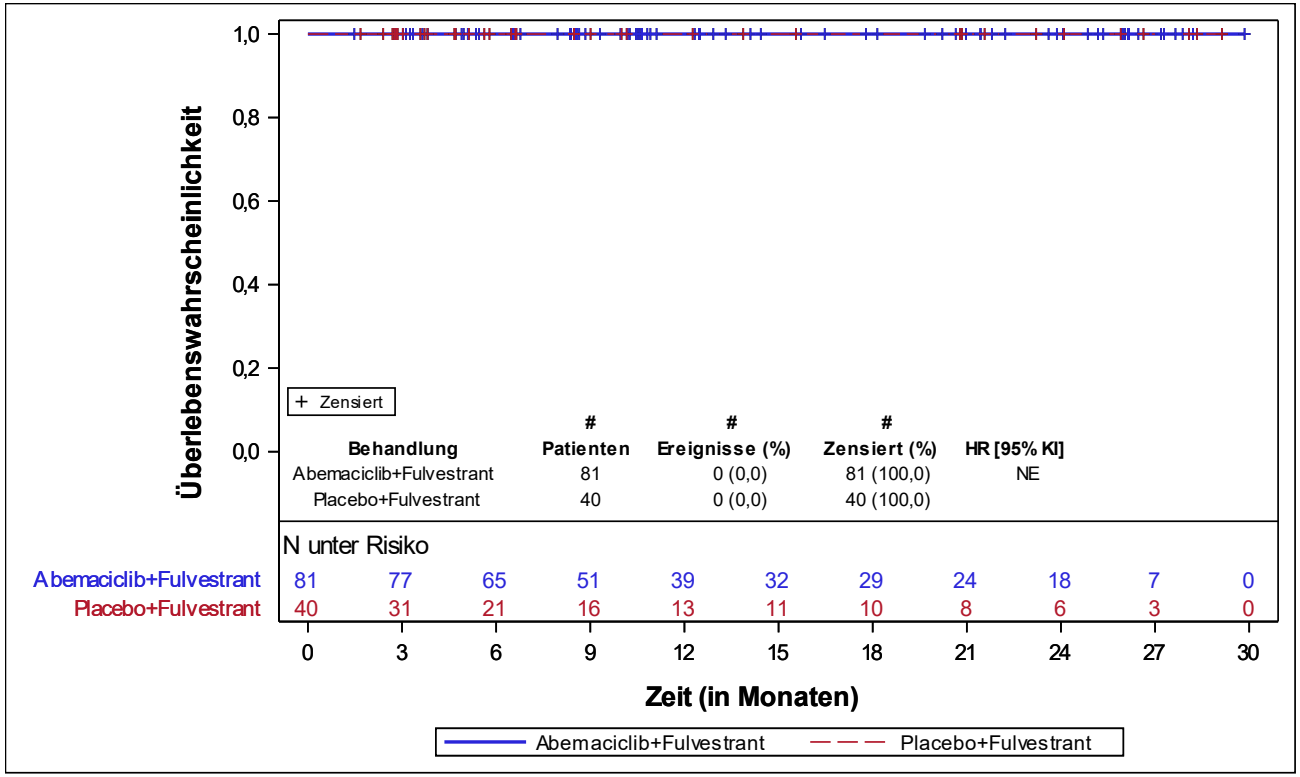
Abbildung 053.1: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alkalische Phosphatase erhöht Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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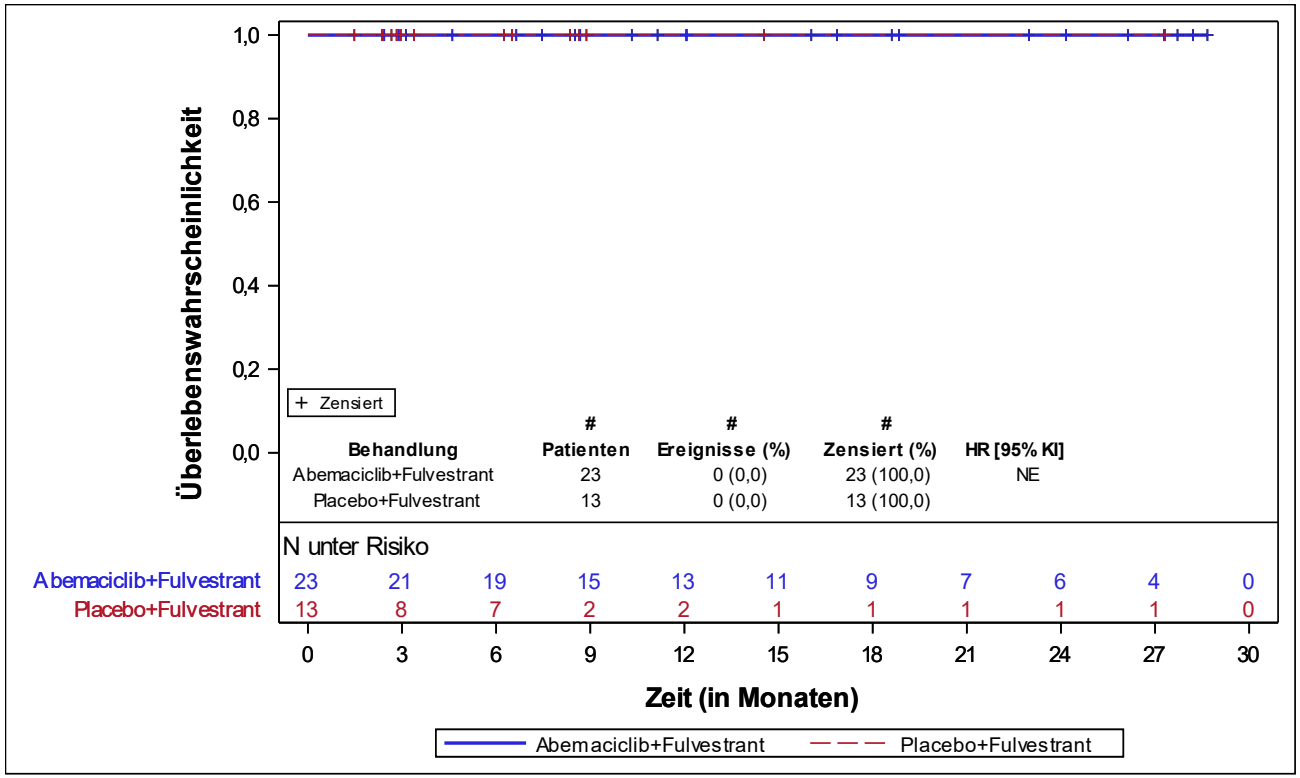
Abbildung 053.2: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alkalische Phosphatase erhöht Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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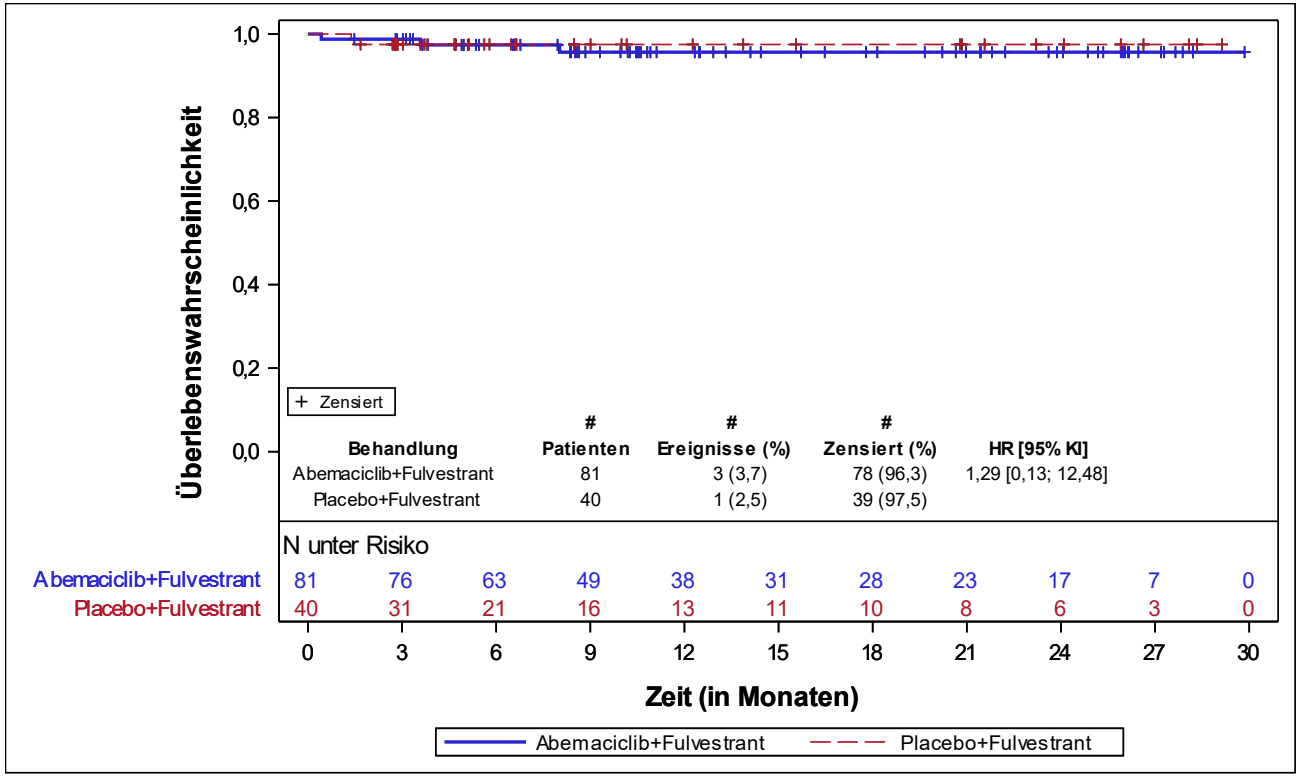
Abbildung 054.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Bilirubin im Blut erhöht (jeglicher Schweregrad) Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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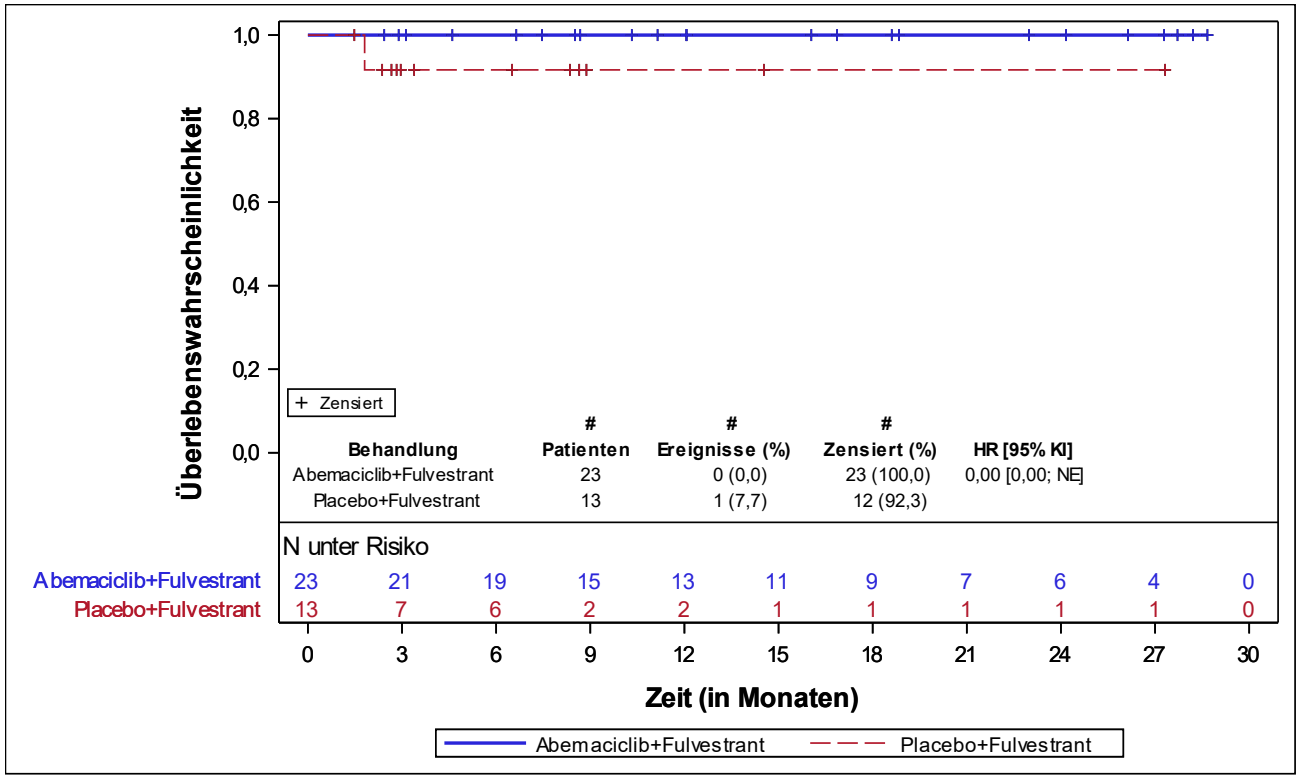
Abbildung 054.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Bilirubin im Blut erhöht (jeglicher Schweregrad) Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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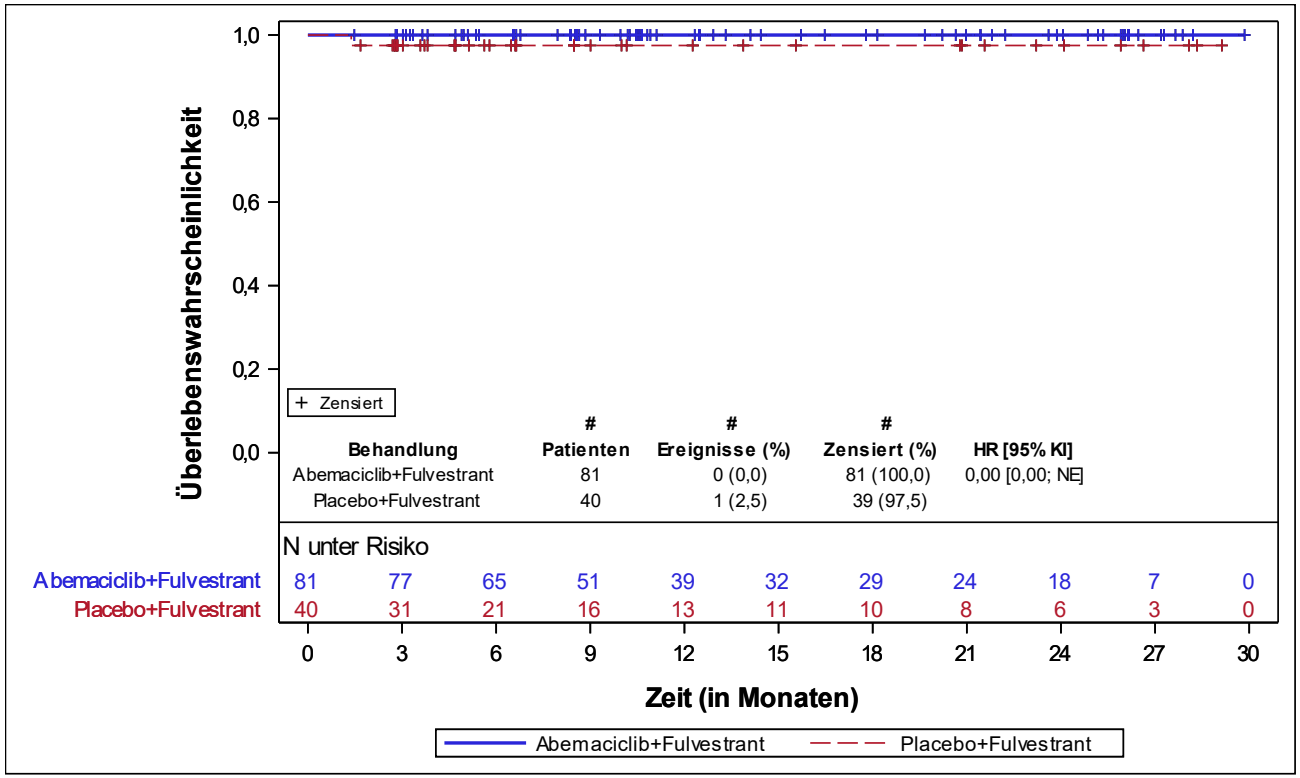
Abbildung 055.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Bilirubin im Blut erhöht Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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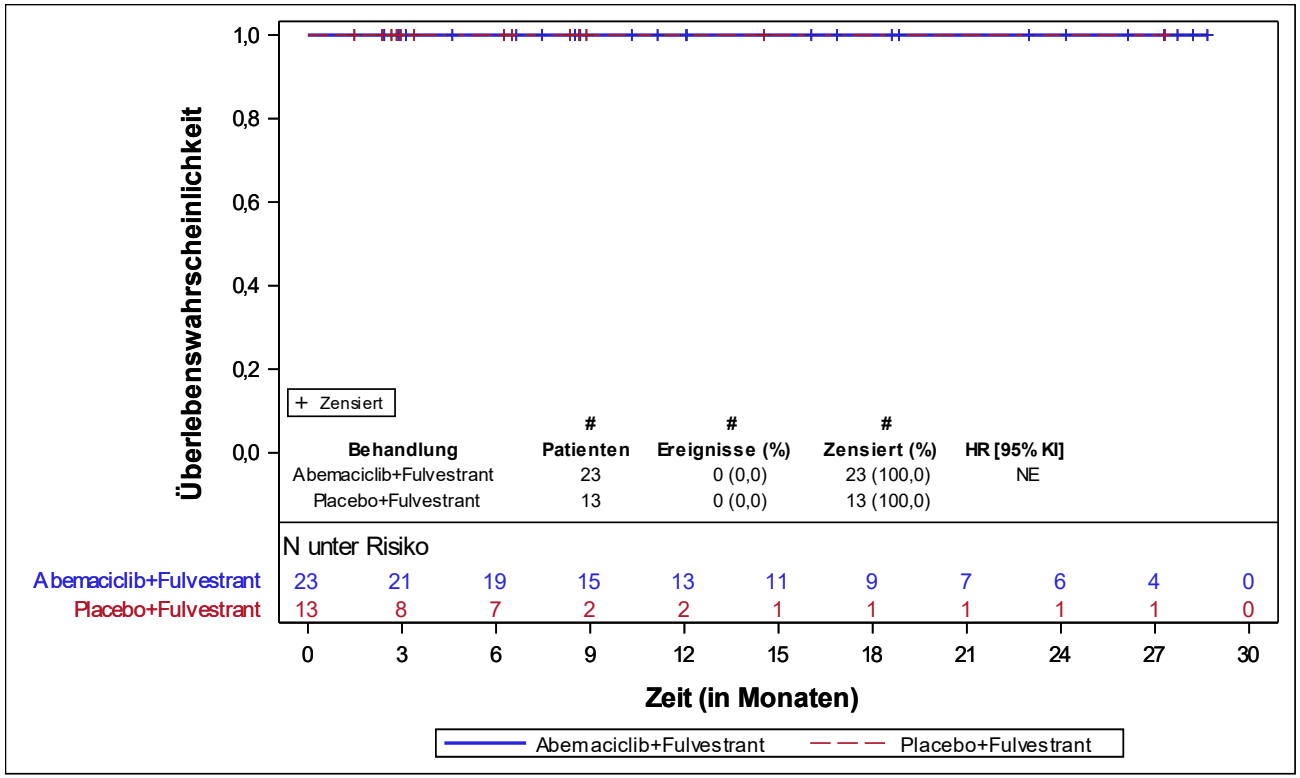
Abbildung 055.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Bilirubin im Blut erhöht Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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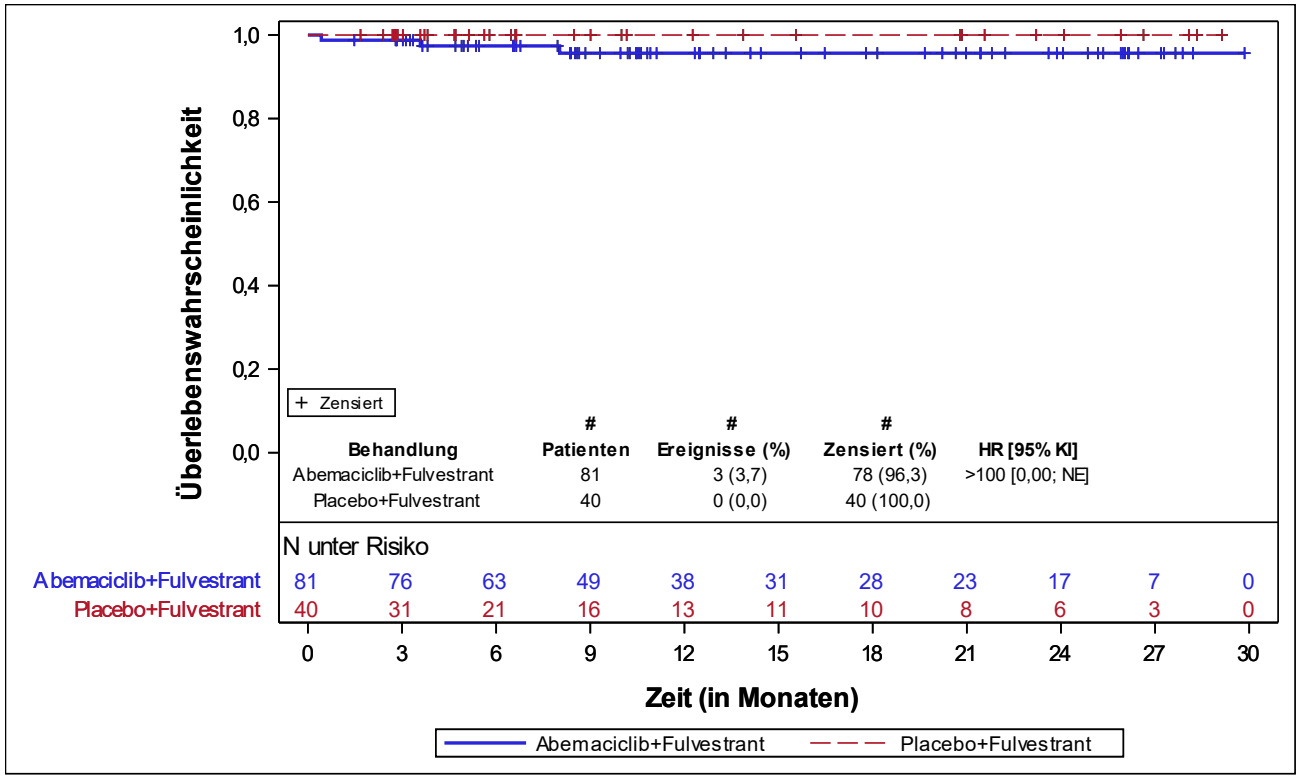
Abbildung 056.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Bilirubin im Blut erhöht Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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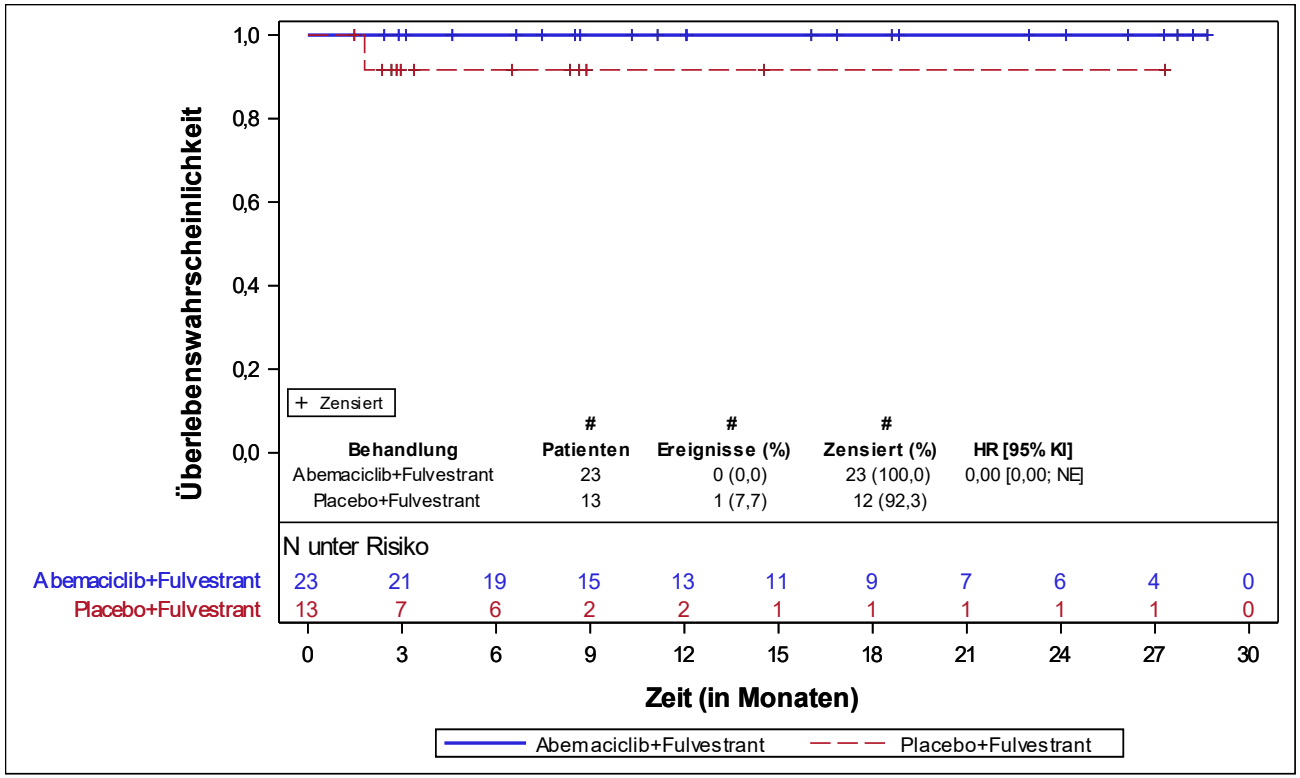
Abbildung 056.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Bilirubin im Blut erhöht Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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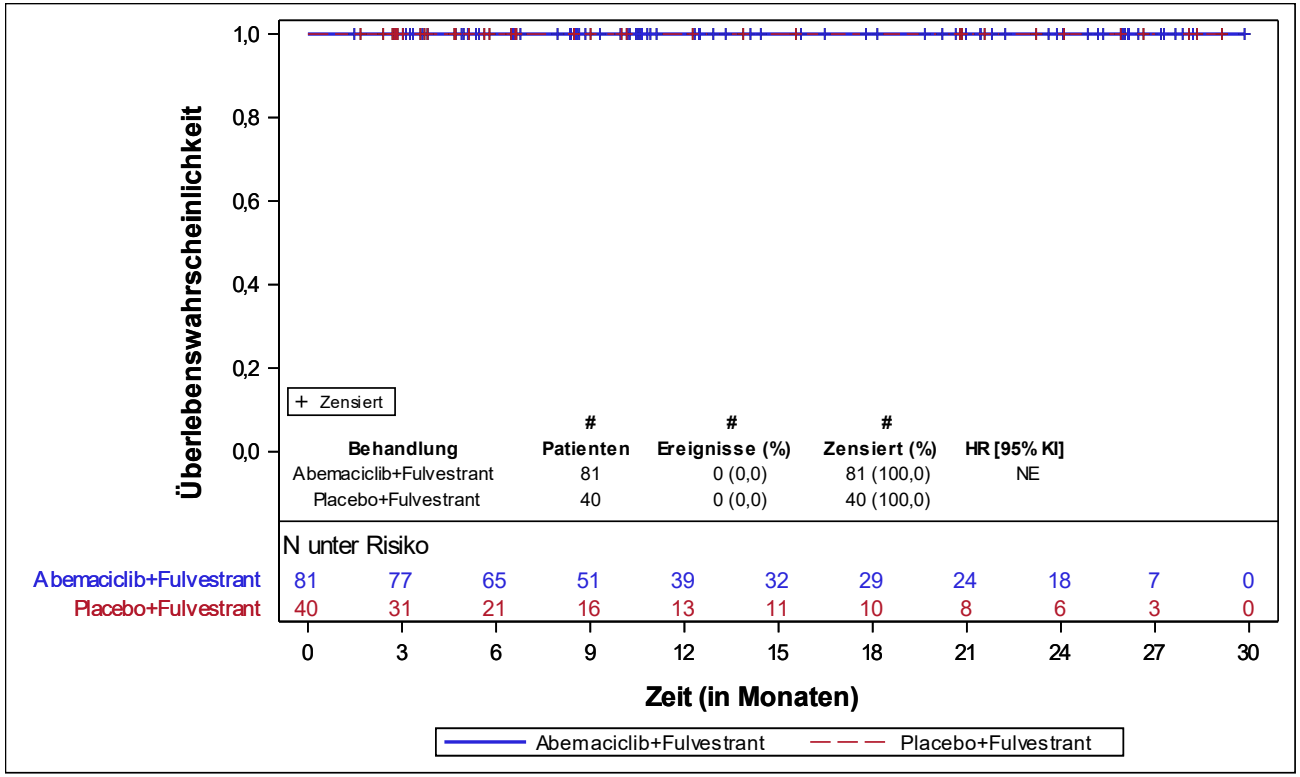
Abbildung 057.1: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Bilirubin im Blut erhöht Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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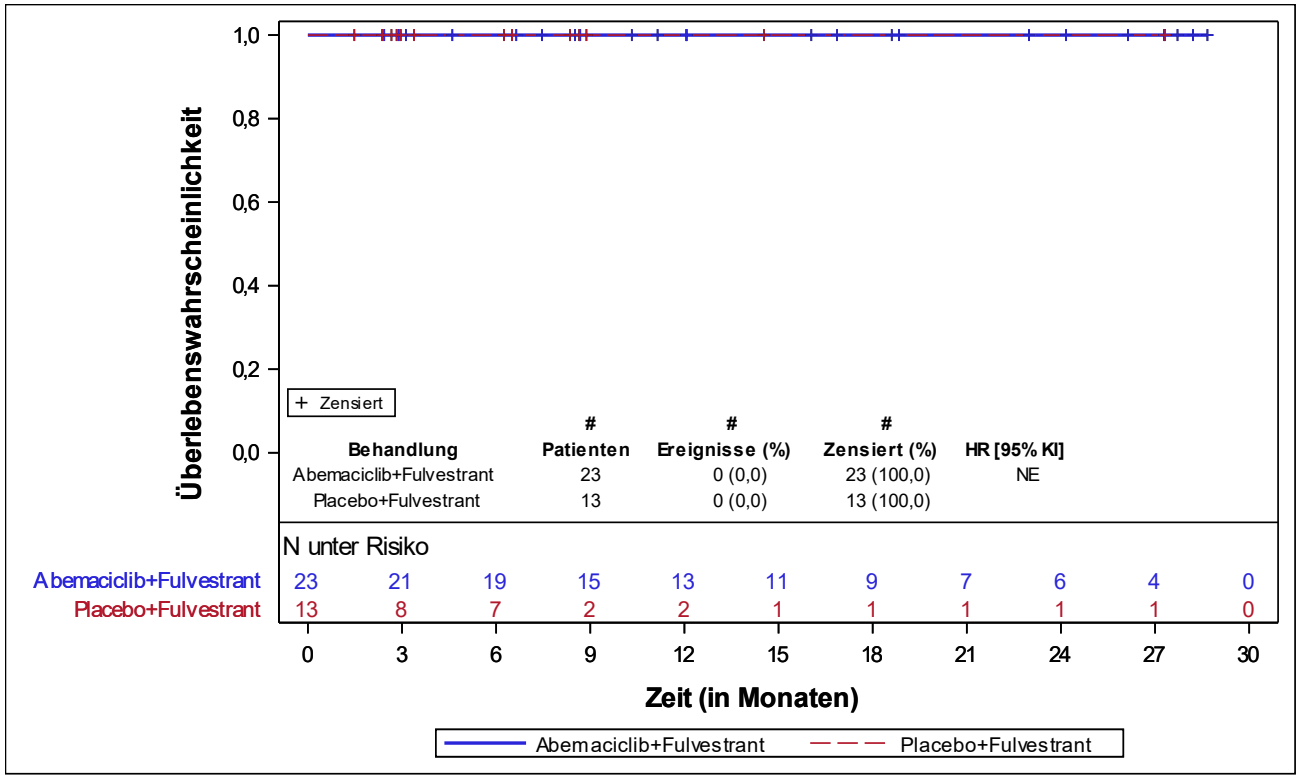
Abbildung 057.2: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Bilirubin im Blut erhöht Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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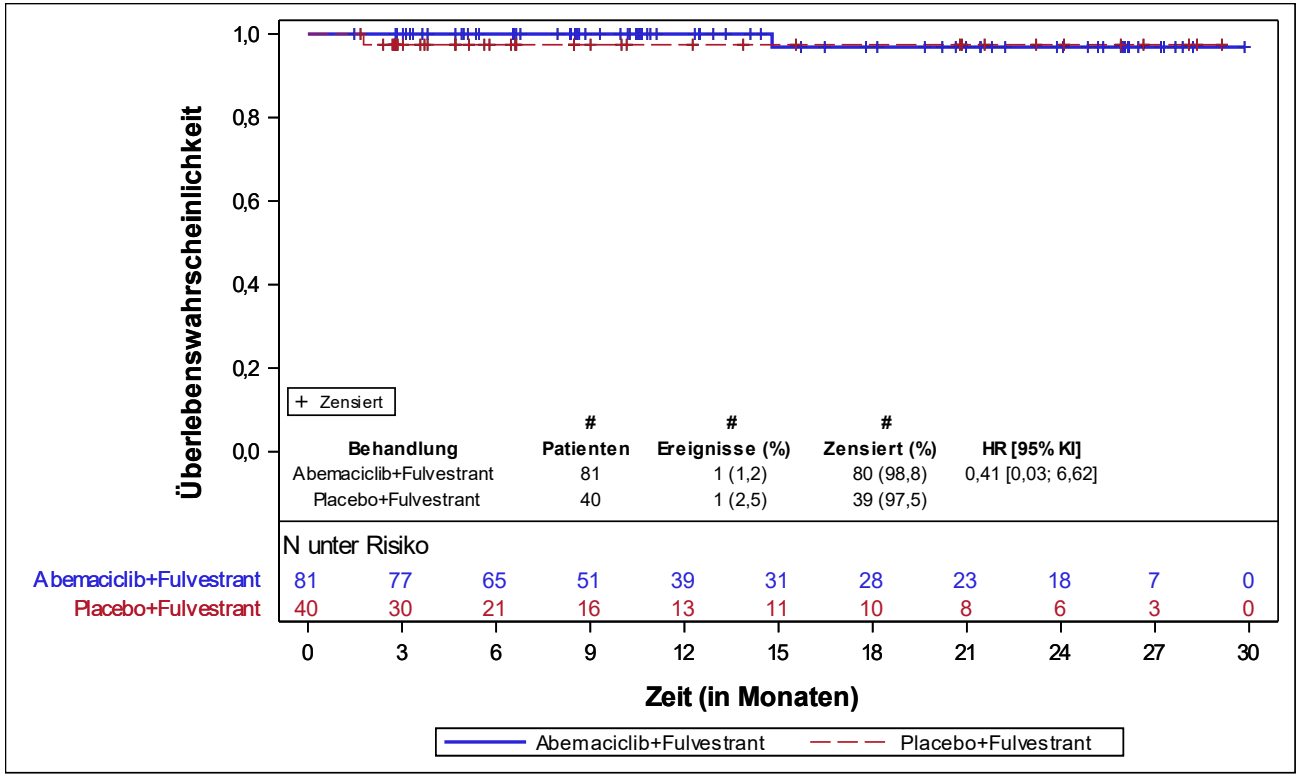
Abbildung 058.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Pneumonitis (jeglicher Schweregrad) Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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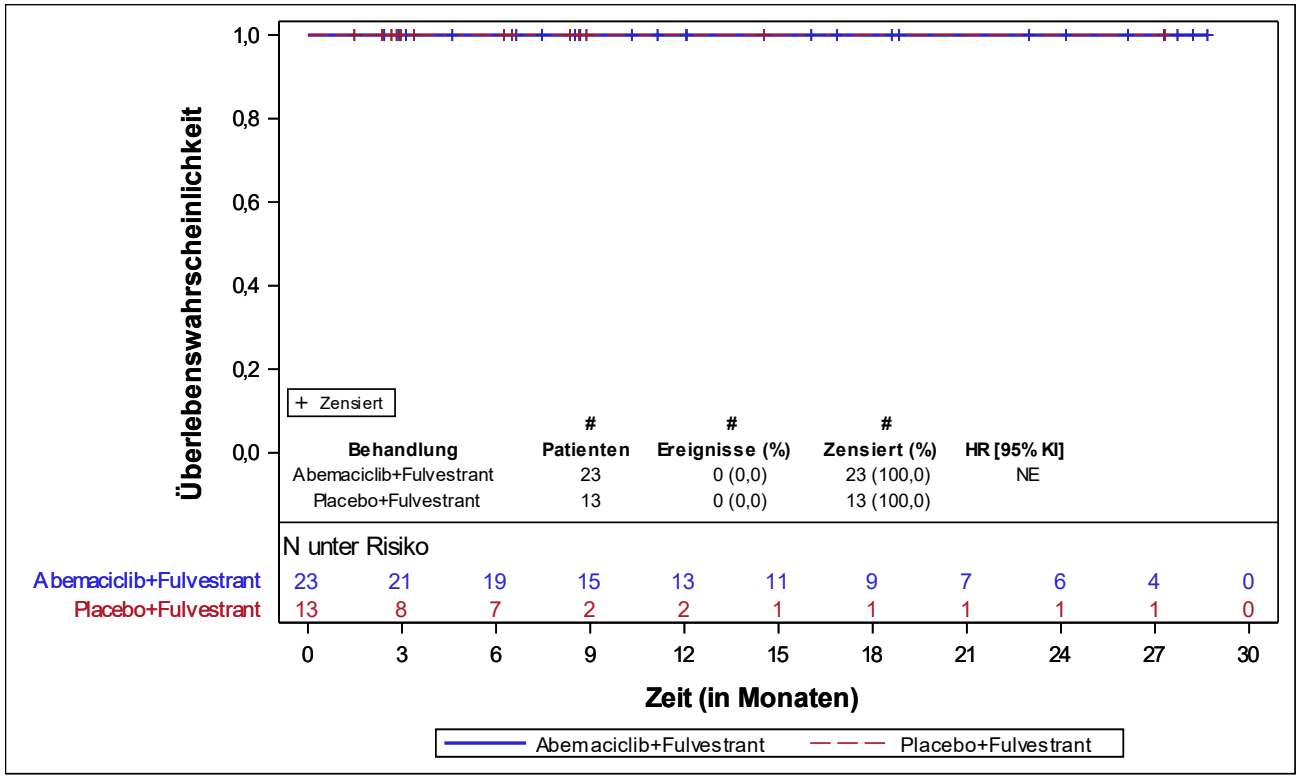
Abbildung 058.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: PT Pneumonitis (jeglicher Schweregrad) Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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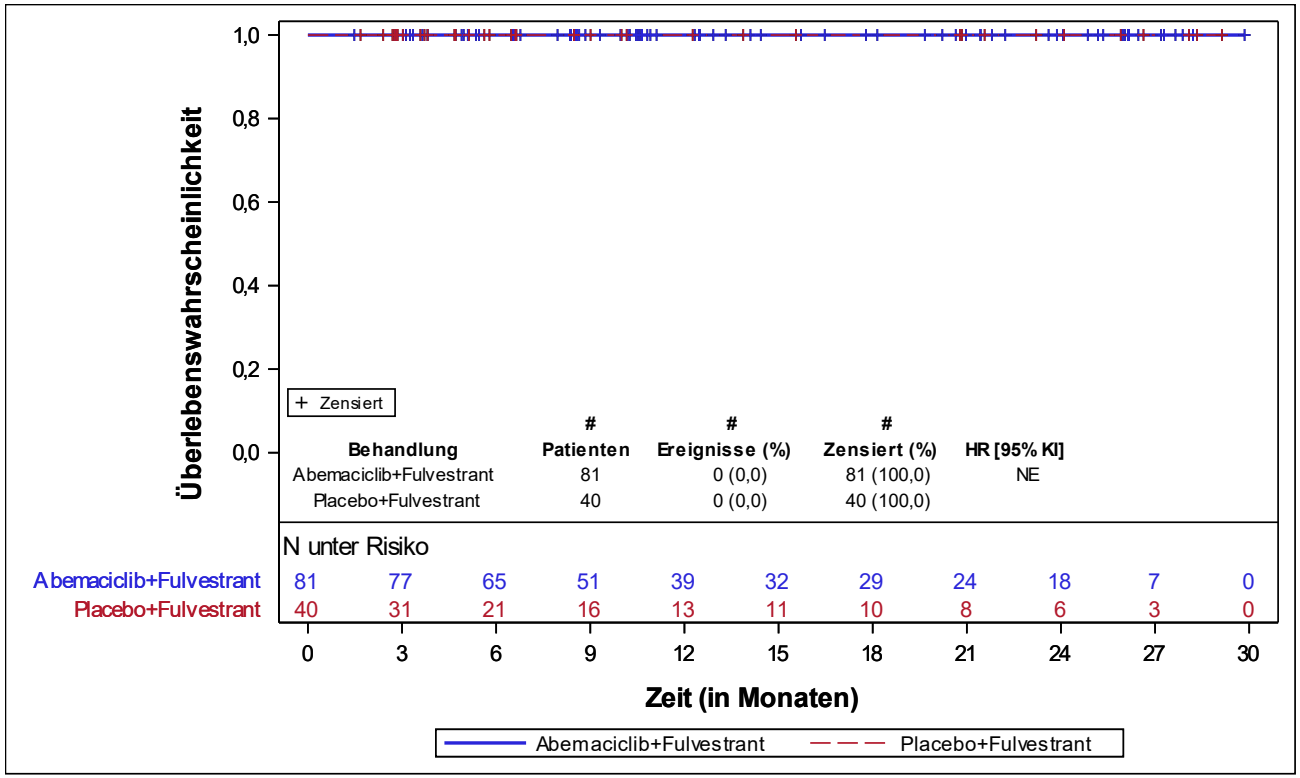
Abbildung 059.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Pneumonitis Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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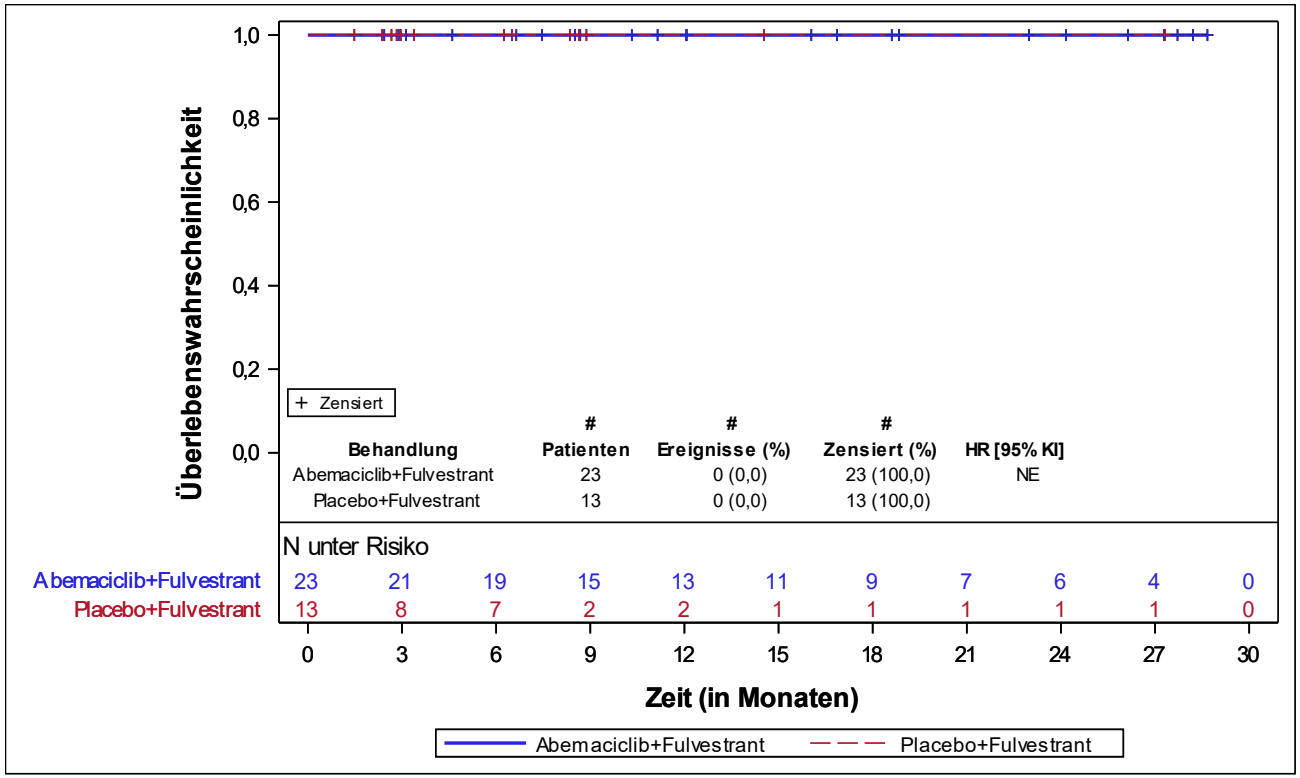
Abbildung 059.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Pneumonitis Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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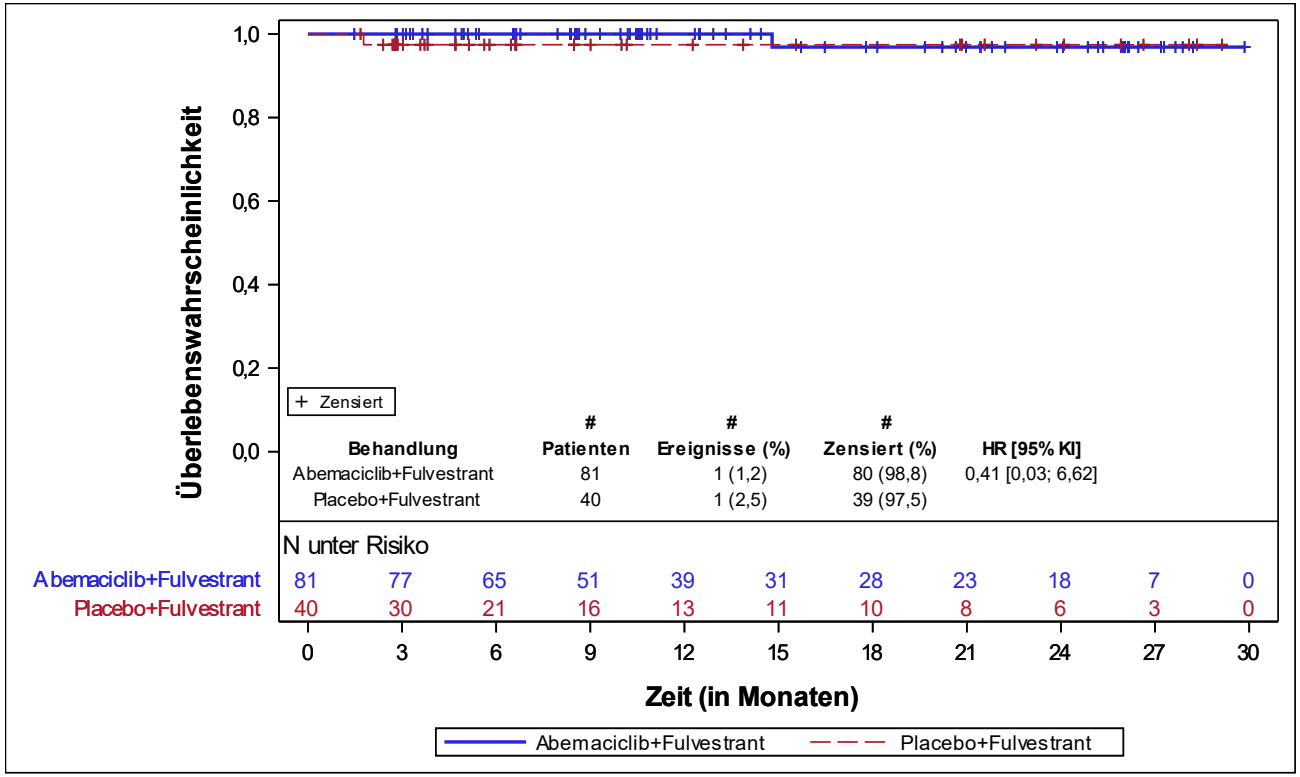
Abbildung 060.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Pneumonitis Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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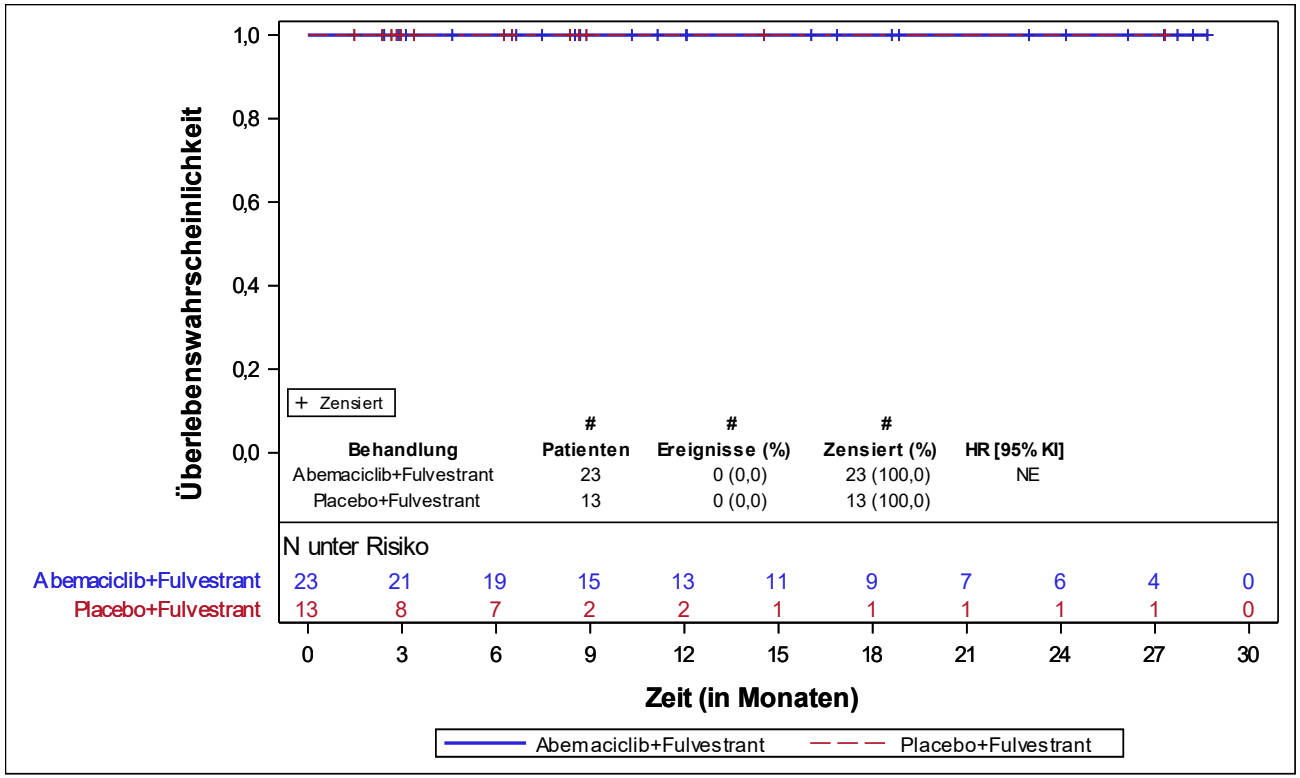
Abbildung 060.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Pneumonitis Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
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Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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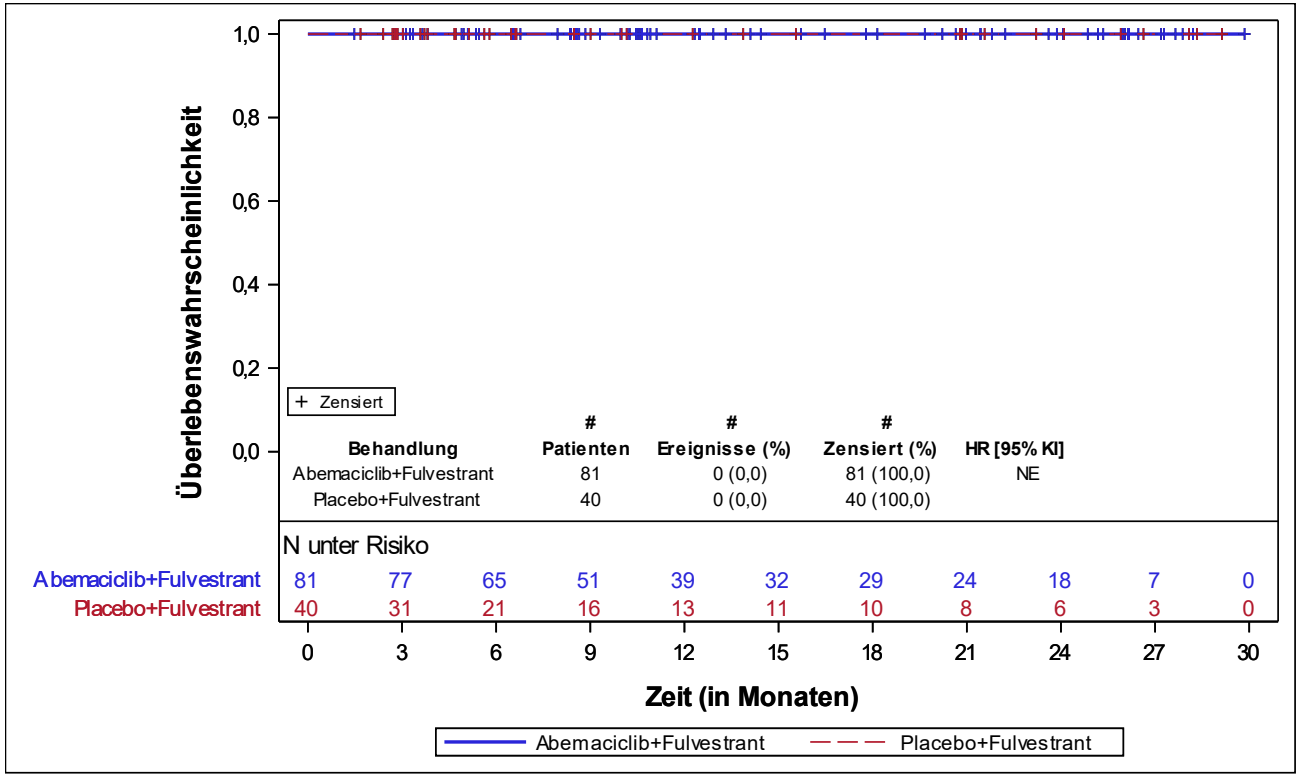
Abbildung 061.1: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Pneumonitis Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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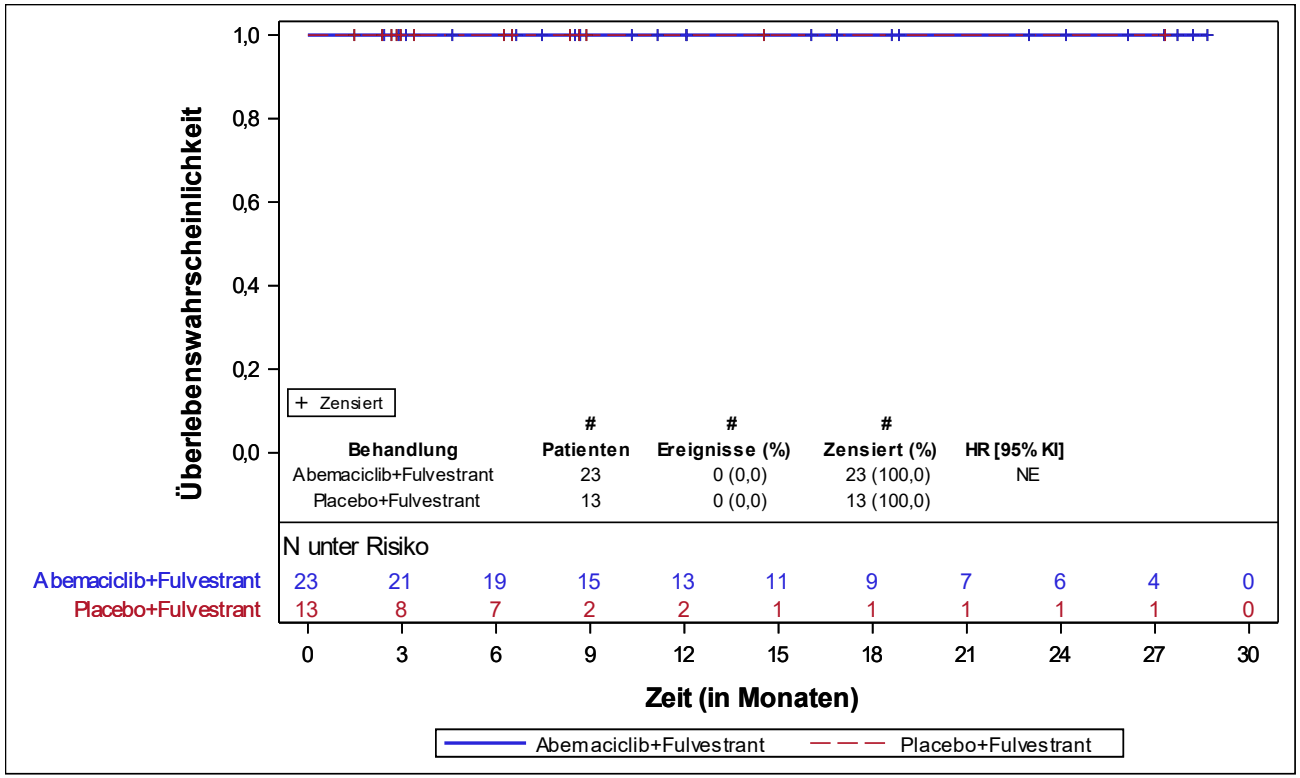
Abbildung 061.2: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Pneumonitis Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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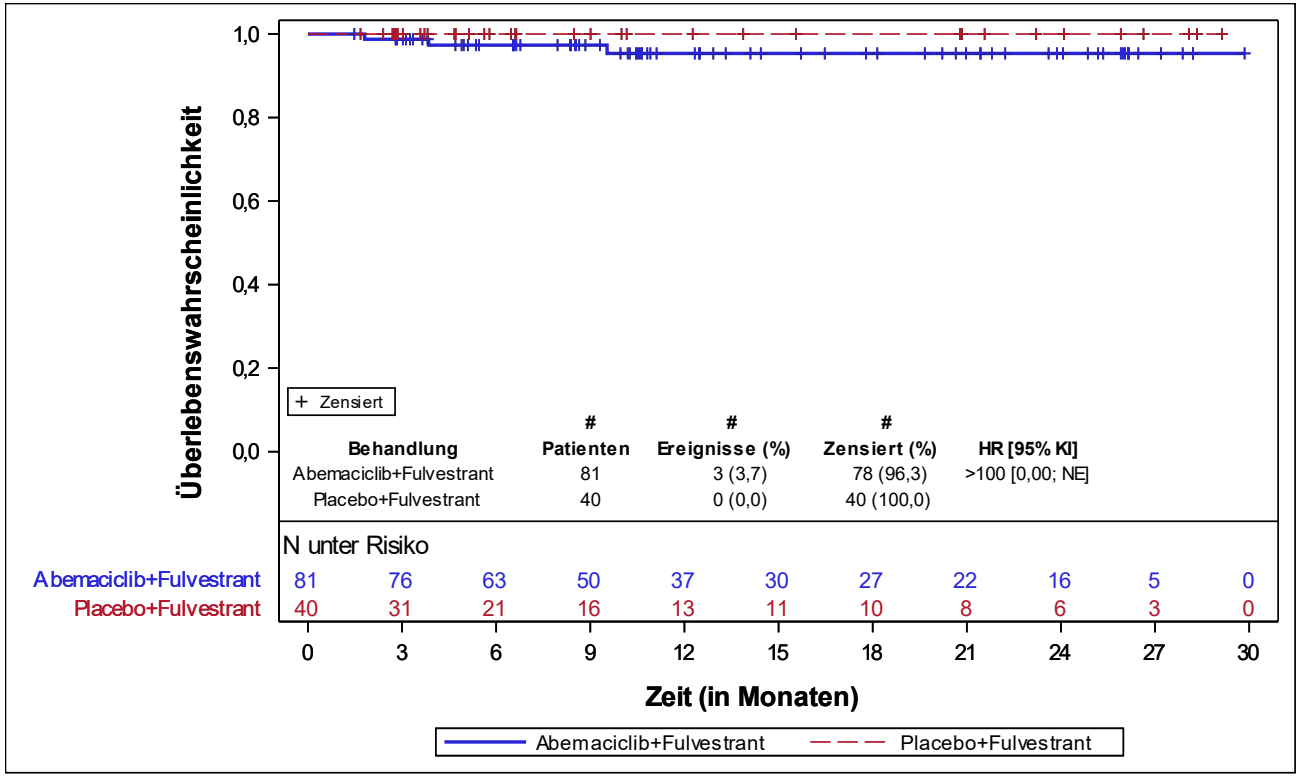
Abbildung 062.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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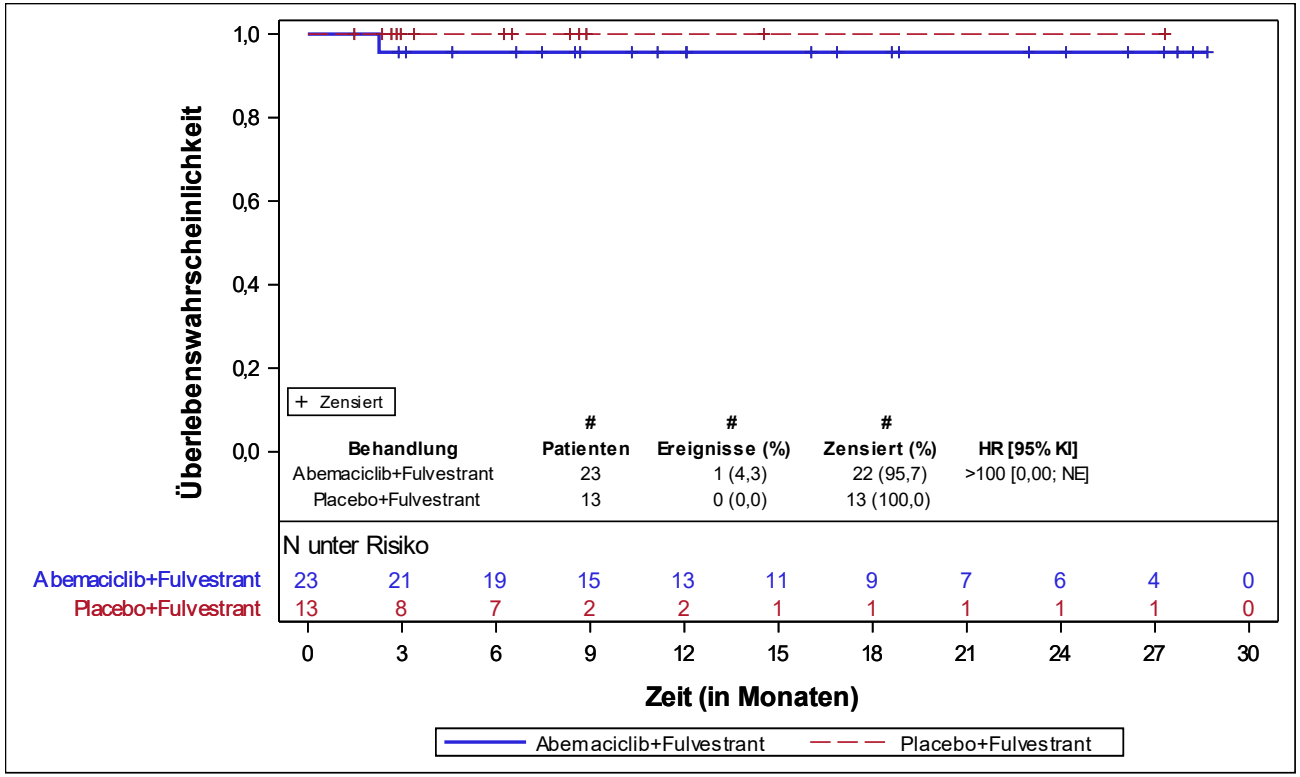
Abbildung 062.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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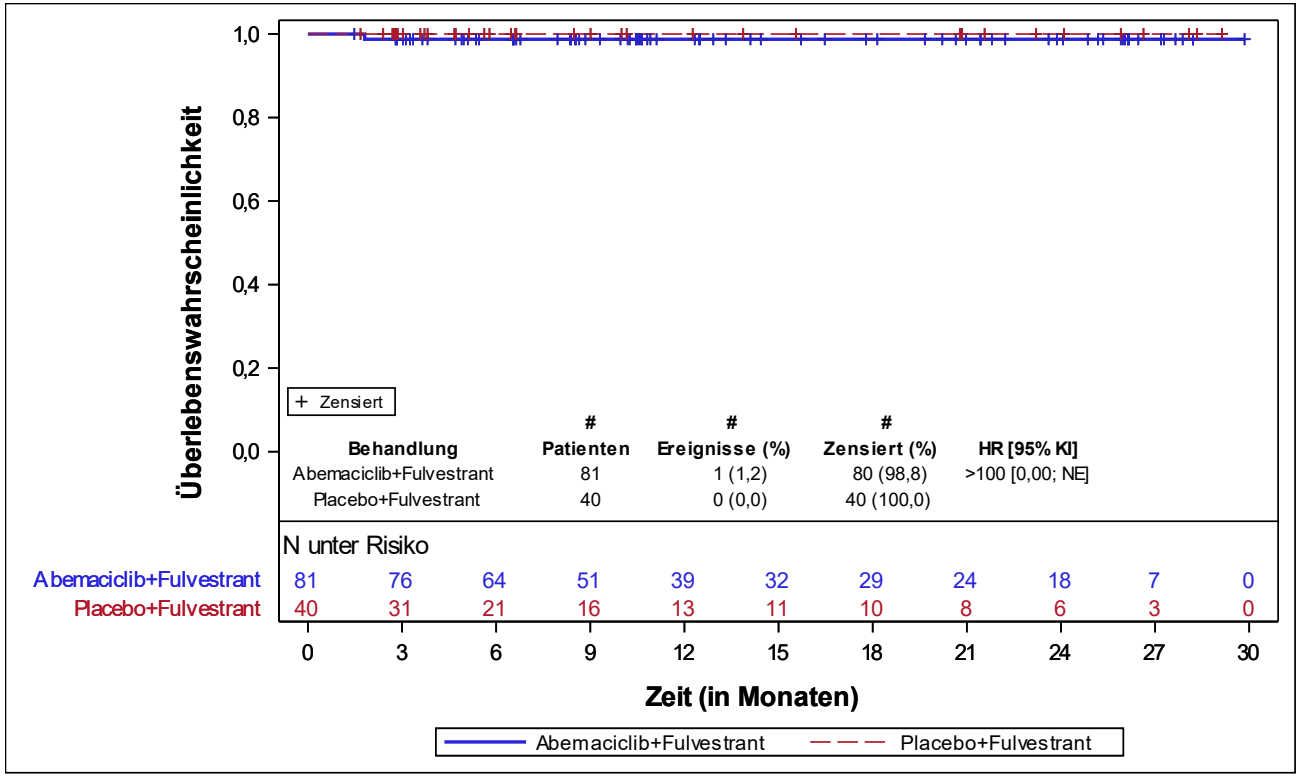
Abbildung 063.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Venöse Thromboembolie Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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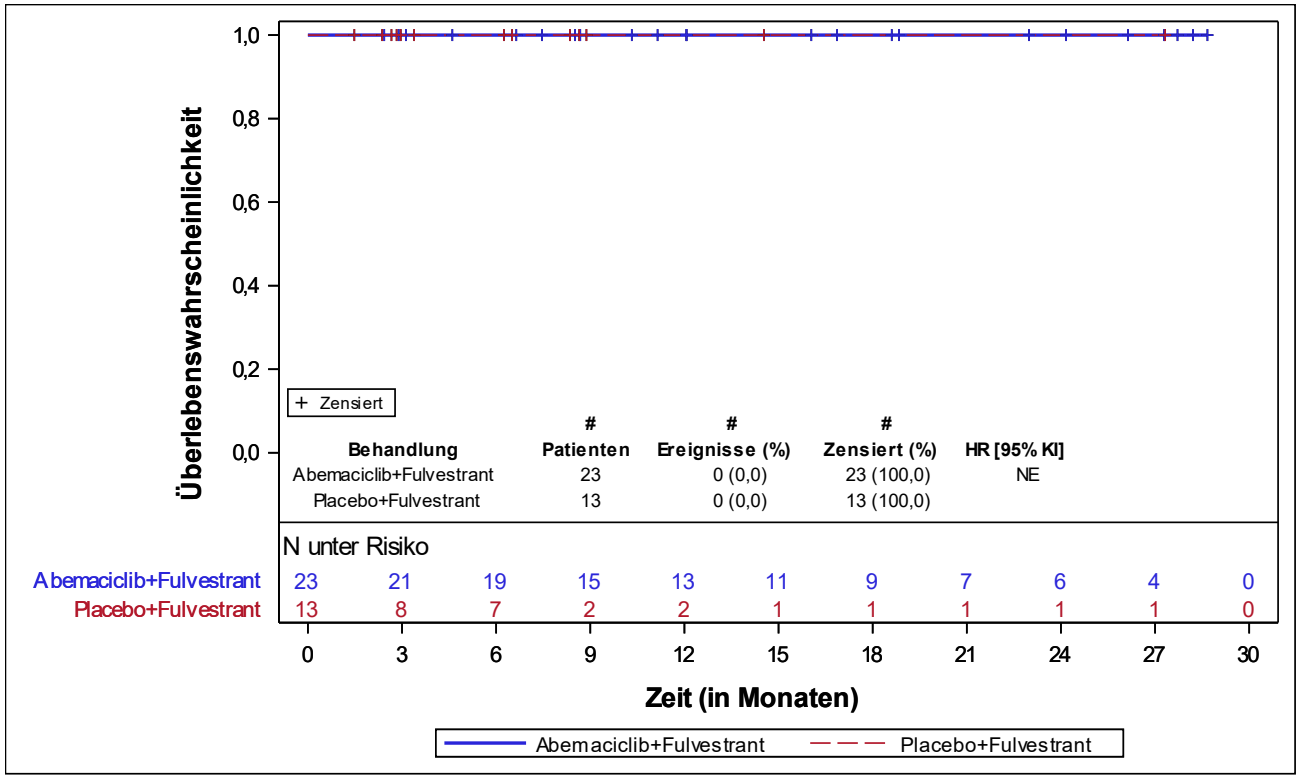
Abbildung 063.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Venöse Thromboembolie Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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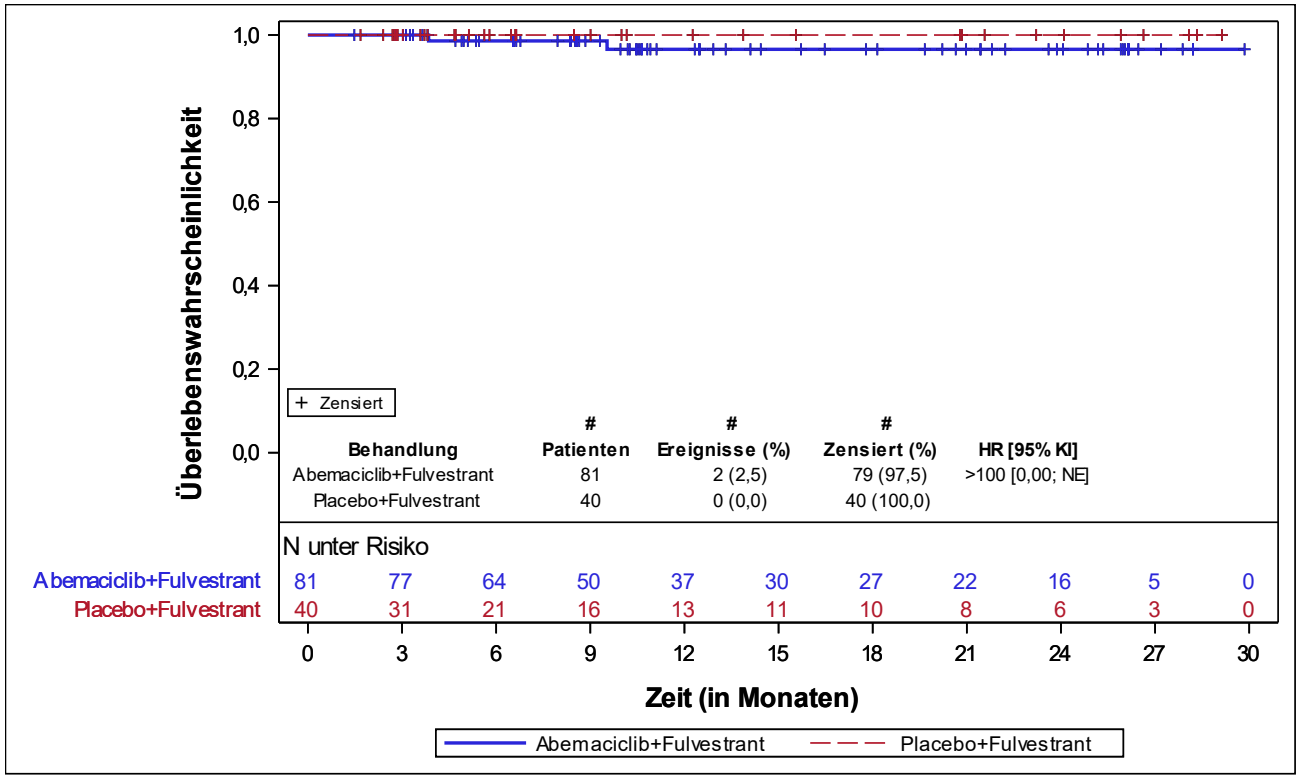
Abbildung 064.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Venöse Thromboembolie Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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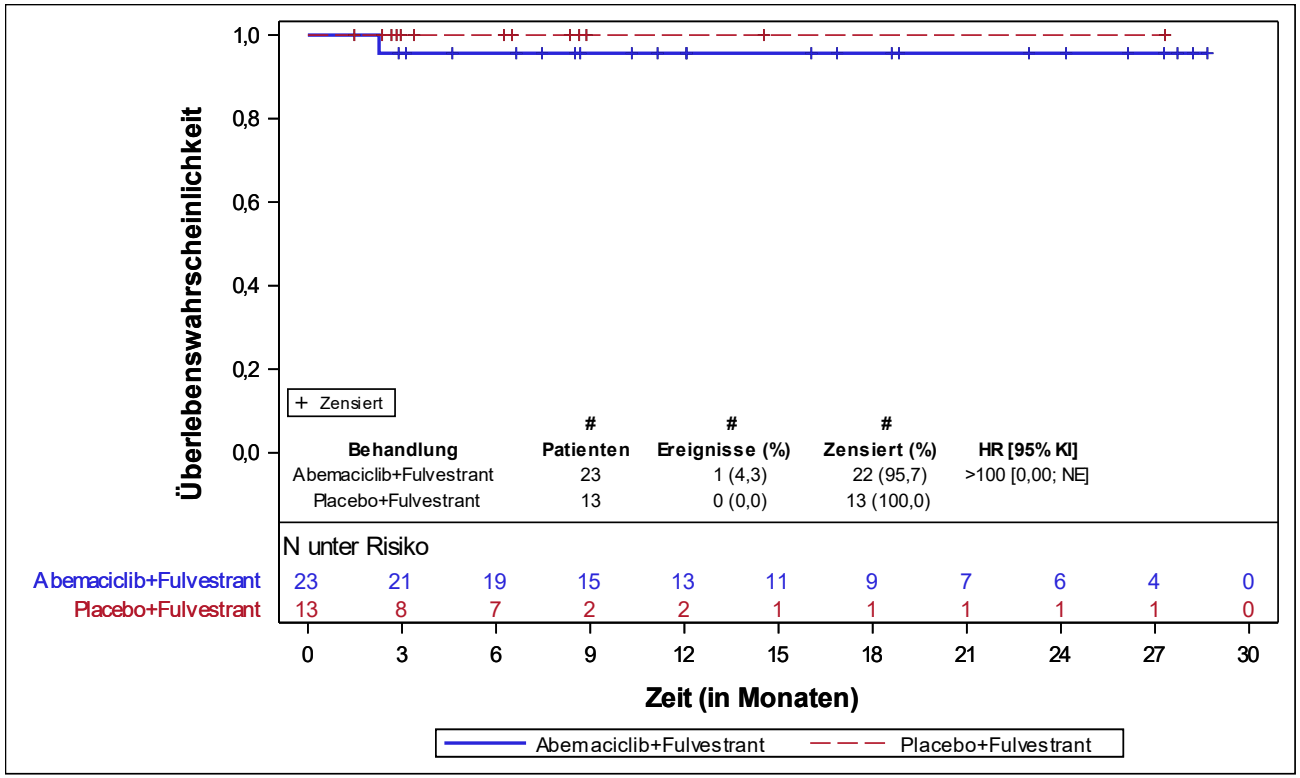
Abbildung 064.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Venöse Thromboembolie Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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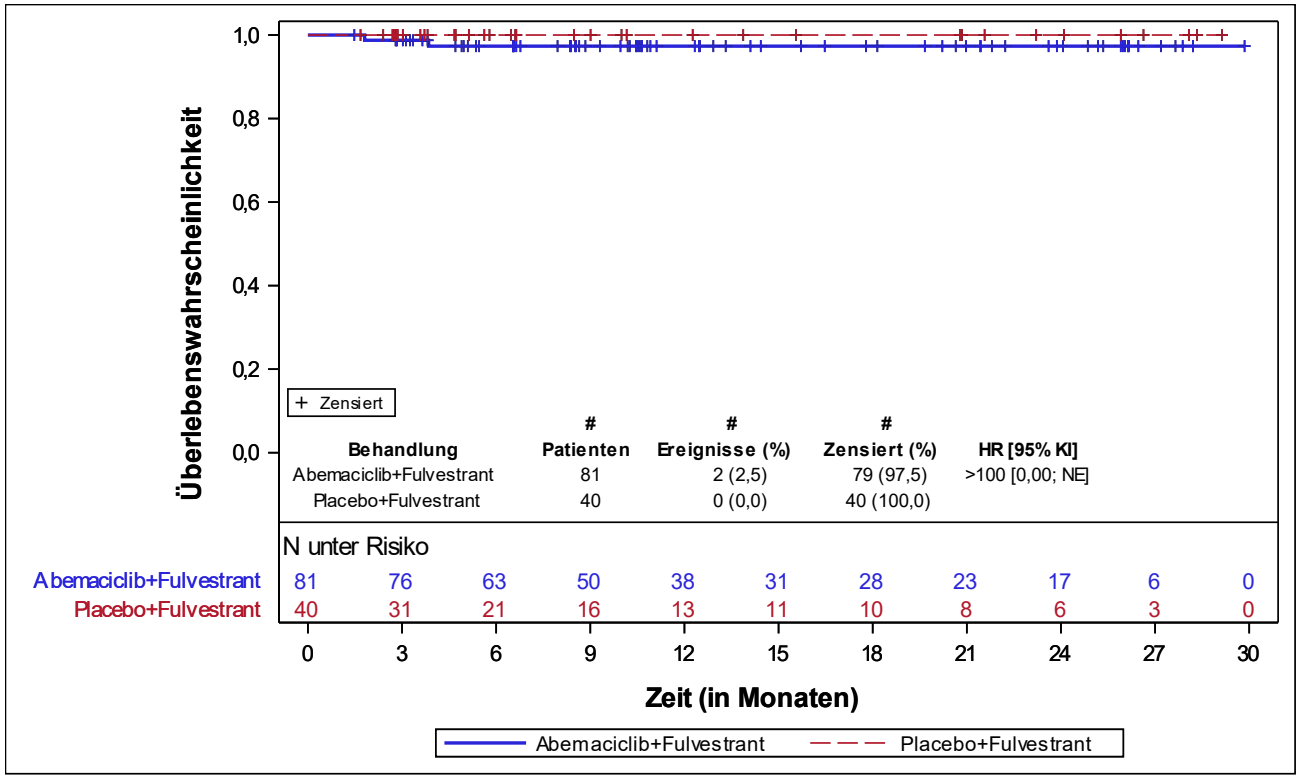
Abbildung 065.1: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: Venöse Thromboembolie Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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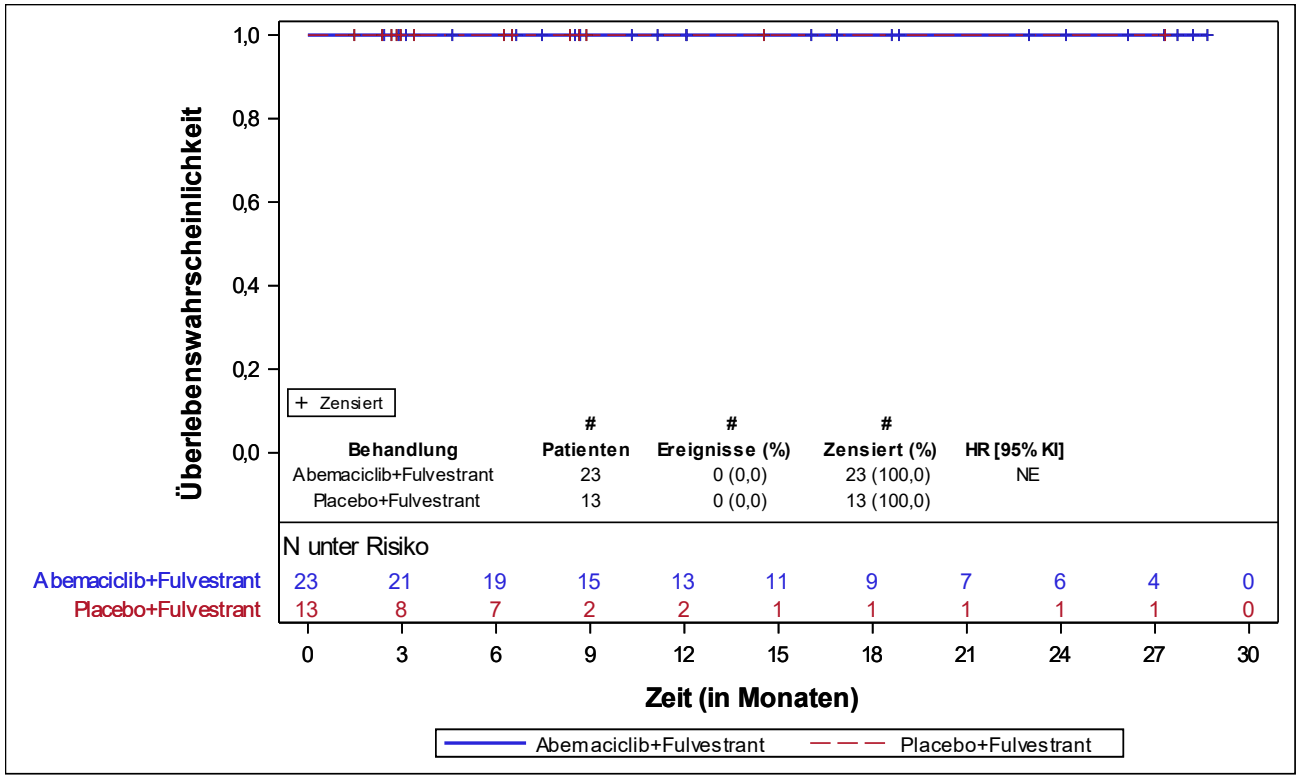
Abbildung 065.2: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: Venöse Thromboembolie Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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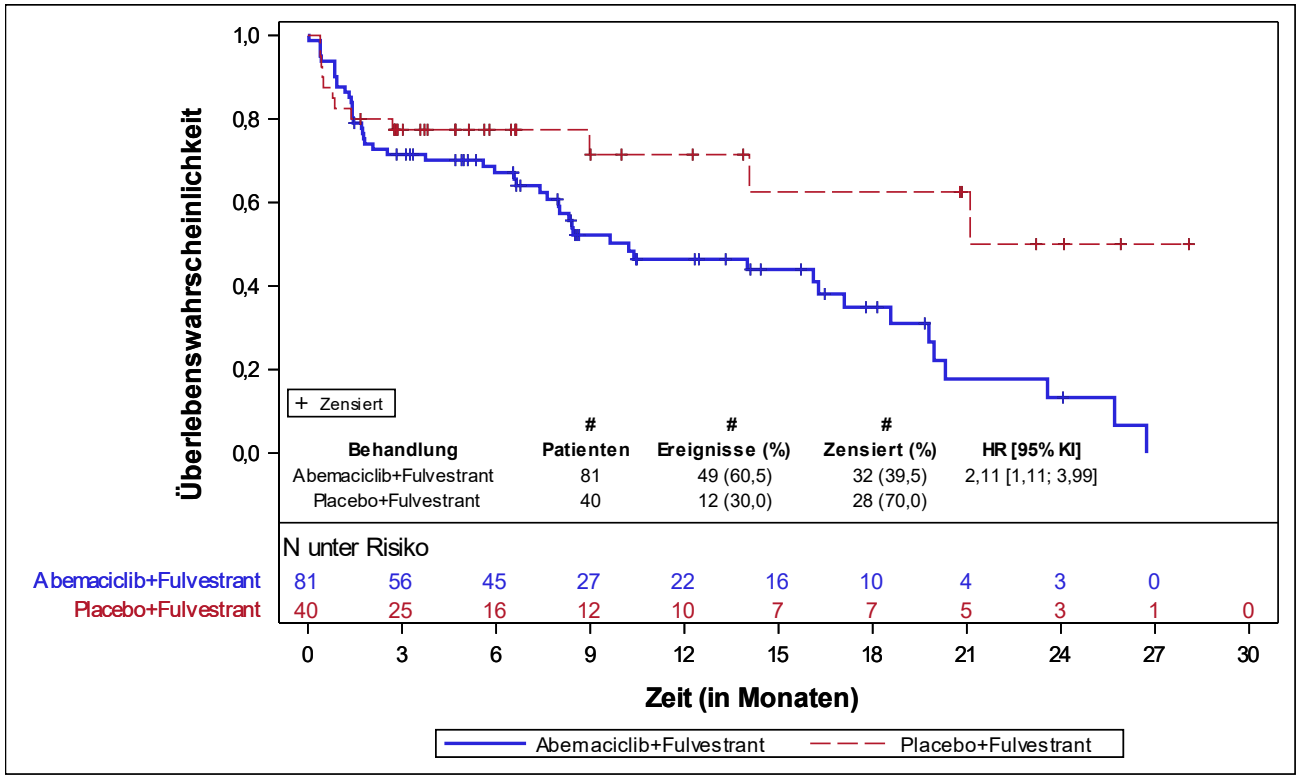
Abbildung 066.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad)
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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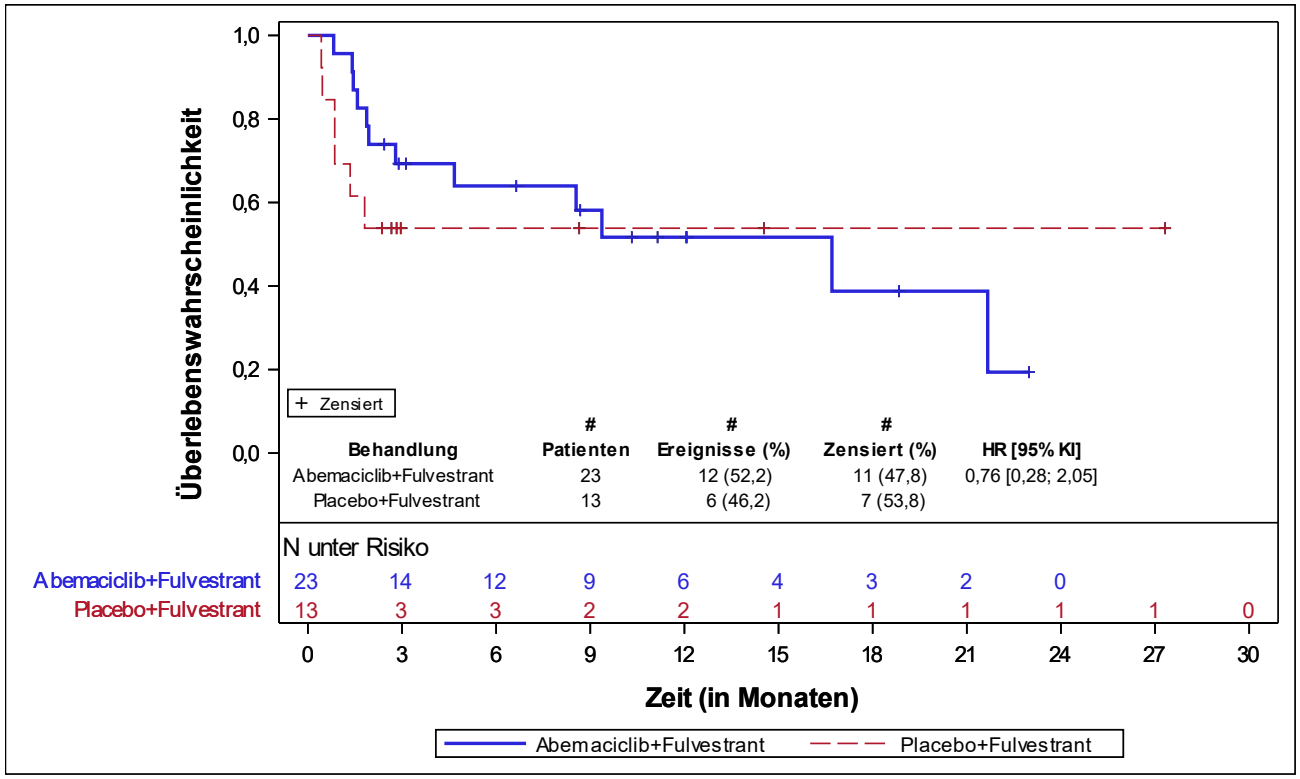
Abbildung 066.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad)
Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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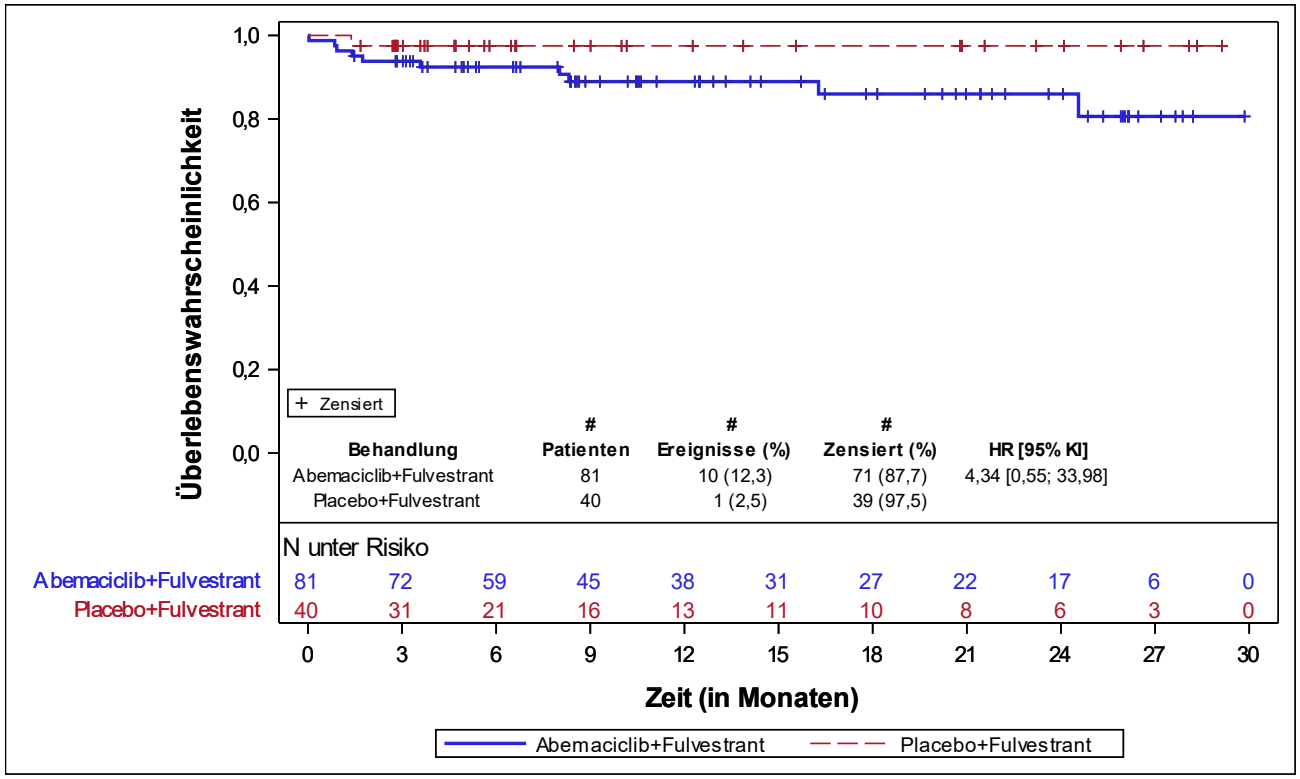
Abbildung 067.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
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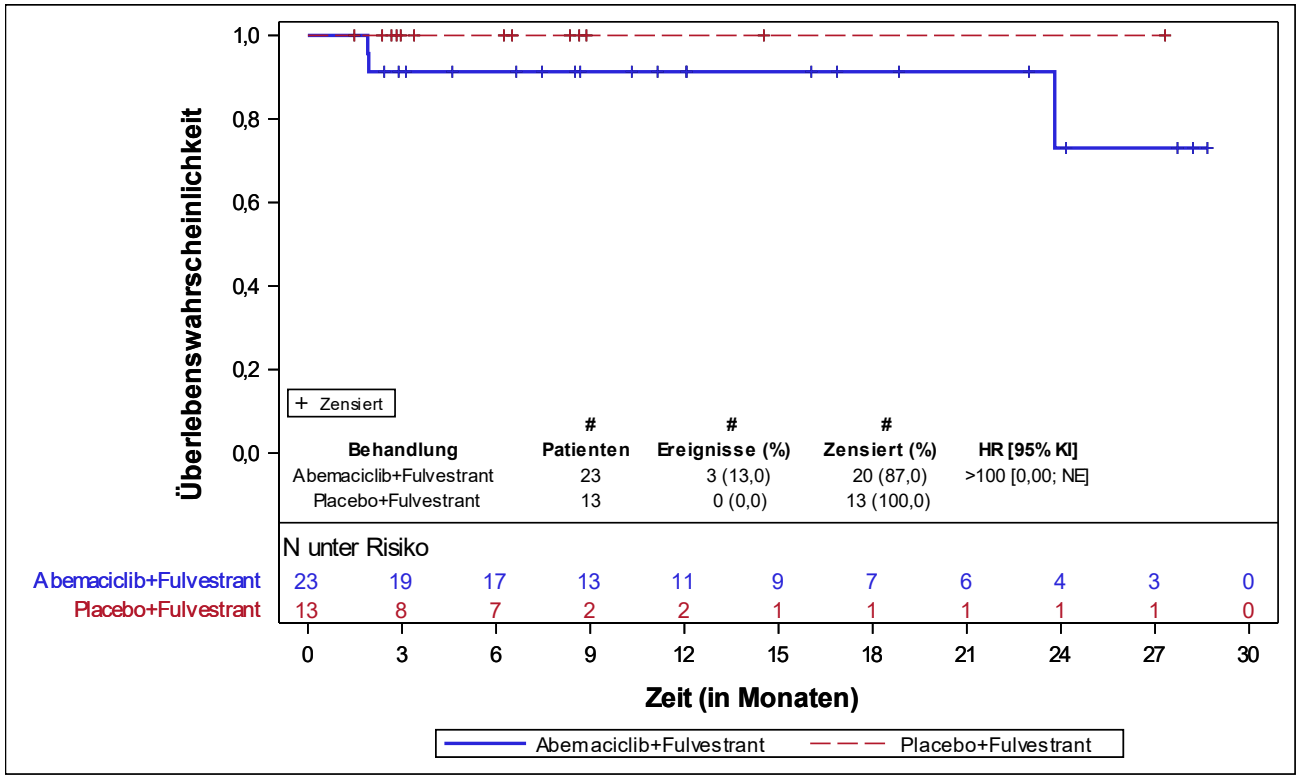
Abbildung 067.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber
Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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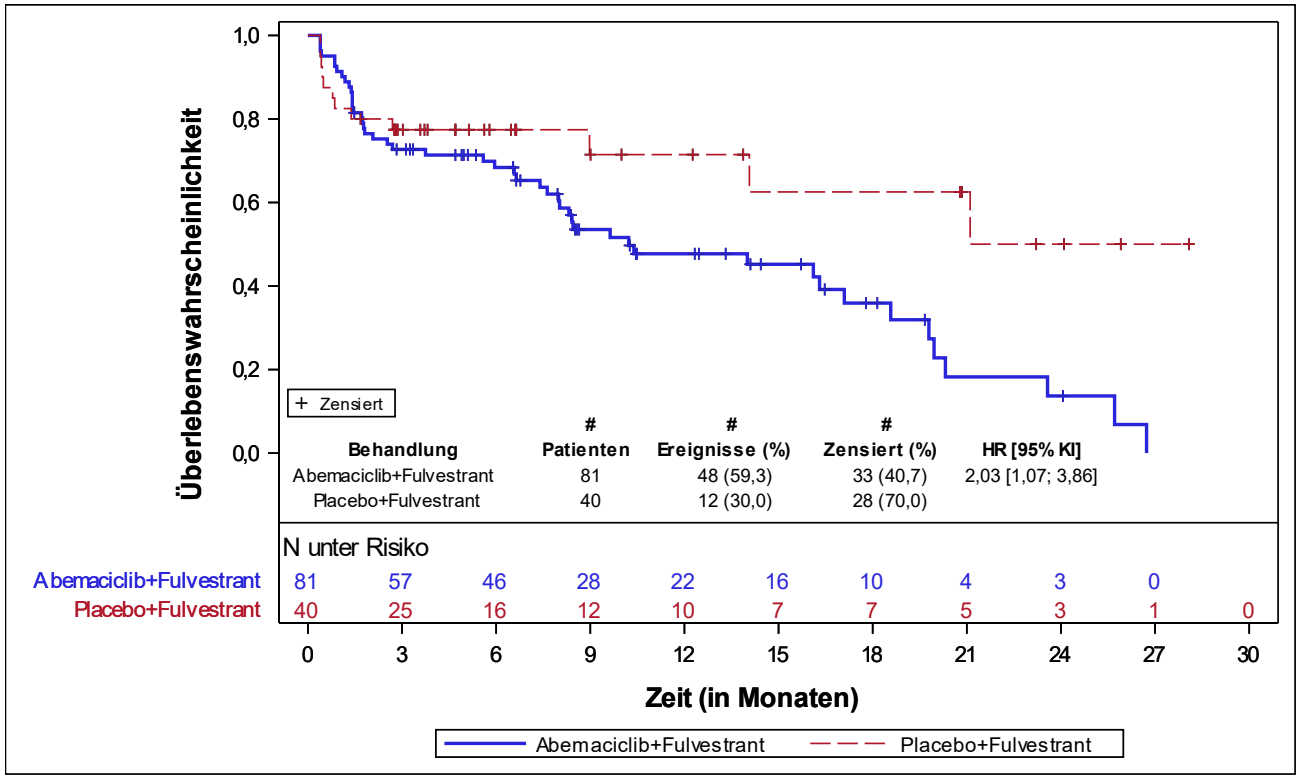
Abbildung 068.1: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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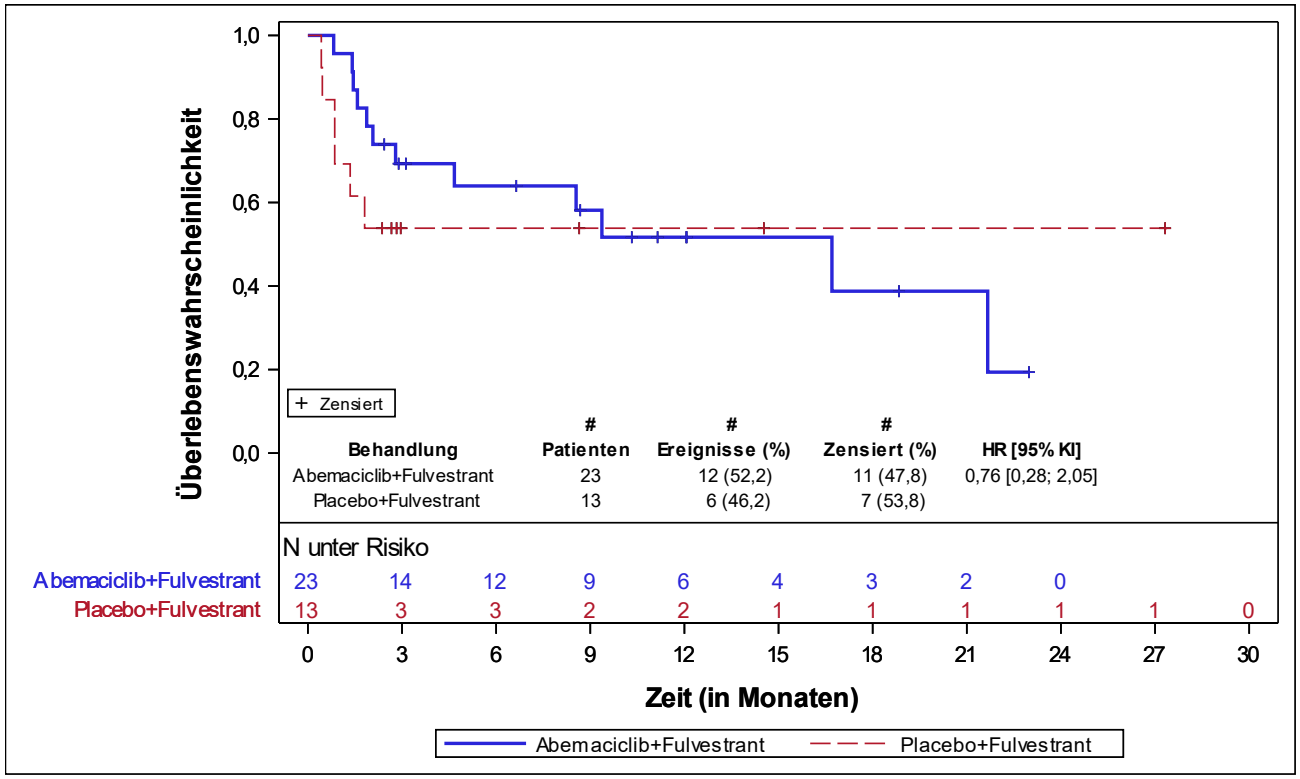
Abbildung 068.2: Kaplan-Meier-Kurven - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber
Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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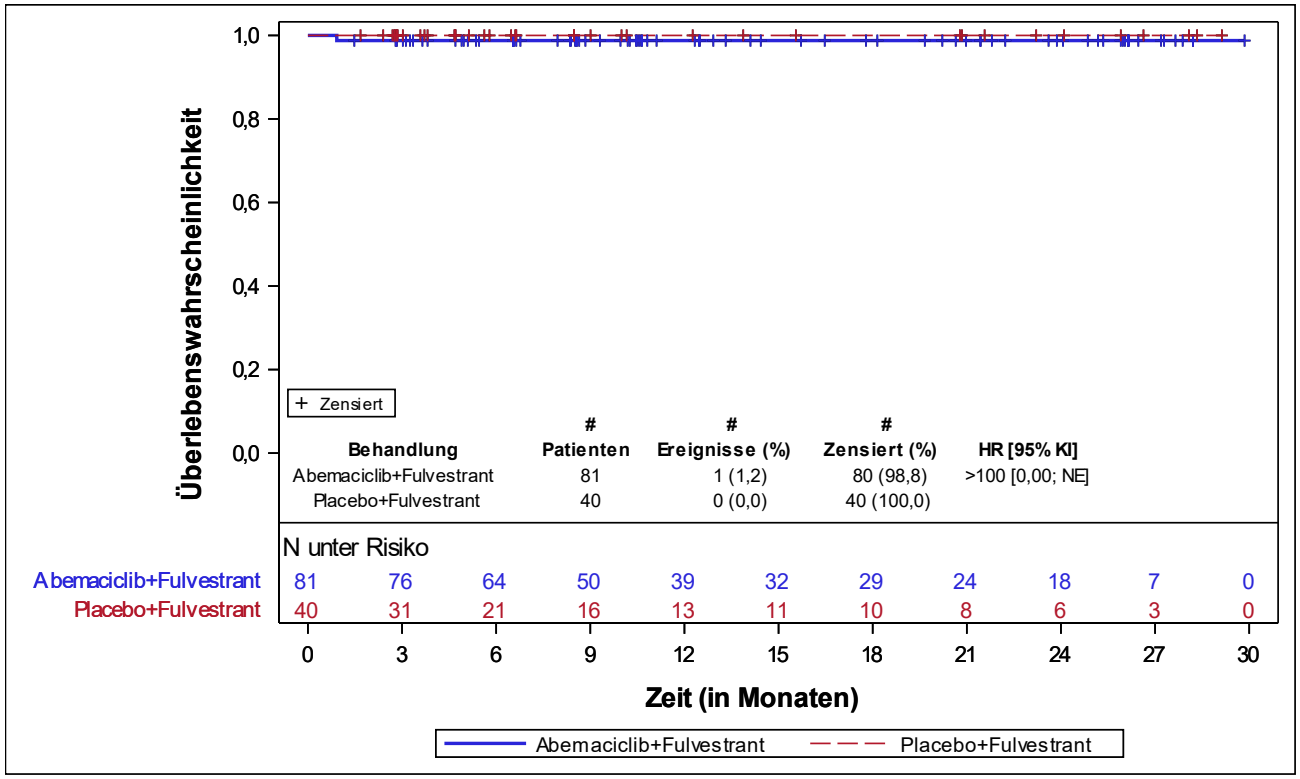
Abbildung 069.1: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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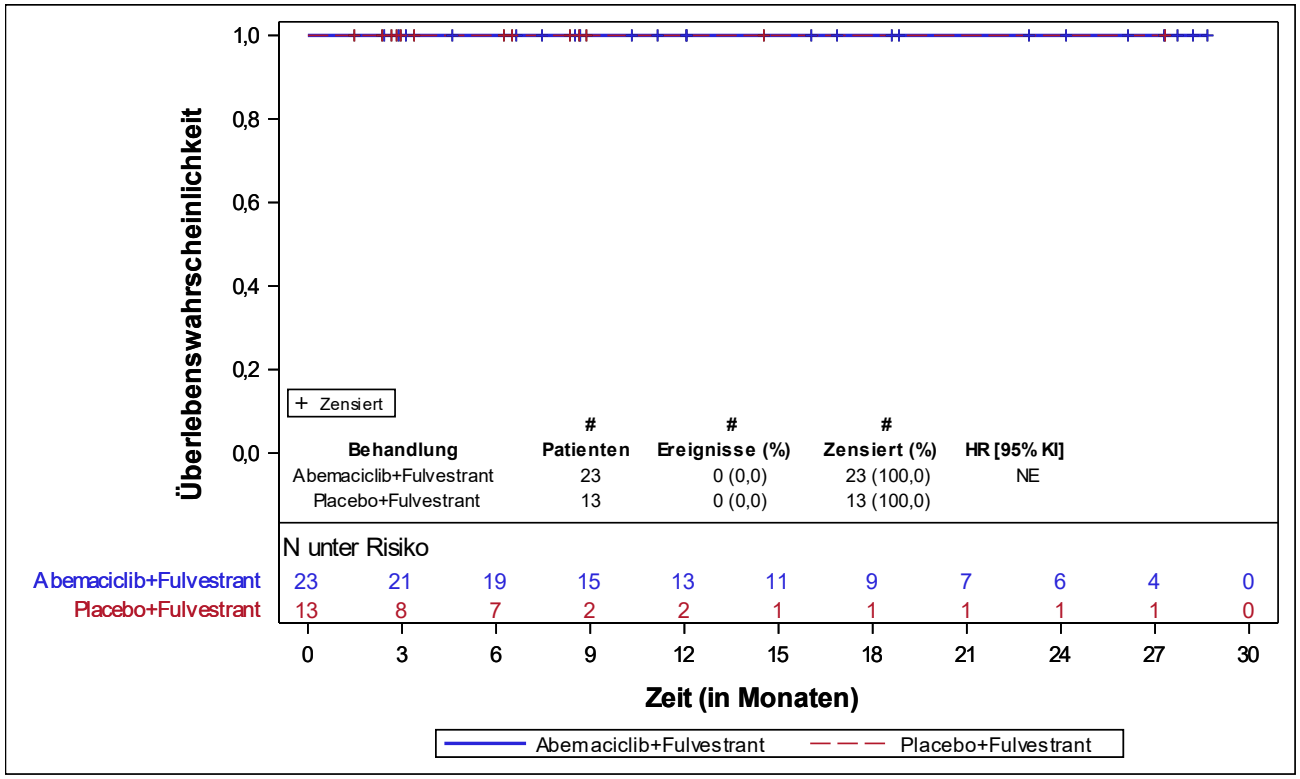
Abbildung 069.2: Kaplan-Meier-Kurven - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber
Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
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Anhang 4-G2.4: Häufige unerwünschte Ereignisse nach SOC und PT - Safety-Population

Anhang 4-G2.4.1: Häufige unerwünschte Ereignisse jeglichen Schweregrades (Ereignisse die bei $\geq$ 10 % der Patienten oder mindestens 10 Patienten und $\geq$ 1% in mindestens einem Behandlungsarm auftraten)

Tabelle 4-131 (Anhang): Ergebnisse für UE jeglichen Grades nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (MONARCH-plus, A1)

Table 012.1: Results for adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Investigations	74/81 (91,4)	0,5 [0,43; 0,85]	19/40 (47,5)	5,9 [3,02; NE]	4,45 [2,62; 7,55] <,0001
White blood cell count decreased	70/81 (86,4)	0,9 [0,82; 0,89]	10/40 (25,0)	NE [15,98; NE]	8,12 [4,09; 16,10] <,0001
Neutrophil count decreased	68/81 (84,0)	0,9 [0,85; 0,89]	8/40 (20,0)	NE [NE; NE]	9,02 [4,29; 18,95] <,0001
Alanine aminotransferase increased	36/81 (44,4)	20,3 [8,42; 25,71]	8/40 (20,0)	NE [20,94; NE]	2,10 [0,97; 4,52] 0,0529
Aspartate aminotransferase increased	36/81 (44,4)	19,8 [9,63; 23,57]	10/40 (25,0)	NE [10,45; NE]	1,66 [0,82; 3,36] 0,1513
Platelet count decreased	34/81 (42,0)	20,7 [9,24; NE]	5/40 (12,5)	NE [NE; NE]	3,94 [1,54; 10,08] 0,0020
Blood creatinine increased	22/81 (27,2)	25,2 [22,13; NE]	0/40 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0012
Lymphocyte count decreased	21/81 (25,9)	NE [25,02; NE]	1/40 (2,5)	NE [NE; NE]	9,39 [1,26; 69,86] 0,0075

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Weight decreased	11/81 (13,6)	NE [NE; NE]	0/40 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0287
Blood alkaline phosphatase increased	7/81 (8,6)	NE [NE; NE]	5/40 (12,5)	NE [NE; NE]	0,57 [0,18; 1,81] 0,3361
Gamma-glutamyltransferase increased	7/81 (8,6)	NE [NE; NE]	4/40 (10,0)	NE [NE; NE]	0,65 [0,19; 2,23] 0,4910
Gastrointestinal disorders	70/81 (86,4)	0,2 [0,13; 0,26]	14/40 (35,0)	NE [4,83; NE]	5,29 [2,95; 9,50] <,0001
Diarrhoea	67/81 (82,7)	0,2 [0,16; 0,36]	6/40 (15,0)	NE [NE; NE]	11,05 [4,76; 25,67] <,0001
Vomiting	21/81 (25,9)	NE [21,76; NE]	6/40 (15,0)	NE [13,05; NE]	1,58 [0,64; 3,92] 0,3183
Nausea	17/81 (21,0)	NE [NE; NE]	8/40 (20,0)	NE [NE; NE]	0,92 [0,40; 2,14] 0,8510
Abdominal pain	12/81 (14,8)	NE [NE; NE]	3/40 (7,5)	NE [NE; NE]	2,06 [0,58; 7,31] 0,2530
Blood and lymphatic system disorders	62/81 (76,5)	2,7 [1,51; 4,34]	8/40 (20,0)	NE [14,96; NE]	6,77 [3,21; 14,30] <,0001
Anaemia	62/81 (76,5)	2,7 [1,51; 4,50]	8/40 (20,0)	NE [14,96; NE]	6,75 [3,20; 14,26] <,0001

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
General disorders and administration site conditions	44/81 (54,3)	11,2 [5,46; 16,93]	20/40 (50,0)	12,5 [3,85; 21,60]	0,92 [0,54; 1,57] 0,7725
Fatigue	15/81 (18,5)	NE [NE; NE]	6/40 (15,0)	NE [NE; NE]	1,12 [0,43; 2,89] 0,8127
Influenza like illness	14/81 (17,3)	NE [NE; NE]	5/40 (12,5)	NE [18,08; NE]	1,01 [0,36; 2,83] 0,9779
Pain	7/81 (8,6)	NE [NE; NE]	10/40 (25,0)	NE [12,46; NE]	0,26 [0,10; 0,68] 0,0031
Metabolism and nutrition disorders	40/81 (49,4)	14,5 [7,36; 24,16]	9/40 (22,5)	NE [14,96; NE]	2,32 [1,12; 4,79] 0,0194
Decreased appetite	18/81 (22,2)	NE [NE; NE]	5/40 (12,5)	NE [NE; NE]	1,75 [0,65; 4,71] 0,2634
Hypokalaemia	13/81 (16,0)	NE [24,43; NE]	2/40 (5,0)	NE [NE; NE]	2,74 [0,62; 12,16] 0,1671
Hypertriglyceridaemia	9/81 (11,1)	NE [NE; NE]	2/40 (5,0)	NE [NE; NE]	1,67 [0,36; 7,76] 0,5054
Infections and infestations	23/81 (28,4)	NE [15,12; NE]	5/40 (12,5)	NE [NE; NE]	1,98 [0,75; 5,22] 0,1589
Upper respiratory tract infection	13/81 (16,0)	NE [NE; NE]	3/40 (7,5)	NE [NE; NE]	1,74 [0,49; 6,13] 0,3825

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Respiratory, thoracic and mediastinal disorders	21/81 (25,9)	NE [14,79; NE]	9/40 (22,5)	NE [16,57; NE]	0,97 [0,44; 2,12] 0,9424
Cough	15/81 (18,5)	NE [NE; NE]	5/40 (12,5)	NE [20,09; NE]	1,17 [0,42; 3,23] 0,7592
Skin and subcutaneous tissue disorders	18/81 (22,2)	NE [NE; NE]	3/40 (7,5)	NE [NE; NE]	2,59 [0,76; 8,82] 0,1135
Nervous system disorders	14/81 (17,3)	NE [NE; NE]	10/40 (25,0)	NE [9,99; NE]	0,54 [0,24; 1,23] 0,1407
Headache	6/81 (7,4)	NE [NE; NE]	5/40 (12,5)	NE [22,19; NE]	0,44 [0,13; 1,44] 0,1618
Musculoskeletal and connective tissue disorders	13/81 (16,0)	NE [NE; NE]	12/40 (30,0)	NE [7,56; NE]	0,41 [0,18; 0,89] 0,0209
Arthralgia	4/81 (4,9)	NE [NE; NE]	4/40 (10,0)	NE [20,32; NE]	0,41 [0,10; 1,64] 0,1911
Back pain	4/81 (4,9)	NE [NE; NE]	4/40 (10,0)	NE [NE; NE]	0,40 [0,10; 1,60] 0,1791
Pain in extremity	2/81 (2,5)	NE [NE; NE]	5/40 (12,5)	NE [NE; NE]	0,17 [0,03; 0,86] 0,0151
Vascular disorders	13/81 (16,0)	NE [NE; NE]	4/40 (10,0)	NE [21,90; NE]	1,44 [0,47; 4,43] 0,5210

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Cardiac disorders	12/81 (14,8)	NE [NE; NE]	4/40 (10,0)	NE [NE; NE]	1,25 [0,40; 3,89] 0,6989
Psychiatric disorders	11/81 (13,6)	NE [NE; NE]	4/40 (10,0)	NE [NE; NE]	1,14 [0,36; 3,59] 0,8241
Insomnia	11/81 (13,6)	NE [NE; NE]	1/40 (2,5)	NE [NE; NE]	4,71 [0,61; 36,58] 0,1020

Data cut-off: 18.05.2020, Safety Population - Postmenopausal (1st line)
1: In months; 2: From Log-rank-Test
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; n: Number of patients with event; N: Total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; SOC: System Organ Class

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_tte.sas
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Tabelle 4-132 (Anhang): Ergebnisse für UE jeglichen Grades nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (MONARCH-plus, B1)

Table 012.2: Results for adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Investigations	22/23 (95,7)	0,6 [0,43; 0,89]	6/13 (46,2)	NE [0,79; NE]	3,40 [1,37; 8,47] 0,0049
Neutrophil count decreased	19/23 (82,6)	1,0 [0,85; 1,45]	2/13 (15,4)	NE [5,36; NE]	8,64 [2,00; 37,40] 0,0006
White blood cell count decreased	18/23 (78,3)	1,0 [0,82; 1,78]	3/13 (23,1)	NE [5,36; NE]	5,64 [1,65; 19,31] 0,0020
Platelet count decreased	14/23 (60,9)	6,4 [0,89; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0033
Aspartate aminotransferase increased	9/23 (39,1)	16,7 [9,37; NE]	5/13 (38,5)	NE [0,85; NE]	0,73 [0,24; 2,20] 0,5802
Blood creatinine increased	9/23 (39,1)	25,5 [8,75; NE]	1/13 (7,7)	NE [NE; NE]	3,63 [0,45; 29,17] 0,1952
Alanine aminotransferase increased	8/23 (34,8)	NE [8,55; NE]	5/13 (38,5)	NE [1,35; NE]	0,64 [0,21; 1,99] 0,4392
Weight decreased	6/23 (26,1)	NE [15,09; NE]	1/13 (7,7)	NE [NE; NE]	2,54 [0,30; 21,49] 0,3717

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Lymphocyte count decreased	5/23 (21,7)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0805
Blood cholesterol increased	4/23 (17,4)	26,5 [21,40; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3232
Monocyte count decreased	3/23 (13,0)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1828
Gastrointestinal disorders	18/23 (78,3)	0,3 [0,13; 0,72]	4/13 (30,8)	12,7 [1,87; NE]	4,68 [1,57; 13,99] 0,0025
Diarrhoea	15/23 (65,2)	0,4 [0,13; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0003
Nausea	5/23 (21,7)	NE [13,48; NE]	2/13 (15,4)	12,7 [12,72; NE]	0,64 [0,11; 3,69] 0,6143
Stomatitis	4/23 (17,4)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1477
Abdominal pain	3/23 (13,0)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2146
Constipation	3/23 (13,0)	NE [NE; NE]	1/13 (7,7)	NE [NE; NE]	1,51 [0,16; 14,69] 0,7211
Vomiting	3/23 (13,0)	NE [NE; NE]	1/13 (7,7)	NE [NE; NE]	1,78 [0,19; 17,12] 0,6124

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Blood and lymphatic system disorders	15/23 (65,2)	1,5 [1,38; NE]	2/13 (15,4)	NE [2,50; NE]	5,61 [1,28; 24,60] 0,0102
Anaemia	15/23 (65,2)	1,5 [1,38; NE]	2/13 (15,4)	NE [2,50; NE]	5,61 [1,28; 24,60] 0,0102
General disorders and administration site conditions	15/23 (65,2)	2,3 [0,85; NE]	4/13 (30,8)	12,7 [2,24; NE]	2,70 [0,89; 8,17] 0,0669
Fatigue	9/23 (39,1)	NE [2,27; NE]	2/13 (15,4)	NE [2,24; NE]	2,72 [0,59; 12,62] 0,1820
Localised oedema	6/23 (26,1)	NE [13,28; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1113
Malaise	3/23 (13,0)	NE [NE; NE]	2/13 (15,4)	26,4 [NE; NE]	0,72 [0,12; 4,43] 0,7262
Metabolism and nutrition disorders	12/23 (52,2)	11,3 [2,70; NE]	2/13 (15,4)	NE [1,87; NE]	2,98 [0,66; 13,39] 0,1338
Decreased appetite	6/23 (26,1)	NE [7,07; NE]	1/13 (7,7)	NE [NE; NE]	3,15 [0,38; 26,29] 0,2631
Hyperkalaemia	3/23 (13,0)	NE [16,04; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3838
Hypertriglyceridaemia	3/23 (13,0)	NE [18,64; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4512

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Hypokalaemia	3/23 (13,0)	NE [17,49; NE]	2/13 (15,4)	NE [2,50; NE]	0,56 [0,09; 3,54] 0,5318
Musculoskeletal and connective tissue disorders	8/23 (34,8)	22,8 [8,12; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0675
Arthralgia	3/23 (13,0)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2146
Infections and infestations	7/23 (30,4)	NE [6,97; NE]	1/13 (7,7)	NE [NE; NE]	3,11 [0,38; 25,52] 0,2668
Upper respiratory tract infection	3/23 (13,0)	NE [NE; NE]	1/13 (7,7)	NE [NE; NE]	1,51 [0,16; 14,61] 0,7183
Skin and subcutaneous tissue disorders	5/23 (21,7)	NE [10,75; NE]	1/13 (7,7)	NE [NE; NE]	2,49 [0,29; 21,65] 0,3935
Pruritus	5/23 (21,7)	NE [10,75; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1844
Psychiatric disorders	4/23 (17,4)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1854
Insomnia	4/23 (17,4)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1854
Eye disorders	3/23 (13,0)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3000

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Nervous system disorders	3/23 (13,0)	NE [NE; NE]	2/13 (15,4)	NE [5,49; NE]	0,60 [0,10; 3,65] 0,5722
Renal and urinary disorders	3/23 (13,0)	NE [17,49; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3229

Data cut-off: 18.05.2020, Safety Population - Postmenopausal (2nd line)
1: In months; 2: From Log-rank-Test
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; n: Number of patients with event; N: Total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; SOC: System Organ Class

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Anhang 4-G2.4.2: Häufige schwerwiegende unerwünschte Ereignisse (Ereignisse die bei $\geq$ 5 % der Patienten oder mindestens 10 Patienten und $\geq$ 1% in mindestens einem Behandlungsarm auftraten)

Tabelle 4-133 (Anhang): Ergebnisse für SUE nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (MONARCH-plus, A1)

Table 013.1: Results for serious adverse events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
No data available					

Data cut-off: 18.05.2020, Safety Population - Postmenopausal (1st line)
1: In months; 2: From Log-rank-Test
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; n: Number of patients with event; N: Total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; SOC: System Organ Class

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Tabelle 4-134 (Anhang): Ergebnisse für SUE nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (MONARCH-plus, B1)

Table 013.2: Results for serious adverse events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Infections and infestations	2/23 (8,7)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4461
Nervous system disorders	1/23 (4,3)	NE [NE; NE]	1/13 (7,7)	NE [NE; NE]	0,36 [0,02; 5,98] 0,4617
Facial nerve disorder	0/23 (0,0)	NE [NE; NE]	1/13 (7,7)	NE [NE; NE]	0,00 [0,00; NE] 0,1482
Transient ischaemic attack	0/23 (0,0)	NE [NE; NE]	1/13 (7,7)	NE [NE; NE]	0,00 [0,00; NE] 0,1482

Data cut-off: 18.05.2020, Safety Population - Postmenopausal (2nd line)
1: In months; 2: From Log-rank-Test
Abbreviations: CI: Confidence interval; HR: Hazard Ratio; n: Number of patients with event; N: Total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; SOC: System Organ Class

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Anhang 4-G2.4.3: Häufige unerwünschte Ereignisse CTCAE Grad $\geq$ 3 (Ereignisse die bei $\geq$ 5 % der Patienten oder mindestens 10 Patienten und $\geq$ 1% in mindestens einem Behandlungsarm auftraten)

Tabelle 4-135 (Anhang): Ergebnisse für UE (CTCAE Grad $\geq$ 3) nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (MONARCH-plus, A1)

Table 014.1: Results for adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Investigations	38/81 (46,9)	16,3 [6,61; NE]	4/40 (10,0)	NE [NE; NE]	5,30 [1,89; 14,85] 0,0004
Neutrophil count decreased	28/81 (34,6)	NE [14,73; NE]	2/40 (5,0)	NE [NE; NE]	7,14 [1,70; 29,99] 0,0017
White blood cell count decreased	23/81 (28,4)	NE [26,73; NE]	2/40 (5,0)	NE [NE; NE]	5,23 [1,23; 22,21] 0,0123
Lymphocyte count decreased	10/81 (12,3)	NE [NE; NE]	0/40 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0381
Blood and lymphatic system disorders	14/81 (17,3)	NE [26,73; NE]	1/40 (2,5)	NE [NE; NE]	5,73 [0,75; 43,71] 0,0568
Anaemia	14/81 (17,3)	NE [26,73; NE]	1/40 (2,5)	NE [NE; NE]	5,73 [0,75; 43,71] 0,0568
Metabolism and nutrition disorders	7/81 (8,6)	NE [NE; NE]	1/40 (2,5)	NE [NE; NE]	2,80 [0,34; 22,83] 0,3153
Gastrointestinal disorders	6/81 (7,4)	NE [NE; NE]	1/40 (2,5)	NE [NE; NE]	2,57 [0,31; 21,39] 0,3663

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Data cut-off: 18.05.2020, Safety Population - Postmenopausal (1st line) 1: In months; 2: From Log-rank-Test Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; n: Number of patients with event; N: Total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; SOC: System Organ Class					

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Tabelle 4-136 (Anhang): Ergebnisse für UE (CTCAE Grad $\geq$ 3) nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (MONARCH-plus, B1)

Table 014.2: Results for adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Investigations	13/23 (56,5)	12,9 [1,94; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0085
Neutrophil count decreased	7/23 (30,4)	NE [3,55; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0551
Lymphocyte count decreased	4/23 (17,4)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1565
White blood cell count decreased	4/23 (17,4)	NE [12,89; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1643
Alanine aminotransferase increased	2/23 (8,7)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3016
Blood and lymphatic system disorders	6/23 (26,1)	NE [17,92; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1121
Anaemia	6/23 (26,1)	NE [17,92; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1121
Infections and infestations	2/23 (8,7)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3858

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
SOC/Preferred term	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Metabolism and nutrition disorders	2/23 (8,7)	NE [22,29; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4330
Renal and urinary disorders	2/23 (8,7)	NE [NE; NE]	0/13 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3497
Respiratory, thoracic and mediastinal disorders	0/23 (0,0)	NE [NE; NE]	1/13 (7,7)	NE [2,73; NE]	0,00 [0,00; NE] 0,1380
Productive cough	0/23 (0,0)	NE [NE; NE]	1/13 (7,7)	NE [2,73; NE]	0,00 [0,00; NE] 0,1380

Data cut-off: 18.05.2020, Safety Population - Postmenopausal (2nd line)
1: In months; 2: From Log-rank-Test
Abbreviations: CI: Confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; n: Number of patients with event; N: Total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; SOC: System Organ Class

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Anhang 4-G2.4.4: Unerwünschte Ereignisse, die zum Behandlungsabbruch führten nach SOC und PT

Tabelle 4-137 (Anhang): Ergebnisse für UE, die zum Behandlungsabbruch mindestens eines der beiden Medikamente führten nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (MONARCH-plus, A1)

Any AE by SOC and PT leading to discontinuation of any (1 or both) study treatment for study MONARCH-plus Page 1 of 1
Safety Population - Postmenopausal (1st line) 01:58 02SEP2021
I3Y-CR-JPBQ PDPM
Data cutoff: 18MAY2020

	LY 2835219 (N =81)		Placebo (N =40)	
	n	(%)	n	(%)
Subjects with >= 1 TEAE leading to discontinuation of any study drug	10	(12.3)	1	(2.5)
Investigations	3	(3.7)	0	(0.0)
White blood cell count decreased	2	(2.5)	0	(0.0)
Platelet count decreased	1	(1.2)	0	(0.0)
Blood and lymphatic system disorders	2	(2.5)	0	(0.0)
Anaemia	2	(2.5)	0	(0.0)
Gastrointestinal disorders	2	(2.5)	0	(0.0)
Abdominal pain	1	(1.2)	0	(0.0)
Small intestinal obstruction	1	(1.2)	0	(0.0)
Cardiac disorders	1	(1.2)	0	(0.0)
Atrioventricular block	1	(1.2)	0	(0.0)
Infections and infestations	1	(1.2)	0	(0.0)
Lung infection	1	(1.2)	0	(0.0)
Musculoskeletal and connective tissue disorders	1	(1.2)	0	(0.0)
Bone pain	1	(1.2)	0	(0.0)
Eye disorders	0	(0.0)	1	(2.5)
Diplopia	0	(0.0)	1	(2.5)

Data cut-off: 18.05.2020
Abbreviations: N = number of subjects in population; n = number of subjects in the specified category;
CTCAE = Common Terminology Criteria for Adverse Events; TEAE = Treatment-Emergent Adverse Event

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_teae_pt_soc_discf.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_teae_pt_soc_discf_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

Tabelle 4-138 (Anhang): Ergebnisse für UE, die zum Behandlungsabbruch mindestens eines der beiden Medikamente führten nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (MONARCH-plus, B1)

Any AE by SOC and PT leading to discontinuation of any (1 or both) study treatment for study MONARCH-plus Page 1 of 1
Safety Population - Postmenopausal (2nd line) 01:58 02SEP2021
I3Y-CR-JPBQ PDPM
Data cutoff: 18MAY2020

	LY 2835219 (N =23)		Placebo (N =13)	
	n	(%)	n	(%)
Subjects with >= 1 TEAE leading to discontinuation of any study drug	2	(8.7)	1	(7.7)
Infections and infestations	1	(4.3)	0	(0.0)
Lung infection	1	(4.3)	0	(0.0)
Investigations	1	(4.3)	0	(0.0)
Neutrophil count decreased	1	(4.3)	0	(0.0)
Nervous system disorders	0	(0.0)	1	(7.7)
Transient ischaemic attack	0	(0.0)	1	(7.7)

Data cut-off: 18.05.2020
Abbreviations: N = number of subjects in population; n = number of subjects in the specified category;
CTCAE = Common Terminology Criteria for Adverse Events; TEAE = Treatment-Emergent Adverse Event

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_teae_pt_soc_discf.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_teae_pt_soc_discf_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

Tabelle 4-139 (Anhang): Ergebnisse für UE, die zum kompletten Behandlungsabbruch führten nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (MONARCH-plus, A1)

Any AE by SOC and PT leading to discontinuation of complete study therapy for study MONARCH-plus — Page 1 of 1
Safety Population - Postmenopausal (1st line) — 01:58 02SEP2021
I3Y-CR-JPBQ — PDPM
Data cutoff: 18MAY2020

	LY 2835219 (N =81)		Placebo (N =40)	
	n	(%)	n	(%)
Subjects with >= 1 TEAE leading to discontinuation of complete study therapy	9	(11.1)	1	(2.5)
Investigations	3	(3.7)	0	(0.0)
White blood cell count decreased	2	(2.5)	0	(0.0)
Platelet count decreased	1	(1.2)	0	(0.0)
Blood and lymphatic system disorders	2	(2.5)	0	(0.0)
Anaemia	2	(2.5)	0	(0.0)
Gastrointestinal disorders	2	(2.5)	0	(0.0)
Abdominal pain	1	(1.2)	0	(0.0)
Small intestinal obstruction	1	(1.2)	0	(0.0)
Cardiac disorders	1	(1.2)	0	(0.0)
Atrioventricular block	1	(1.2)	0	(0.0)
Infections and infestations	1	(1.2)	0	(0.0)
Lung infection	1	(1.2)	0	(0.0)
Eye disorders	0	(0.0)	1	(2.5)
Diplopia	0	(0.0)	1	(2.5)

Data cut-off: 18.05.2020
Abbreviations: N = number of subjects in population; n = number of subjects in the specified category;
CTCAE = Common Terminology Criteria for Adverse Events; TEAE = Treatment-Emergent Adverse Event

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_teae_pt_soc_disca.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_teae_pt_soc_disca_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

Tabelle 4-140 (Anhang): Ergebnisse für UE, die zum kompletten Behandlungsabbruch führten nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (MONARCH-plus, B1)

Any AE by SOC and PT leading to discontinuation of complete study therapy for study MONARCH-plus — Page 1 of 1
Safety Population - Postmenopausal (2nd line) — 01:58 02SEP2021
I3Y-CR-JPBQ — PDPM
Data cutoff: 18MAY2020

	LY 2835219 (N =23)		Placebo (N =13)	
	n	(%)	n	(%)
Subjects with >= 1 TEAE leading to discontinuation of complete study therapy	2	(8.7)	1	(7.7)
Infections and infestations	1	(4.3)	0	(0.0)
Lung infection	1	(4.3)	0	(0.0)
Investigations	1	(4.3)	0	(0.0)
Neutrophil count decreased	1	(4.3)	0	(0.0)
Nervous system disorders	0	(0.0)	1	(7.7)
Transient ischaemic attack	0	(0.0)	1	(7.7)

Data cut-off: 18.05.2020
Abbreviations: N = number of subjects in population; n = number of subjects in the specified category;
CTCAE = Common Terminology Criteria for Adverse Events; TEAE = Treatment-Emergent Adverse Event

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_teae_pt_soc_disca.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_teae_pt_soc_disca_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

Anhang 4-G2.5: Subgruppenanalyse der Studie MONARCH-plus

Tabelle 4-141 (Anhang): Ergebnisse der Interaktionstests (MONARCH-plus)

Tabelle 100.1: Ergebnis des Interaktionsterms der Subgruppenanalysen je Endpunkt für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Subgruppe											
Endpunkt	**Alter**	**Anzahl betroffener Organe**	**Art der Erkrankung**	**ECOG-PS zu Baseline**	**Ethnische Zugehörigkeit**	**Land**	**Messbare Erkrankung zu Baseline**	**Progesteronrezeptorstatus**	**Sensitivität gegenüber endokriner Therapie**	**Tumorgrad**	**Vorangegangene antiöstrogene Therapie**	**Vorherige (neo-)adjuvante Chemotherapie**
Mortalität / Morbidität												
Gesamtüberlebenszeit	0,4057	0,2714	**0,0401**	**0,0351**	NB	0,5341	**0,0322**	0,5940	0,1855	0,1442	0,3489	0,9919
Progressionsfreie Überlebenszeit	0,9034	0,6007	0,3114	0,4559	NB	0,9635	0,1004	0,5365	0,9134	0,5101	0,3175	0,9812
Symptomatik												
Appetitlosigkeit	0,2432	0,2894	0,9660	**0,0053**	NB	0,8962	0,9326	0,0756	0,4235	0,3338	0,5319	NB
Diarrhö	0,3863	0,9999	NB	0,9908	NB	0,9946	0,9921	0,9937	0,4611	NB	0,5626	NB
Dyspnoe	0,6940	NB	0,4787	0,6427	NB	0,9865	0,2535	0,1838	0,1850	NB	0,6786	NB
Fatigue	0,9120	0,5050	0,9272	0,7516	NB	0,8729	0,7504	0,1976	0,4125	0,7725	0,7131	NB
Finanzielle Schwierigkeiten	0,4187	NB	0,4187	0,9892	NB	0,9919	0,2440	0,3330	0,9160	NB	0,9928	NB
Verstopfung	0,5456	NB	0,7564	0,3004	NB	0,1741	0,5244	0,5795	0,4035	0,2330	0,3647	NB
Schlaflosigkeit	0,1783	0,2045	0,2105	0,0857	NB	0,1121	0,8494	0,3217	0,8179	**0,0392**	0,2334	NB
Übelkeit und Erbrechen	0,0524	0,7147	0,0647	0,1145	NB	0,5664	0,1596	0,8850	0,2168	0,7019	0,3569	NB
Schmerz	0,3331	0,8539	0,9464	0,3774	NB	0,6704	0,3587	0,8888	0,4754	0,7579	0,9500	NB
mBPI-sf: Schmerz	0,4132	0,8996	0,2854	0,1716	NB	0,7654	0,4675	0,2776	0,9691	0,1751	0,4311	NB
Gesundheitsbezogene Lebensqualität												
Globaler Gesundheitsstatus	0,8018	0,3834	0,4124	0,9838	NB	0,7074	0,7267	**0,0389**	0,6290	0,9950	0,4186	NB
Kognitive Funktion	0,4765	0,7030	0,5122	0,1430	NB	0,1446	0,7545	0,4184	0,3970	0,0552	0,0944	NB
Emotionale Funktion	0,7670	0,9741	0,9420	0,1648	NB	0,8354	0,6345	0,9656	0,8402	0,3660	0,4372	NB

Endpunkt	Subgruppe											
	Alter	Anzahl betroffener Organe	Art der Erkrankung	ECOG-PS zu Baseline	Ethnische Zugehörigkeit	Land	Messbare Erkrankung zu Baseline	Progesteronrezeptorstatus	Sensitivität gegenüber endokriner Therapie	Tumorgrad	Vorangegangene antiöstrogene Therapie	Vorherige (neo-)adjuvante Chemotherapie
Körperliche Funktion	0,7012	0,4709	0,9633	**0,0448**	NB	0,6144	0,3257	0,3697	0,9382	0,9444	0,8312	NB
Rollenfunktion	0,3344	**0,0398**	0,0933	0,6894	NB	0,8296	0,9878	0,1423	0,7505	0,2396	0,5397	NB
Soziale Funktion	0,8385	0,3749	0,7497	0,9953	NB	0,5315	0,8851	0,2439	0,3529	0,2679	0,4158	NB
Unerwünschte Ereignisse												
Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad)	0,3461	0,2499	0,8193	0,3017	NB	0,0630	0,3796	0,5015	0,0532	0,5053	0,8098	0,4452
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis	0,7190	0,3176	0,8842	0,7958	NB	0,7336	0,6581	0,7711	0,8124	0,2630	0,6458	0,9923
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3	0,9115	0,3942	0,0808	0,5563	NB	0,7389	0,2915	0,1022	0,4100	0,7857	0,4258	0,9870
Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse	NB	NB	NB	NB	NB	NB	0,9953	0,9937	NB	NB	NB	NB
Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse	NB	NB	NB	NB	NB	NB	NB	0,9998	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad)	0,9823	0,9815	0,1458	0,3121	NB	0,3332	0,1853	0,4100	0,9007	0,9696	0,2981	0,9874
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie	0,1499	0,9157	0,9915	0,8367	NB	0,9898	0,9895	0,4827	0,6367	0,9999	0,9914	0,9925
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie	0,8826	0,9810	0,1448	0,2888	NB	0,3893	0,1940	0,2720	0,9366	0,9514	0,3089	0,9870
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: Neutropenie	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad)	0,5696	0,0874	0,9155	0,7488	NB	0,1030	0,5186	0,7563	0,2876	0,7679	0,2999	0,9907
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB

Endpunkt	Subgruppe											
	Alter	Anzahl betroffener Organe	Art der Erkrankung	ECOG-PS zu Baseline	Ethnische Zugehörigkeit	Land	Messbare Erkrankung zu Baseline	Progesteronrezeptorstatus	Sensitivität gegenüber endokriner Therapie	Tumorgrad	Vorangegangene antiöstrogene Therapie	Vorherige (neo-)adjuvante Chemotherapie
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen	0,3913	0,1265	0,6643	0,8328	NB	0,0661	0,6730	0,6351	0,4766	0,8399	0,6153	0,9911
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad)	0,5982	0,9999	0,0629	0,2525	NB	**0,0408**	0,3508	0,8656	0,4329	0,3657	0,5850	0,9880
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe	0,5982	0,9999	0,0629	0,2525	NB	**0,0408**	0,3508	0,8656	0,4329	0,3657	0,5850	0,9880
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Diarrhoe	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad)	0,9999	1,0000	0,9999	0,9999	NB	1,0000	0,9999	1,0000	0,9999	NB	0,9998	1,0000
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Kreatinin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht	0,9999	1,0000	0,9999	0,9999	NB	1,0000	0,9999	1,0000	0,9999	NB	0,9998	1,0000
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Kreatinin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad)	0,3680	0,7100	0,2056	0,2625	NB	0,9913	0,5948	0,6766	0,1408	0,9364	0,7715	0,9875
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht	0,3478	0,6139	0,1828	0,2880	NB	0,9914	0,5674	0,5575	0,1618	0,9590	0,8177	0,9876

Endpunkt	Subgruppe											
	Alter	Anzahl betroffener Organe	Art der Erkrankung	ECOG-PS zu Baseline	Ethnische Zugehörigkeit	Land	Messbare Erkrankung zu Baseline	Progesteronrezeptorstatus	Sensitivität gegenüber endokriner Therapie	Tumorgrad	Vorangegangene antiöstrogene Therapie	Vorherige (neo-)adjuvante Chemotherapie
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alaninaminotransferase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad)	0,1583	0,3556	0,1576	0,4451	NB	0,9911	0,5602	0,4516	**0,0440**	0,4091	0,8707	0,9908
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht	0,1590	0,3488	0,1562	0,4417	NB	0,9911	0,5616	0,4545	**0,0426**	0,4104	0,8744	0,9908
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Aspartataminotransferase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad)	0,9999	NB	NB	NB	NB	0,9921	NB	NB	NB	NB	0,9943	0,9999
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alkalische Phosphatase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht	0,9998	NB	NB	NB	NB	0,9998	NB	NB	NB	NB	NB	0,9999
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alkalische Phosphatase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Bilirubin im Blut erhöht (jeglicher Schweregrad)	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Bilirubin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Bilirubin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Bilirubin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB

Endpunkt	Subgruppe											
	Alter	Anzahl betroffener Organe	Art der Erkrankung	ECOG-PS zu Baseline	Ethnische Zugehörigkeit	Land	Messbare Erkrankung zu Baseline	Progesteronrezeptorstatus	Sensitivität gegenüber endokriner Therapie	Tumorgrad	Vorangegangene antiöstrogene Therapie	Vorherige (neo-)adjuvante Chemotherapie
Zeit bis zum ersten unerwünschten Ereignis: PT Pneumonitis (jeglicher Schweregrad)	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Pneumonitis	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Pneumonitis	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Pneumonitis	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad)	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Venöse Thromboembolie	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Venöse Thromboembolie	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: Venöse Thromboembolie	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad)	0,1288	0,7954	0,6274	0,3804	NB	0,9889	0,5691	0,6937	**0,0214**	0,7087	0,8158	0,9888
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber	NB	NB	NB	NB	NB	0,9934	0,9943	NB	NB	NB	0,9997	0,9998
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber	0,1148	0,7774	0,5442	0,4306	NB	0,9898	0,6169	0,8351	**0,0140**	0,7853	0,7743	0,9888
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB

Endpunkt	Subgruppe											
	Alter	Anzahl betroffener Organe	Art der Erkrankung	ECOG-PS zu Baseline	Ethnische Zugehörigkeit	Land	Messbare Erkrankung zu Baseline	Progesteronrezeptorstatus	Sensitivität gegenüber endokriner Therapie	Tumorgrad	Vorangegangene antiöstrogene Therapie	Vorherige (neo-)adjuvante Chemotherapie
Datenschnitt: 18.05.2020 Diese Tabelle zeigt p-Werte der Interaktionsterme von Subgruppenfaktor und Behandlungsgruppe aus Cox-Proportional-Hazard-Modellen. NB: nicht berechnet. Ein Interaktionstest wird nur gerechnet, wenn jede Subgruppenkategorie mindestens 10 Patienten umfasst und mindestens 10 Ereignisse in einer der Subgruppenkategorien aufgetreten sind. Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; PT: Preferred Term; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; SMQ: Standardised MedDRA Queries; SOC: System Organ Class.												

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_interact.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t100_interact_all_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 100.2: Ergebnis des Interaktionsterms der Subgruppenanalysen je Endpunkt für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

Endpunkt	Subgruppe													
	Alter	Anzahl betroffener Organe	Anzahl vorangegangener endokriner Behandlungen	Art der Erkrankung	Art der vorherigen endokrinen Therapie	ECOG-PS zu Baseline	Ethnische Zugehörigkeit	Land	Messbare Erkrankung zu Baseline	Progesteronrezeptorstatus	Sensitivität gegenüber endokriner Therapie	Tumorgrad	Vorangegangene antiöstrogene Therapie	Vorherige (neo-)adjuvante Chemotherapie
Mortalität / Morbidität														
Gesamtüberlebenszeit	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Progressionsfreie Überlebenszeit	**0,0487**	NB	0,0603	NB	NB	0,9602	NB	NB	NB	NB	NB	NB	0,1741	0,9210
Symptomatik														
Appetitlosigkeit	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Diarrhö	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Dyspnoe	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Fatigue	0,5496	NB	0,9341	NB	NB	NB	NB	NB	NB	NB	NB	NB	0,7147	0,2669
Finanzielle Schwierigkeiten	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Verstopfung	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Schlaflosigkeit	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Übelkeit und Erbrechen	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Schmerz	0,9955	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
mBPI-sf: Schmerz	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Gesundheitsbezogene Lebensqualität														
Globaler Gesundheitsstatus	0,7761	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Kognitive Funktion	0,2896	NB	0,8550	NB	NB	NB	NB	NB	NB	NB	NB	NB	0,6308	NB
Emotionale Funktion	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB

	Subgruppe													
Endpunkt	**Alter**	**Anzahl betroffener Organe**	**Anzahl vorangegangener endokriner Behandlungen**	**Art der Erkrankung**	**Art der vorherigen endokrinen Therapie**	**ECOG-PS zu Baseline**	**Ethnische Zugehörigkeit**	**Land**	**Messbare Erkrankung zu Baseline**	**Progesteronrezeptorstatus**	**Sensitivität gegenüber endokriner Therapie**	**Tumorgrad**	**Vorangegangene antiöstrogene Therapie**	**Vorherige (neo-)adjuvante Chemotherapie**
Körperliche Funktion	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Rollenfunktion	0,0869	NB	0,3833	NB	NB	NB	NB	NB	NB	NB	NB	NB	0,5151	NB
Soziale Funktion	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Unerwünschte Ereignisse														
Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad)	0,3701	NB	0,9331	NB	NB	0,5888	NB	NB	NB	NB	NB	NB	0,8439	0,9734
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3	0,9924	NB	0,9935	NB	NB	0,9936	NB	NB	NB	NB	NB	NB	NB	0,9945
Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad)	0,9934	NB	0,9939	NB	NB	0,5860	NB	NB	NB	NB	NB	NB	0,9929	0,5618
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie	0,9934	NB	0,9939	NB	NB	0,5035	NB	NB	NB	NB	NB	NB	0,9929	0,5419
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: Neutropenie	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad)	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB

Endpunkt	Subgruppe													
	Alter	Anzahl betroffener Organe	Anzahl vorangegangener endokriner Behandlungen	Art der Erkrankung	Art der vorherigen endokrinen Therapie	ECOG-PS zu Baseline	Ethnische Zugehörigkeit	Land	Messbare Erkrankung zu Baseline	Progesteronrezeptorstatus	Sensitivität gegenüber endokriner Therapie	Tumorgrad	Vorangegangene antiöstrogene Therapie	Vorherige (neo-)adjuvante Chemotherapie
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad)	1,0000	NB	0,9999	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe	1,0000	NB	0,9999	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Diarrhoe	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad)	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Kreatinin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Kreatinin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad)	0,9942	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB

Endpunkt	Subgruppe													
	Alter	Anzahl betroffener Organe	Anzahl vorangegangener endokriner Behandlungen	Art der Erkrankung	Art der vorherigen endokrinen Therapie	ECOG-PS zu Baseline	Ethnische Zugehörigkeit	Land	Messbare Erkrankung zu Baseline	Progesteronrezeptorstatus	Sensitivität gegenüber endokriner Therapie	Tumorgrad	Vorangegangene antiöstrogene Therapie	Vorherige (neo-)adjuvante Chemotherapie
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht	0,9942	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alaninaminotransferase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad)	0,0869	NB	0,7570	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Aspartataminotransferase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad)	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alkalische Phosphatase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alkalische Phosphatase erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Bilirubin im Blut erhöht (jeglicher Schweregrad)	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Bilirubin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Bilirubin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB

Endpunkt	Subgruppe													
	Alter	Anzahl betroffener Organe	Anzahl vorangegangener endokriner Behandlungen	Art der Erkrankung	Art der vorherigen endokrinen Therapie	ECOG-PS zu Baseline	Ethnische Zugehörigkeit	Land	Messbare Erkrankung zu Baseline	Progesteronrezeptorstatus	Sensitivität gegenüber endokriner Therapie	Tumorgrad	Vorangegangene antiöstrogene Therapie	Vorherige (neo-)adjuvante Chemotherapie
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Bilirubin im Blut erhöht	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: PT Pneumonitis (jeglicher Schweregrad)	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Pneumonitis	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Pneumonitis	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Pneumonitis	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad)	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Venöse Thromboembolie	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Venöse Thromboembolie	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: Venöse Thromboembolie	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad)	**0,0138**	NB	0,9749	NB	NB	0,1906	NB	NB	NB	NB	NB	NB	0,6772	0,6366
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB
Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber	**0,0138**	NB	0,9749	NB	NB	0,1906	NB	NB	NB	NB	NB	NB	0,6772	0,6366

Endpunkt	Subgruppe													
	Alter	Anzahl betroffener Organe	Anzahl vorangegangener endokriner Behandlungen	Art der Erkrankung	Art der vorherigen endokrinen Therapie	ECOG-PS zu Baseline	Ethnische Zugehörigkeit	Land	Messbare Erkrankung zu Baseline	Progesteronrezeptorstatus	Sensitivität gegenüber endokriner Therapie	Tumorgrad	Vorangegangene antiöstrogene Therapie	Vorherige (neo-)adjuvante Chemotherapie
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB	NB

Datenschnitt: 18.05.2020
Diese Tabelle zeigt p-Werte der Interaktionsterme von Subgruppenfaktor und Behandlungsgruppe aus Cox-Proportional-Hazard-Modellen.
NB: nicht berechnet. Ein Interaktionstest wird nur gerechnet, wenn jede Subgruppenkategorie mindestens 10 Patienten umfasst und mindestens 10 Ereignisse in einer der Subgruppenkategorien aufgetreten sind.
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; PT: Preferred Term; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; SMQ: Standardised MedDRA Queries; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_interact.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t100_interact_all_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 200.1: Interaction term results of the subgroup analysis for adverse events according SOC/PT - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

SOC/Preferred term	Subgroup											
	Age	Organs involved	Nature of disease	ECOG-PS at Baseline	Race	Country	Measurable disease at baseline	Progesterone receptor	Sensitivity against endocrine therapy	Tumor grade	Previous anti-estrogene therapy	Received prior (neo)adjuvant chemotherapy
Time to first occurrence of adverse event												
Investigations	0,2739	0,5623	0,1792	0,6336	NE	0,9770	0,3186	0,8150	0,3262	0,8287	0,3266	0,9888
White blood cell count decreased	0,4938	0,7051	0,2135	0,1193	NE	0,3292	0,3128	0,5885	0,5195	0,8976	0,9885	0,9863
Neutrophil count decreased	0,9823	0,9815	0,1458	0,3121	NE	0,3332	0,1853	0,4100	0,9007	0,9696	0,2981	0,9874
Platelet count decreased	0,5625	0,9418	0,6696	0,8809	NE	0,9916	0,5682	0,2729	0,9856	0,4037	0,5253	0,9902
Blood creatinine increased	0,9999	1,0000	0,9999	0,9999	NE	1,0000	0,9999	1,0000	0,9999	NE	0,9998	1,0000
Lymphocyte count decreased	0,9927	1,0000	0,9900	0,9919	NE	0,9911	0,9921	0,9916	0,9914	1,0000	0,9930	0,9933
Weight decreased	NE	NE	NE	NE	NE	0,9978	NE	NE	NE	NE	0,9998	1,0000
Gastrointestinal disorders	0,6680	0,7165	0,1594	0,4387	NE	0,2796	0,7262	0,3470	0,8148	0,4231	0,3233	0,8079
Diarrhoea	0,5982	0,9999	0,0629	0,2525	NE	**0,0408**	0,3508	0,8656	0,4329	0,3657	0,5850	0,9880
Blood and lymphatic system disorders	0,9465	0,2949	0,6577	0,7483	NE	**0,0306**	0,9219	0,8649	0,3244	0,9470	0,3808	0,9858
Anaemia	0,9564	0,2868	0,6820	0,7428	NE	**0,0306**	0,9212	0,8898	0,3151	0,9418	0,3846	0,9858
General disorders and administration site conditions												
Pain	0,9910	0,9707	0,2577	0,7781	NE	0,6713	0,1660	0,3699	0,0685	0,2820	0,6778	0,9922
Metabolism and nutrition disorders	0,1000	0,2067	0,6385	0,8377	NE	0,9728	0,4625	0,8062	0,4098	0,9500	0,9868	0,9868
Musculoskeletal and connective tissue disorders	0,8659	0,6730	0,7920	0,7389	NE	0,9935	0,5665	0,9767	0,6982	0,4325	0,6109	0,9914
Pain in extremity	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Time to first occurrence of adverse event with CTCAE grade ≥ 3												

SOC/Preferred term	Subgroup											
	Age	Organs involved	Nature of disease	ECOG-PS at Baseline	Race	Country	Measurable disease at baseline	Progesterone receptor	Sensitivity against endocrine therapy	Tumor grade	Previous anti-estrogene therapy	Received prior (neo)adjuvant chemotherapy
Investigations	0,9372	0,8195	0,3360	0,7412	NE	0,9912	0,8397	0,0741	0,8195	0,9978	0,9888	0,9912
Neutrophil count decreased	0,1499	0,9157	0,9915	0,8367	NE	0,9898	0,9895	0,4827	0,6367	0,9999	0,9914	0,9925
White blood cell count decreased	0,5327	0,7602	0,9925	0,6280	NE	0,9913	0,9907	0,3459	0,5045	1,0000	0,9921	0,9928
Lymphocyte count decreased	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Data cut-off: 18.05.2020, Safety-Population
The table shows p-values of the interaction term of subgroup factor and treatment group from Cox proportional hazard model.
NE: not evaluable/not calculated. Only endpoints with p-value <0.05 in main model are taken into account. The interaction test is only performed if each subgroup category comprises at least 10 patients and at least 10 events have occurred in one of the subgroup categories.
Abbreviations: CTCAE: common terminology criteria for adverse events; PT: Preferred Term; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_interact_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t200_interact_aesocpt_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 200.2: Interaction term results of the subgroup analysis for adverse events according SOC/PT - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (2nd line)

SOC/Preferred term	Subgroup													
	Age	Organs involved	Prior lines of endocrine therapy	Nature of disease	Most recent endocrine therapy	ECOG-PS at Baseline	Race	Country	Measurable disease at baseline	Progesterone receptor	Sensitivity against endocrine therapy	Tumor grade	Previous anti-estrogene therapy	Received prior (neo)adjuvant chemotherapy
Time to first occurrence of adverse event														
Investigations	0,1138	NE	0,5589	NE	NE	0,5872	NE	NE	NE	NE	NE	NE	0,9349	0,7079
Neutrophil count decreased	0,9934	NE	0,9939	NE	NE	0,5860	NE	NE	NE	NE	NE	NE	0,9929	0,5618
White blood cell count decreased	0,9933	NE	0,9939	NE	NE	0,4564	NE	NE	NE	NE	NE	NE	0,9930	0,6759
Platelet count decreased	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Gastrointestinal disorders	0,4015	NE	0,6119	NE	NE	0,5300	NE	NE	NE	NE	NE	NE	0,6057	0,4111
Diarrhoea	1,0000	NE	0,9999	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Blood and lymphatic system disorders	0,7554	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	0,9926	NE
Anaemia	0,7554	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	0,9926	NE
Time to first occurrence of adverse event with CTCAE grade ≥ 3														
Investigations	NE	NE	0,9998	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Data cut-off: 18.05.2020, Safety-Population
The table shows p-values of the interaction term of subgroup factor and treatment group from Cox proportional hazard model.
NE: not evaluable/not calculated. Only endpoints with p-value <0.05 in main model are taken into account. The interaction test is only performed if each subgroup category comprises at least 10 patients and at least 10 events have occurred in one of the subgroup categories.
Abbreviations: CTCAE: common terminology criteria for adverse events; PT: Preferred Term; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_interact_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t200_interact_aesocpt_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 4-142 (Anhang): Ergebnisse der Subgruppenanalyse interagierender Subgruppen (MONARCH-plus)

Tabelle 101.1.1: Interagierende Subgruppen für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Art der Erkrankung (p-Wert des Interaktionsterms: 0,0401)					
Viszerale Metastasen	17/47 (36,2)	NE [24,20; NE]	7/21 (33,3)	NE [18,44; NE]	0,93 [0,38; 2,25] 0,8708
Nicht-viszerale Metastasen	3/34 (8,8)	NE [NE; NE]	7/19 (36,8)	NE [14,96; NE]	0,17 [0,04; 0,66] 0,0040
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,0351)					
0	7/27 (25,9)	NE [26,07; NE]	2/14 (14,3)	NE [NE; NE]	2,00 [0,41; 9,70] 0,3804
1	13/54 (24,1)	NE [26,93; NE]	12/26 (46,2)	23,9 [15,65; NE]	0,31 [0,14; 0,68] 0,0024
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,0322)					
Ja	19/62 (30,6)	NE [26,93; NE]	8/26 (30,8)	NE [23,90; NE]	0,89 [0,39; 2,03] 0,7761
Nein	1/19 (5,3)	NE [25,97; NE]	6/14 (42,9)	NE [10,26; NE]	0,08 [0,01; 0,64] 0,0026

Datenschnitt: 18.05.2020, ITT-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_os_popa1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 102.2.1: Interagierende Subgruppen für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,0487)					
< 65 Jahre	9/16 (56,3)	18,8 [7,59; NE]	7/9 (77,8)	5,6 [1,41; NE]	0,13 [0,04; 0,45] 0,0003
≥ 65 Jahre	5/7 (71,4)	15,8 [1,84; NE]	3/4 (75,0)	8,1 [1,68; NE]	1,00 [0,23; 4,24] 0,9947

Datenschnitt: 18.05.2020, ITT-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_pfs_popa2_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 103.1.1: Interagierende Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,0053)					
0	13/27 (48,1)	20,7 [1,02; NE]	3/14 (21,4)	NE [2,83; NE]	2,85 [0,80; 10,12] 0,0892
1	8/54 (14,8)	NE [24,26; NE]	9/26 (34,6)	16,9 [5,00; NE]	0,30 [0,11; 0,78] 0,0088

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwaplo6_popa1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 109.1.1: Interagierende Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Tumorgrad (p-Wert des Interaktionsterms: 0,0392)					
Hoch	2/11 (18,2)	NE [6,77; NE]	4/7 (57,1)	2,9 [0,99; NE]	0,15 [0,03; 0,85] 0,0158
Niedrig/mittel	8/31 (25,8)	NE [17,06; NE]	6/17 (35,3)	10,2 [5,00; NE]	0,45 [0,15; 1,31] 0,1321
Unbekannt	8/39 (20,5)	NE [16,70; NE]	1/16 (6,3)	NE [NE; NE]	3,70 [0,46; 29,57] 0,1872

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwinso6_popa1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 113.1.1: Interagierende Subgruppen für die Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,0389)					
Positiv	23/63 (36,5)	22,8 [17,03; 28,04]	5/30 (16,7)	NE [10,16; NE]	1,83 [0,70; 4,83] 0,2131
Negativ	3/18 (16,7)	NE [NE; NE]	4/10 (40,0)	5,0 [2,60; NE]	0,26 [0,06; 1,18] 0,0605

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwghs6_popa1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 116.1.1: Interagierende Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,0448)					
0	9/27 (33,3)	20,7 [6,64; NE]	1/14 (7,1)	NE [NE; NE]	4,65 [0,59; 36,85] 0,1096
1	12/54 (22,2)	NE [23,61; NE]	8/26 (30,8)	NE [5,00; NE]	0,48 [0,19; 1,18] 0,1011

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwphys6_popa1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 117.1.1: Interagierende Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,0398)					
1	11/43 (25,6)	NE [19,82; NE]	1/26 (3,8)	NE [NE; NE]	5,53 [0,71; 42,98] 0,0663
2	8/24 (33,3)	20,7 [9,86; NE]	3/5 (60,0)	3,9 [0,07; NE]	0,47 [0,12; 1,84] 0,2687
≥ 3	4/14 (28,6)	NE [11,47; NE]	5/9 (55,6)	8,7 [0,07; NE]	0,23 [0,05; 0,99] 0,0362

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwrole6_popa1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 132.1.1: Interagierende Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Land (p-Wert des Interaktionsterms: 0,0408)					
China	58/71 (81,7)	0,2 [0,16; 0,36]	3/33 (9,1)	NE [NE; NE]	18,67 [5,81; 59,99] <,0001
Andere	9/10 (90,0)	0,4 [0,03; 0,99]	3/7 (42,9)	10,7 [0,03; NE]	4,55 [0,96; 21,61] 0,0369

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttdiaesi_popa1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 134.1.1: Interagierende Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Land (p-Wert des Interaktionsterms: 0,0408)					
China	58/71 (81,7)	0,2 [0,16; 0,36]	3/33 (9,1)	NE [NE; NE]	18,67 [5,81; 59,99] <,0001
Andere	9/10 (90,0)	0,4 [0,03; 0,99]	3/7 (42,9)	10,7 [0,03; NE]	4,55 [0,96; 21,61] 0,0369

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttdi2aesi_popa1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 144.1.1: Interagierende Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,0440)					
Primäre Resistenz	12/30 (40,0)	18,6 [8,45; NE]	6/17 (35,3)	14,1 [0,49; NE]	0,73 [0,26; 2,02] 0,5457
Sekundäre Resistenz	24/51 (47,1)	16,5 [7,63; NE]	4/23 (17,4)	NE [10,45; NE]	3,09 [1,07; 8,92] 0,0279

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttasaesi_popa1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 146.1.1: Interagierende Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,0426)					
Primäre Resistenz	12/30 (40,0)	18,6 [8,45; NE]	6/17 (35,3)	14,1 [0,49; NE]	0,72 [0,26; 1,99] 0,5332
Sekundäre Resistenz	24/51 (47,1)	16,5 [7,63; NE]	4/23 (17,4)	NE [10,45; NE]	3,09 [1,07; 8,92] 0,0279

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttas2aesi_popa1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 164.1.1: Interagierende Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,0214)					
Primäre Resistenz	16/30 (53,3)	16,1 [8,42; 19,96]	7/17 (41,2)	14,1 [0,49; NE]	0,93 [0,37; 2,31] 0,8766
Sekundäre Resistenz	33/51 (64,7)	8,3 [6,58; 16,27]	5/23 (21,7)	NE [8,98; NE]	3,66 [1,42; 9,44] 0,0041

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SMQ: Standardised MedDRA Queries.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_tthepsmq_popa1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 164.2.1: Interagierende Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,0138)					
< 65 Jahre	7/16 (43,8)	16,7 [8,55; NE]	5/9 (55,6)	1,8 [0,43; NE]	0,22 [0,05; 0,88] 0,0205
≥ 65 Jahre	5/7 (71,4)	1,9 [0,82; NE]	1/4 (25,0)	NE [0,85; NE]	3,38 [0,39; 29,12] 0,2404

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SMQ: Standardised MedDRA Queries.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_tthepsmq_popa2_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 166.1.1: Interagierende Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,0140)					
Primäre Resistenz	15/30 (50,0)	17,1 [8,42; 19,96]	7/17 (41,2)	14,1 [0,49; NE]	0,83 [0,33; 2,09] 0,6890
Sekundäre Resistenz	33/51 (64,7)	8,3 [6,58; 16,31]	5/23 (21,7)	NE [8,98; NE]	3,65 [1,41; 9,41] 0,0042

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SMQ: Standardised MedDRA Queries.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_tthep2smq_popa1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 166.2.1: Interagierende Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,0138)					
< 65 Jahre	7/16 (43,8)	16,7 [8,55; NE]	5/9 (55,6)	1,8 [0,43; NE]	0,22 [0,05; 0,88] 0,0205
≥ 65 Jahre	5/7 (71,4)	1,9 [0,82; NE]	1/4 (25,0)	NE [0,85; NE]	3,38 [0,39; 29,12] 0,2404

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SMQ: Standardised MedDRA Queries.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_tthep2smq_popa2_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 201.1.1: Interacting Subgroups: Time to adverse event according PT - Blood and lymphatic system disorders/Anaemia - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Country (p-value of the interaction term: 0,0306)					
China	60/71 (84,5)	1,8 [1,41; 2,79]	6/33 (18,2)	NE [14,96; NE]	8,80 [3,77; 20,57] <,0001
Other	2/10 (20,0)	NE [0,46; NE]	2/7 (28,6)	6,7 [2,56; NE]	0,70 [0,10; 5,01] 0,7203

Data cut-off: 18.05.2020, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t201_aesocpt_tte_sub_popa1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 203.1.1: Interacting Subgroups: Time to adverse event according PT - Gastrointestinal disorders/Diarrhoea - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Country (p-value of the interaction term: 0,0408)					
China	58/71 (81,7)	0,2 [0,16; 0,36]	3/33 (9,1)	NE [NE; NE]	18,67 [5,81; 59,99] <,0001
Other	9/10 (90,0)	0,4 [0,03; 0,99]	3/7 (42,9)	10,7 [0,03; NE]	4,55 [0,96; 21,61] 0,0369

Data cut-off: 18.05.2020, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t203_aesocpt_tte_sub_popa1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 210.1.1: Interacting Subgroups: Time to adverse event according SOC - Blood and lymphatic system disorders - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Country (p-value of the interaction term: 0,0306)					
China	60/71 (84,5)	1,8 [1,41; 2,79]	6/33 (18,2)	NE [14,96; NE]	8,82 [3,77; 20,60] <,0001
Other	2/10 (20,0)	NE [0,46; NE]	2/7 (28,6)	6,7 [2,56; NE]	0,70 [0,10; 5,01] 0,7203

Data cut-off: 18.05.2020, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
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Tabelle 4-143 (Anhang): Ergebnisse der Subgruppenanalyse nicht interagierender Subgruppen (MONARCH-plus)

Tabelle 101.1.2: Subgruppen für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,4057)					
< 65 Jahre	14/62 (22,6)	NE [NE; NE]	11/30 (36,7)	NE [19,79; NE]	0,46 [0,21; 1,02] 0,0500
≥ 65 Jahre	6/19 (31,6)	NE [22,09; NE]	3/10 (30,0)	NE [3,39; NE]	0,96 [0,24; 3,84] 0,9522
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,2714)					
1	6/43 (14,0)	NE [NE; NE]	9/26 (34,6)	NE [18,44; NE]	0,33 [0,12; 0,92] 0,0266
2	6/24 (25,0)	NE [26,93; NE]	3/5 (60,0)	23,9 [6,28; NE]	0,41 [0,10; 1,66] 0,1981
≥ 3	8/14 (57,1)	22,1 [16,87; NE]	2/9 (22,2)	NE [10,95; NE]	1,62 [0,34; 7,65] 0,5371
Land (p-Wert des Interaktionsterms: 0,5341)					
China	19/71 (26,8)	NE [NE; NE]	12/33 (36,4)	NE [19,92; NE]	0,59 [0,29; 1,22] 0,1501
Andere	1/10 (10,0)	NE [7,96; NE]	2/7 (28,6)	NE [10,26; NE]	0,29 [0,03; 3,22] 0,2842
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,5940)					
Positiv	14/63 (22,2)	NE [NE; NE]	11/30 (36,7)	NE [19,79; NE]	0,49 [0,22; 1,09] 0,0742
Negativ	6/18 (33,3)	NE [20,75; NE]	3/10 (30,0)	NE [6,28; NE]	0,73 [0,18; 2,93] 0,6581
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,1855)					
Primäre Resistenz	7/30 (23,3)	NE [26,07; NE]	8/17 (47,1)	19,9 [14,96; NE]	0,33 [0,12; 0,93] 0,0269
Sekundäre Resistenz	13/51 (25,5)	NE [NE; NE]	6/23 (26,1)	NE [23,90; NE]	0,89 [0,34; 2,34] 0,8073
Tumorgrad (p-Wert des Interaktionsterms: 0,1442)					
Hoch	2/11 (18,2)	NE [22,09; NE]	3/7 (42,9)	19,8 [3,39; NE]	0,21 [0,03; 1,30] 0,0661

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Niedrig/mittel	5/31 (16,1)	NE [NE; NE]	6/17 (35,3)	25,5 [15,65; NE]	0,31 [0,09; 1,06] 0,0491
Unbekannt	13/39 (33,3)	NE [24,20; NE]	5/16 (31,3)	NE [11,57; NE]	1,08 [0,38; 3,04] 0,8907
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,3489)					
Ja	2/17 (11,8)	NE [NE; NE]	4/10 (40,0)	NE [14,96; NE]	0,28 [0,05; 1,51] 0,1126
Nein	18/64 (28,1)	NE [26,93; NE]	10/30 (33,3)	NE [19,79; NE]	0,64 [0,29; 1,38] 0,2467
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9919)					
Ja	19/72 (26,4)	NE [NE; NE]	14/39 (35,9)	NE [19,79; NE]	0,58 [0,29; 1,15] 0,1133
Nein	1/9 (11,1)	NE [22,09; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,7055

Datenschnitt: 18.05.2020, ITT-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_os_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 102.1.2: Subgruppen für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9034)					
< 65 Jahre	42/62 (67,7)	11,3 [9,27; 18,81]	23/30 (76,7)	7,5 [2,73; 12,79]	0,62 [0,38; 1,04] 0,0683
≥ 65 Jahre	15/19 (78,9)	11,5 [5,79; 25,94]	8/10 (80,0)	5,2 [1,78; 19,59]	0,67 [0,28; 1,59] 0,3634
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,6007)					
1	26/43 (60,5)	17,0 [9,50; 25,97]	19/26 (73,1)	7,8 [3,72; 19,59]	0,66 [0,36; 1,19] 0,1634
2	19/24 (79,2)	11,3 [7,40; 15,48]	5/5 (100,0)	1,8 [1,78; NE]	0,38 [0,14; 1,07] 0,0577
≥ 3	12/14 (85,7)	9,4 [5,49; 19,59]	7/9 (77,8)	3,6 [1,48; 8,35]	0,37 [0,14; 0,99] 0,0406
Art der Erkrankung (p-Wert des Interaktionsterms: 0,3114)					
Viszerale Metastasen	38/47 (80,9)	9,6 [7,40; 11,41]	16/21 (76,2)	3,7 [1,84; 8,35]	0,70 [0,39; 1,27] 0,2386
Nicht-viszerale Metastasen	19/34 (55,9)	18,0 [12,20; NE]	15/19 (78,9)	8,1 [3,65; 19,86]	0,45 [0,22; 0,90] 0,0211
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,4559)					
0	20/27 (74,1)	7,5 [4,60; 16,77]	12/14 (85,7)	5,4 [1,78; 14,66]	0,78 [0,38; 1,60] 0,4881
1	37/54 (68,5)	14,7 [9,99; 22,55]	19/26 (73,1)	7,5 [1,97; 12,89]	0,56 [0,32; 0,97] 0,0381
Land (p-Wert des Interaktionsterms: 0,9635)					
China	49/71 (69,0)	13,1 [9,60; 19,59]	25/33 (75,8)	5,6 [2,73; 12,89]	0,65 [0,40; 1,05] 0,0759
Andere	8/10 (80,0)	8,4 [1,87; 11,28]	6/7 (85,7)	7,4 [1,84; NE]	0,61 [0,21; 1,79] 0,3622
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,1004)					
Ja	47/62 (75,8)	10,0 [7,59; 11,47]	20/26 (76,9)	4,7 [2,73; 12,89]	0,77 [0,45; 1,31] 0,3367

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Nein	10/19 (52,6)	24,1 [13,05; NE]	11/14 (78,6)	7,4 [1,97; 14,66]	0,33 [0,14; 0,82] 0,0121
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,5365)					
Positiv	41/63 (65,1)	14,7 [9,99; 19,59]	24/30 (80,0)	5,7 [3,65; 12,89]	0,58 [0,35; 0,96] 0,0339
Negativ	16/18 (88,9)	9,5 [5,59; 13,05]	7/10 (70,0)	4,7 [1,48; NE]	0,77 [0,31; 1,92] 0,5768
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9134)					
Primäre Resistenz	24/30 (80,0)	10,9 [9,24; 13,05]	13/17 (76,5)	3,9 [1,84; 12,79]	0,64 [0,32; 1,27] 0,2015
Sekundäre Resistenz	33/51 (64,7)	14,7 [7,59; 25,94]	18/23 (78,3)	8,1 [3,65; 14,66]	0,60 [0,33; 1,07] 0,0811
Tumorgrad (p-Wert des Interaktionsterms: 0,5101)					
Hoch	9/11 (81,8)	9,6 [2,01; 25,97]	6/7 (85,7)	1,8 [1,48; 11,21]	0,41 [0,14; 1,20] 0,1123
Niedrig/mittel	23/31 (74,2)	11,5 [9,27; 18,02]	13/17 (76,5)	5,5 [3,65; 8,35]	0,52 [0,26; 1,03] 0,0562
Unbekannt	25/39 (64,1)	16,8 [7,50; 24,07]	12/16 (75,0)	10,5 [1,97; 25,68]	0,84 [0,42; 1,69] 0,6261
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,3175)					
Ja	10/17 (58,8)	22,6 [4,60; NE]	9/10 (90,0)	5,4 [1,97; 7,53]	0,43 [0,17; 1,08] 0,0646
Nein	47/64 (73,4)	11,3 [9,50; 15,48]	22/30 (73,3)	8,1 [1,87; 12,89]	0,72 [0,43; 1,19] 0,2042
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9812)					
Ja	50/72 (69,4)	13,1 [9,60; 18,81]	31/39 (79,5)	5,5 [3,65; 11,21]	0,56 [0,35; 0,87] 0,0097
Nein	7/9 (77,8)	5,8 [1,81; 11,41]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2244

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Datenschnitt: 18.05.2020, ITT-Population 1: In Monaten; 2: Aus Log-rank-Test Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie.					

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_pfs_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 102.2.2: Subgruppen für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Anzahl vorangegangener endokriner Behandlungen (p-Wert des Interaktionsterms: 0,0603)					
Erstlinie	4/9 (44,4)	NE [1,84; NE]	5/5 (100,0)	1,9 [1,68; NE]	0,11 [0,02; 0,61] 0,0028
Zweitlinie	10/14 (71,4)	13,4 [5,62; NE]	5/8 (62,5)	7,7 [1,41; NE]	0,55 [0,18; 1,68] 0,2886
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9602)					
0	6/8 (75,0)	10,1 [5,33; NE]	5/7 (71,4)	5,2 [1,41; NE]	0,36 [0,10; 1,27] 0,0996
1	8/15 (53,3)	15,8 [3,16; NE]	5/6 (83,3)	6,5 [1,68; NE]	0,37 [0,12; 1,15] 0,0734
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,1741)					
Ja	8/12 (66,7)	10,1 [3,16; NE]	4/7 (57,1)	7,4 [1,41; NE]	0,58 [0,17; 1,98] 0,3826
Nein	6/11 (54,5)	15,8 [5,33; NE]	6/6 (100,0)	2,3 [1,68; NE]	0,18 [0,05; 0,66] 0,0039
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9210)					
Ja	7/11 (63,6)	17,5 [7,43; NE]	4/6 (66,7)	7,4 [1,41; NE]	0,35 [0,10; 1,28] 0,0982
Nein	7/12 (58,3)	10,9 [2,89; NE]	6/7 (85,7)	2,7 [1,68; NE]	0,37 [0,12; 1,11] 0,0653

Datenschnitt: 18.05.2020, ITT-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_pfs_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 103.1.2: Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,2432)					
< 65 Jahre	16/62 (25,8)	NE [21,11; NE]	7/30 (23,3)	NE [16,87; NE]	1,03 [0,42; 2,51] 0,9491
≥ 65 Jahre	5/19 (26,3)	24,3 [8,52; NE]	5/10 (50,0)	5,6 [0,99; NE]	0,37 [0,10; 1,31] 0,1051
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,2894)					
1	9/43 (20,9)	NE [22,22; NE]	4/26 (15,4)	NE [NE; NE]	1,21 [0,37; 3,93] 0,7583
2	9/24 (37,5)	20,7 [6,64; NE]	3/5 (60,0)	16,9 [0,99; NE]	0,54 [0,14; 2,09] 0,3596
≥ 3	3/14 (21,4)	NE [1,94; NE]	5/9 (55,6)	10,2 [0,07; NE]	0,33 [0,08; 1,38] 0,1095
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9660)					
Viszerale Metastasen	15/47 (31,9)	22,2 [13,64; NE]	8/21 (38,1)	NE [2,01; NE]	0,73 [0,31; 1,72] 0,4676
Nicht-viszerale Metastasen	6/34 (17,6)	NE [24,26; NE]	4/19 (21,1)	NE [5,56; NE]	0,64 [0,17; 2,40] 0,4855
Land (p-Wert des Interaktionsterms: 0,8962)					
China	16/71 (22,5)	NE [24,26; NE]	8/33 (24,2)	NE [16,87; NE]	0,85 [0,36; 2,00] 0,7180
Andere	5/10 (50,0)	22,2 [0,99; NE]	4/7 (57,1)	5,6 [2,01; NE]	0,51 [0,13; 2,07] 0,3412
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9326)					
Ja	16/62 (25,8)	NE [20,71; NE]	8/26 (30,8)	NE [5,00; NE]	0,73 [0,31; 1,72] 0,4752
Nein	5/19 (26,3)	NE [21,11; NE]	4/14 (28,6)	NE [3,72; NE]	0,74 [0,18; 2,99] 0,6591
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,0756)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Positiv	18/63 (28,6)	NE [21,11; NE]	7/30 (23,3)	NE [10,16; NE]	1,10 [0,46; 2,65] 0,8321
Negativ	3/18 (16,7)	NE [NE; NE]	5/10 (50,0)	2,8 [0,95; NE]	0,27 [0,06; 1,14] 0,0588
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,4235)					
Primäre Resistenz	9/30 (30,0)	NE [21,11; NE]	4/17 (23,5)	NE [2,01; NE]	1,11 [0,34; 3,64] 0,8722
Sekundäre Resistenz	12/51 (23,5)	NE [22,22; NE]	8/23 (34,8)	NE [5,56; NE]	0,59 [0,24; 1,46] 0,2523
Tumorgrad (p-Wert des Interaktionsterms: 0,3338)					
Hoch	3/11 (27,3)	24,3 [8,52; NE]	3/7 (42,9)	NE [0,99; NE]	0,23 [0,04; 1,48] 0,1128
Niedrig/mittel	10/31 (32,3)	22,2 [13,64; NE]	5/17 (29,4)	16,9 [10,16; NE]	0,82 [0,28; 2,44] 0,7201
Unbekannt	8/39 (20,5)	NE [20,71; NE]	4/16 (25,0)	NE [5,00; NE]	0,96 [0,29; 3,20] 0,9459
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,5319)					
Ja	5/17 (29,4)	NE [8,52; NE]	2/10 (20,0)	16,9 [5,56; NE]	0,82 [0,15; 4,49] 0,8198
Nein	16/64 (25,0)	NE [21,11; NE]	10/30 (33,3)	NE [3,72; NE]	0,67 [0,30; 1,47] 0,3090

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwaplo6_popa1_2.rtf
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Tabelle 104.1.2: Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	n/N (%)	Mediane Ereigniszeit[1]	n/N (%)	Mediane Ereigniszeit[1]	HR [95% KI] p-Wert[2]
Alter (p-Wert des Interaktionsterms: 0,3863)					
< 65 Jahre	12/62 (19,4)	25,3 [19,46; NE]	1/30 (3,3)	NE [NE; NE]	6,29 [0,81; 48,62] 0,0436
≥ 65 Jahre	3/19 (15,8)	NE [NE; NE]	1/10 (10,0)	NE [5,00; NE]	1,54 [0,16; 14,80] 0,7156
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,9999)					
1	11/43 (25,6)	25,3 [14,70; NE]	0/26 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0058
2	3/24 (12,5)	NE [NE; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4063
≥ 3	1/14 (7,1)	NE [NE; NE]	2/9 (22,2)	NE [5,00; NE]	0,22 [0,02; 2,43] 0,1749
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9908)					
0	6/27 (22,2)	NE [19,46; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0572
1	9/54 (16,7)	25,3 [25,32; NE]	2/26 (7,7)	NE [NE; NE]	1,96 [0,42; 9,09] 0,3862
Land (p-Wert des Interaktionsterms: 0,9946)					
China	14/71 (19,7)	NE [25,32; NE]	2/33 (6,1)	NE [NE; NE]	3,43 [0,77; 15,15] 0,0854
Andere	1/10 (10,0)	19,5 [NE; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3173
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9921)					
Ja	9/62 (14,5)	NE [25,32; NE]	2/26 (7,7)	NE [8,71; NE]	1,90 [0,40; 8,92] 0,4101
Nein	6/19 (31,6)	NE [0,99; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0197
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9937)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Positiv	12/63 (19,0)	25,3 [25,32; NE]	2/30 (6,7)	NE [NE; NE]	3,06 [0,68; 13,77] 0,1259
Negativ	3/18 (16,7)	NE [NE; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2113
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,4611)					
Primäre Resistenz	3/30 (10,0)	NE [NE; NE]	1/17 (5,9)	NE [8,71; NE]	1,42 [0,15; 13,83] 0,7739
Sekundäre Resistenz	12/51 (23,5)	25,3 [19,46; NE]	1/23 (4,3)	NE [NE; NE]	5,53 [0,72; 42,54] 0,0645
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,5626)					
Ja	4/17 (23,5)	NE [19,46; NE]	1/10 (10,0)	NE [8,71; NE]	2,05 [0,22; 18,75] 0,5169
Nein	11/64 (17,2)	25,3 [25,32; NE]	1/30 (3,3)	NE [NE; NE]	5,59 [0,72; 43,60] 0,0645

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwdiar6_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 105.1.2: Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,6940)					
< 65 Jahre	10/62 (16,1)	NE [NE; NE]	6/30 (20,0)	NE [NE; NE]	0,73 [0,27; 2,02] 0,5497
≥ 65 Jahre	1/19 (5,3)	NE [NE; NE]	1/10 (10,0)	NE [5,00; NE]	0,31 [0,02; 4,97] 0,3784
Art der Erkrankung (p-Wert des Interaktionsterms: 0,4787)					
Viszerale Metastasen	7/47 (14,9)	NE [NE; NE]	5/21 (23,8)	NE [5,13; NE]	0,48 [0,15; 1,52] 0,2057
Nicht-viszerale Metastasen	4/34 (11,8)	NE [NE; NE]	2/19 (10,5)	NE [NE; NE]	0,94 [0,17; 5,21] 0,9475
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,6427)					
0	4/27 (14,8)	NE [9,57; NE]	4/14 (28,6)	NE [5,00; NE]	0,53 [0,13; 2,13] 0,3644
1	7/54 (13,0)	NE [NE; NE]	3/26 (11,5)	NE [NE; NE]	0,90 [0,23; 3,51] 0,8818
Land (p-Wert des Interaktionsterms: 0,9865)					
China	9/71 (12,7)	NE [NE; NE]	5/33 (15,2)	NE [NE; NE]	0,71 [0,24; 2,14] 0,5450
Andere	2/10 (20,0)	NE [1,87; NE]	2/7 (28,6)	NE [1,87; NE]	0,72 [0,10; 5,12] 0,7401
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,2535)					
Ja	8/62 (12,9)	NE [NE; NE]	6/26 (23,1)	NE [5,13; NE]	0,45 [0,16; 1,31] 0,1325
Nein	3/19 (15,8)	NE [19,99; NE]	1/14 (7,1)	NE [NE; NE]	1,45 [0,15; 14,38] 0,7510
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,1838)					
Positiv	8/63 (12,7)	NE [NE; NE]	3/30 (10,0)	NE [NE; NE]	1,14 [0,30; 4,30] 0,8504

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Negativ	3/18 (16,7)	NE [8,81; NE]	4/10 (40,0)	5,0 [0,99; NE]	0,28 [0,06; 1,27] 0,0794
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,1850)					
Primäre Resistenz	3/30 (10,0)	NE [NE; NE]	4/17 (23,5)	NE [2,60; NE]	0,35 [0,08; 1,56] 0,1473
Sekundäre Resistenz	8/51 (15,7)	NE [NE; NE]	3/23 (13,0)	NE [NE; NE]	1,15 [0,30; 4,33] 0,8386
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,6786)					
Ja	2/17 (11,8)	NE [NE; NE]	1/10 (10,0)	NE [5,00; NE]	1,33 [0,12; 14,67] 0,8154
Nein	9/64 (14,1)	NE [NE; NE]	6/30 (20,0)	NE [NE; NE]	0,61 [0,22; 1,73] 0,3493

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwdysp6_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 106.1.2: Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9120)					
< 65 Jahre	28/62 (45,2)	19,8 [7,66; NE]	11/30 (36,7)	NE [8,71; NE]	1,16 [0,58; 2,33] 0,6752
≥ 65 Jahre	9/19 (47,4)	21,1 [3,88; NE]	4/10 (40,0)	5,6 [0,99; NE]	1,10 [0,34; 3,60] 0,8803
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,5050)					
1	14/43 (32,6)	NE [19,82; NE]	7/26 (26,9)	NE [9,01; NE]	1,18 [0,48; 2,94] 0,7226
2	13/24 (54,2)	16,4 [3,88; NE]	4/5 (80,0)	2,8 [0,07; NE]	0,61 [0,19; 1,96] 0,4155
≥ 3	10/14 (71,4)	5,7 [0,99; 20,05]	4/9 (44,4)	10,2 [0,07; NE]	1,20 [0,37; 3,93] 0,7597
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9272)					
Viszerale Metastasen	25/47 (53,2)	19,7 [5,79; 20,71]	9/21 (42,9)	10,2 [1,05; NE]	1,11 [0,52; 2,39] 0,7847
Nicht-viszerale Metastasen	12/34 (35,3)	NE [1,97; NE]	6/19 (31,6)	NE [5,56; NE]	1,06 [0,39; 2,87] 0,9209
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,7516)					
0	11/27 (40,7)	20,7 [1,97; NE]	5/14 (35,7)	12,2 [2,83; NE]	1,31 [0,45; 3,78] 0,6209
1	26/54 (48,1)	19,8 [8,52; NE]	10/26 (38,5)	NE [5,56; NE]	1,04 [0,50; 2,17] 0,9119
Land (p-Wert des Interaktionsterms: 0,8729)					
China	31/71 (43,7)	20,1 [10,88; NE]	11/33 (33,3)	NE [8,71; NE]	1,21 [0,61; 2,41] 0,5815
Andere	6/10 (60,0)	5,8 [0,95; NE]	4/7 (57,1)	10,2 [0,16; NE]	1,08 [0,30; 3,83] 0,9218
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,7504)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	30/62 (48,4)	19,7 [7,66; 21,14]	10/26 (38,5)	12,2 [5,00; NE]	1,16 [0,57; 2,37] 0,6852
Nein	7/19 (36,8)	24,3 [0,99; NE]	5/14 (35,7)	NE [0,99; NE]	1,03 [0,31; 3,39] 0,9800
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,1976)					
Positiv	27/63 (42,9)	20,7 [8,52; NE]	8/30 (26,7)	NE [8,71; NE]	1,55 [0,70; 3,41] 0,2719
Negativ	10/18 (55,6)	9,3 [1,94; NE]	7/10 (70,0)	5,0 [0,07; 12,23]	0,66 [0,25; 1,75] 0,3946
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,4125)					
Primäre Resistenz	18/30 (60,0)	10,9 [1,94; 20,05]	6/17 (35,3)	NE [0,99; NE]	1,57 [0,62; 4,01] 0,3377
Sekundäre Resistenz	19/51 (37,3)	24,3 [8,52; NE]	9/23 (39,1)	12,2 [5,56; NE]	0,91 [0,41; 2,03] 0,8161
Tumorgrad (p-Wert des Interaktionsterms: 0,7725)					
Hoch	10/11 (90,9)	1,2 [0,07; 21,14]	4/7 (57,1)	6,6 [0,07; NE]	0,91 [0,27; 3,09] 0,9043
Niedrig/mittel	13/31 (41,9)	19,8 [4,64; NE]	6/17 (35,3)	NE [5,00; NE]	1,09 [0,42; 2,88] 0,8635
Unbekannt	14/39 (35,9)	20,7 [9,30; NE]	5/16 (31,3)	NE [5,56; NE]	1,30 [0,47; 3,62] 0,6162
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,7131)					
Ja	8/17 (47,1)	20,7 [1,97; NE]	3/10 (30,0)	8,7 [5,00; NE]	1,32 [0,34; 5,03] 0,6879
Nein	29/64 (45,3)	19,8 [7,66; NE]	12/30 (40,0)	12,2 [2,83; NE]	1,05 [0,54; 2,07] 0,8792

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwfati6_popa1_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 106.2.2: Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,5496)					
< 65 Jahre	7/16 (43,8)	NE [1,94; NE]	5/9 (55,6)	5,8 [0,07; NE]	0,49 [0,15; 1,62] 0,2260
≥ 65 Jahre	2/7 (28,6)	NE [0,07; NE]	3/4 (75,0)	13,2 [0,07; NE]	1,20 [0,16; 8,84] 0,9096
Anzahl vorangegangener endokriner Behandlungen (p-Wert des Interaktionsterms: 0,9341)					
Erstlinie	4/9 (44,4)	5,6 [0,07; NE]	3/5 (60,0)	1,0 [0,07; NE]	0,64 [0,14; 2,93] 0,5936
Zweitlinie	5/14 (35,7)	NE [0,07; NE]	5/8 (62,5)	7,2 [1,91; NE]	0,54 [0,15; 1,90] 0,2984
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,7147)					
Ja	6/12 (50,0)	13,1 [0,07; NE]	5/7 (71,4)	5,8 [1,91; NE]	0,65 [0,19; 2,16] 0,4454
Nein	3/11 (27,3)	NE [0,07; NE]	3/6 (50,0)	NE [0,07; NE]	0,56 [0,11; 2,83] 0,4968
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,2669)					
Ja	3/11 (27,3)	NE [0,07; NE]	4/6 (66,7)	7,2 [1,91; NE]	0,29 [0,06; 1,35] 0,0949
Nein	6/12 (50,0)	2,0 [0,07; NE]	4/7 (57,1)	3,8 [0,07; NE]	1,05 [0,29; 3,75] 0,9385

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
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Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwfati6_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 107.1.2: Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,4187)					
< 65 Jahre	9/62 (14,5)	NE [24,23; NE]	2/30 (6,7)	NE [19,86; NE]	1,78 [0,38; 8,28] 0,4546
≥ 65 Jahre	4/19 (21,1)	NE [13,64; NE]	2/10 (20,0)	NE [0,07; NE]	0,70 [0,13; 3,93] 0,6882
Art der Erkrankung (p-Wert des Interaktionsterms: 0,4187)					
Viszerale Metastasen	8/47 (17,0)	NE [20,05; NE]	2/21 (9,5)	NE [NE; NE]	1,39 [0,29; 6,60] 0,6733
Nicht-viszerale Metastasen	5/34 (14,7)	NE [24,23; NE]	2/19 (10,5)	23,0 [19,86; NE]	0,28 [0,04; 2,12] 0,1916
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9892)					
0	4/27 (14,8)	NE [17,33; NE]	2/14 (14,3)	NE [23,01; NE]	1,11 [0,20; 6,15] 0,9062
1	9/54 (16,7)	25,3 [24,23; NE]	2/26 (7,7)	NE [19,86; NE]	1,25 [0,27; 5,88] 0,7770
Land (p-Wert des Interaktionsterms: 0,9919)					
China	11/71 (15,5)	NE [24,23; NE]	4/33 (12,1)	NE [19,86; NE]	1,04 [0,33; 3,27] 0,9475
Andere	2/10 (20,0)	NE [4,70; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3057
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,2440)					
Ja	10/62 (16,1)	25,3 [25,32; NE]	2/26 (7,7)	NE [NE; NE]	1,93 [0,41; 8,94] 0,3947
Nein	3/19 (15,8)	NE [24,23; NE]	2/14 (14,3)	23,0 [19,86; NE]	0,13 [0,01; 1,44] 0,0501
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,3330)					
Positiv	12/63 (19,0)	NE [24,23; NE]	3/30 (10,0)	NE [19,86; NE]	1,56 [0,44; 5,55] 0,4888

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Negativ	1/18 (5,6)	NE [NE; NE]	1/10 (10,0)	NE [0,07; NE]	0,36 [0,02; 6,11] 0,4653
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9160)					
Primäre Resistenz	2/30 (6,7)	NE [20,05; NE]	1/17 (5,9)	NE [23,01; NE]	1,29 [0,11; 14,69] 0,8347
Sekundäre Resistenz	11/51 (21,6)	25,3 [24,23; NE]	3/23 (13,0)	NE [19,86; NE]	1,27 [0,35; 4,63] 0,7122
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9928)					
Ja	3/17 (17,6)	NE [9,60; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2687
Nein	10/64 (15,6)	25,3 [24,23; NE]	4/30 (13,3)	NE [19,86; NE]	0,95 [0,30; 3,04] 0,9326

Datenschnitt: 18.05.2020, Safety-Population
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Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
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Tabelle 108.1.2: Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,5456)					
< 65 Jahre	9/62 (14,5)	NE [NE; NE]	5/30 (16,7)	NE [20,91; NE]	0,73 [0,25; 2,19] 0,5770
≥ 65 Jahre	2/19 (10,5)	NE [18,05; NE]	2/10 (20,0)	20,6 [5,56; NE]	0,28 [0,04; 2,01] 0,1768
Art der Erkrankung (p-Wert des Interaktionsterms: 0,7564)					
Viszerale Metastasen	8/47 (17,0)	NE [NE; NE]	5/21 (23,8)	NE [3,88; NE]	0,49 [0,16; 1,51] 0,2068
Nicht-viszerale Metastasen	3/34 (8,8)	NE [NE; NE]	2/19 (10,5)	NE [20,91; NE]	0,71 [0,12; 4,29] 0,7067
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,3004)					
0	5/27 (18,5)	NE [8,32; NE]	2/14 (14,3)	NE [NE; NE]	1,17 [0,23; 6,06] 0,8488
1	6/54 (11,1)	NE [NE; NE]	5/26 (19,2)	20,9 [20,61; NE]	0,41 [0,12; 1,34] 0,1268
Land (p-Wert des Interaktionsterms: 0,1741)					
China	6/71 (8,5)	NE [NE; NE]	5/33 (15,2)	NE [20,91; NE]	0,42 [0,13; 1,39] 0,1455
Andere	5/10 (50,0)	7,4 [0,95; NE]	2/7 (28,6)	20,6 [5,56; NE]	1,80 [0,35; 9,33] 0,4768
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,5244)					
Ja	9/62 (14,5)	NE [NE; NE]	6/26 (23,1)	20,9 [20,61; NE]	0,49 [0,17; 1,37] 0,1648
Nein	2/19 (10,5)	NE [18,05; NE]	1/14 (7,1)	NE [5,56; NE]	1,15 [0,10; 13,27] 0,9133
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,5795)					
Positiv	9/63 (14,3)	NE [NE; NE]	5/30 (16,7)	NE [20,61; NE]	0,69 [0,23; 2,08] 0,5121

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Negativ	2/18 (11,1)	NE [NE; NE]	2/10 (20,0)	NE [2,60; NE]	0,36 [0,05; 2,62] 0,2930
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,4035)					
Primäre Resistenz	7/30 (23,3)	NE [18,05; NE]	3/17 (17,6)	NE [2,89; NE]	0,96 [0,25; 3,73] 0,9494
Sekundäre Resistenz	4/51 (7,8)	NE [NE; NE]	4/23 (17,4)	NE [20,61; NE]	0,36 [0,09; 1,46] 0,1379
Tumorgrad (p-Wert des Interaktionsterms: 0,2330)					
Hoch	1/11 (9,1)	NE [2,37; NE]	2/7 (28,6)	3,9 [2,89; NE]	0,14 [0,01; 1,56] 0,0621
Niedrig/mittel	8/31 (25,8)	NE [18,05; NE]	3/17 (17,6)	20,9 [20,61; NE]	1,00 [0,26; 3,82] 0,9953
Unbekannt	2/39 (5,1)	NE [NE; NE]	2/16 (12,5)	NE [5,56; NE]	0,42 [0,06; 3,02] 0,3769
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,3647)					
Ja	1/17 (5,9)	NE [NE; NE]	2/10 (20,0)	20,9 [5,56; NE]	0,18 [0,02; 1,97] 0,1121
Nein	10/64 (15,6)	NE [NE; NE]	5/30 (16,7)	NE [20,61; NE]	0,76 [0,26; 2,23] 0,6188

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
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Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwcons6_popa1_2.rtf
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Tabelle 109.1.2: Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	n/N (%)	Mediane Ereigniszeit[1]	n/N (%)	Mediane Ereigniszeit[1]	HR [95% KI] p-Wert[2]
Alter (p-Wert des Interaktionsterms: 0,1783)					
< 65 Jahre	15/62 (24,2)	NE [22,62; NE]	7/30 (23,3)	NE [10,16; NE]	0,89 [0,36; 2,18] 0,7897
≥ 65 Jahre	3/19 (15,8)	NE [9,40; NE]	4/10 (40,0)	5,0 [0,99; NE]	0,22 [0,05; 1,03] 0,0402
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,2045)					
1	7/43 (16,3)	NE [NE; NE]	2/26 (7,7)	NE [NE; NE]	1,73 [0,36; 8,36] 0,4888
2	6/24 (25,0)	16,7 [9,40; NE]	3/5 (60,0)	4,4 [2,89; NE]	0,35 [0,09; 1,45] 0,1275
≥ 3	5/14 (35,7)	22,6 [3,88; NE]	6/9 (66,7)	8,7 [0,07; NE]	0,30 [0,08; 1,08] 0,0515
Art der Erkrankung (p-Wert des Interaktionsterms: 0,2105)					
Viszerale Metastasen	10/47 (21,3)	NE [16,70; NE]	8/21 (38,1)	10,2 [3,88; NE]	0,43 [0,17; 1,08] 0,0642
Nicht-viszerale Metastasen	8/34 (23,5)	NE [22,62; NE]	3/19 (15,8)	NE [NE; NE]	1,17 [0,31; 4,47] 0,8141
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,0857)					
0	7/27 (25,9)	NE [8,32; NE]	2/14 (14,3)	NE [5,00; NE]	1,93 [0,40; 9,32] 0,3990
1	11/54 (20,4)	NE [22,62; NE]	9/26 (34,6)	NE [3,88; NE]	0,39 [0,16; 0,95] 0,0314
Land (p-Wert des Interaktionsterms: 0,1121)					
China	17/71 (23,9)	NE [22,62; NE]	7/33 (21,2)	NE [8,71; NE]	0,92 [0,38; 2,22] 0,8567
Andere	1/10 (10,0)	NE [4,11; NE]	4/7 (57,1)	10,2 [1,08; NE]	0,14 [0,02; 1,22] 0,0369
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,8494)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	14/62 (22,6)	NE [22,62; NE]	8/26 (30,8)	NE [5,00; NE]	0,60 [0,25; 1,43] 0,2446
Nein	4/19 (21,1)	NE [17,06; NE]	3/14 (21,4)	NE [3,72; NE]	0,78 [0,17; 3,59] 0,7542
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,3217)					
Positiv	14/63 (22,2)	NE [22,62; NE]	7/30 (23,3)	NE [8,71; NE]	0,79 [0,32; 1,97] 0,6177
Negativ	4/18 (22,2)	NE [9,30; NE]	4/10 (40,0)	5,0 [0,99; NE]	0,38 [0,09; 1,56] 0,1639
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,8179)					
Primäre Resistenz	9/30 (30,0)	NE [16,70; NE]	5/17 (29,4)	NE [2,89; NE]	0,65 [0,22; 1,96] 0,4438
Sekundäre Resistenz	9/51 (17,6)	NE [NE; NE]	6/23 (26,1)	NE [5,00; NE]	0,60 [0,21; 1,70] 0,3353
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,2334)					
Ja	6/17 (35,3)	NE [2,76; NE]	2/10 (20,0)	NE [5,00; NE]	1,48 [0,29; 7,52] 0,6350
Nein	12/64 (18,8)	NE [NE; NE]	9/30 (30,0)	NE [3,88; NE]	0,48 [0,20; 1,14] 0,0886

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
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Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwinso6_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 110.1.2: Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,0524)					
< 65 Jahre	13/62 (21,0)	NE [21,11; NE]	4/30 (13,3)	NE [16,87; NE]	1,31 [0,43; 4,03] 0,6432
≥ 65 Jahre	3/19 (15,8)	NE [24,26; NE]	5/10 (50,0)	5,6 [0,99; NE]	0,21 [0,05; 0,92] 0,0238
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,7147)					
1	5/43 (11,6)	NE [24,26; NE]	7/26 (26,9)	NE [7,66; NE]	0,34 [0,11; 1,06] 0,0515
2	9/24 (37,5)	20,7 [7,89; NE]	2/5 (40,0)	16,9 [2,83; NE]	0,74 [0,15; 3,58] 0,6876
≥ 3	2/14 (14,3)	NE [NE; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2921
Art der Erkrankung (p-Wert des Interaktionsterms: 0,0647)					
Viszerale Metastasen	12/47 (25,5)	NE [20,71; NE]	3/21 (14,3)	NE [20,61; NE]	1,43 [0,40; 5,10] 0,5847
Nicht-viszerale Metastasen	4/34 (11,8)	NE [24,26; NE]	6/19 (31,6)	NE [5,56; NE]	0,22 [0,05; 0,90] 0,0207
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,1145)					
0	9/27 (33,3)	NE [7,89; NE]	3/14 (21,4)	NE [7,66; NE]	1,43 [0,39; 5,32] 0,5974
1	7/54 (13,0)	NE [24,26; NE]	6/26 (23,1)	20,6 [16,87; NE]	0,38 [0,12; 1,13] 0,0702
Land (p-Wert des Interaktionsterms: 0,5664)					
China	12/71 (16,9)	NE [24,26; NE]	5/33 (15,2)	NE [16,87; NE]	0,90 [0,31; 2,55] 0,8321
Andere	4/10 (40,0)	NE [0,99; NE]	4/7 (57,1)	5,6 [0,95; NE]	0,60 [0,15; 2,44] 0,4731
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,1596)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	13/62 (21,0)	NE [NE; NE]	4/26 (15,4)	NE [16,87; NE]	1,12 [0,36; 3,44] 0,8580
Nein	3/19 (15,8)	NE [21,11; NE]	5/14 (35,7)	NE [3,72; NE]	0,23 [0,04; 1,21] 0,0601
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,8850)					
Positiv	12/63 (19,0)	NE [24,26; NE]	7/30 (23,3)	NE [16,87; NE]	0,66 [0,26; 1,68] 0,3704
Negativ	4/18 (22,2)	NE [7,99; NE]	2/10 (20,0)	NE [0,95; NE]	0,74 [0,13; 4,14] 0,7336
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,2168)					
Primäre Resistenz	7/30 (23,3)	NE [21,11; NE]	2/17 (11,8)	NE [NE; NE]	1,49 [0,31; 7,25] 0,6163
Sekundäre Resistenz	9/51 (17,6)	NE [24,26; NE]	7/23 (30,4)	20,6 [7,66; NE]	0,44 [0,16; 1,21] 0,1023
Tumorgrad (p-Wert des Interaktionsterms: 0,7019)					
Hoch	3/11 (27,3)	24,3 [8,52; NE]	2/7 (28,6)	NE [0,95; NE]	0,35 [0,05; 2,69] 0,2966
Niedrig/mittel	6/31 (19,4)	NE [21,11; NE]	3/17 (17,6)	20,6 [16,87; NE]	0,72 [0,18; 2,96] 0,6512
Unbekannt	7/39 (17,9)	NE [20,71; NE]	4/16 (25,0)	NE [5,56; NE]	0,75 [0,22; 2,58] 0,6421
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,3569)					
Ja	6/17 (35,3)	NE [7,89; NE]	2/10 (20,0)	16,9 [5,56; NE]	1,04 [0,20; 5,33] 0,9564
Nein	10/64 (15,6)	NE [24,26; NE]	7/30 (23,3)	NE [7,66; NE]	0,55 [0,21; 1,45] 0,2162

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwnavo6_popa1_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
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Tabelle 111.1.2: Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,3331)					
< 65 Jahre	13/62 (21,0)	NE [22,49; NE]	8/30 (26,7)	NE [12,23; NE]	0,69 [0,28; 1,66] 0,3972
≥ 65 Jahre	2/19 (10,5)	NE [13,64; NE]	3/10 (30,0)	20,6 [0,99; NE]	0,26 [0,04; 1,60] 0,1193
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,8539)					
1	7/43 (16,3)	NE [22,49; NE]	6/26 (23,1)	NE [12,23; NE]	0,62 [0,21; 1,86] 0,3919
2	5/24 (20,8)	NE [13,64; NE]	2/5 (40,0)	NE [0,07; NE]	0,40 [0,08; 2,12] 0,2695
≥ 3	3/14 (21,4)	NE [10,88; NE]	3/9 (33,3)	NE [0,07; NE]	0,45 [0,09; 2,33] 0,3298
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9464)					
Viszerale Metastasen	9/47 (19,1)	NE [17,03; NE]	6/21 (28,6)	NE [8,71; NE]	0,52 [0,18; 1,48] 0,2163
Nicht-viszerale Metastasen	6/34 (17,6)	NE [22,49; NE]	5/19 (26,3)	NE [3,88; NE]	0,58 [0,17; 1,93] 0,3695
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,3774)					
0	5/27 (18,5)	NE [17,03; NE]	3/14 (21,4)	NE [3,88; NE]	0,93 [0,22; 3,90] 0,9154
1	10/54 (18,5)	NE [22,49; NE]	8/26 (30,8)	NE [8,71; NE]	0,43 [0,17; 1,10] 0,0703
Land (p-Wert des Interaktionsterms: 0,6704)					
China	13/71 (18,3)	NE [22,49; NE]	8/33 (24,2)	NE [12,23; NE]	0,64 [0,26; 1,54] 0,3125
Andere	2/10 (20,0)	NE [3,72; NE]	3/7 (42,9)	20,6 [1,08; NE]	0,43 [0,07; 2,63] 0,3511
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,3587)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	10/62 (16,1)	NE [NE; NE]	8/26 (30,8)	20,6 [8,71; NE]	0,44 [0,17; 1,12] 0,0750
Nein	5/19 (26,3)	NE [21,11; NE]	3/14 (21,4)	NE [2,07; NE]	1,10 [0,26; 4,70] 0,9009
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,8888)					
Positiv	9/63 (14,3)	NE [NE; NE]	6/30 (20,0)	NE [20,61; NE]	0,60 [0,21; 1,69] 0,3318
Negativ	6/18 (33,3)	NE [1,02; NE]	5/10 (50,0)	3,9 [0,07; NE]	0,57 [0,17; 1,87] 0,3240
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,4754)					
Primäre Resistenz	7/30 (23,3)	NE [21,11; NE]	7/17 (41,2)	8,7 [1,08; NE]	0,43 [0,15; 1,24] 0,1045
Sekundäre Resistenz	8/51 (15,7)	NE [NE; NE]	4/23 (17,4)	NE [12,23; NE]	0,75 [0,22; 2,51] 0,6384
Tumorgrad (p-Wert des Interaktionsterms: 0,7579)					
Hoch	5/11 (45,5)	22,5 [1,22; NE]	3/7 (42,9)	12,2 [0,07; NE]	0,48 [0,10; 2,19] 0,3315
Niedrig/mittel	5/31 (16,1)	NE [21,11; NE]	5/17 (29,4)	20,6 [3,88; NE]	0,36 [0,10; 1,26] 0,0954
Unbekannt	5/39 (12,8)	NE [NE; NE]	3/16 (18,8)	NE [NE; NE]	0,73 [0,17; 3,08] 0,6662
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9500)					
Ja	4/17 (23,5)	NE [17,03; NE]	3/10 (30,0)	NE [2,07; NE]	0,57 [0,12; 2,70] 0,4780
Nein	11/64 (17,2)	NE [NE; NE]	8/30 (26,7)	NE [12,23; NE]	0,56 [0,23; 1,40] 0,2089

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwpain6_popa1_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 111.2.2: Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9955)					
< 65 Jahre	5/16 (31,3)	NE [5,72; NE]	5/9 (55,6)	3,1 [0,07; NE]	0,21 [0,06; 0,82] 0,0141
≥ 65 Jahre	0/7 (0,0)	NE [NE; NE]	1/4 (25,0)	NE [11,54; NE]	0,00 [0,00; NE] 0,4795

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 112.1.2: Subgruppen für die Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ - Anstieg des Scores um ≥2 Punkte gegenüber der Baseline aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,4132)					
< 65 Jahre	21/62 (33,9)	NE [11,47; NE]	7/30 (23,3)	NE [3,75; NE]	1,43 [0,61; 3,37] 0,4137
≥ 65 Jahre	5/19 (26,3)	NE [1,87; NE]	3/10 (30,0)	NE [0,95; NE]	0,78 [0,18; 3,31] 0,7402
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,8996)					
1	8/43 (18,6)	NE [21,11; NE]	5/26 (19,2)	NE [10,26; NE]	0,92 [0,30; 2,83] 0,8876
2	13/24 (54,2)	11,5 [5,59; 14,63]	3/5 (60,0)	2,9 [0,99; NE]	0,79 [0,22; 2,81] 0,7190
≥ 3	5/14 (35,7)	NE [0,99; NE]	2/9 (22,2)	NE [0,07; NE]	1,63 [0,32; 8,42] 0,5538
Art der Erkrankung (p-Wert des Interaktionsterms: 0,2854)					
Viszerale Metastasen	21/47 (44,7)	11,5 [5,59; NE]	6/21 (28,6)	NE [2,60; NE]	1,46 [0,59; 3,63] 0,4123
Nicht-viszerale Metastasen	5/34 (14,7)	NE [21,11; NE]	4/19 (21,1)	NE [10,26; NE]	0,59 [0,16; 2,22] 0,4273
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,1716)					
0	11/27 (40,7)	11,5 [2,37; NE]	3/14 (21,4)	NE [2,60; NE]	2,37 [0,66; 8,56] 0,1746
1	15/54 (27,8)	NE [14,63; NE]	7/26 (26,9)	NE [3,75; NE]	0,82 [0,33; 2,01] 0,6593
Land (p-Wert des Interaktionsterms: 0,7654)					
China	19/71 (26,8)	NE [14,63; NE]	6/33 (18,2)	NE [NE; NE]	1,36 [0,54; 3,40] 0,5167
Andere	7/10 (70,0)	2,4 [0,95; NE]	4/7 (57,1)	10,3 [0,95; NE]	1,59 [0,46; 5,51] 0,4598
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,4675)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	23/62 (37,1)	14,6 [8,32; NE]	7/26 (26,9)	NE [2,89; NE]	1,27 [0,54; 2,97] 0,5823
Nein	3/19 (15,8)	NE [21,11; NE]	3/14 (21,4)	NE [10,26; NE]	0,58 [0,11; 3,00] 0,5126
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,2776)					
Positiv	21/63 (33,3)	NE [11,54; NE]	6/30 (20,0)	NE [10,26; NE]	1,58 [0,64; 3,93] 0,3159
Negativ	5/18 (27,8)	NE [1,94; NE]	4/10 (40,0)	2,9 [2,01; NE]	0,65 [0,17; 2,44] 0,4911
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9691)					
Primäre Resistenz	12/30 (40,0)	21,1 [5,59; NE]	5/17 (29,4)	NE [2,27; NE]	1,19 [0,41; 3,41] 0,7509
Sekundäre Resistenz	14/51 (27,5)	NE [13,64; NE]	5/23 (21,7)	NE [10,26; NE]	1,28 [0,46; 3,55] 0,6371
Tumorgrad (p-Wert des Interaktionsterms: 0,1751)					
Hoch	2/11 (18,2)	NE [2,37; NE]	2/7 (28,6)	2,9 [0,99; NE]	0,37 [0,05; 2,74] 0,3108
Niedrig/mittel	13/31 (41,9)	14,6 [8,32; NE]	6/17 (35,3)	10,3 [2,04; NE]	0,87 [0,33; 2,32] 0,7901
Unbekannt	11/39 (28,2)	NE [11,54; NE]	2/16 (12,5)	NE [NE; NE]	2,90 [0,64; 13,09] 0,1506
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,4311)					
Ja	4/17 (23,5)	NE [5,82; NE]	3/10 (30,0)	NE [0,95; NE]	0,79 [0,18; 3,56] 0,7498
Nein	22/64 (34,4)	21,1 [11,54; NE]	7/30 (23,3)	NE [10,26; NE]	1,41 [0,60; 3,31] 0,4244

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
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Tabelle 113.1.2: Subgruppen für die Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,8018)					
< 65 Jahre	19/62 (30,6)	22,8 [20,05; NE]	7/30 (23,3)	NE [10,16; NE]	1,09 [0,45; 2,60] 0,8544
≥ 65 Jahre	7/19 (36,8)	24,3 [8,52; NE]	2/10 (20,0)	NE [2,83; NE]	1,24 [0,25; 6,07] 0,7867
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,3834)					
1	10/43 (23,3)	26,9 [21,11; NE]	5/26 (19,2)	NE [15,52; NE]	0,98 [0,33; 2,87] 0,9705
2	9/24 (37,5)	15,7 [8,52; NE]	3/5 (60,0)	5,0 [2,83; NE]	0,40 [0,11; 1,54] 0,1695
≥ 3	7/14 (50,0)	20,1 [0,99; NE]	1/9 (11,1)	NE [10,16; NE]	2,75 [0,32; 23,59] 0,3404
Art der Erkrankung (p-Wert des Interaktionsterms: 0,4124)					
Viszerale Metastasen	15/47 (31,9)	22,8 [11,54; NE]	4/21 (19,0)	NE [10,16; NE]	1,31 [0,43; 3,96] 0,6311
Nicht-viszerale Metastasen	11/34 (32,4)	26,9 [20,45; 28,04]	5/19 (26,3)	NE [9,27; NE]	0,72 [0,23; 2,22] 0,5642
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9838)					
0	8/27 (29,6)	20,4 [8,32; NE]	4/14 (28,6)	NE [5,00; NE]	1,08 [0,32; 3,59] 0,9020
1	18/54 (33,3)	24,3 [20,05; 28,04]	5/26 (19,2)	NE [9,27; NE]	1,16 [0,43; 3,15] 0,7715
Land (p-Wert des Interaktionsterms: 0,7074)					
China	21/71 (29,6)	24,3 [20,05; 28,04]	7/33 (21,2)	NE [15,52; NE]	1,15 [0,49; 2,71] 0,7489
Andere	5/10 (50,0)	8,5 [0,95; NE]	2/7 (28,6)	10,2 [5,00; NE]	1,71 [0,33; 8,81] 0,5188
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,7267)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	19/62 (30,6)	22,8 [15,75; NE]	7/26 (26,9)	NE [9,27; NE]	0,93 [0,39; 2,22] 0,8741
Nein	7/19 (36,8)	24,3 [20,45; 28,04]	2/14 (14,3)	NE [15,52; NE]	0,94 [0,17; 5,24] 0,9473
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,6290)					
Primäre Resistenz	8/30 (26,7)	NE [20,05; NE]	4/17 (23,5)	NE [2,60; NE]	0,84 [0,25; 2,83] 0,7846
Sekundäre Resistenz	18/51 (35,3)	24,3 [15,75; NE]	5/23 (21,7)	NE [9,27; NE]	1,20 [0,44; 3,29] 0,7266
Tumorgrad (p-Wert des Interaktionsterms: 0,9950)					
Hoch	6/11 (54,5)	24,3 [2,37; NE]	1/7 (14,3)	NE [2,89; NE]	0,87 [0,10; 8,02] 0,9051
Niedrig/mittel	9/31 (29,0)	21,1 [15,75; NE]	3/17 (17,6)	NE [9,27; NE]	1,06 [0,28; 3,98] 0,9262
Unbekannt	11/39 (28,2)	26,9 [17,03; NE]	5/16 (31,3)	NE [2,83; NE]	1,07 [0,37; 3,10] 0,9012
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,4186)					
Ja	8/17 (47,1)	22,8 [3,85; NE]	2/10 (20,0)	NE [2,07; NE]	2,13 [0,44; 10,27] 0,3342
Nein	18/64 (28,1)	24,3 [20,05; NE]	7/30 (23,3)	NE [9,27; NE]	0,98 [0,41; 2,35] 0,9652

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwghs6_popa1_2.rtf
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Tabelle 113.2.2: Subgruppen für die Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,7761)					
< 65 Jahre	7/16 (43,8)	NE [4,80; NE]	4/9 (44,4)	8,6 [0,07; NE]	0,42 [0,12; 1,53] 0,1774
≥ 65 Jahre	1/7 (14,3)	NE [1,02; NE]	2/4 (50,0)	NE [1,02; NE]	0,50 [0,04; 5,54] 0,5439

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwghs6_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 114.1.2: Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,4765)					
< 65 Jahre	25/62 (40,3)	20,1 [10,52; NE]	12/30 (40,0)	19,9 [2,60; NE]	0,91 [0,45; 1,80] 0,7691
≥ 65 Jahre	6/19 (31,6)	24,3 [7,56; NE]	4/10 (40,0)	7,6 [0,07; NE]	0,48 [0,13; 1,71] 0,2504
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,7030)					
1	11/43 (25,6)	NE [24,23; NE]	8/26 (30,8)	19,9 [11,11; NE]	0,71 [0,29; 1,78] 0,4585
2	14/24 (58,3)	8,5 [5,59; NE]	3/5 (60,0)	5,0 [0,07; NE]	0,90 [0,25; 3,30] 0,8802
≥ 3	6/14 (42,9)	20,1 [3,88; NE]	5/9 (55,6)	7,6 [0,07; NE]	0,41 [0,11; 1,45] 0,1540
Art der Erkrankung (p-Wert des Interaktionsterms: 0,5122)					
Viszerale Metastasen	23/47 (48,9)	14,5 [7,56; NE]	10/21 (47,6)	16,0 [0,99; NE]	0,83 [0,39; 1,75] 0,6313
Nicht-viszerale Metastasen	8/34 (23,5)	NE [24,23; NE]	6/19 (31,6)	19,9 [7,56; NE]	0,46 [0,15; 1,44] 0,1678
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,1430)					
0	9/27 (33,3)	20,7 [6,64; NE]	3/14 (21,4)	NE [5,00; NE]	1,76 [0,47; 6,53] 0,4031
1	22/54 (40,7)	24,2 [10,52; NE]	13/26 (50,0)	11,1 [0,99; NE]	0,56 [0,28; 1,12] 0,1018
Land (p-Wert des Interaktionsterms: 0,1446)					
China	27/71 (38,0)	24,2 [14,50; NE]	10/33 (30,3)	NE [11,11; NE]	1,08 [0,52; 2,24] 0,8076
Andere	4/10 (40,0)	NE [1,87; NE]	6/7 (85,7)	7,6 [0,95; NE]	0,35 [0,10; 1,28] 0,0996
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,7545)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	25/62 (40,3)	20,1 [9,96; NE]	11/26 (42,3)	16,0 [2,60; NE]	0,78 [0,38; 1,59] 0,5036
Nein	6/19 (31,6)	24,3 [14,70; NE]	5/14 (35,7)	19,9 [1,08; NE]	0,53 [0,14; 2,00] 0,3289
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,4184)					
Positiv	23/63 (36,5)	24,2 [14,70; NE]	10/30 (33,3)	19,9 [7,63; NE]	0,93 [0,44; 1,95] 0,8511
Negativ	8/18 (44,4)	18,2 [1,94; NE]	6/10 (60,0)	2,6 [0,07; NE]	0,53 [0,18; 1,56] 0,2345
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,3970)					
Primäre Resistenz	13/30 (43,3)	18,2 [5,59; NE]	6/17 (35,3)	NE [0,99; NE]	1,07 [0,40; 2,83] 0,9088
Sekundäre Resistenz	18/51 (35,3)	24,3 [14,50; NE]	10/23 (43,5)	16,0 [7,56; NE]	0,62 [0,28; 1,36] 0,2306
Tumorgrad (p-Wert des Interaktionsterms: 0,0552)					
Hoch	5/11 (45,5)	24,3 [3,88; NE]	4/7 (57,1)	1,0 [0,07; NE]	0,29 [0,07; 1,24] 0,0845
Niedrig/mittel	11/31 (35,5)	NE [7,56; NE]	9/17 (52,9)	11,1 [5,00; 19,86]	0,52 [0,21; 1,26] 0,1259
Unbekannt	15/39 (38,5)	20,1 [14,50; NE]	3/16 (18,8)	NE [NE; NE]	2,39 [0,69; 8,30] 0,1515
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,0944)					
Ja	8/17 (47,1)	20,7 [2,76; NE]	1/10 (10,0)	NE [5,00; NE]	4,06 [0,50; 32,99] 0,1578
Nein	23/64 (35,9)	24,2 [14,70; NE]	15/30 (50,0)	11,1 [1,08; NE]	0,60 [0,31; 1,14] 0,1174

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
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Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwcogn6_popa1_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 114.2.2: Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,2896)					
< 65 Jahre	8/16 (50,0)	14,2 [7,46; NE]	3/9 (33,3)	NE [0,07; NE]	0,50 [0,12; 2,18] 0,3603
≥ 65 Jahre	2/7 (28,6)	NE [1,02; NE]	1/4 (25,0)	NE [2,14; NE]	2,30 [0,21; 25,65] 0,4855
Anzahl vorangegangener endokriner Behandlungen (p-Wert des Interaktionsterms: 0,8550)					
Erstlinie	3/9 (33,3)	14,2 [1,02; NE]	1/5 (20,0)	NE [2,14; NE]	0,69 [0,04; 11,04] 0,7919
Zweitlinie	7/14 (50,0)	11,3 [1,97; NE]	3/8 (37,5)	NE [0,07; NE]	0,96 [0,25; 3,74] 0,9784
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,6308)					
Ja	7/12 (58,3)	8,6 [1,94; NE]	3/7 (42,9)	NE [0,07; NE]	0,78 [0,20; 3,07] 0,7522
Nein	3/11 (27,3)	NE [1,02; NE]	1/6 (16,7)	NE [2,14; NE]	1,33 [0,13; 13,70] 0,8112

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwcogn6_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 115.1.2: Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,7670)					
< 65 Jahre	12/62 (19,4)	NE [20,71; NE]	7/30 (23,3)	NE [10,16; NE]	0,71 [0,28; 1,80] 0,4656
≥ 65 Jahre	6/19 (31,6)	24,3 [8,52; NE]	4/10 (40,0)	18,0 [0,99; NE]	0,48 [0,13; 1,73] 0,2538
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,9741)					
1	4/43 (9,3)	NE [NE; NE]	4/26 (15,4)	NE [17,95; NE]	0,49 [0,12; 1,97] 0,3055
2	8/24 (33,3)	20,7 [13,64; NE]	3/5 (60,0)	4,4 [2,89; NE]	0,52 [0,13; 2,11] 0,3464
≥ 3	6/14 (42,9)	20,1 [3,88; NE]	4/9 (44,4)	10,2 [0,07; NE]	0,52 [0,14; 1,96] 0,3210
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9420)					
Viszerale Metastasen	14/47 (29,8)	20,7 [13,64; NE]	8/21 (38,1)	18,0 [3,88; NE]	0,59 [0,25; 1,42] 0,2391
Nicht-viszerale Metastasen	4/34 (11,8)	NE [24,26; NE]	3/19 (15,8)	NE [NE; NE]	0,54 [0,11; 2,69] 0,4471
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,1648)					
0	6/27 (22,2)	NE [20,71; NE]	2/14 (14,3)	NE [5,00; NE]	1,65 [0,33; 8,21] 0,5350
1	12/54 (22,2)	NE [24,26; NE]	9/26 (34,6)	18,0 [3,88; NE]	0,42 [0,18; 1,02] 0,0478
Land (p-Wert des Interaktionsterms: 0,8354)					
China	14/71 (19,7)	NE [24,26; NE]	8/33 (24,2)	NE [8,71; NE]	0,66 [0,28; 1,58] 0,3523
Andere	4/10 (40,0)	NE [1,91; NE]	3/7 (42,9)	10,2 [5,00; NE]	0,81 [0,18; 3,68] 0,7879
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,6345)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	16/62 (25,8)	NE [16,70; NE]	10/26 (38,5)	18,0 [3,88; NE]	0,54 [0,24; 1,19] 0,1221
Nein	2/19 (10,5)	NE [24,26; NE]	1/14 (7,1)	NE [NE; NE]	0,72 [0,04; 11,73] 0,8198
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9656)					
Positiv	13/63 (20,6)	NE [24,26; NE]	8/30 (26,7)	NE [10,16; NE]	0,63 [0,26; 1,53] 0,3045
Negativ	5/18 (27,8)	16,7 [10,88; NE]	3/10 (30,0)	NE [0,95; NE]	0,62 [0,15; 2,65] 0,5197
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,8402)					
Primäre Resistenz	10/30 (33,3)	20,1 [10,88; NE]	6/17 (35,3)	NE [2,89; NE]	0,65 [0,23; 1,80] 0,4054
Sekundäre Resistenz	8/51 (15,7)	NE [24,26; NE]	5/23 (21,7)	NE [10,16; NE]	0,57 [0,19; 1,78] 0,3296
Tumorgrad (p-Wert des Interaktionsterms: 0,3660)					
Hoch	6/11 (54,5)	17,6 [1,91; NE]	3/7 (42,9)	3,9 [0,99; NE]	0,36 [0,08; 1,59] 0,1627
Niedrig/mittel	4/31 (12,9)	NE [NE; NE]	5/17 (29,4)	18,0 [8,71; NE]	0,32 [0,09; 1,21] 0,0786
Unbekannt	8/39 (20,5)	NE [20,05; NE]	3/16 (18,8)	NE [NE; NE]	1,15 [0,30; 4,35] 0,8325
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,4372)					
Ja	5/17 (29,4)	NE [8,52; NE]	2/10 (20,0)	NE [5,00; NE]	1,01 [0,19; 5,33] 0,9942
Nein	13/64 (20,3)	NE [24,26; NE]	9/30 (30,0)	NE [10,16; NE]	0,53 [0,23; 1,25] 0,1424

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwemo6_popa1_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 116.1.2: Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,7012)					
< 65 Jahre	15/62 (24,2)	NE [21,11; NE]	6/30 (20,0)	NE [9,01; NE]	0,98 [0,38; 2,54] 0,9700
≥ 65 Jahre	6/19 (31,6)	24,3 [8,52; NE]	3/10 (30,0)	NE [0,99; NE]	0,79 [0,20; 3,20] 0,7472
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,4709)					
1	9/43 (20,9)	NE [24,26; NE]	4/26 (15,4)	NE [NE; NE]	1,19 [0,36; 3,88] 0,7749
2	8/24 (33,3)	20,7 [9,86; NE]	1/5 (20,0)	NE [0,07; NE]	1,15 [0,13; 9,86] 0,9015
≥ 3	4/14 (28,6)	NE [7,79; NE]	4/9 (44,4)	8,7 [0,07; NE]	0,40 [0,10; 1,63] 0,1858
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9633)					
Viszerale Metastasen	15/47 (31,9)	23,6 [12,46; NE]	6/21 (28,6)	NE [5,00; NE]	0,86 [0,33; 2,22] 0,7467
Nicht-viszerale Metastasen	6/34 (17,6)	NE [24,26; NE]	3/19 (15,8)	NE [9,01; NE]	0,79 [0,19; 3,33] 0,7453
Land (p-Wert des Interaktionsterms: 0,6144)					
China	16/71 (22,5)	NE [23,61; NE]	7/33 (21,2)	NE [9,01; NE]	0,83 [0,34; 2,03] 0,6898
Andere	5/10 (50,0)	12,5 [0,99; NE]	2/7 (28,6)	NE [0,16; NE]	1,42 [0,27; 7,34] 0,6658
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,3257)					
Ja	17/62 (27,4)	NE [20,71; NE]	5/26 (19,2)	NE [8,71; NE]	1,16 [0,43; 3,14] 0,7765
Nein	4/19 (21,1)	NE [21,11; NE]	4/14 (28,6)	NE [3,72; NE]	0,45 [0,10; 2,05] 0,2905
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,3697)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Positiv	15/63 (23,8)	NE [21,11; NE]	5/30 (16,7)	NE [NE; NE]	1,17 [0,43; 3,24] 0,7583
Negativ	6/18 (33,3)	23,6 [7,79; NE]	4/10 (40,0)	9,0 [0,07; NE]	0,49 [0,13; 1,83] 0,2753
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9382)					
Primäre Resistenz	11/30 (36,7)	21,1 [9,86; NE]	5/17 (29,4)	NE [2,60; NE]	0,83 [0,28; 2,43] 0,7375
Sekundäre Resistenz	10/51 (19,6)	NE [24,26; NE]	4/23 (17,4)	NE [9,01; NE]	0,99 [0,31; 3,18] 0,9865
Tumorgrad (p-Wert des Interaktionsterms: 0,9444)					
Hoch	7/11 (63,6)	7,8 [1,91; NE]	2/7 (28,6)	NE [0,07; NE]	0,90 [0,18; 4,60] 0,9107
Niedrig/mittel	8/31 (25,8)	NE [13,64; NE]	3/17 (17,6)	NE [8,71; NE]	0,97 [0,25; 3,69] 0,9591
Unbekannt	6/39 (15,4)	NE [20,71; NE]	4/16 (25,0)	NE [5,00; NE]	0,67 [0,19; 2,39] 0,5371
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,8312)					
Ja	5/17 (29,4)	NE [8,52; NE]	2/10 (20,0)	NE [3,72; NE]	1,09 [0,20; 5,86] 0,9156
Nein	16/64 (25,0)	NE [21,11; NE]	7/30 (23,3)	NE [9,01; NE]	0,86 [0,36; 2,11] 0,7488

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwphys6_popa1_2.rtf
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Tabelle 117.1.2: Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,3344)					
< 65 Jahre	18/62 (29,0)	23,7 [16,90; NE]	6/30 (20,0)	NE [10,16; NE]	1,25 [0,50; 3,16] 0,6264
≥ 65 Jahre	5/19 (26,3)	24,3 [13,64; NE]	3/10 (30,0)	NE [0,07; NE]	0,62 [0,15; 2,64] 0,5303
Art der Erkrankung (p-Wert des Interaktionsterms: 0,0933)					
Viszerale Metastasen	14/47 (29,8)	20,7 [13,64; NE]	8/21 (38,1)	10,2 [2,27; NE]	0,58 [0,24; 1,38] 0,2214
Nicht-viszerale Metastasen	9/34 (26,5)	NE [16,90; NE]	1/19 (5,3)	NE [NE; NE]	3,57 [0,44; 29,11] 0,2050
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,6894)					
0	7/27 (25,9)	NE [9,86; NE]	3/14 (21,4)	NE [3,88; NE]	1,21 [0,31; 4,67] 0,7768
1	16/54 (29,6)	24,3 [19,82; NE]	6/26 (23,1)	NE [8,71; NE]	0,85 [0,33; 2,19] 0,7424
Land (p-Wert des Interaktionsterms: 0,8296)					
China	19/71 (26,8)	24,3 [20,05; NE]	7/33 (21,2)	NE [NE; NE]	1,03 [0,43; 2,45] 0,9297
Andere	4/10 (40,0)	11,5 [0,95; NE]	2/7 (28,6)	10,2 [3,88; NE]	1,16 [0,21; 6,33] 0,8675
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9878)					
Ja	15/62 (24,2)	NE [19,82; NE]	9/26 (34,6)	NE [3,88; NE]	0,56 [0,24; 1,28] 0,1681
Nein	8/19 (42,1)	24,3 [5,59; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0593
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,1423)					
Positiv	19/63 (30,2)	24,3 [19,82; NE]	5/30 (16,7)	NE [10,16; NE]	1,47 [0,55; 3,96] 0,4338

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Negativ	4/18 (22,2)	NE [9,86; NE]	4/10 (40,0)	3,9 [0,07; NE]	0,39 [0,10; 1,57] 0,1738
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,7505)					
Primäre Resistenz	10/30 (33,3)	20,1 [9,86; NE]	4/17 (23,5)	NE [2,89; NE]	1,00 [0,31; 3,23] 0,9988
Sekundäre Resistenz	13/51 (25,5)	NE [20,71; NE]	5/23 (21,7)	NE [10,16; NE]	0,89 [0,31; 2,52] 0,8343
Tumorgrad (p-Wert des Interaktionsterms: 0,2396)					
Hoch	5/11 (45,5)	24,3 [1,22; NE]	2/7 (28,6)	NE [0,07; NE]	0,63 [0,11; 3,61] 0,5989
Niedrig/mittel	7/31 (22,6)	NE [13,64; NE]	5/17 (29,4)	NE [3,88; NE]	0,54 [0,17; 1,71] 0,2851
Unbekannt	11/39 (28,2)	23,7 [16,90; NE]	2/16 (12,5)	NE [NE; NE]	2,51 [0,55; 11,39] 0,2105
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,5397)					
Ja	5/17 (29,4)	NE [14,50; NE]	3/10 (30,0)	NE [2,27; NE]	0,76 [0,18; 3,27] 0,7102
Nein	18/64 (28,1)	24,3 [16,90; NE]	6/30 (20,0)	NE [NE; NE]	1,17 [0,46; 2,95] 0,7201

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; RCT: Randomisierte kontrollierte Studie.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttwrole6_popa1_2.rtf
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Tabelle 117.2.2: Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,0869)					
< 65 Jahre	7/16 (43,8)	NE [3,88; NE]	4/9 (44,4)	8,6 [0,07; NE]	0,38 [0,10; 1,45] 0,1485
≥ 65 Jahre	3/7 (42,9)	3,3 [0,07; NE]	1/4 (25,0)	NE [2,14; NE]	3,60 [0,37; 34,81] 0,2379
Anzahl vorangegangener endokriner Behandlungen (p-Wert des Interaktionsterms: 0,3833)					
Erstlinie	4/9 (44,4)	11,1 [1,02; NE]	1/5 (20,0)	NE [2,14; NE]	1,71 [0,17; 17,16] 0,6463
Zweitlinie	6/14 (42,9)	9,4 [1,97; NE]	4/8 (50,0)	8,6 [0,07; NE]	0,63 [0,18; 2,24] 0,4827
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,5151)					
Ja	7/12 (58,3)	8,6 [0,99; NE]	4/7 (57,1)	1,9 [0,07; NE]	0,62 [0,18; 2,17] 0,4786
Nein	3/11 (27,3)	NE [1,02; NE]	1/6 (16,7)	NE [2,14; NE]	1,33 [0,13; 13,73] 0,8122

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
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Tabelle 118.1.2: Subgruppen für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	n/N (%)	Mediane Ereigniszeit[1]	n/N (%)	Mediane Ereigniszeit[1]	HR [95% KI] p-Wert[2]
Alter (p-Wert des Interaktionsterms: 0,8385)					
< 65 Jahre	17/62 (27,4)	NE [20,05; NE]	12/30 (40,0)	20,1 [9,01; NE]	0,56 [0,27; 1,18] 0,1258
≥ 65 Jahre	5/19 (26,3)	24,3 [13,64; NE]	4/10 (40,0)	NE [0,99; NE]	0,48 [0,13; 1,83] 0,2855
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,3749)					
1	8/43 (18,6)	NE [24,26; NE]	6/26 (23,1)	NE [20,12; NE]	0,67 [0,23; 1,92] 0,4517
2	8/24 (33,3)	NE [5,82; NE]	5/5 (100,0)	2,8 [0,07; NE]	0,26 [0,08; 0,80] 0,0120
≥ 3	6/14 (42,9)	20,1 [5,59; NE]	5/9 (55,6)	7,6 [0,07; NE]	0,33 [0,09; 1,25] 0,0884
Art der Erkrankung (p-Wert des Interaktionsterms: 0,7497)					
Viszerale Metastasen	16/47 (34,0)	NE [13,64; NE]	10/21 (47,6)	10,2 [0,99; NE]	0,52 [0,23; 1,15] 0,1048
Nicht-viszerale Metastasen	6/34 (17,6)	NE [22,62; NE]	6/19 (31,6)	20,1 [9,01; NE]	0,31 [0,09; 1,04] 0,0464
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9953)					
0	5/27 (18,5)	NE [NE; NE]	5/14 (35,7)	20,1 [2,83; NE]	0,53 [0,15; 1,85] 0,3161
1	17/54 (31,5)	24,3 [20,05; NE]	11/26 (42,3)	16,9 [1,05; NE]	0,52 [0,24; 1,12] 0,0894
Land (p-Wert des Interaktionsterms: 0,5315)					
China	18/71 (25,4)	NE [22,62; NE]	13/33 (39,4)	20,1 [5,00; NE]	0,51 [0,25; 1,04] 0,0609
Andere	4/10 (40,0)	NE [0,95; NE]	3/7 (42,9)	10,2 [0,95; NE]	0,86 [0,19; 3,85] 0,8421
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,8851)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	18/62 (29,0)	NE [20,05; NE]	12/26 (46,2)	16,9 [1,05; NE]	0,48 [0,23; 1,01] 0,0495
Nein	4/19 (21,1)	NE [16,90; NE]	4/14 (28,6)	20,1 [9,01; NE]	0,39 [0,09; 1,79] 0,2121
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,2439)					
Positiv	17/63 (27,0)	NE [22,62; NE]	10/30 (33,3)	NE [10,16; NE]	0,68 [0,31; 1,50] 0,3427
Negativ	5/18 (27,8)	NE [7,79; NE]	6/10 (60,0)	5,0 [0,07; NE]	0,27 [0,08; 0,88] 0,0202
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,3529)					
Primäre Resistenz	7/30 (23,3)	NE [20,05; NE]	7/17 (41,2)	20,1 [0,95; NE]	0,39 [0,13; 1,14] 0,0786
Sekundäre Resistenz	15/51 (29,4)	NE [16,90; NE]	9/23 (39,1)	16,9 [5,00; NE]	0,67 [0,29; 1,55] 0,3516
Tumorgrad (p-Wert des Interaktionsterms: 0,2679)					
Hoch	5/11 (45,5)	24,3 [6,71; NE]	5/7 (71,4)	1,0 [0,07; NE]	0,22 [0,06; 0,86] 0,0254
Niedrig/mittel	8/31 (25,8)	NE [22,62; NE]	6/17 (35,3)	16,9 [5,00; NE]	0,51 [0,18; 1,50] 0,2168
Unbekannt	9/39 (23,1)	NE [16,90; NE]	5/16 (31,3)	NE [5,00; NE]	0,81 [0,27; 2,41] 0,7024
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,4158)					
Ja	6/17 (35,3)	NE [3,75; NE]	3/10 (30,0)	16,9 [0,07; NE]	0,95 [0,23; 3,91] 0,9471
Nein	16/64 (25,0)	NE [20,05; NE]	13/30 (43,3)	20,1 [2,83; NE]	0,47 [0,23; 0,98] 0,0397

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
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Tabelle 119.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,3461)					
< 65 Jahre	62/62 (100,0)	0,1 [0,07; 0,20]	26/30 (86,7)	0,9 [0,39; 2,07]	4,00 [2,32; 6,91] <,0001
≥ 65 Jahre	19/19 (100,0)	0,1 [0,03; 0,26]	8/10 (80,0)	1,6 [0,10; NE]	6,00 [1,91; 18,82] 0,0006
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,2499)					
1	43/43 (100,0)	0,1 [0,07; 0,20]	21/26 (80,8)	1,0 [0,43; 3,65]	5,21 [2,76; 9,82] <,0001
2	24/24 (100,0)	0,1 [0,07; 0,36]	4/5 (80,0)	0,4 [0,03; NE]	2,93 [0,85; 10,09] 0,0642
≥ 3	14/14 (100,0)	0,2 [0,07; 0,43]	9/9 (100,0)	1,3 [0,07; 3,85]	4,11 [1,31; 12,91] 0,0090
Art der Erkrankung (p-Wert des Interaktionsterms: 0,8193)					
Viszerale Metastasen	47/47 (100,0)	0,1 [0,07; 0,20]	17/21 (81,0)	1,3 [0,23; 3,65]	4,79 [2,34; 9,80] <,0001
Nicht-viszerale Metastasen	34/34 (100,0)	0,2 [0,07; 0,30]	17/19 (89,5)	0,9 [0,39; 2,86]	4,43 [2,16; 9,06] <,0001
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,3017)					
0	27/27 (100,0)	0,2 [0,07; 0,36]	10/14 (71,4)	1,5 [0,26; 14,07]	5,56 [2,22; 13,94] <,0001
1	54/54 (100,0)	0,1 [0,07; 0,16]	24/26 (92,3)	0,9 [0,39; 2,07]	3,89 [2,17; 6,98] <,0001
Land (p-Wert des Interaktionsterms: 0,0630)					
China	71/71 (100,0)	0,2 [0,10; 0,20]	27/33 (81,8)	1,3 [0,46; 3,65]	5,96 [3,34; 10,62] <,0001
Andere	10/10 (100,0)	0,1 [0,03; 0,16]	7/7 (100,0)	0,1 [0,03; 1,41]	1,66 [0,60; 4,63] 0,3206
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,3796)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	62/62 (100,0)	0,2 [0,10; 0,26]	22/26 (84,6)	0,5 [0,26; 2,86]	4,04 [2,21; 7,41] <,0001
Nein	19/19 (100,0)	0,1 [0,03; 0,20]	12/14 (85,7)	1,3 [0,39; 4,01]	5,52 [2,27; 13,39] <,0001
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,5015)					
Positiv	63/63 (100,0)	0,1 [0,07; 0,16]	26/30 (86,7)	1,0 [0,39; 2,86]	4,81 [2,74; 8,45] <,0001
Negativ	18/18 (100,0)	0,2 [0,07; 0,43]	8/10 (80,0)	1,1 [0,03; 13,05]	3,81 [1,36; 10,65] 0,0059
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,0532)					
Primäre Resistenz	30/30 (100,0)	0,2 [0,07; 0,39]	15/17 (88,2)	0,4 [0,20; 2,07]	2,54 [1,27; 5,09] 0,0055
Sekundäre Resistenz	51/51 (100,0)	0,1 [0,07; 0,20]	19/23 (82,6)	1,5 [0,46; 3,85]	7,74 [3,62; 16,55] <,0001
Tumorgrad (p-Wert des Interaktionsterms: 0,5053)					
Hoch	11/11 (100,0)	0,1 [0,07; 0,26]	7/7 (100,0)	0,4 [0,03; 1,28]	4,98 [1,11; 22,22] 0,0208
Niedrig/mittel	31/31 (100,0)	0,1 [0,07; 0,16]	15/17 (88,2)	0,5 [0,13; 2,10]	3,50 [1,73; 7,08] 0,0003
Unbekannt	39/39 (100,0)	0,2 [0,10; 0,36]	12/16 (75,0)	2,9 [0,46; 14,07]	6,45 [2,79; 14,93] <,0001
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,8098)					
Ja	17/17 (100,0)	0,1 [0,07; 0,36]	8/10 (80,0)	0,4 [0,03; 2,86]	3,25 [1,25; 8,47] 0,0096
Nein	64/64 (100,0)	0,2 [0,10; 0,20]	26/30 (86,7)	1,2 [0,46; 3,65]	4,83 [2,75; 8,47] <,0001
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,4452)					
Ja	72/72 (100,0)	0,2 [0,10; 0,20]	33/39 (84,6)	0,9 [0,39; 2,07]	4,55 [2,72; 7,64] <,0001
Nein	9/9 (100,0)	0,1 [0,03; 0,30]	1/1 (100,0)	13,1 [NE; NE]	>100 [0,00; NE] 0,0911

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Datenschnitt: 18.05.2020, Safety-Population 1: In Monaten; 2: Aus Log-rank-Test Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie.					

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttteae_popa1_2.rtf
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/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 119.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,3701)					
< 65 Jahre	16/16 (100,0)	0,2 [0,07; 0,46]	7/9 (77,8)	0,7 [0,39; NE]	2,67 [1,08; 6,58] 0,0255
≥ 65 Jahre	7/7 (100,0)	0,2 [0,10; 0,85]	2/4 (50,0)	NE [0,85; NE]	10,29 [1,20; 88,49] 0,0112
Anzahl vorangegangener endokriner Behandlungen (p-Wert des Interaktionsterms: 0,9331)					
Erstlinie	9/9 (100,0)	0,2 [0,07; 0,85]	3/5 (60,0)	0,9 [0,46; NE]	3,33 [0,85; 13,07] 0,0639
Zweitlinie	14/14 (100,0)	0,3 [0,07; 0,53]	6/8 (75,0)	0,8 [0,39; NE]	3,75 [1,32; 10,67] 0,0083
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,5888)					
0	8/8 (100,0)	0,1 [0,03; 0,30]	5/7 (71,4)	0,8 [0,43; NE]	4,08 [1,26; 13,20] 0,0132
1	15/15 (100,0)	0,4 [0,10; 0,53]	4/6 (66,7)	1,5 [0,39; NE]	3,26 [1,05; 10,13] 0,0285
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,8439)					
Ja	12/12 (100,0)	0,1 [0,03; 0,53]	6/7 (85,7)	0,8 [0,39; 2,20]	3,88 [1,31; 11,48] 0,0094
Nein	11/11 (100,0)	0,2 [0,13; 0,85]	3/6 (50,0)	NE [0,46; NE]	3,95 [1,08; 14,41] 0,0209
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9734)					
Ja	11/11 (100,0)	0,1 [0,03; 0,46]	5/6 (83,3)	0,8 [0,39; NE]	3,80 [1,17; 12,39] 0,0185
Nein	12/12 (100,0)	0,2 [0,13; 0,85]	4/7 (57,1)	0,9 [0,46; NE]	3,41 [1,08; 10,70] 0,0243

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
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/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 120.1.2: Subgruppen - Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,7190)					
< 65 Jahre	14/62 (22,6)	26,7 [20,38; NE]	2/30 (6,7)	NE [NE; NE]	2,89 [0,66; 12,73] 0,1418
≥ 65 Jahre	4/19 (21,1)	NE [16,24; NE]	1/10 (10,0)	NE [0,16; NE]	1,92 [0,21; 17,20] 0,5538
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,3176)					
1	9/43 (20,9)	NE [26,73; NE]	1/26 (3,8)	NE [NE; NE]	5,11 [0,65; 40,35] 0,0847
2	8/24 (33,3)	20,4 [10,22; NE]	1/5 (20,0)	NE [2,63; NE]	1,37 [0,17; 11,27] 0,7659
≥ 3	1/14 (7,1)	NE [15,78; NE]	1/9 (11,1)	NE [1,45; NE]	0,00 [0,00; NE] 0,2123
Art der Erkrankung (p-Wert des Interaktionsterms: 0,8842)					
Viszerale Metastasen	11/47 (23,4)	NE [15,78; NE]	2/21 (9,5)	NE [NE; NE]	2,12 [0,47; 9,59] 0,3194
Nicht-viszerale Metastasen	7/34 (20,6)	NE [26,73; NE]	1/19 (5,3)	NE [NE; NE]	2,83 [0,34; 23,59] 0,3137
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,7958)					
0	6/27 (22,2)	26,7 [20,38; NE]	1/14 (7,1)	NE [NE; NE]	3,37 [0,40; 28,35] 0,2351
1	12/54 (22,2)	NE [18,18; NE]	2/26 (7,7)	NE [NE; NE]	2,26 [0,50; 10,14] 0,2742
Land (p-Wert des Interaktionsterms: 0,7336)					
China	15/71 (21,1)	NE [26,73; NE]	2/33 (6,1)	NE [NE; NE]	3,08 [0,70; 13,52] 0,1155
Andere	3/10 (30,0)	NE [1,81; NE]	1/7 (14,3)	NE [0,16; NE]	1,61 [0,16; 15,95] 0,6795
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,6581)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	14/62 (22,6)	26,7 [18,18; NE]	2/26 (7,7)	NE [NE; NE]	3,50 [0,75; 16,26] 0,0929
Nein	4/19 (21,1)	NE [16,24; NE]	1/14 (7,1)	NE [NE; NE]	1,97 [0,21; 18,15] 0,5420
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,7711)					
Positiv	14/63 (22,2)	NE [26,73; NE]	2/30 (6,7)	NE [NE; NE]	2,96 [0,67; 13,08] 0,1320
Negativ	4/18 (22,2)	20,4 [10,22; NE]	1/10 (10,0)	NE [1,45; NE]	2,23 [0,24; 20,60] 0,4690
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,8124)					
Primäre Resistenz	7/30 (23,3)	20,4 [15,78; NE]	1/17 (5,9)	NE [NE; NE]	2,89 [0,35; 23,85] 0,3027
Sekundäre Resistenz	11/51 (21,6)	26,7 [26,73; NE]	2/23 (8,7)	NE [NE; NE]	2,30 [0,51; 10,40] 0,2644
Tumorgrad (p-Wert des Interaktionsterms: 0,2630)					
Hoch	2/11 (18,2)	NE [16,24; NE]	2/7 (28,6)	NE [1,45; NE]	0,51 [0,07; 3,71] 0,5016
Niedrig/mittel	6/31 (19,4)	NE [26,73; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1561
Unbekannt	10/39 (25,6)	NE [15,78; NE]	1/16 (6,3)	NE [NE; NE]	3,99 [0,51; 31,19] 0,1536
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,6458)					
Ja	4/17 (23,5)	26,7 [18,18; NE]	1/10 (10,0)	NE [0,16; NE]	1,67 [0,18; 15,29] 0,6442
Nein	14/64 (21,9)	NE [20,38; NE]	2/30 (6,7)	NE [NE; NE]	2,98 [0,68; 13,14] 0,1297
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9923)					
Ja	17/72 (23,6)	NE [20,38; NE]	3/39 (7,7)	NE [NE; NE]	2,51 [0,73; 8,59] 0,1294
Nein	1/9 (11,1)	NE [2,40; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,7389

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Datenschnitt: 18.05.2020, Safety-Population 1: In Monaten; 2: Aus Log-rank-Test Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie.					

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Tabelle 121.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9115)					
< 65 Jahre	38/62 (61,3)	8,4 [2,99; 14,73]	6/30 (20,0)	NE [NE; NE]	3,83 [1,62; 9,07] 0,0010
≥ 65 Jahre	14/19 (73,7)	11,0 [0,99; 18,08]	2/10 (20,0)	NE [4,73; NE]	3,92 [0,88; 17,37] 0,0533
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,3942)					
1	26/43 (60,5)	12,1 [5,59; 14,73]	3/26 (11,5)	NE [NE; NE]	6,40 [1,94; 21,16] 0,0005
2	16/24 (66,7)	6,4 [0,92; 16,27]	2/5 (40,0)	NE [2,60; NE]	1,93 [0,44; 8,44] 0,3775
≥ 3	10/14 (71,4)	1,6 [0,89; NE]	3/9 (33,3)	4,7 [1,38; NE]	2,65 [0,71; 9,82] 0,1320
Art der Erkrankung (p-Wert des Interaktionsterms: 0,0808)					
Viszerale Metastasen	29/47 (61,7)	6,4 [1,41; 15,78]	7/21 (33,3)	NE [4,50; NE]	2,27 [0,99; 5,19] 0,0470
Nicht-viszerale Metastasen	23/34 (67,6)	11,0 [4,54; 16,27]	1/19 (5,3)	NE [NE; NE]	15,50 [2,09; 114,93] 0,0003
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,5563)					
0	15/27 (55,6)	8,4 [2,40; 14,73]	2/14 (14,3)	NE [NE; NE]	5,47 [1,23; 24,24] 0,0126
1	37/54 (68,5)	9,3 [1,71; 13,58]	6/26 (23,1)	NE [7,36; NE]	3,40 [1,43; 8,07] 0,0032
Land (p-Wert des Interaktionsterms: 0,7389)					
China	46/71 (64,8)	9,3 [2,99; 13,58]	7/33 (21,2)	NE [NE; NE]	3,83 [1,73; 8,49] 0,0004
Andere	6/10 (60,0)	5,3 [0,03; NE]	1/7 (14,3)	10,7 [NE; NE]	>100 [0,00; NE] 0,0250
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,2915)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	39/62 (62,9)	8,4 [1,74; 14,73]	7/26 (26,9)	NE [4,73; NE]	3,14 [1,40; 7,05] 0,0034
Nein	13/19 (68,4)	9,3 [2,10; 24,36]	1/14 (7,1)	NE [7,36; NE]	9,37 [1,22; 71,82] 0,0086
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,1022)					
Positiv	42/63 (66,7)	8,4 [3,65; 12,23]	4/30 (13,3)	NE [10,72; NE]	6,20 [2,22; 17,31] <,0001
Negativ	10/18 (55,6)	16,3 [0,89; NE]	4/10 (40,0)	NE [1,38; NE]	1,77 [0,55; 5,65] 0,3373
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,4100)					
Primäre Resistenz	18/30 (60,0)	12,2 [2,66; 18,18]	4/17 (23,5)	NE [4,50; NE]	2,97 [1,00; 8,85] 0,0404
Sekundäre Resistenz	34/51 (66,7)	6,6 [1,74; 13,05]	4/23 (17,4)	NE [10,72; NE]	5,12 [1,81; 14,43] 0,0006
Tumorgrad (p-Wert des Interaktionsterms: 0,7857)					
Hoch	9/11 (81,8)	3,0 [0,82; 9,34]	3/7 (42,9)	NE [1,38; NE]	2,64 [0,70; 9,93] 0,1380
Niedrig/mittel	20/31 (64,5)	10,2 [2,66; 14,73]	2/17 (11,8)	NE [10,72; NE]	5,77 [1,34; 24,75] 0,0077
Unbekannt	23/39 (59,0)	13,1 [1,45; 18,18]	3/16 (18,8)	NE [7,36; NE]	4,10 [1,23; 13,67] 0,0128
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,4258)					
Ja	12/17 (70,6)	9,3 [0,89; 14,73]	1/10 (10,0)	NE [4,50; NE]	7,50 [0,97; 58,13] 0,0237
Nein	40/64 (62,5)	6,6 [2,99; 13,58]	7/30 (23,3)	NE [10,72; NE]	3,35 [1,50; 7,49] 0,0018
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9870)					
Ja	49/72 (68,1)	6,6 [2,66; 12,23]	8/39 (20,5)	NE [10,72; NE]	3,97 [1,88; 8,40] <,0001
Nein	3/9 (33,3)	13,1 [0,82; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2830

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Datenschnitt: 18.05.2020, Safety-Population 1: In Monaten; 2: Aus Log-rank-Test Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie.					

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttgr3_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 121.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9924)					
< 65 Jahre	9/16 (56,3)	12,9 [1,94; NE]	1/9 (11,1)	NE [2,73; NE]	3,85 [0,47; 31,35] 0,1748
≥ 65 Jahre	7/7 (100,0)	1,4 [0,39; 3,58]	0/4 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0094
Anzahl vorangegangener endokriner Behandlungen (p-Wert des Interaktionsterms: 0,9935)					
Erstlinie	5/9 (55,6)	22,3 [0,95; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1681
Zweitlinie	11/14 (78,6)	4,1 [0,89; 12,89]	1/8 (12,5)	NE [2,73; NE]	9,49 [1,21; 74,42] 0,0093
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9936)					
0	7/8 (87,5)	4,2 [0,89; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0178
1	9/15 (60,0)	12,9 [0,95; NE]	1/6 (16,7)	NE [2,73; NE]	3,90 [0,49; 30,89] 0,1651
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9945)					
Ja	10/11 (90,9)	2,7 [0,89; 12,89]	1/6 (16,7)	NE [2,73; NE]	6,77 [0,86; 53,02] 0,0351
Nein	6/12 (50,0)	22,3 [0,95; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0830

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 122.1.2: Subgruppen - Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9953)					
Ja	9/62 (14,5)	26,8 [26,83; NE]	1/26 (3,8)	NE [NE; NE]	3,92 [0,48; 32,25] 0,1754
Nein	1/19 (5,3)	NE [NE; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,6310
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9937)					
Positiv	9/63 (14,3)	NE [26,83; NE]	1/30 (3,3)	NE [NE; NE]	3,31 [0,42; 26,20] 0,2292
Negativ	1/18 (5,6)	NE [10,32; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,5637

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttdiscf_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 123.1.2: Subgruppen - Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,9998)					
Positiv	9/63 (14,3)	NE [26,83; NE]	1/30 (3,3)	NE [NE; NE]	3,30 [0,42; 26,09] 0,2310
Negativ	0/18 (0,0)	NE [NE; NE]	0/10 (0,0)	NE [NE; NE]	NE

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttdisca_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 124.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9823)					
< 65 Jahre	53/62 (85,5)	0,9 [0,85; 0,89]	6/30 (20,0)	NE [NE; NE]	9,50 [4,02; 22,48] <,0001
≥ 65 Jahre	15/19 (78,9)	0,9 [0,49; 0,92]	2/10 (20,0)	NE [4,27; NE]	7,71 [1,74; 34,24] 0,0018
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,9815)					
1	34/43 (79,1)	0,9 [0,82; 1,45]	6/26 (23,1)	NE [5,85; NE]	6,65 [2,76; 16,05] <,0001
2	22/24 (91,7)	0,9 [0,46; 0,92]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0014
≥ 3	12/14 (85,7)	0,9 [0,49; 0,92]	2/9 (22,2)	NE [4,27; NE]	8,38 [1,83; 38,28] 0,0014
Art der Erkrankung (p-Wert des Interaktionsterms: 0,1458)					
Viszerale Metastasen	39/47 (83,0)	0,9 [0,85; 0,89]	6/21 (28,6)	NE [4,27; NE]	5,70 [2,39; 13,57] <,0001
Nicht-viszerale Metastasen	29/34 (85,3)	0,9 [0,79; 0,92]	2/19 (10,5)	NE [NE; NE]	18,12 [4,22; 77,85] <,0001
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,3121)					
0	21/27 (77,8)	0,9 [0,82; 0,89]	4/14 (28,6)	NE [3,65; NE]	4,87 [1,65; 14,40] 0,0021
1	47/54 (87,0)	0,9 [0,82; 0,92]	4/26 (15,4)	NE [5,85; NE]	12,94 [4,61; 36,31] <,0001
Land (p-Wert des Interaktionsterms: 0,3332)					
China	64/71 (90,1)	0,9 [0,82; 0,89]	7/33 (21,2)	NE [NE; NE]	10,46 [4,72; 23,14] <,0001
Andere	4/10 (40,0)	8,3 [0,49; NE]	1/7 (14,3)	NE [5,85; NE]	3,27 [0,36; 29,35] 0,2622
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,1853)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	52/62 (83,9)	0,9 [0,85; 0,89]	7/26 (26,9)	NE [4,31; NE]	6,33 [2,85; 14,07] <,0001
Nein	16/19 (84,2)	0,9 [0,39; 1,78]	1/14 (7,1)	NE [NE; NE]	25,76 [3,36; 197,34] <,0001
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,4100)					
Positiv	51/63 (81,0)	0,9 [0,82; 0,89]	5/30 (16,7)	NE [NE; NE]	10,28 [4,06; 26,00] <,0001
Negativ	17/18 (94,4)	0,9 [0,82; 1,02]	3/10 (30,0)	NE [0,39; NE]	7,03 [1,99; 24,86] 0,0007
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9007)					
Primäre Resistenz	24/30 (80,0)	0,9 [0,82; 1,45]	3/17 (17,6)	NE [3,65; NE]	8,65 [2,58; 28,98] <,0001
Sekundäre Resistenz	44/51 (86,3)	0,9 [0,82; 0,89]	5/23 (21,7)	NE [5,85; NE]	9,31 [3,61; 24,00] <,0001
Tumorgrad (p-Wert des Interaktionsterms: 0,9696)					
Hoch	8/11 (72,7)	0,9 [0,49; NE]	1/7 (14,3)	NE [0,39; NE]	6,75 [0,84; 54,40] 0,0384
Niedrig/mittel	24/31 (77,4)	0,9 [0,82; 1,45]	3/17 (17,6)	NE [5,85; NE]	8,31 [2,47; 27,93] <,0001
Unbekannt	36/39 (92,3)	0,9 [0,79; 0,89]	4/16 (25,0)	NE [3,65; NE]	10,67 [3,70; 30,79] <,0001
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,2981)					
Ja	16/17 (94,1)	0,9 [0,43; 0,92]	1/10 (10,0)	NE [3,02; NE]	21,75 [2,84; 166,88] <,0001
Nein	52/64 (81,3)	0,9 [0,82; 0,89]	7/30 (23,3)	NE [4,31; NE]	7,10 [3,19; 15,80] <,0001
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9874)					
Ja	63/72 (87,5)	0,9 [0,85; 0,89]	8/39 (20,5)	NE [NE; NE]	9,53 [4,52; 20,10] <,0001
Nein	5/9 (55,6)	0,9 [0,43; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3838

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Datenschnitt: 18.05.2020, Safety-Population 1: In Monaten; 2: Aus Log-rank-Test Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie. Neutropenie: PT Neutropenia, Febrile neutropenia, Neutrophil count decreased.					

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttnpaesi_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 124.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	n/N (%)	Mediane Ereigniszeit[1]	n/N (%)	Mediane Ereigniszeit[1]	HR [95% KI] p-Wert[2]
Alter (p-Wert des Interaktionsterms: 0,9934)					
< 65 Jahre	12/16 (75,0)	1,0 [0,46; 3,68]	2/9 (22,2)	NE [0,79; NE]	5,14 [1,14; 23,15] 0,0180
≥ 65 Jahre	7/7 (100,0)	1,0 [0,82; 1,78]	0/4 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0080
Anzahl vorangegangener endokriner Behandlungen (p-Wert des Interaktionsterms: 0,9939)					
Erstlinie	6/9 (66,7)	1,0 [0,82; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0268
Zweitlinie	13/14 (92,9)	0,9 [0,43; 1,78]	2/8 (25,0)	NE [0,79; NE]	7,69 [1,66; 35,66] 0,0028
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,5860)					
0	8/8 (100,0)	0,9 [0,39; 0,99]	1/7 (14,3)	NE [0,79; NE]	14,77 [1,75; 124,87] 0,0021
1	11/15 (73,3)	1,4 [0,82; 17,42]	1/6 (16,7)	NE [5,36; NE]	6,84 [0,88; 53,29] 0,0337
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9929)					
Ja	11/12 (91,7)	0,9 [0,39; 3,68]	2/7 (28,6)	NE [0,79; NE]	6,16 [1,31; 28,91] 0,0100
Nein	8/11 (72,7)	1,0 [0,82; NE]	0/6 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0084
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,5618)					
Ja	11/11 (100,0)	0,9 [0,39; 1,78]	1/6 (16,7)	NE [5,36; NE]	13,92 [1,74; 111,56] 0,0017
Nein	8/12 (66,7)	1,2 [0,85; NE]	1/7 (14,3)	NE [0,79; NE]	5,90 [0,73; 47,59] 0,0598

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie.
Neutropenie: PT Neutropenia, Febrile neutropenia, Neutrophil count decreased.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttnpaesi_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 125.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,1499)					
< 65 Jahre	25/62 (40,3)	20,0 [10,16; NE]	1/30 (3,3)	NE [NE; NE]	13,13 [1,78; 96,98] 0,0010
≥ 65 Jahre	3/19 (15,8)	NE [18,31; NE]	1/10 (10,0)	NE [4,73; NE]	1,53 [0,16; 14,73] 0,7112
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,9157)					
1	13/43 (30,2)	NE [14,73; NE]	1/26 (3,8)	NE [NE; NE]	7,77 [1,02; 59,45] 0,0194
2	8/24 (33,3)	NE [1,45; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1855
≥ 3	7/14 (50,0)	10,1 [0,89; NE]	1/9 (11,1)	NE [4,73; NE]	4,65 [0,56; 38,34] 0,1173
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9915)					
Viszerale Metastasen	16/47 (34,0)	NE [10,13; NE]	2/21 (9,5)	NE [NE; NE]	3,77 [0,86; 16,46] 0,0585
Nicht-viszerale Metastasen	12/34 (35,3)	NE [11,18; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0122
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,8367)					
0	10/27 (37,0)	10,3 [9,90; NE]	1/14 (7,1)	NE [NE; NE]	6,79 [0,86; 53,34] 0,0351
1	18/54 (33,3)	NE [18,31; NE]	1/26 (3,8)	NE [NE; NE]	9,01 [1,20; 67,56] 0,0095
Land (p-Wert des Interaktionsterms: 0,9898)					
China	26/71 (36,6)	NE [14,73; NE]	2/33 (6,1)	NE [NE; NE]	6,30 [1,49; 26,58] 0,0041
Andere	2/10 (20,0)	NE [0,95; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3127
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9895)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	21/62 (33,9)	NE [10,16; NE]	2/26 (7,7)	NE [NE; NE]	4,82 [1,13; 20,58] 0,0189
Nein	7/19 (36,8)	NE [10,26; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0688
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,4827)					
Positiv	22/63 (34,9)	NE [14,73; NE]	1/30 (3,3)	NE [NE; NE]	10,53 [1,42; 78,17] 0,0041
Negativ	6/18 (33,3)	NE [0,89; NE]	1/10 (10,0)	NE [1,84; NE]	3,71 [0,45; 30,93] 0,1959
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,6367)					
Primäre Resistenz	9/30 (30,0)	NE [9,90; NE]	1/17 (5,9)	NE [NE; NE]	5,18 [0,65; 41,07] 0,0831
Sekundäre Resistenz	19/51 (37,3)	20,0 [10,26; NE]	1/23 (4,3)	NE [NE; NE]	9,43 [1,26; 70,42] 0,0074
Tumorgrad (p-Wert des Interaktionsterms: 0,9999)					
Hoch	5/11 (45,5)	11,2 [0,82; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0699
Niedrig/mittel	10/31 (32,3)	NE [10,16; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0275
Unbekannt	13/39 (33,3)	NE [10,13; NE]	2/16 (12,5)	NE [NE; NE]	3,09 [0,70; 13,70] 0,1191
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9914)					
Ja	8/17 (47,1)	11,2 [0,89; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0326
Nein	20/64 (31,3)	NE [18,31; NE]	2/30 (6,7)	NE [NE; NE]	4,79 [1,12; 20,54] 0,0197
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9925)					
Ja	27/72 (37,5)	NE [11,18; NE]	2/39 (5,1)	NE [NE; NE]	7,29 [1,73; 30,70] 0,0015
Nein	1/9 (11,1)	NE [0,82; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,7389

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Datenschnitt: 18.05.2020, Safety-Population 1: In Monaten; 2: Aus Log-rank-Test Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie. Neutropenie: PT Neutropenia, Febrile neutropenia, Neutrophil count decreased.					

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttnp3aesi_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 126.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,8826)					
< 65 Jahre	52/62 (83,9)	0,9 [0,85; 1,41]	6/30 (20,0)	NE [NE; NE]	8,48 [3,59; 20,07] <,0001
≥ 65 Jahre	15/19 (78,9)	0,9 [0,49; 0,92]	2/10 (20,0)	NE [4,27; NE]	7,71 [1,74; 34,24] 0,0018
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,9810)					
1	33/43 (76,7)	0,9 [0,82; 1,78]	6/26 (23,1)	NE [5,85; NE]	6,06 [2,51; 14,63] <,0001
2	22/24 (91,7)	0,9 [0,49; 1,02]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0019
≥ 3	12/14 (85,7)	0,9 [0,49; 1,28]	2/9 (22,2)	NE [4,27; NE]	7,04 [1,56; 31,86] 0,0035
Art der Erkrankung (p-Wert des Interaktionsterms: 0,1448)					
Viszerale Metastasen	38/47 (80,9)	0,9 [0,85; 1,02]	6/21 (28,6)	NE [4,27; NE]	5,07 [2,13; 12,08] <,0001
Nicht-viszerale Metastasen	29/34 (85,3)	0,9 [0,79; 1,64]	2/19 (10,5)	NE [NE; NE]	17,26 [4,03; 73,97] <,0001
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,2888)					
0	21/27 (77,8)	0,9 [0,82; 1,64]	4/14 (28,6)	NE [3,65; NE]	4,56 [1,55; 13,44] 0,0029
1	46/54 (85,2)	0,9 [0,82; 1,15]	4/26 (15,4)	NE [5,85; NE]	11,52 [4,11; 32,28] <,0001
Land (p-Wert des Interaktionsterms: 0,3893)					
China	63/71 (88,7)	0,9 [0,82; 0,89]	7/33 (21,2)	NE [NE; NE]	9,19 [4,16; 20,29] <,0001
Andere	4/10 (40,0)	8,3 [0,49; NE]	1/7 (14,3)	NE [5,85; NE]	3,27 [0,36; 29,35] 0,2622
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,1940)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	51/62 (82,3)	0,9 [0,85; 1,02]	7/26 (26,9)	NE [4,31; NE]	5,69 [2,56; 12,64] <,0001
Nein	16/19 (84,2)	0,9 [0,39; 2,66]	1/14 (7,1)	NE [NE; NE]	24,39 [3,20; 186,10] <,0001
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,2720)					
Positiv	51/63 (81,0)	0,9 [0,82; 0,89]	5/30 (16,7)	NE [NE; NE]	9,92 [3,93; 25,08] <,0001
Negativ	16/18 (88,9)	1,2 [0,85; 1,45]	3/10 (30,0)	NE [0,39; NE]	4,96 [1,42; 17,31] 0,0060
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9366)					
Primäre Resistenz	24/30 (80,0)	0,9 [0,82; 1,45]	3/17 (17,6)	NE [3,65; NE]	8,12 [2,43; 27,17] <,0001
Sekundäre Resistenz	43/51 (84,3)	0,9 [0,82; 1,02]	5/23 (21,7)	NE [5,85; NE]	8,38 [3,25; 21,61] <,0001
Tumorgrad (p-Wert des Interaktionsterms: 0,9514)					
Hoch	8/11 (72,7)	1,6 [0,49; NE]	1/7 (14,3)	NE [0,39; NE]	5,93 [0,74; 47,67] 0,0574
Niedrig/mittel	24/31 (77,4)	0,9 [0,82; 1,78]	3/17 (17,6)	NE [5,85; NE]	8,09 [2,41; 27,16] <,0001
Unbekannt	35/39 (89,7)	0,9 [0,79; 1,02]	4/16 (25,0)	NE [3,65; NE]	9,03 [3,15; 25,91] <,0001
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,3089)					
Ja	16/17 (94,1)	0,9 [0,43; 1,74]	1/10 (10,0)	NE [3,02; NE]	20,04 [2,63; 152,79] <,0001
Nein	51/64 (79,7)	0,9 [0,85; 1,15]	7/30 (23,3)	NE [4,31; NE]	6,49 [2,92; 14,44] <,0001
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9870)					
Ja	62/72 (86,1)	0,9 [0,85; 1,02]	8/39 (20,5)	NE [NE; NE]	8,48 [4,03; 17,86] <,0001
Nein	5/9 (55,6)	0,9 [0,43; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3838

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Datenschnitt: 18.05.2020, Safety-Population 1: In Monaten; 2: Aus Log-rank-Test Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie. Neutropenie: PT Neutropenia, Febrile neutropenia, Neutrophil count decreased.					

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttnp2aesi_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 126.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	n/N (%)	Mediane Ereigniszeit[1]	n/N (%)	Mediane Ereigniszeit[1]	HR [95% KI] p-Wert[2]
Alter (p-Wert des Interaktionsterms: 0,9934)					
< 65 Jahre	12/16 (75,0)	1,1 [0,46; 3,68]	2/9 (22,2)	NE [0,79; NE]	5,14 [1,14; 23,15] 0,0178
≥ 65 Jahre	7/7 (100,0)	1,0 [0,82; 1,78]	0/4 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0077
Anzahl vorangegangener endokriner Behandlungen (p-Wert des Interaktionsterms: 0,9939)					
Erstlinie	6/9 (66,7)	1,0 [0,82; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0268
Zweitlinie	13/14 (92,9)	1,1 [0,43; 1,78]	2/8 (25,0)	NE [0,79; NE]	7,69 [1,66; 35,66] 0,0028
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,5035)					
0	8/8 (100,0)	0,9 [0,39; 1,12]	1/7 (14,3)	NE [0,79; NE]	14,77 [1,75; 124,87] 0,0018
1	11/15 (73,3)	1,4 [0,82; 17,42]	1/6 (16,7)	NE [5,36; NE]	6,84 [0,88; 53,29] 0,0339
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9929)					
Ja	11/12 (91,7)	1,2 [0,39; 3,68]	2/7 (28,6)	NE [0,79; NE]	6,16 [1,31; 28,91] 0,0103
Nein	8/11 (72,7)	1,0 [0,82; NE]	0/6 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0084
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,5419)					
Ja	11/11 (100,0)	0,9 [0,39; 1,78]	1/6 (16,7)	NE [5,36; NE]	13,92 [1,74; 111,56] 0,0017
Nein	8/12 (66,7)	1,4 [0,85; NE]	1/7 (14,3)	NE [0,79; NE]	5,90 [0,73; 47,59] 0,0612

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie.
Neutropenie: PT Neutropenia, Febrile neutropenia, Neutrophil count decreased.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
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/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 128.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,5696)					
< 65 Jahre	16/62 (25,8)	NE [12,46; NE]	3/30 (10,0)	NE [NE; NE]	2,32 [0,67; 7,98] 0,1691
≥ 65 Jahre	7/19 (36,8)	18,9 [15,12; NE]	2/10 (20,0)	NE [0,23; NE]	1,52 [0,31; 7,36] 0,6033
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,0874)					
1	13/43 (30,2)	NE [13,15; NE]	2/26 (7,7)	NE [NE; NE]	3,77 [0,85; 16,72] 0,0603
2	5/24 (20,8)	NE [10,98; NE]	2/5 (40,0)	NE [0,23; NE]	0,30 [0,06; 1,59] 0,1336
≥ 3	5/14 (35,7)	17,3 [7,33; NE]	1/9 (11,1)	NE [4,50; NE]	1,75 [0,19; 16,05] 0,6160
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9155)					
Viszerale Metastasen	15/47 (31,9)	17,3 [10,98; NE]	3/21 (14,3)	NE [NE; NE]	1,74 [0,50; 6,07] 0,3779
Nicht-viszerale Metastasen	8/34 (23,5)	NE [13,15; NE]	2/19 (10,5)	NE [NE; NE]	2,02 [0,43; 9,52] 0,3643
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,7488)					
0	9/27 (33,3)	17,3 [6,21; NE]	2/14 (14,3)	NE [NE; NE]	2,32 [0,50; 10,77] 0,2674
1	14/54 (25,9)	NE [15,12; NE]	3/26 (11,5)	NE [NE; NE]	1,81 [0,52; 6,32] 0,3458
Land (p-Wert des Interaktionsterms: 0,1030)					
China	21/71 (29,6)	NE [15,12; NE]	3/33 (9,1)	NE [NE; NE]	3,02 [0,90; 10,15] 0,0599
Andere	2/10 (20,0)	NE [3,39; NE]	2/7 (28,6)	NE [0,23; NE]	0,54 [0,08; 3,95] 0,5421
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,5186)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	17/62 (27,4)	NE [15,12; NE]	4/26 (15,4)	NE [NE; NE]	1,59 [0,53; 4,76] 0,3993
Nein	6/19 (31,6)	NE [8,71; NE]	1/14 (7,1)	NE [NE; NE]	3,41 [0,41; 28,60] 0,2293
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,7563)					
Positiv	20/63 (31,7)	NE [13,15; NE]	4/30 (13,3)	NE [NE; NE]	2,06 [0,70; 6,04] 0,1780
Negativ	3/18 (16,7)	NE [NE; NE]	1/10 (10,0)	NE [0,23; NE]	1,61 [0,17; 15,47] 0,6773
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,2876)					
Primäre Resistenz	8/30 (26,7)	NE [15,12; NE]	3/17 (17,6)	NE [4,50; NE]	1,16 [0,30; 4,45] 0,8236
Sekundäre Resistenz	15/51 (29,4)	NE [12,46; NE]	2/23 (8,7)	NE [NE; NE]	3,26 [0,74; 14,25] 0,0967
Tumorgrad (p-Wert des Interaktionsterms: 0,7679)					
Hoch	4/11 (36,4)	15,1 [3,39; NE]	1/7 (14,3)	NE [2,63; NE]	2,28 [0,25; 20,98] 0,4549
Niedrig/mittel	9/31 (29,0)	NE [17,33; NE]	4/17 (23,5)	NE [4,50; NE]	0,91 [0,28; 2,99] 0,8825
Unbekannt	10/39 (25,6)	NE [11,93; NE]	0/16 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0361
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,2999)					
Ja	7/17 (41,2)	13,2 [6,21; NE]	3/10 (30,0)	NE [0,23; NE]	1,09 [0,28; 4,24] 0,9051
Nein	16/64 (25,0)	NE [17,33; NE]	2/30 (6,7)	NE [NE; NE]	3,33 [0,76; 14,49] 0,0892
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9907)					
Ja	22/72 (30,6)	NE [15,12; NE]	5/39 (12,8)	NE [NE; NE]	1,94 [0,73; 5,14] 0,1737
Nein	1/9 (11,1)	NE [0,46; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,7389

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Datenschnitt: 18.05.2020, Safety-Population 1: In Monaten; 2: Aus Log-rank-Test Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SOC: System Organ Class.					

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Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 130.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,3913)					
< 65 Jahre	15/62 (24,2)	NE [12,46; NE]	2/30 (6,7)	NE [NE; NE]	3,31 [0,76; 14,49] 0,0920
≥ 65 Jahre	7/19 (36,8)	18,9 [15,12; NE]	2/10 (20,0)	NE [0,23; NE]	1,52 [0,31; 7,36] 0,6033
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,1265)					
1	12/43 (27,9)	NE [13,15; NE]	2/26 (7,7)	NE [NE; NE]	3,43 [0,77; 15,32] 0,0863
2	5/24 (20,8)	NE [10,98; NE]	2/5 (40,0)	NE [0,23; NE]	0,30 [0,06; 1,59] 0,1336
≥ 3	5/14 (35,7)	17,3 [7,33; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1522
Art der Erkrankung (p-Wert des Interaktionsterms: 0,6643)					
Viszerale Metastasen	15/47 (31,9)	17,3 [10,98; NE]	2/21 (9,5)	NE [NE; NE]	2,72 [0,62; 11,98] 0,1670
Nicht-viszerale Metastasen	7/34 (20,6)	NE [NE; NE]	2/19 (10,5)	NE [NE; NE]	1,73 [0,36; 8,33] 0,4904
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,8328)					
0	8/27 (29,6)	NE [6,38; NE]	2/14 (14,3)	NE [NE; NE]	2,02 [0,43; 9,50] 0,3660
1	14/54 (25,9)	NE [15,12; NE]	2/26 (7,7)	NE [NE; NE]	2,77 [0,63; 12,24] 0,1597
Land (p-Wert des Interaktionsterms: 0,0661)					
China	20/71 (28,2)	NE [15,12; NE]	2/33 (6,1)	NE [NE; NE]	4,36 [1,02; 18,68] 0,0303
Andere	2/10 (20,0)	NE [3,39; NE]	2/7 (28,6)	NE [0,23; NE]	0,54 [0,08; 3,95] 0,5421
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,6730)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	16/62 (25,8)	NE [15,12; NE]	3/26 (11,5)	NE [NE; NE]	2,05 [0,59; 7,07] 0,2458
Nein	6/19 (31,6)	NE [8,71; NE]	1/14 (7,1)	NE [NE; NE]	3,41 [0,41; 28,60] 0,2293
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,6351)					
Positiv	19/63 (30,2)	NE [13,15; NE]	3/30 (10,0)	NE [NE; NE]	2,62 [0,78; 8,88] 0,1071
Negativ	3/18 (16,7)	NE [NE; NE]	1/10 (10,0)	NE [0,23; NE]	1,61 [0,17; 15,47] 0,6773
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,4766)					
Primäre Resistenz	7/30 (23,3)	NE [15,12; NE]	2/17 (11,8)	NE [NE; NE]	1,58 [0,32; 7,71] 0,5668
Sekundäre Resistenz	15/51 (29,4)	NE [12,46; NE]	2/23 (8,7)	NE [NE; NE]	3,26 [0,74; 14,25] 0,0967
Tumorgrad (p-Wert des Interaktionsterms: 0,8399)					
Hoch	4/11 (36,4)	15,1 [3,39; NE]	1/7 (14,3)	NE [2,63; NE]	2,28 [0,25; 20,98] 0,4549
Niedrig/mittel	8/31 (25,8)	NE [17,33; NE]	3/17 (17,6)	NE [NE; NE]	1,10 [0,29; 4,16] 0,8932
Unbekannt	10/39 (25,6)	NE [11,93; NE]	0/16 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0361
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,6153)					
Ja	7/17 (41,2)	13,2 [6,21; NE]	2/10 (20,0)	NE [0,23; NE]	1,67 [0,35; 8,05] 0,5201
Nein	15/64 (23,4)	NE [17,33; NE]	2/30 (6,7)	NE [NE; NE]	3,09 [0,70; 13,53] 0,1150
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9911)					
Ja	21/72 (29,2)	NE [15,12; NE]	4/39 (10,3)	NE [NE; NE]	2,33 [0,80; 6,79] 0,1116
Nein	1/9 (11,1)	NE [0,46; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,7389

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Datenschnitt: 18.05.2020, Safety-Population 1: In Monaten; 2: Aus Log-rank-Test Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SOC: System Organ Class.					

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Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 132.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,5982)					
< 65 Jahre	51/62 (82,3)	0,2 [0,13; 0,49]	4/30 (13,3)	NE [NE; NE]	12,35 [4,43; 34,44] <,0001
≥ 65 Jahre	16/19 (84,2)	0,3 [0,13; 0,46]	2/10 (20,0)	NE [0,13; NE]	7,73 [1,75; 34,15] 0,0016
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,9999)					
1	37/43 (86,0)	0,2 [0,13; 0,36]	6/26 (23,1)	NE [10,72; NE]	8,21 [3,40; 19,85] <,0001
2	17/24 (70,8)	0,2 [0,13; 6,67]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0193
≥ 3	13/14 (92,9)	0,3 [0,07; 0,56]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Art der Erkrankung (p-Wert des Interaktionsterms: 0,0629)					
Viszerale Metastasen	41/47 (87,2)	0,2 [0,13; 0,36]	1/21 (4,8)	NE [10,72; NE]	41,07 [5,61; 300,69] <,0001
Nicht-viszerale Metastasen	26/34 (76,5)	0,3 [0,16; 0,95]	5/19 (26,3)	NE [4,67; NE]	5,04 [1,91; 13,27] 0,0003
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,2525)					
0	24/27 (88,9)	0,2 [0,10; 0,53]	1/14 (7,1)	NE [NE; NE]	28,51 [3,80; 213,74] <,0001
1	43/54 (79,6)	0,2 [0,16; 0,46]	5/26 (19,2)	NE [10,72; NE]	7,58 [2,98; 19,29] <,0001
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,3508)					
Ja	52/62 (83,9)	0,3 [0,13; 0,46]	3/26 (11,5)	NE [10,72; NE]	15,71 [4,87; 50,71] <,0001
Nein	15/19 (78,9)	0,2 [0,10; 1,05]	3/14 (21,4)	NE [4,67; NE]	6,21 [1,76; 21,90] 0,0013
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,8656)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Positiv	54/63 (85,7)	0,2 [0,16; 0,36]	5/30 (16,7)	NE [10,72; NE]	10,80 [4,27; 27,28] <,0001
Negativ	13/18 (72,2)	0,3 [0,10; 1,61]	1/10 (10,0)	NE [1,84; NE]	12,95 [1,67; 100,10] 0,0017
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,4329)					
Primäre Resistenz	23/30 (76,7)	0,2 [0,13; 1,25]	3/17 (17,6)	NE [4,67; NE]	7,03 [2,10; 23,60] 0,0002
Sekundäre Resistenz	44/51 (86,3)	0,2 [0,13; 0,39]	3/23 (13,0)	NE [10,72; NE]	15,30 [4,68; 50,05] <,0001
Tumorgrad (p-Wert des Interaktionsterms: 0,3657)					
Hoch	10/11 (90,9)	0,3 [0,13; 0,99]	2/7 (28,6)	NE [0,03; NE]	6,85 [1,40; 33,65] 0,0078
Niedrig/mittel	27/31 (87,1)	0,2 [0,10; 0,72]	1/17 (5,9)	NE [10,72; NE]	30,80 [4,15; 228,49] <,0001
Unbekannt	30/39 (76,9)	0,3 [0,13; 0,49]	3/16 (18,8)	NE [4,67; NE]	7,55 [2,28; 24,96] 0,0001
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,5850)					
Ja	15/17 (88,2)	0,2 [0,07; 0,99]	1/10 (10,0)	NE [0,13; NE]	17,57 [2,28; 135,12] 0,0002
Nein	52/64 (81,3)	0,2 [0,16; 0,39]	5/30 (16,7)	NE [10,72; NE]	9,67 [3,83; 24,41] <,0001
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9880)					
Ja	58/72 (80,6)	0,2 [0,16; 0,39]	6/39 (15,4)	NE [NE; NE]	10,01 [4,29; 23,38] <,0001
Nein	9/9 (100,0)	0,1 [0,03; 0,46]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0957

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttdiaesi_popa1_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 132.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 1,0000)					
< 65 Jahre	11/16 (68,8)	0,4 [0,13; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0018
≥ 65 Jahre	4/7 (57,1)	0,5 [0,10; NE]	0/4 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0826
Anzahl vorangegangener endokriner Behandlungen (p-Wert des Interaktionsterms: 0,9999)					
Erstlinie	5/9 (55,6)	0,5 [0,13; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0533
Zweitlinie	10/14 (71,4)	0,4 [0,10; NE]	0/8 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0025

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttdiaesi_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 134.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,5982)					
< 65 Jahre	51/62 (82,3)	0,2 [0,13; 0,49]	4/30 (13,3)	NE [NE; NE]	12,35 [4,43; 34,44] <,0001
≥ 65 Jahre	16/19 (84,2)	0,3 [0,13; 0,46]	2/10 (20,0)	NE [0,13; NE]	7,73 [1,75; 34,15] 0,0016
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,9999)					
1	37/43 (86,0)	0,2 [0,13; 0,36]	6/26 (23,1)	NE [10,72; NE]	8,21 [3,40; 19,85] <,0001
2	17/24 (70,8)	0,2 [0,13; 6,67]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0193
≥ 3	13/14 (92,9)	0,3 [0,07; 0,56]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Art der Erkrankung (p-Wert des Interaktionsterms: 0,0629)					
Viszerale Metastasen	41/47 (87,2)	0,2 [0,13; 0,36]	1/21 (4,8)	NE [10,72; NE]	41,07 [5,61; 300,69] <,0001
Nicht-viszerale Metastasen	26/34 (76,5)	0,3 [0,16; 0,95]	5/19 (26,3)	NE [4,67; NE]	5,04 [1,91; 13,27] 0,0003
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,2525)					
0	24/27 (88,9)	0,2 [0,10; 0,53]	1/14 (7,1)	NE [NE; NE]	28,51 [3,80; 213,74] <,0001
1	43/54 (79,6)	0,2 [0,16; 0,46]	5/26 (19,2)	NE [10,72; NE]	7,58 [2,98; 19,29] <,0001
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,3508)					
Ja	52/62 (83,9)	0,3 [0,13; 0,46]	3/26 (11,5)	NE [10,72; NE]	15,71 [4,87; 50,71] <,0001
Nein	15/19 (78,9)	0,2 [0,10; 1,05]	3/14 (21,4)	NE [4,67; NE]	6,21 [1,76; 21,90] 0,0013
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,8656)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Positiv	54/63 (85,7)	0,2 [0,16; 0,36]	5/30 (16,7)	NE [10,72; NE]	10,80 [4,27; 27,28] <,0001
Negativ	13/18 (72,2)	0,3 [0,10; 1,61]	1/10 (10,0)	NE [1,84; NE]	12,95 [1,67; 100,10] 0,0017
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,4329)					
Primäre Resistenz	23/30 (76,7)	0,2 [0,13; 1,25]	3/17 (17,6)	NE [4,67; NE]	7,03 [2,10; 23,60] 0,0002
Sekundäre Resistenz	44/51 (86,3)	0,2 [0,13; 0,39]	3/23 (13,0)	NE [10,72; NE]	15,30 [4,68; 50,05] <,0001
Tumorgrad (p-Wert des Interaktionsterms: 0,3657)					
Hoch	10/11 (90,9)	0,3 [0,13; 0,99]	2/7 (28,6)	NE [0,03; NE]	6,85 [1,40; 33,65] 0,0078
Niedrig/mittel	27/31 (87,1)	0,2 [0,10; 0,72]	1/17 (5,9)	NE [10,72; NE]	30,80 [4,15; 228,49] <,0001
Unbekannt	30/39 (76,9)	0,3 [0,13; 0,49]	3/16 (18,8)	NE [4,67; NE]	7,55 [2,28; 24,96] 0,0001
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,5850)					
Ja	15/17 (88,2)	0,2 [0,07; 0,99]	1/10 (10,0)	NE [0,13; NE]	17,57 [2,28; 135,12] 0,0002
Nein	52/64 (81,3)	0,2 [0,16; 0,39]	5/30 (16,7)	NE [10,72; NE]	9,67 [3,83; 24,41] <,0001
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9880)					
Ja	58/72 (80,6)	0,2 [0,16; 0,39]	6/39 (15,4)	NE [NE; NE]	10,01 [4,29; 23,38] <,0001
Nein	9/9 (100,0)	0,1 [0,03; 0,46]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0957

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttdi2aesi_popa1_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 134.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 1,0000)					
< 65 Jahre	11/16 (68,8)	0,4 [0,13; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0018
≥ 65 Jahre	4/7 (57,1)	0,5 [0,10; NE]	0/4 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0826
Anzahl vorangegangener endokriner Behandlungen (p-Wert des Interaktionsterms: 0,9999)					
Erstlinie	5/9 (55,6)	0,5 [0,13; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0533
Zweitlinie	10/14 (71,4)	0,4 [0,10; NE]	0/8 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0025

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttdi2aesi_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 136.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	n/N (%)	Mediane Ereigniszeit[1]	n/N (%)	Mediane Ereigniszeit[1]	HR [95% KI] p-Wert[2]
Alter (p-Wert des Interaktionsterms: 0,9999)					
< 65 Jahre	15/62 (24,2)	25,2 [23,08; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0092
≥ 65 Jahre	7/19 (36,8)	22,1 [2,79; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0507
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 1,0000)					
1	14/43 (32,6)	25,2 [22,13; NE]	0/26 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0029
2	5/24 (20,8)	NE [13,78; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3698
≥ 3	3/14 (21,4)	NE [17,85; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2981
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9999)					
Viszerale Metastasen	11/47 (23,4)	NE [23,08; NE]	0/21 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0244
Nicht-viszerale Metastasen	11/34 (32,4)	25,2 [17,85; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0305
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9999)					
0	5/27 (18,5)	NE [23,08; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0897
1	17/54 (31,5)	25,2 [17,85; NE]	0/26 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0091
Land (p-Wert des Interaktionsterms: 1,0000)					
China	20/71 (28,2)	NE [22,13; NE]	0/33 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0026
Andere	2/10 (20,0)	23,1 [2,79; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4028
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9999)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	16/62 (25,8)	25,2 [17,85; NE]	0/26 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0072
Nein	6/19 (31,6)	NE [14,17; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0764
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 1,0000)					
Positiv	18/63 (28,6)	25,2 [22,13; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0034
Negativ	4/18 (22,2)	NE [9,21; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1766
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9999)					
Primäre Resistenz	6/30 (20,0)	NE [14,17; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1189
Sekundäre Resistenz	16/51 (31,4)	25,2 [22,13; NE]	0/23 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0090
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9998)					
Ja	9/17 (52,9)	23,1 [2,76; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0367
Nein	13/64 (20,3)	NE [22,13; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0145
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 1,0000)					
Ja	20/72 (27,8)	NE [22,13; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0018
Nein	2/9 (22,2)	25,2 [0,49; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,7389

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttcraesi_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 138.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9999)					
< 65 Jahre	15/62 (24,2)	25,2 [23,08; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0092
≥ 65 Jahre	7/19 (36,8)	22,1 [2,79; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0507
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 1,0000)					
1	14/43 (32,6)	25,2 [22,13; NE]	0/26 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0029
2	5/24 (20,8)	NE [13,78; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3698
≥ 3	3/14 (21,4)	NE [17,85; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2981
Art der Erkrankung (p-Wert des Interaktionsterms: 0,9999)					
Viszerale Metastasen	11/47 (23,4)	NE [23,08; NE]	0/21 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0244
Nicht-viszerale Metastasen	11/34 (32,4)	25,2 [17,85; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0305
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,9999)					
0	5/27 (18,5)	NE [23,08; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0897
1	17/54 (31,5)	25,2 [17,85; NE]	0/26 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0091
Land (p-Wert des Interaktionsterms: 1,0000)					
China	20/71 (28,2)	NE [22,13; NE]	0/33 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0026
Andere	2/10 (20,0)	23,1 [2,79; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4028
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9999)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	16/62 (25,8)	25,2 [17,85; NE]	0/26 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0072
Nein	6/19 (31,6)	NE [14,17; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0764
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 1,0000)					
Positiv	18/63 (28,6)	25,2 [22,13; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0034
Negativ	4/18 (22,2)	NE [9,21; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1766
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,9999)					
Primäre Resistenz	6/30 (20,0)	NE [14,17; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1189
Sekundäre Resistenz	16/51 (31,4)	25,2 [22,13; NE]	0/23 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0090
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9998)					
Ja	9/17 (52,9)	23,1 [2,76; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0367
Nein	13/64 (20,3)	NE [22,13; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0145
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 1,0000)					
Ja	20/72 (27,8)	NE [22,13; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0018
Nein	2/9 (22,2)	25,2 [0,49; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,7389

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttcr2aesi_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 140.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,3680)					
< 65 Jahre	27/62 (43,5)	20,3 [8,42; 25,71]	7/30 (23,3)	NE [20,94; NE]	1,73 [0,75; 3,98] 0,1936
≥ 65 Jahre	9/19 (47,4)	10,4 [1,41; NE]	1/10 (10,0)	NE [0,43; NE]	4,70 [0,59; 37,33] 0,1078
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,7100)					
1	21/43 (48,8)	20,3 [7,40; NE]	5/26 (19,2)	NE [20,94; NE]	2,62 [0,99; 6,97] 0,0443
2	7/24 (29,2)	23,6 [7,63; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3490
≥ 3	8/14 (57,1)	14,0 [1,71; NE]	3/9 (33,3)	NE [0,39; NE]	1,12 [0,28; 4,48] 0,8681
Art der Erkrankung (p-Wert des Interaktionsterms: 0,2056)					
Viszerale Metastasen	17/47 (36,2)	16,1 [8,32; NE]	5/21 (23,8)	NE [NE; NE]	1,30 [0,47; 3,56] 0,6082
Nicht-viszerale Metastasen	19/34 (55,9)	10,4 [5,79; 25,71]	3/19 (15,8)	NE [20,94; NE]	3,65 [1,08; 12,37] 0,0260
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,2625)					
0	11/27 (40,7)	20,3 [7,40; NE]	5/14 (35,7)	20,9 [2,70; NE]	1,26 [0,43; 3,69] 0,6750
1	25/54 (46,3)	20,6 [8,42; NE]	3/26 (11,5)	NE [NE; NE]	3,35 [1,01; 11,13] 0,0362
Land (p-Wert des Interaktionsterms: 0,9913)					
China	35/71 (49,3)	16,1 [7,99; 25,71]	8/33 (24,2)	NE [20,94; NE]	1,90 [0,88; 4,11] 0,0952
Andere	1/10 (10,0)	NE [7,40; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4795
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,5948)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	27/62 (43,5)	16,1 [7,99; NE]	6/26 (23,1)	NE [NE; NE]	1,74 [0,71; 4,22] 0,2156
Nein	9/19 (47,4)	20,6 [6,64; NE]	2/14 (14,3)	NE [6,54; NE]	2,86 [0,61; 13,30] 0,1631
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,6766)					
Positiv	29/63 (46,0)	16,1 [7,63; 25,71]	6/30 (20,0)	NE [20,94; NE]	2,30 [0,95; 5,56] 0,0568
Negativ	7/18 (38,9)	23,6 [7,99; NE]	2/10 (20,0)	NE [0,49; NE]	1,51 [0,31; 7,28] 0,6076
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,1408)					
Primäre Resistenz	10/30 (33,3)	23,6 [16,11; NE]	4/17 (23,5)	20,9 [20,94; NE]	1,14 [0,35; 3,66] 0,8280
Sekundäre Resistenz	26/51 (51,0)	10,4 [6,64; 25,71]	4/23 (17,4)	NE [NE; NE]	3,17 [1,11; 9,10] 0,0231
Tumorgrad (p-Wert des Interaktionsterms: 0,9364)					
Hoch	3/11 (27,3)	NE [2,07; NE]	1/7 (14,3)	NE [1,38; NE]	1,71 [0,18; 16,45] 0,6393
Niedrig/mittel	12/31 (38,7)	20,6 [7,40; NE]	3/17 (17,6)	NE [NE; NE]	2,00 [0,56; 7,14] 0,2722
Unbekannt	21/39 (53,8)	10,4 [6,64; 25,71]	4/16 (25,0)	NE [6,54; NE]	2,32 [0,79; 6,78] 0,1145
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,7715)					
Ja	9/17 (52,9)	9,6 [7,40; NE]	2/10 (20,0)	NE [0,39; NE]	1,26 [0,25; 6,28] 0,7751
Nein	27/64 (42,2)	20,3 [8,42; NE]	6/30 (20,0)	NE [20,94; NE]	2,23 [0,92; 5,43] 0,0689
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9875)					
Ja	34/72 (47,2)	20,3 [8,42; 25,71]	8/39 (20,5)	NE [20,94; NE]	2,04 [0,94; 4,42] 0,0644
Nein	2/9 (22,2)	8,0 [0,43; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4380

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Datenschnitt: 18.05.2020, Safety-Population 1: In Monaten; 2: Aus Log-rank-Test Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.					

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttalaesi_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 140.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9942)					
< 65 Jahre	5/16 (31,3)	NE [9,37; NE]	5/9 (55,6)	6,4 [0,43; NE]	0,18 [0,04; 0,80] 0,0129
≥ 65 Jahre	3/7 (42,9)	NE [0,82; NE]	0/4 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1540

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttalaesi_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 142.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,3478)					
< 65 Jahre	26/62 (41,9)	20,3 [9,63; NE]	7/30 (23,3)	NE [20,94; NE]	1,67 [0,72; 3,85] 0,2263
≥ 65 Jahre	9/19 (47,4)	10,4 [1,41; NE]	1/10 (10,0)	NE [0,43; NE]	4,70 [0,59; 37,33] 0,1078
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,6139)					
1	21/43 (48,8)	20,3 [7,40; NE]	5/26 (19,2)	NE [20,94; NE]	2,62 [0,99; 6,96] 0,0449
2	7/24 (29,2)	23,6 [7,63; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3490
≥ 3	7/14 (50,0)	14,0 [1,71; NE]	3/9 (33,3)	NE [0,39; NE]	0,97 [0,23; 4,05] 0,9702
Art der Erkrankung (p-Wert des Interaktionsterms: 0,1828)					
Viszerale Metastasen	16/47 (34,0)	23,6 [14,01; NE]	5/21 (23,8)	NE [NE; NE]	1,25 [0,45; 3,44] 0,6668
Nicht-viszerale Metastasen	19/34 (55,9)	10,4 [5,79; 25,71]	3/19 (15,8)	NE [20,94; NE]	3,64 [1,07; 12,33] 0,0265
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,2880)					
0	11/27 (40,7)	20,3 [7,40; NE]	5/14 (35,7)	20,9 [2,70; NE]	1,26 [0,43; 3,69] 0,6750
1	24/54 (44,4)	20,6 [9,63; NE]	3/26 (11,5)	NE [NE; NE]	3,23 [0,97; 10,75] 0,0437
Land (p-Wert des Interaktionsterms: 0,9914)					
China	34/71 (47,9)	20,3 [7,99; 25,71]	8/33 (24,2)	NE [20,94; NE]	1,86 [0,86; 4,02] 0,1098
Andere	1/10 (10,0)	NE [7,40; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4795
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,5674)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	26/62 (41,9)	16,1 [7,99; NE]	6/26 (23,1)	NE [NE; NE]	1,68 [0,69; 4,10] 0,2459
Nein	9/19 (47,4)	20,6 [6,64; NE]	2/14 (14,3)	NE [6,54; NE]	2,86 [0,61; 13,30] 0,1631
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,5575)					
Positiv	29/63 (46,0)	16,1 [7,63; 25,71]	6/30 (20,0)	NE [20,94; NE]	2,30 [0,95; 5,55] 0,0572
Negativ	6/18 (33,3)	23,6 [7,99; NE]	2/10 (20,0)	NE [0,49; NE]	1,30 [0,26; 6,48] 0,7466
Sensitivität gegenüber endokriner Therapie (p-Wert des Interaktionsterms: 0,1618)					
Primäre Resistenz	10/30 (33,3)	23,6 [16,11; NE]	4/17 (23,5)	20,9 [20,94; NE]	1,13 [0,35; 3,64] 0,8387
Sekundäre Resistenz	25/51 (49,0)	14,0 [6,64; NE]	4/23 (17,4)	NE [NE; NE]	3,03 [1,05; 8,73] 0,0301
Tumorgrad (p-Wert des Interaktionsterms: 0,9590)					
Hoch	3/11 (27,3)	NE [2,07; NE]	1/7 (14,3)	NE [1,38; NE]	1,71 [0,18; 16,45] 0,6393
Niedrig/mittel	12/31 (38,7)	20,6 [7,40; NE]	3/17 (17,6)	NE [NE; NE]	2,00 [0,56; 7,14] 0,2722
Unbekannt	20/39 (51,3)	14,0 [6,64; 25,71]	4/16 (25,0)	NE [6,54; NE]	2,20 [0,75; 6,48] 0,1405
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,8177)					
Ja	9/17 (52,9)	9,6 [7,40; NE]	2/10 (20,0)	NE [0,39; NE]	1,26 [0,25; 6,28] 0,7751
Nein	26/64 (40,6)	20,6 [10,39; NE]	6/30 (20,0)	NE [20,94; NE]	2,15 [0,88; 5,25] 0,0845
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9876)					
Ja	33/72 (45,8)	20,3 [9,63; NE]	8/39 (20,5)	NE [20,94; NE]	1,99 [0,92; 4,32] 0,0759
Nein	2/9 (22,2)	8,0 [0,43; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4380

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Datenschnitt: 18.05.2020, Safety-Population 1: In Monaten; 2: Aus Log-rank-Test Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.					

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttal2aesi_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 142.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9942)					
< 65 Jahre	5/16 (31,3)	NE [9,37; NE]	5/9 (55,6)	6,4 [0,43; NE]	0,18 [0,04; 0,80] 0,0129
≥ 65 Jahre	3/7 (42,9)	NE [0,82; NE]	0/4 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1540

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttal2aesi_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 144.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,1583)					
< 65 Jahre	25/62 (40,3)	20,0 [9,63; NE]	9/30 (30,0)	21,1 [10,45; NE]	1,22 [0,57; 2,63] 0,5990
≥ 65 Jahre	11/19 (57,9)	10,4 [1,41; NE]	1/10 (10,0)	NE [0,43; NE]	6,12 [0,78; 47,74] 0,0499
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,3556)					
1	21/43 (48,8)	18,6 [8,45; 25,71]	6/26 (23,1)	NE [10,45; NE]	2,25 [0,91; 5,59] 0,0730
2	10/24 (41,7)	17,1 [6,58; NE]	1/5 (20,0)	NE [0,39; NE]	1,38 [0,17; 11,18] 0,7523
≥ 3	5/14 (35,7)	NE [1,71; NE]	3/9 (33,3)	NE [0,39; NE]	0,80 [0,19; 3,38] 0,7592
Art der Erkrankung (p-Wert des Interaktionsterms: 0,1576)					
Viszerale Metastasen	19/47 (40,4)	17,1 [7,63; NE]	7/21 (33,3)	21,1 [3,58; NE]	0,98 [0,41; 2,37] 0,9674
Nicht-viszerale Metastasen	17/34 (50,0)	20,0 [8,42; NE]	3/19 (15,8)	NE [10,45; NE]	3,02 [0,88; 10,34] 0,0645
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,4451)					
0	13/27 (48,1)	8,0 [5,95; NE]	6/14 (42,9)	14,1 [3,58; NE]	1,34 [0,50; 3,59] 0,5539
1	23/54 (42,6)	20,0 [10,39; NE]	4/26 (15,4)	NE [NE; NE]	2,34 [0,81; 6,79] 0,1060
Land (p-Wert des Interaktionsterms: 0,9911)					
China	35/71 (49,3)	18,6 [8,45; 23,57]	10/33 (30,3)	21,1 [10,45; NE]	1,50 [0,74; 3,03] 0,2570
Andere	1/10 (10,0)	NE [7,40; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4795
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,5602)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	29/62 (46,8)	17,1 [7,63; 23,57]	7/26 (26,9)	NE [21,11; NE]	1,69 [0,73; 3,88] 0,2094
Nein	7/19 (36,8)	20,3 [16,50; NE]	3/14 (21,4)	14,1 [8,98; NE]	0,82 [0,21; 3,25] 0,7787
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,4516)					
Positiv	29/63 (46,0)	18,6 [8,45; 25,71]	7/30 (23,3)	21,1 [10,45; NE]	1,96 [0,86; 4,48] 0,1042
Negativ	7/18 (38,9)	23,6 [8,32; NE]	3/10 (30,0)	NE [0,49; NE]	1,01 [0,26; 3,92] 0,9906
Tumorgrad (p-Wert des Interaktionsterms: 0,4091)					
Hoch	3/11 (27,3)	16,5 [8,45; NE]	2/7 (28,6)	NE [0,39; NE]	0,80 [0,13; 4,97] 0,8108
Niedrig/mittel	13/31 (41,9)	19,8 [7,99; 20,32]	2/17 (11,8)	NE [NE; NE]	4,30 [0,94; 19,58] 0,0414
Unbekannt	20/39 (51,3)	17,1 [6,58; NE]	6/16 (37,5)	14,1 [8,98; NE]	1,34 [0,54; 3,36] 0,5280
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,8707)					
Ja	9/17 (52,9)	9,6 [5,95; NE]	2/10 (20,0)	NE [0,39; NE]	1,34 [0,27; 6,62] 0,7154
Nein	27/64 (42,2)	19,8 [10,39; 25,71]	8/30 (26,7)	NE [10,45; NE]	1,76 [0,79; 3,90] 0,1592
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9908)					
Ja	34/72 (47,2)	19,8 [9,63; 25,71]	10/39 (25,6)	21,1 [10,45; NE]	1,58 [0,78; 3,21] 0,2012
Nein	2/9 (22,2)	8,0 [0,43; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4380

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttasaesi_popa1_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 144.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,0869)					
< 65 Jahre	6/16 (37,5)	21,7 [9,37; NE]	4/9 (44,4)	NE [0,43; NE]	0,28 [0,06; 1,27] 0,0783
≥ 65 Jahre	3/7 (42,9)	13,7 [0,82; NE]	1/4 (25,0)	NE [0,85; NE]	2,53 [0,24; 26,31] 0,4249
Anzahl vorangegangener endokriner Behandlungen (p-Wert des Interaktionsterms: 0,7570)					
Erstlinie	3/9 (33,3)	16,7 [0,82; NE]	1/5 (20,0)	NE [0,85; NE]	1,12 [0,10; 12,35] 0,9279
Zweitlinie	6/14 (42,9)	13,7 [4,67; NE]	4/8 (50,0)	NE [0,43; NE]	0,66 [0,18; 2,41] 0,5304

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttasaesi_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 146.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,1590)					
< 65 Jahre	25/62 (40,3)	20,0 [9,63; NE]	9/30 (30,0)	21,1 [10,45; NE]	1,22 [0,57; 2,62] 0,6043
≥ 65 Jahre	11/19 (57,9)	10,4 [1,41; NE]	1/10 (10,0)	NE [0,43; NE]	6,12 [0,78; 47,74] 0,0494
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,3488)					
1	21/43 (48,8)	18,6 [8,45; 25,71]	6/26 (23,1)	NE [10,45; NE]	2,25 [0,90; 5,58] 0,0738
2	10/24 (41,7)	17,1 [6,58; NE]	1/5 (20,0)	NE [0,39; NE]	1,38 [0,17; 11,18] 0,7523
≥ 3	5/14 (35,7)	NE [1,78; NE]	3/9 (33,3)	NE [0,39; NE]	0,78 [0,19; 3,31] 0,7386
Art der Erkrankung (p-Wert des Interaktionsterms: 0,1562)					
Viszerale Metastasen	19/47 (40,4)	17,1 [7,63; NE]	7/21 (33,3)	21,1 [3,58; NE]	0,98 [0,41; 2,37] 0,9678
Nicht-viszerale Metastasen	17/34 (50,0)	20,0 [8,42; NE]	3/19 (15,8)	NE [10,45; NE]	3,01 [0,88; 10,30] 0,0655
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,4417)					
0	13/27 (48,1)	8,0 [5,95; NE]	6/14 (42,9)	14,1 [3,58; NE]	1,34 [0,50; 3,57] 0,5594
1	23/54 (42,6)	20,0 [10,39; NE]	4/26 (15,4)	NE [NE; NE]	2,34 [0,81; 6,79] 0,1060
Land (p-Wert des Interaktionsterms: 0,9911)					
China	35/71 (49,3)	18,6 [8,45; 23,57]	10/33 (30,3)	21,1 [10,45; NE]	1,50 [0,74; 3,03] 0,2576
Andere	1/10 (10,0)	NE [7,40; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4795
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,5616)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	29/62 (46,8)	17,1 [7,63; 23,57]	7/26 (26,9)	NE [21,11; NE]	1,69 [0,73; 3,87] 0,2115
Nein	7/19 (36,8)	20,3 [16,50; NE]	3/14 (21,4)	14,1 [8,98; NE]	0,82 [0,21; 3,25] 0,7787
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,4545)					
Positiv	29/63 (46,0)	18,6 [8,45; 25,71]	7/30 (23,3)	21,1 [10,45; NE]	1,95 [0,85; 4,47] 0,1054
Negativ	7/18 (38,9)	23,6 [8,32; NE]	3/10 (30,0)	NE [0,49; NE]	1,01 [0,26; 3,92] 0,9906
Tumorgrad (p-Wert des Interaktionsterms: 0,4104)					
Hoch	3/11 (27,3)	16,5 [8,45; NE]	2/7 (28,6)	NE [0,39; NE]	0,80 [0,13; 4,97] 0,8108
Niedrig/mittel	13/31 (41,9)	19,8 [7,99; 20,32]	2/17 (11,8)	NE [NE; NE]	4,27 [0,94; 19,44] 0,0432
Unbekannt	20/39 (51,3)	17,1 [6,58; NE]	6/16 (37,5)	14,1 [8,98; NE]	1,34 [0,54; 3,36] 0,5280
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,8744)					
Ja	9/17 (52,9)	9,6 [5,95; NE]	2/10 (20,0)	NE [0,39; NE]	1,34 [0,27; 6,62] 0,7154
Nein	27/64 (42,2)	19,8 [10,39; 25,71]	8/30 (26,7)	NE [10,45; NE]	1,76 [0,79; 3,89] 0,1608
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9908)					
Ja	34/72 (47,2)	19,8 [9,63; 25,71]	10/39 (25,6)	21,1 [10,45; NE]	1,58 [0,78; 3,20] 0,2024
Nein	2/9 (22,2)	8,0 [0,43; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4380

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttas2aesi_popa1_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 148.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9999)					
< 65 Jahre	7/62 (11,3)	NE [NE; NE]	5/30 (16,7)	NE [10,98; NE]	0,55 [0,17; 1,74] 0,3019
≥ 65 Jahre	0/19 (0,0)	NE [NE; NE]	0/10 (0,0)	NE [NE; NE]	NE
Land (p-Wert des Interaktionsterms: 0,9921)					
China	6/71 (8,5)	NE [NE; NE]	5/33 (15,2)	NE [10,98; NE]	0,44 [0,13; 1,46] 0,1683
Andere	1/10 (10,0)	NE [0,03; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4028
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9943)					
Ja	1/17 (5,9)	NE [23,57; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,7055
Nein	6/64 (9,4)	NE [NE; NE]	5/30 (16,7)	NE [10,98; NE]	0,48 [0,15; 1,59] 0,2185
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9999)					
Ja	7/72 (9,7)	NE [NE; NE]	5/39 (12,8)	NE [NE; NE]	0,59 [0,19; 1,89] 0,3713
Nein	0/9 (0,0)	NE [NE; NE]	0/1 (0,0)	NE [NE; NE]	NE

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttapaesi_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 150.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,9998)					
< 65 Jahre	5/62 (8,1)	NE [NE; NE]	5/30 (16,7)	NE [10,98; NE]	0,37 [0,11; 1,28] 0,1028
≥ 65 Jahre	0/19 (0,0)	NE [NE; NE]	0/10 (0,0)	NE [NE; NE]	NE
Land (p-Wert des Interaktionsterms: 0,9998)					
China	5/71 (7,0)	NE [NE; NE]	5/33 (15,2)	NE [10,98; NE]	0,36 [0,10; 1,25] 0,0932
Andere	0/10 (0,0)	NE [NE; NE]	0/7 (0,0)	NE [NE; NE]	NE
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9999)					
Ja	5/72 (6,9)	NE [NE; NE]	5/39 (12,8)	NE [NE; NE]	0,40 [0,11; 1,38] 0,1321
Nein	0/9 (0,0)	NE [NE; NE]	0/1 (0,0)	NE [NE; NE]	NE

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; PT: Preferred Term; RCT: Randomisierte kontrollierte Studie.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_ttap2aesi_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 164.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,1288)					
< 65 Jahre	37/62 (59,7)	10,2 [7,63; 19,79]	11/30 (36,7)	21,1 [8,98; NE]	1,58 [0,80; 3,12] 0,1792
≥ 65 Jahre	12/19 (63,2)	8,4 [1,38; NE]	1/10 (10,0)	NE [0,43; NE]	7,71 [0,98; 60,65] 0,0237
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,7954)					
1	28/43 (65,1)	9,6 [6,64; 19,79]	8/26 (30,8)	21,1 [8,98; NE]	2,32 [1,05; 5,13] 0,0326
2	13/24 (54,2)	16,3 [3,75; NE]	1/5 (20,0)	NE [0,39; NE]	2,25 [0,29; 17,69] 0,4221
≥ 3	8/14 (57,1)	14,0 [1,45; NE]	3/9 (33,3)	NE [0,39; NE]	1,18 [0,29; 4,74] 0,8102
Art der Erkrankung (p-Wert des Interaktionsterms: 0,6274)					
Viszerale Metastasen	26/47 (55,3)	8,4 [6,58; 17,10]	7/21 (33,3)	21,1 [2,70; NE]	1,71 [0,73; 4,01] 0,2138
Nicht-viszerale Metastasen	23/34 (67,6)	10,2 [5,59; 19,96]	5/19 (26,3)	NE [8,98; NE]	2,44 [0,92; 6,45] 0,0644
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,3804)					
0	15/27 (55,6)	8,0 [2,53; 20,32]	6/14 (42,9)	14,1 [1,38; NE]	1,48 [0,57; 3,88] 0,4240
1	34/54 (63,0)	10,2 [6,64; 18,58]	6/26 (23,1)	NE [8,98; NE]	2,65 [1,11; 6,37] 0,0230
Land (p-Wert des Interaktionsterms: 0,9889)					
China	47/71 (66,2)	8,4 [6,58; 16,27]	12/33 (36,4)	21,1 [8,98; NE]	1,83 [0,97; 3,48] 0,0590
Andere	2/10 (20,0)	NE [0,03; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2544
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,5691)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	38/62 (61,3)	8,4 [6,58; 16,11]	8/26 (30,8)	21,1 [21,11; NE]	2,24 [1,03; 4,86] 0,0358
Nein	11/19 (57,9)	18,6 [6,64; NE]	4/14 (28,6)	14,1 [8,98; NE]	1,52 [0,48; 4,84] 0,4736
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,6937)					
Positiv	36/63 (57,1)	10,4 [6,58; 19,79]	9/30 (30,0)	21,1 [14,07; NE]	1,99 [0,95; 4,16] 0,0620
Negativ	13/18 (72,2)	8,4 [2,07; 17,10]	3/10 (30,0)	NE [0,49; NE]	2,54 [0,72; 8,97] 0,1352
Tumorgrad (p-Wert des Interaktionsterms: 0,7087)					
Hoch	4/11 (36,4)	9,6 [2,07; NE]	2/7 (28,6)	NE [0,39; NE]	1,06 [0,19; 5,80] 0,9496
Niedrig/mittel	18/31 (58,1)	18,6 [2,53; 20,32]	3/17 (17,6)	NE [NE; NE]	3,43 [0,99; 11,81] 0,0380
Unbekannt	27/39 (69,2)	8,3 [5,95; 16,11]	7/16 (43,8)	14,1 [0,79; NE]	1,67 [0,72; 3,85] 0,2266
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,8158)					
Ja	13/17 (76,5)	8,0 [1,78; 14,01]	2/10 (20,0)	NE [0,39; NE]	1,86 [0,40; 8,68] 0,4199
Nein	36/64 (56,3)	16,1 [6,64; 18,58]	10/30 (33,3)	21,1 [8,98; NE]	2,04 [0,99; 4,19] 0,0475
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9888)					
Ja	46/72 (63,9)	10,2 [7,40; 17,10]	12/39 (30,8)	21,1 [8,98; NE]	1,99 [1,05; 3,78] 0,0313
Nein	3/9 (33,3)	8,0 [0,43; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3957

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SMQ: Standardised MedDRA Queries.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_tthepsmq_popa1_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 164.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Anzahl vorangegangener endokriner Behandlungen (p-Wert des Interaktionsterms: 0,9749)					
Erstlinie	5/9 (55,6)	16,7 [0,82; NE]	2/5 (40,0)	NE [0,46; NE]	0,90 [0,16; 4,91] 0,8990
Zweitlinie	7/14 (50,0)	9,4 [1,94; NE]	4/8 (50,0)	NE [0,43; NE]	0,78 [0,23; 2,72] 0,7013
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,1906)					
0	4/8 (50,0)	16,7 [2,79; NE]	4/7 (57,1)	1,3 [0,43; NE]	0,30 [0,06; 1,43] 0,1133
1	8/15 (53,3)	15,1 [1,45; NE]	2/6 (33,3)	NE [0,85; NE]	1,61 [0,34; 7,60] 0,5430
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,6772)					
Ja	6/12 (50,0)	21,7 [1,58; NE]	4/7 (57,1)	1,8 [0,43; NE]	0,65 [0,18; 2,33] 0,5016
Nein	6/11 (54,5)	16,7 [1,41; NE]	2/6 (33,3)	NE [0,46; NE]	1,03 [0,20; 5,37] 0,9765
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,6366)					
Ja	7/11 (63,6)	9,4 [1,58; NE]	3/6 (50,0)	NE [0,43; NE]	0,96 [0,24; 3,81] 0,9580
Nein	5/12 (41,7)	16,7 [1,45; NE]	3/7 (42,9)	NE [0,46; NE]	0,61 [0,13; 2,72] 0,5090

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SMQ: Standardised MedDRA Queries.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_tthepsmq_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 165.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Land (p-Wert des Interaktionsterms: 0,9934)					
China	9/71 (12,7)	NE [NE; NE]	1/33 (3,0)	NE [NE; NE]	3,57 [0,45; 28,27] 0,1978
Andere	1/10 (10,0)	NE [0,03; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4028
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,9943)					
Ja	9/62 (14,5)	NE [NE; NE]	1/26 (3,8)	NE [NE; NE]	3,51 [0,44; 27,76] 0,2041
Nein	1/19 (5,3)	NE [24,56; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,6374
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,9997)					
Ja	0/17 (0,0)	NE [NE; NE]	0/10 (0,0)	NE [NE; NE]	NE
Nein	10/64 (15,6)	NE [NE; NE]	1/30 (3,3)	NE [NE; NE]	4,33 [0,55; 33,88] 0,1272
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9998)					
Ja	10/72 (13,9)	NE [NE; NE]	1/39 (2,6)	NE [NE; NE]	4,63 [0,59; 36,31] 0,1090
Nein	0/9 (0,0)	NE [NE; NE]	0/1 (0,0)	NE [NE; NE]	NE

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SMQ: Standardised MedDRA Queries.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_tthep3smq_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 166.1.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal A1 (Erstlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Alter (p-Wert des Interaktionsterms: 0,1148)					
< 65 Jahre	36/62 (58,1)	14,0 [7,99; 19,79]	11/30 (36,7)	21,1 [8,98; NE]	1,51 [0,76; 2,98] 0,2317
≥ 65 Jahre	12/19 (63,2)	8,4 [1,38; NE]	1/10 (10,0)	NE [0,43; NE]	7,71 [0,98; 60,65] 0,0237
Anzahl betroffener Organe (p-Wert des Interaktionsterms: 0,7774)					
1	28/43 (65,1)	9,6 [6,64; 19,79]	8/26 (30,8)	21,1 [8,98; NE]	2,32 [1,05; 5,13] 0,0326
2	12/24 (50,0)	16,3 [5,95; NE]	1/5 (20,0)	NE [0,39; NE]	1,97 [0,25; 15,67] 0,5080
≥ 3	8/14 (57,1)	14,0 [1,71; NE]	3/9 (33,3)	NE [0,39; NE]	1,12 [0,28; 4,48] 0,8681
Art der Erkrankung (p-Wert des Interaktionsterms: 0,5442)					
Viszerale Metastasen	25/47 (53,2)	14,0 [7,40; 17,10]	7/21 (33,3)	21,1 [2,70; NE]	1,59 [0,67; 3,76] 0,2818
Nicht-viszerale Metastasen	23/34 (67,6)	10,2 [5,59; 19,96]	5/19 (26,3)	NE [8,98; NE]	2,44 [0,92; 6,45] 0,0644
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,4306)					
0	15/27 (55,6)	8,0 [2,53; 20,32]	6/14 (42,9)	14,1 [1,38; NE]	1,48 [0,57; 3,88] 0,4240
1	33/54 (61,1)	10,4 [8,02; 18,58]	6/26 (23,1)	NE [8,98; NE]	2,52 [1,05; 6,07] 0,0325
Land (p-Wert des Interaktionsterms: 0,9898)					
China	47/71 (66,2)	8,4 [6,58; 16,31]	12/33 (36,4)	21,1 [8,98; NE]	1,83 [0,96; 3,48] 0,0598
Andere	1/10 (10,0)	NE [7,40; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4795
Messbare Erkrankung zu Baseline (p-Wert des Interaktionsterms: 0,6169)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Ja	37/62 (59,7)	8,4 [7,40; 16,31]	8/26 (30,8)	21,1 [21,11; NE]	2,14 [0,98; 4,65] 0,0490
Nein	11/19 (57,9)	18,6 [6,64; NE]	4/14 (28,6)	14,1 [8,98; NE]	1,52 [0,48; 4,84] 0,4736
Progesteronrezeptorstatus (p-Wert des Interaktionsterms: 0,8351)					
Positiv	36/63 (57,1)	10,4 [6,58; 19,79]	9/30 (30,0)	21,1 [14,07; NE]	1,98 [0,95; 4,15] 0,0625
Negativ	12/18 (66,7)	10,2 [7,99; 17,10]	3/10 (30,0)	NE [0,49; NE]	2,18 [0,61; 7,82] 0,2193
Tumorgrad (p-Wert des Interaktionsterms: 0,7853)					
Hoch	4/11 (36,4)	9,6 [2,07; NE]	2/7 (28,6)	NE [0,39; NE]	1,06 [0,19; 5,80] 0,9496
Niedrig/mittel	17/31 (54,8)	18,6 [5,59; 20,32]	3/17 (17,6)	NE [NE; NE]	3,11 [0,90; 10,81] 0,0595
Unbekannt	27/39 (69,2)	8,3 [5,95; 16,11]	7/16 (43,8)	14,1 [0,79; NE]	1,67 [0,72; 3,85] 0,2266
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,7743)					
Ja	13/17 (76,5)	8,0 [1,78; 14,01]	2/10 (20,0)	NE [0,39; NE]	1,86 [0,40; 8,68] 0,4199
Nein	35/64 (54,7)	16,1 [8,02; 19,79]	10/30 (33,3)	21,1 [8,98; NE]	1,95 [0,95; 4,02] 0,0645
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,9888)					
Ja	45/72 (62,5)	10,2 [7,40; 17,10]	12/39 (30,8)	21,1 [8,98; NE]	1,92 [1,01; 3,64] 0,0432
Nein	3/9 (33,3)	8,0 [0,43; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3957

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SMQ: Standardised MedDRA Queries.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_tthep2smq_popa1_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Tabelle 166.2.2: Subgruppen - Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel für Studie MONARCH-plus - Postmenopausal B1 (Zweitlinie)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgruppe	**n/N (%)**	**Mediane Ereigniszeit[1]**	**n/N (%)**	**Mediane Ereigniszeit[1]**	**HR [95% KI] p-Wert[2]**
Anzahl vorangegangener endokriner Behandlungen (p-Wert des Interaktionsterms: 0,9749)					
Erstlinie	5/9 (55,6)	16,7 [0,82; NE]	2/5 (40,0)	NE [0,46; NE]	0,90 [0,16; 4,91] 0,8990
Zweitlinie	7/14 (50,0)	9,4 [2,07; NE]	4/8 (50,0)	NE [0,43; NE]	0,78 [0,23; 2,72] 0,7013
ECOG-PS zu Baseline (p-Wert des Interaktionsterms: 0,1906)					
0	4/8 (50,0)	16,7 [2,79; NE]	4/7 (57,1)	1,3 [0,43; NE]	0,30 [0,06; 1,43] 0,1133
1	8/15 (53,3)	15,1 [1,45; NE]	2/6 (33,3)	NE [0,85; NE]	1,61 [0,34; 7,60] 0,5430
Vorangegangene antiöstrogene Therapie (p-Wert des Interaktionsterms: 0,6772)					
Ja	6/12 (50,0)	21,7 [1,58; NE]	4/7 (57,1)	1,8 [0,43; NE]	0,65 [0,18; 2,33] 0,5016
Nein	6/11 (54,5)	16,7 [1,41; NE]	2/6 (33,3)	NE [0,46; NE]	1,03 [0,20; 5,37] 0,9765
Vorherige (neo-)adjuvante Chemotherapie (p-Wert des Interaktionsterms: 0,6366)					
Ja	7/11 (63,6)	9,4 [1,58; NE]	3/6 (50,0)	NE [0,43; NE]	0,96 [0,24; 3,81] 0,9580
Nein	5/12 (41,7)	16,7 [1,45; NE]	3/7 (42,9)	NE [0,46; NE]	0,61 [0,13; 2,72] 0,5090

Datenschnitt: 18.05.2020, Safety-Population
1: In Monaten; 2: Aus Log-rank-Test
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; KI: Konfidenzintervall; n: Anzahl Patientinnen mit Ereignis; N: Gesamtzahl der Patientinnen in der Analyse; NE: Nicht errechenbar/nicht erreicht; RCT: Randomisierte kontrollierte Studie; SMQ: Standardised MedDRA Queries.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t_ttesub_tthep2smq_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 201.1.2: Subgroups: Time to adverse event according PT - Blood and lymphatic system disorders/Anaemia - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,9564)					
< 65 years	48/62 (77,4)	2,7 [1,51; 4,73]	6/30 (20,0)	NE [14,96; NE]	7,05 [2,97; 16,71] <,0001
≥ 65 years	14/19 (73,7)	1,8 [1,05; 14,86]	2/10 (20,0)	NE [2,56; NE]	5,53 [1,25; 24,49] 0,0118
Organs involved (p-value of the interaction term: 0,2868)					
1	33/43 (76,7)	1,8 [1,41; 7,56]	4/26 (15,4)	NE [14,96; NE]	9,97 [3,47; 28,64] <,0001
2	18/24 (75,0)	3,2 [1,41; 8,42]	2/5 (40,0)	16,7 [1,41; NE]	2,31 [0,53; 10,17] 0,2534
≥ 3	11/14 (78,6)	2,2 [0,85; 6,48]	2/9 (22,2)	NE [4,27; NE]	4,95 [1,09; 22,47] 0,0219
Nature of disease (p-value of the interaction term: 0,6820)					
Visceral	34/47 (72,3)	2,8 [1,41; 6,51]	4/21 (19,0)	NE [6,71; NE]	5,39 [1,90; 15,28] 0,0004
Non-visceral	28/34 (82,4)	1,8 [1,41; 2,79]	4/19 (21,1)	NE [14,96; NE]	8,68 [2,97; 25,42] <,0001
ECOG-PS at Baseline (p-value of the interaction term: 0,7428)					
0	18/27 (66,7)	2,8 [1,05; 15,81]	2/14 (14,3)	NE [14,96; NE]	7,57 [1,74; 32,94] 0,0016
1	44/54 (81,5)	2,7 [1,51; 4,73]	6/26 (23,1)	NE [6,71; NE]	6,17 [2,59; 14,68] <,0001
Measurable disease at baseline (p-value of the interaction term: 0,9212)					
Yes	47/62 (75,8)	2,8 [1,41; 6,41]	5/26 (19,2)	NE [16,73; NE]	6,75 [2,64; 17,28] <,0001
No	15/19 (78,9)	1,7 [1,05; 4,50]	3/14 (21,4)	NE [4,60; NE]	6,98 [2,00; 24,38] 0,0005
Progesterone receptor (p-value of the interaction term: 0,8898)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Positive	46/63 (73,0)	2,7 [1,41; 4,73]	6/30 (20,0)	NE [14,96; NE]	6,58 [2,78; 15,57] <,0001
Negative	16/18 (88,9)	2,7 [0,85; 6,41]	2/10 (20,0)	NE [1,81; NE]	6,01 [1,37; 26,30] 0,0067
Sensitivity against endocrine therapy (p-value of the interaction term: 0,3151)					
Primary resistance	23/30 (76,7)	1,8 [1,38; 6,41]	2/17 (11,8)	NE [NE; NE]	9,92 [2,33; 42,17] 0,0001
Secondary resistance	39/51 (76,5)	2,8 [1,51; 6,51]	6/23 (26,1)	NE [6,71; NE]	5,30 [2,22; 12,66] <,0001
Tumor grade (p-value of the interaction term: 0,9418)					
High	8/11 (72,7)	1,4 [0,82; NE]	1/7 (14,3)	NE [1,41; NE]	7,27 [0,90; 58,53] 0,0285
Low/intermediate	22/31 (71,0)	2,8 [1,41; 6,48]	3/17 (17,6)	NE [6,71; NE]	6,98 [2,04; 23,93] 0,0004
Unknown	32/39 (82,1)	2,7 [1,08; 6,51]	4/16 (25,0)	NE [4,60; NE]	6,00 [2,10; 17,13] 0,0002
Previous anti-estrogene therapy (p-value of the interaction term: 0,3846)					
Yes	13/17 (76,5)	1,7 [0,89; 6,41]	1/10 (10,0)	NE [16,73; NE]	13,95 [1,81; 107,76] 0,0011
No	49/64 (76,6)	2,7 [1,41; 5,69]	7/30 (23,3)	NE [6,71; NE]	5,66 [2,52; 12,71] <,0001
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 0,9858)					
Yes	57/72 (79,2)	2,7 [1,51; 3,68]	8/39 (20,5)	NE [14,96; NE]	6,53 [3,09; 13,81] <,0001
No	5/9 (55,6)	13,6 [1,05; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2246

Data cut-off: 18.05.2020, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t201_aesocpt_tte_sub_popa1_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 202.1.2: Subgroups: Time to adverse event according PT - Investigations/Blood creatinine increased - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,9999)					
< 65 years	15/62 (24,2)	25,2 [23,08; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0092
≥ 65 years	7/19 (36,8)	22,1 [2,79; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0507
Organs involved (p-value of the interaction term: 1,0000)					
1	14/43 (32,6)	25,2 [22,13; NE]	0/26 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0029
2	5/24 (20,8)	NE [13,78; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3698
≥ 3	3/14 (21,4)	NE [17,85; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2981
Nature of disease (p-value of the interaction term: 0,9999)					
Visceral	11/47 (23,4)	NE [23,08; NE]	0/21 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0244
Non-visceral	11/34 (32,4)	25,2 [17,85; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0305
ECOG-PS at Baseline (p-value of the interaction term: 0,9999)					
0	5/27 (18,5)	NE [23,08; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0897
1	17/54 (31,5)	25,2 [17,85; NE]	0/26 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0091
Country (p-value of the interaction term: 1,0000)					
China	20/71 (28,2)	NE [22,13; NE]	0/33 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0026
Other	2/10 (20,0)	23,1 [2,79; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4028
Measurable disease at baseline (p-value of the interaction term: 0,9999)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	16/62 (25,8)	25,2 [17,85; NE]	0/26 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0072
No	6/19 (31,6)	NE [14,17; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0764
Progesterone receptor (p-value of the interaction term: 1,0000)					
Positive	18/63 (28,6)	25,2 [22,13; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0034
Negative	4/18 (22,2)	NE [9,21; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1766
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9999)					
Primary resistance	6/30 (20,0)	NE [14,17; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1189
Secondary resistance	16/51 (31,4)	25,2 [22,13; NE]	0/23 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0090
Previous anti-estrogene therapy (p-value of the interaction term: 0,9998)					
Yes	9/17 (52,9)	23,1 [2,76; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0367
No	13/64 (20,3)	NE [22,13; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0145
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 1,0000)					
Yes	20/72 (27,8)	NE [22,13; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0018
No	2/9 (22,2)	25,2 [0,49; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,7389

Data cut-off: 18.05.2020, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t202_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 203.1.2: Subgroups: Time to adverse event according PT - Gastrointestinal disorders/Diarrhoea - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,5982)					
< 65 years	51/62 (82,3)	0,2 [0,13; 0,49]	4/30 (13,3)	NE [NE; NE]	12,35 [4,43; 34,44] <,0001
≥ 65 years	16/19 (84,2)	0,3 [0,13; 0,46]	2/10 (20,0)	NE [0,13; NE]	7,73 [1,75; 34,15] 0,0016
Organs involved (p-value of the interaction term: 0,9999)					
1	37/43 (86,0)	0,2 [0,13; 0,36]	6/26 (23,1)	NE [10,72; NE]	8,21 [3,40; 19,85] <,0001
2	17/24 (70,8)	0,2 [0,13; 6,67]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0193
≥ 3	13/14 (92,9)	0,3 [0,07; 0,56]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
Nature of disease (p-value of the interaction term: 0,0629)					
Visceral	41/47 (87,2)	0,2 [0,13; 0,36]	1/21 (4,8)	NE [10,72; NE]	41,07 [5,61; 300,69] <,0001
Non-visceral	26/34 (76,5)	0,3 [0,16; 0,95]	5/19 (26,3)	NE [4,67; NE]	5,04 [1,91; 13,27] 0,0003
ECOG-PS at Baseline (p-value of the interaction term: 0,2525)					
0	24/27 (88,9)	0,2 [0,10; 0,53]	1/14 (7,1)	NE [NE; NE]	28,51 [3,80; 213,74] <,0001
1	43/54 (79,6)	0,2 [0,16; 0,46]	5/26 (19,2)	NE [10,72; NE]	7,58 [2,98; 19,29] <,0001
Measurable disease at baseline (p-value of the interaction term: 0,3508)					
Yes	52/62 (83,9)	0,3 [0,13; 0,46]	3/26 (11,5)	NE [10,72; NE]	15,71 [4,87; 50,71] <,0001
No	15/19 (78,9)	0,2 [0,10; 1,05]	3/14 (21,4)	NE [4,67; NE]	6,21 [1,76; 21,90] 0,0013
Progesterone receptor (p-value of the interaction term: 0,8656)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Positive	54/63 (85,7)	0,2 [0,16; 0,36]	5/30 (16,7)	NE [10,72; NE]	10,80 [4,27; 27,28] <,0001
Negative	13/18 (72,2)	0,3 [0,10; 1,61]	1/10 (10,0)	NE [1,84; NE]	12,95 [1,67; 100,10] 0,0017
Sensitivity against endocrine therapy (p-value of the interaction term: 0,4329)					
Primary resistance	23/30 (76,7)	0,2 [0,13; 1,25]	3/17 (17,6)	NE [4,67; NE]	7,03 [2,10; 23,60] 0,0002
Secondary resistance	44/51 (86,3)	0,2 [0,13; 0,39]	3/23 (13,0)	NE [10,72; NE]	15,30 [4,68; 50,05] <,0001
Tumor grade (p-value of the interaction term: 0,3657)					
High	10/11 (90,9)	0,3 [0,13; 0,99]	2/7 (28,6)	NE [0,03; NE]	6,85 [1,40; 33,65] 0,0078
Low/intermediate	27/31 (87,1)	0,2 [0,10; 0,72]	1/17 (5,9)	NE [10,72; NE]	30,80 [4,15; 228,49] <,0001
Unknown	30/39 (76,9)	0,3 [0,13; 0,49]	3/16 (18,8)	NE [4,67; NE]	7,55 [2,28; 24,96] 0,0001
Previous anti-estrogene therapy (p-value of the interaction term: 0,5850)					
Yes	15/17 (88,2)	0,2 [0,07; 0,99]	1/10 (10,0)	NE [0,13; NE]	17,57 [2,28; 135,12] 0,0002
No	52/64 (81,3)	0,2 [0,16; 0,39]	5/30 (16,7)	NE [10,72; NE]	9,67 [3,83; 24,41] <,0001
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 0,9880)					
Yes	58/72 (80,6)	0,2 [0,16; 0,39]	6/39 (15,4)	NE [NE; NE]	10,01 [4,29; 23,38] <,0001
No	9/9 (100,0)	0,1 [0,03; 0,46]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0957

Data cut-off: 18.05.2020, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t203_aesocpt_tte_sub_popa1_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 204.1.2: Subgroups: Time to adverse event according PT - Investigations/Lymphocyte count decreased - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,9927)					
< 65 years	15/62 (24,2)	NE [25,02; NE]	1/30 (3,3)	NE [NE; NE]	6,38 [0,84; 48,35] 0,0395
≥ 65 years	6/19 (31,6)	NE [10,98; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0838
Organs involved (p-value of the interaction term: 1,0000)					
1	11/43 (25,6)	NE [25,02; NE]	1/26 (3,8)	NE [NE; NE]	6,27 [0,81; 48,59] 0,0442
2	7/24 (29,2)	NE [10,98; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2496
≥ 3	3/14 (21,4)	NE [8,32; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2134
Nature of disease (p-value of the interaction term: 0,9900)					
Visceral	10/47 (21,3)	NE [14,93; NE]	0/21 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0425
Non-visceral	11/34 (32,4)	NE [10,98; NE]	1/19 (5,3)	NE [NE; NE]	5,15 [0,66; 40,10] 0,0809
ECOG-PS at Baseline (p-value of the interaction term: 0,9919)					
0	10/27 (37,0)	9,2 [7,99; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0122
1	11/54 (20,4)	NE [NE; NE]	1/26 (3,8)	NE [NE; NE]	4,31 [0,55; 33,61] 0,1291
Country (p-value of the interaction term: 0,9911)					
China	18/71 (25,4)	NE [25,02; NE]	1/33 (3,0)	NE [NE; NE]	7,32 [0,98; 54,94] 0,0232
Other	3/10 (30,0)	NE [0,85; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1163
Measurable disease at baseline (p-value of the interaction term: 0,9921)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	16/62 (25,8)	NE [18,08; NE]	0/26 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0110
No	5/19 (26,3)	NE [8,22; NE]	1/14 (7,1)	NE [NE; NE]	2,97 [0,34; 25,90] 0,3019
Progesterone receptor (p-value of the interaction term: 0,9916)					
Positive	15/63 (23,8)	NE [25,02; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0107
Negative	6/18 (33,3)	NE [7,99; NE]	1/10 (10,0)	NE [1,78; NE]	2,74 [0,32; 23,17] 0,3358
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9914)					
Primary resistance	6/30 (20,0)	25,0 [25,02; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0646
Secondary resistance	15/51 (29,4)	NE [14,93; NE]	1/23 (4,3)	NE [NE; NE]	6,71 [0,89; 50,86] 0,0328
Tumor grade (p-value of the interaction term: 1,0000)					
High	3/11 (27,3)	NE [1,05; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1984
Low/intermediate	10/31 (32,3)	NE [10,98; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0319
Unknown	8/39 (20,5)	NE [18,08; NE]	1/16 (6,3)	NE [NE; NE]	3,19 [0,40; 25,53] 0,2478
Previous anti-estrogene therapy (p-value of the interaction term: 0,9930)					
Yes	5/17 (29,4)	NE [7,99; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1698
No	16/64 (25,0)	NE [25,02; NE]	1/30 (3,3)	NE [NE; NE]	7,18 [0,95; 54,18] 0,0254
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 0,9933)					
Yes	19/72 (26,4)	NE [25,02; NE]	1/39 (2,6)	NE [NE; NE]	8,91 [1,19; 66,69] 0,0100
No	2/9 (22,2)	8,0 [1,05; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4380

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 18.05.2020, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.					

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t204_aesocpt_tte_sub_popa1_2.rtf
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/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 205.1.2: Subgroups: Time to adverse event according PT - Investigations/Neutrophil count decreased - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,9823)					
< 65 years	53/62 (85,5)	0,9 [0,85; 0,89]	6/30 (20,0)	NE [NE; NE]	9,50 [4,02; 22,48] <,0001
≥ 65 years	15/19 (78,9)	0,9 [0,49; 0,92]	2/10 (20,0)	NE [4,27; NE]	7,71 [1,74; 34,24] 0,0018
Organs involved (p-value of the interaction term: 0,9815)					
1	34/43 (79,1)	0,9 [0,82; 1,45]	6/26 (23,1)	NE [5,85; NE]	6,65 [2,76; 16,05] <,0001
2	22/24 (91,7)	0,9 [0,46; 0,92]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0014
≥ 3	12/14 (85,7)	0,9 [0,49; 0,92]	2/9 (22,2)	NE [4,27; NE]	8,38 [1,83; 38,28] 0,0014
Nature of disease (p-value of the interaction term: 0,1458)					
Visceral	39/47 (83,0)	0,9 [0,85; 0,89]	6/21 (28,6)	NE [4,27; NE]	5,70 [2,39; 13,57] <,0001
Non-visceral	29/34 (85,3)	0,9 [0,79; 0,92]	2/19 (10,5)	NE [NE; NE]	18,12 [4,22; 77,85] <,0001
ECOG-PS at Baseline (p-value of the interaction term: 0,3121)					
0	21/27 (77,8)	0,9 [0,82; 0,89]	4/14 (28,6)	NE [3,65; NE]	4,87 [1,65; 14,40] 0,0021
1	47/54 (87,0)	0,9 [0,82; 0,92]	4/26 (15,4)	NE [5,85; NE]	12,94 [4,61; 36,31] <,0001
Country (p-value of the interaction term: 0,3332)					
China	64/71 (90,1)	0,9 [0,82; 0,89]	7/33 (21,2)	NE [NE; NE]	10,46 [4,72; 23,14] <,0001
Other	4/10 (40,0)	8,3 [0,49; NE]	1/7 (14,3)	NE [5,85; NE]	3,27 [0,36; 29,35] 0,2622
Measurable disease at baseline (p-value of the interaction term: 0,1853)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	52/62 (83,9)	0,9 [0,85; 0,89]	7/26 (26,9)	NE [4,31; NE]	6,33 [2,85; 14,07] <,0001
No	16/19 (84,2)	0,9 [0,39; 1,78]	1/14 (7,1)	NE [NE; NE]	25,76 [3,36; 197,34] <,0001
Progesterone receptor (p-value of the interaction term: 0,4100)					
Positive	51/63 (81,0)	0,9 [0,82; 0,89]	5/30 (16,7)	NE [NE; NE]	10,28 [4,06; 26,00] <,0001
Negative	17/18 (94,4)	0,9 [0,82; 1,02]	3/10 (30,0)	NE [0,39; NE]	7,03 [1,99; 24,86] 0,0007
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9007)					
Primary resistance	24/30 (80,0)	0,9 [0,82; 1,45]	3/17 (17,6)	NE [3,65; NE]	8,65 [2,58; 28,98] <,0001
Secondary resistance	44/51 (86,3)	0,9 [0,82; 0,89]	5/23 (21,7)	NE [5,85; NE]	9,31 [3,61; 24,00] <,0001
Tumor grade (p-value of the interaction term: 0,9696)					
High	8/11 (72,7)	0,9 [0,49; NE]	1/7 (14,3)	NE [0,39; NE]	6,75 [0,84; 54,40] 0,0384
Low/intermediate	24/31 (77,4)	0,9 [0,82; 1,45]	3/17 (17,6)	NE [5,85; NE]	8,31 [2,47; 27,93] <,0001
Unknown	36/39 (92,3)	0,9 [0,79; 0,89]	4/16 (25,0)	NE [3,65; NE]	10,67 [3,70; 30,79] <,0001
Previous anti-estrogene therapy (p-value of the interaction term: 0,2981)					
Yes	16/17 (94,1)	0,9 [0,43; 0,92]	1/10 (10,0)	NE [3,02; NE]	21,75 [2,84; 166,88] <,0001
No	52/64 (81,3)	0,9 [0,82; 0,89]	7/30 (23,3)	NE [4,31; NE]	7,10 [3,19; 15,80] <,0001
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 0,9874)					
Yes	63/72 (87,5)	0,9 [0,85; 0,89]	8/39 (20,5)	NE [NE; NE]	9,53 [4,52; 20,10] <,0001
No	5/9 (55,6)	0,9 [0,43; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3838

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 18.05.2020, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.					

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t205_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 206.1.2: Subgroups: Time to adverse event according PT - General disorders and administration site conditions/Pain - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,9910)					
< 65 years	7/62 (11,3)	NE [NE; NE]	6/30 (20,0)	NE [14,14; NE]	0,41 [0,14; 1,24] 0,1046
≥ 65 years	0/19 (0,0)	NE [NE; NE]	4/10 (40,0)	12,5 [0,49; NE]	0,00 [0,00; NE] 0,0021
Organs involved (p-value of the interaction term: 0,9707)					
1	3/43 (7,0)	NE [NE; NE]	8/26 (30,8)	22,4 [12,46; NE]	0,17 [0,04; 0,65] 0,0032
2	3/24 (12,5)	NE [18,54; NE]	2/5 (40,0)	NE [2,60; NE]	0,32 [0,05; 1,94] 0,1940
≥ 3	1/14 (7,1)	NE [10,68; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,6831
Nature of disease (p-value of the interaction term: 0,2577)					
Visceral	4/47 (8,5)	NE [NE; NE]	3/21 (14,3)	NE [12,46; NE]	0,52 [0,12; 2,37] 0,3935
Non-visceral	3/34 (8,8)	NE [NE; NE]	7/19 (36,8)	NE [2,89; NE]	0,17 [0,04; 0,68] 0,0045
ECOG-PS at Baseline (p-value of the interaction term: 0,7781)					
0	1/27 (3,7)	NE [NE; NE]	3/14 (21,4)	22,4 [14,14; NE]	0,19 [0,02; 1,88] 0,1156
1	6/54 (11,1)	NE [NE; NE]	7/26 (26,9)	NE [12,46; NE]	0,26 [0,09; 0,81] 0,0124
Country (p-value of the interaction term: 0,6713)					
China	6/71 (8,5)	NE [NE; NE]	7/33 (21,2)	NE [14,14; NE]	0,31 [0,10; 0,93] 0,0267
Other	1/10 (10,0)	NE [10,68; NE]	3/7 (42,9)	12,5 [0,49; NE]	0,22 [0,02; 2,16] 0,1566
Measurable disease at baseline (p-value of the interaction term: 0,1660)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	6/62 (9,7)	NE [NE; NE]	5/26 (19,2)	NE [12,46; NE]	0,42 [0,13; 1,39] 0,1423
No	1/19 (5,3)	NE [NE; NE]	5/14 (35,7)	14,1 [1,15; NE]	0,10 [0,01; 0,93] 0,0153
Progesterone receptor (p-value of the interaction term: 0,3699)					
Positive	4/63 (6,3)	NE [NE; NE]	7/30 (23,3)	22,4 [12,46; NE]	0,19 [0,05; 0,65] 0,0032
Negative	3/18 (16,7)	NE [18,54; NE]	3/10 (30,0)	NE [0,92; NE]	0,46 [0,09; 2,34] 0,3413
Sensitivity against endocrine therapy (p-value of the interaction term: 0,0685)					
Primary resistance	4/30 (13,3)	NE [18,54; NE]	2/17 (11,8)	NE [22,42; NE]	0,90 [0,16; 5,19] 0,9070
Secondary resistance	3/51 (5,9)	NE [NE; NE]	8/23 (34,8)	14,1 [4,01; NE]	0,13 [0,03; 0,50] 0,0005
Tumor grade (p-value of the interaction term: 0,2820)					
High	0/11 (0,0)	NE [NE; NE]	2/7 (28,6)	NE [1,15; NE]	0,00 [0,00; NE] 0,0535
Low/intermediate	1/31 (3,2)	NE [NE; NE]	4/17 (23,5)	12,5 [4,01; NE]	0,06 [0,01; 0,57] 0,0018
Unknown	6/39 (15,4)	NE [NE; NE]	4/16 (25,0)	NE [14,14; NE]	0,63 [0,18; 2,23] 0,4675
Previous anti-estrogene therapy (p-value of the interaction term: 0,6778)					
Yes	2/17 (11,8)	NE [18,54; NE]	2/10 (20,0)	NE [0,49; NE]	0,46 [0,06; 3,36] 0,4326
No	5/64 (7,8)	NE [NE; NE]	8/30 (26,7)	22,4 [12,46; NE]	0,22 [0,07; 0,68] 0,0041
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 0,9922)					
Yes	6/72 (8,3)	NE [NE; NE]	10/39 (25,6)	22,4 [12,46; NE]	0,22 [0,08; 0,63] 0,0019
No	1/9 (11,1)	13,4 [NE; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3173

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 18.05.2020, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.					

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t206_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 207.1.2: Subgroups: Time to adverse event according PT - Investigations/Platelet count decreased - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,5625)					
< 65 years	24/62 (38,7)	21,8 [8,58; NE]	4/30 (13,3)	NE [NE; NE]	3,21 [1,11; 9,27] 0,0226
≥ 65 years	10/19 (52,6)	11,2 [0,82; NE]	1/10 (10,0)	NE [1,41; NE]	6,91 [0,88; 54,16] 0,0327
Organs involved (p-value of the interaction term: 0,9418)					
1	16/43 (37,2)	NE [9,24; NE]	4/26 (15,4)	NE [NE; NE]	2,95 [0,98; 8,82] 0,0437
2	11/24 (45,8)	16,3 [1,45; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1110
≥ 3	7/14 (50,0)	8,6 [0,85; NE]	1/9 (11,1)	NE [0,85; NE]	4,40 [0,54; 36,23] 0,1283
Nature of disease (p-value of the interaction term: 0,6696)					
Visceral	19/47 (40,4)	NE [5,49; NE]	2/21 (9,5)	NE [NE; NE]	4,81 [1,12; 20,67] 0,0192
Non-visceral	15/34 (44,1)	20,7 [8,58; NE]	3/19 (15,8)	NE [NE; NE]	3,18 [0,92; 11,00] 0,0544
ECOG-PS at Baseline (p-value of the interaction term: 0,8809)					
0	12/27 (44,4)	9,2 [0,85; NE]	2/14 (14,3)	NE [4,54; NE]	4,13 [0,92; 18,50] 0,0455
1	22/54 (40,7)	21,8 [11,21; NE]	3/26 (11,5)	NE [NE; NE]	3,80 [1,14; 12,71] 0,0200
Country (p-value of the interaction term: 0,9916)					
China	32/71 (45,1)	20,7 [6,44; NE]	5/33 (15,2)	NE [NE; NE]	3,55 [1,38; 9,12] 0,0050
Other	2/10 (20,0)	NE [1,45; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2424
Measurable disease at baseline (p-value of the interaction term: 0,5682)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	27/62 (43,5)	16,3 [6,44; NE]	3/26 (11,5)	NE [NE; NE]	4,44 [1,34; 14,67] 0,0074
No	7/19 (36,8)	NE [0,82; NE]	2/14 (14,3)	NE [NE; NE]	2,68 [0,55; 13,03] 0,2051
Progesterone receptor (p-value of the interaction term: 0,2729)					
Positive	24/63 (38,1)	NE [9,24; NE]	2/30 (6,7)	NE [NE; NE]	6,61 [1,56; 28,01] 0,0030
Negative	10/18 (55,6)	16,3 [0,85; NE]	3/10 (30,0)	NE [1,81; NE]	2,40 [0,64; 8,94] 0,1801
Sensitivity against endocrine therapy (p-value of the interaction term: 0,9856)					
Primary resistance	12/30 (40,0)	NE [5,49; NE]	2/17 (11,8)	NE [NE; NE]	3,64 [0,81; 16,34] 0,0706
Secondary resistance	22/51 (43,1)	20,7 [9,24; NE]	3/23 (13,0)	NE [NE; NE]	4,07 [1,22; 13,60] 0,0138
Tumor grade (p-value of the interaction term: 0,4037)					
High	4/11 (36,4)	NE [0,49; NE]	2/7 (28,6)	4,5 [1,41; NE]	1,43 [0,26; 7,91] 0,6959
Low/intermediate	12/31 (38,7)	NE [8,58; NE]	1/17 (5,9)	NE [NE; NE]	6,67 [0,87; 51,38] 0,0349
Unknown	18/39 (46,2)	20,7 [0,92; NE]	2/16 (12,5)	NE [NE; NE]	4,77 [1,10; 20,64] 0,0212
Previous anti-estrogene therapy (p-value of the interaction term: 0,5253)					
Yes	10/17 (58,8)	8,6 [0,82; NE]	1/10 (10,0)	NE [0,85; NE]	6,41 [0,82; 50,32] 0,0417
No	24/64 (37,5)	NE [11,21; NE]	4/30 (13,3)	NE [NE; NE]	3,27 [1,13; 9,43] 0,0208
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 0,9902)					
Yes	32/72 (44,4)	20,7 [8,58; NE]	5/39 (12,8)	NE [NE; NE]	3,92 [1,53; 10,08] 0,0022
No	2/9 (22,2)	NE [0,49; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,6270

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 18.05.2020, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.					

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t207_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 208.1.2: Subgroups: Time to adverse event according PT - Investigations/Weight decreased - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Country (p-value of the interaction term: 0,9978)					
China	11/71 (15,5)	NE [NE; NE]	0/33 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0346
Other	0/10 (0,0)	NE [NE; NE]	0/7 (0,0)	NE [NE; NE]	NE
Previous anti-estrogene therapy (p-value of the interaction term: 0,9998)					
Yes	1/17 (5,9)	NE [NE; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4227
No	10/64 (15,6)	NE [NE; NE]	0/30 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0413
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 1,0000)					
Yes	10/72 (13,9)	NE [NE; NE]	0/39 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0295
No	1/9 (11,1)	NE [7,69; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,5637

Data cut-off: 18.05.2020, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 209.1.2: Subgroups: Time to adverse event according PT - Investigations/White blood cell count decreased - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,4938)					
< 65 years	54/62 (87,1)	0,9 [0,79; 0,92]	8/30 (26,7)	NE [4,31; NE]	7,01 [3,28; 14,96] <,0001
≥ 65 years	16/19 (84,2)	0,9 [0,49; 0,85]	2/10 (20,0)	NE [4,27; NE]	18,30 [2,39; 140,30] 0,0002
Organs involved (p-value of the interaction term: 0,7051)					
1	35/43 (81,4)	0,9 [0,82; 1,41]	7/26 (26,9)	NE [15,98; NE]	6,57 [2,82; 15,29] <,0001
2	22/24 (91,7)	0,9 [0,43; 0,92]	1/5 (20,0)	NE [0,89; NE]	9,50 [1,27; 71,09] 0,0069
≥ 3	13/14 (92,9)	0,5 [0,39; 0,92]	2/9 (22,2)	NE [4,27; NE]	11,47 [2,48; 52,97] 0,0002
Nature of disease (p-value of the interaction term: 0,2135)					
Visceral	41/47 (87,2)	0,9 [0,49; 0,89]	7/21 (33,3)	16,0 [4,27; NE]	5,65 [2,50; 12,73] <,0001
Non-visceral	29/34 (85,3)	0,9 [0,79; 0,89]	3/19 (15,8)	NE [NE; NE]	11,00 [3,28; 36,94] <,0001
ECOG-PS at Baseline (p-value of the interaction term: 0,1193)					
0	22/27 (81,5)	0,9 [0,79; 1,41]	5/14 (35,7)	NE [1,81; NE]	4,10 [1,52; 11,00] 0,0028
1	48/54 (88,9)	0,9 [0,56; 0,89]	5/26 (19,2)	NE [15,98; NE]	14,25 [5,04; 40,28] <,0001
Country (p-value of the interaction term: 0,3292)					
China	66/71 (93,0)	0,9 [0,79; 0,85]	9/33 (27,3)	NE [4,31; NE]	8,84 [4,31; 18,10] <,0001
Other	4/10 (40,0)	18,5 [0,49; NE]	1/7 (14,3)	16,0 [NE; NE]	2,50 [0,26; 24,16] 0,4115
Measurable disease at baseline (p-value of the interaction term: 0,3128)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	54/62 (87,1)	0,9 [0,79; 0,89]	8/26 (30,8)	NE [4,27; NE]	6,52 [3,04; 14,00] <,0001
No	16/19 (84,2)	0,9 [0,43; 1,41]	2/14 (14,3)	NE [NE; NE]	13,22 [2,92; 59,91] <,0001
Progesterone receptor (p-value of the interaction term: 0,5885)					
Positive	53/63 (84,1)	0,9 [0,79; 0,89]	7/30 (23,3)	NE [15,98; NE]	8,61 [3,82; 19,39] <,0001
Negative	17/18 (94,4)	0,9 [0,79; 1,41]	3/10 (30,0)	NE [0,39; NE]	6,23 [1,78; 21,84] 0,0013
Sensitivity against endocrine therapy (p-value of the interaction term: 0,5195)					
Primary resistance	26/30 (86,7)	0,9 [0,82; 0,89]	3/17 (17,6)	NE [3,65; NE]	10,67 [3,19; 35,70] <,0001
Secondary resistance	44/51 (86,3)	0,9 [0,49; 0,92]	7/23 (30,4)	NE [4,31; NE]	6,72 [2,93; 15,38] <,0001
Tumor grade (p-value of the interaction term: 0,8976)					
High	9/11 (81,8)	0,9 [0,43; 0,89]	2/7 (28,6)	NE [0,39; NE]	4,79 [1,00; 22,87] 0,0371
Low/intermediate	24/31 (77,4)	0,9 [0,82; 1,41]	3/17 (17,6)	NE [15,98; NE]	9,31 [2,74; 31,55] <,0001
Unknown	37/39 (94,9)	0,9 [0,46; 0,92]	5/16 (31,3)	NE [3,65; NE]	9,13 [3,46; 24,08] <,0001
Previous anti-estrogene therapy (p-value of the interaction term: 0,9885)					
Yes	15/17 (88,2)	0,9 [0,43; 1,74]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] <,0001
No	55/64 (85,9)	0,9 [0,82; 0,89]	10/30 (33,3)	NE [4,27; NE]	6,31 [3,06; 13,00] <,0001
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 0,9863)					
Yes	65/72 (90,3)	0,9 [0,79; 0,85]	10/39 (25,6)	NE [15,98; NE]	8,66 [4,36; 17,19] <,0001
No	5/9 (55,6)	1,4 [0,43; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3880

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 18.05.2020, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.					

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t209_aesocpt_tte_sub_popa1_2.rtf
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/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 210.1.2: Subgroups: Time to adverse event according SOC - Blood and lymphatic system disorders - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,9465)					
< 65 years	48/62 (77,4)	2,7 [1,51; 4,34]	6/30 (20,0)	NE [14,96; NE]	7,09 [2,99; 16,79] <,0001
≥ 65 years	14/19 (73,7)	1,8 [1,05; 14,86]	2/10 (20,0)	NE [2,56; NE]	5,53 [1,25; 24,49] 0,0118
Organs involved (p-value of the interaction term: 0,2949)					
1	33/43 (76,7)	1,8 [1,41; 7,56]	4/26 (15,4)	NE [14,96; NE]	9,97 [3,47; 28,64] <,0001
2	18/24 (75,0)	3,2 [1,41; 6,51]	2/5 (40,0)	16,7 [1,41; NE]	2,31 [0,53; 10,18] 0,2524
≥ 3	11/14 (78,6)	2,2 [0,85; 6,48]	2/9 (22,2)	NE [4,27; NE]	4,95 [1,09; 22,47] 0,0219
Nature of disease (p-value of the interaction term: 0,6577)					
Visceral	34/47 (72,3)	2,8 [1,41; 6,51]	4/21 (19,0)	NE [6,71; NE]	5,39 [1,90; 15,28] 0,0004
Non-visceral	28/34 (82,4)	1,8 [1,41; 2,79]	4/19 (21,1)	NE [14,96; NE]	8,77 [3,00; 25,68] <,0001
ECOG-PS at Baseline (p-value of the interaction term: 0,7483)					
0	18/27 (66,7)	2,8 [1,05; 15,81]	2/14 (14,3)	NE [14,96; NE]	7,57 [1,74; 32,94] 0,0016
1	44/54 (81,5)	2,7 [1,51; 4,50]	6/26 (23,1)	NE [6,71; NE]	6,21 [2,61; 14,76] <,0001
Measurable disease at baseline (p-value of the interaction term: 0,9219)					
Yes	47/62 (75,8)	2,8 [1,41; 5,69]	5/26 (19,2)	NE [16,73; NE]	6,76 [2,64; 17,30] <,0001
No	15/19 (78,9)	1,7 [1,05; 4,50]	3/14 (21,4)	NE [4,60; NE]	6,98 [2,00; 24,38] 0,0005
Progesterone receptor (p-value of the interaction term: 0,8649)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Positive	46/63 (73,0)	2,7 [1,41; 4,73]	6/30 (20,0)	NE [14,96; NE]	6,58 [2,78; 15,57] <,0001
Negative	16/18 (88,9)	2,7 [0,85; 5,69]	2/10 (20,0)	NE [1,81; NE]	6,02 [1,38; 26,22] 0,0064
Sensitivity against endocrine therapy (p-value of the interaction term: 0,3244)					
Primary resistance	23/30 (76,7)	1,8 [1,38; 6,41]	2/17 (11,8)	NE [NE; NE]	9,92 [2,33; 42,17] 0,0001
Secondary resistance	39/51 (76,5)	2,8 [1,51; 5,69]	6/23 (26,1)	NE [6,71; NE]	5,34 [2,24; 12,76] <,0001
Tumor grade (p-value of the interaction term: 0,9470)					
High	8/11 (72,7)	1,4 [0,82; NE]	1/7 (14,3)	NE [1,41; NE]	7,27 [0,90; 58,53] 0,0285
Low/intermediate	22/31 (71,0)	2,8 [1,41; 6,48]	3/17 (17,6)	NE [6,71; NE]	6,98 [2,04; 23,93] 0,0004
Unknown	32/39 (82,1)	2,7 [1,08; 6,41]	4/16 (25,0)	NE [4,60; NE]	6,03 [2,11; 17,22] 0,0001
Previous anti-estrogene therapy (p-value of the interaction term: 0,3808)					
Yes	13/17 (76,5)	1,7 [0,89; 6,41]	1/10 (10,0)	NE [16,73; NE]	13,95 [1,81; 107,76] 0,0011
No	49/64 (76,6)	2,7 [1,41; 4,73]	7/30 (23,3)	NE [6,71; NE]	5,66 [2,52; 12,70] <,0001
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 0,9858)					
Yes	57/72 (79,2)	2,7 [1,51; 3,68]	8/39 (20,5)	NE [14,96; NE]	6,57 [3,11; 13,87] <,0001
No	5/9 (55,6)	13,6 [1,05; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2246

Data cut-off: 18.05.2020, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t210_aesocpt_tte_sub_popa1_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 211.1.2: Subgroups: Time to adverse event according SOC - Gastrointestinal disorders - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,6680)					
< 65 years	52/62 (83,9)	0,2 [0,10; 0,26]	9/30 (30,0)	NE [2,79; NE]	5,55 [2,71; 11,38] <,0001
≥ 65 years	18/19 (94,7)	0,2 [0,10; 0,30]	5/10 (50,0)	13,1 [0,13; NE]	5,24 [1,86; 14,81] 0,0007
Organs involved (p-value of the interaction term: 0,7165)					
1	39/43 (90,7)	0,2 [0,10; 0,20]	12/26 (46,2)	13,1 [1,87; NE]	4,97 [2,52; 9,79] <,0001
2	18/24 (75,0)	0,2 [0,10; 3,95]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0160
≥ 3	13/14 (92,9)	0,3 [0,07; 0,56]	2/9 (22,2)	NE [1,68; NE]	13,79 [2,88; 66,08] <,0001
Nature of disease (p-value of the interaction term: 0,1594)					
Visceral	42/47 (89,4)	0,2 [0,10; 0,26]	5/21 (23,8)	NE [4,83; NE]	8,17 [3,19; 20,93] <,0001
Non-visceral	28/34 (82,4)	0,2 [0,10; 0,36]	9/19 (47,4)	13,1 [1,84; NE]	3,43 [1,60; 7,38] 0,0009
ECOG-PS at Baseline (p-value of the interaction term: 0,4387)					
0	25/27 (92,6)	0,2 [0,10; 0,53]	4/14 (28,6)	NE [1,78; NE]	8,07 [2,75; 23,68] <,0001
1	45/54 (83,3)	0,2 [0,10; 0,26]	10/26 (38,5)	NE [2,79; NE]	4,21 [2,10; 8,46] <,0001
Country (p-value of the interaction term: 0,2796)					
China	60/71 (84,5)	0,2 [0,13; 0,26]	10/33 (30,3)	NE [13,05; NE]	6,12 [3,10; 12,08] <,0001
Other	10/10 (100,0)	0,3 [0,03; 0,89]	4/7 (57,1)	4,8 [0,03; NE]	4,48 [1,17; 17,21] 0,0188
Measurable disease at baseline (p-value of the interaction term: 0,7262)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	53/62 (85,5)	0,2 [0,13; 0,36]	9/26 (34,6)	NE [4,83; NE]	5,25 [2,56; 10,76] <,0001
No	17/19 (89,5)	0,2 [0,03; 0,20]	5/14 (35,7)	NE [1,15; NE]	5,73 [2,03; 16,18] 0,0003
Progesterone receptor (p-value of the interaction term: 0,3470)					
Positive	56/63 (88,9)	0,2 [0,10; 0,20]	10/30 (33,3)	NE [2,79; NE]	6,02 [3,02; 11,98] <,0001
Negative	14/18 (77,8)	0,3 [0,10; 1,61]	4/10 (40,0)	13,1 [0,36; NE]	3,45 [1,12; 10,60] 0,0218
Sensitivity against endocrine therapy (p-value of the interaction term: 0,8148)					
Primary resistance	25/30 (83,3)	0,2 [0,13; 0,89]	5/17 (29,4)	NE [0,59; NE]	4,52 [1,72; 11,90] 0,0007
Secondary resistance	45/51 (88,2)	0,2 [0,10; 0,26]	9/23 (39,1)	NE [2,10; NE]	6,05 [2,89; 12,67] <,0001
Tumor grade (p-value of the interaction term: 0,4231)					
High	11/11 (100,0)	0,2 [0,07; 0,30]	5/7 (71,4)	1,8 [0,03; NE]	4,32 [1,27; 14,65] 0,0127
Low/intermediate	29/31 (93,5)	0,1 [0,07; 0,26]	5/17 (29,4)	NE [2,10; NE]	7,61 [2,88; 20,12] <,0001
Unknown	30/39 (76,9)	0,2 [0,10; 0,49]	4/16 (25,0)	NE [2,79; NE]	5,57 [1,95; 15,93] 0,0003
Previous anti-estrogene therapy (p-value of the interaction term: 0,3233)					
Yes	15/17 (88,2)	0,1 [0,07; 0,53]	2/10 (20,0)	NE [0,03; NE]	7,79 [1,75; 34,72] 0,0015
No	55/64 (85,9)	0,2 [0,13; 0,26]	12/30 (40,0)	NE [2,10; NE]	4,70 [2,49; 8,87] <,0001
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 0,8079)					
Yes	61/72 (84,7)	0,2 [0,13; 0,26]	13/39 (33,3)	NE [4,83; NE]	5,17 [2,81; 9,50] <,0001
No	9/9 (100,0)	0,1 [0,03; 0,46]	1/1 (100,0)	13,1 [NE; NE]	>100 [0,00; NE] 0,0911

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 18.05.2020, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.					

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t211_aesocpt_tte_sub_popa1_2.rtf
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/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 212.1.2: Subgroups: Time to adverse event according SOC - Investigations - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,2739)					
< 65 years	56/62 (90,3)	0,5 [0,43; 0,85]	15/30 (50,0)	5,5 [1,78; NE]	3,82 [2,10; 6,94] <,0001
≥ 65 years	18/19 (94,7)	0,5 [0,39; 0,85]	4/10 (40,0)	NE [0,43; NE]	7,45 [2,34; 23,74] 0,0002
Organs involved (p-value of the interaction term: 0,5623)					
1	38/43 (88,4)	0,8 [0,43; 0,85]	13/26 (50,0)	14,1 [1,51; NE]	3,85 [1,98; 7,50] <,0001
2	23/24 (95,8)	0,5 [0,39; 0,85]	1/5 (20,0)	NE [0,39; NE]	10,04 [1,33; 75,67] 0,0054
≥ 3	13/14 (92,9)	0,4 [0,39; 0,92]	5/9 (55,6)	4,3 [0,39; NE]	4,03 [1,37; 11,82] 0,0071
Nature of disease (p-value of the interaction term: 0,1792)					
Visceral	43/47 (91,5)	0,5 [0,43; 0,85]	12/21 (57,1)	4,3 [1,51; NE]	3,24 [1,68; 6,24] 0,0002
Non-visceral	31/34 (91,2)	0,5 [0,39; 0,85]	7/19 (36,8)	NE [1,41; NE]	6,28 [2,56; 15,40] <,0001
ECOG-PS at Baseline (p-value of the interaction term: 0,6336)					
0	24/27 (88,9)	0,5 [0,39; 0,89]	7/14 (50,0)	14,1 [0,49; NE]	3,76 [1,52; 9,33] 0,0023
1	50/54 (92,6)	0,5 [0,43; 0,85]	12/26 (46,2)	5,9 [1,78; NE]	4,86 [2,52; 9,36] <,0001
Country (p-value of the interaction term: 0,9770)					
China	69/71 (97,2)	0,5 [0,43; 0,85]	18/33 (54,5)	4,3 [1,51; NE]	4,99 [2,85; 8,73] <,0001
Other	5/10 (50,0)	7,4 [0,03; NE]	1/7 (14,3)	NE [5,85; NE]	4,16 [0,48; 35,78] 0,1580
Measurable disease at baseline (p-value of the interaction term: 0,3186)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	58/62 (93,5)	0,8 [0,43; 0,85]	14/26 (53,8)	4,3 [1,51; NE]	3,64 [2,00; 6,63] <,0001
No	16/19 (84,2)	0,4 [0,39; 0,89]	5/14 (35,7)	14,1 [1,41; NE]	6,45 [2,10; 19,85] 0,0003
Progesterone receptor (p-value of the interaction term: 0,8150)					
Positive	56/63 (88,9)	0,5 [0,43; 0,85]	15/30 (50,0)	5,9 [3,02; NE]	4,19 [2,29; 7,66] <,0001
Negative	18/18 (100,0)	0,9 [0,43; 0,92]	4/10 (40,0)	NE [0,39; NE]	5,22 [1,72; 15,86] 0,0014
Sensitivity against endocrine therapy (p-value of the interaction term: 0,3262)					
Primary resistance	26/30 (86,7)	0,8 [0,46; 0,89]	8/17 (47,1)	3,6 [0,49; NE]	3,27 [1,41; 7,60] 0,0038
Secondary resistance	48/51 (94,1)	0,5 [0,43; 0,85]	11/23 (47,8)	5,9 [1,78; NE]	5,56 [2,80; 11,04] <,0001
Tumor grade (p-value of the interaction term: 0,8287)					
High	10/11 (90,9)	0,9 [0,39; 0,89]	4/7 (57,1)	1,4 [0,39; NE]	3,06 [0,90; 10,45] 0,0595
Low/intermediate	26/31 (83,9)	0,9 [0,43; 0,89]	6/17 (35,3)	NE [2,70; NE]	4,39 [1,79; 10,79] 0,0005
Unknown	38/39 (97,4)	0,4 [0,39; 0,85]	9/16 (56,3)	5,5 [0,79; NE]	6,09 [2,67; 13,87] <,0001
Previous anti-estrogene therapy (p-value of the interaction term: 0,3266)					
Yes	17/17 (100,0)	0,4 [0,39; 0,92]	3/10 (30,0)	NE [0,39; NE]	5,98 [1,72; 20,81] 0,0014
No	57/64 (89,1)	0,8 [0,46; 0,85]	16/30 (53,3)	5,5 [1,78; NE]	4,01 [2,23; 7,22] <,0001
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 0,9888)					
Yes	68/72 (94,4)	0,5 [0,43; 0,85]	19/39 (48,7)	5,9 [2,70; NE]	4,95 [2,89; 8,50] <,0001
No	6/9 (66,7)	0,9 [0,43; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1991

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 18.05.2020, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.					

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t212_aesocpt_tte_sub_popa1_2.rtf
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/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 213.1.2: Subgroups: Time to adverse event according SOC - Metabolism and nutrition disorders - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,1000)					
< 65 years	27/62 (43,5)	18,5 [12,10; NE]	8/30 (26,7)	NE [10,16; NE]	1,58 [0,71; 3,47] 0,2561
≥ 65 years	13/19 (68,4)	7,4 [1,08; NE]	1/10 (10,0)	NE [2,10; NE]	9,13 [1,18; 70,94] 0,0111
Organs involved (p-value of the interaction term: 0,2067)					
1	26/43 (60,5)	8,0 [3,65; 23,70]	5/26 (19,2)	NE [14,96; NE]	3,87 [1,48; 10,12] 0,0029
2	8/24 (33,3)	18,5 [5,79; NE]	1/5 (20,0)	NE [2,63; NE]	1,45 [0,18; 11,70] 0,7253
≥ 3	6/14 (42,9)	17,9 [1,51; NE]	3/9 (33,3)	NE [0,66; NE]	0,94 [0,22; 3,99] 0,9353
Nature of disease (p-value of the interaction term: 0,6385)					
Visceral	21/47 (44,7)	18,5 [5,79; NE]	5/21 (23,8)	NE [3,81; NE]	1,67 [0,63; 4,44] 0,3011
Non-visceral	19/34 (55,9)	14,5 [3,65; 24,16]	4/19 (21,1)	NE [10,16; NE]	2,65 [0,90; 7,84] 0,0661
ECOG-PS at Baseline (p-value of the interaction term: 0,8377)					
0	13/27 (48,1)	5,8 [3,48; NE]	4/14 (28,6)	NE [3,81; NE]	2,11 [0,69; 6,49] 0,1821
1	27/54 (50,0)	14,5 [7,63; 24,16]	5/26 (19,2)	NE [10,16; NE]	2,47 [0,95; 6,43] 0,0554
Country (p-value of the interaction term: 0,9728)					
China	34/71 (47,9)	17,9 [7,63; 24,16]	7/33 (21,2)	NE [14,96; NE]	2,43 [1,07; 5,51] 0,0279
Other	6/10 (60,0)	3,6 [0,07; NE]	2/7 (28,6)	NE [0,66; NE]	2,46 [0,49; 12,31] 0,2565
Measurable disease at baseline (p-value of the interaction term: 0,4625)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	28/62 (45,2)	17,9 [7,63; NE]	6/26 (23,1)	NE [NE; NE]	1,97 [0,80; 4,86] 0,1324
No	12/19 (63,2)	4,7 [1,15; 24,16]	3/14 (21,4)	NE [10,16; NE]	3,43 [0,96; 12,20] 0,0428
Progesterone receptor (p-value of the interaction term: 0,8062)					
Positive	32/63 (50,8)	13,5 [5,79; 24,16]	7/30 (23,3)	NE [10,16; NE]	2,41 [1,06; 5,48] 0,0306
Negative	8/18 (44,4)	14,5 [4,24; NE]	2/10 (20,0)	NE [1,51; NE]	1,79 [0,38; 8,49] 0,4552
Sensitivity against endocrine therapy (p-value of the interaction term: 0,4098)					
Primary resistance	15/30 (50,0)	12,1 [3,65; NE]	3/17 (17,6)	NE [10,16; NE]	2,99 [0,86; 10,35] 0,0698
Secondary resistance	25/51 (49,0)	17,9 [7,63; 26,73]	6/23 (26,1)	NE [14,96; NE]	1,84 [0,76; 4,49] 0,1724
Tumor grade (p-value of the interaction term: 0,9500)					
High	8/11 (72,7)	7,4 [0,95; NE]	2/7 (28,6)	NE [1,51; NE]	2,13 [0,44; 10,36] 0,3364
Low/intermediate	17/31 (54,8)	12,1 [2,89; NE]	4/17 (23,5)	NE [3,81; NE]	2,20 [0,73; 6,59] 0,1495
Unknown	15/39 (38,5)	18,5 [8,02; NE]	3/16 (18,8)	NE [10,16; NE]	2,42 [0,70; 8,38] 0,1497
Previous anti-estrogene therapy (p-value of the interaction term: 0,9868)					
Yes	10/17 (58,8)	18,5 [2,93; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0158
No	30/64 (46,9)	13,5 [7,36; NE]	9/30 (30,0)	NE [10,16; NE]	1,69 [0,80; 3,58] 0,1676
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 0,9868)					
Yes	34/72 (47,2)	17,9 [8,02; 26,73]	9/39 (23,1)	NE [14,96; NE]	2,06 [0,98; 4,30] 0,0506
No	6/9 (66,7)	7,6 [0,16; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1586

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 18.05.2020, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.					

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t213_aesocpt_tte_sub_popa1_2.rtf
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/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 214.1.2: Subgroups: Time to adverse event according SOC - Musculoskeletal and connective tissue disorders - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,8659)					
< 65 years	10/62 (16,1)	NE [NE; NE]	9/30 (30,0)	NE [7,56; NE]	0,41 [0,17; 1,02] 0,0478
≥ 65 years	3/19 (15,8)	NE [NE; NE]	3/10 (30,0)	NE [2,33; NE]	0,48 [0,10; 2,43] 0,3678
Organs involved (p-value of the interaction term: 0,6730)					
1	8/43 (18,6)	NE [NE; NE]	8/26 (30,8)	NE [6,54; NE]	0,50 [0,19; 1,33] 0,1553
2	4/24 (16,7)	NE [NE; NE]	2/5 (40,0)	3,0 [0,76; NE]	0,25 [0,04; 1,46] 0,0990
≥ 3	1/14 (7,1)	NE [NE; NE]	2/9 (22,2)	NE [1,41; NE]	0,27 [0,02; 3,06] 0,2604
Nature of disease (p-value of the interaction term: 0,7920)					
Visceral	8/47 (17,0)	NE [NE; NE]	7/21 (33,3)	13,8 [6,54; NE]	0,38 [0,13; 1,06] 0,0540
Non-visceral	5/34 (14,7)	NE [NE; NE]	5/19 (26,3)	NE [5,33; NE]	0,43 [0,12; 1,51] 0,1766
ECOG-PS at Baseline (p-value of the interaction term: 0,7389)					
0	4/27 (14,8)	NE [NE; NE]	5/14 (35,7)	13,8 [3,02; NE]	0,34 [0,09; 1,25] 0,0878
1	9/54 (16,7)	NE [NE; NE]	7/26 (26,9)	NE [6,54; NE]	0,45 [0,16; 1,23] 0,1108
Country (p-value of the interaction term: 0,9935)					
China	10/71 (14,1)	NE [NE; NE]	8/33 (24,2)	NE [13,81; NE]	0,44 [0,17; 1,13] 0,0794
Other	3/10 (30,0)	NE [0,03; NE]	4/7 (57,1)	7,6 [1,41; NE]	0,29 [0,05; 1,62] 0,1354
Measurable disease at baseline (p-value of the interaction term: 0,5665)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	11/62 (17,7)	NE [NE; NE]	8/26 (30,8)	14,0 [6,54; NE]	0,44 [0,18; 1,10] 0,0714
No	2/19 (10,5)	NE [NE; NE]	4/14 (28,6)	NE [3,42; NE]	0,34 [0,06; 1,86] 0,1909
Progesterone receptor (p-value of the interaction term: 0,9767)					
Positive	10/63 (15,9)	NE [NE; NE]	9/30 (30,0)	14,0 [6,54; NE]	0,40 [0,16; 0,99] 0,0408
Negative	3/18 (16,7)	NE [10,22; NE]	3/10 (30,0)	NE [0,26; NE]	0,40 [0,08; 2,02] 0,2512
Sensitivity against endocrine therapy (p-value of the interaction term: 0,6982)					
Primary resistance	7/30 (23,3)	NE [10,22; NE]	7/17 (41,2)	13,8 [1,41; NE]	0,35 [0,12; 1,03] 0,0476
Secondary resistance	6/51 (11,8)	NE [NE; NE]	5/23 (21,7)	NE [7,56; NE]	0,47 [0,14; 1,54] 0,2014
Tumor grade (p-value of the interaction term: 0,4325)					
High	2/11 (18,2)	NE [0,89; NE]	1/7 (14,3)	NE [0,76; NE]	1,19 [0,11; 13,10] 0,8890
Low/intermediate	8/31 (25,8)	NE [10,42; NE]	6/17 (35,3)	14,0 [3,02; NE]	0,49 [0,17; 1,43] 0,1818
Unknown	3/39 (7,7)	NE [NE; NE]	5/16 (31,3)	NE [5,33; NE]	0,21 [0,05; 0,89] 0,0194
Previous anti-estrogene therapy (p-value of the interaction term: 0,6109)					
Yes	2/17 (11,8)	NE [NE; NE]	3/10 (30,0)	NE [0,43; NE]	0,33 [0,05; 1,99] 0,2039
No	11/64 (17,2)	NE [NE; NE]	9/30 (30,0)	NE [7,56; NE]	0,46 [0,19; 1,12] 0,0804
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 0,9914)					
Yes	12/72 (16,7)	NE [NE; NE]	12/39 (30,8)	14,0 [7,56; NE]	0,39 [0,17; 0,88] 0,0182
No	1/9 (11,1)	NE [3,62; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,6831

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 18.05.2020, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.					

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t214_aesocpt_tte_sub_popa1_2.rtf
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Table 215.1.2: Subgroups: Time to adverse event with CTCAE grade >= 3 according PT - Investigations/Neutrophil count decreased - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,1499)					
< 65 years	25/62 (40,3)	20,0 [10,16; NE]	1/30 (3,3)	NE [NE; NE]	13,13 [1,78; 96,98] 0,0010
≥ 65 years	3/19 (15,8)	NE [18,31; NE]	1/10 (10,0)	NE [4,73; NE]	1,53 [0,16; 14,73] 0,7112
Organs involved (p-value of the interaction term: 0,9157)					
1	13/43 (30,2)	NE [14,73; NE]	1/26 (3,8)	NE [NE; NE]	7,77 [1,02; 59,45] 0,0194
2	8/24 (33,3)	NE [1,45; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1855
≥ 3	7/14 (50,0)	10,1 [0,89; NE]	1/9 (11,1)	NE [4,73; NE]	4,65 [0,56; 38,34] 0,1173
Nature of disease (p-value of the interaction term: 0,9915)					
Visceral	16/47 (34,0)	NE [10,13; NE]	2/21 (9,5)	NE [NE; NE]	3,77 [0,86; 16,46] 0,0585
Non-visceral	12/34 (35,3)	NE [11,18; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0122
ECOG-PS at Baseline (p-value of the interaction term: 0,8367)					
0	10/27 (37,0)	10,3 [9,90; NE]	1/14 (7,1)	NE [NE; NE]	6,79 [0,86; 53,34] 0,0351
1	18/54 (33,3)	NE [18,31; NE]	1/26 (3,8)	NE [NE; NE]	9,01 [1,20; 67,56] 0,0095
Country (p-value of the interaction term: 0,9898)					
China	26/71 (36,6)	NE [14,73; NE]	2/33 (6,1)	NE [NE; NE]	6,30 [1,49; 26,58] 0,0041
Other	2/10 (20,0)	NE [0,95; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,3127
Measurable disease at baseline (p-value of the interaction term: 0,9895)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	21/62 (33,9)	NE [10,16; NE]	2/26 (7,7)	NE [NE; NE]	4,82 [1,13; 20,58] 0,0189
No	7/19 (36,8)	NE [10,26; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0688
Progesterone receptor (p-value of the interaction term: 0,4827)					
Positive	22/63 (34,9)	NE [14,73; NE]	1/30 (3,3)	NE [NE; NE]	10,53 [1,42; 78,17] 0,0041
Negative	6/18 (33,3)	NE [0,89; NE]	1/10 (10,0)	NE [1,84; NE]	3,71 [0,45; 30,93] 0,1959
Sensitivity against endocrine therapy (p-value of the interaction term: 0,6367)					
Primary resistance	9/30 (30,0)	NE [9,90; NE]	1/17 (5,9)	NE [NE; NE]	5,18 [0,65; 41,07] 0,0831
Secondary resistance	19/51 (37,3)	20,0 [10,26; NE]	1/23 (4,3)	NE [NE; NE]	9,43 [1,26; 70,42] 0,0074
Tumor grade (p-value of the interaction term: 0,9999)					
High	5/11 (45,5)	11,2 [0,82; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0699
Low/intermediate	10/31 (32,3)	NE [10,16; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0275
Unknown	13/39 (33,3)	NE [10,13; NE]	2/16 (12,5)	NE [NE; NE]	3,09 [0,70; 13,70] 0,1191
Previous anti-estrogene therapy (p-value of the interaction term: 0,9914)					
Yes	8/17 (47,1)	11,2 [0,89; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0326
No	20/64 (31,3)	NE [18,31; NE]	2/30 (6,7)	NE [NE; NE]	4,79 [1,12; 20,54] 0,0197
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 0,9925)					
Yes	27/72 (37,5)	NE [11,18; NE]	2/39 (5,1)	NE [NE; NE]	7,29 [1,73; 30,70] 0,0015
No	1/9 (11,1)	NE [0,82; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,7389

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 18.05.2020, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.					

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t215_aesocpt_tte_sub_popa1_2.rtf
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/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 216.1.2: Subgroups: Time to adverse event with CTCAE grade >= 3 according PT - Investigations/White blood cell count decreased - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,5327)					
< 65 years	17/62 (27,4)	NE [26,73; NE]	1/30 (3,3)	NE [NE; NE]	7,61 [1,01; 57,24] 0,0201
≥ 65 years	6/19 (31,6)	NE [10,98; NE]	1/10 (10,0)	NE [4,73; NE]	2,88 [0,34; 24,04] 0,3066
Organs involved (p-value of the interaction term: 0,7602)					
1	10/43 (23,3)	NE [18,08; NE]	1/26 (3,8)	NE [NE; NE]	5,56 [0,71; 43,49] 0,0653
2	9/24 (37,5)	NE [10,98; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1813
≥ 3	4/14 (28,6)	NE [1,35; NE]	1/9 (11,1)	NE [4,73; NE]	2,12 [0,23; 19,44] 0,4963
Nature of disease (p-value of the interaction term: 0,9925)					
Visceral	13/47 (27,7)	NE [12,23; NE]	2/21 (9,5)	NE [NE; NE]	2,91 [0,65; 12,95] 0,1422
Non-visceral	10/34 (29,4)	NE [16,34; NE]	0/19 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0475
ECOG-PS at Baseline (p-value of the interaction term: 0,6280)					
0	6/27 (22,2)	26,7 [9,90; NE]	1/14 (7,1)	NE [NE; NE]	3,57 [0,43; 29,91] 0,2118
1	17/54 (31,5)	NE [18,08; NE]	1/26 (3,8)	NE [NE; NE]	7,17 [0,95; 54,00] 0,0257
Country (p-value of the interaction term: 0,9913)					
China	22/71 (31,0)	NE [18,08; NE]	2/33 (6,1)	NE [NE; NE]	4,71 [1,11; 20,06] 0,0209
Other	1/10 (10,0)	NE [1,45; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,4028
Measurable disease at baseline (p-value of the interaction term: 0,9907)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	17/62 (27,4)	26,7 [18,08; NE]	2/26 (7,7)	NE [NE; NE]	4,01 [0,92; 17,60] 0,0473
No	6/19 (31,6)	NE [6,61; NE]	0/14 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0800
Progesterone receptor (p-value of the interaction term: 0,3459)					
Positive	19/63 (30,2)	NE [18,08; NE]	1/30 (3,3)	NE [NE; NE]	8,21 [1,10; 61,42] 0,0143
Negative	4/18 (22,2)	NE [12,23; NE]	1/10 (10,0)	NE [1,81; NE]	2,43 [0,27; 21,72] 0,4129
Sensitivity against endocrine therapy (p-value of the interaction term: 0,5045)					
Primary resistance	6/30 (20,0)	NE [NE; NE]	1/17 (5,9)	NE [NE; NE]	2,94 [0,35; 24,83] 0,2987
Secondary resistance	17/51 (33,3)	26,7 [16,34; NE]	1/23 (4,3)	NE [NE; NE]	7,27 [0,97; 54,69] 0,0240
Tumor grade (p-value of the interaction term: 1,0000)					
High	4/11 (36,4)	16,3 [0,95; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1359
Low/intermediate	8/31 (25,8)	NE [26,73; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0855
Unknown	11/39 (28,2)	NE [12,23; NE]	2/16 (12,5)	NE [NE; NE]	2,38 [0,53; 10,73] 0,2453
Previous anti-estrogene therapy (p-value of the interaction term: 0,9921)					
Yes	5/17 (29,4)	26,7 [9,34; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1066
No	18/64 (28,1)	NE [18,08; NE]	2/30 (6,7)	NE [NE; NE]	3,97 [0,92; 17,12] 0,0462
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 0,9928)					
Yes	22/72 (30,6)	NE [18,08; NE]	2/39 (5,1)	NE [NE; NE]	5,17 [1,21; 22,04] 0,0134
No	1/9 (11,1)	NE [0,95; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,7389

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 18.05.2020, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.					

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 217.1.2: Subgroups: Time to adverse event with CTCAE grade >= 3 according SOC - Investigations - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (1st line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,9372)					
< 65 years	29/62 (46,8)	14,7 [6,44; NE]	3/30 (10,0)	NE [NE; NE]	5,36 [1,63; 17,59] 0,0019
≥ 65 years	9/19 (47,4)	18,1 [1,41; NE]	1/10 (10,0)	NE [4,73; NE]	5,06 [0,64; 40,10] 0,0878
Organs involved (p-value of the interaction term: 0,8195)					
1	18/43 (41,9)	18,1 [7,86; NE]	2/26 (7,7)	NE [NE; NE]	5,88 [1,36; 25,35] 0,0070
2	12/24 (50,0)	11,0 [0,92; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0951
≥ 3	8/14 (57,1)	1,6 [0,89; NE]	2/9 (22,2)	NE [1,38; NE]	3,41 [0,72; 16,15] 0,1004
Nature of disease (p-value of the interaction term: 0,3360)					
Visceral	20/47 (42,6)	NE [1,45; NE]	3/21 (14,3)	NE [4,73; NE]	3,56 [1,05; 11,99] 0,0293
Non-visceral	18/34 (52,9)	16,3 [6,61; NE]	1/19 (5,3)	NE [NE; NE]	10,66 [1,42; 79,82] 0,0040
ECOG-PS at Baseline (p-value of the interaction term: 0,7412)					
0	13/27 (48,1)	10,2 [3,58; NE]	2/14 (14,3)	NE [NE; NE]	4,76 [1,06; 21,45] 0,0259
1	25/54 (46,3)	18,1 [6,61; NE]	2/26 (7,7)	NE [NE; NE]	6,38 [1,51; 26,97] 0,0038
Country (p-value of the interaction term: 0,9912)					
China	35/71 (49,3)	16,3 [6,51; NE]	4/33 (12,1)	NE [NE; NE]	4,58 [1,63; 12,88] 0,0016
Other	3/10 (30,0)	10,2 [0,03; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,1606
Measurable disease at baseline (p-value of the interaction term: 0,8397)					

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Yes	29/62 (46,8)	14,7 [3,58; NE]	3/26 (11,5)	NE [NE; NE]	5,00 [1,52; 16,44] 0,0032
No	9/19 (47,4)	16,3 [6,51; NE]	1/14 (7,1)	NE [7,36; NE]	5,55 [0,70; 43,98] 0,0675
Progesterone receptor (p-value of the interaction term: 0,0741)					
Positive	30/63 (47,6)	14,7 [6,51; NE]	1/30 (3,3)	NE [NE; NE]	15,89 [2,17; 116,54] 0,0002
Negative	8/18 (44,4)	16,3 [0,89; NE]	3/10 (30,0)	NE [1,38; NE]	1,84 [0,49; 6,96] 0,3695
Sensitivity against endocrine therapy (p-value of the interaction term: 0,8195)					
Primary resistance	11/30 (36,7)	NE [3,58; NE]	1/17 (5,9)	NE [NE; NE]	7,02 [0,90; 54,47] 0,0299
Secondary resistance	27/51 (52,9)	11,0 [6,51; NE]	3/23 (13,0)	NE [NE; NE]	4,92 [1,49; 16,21] 0,0038
Tumor grade (p-value of the interaction term: 0,9978)					
High	5/11 (45,5)	16,3 [0,82; NE]	1/7 (14,3)	NE [1,38; NE]	3,30 [0,38; 28,43] 0,2521
Low/intermediate	15/31 (48,4)	11,0 [4,54; NE]	0/17 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0032
Unknown	18/39 (46,2)	18,1 [1,74; NE]	3/16 (18,8)	NE [7,36; NE]	3,00 [0,88; 10,20] 0,0649
Previous anti-estrogene therapy (p-value of the interaction term: 0,9888)					
Yes	9/17 (52,9)	10,2 [0,89; NE]	0/10 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0203
No	29/64 (45,3)	16,3 [6,51; NE]	4/30 (13,3)	NE [NE; NE]	3,81 [1,34; 10,84] 0,0070
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 0,9912)					
Yes	37/72 (51,4)	14,7 [6,44; NE]	4/39 (10,3)	NE [NE; NE]	5,52 [1,97; 15,51] 0,0003
No	1/9 (11,1)	NE [0,82; NE]	0/1 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,7389

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Data cut-off: 18.05.2020, Safety-Population 1: In months; 2: From Log-rank-Test Abbreviations: CI: confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.					

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t217_aesocpt_tte_sub_popa1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam,
/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 218.2.2: Subgroups: Time to adverse event according PT - Blood and lymphatic system disorders/Anaemia - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,7554)					
< 65 years	9/16 (56,3)	4,1 [1,41; NE]	1/9 (11,1)	NE [0,46; NE]	5,54 [0,70; 43,80] 0,0676
≥ 65 years	6/7 (85,7)	1,0 [0,49; 1,78]	1/4 (25,0)	NE [2,50; NE]	8,22 [0,93; 72,97] 0,0297
Previous anti-estrogene therapy (p-value of the interaction term: 0,9926)					
Yes	7/12 (58,3)	4,1 [0,99; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0190
No	8/11 (72,7)	1,5 [0,82; NE]	2/6 (33,3)	NE [0,46; NE]	3,13 [0,65; 15,09] 0,1352

Data cut-off: 18.05.2020, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t218_aesocpt_tte_sub_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 219.2.2: Subgroups: Time to adverse event according PT - Gastrointestinal disorders/Diarrhoea - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 1,0000)					
< 65 years	11/16 (68,8)	0,4 [0,13; NE]	0/9 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0018
≥ 65 years	4/7 (57,1)	0,5 [0,10; NE]	0/4 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0826
Prior lines of endocrine therapy (p-value of the interaction term: 0,9999)					
1 line	5/9 (55,6)	0,5 [0,13; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0533
2 lines	10/14 (71,4)	0,4 [0,10; NE]	0/8 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0025

Data cut-off: 18.05.2020, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/t219_aesocpt_tte_sub_popa2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 220.2.2: Subgroups: Time to adverse event according PT - Investigations/Neutrophil count decreased - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,9934)					
< 65 years	12/16 (75,0)	1,0 [0,46; 3,68]	2/9 (22,2)	NE [0,79; NE]	5,14 [1,14; 23,15] 0,0180
≥ 65 years	7/7 (100,0)	1,0 [0,82; 1,78]	0/4 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0080
Prior lines of endocrine therapy (p-value of the interaction term: 0,9939)					
1 line	6/9 (66,7)	1,0 [0,82; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0268
2 lines	13/14 (92,9)	0,9 [0,43; 1,78]	2/8 (25,0)	NE [0,79; NE]	7,69 [1,66; 35,66] 0,0028
ECOG-PS at Baseline (p-value of the interaction term: 0,5860)					
0	8/8 (100,0)	0,9 [0,39; 0,99]	1/7 (14,3)	NE [0,79; NE]	14,77 [1,75; 124,87] 0,0021
1	11/15 (73,3)	1,4 [0,82; 17,42]	1/6 (16,7)	NE [5,36; NE]	6,84 [0,88; 53,29] 0,0337
Previous anti-estrogene therapy (p-value of the interaction term: 0,9929)					
Yes	11/12 (91,7)	0,9 [0,39; 3,68]	2/7 (28,6)	NE [0,79; NE]	6,16 [1,31; 28,91] 0,0100
No	8/11 (72,7)	1,0 [0,82; NE]	0/6 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0084
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 0,5618)					
Yes	11/11 (100,0)	0,9 [0,39; 1,78]	1/6 (16,7)	NE [5,36; NE]	13,92 [1,74; 111,56] 0,0017
No	8/12 (66,7)	1,2 [0,85; NE]	1/7 (14,3)	NE [0,79; NE]	5,90 [0,73; 47,59] 0,0598

Data cut-off: 18.05.2020, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_gba_aesocpt_sub.sas
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/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 221.2.2: Subgroups: Time to adverse event according PT - Investigations/White blood cell count decreased - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,9933)					
< 65 years	12/16 (75,0)	1,0 [0,46; 3,68]	3/9 (33,3)	5,6 [0,79; NE]	3,45 [0,97; 12,32] 0,0440
≥ 65 years	6/7 (85,7)	1,4 [0,39; 1,91]	0/4 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0139
Prior lines of endocrine therapy (p-value of the interaction term: 0,9939)					
1 line	5/9 (55,6)	1,4 [0,39; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0535
2 lines	13/14 (92,9)	0,9 [0,43; 1,78]	3/8 (37,5)	NE [0,79; NE]	15,73 [1,97; 125,40] 0,0008
ECOG-PS at Baseline (p-value of the interaction term: 0,4564)					
0	7/8 (87,5)	1,0 [0,39; 1,41]	1/7 (14,3)	NE [0,79; NE]	10,02 [1,21; 83,24] 0,0103
1	11/15 (73,3)	1,4 [0,46; 3,68]	2/6 (33,3)	NE [5,36; NE]	3,95 [0,86; 18,07] 0,0573
Previous anti-estrogene therapy (p-value of the interaction term: 0,9930)					
Yes	11/12 (91,7)	0,9 [0,39; 1,91]	3/7 (42,9)	5,6 [0,79; NE]	12,57 [1,56; 101,14] 0,0030
No	7/11 (63,6)	1,4 [0,46; NE]	0/6 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0186
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 0,6759)					
Yes	11/11 (100,0)	0,9 [0,39; 1,78]	2/6 (33,3)	NE [5,36; NE]	>100 [0,00; NE] 0,0003
No	7/12 (58,3)	1,4 [0,82; NE]	1/7 (14,3)	NE [0,79; NE]	4,91 [0,60; 40,08] 0,1005

Data cut-off: 18.05.2020, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; PT: Preferred Term; RCT: randomized controlled trial.

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/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 222.2.2: Subgroups: Time to adverse event according SOC - Blood and lymphatic system disorders - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,7554)					
< 65 years	9/16 (56,3)	4,1 [1,41; NE]	1/9 (11,1)	NE [0,46; NE]	5,54 [0,70; 43,80] 0,0676
≥ 65 years	6/7 (85,7)	1,0 [0,49; 1,78]	1/4 (25,0)	NE [2,50; NE]	8,22 [0,93; 72,97] 0,0297
Previous anti-estrogene therapy (p-value of the interaction term: 0,9926)					
Yes	7/12 (58,3)	4,1 [0,99; NE]	0/7 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0190
No	8/11 (72,7)	1,5 [0,82; NE]	2/6 (33,3)	NE [0,46; NE]	3,13 [0,65; 15,09] 0,1352

Data cut-off: 18.05.2020, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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Table 223.2.2: Subgroups: Time to adverse event according SOC - Gastrointestinal disorders - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	n/N (%)	Median time to event[1]	n/N (%)	Median time to event[1]	HR [95% CI] p-value[2]
Age (p-value of the interaction term: 0,4015)					
< 65 years	13/16 (81,3)	0,2 [0,07; 0,72]	2/9 (22,2)	NE [0,39; NE]	6,73 [1,50; 30,15] 0,0041
≥ 65 years	5/7 (71,4)	0,5 [0,10; NE]	2/4 (50,0)	12,7 [1,87; NE]	5,13 [0,58; 45,23] 0,1043
Prior lines of endocrine therapy (p-value of the interaction term: 0,6119)					
1 line	7/9 (77,8)	0,3 [0,07; NE]	1/5 (20,0)	NE [1,87; NE]	7,72 [0,92; 64,77] 0,0285
2 lines	11/14 (78,6)	0,3 [0,07; 1,12]	3/8 (37,5)	12,7 [0,39; NE]	3,56 [0,99; 12,89] 0,0387
ECOG-PS at Baseline (p-value of the interaction term: 0,5300)					
0	7/8 (87,5)	0,1 [0,03; 1,35]	2/7 (28,6)	NE [0,66; NE]	7,22 [1,43; 36,35] 0,0068
1	11/15 (73,3)	0,5 [0,10; 1,12]	2/6 (33,3)	12,7 [0,39; NE]	3,56 [0,78; 16,19] 0,0801
Previous anti-estrogene therapy (p-value of the interaction term: 0,6057)					
Yes	10/12 (83,3)	0,1 [0,07; 1,12]	3/7 (42,9)	12,7 [0,39; NE]	3,51 [0,95; 12,93] 0,0447
No	8/11 (72,7)	0,5 [0,13; NE]	1/6 (16,7)	NE [1,87; NE]	7,93 [0,97; 64,67] 0,0232
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 0,4111)					
Yes	9/11 (81,8)	0,1 [0,07; 0,72]	3/6 (50,0)	12,7 [0,39; NE]	2,86 [0,76; 10,76] 0,1081
No	9/12 (75,0)	0,5 [0,13; NE]	1/7 (14,3)	NE [1,87; NE]	9,88 [1,23; 79,56] 0,0090

Data cut-off: 18.05.2020, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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/lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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Table 224.2.2: Subgroups: Time to adverse event according SOC - Investigations - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Age (p-value of the interaction term: 0,1138)					
< 65 years	15/16 (93,8)	0,7 [0,43; 0,99]	5/9 (55,6)	1,8 [0,43; NE]	1,95 [0,70; 5,47] 0,1963
≥ 65 years	7/7 (100,0)	0,5 [0,36; 0,89]	1/4 (25,0)	NE [0,85; NE]	8,78 [1,04; 74,11] 0,0168
Prior lines of endocrine therapy (p-value of the interaction term: 0,5589)					
1 line	8/9 (88,9)	0,9 [0,36; NE]	2/5 (40,0)	NE [0,46; NE]	2,14 [0,43; 10,68] 0,3370
2 lines	14/14 (100,0)	0,6 [0,39; 0,89]	4/8 (50,0)	NE [0,43; NE]	4,22 [1,33; 13,36] 0,0089
ECOG-PS at Baseline (p-value of the interaction term: 0,5872)					
0	8/8 (100,0)	0,5 [0,39; 0,92]	4/7 (57,1)	0,9 [0,43; NE]	2,48 [0,73; 8,38] 0,1260
1	14/15 (93,3)	0,8 [0,39; 1,58]	2/6 (33,3)	NE [0,85; NE]	4,88 [1,10; 21,69] 0,0207
Previous anti-estrogene therapy (p-value of the interaction term: 0,9349)					
Yes	12/12 (100,0)	0,6 [0,39; 0,89]	4/7 (57,1)	1,8 [0,43; NE]	3,40 [1,06; 10,88] 0,0305
No	10/11 (90,9)	0,9 [0,39; 3,72]	2/6 (33,3)	NE [0,46; NE]	3,64 [0,79; 16,74] 0,0719
Received prior (neo)adjuvant chemotherapy (p-value of the interaction term: 0,7079)					
Yes	11/11 (100,0)	0,5 [0,39; 0,99]	3/6 (50,0)	NE [0,43; NE]	4,16 [1,11; 15,51] 0,0223
No	11/12 (91,7)	0,7 [0,39; 3,72]	3/7 (42,9)	NE [0,46; NE]	2,82 [0,78; 10,17] 0,0951

Data cut-off: 18.05.2020, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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Table 225.2.2: Subgroups: Time to adverse event with CTCAE grade >= 3 according SOC - Investigations - from RCT with medical drug to be assessed for study MONARCH-plus - Safety Population - Postmenopausal (2nd line)

	Abemaciclib+Fulvestrant		Placebo+Fulvestrant		
Subgroup	**n/N (%)**	**Median time to event[1]**	**n/N (%)**	**Median time to event[1]**	**HR [95% CI] p-value[2]**
Prior lines of endocrine therapy (p-value of the interaction term: 0,9998)					
1 line	3/9 (33,3)	NE [0,95; NE]	0/5 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,2533
2 lines	10/14 (71,4)	6,4 [0,99; 13,25]	0/8 (0,0)	NE [NE; NE]	>100 [0,00; NE] 0,0068

Data cut-off: 18.05.2020, Safety-Population
1: In months; 2: From Log-rank-Test
Abbreviations: CI: confidence interval; CTCAE: Common Terminology Criteria for Adverse Events; HR: Hazard Ratio; n: number of patients with event; N: total number of patients in analysis; NE: Not evaluable/not reached; RCT: randomized controlled trial; SOC: System Organ Class.

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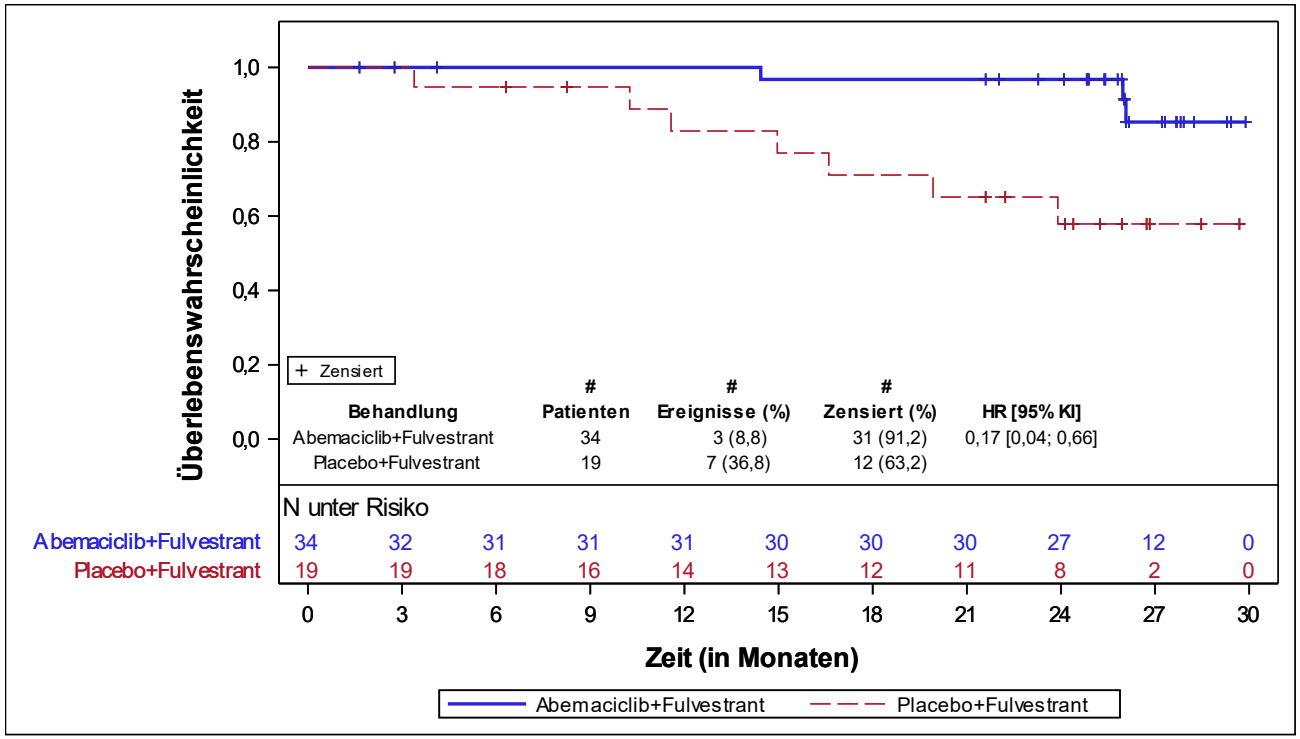
Abbildung 155 (Anhang): Kaplan-Meier-Kurven der Subgruppenanalysen (MONARCH-plus)

Abbildung 175: Kaplan-Meier-Kurven für Gesamtüberleben
Subgruppenanalyse für Art der Erkrankung = Nicht-viszerale Metastasen
ITT Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, ITT-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/f_gba_tte_km_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/f175_km_sub_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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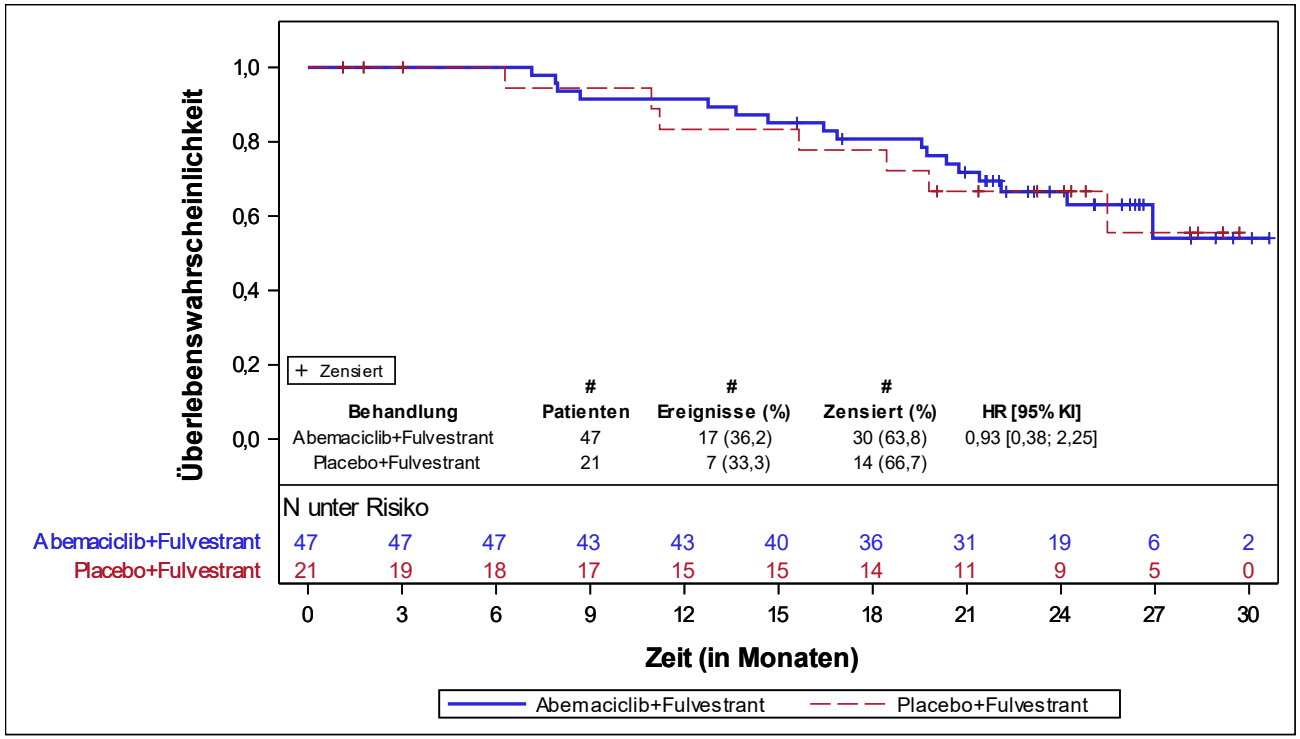
Abbildung 176: Kaplan-Meier-Kurven für Gesamtüberleben
Subgruppenanalyse für Art der Erkrankung = Viszerale Metastasen
ITT Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, ITT-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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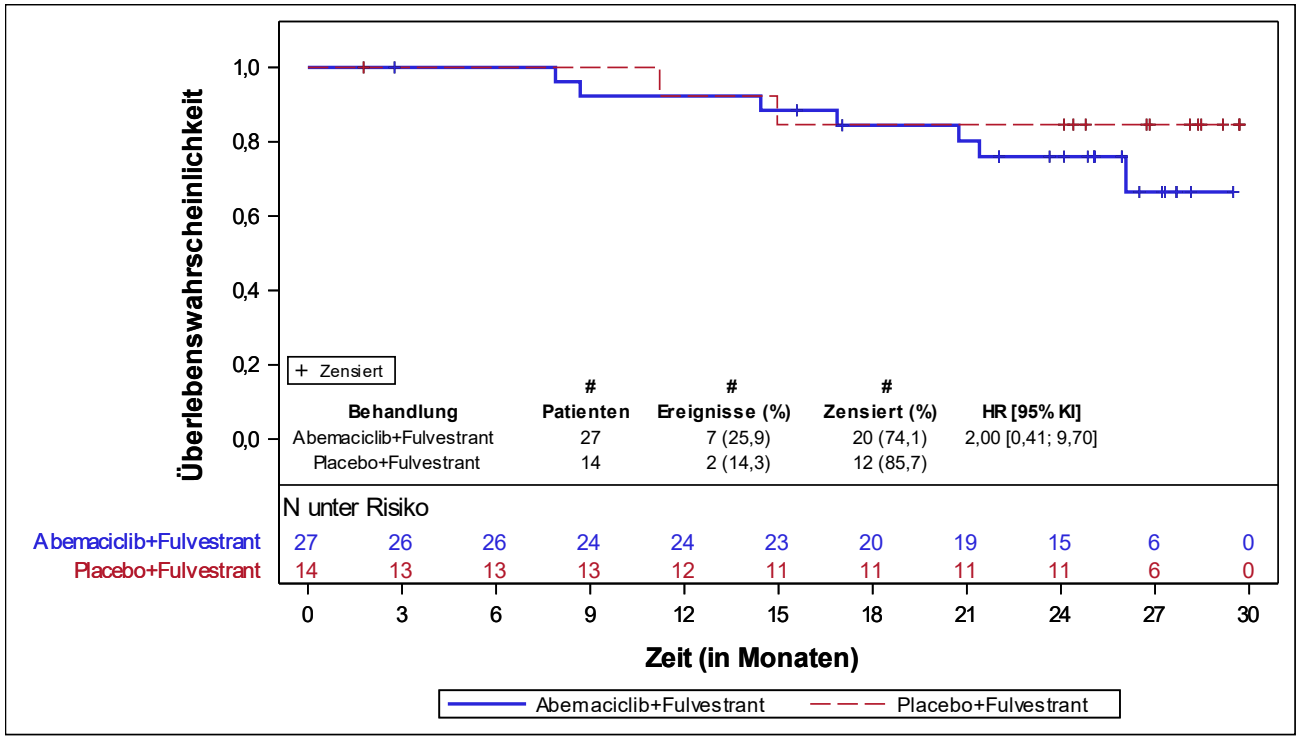
Abbildung 177: Kaplan-Meier-Kurven für Gesamtüberleben
Subgruppenanalyse für ECOG-PS zu Baseline = 0
ITT Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, ITT-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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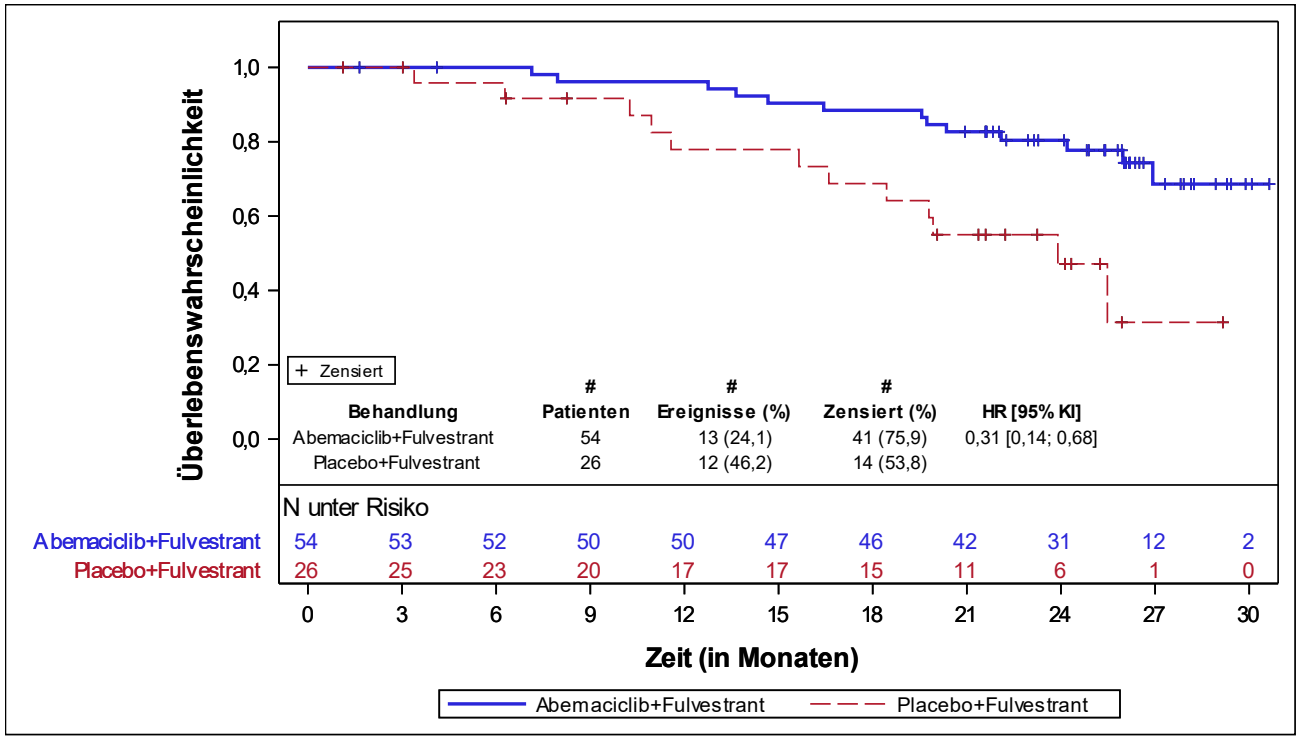
Abbildung 178: Kaplan-Meier-Kurven für Gesamtüberleben
Subgruppenanalyse für ECOG-PS zu Baseline = 1
ITT Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, ITT-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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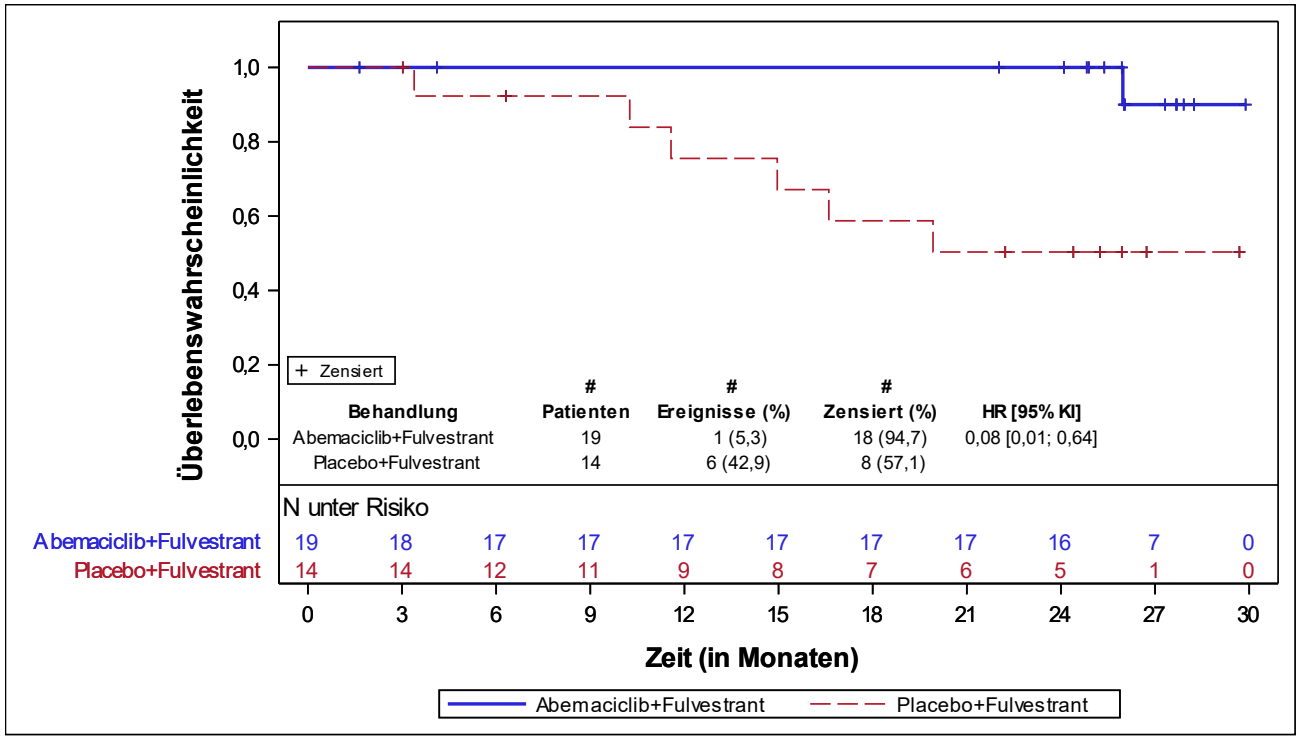
Abbildung 179: Kaplan-Meier-Kurven für Gesamtüberleben
Subgruppenanalyse für Messbare Erkrankung zu Baseline = Nein
ITT Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, ITT-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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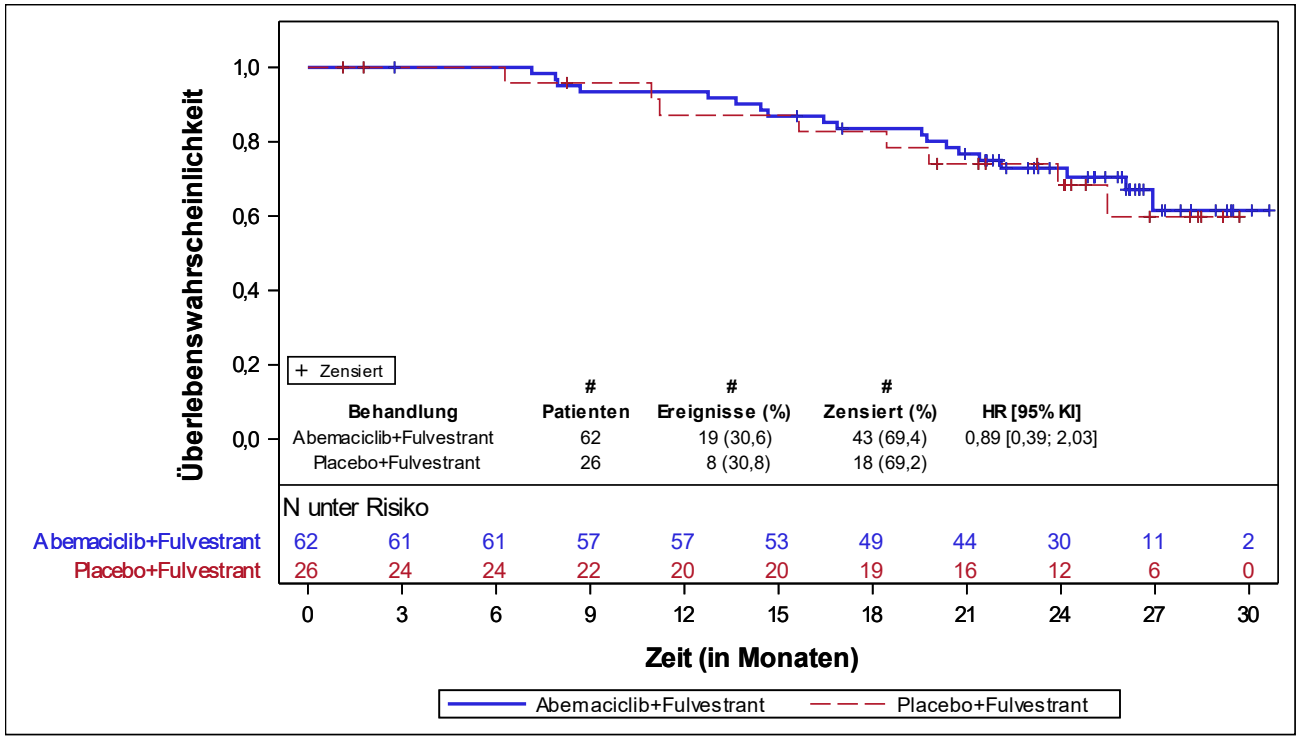
Abbildung 180: Kaplan-Meier-Kurven für Gesamtüberleben
Subgruppenanalyse für Messbare Erkrankung zu Baseline = Ja
ITT Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, ITT-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/f_gba_tte_km_sub.sas
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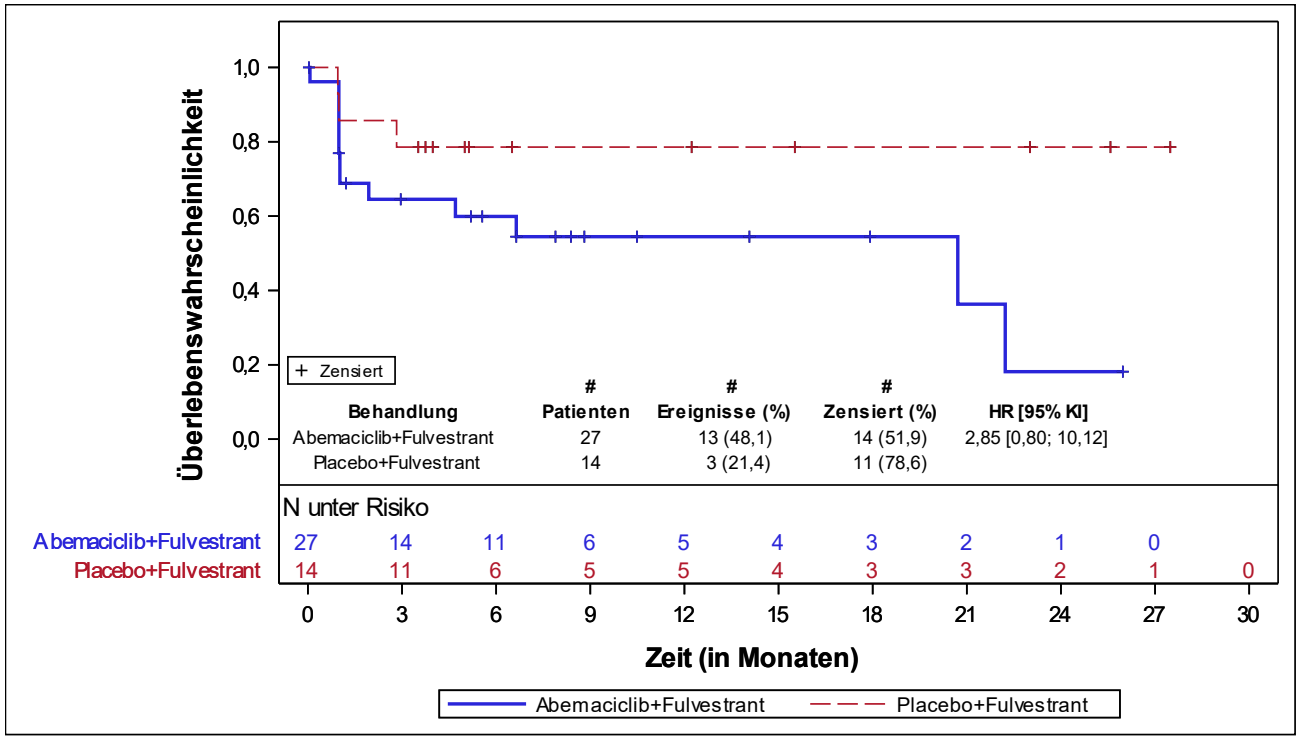
Abbildung 181: Kaplan-Meier-Kurven für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte), Subgruppenanalyse für ECOG-PS zu Baseline = 0
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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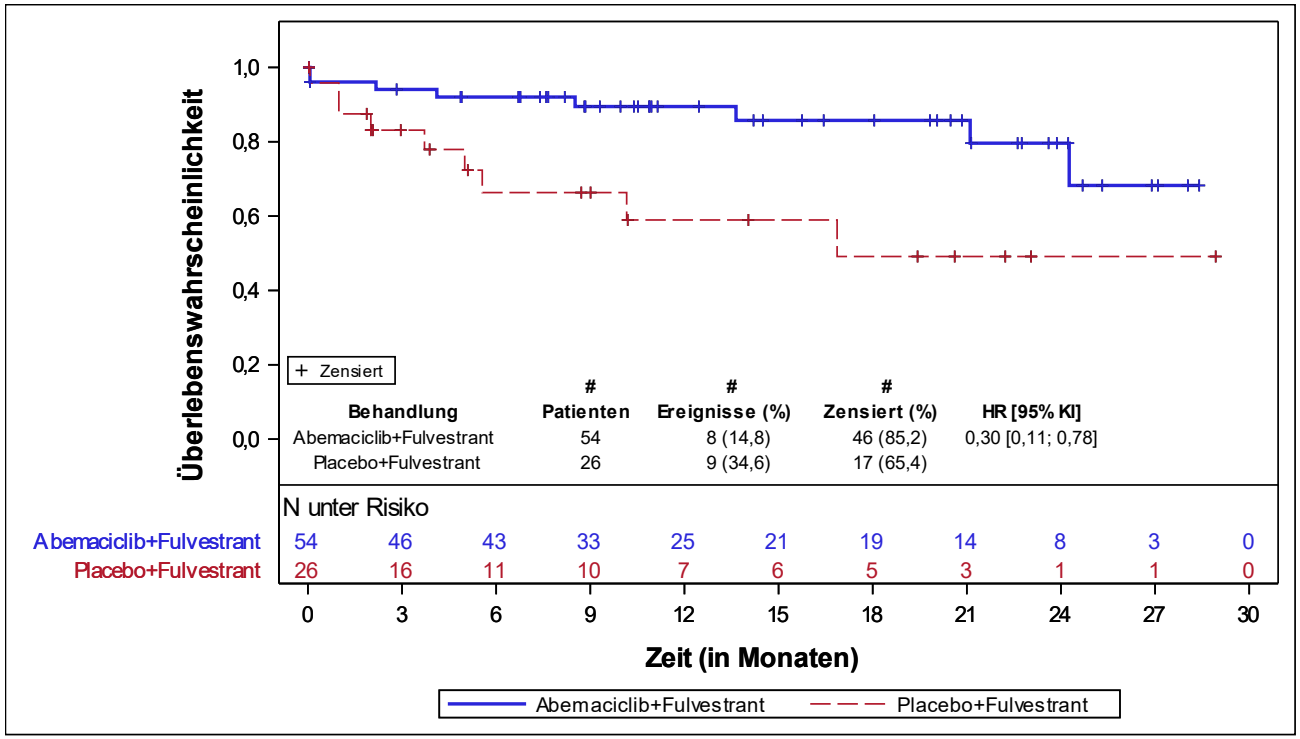
Abbildung 182: Kaplan-Meier-Kurven für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte), Subgruppenanalyse für ECOG-PS zu Baseline = 1
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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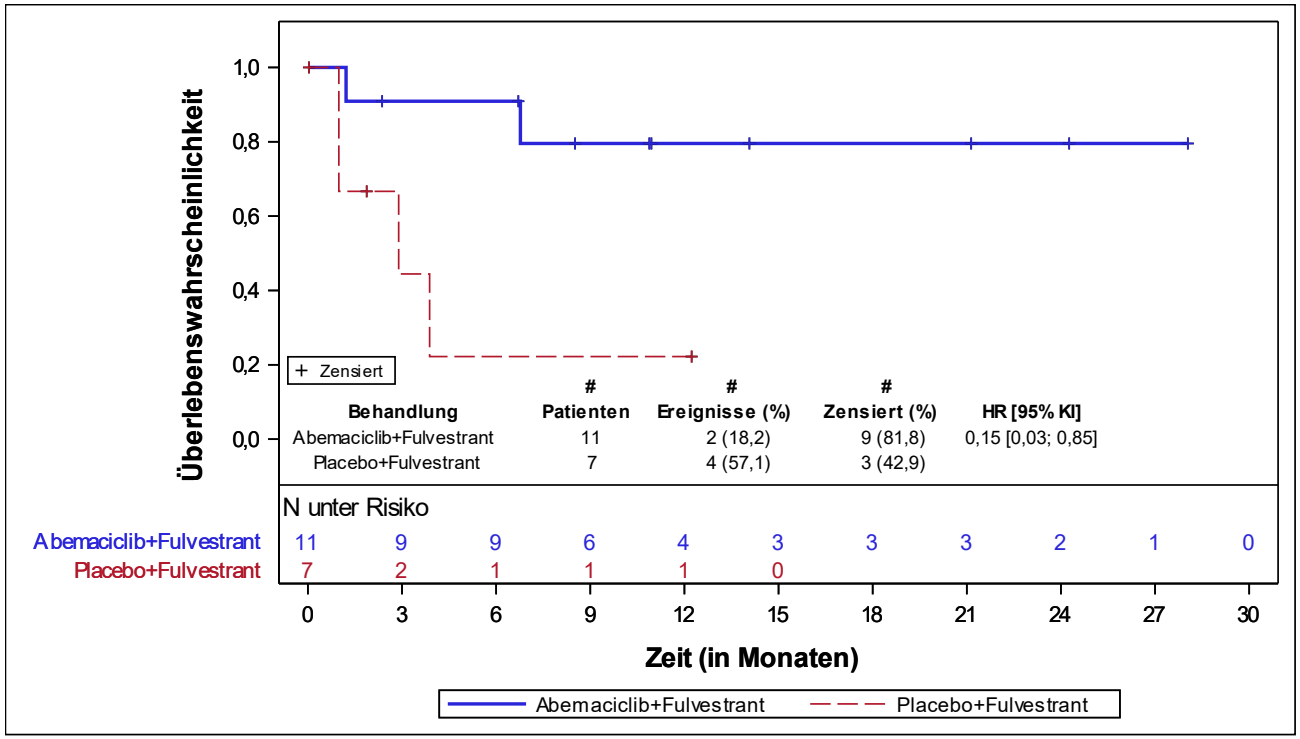
Abbildung 183: Kaplan-Meier-Kurven für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte), Subgruppenanalyse für Tumorgrad = Hoch
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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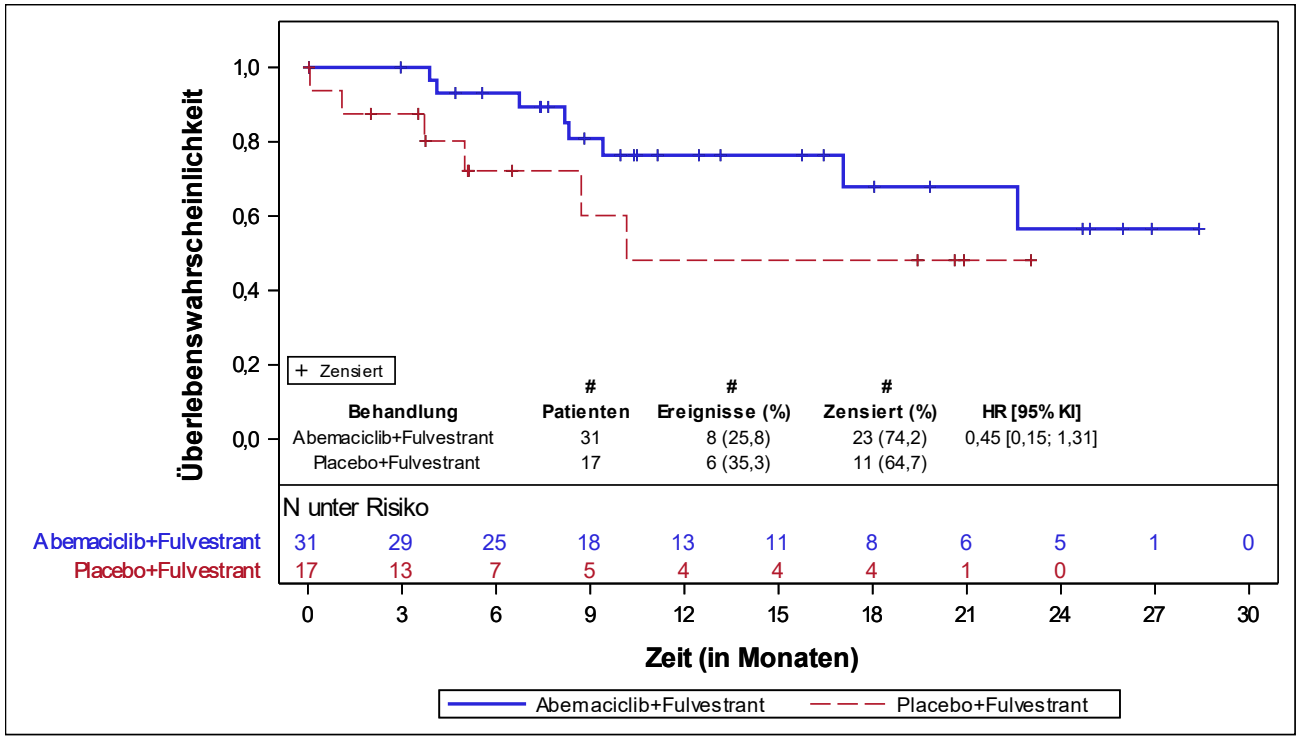
Abbildung 184: Kaplan-Meier-Kurven für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte), Subgruppenanalyse für Tumorgrad = Niedrig/mittel
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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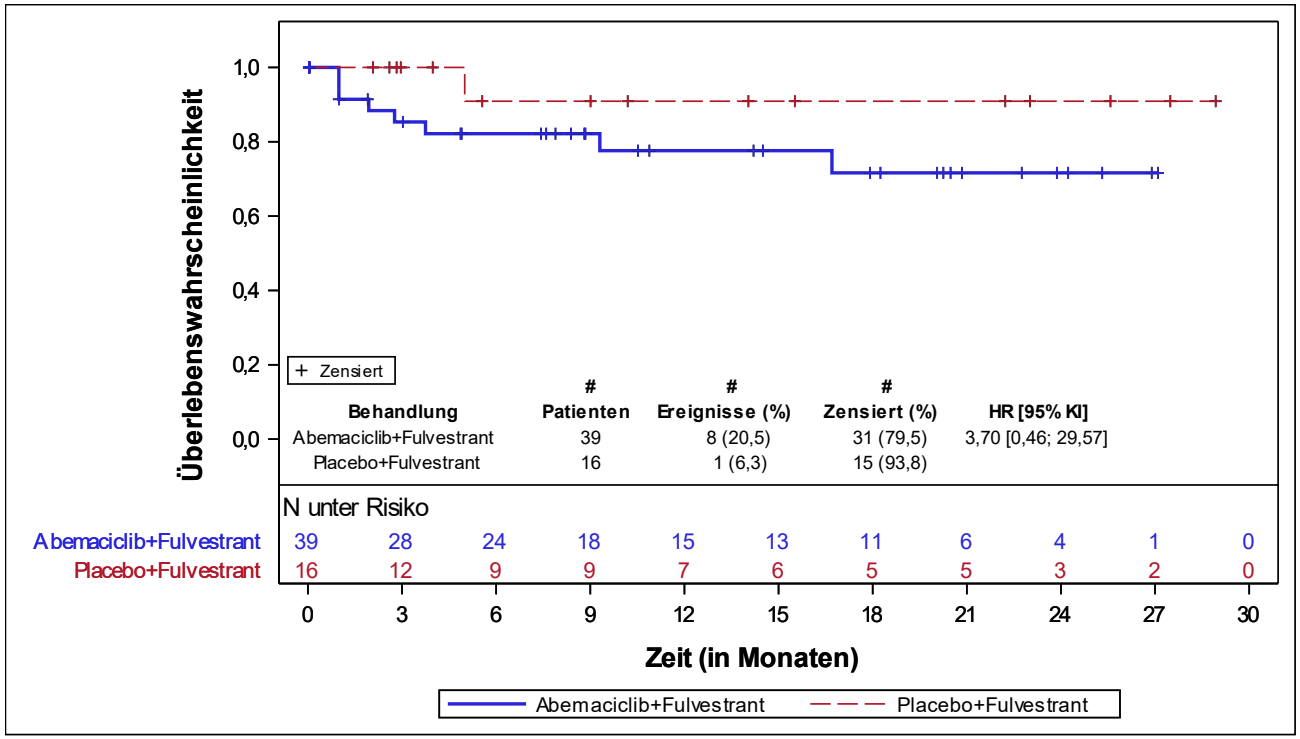
Abbildung 185: Kaplan-Meier-Kurven für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte), Subgruppenanalyse für Tumorgrad = Unbekannt
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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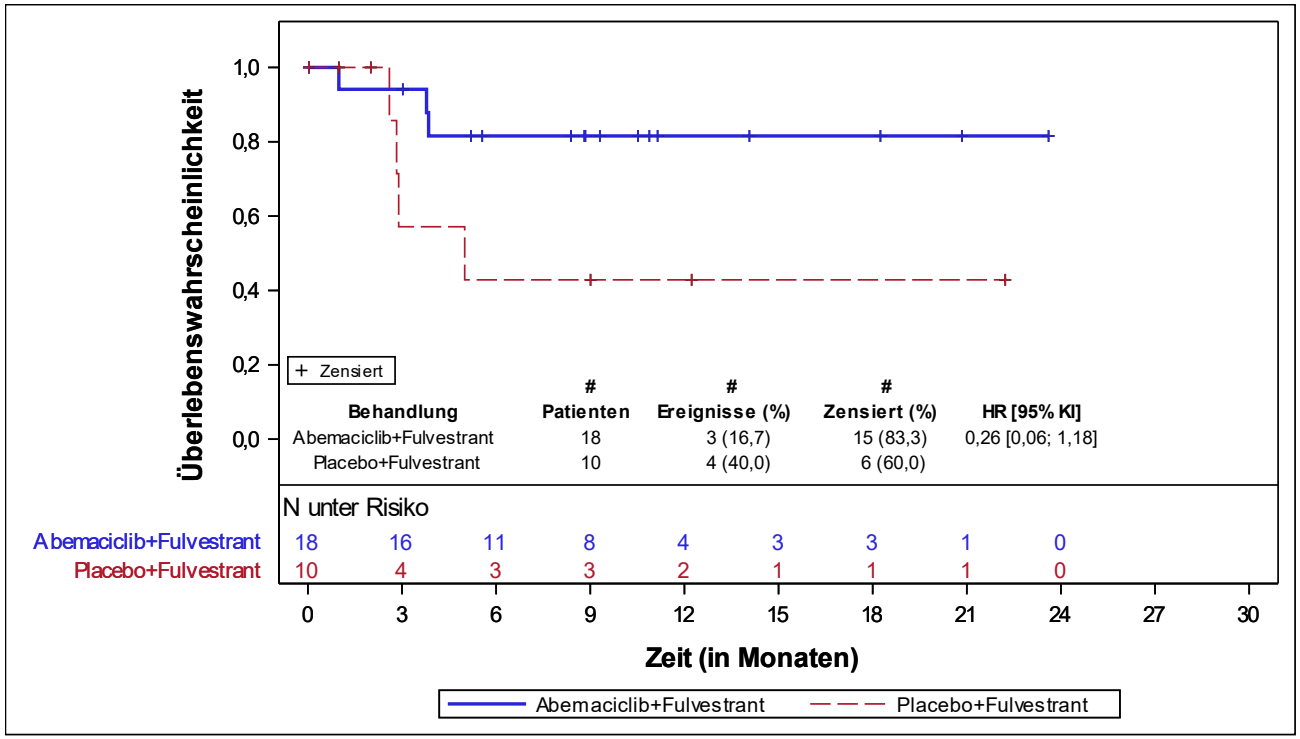
Abbildung 186: Kaplan-Meier-Kurven für die Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte), Subgruppenanalyse für Progesteronrezeptorstatus = Negativ
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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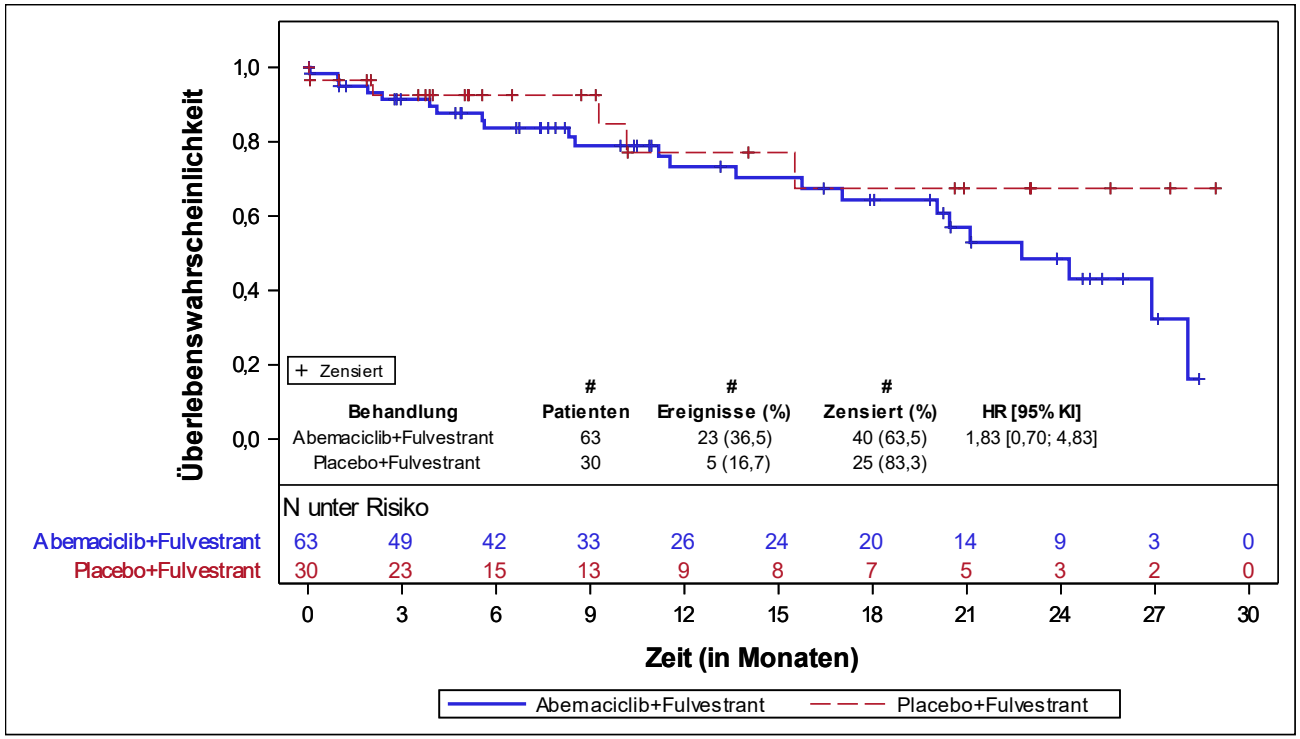
Abbildung 187: Kaplan-Meier-Kurven für die Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte), Subgruppenanalyse für Progesteronrezeptorstatus = Positiv
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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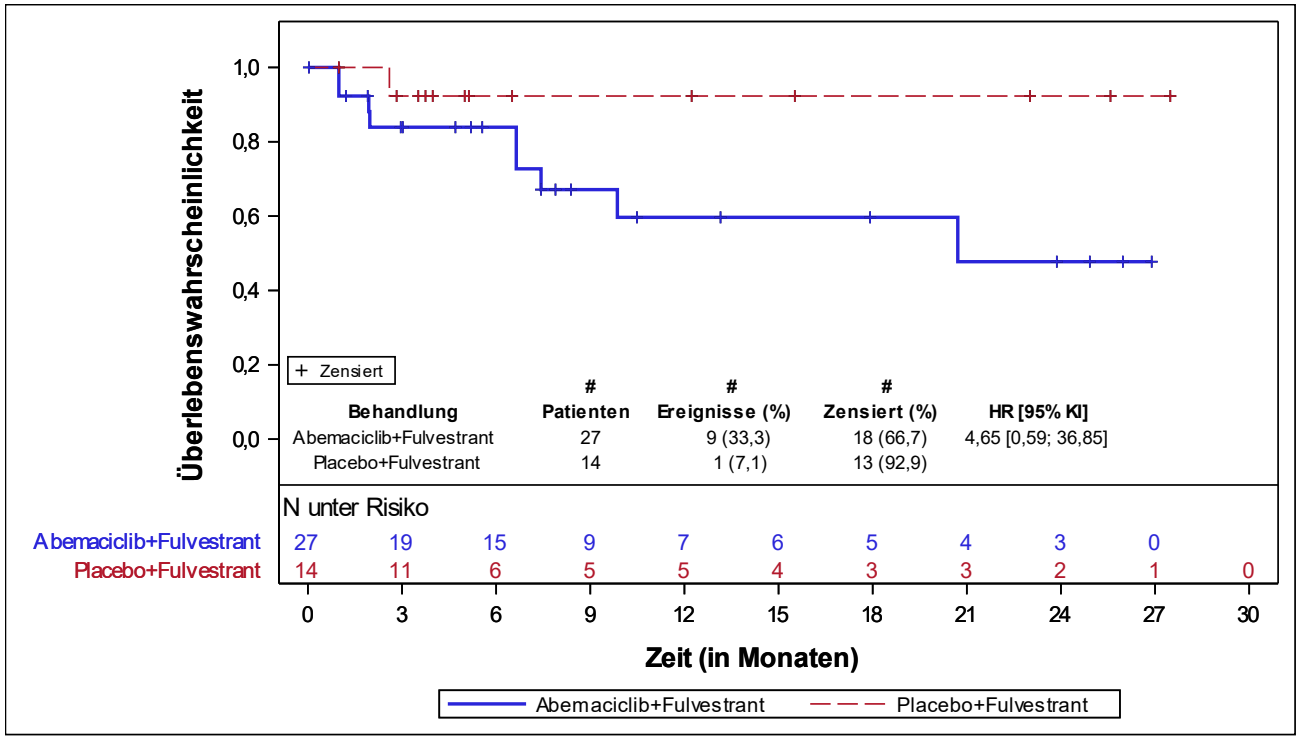
Abbildung 188: Kaplan-Meier-Kurven für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte), Subgruppenanalyse für ECOG-PS zu Baseline = 0
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/f188_km_sub_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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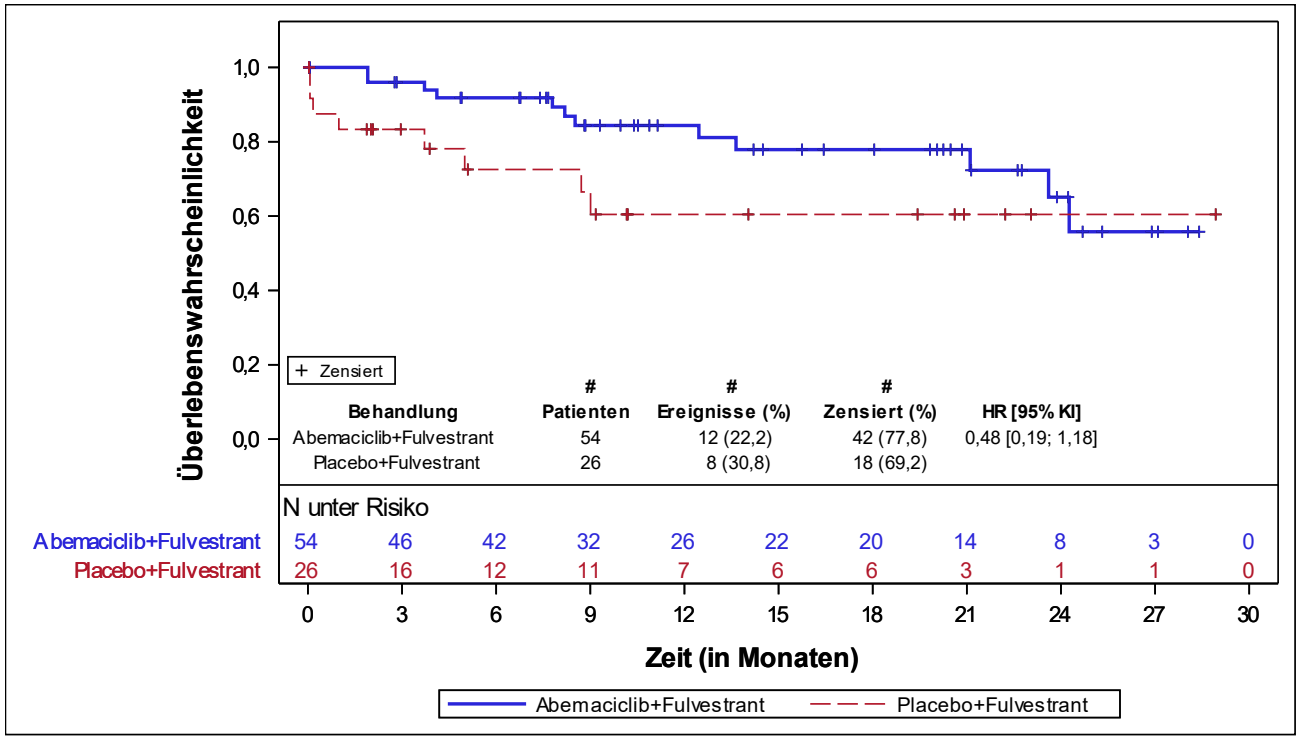
Abbildung 189: Kaplan-Meier-Kurven für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte), Subgruppenanalyse für ECOG-PS zu Baseline = 1
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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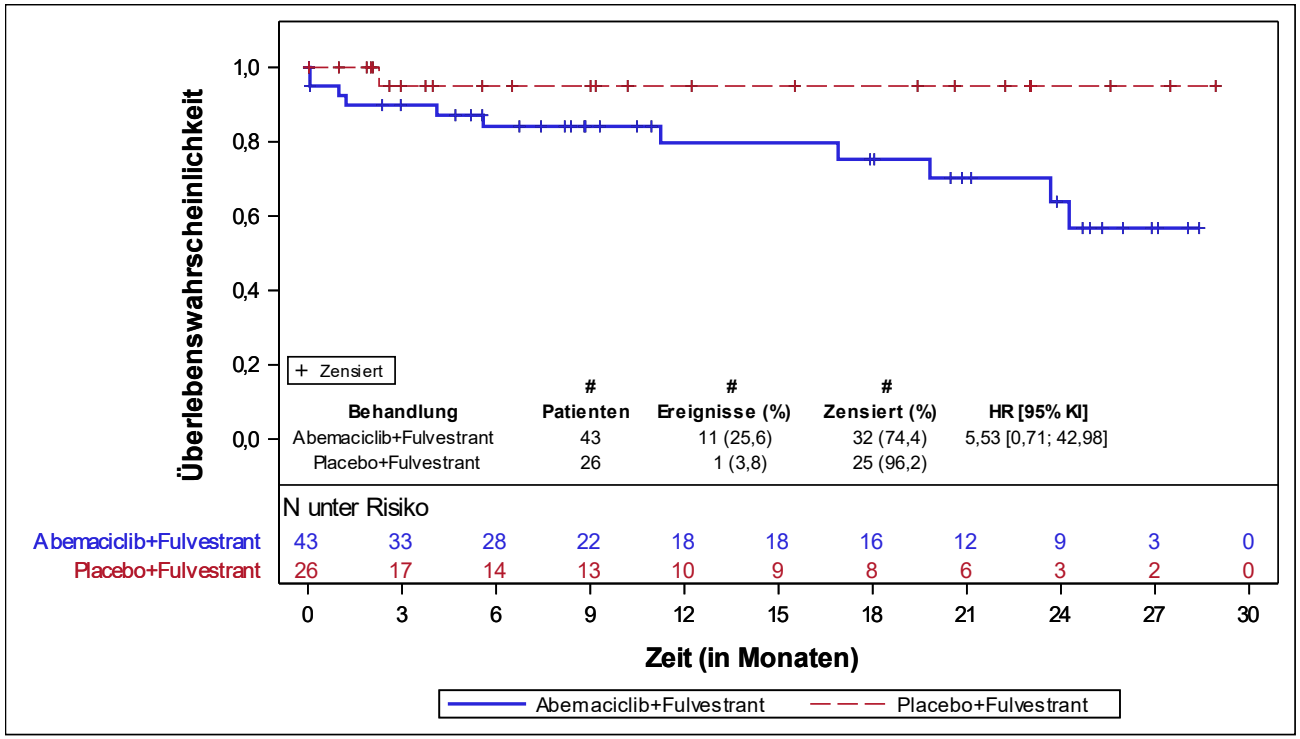
Abbildung 190: Kaplan-Meier-Kurven für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte), Subgruppenanalyse für Anzahl betroffener Organe = 1
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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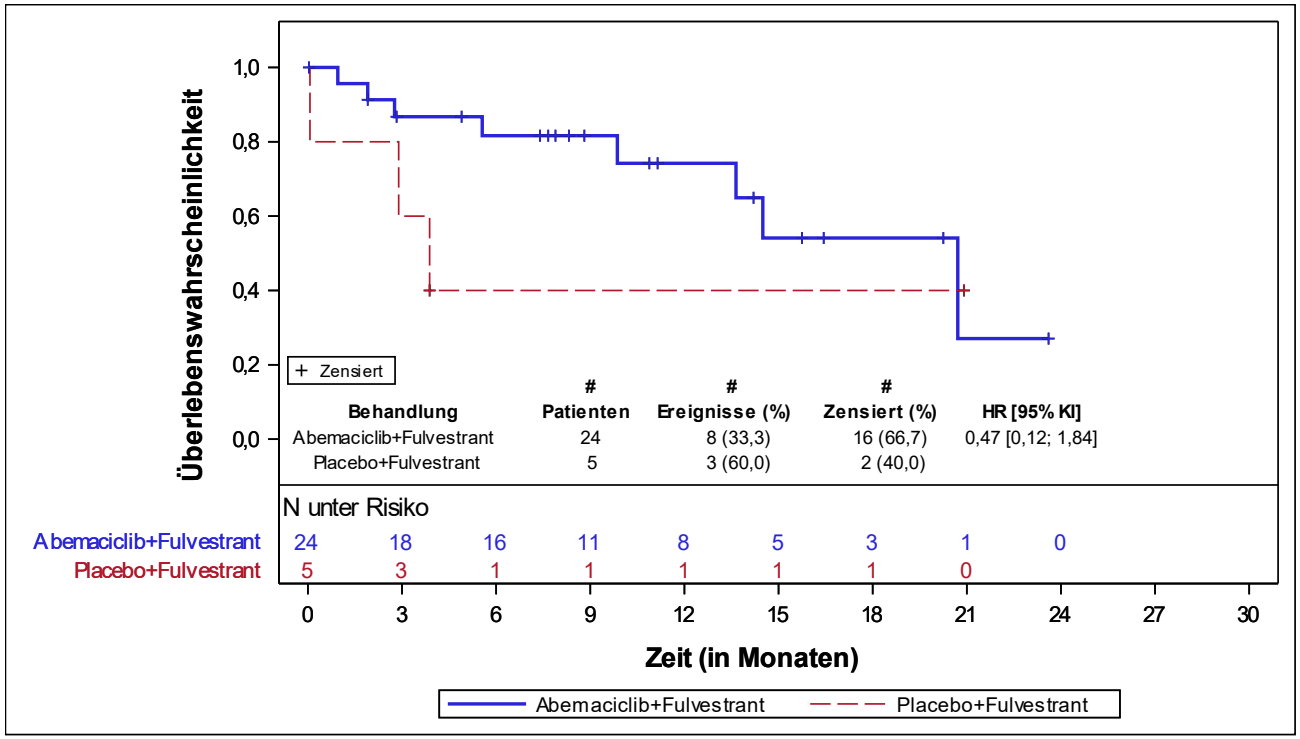
Abbildung 191: Kaplan-Meier-Kurven für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte), Subgruppenanalyse für Anzahl betroffener Organe = 2
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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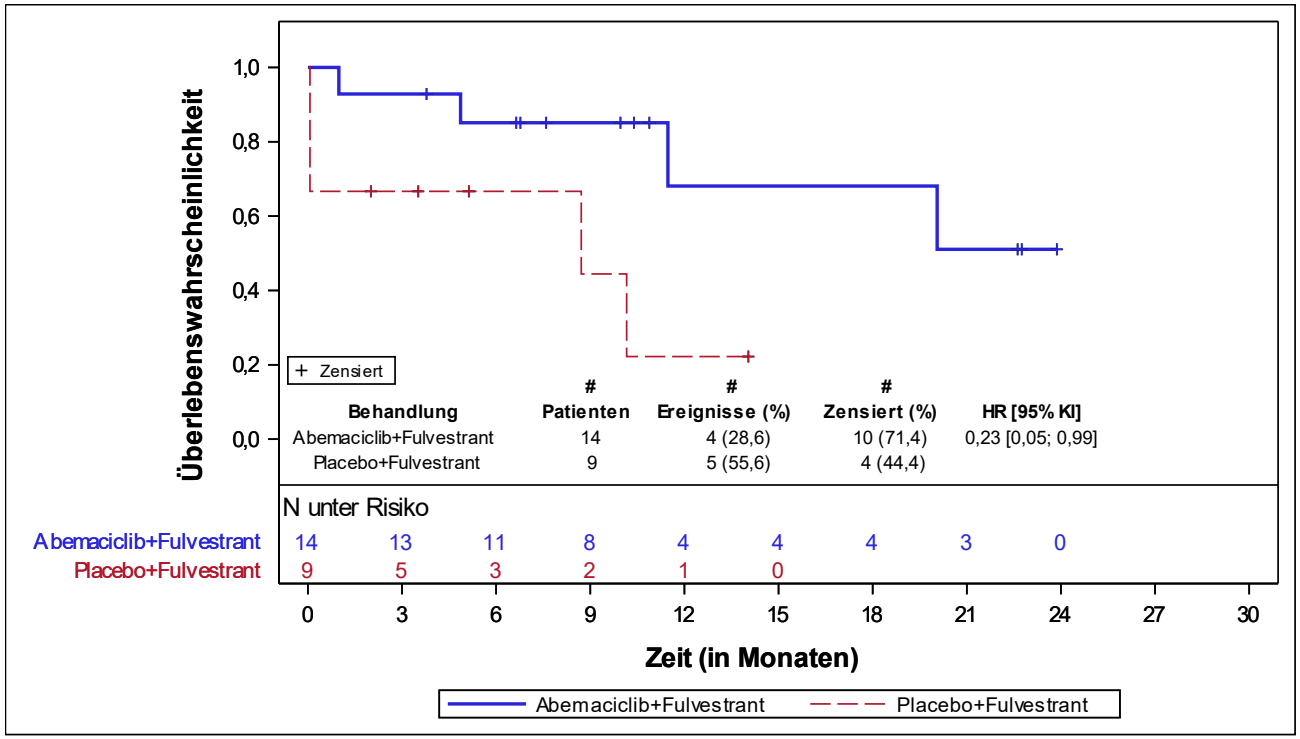
Abbildung 192: Kaplan-Meier-Kurven für die Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte), Subgruppenanalyse für Anzahl betroffener Organe = ≥ 3
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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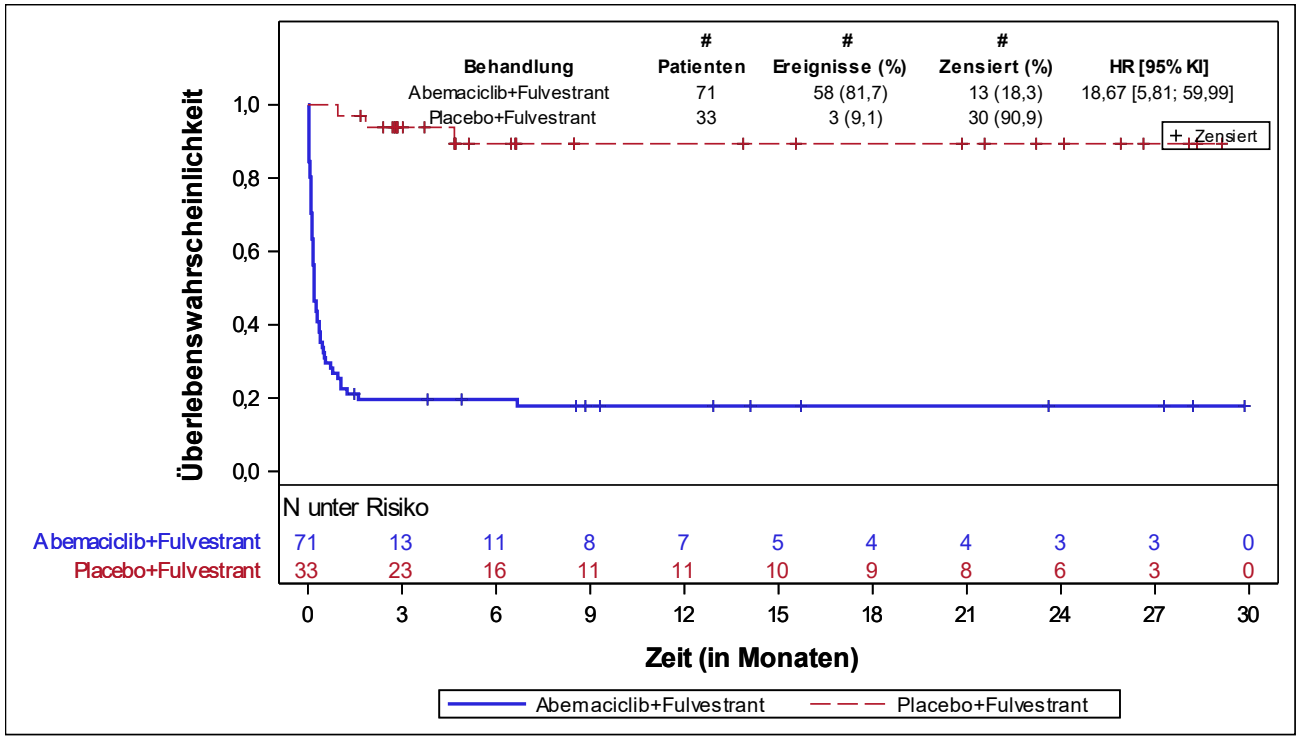
Abbildung 193: Kaplan-Meier-Kurven für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad)
Subgruppenanalyse für Land = China
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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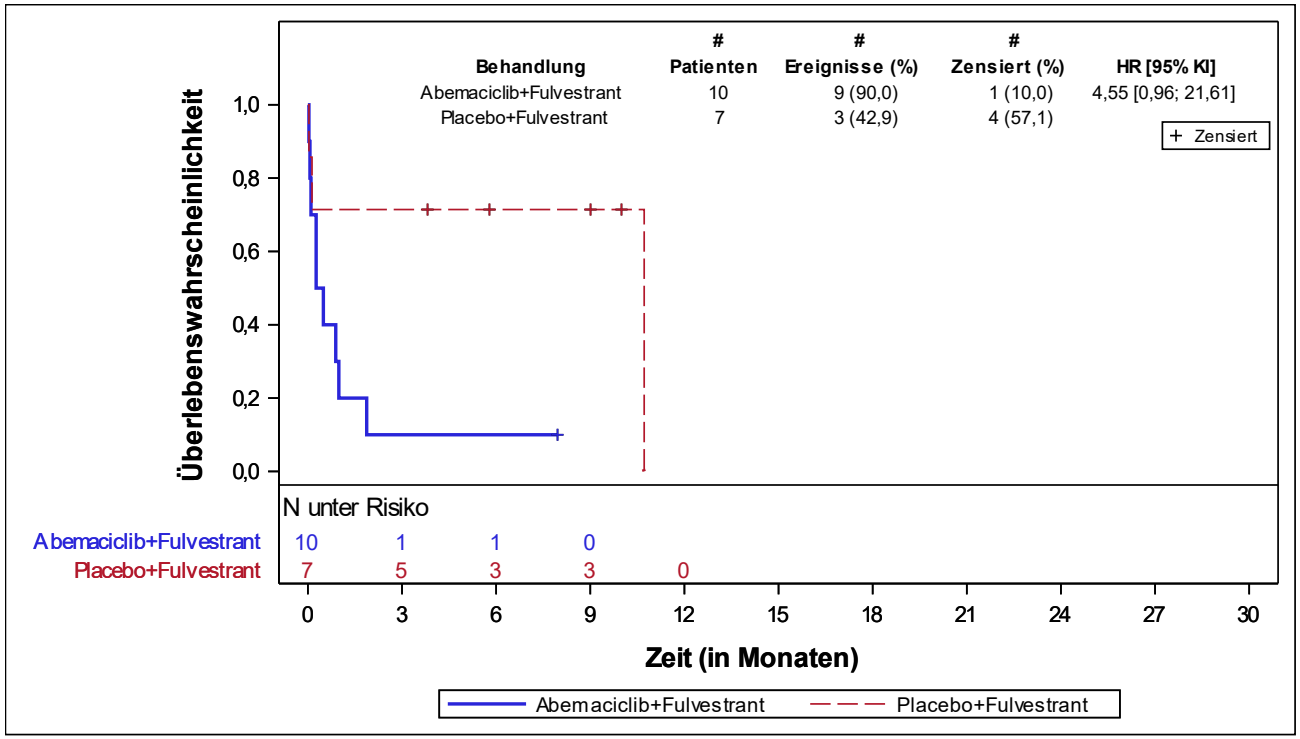
Abbildung 194: Kaplan-Meier-Kurven für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad)
Subgruppenanalyse für Land = Andere
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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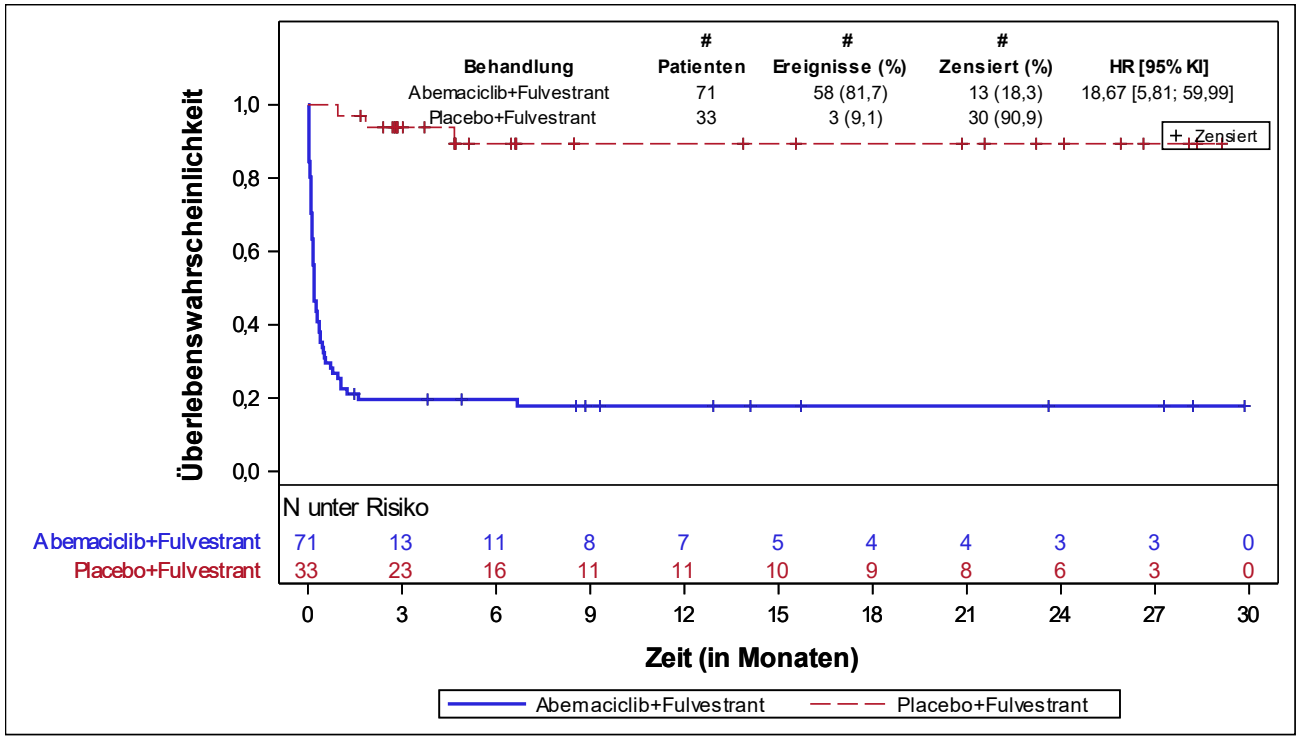
Abbildung 195: Kaplan-Meier-Kurven für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe
Subgruppenanalyse für Land = China
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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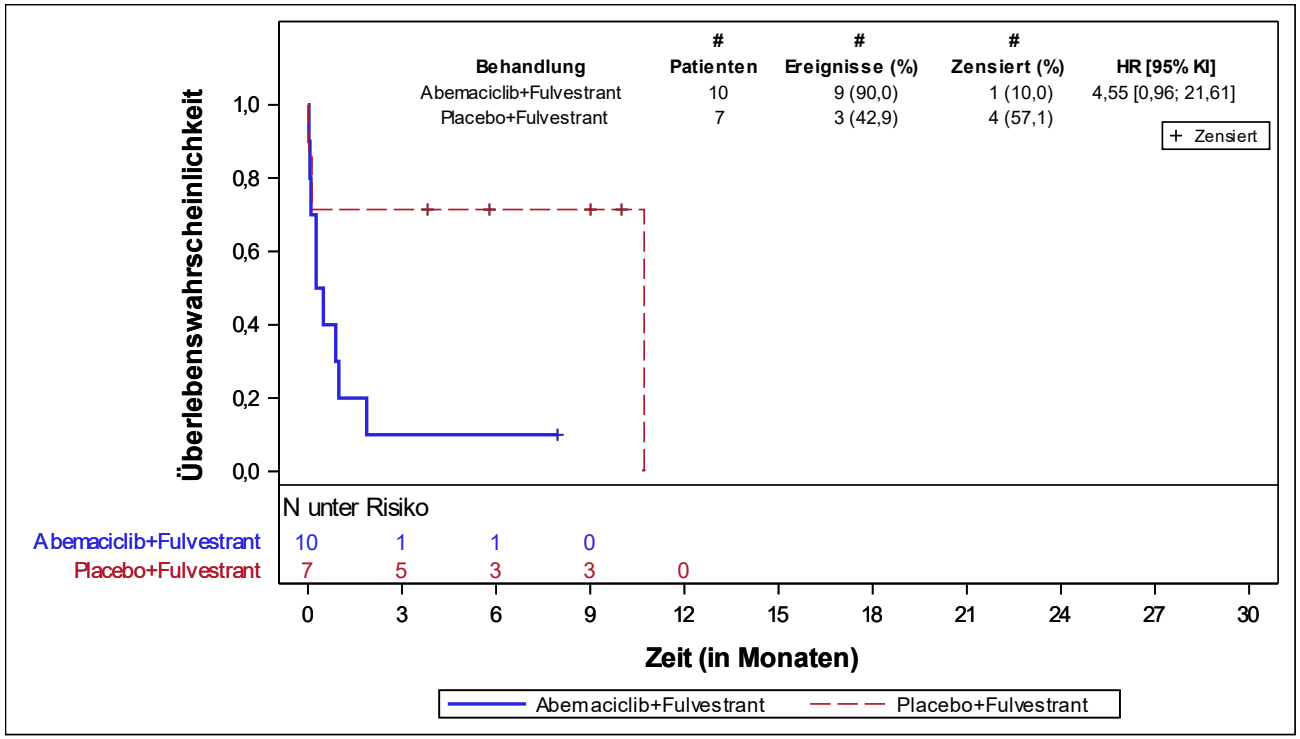
Abbildung 196: Kaplan-Meier-Kurven für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe
Subgruppenanalyse für Land = Andere
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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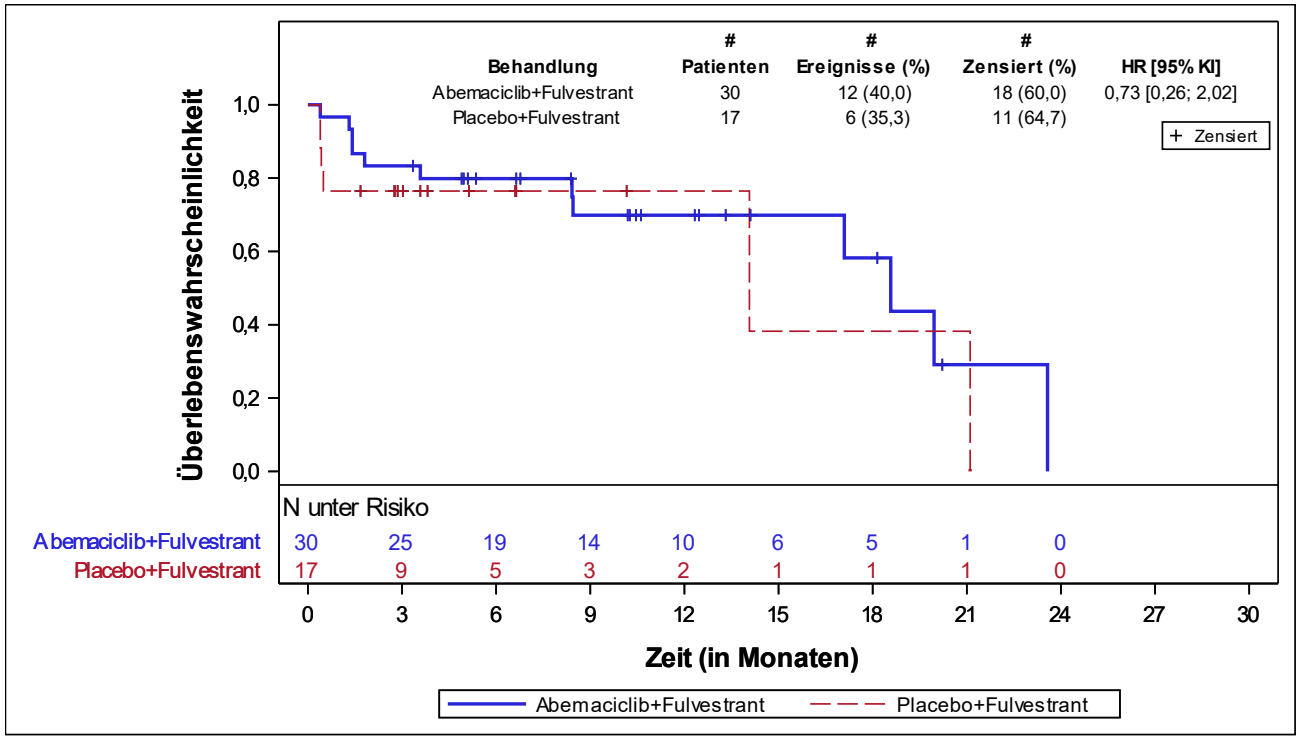
Abbildung 197: Kaplan-Meier-Kurven für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie = Primäre Resistenz
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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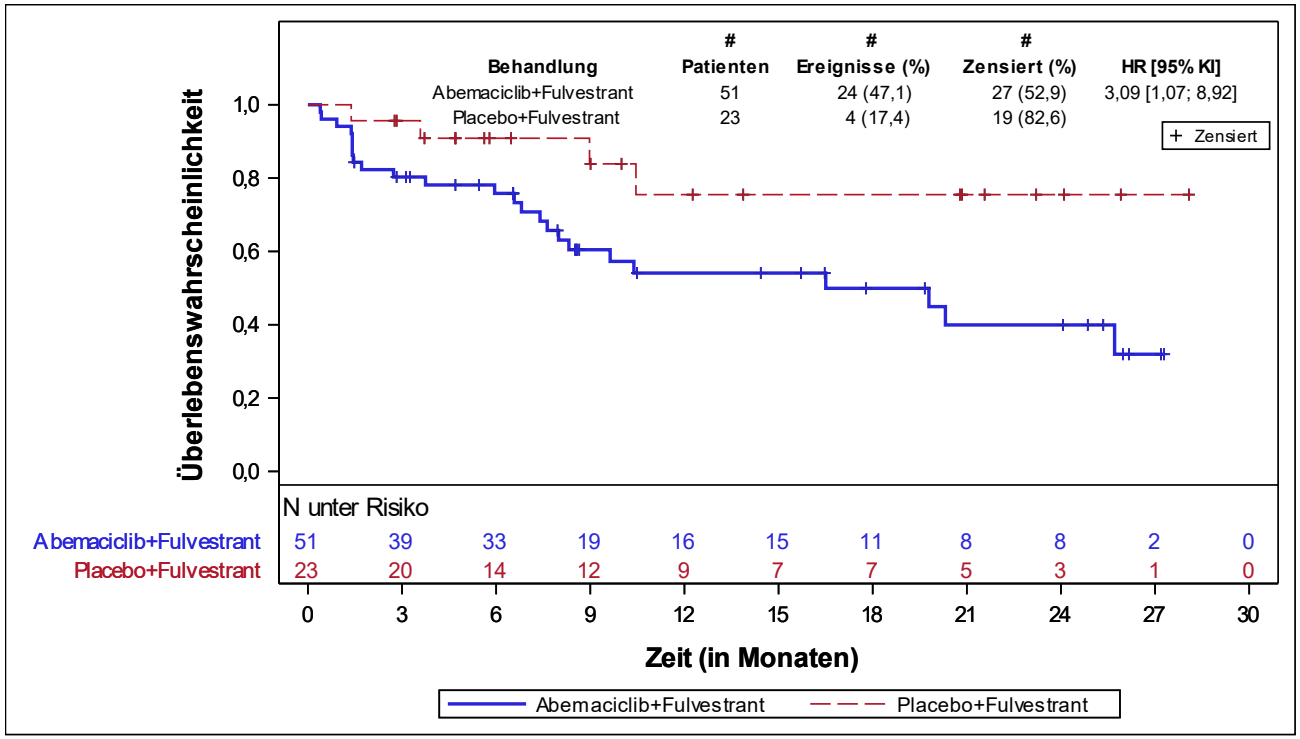
Abbildung 198: Kaplan-Meier-Kurven für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie = Sekundäre Resistenz
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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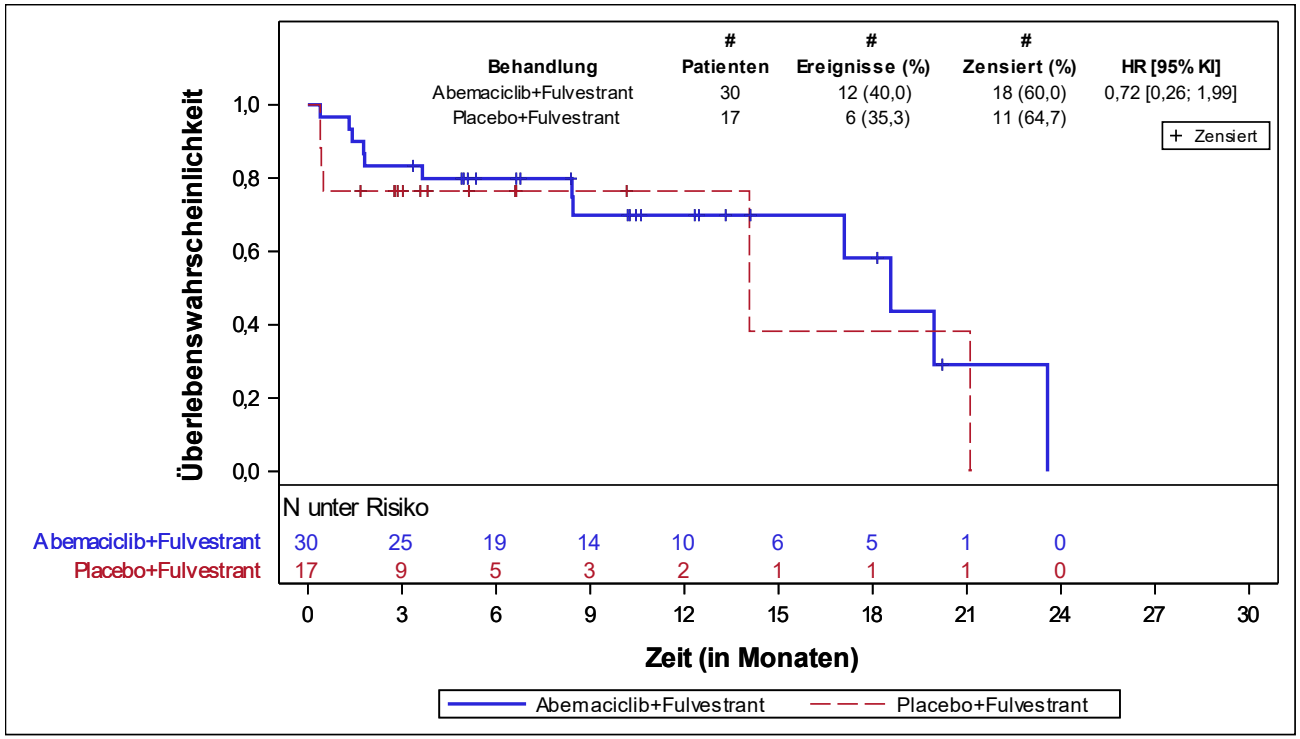
Abbildung 199: Kaplan-Meier-Kurven für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie = Primäre Resistenz
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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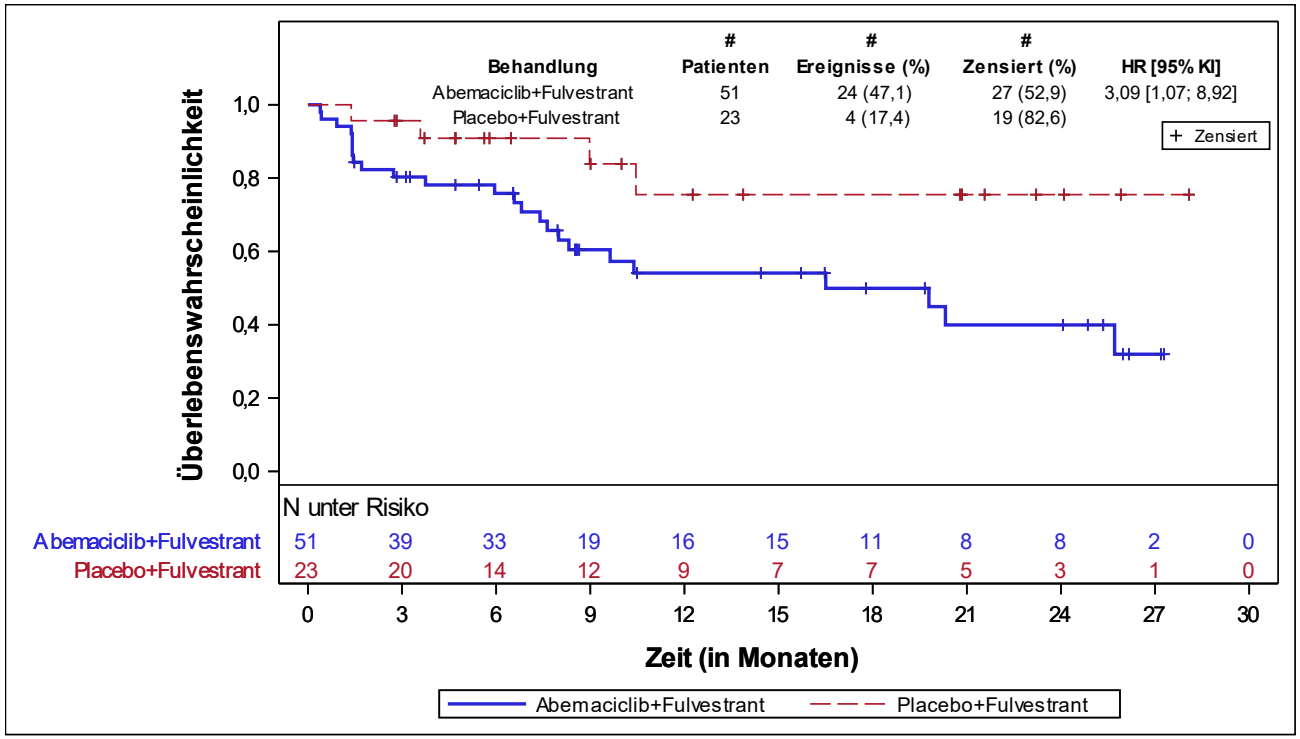
Abbildung 200: Kaplan-Meier-Kurven für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie = Sekundäre Resistenz
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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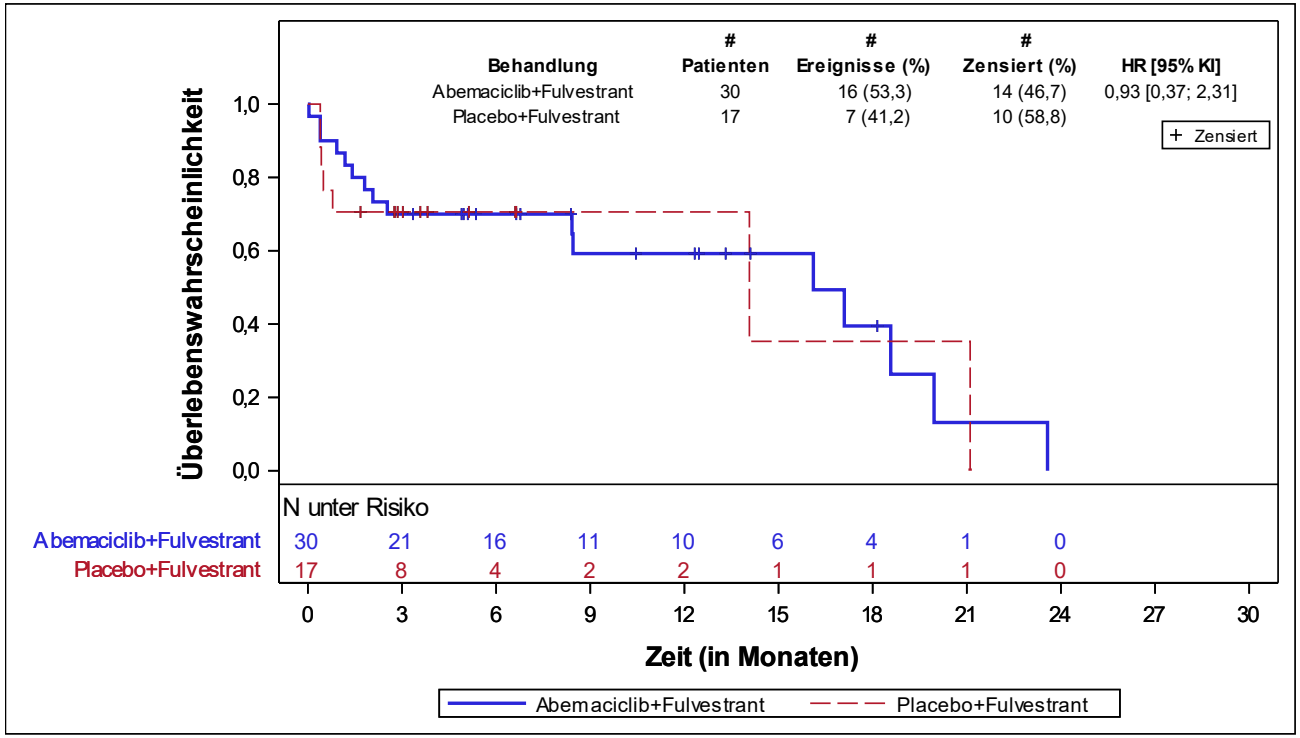
Abbildung 201: Kaplan-Meier-Kurven für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie = Primäre Resistenz
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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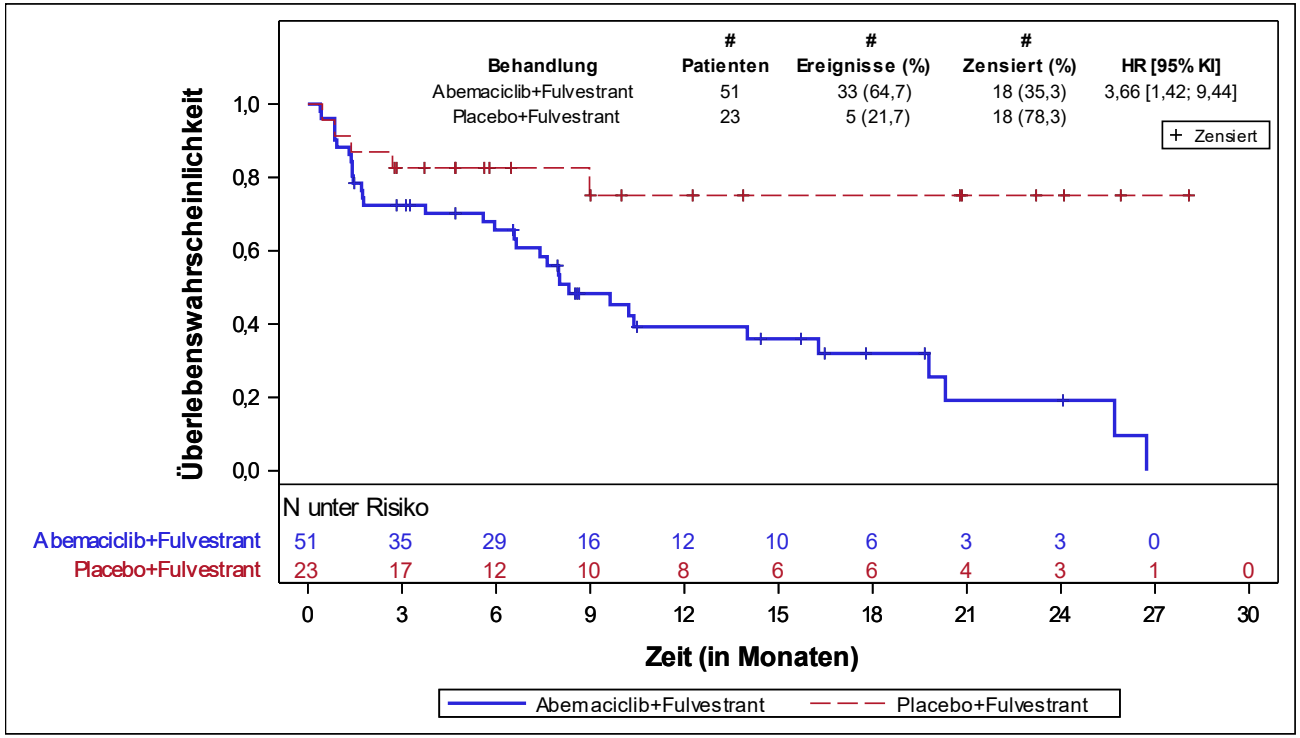
Abbildung 202: Kaplan-Meier-Kurven für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie = Sekundäre Resistenz
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
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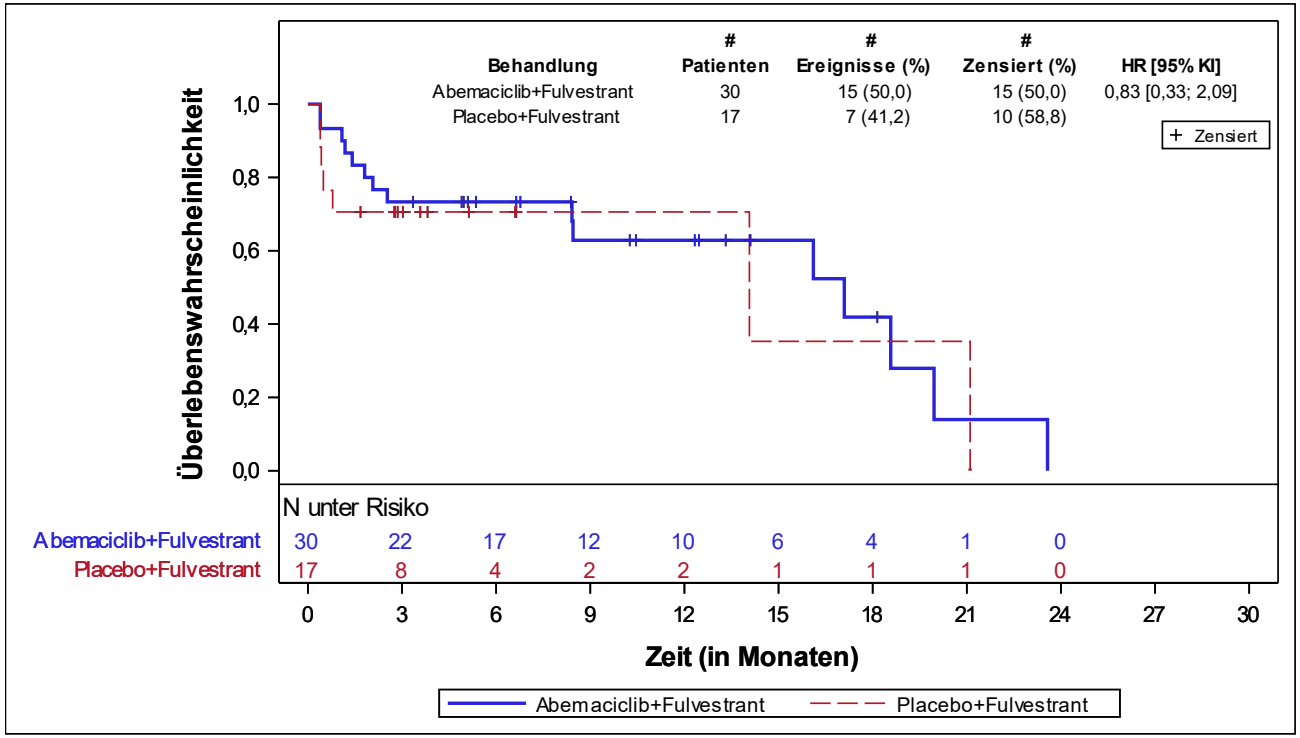
Abbildung 203: Kaplan-Meier-Kurven für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie = Primäre Resistenz
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/f_gba_tte_km_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/f203_km_sub_popa1.rtf
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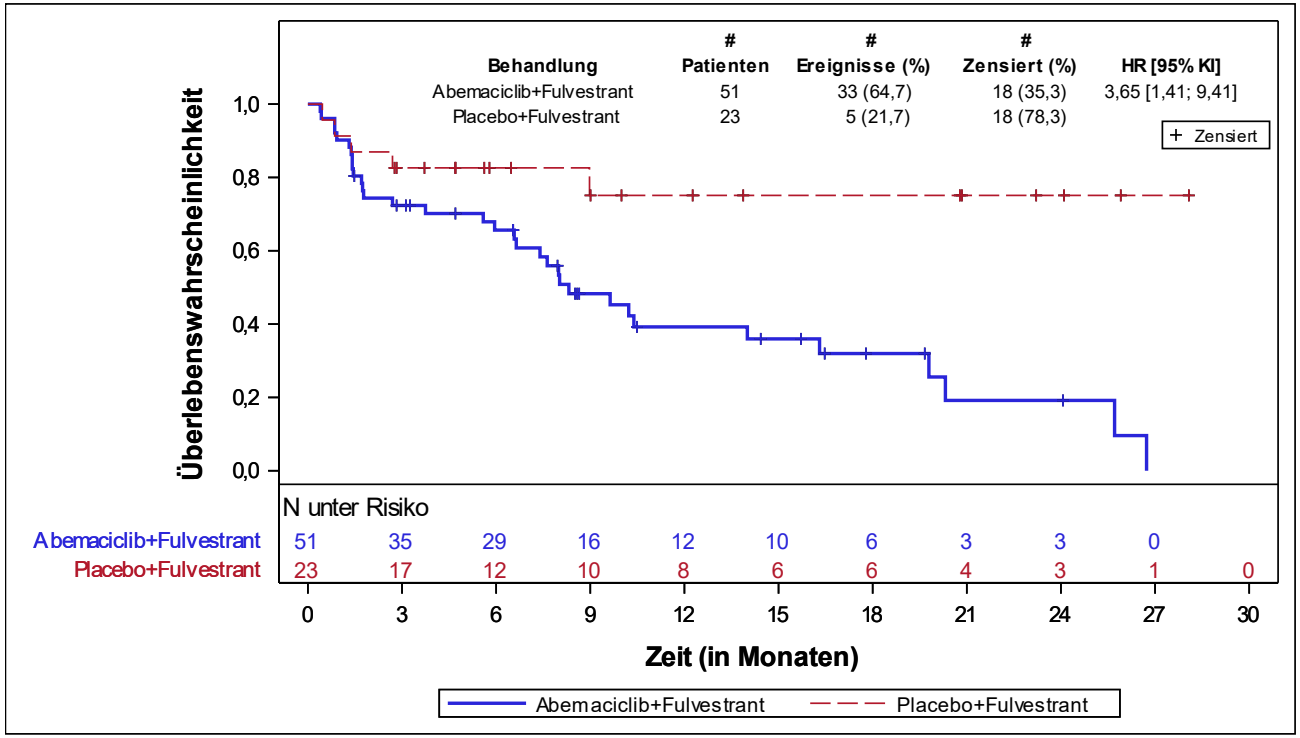
Abbildung 204: Kaplan-Meier-Kurven für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie = Sekundäre Resistenz
Safety Population - Postmenopausal A1 (Erstlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/f_gba_tte_km_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/f204_km_sub_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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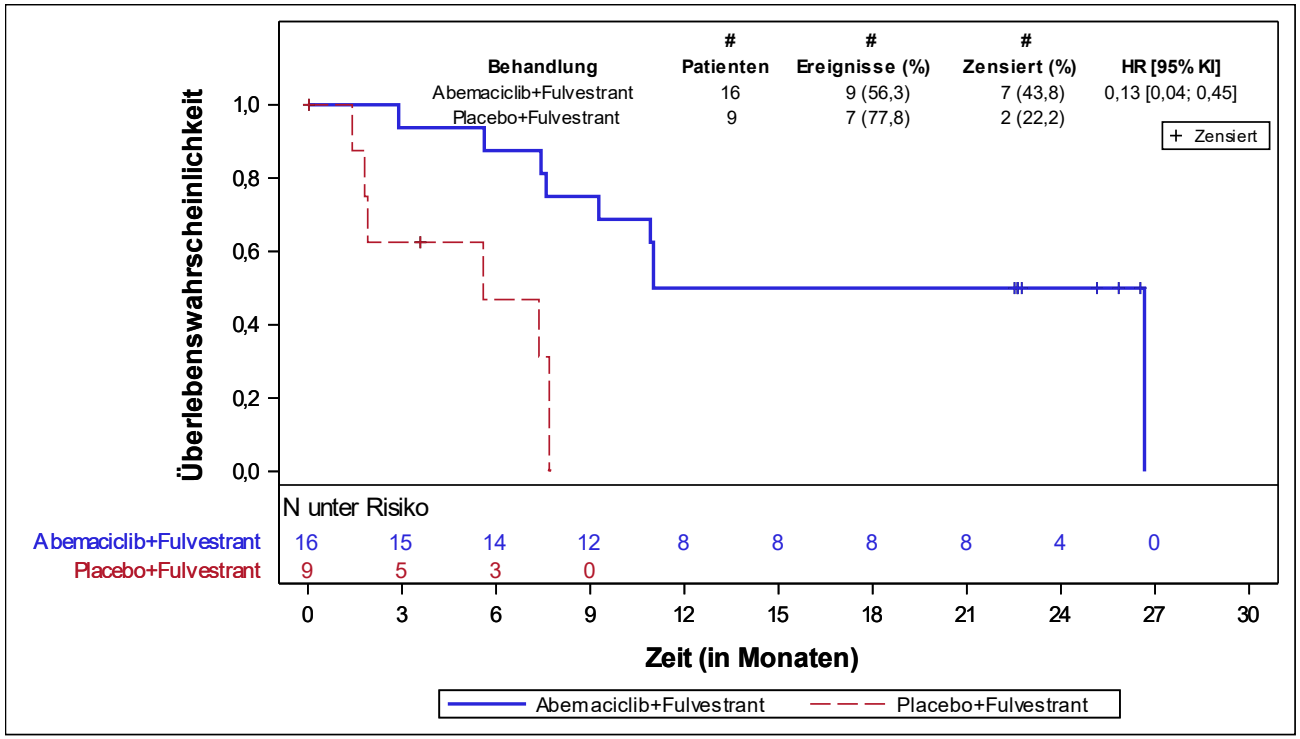
Abbildung 205: Kaplan-Meier-Kurven für progessionsfreies Überleben
Subgruppenanalyse für Alter = < 65 Jahre
ITT Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, ITT-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/f_gba_tte_km_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/f205_km_sub_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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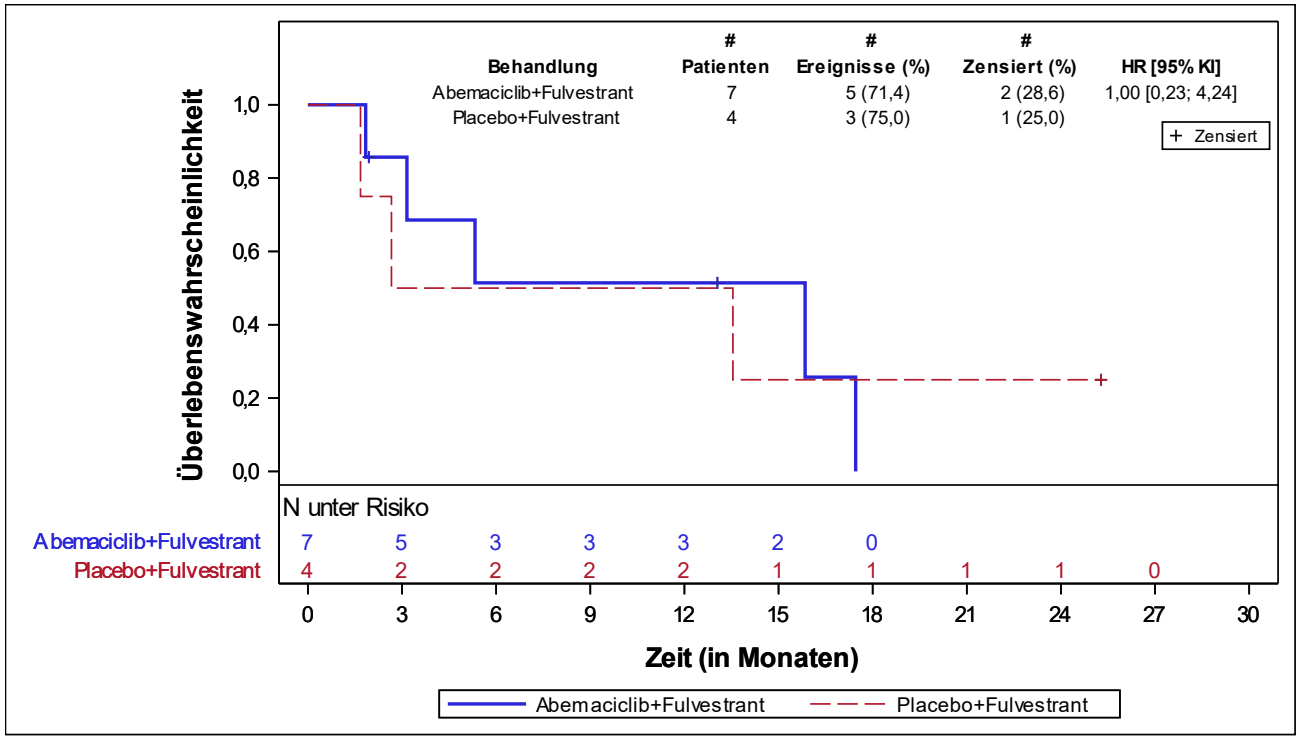
Abbildung 206: Kaplan-Meier-Kurven für progessionsfreies Überleben
Subgruppenanalyse für Alter = ≥ 65 Jahre
ITT Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, ITT-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/f_gba_tte_km_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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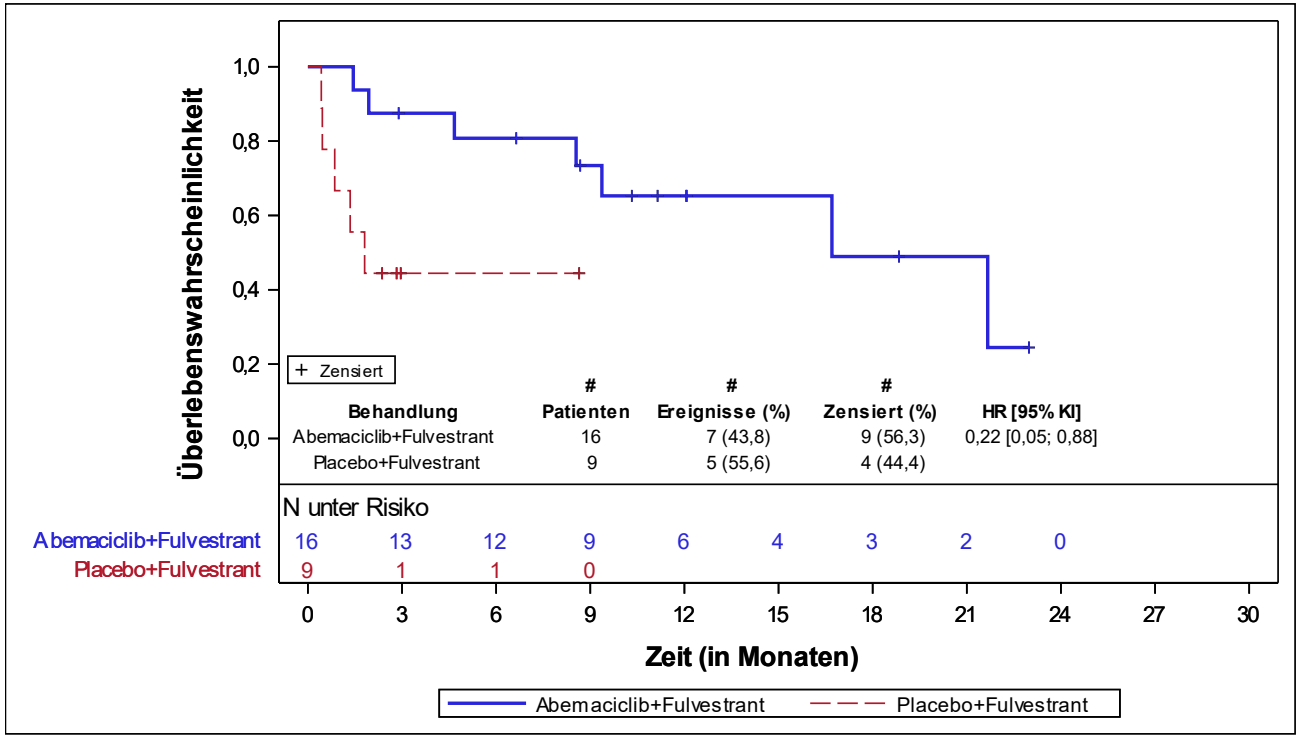
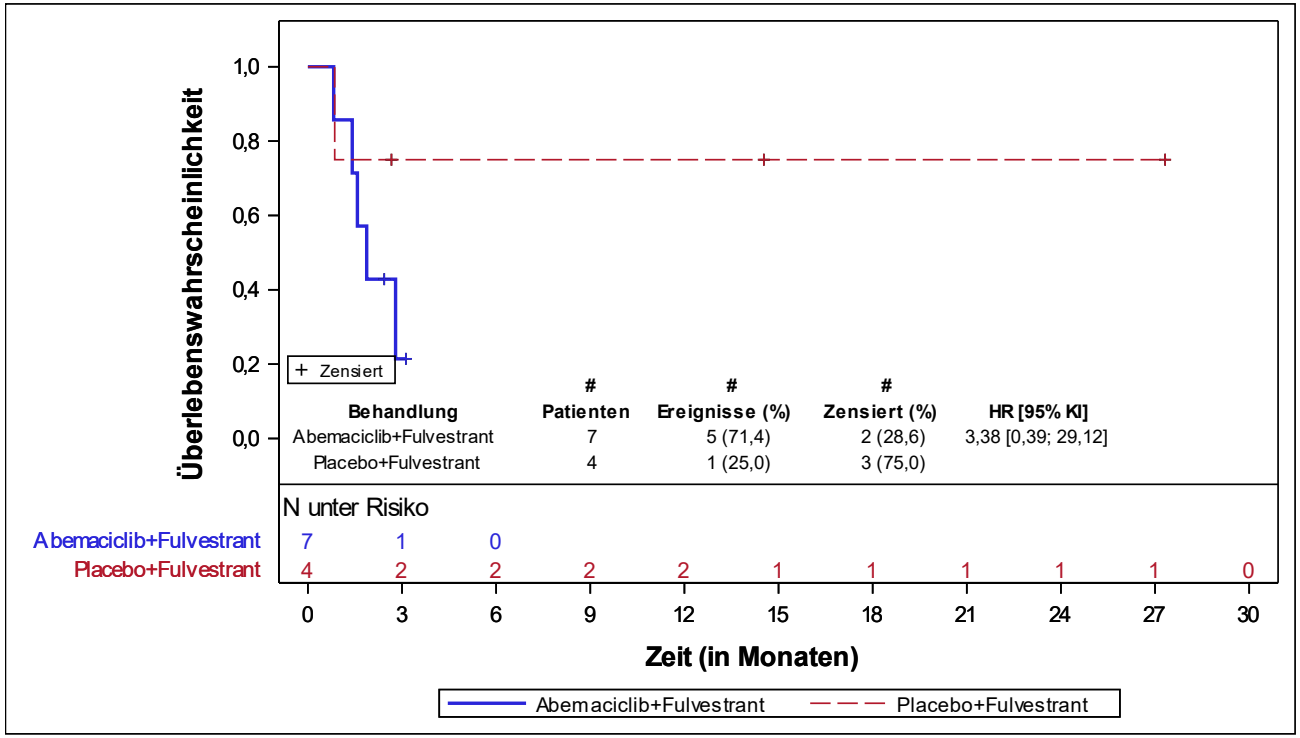
Abbildung 207: Kaplan-Meier-Kurven für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad)
Subgruppenanalyse für Alter = < 65 Jahre
Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/f_gba_tte_km_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/f207_km_sub_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
16SEP2021 / 08:53

Abbildung 208: Kaplan-Meier-Kurven für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad)
Subgruppenanalyse für Alter = ≥ 65 Jahre
Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/f_gba_tte_km_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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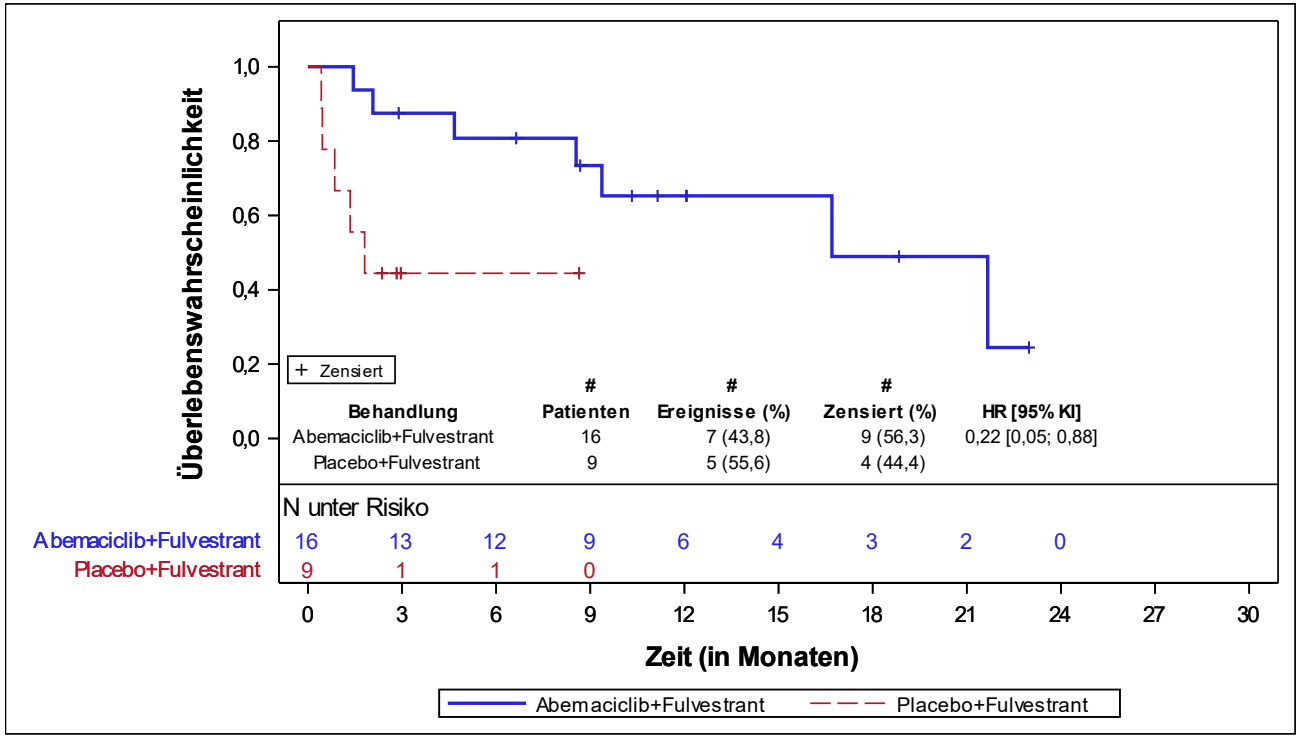
Abbildung 209: Kaplan-Meier-Kurven für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber
Subgruppenanalyse für Alter = < 65 Jahre
Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/f_gba_tte_km_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/f209_km_sub_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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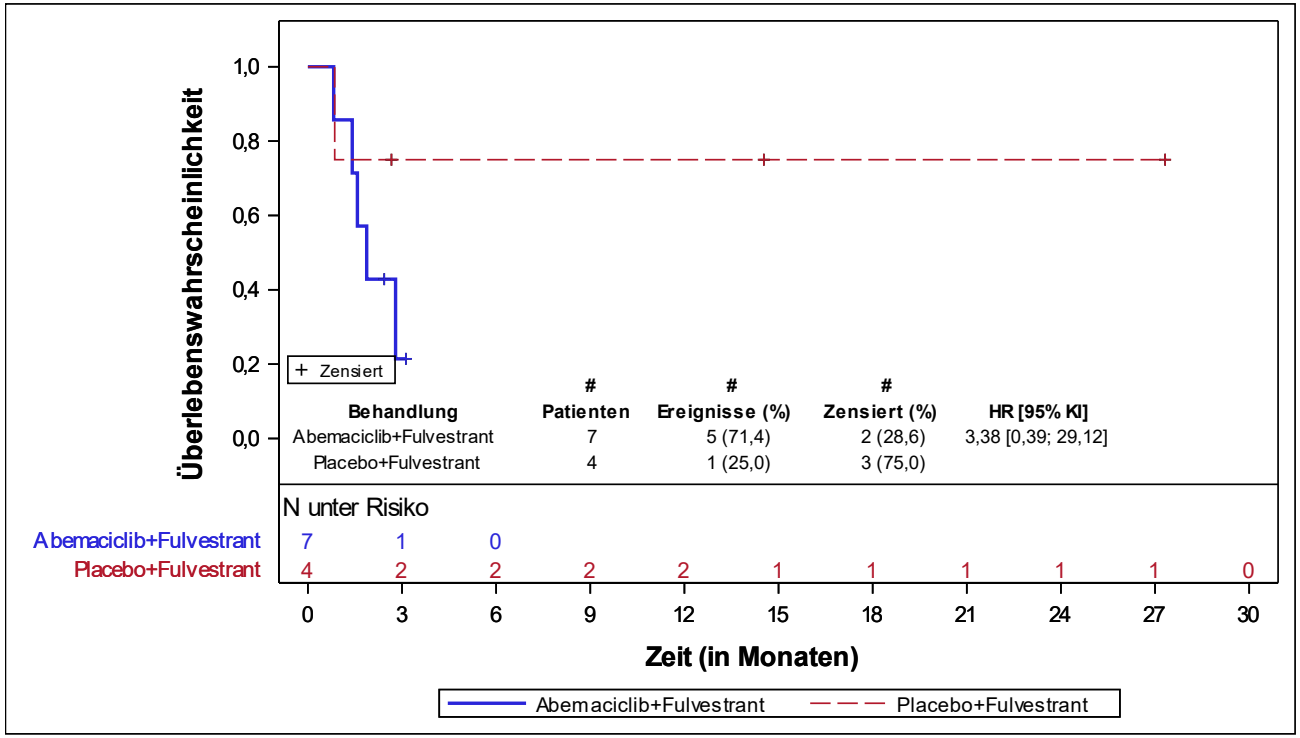
Abbildung 210: Kaplan-Meier-Kurven für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber
Subgruppenanalyse für Alter = ≥ 65 Jahre
Safety Population - Postmenopausal B1 (Zweitlinie) (Studie MONARCH-plus)



Datenschnitt: 18.05.2020, Safety-Population
Abkürzungen: HR: Hazard Ratio; KI: Konfidenzintervall; N: Anzahl der Patienten; NE: Nicht errechenbar/nicht erreicht; #: Anzahl
Zensierte Patienten sind auf den Kaplan-Meier-Kurven gekennzeichnet anhand der Symbole in der Legende
Die Anzahl der Patienten unter der Abbildung beschreibt die Patienten unter Risiko zu den entsprechenden Zeitpunkten
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/f_gba_tte_km_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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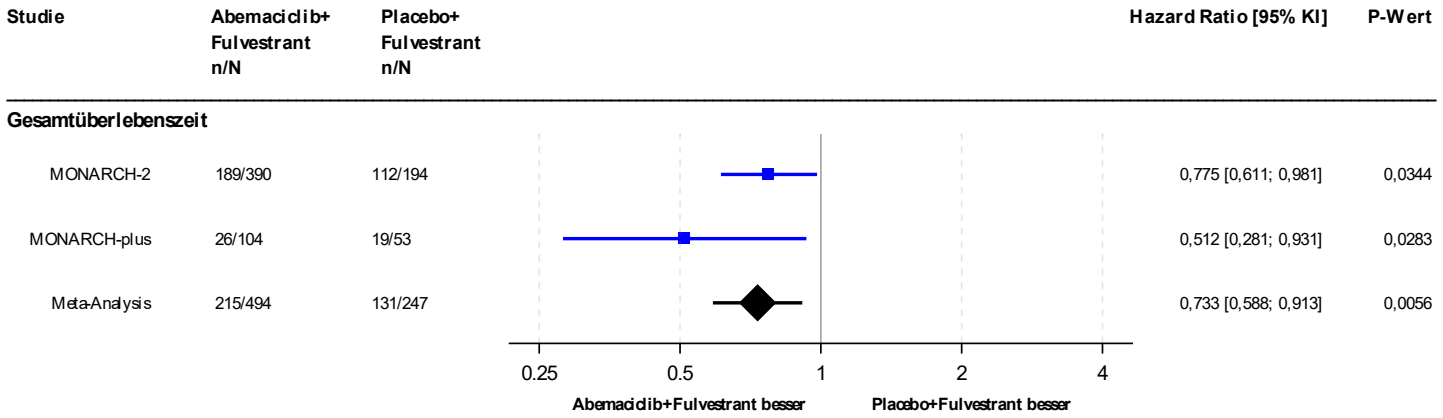
Anhang 4-G3: Weitere Analysen der Meta-analyse der Studien MONARCH-2 und MONARCH-plus

Anhang 4-G3.1: Gesamtüberlebens

Abbildung 156 (Anhang): Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel (Meta-analyse der Studien MONARCH-2 und MONARCH-plus, Postmenopausale Patientinnen)

Abbildung 1001: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel - stratifizierte Analyse Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausale Patientinnen



Heterogenität: Cochran Q-test=1,5950, P-Wert=0,2066, I2 Index=37,3%
Abkürzungen: ITT: Intention to Treat; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_os_suppana.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_os_suppana.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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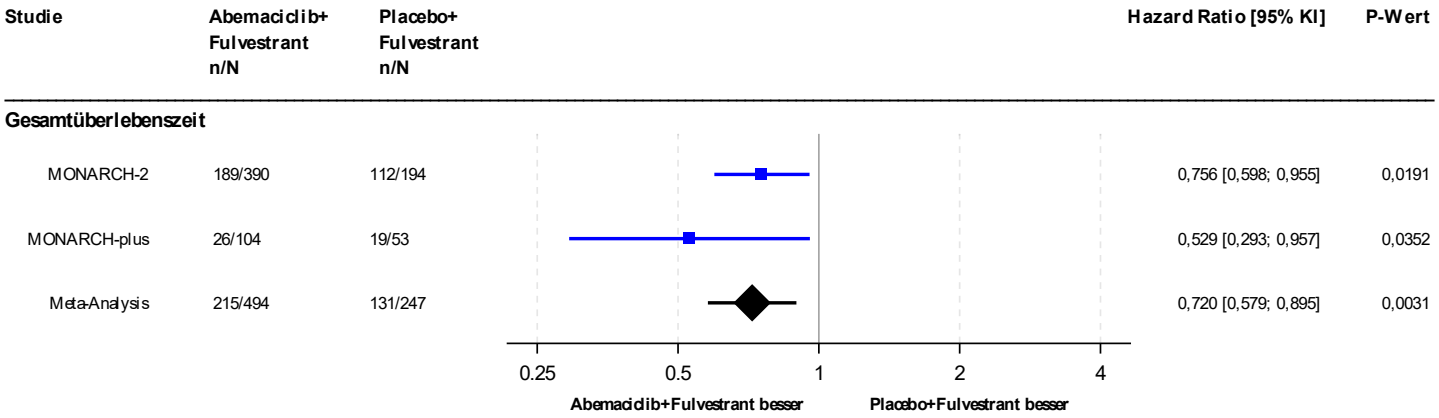
Abbildung 1002: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel - unstratifizierte Analyse Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausale Patientinnen



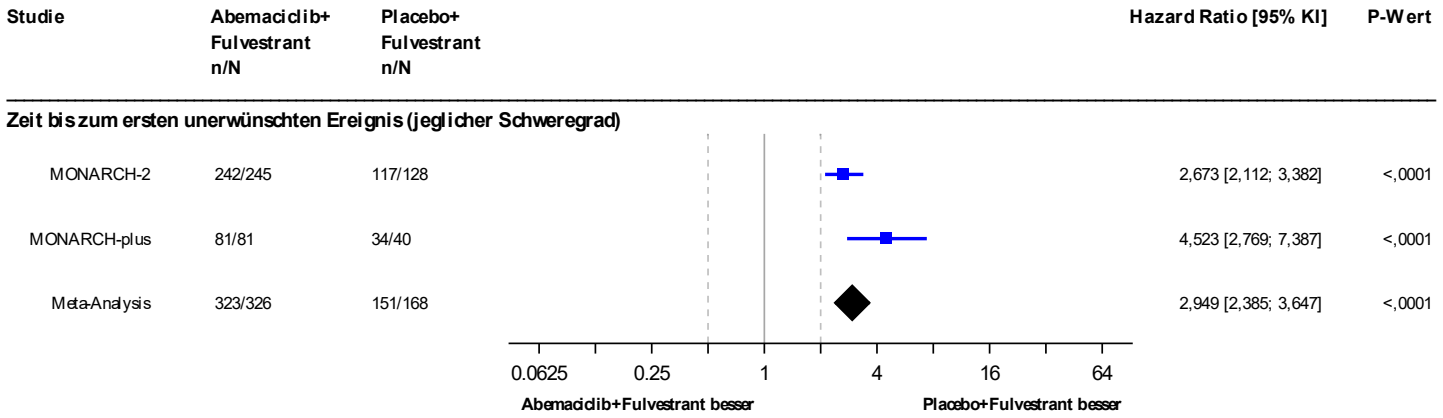
Heterogenität: Cochran Q-test=1,2028, P-Wert=0,2728, I2 Index=16,9%
Abkürzungen: ITT: Intention to Treat; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_os_suppana.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_os_suppana_unstr.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
16AUG2021 / 03:47

Anhang 4-G3.2: Unerwünschte Ereinisse (Forest-Plots)- Safety-Population

Abbildung 157 (Anhang): Metaanalyse der Ergebnisse für unerwünschte Ereignisse aus RCT mit dem zu bewertenden Arzneimittel (Meta-analyse der Studien MONARCH-2 und MONARCH-plus, Postmenopausale Patientinnen)

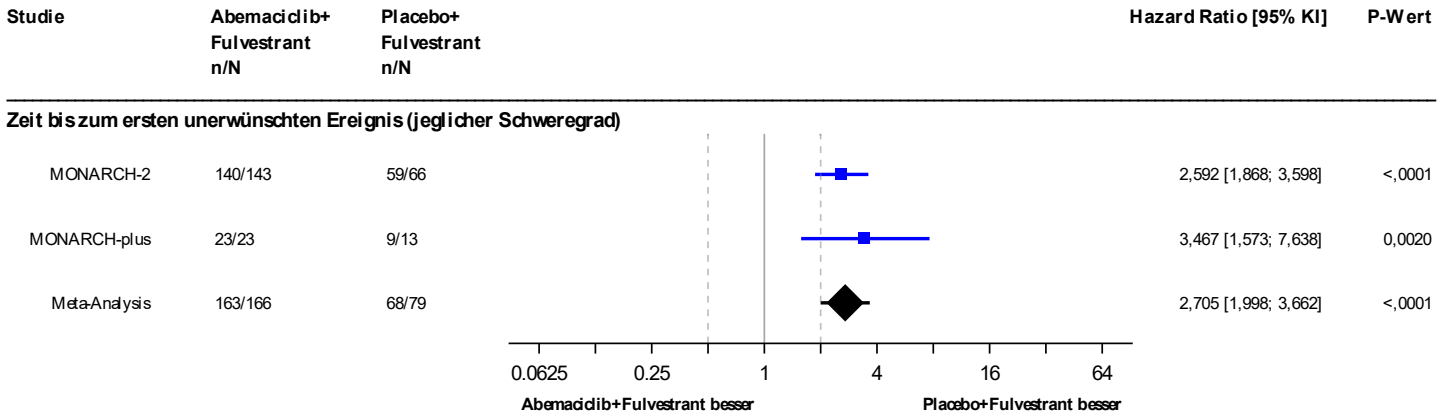
Abbildung 1005.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=3,5905, P-Wert=0,0581, I2 Index=72,1%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttteae_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
03SEP2021 / 05:41

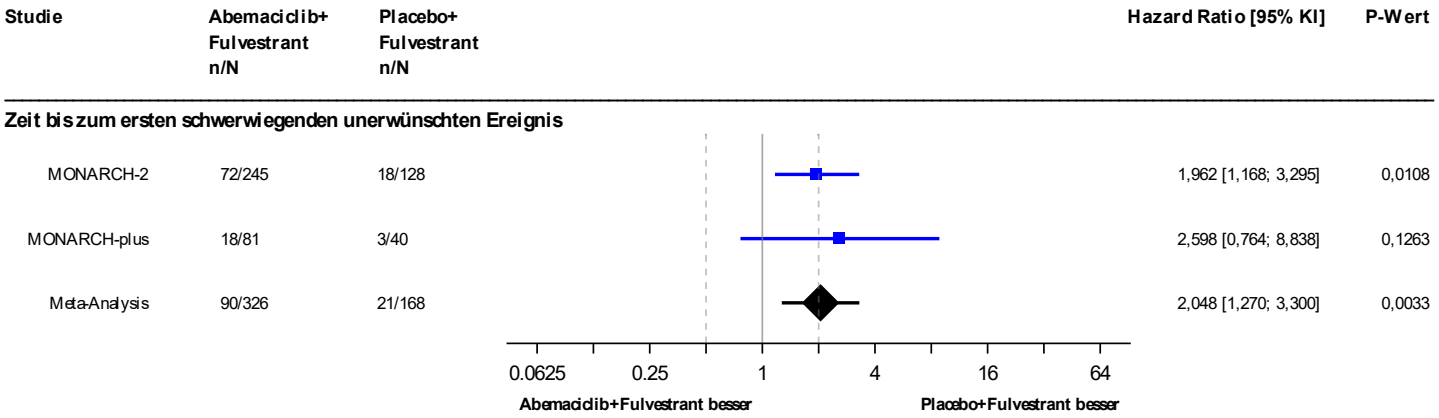
Abbildung 1005.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,4439, P-Wert=0,5052, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttteae_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
03SEP2021 / 05:41

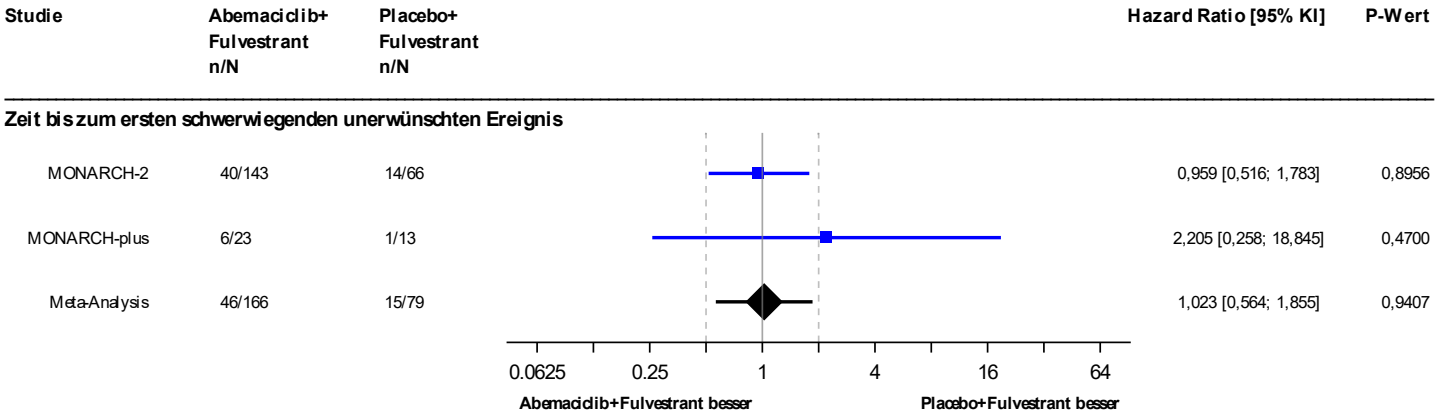
Abbildung 1006.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1715, P-Wert=0,6788, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttsae_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
03SEP2021 / 05:41

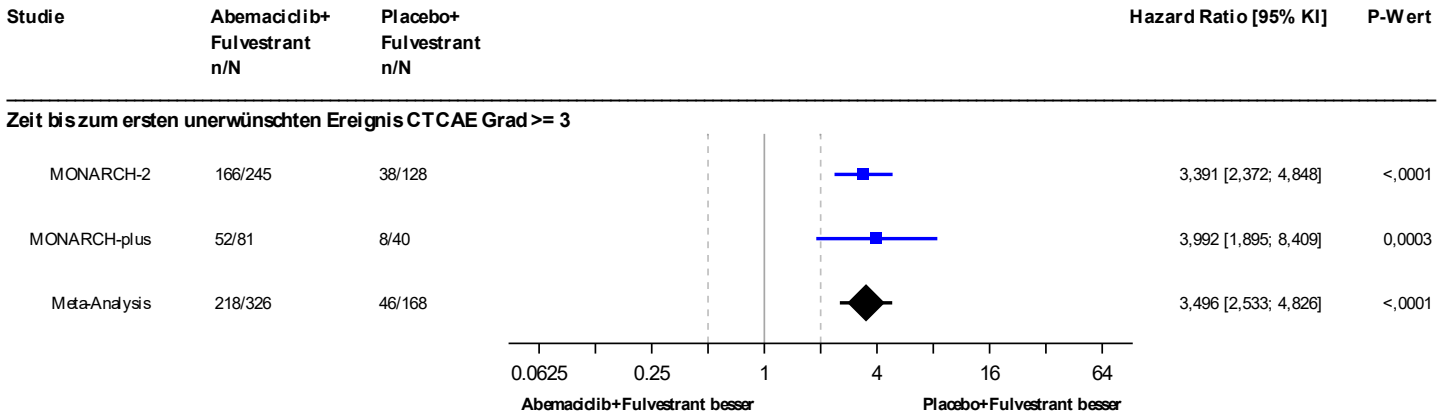
Abbildung 1006.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,5336, P-Wert=0,4651, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttsae_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
03SEP2021 / 05:41

Abbildung 1007.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1496, P-Wert=0,6989, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttgr3_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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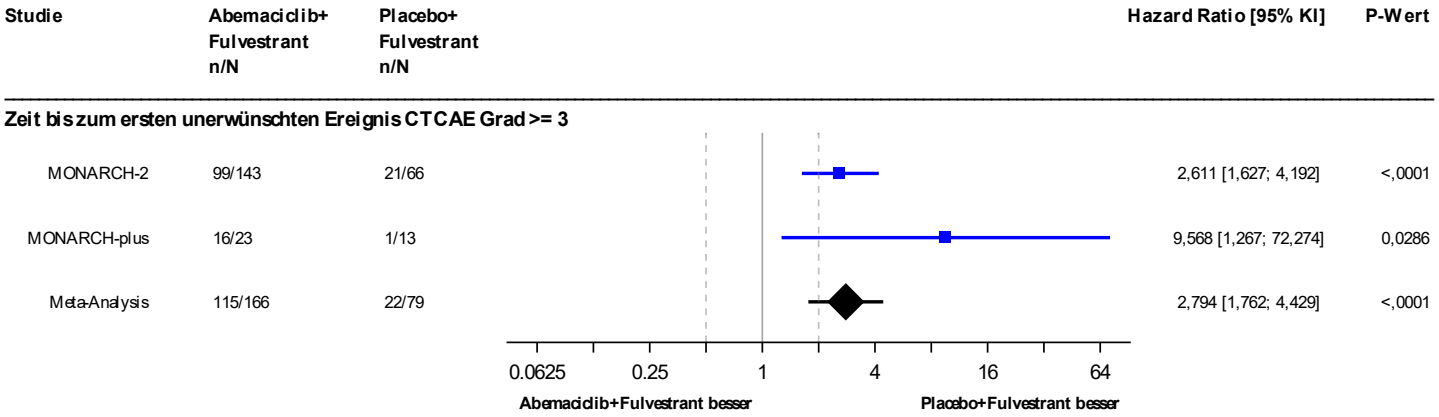
Abbildung 1007.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,5020, P-Wert=0,2204, I2 Index=33,4%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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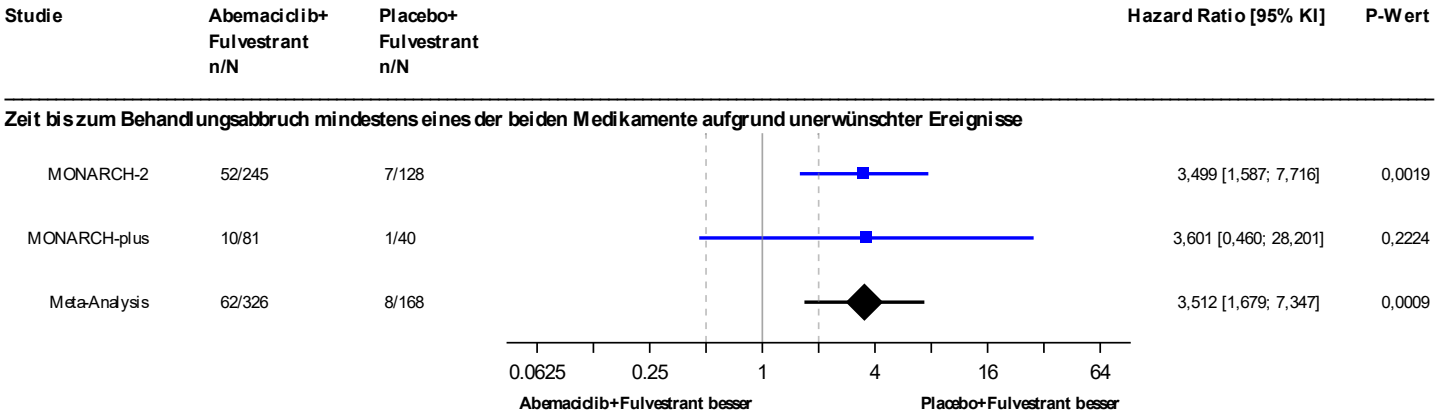
Abbildung 1008.1: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0007, P-Wert=0,9796, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttdiscf_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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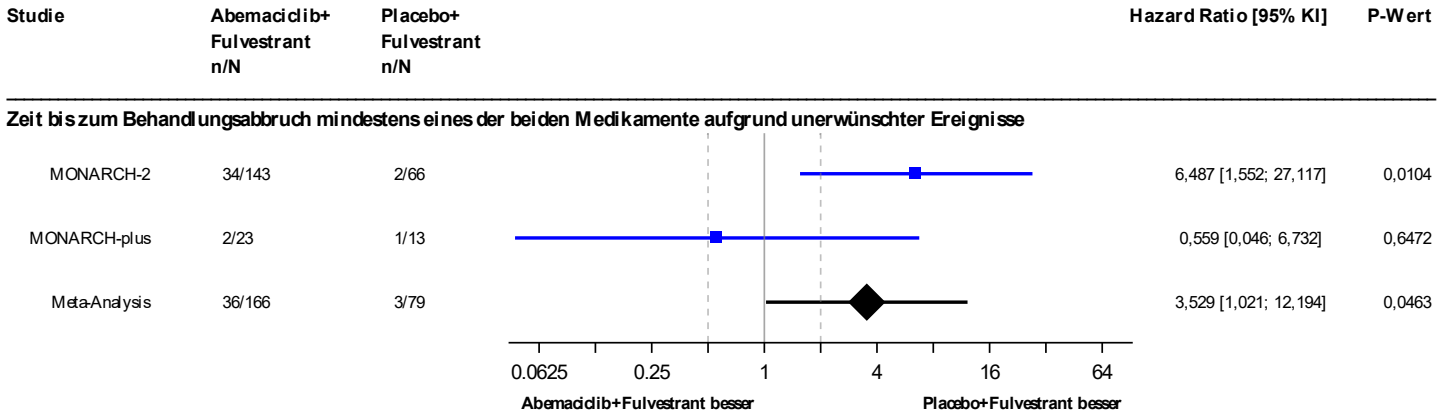
Abbildung 1008.2: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=2,8015, P-Wert=0,0942, I2 Index=64,3%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttdiscf_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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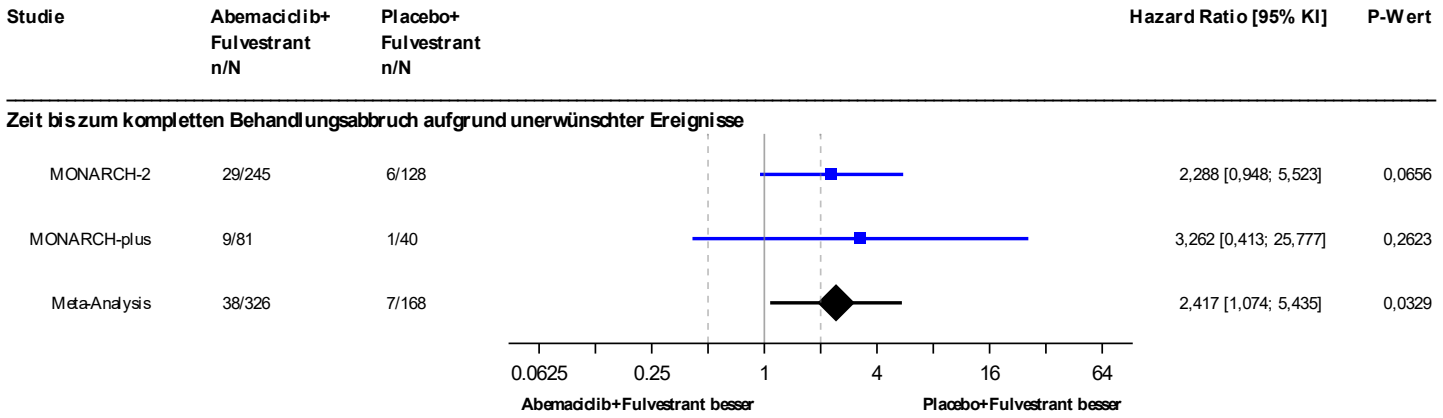
Abbildung 1009.1: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0956, P-Wert=0,7571, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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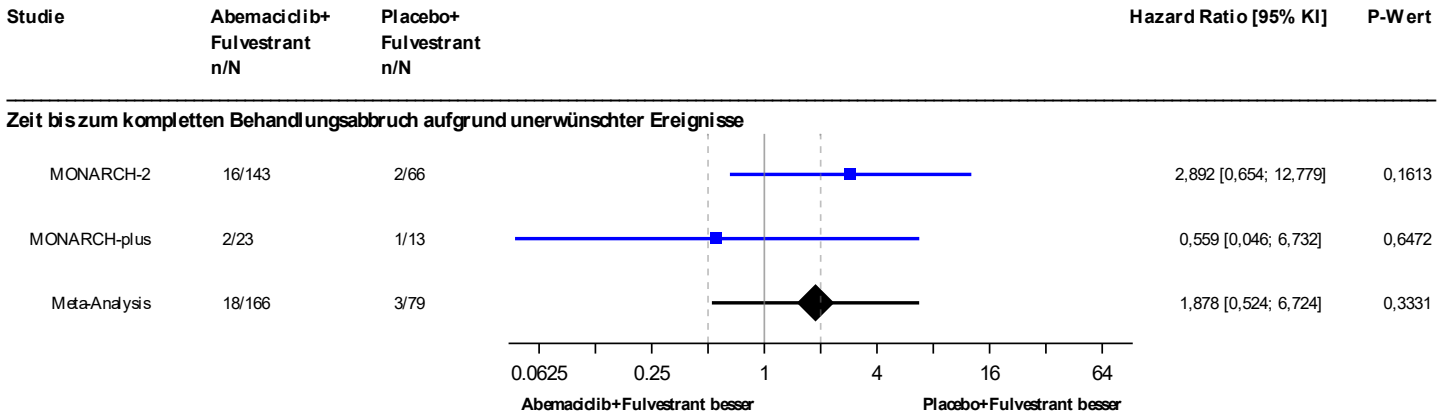
Abbildung 1009.2: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,2347, P-Wert=0,2665, I2 Index=19,0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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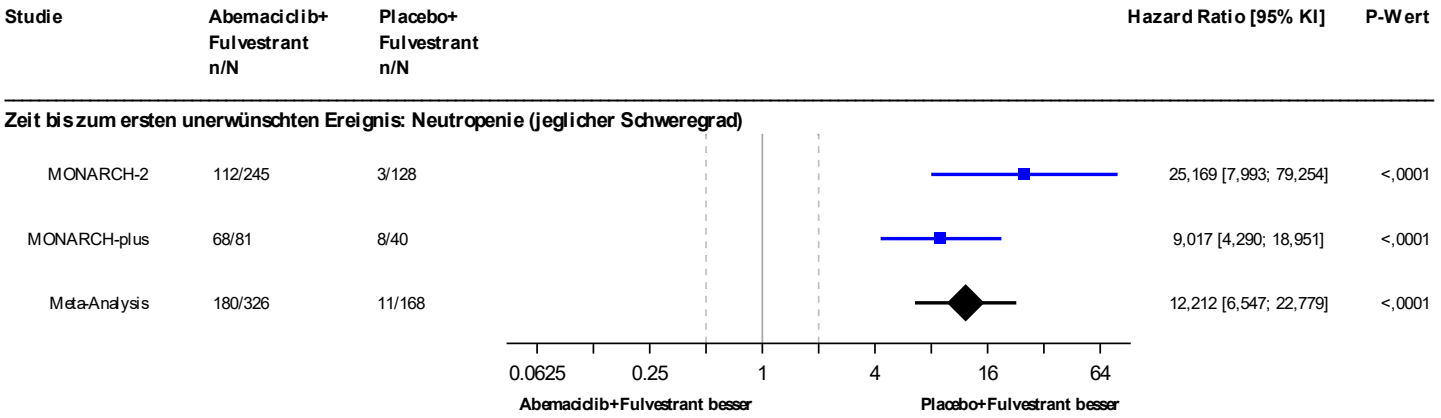
Abbildung 1010.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,1678, P-Wert=0,1409, I2 Index=53,9%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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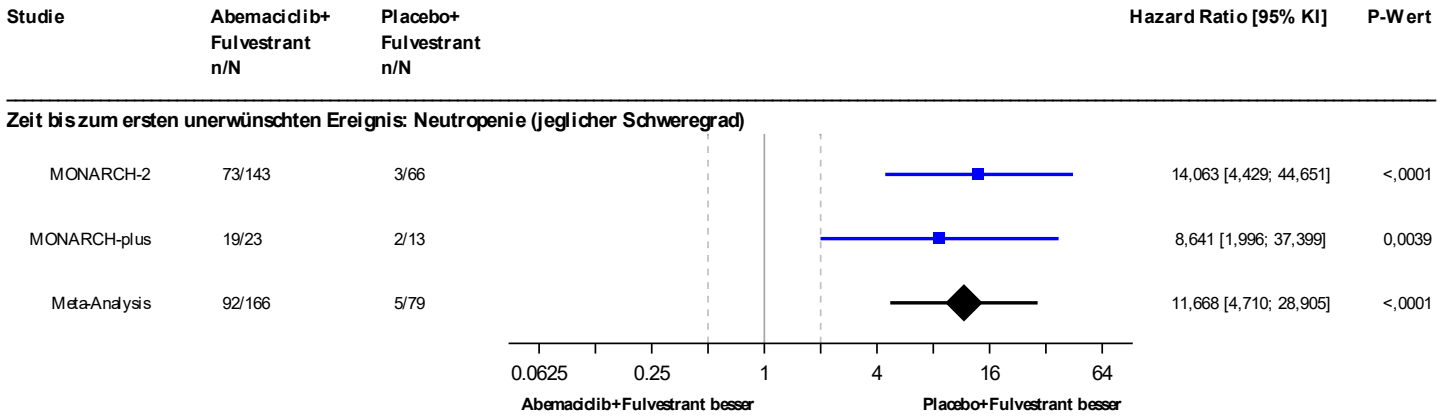
Abbildung 1010.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2618, P-Wert=0,6089, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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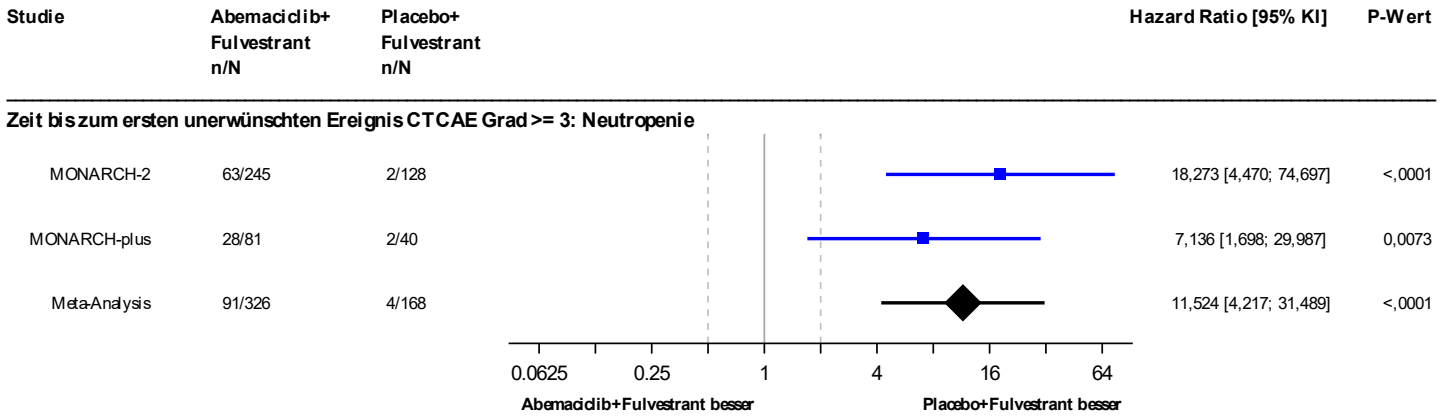
Abbildung 1011.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,8400, P-Wert=0,3594, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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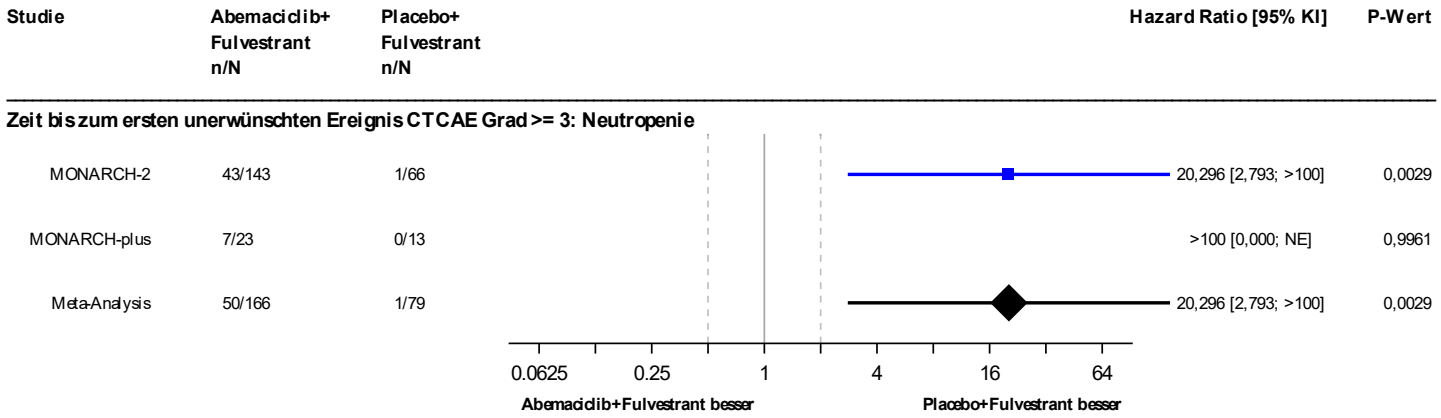
Abbildung 1011.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9968, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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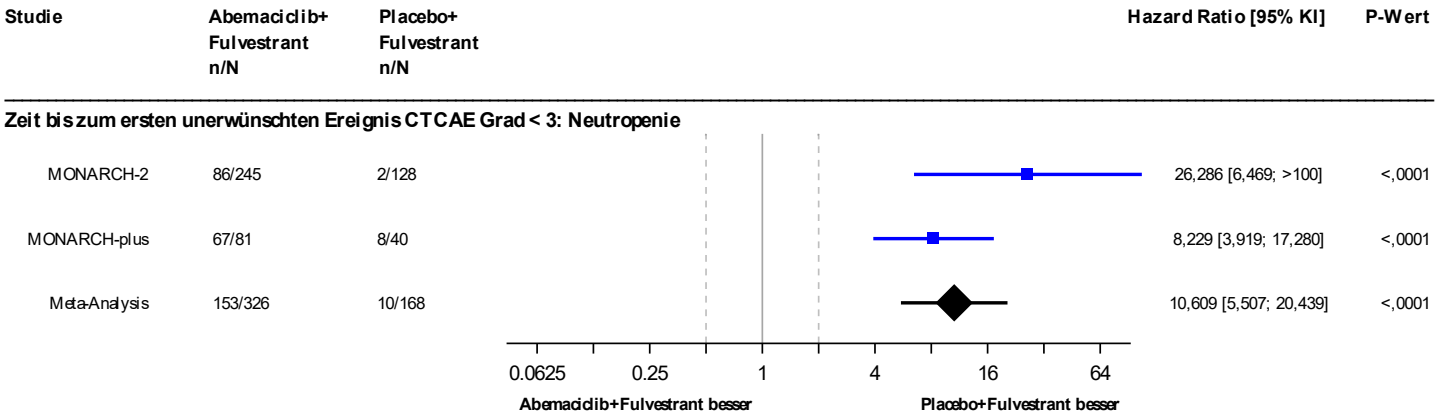
Abbildung 1012.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,0595, P-Wert=0,1513, I2 Index=51,4%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttnp2aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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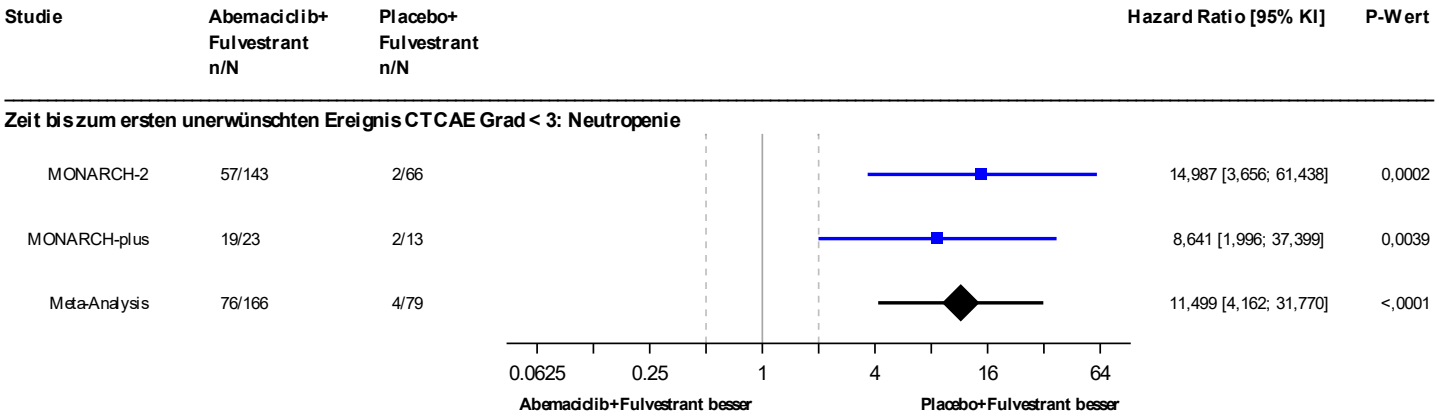
Abbildung 1012.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2816, P-Wert=0,5957, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttnp2aesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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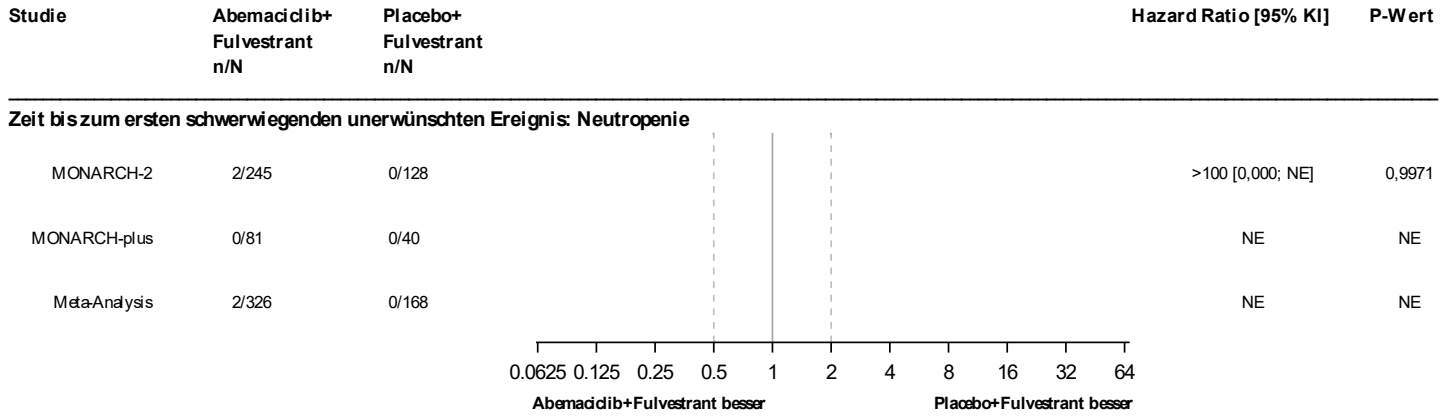
Abbildung 1013.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttnpsaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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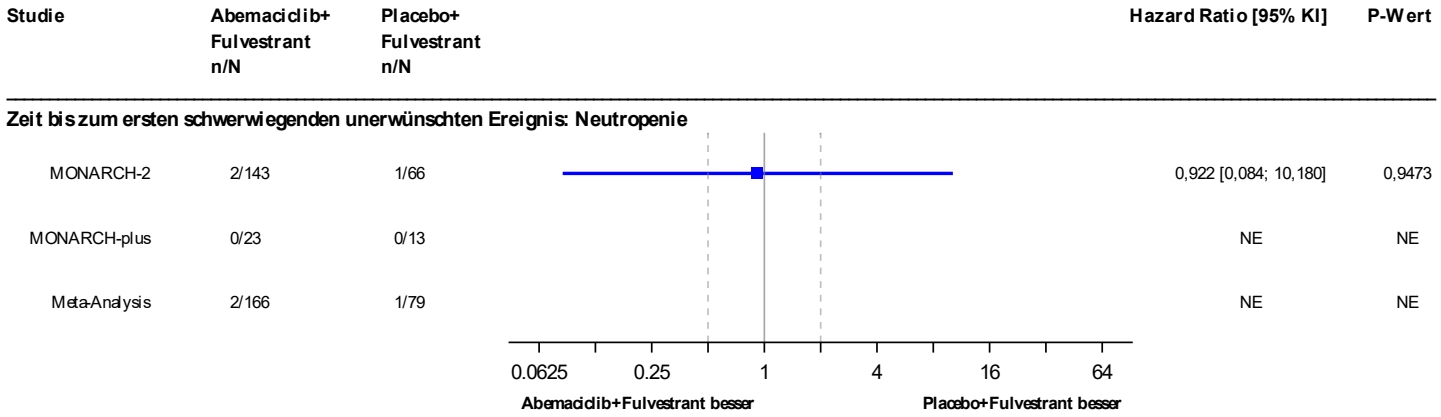
Abbildung 1013.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttnpsaesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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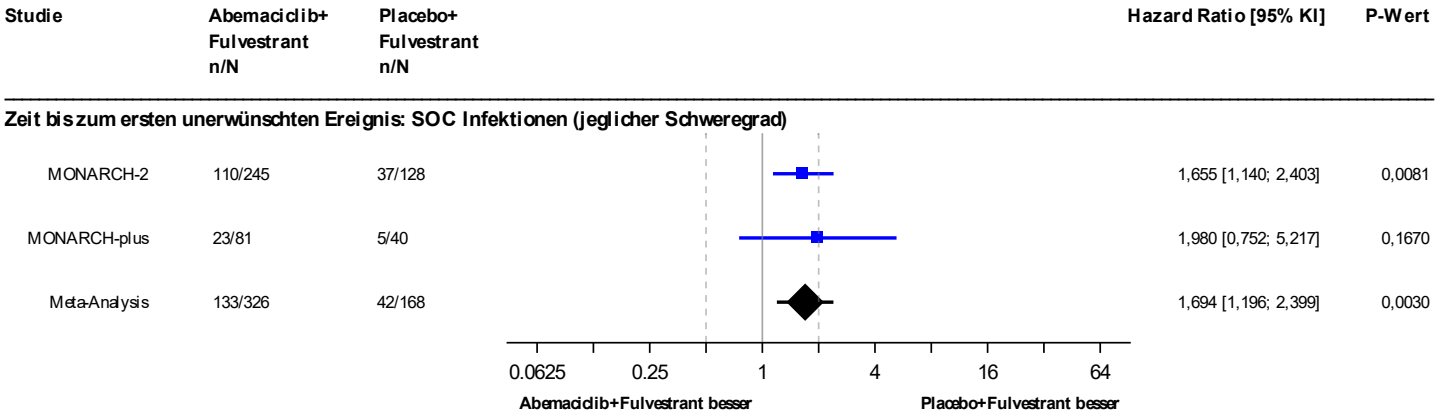
Abbildung 1014.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1146, P-Wert=0,7350, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttifaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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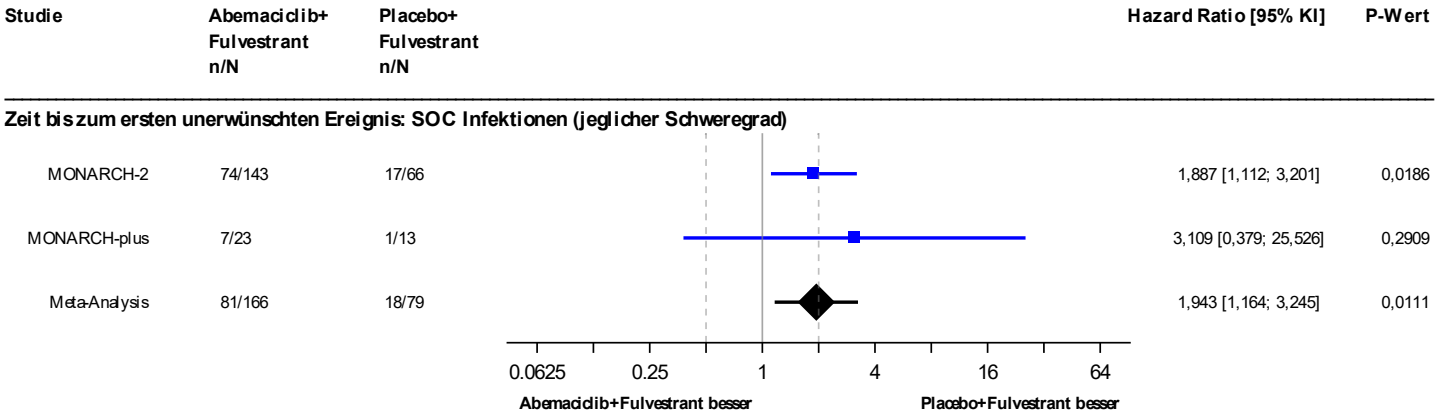
Abbildung 1014.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2035, P-Wert=0,6519, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttifaesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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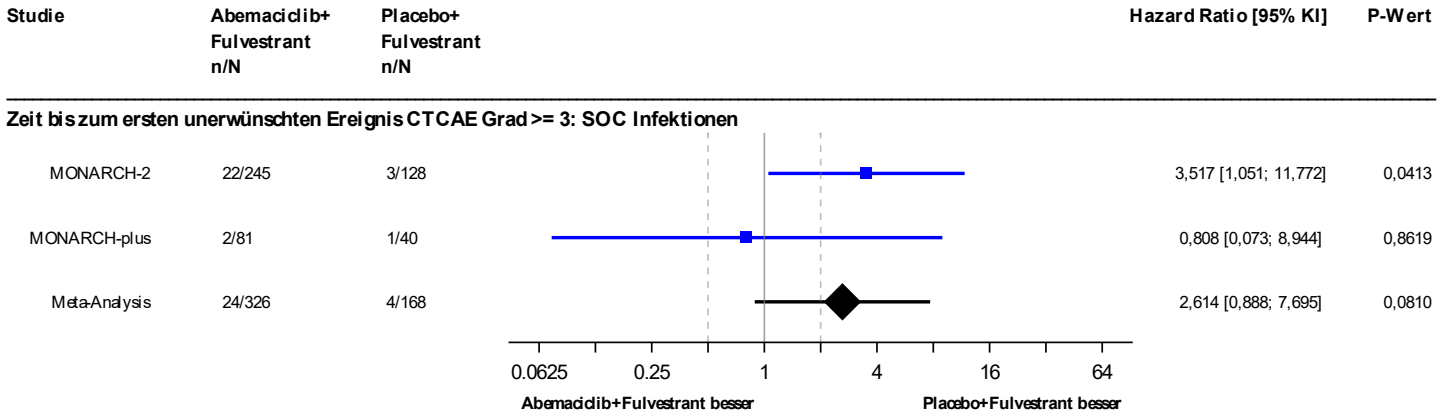
Abbildung 1015.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,1479, P-Wert=0,2840, I2 Index=12,9%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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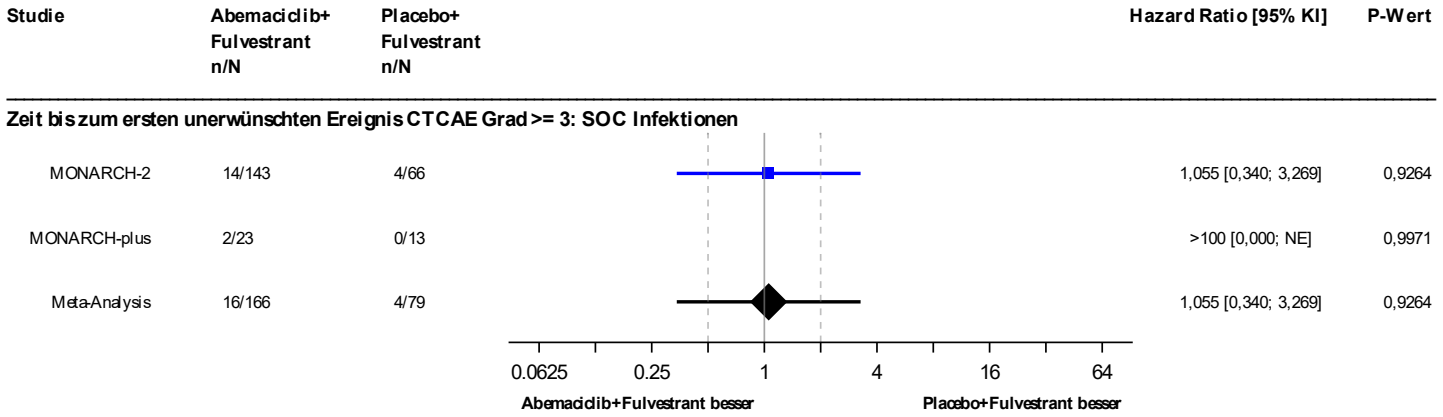
Abbildung 1015.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9971, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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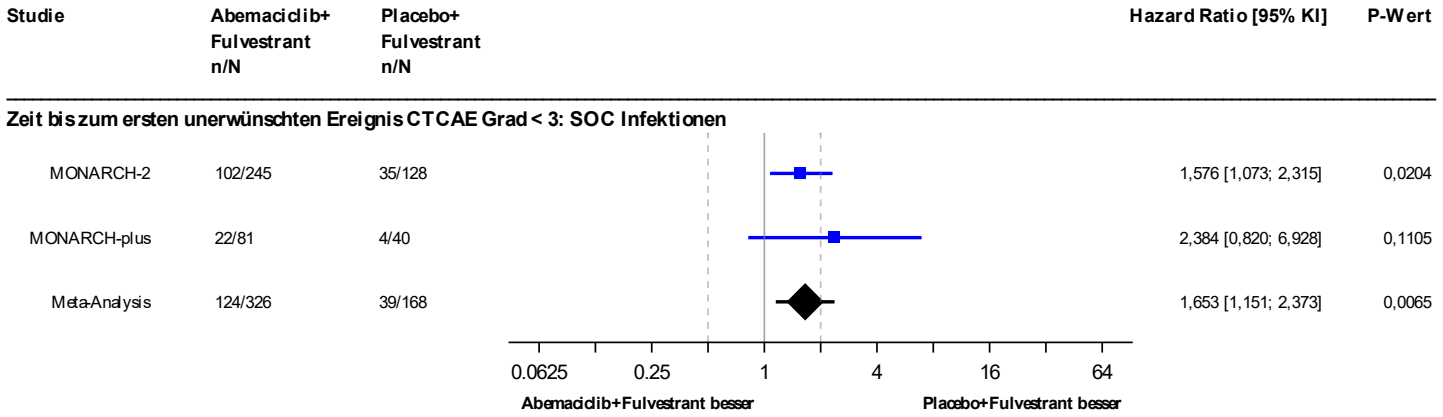
Abbildung 1016.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,5117, P-Wert=0,4744, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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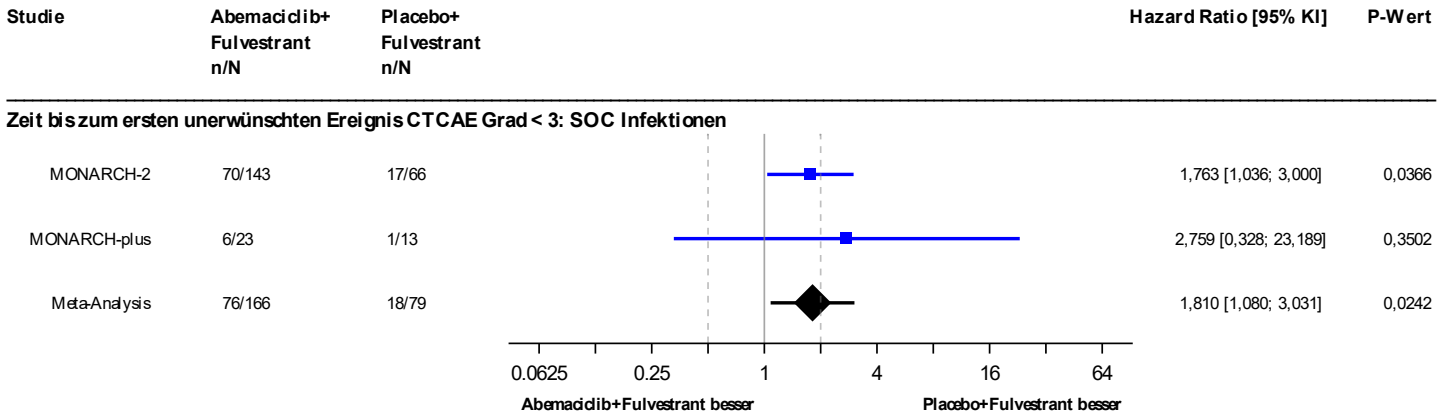
Abbildung 1016.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1600, P-Wert=0,6891, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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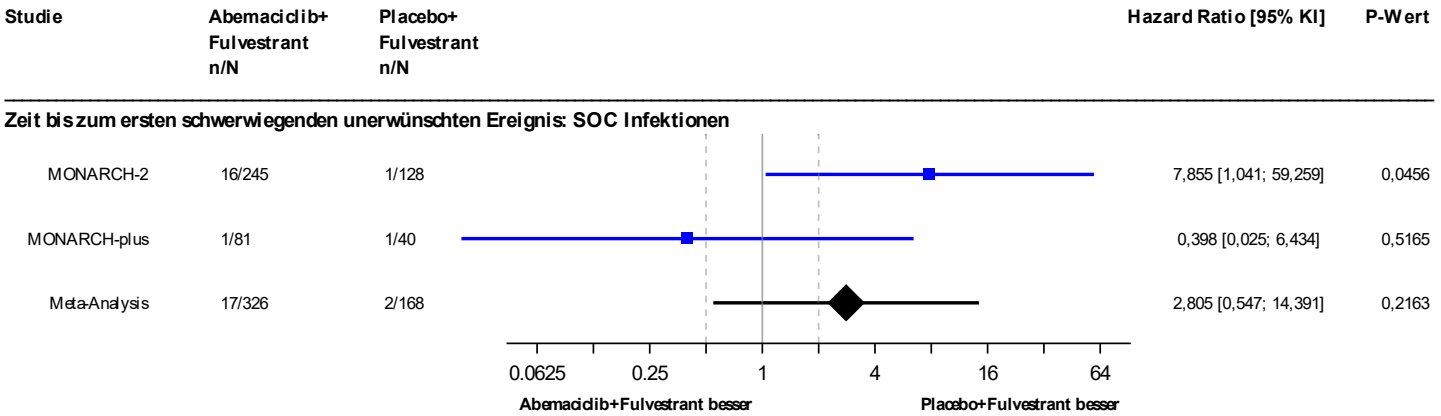
Abbildung 1017.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,8889, P-Wert=0,0892, I2 Index=65,4%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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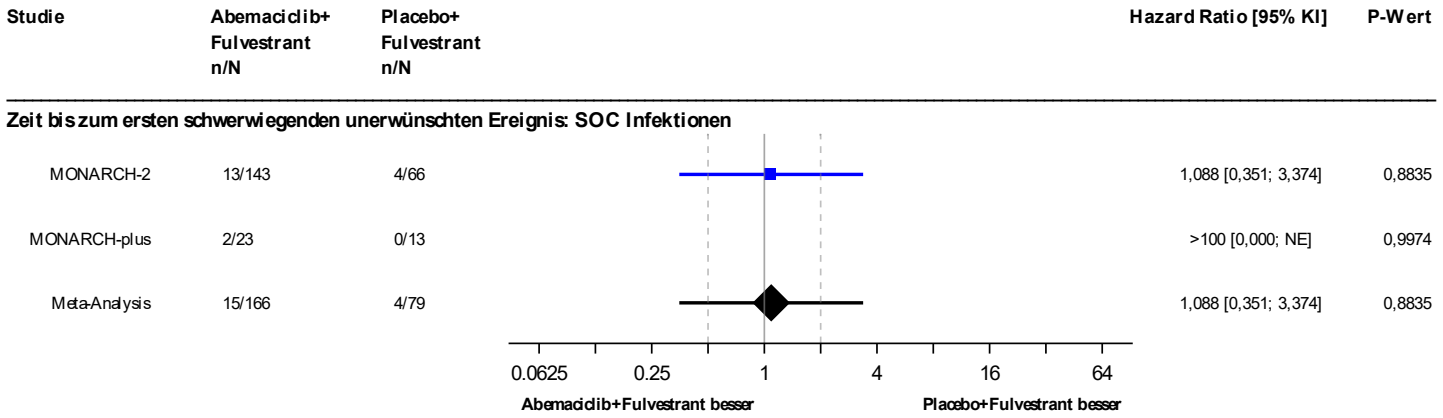
Abbildung 1017.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9974, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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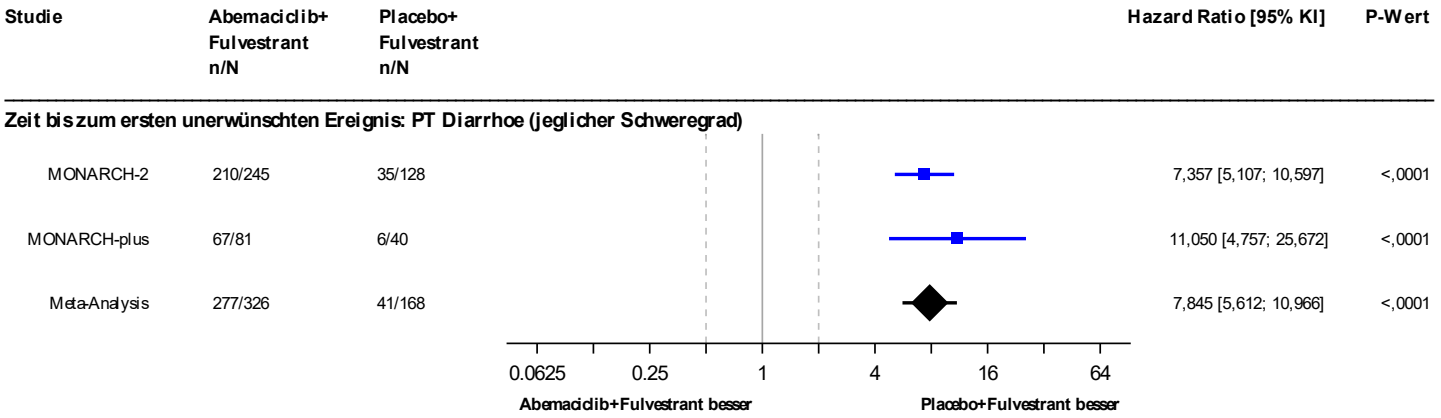
Abbildung 1018.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7535, P-Wert=0,3854, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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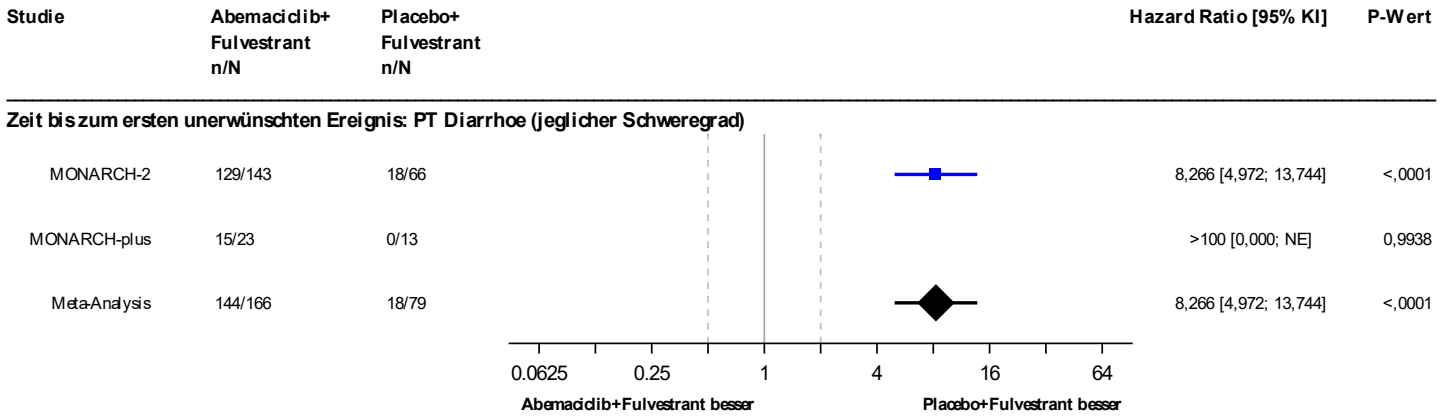
Abbildung 1018.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9946, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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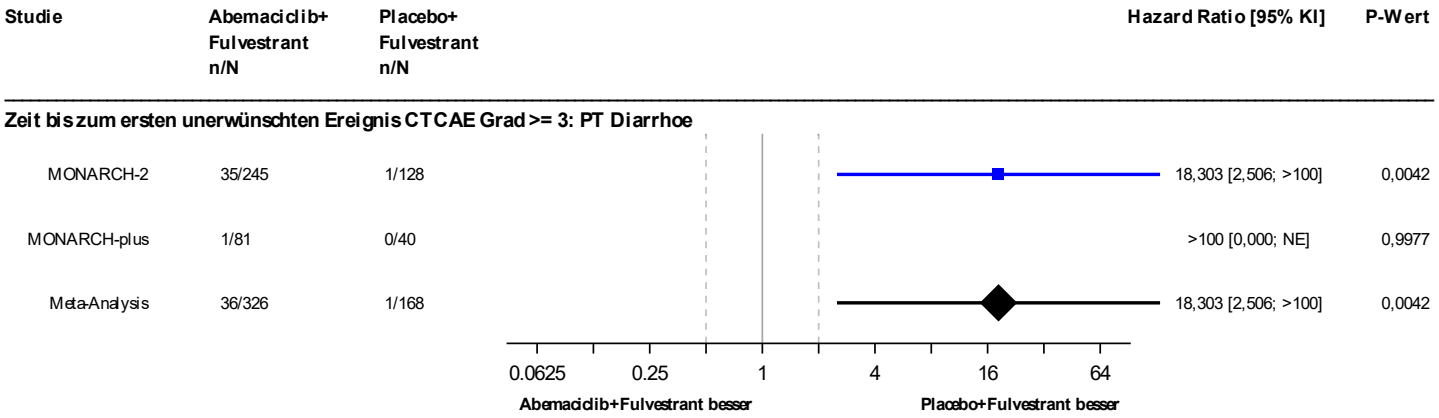
Abbildung 1019.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9981, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttdi3aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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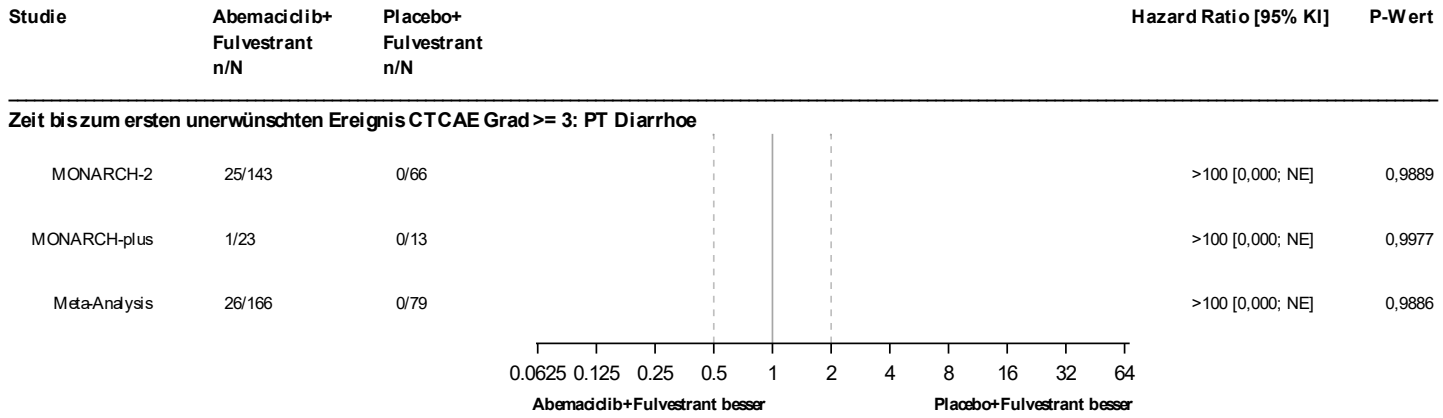
Abbildung 1019.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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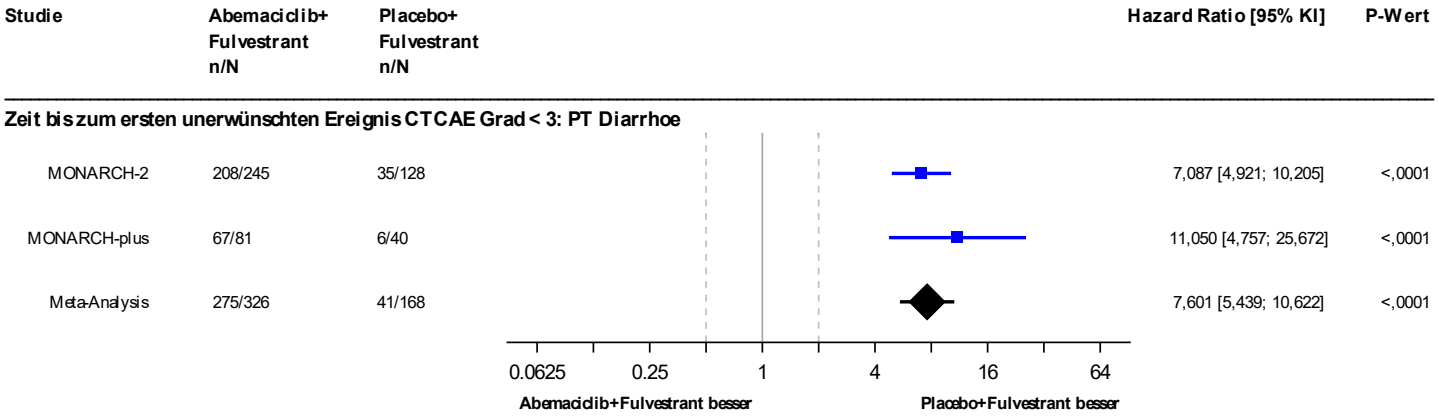
Abbildung 1020.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,8988, P-Wert=0,3431, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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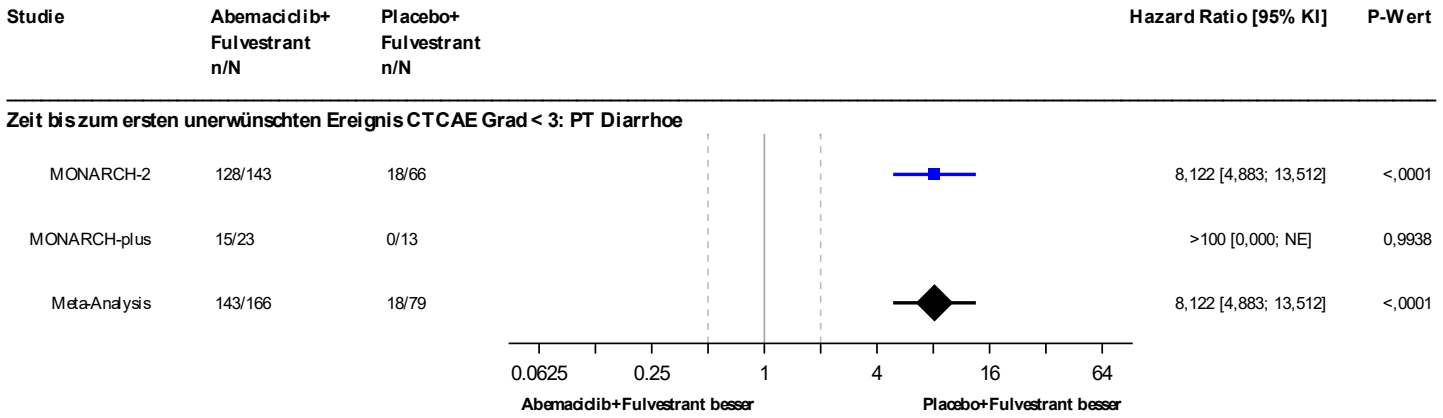
Abbildung 1020.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9945, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttdi2aesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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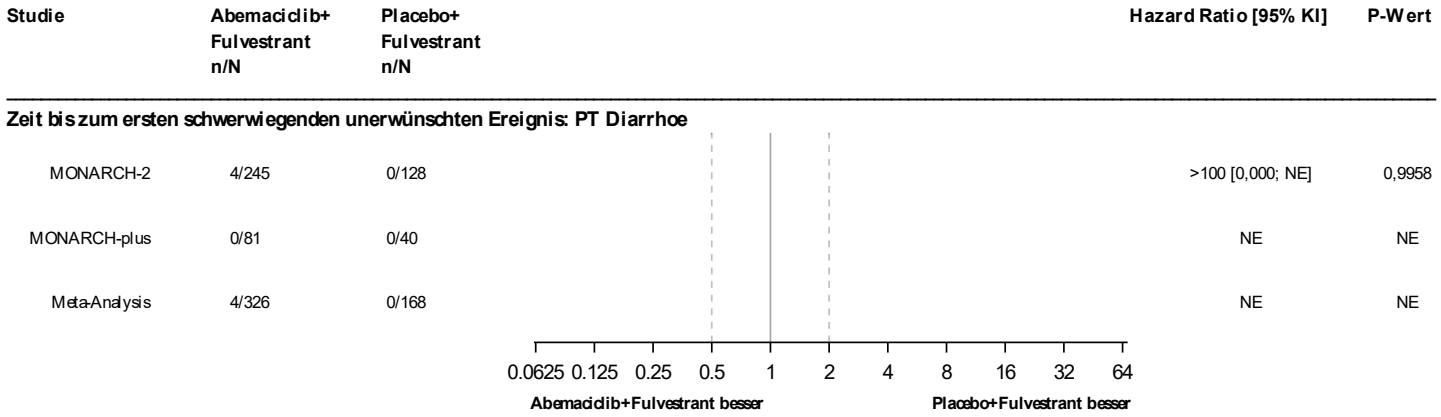
Abbildung 1021.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttdisaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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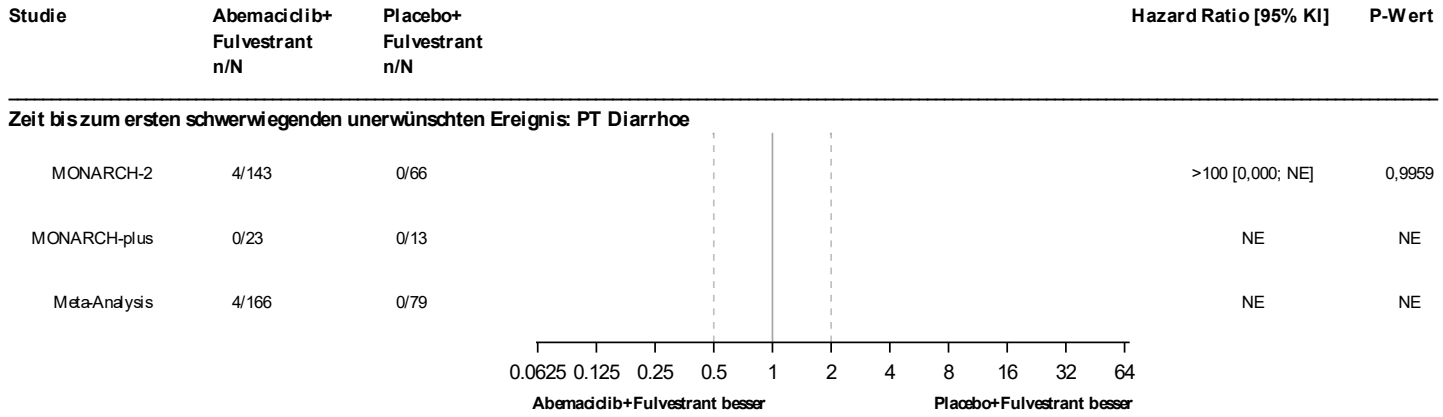
Abbildung 1021.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttdisaesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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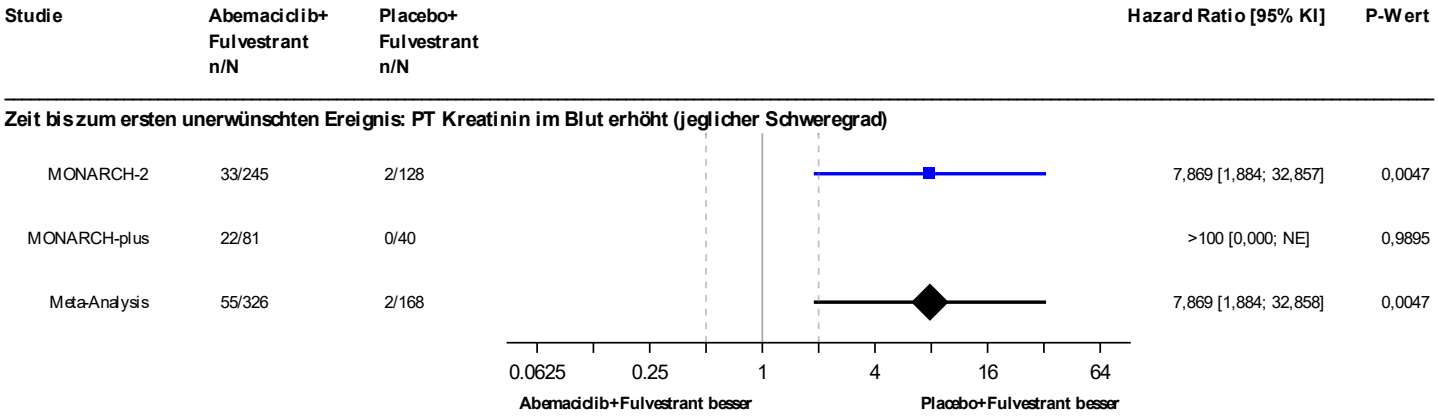
Abbildung 1022.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9908, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttcraesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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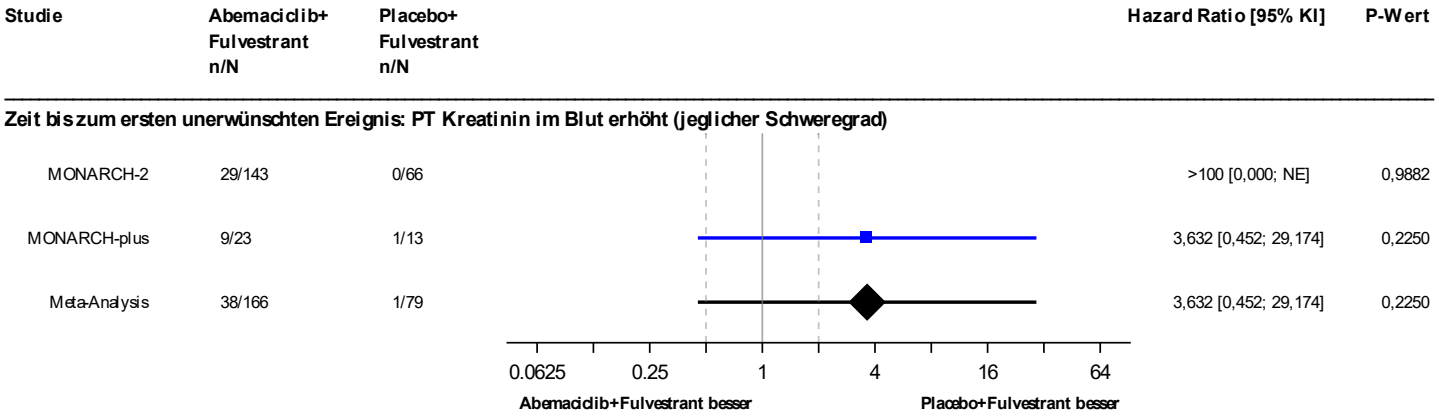
Abbildung 1022.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0002, P-Wert=0,9891, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttcraesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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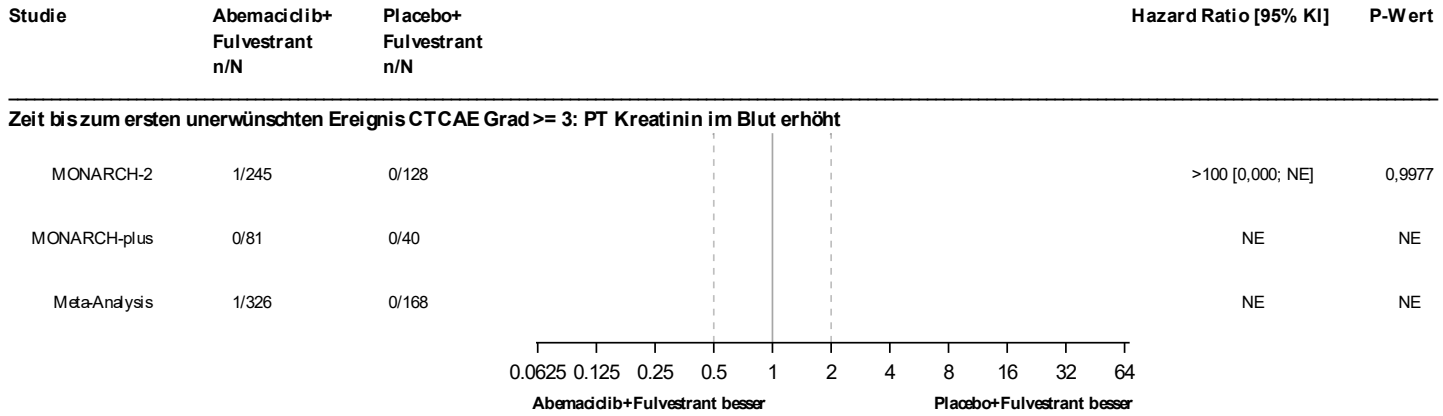
Abbildung 1023.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttcr3aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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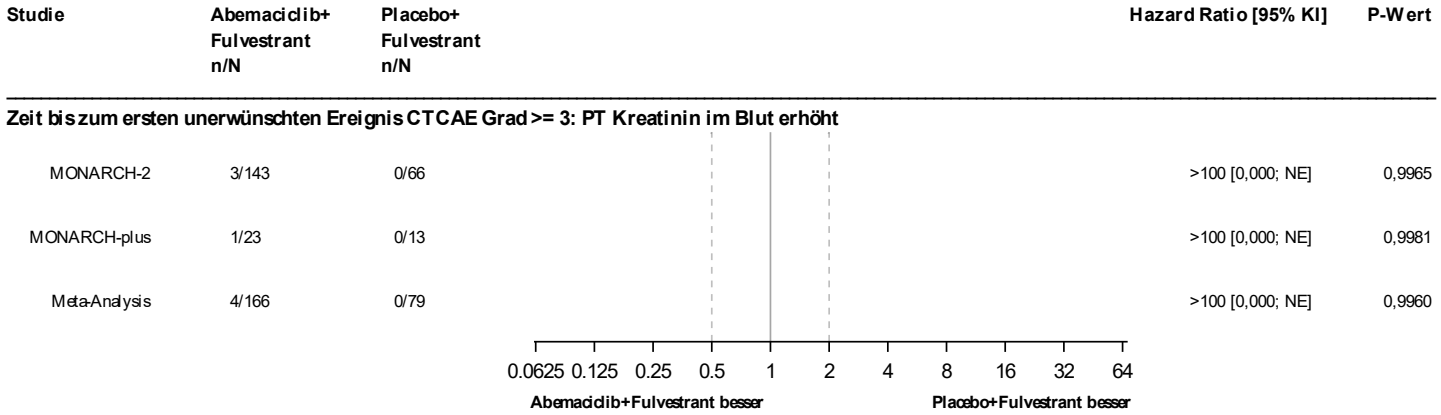
Abbildung 1023.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttcr3aesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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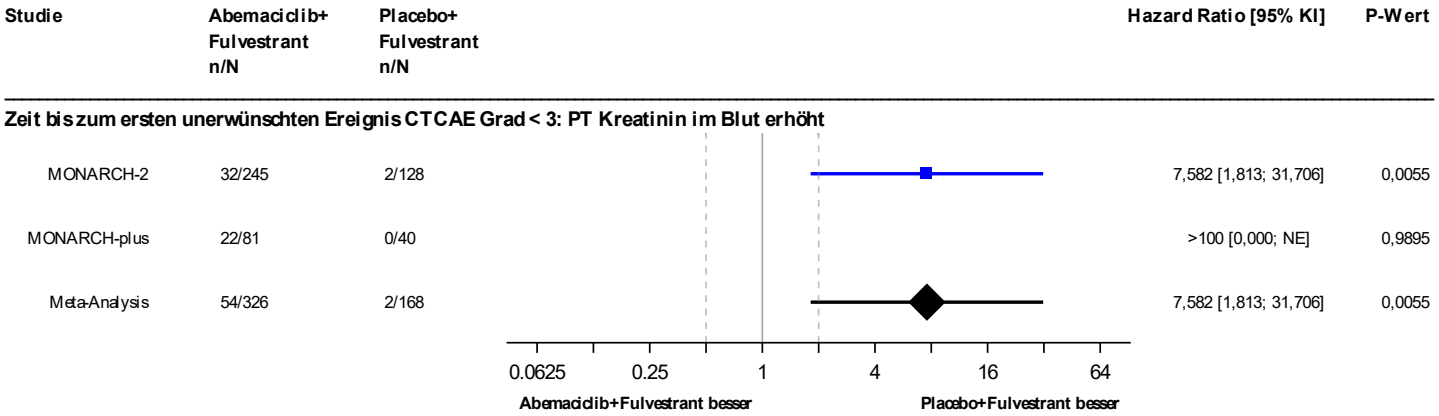
Abbildung 1024.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9908, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttcr2aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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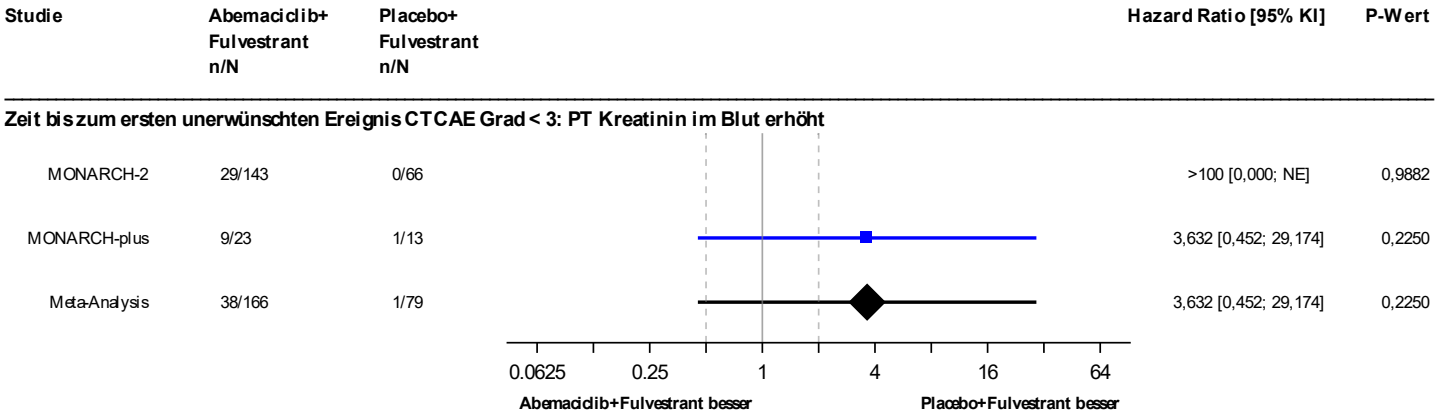
Abbildung 1024.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0002, P-Wert=0,9891, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttcr2aesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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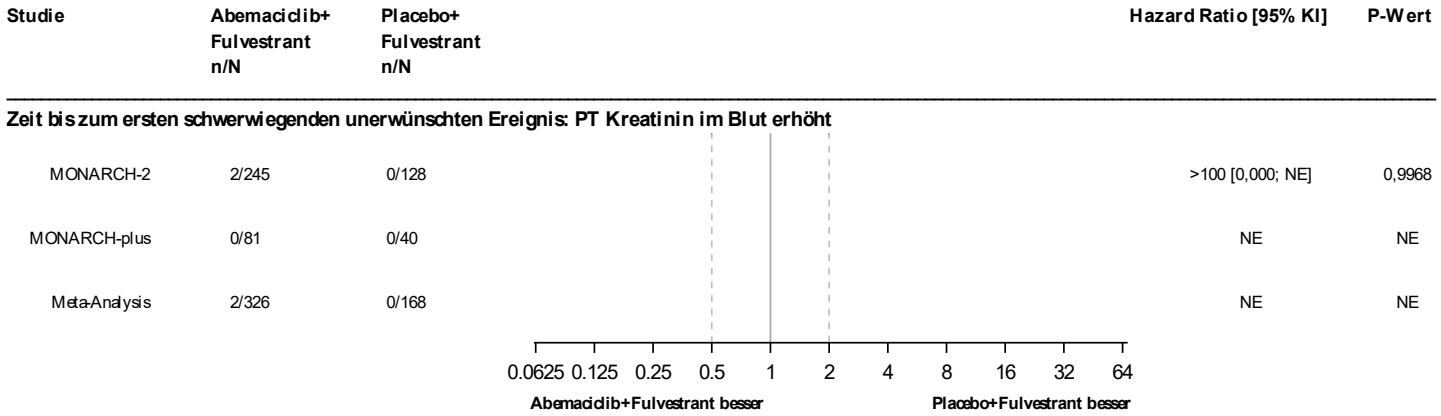
Abbildung 1025.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttcrsaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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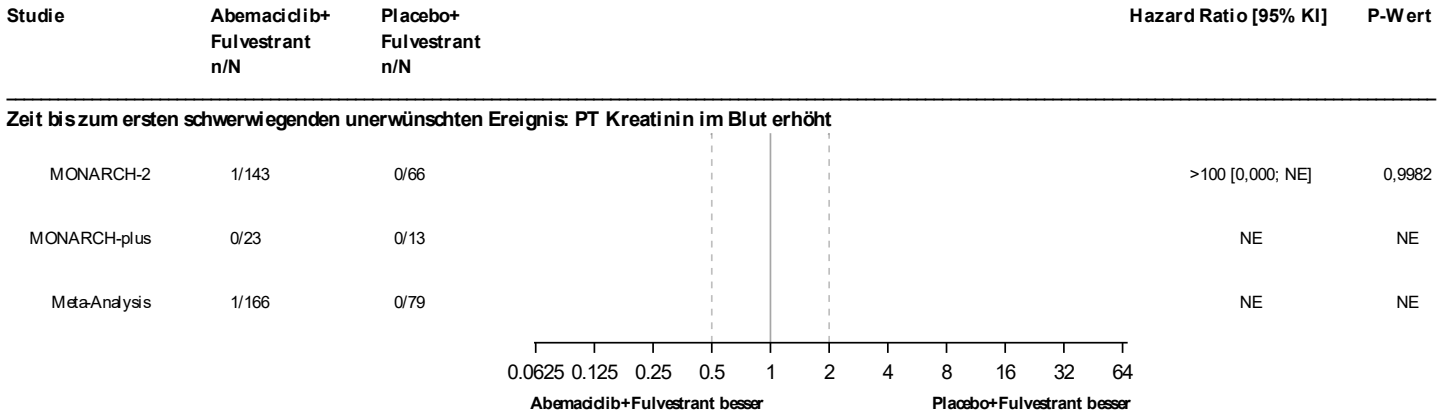
Abbildung 1025.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttcrsaesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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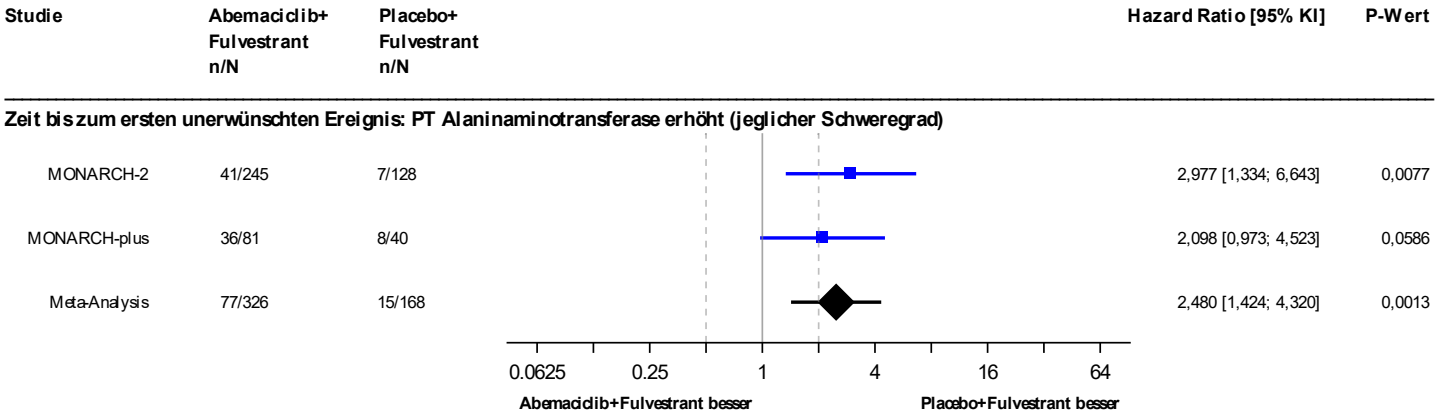
Abbildung 1026.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3814, P-Wert=0,5369, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttalaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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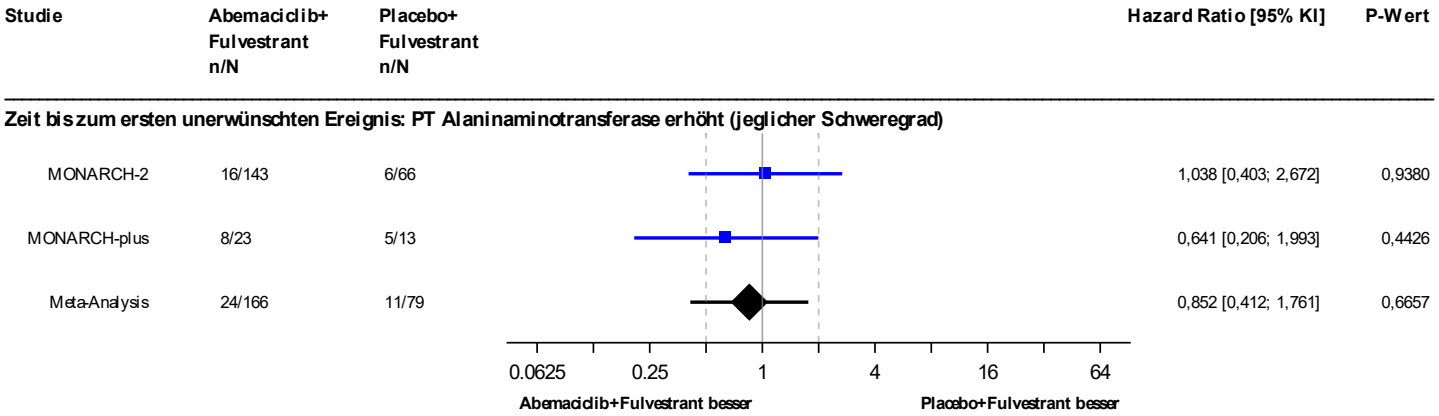
Abbildung 1026.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,4088, P-Wert=0,5226, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttalaesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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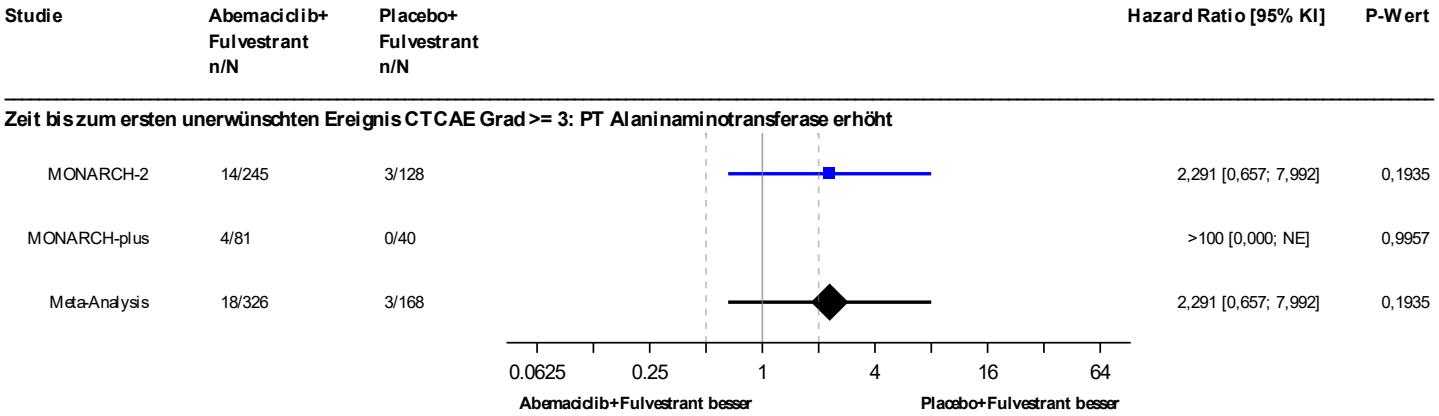
Abbildung 1027.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9959, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttal3aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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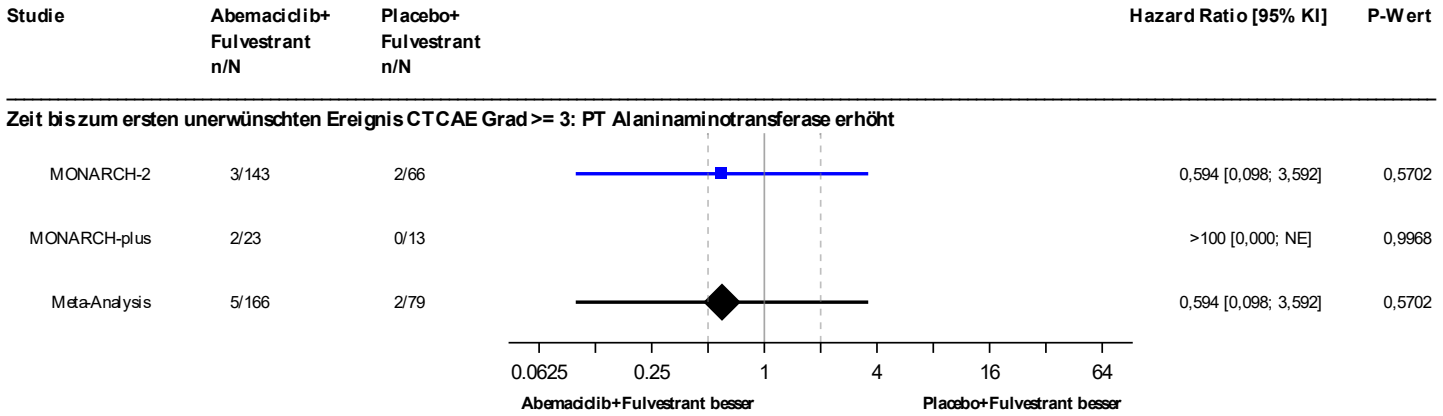
Abbildung 1027.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9967, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttal3aesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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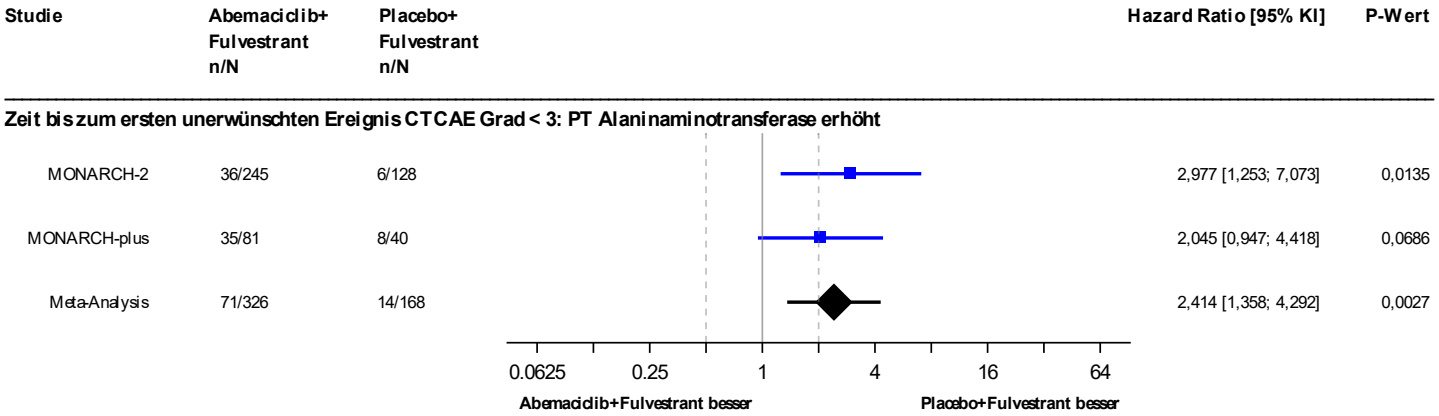
Abbildung 1028.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4029, P-Wert=0,5256, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttal2aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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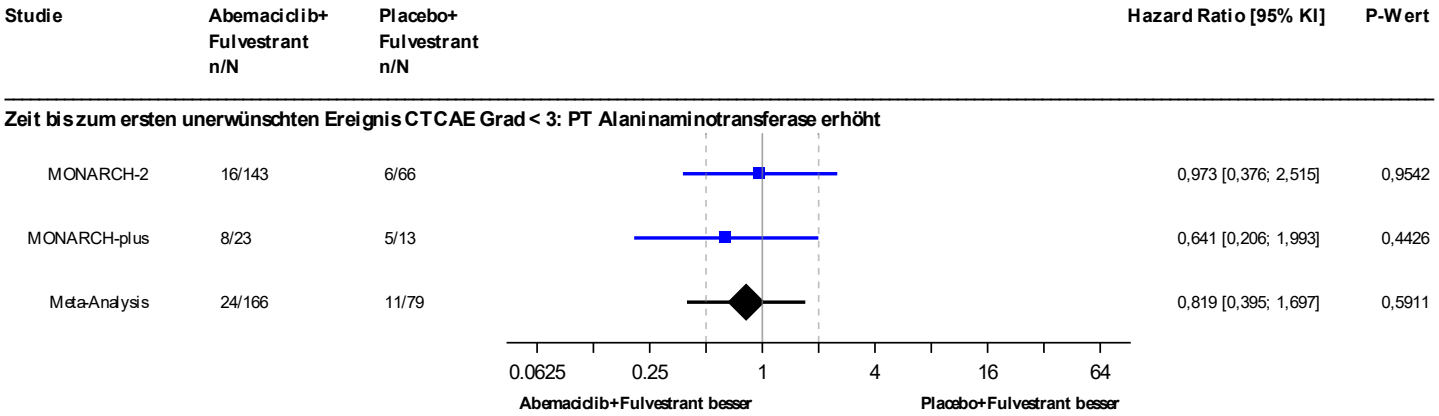
Abbildung 1028.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3041, P-Wert=0,5813, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttal2aesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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Abbildung 1029.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

Studie	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% KI]	P-Wert
Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alaninaminotransferase erhöht				
MONARCH-2	1/245	0/128	>100 [0,000; NE]	0,9977
MONARCH-plus	0/81	0/40	NE	NE
Meta-Analysis	1/326	0/168	NE	NE

Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttalsaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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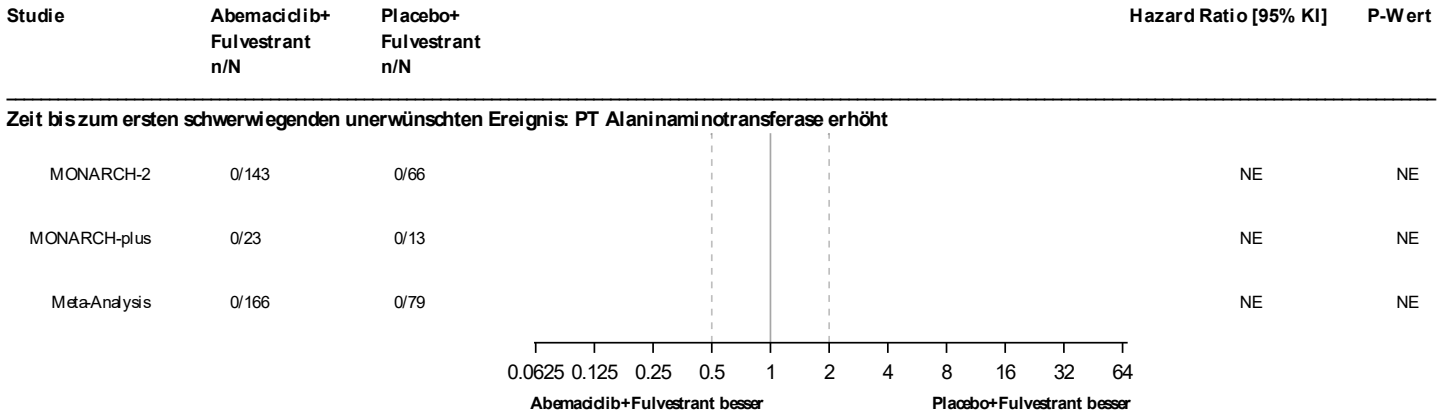
Abbildung 1029.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttalsaesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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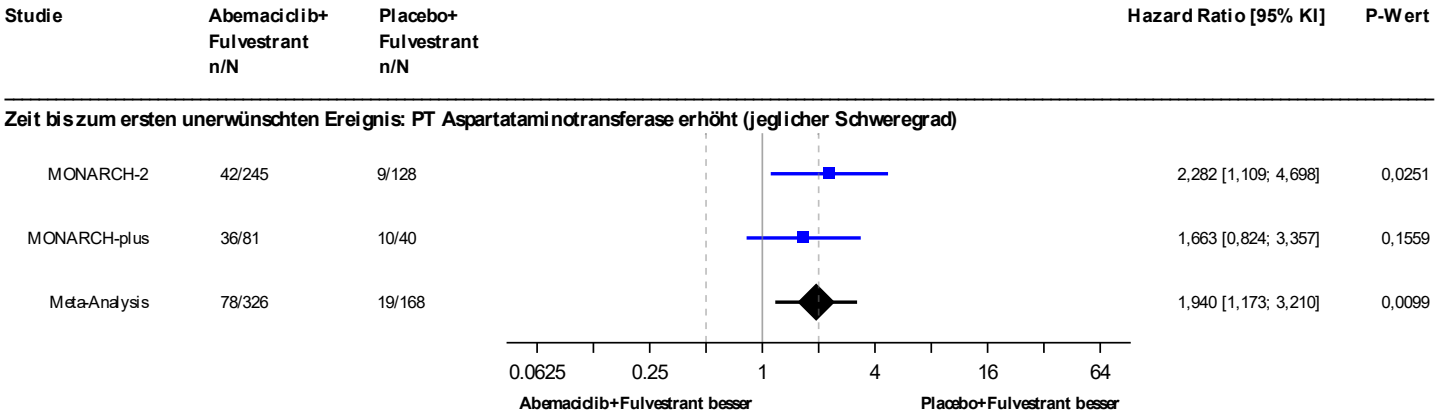
Abbildung 1030.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3795, P-Wert=0,5379, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttasaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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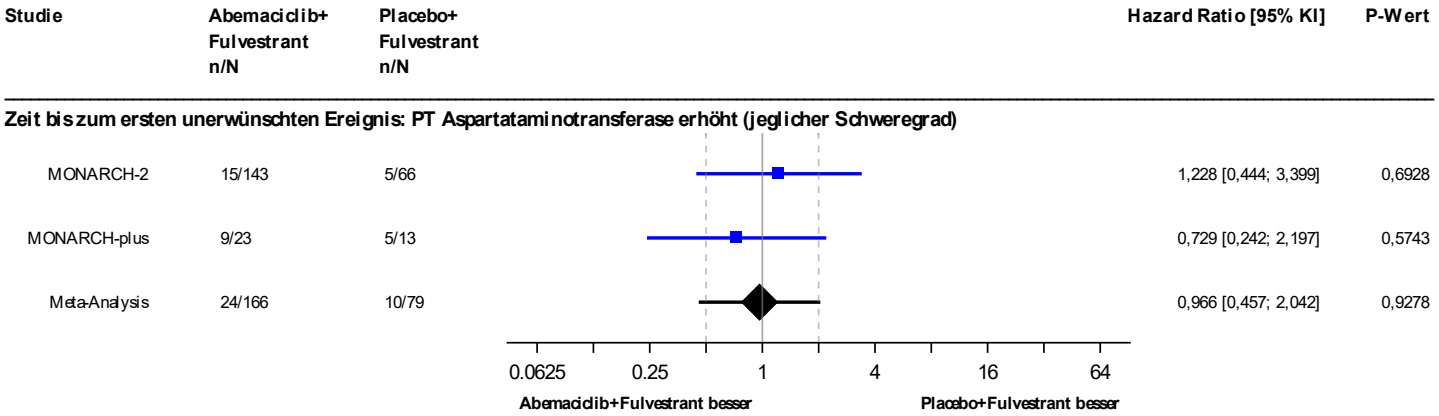
Abbildung 1030.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,4635, P-Wert=0,4960, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttasaesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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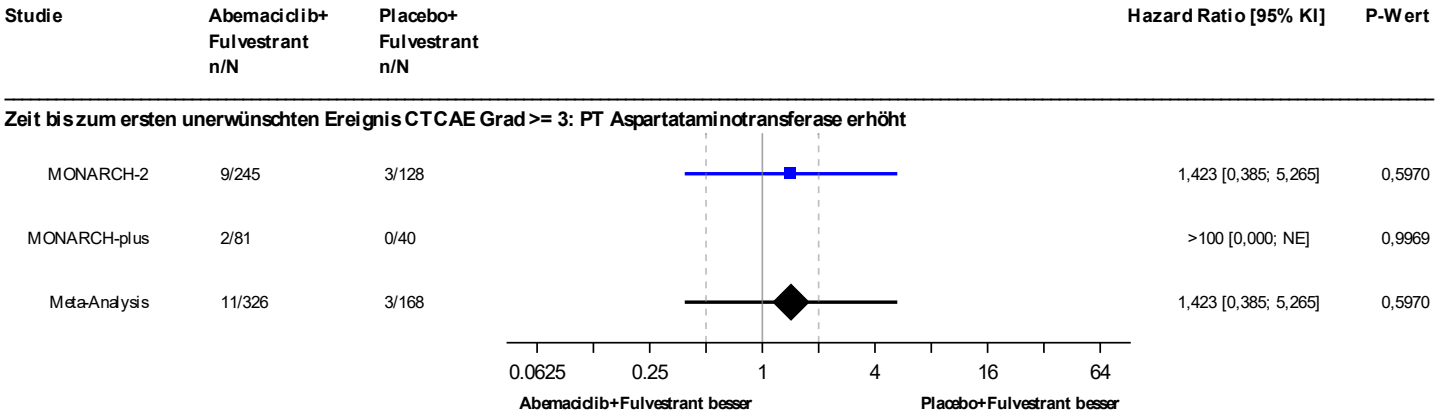
Abbildung 1031.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9970, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttas3aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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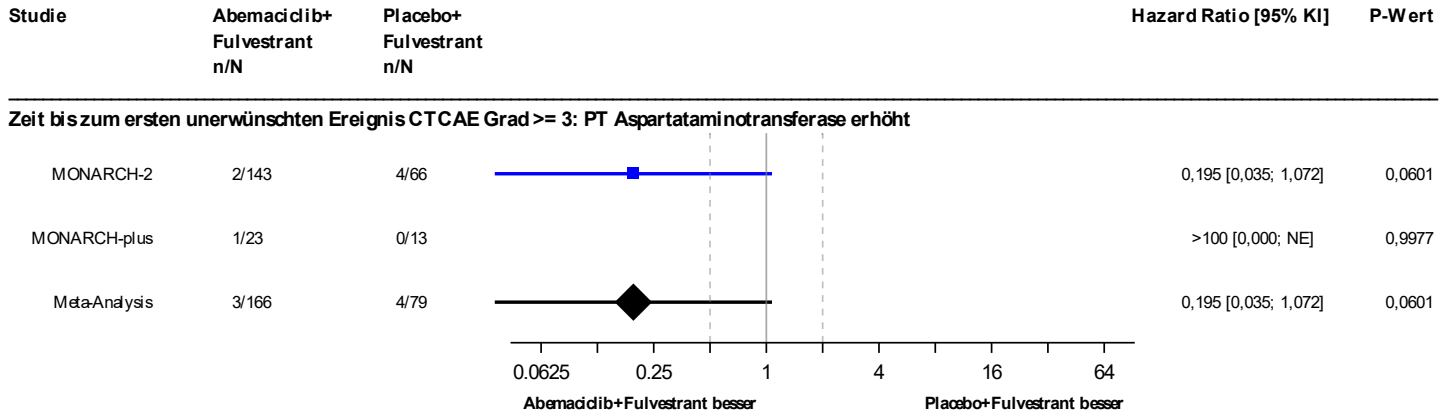
Abbildung 1031.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9975, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttas3aesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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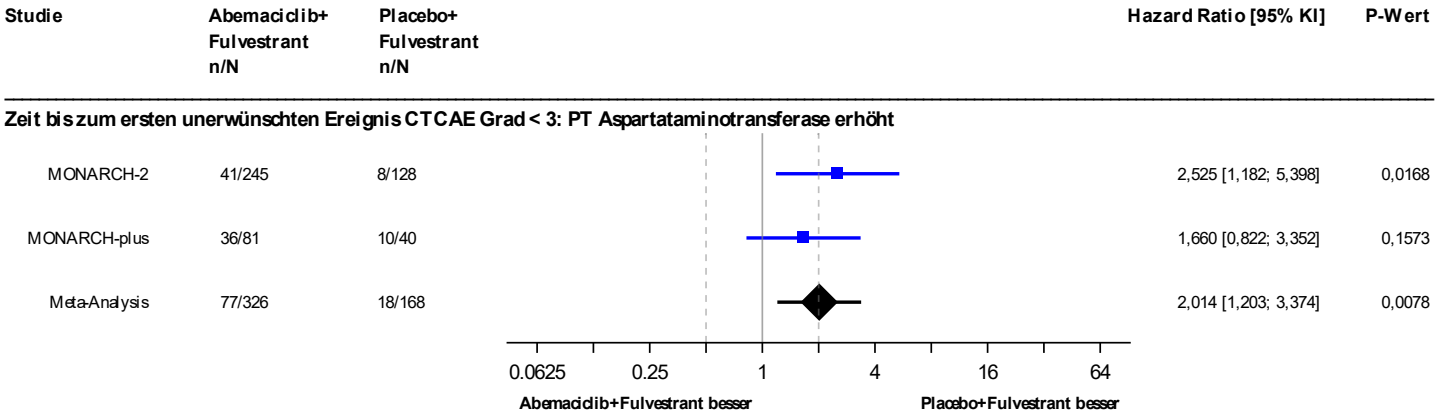
Abbildung 1032.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6314, P-Wert=0,4268, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttas2aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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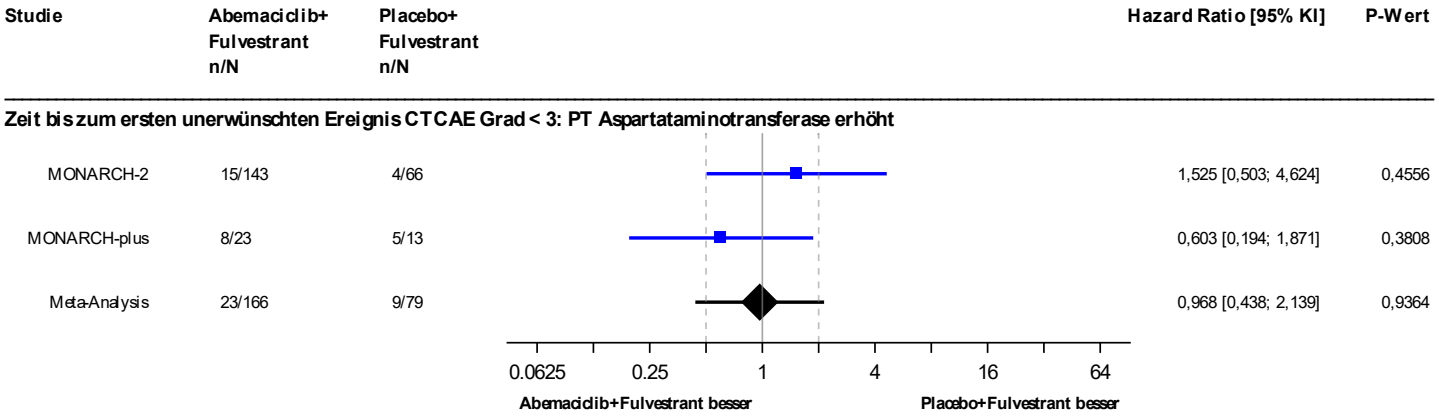
Abbildung 1032.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,3185, P-Wert=0,2509, I2 Index=24,2%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttas2aesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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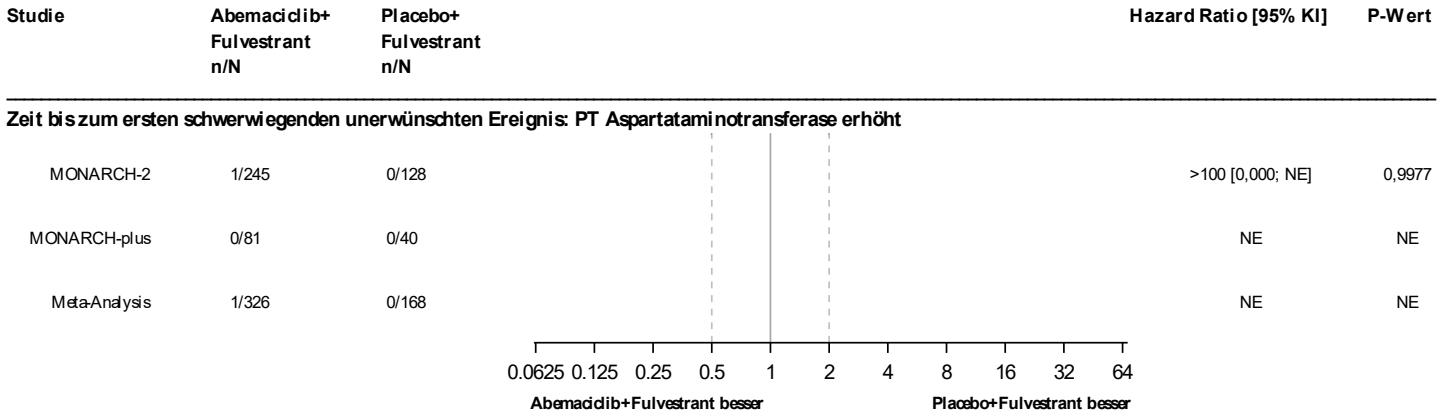
Abbildung 1033.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttassaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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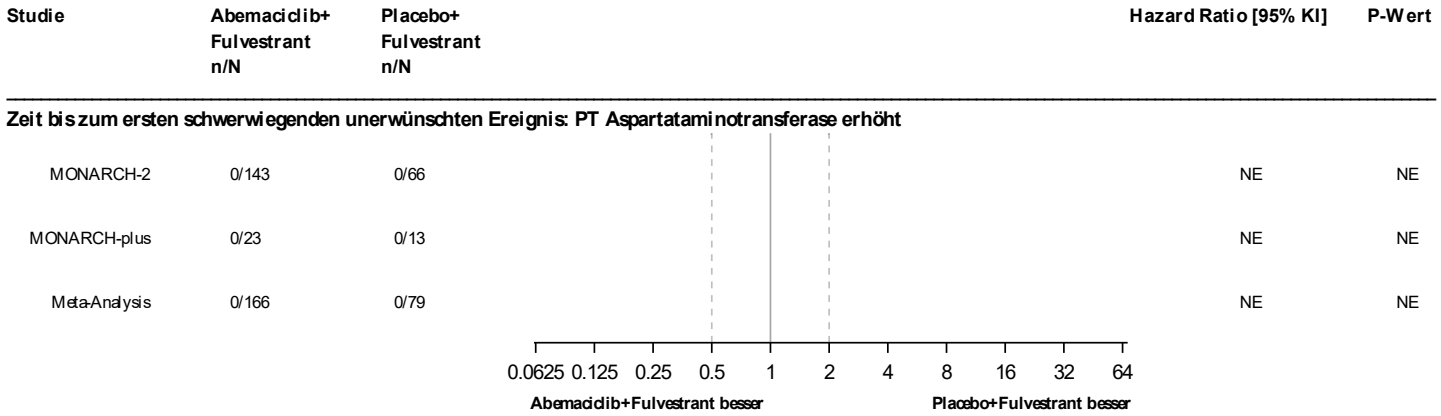
Abbildung 1033.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttassaesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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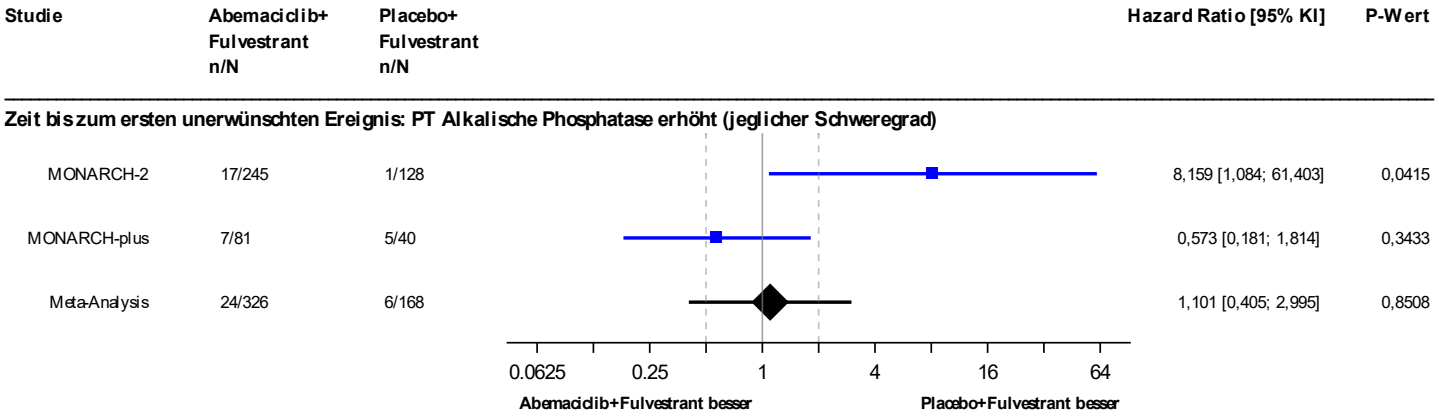
Abbildung 1034.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=5,0182, P-Wert=0,0251, I2 Index=80,1%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttapaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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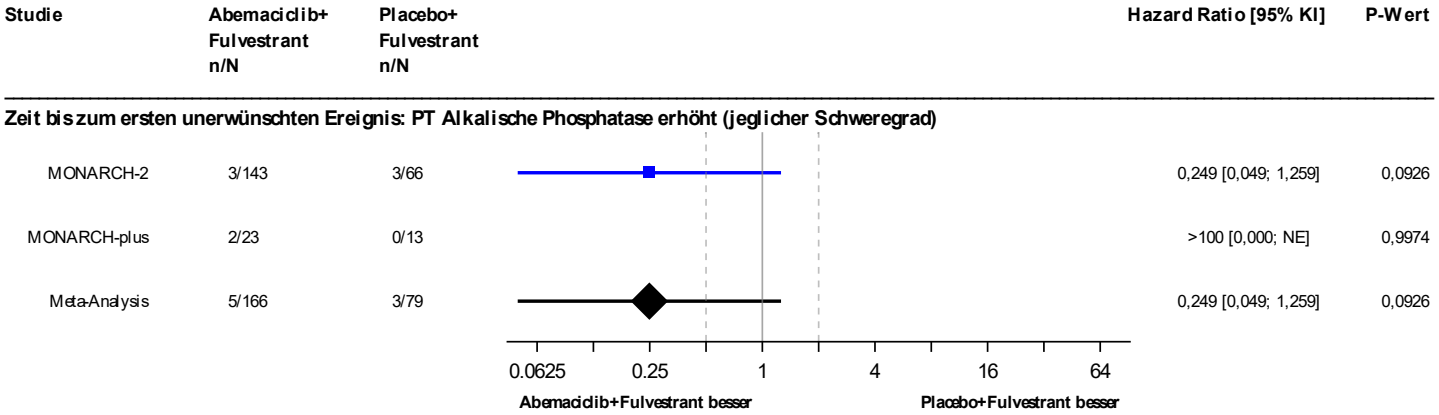
Abbildung 1034.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9972, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttapaesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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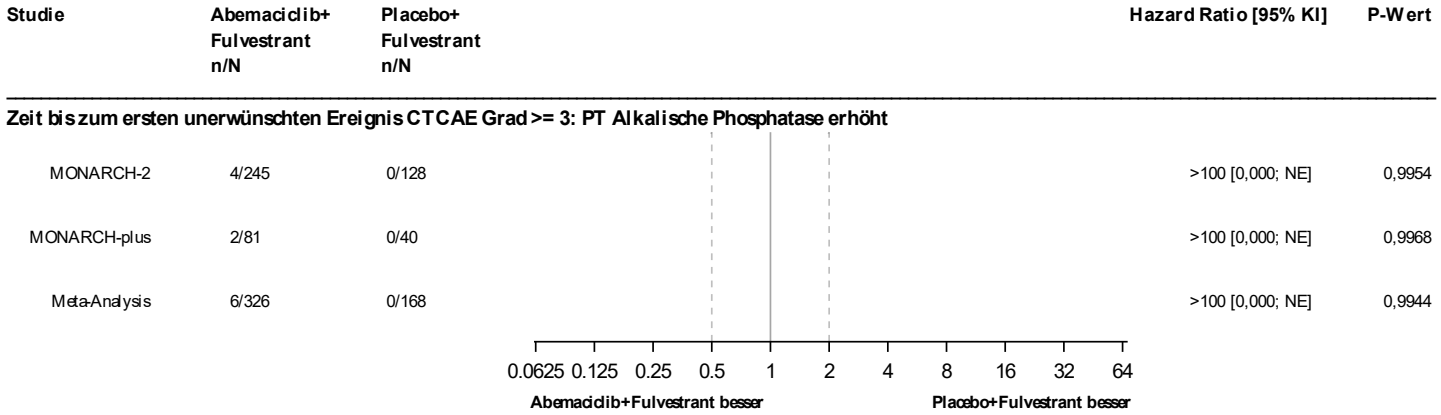
Abbildung 1035.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttap3aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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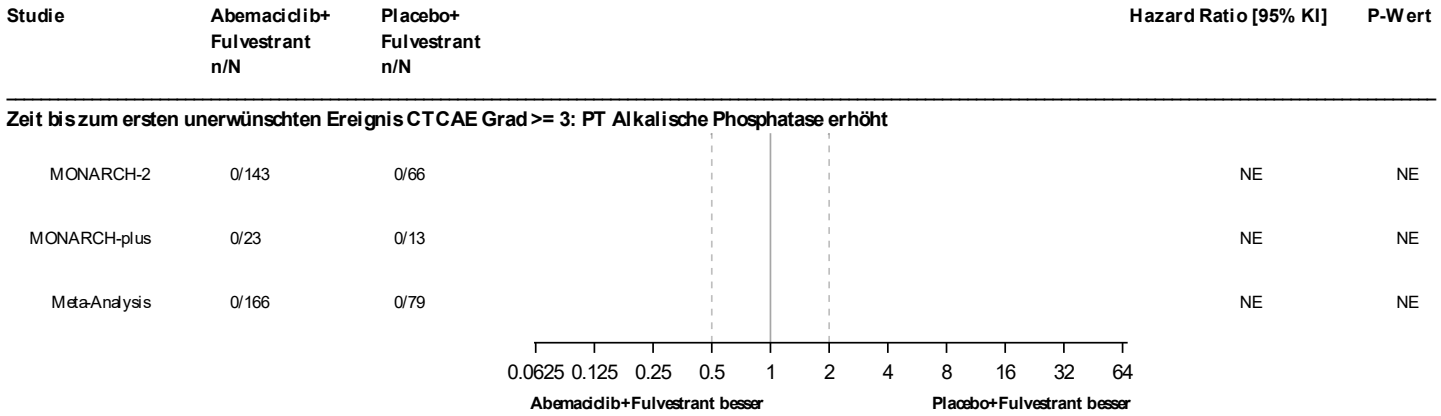
Abbildung 1035.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttap3aesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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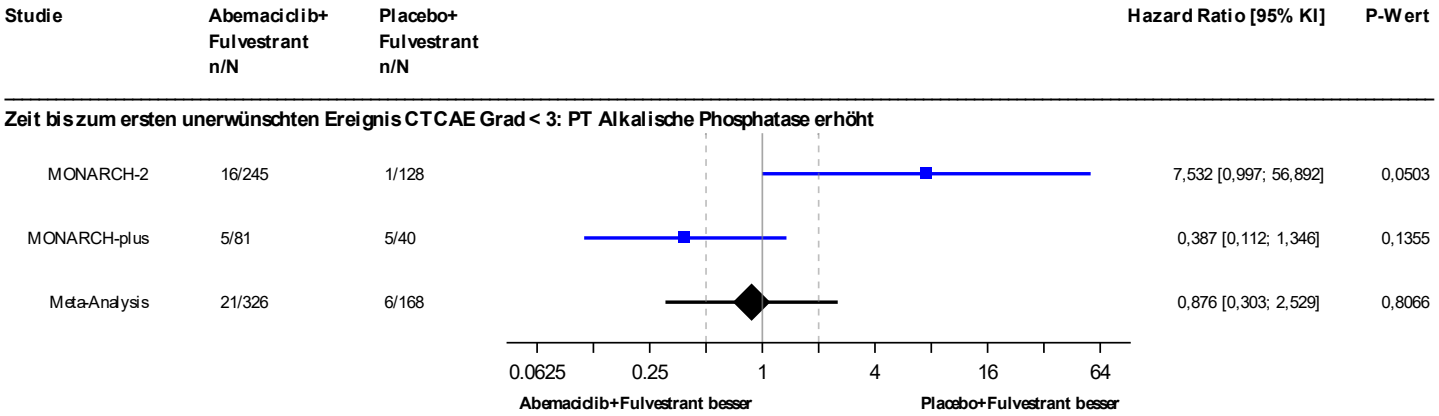
Abbildung 1036.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=5,9995, P-Wert=0,0143, I2 Index=83,3%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttap2aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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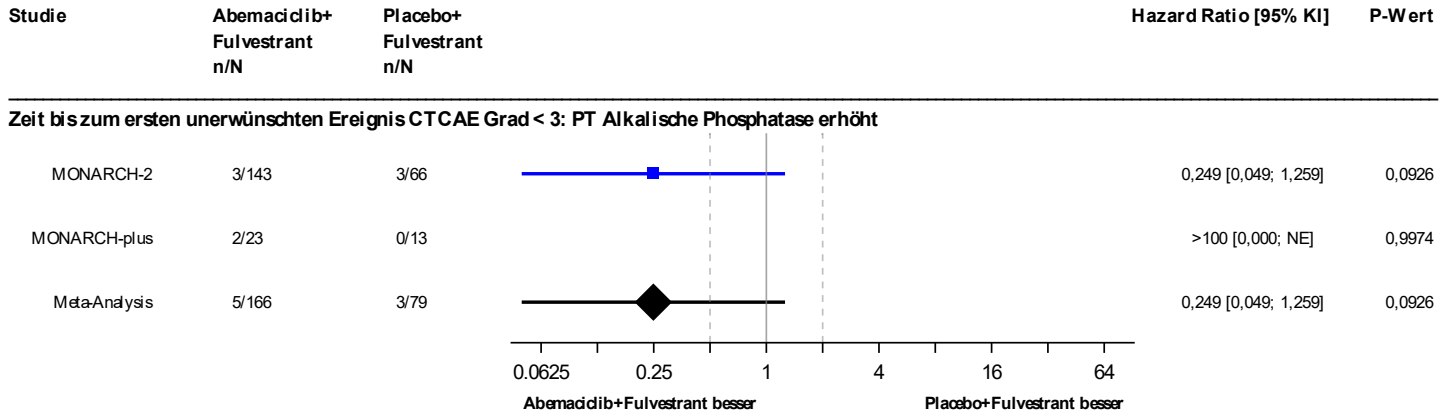
Abbildung 1036.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9972, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttap2aesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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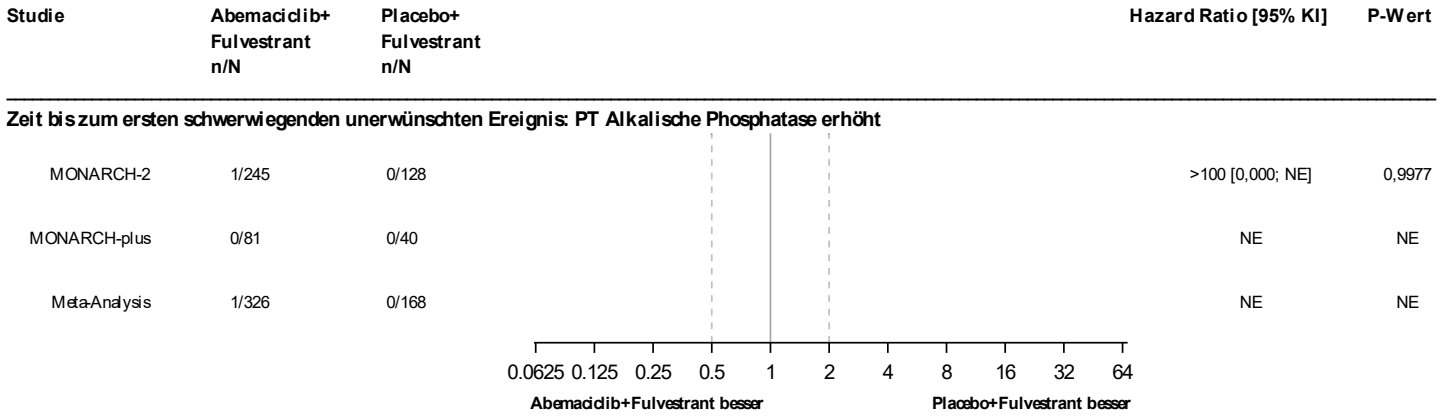
Abbildung 1037.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttapsaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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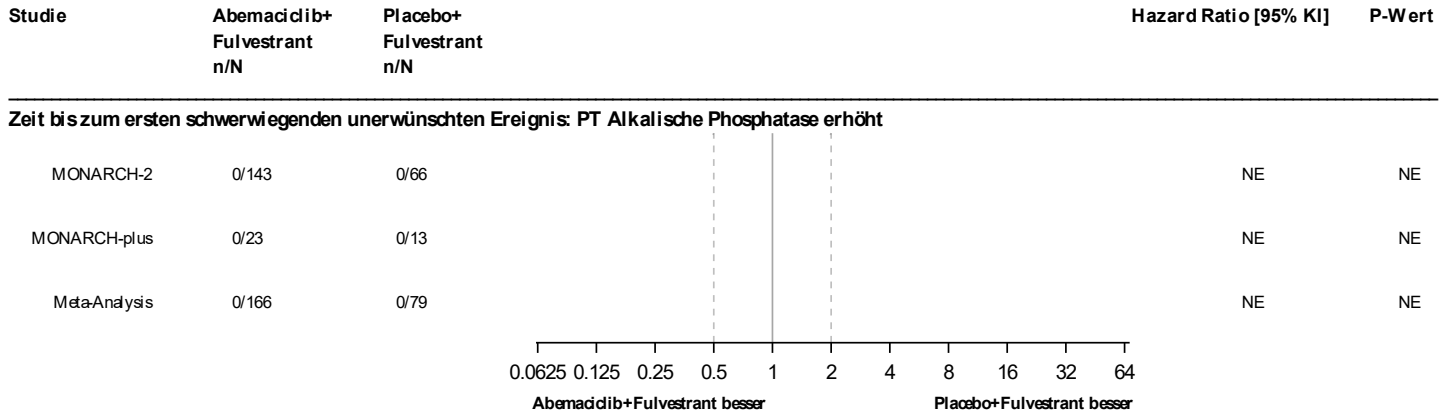
Abbildung 1037.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttapsaesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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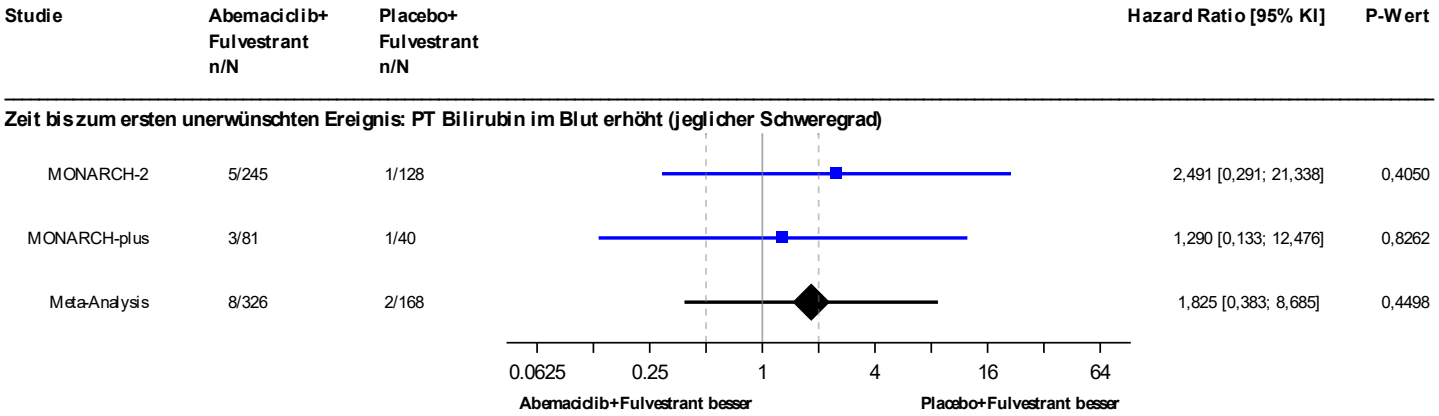
Abbildung 1038.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Bilirubin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1705, P-Wert=0,6797, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttbiaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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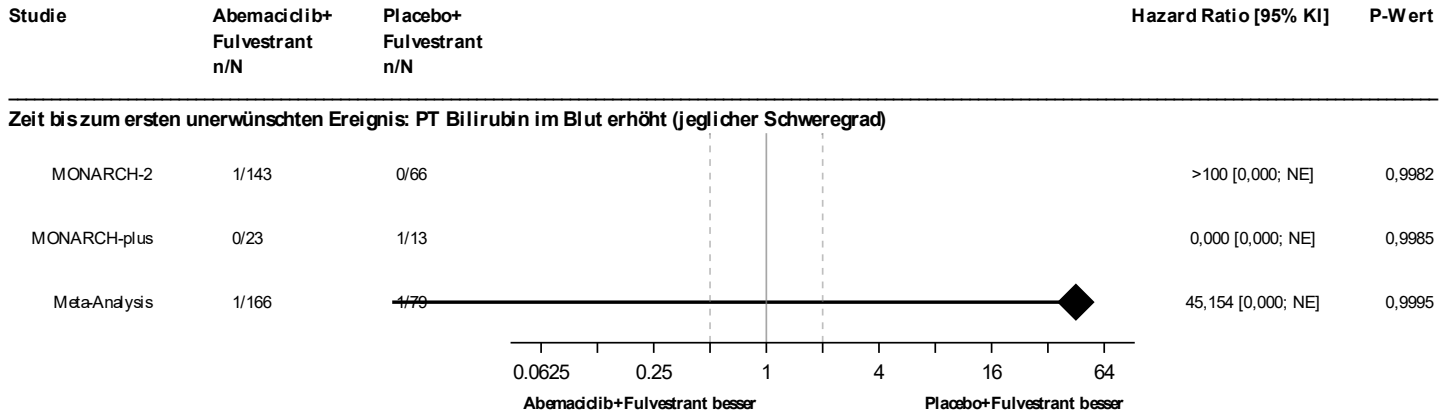
Abbildung 1038.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Bilirubin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9977, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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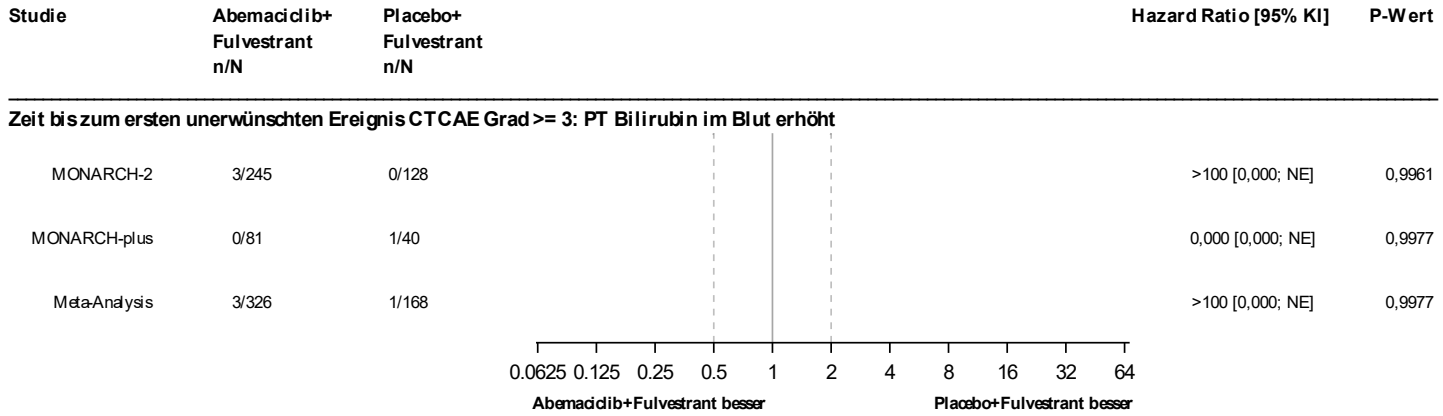
Abbildung 1039.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Bilirubin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9961, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttbi3aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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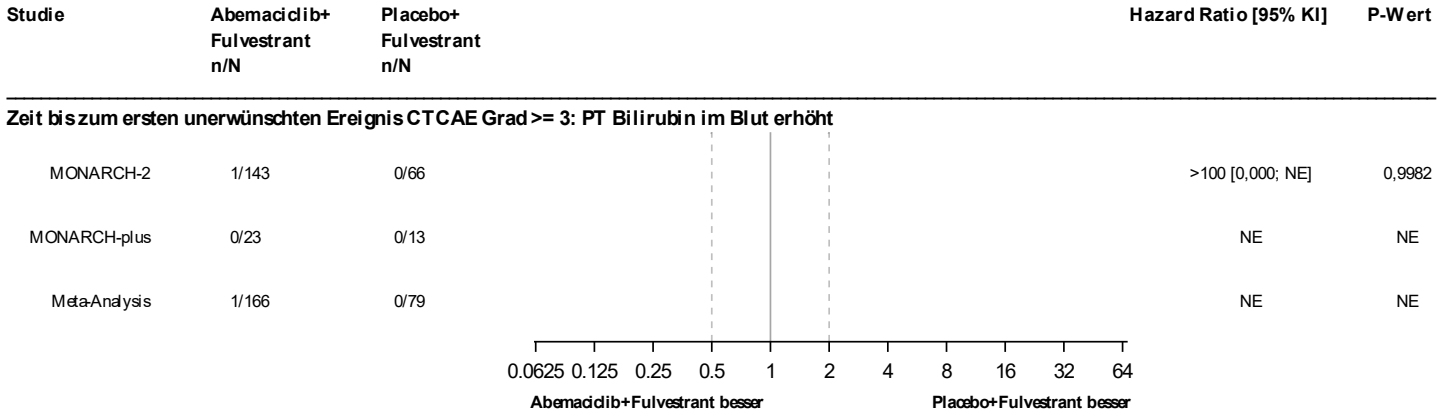
Abbildung 1039.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Bilirubin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttbi3aesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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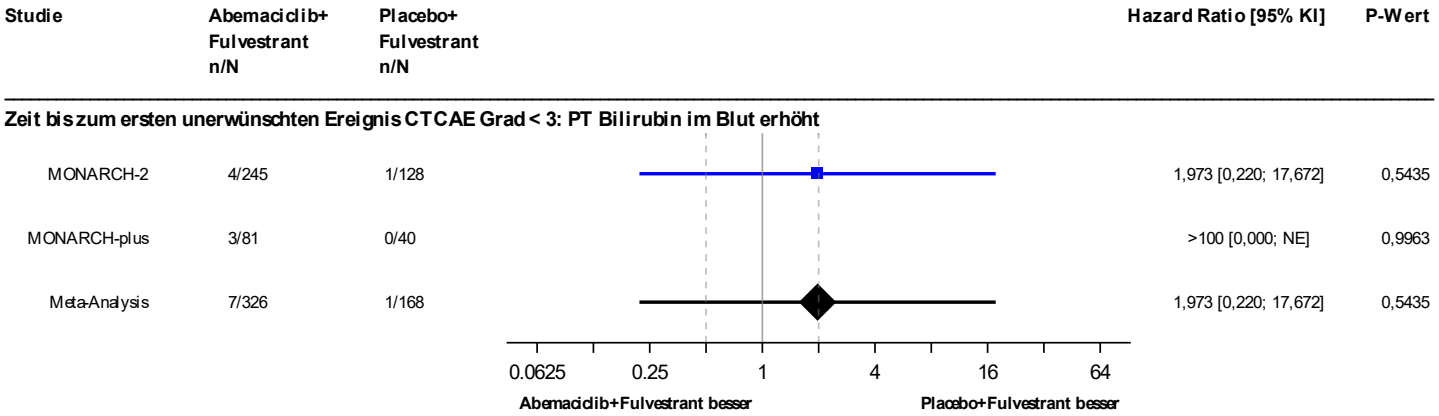
Abbildung 1040.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Bilirubin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9965, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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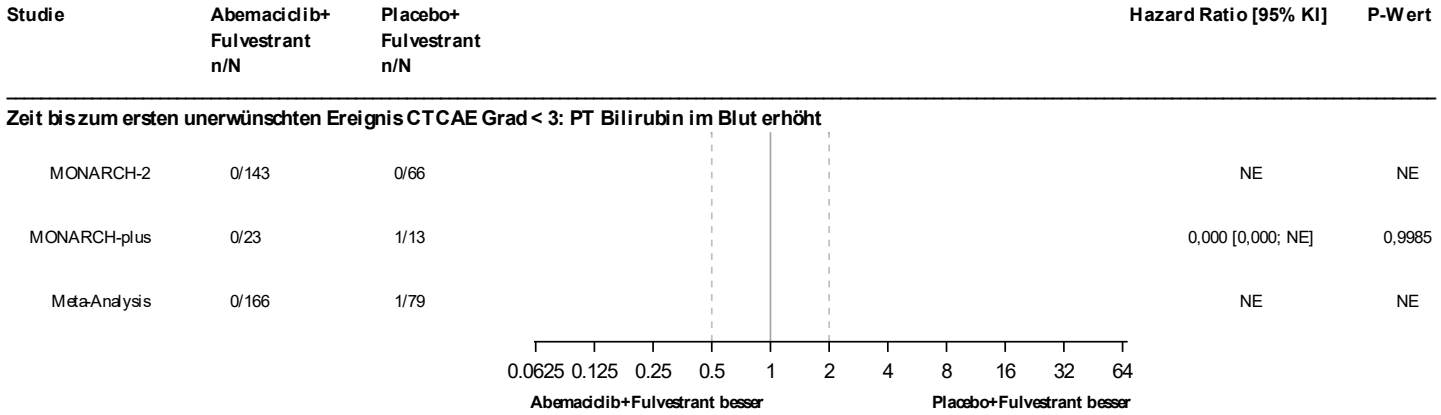
Abbildung 1040.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Bilirubin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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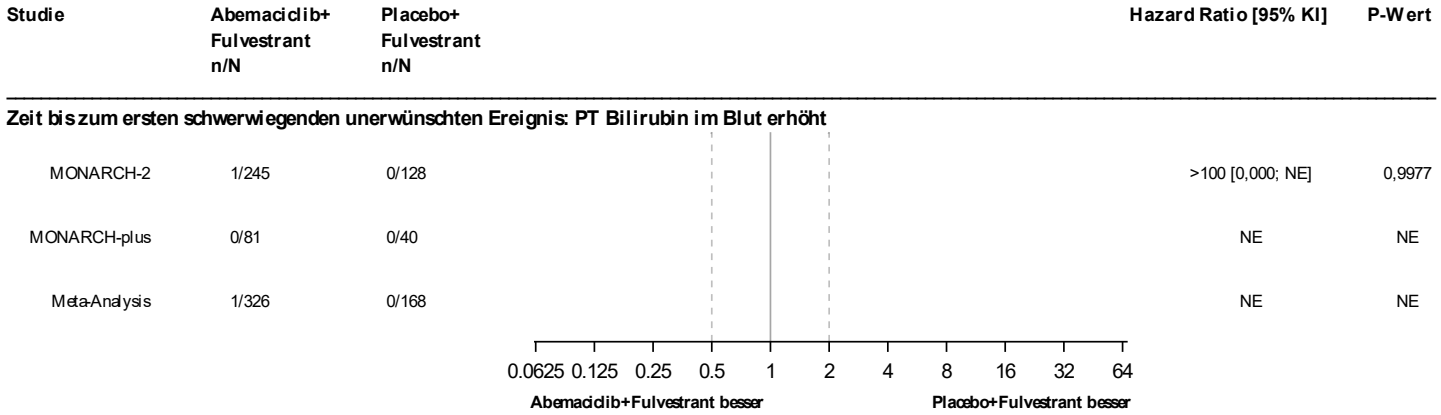
Abbildung 1041.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Bilirubin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttbisaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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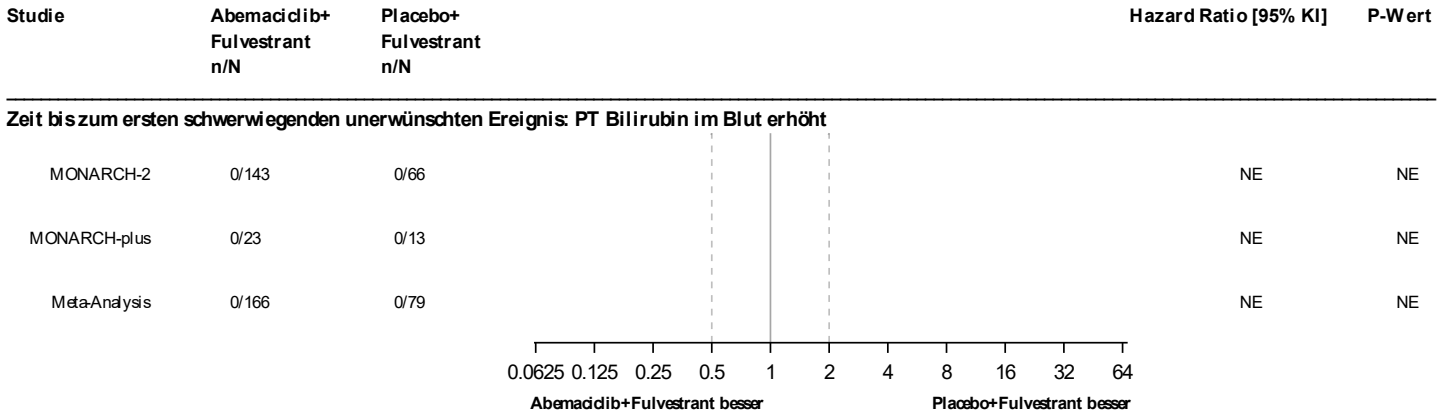
Abbildung 1041.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Bilirubin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttbisaesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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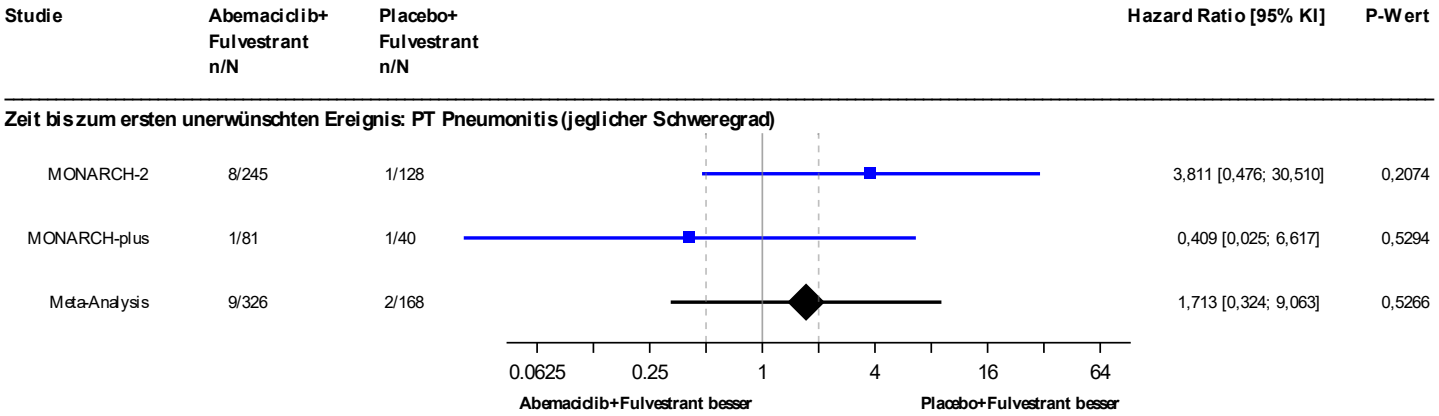
Abbildung 1042.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Pneumonitis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,5841, P-Wert=0,2082, I2 Index=36,9%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttpnaesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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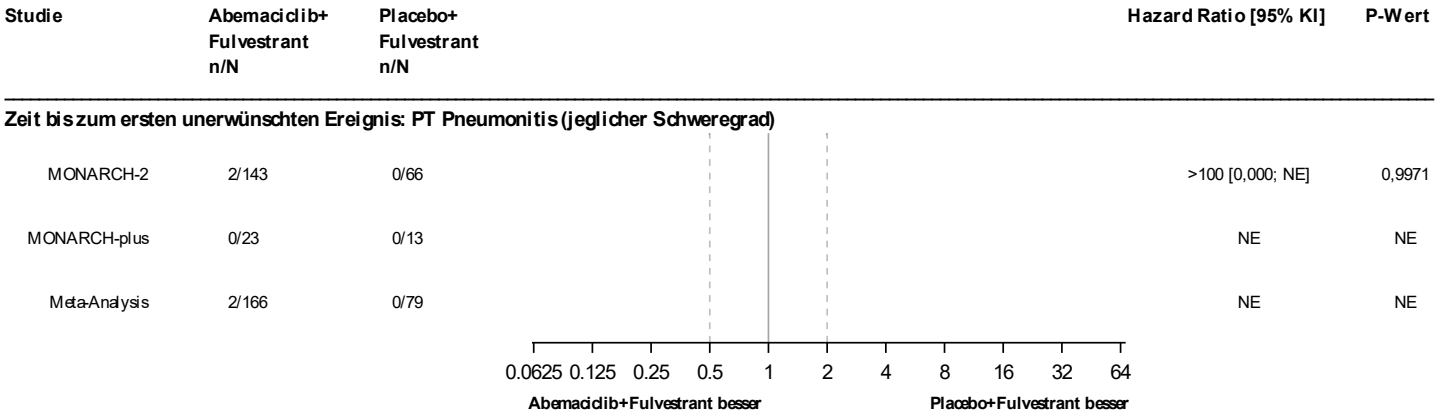
Abbildung 1042.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Pneumonitis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttpnaesi_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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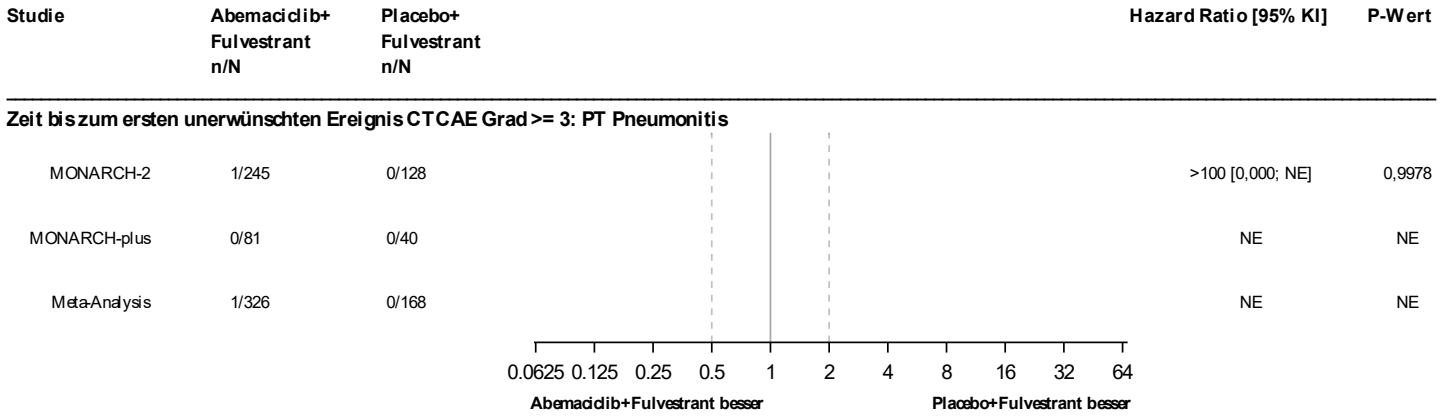
Abbildung 1043.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Pneumonitis aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttpn3aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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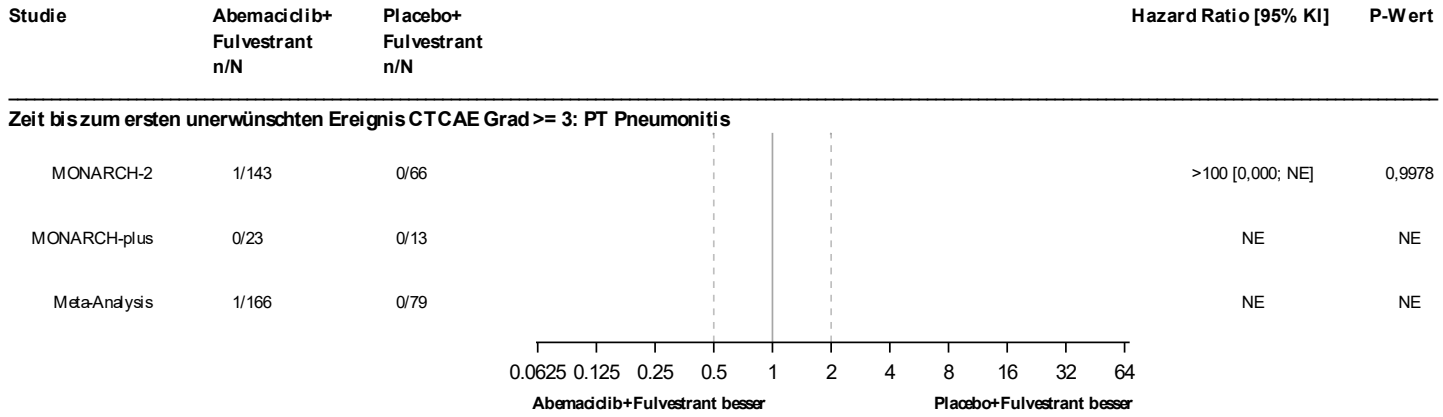
Abbildung 1043.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Pneumonitis aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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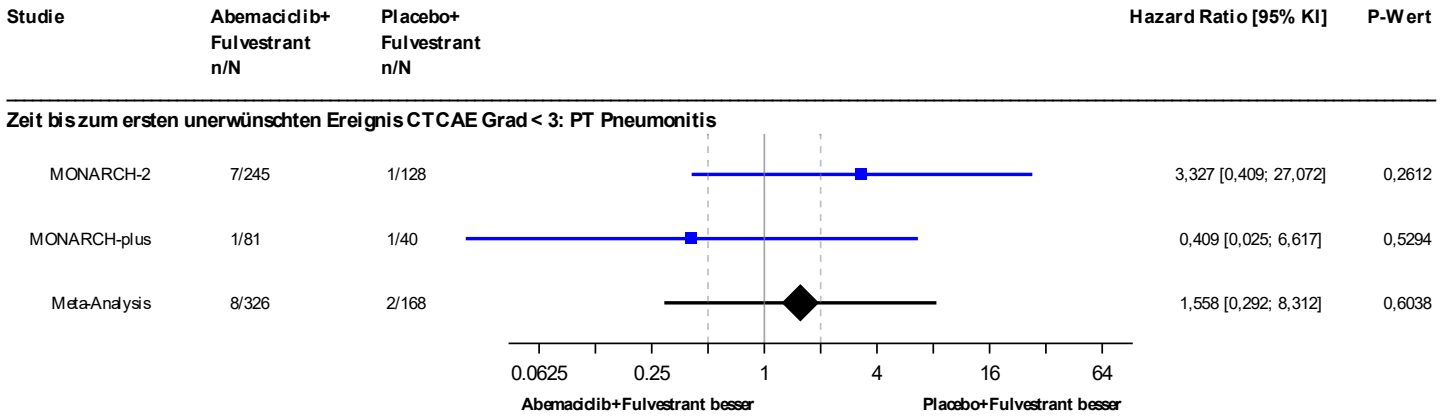
Abbildung 1044.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Pneumonitis aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,3889, P-Wert=0,2386, I2 Index=28,0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttpn2aesi_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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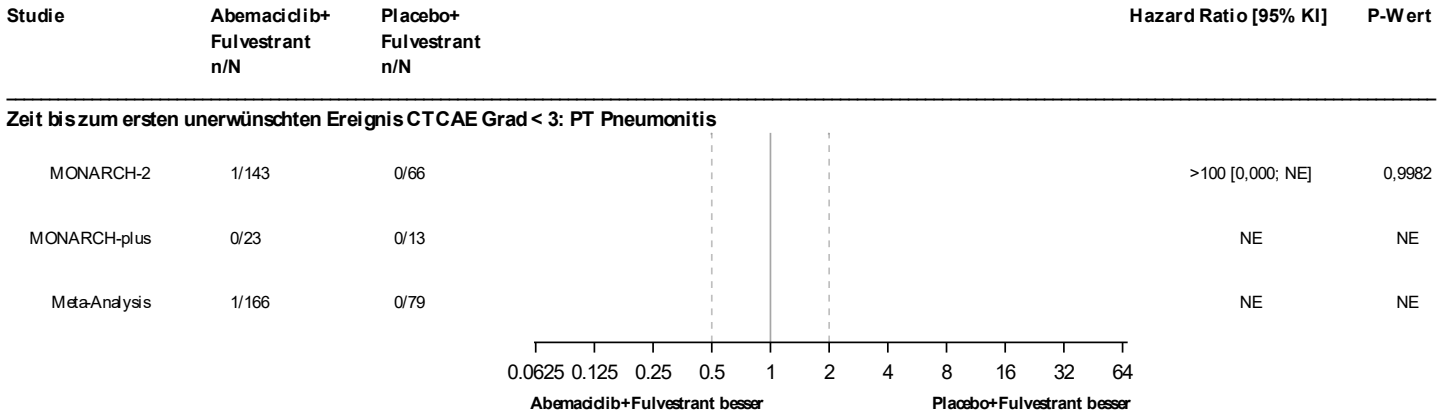
Abbildung 1044.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Pneumonitis aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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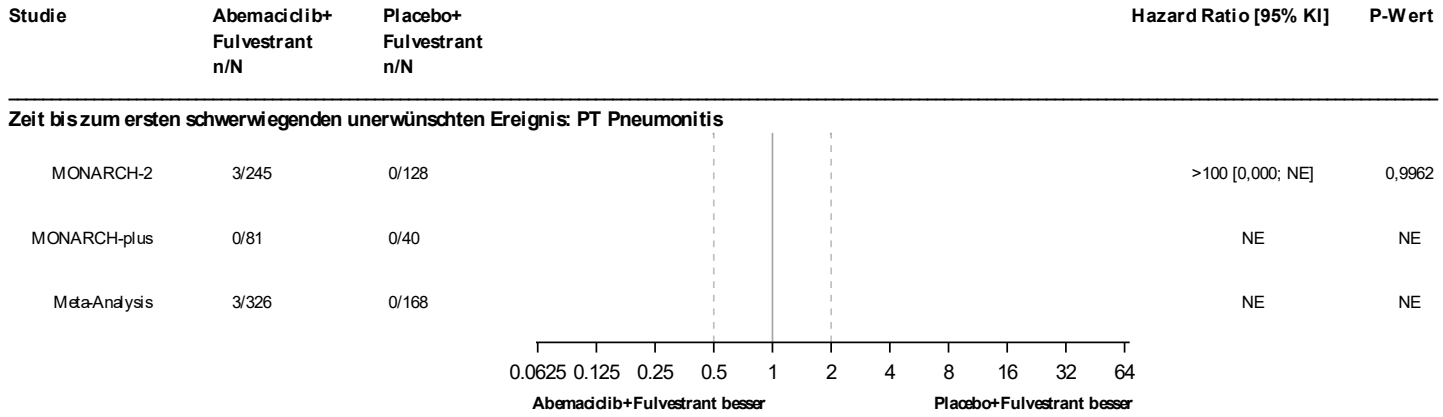
Abbildung 1045.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Pneumonitis aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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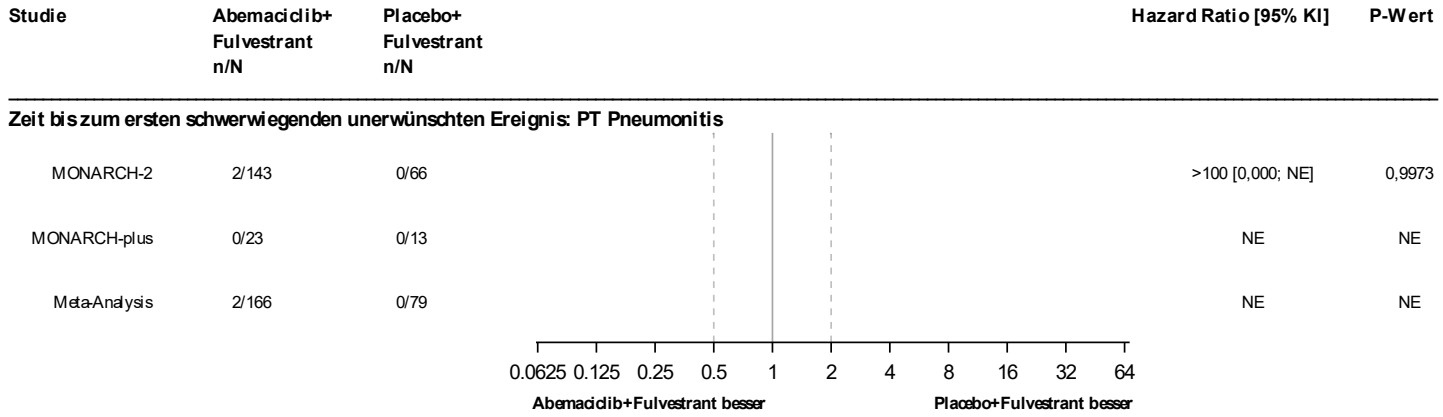
Abbildung 1045.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: PT Pneumonitis aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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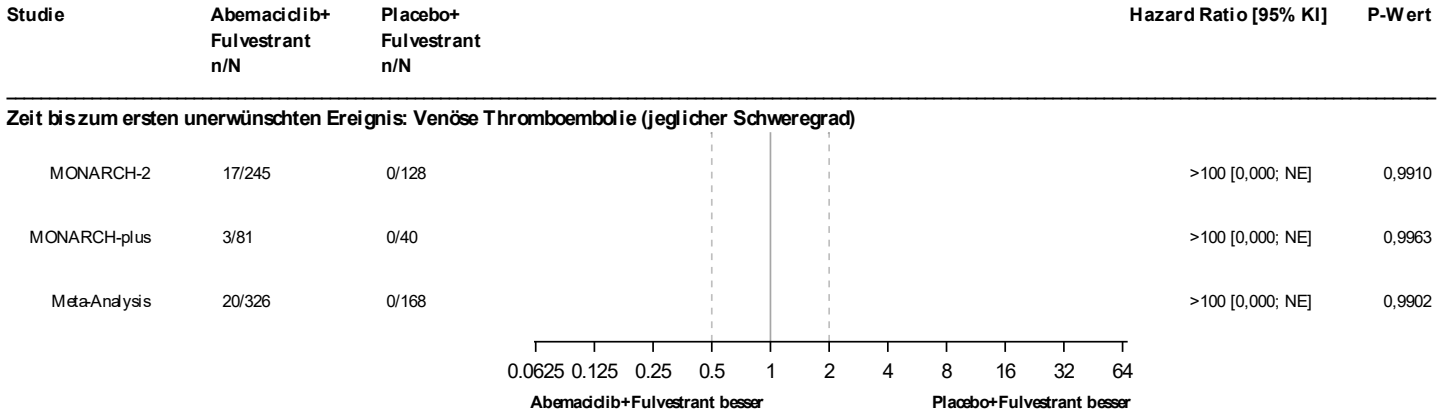
Abbildung 1046.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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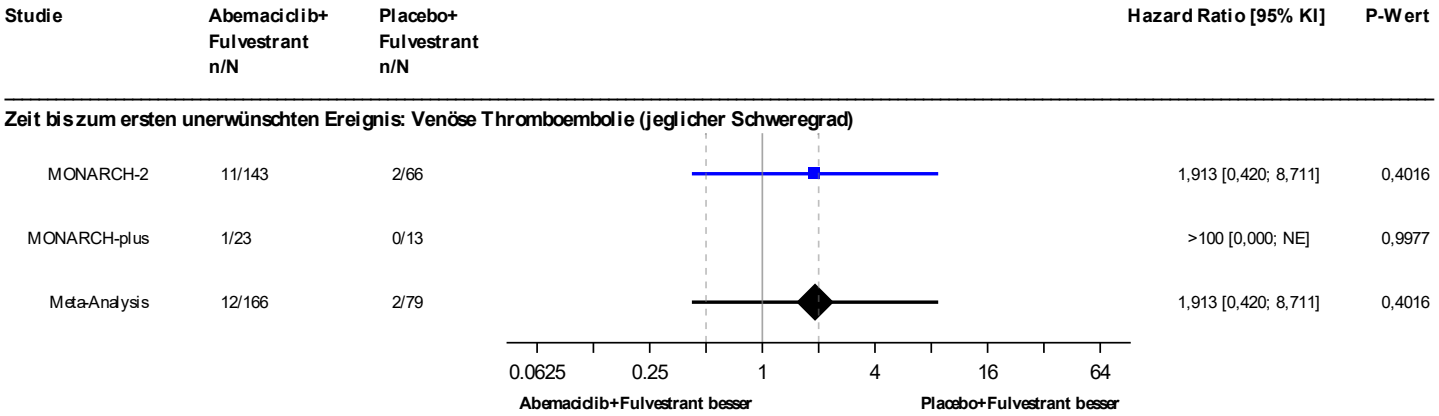
Abbildung 1046.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9978, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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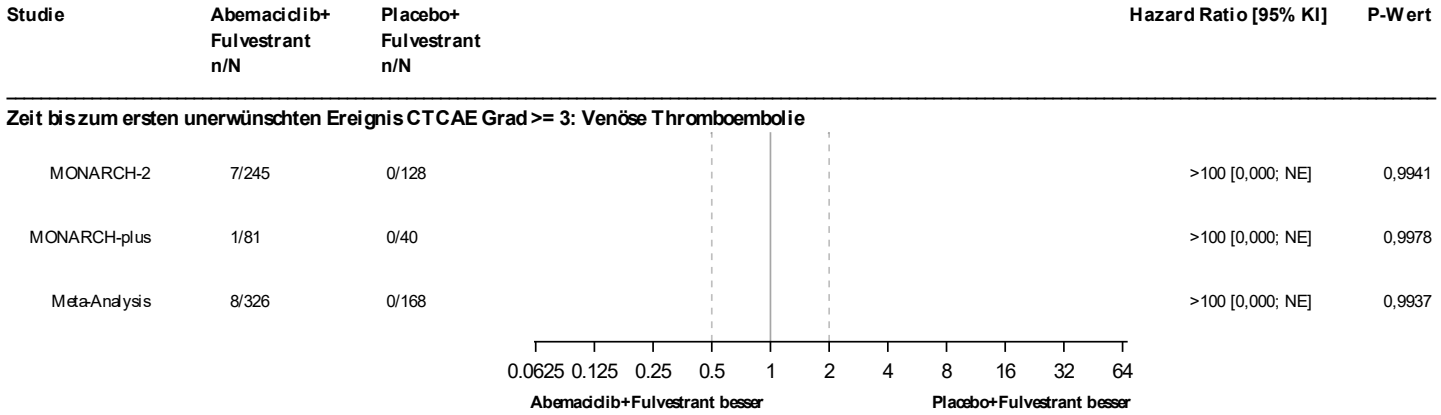
Abbildung 1047.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Venöse Thromboembolie aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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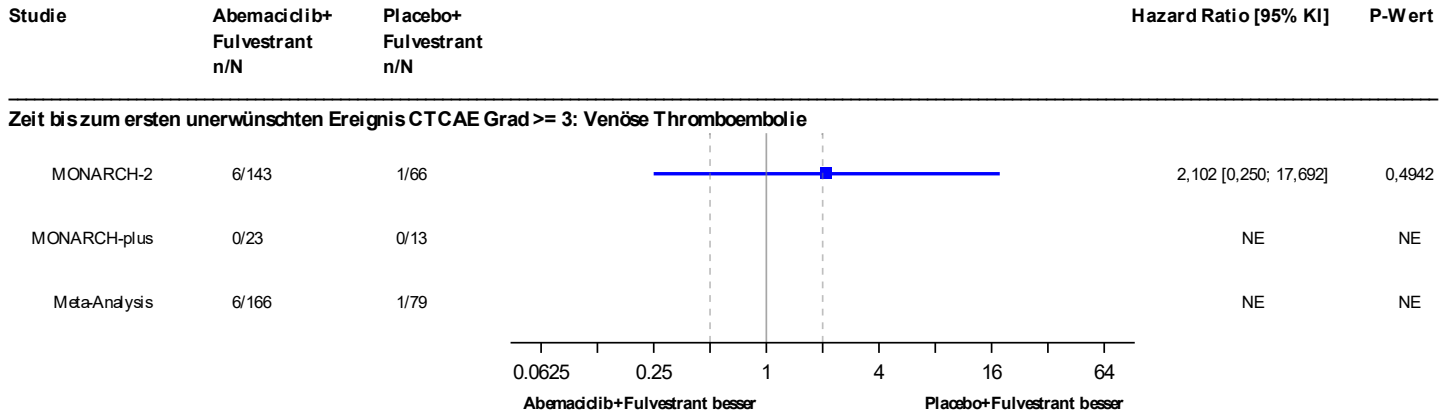
Abbildung 1047.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Venöse Thromboembolie aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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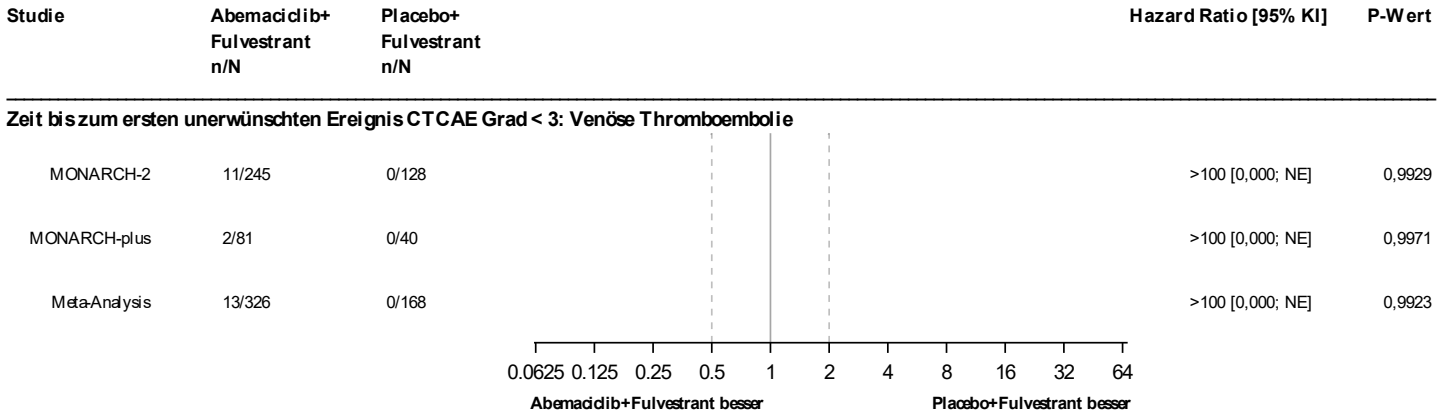
Abbildung 1048.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Venöse Thromboembolie aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttvte2aesi_popa1.rtf
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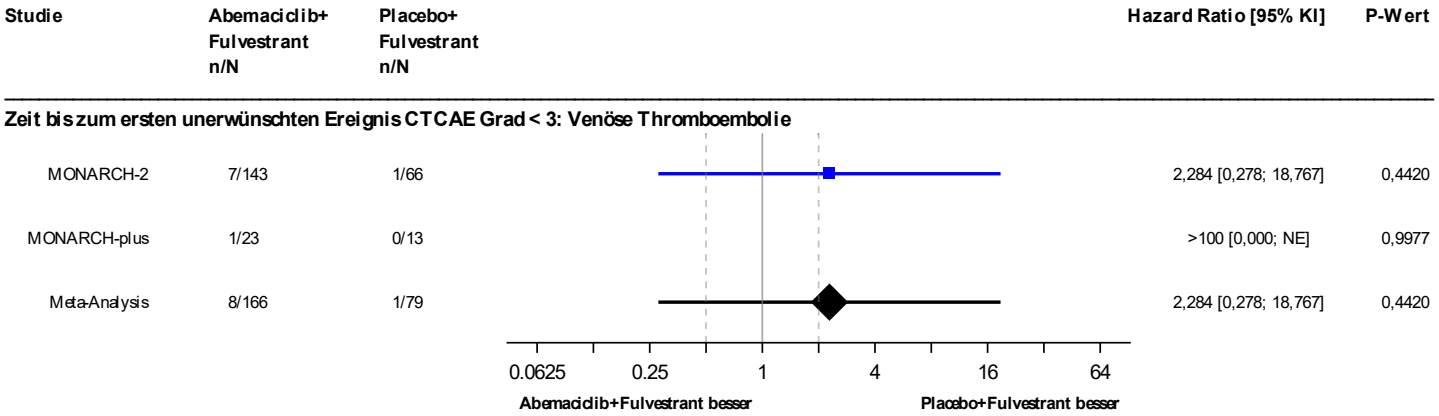
Abbildung 1048.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Venöse Thromboembolie aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9978, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttvte2aesi_popa2.rtf
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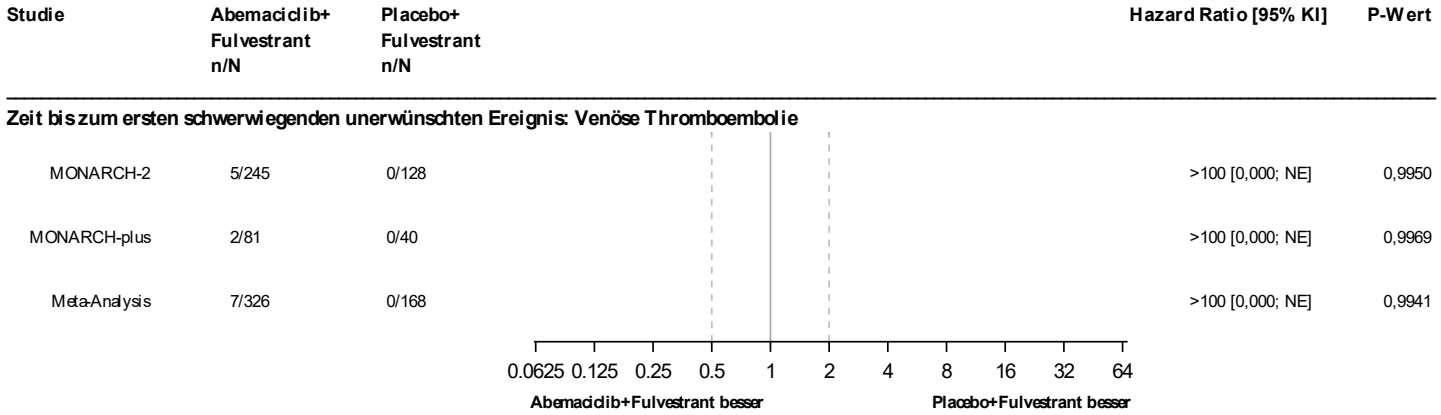
Abbildung 1049.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: Venöse Thromboembolie aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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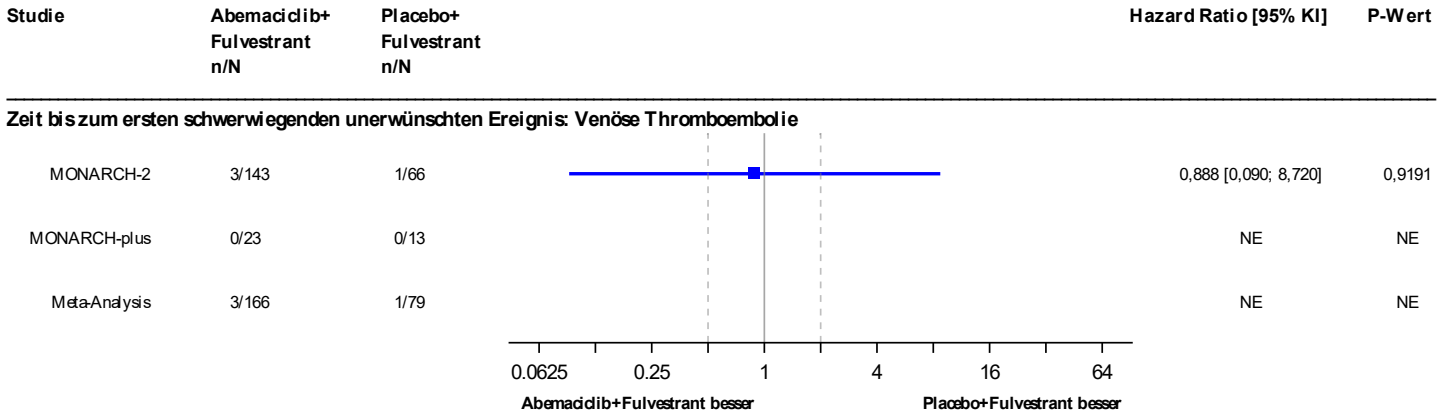
Abbildung 1049.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: Venöse Thromboembolie aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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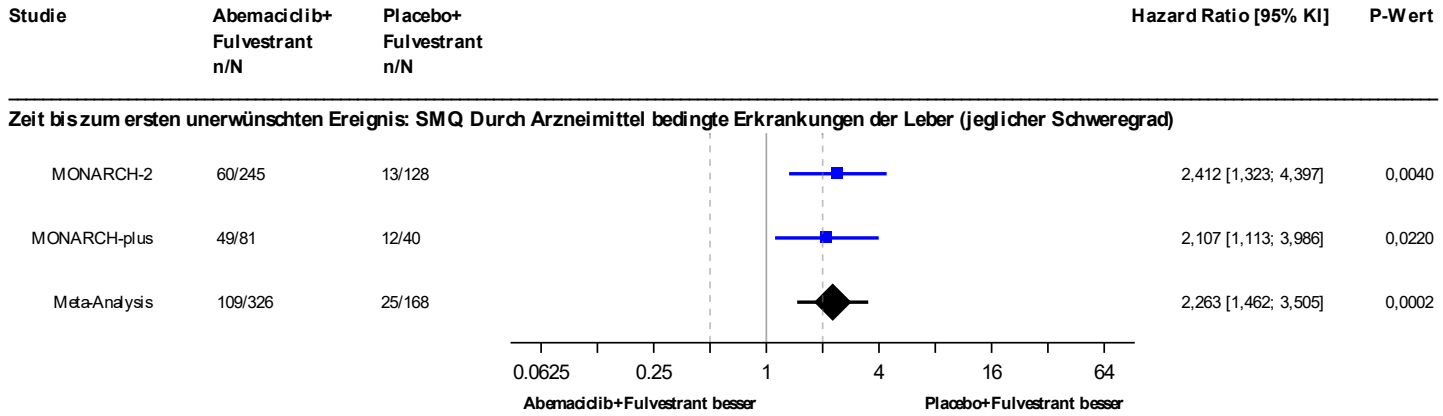
Abbildung 1050.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0918, P-Wert=0,7619, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_tthepsmq_popa1.rtf
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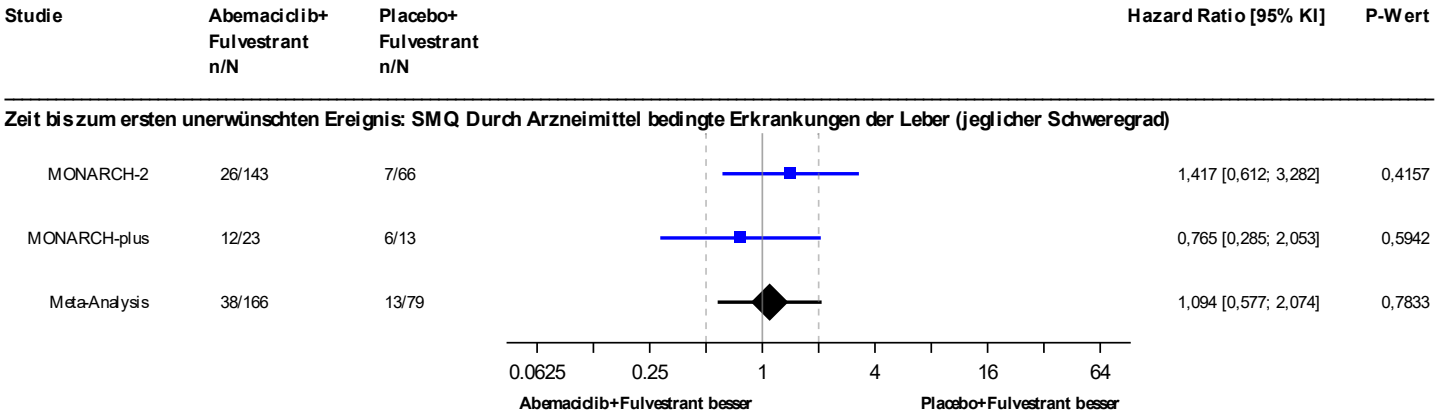
Abbildung 1050.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,8705, P-Wert=0,3508, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_tthepsmq_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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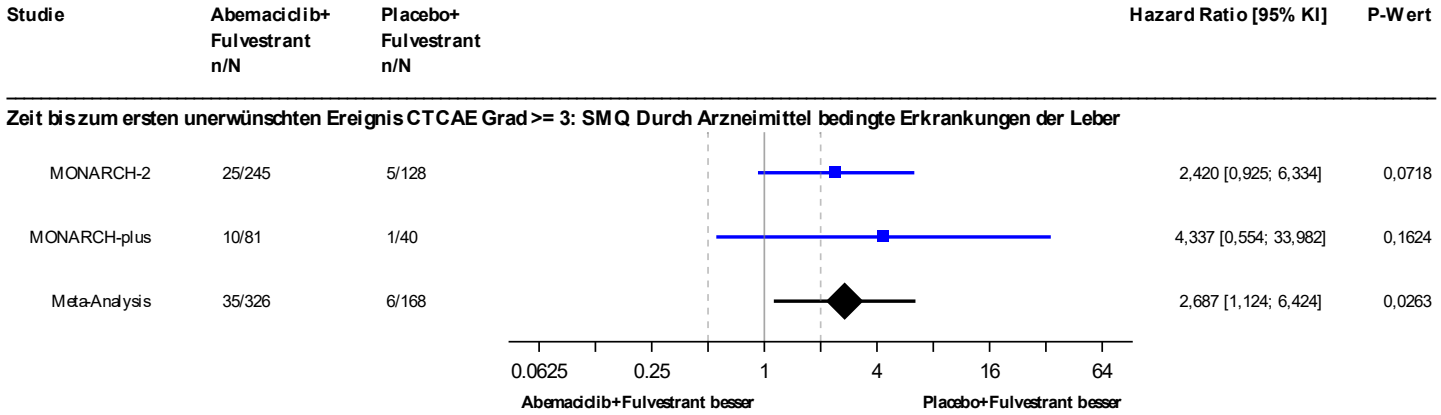
Abbildung 1051.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2533, P-Wert=0,6148, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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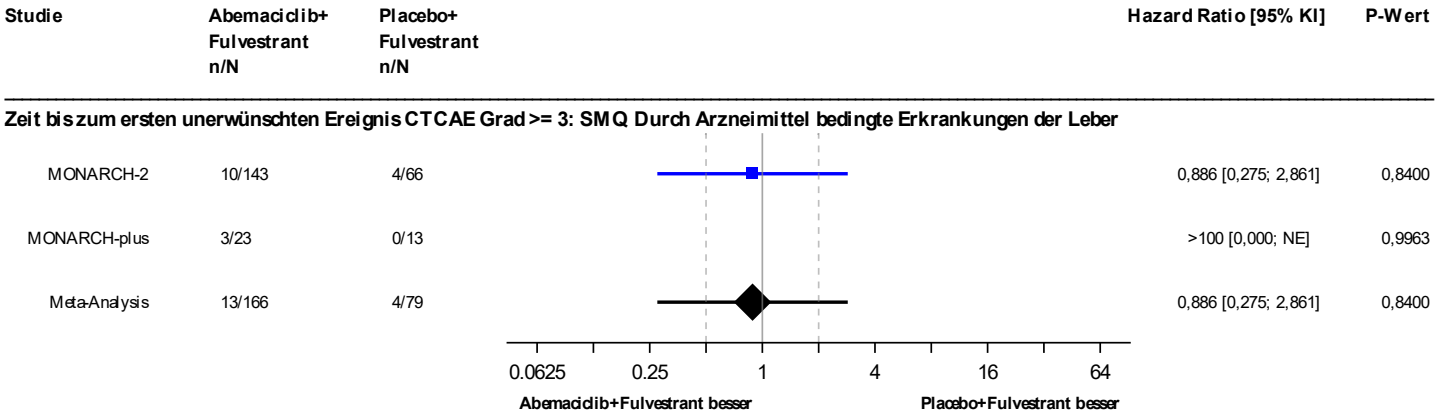
Abbildung 1051.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9963, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_tthep3smq_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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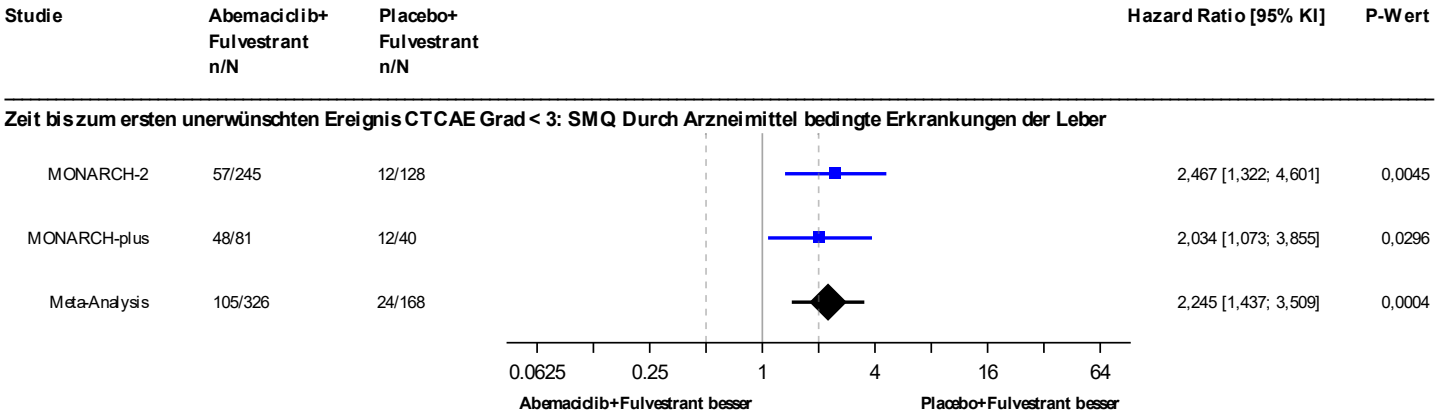
Abbildung 1052.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1792, P-Wert=0,6720, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_tthep2smq_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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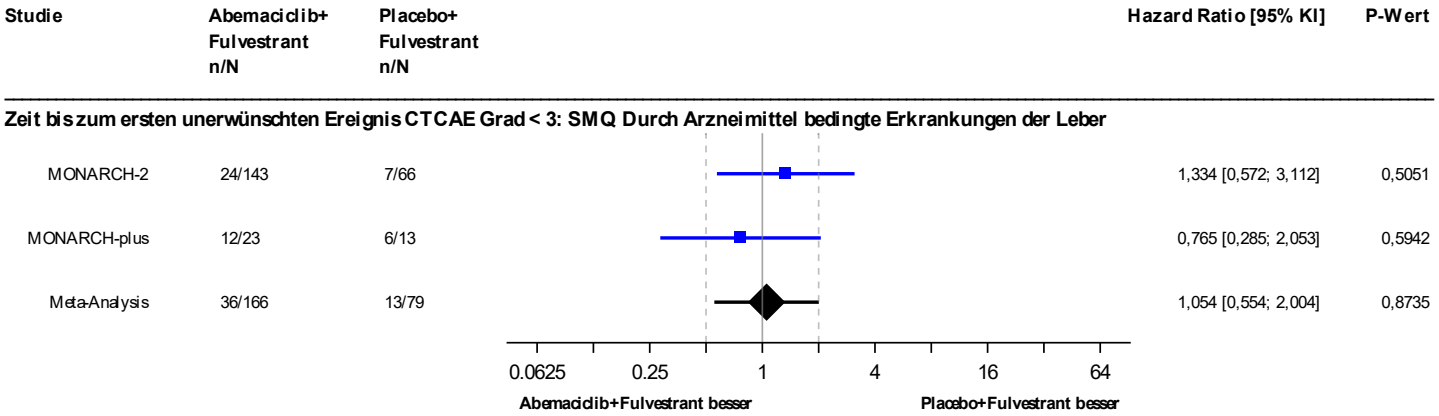
Abbildung 1052.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,7028, P-Wert=0,4019, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_tthep2smq_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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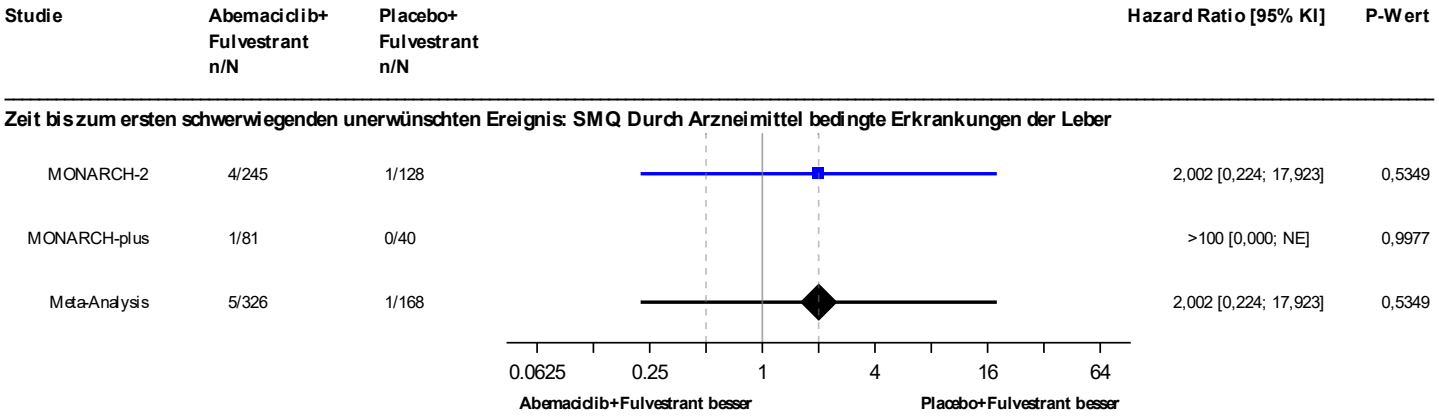
Abbildung 1053.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9978, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_tthepssmq_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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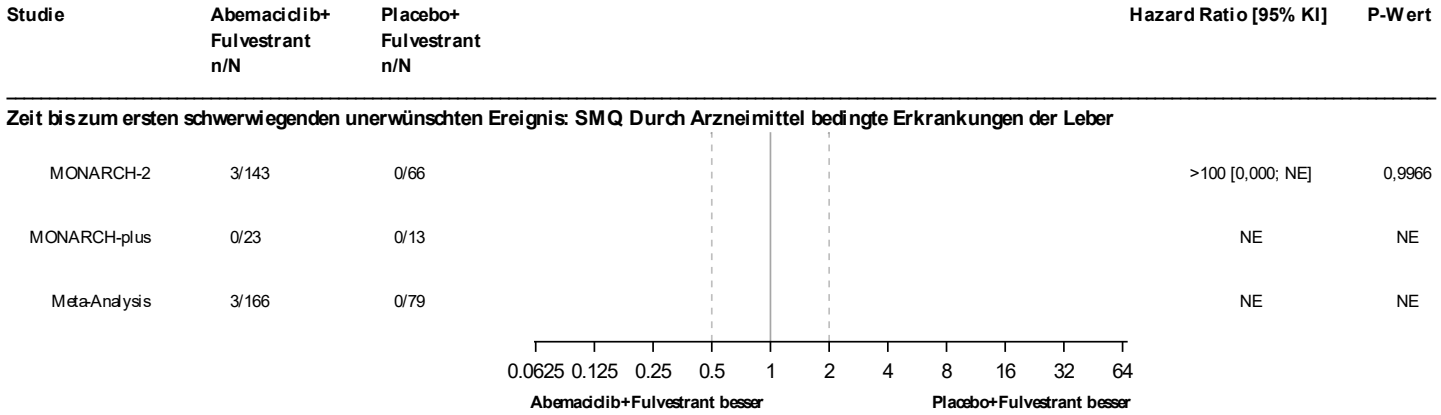
Abbildung 1053.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel - Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.
Metaanalyse mit festen Effekten, basierend auf aggregierten Daten.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_ae.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/output/shared/tfl/german_dossier, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier
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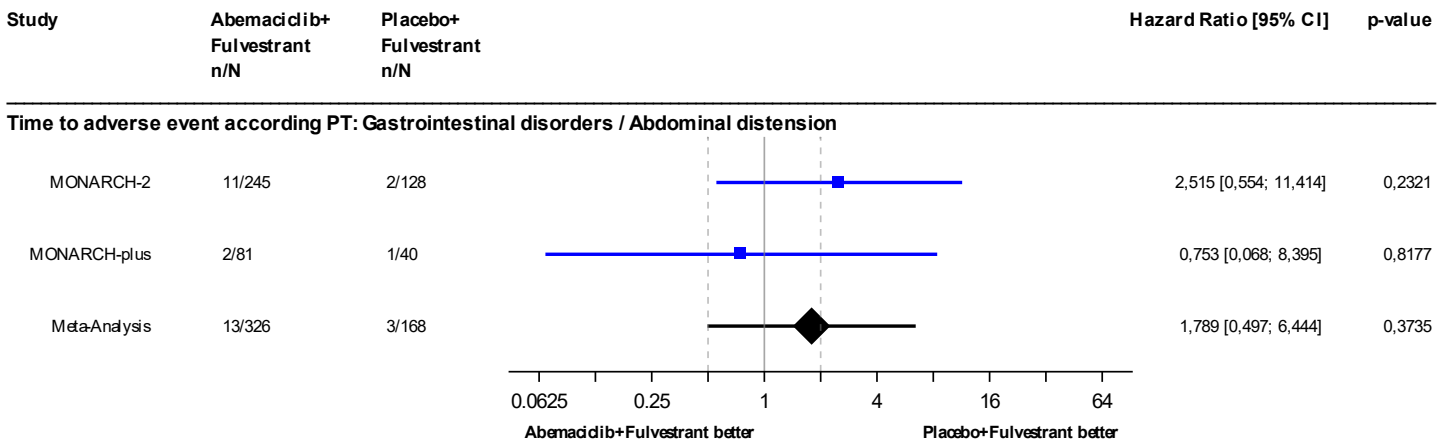
Anhang 4-G3.3: Häufige unerwünschte Ereignisse nach SOC und PT - Safety-Population

Abbildung 158 (Anhang): Ergebnisse für UE nach SOC und PT aus RCT mit dem zu bewertenden Arzneimittel (Meta-analyse der Studien MONARCH-2 und MONARCH-plus)

Figure 1101: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal distension
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6895, p-value=0,4063, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep001_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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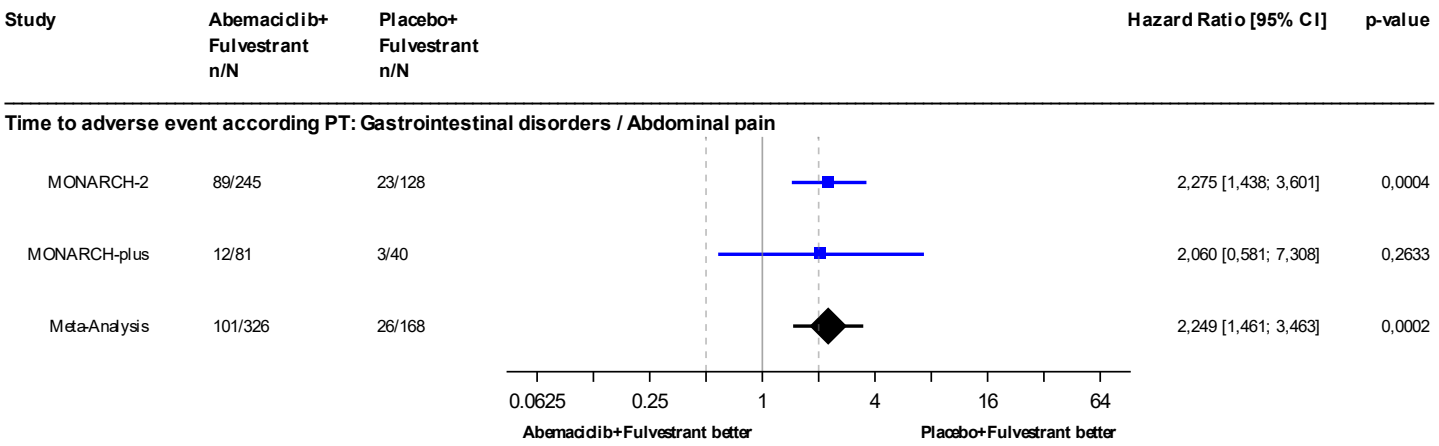
Figure 1102: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0209, p-value=0,8849, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep002_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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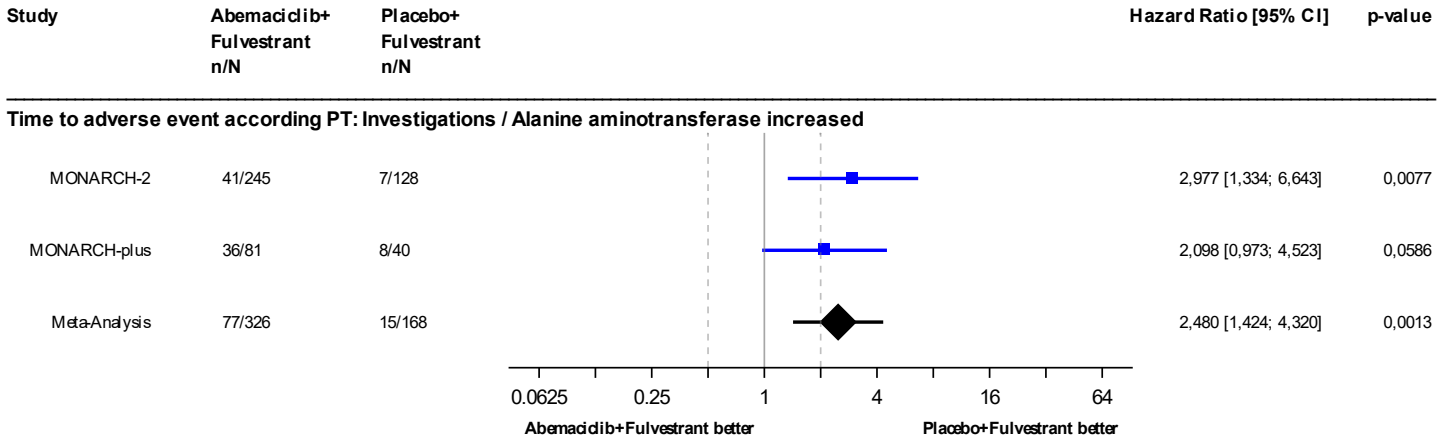
**Figure 1103: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,3814, p-value=0,5369, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep003_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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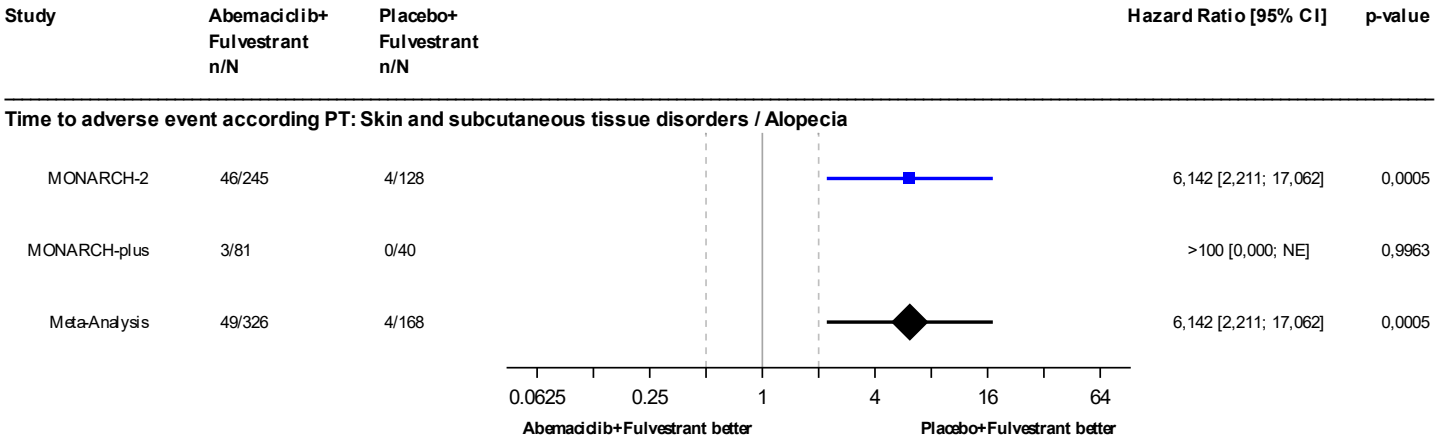
Figure 1104: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9967, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep004_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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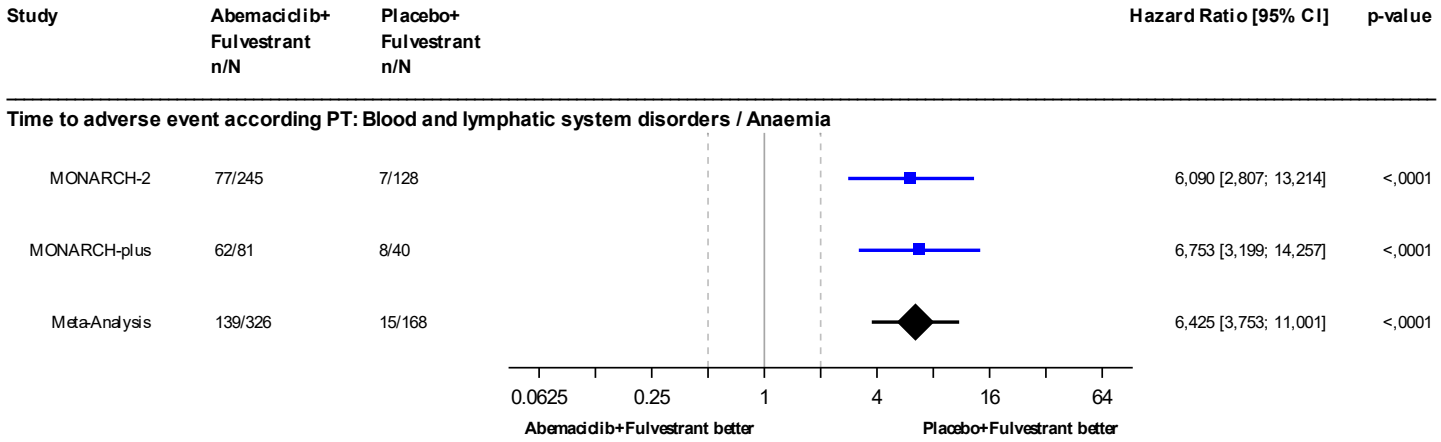
**Figure 1105: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0354, p-value=0,8508, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep005_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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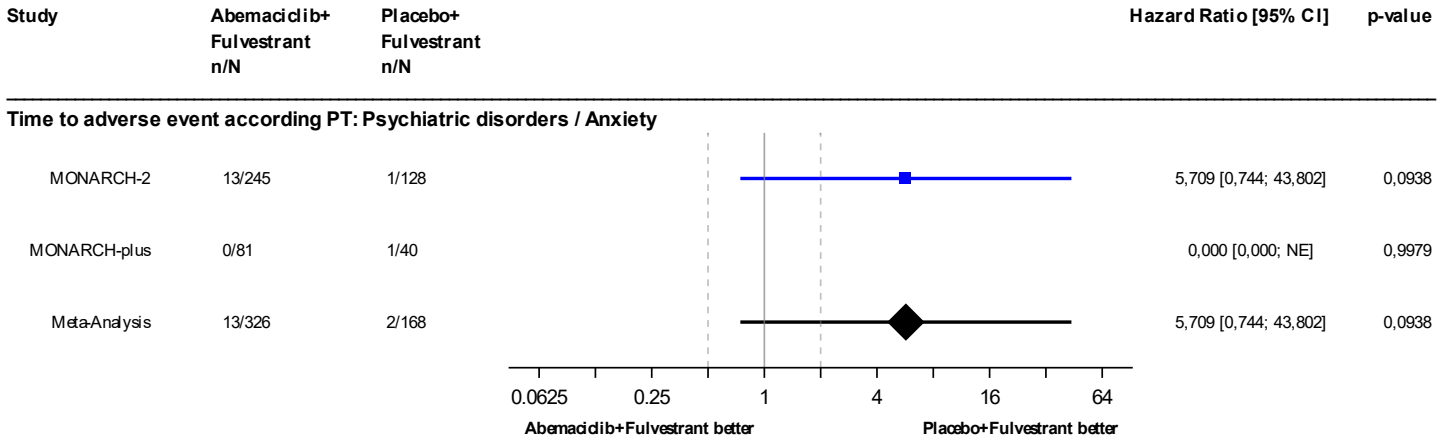
Figure 1106: Metaanalysis results for adverse events according PT[1] -
Psychiatric disorders / Anxiety
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9977, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep006_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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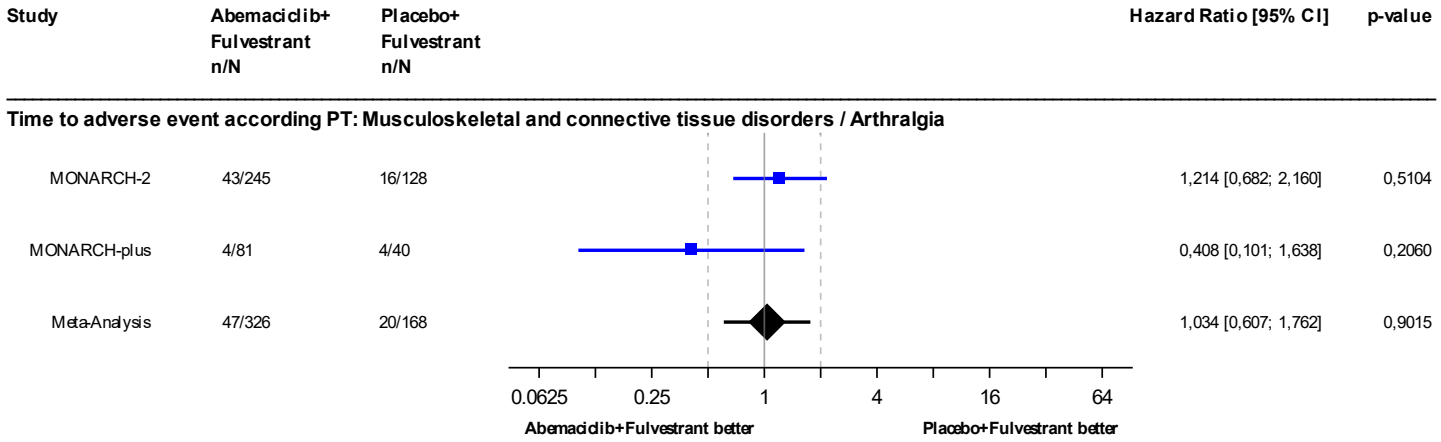
**Figure 1107: Metaanalysis results for adverse events according PT[1] -
Musculoskeletal and connective tissue disorders / Arthralgia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=2,0175, p-value=0,1555, I2 index=50,4%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep007_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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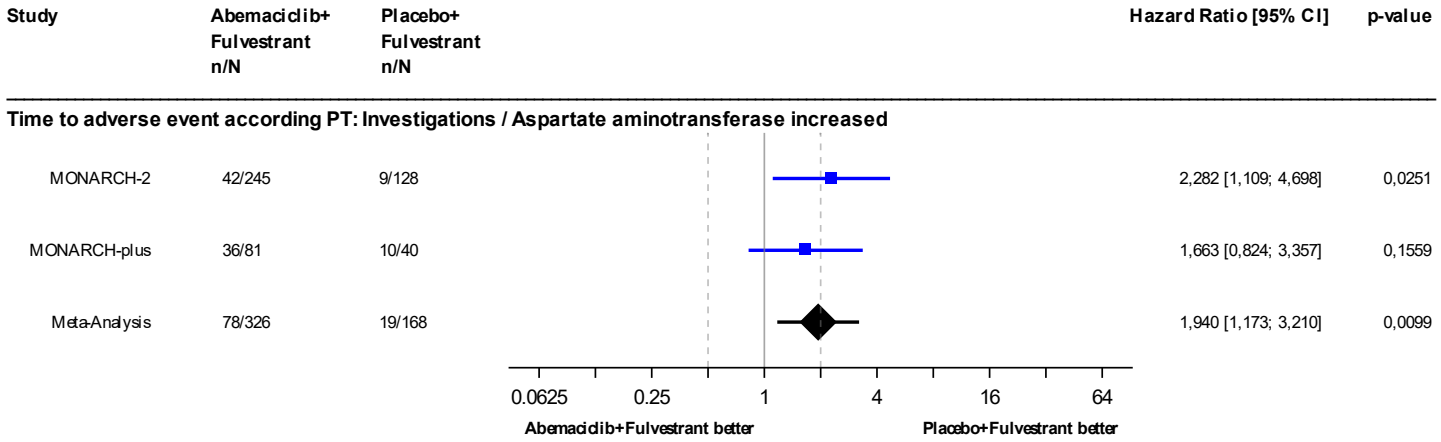
**Figure 1108: Metaanalysis results for adverse events according PT[1] -
Investigations / Aspartate aminotransferase increased
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,3795, p-value=0,5379, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep008_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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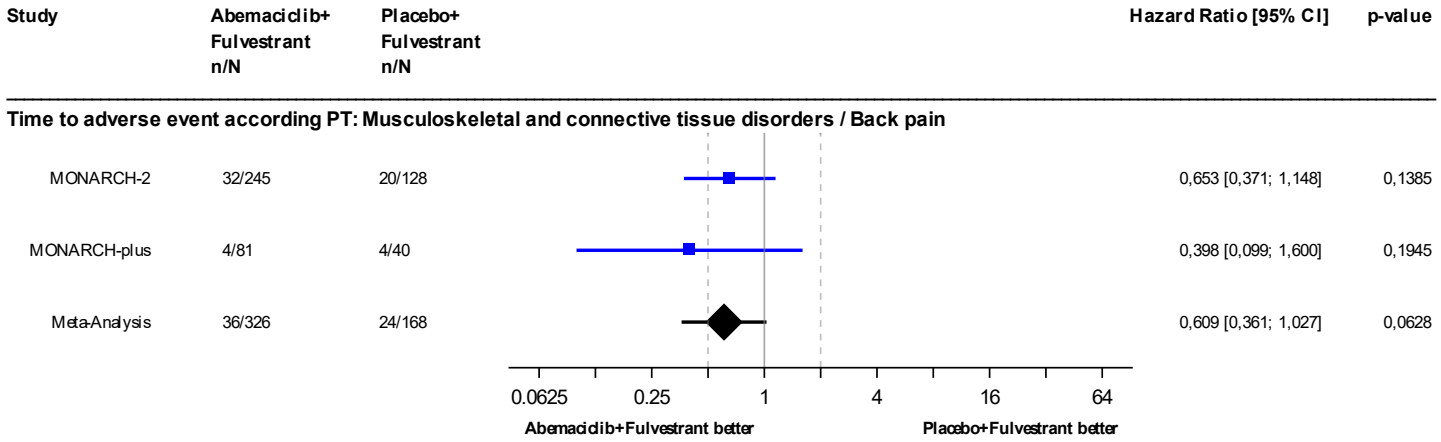
**Figure 1109: Metaanalysis results for adverse events according PT[1] -
Musculoskeletal and connective tissue disorders / Back pain
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,4171, p-value=0,5184, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep009_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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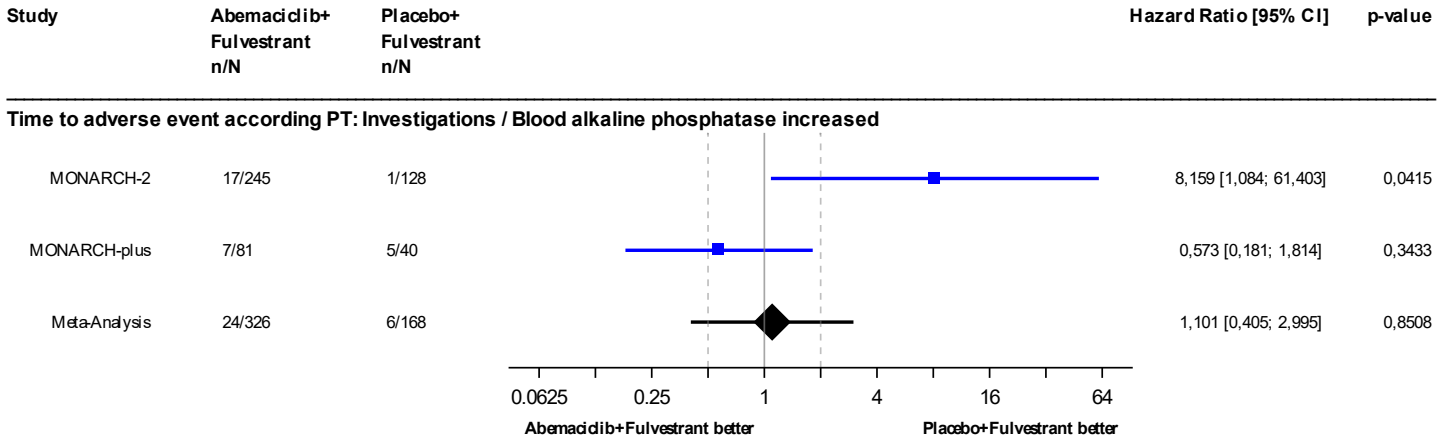
Figure 1110: Metaanalysis results for adverse events according PT[1] - Investigations / Blood alkaline phosphatase increased Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=5,0182, p-value=0,0251, I2 index=80,1%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep010_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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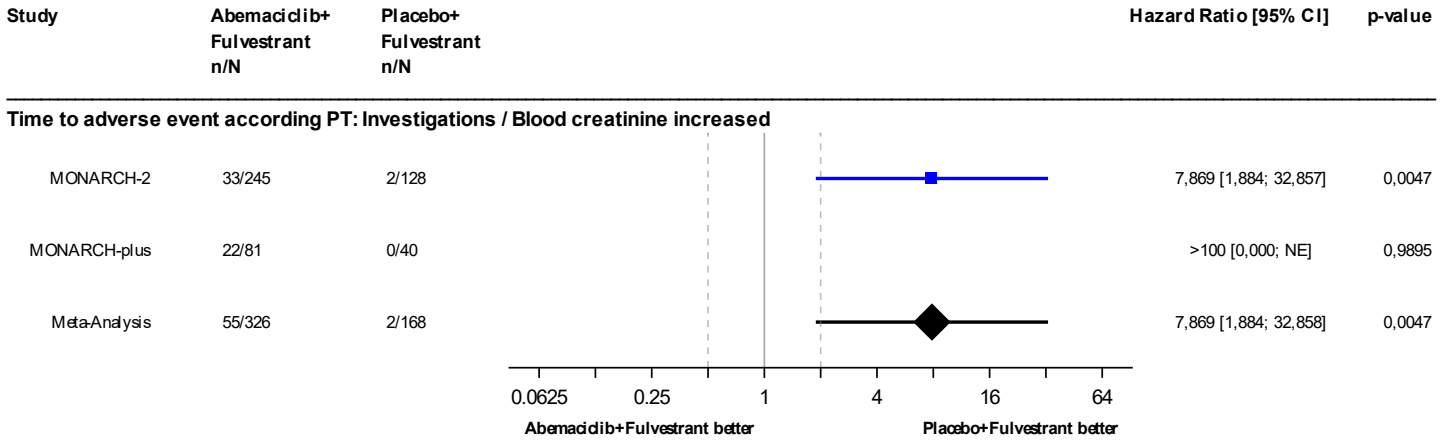
Figure 1111: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9908, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep011_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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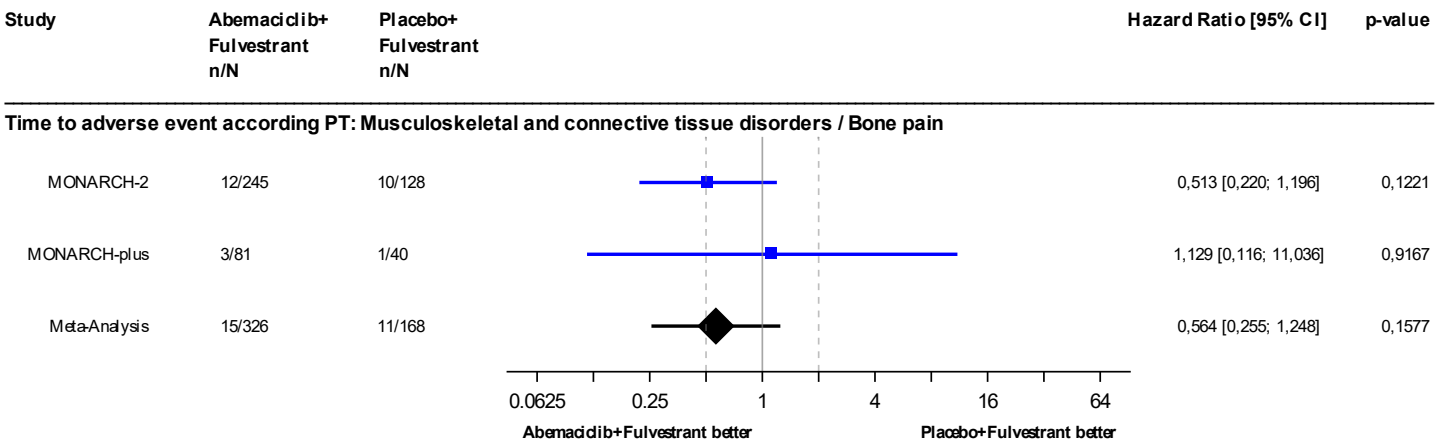
**Figure 1112: Metaanalysis results for adverse events according PT[1] -
Musculoskeletal and connective tissue disorders / Bone pain
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,4047, p-value=0,5247, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep012_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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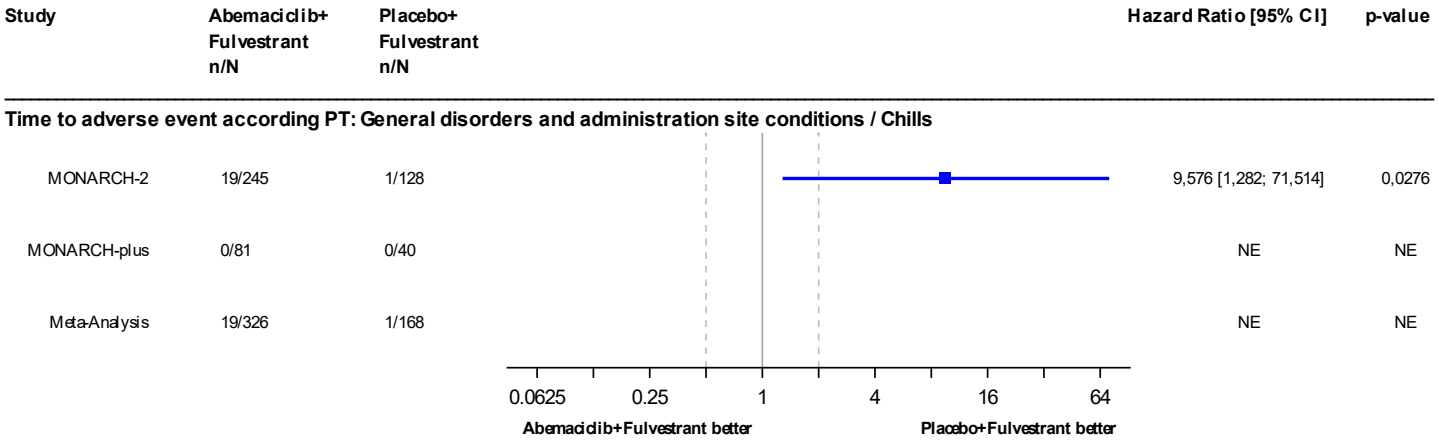
**Figure 1113: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Chills
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep013_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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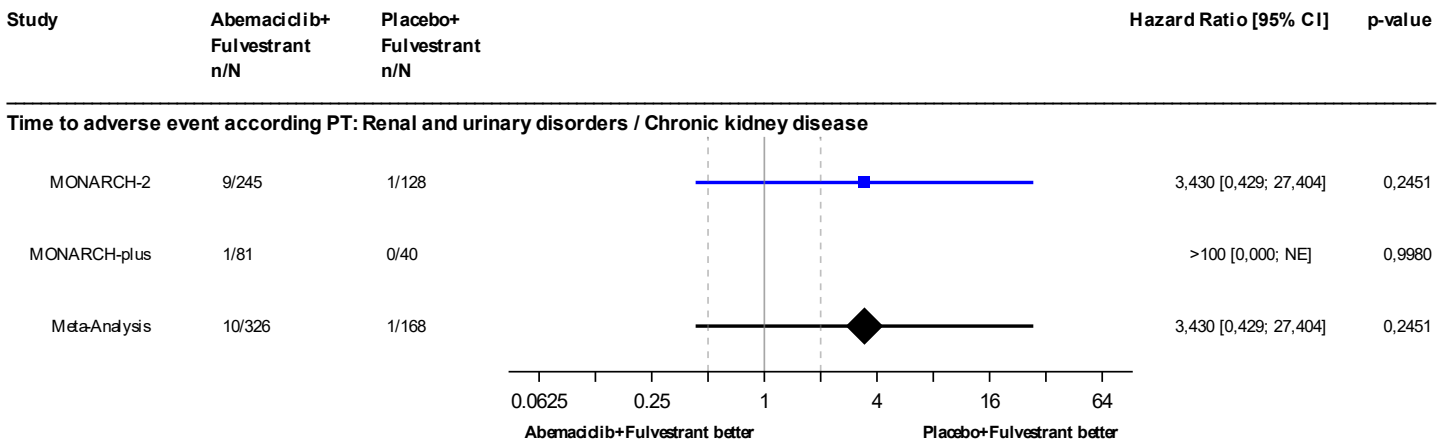
Figure 1114: Metaanalysis results for adverse events according PT[1] -
Renal and urinary disorders / Chronic kidney disease
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9982, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep014_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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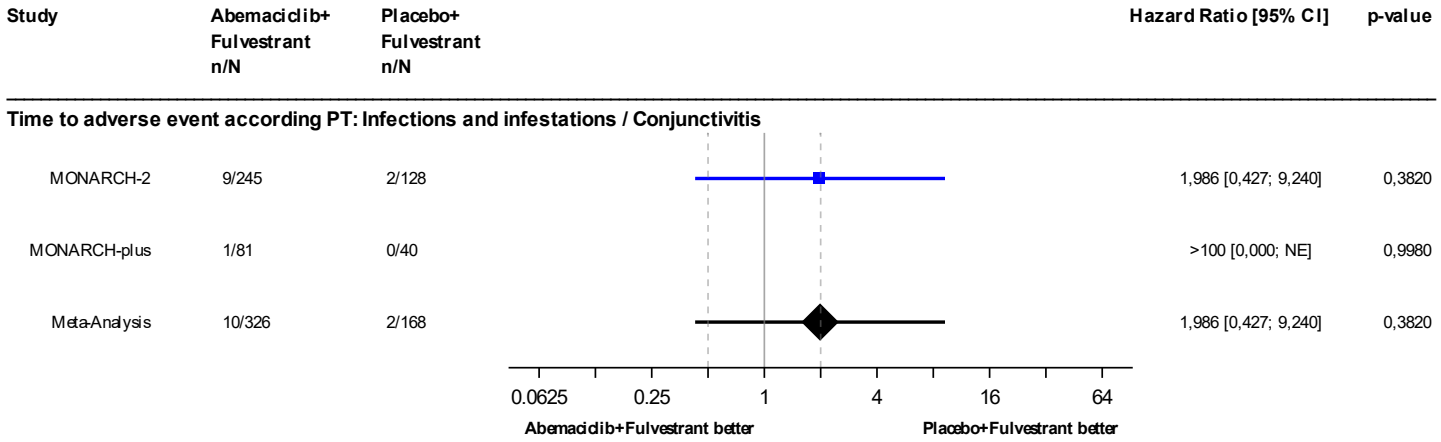
Figure 1115: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Conjunctivitis
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9981, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep015_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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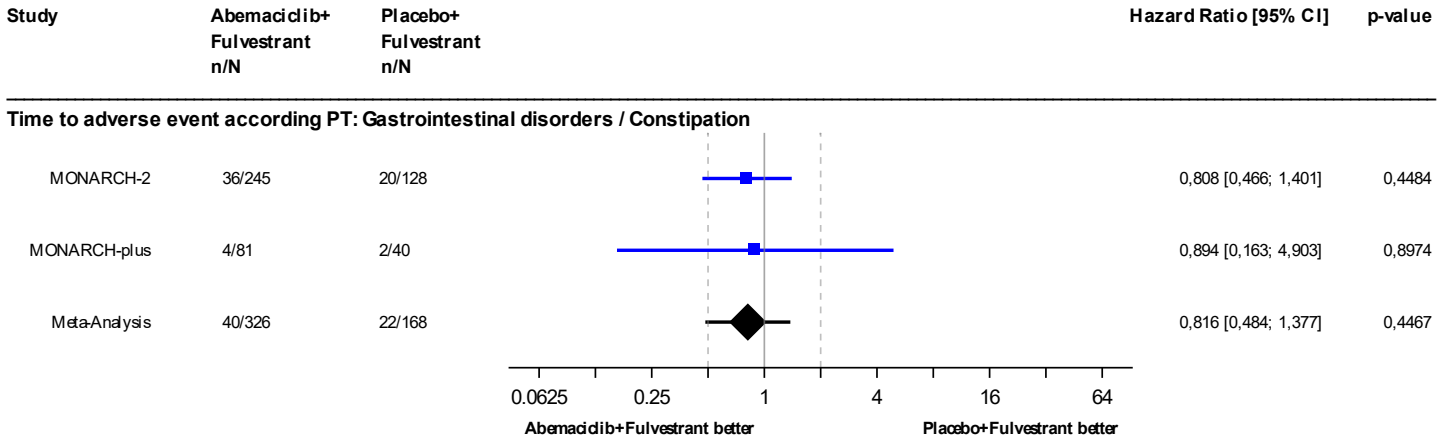
Figure 1116: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Constipation
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0122, p-value=0,9121, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep016_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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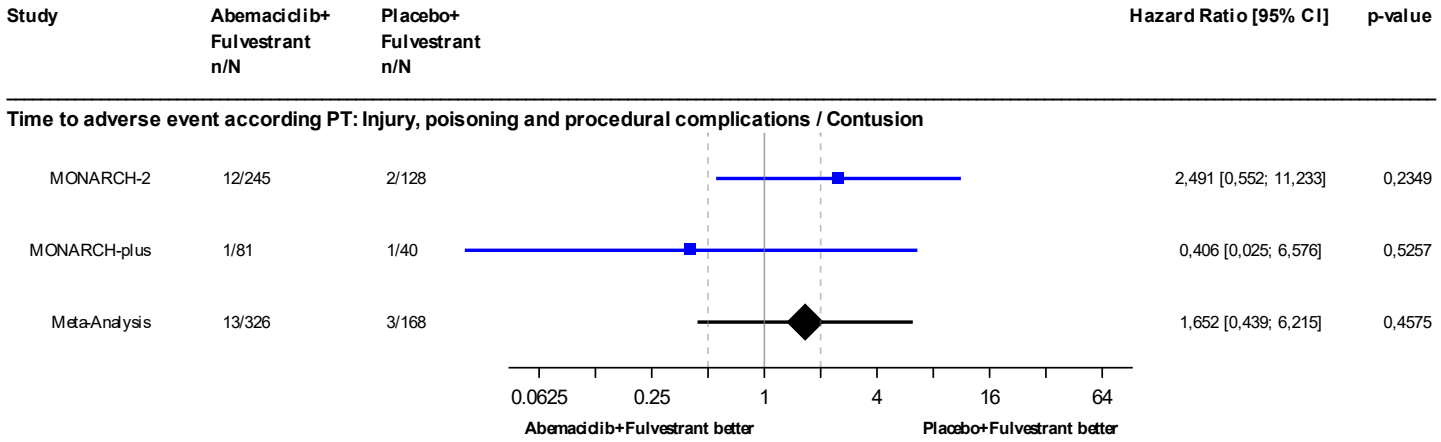
**Figure 1117: Metaanalysis results for adverse events according PT[1] -
Injury, poisoning and procedural complications / Contusion
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=1,2615, p-value=0,2614, I2 index=20,7%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep017_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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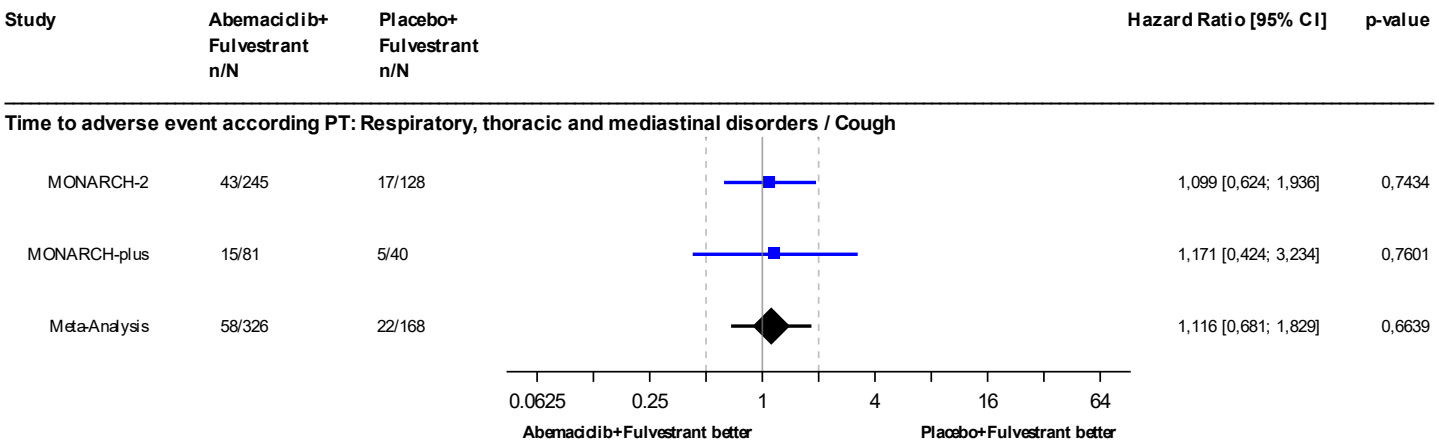
**Figure 1118: Metaanalysis results for adverse events according PT[1] -
Respiratory, thoracic and mediastinal disorders / Cough
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0115, p-value=0,9145, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep018_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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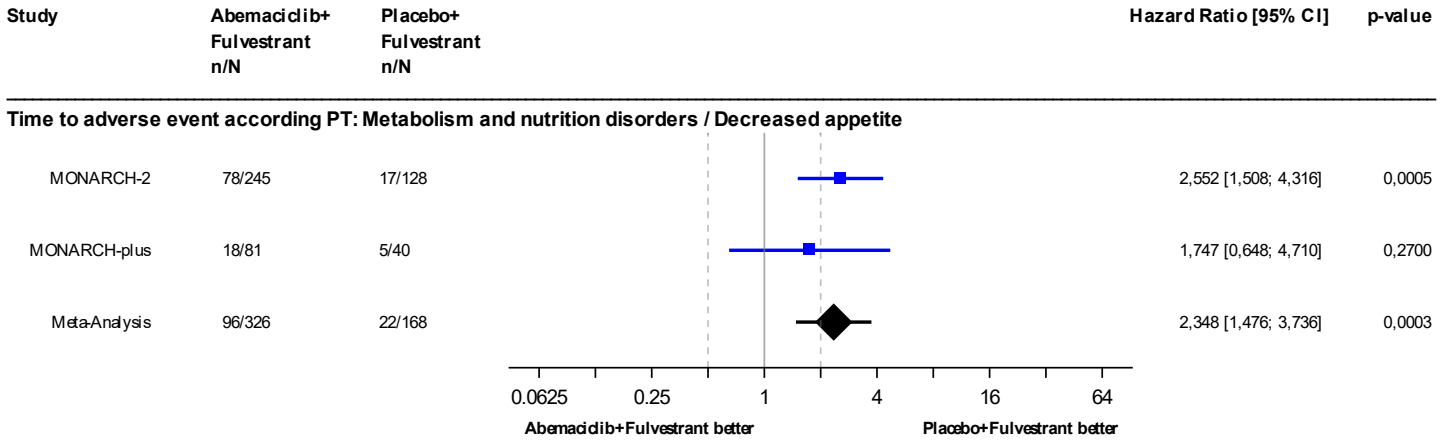
Figure 1119: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4372, p-value=0,5085, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep019_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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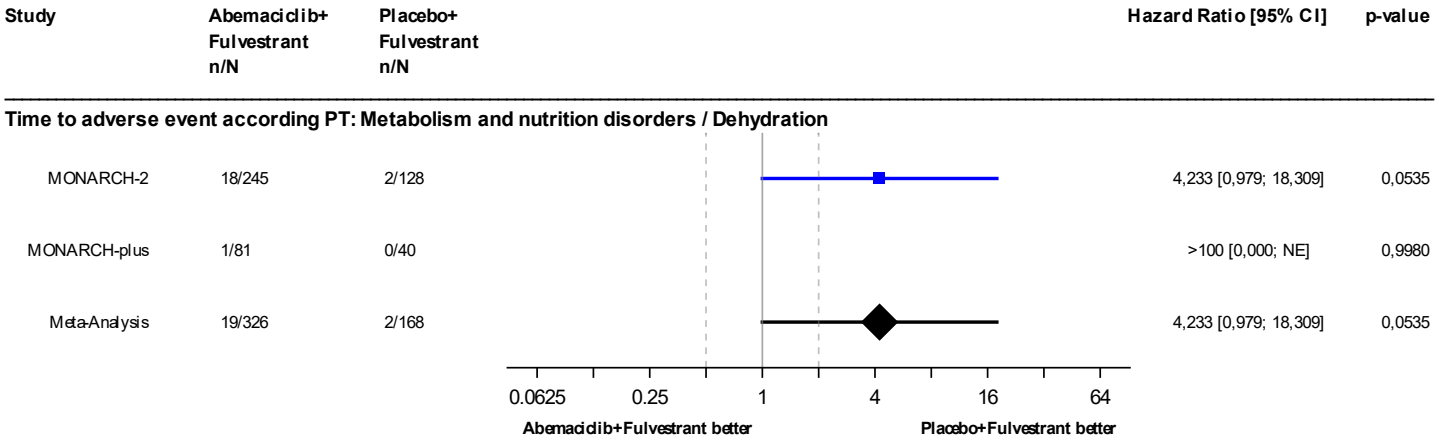
**Figure 1120: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Dehydration
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9982, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep020_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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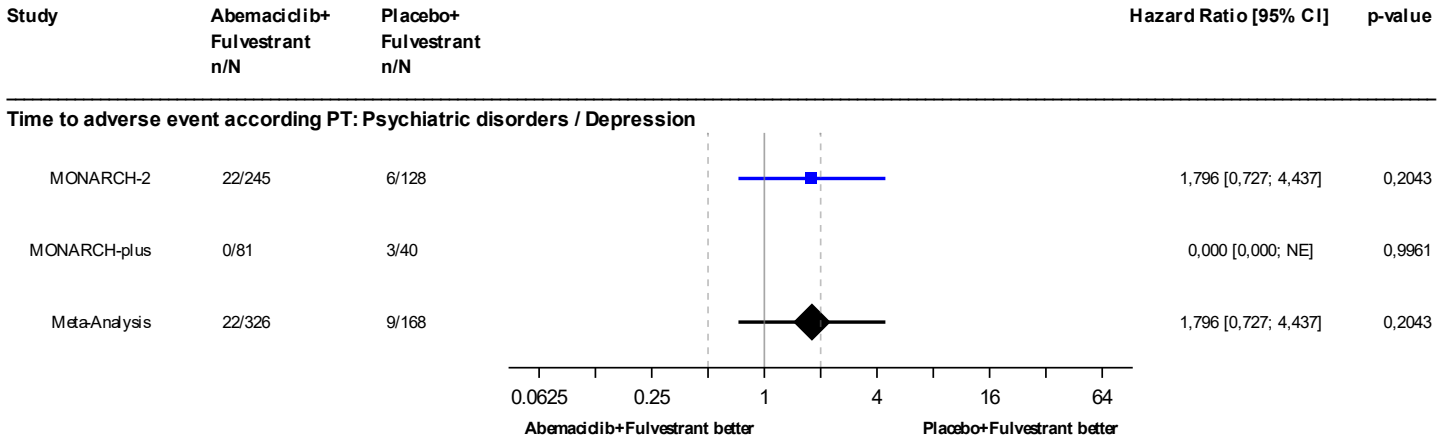
Figure 1121: Metaanalysis results for adverse events according PT[1] -
Psychiatric disorders / Depression
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9960, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep021_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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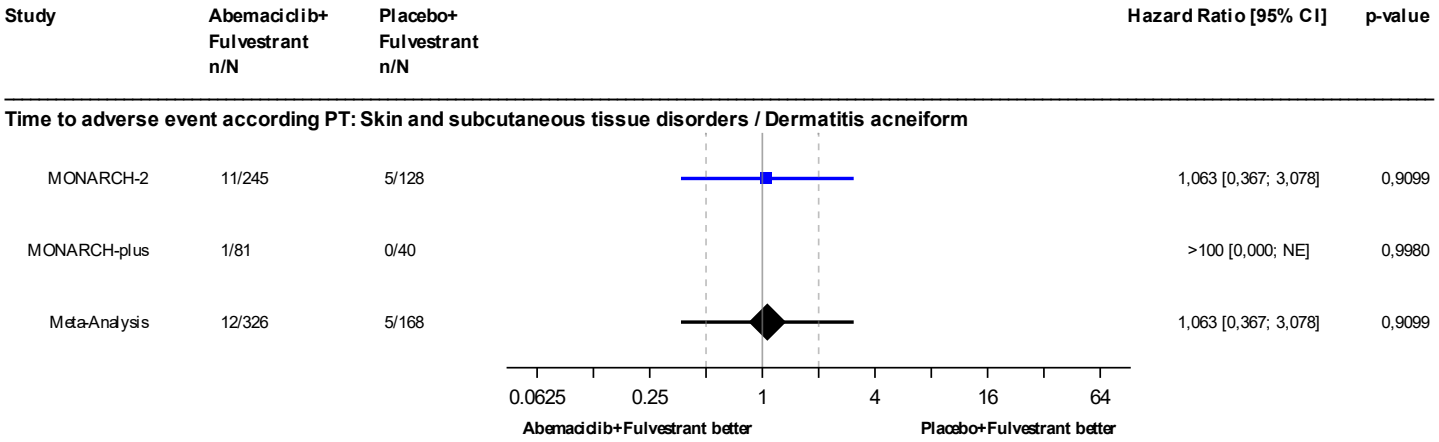
Figure 1122: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Dermatitis acneiform
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep022_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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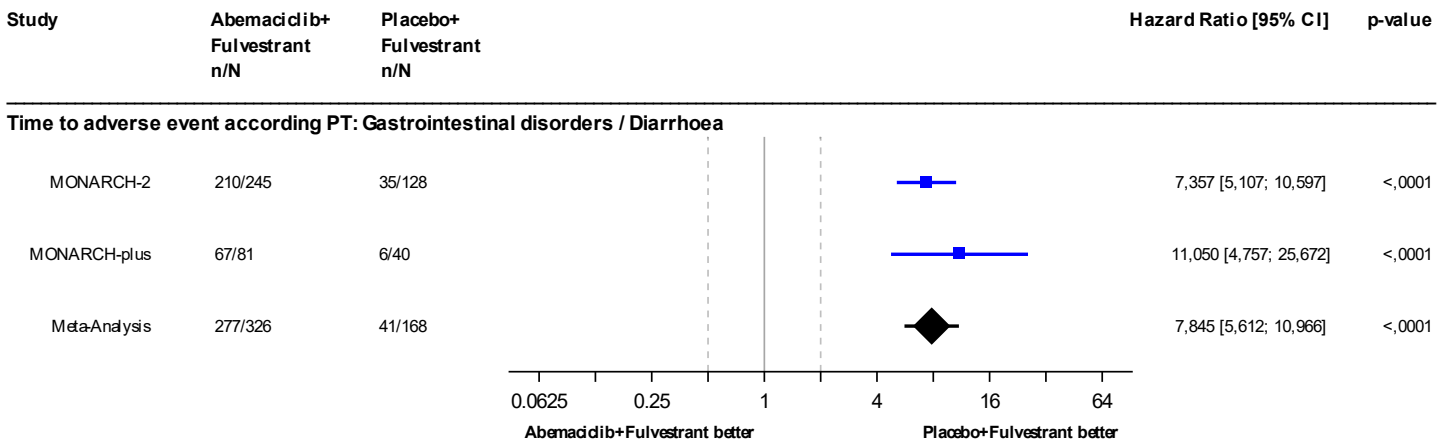
Figure 1123: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,7535, p-value=0,3854, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep023_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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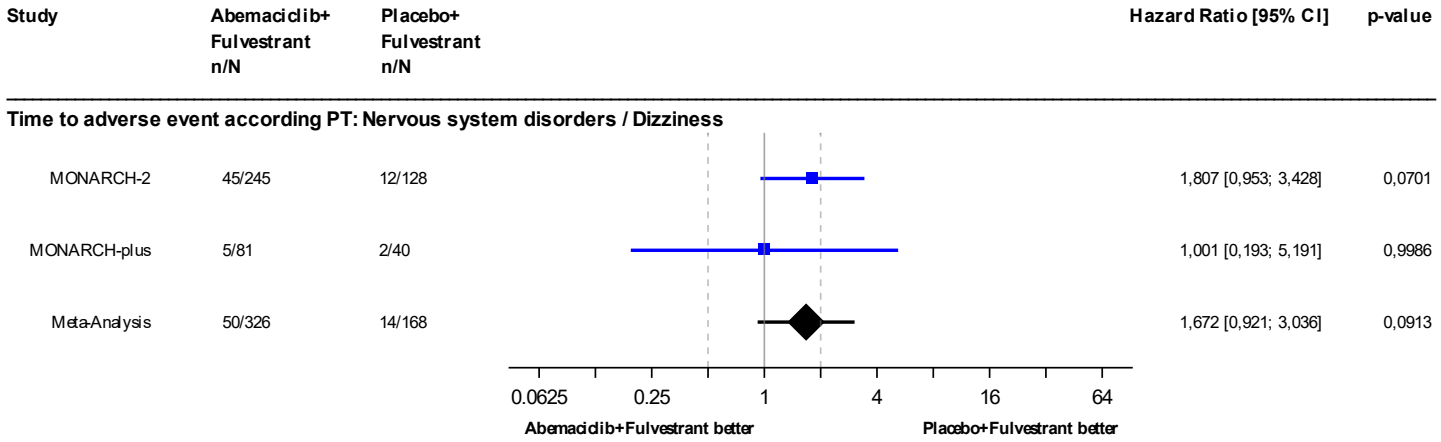
Figure 1124: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dizziness
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4292, p-value=0,5124, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep024_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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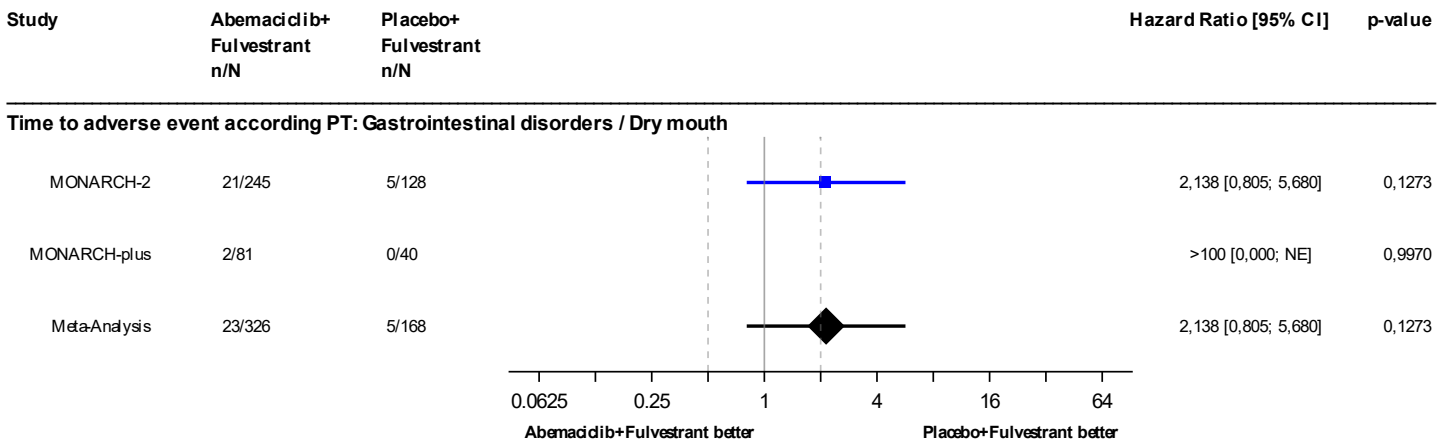
Figure 1125: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Dry mouth
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9971, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep025_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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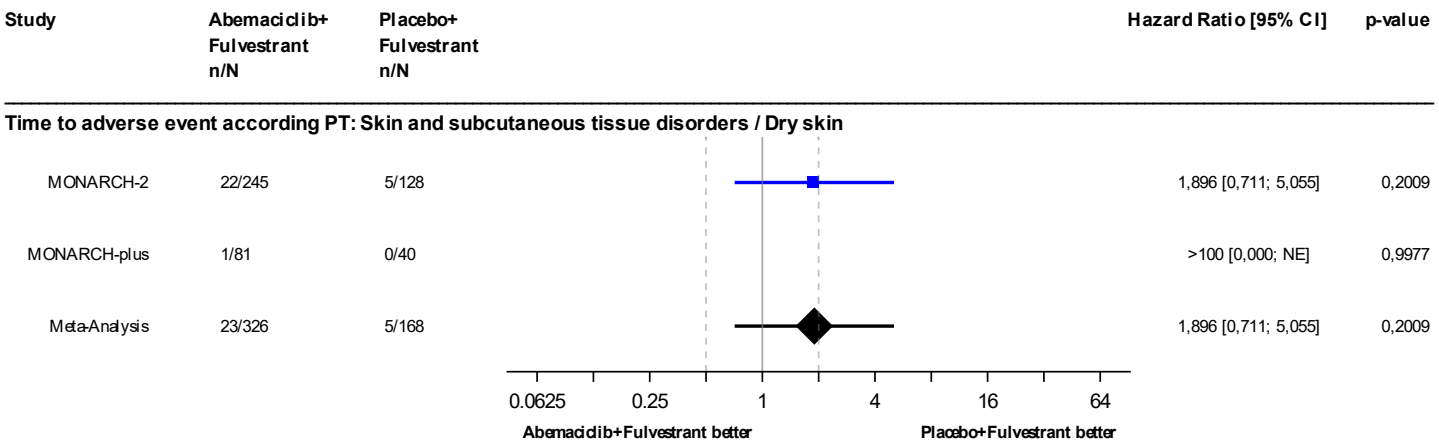
**Figure 1126: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Dry skin
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9978, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep026_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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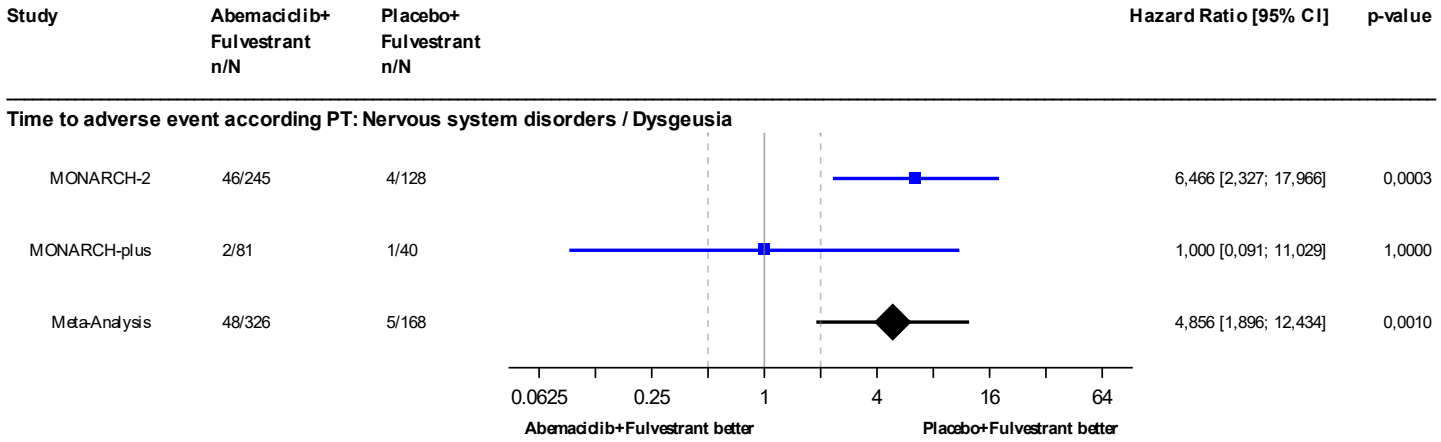
Figure 1127: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,9664, p-value=0,1608, I2 index=49,1%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep027_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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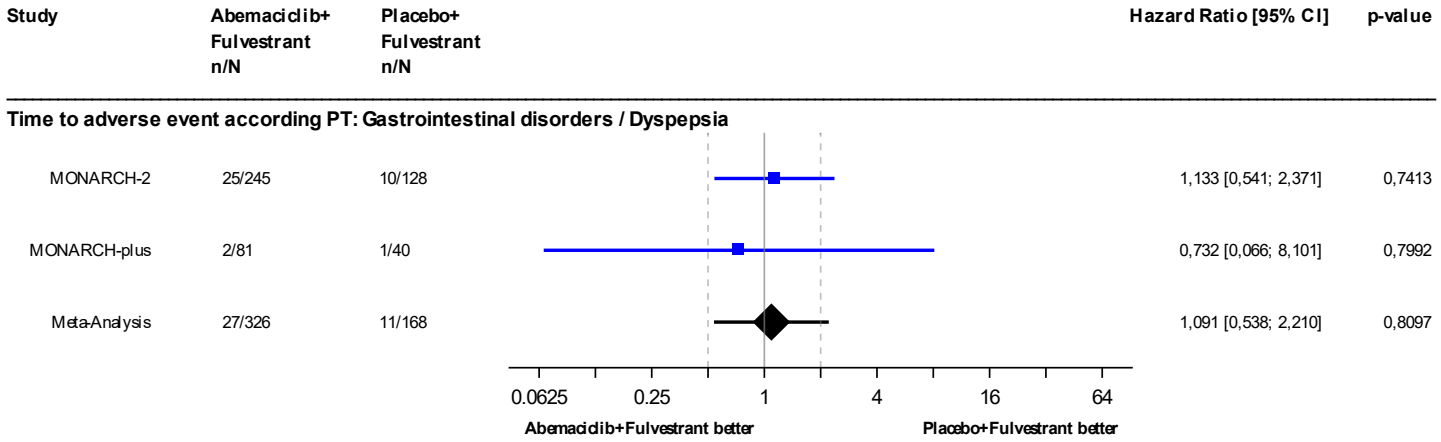
Figure 1128: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Dyspepsia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1157, p-value=0,7337, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep028_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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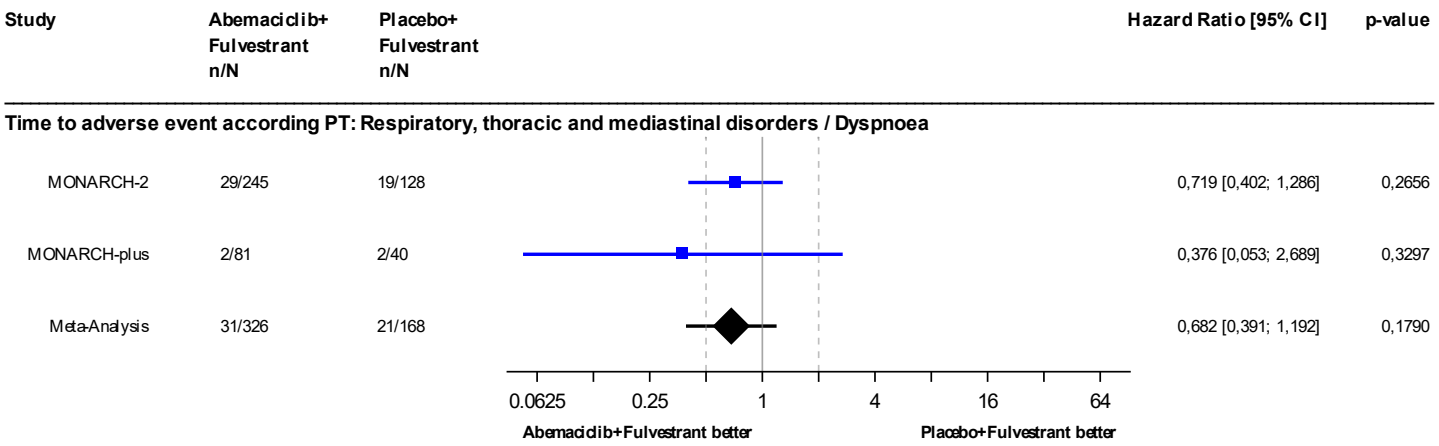
**Figure 1129: Metaanalysis results for adverse events according PT[1] -
Respiratory, thoracic and mediastinal disorders / Dyspnoea
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,3833, p-value=0,5358, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep029_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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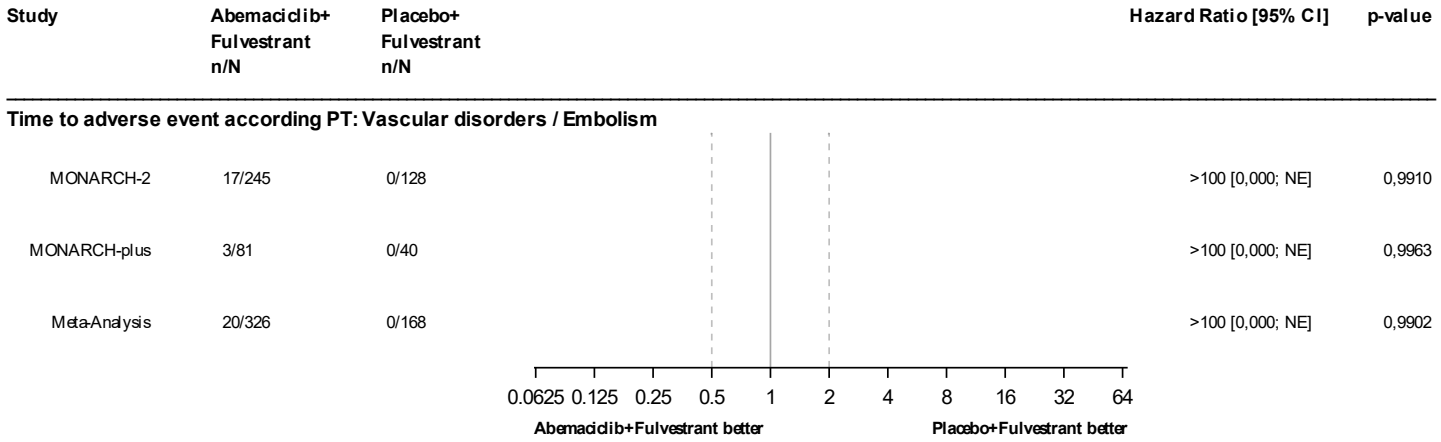
Figure 1130: Metaanalysis results for adverse events according PT[1] -
Vascular disorders / Embolism
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep030_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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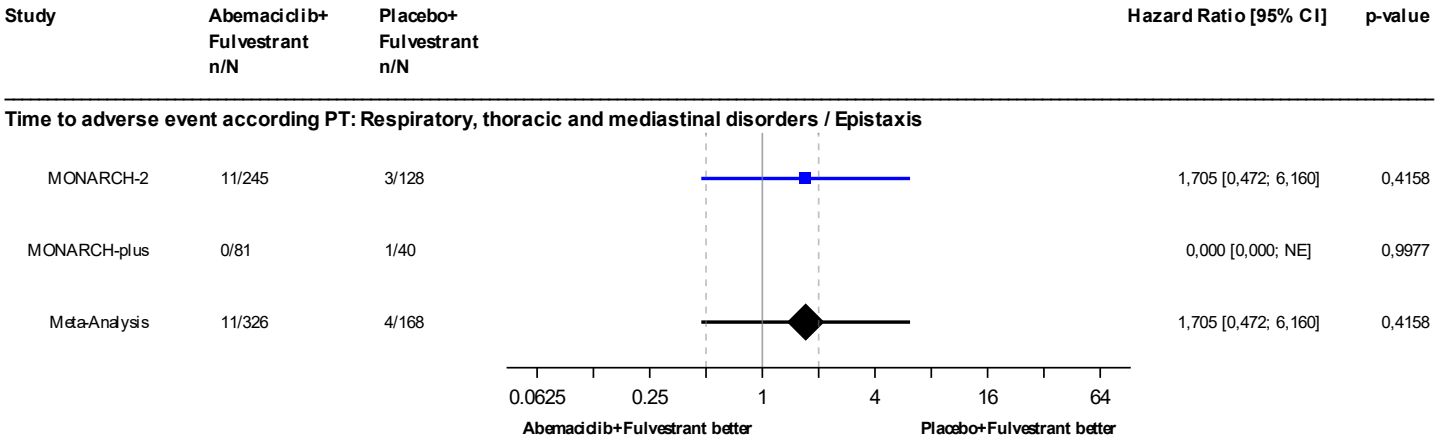
**Figure 1131: Metaanalysis results for adverse events according PT[1] -
Respiratory, thoracic and mediastinal disorders / Epistaxis
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9976, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep031_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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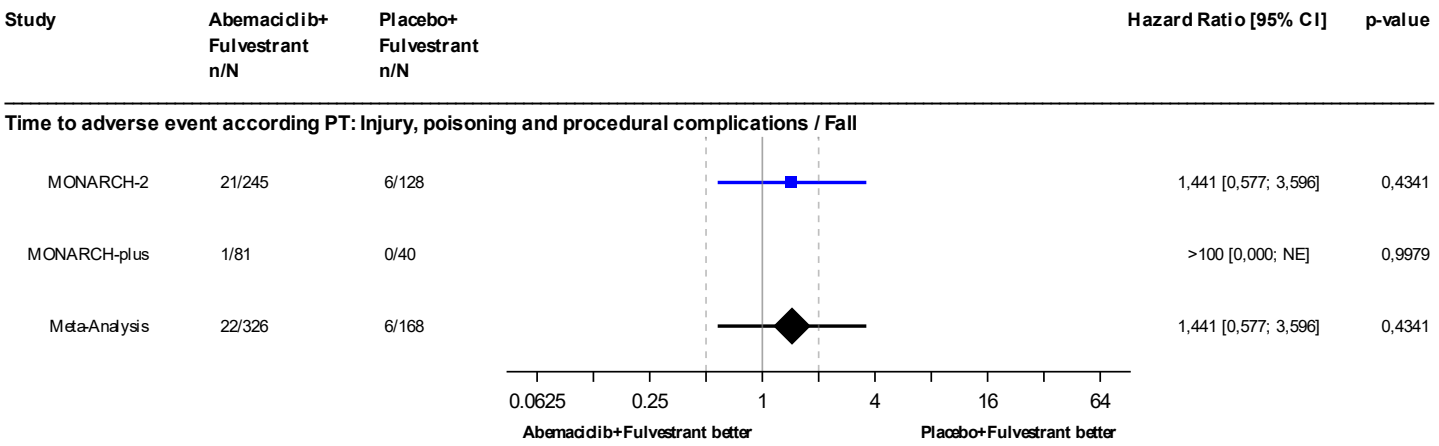
Figure 1132: Metaanalysis results for adverse events according PT[1] -
Injury, poisoning and procedural complications / Fall
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9979, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep032_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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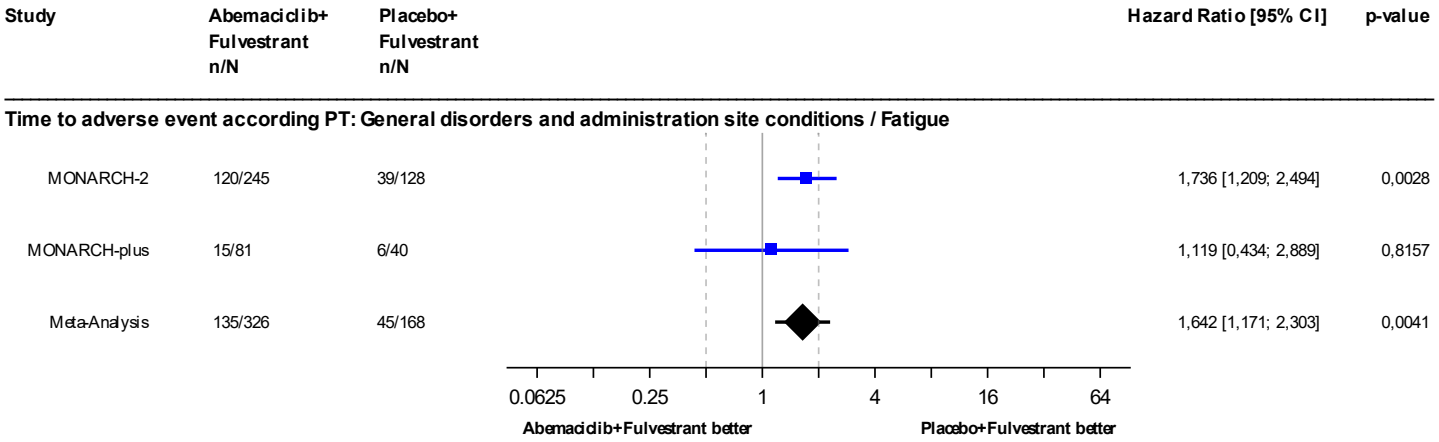
**Figure 1133: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,7187, p-value=0,3966, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep033_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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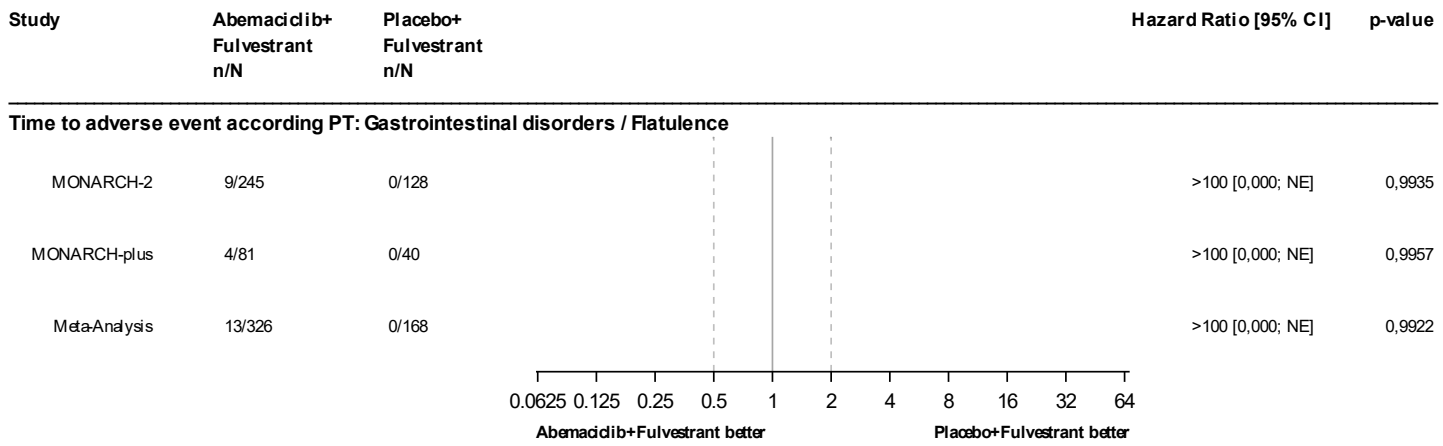
Figure 1134: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Flatulence
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep034_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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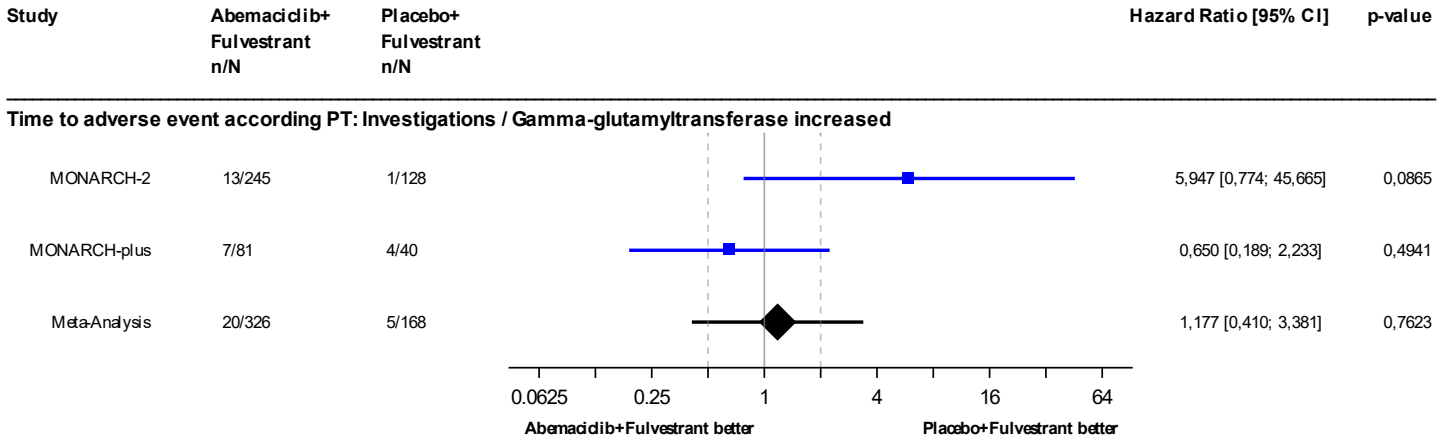
Figure 1135: Metaanalysis results for adverse events according PT[1] - Investigations / Gamma-glutamyltransferase increased Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=3,3148, p-value=0,0687, I2 index=69,8%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep035_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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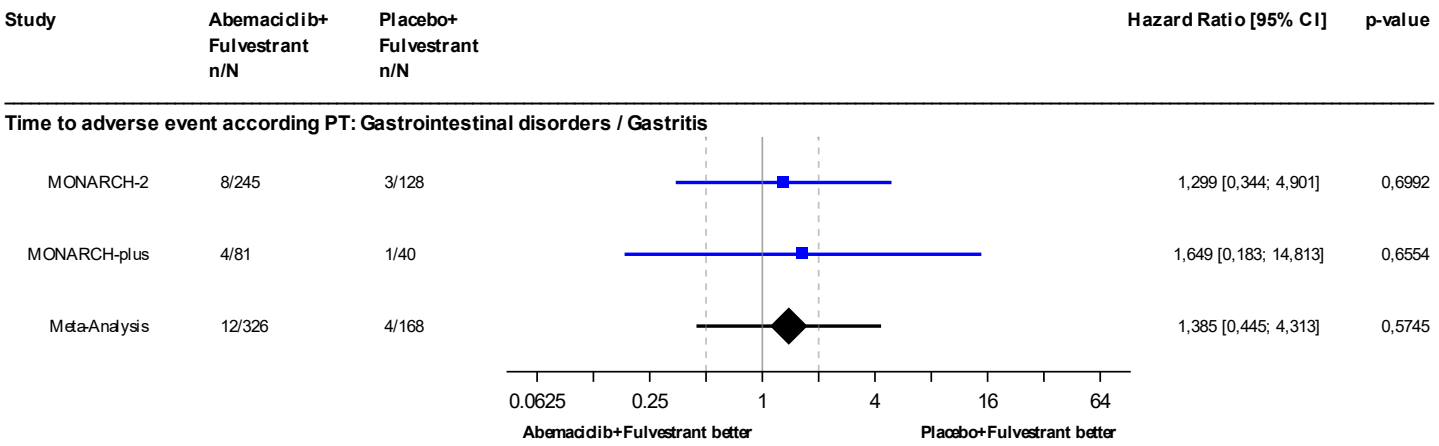
Figure 1136: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Gastritis
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0331, p-value=0,8556, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep036_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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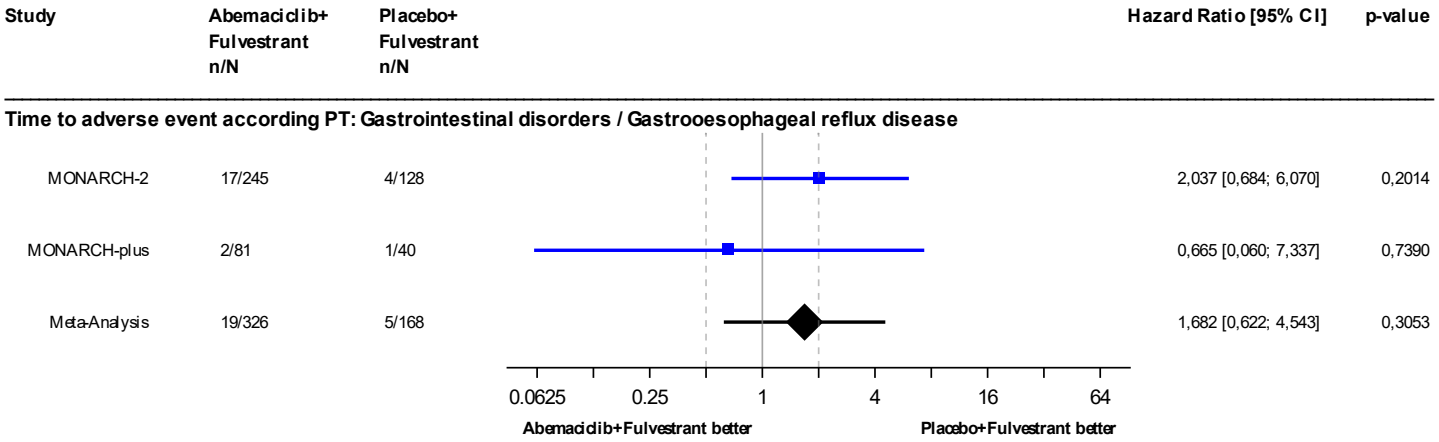
Figure 1137: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Gastrooesophageal reflux disease
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6924, p-value=0,4053, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep037_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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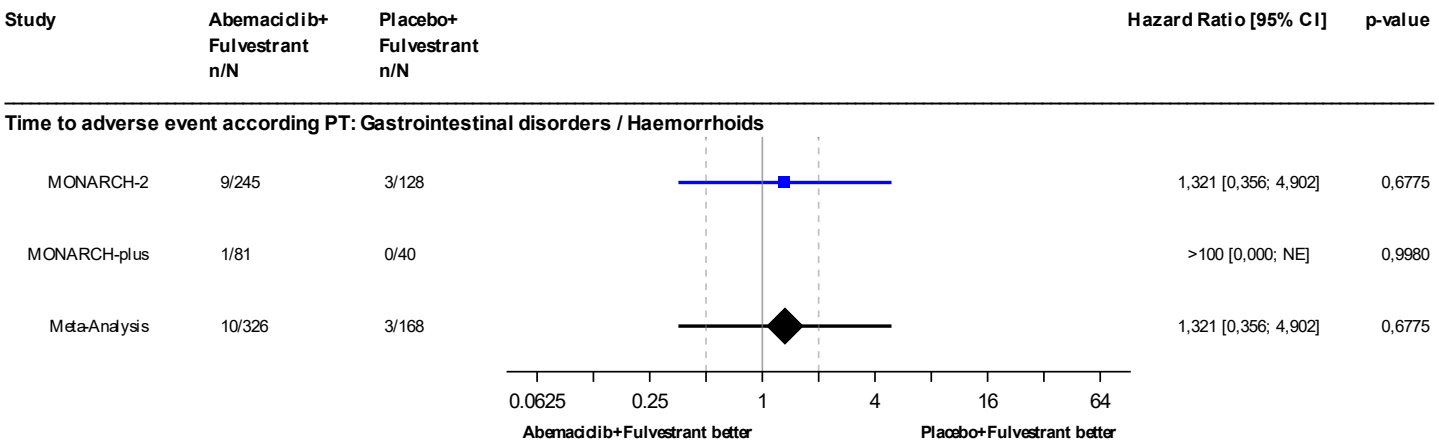
Figure 1138: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Haemorrhoids
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9981, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep038_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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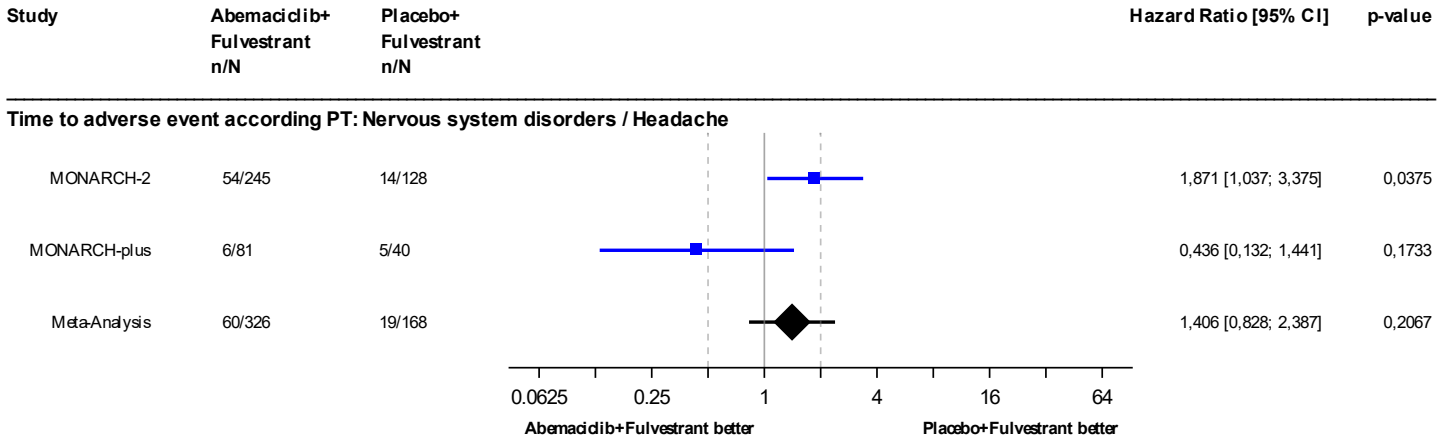
Figure 1139: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Headache
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=4,5858, p-value=0,0322, I2 index=78,2%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep039_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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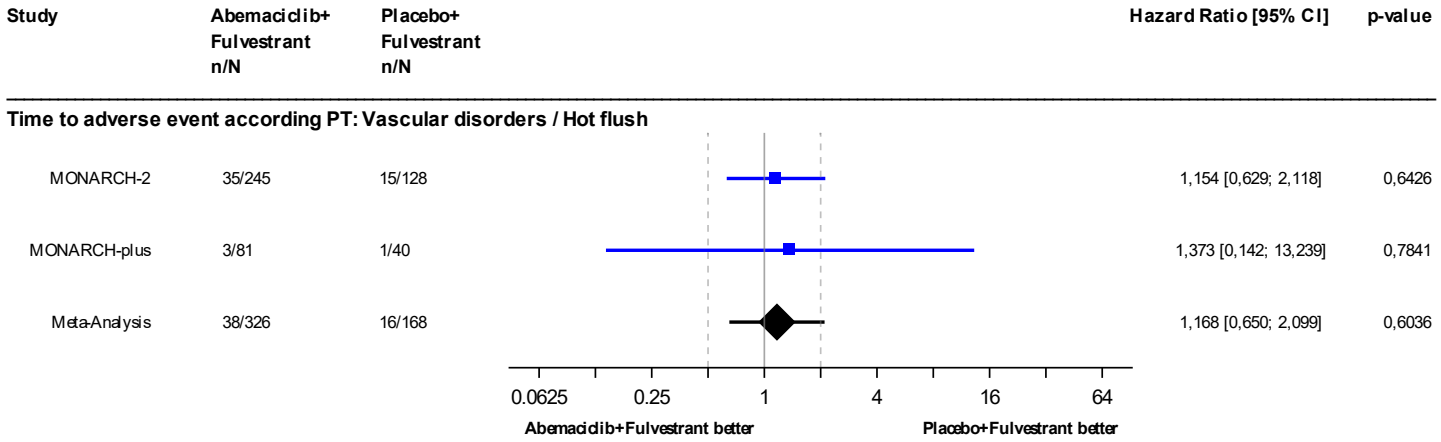
Figure 1140: Metaanalysis results for adverse events according PT[1] -
Vascular disorders / Hot flush
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0209, p-value=0,8850, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep040_popa1.rtf
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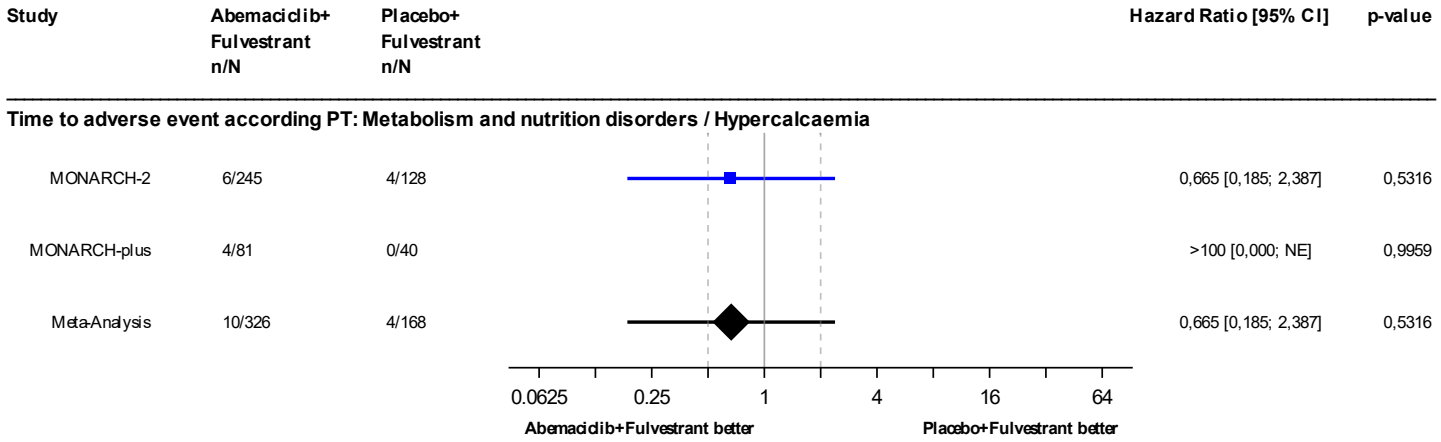
Figure 1141: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypercalcaemia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9958, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep041_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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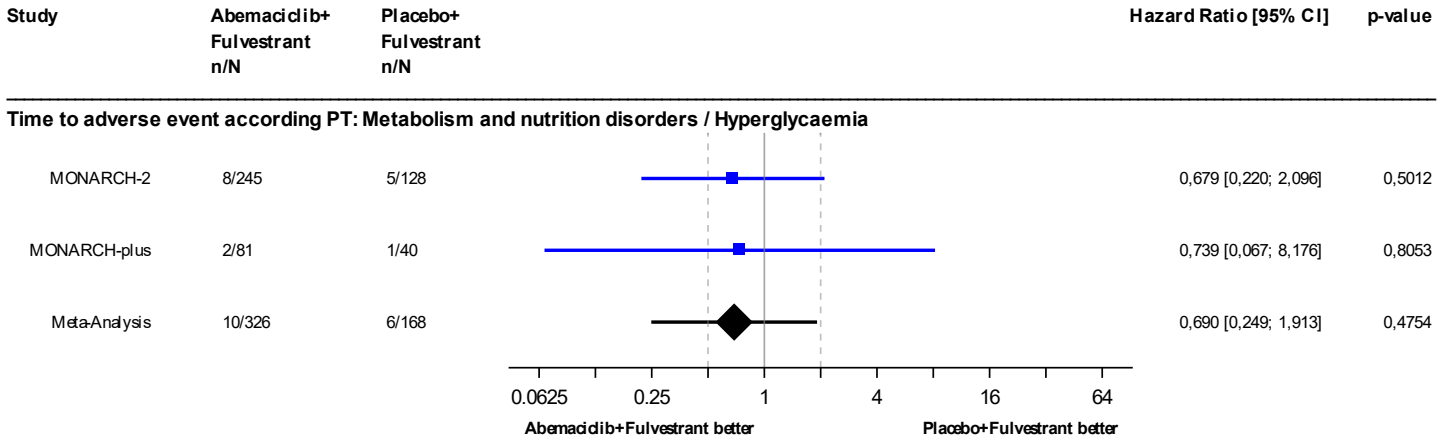
Figure 1142: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hyperglycaemia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0039, p-value=0,9504, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep042_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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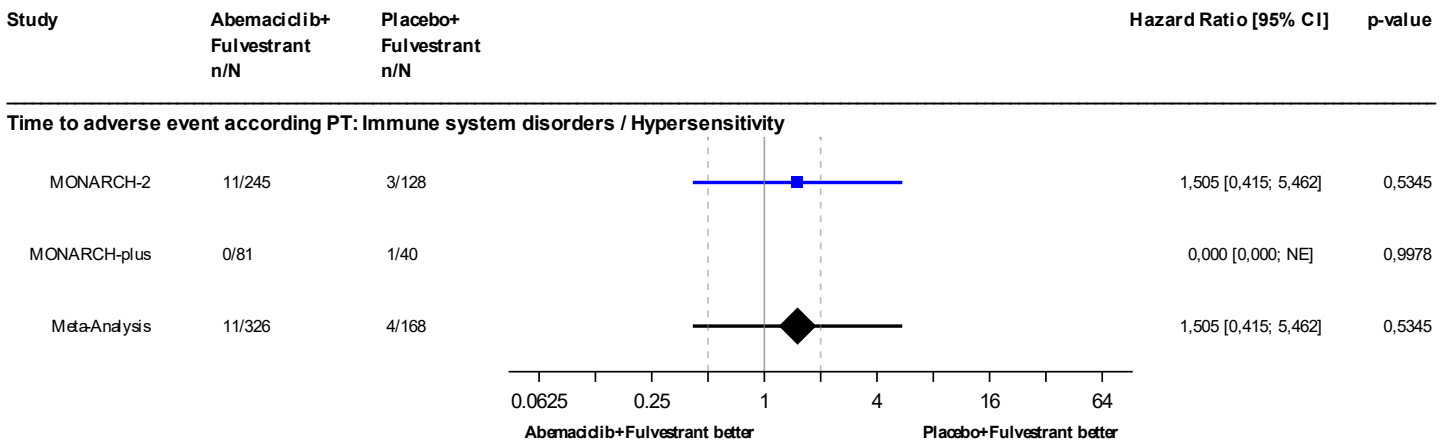
Figure 1143: Metaanalysis results for adverse events according PT[1] -
Immune system disorders / Hypersensitivity
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9978, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep043_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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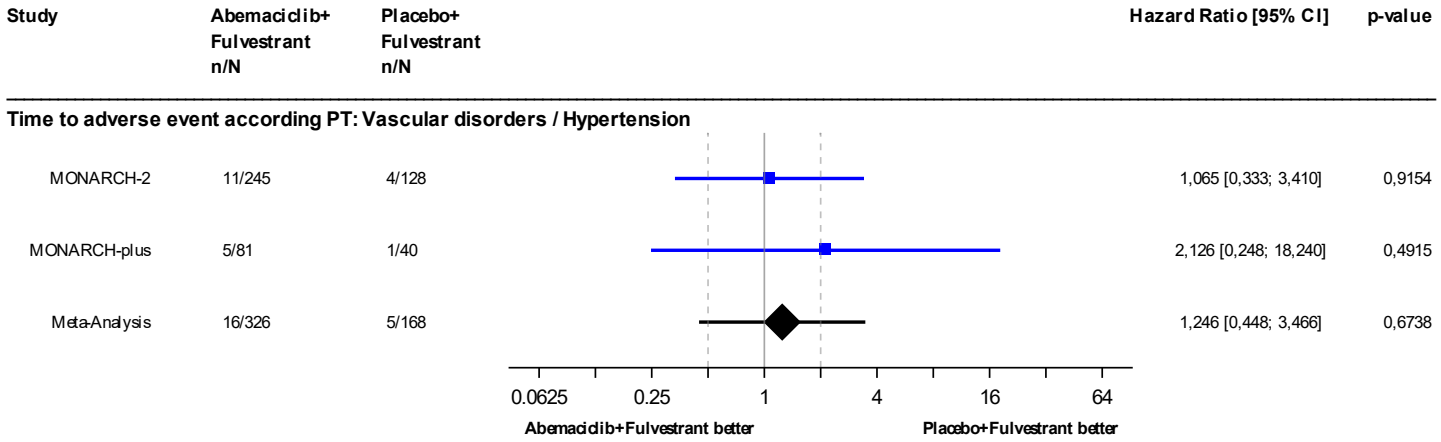
Figure 1144: Metaanalysis results for adverse events according PT[1] -
Vascular disorders / Hypertension
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3073, p-value=0,5794, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep044_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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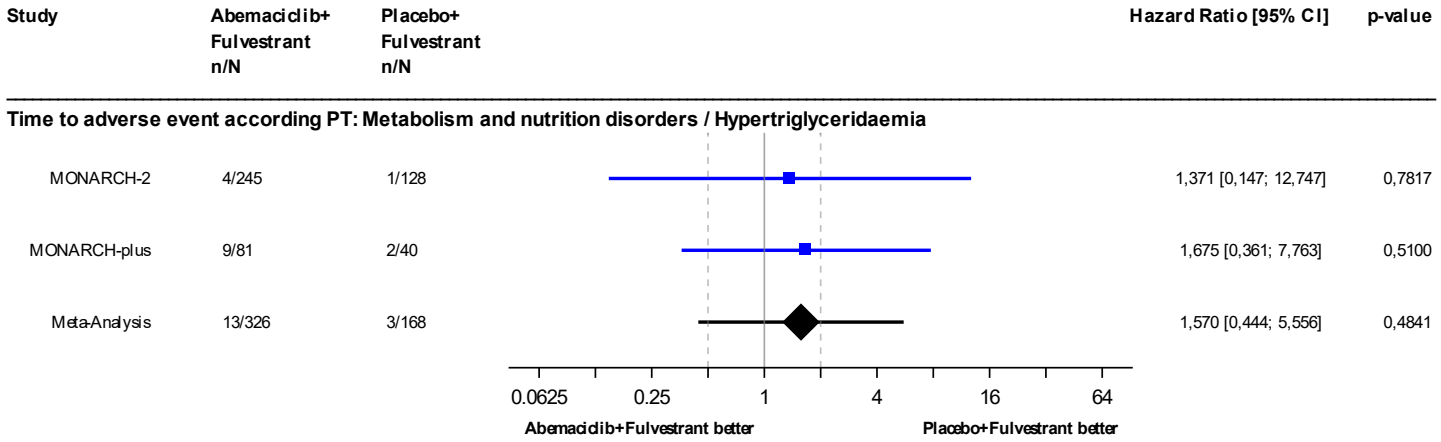
Figure 1145: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypertriglyceridaemia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0210, p-value=0,8847, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep045_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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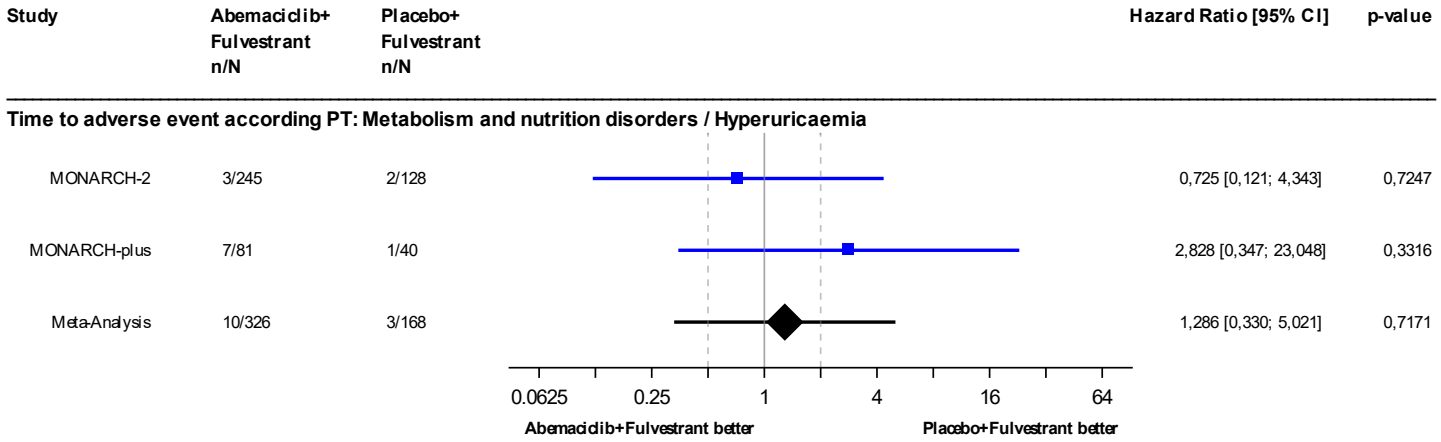
Figure 1146: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hyperuricaemia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,9355, p-value=0,3334, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep046_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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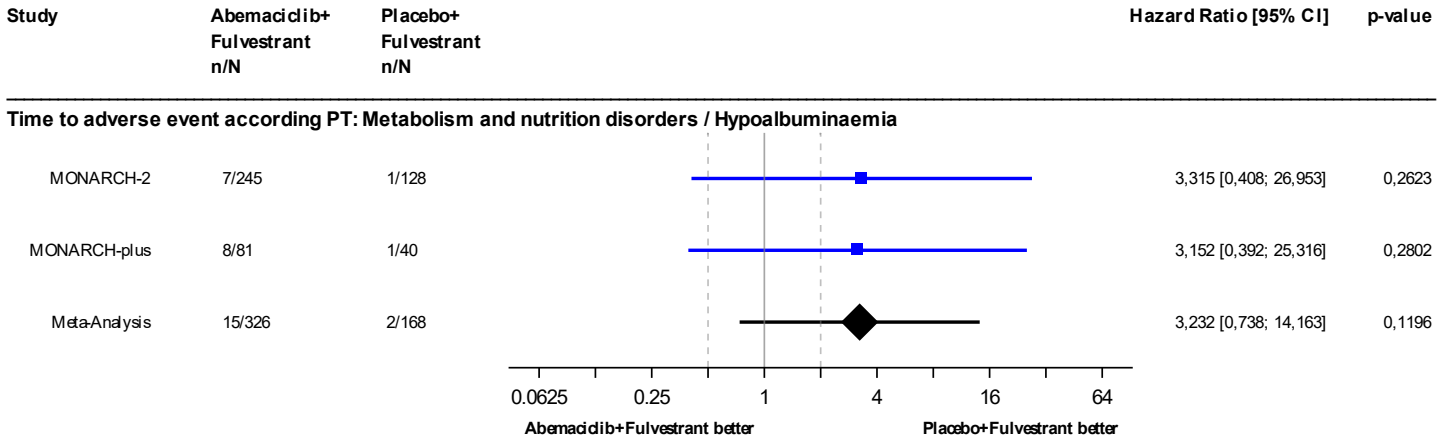
Figure 1147: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypoalbuminaemia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0011, p-value=0,9732, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep047_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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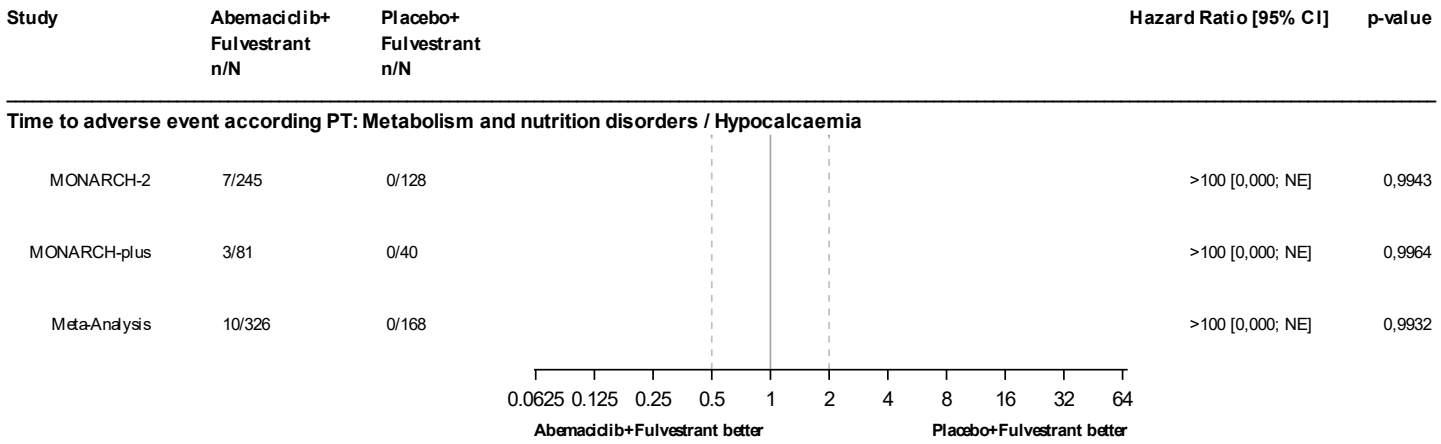
Figure 1148: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypocalcaemia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep048_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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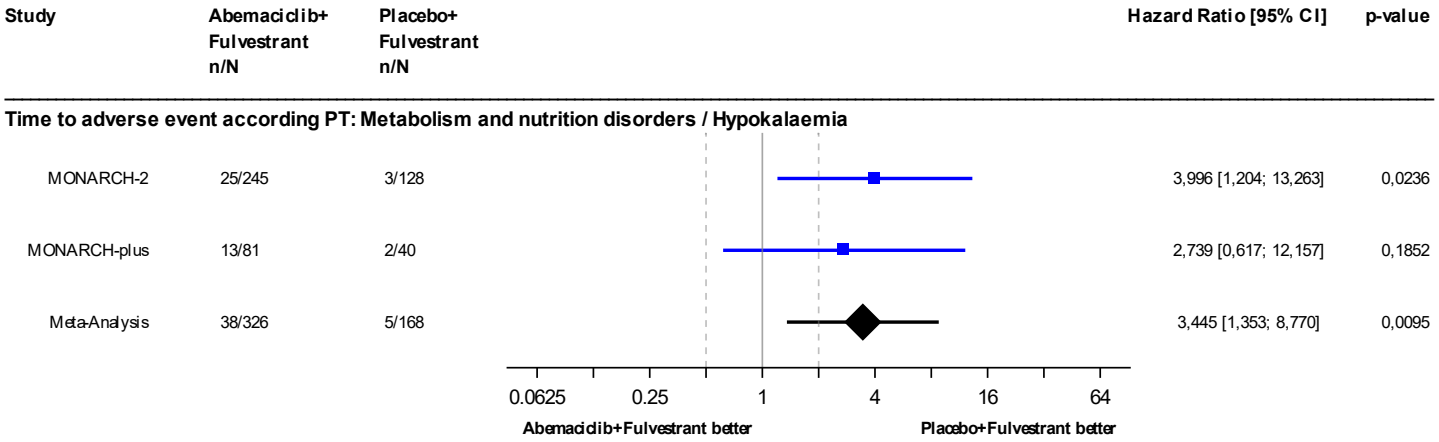
Figure 1149: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1498, p-value=0,6987, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep049_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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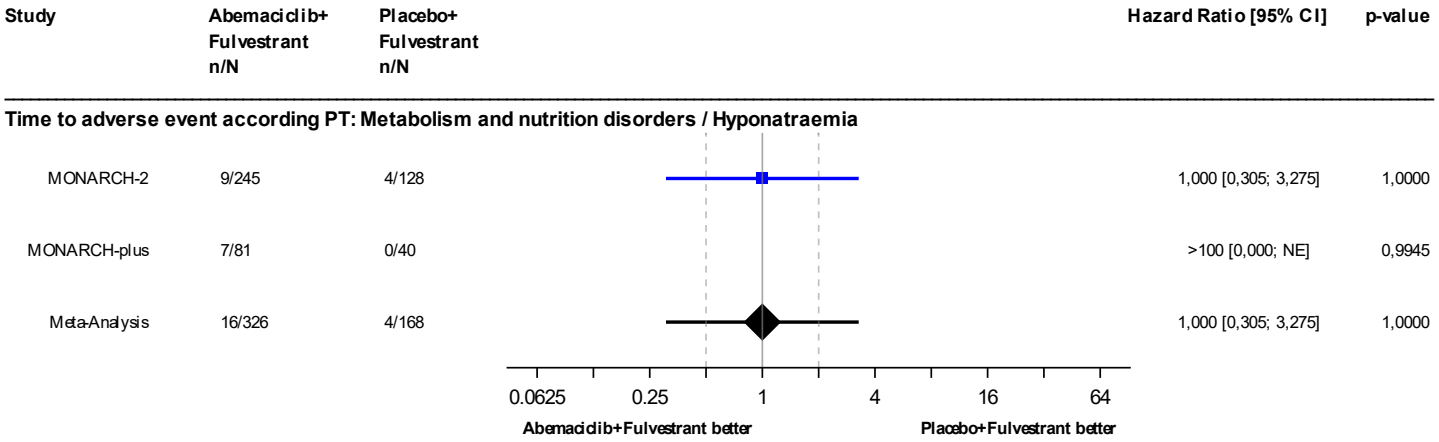
Figure 1150: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hyponatraemia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9945, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep050_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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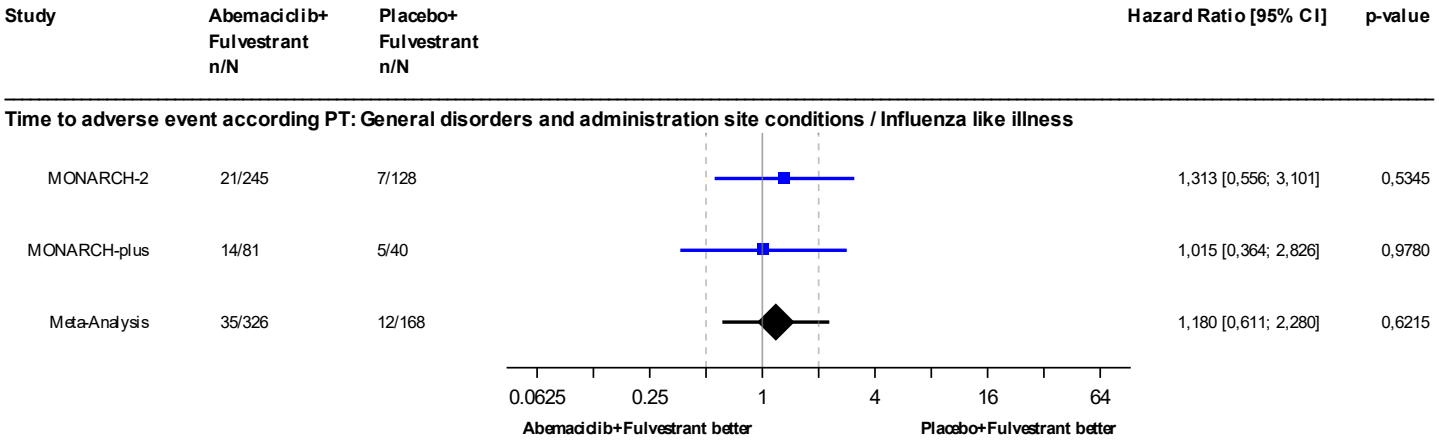
**Figure 1151: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Influenza like illness
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,1430, p-value=0,7054, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep051_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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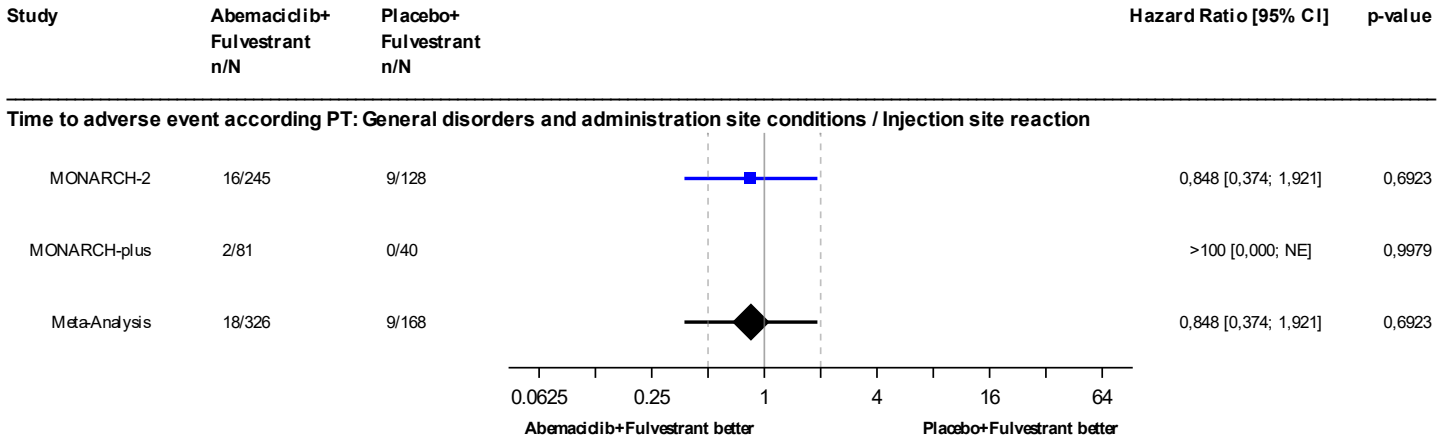
**Figure 1152: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Injection site reaction
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9979, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep052_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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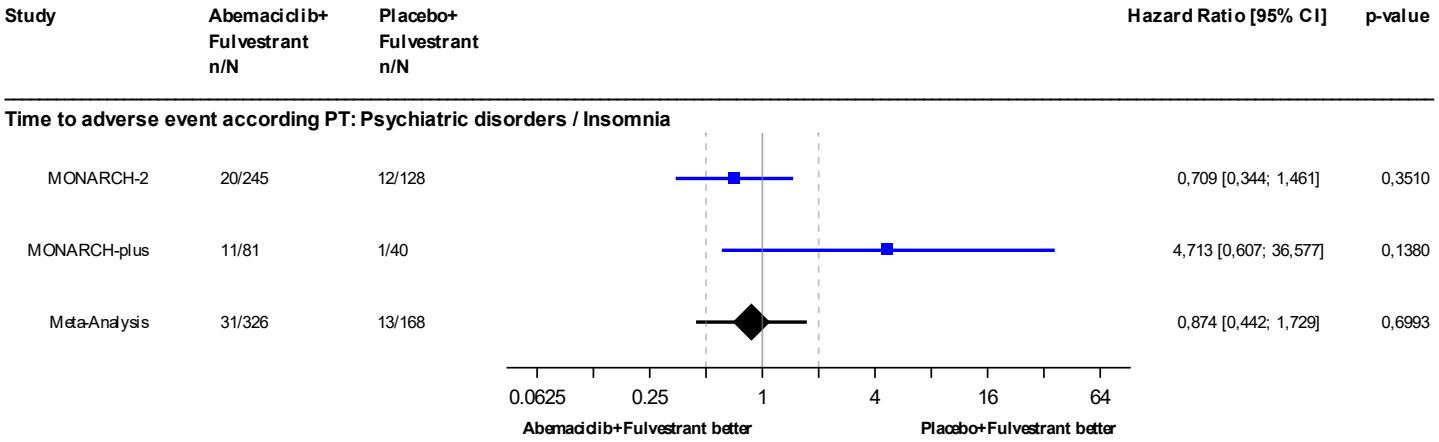
Figure 1153: Metaanalysis results for adverse events according PT[1] -
Psychiatric disorders / Insomnia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,9203, p-value=0,0875, I2 index=65,8%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep053_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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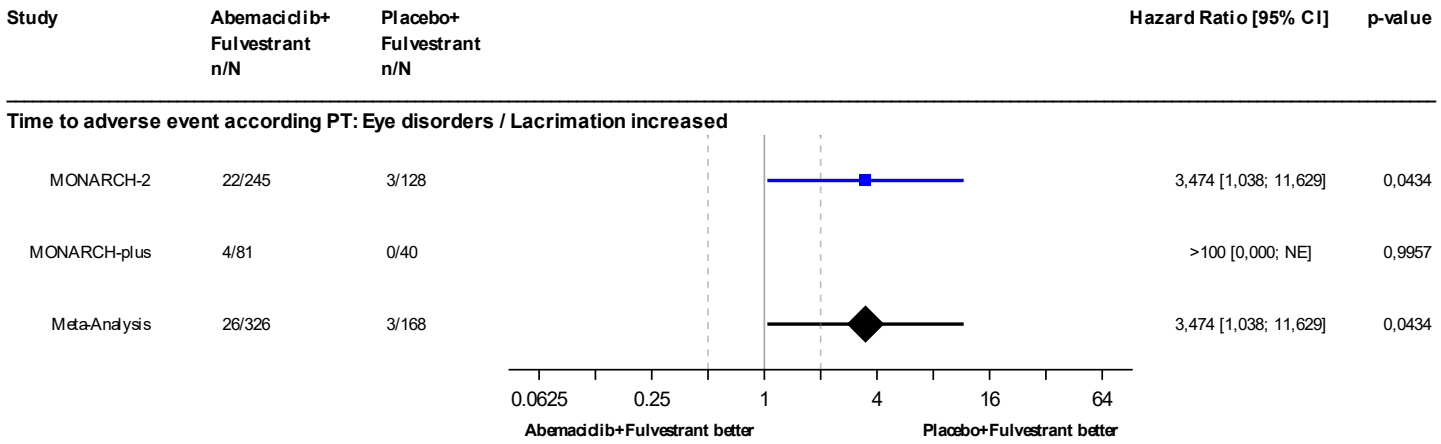
Figure 1154: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9960, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep054_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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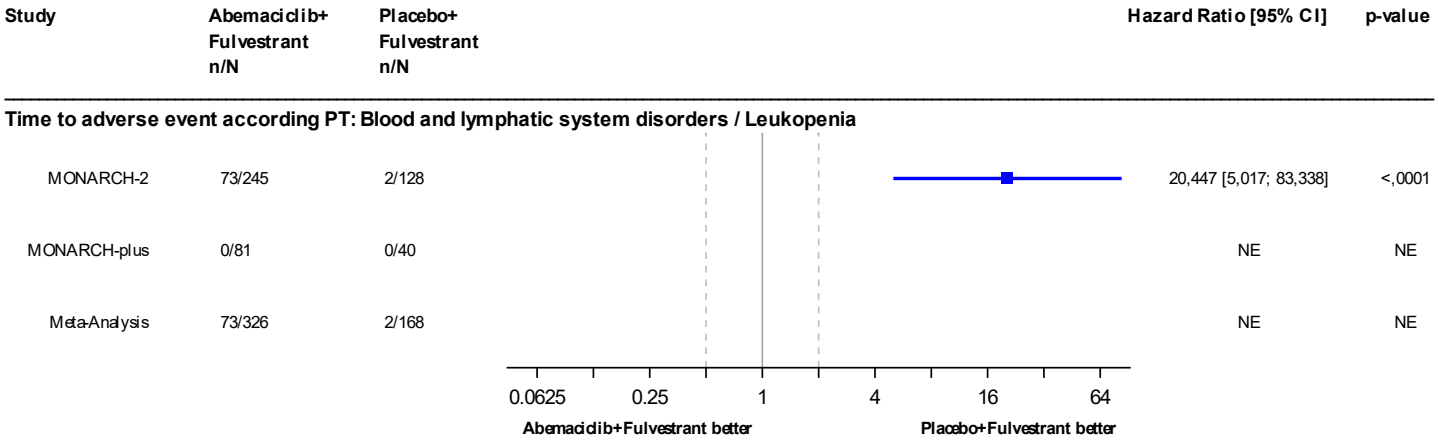
Figure 1155: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Leukopenia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep055_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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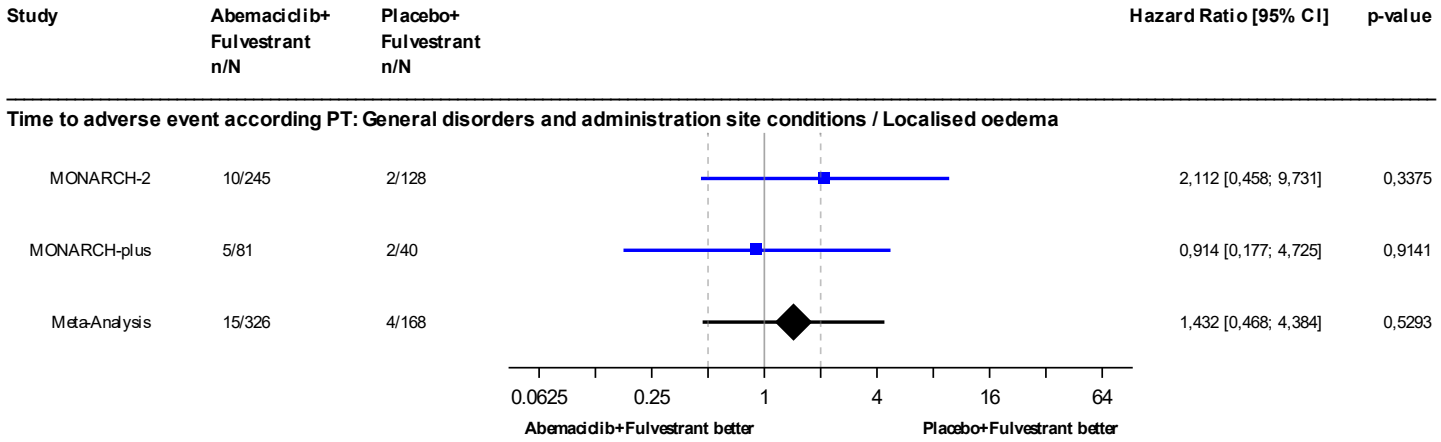
**Figure 1156: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Localised oedema
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,5359, p-value=0,4641, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep056_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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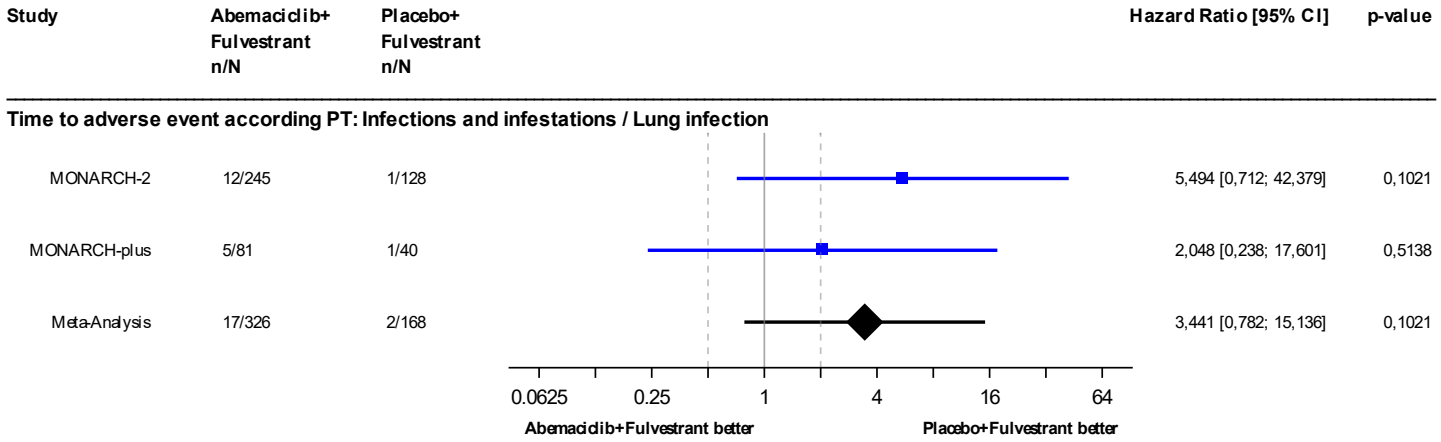
Figure 1157: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Lung infection
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4253, p-value=0,5143, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep057_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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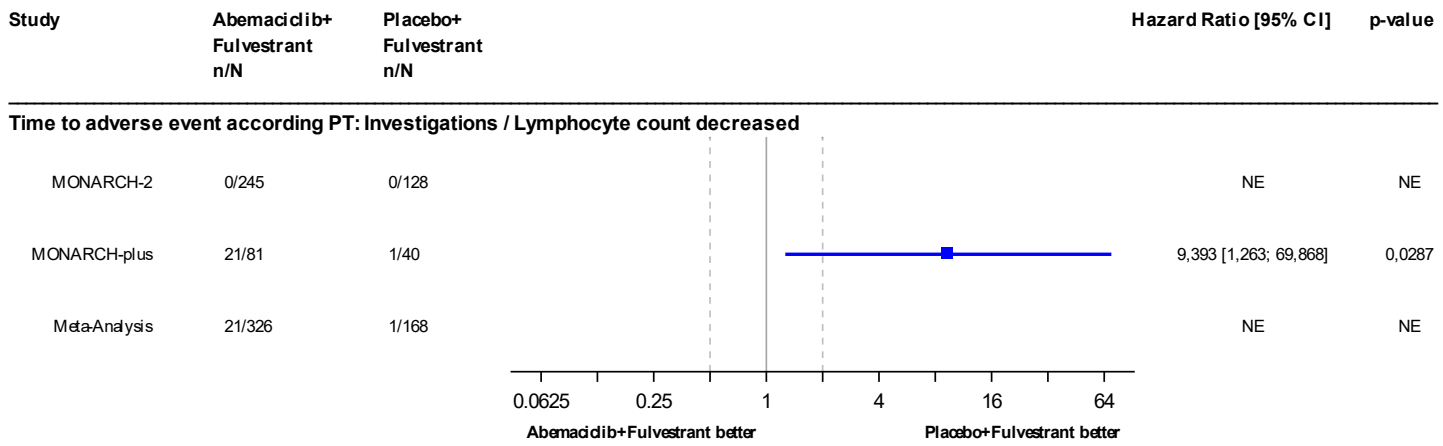
Figure 1158: Metaanalysis results for adverse events according PT[1] -
Investigations / Lymphocyte count decreased
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep058_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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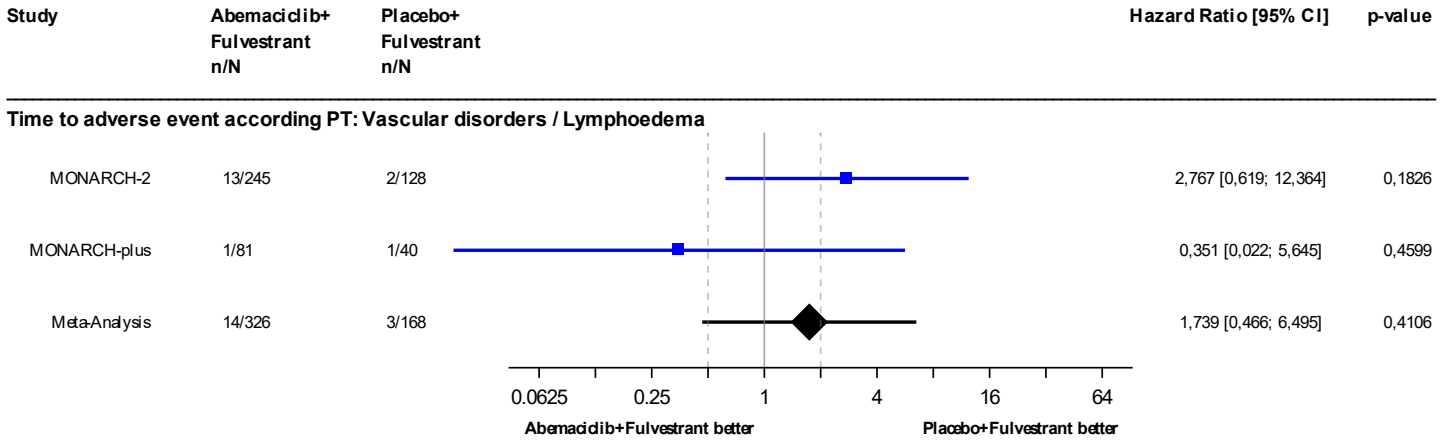
Figure 1159: Metaanalysis results for adverse events according PT[1] -
Vascular disorders / Lymphoedema
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,6456, p-value=0,1996, I2 index=39,2%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep059_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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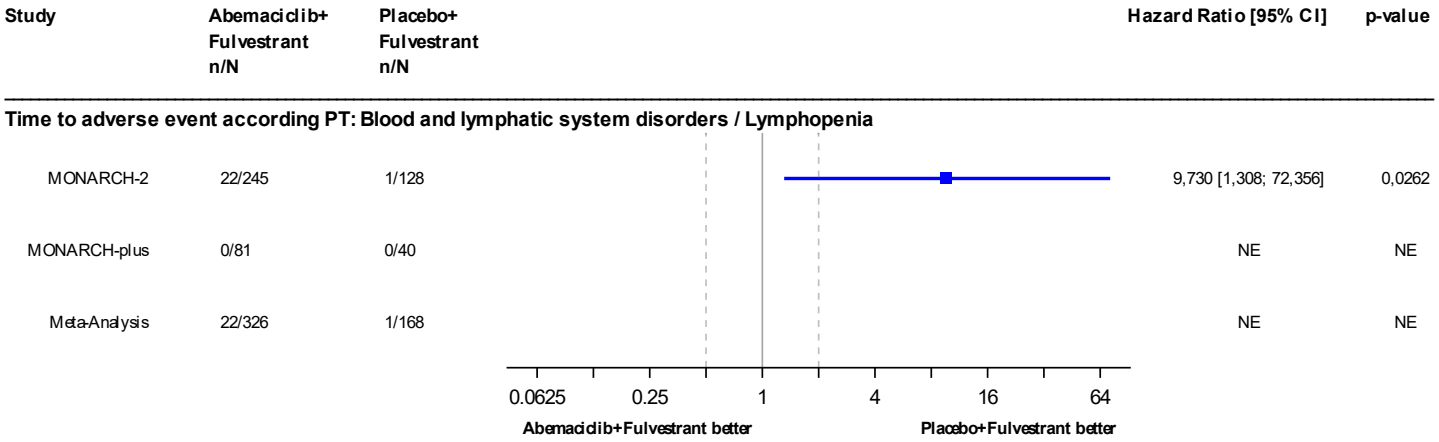
**Figure 1160: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Lymphopenia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep060_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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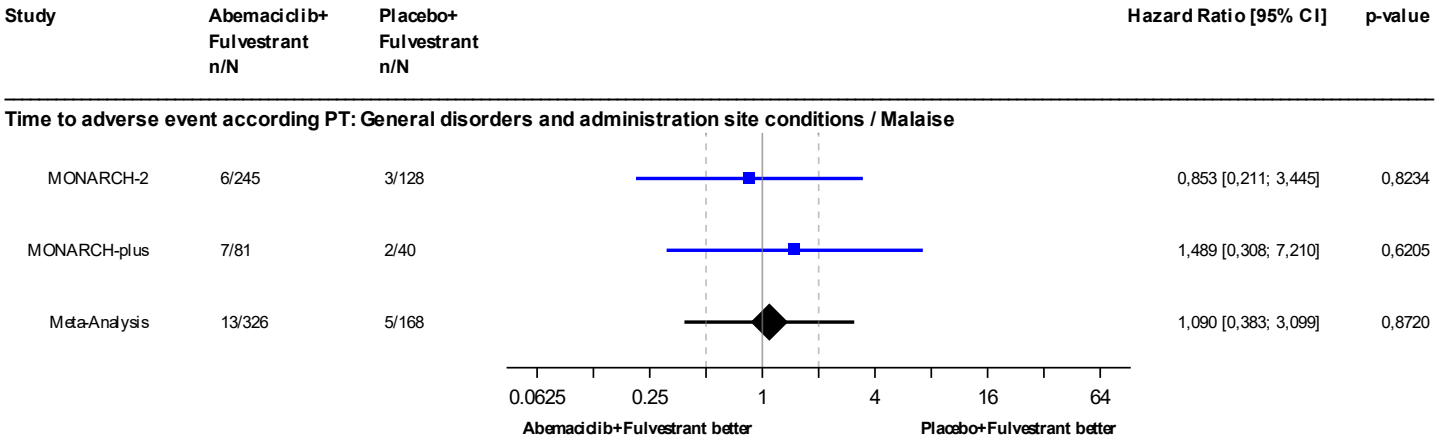
**Figure 1161: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Malaise
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,2690, p-value=0,6040, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep061_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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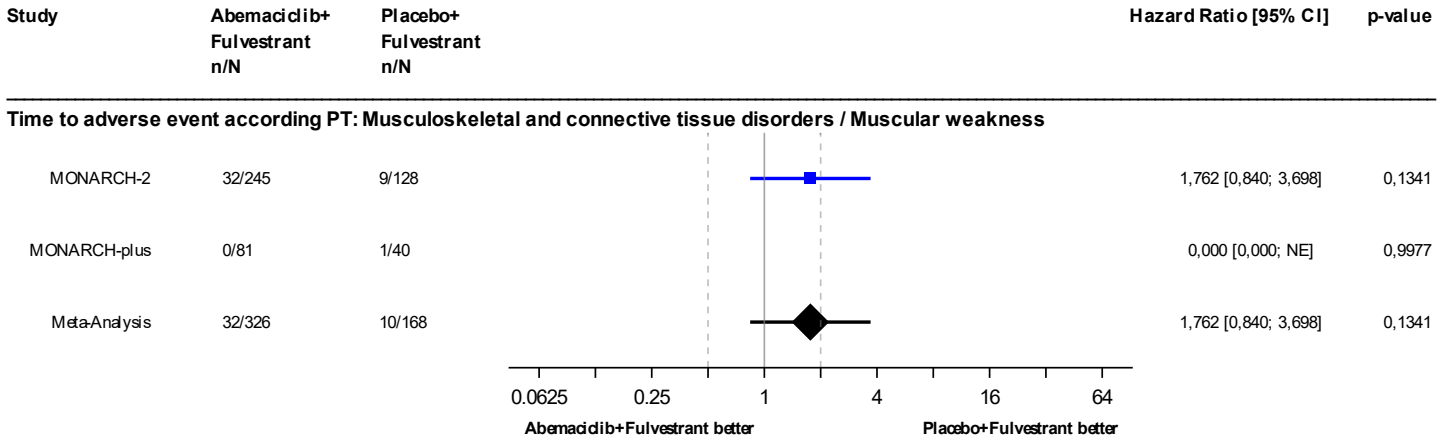
**Figure 1162: Metaanalysis results for adverse events according PT[1] -
Musculoskeletal and connective tissue disorders / Muscular weakness
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9976, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep062_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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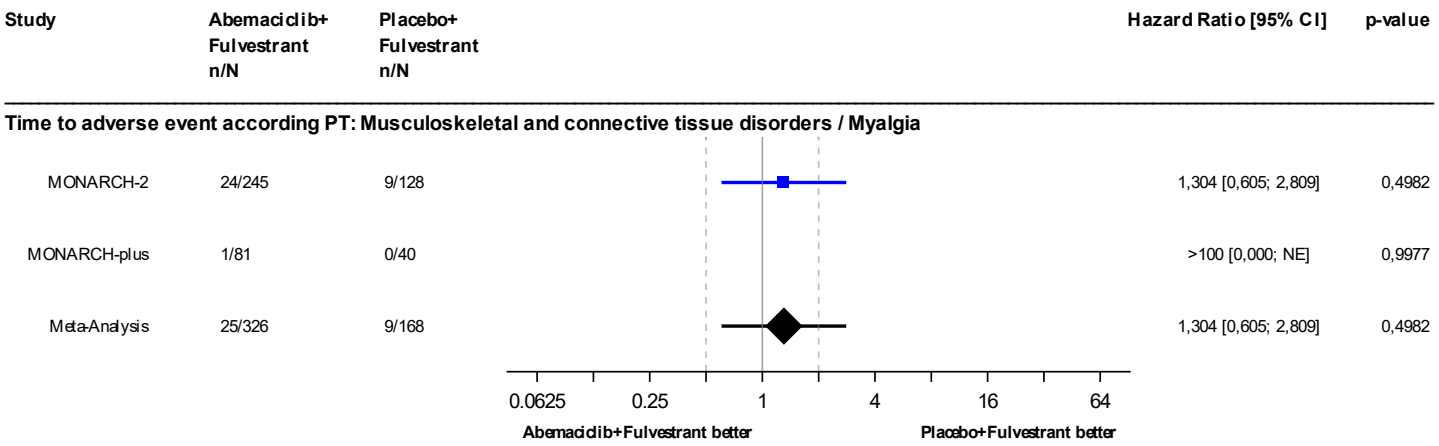
**Figure 1163: Metaanalysis results for adverse events according PT[1] -
Musculoskeletal and connective tissue disorders / Myalgia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9978, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep063_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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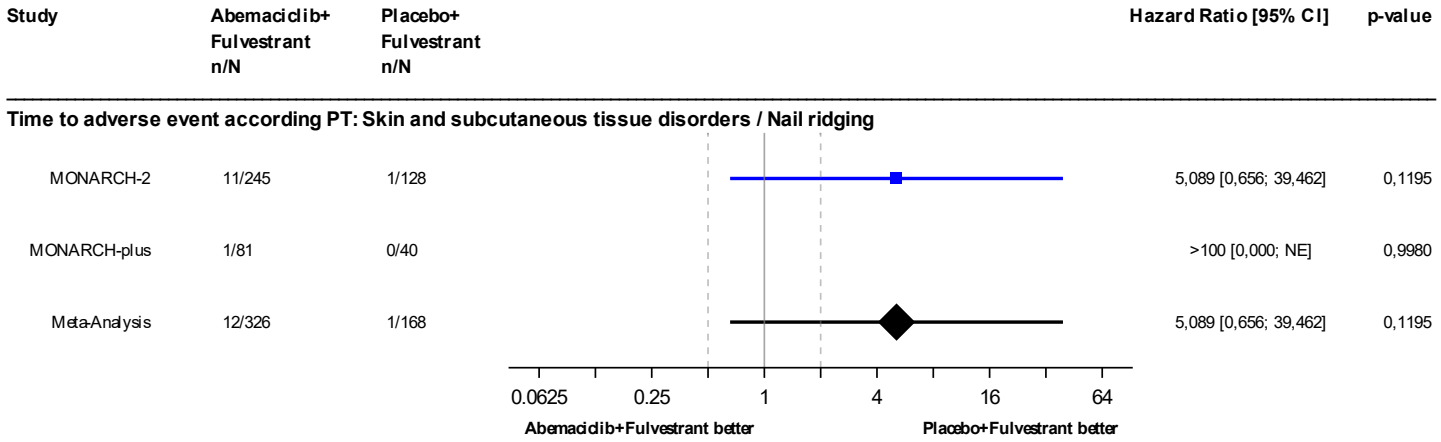
Figure 1164: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Nail ridging
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9982, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep064_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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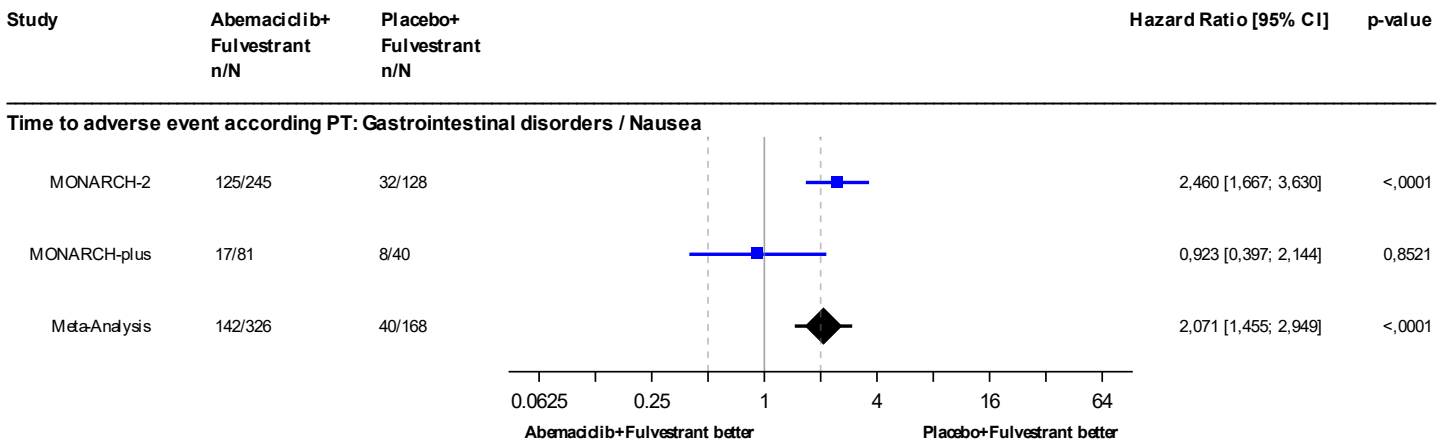
Figure 1165: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=4,2829, p-value=0,0385, I2 index=76,7%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep065_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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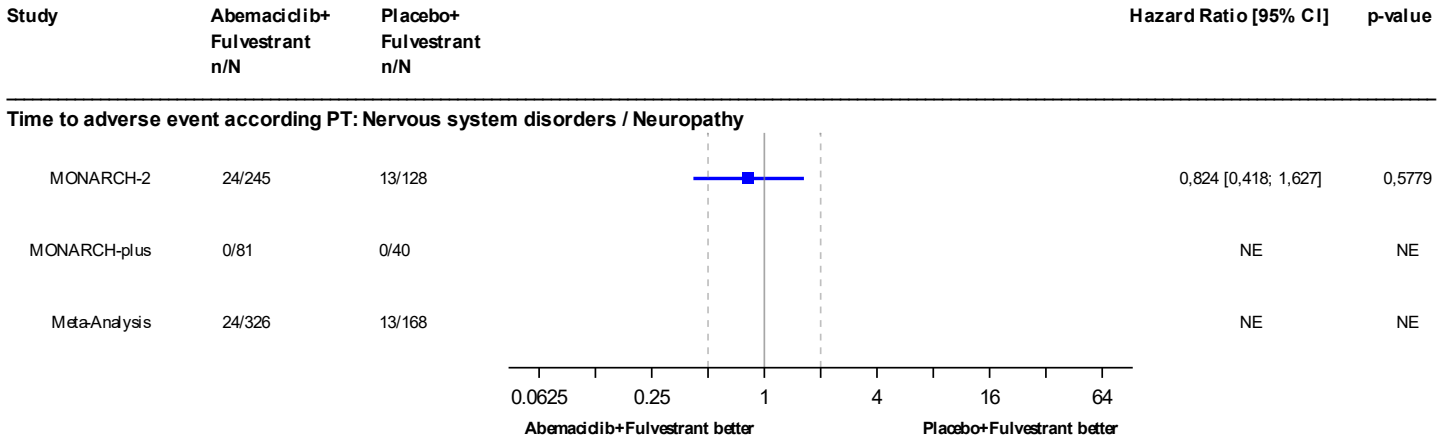
Figure 1166: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Neuropathy
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep066_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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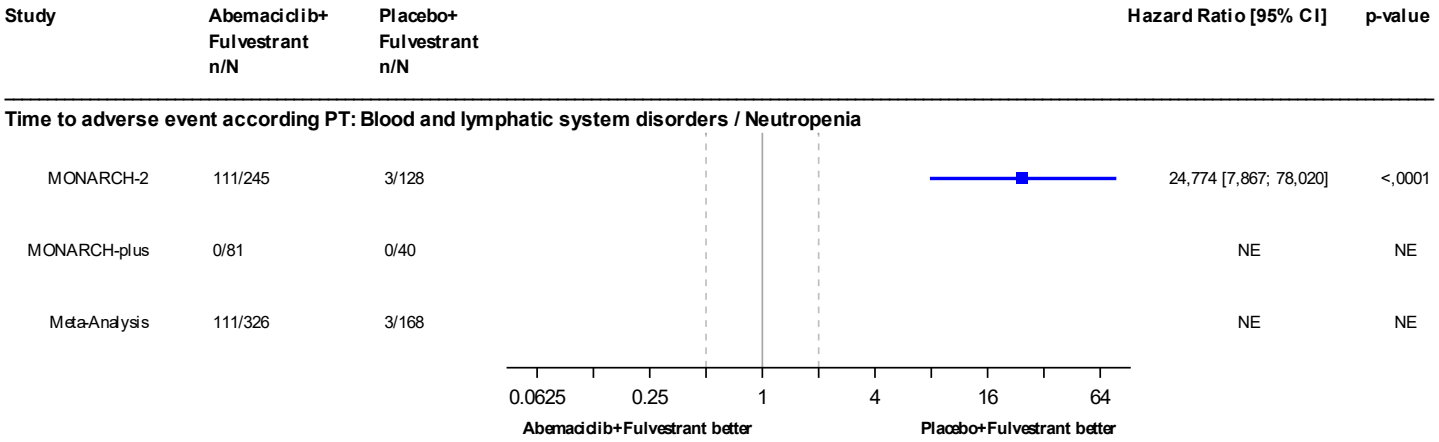
Figure 1167: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Neutropenia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep067_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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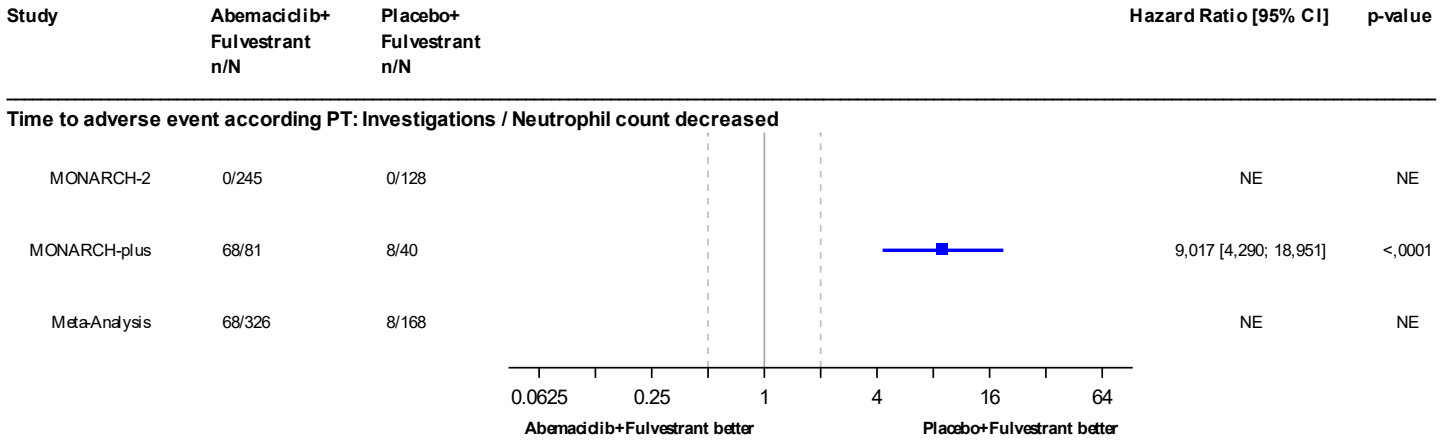
**Figure 1168: Metaanalysis results for adverse events according PT[1] -
Investigations / Neutrophil count decreased
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep068_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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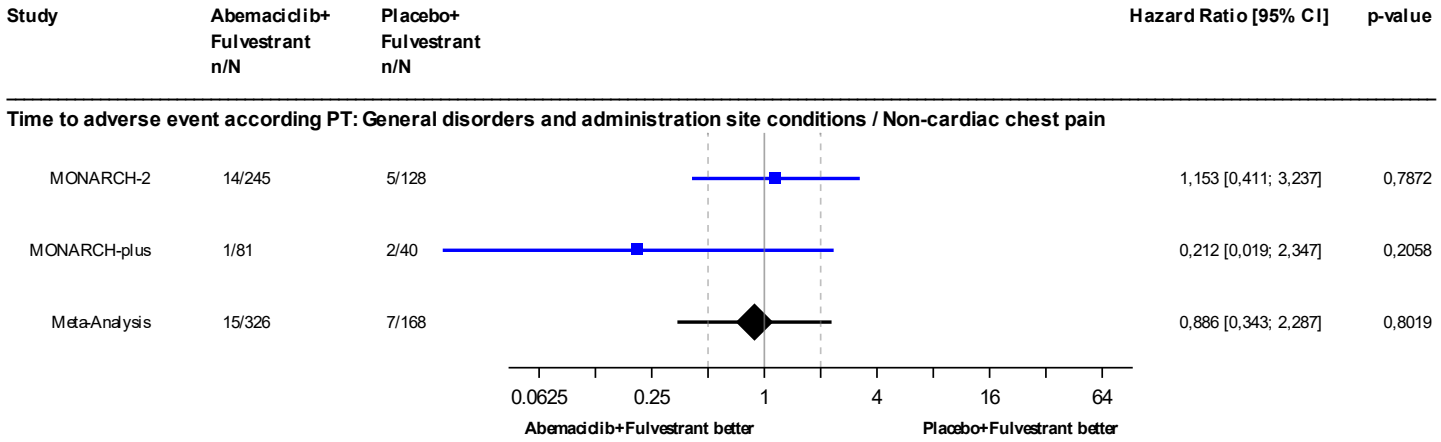
**Figure 1169: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Non-cardiac chest pain
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=1,6103, p-value=0,2044, I2 index=37,9%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep069_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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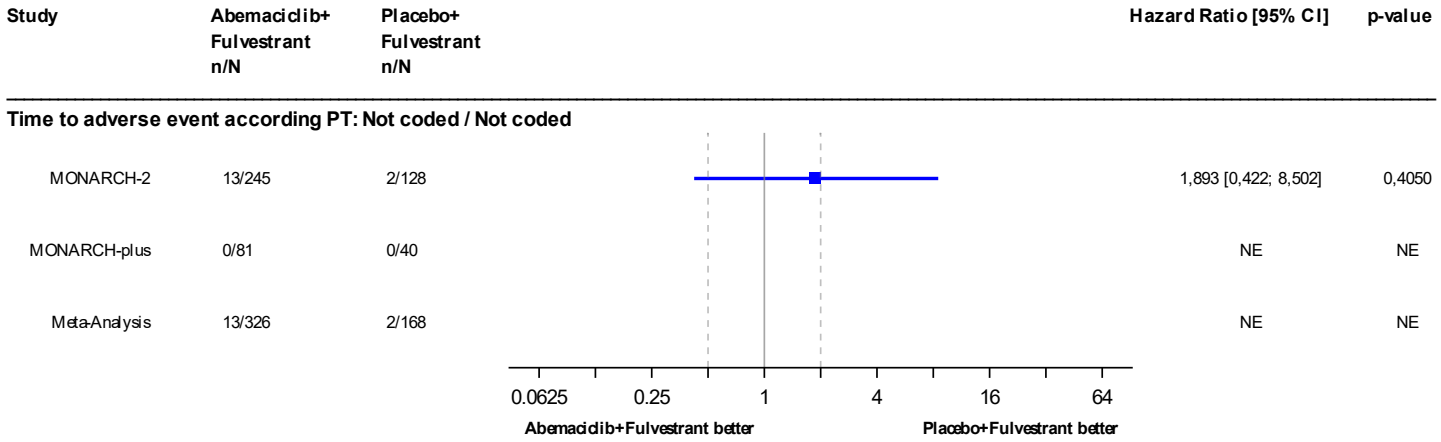
Figure 1170: Metaanalysis results for adverse events according PT[1] -
Not coded / Not coded
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep070_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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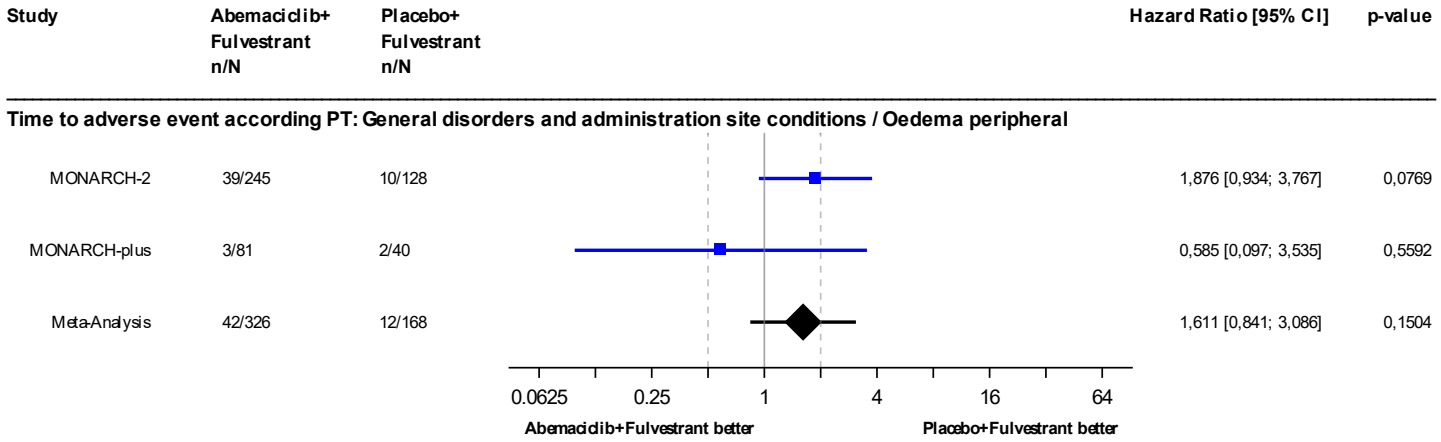
**Figure 1171: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Oedema peripheral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=1,4014, p-value=0,2365, I2 index=28,6%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep071_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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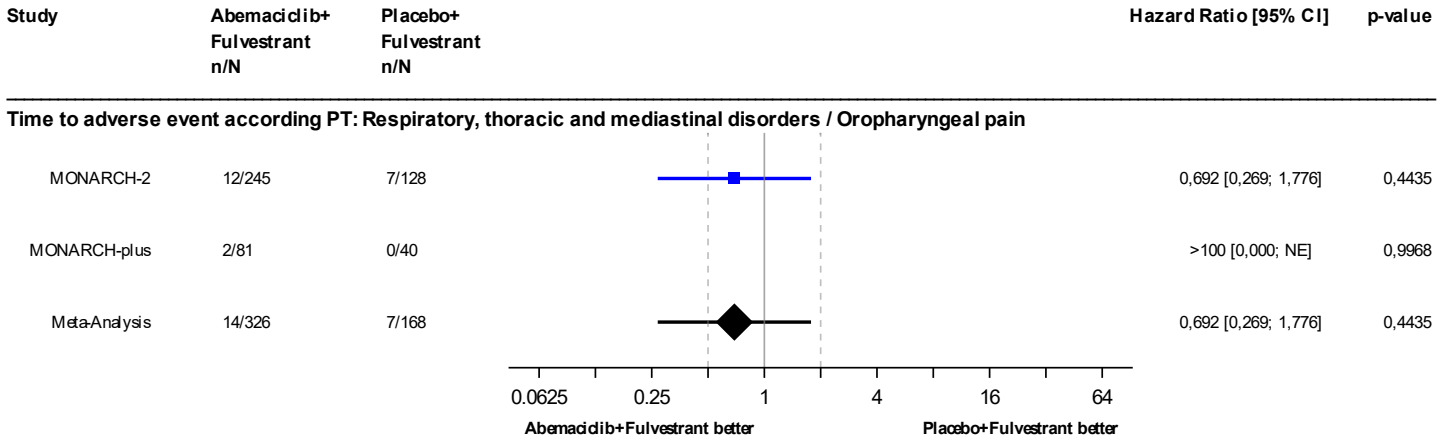
**Figure 1172: Metaanalysis results for adverse events according PT[1] -
Respiratory, thoracic and mediastinal disorders / Oropharyngeal pain
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9967, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep072_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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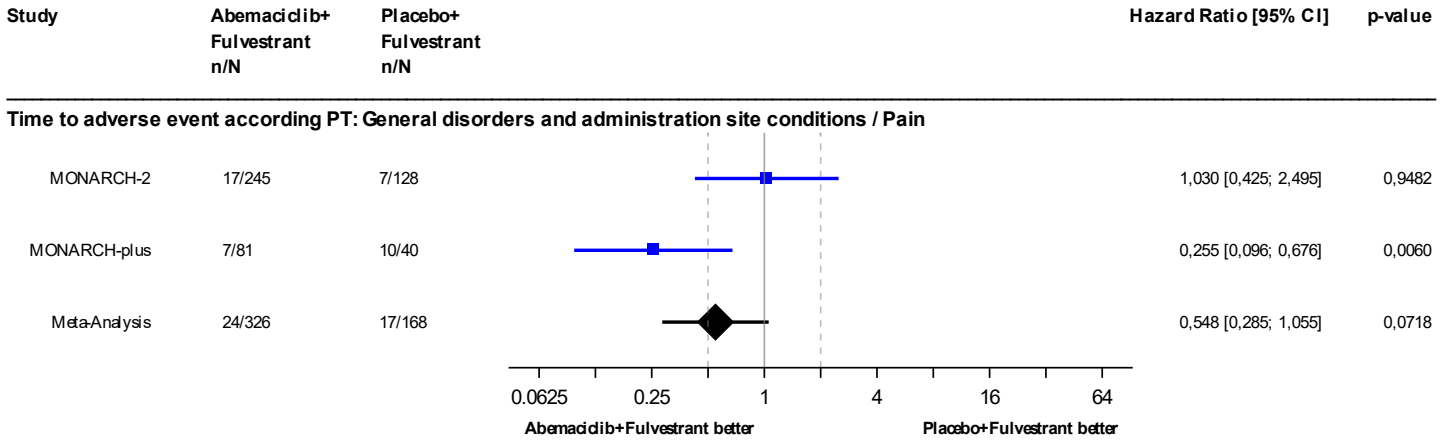
**Figure 1173: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Pain
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=4,3203, p-value=0,0377, I2 index=76,9%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep073_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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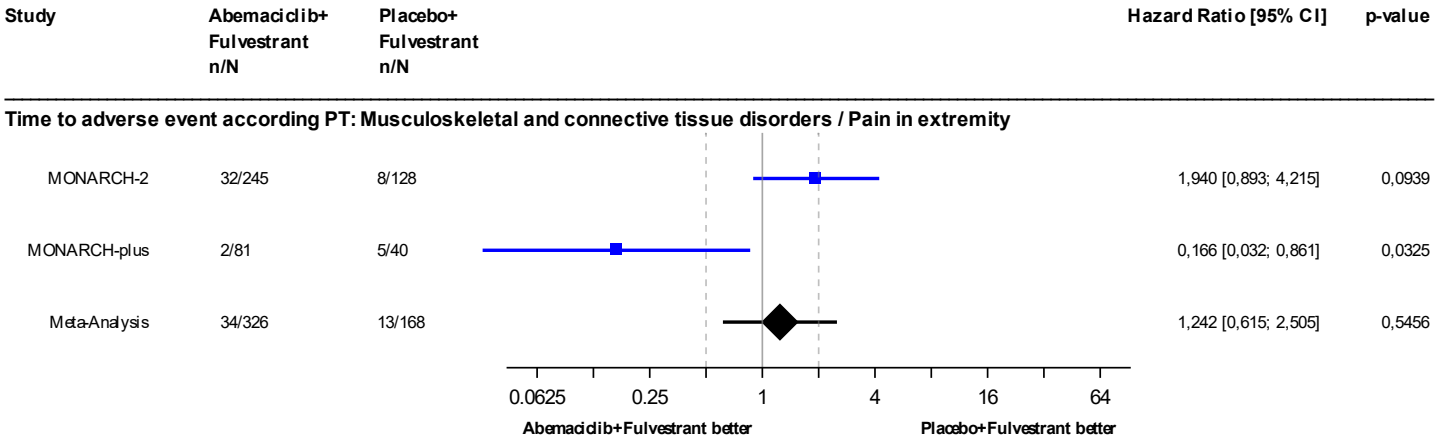
**Figure 1174: Metaanalysis results for adverse events according PT[1] -
Musculoskeletal and connective tissue disorders / Pain in extremity
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=7,0113, p-value=0,0081, I2 index=85,7%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep074_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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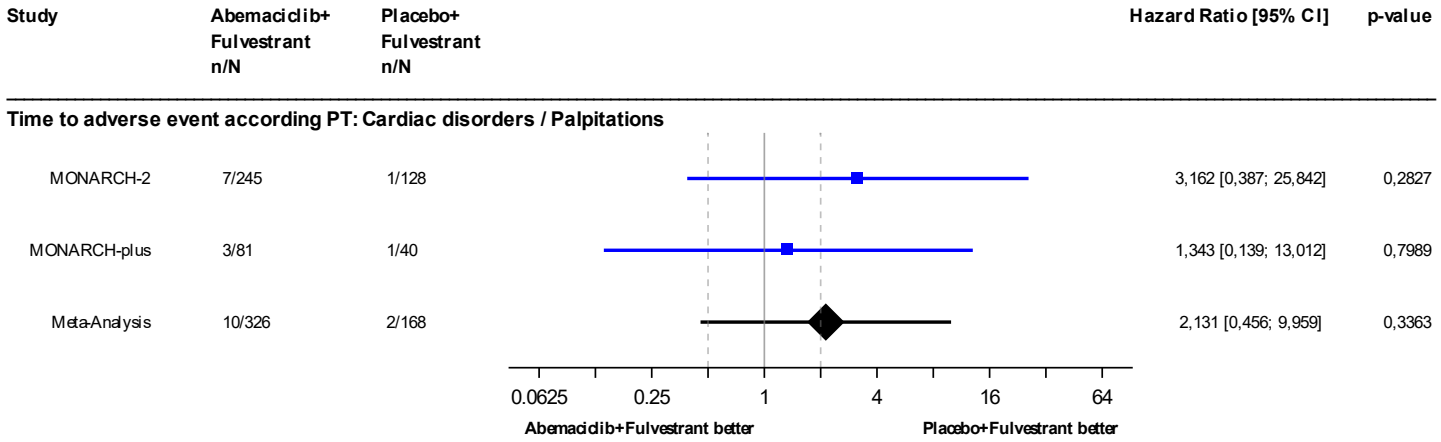
Figure 1175: Metaanalysis results for adverse events according PT[1] -
Cardiac disorders / Palpitations
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2943, p-value=0,5875, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep075_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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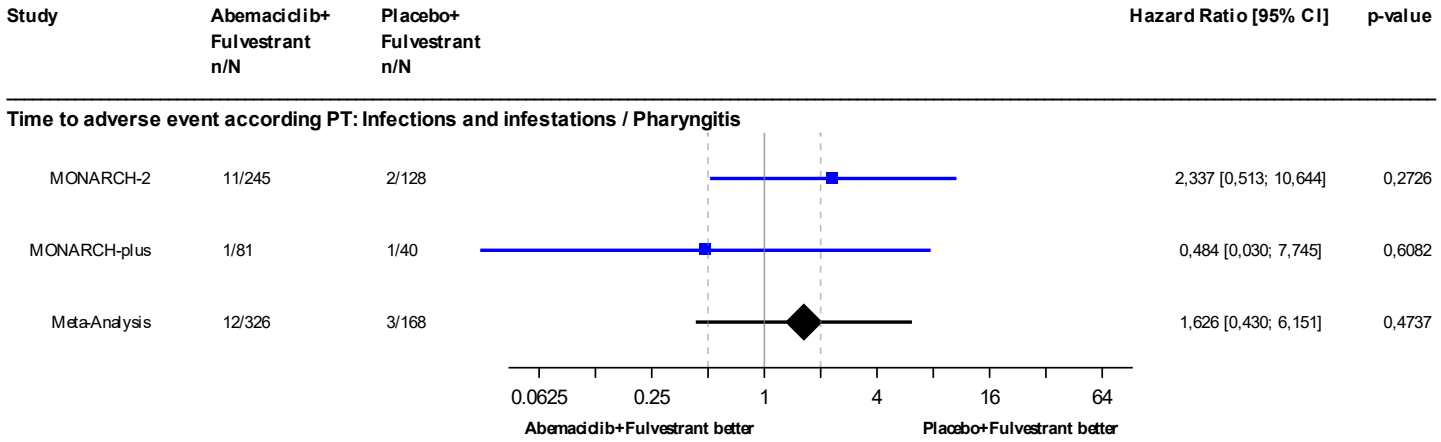
Figure 1176: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Pharyngitis
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,9529, p-value=0,3290, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep076_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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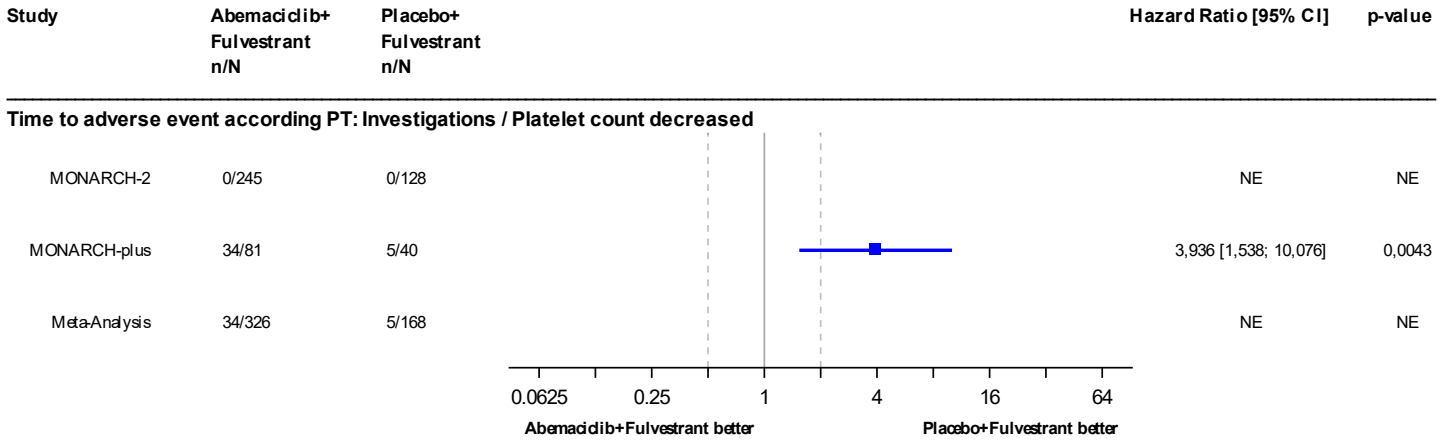
Figure 1177: Metaanalysis results for adverse events according PT[1] -
Investigations / Platelet count decreased
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep077_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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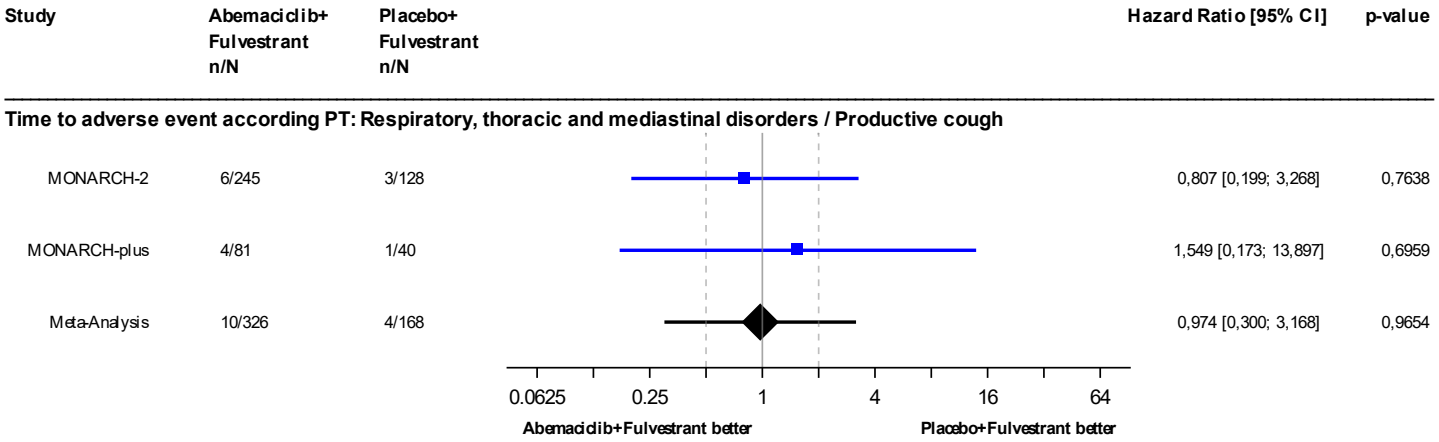
Figure 1178: Metaanalysis results for adverse events according PT[1] - Respiratory, thoracic and mediastinal disorders / Productive cough Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2412, p-value=0,6233, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep078_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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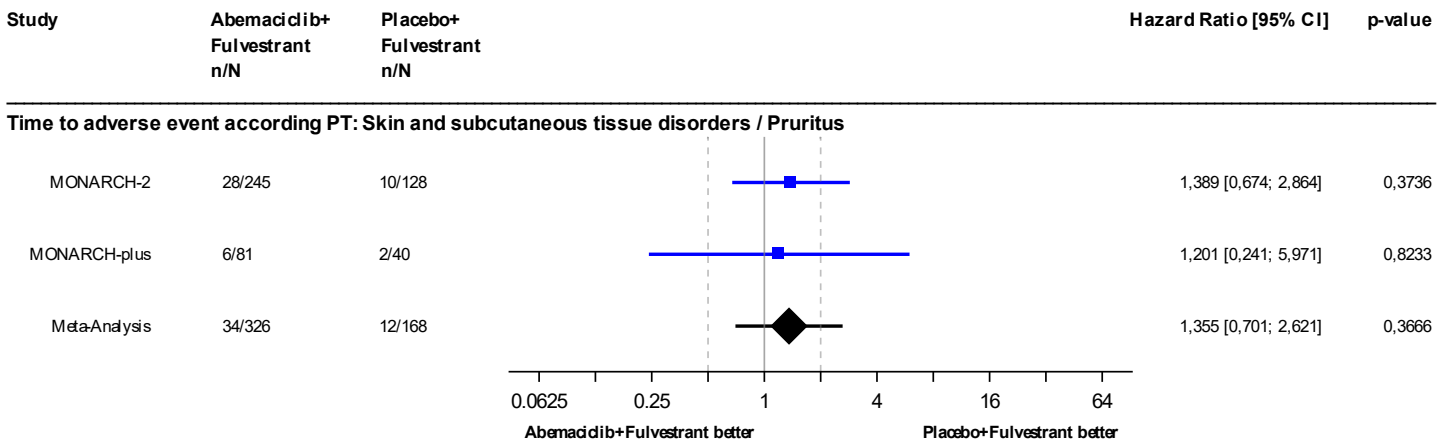
**Figure 1179: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Pruritus
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0263, p-value=0,8711, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep079_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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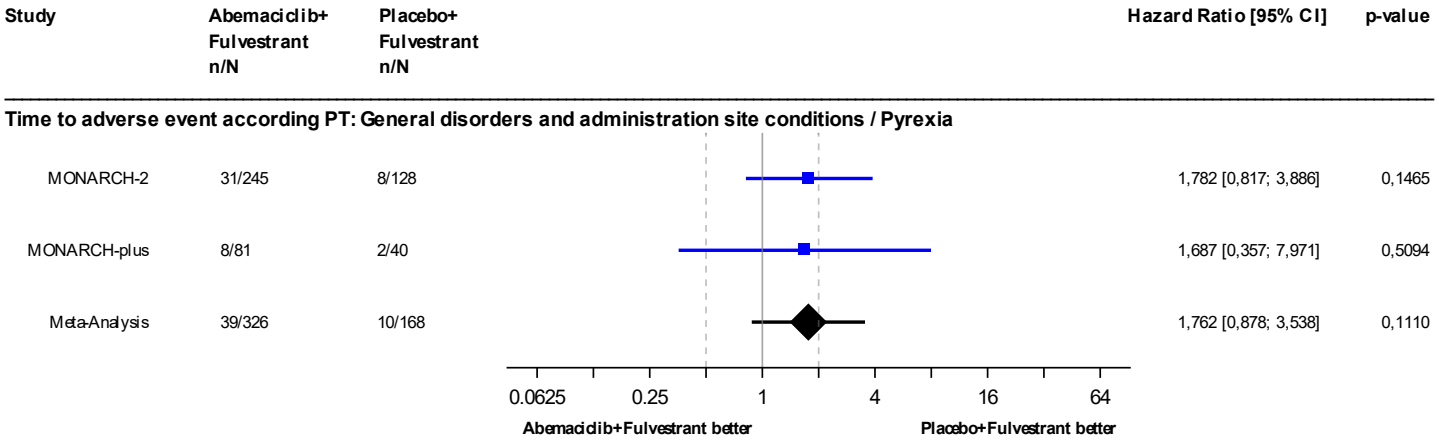
**Figure 1180: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Pyrexia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0038, p-value=0,9506, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep080_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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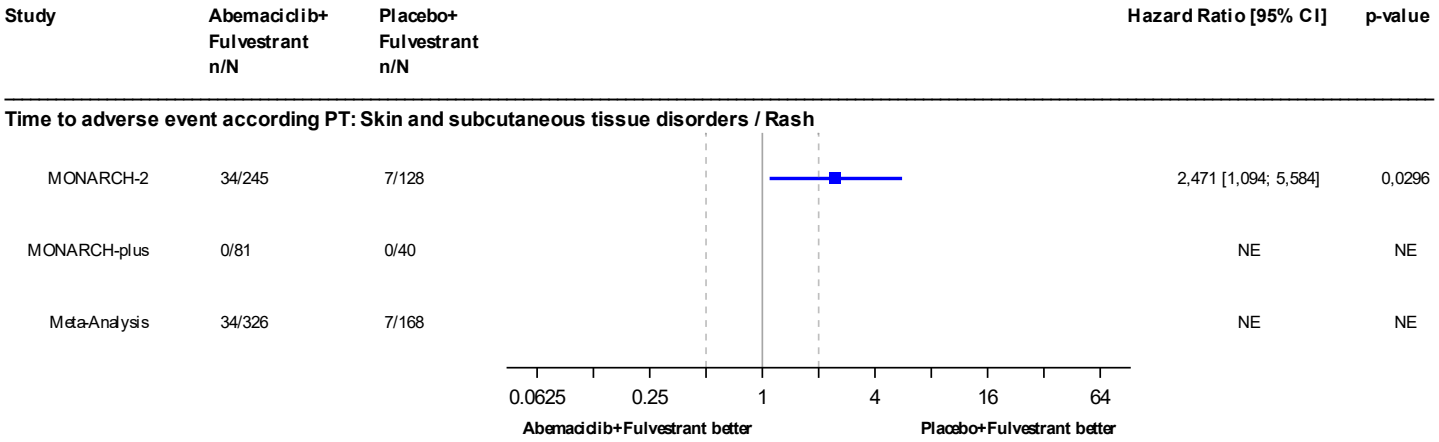
Figure 1181: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Rash
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep081_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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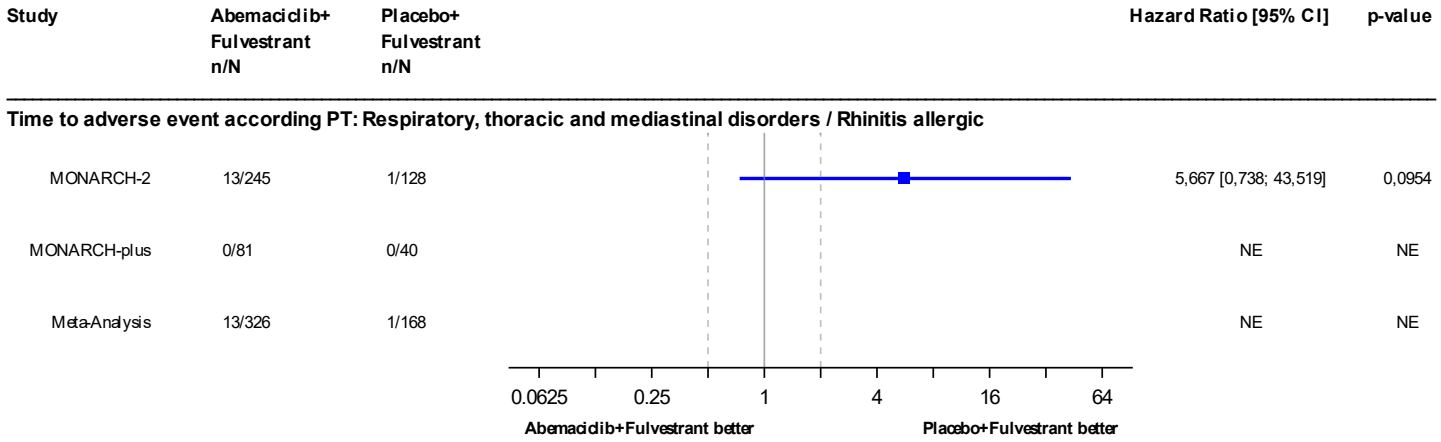
**Figure 1182: Metaanalysis results for adverse events according PT[1] -
Respiratory, thoracic and mediastinal disorders / Rhinitis allergic
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep082_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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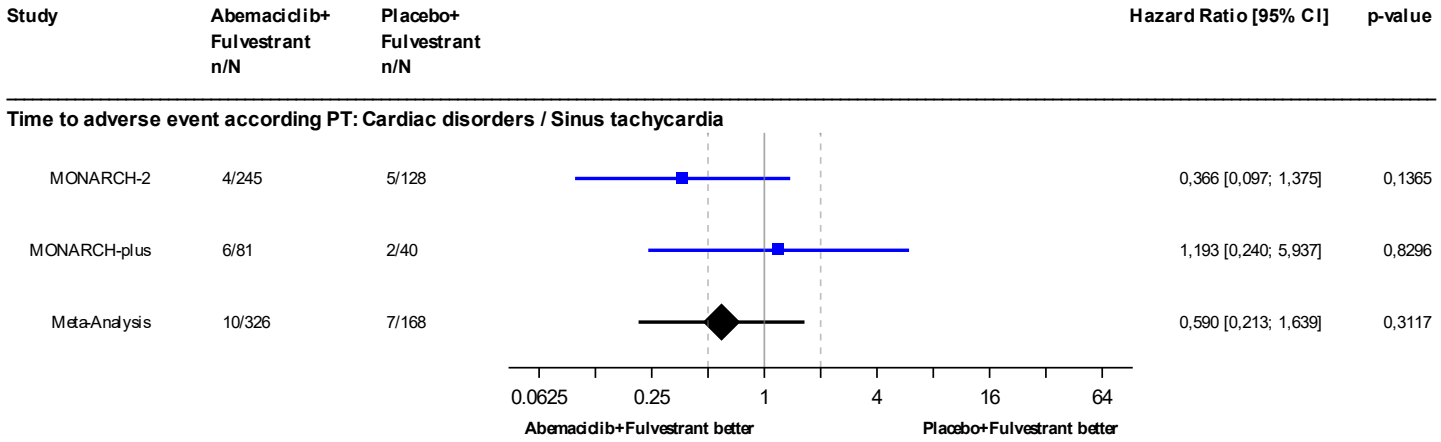
Figure 1183: Metaanalysis results for adverse events according PT[1] -
Cardiac disorders / Sinus tachycardia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,2401, p-value=0,2654, I2 index=19,4%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep083_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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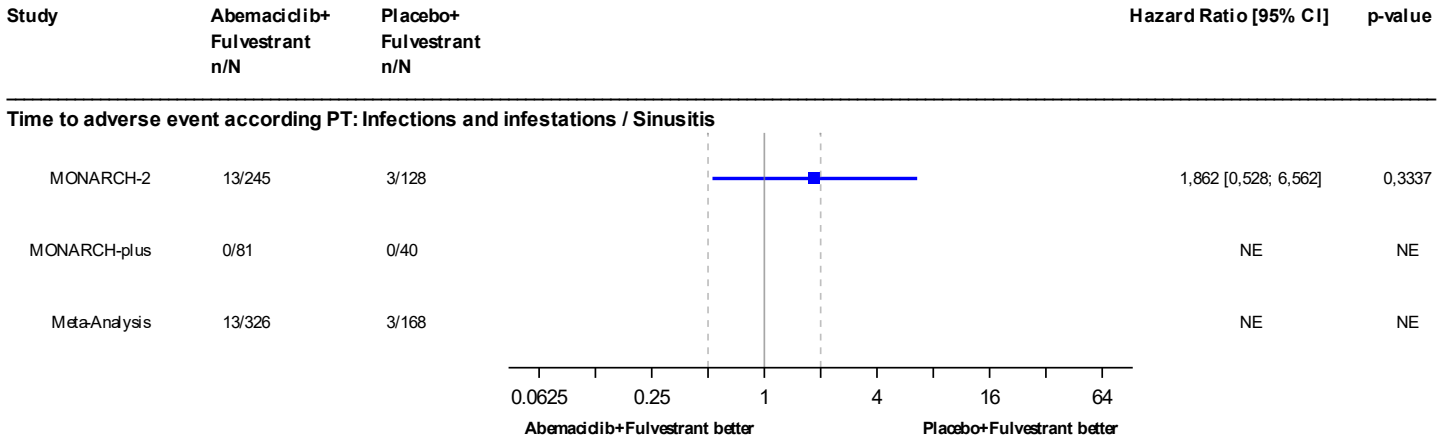
Figure 1184: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Sinusitis
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep084_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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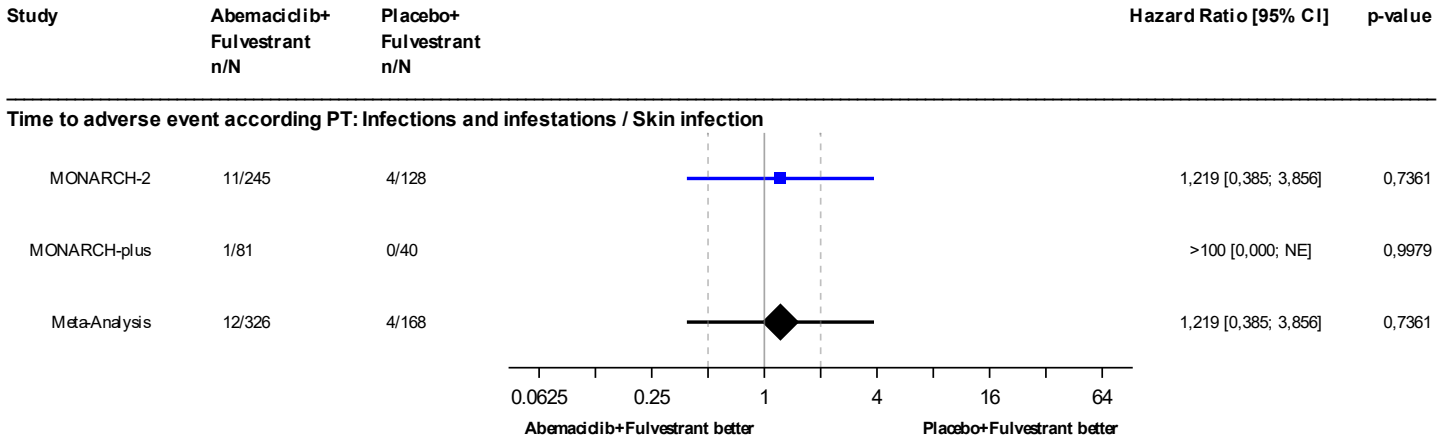
Figure 1185: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Skin infection
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9979, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep085_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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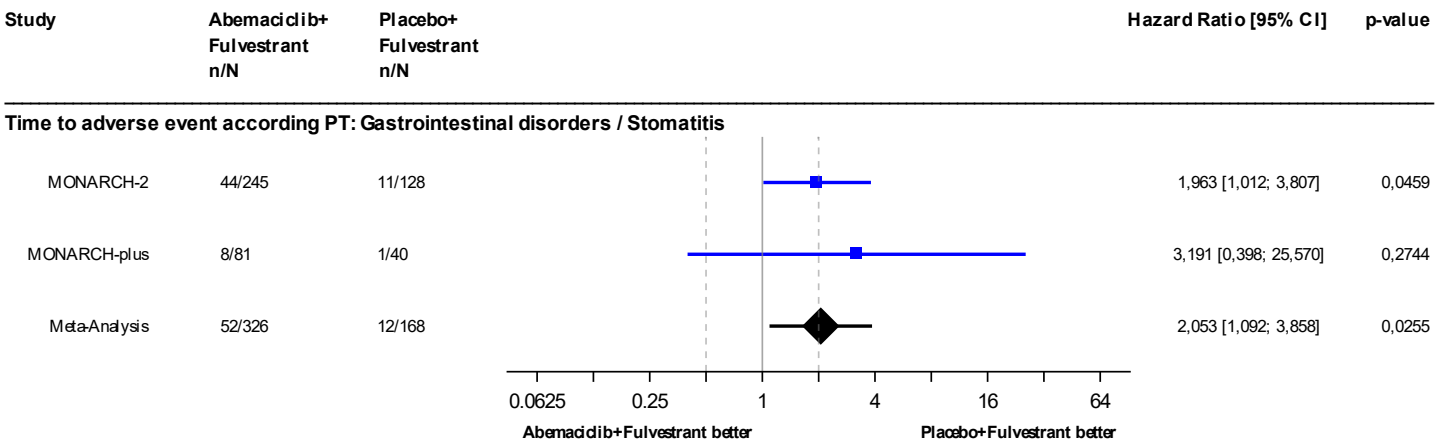
Figure 1186: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1902, p-value=0,6627, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep086_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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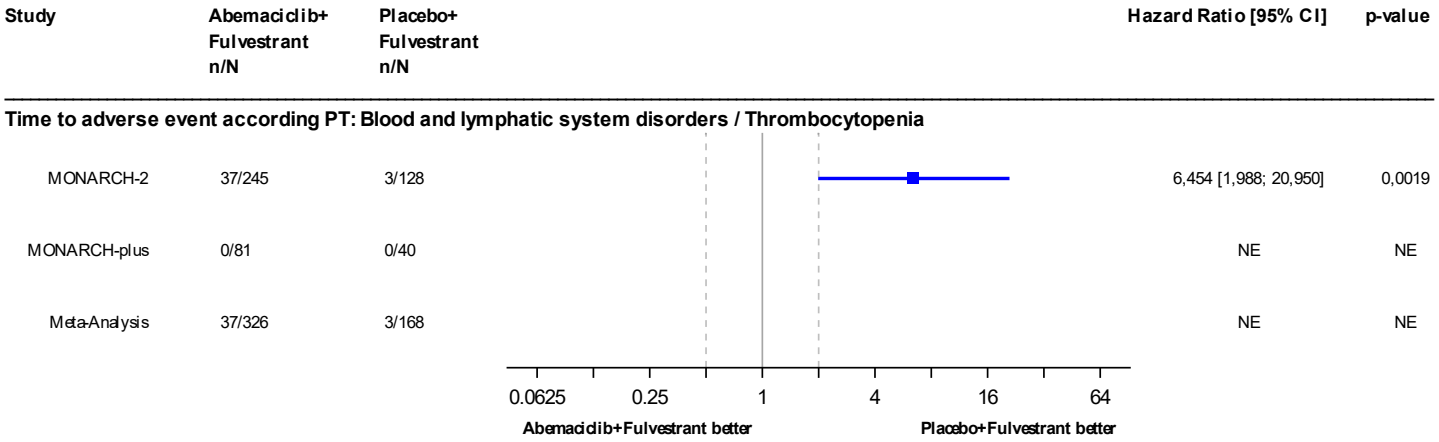
**Figure 1187: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Thrombocytopenia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep087_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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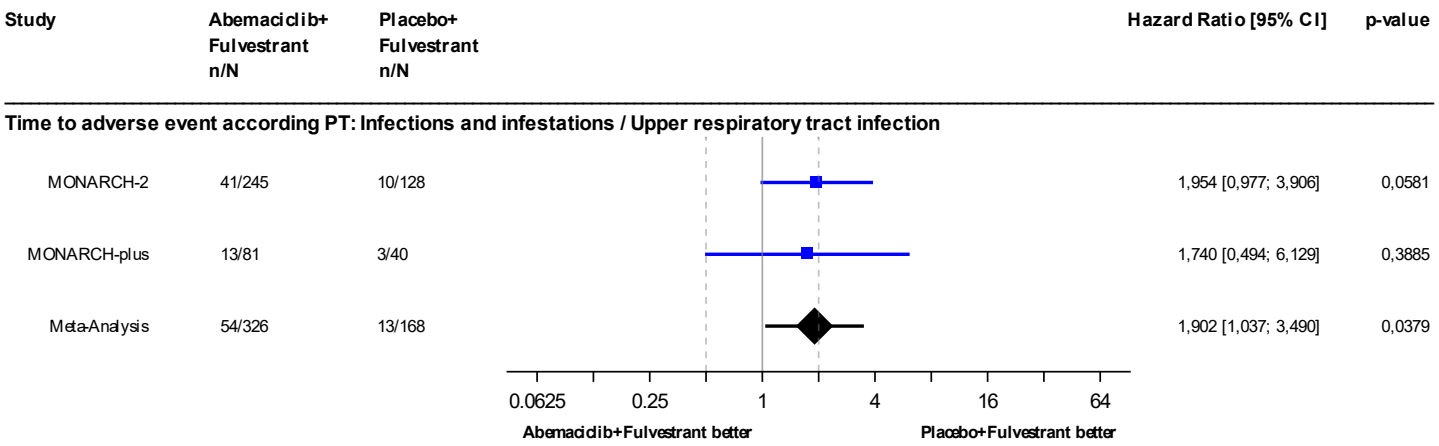
Figure 1188: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0250, p-value=0,8745, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep088_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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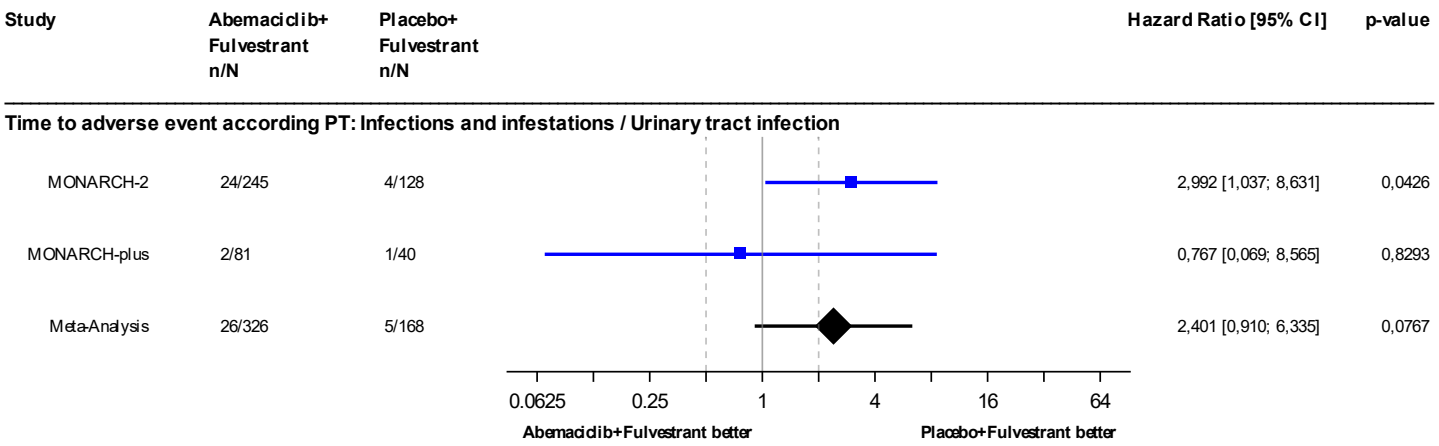
Figure 1189: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Urinary tract infection
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,0252, p-value=0,3113, I2 index=2,5%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep089_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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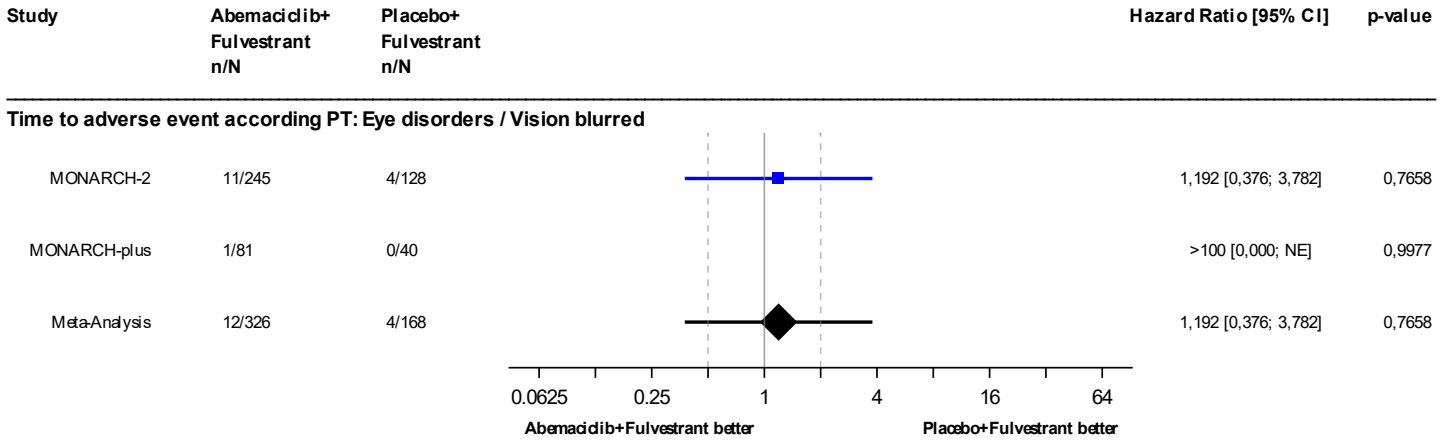
Figure 1190: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Vision blurred
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9978, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep090_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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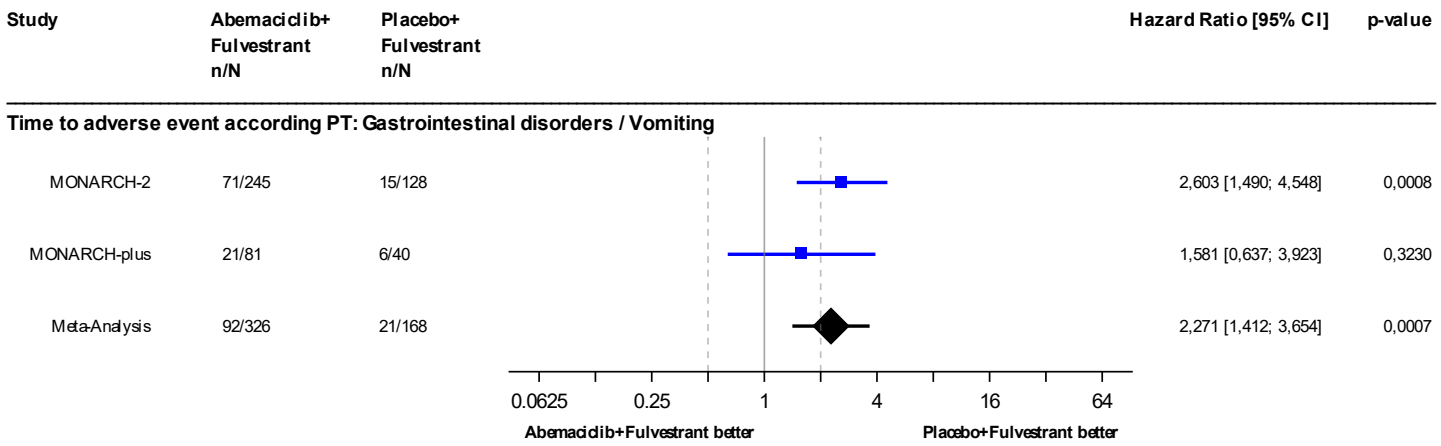
Figure 1191: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,8402, p-value=0,3594, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep091_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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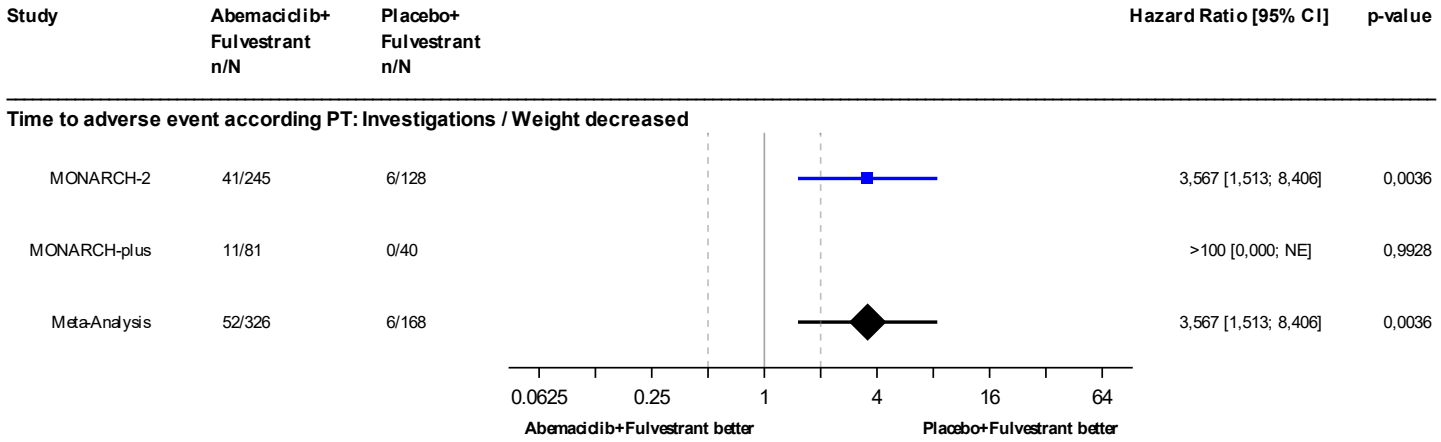
Figure 1192: Metaanalysis results for adverse events according PT[1] -
Investigations / Weight decreased
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9933, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep092_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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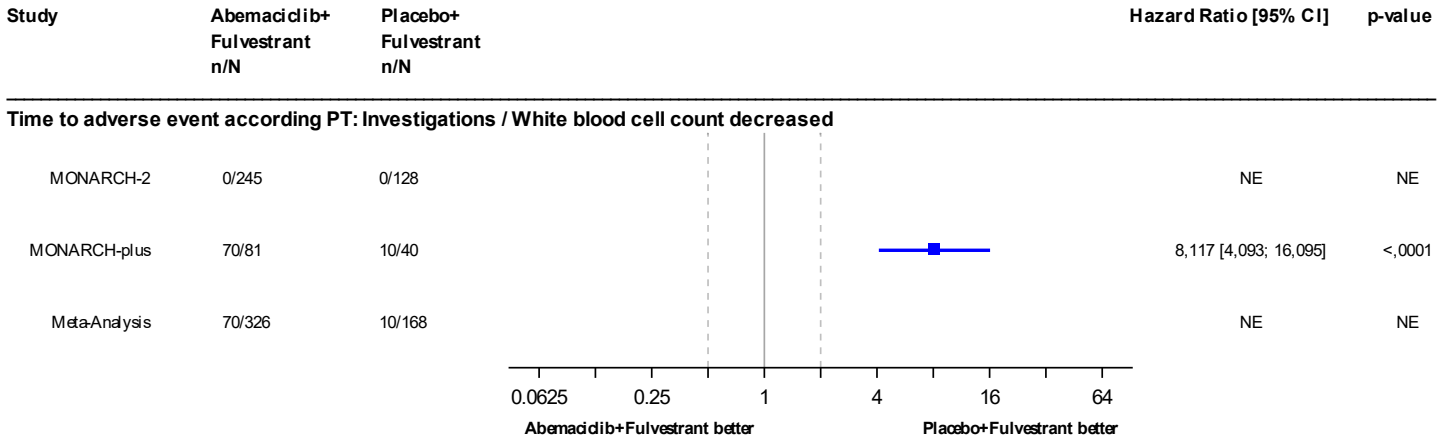
Figure 1193: Metaanalysis results for adverse events according PT[1] -
Investigations / White blood cell count decreased
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep093_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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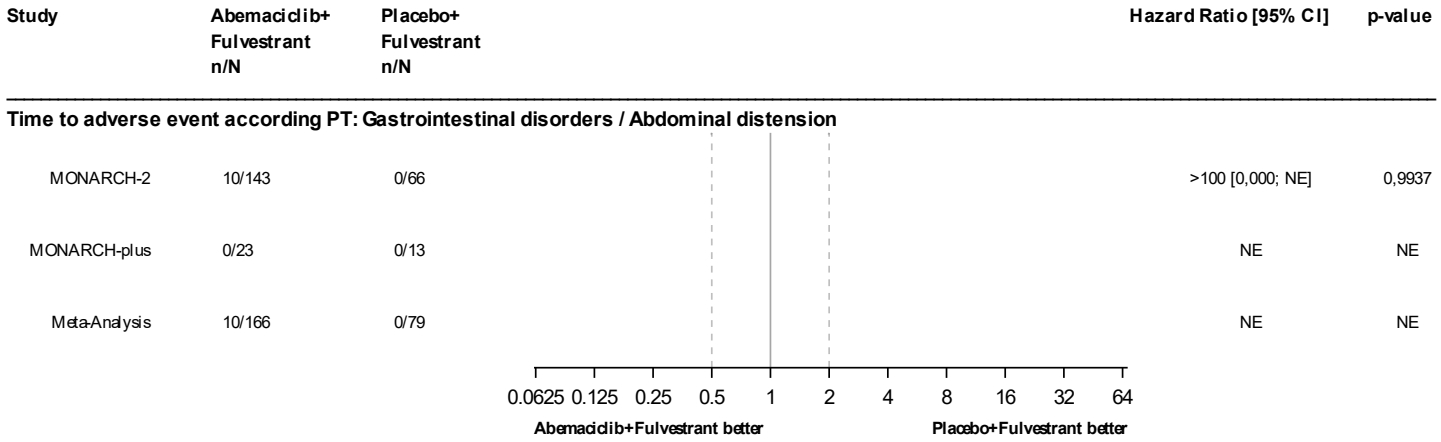
Figure 1194: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal distension
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep001_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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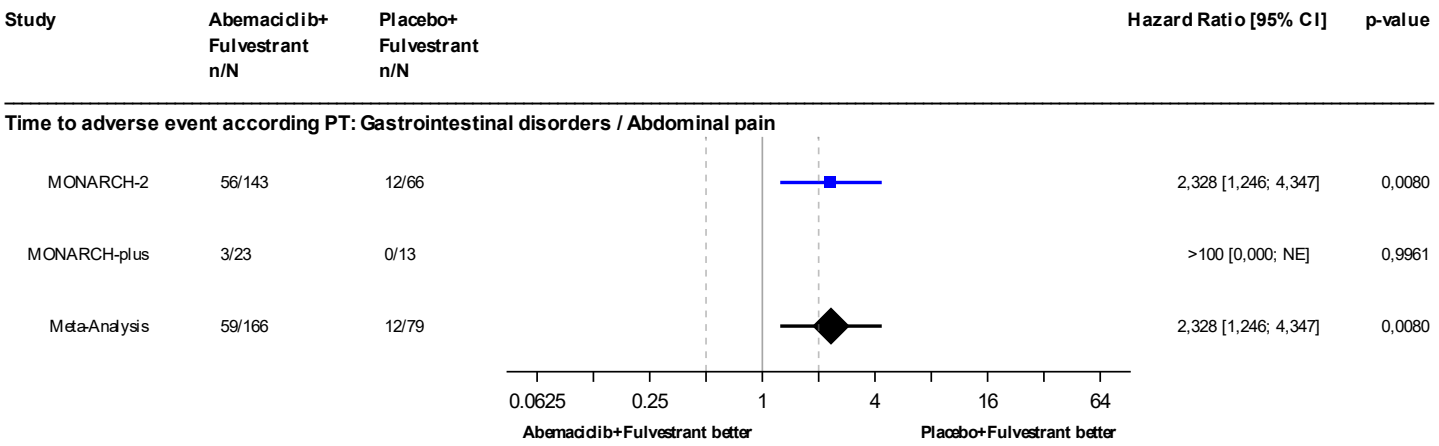
Figure 1195: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9963, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep002_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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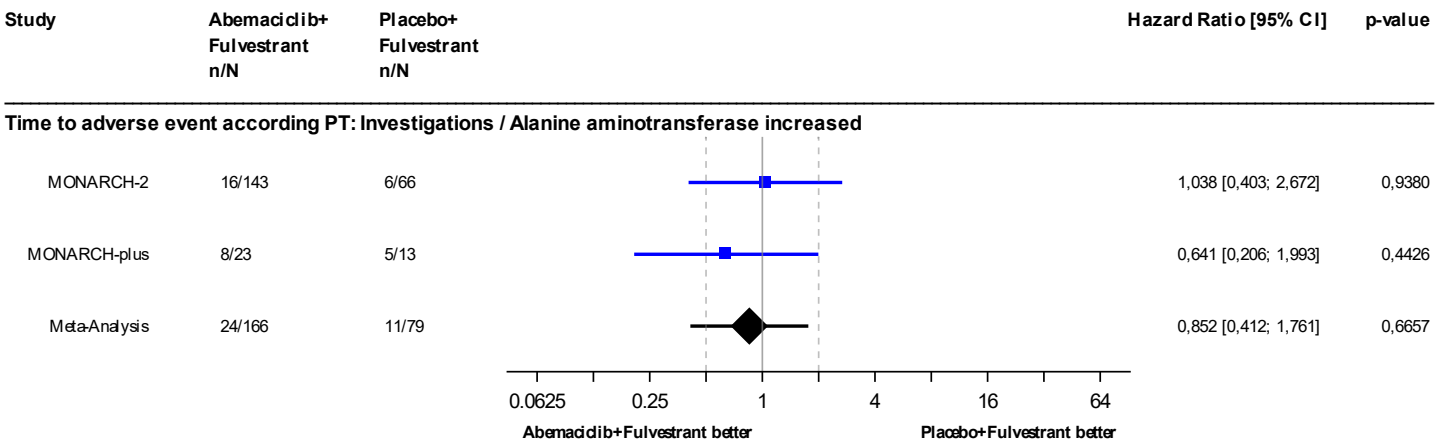
Figure 1196: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4088, p-value=0,5226, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep003_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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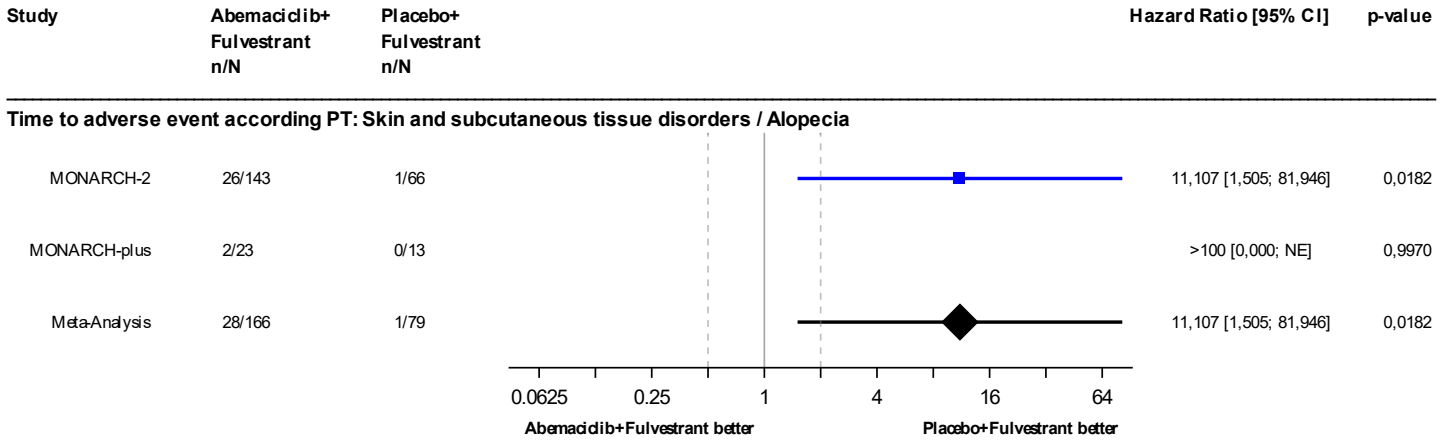
Figure 1197: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9975, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep004_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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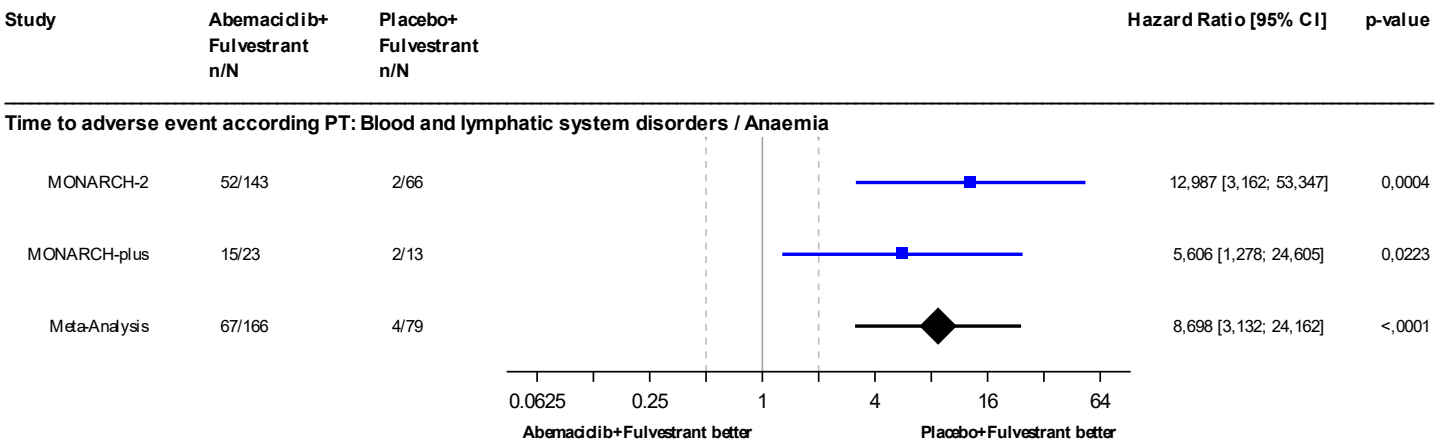
Figure 1198: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6480, p-value=0,4208, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep005_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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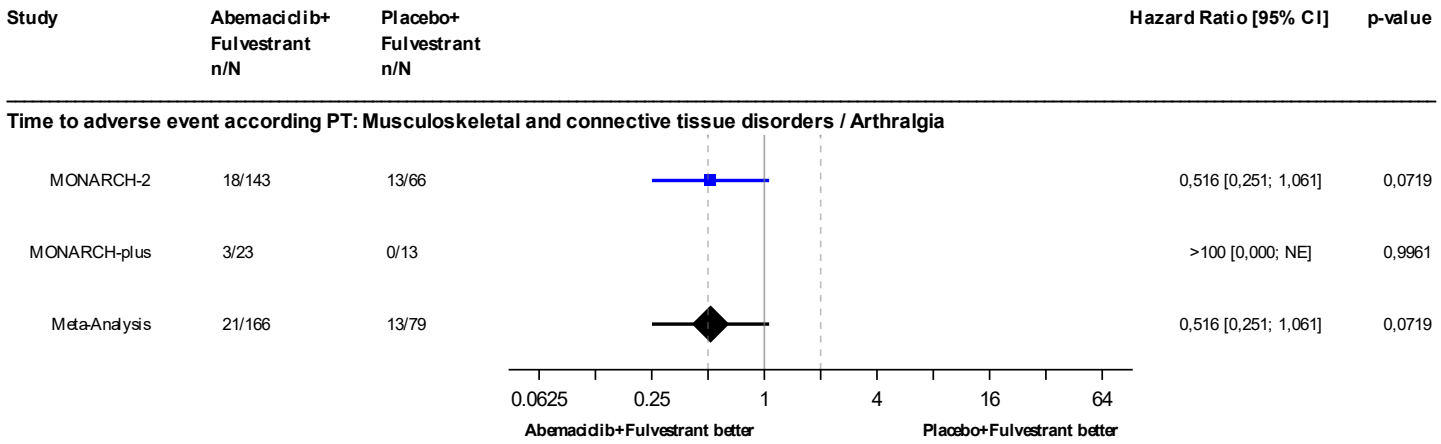
Figure 1199: Metaanalysis results for adverse events according PT[1] -
Musculoskeletal and connective tissue disorders / Arthralgia
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9959, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep006_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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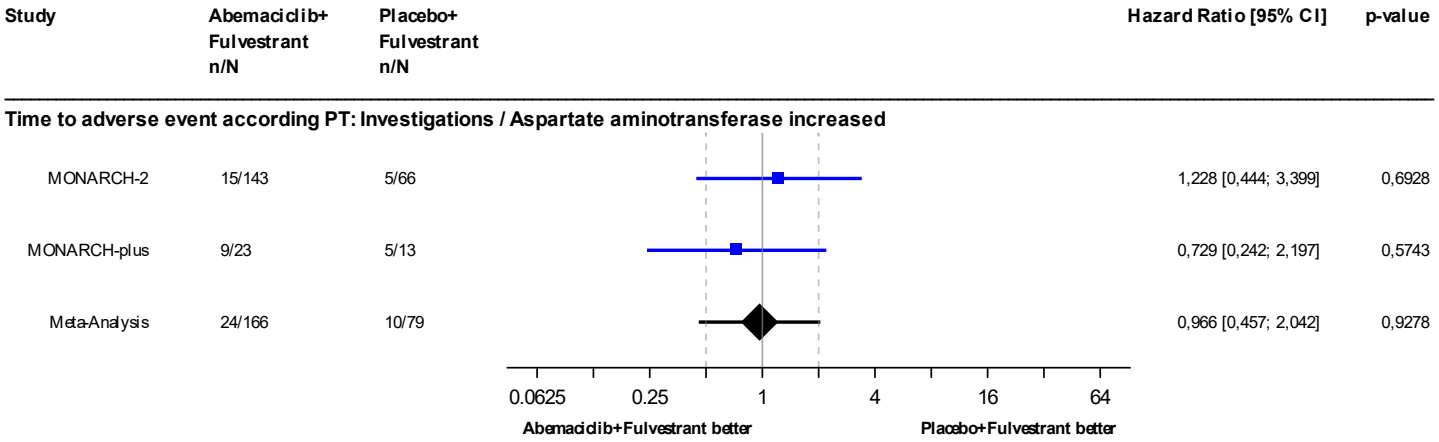
**Figure 1200: Metaanalysis results for adverse events according PT[1] -
Investigations / Aspartate aminotransferase increased
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,4635, p-value=0,4960, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep007_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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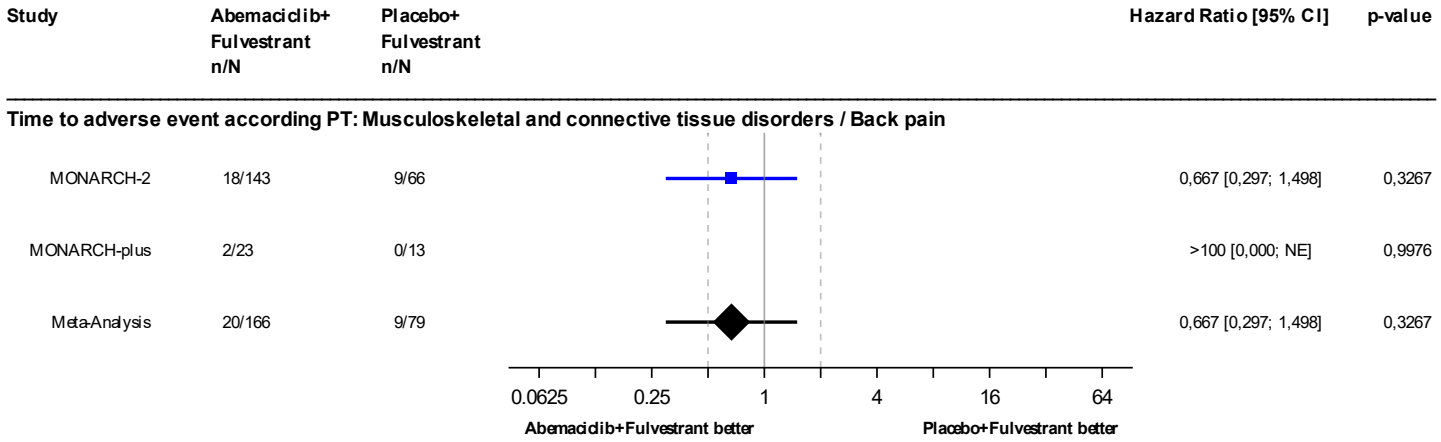
**Figure 1201: Metaanalysis results for adverse events according PT[1] -
Musculoskeletal and connective tissue disorders / Back pain
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9976, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep008_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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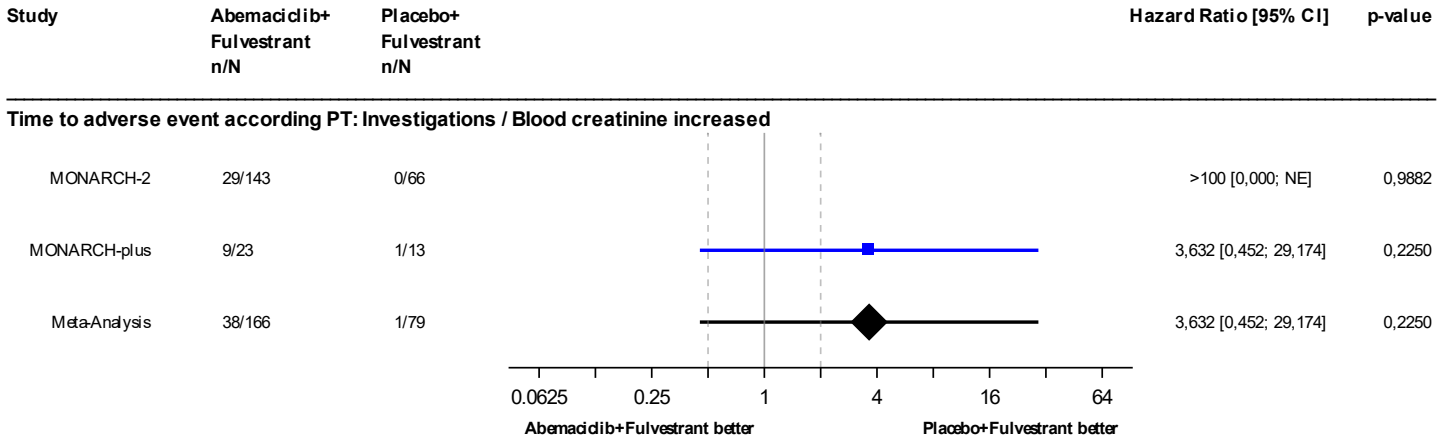
Figure 1202: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0002, p-value=0,9891, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep009_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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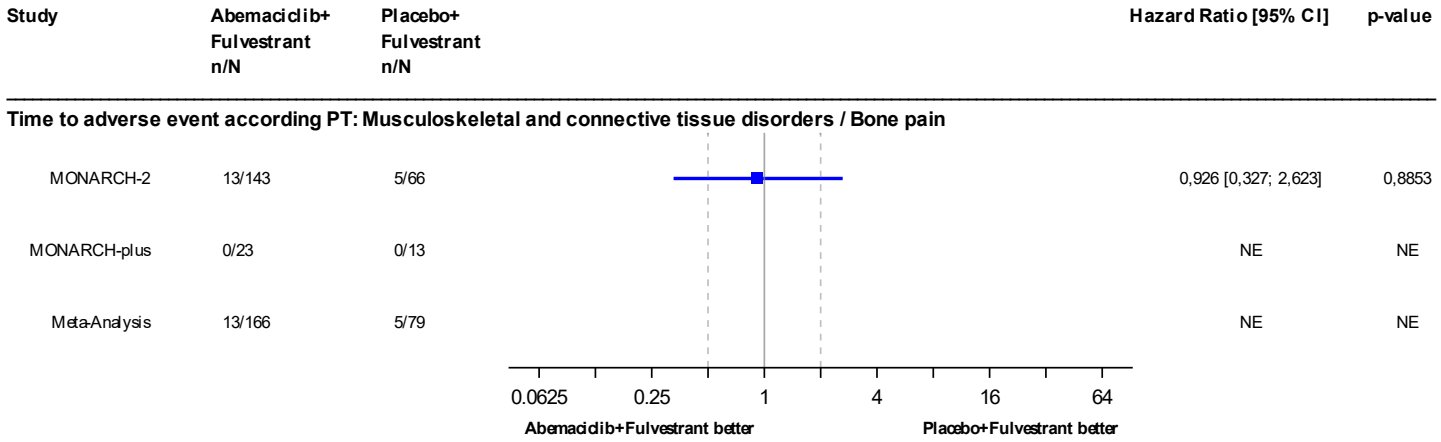
**Figure 1203: Metaanalysis results for adverse events according PT[1] -
Musculoskeletal and connective tissue disorders / Bone pain
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep010_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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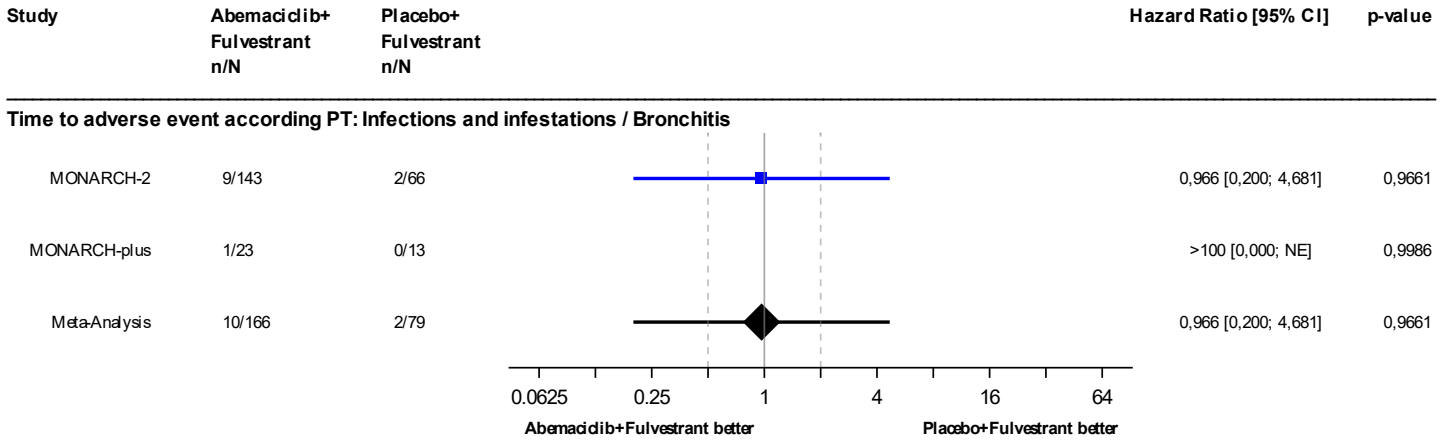
Figure 1204: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Bronchitis
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep011_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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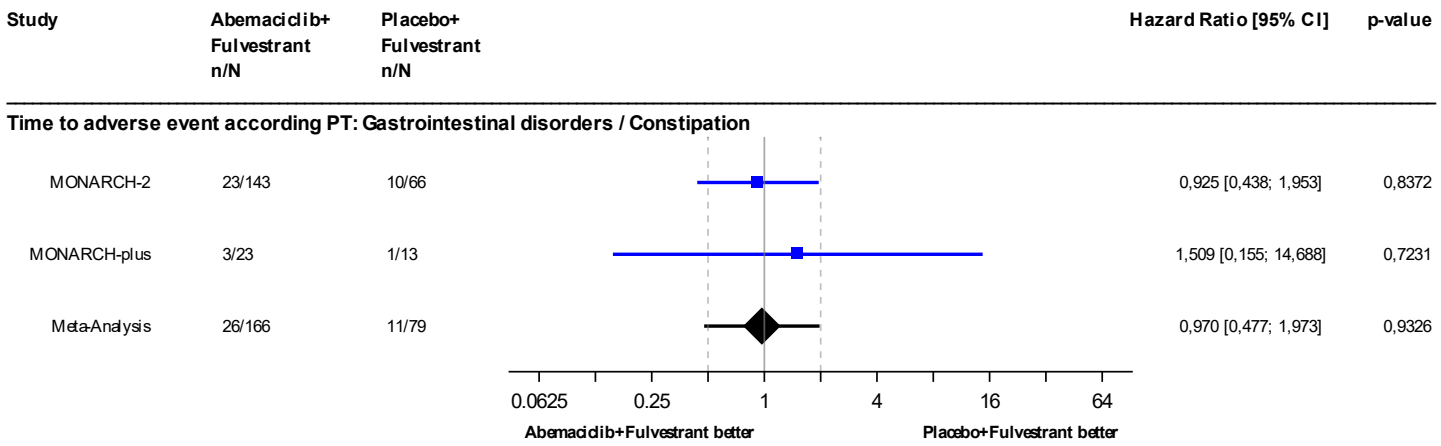
Figure 1205: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Constipation
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1606, p-value=0,6886, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep012_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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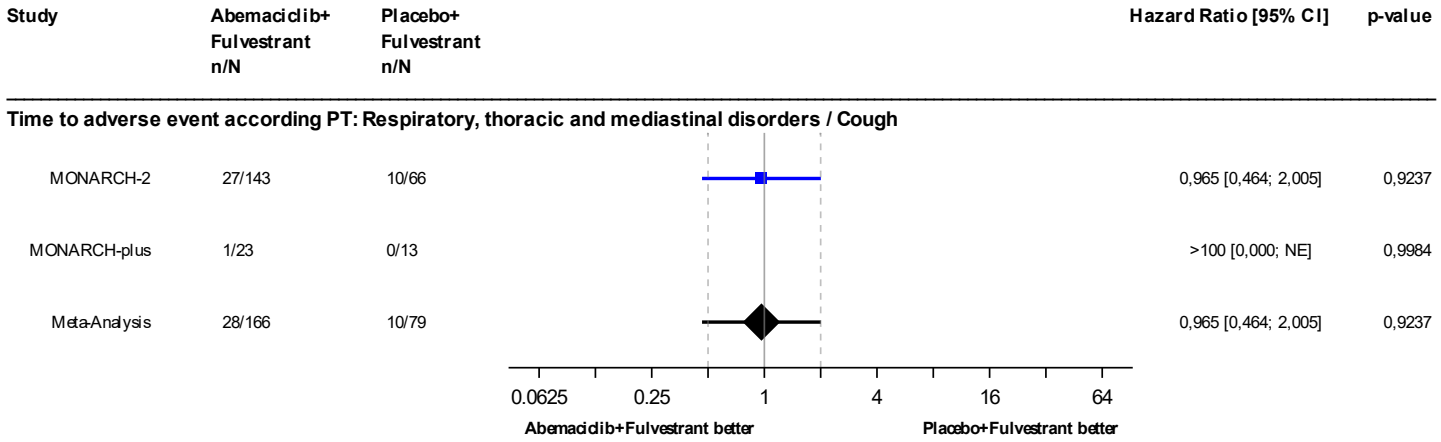
**Figure 1206: Metaanalysis results for adverse events according PT[1] -
Respiratory, thoracic and mediastinal disorders / Cough
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9984, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep013_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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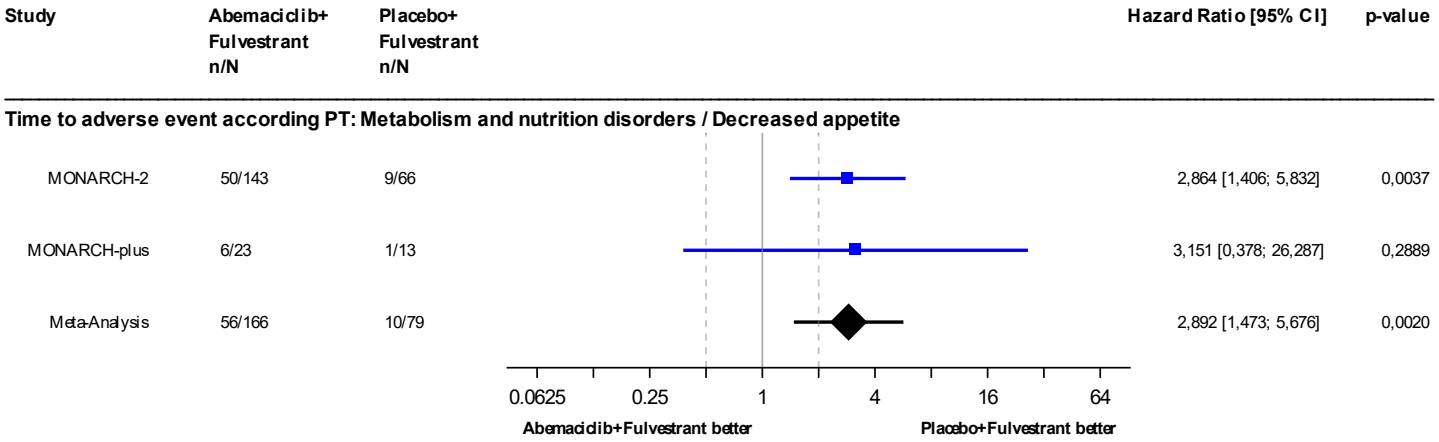
Figure 1207: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0070, p-value=0,9332, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep014_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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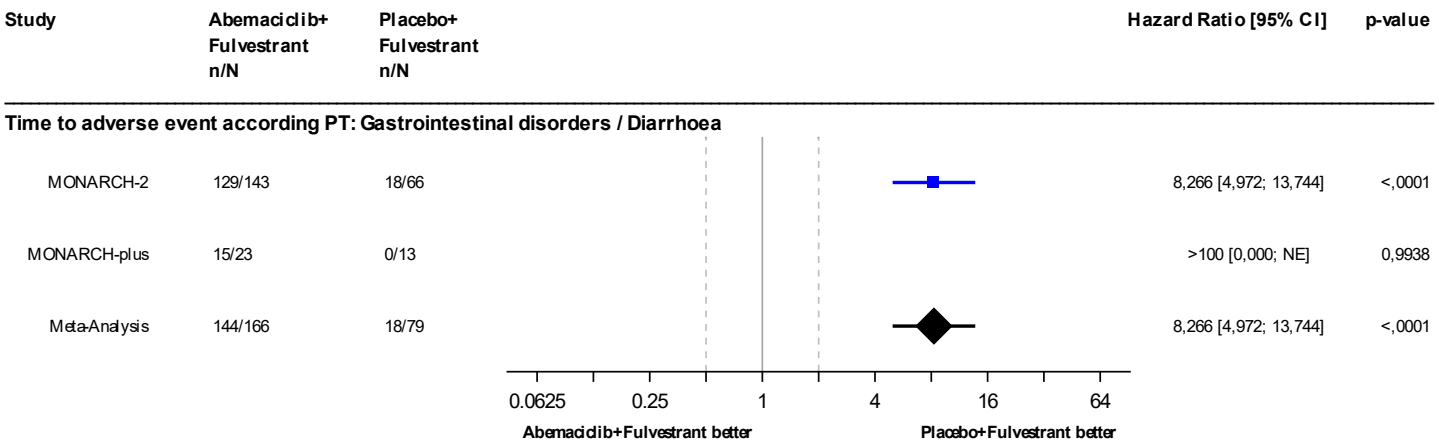
Figure 1208: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9946, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep015_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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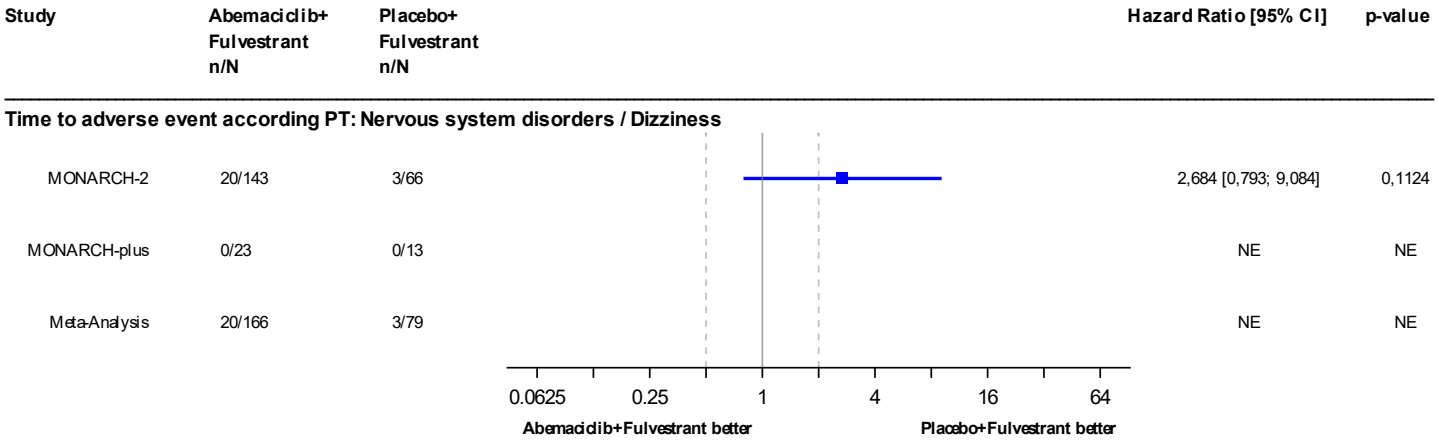
Figure 1209: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dizziness
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep016_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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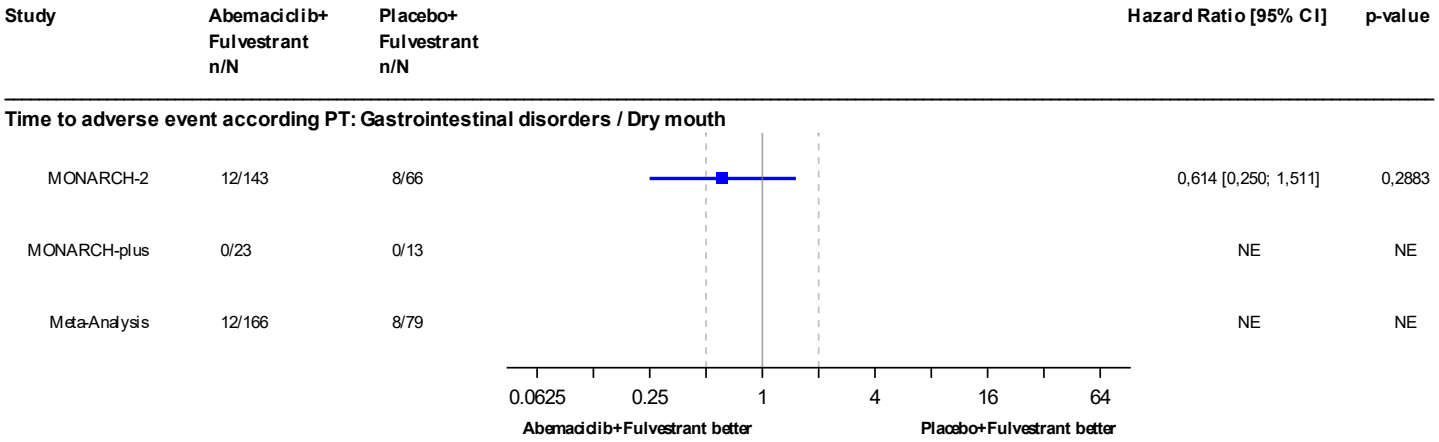
Figure 1210: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Dry mouth
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep017_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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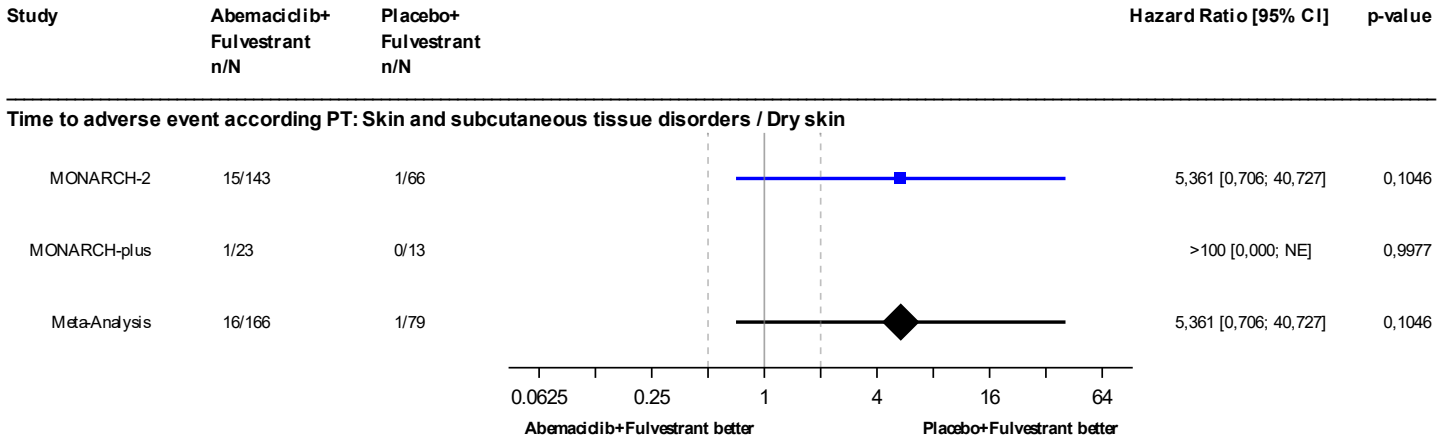
Figure 1211: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Dry skin
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9979, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep018_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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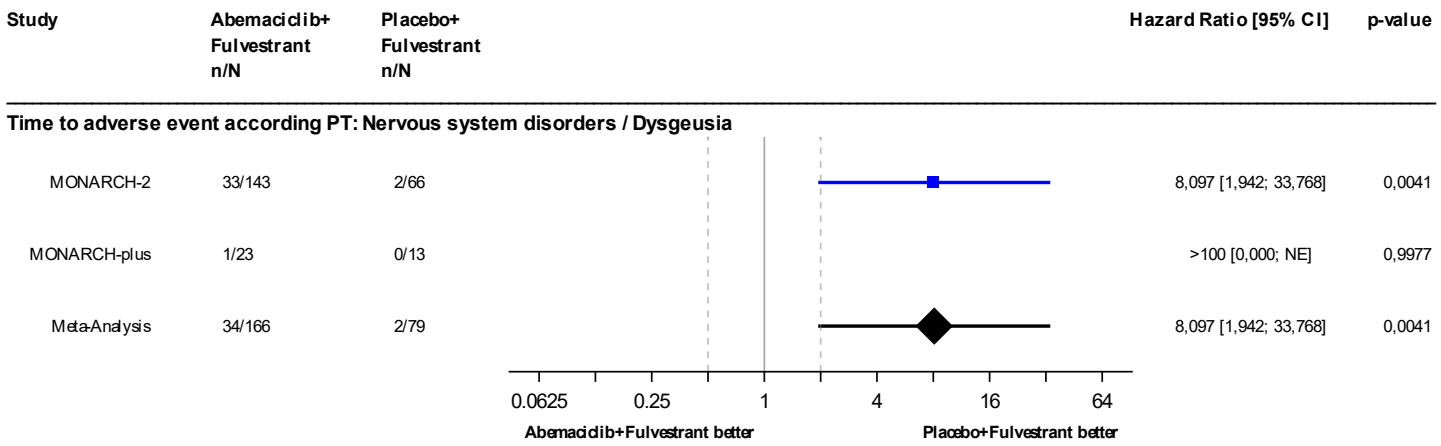
Figure 1212: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep019_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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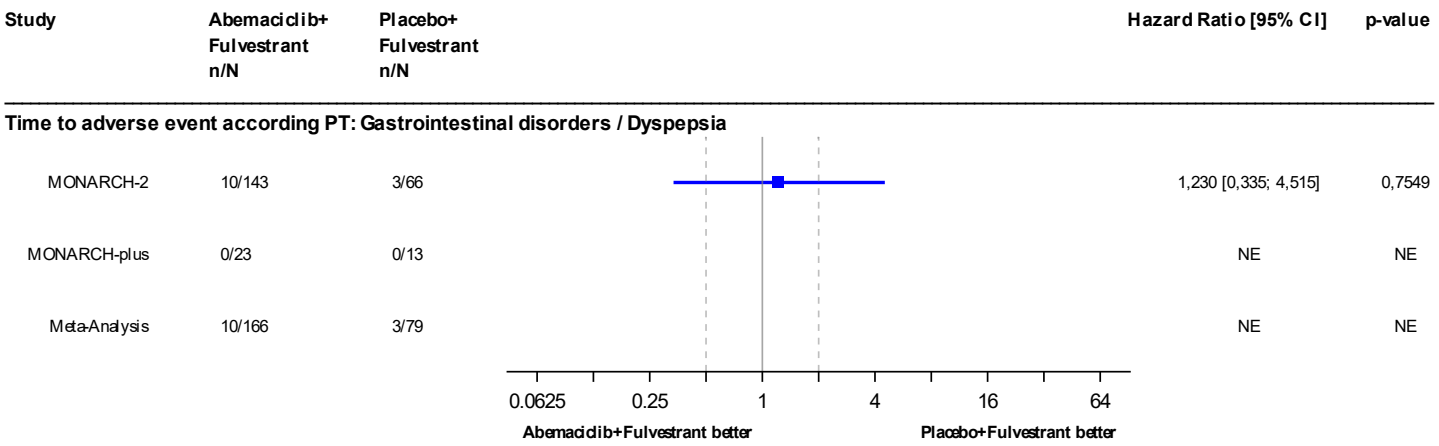
Figure 1213: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Dyspepsia
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep020_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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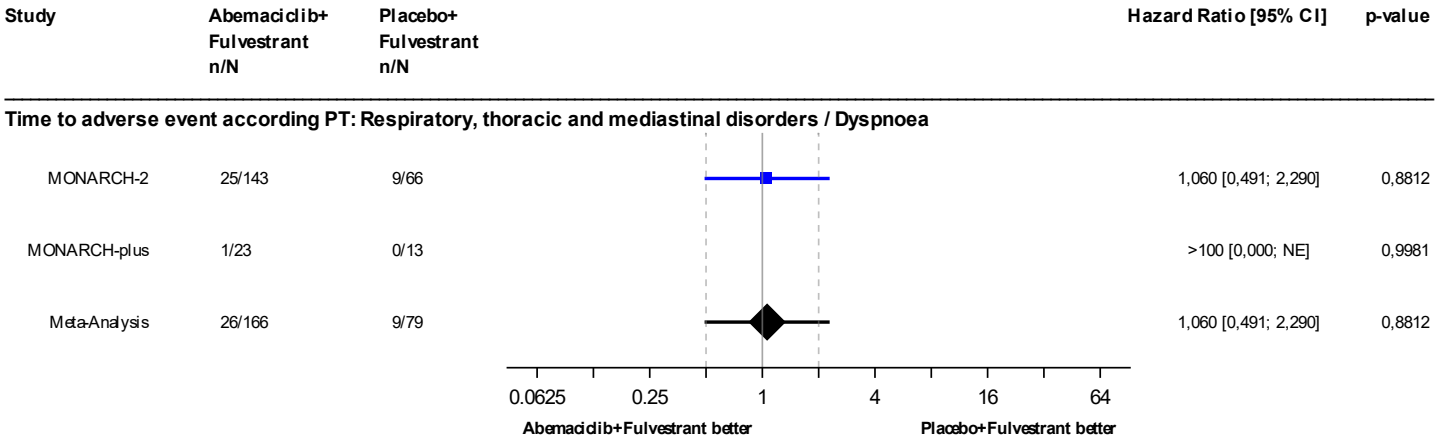
**Figure 1214: Metaanalysis results for adverse events according PT[1] -
Respiratory, thoracic and mediastinal disorders / Dyspnoea
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9981, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep021_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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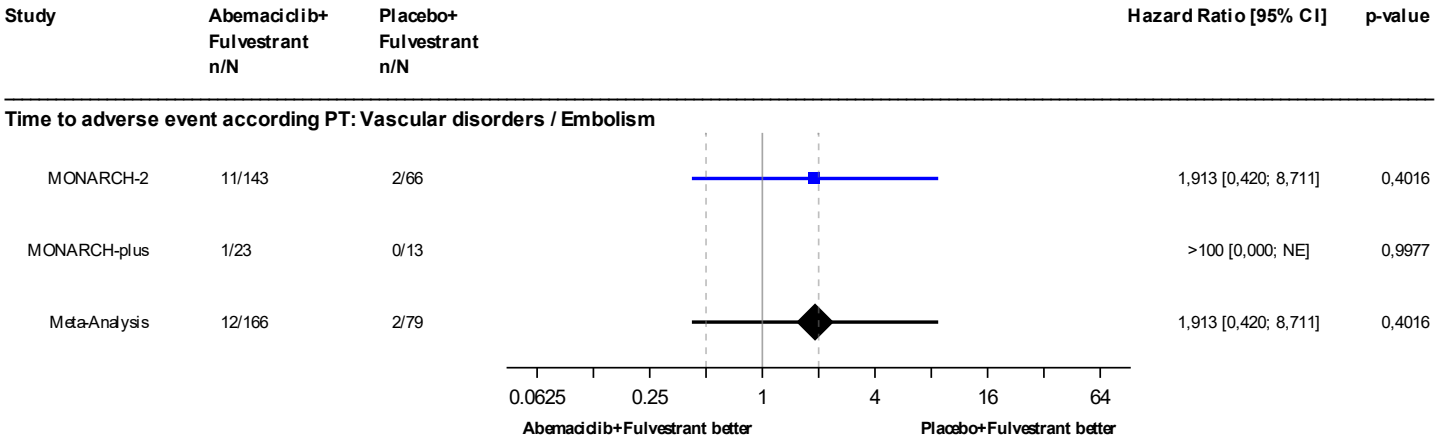
Figure 1215: Metaanalysis results for adverse events according PT[1] -
Vascular disorders / Embolism
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9978, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep022_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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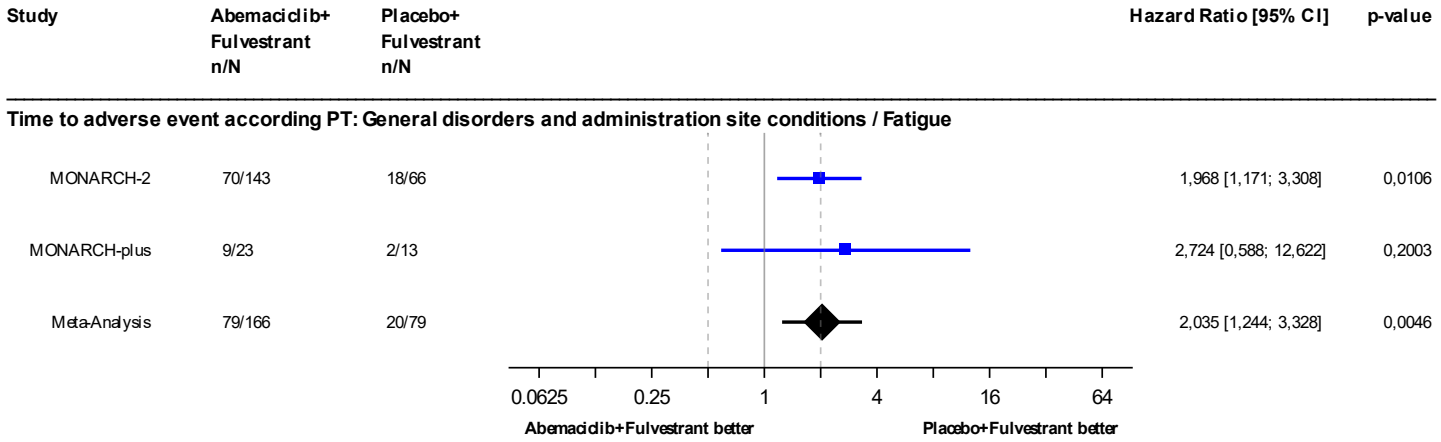
**Figure 1216: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,1547, p-value=0,6941, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep023_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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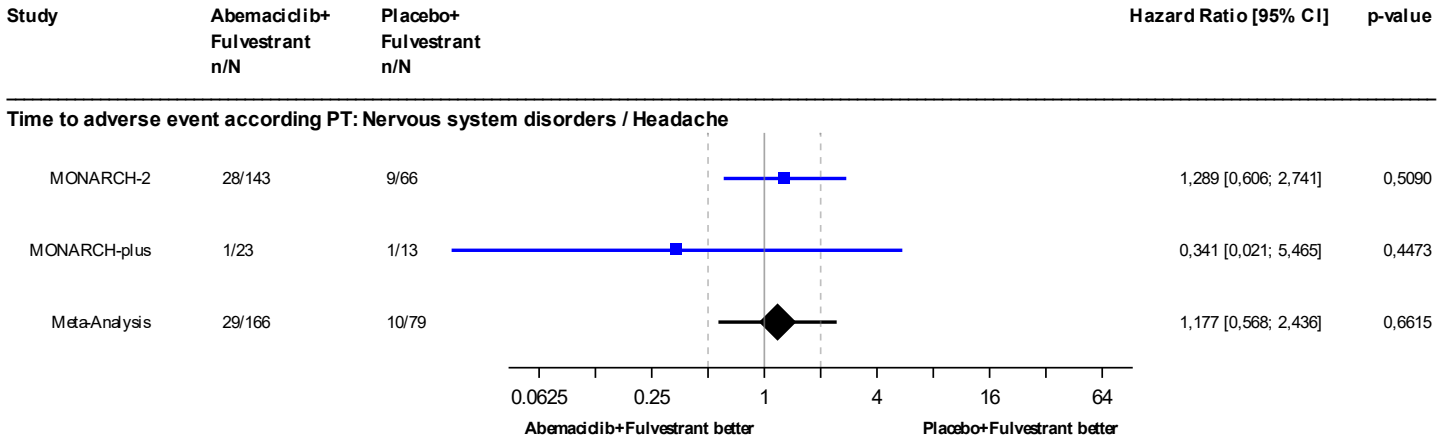
Figure 1217: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Headache
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,8220, p-value=0,3646, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep024_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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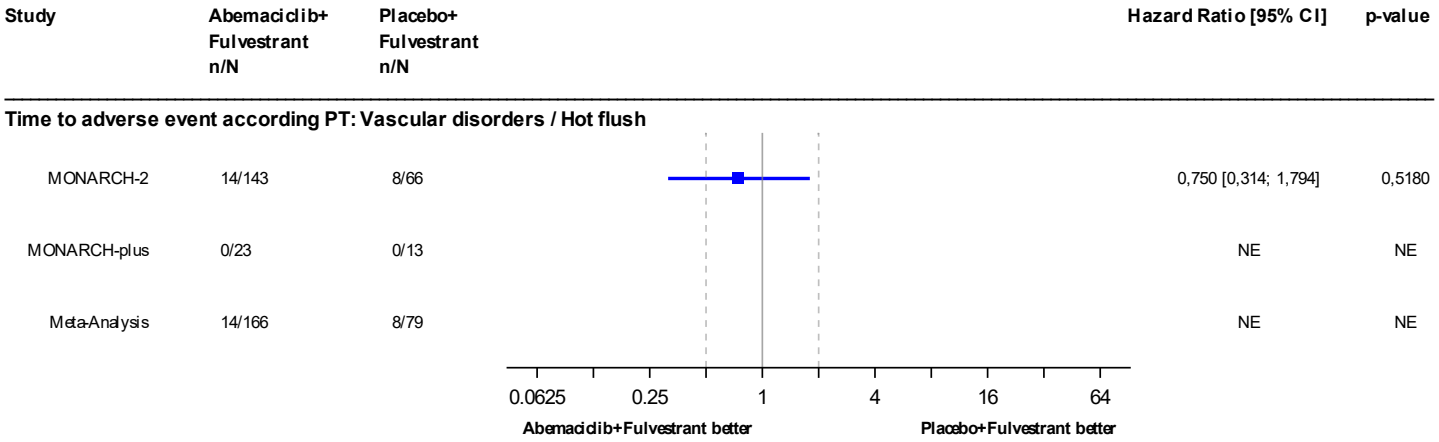
Figure 1218: Metaanalysis results for adverse events according PT[1] -
Vascular disorders / Hot flush
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep025_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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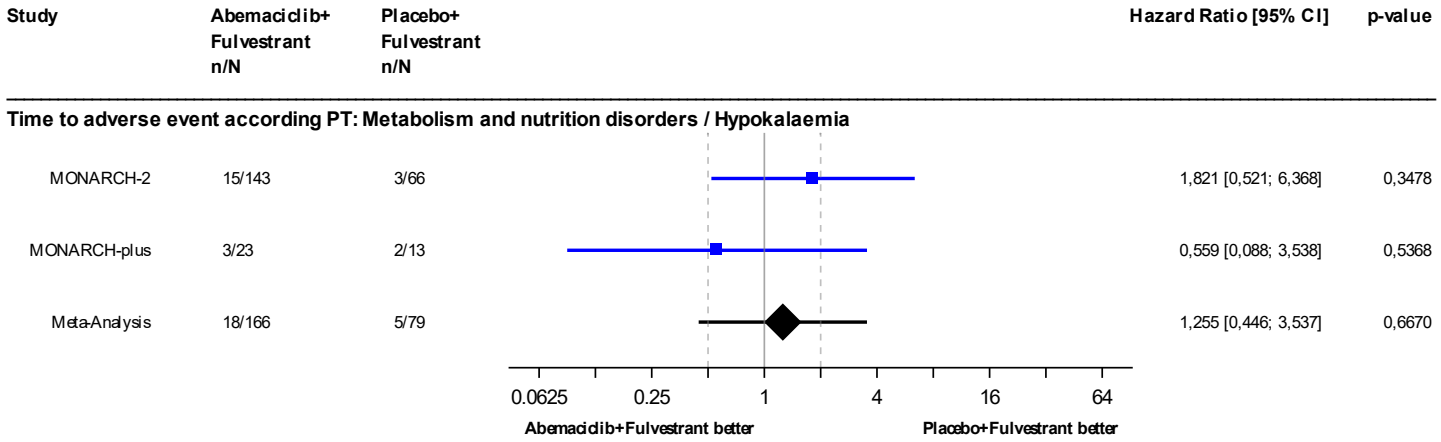
Figure 1219: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,0780, p-value=0,2991, I2 index=7,2%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep026_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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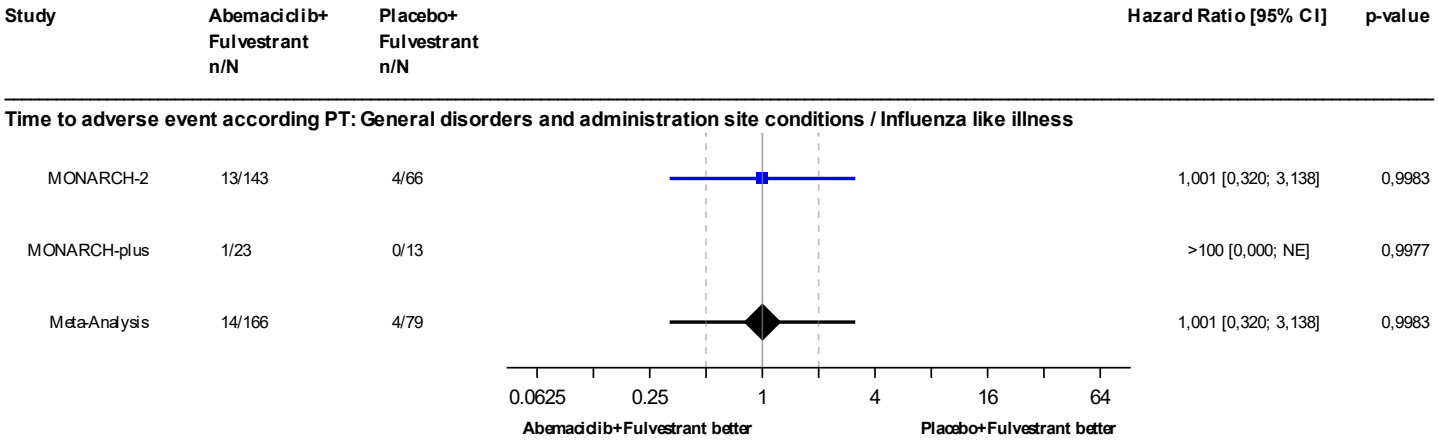
**Figure 1220: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Influenza like illness
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9977, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep027_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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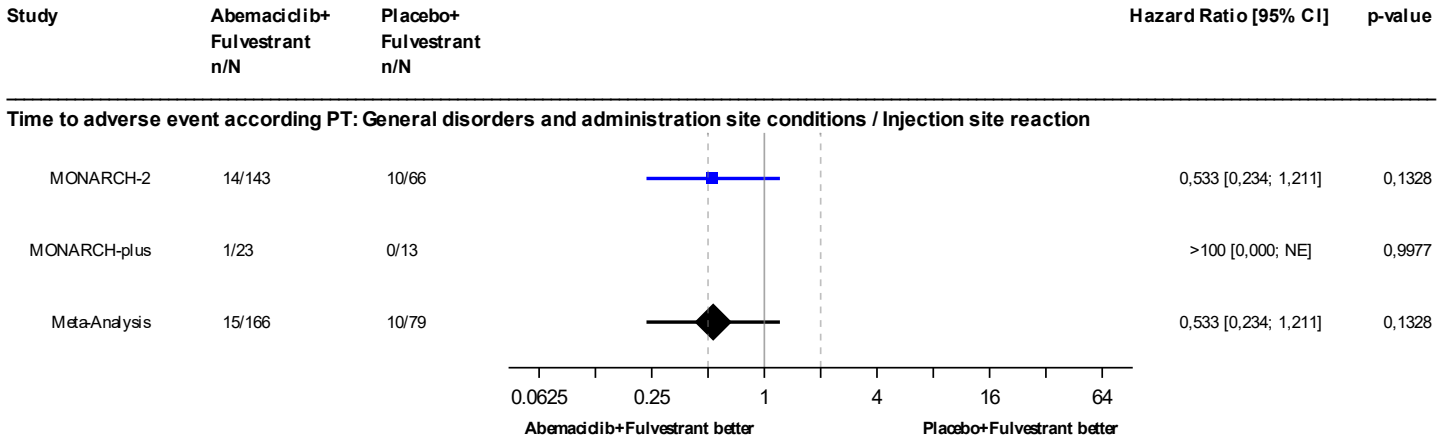
**Figure 1221: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Injection site reaction
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9976, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep028_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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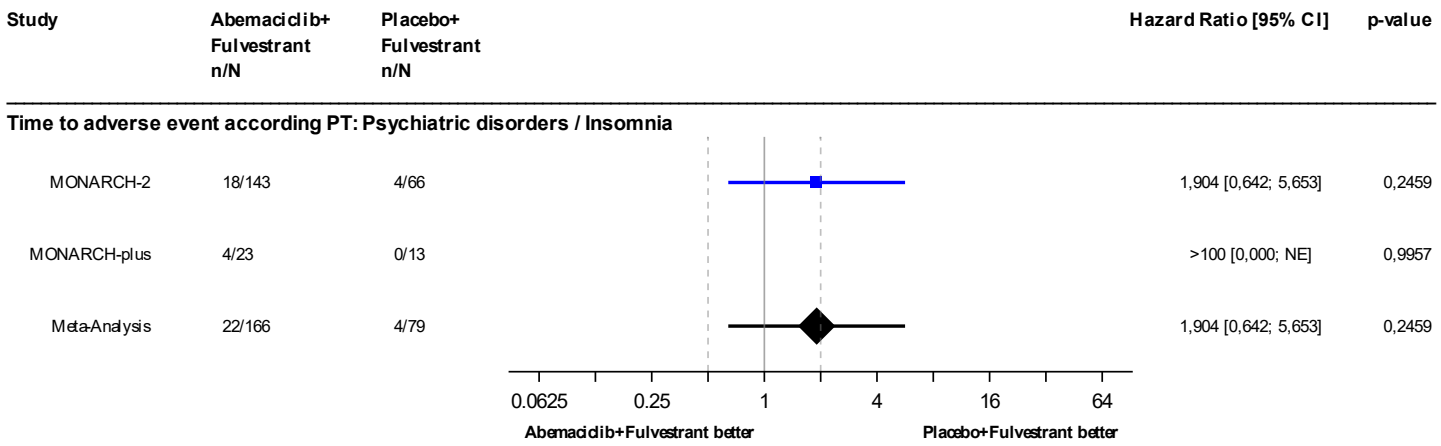
Figure 1222: Metaanalysis results for adverse events according PT[1] -
Psychiatric disorders / Insomnia
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9958, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep029_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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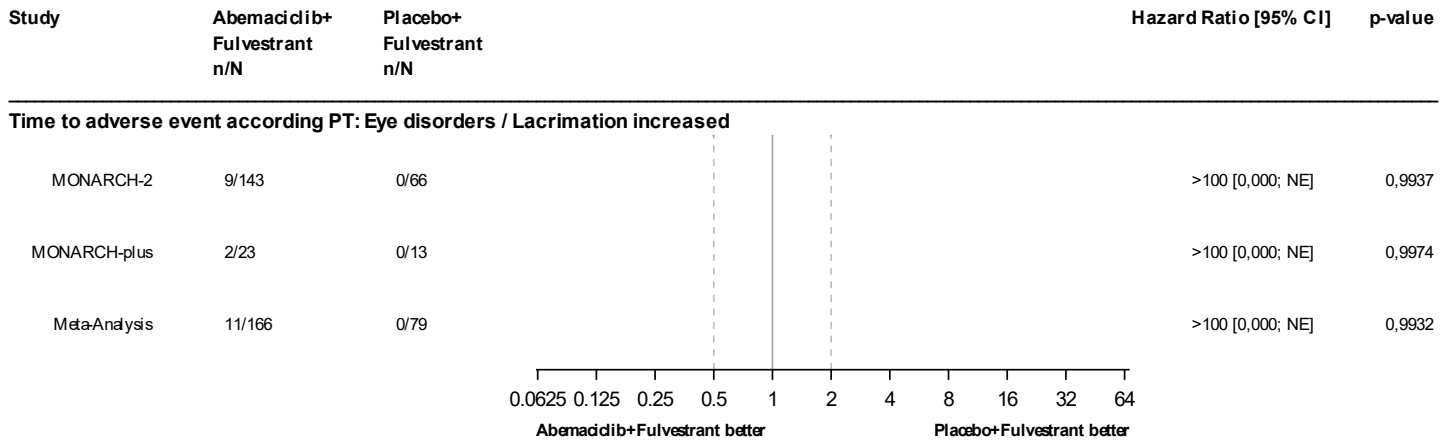
Figure 1223: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep030_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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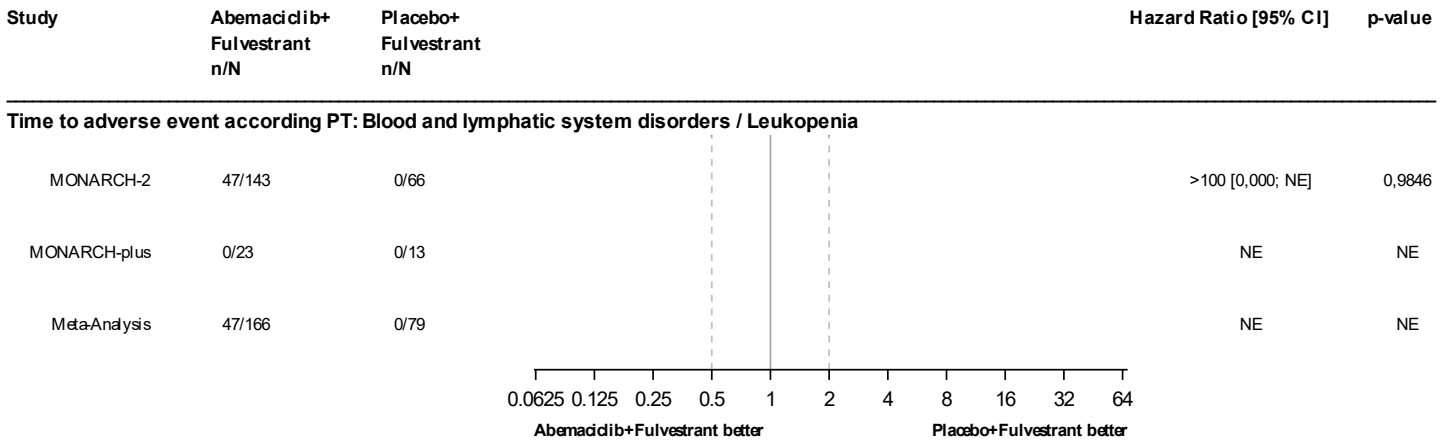
Figure 1224: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Leukopenia
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep031_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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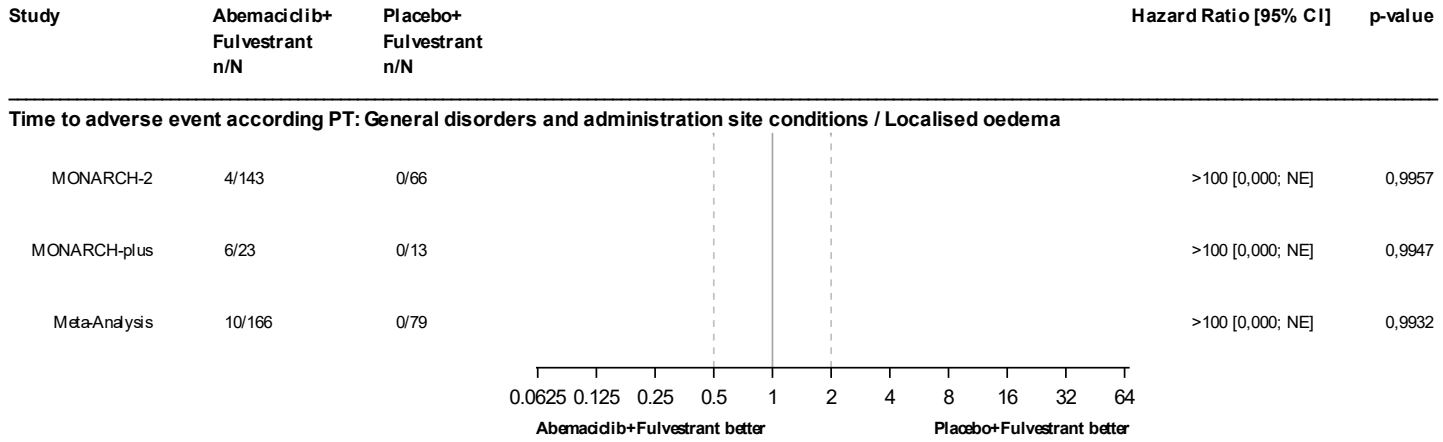
**Figure 1225: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Localised oedema
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep032_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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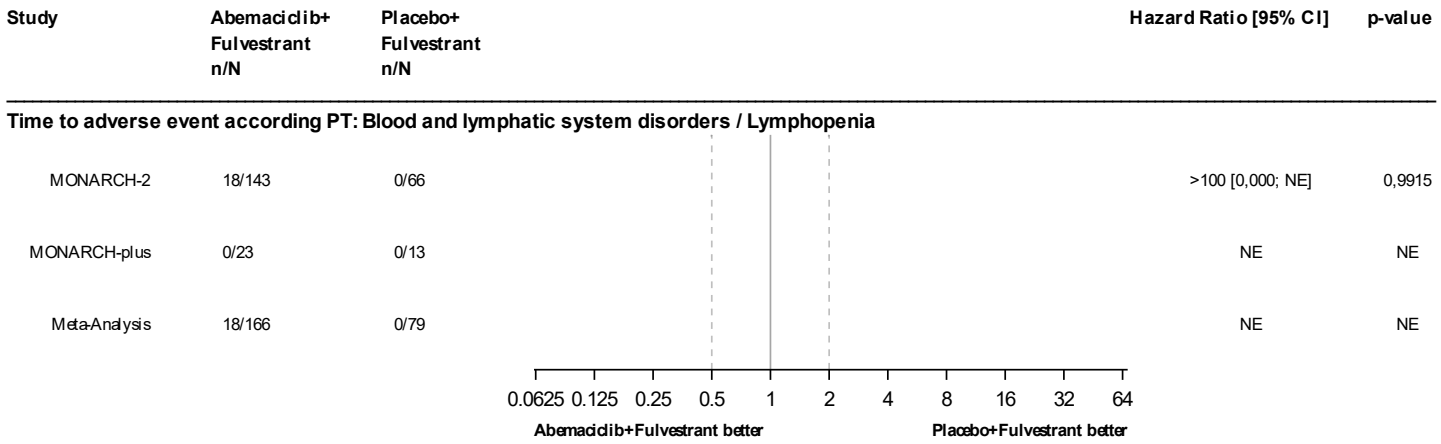
Figure 1226: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Lymphopenia
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep033_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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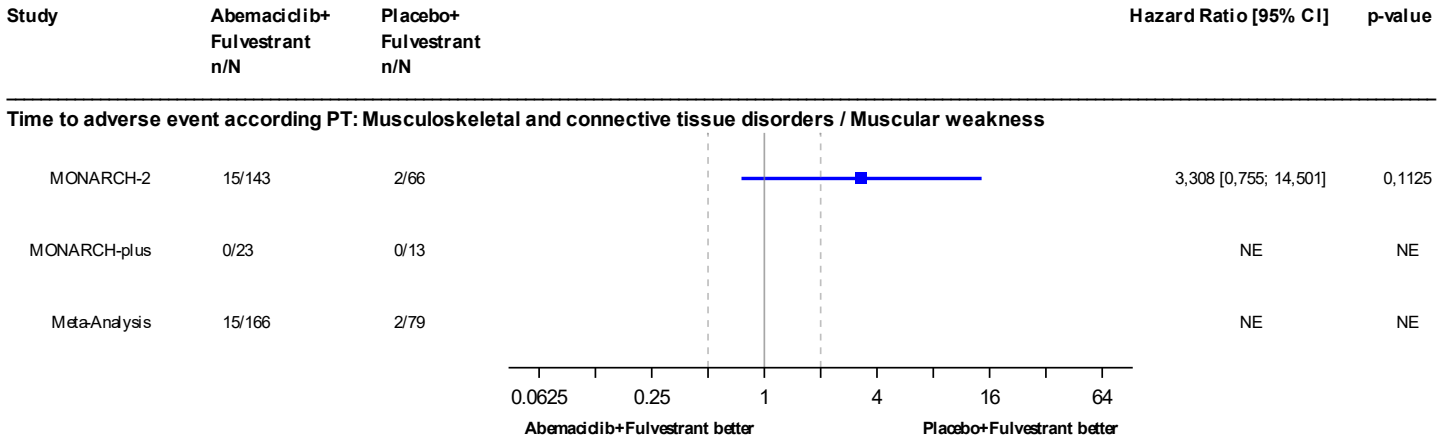
Figure 1227: Metaanalysis results for adverse events according PT[1] - Musculoskeletal and connective tissue disorders / Muscular weakness Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep034_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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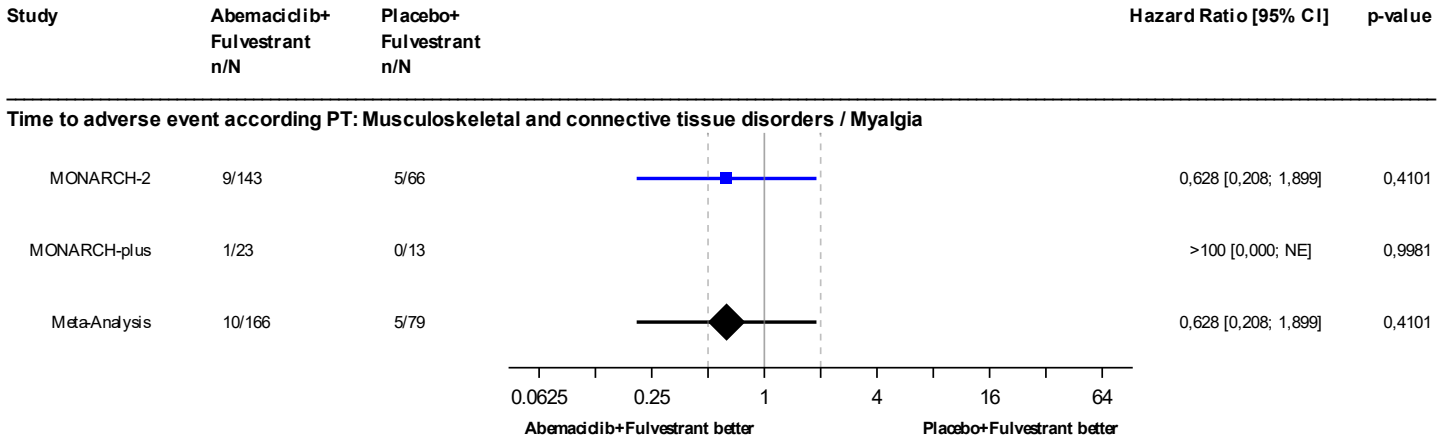
**Figure 1228: Metaanalysis results for adverse events according PT[1] -
Musculoskeletal and connective tissue disorders / Myalgia
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep035_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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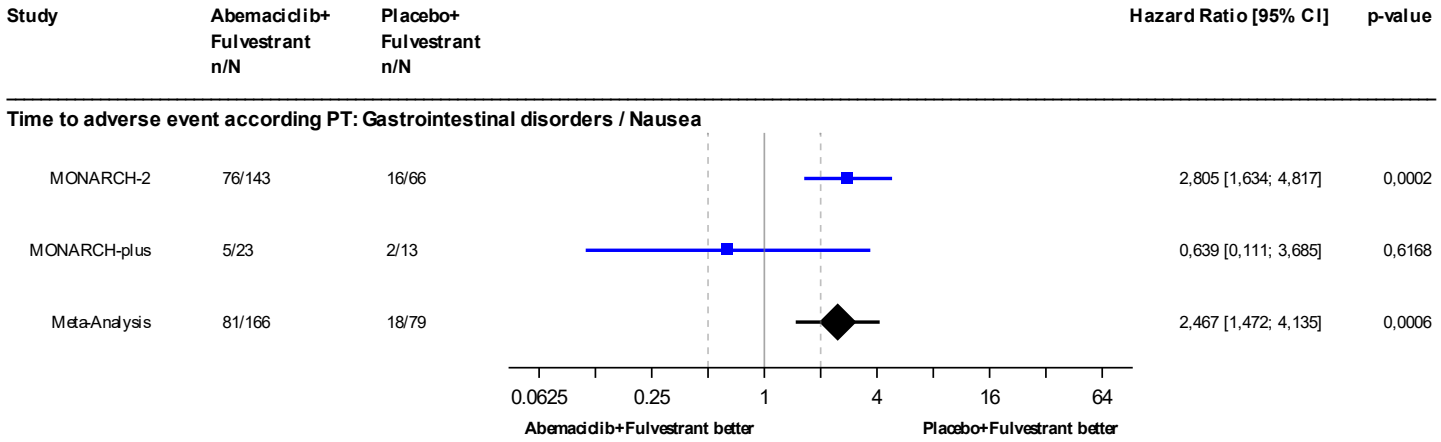
Figure 1229: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,5000, p-value=0,1138, I2 index=60,0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep036_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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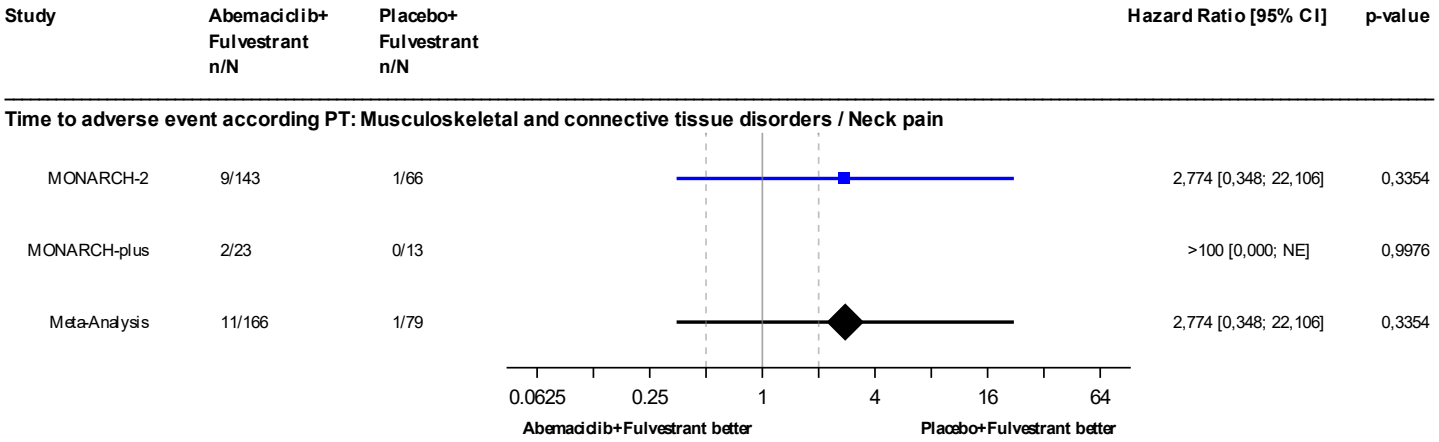
**Figure 1230: Metaanalysis results for adverse events according PT[1] -
Musculoskeletal and connective tissue disorders / Neck pain
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9977, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep037_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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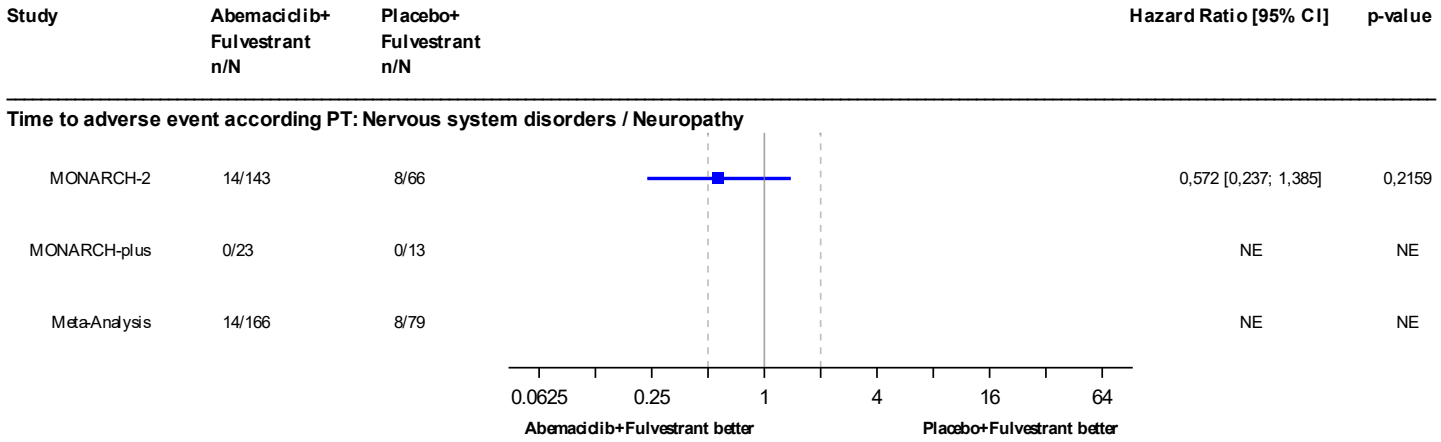
Figure 1231: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Neuropathy
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep038_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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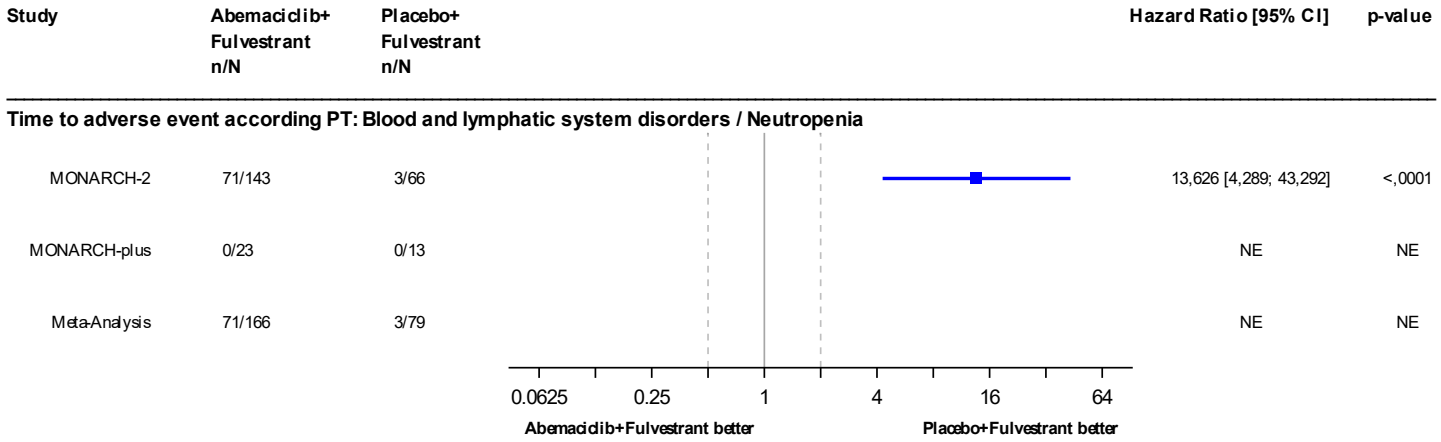
Figure 1232: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Neutropenia
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep039_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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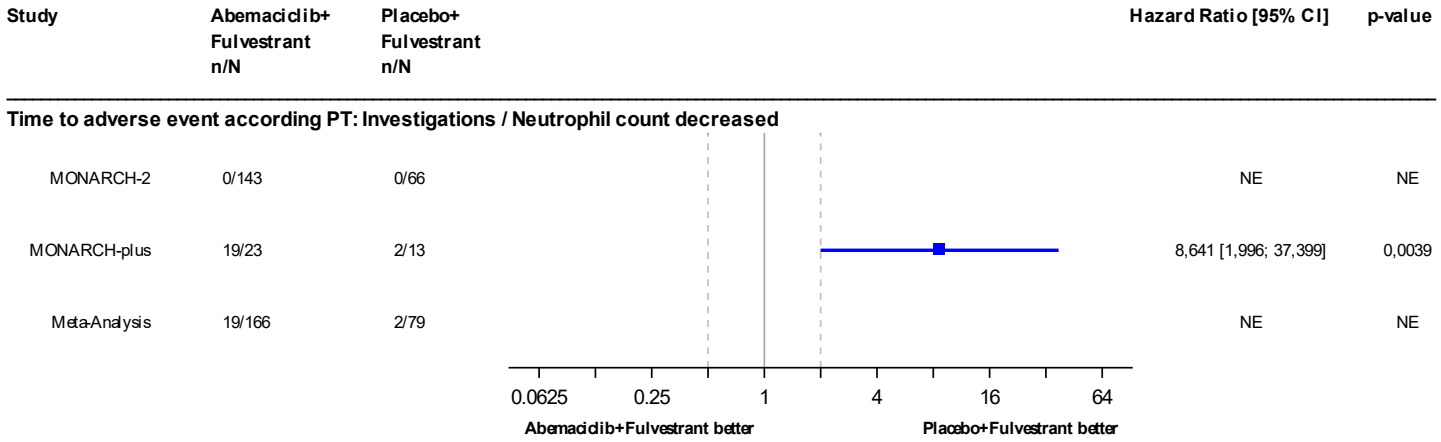
Figure 1233: Metaanalysis results for adverse events according PT[1] -
Investigations / Neutrophil count decreased
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep040_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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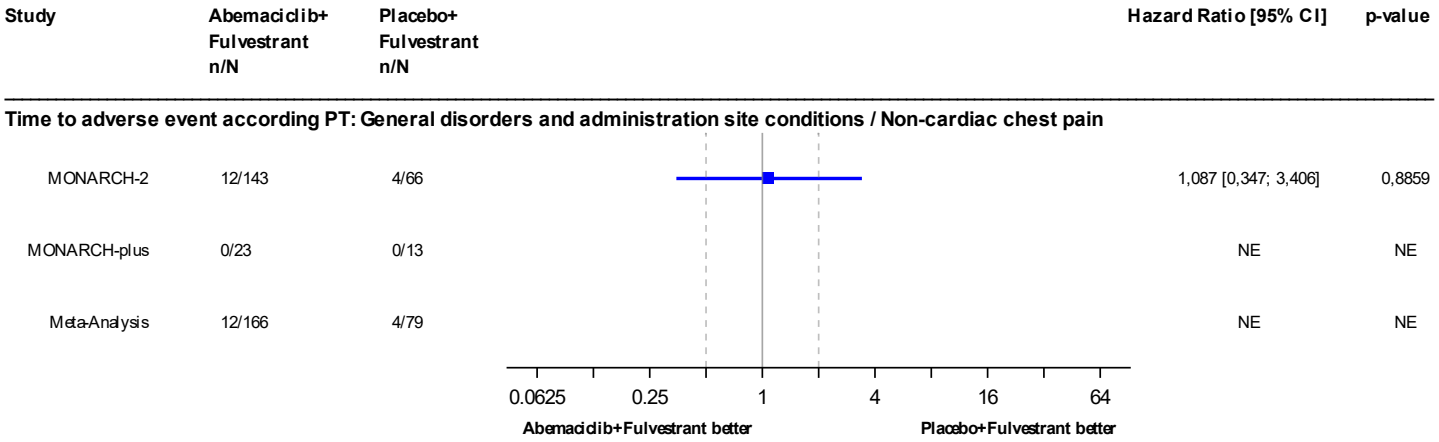
**Figure 1234: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Non-cardiac chest pain
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep041_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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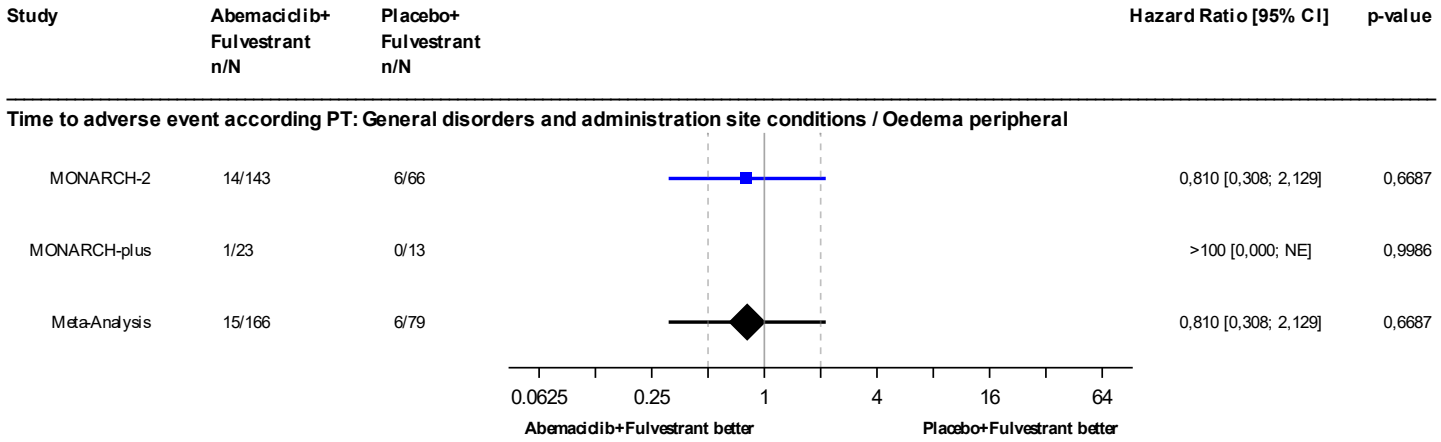
**Figure 1235: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Oedema peripheral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep042_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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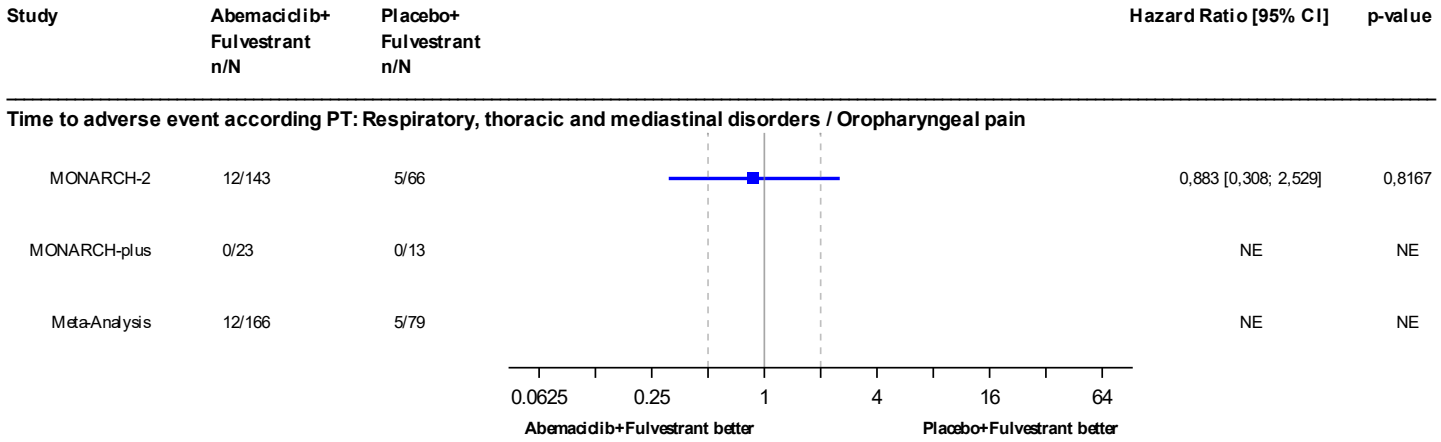
Figure 1236: Metaanalysis results for adverse events according PT[1] - Respiratory, thoracic and mediastinal disorders / Oropharyngeal pain Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep043_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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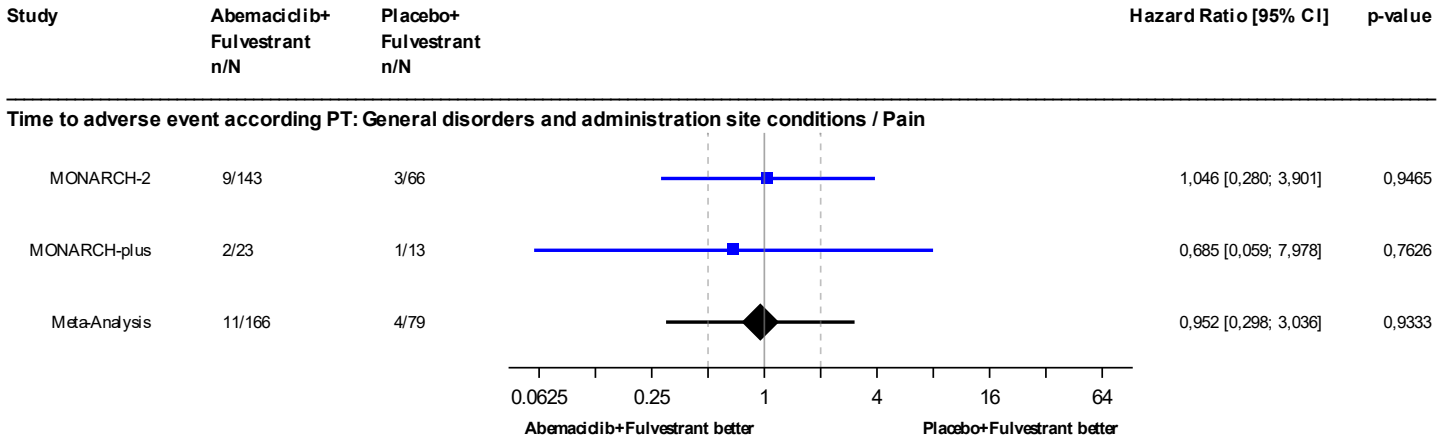
Figure 1237: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Pain
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0888, p-value=0,7657, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep044_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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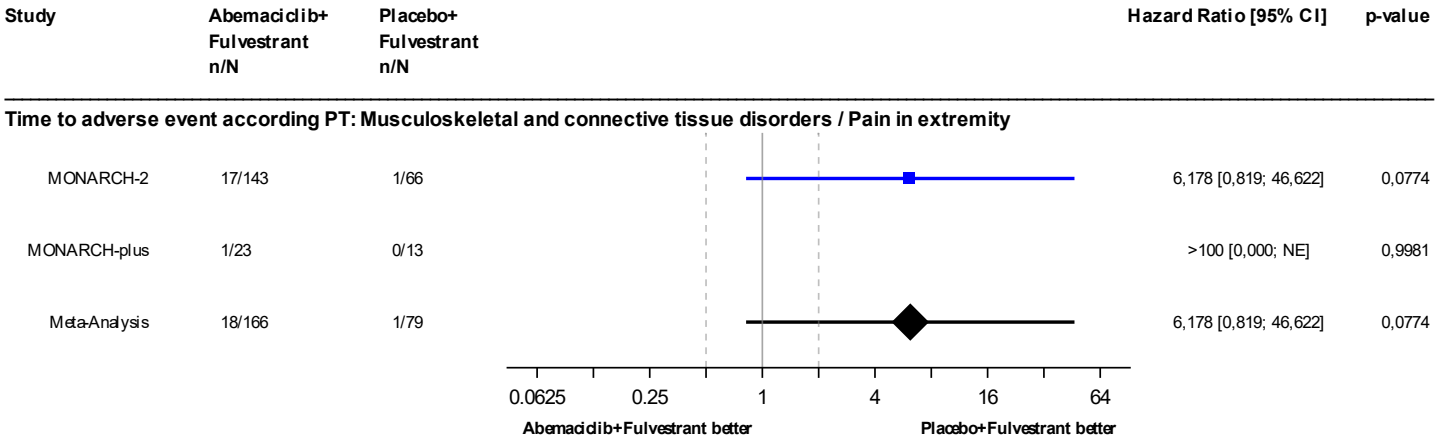
Figure 1238: Metaanalysis results for adverse events according PT[1] - Musculoskeletal and connective tissue disorders / Pain in extremity Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9983, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep045_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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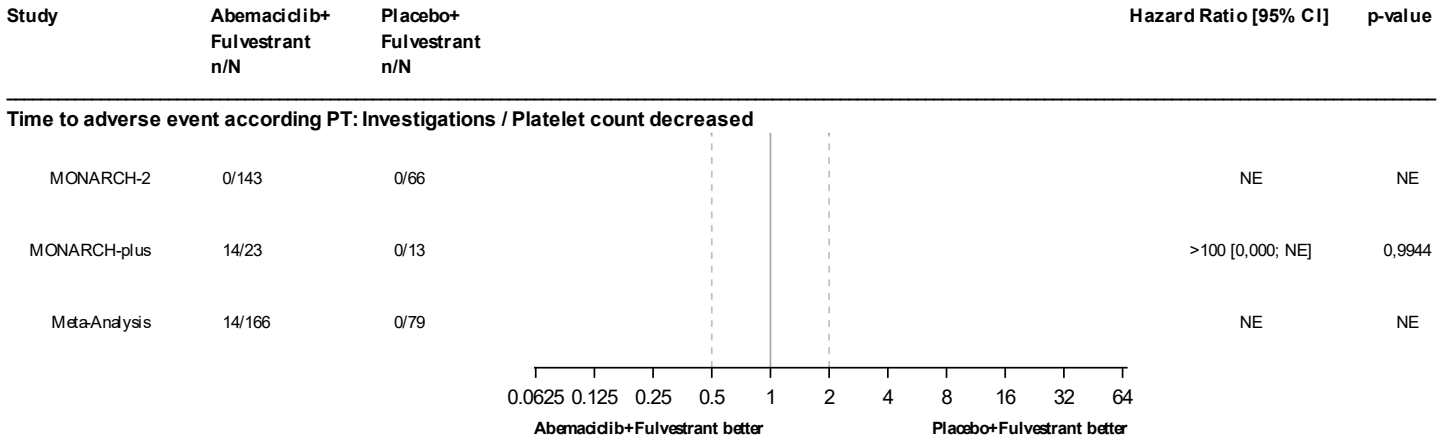
Figure 1239: Metaanalysis results for adverse events according PT[1] -
Investigations / Platelet count decreased
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep046_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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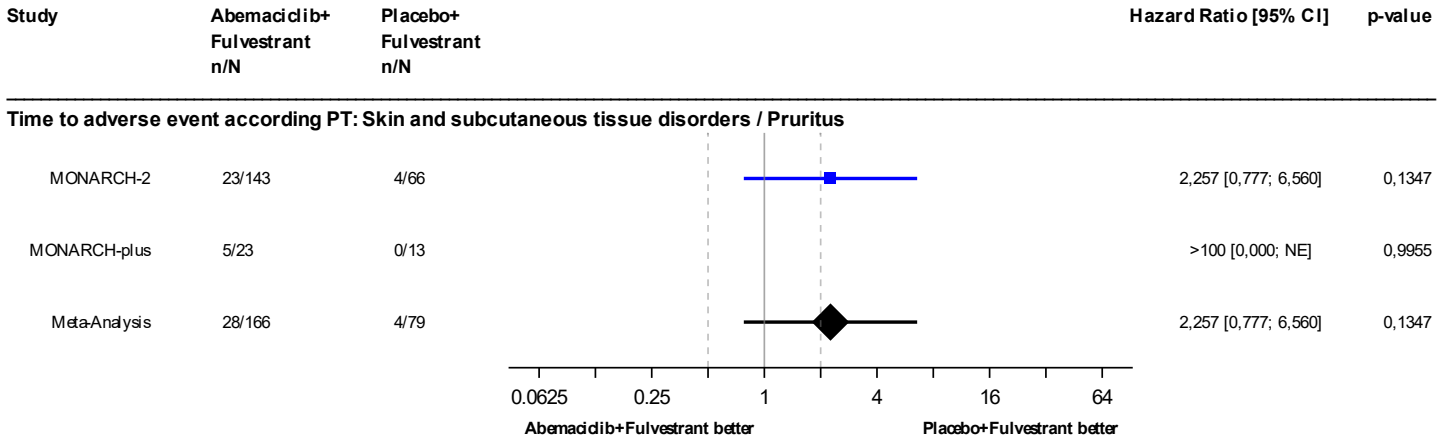
Figure 1240: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Pruritus
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9957, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep047_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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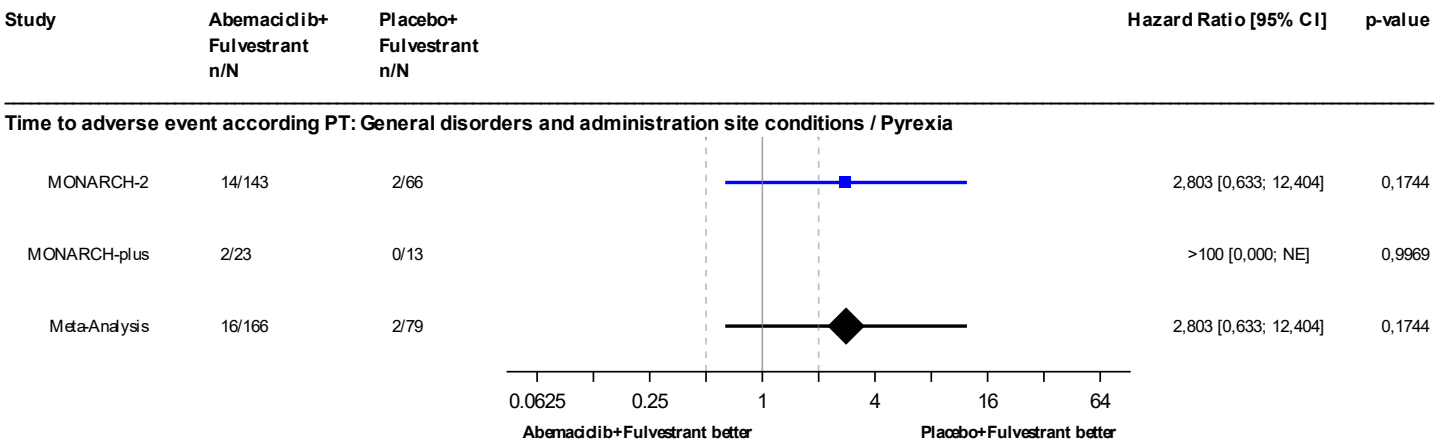
Figure 1241: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Pyrexia
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9971, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep048_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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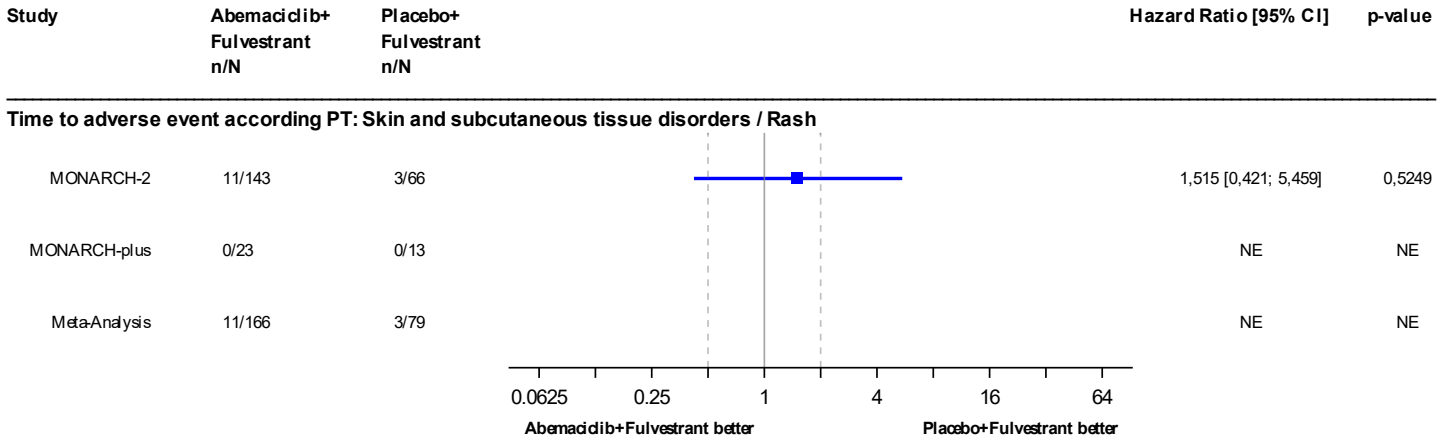
Figure 1242: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Rash
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep049_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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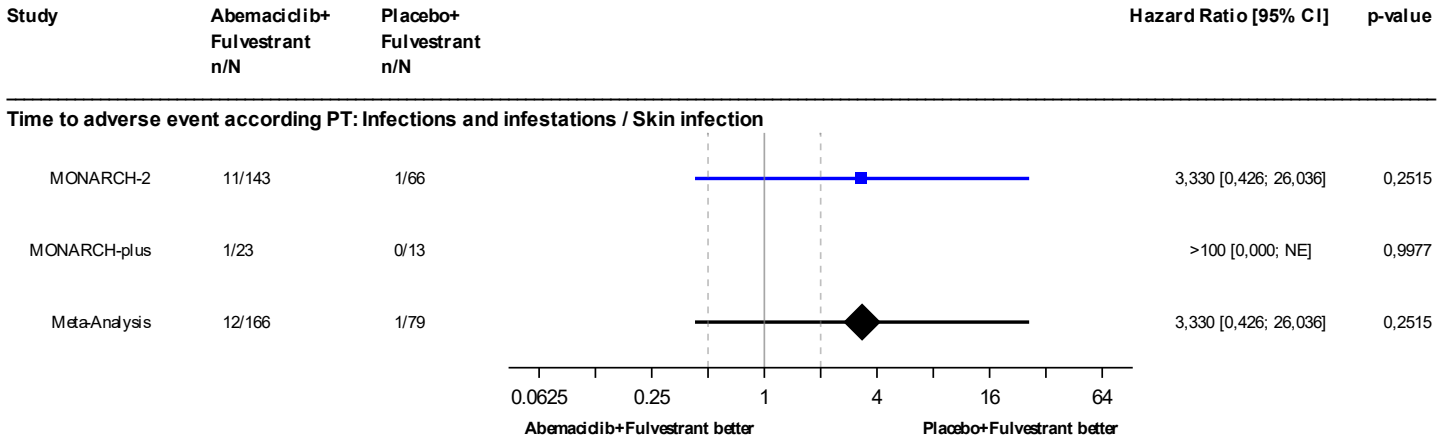
Figure 1243: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Skin infection
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9978, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep050_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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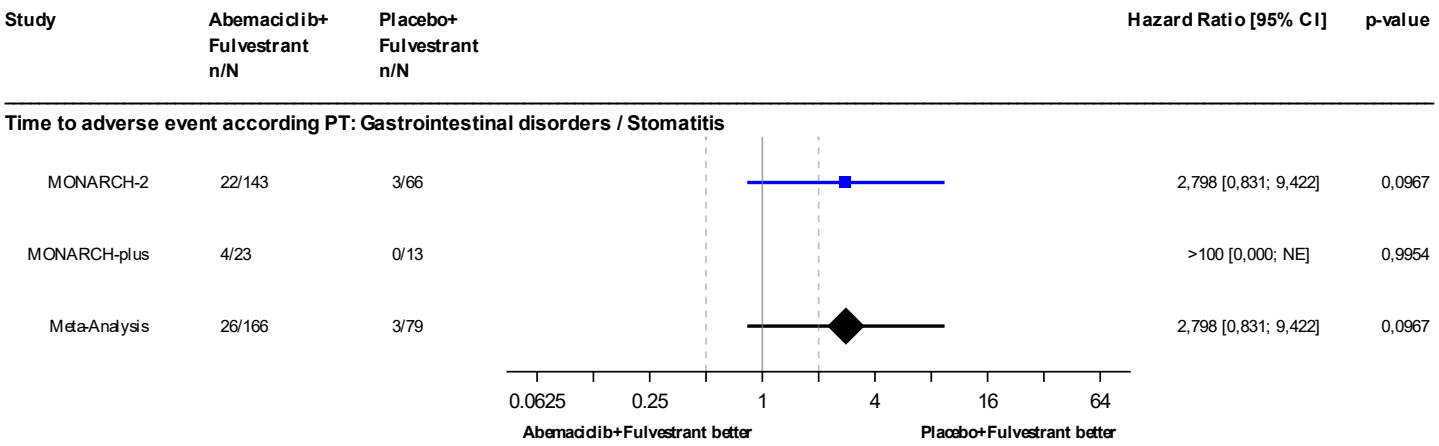
Figure 1244: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9957, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep051_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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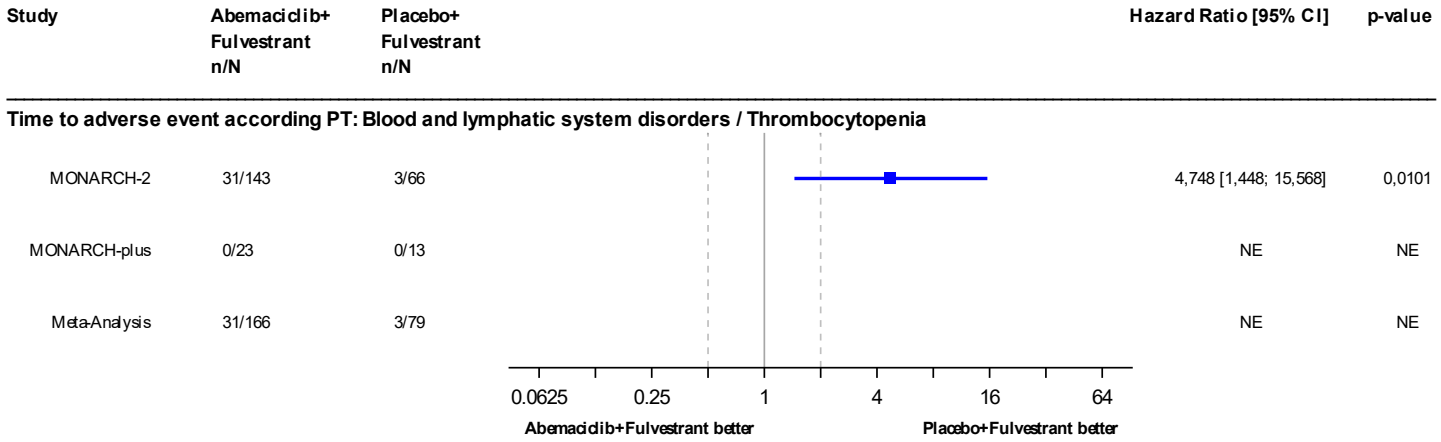
**Figure 1245: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Thrombocytopenia
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep052_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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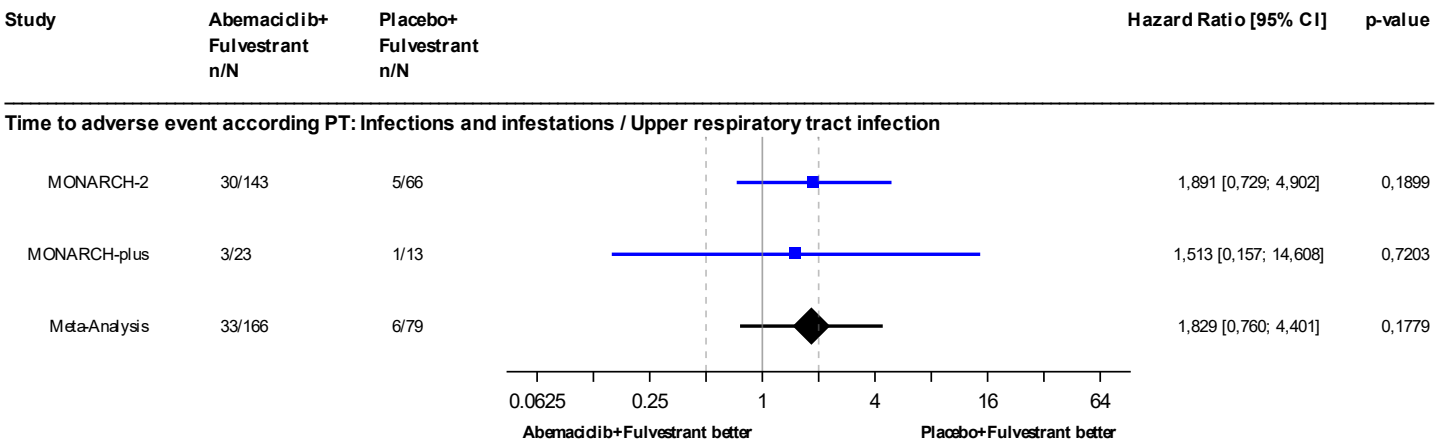
Figure 1246: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0316, p-value=0,8589, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep053_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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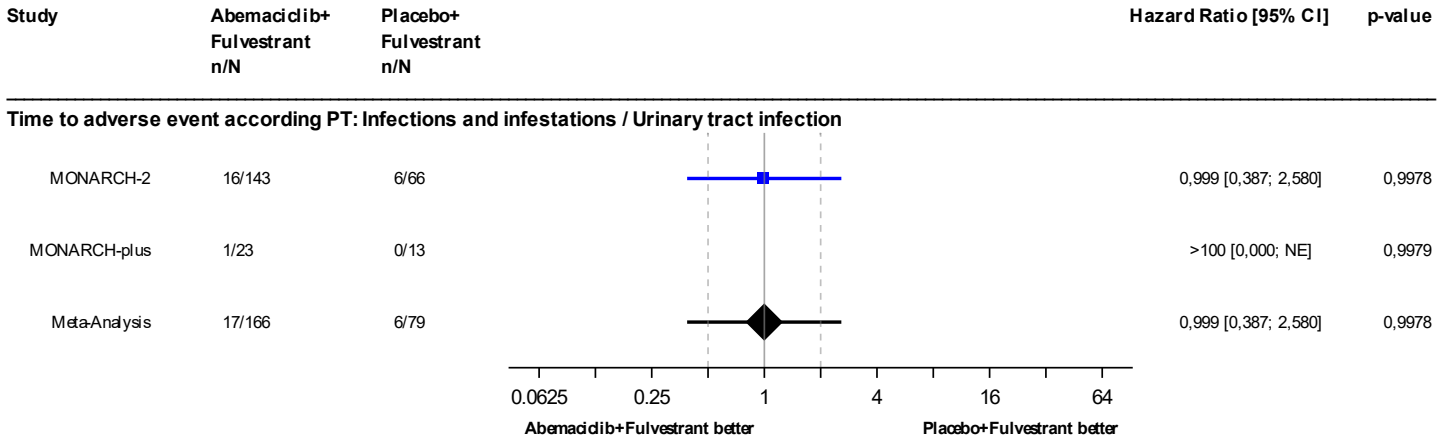
Figure 1247: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Urinary tract infection
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9979, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep054_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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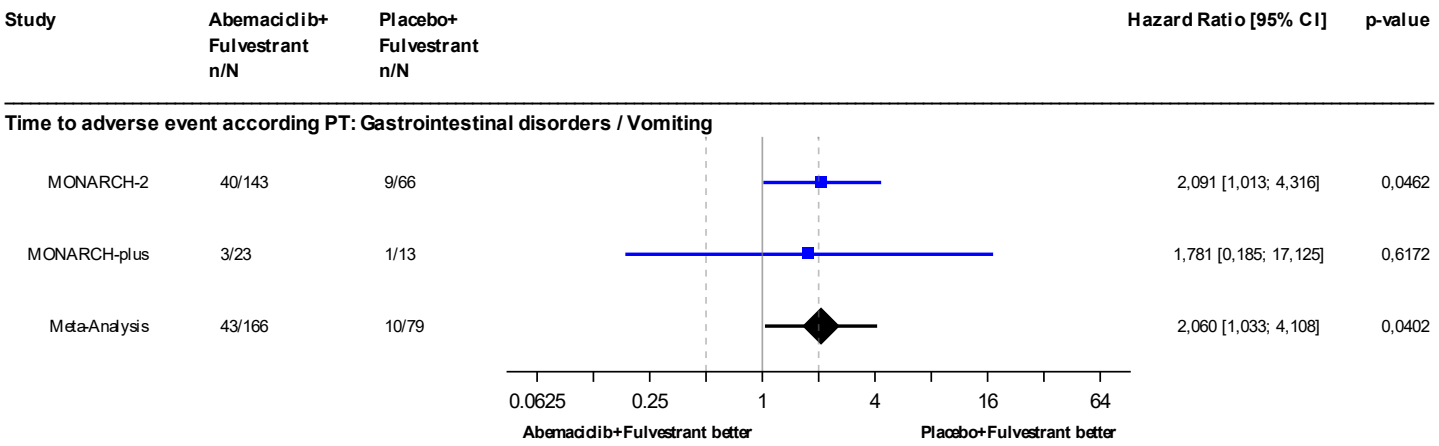
Figure 1248: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0175, p-value=0,8948, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep055_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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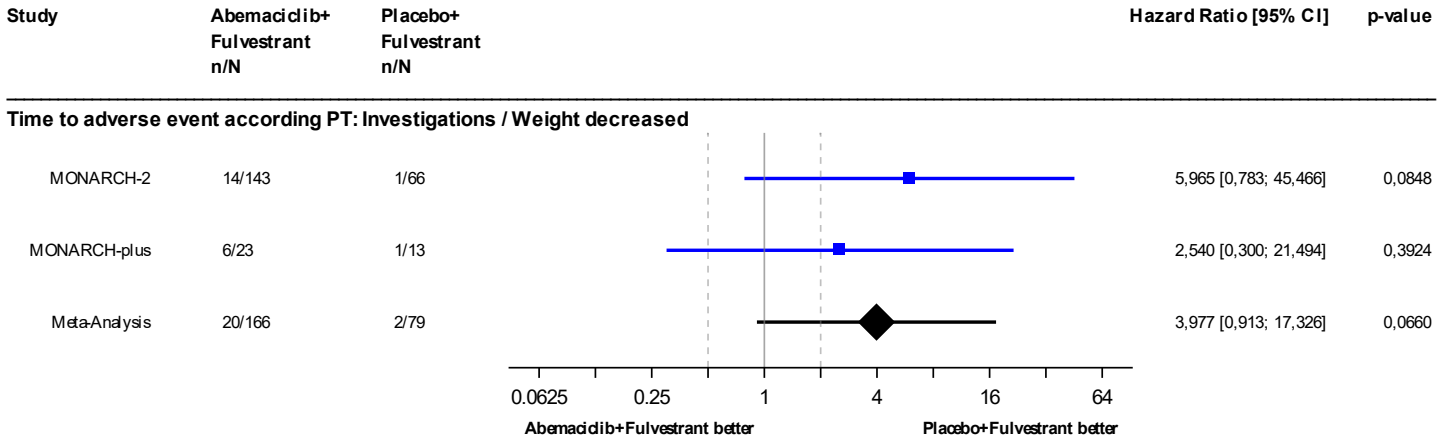
Figure 1249: Metaanalysis results for adverse events according PT[1] -
Investigations / Weight decreased
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3225, p-value=0,5701, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep056_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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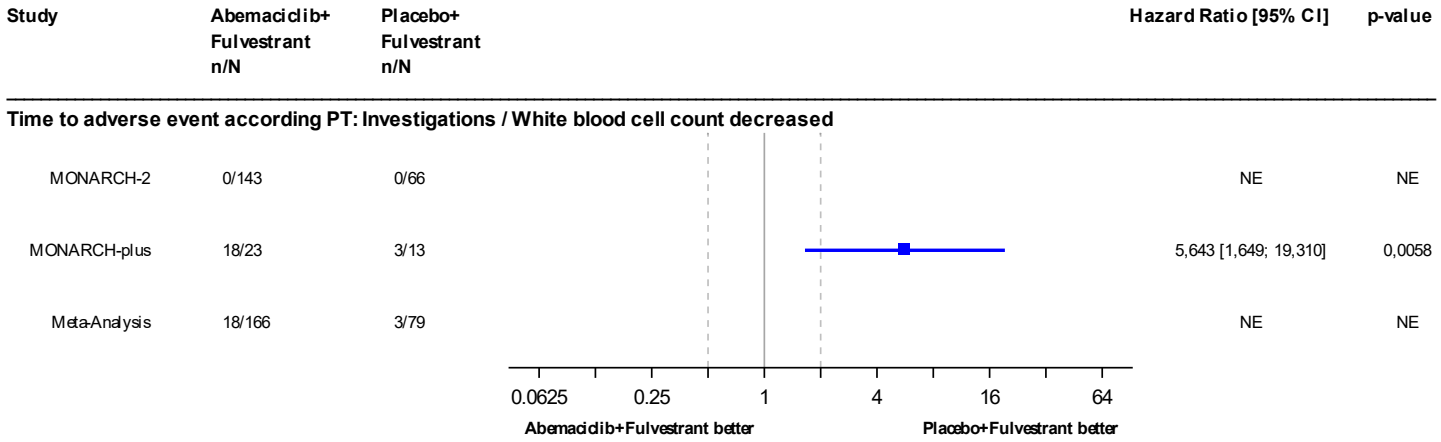
Figure 1250: Metaanalysis results for adverse events according PT[1] -
Investigations / White blood cell count decreased
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraep057_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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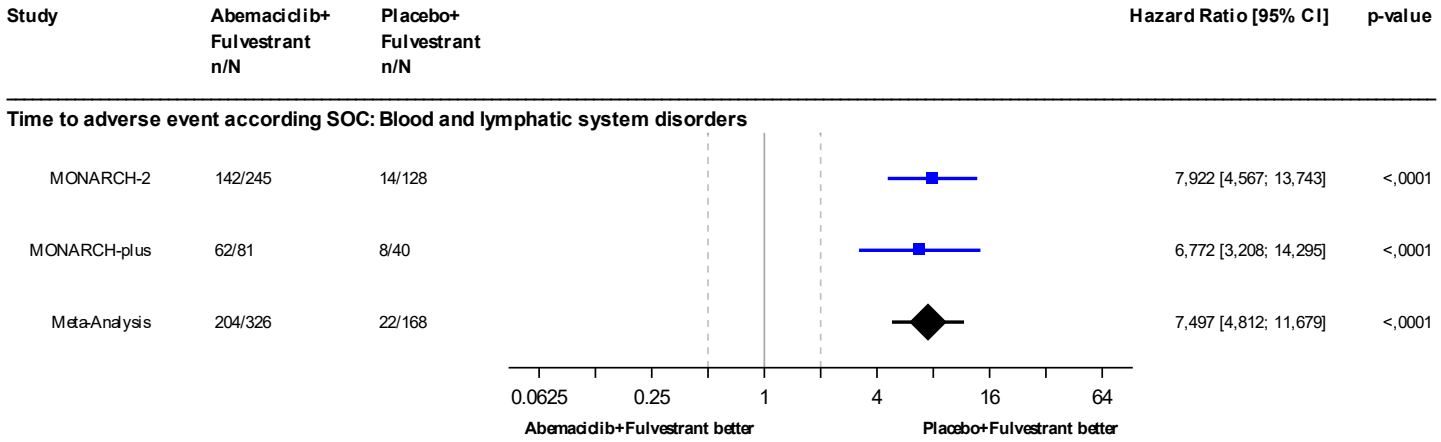
**Figure 1251: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,1098, p-value=0,7404, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes001_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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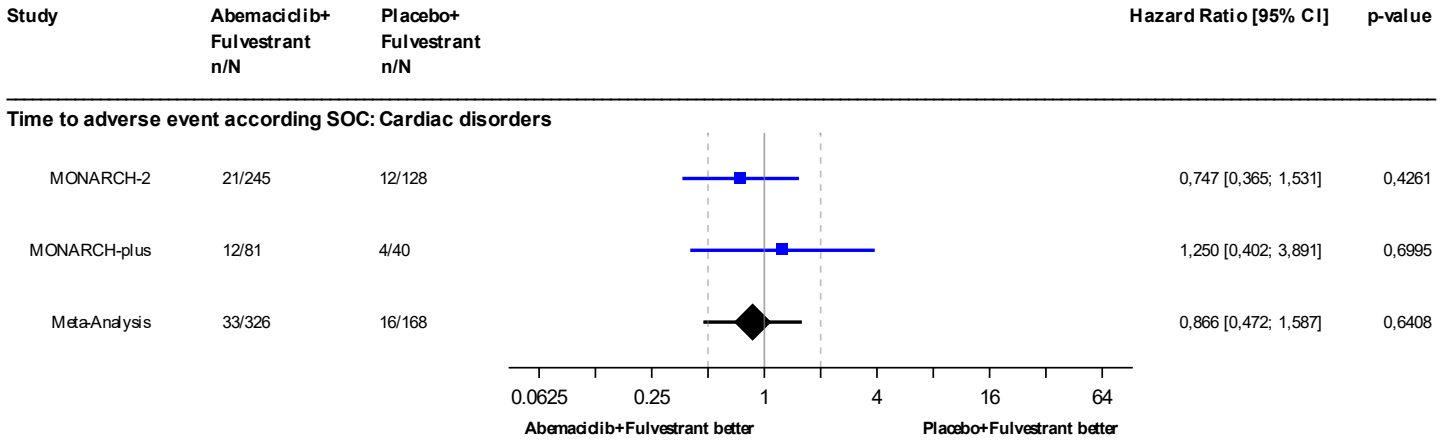
Figure 1252: Metaanalysis results for adverse events according SOC[1] -
Cardiac disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5647, p-value=0,4524, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes002_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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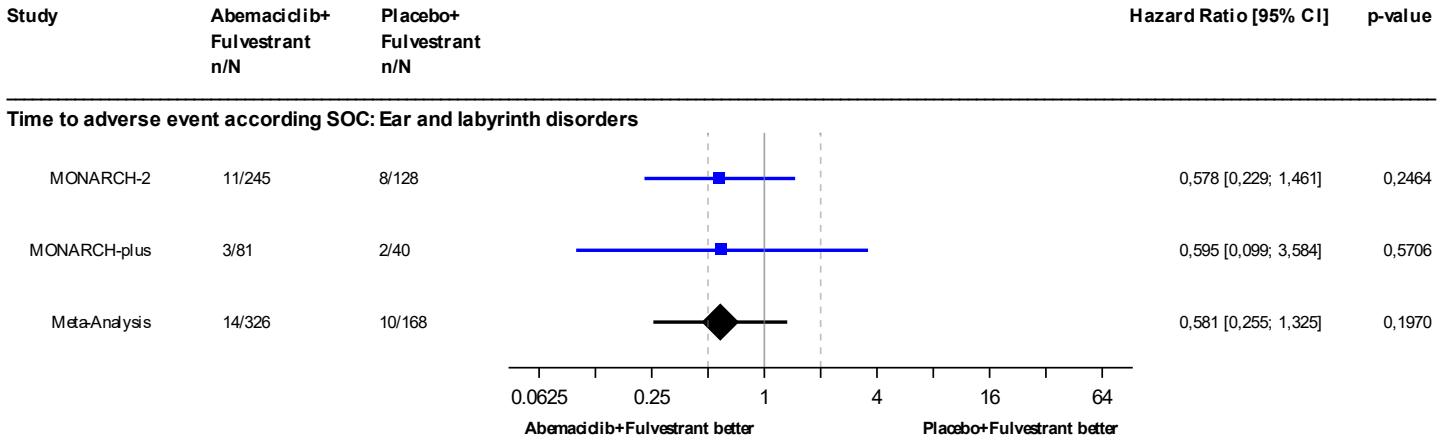
**Figure 1253: Metaanalysis results for adverse events according SOC[1] -
Ear and labyrinth disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0008, p-value=0,9780, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes003_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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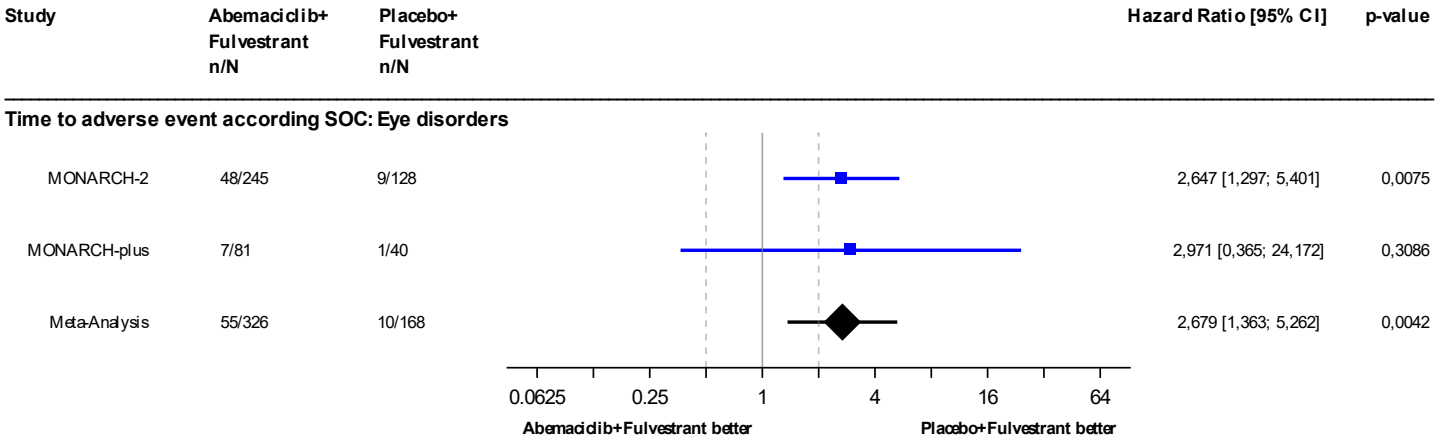
Figure 1254: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0105, p-value=0,9184, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes004_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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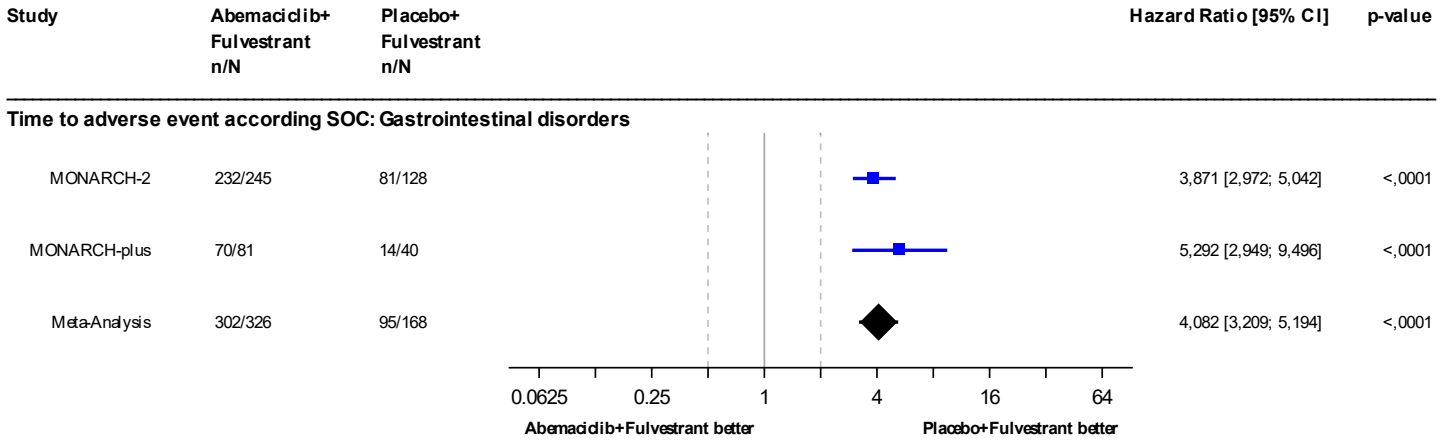
**Figure 1255: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,9125, p-value=0,3394, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes005_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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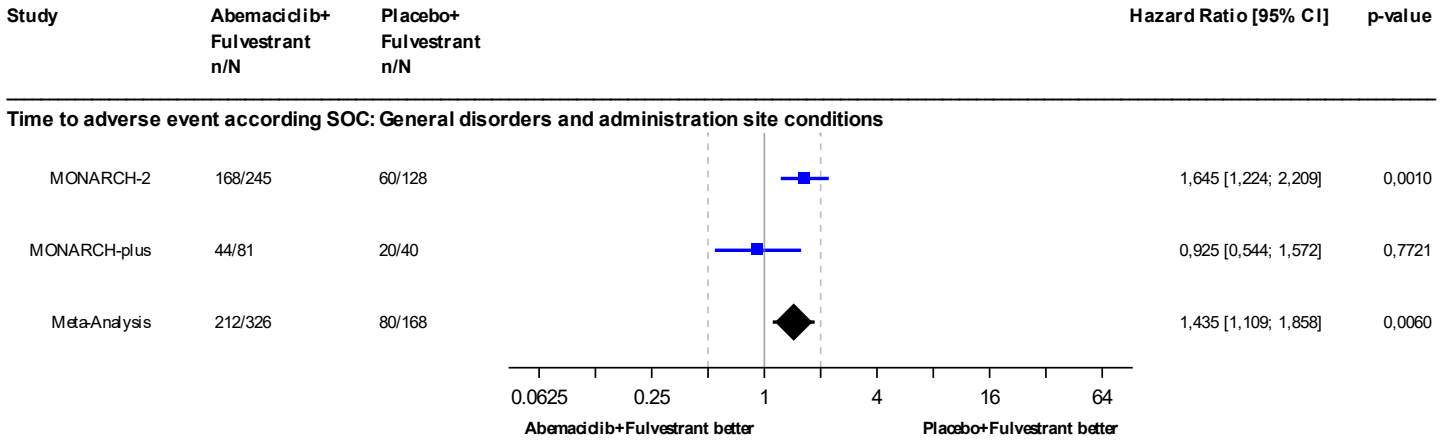
**Figure 1256: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=3,4512, p-value=0,0632, I2 index=71,0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes006_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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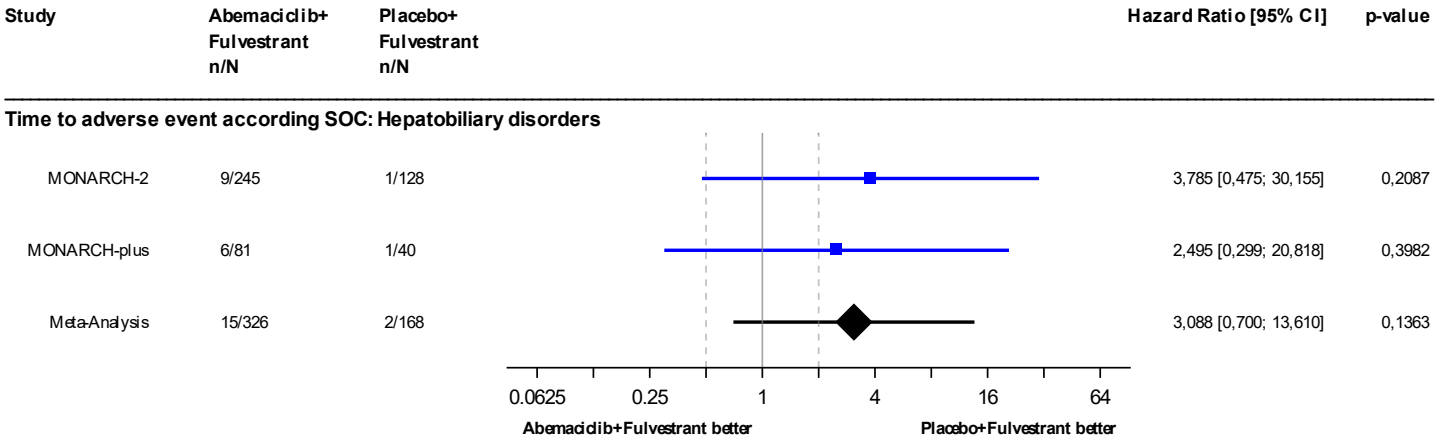
Figure 1257: Metaanalysis results for adverse events according SOC[1] - Hepatobiliary disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0757, p-value=0,7832, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes007_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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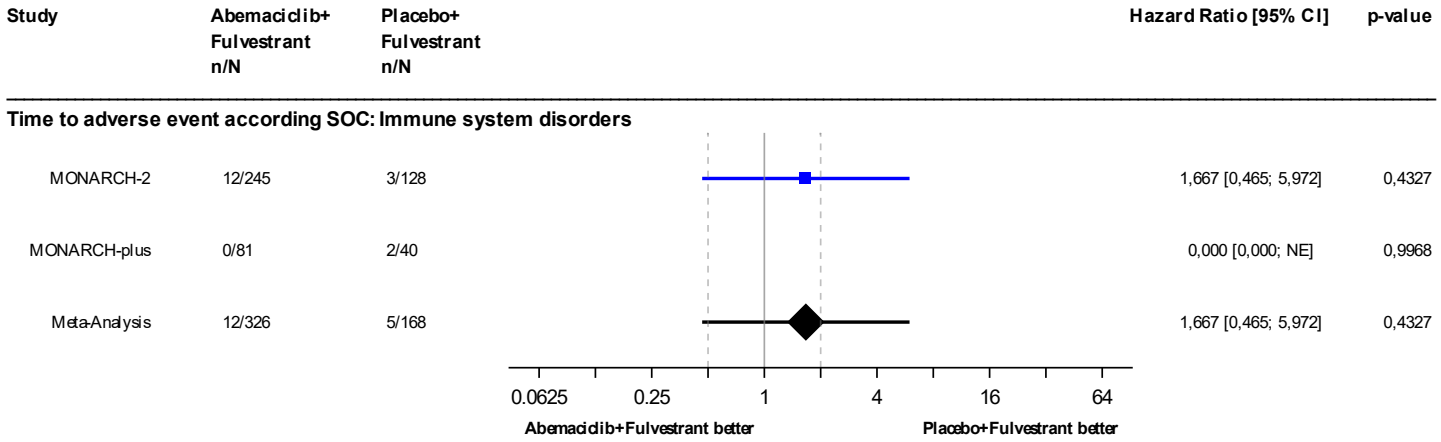
Figure 1258: Metaanalysis results for adverse events according SOC[1] -
Immune system disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9967, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes008_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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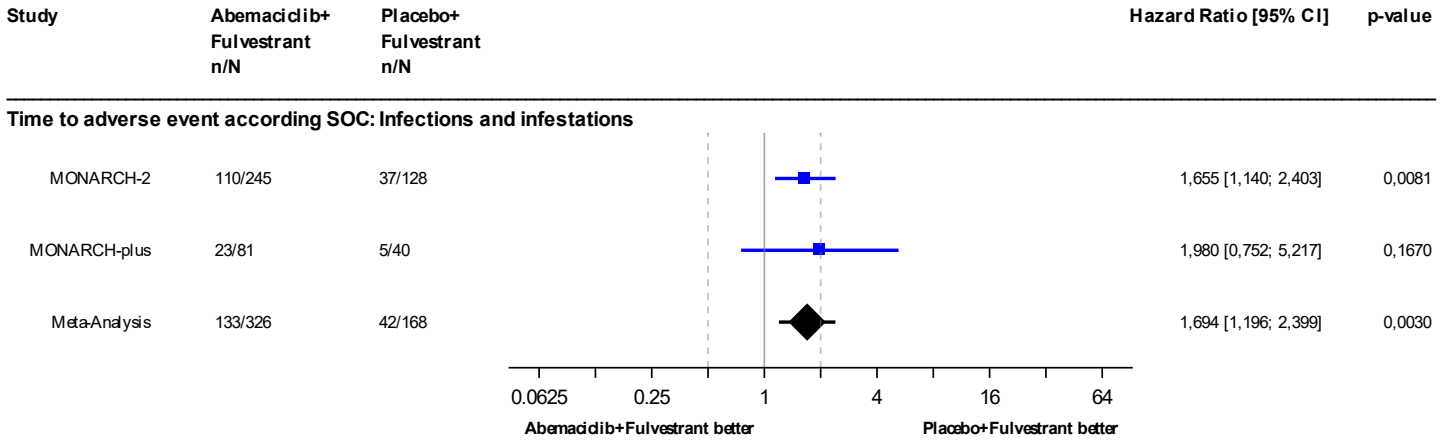
**Figure 1259: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,1146, p-value=0,7350, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes009_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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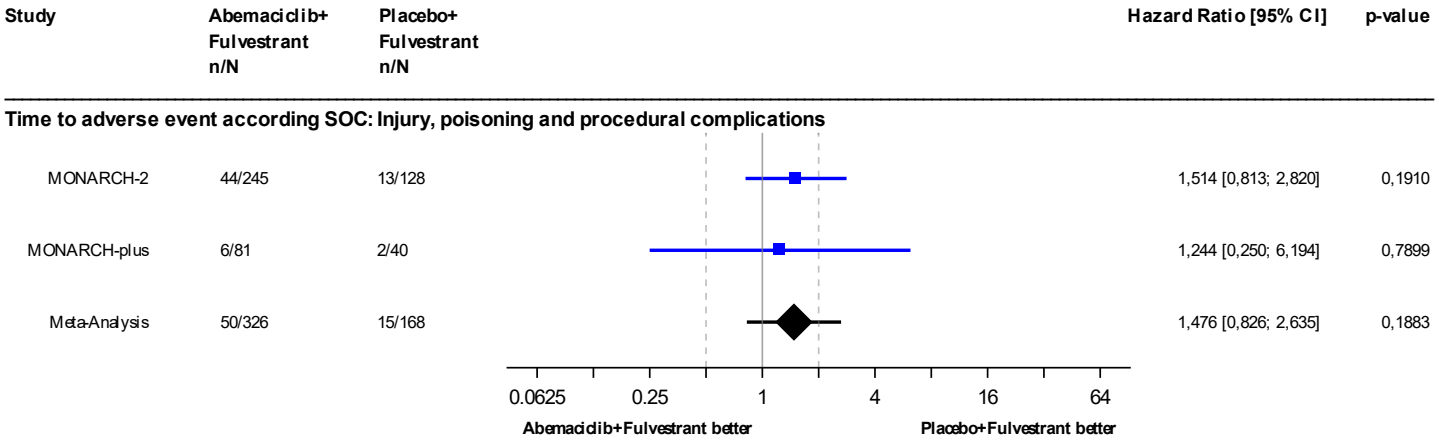
**Figure 1260: Metaanalysis results for adverse events according SOC[1] -
Injury, poisoning and procedural complications
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0501, p-value=0,8229, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes010_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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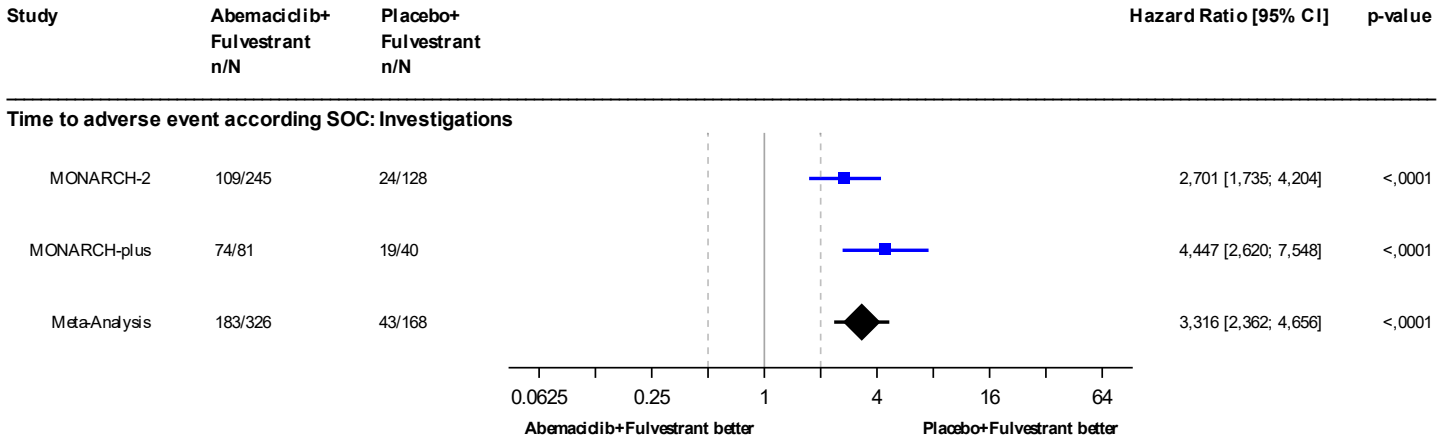
Figure 1261: Metaanalysis results for adverse events according SOC[1] - Investigations
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,0082, p-value=0,1565, I2 index=50,2%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes011_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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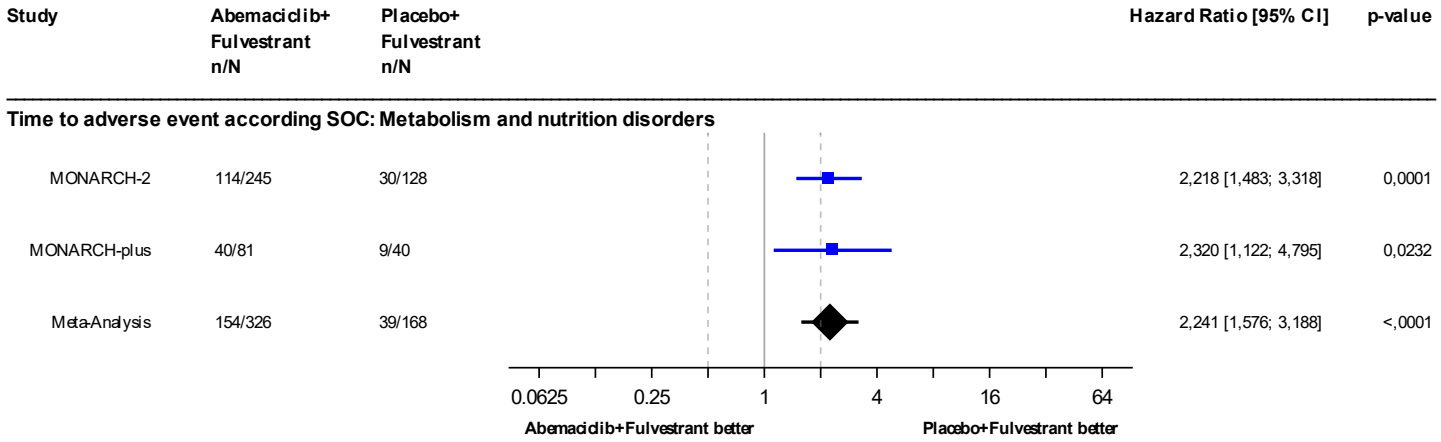
Figure 1262: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0112, p-value=0,9157, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes012_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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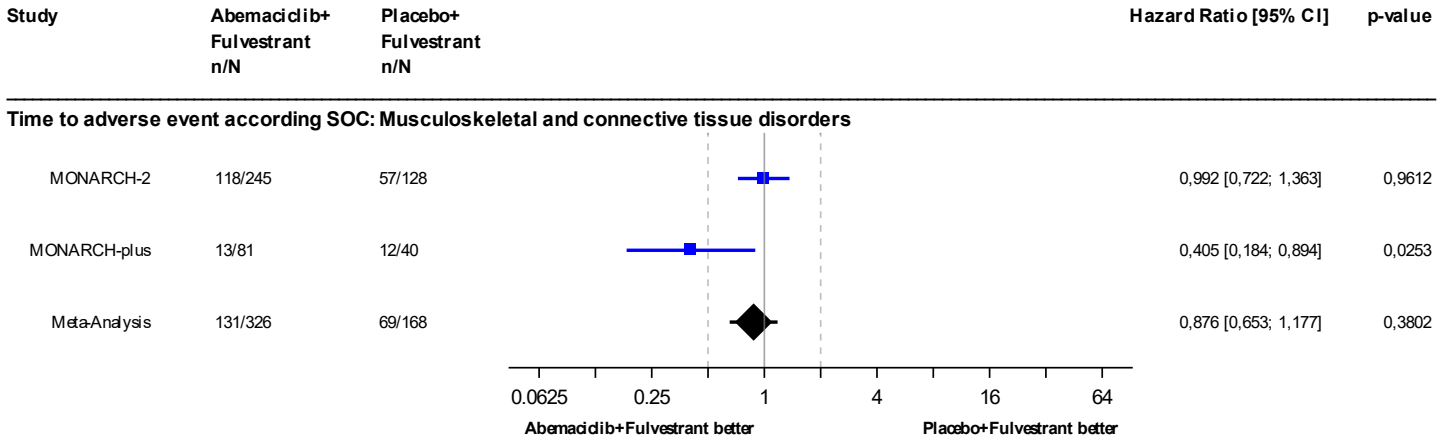
Figure 1263: Metaanalysis results for adverse events according SOC[1] - Musculoskeletal and connective tissue disorders Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=4,2338, p-value=0,0396, I2 index=76,4%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes013_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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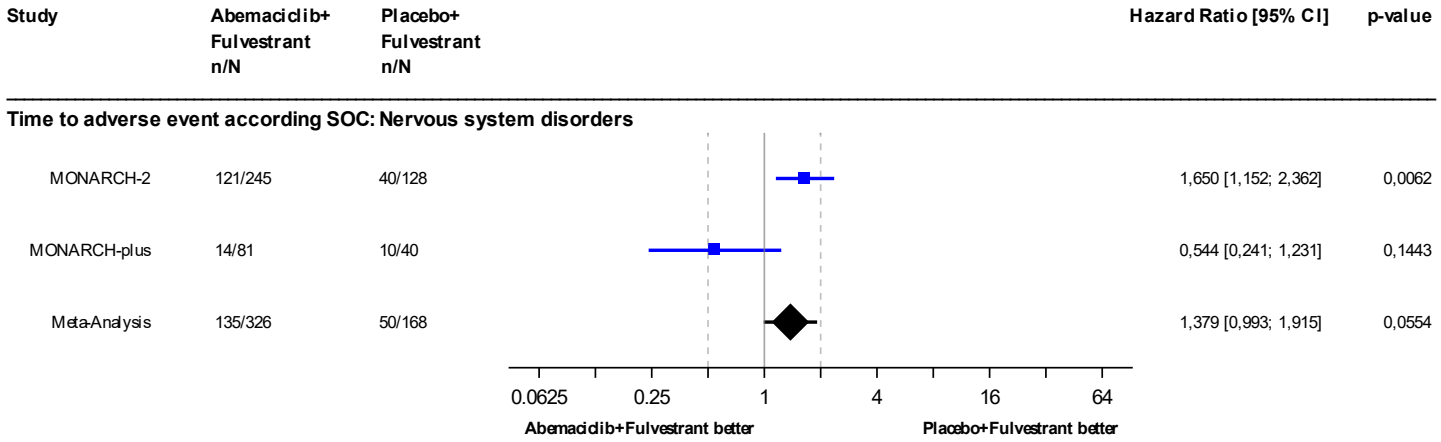
**Figure 1264: Metaanalysis results for adverse events according SOC[1] -
Nervous system disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=5,9415, p-value=0,0148, I2 index=83,2%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes014_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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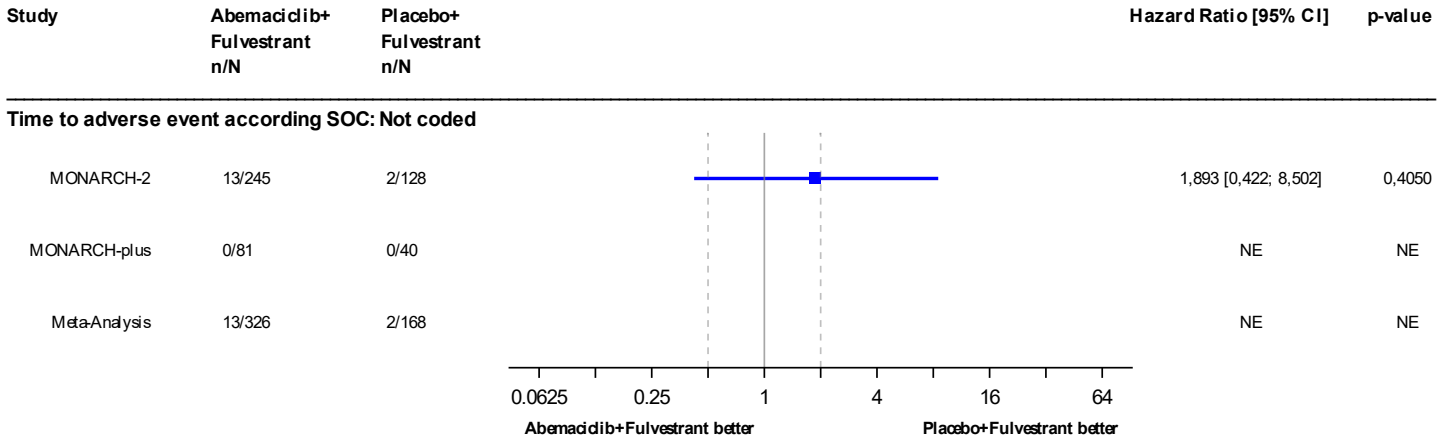
Figure 1265: Metaanalysis results for adverse events according SOC[1] -
Not coded
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes015_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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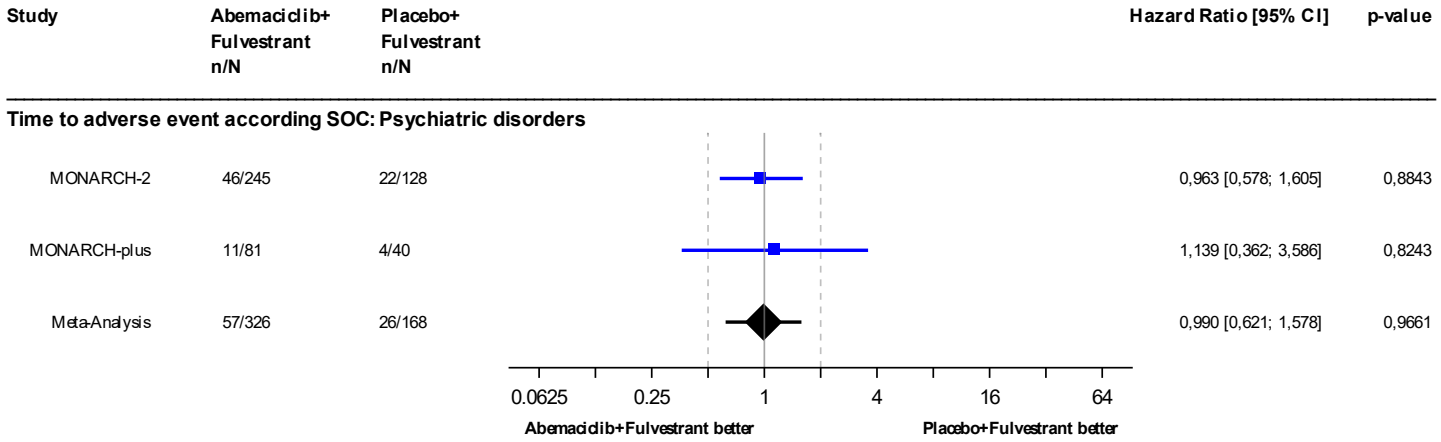
Figure 1266: Metaanalysis results for adverse events according SOC[1] -
Psychiatric disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0687, p-value=0,7933, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes016_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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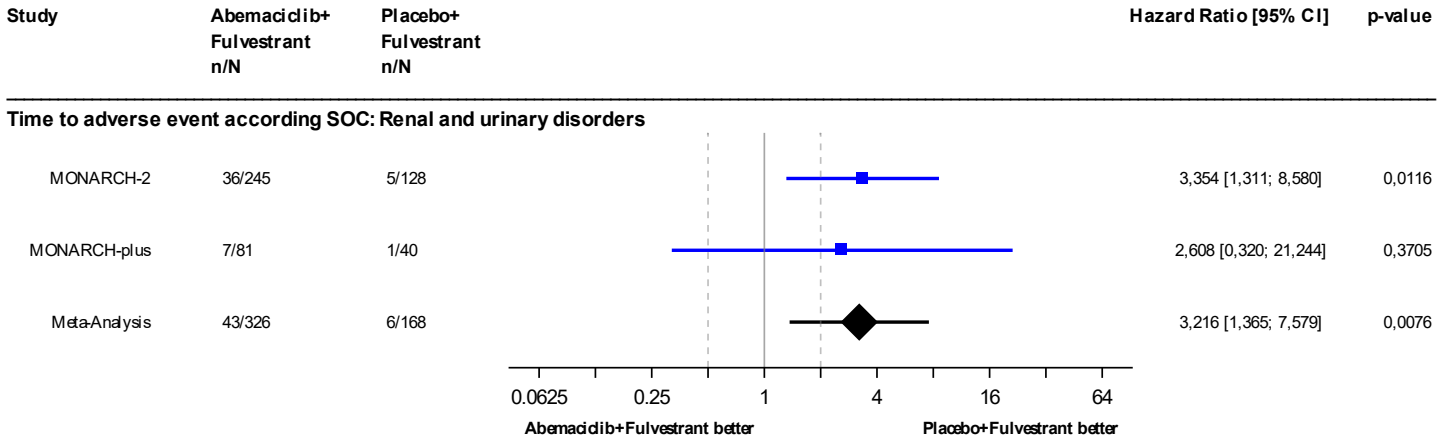
**Figure 1267: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0461, p-value=0,8300, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes017_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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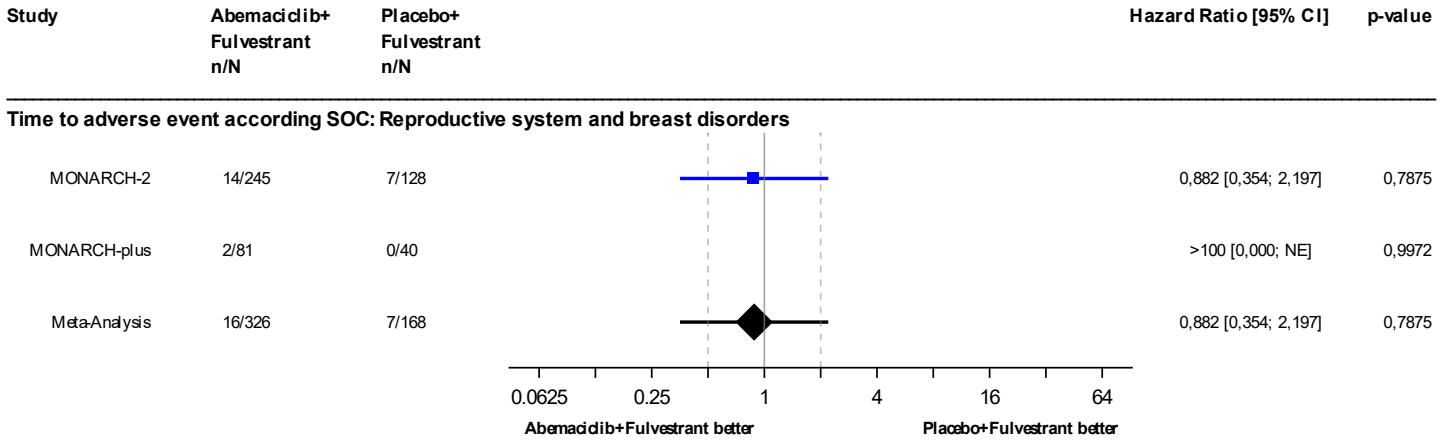
**Figure 1268: Metaanalysis results for adverse events according SOC[1] -
Reproductive system and breast disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9971, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes018_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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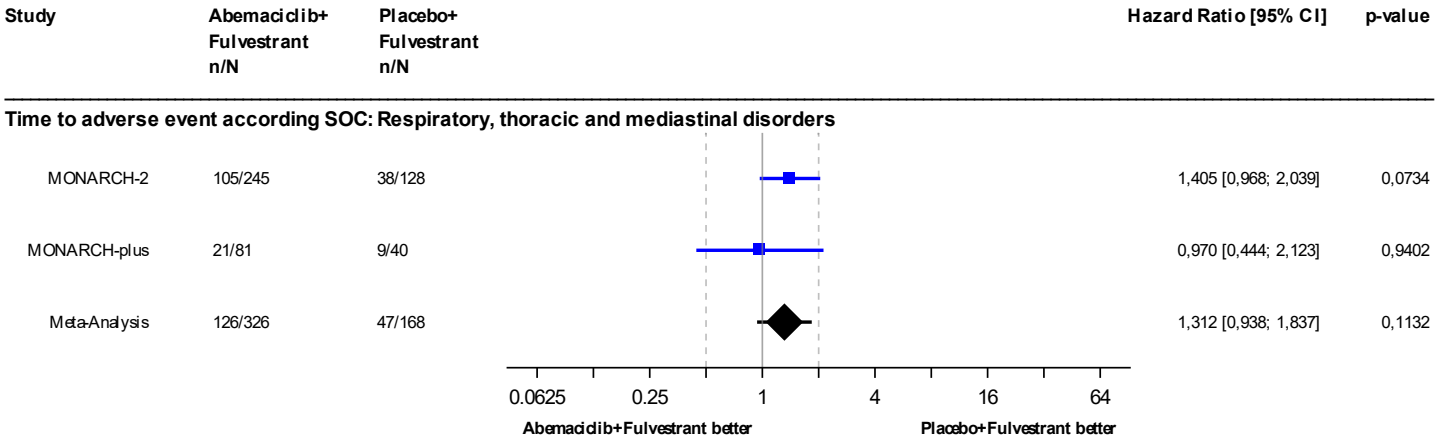
Figure 1269: Metaanalysis results for adverse events according SOC[1] - Respiratory, thoracic and mediastinal disorders Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,7004, p-value=0,4026, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes019_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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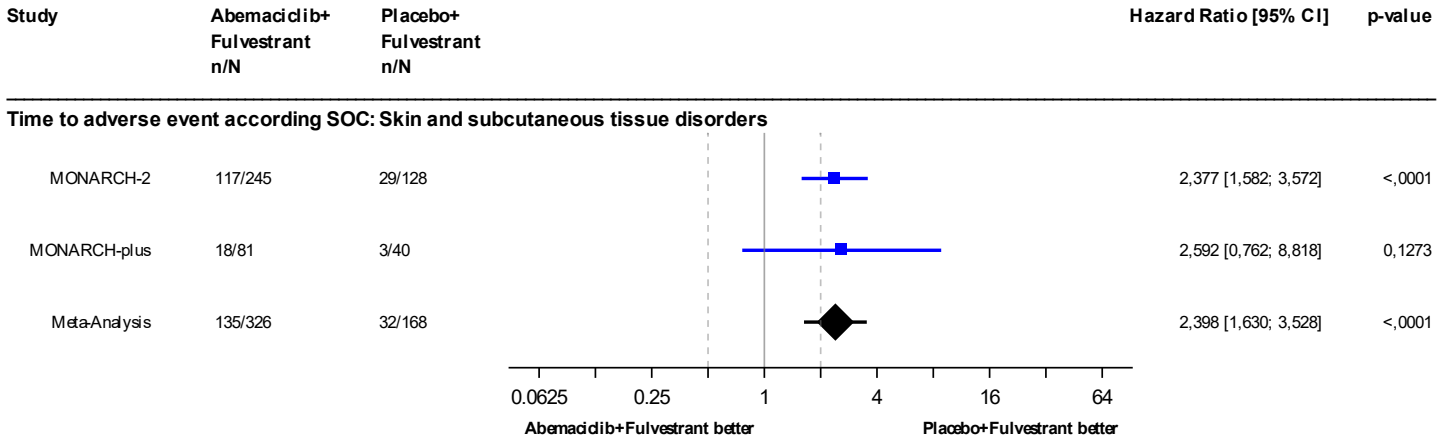
**Figure 1270: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0173, p-value=0,8955, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes020_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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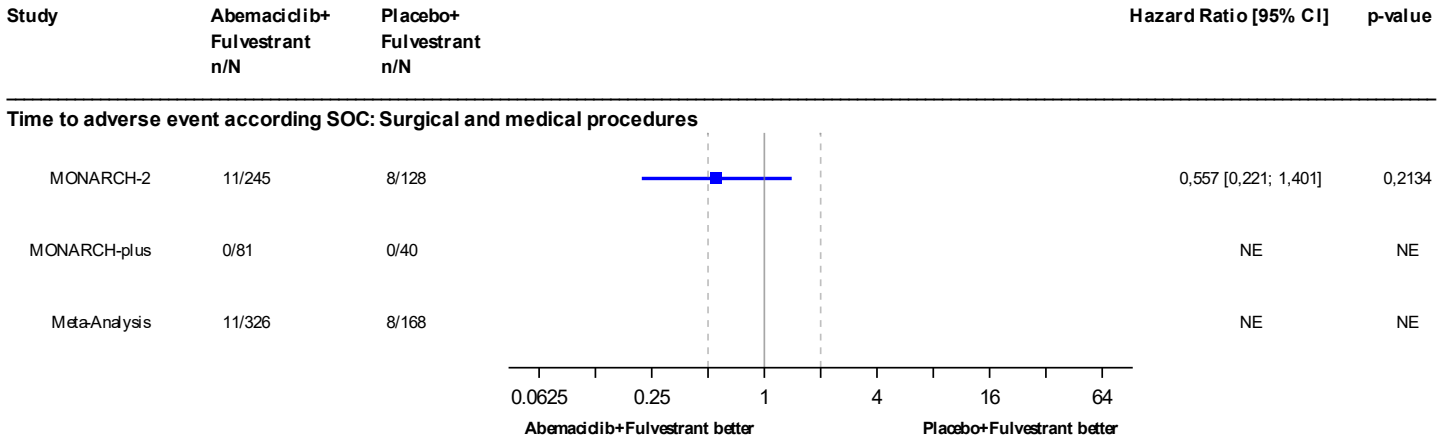
**Figure 1271: Metaanalysis results for adverse events according SOC[1] -
Surgical and medical procedures
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes021_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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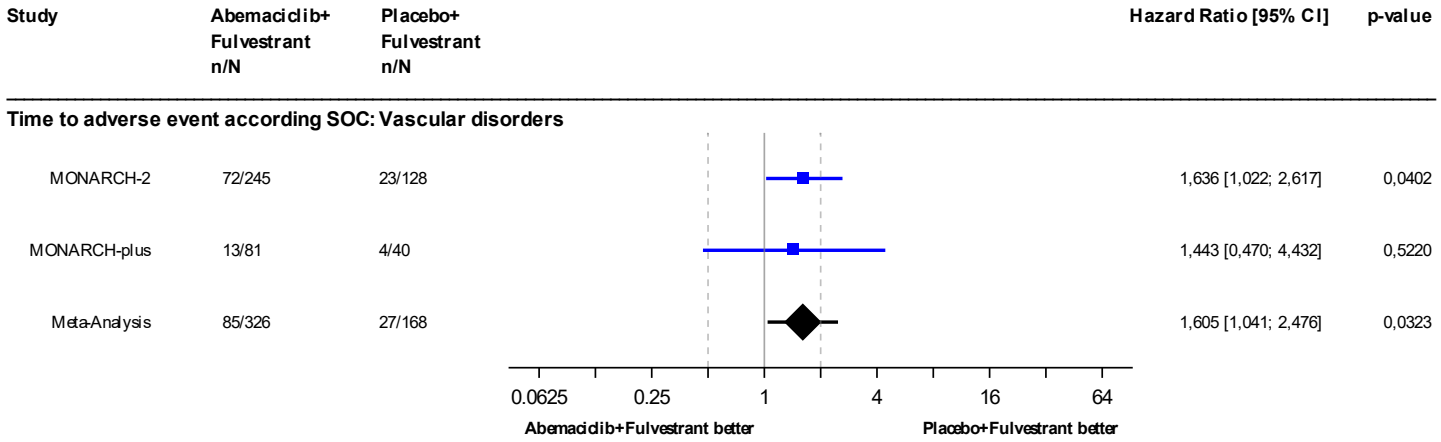
Figure 1272: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0408, p-value=0,8400, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes022_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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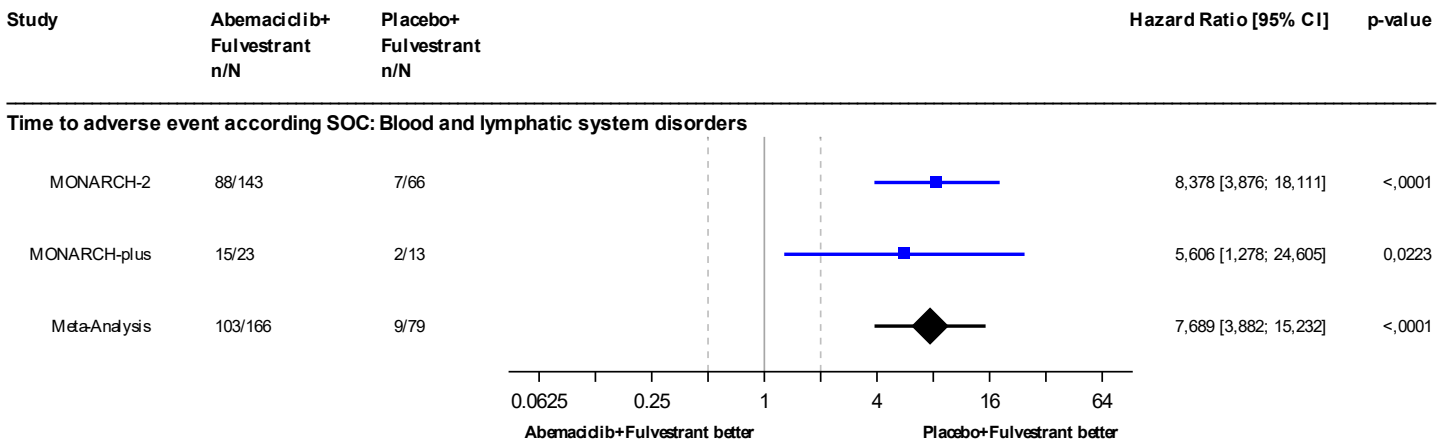
Figure 1273: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2229, p-value=0,6368, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes001_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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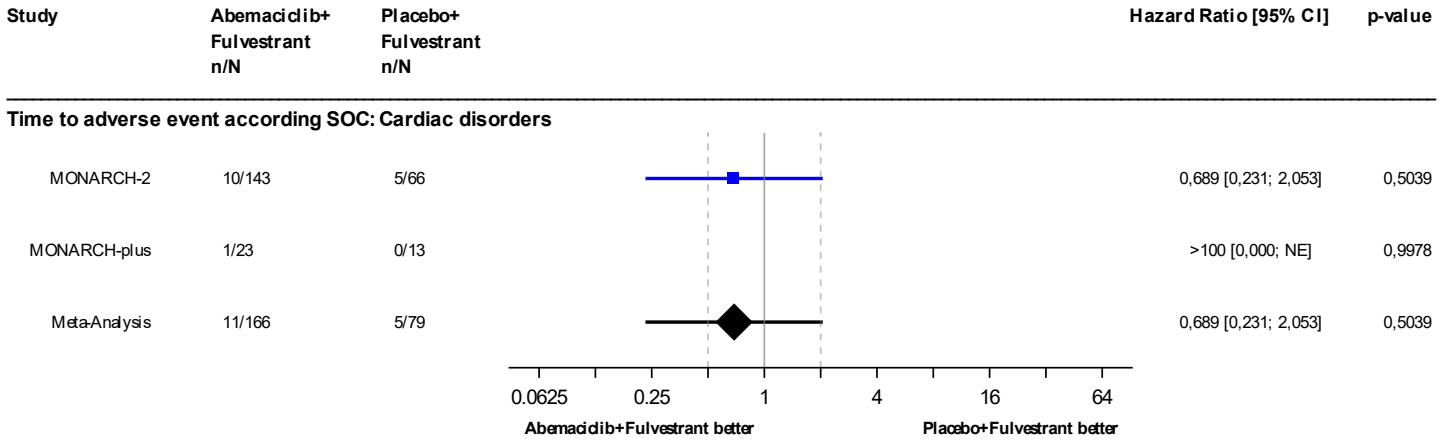
Figure 1274: Metaanalysis results for adverse events according SOC[1] -
Cardiac disorders
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9977, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes002_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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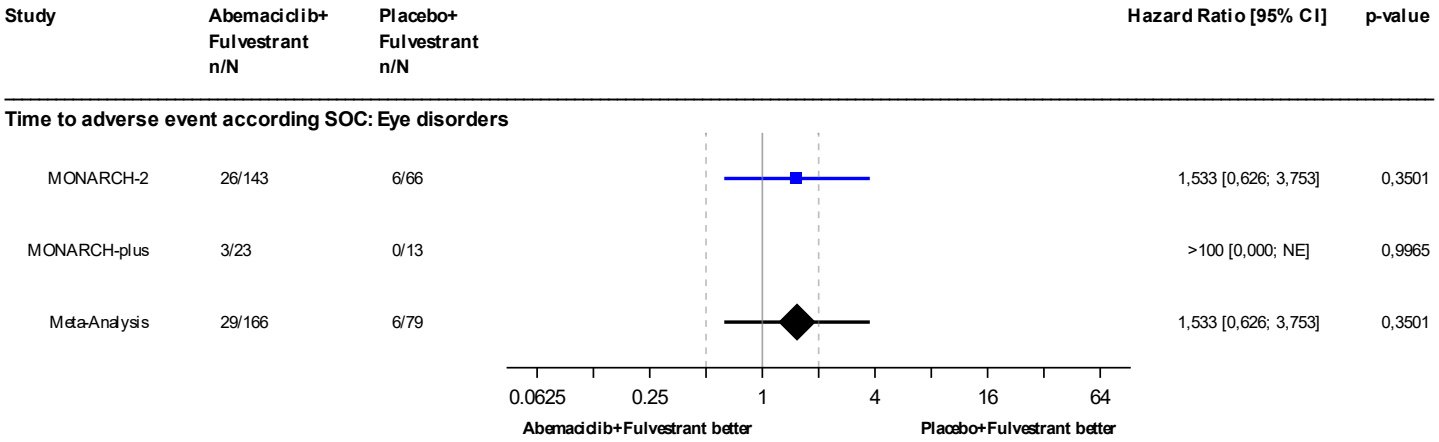
Figure 1275: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9966, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes003_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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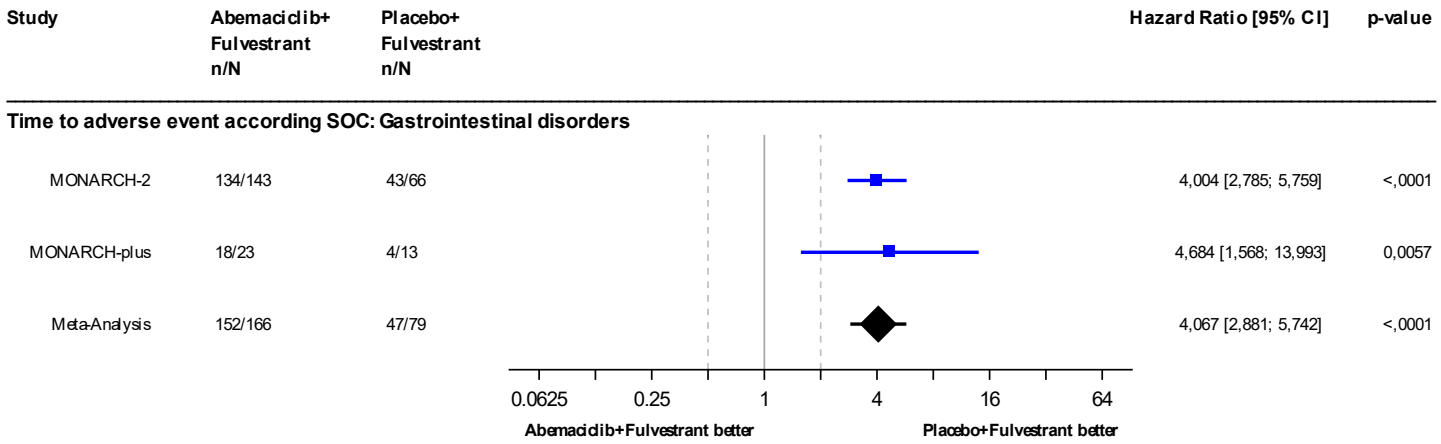
Figure 1276: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0711, p-value=0,7898, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes004_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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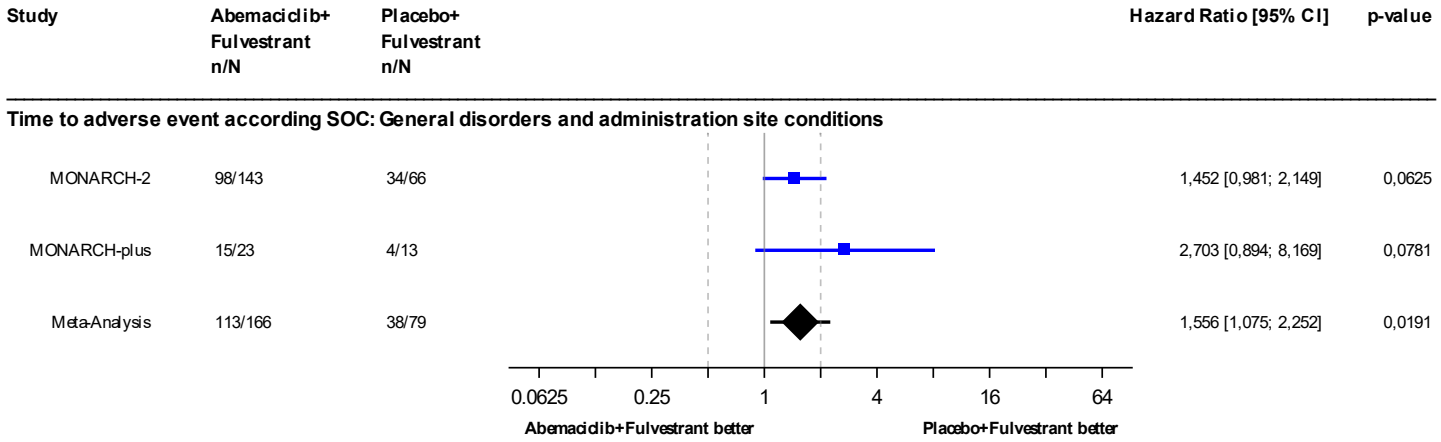
**Figure 1277: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=1,0778, p-value=0,2992, I2 index=7,2%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes005_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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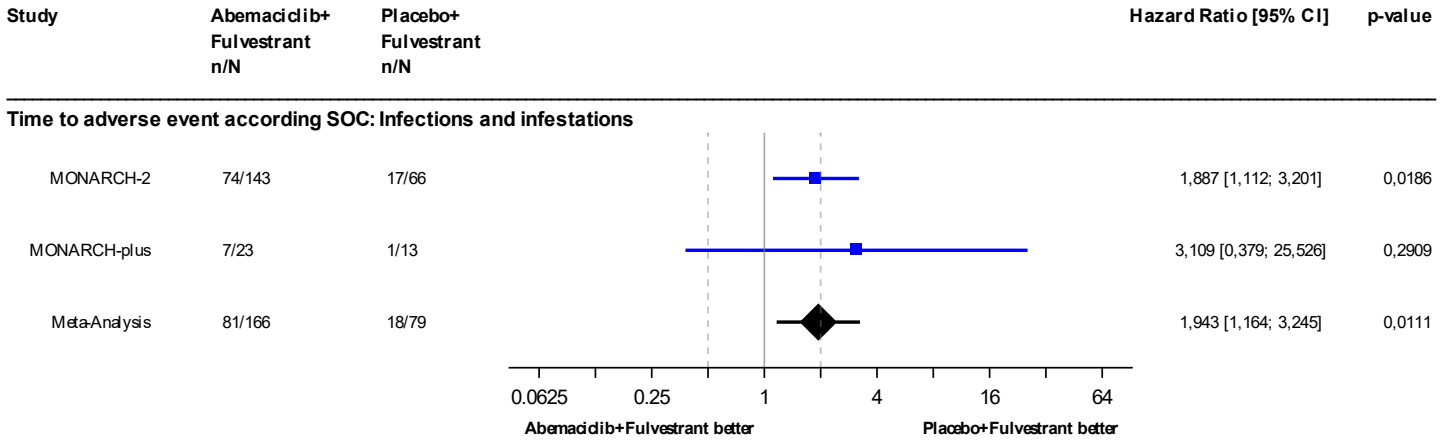
**Figure 1278: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,2035, p-value=0,6519, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes006_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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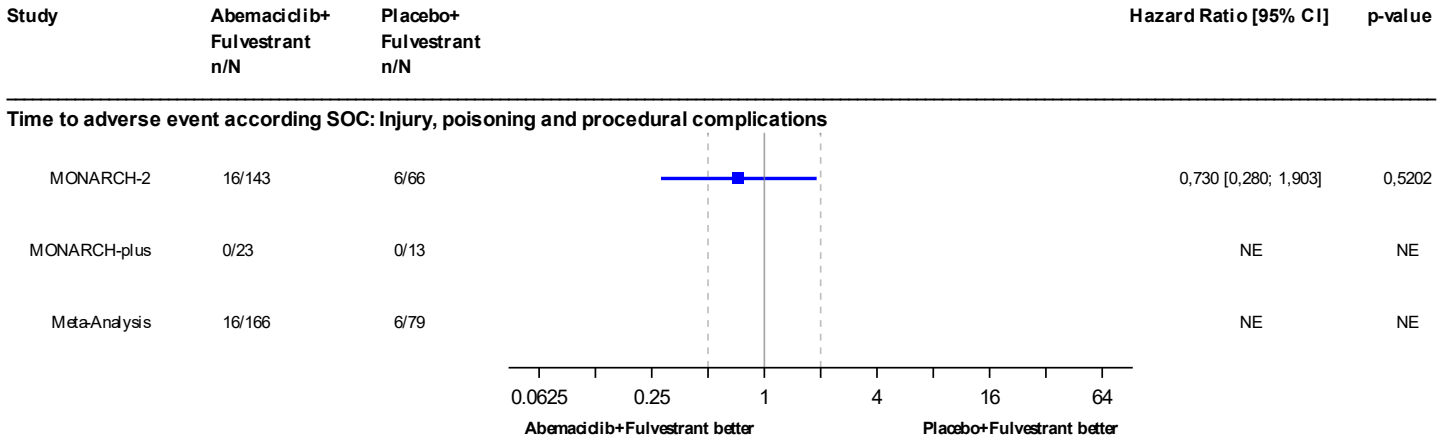
**Figure 1279: Metaanalysis results for adverse events according SOC[1] -
Injury, poisoning and procedural complications
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes007_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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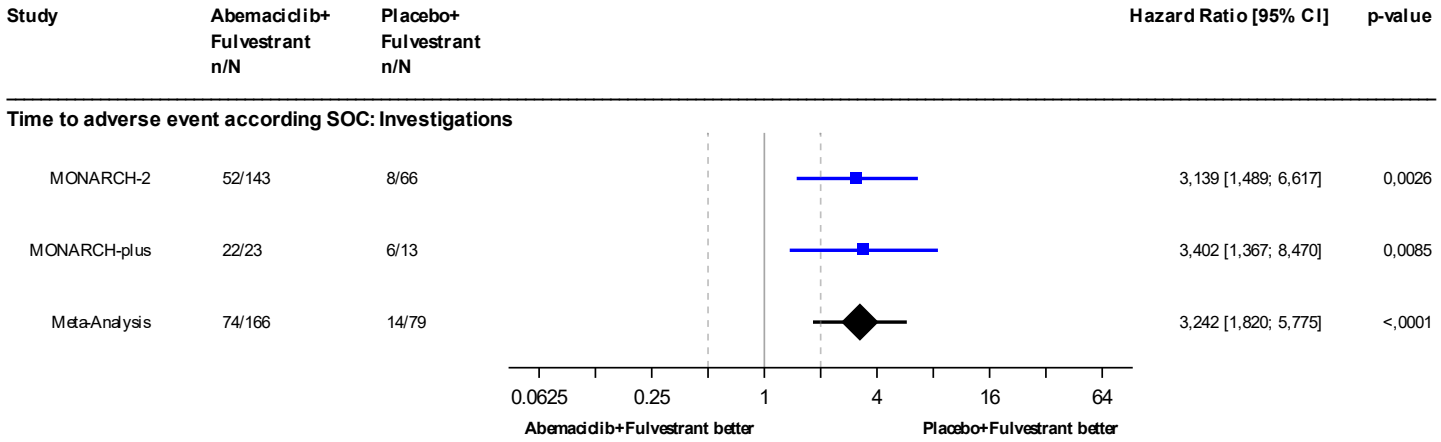
Figure 1280: Metaanalysis results for adverse events according SOC[1] - Investigations
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0180, p-value=0,8934, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes008_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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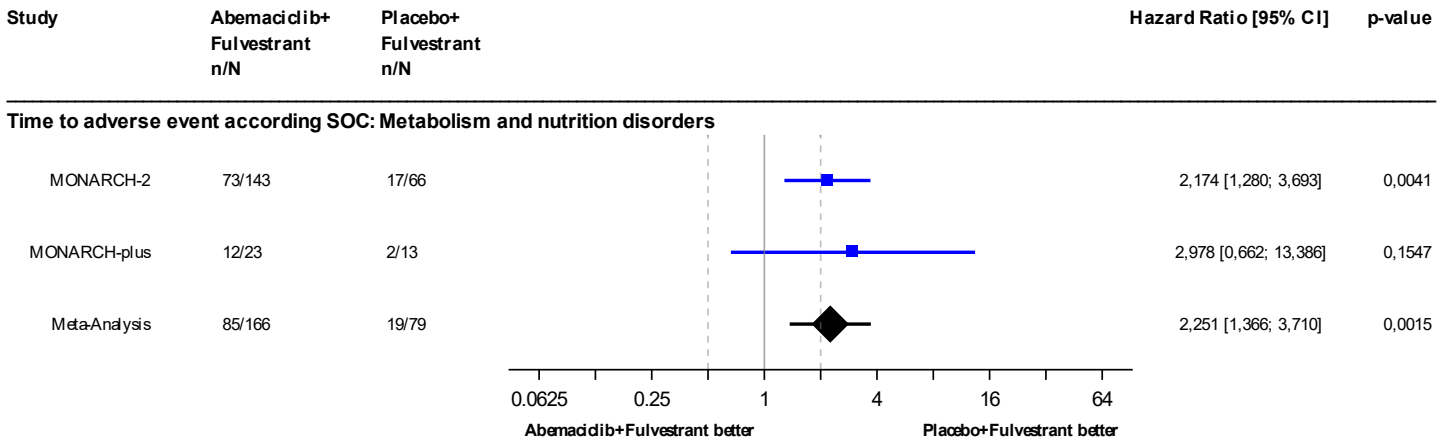
Figure 1281: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1497, p-value=0,6989, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes009_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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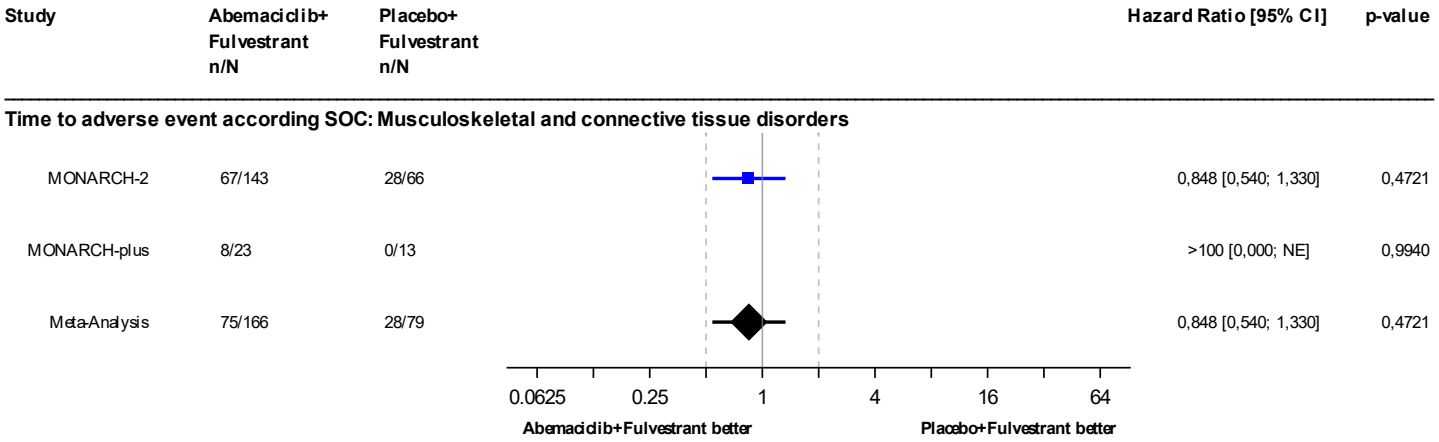
Figure 1282: Metaanalysis results for adverse events according SOC[1] - Musculoskeletal and connective tissue disorders Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9939, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes010_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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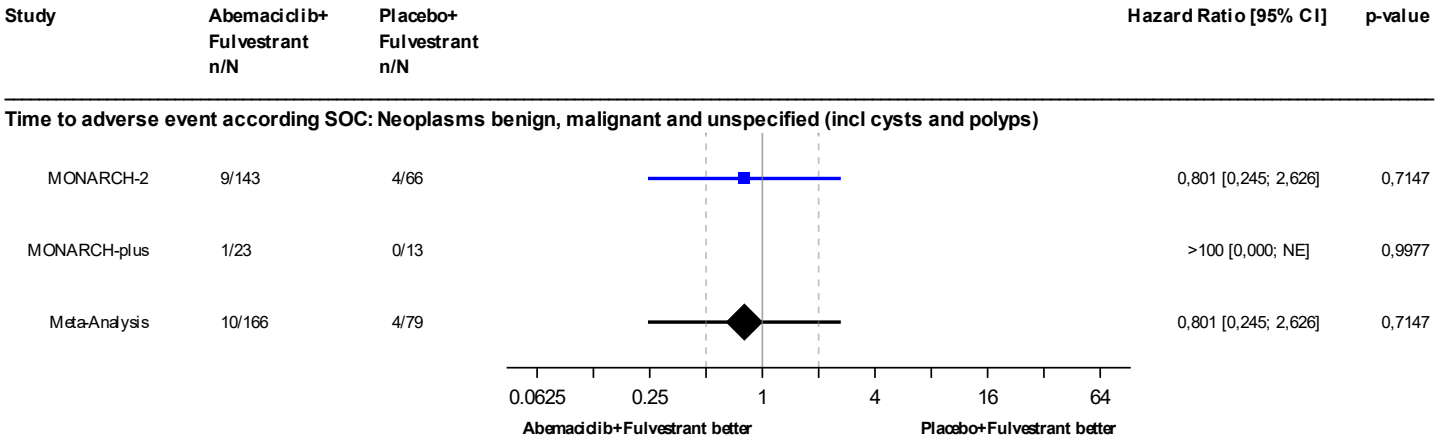
**Figure 1283: Metaanalysis results for adverse events according SOC[1] -
Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9976, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes011_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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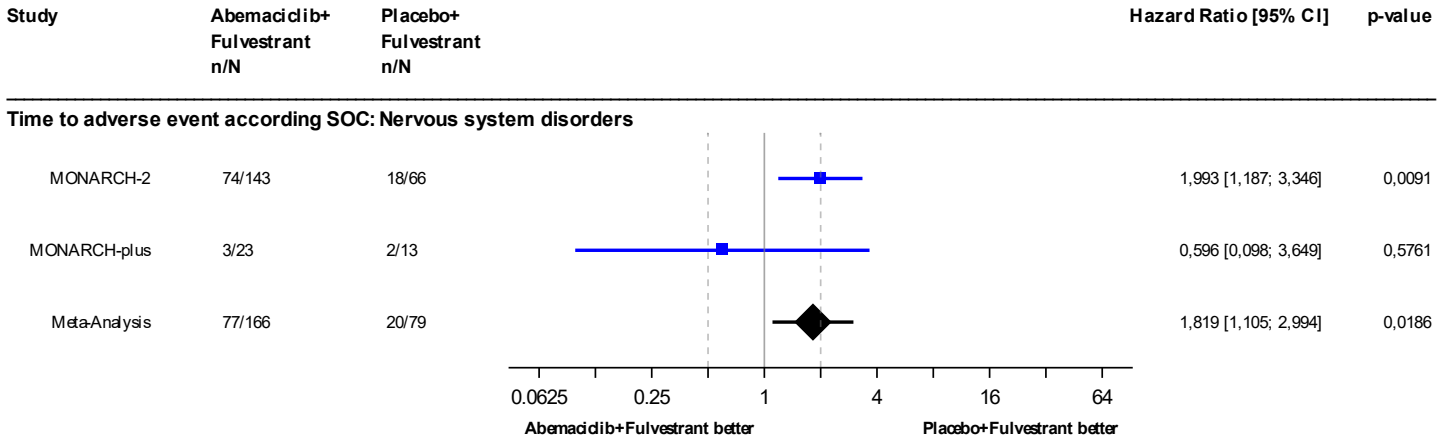
**Figure 1284: Metaanalysis results for adverse events according SOC[1] -
Nervous system disorders
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=1,5752, p-value=0,2094, I2 index=36,5%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes012_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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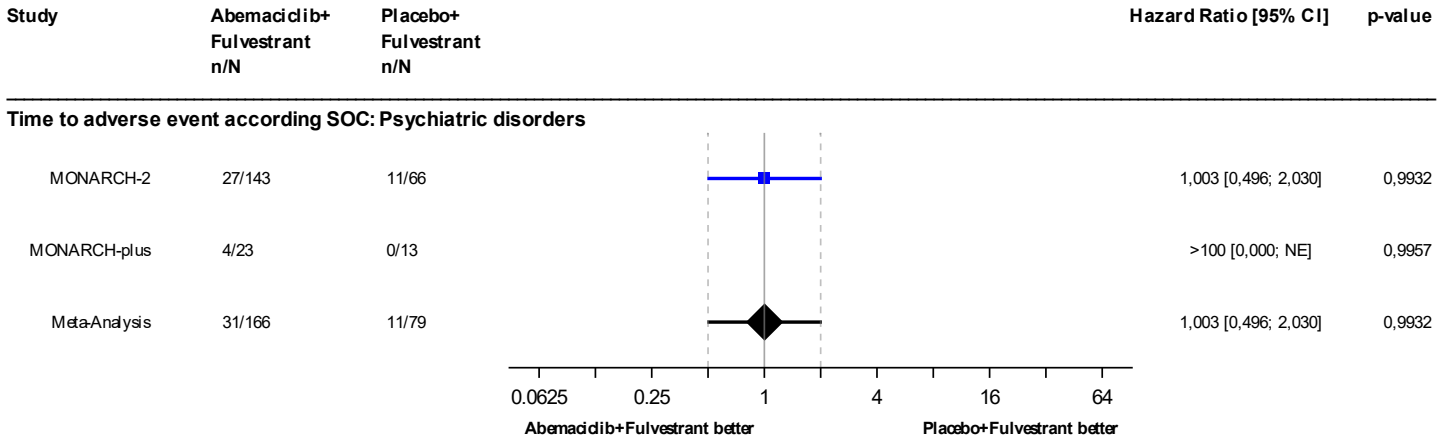
Figure 1285: Metaanalysis results for adverse events according SOC[1] -
Psychiatric disorders
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9957, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes013_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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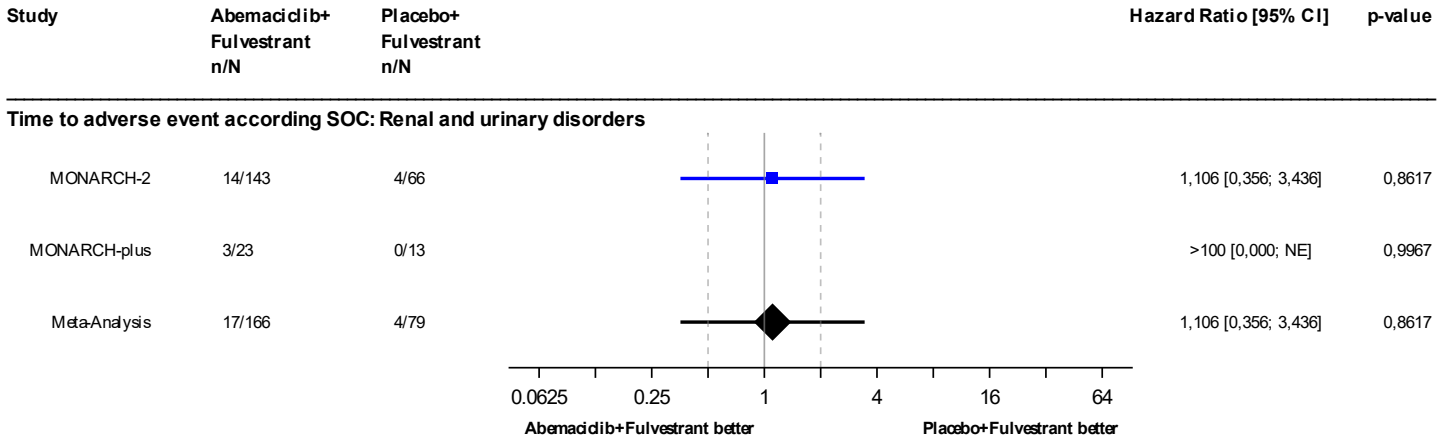
Figure 1286: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9967, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes014_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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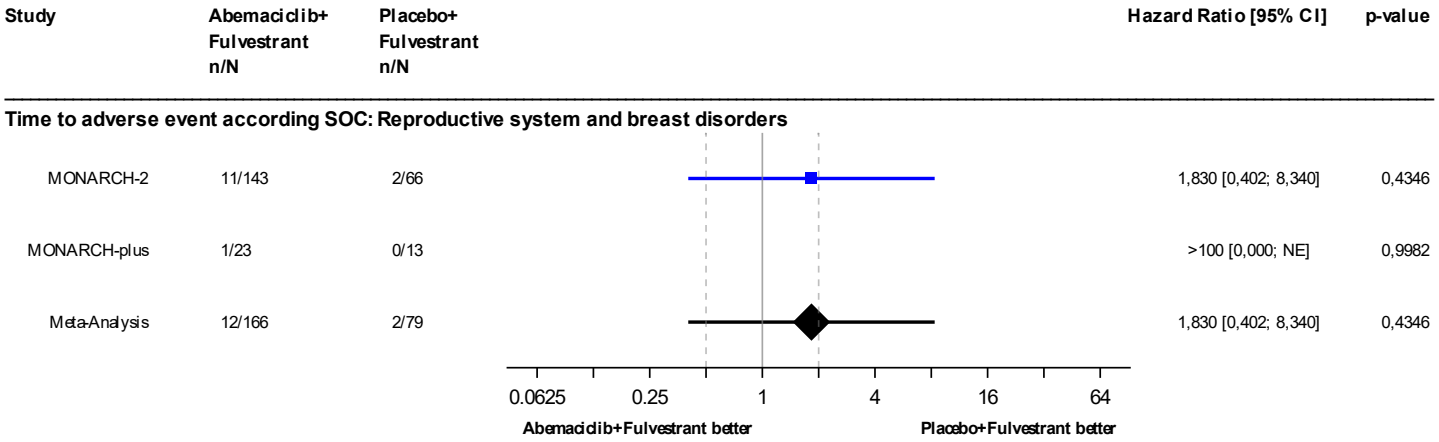
Figure 1287: Metaanalysis results for adverse events according SOC[1] -
Reproductive system and breast disorders
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9982, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes015_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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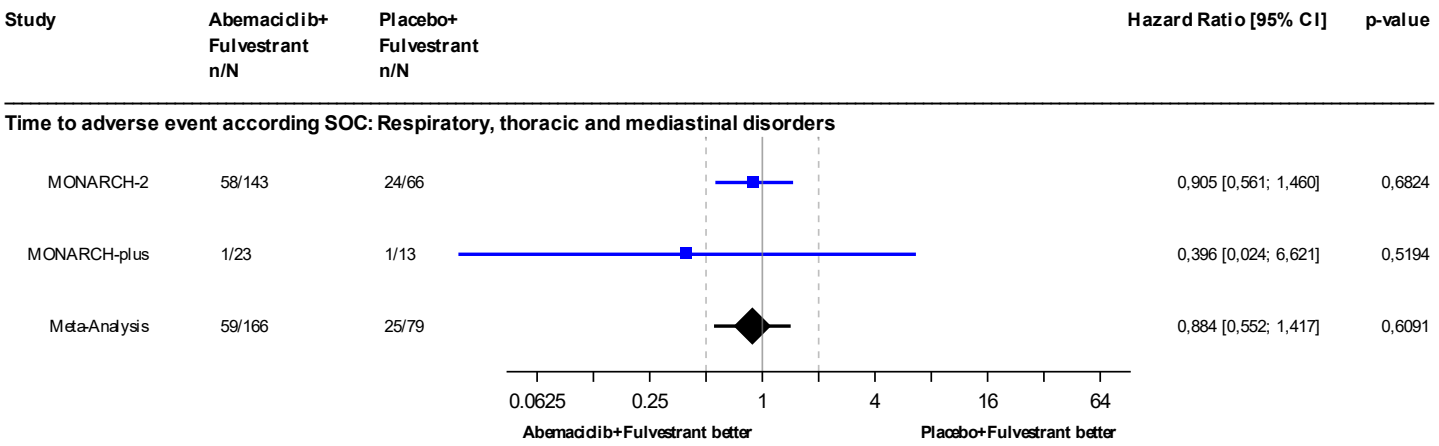
**Figure 1288: Metaanalysis results for adverse events according SOC[1] -
Respiratory, thoracic and mediastinal disorders
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,3210, p-value=0,5710, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes016_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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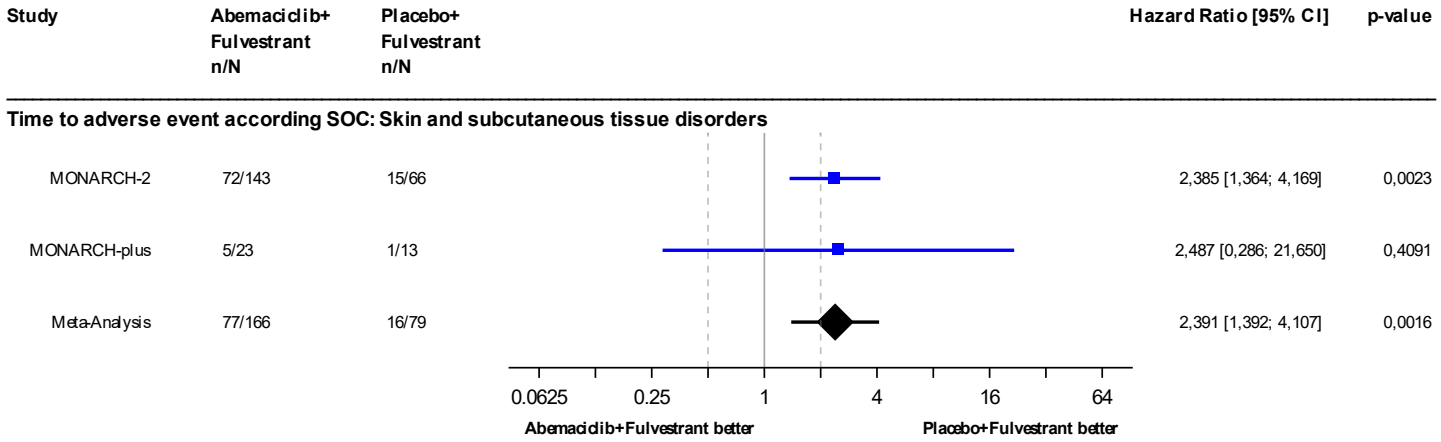
**Figure 1289: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0014, p-value=0,9705, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes017_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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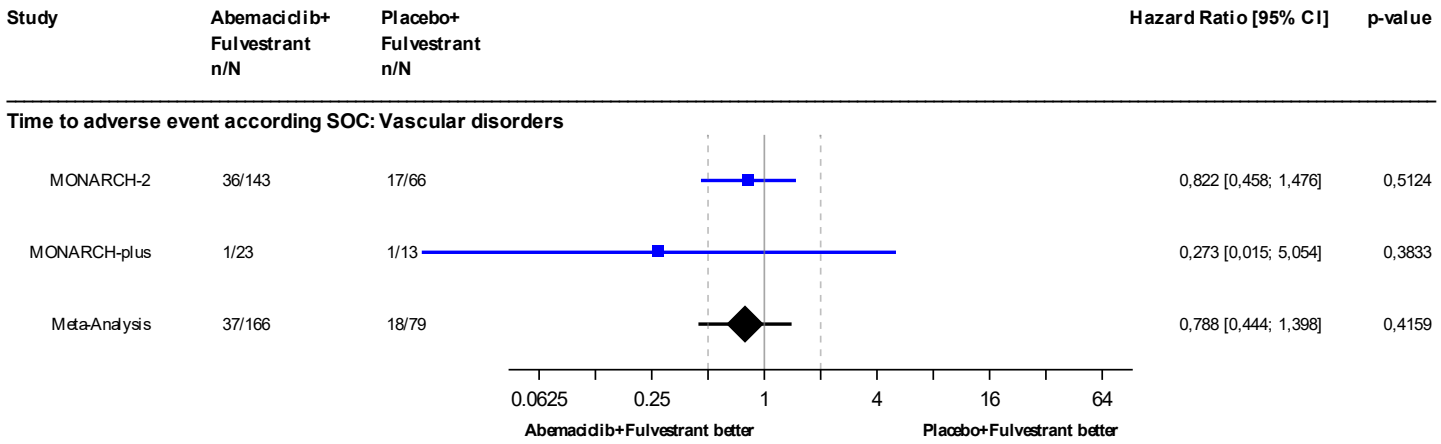
Figure 1290: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5274, p-value=0,4677, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttiraes018_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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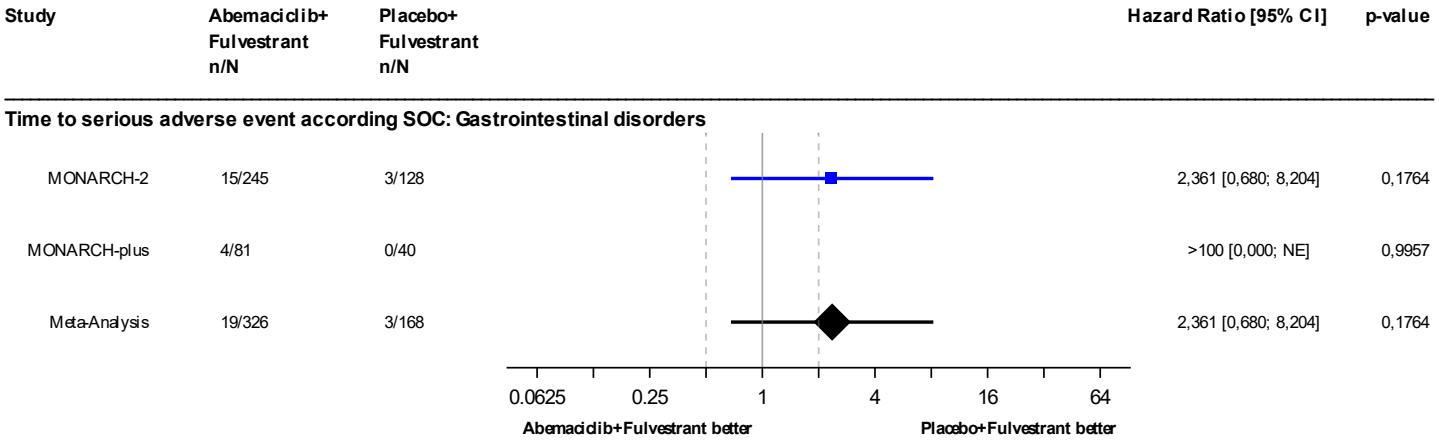
Figure 1291: Metaanalysis results for serious adverse events according SOC[1] - Gastrointestinal disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9959, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Serious adverse events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirsaes001_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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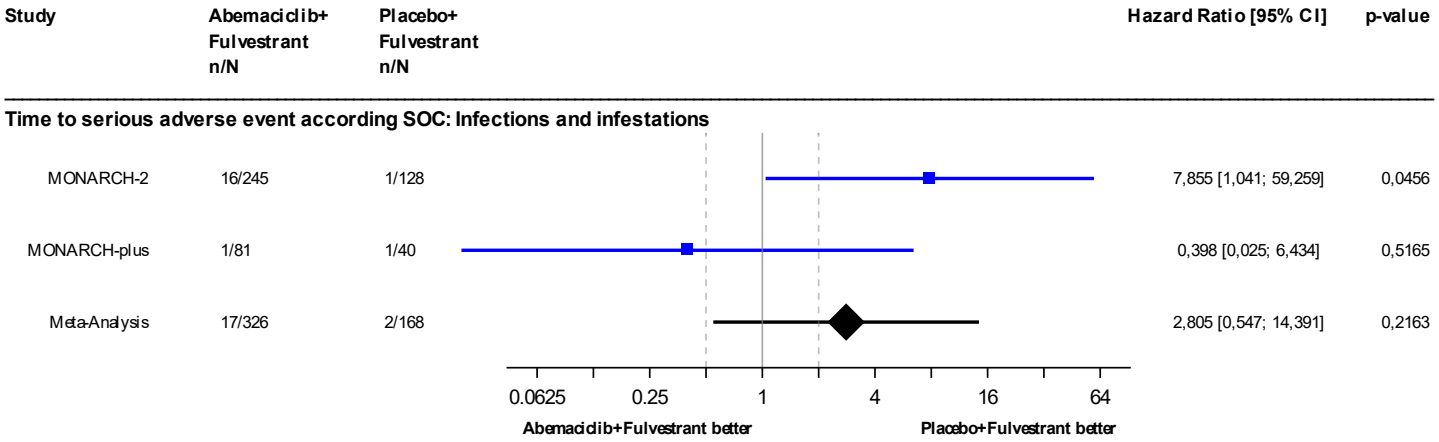
Figure 1292: Metaanalysis results for serious adverse events according SOC[1] - Infections and infestations
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,8889, p-value=0,0892, I2 index=65,4%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Serious adverse events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirsaes002_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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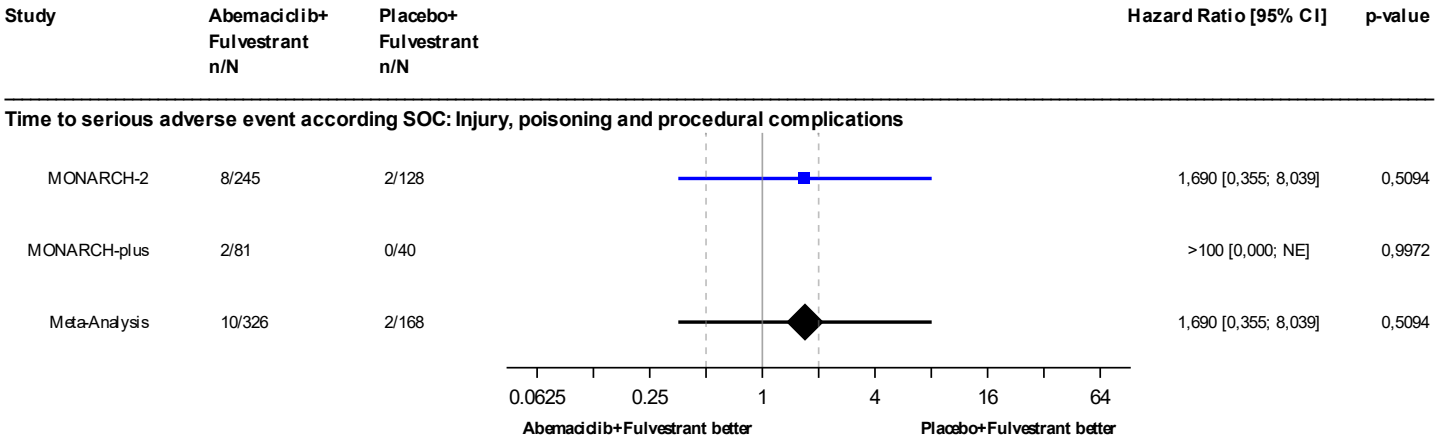
Figure 1293: Metaanalysis results for serious adverse events according SOC[1] - Injury, poisoning and procedural complications Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9973, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Serious adverse events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirsaes003_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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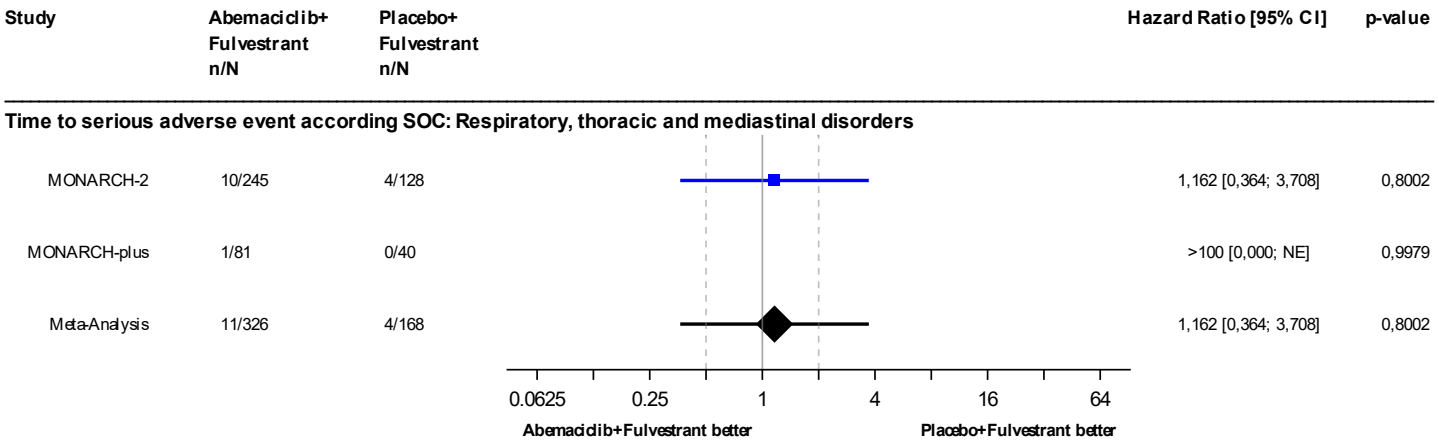
Figure 1294: Metaanalysis results for serious adverse events according SOC[1] - Respiratory, thoracic and mediastinal disorders Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9979, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Serious adverse events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirsaes004_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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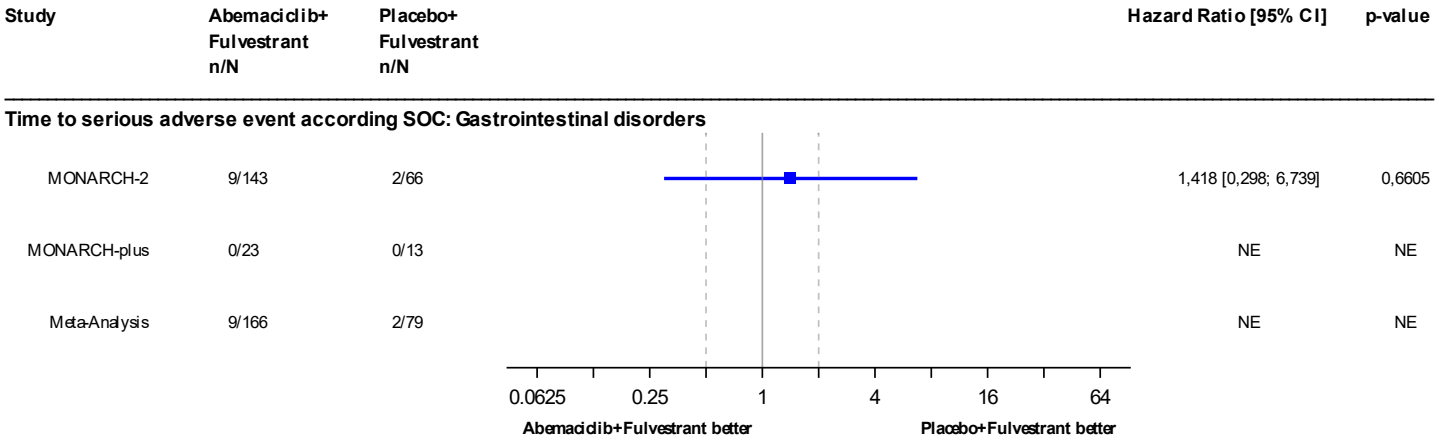
Figure 1295: Metaanalysis results for serious adverse events according SOC[1] - Gastrointestinal disorders
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Serious adverse events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirsaes001_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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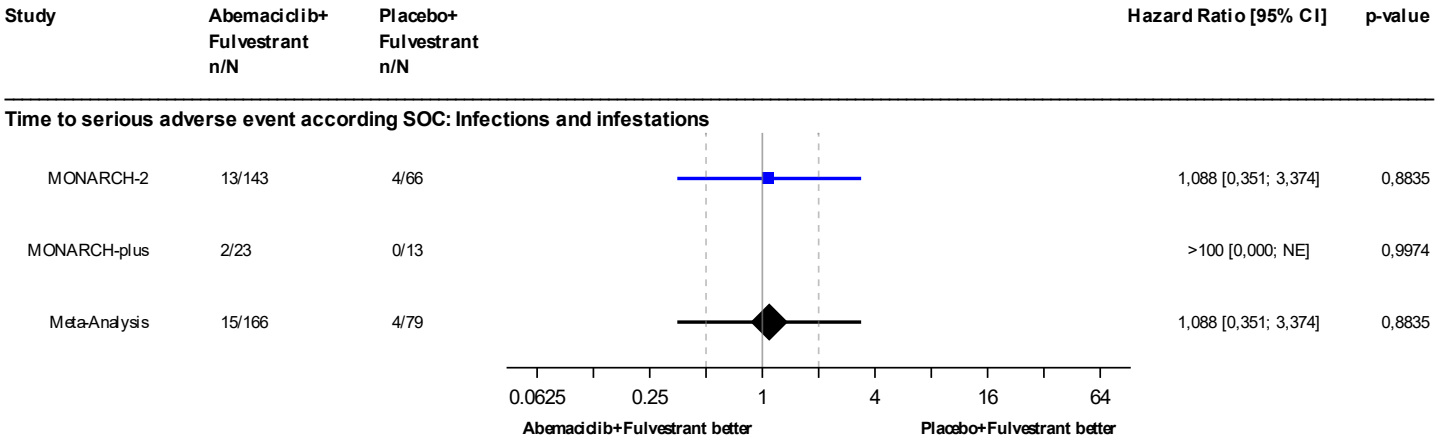
Figure 1296: Metaanalysis results for serious adverse events according SOC[1] - Infections and infestations
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9974, I2 index=0%.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Serious adverse events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirsaes002_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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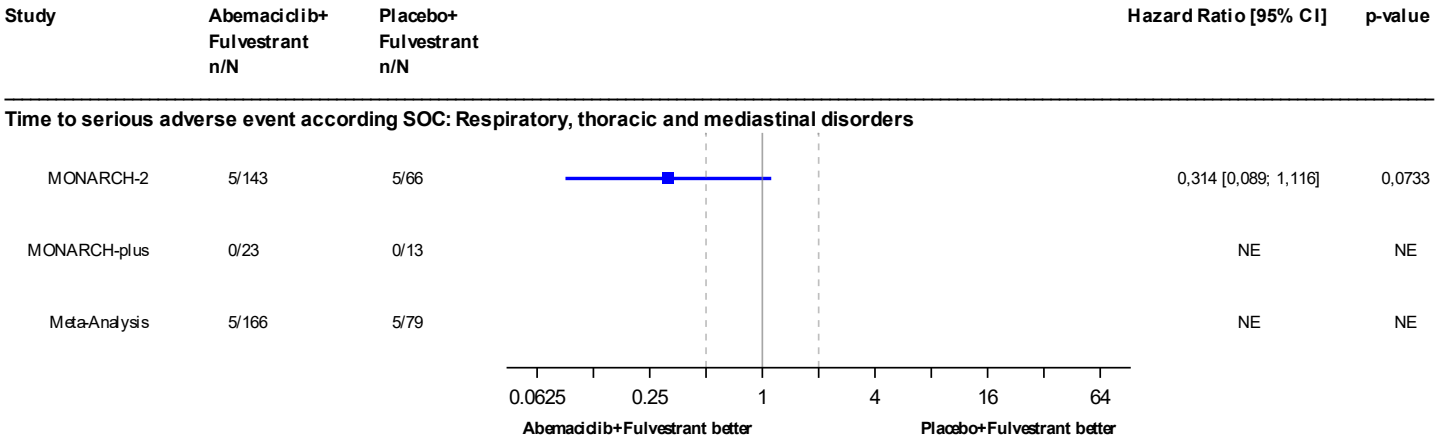
Figure 1297: Metaanalysis results for serious adverse events according SOC[1] - Respiratory, thoracic and mediastinal disorders Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Serious adverse events occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirsaes003_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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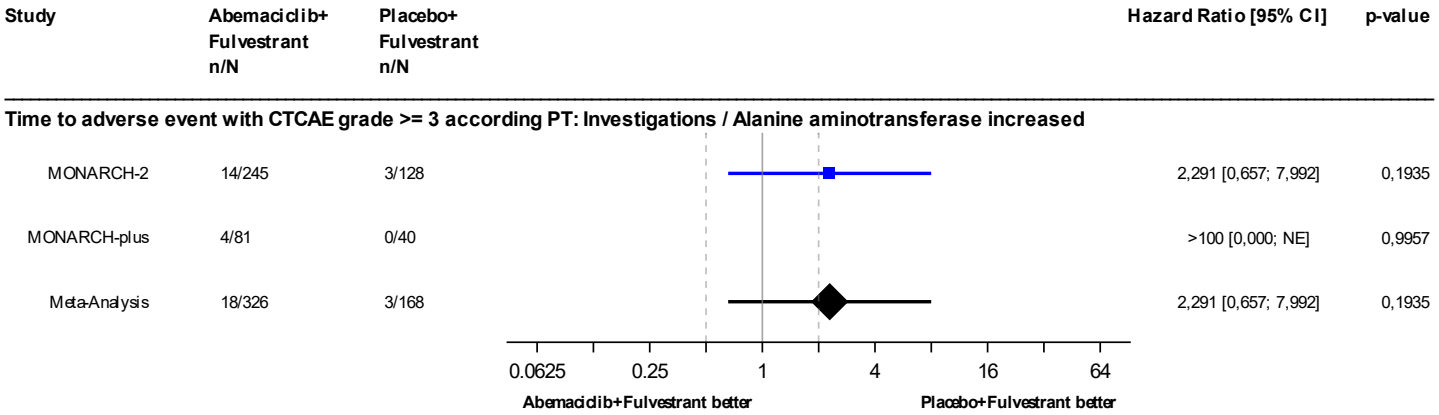
Figure 1298: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Investigations / Alanine aminotransferase increased
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9959, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3p001_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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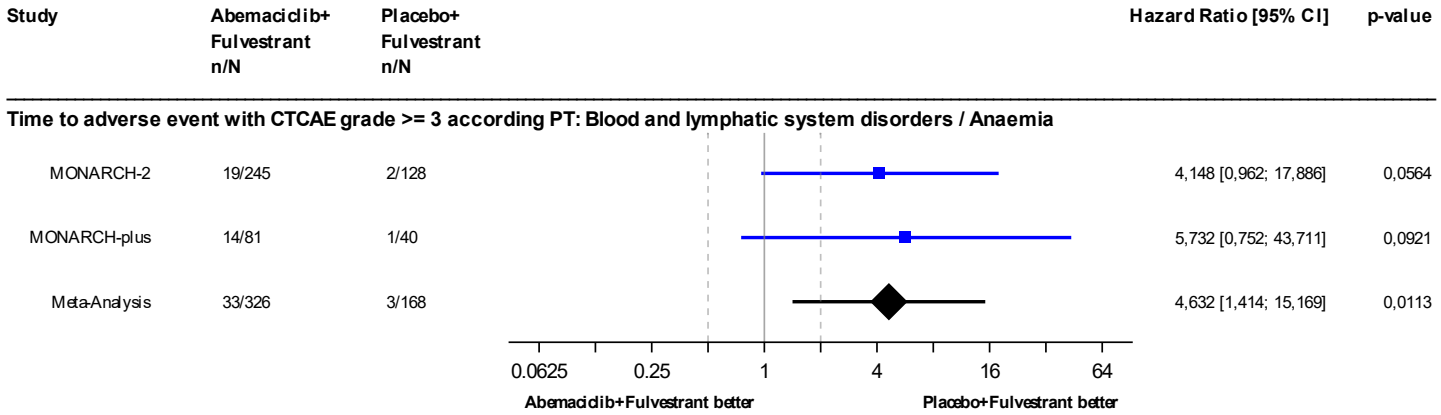
Figure 1299: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Blood and lymphatic system disorders / Anaemia Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0642, p-value=0,8000, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3p002_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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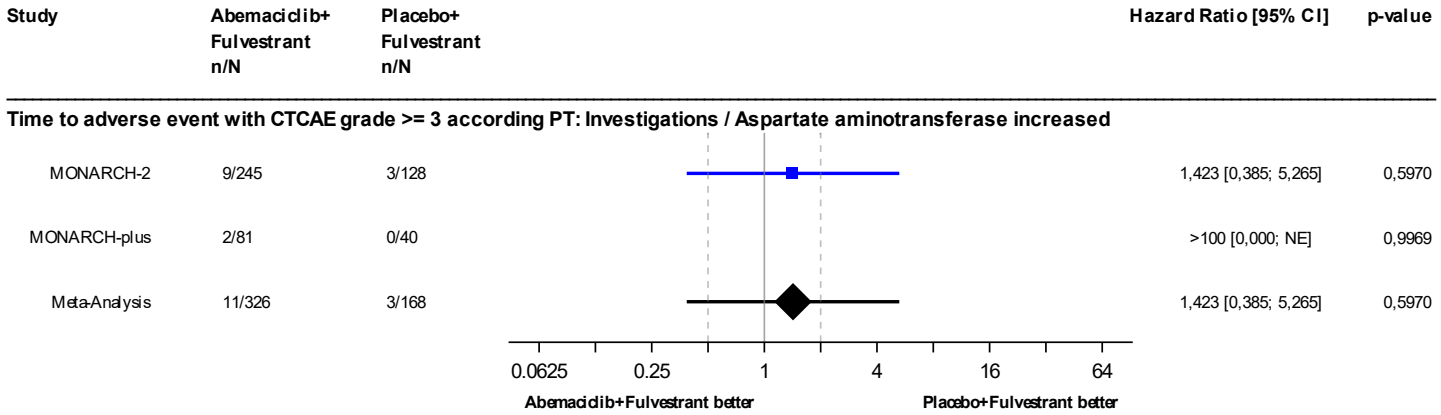
Figure 1300: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Investigations / Aspartate aminotransferase increased
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9970, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3p003_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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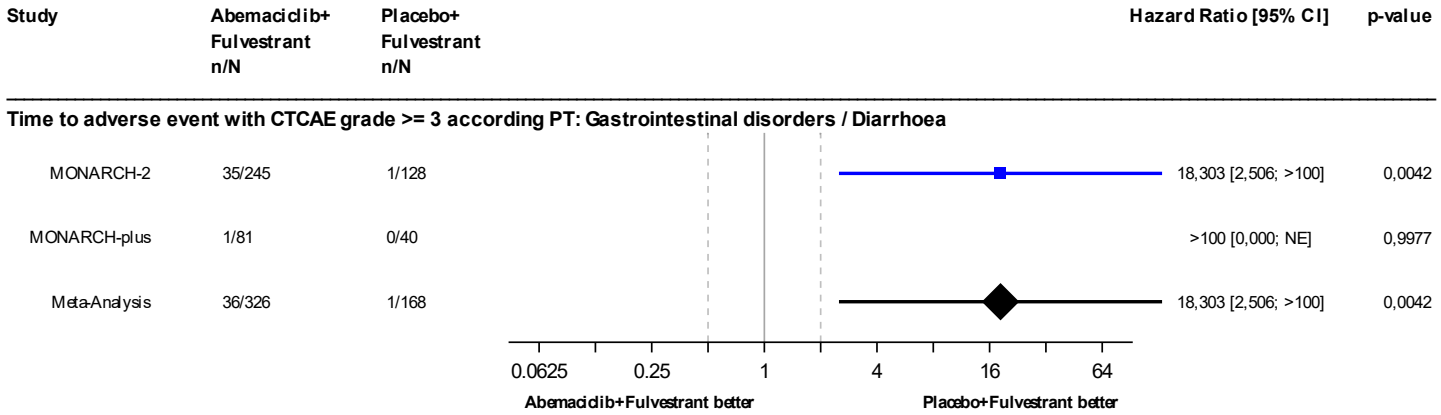
Figure 1301: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9981, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3p004_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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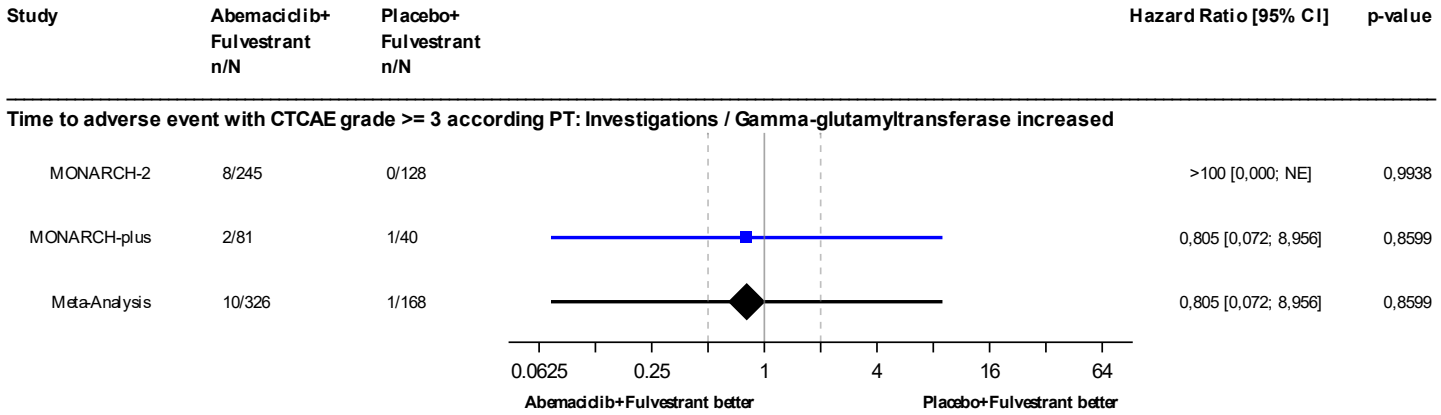
Figure 1302: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Investigations / Gamma-glutamyltransferase increased
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9937, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3p005_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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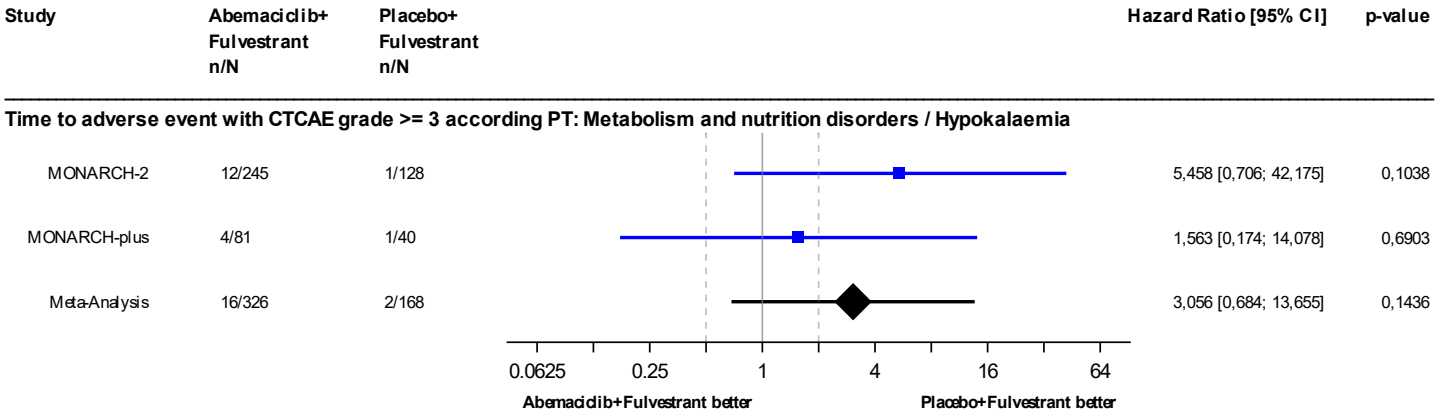
Figure 1303: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Metabolism and nutrition disorders / Hypokalaemia
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6665, p-value=0,4143, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3p006_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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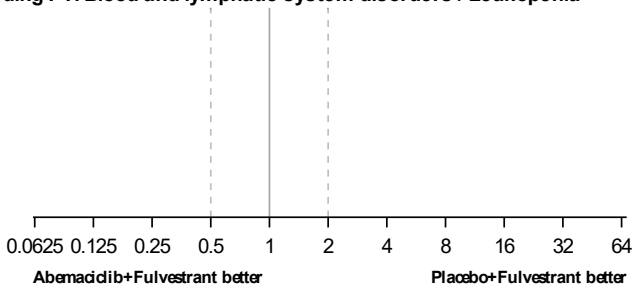
Figure 1304: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Blood and lymphatic system disorders / Leukopenia Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)

Study	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% CI]	p-value
Time to adverse event with CTCAE grade >= 3 according PT: Blood and lymphatic system disorders / Leukopenia				
MONARCH-2	21/245	0/128	>100 [0,000; NE]	0,9897
MONARCH-plus	0/81	0/40	NE	NE
Meta-Analysis	21/326	0/168	NE	NE



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3p007_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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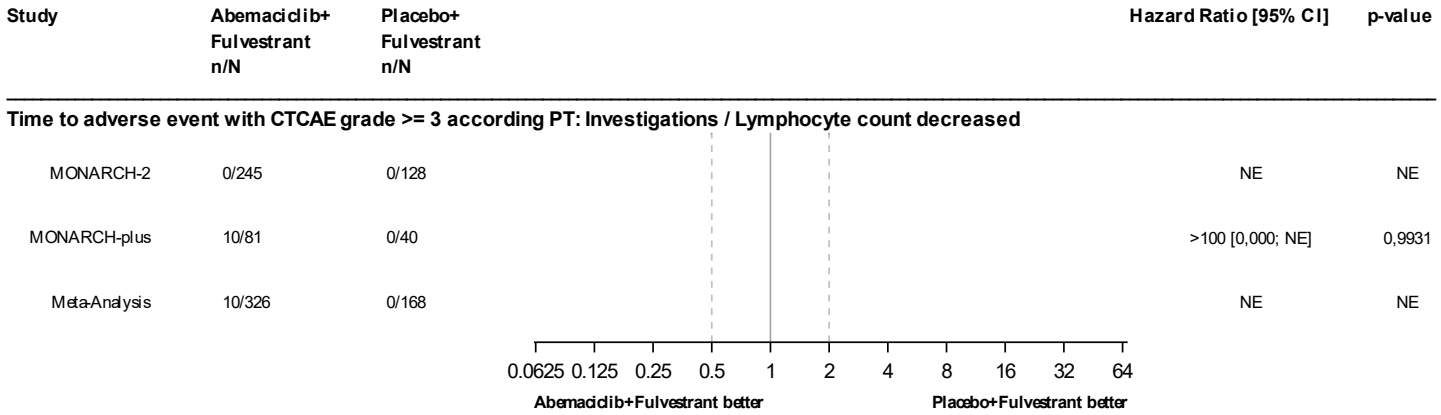
Figure 1305: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Investigations / Lymphocyte count decreased
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3p008_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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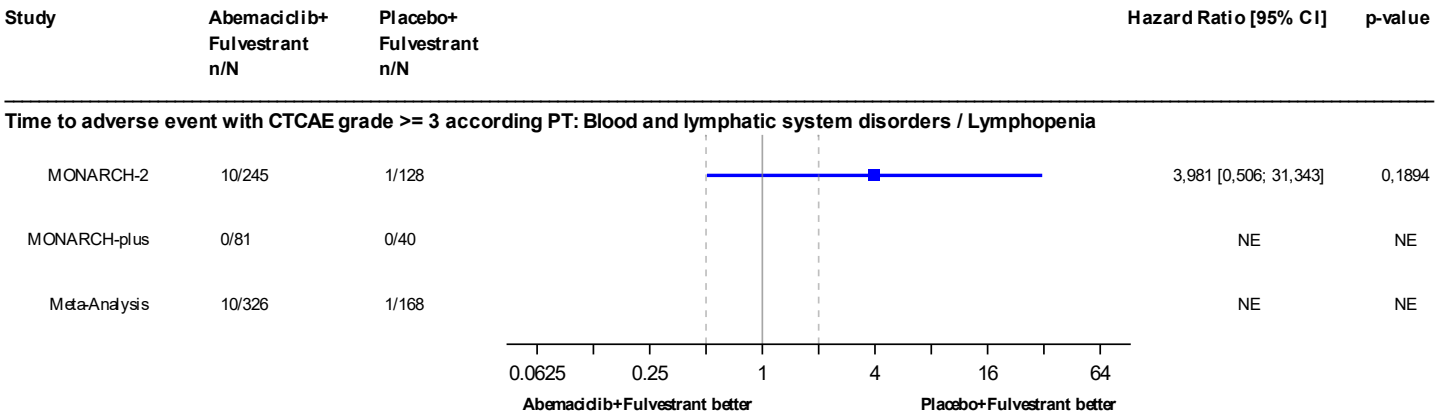
Figure 1306: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Blood and lymphatic system disorders / Lymphopenia Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3p009_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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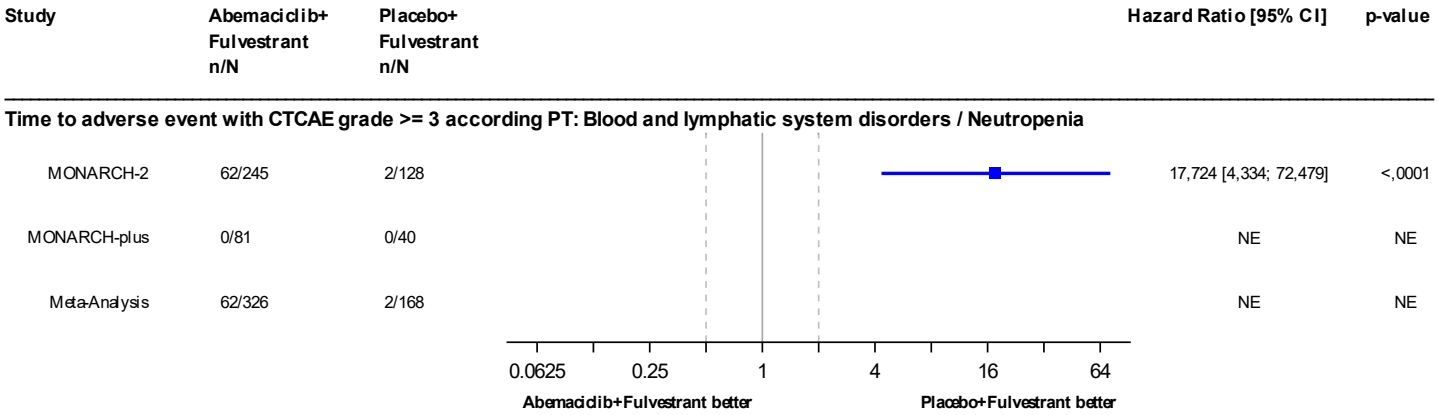
Figure 1307: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Blood and lymphatic system disorders / Neutropenia Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3p010_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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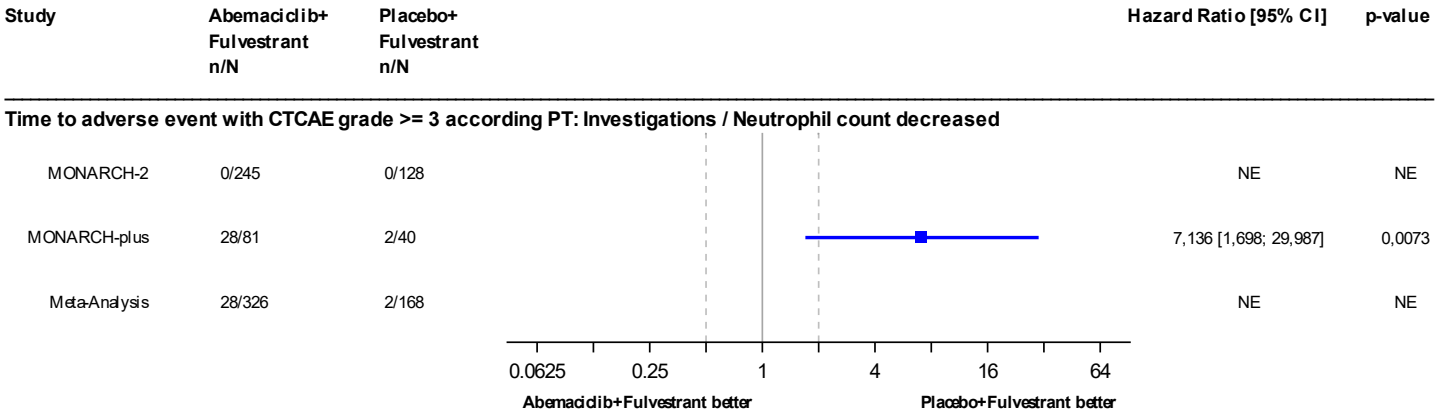
Figure 1308: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Investigations / Neutrophil count decreased
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3p011_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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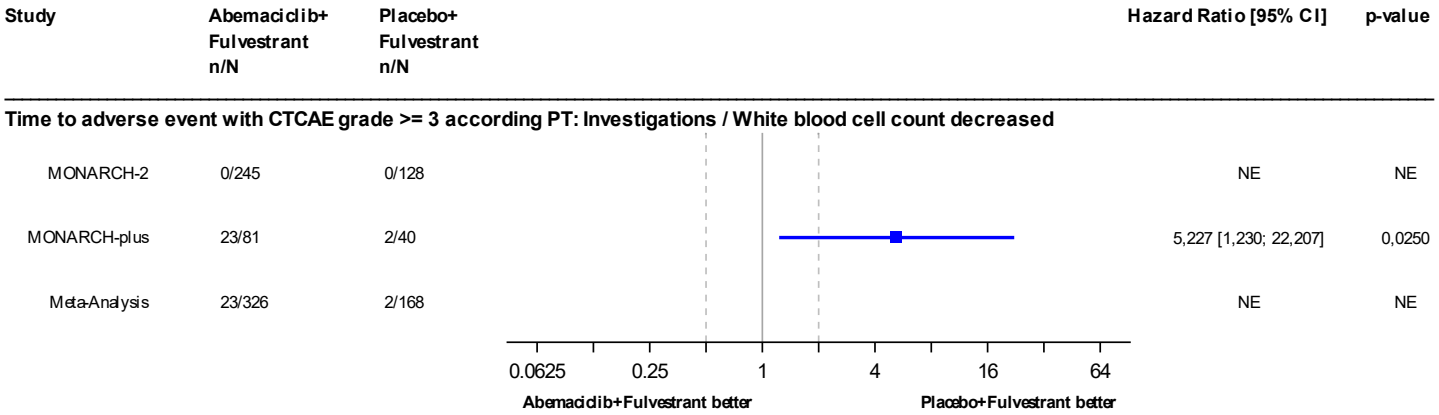
Figure 1309: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Investigations / White blood cell count decreased
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3p012_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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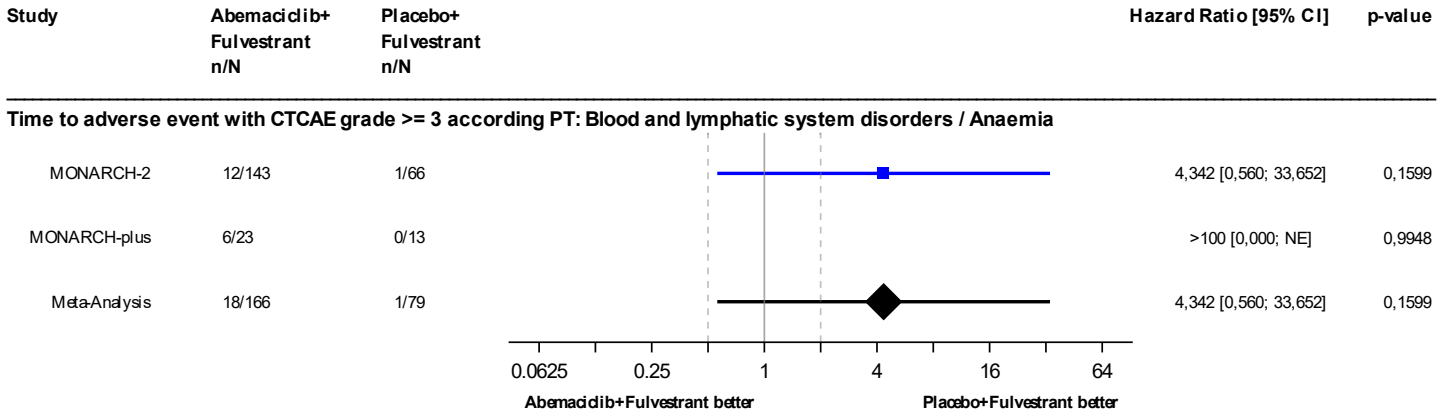
Figure 1310: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Blood and lymphatic system disorders / Anaemia Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9953, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3p001_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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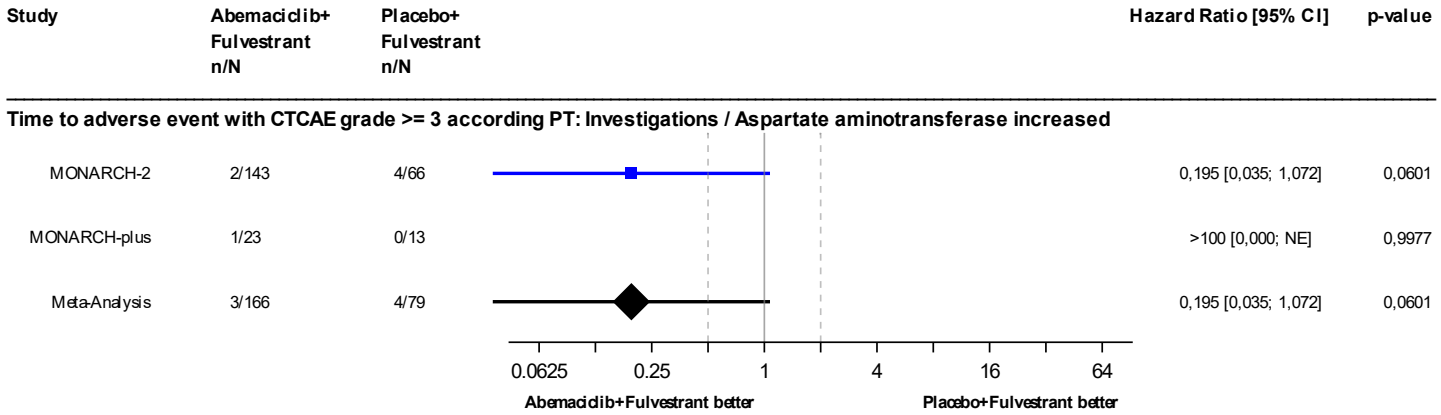
Figure 1311: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Investigations / Aspartate aminotransferase increased
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9975, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3p002_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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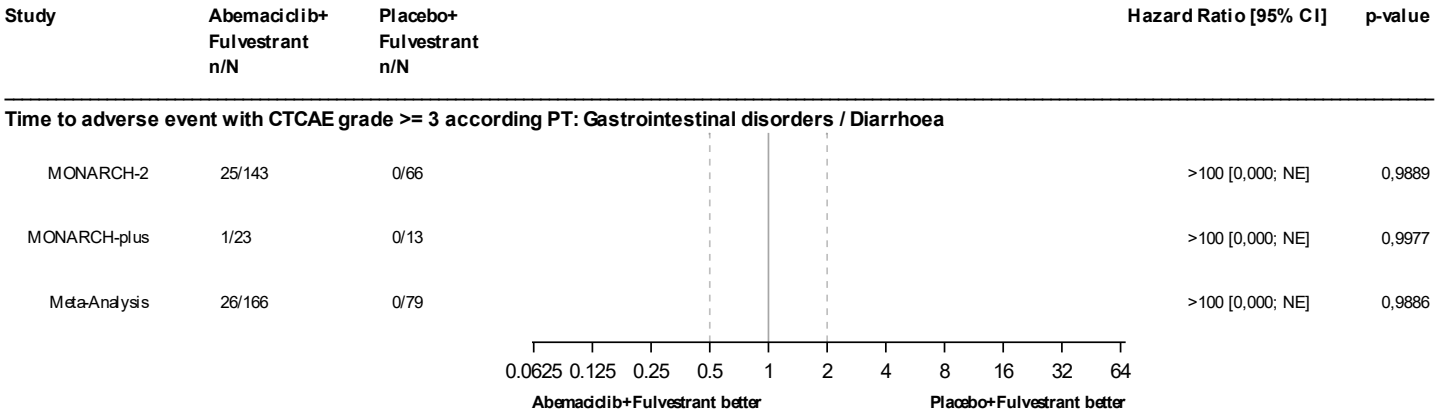
Figure 1312: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3p003_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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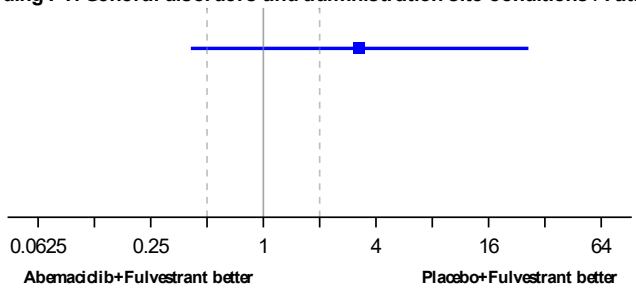
Figure 1313: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - General disorders and administration site conditions / Fatigue Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)

Study	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% CI]	p-value
Time to adverse event with CTCAE grade >= 3 according PT: General disorders and administration site conditions / Fatigue				
MONARCH-2	9/143	1/66	3,271 [0,410; 26,116]	0,2636
MONARCH-plus	0/23	0/13	NE	NE
Meta-Analysis	9/166	1/79	NE	NE



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3p004_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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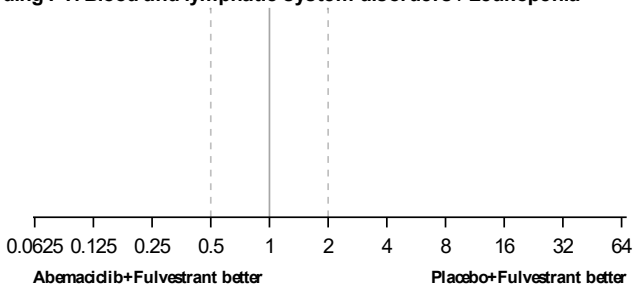
Figure 1314: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Blood and lymphatic system disorders / Leukopenia Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)

Study	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% CI]	p-value
Time to adverse event with CTCAE grade >= 3 according PT: Blood and lymphatic system disorders / Leukopenia				
MONARCH-2	13/143	0/66	>100 [0,000; NE]	0,9923
MONARCH-plus	0/23	0/13	NE	NE
Meta-Analysis	13/166	0/79	NE	NE



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3p005_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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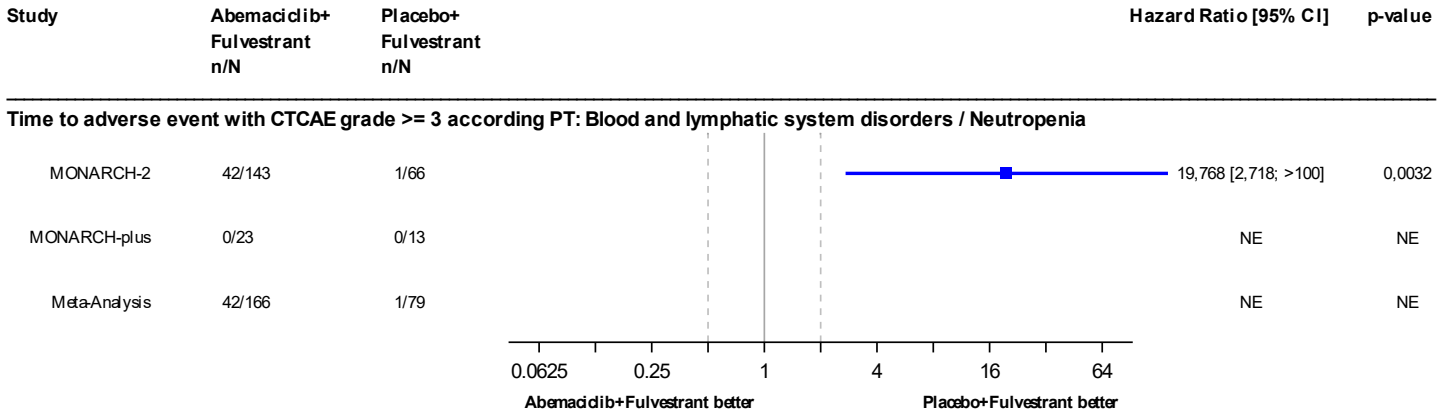
Figure 1315: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Blood and lymphatic system disorders / Neutropenia Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3p006_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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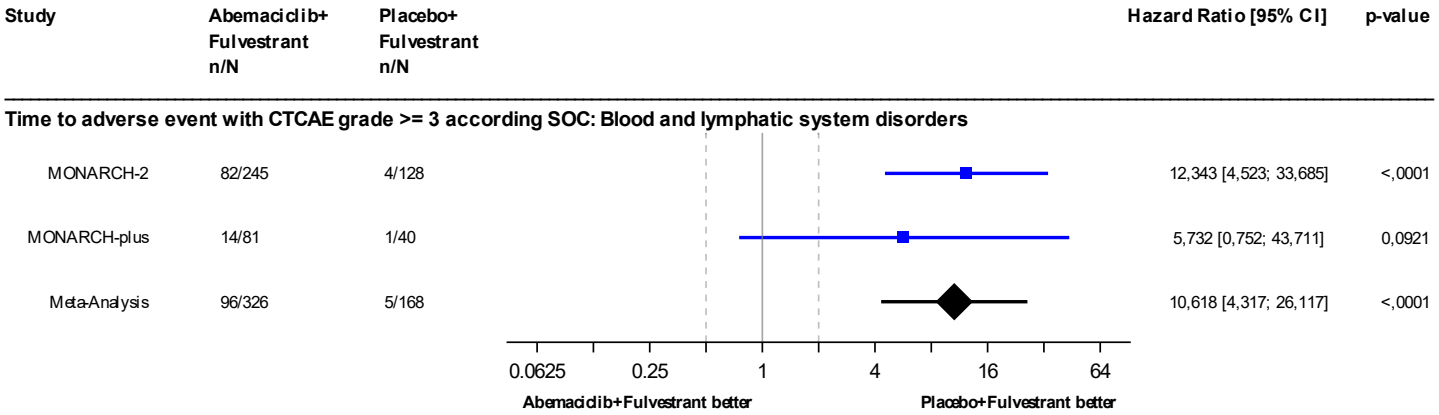
Figure 1316: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Blood and lymphatic system disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4401, p-value=0,5071, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3s001_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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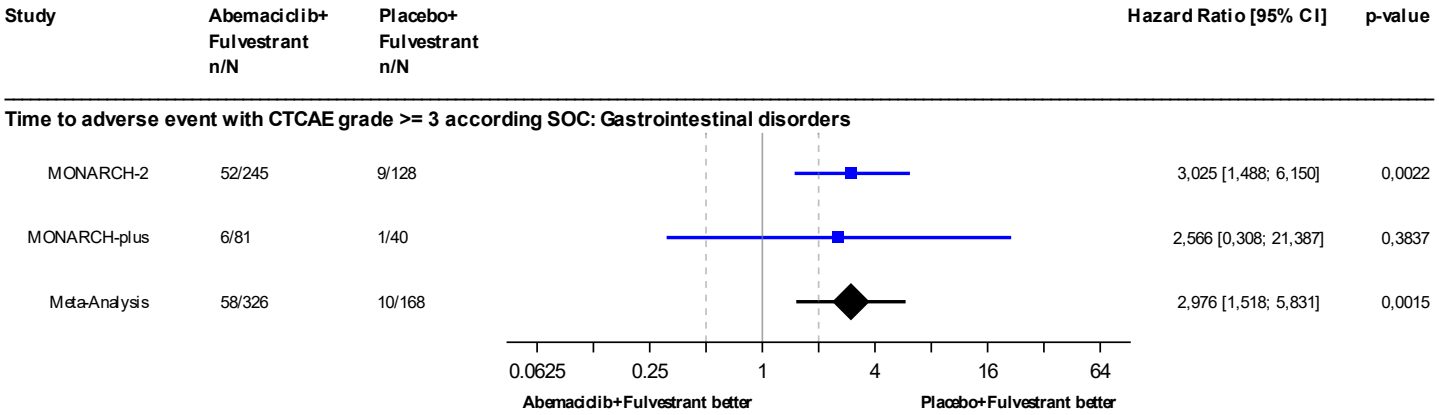
Figure 1317: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0208, p-value=0,8852, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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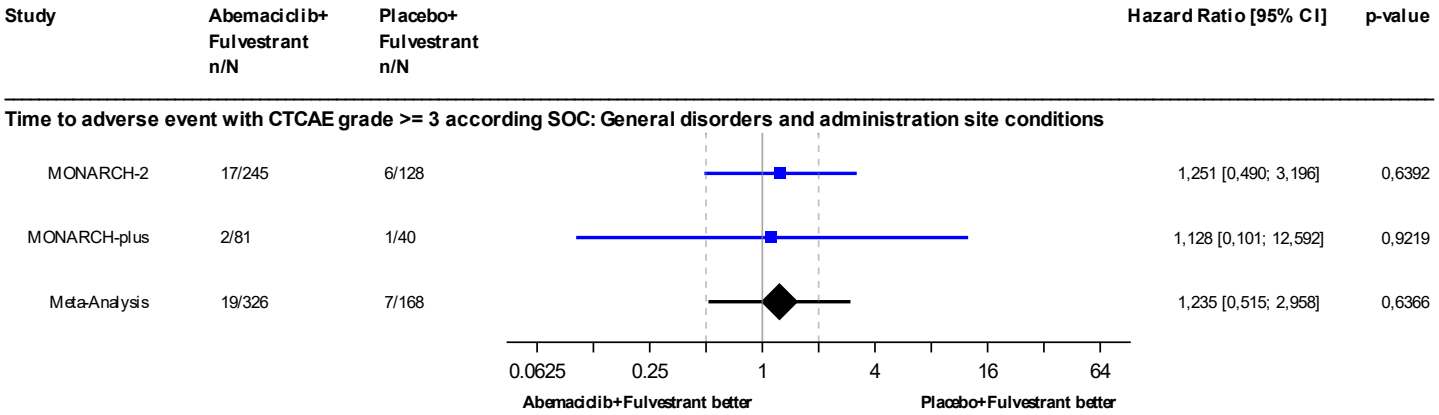
Figure 1318: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - General disorders and administration site conditions Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0062, p-value=0,9375, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3s003_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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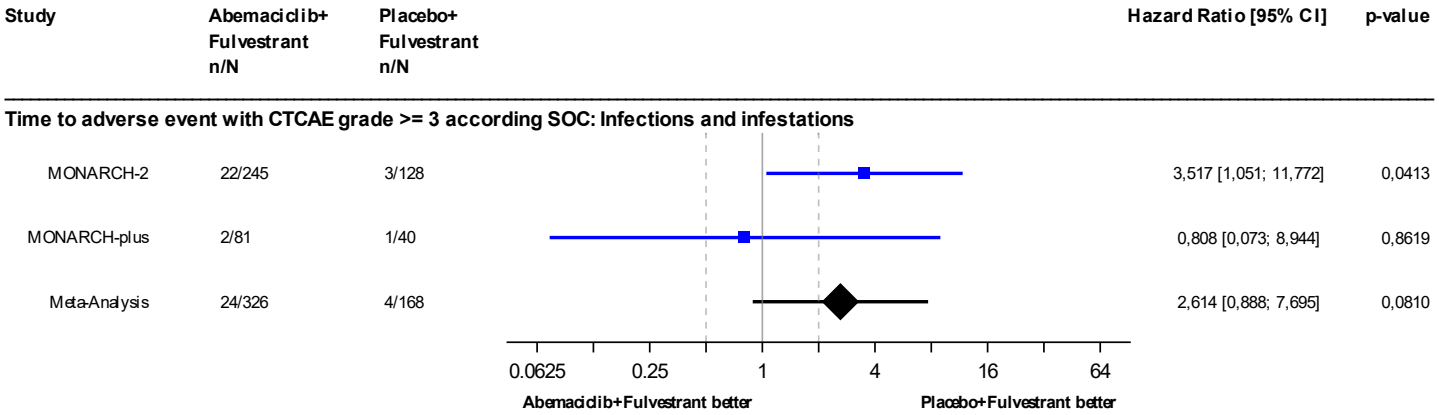
Figure 1319: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Infections and infestations
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,1479, p-value=0,2840, I2 index=12,9%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3s004_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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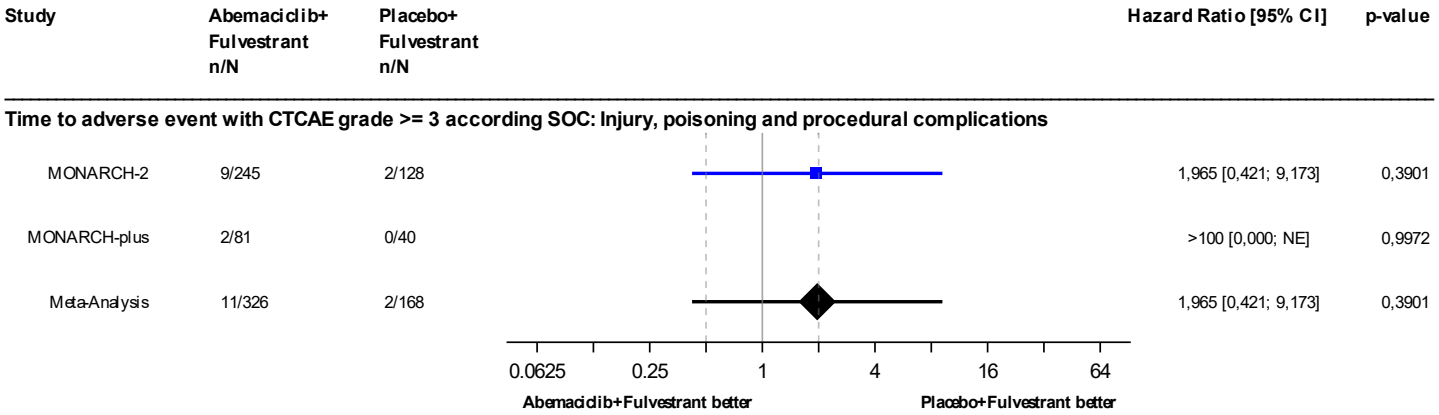
Figure 1320: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Injury, poisoning and procedural complications
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9973, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3s005_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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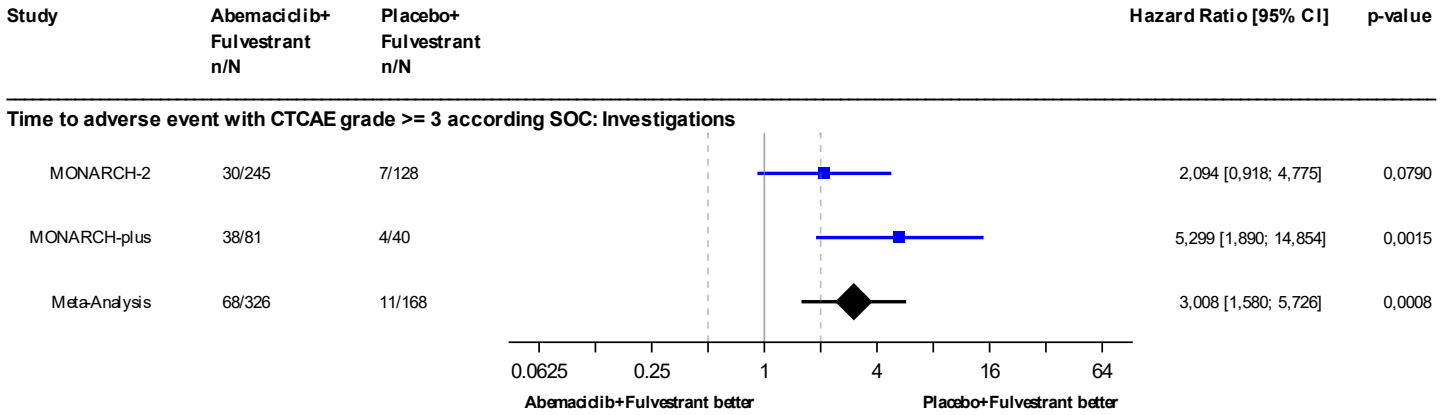
Figure 1321: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,9014, p-value=0,1679, I2 index=47,4%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3s006_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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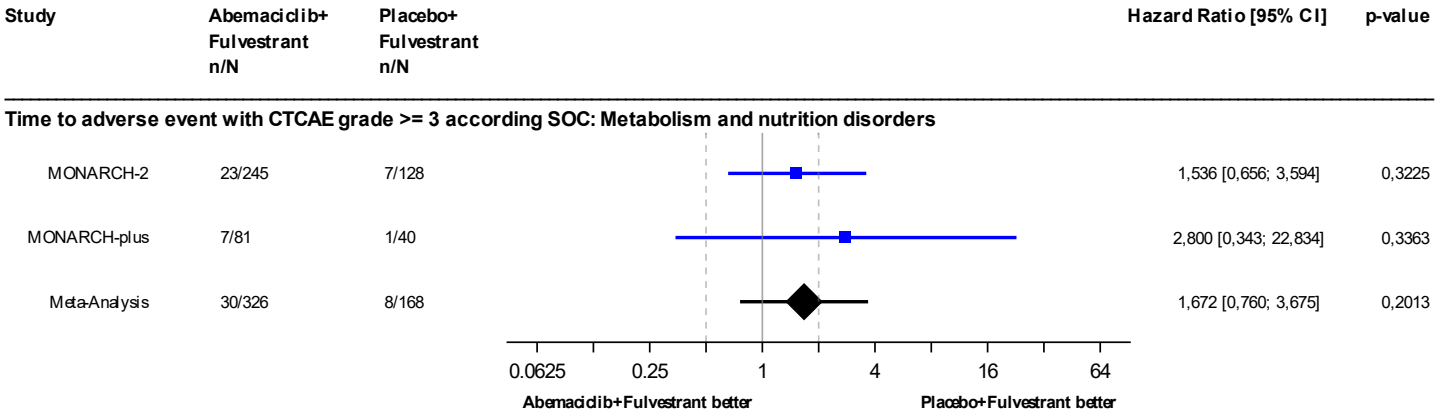
Figure 1322: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Metabolism and nutrition disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2701, p-value=0,6032, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3s007_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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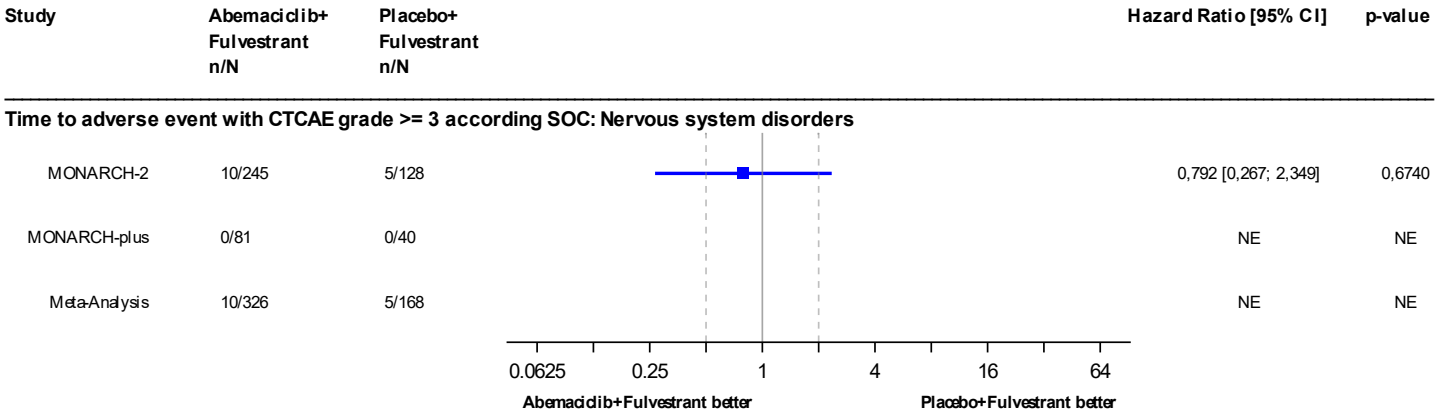
Figure 1323: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Nervous system disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3s008_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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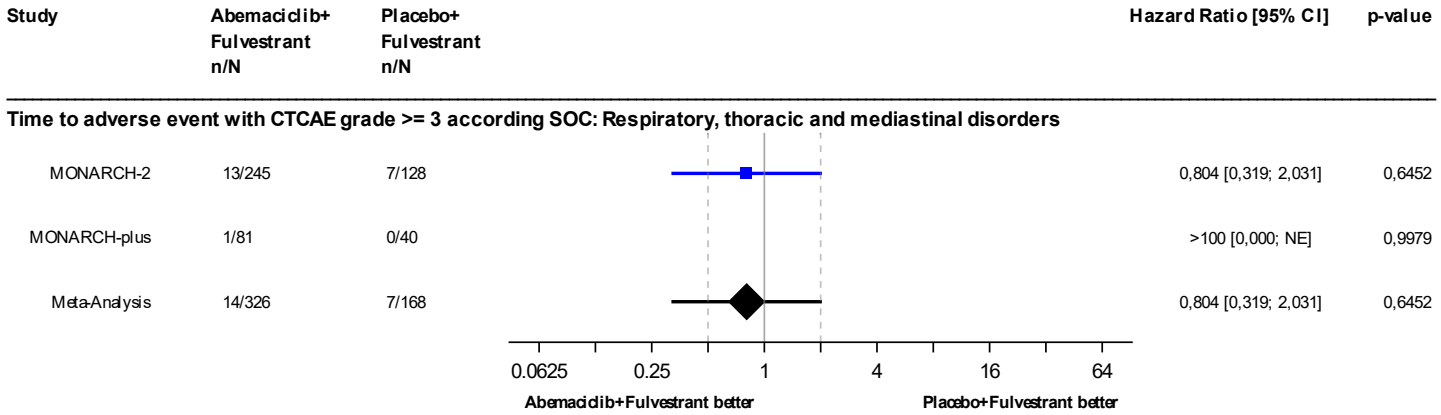
Figure 1324: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Respiratory, thoracic and mediastinal disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9978, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3s009_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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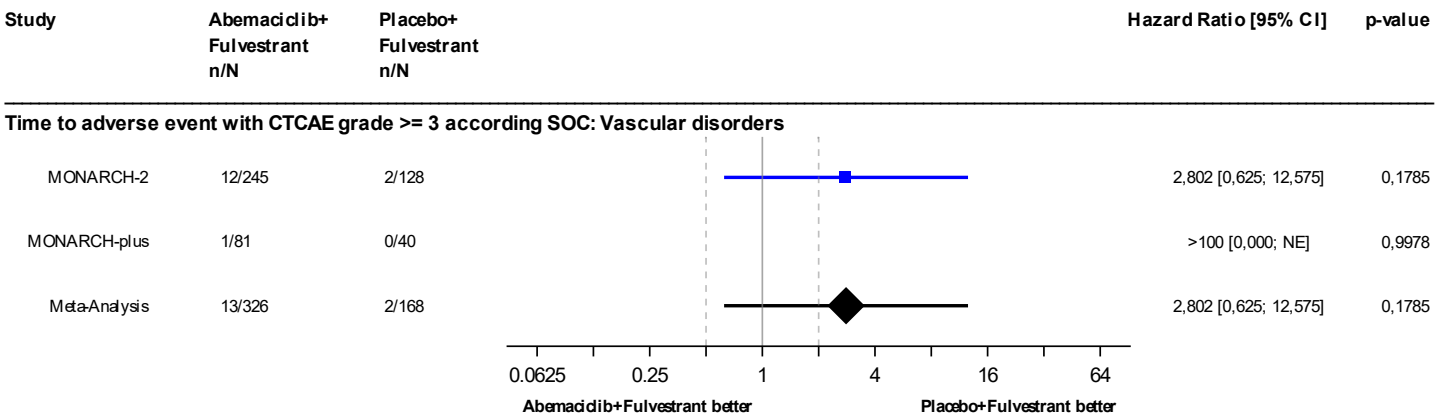
Figure 1325: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Vascular disorders
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9979, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3s010_popa1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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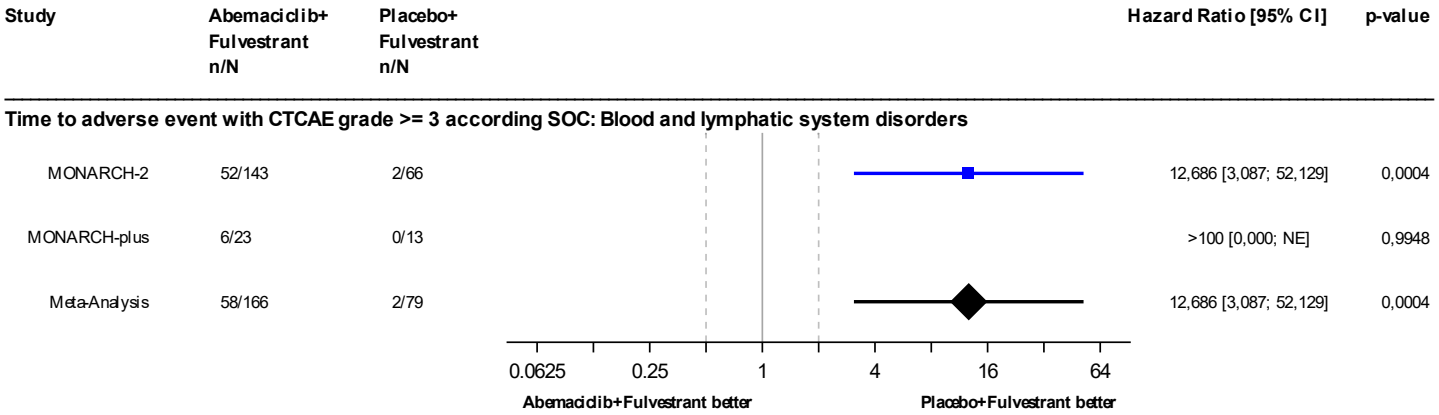
Figure 1326: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Blood and lymphatic system disorders
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9956, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3s001_popa2.rtf
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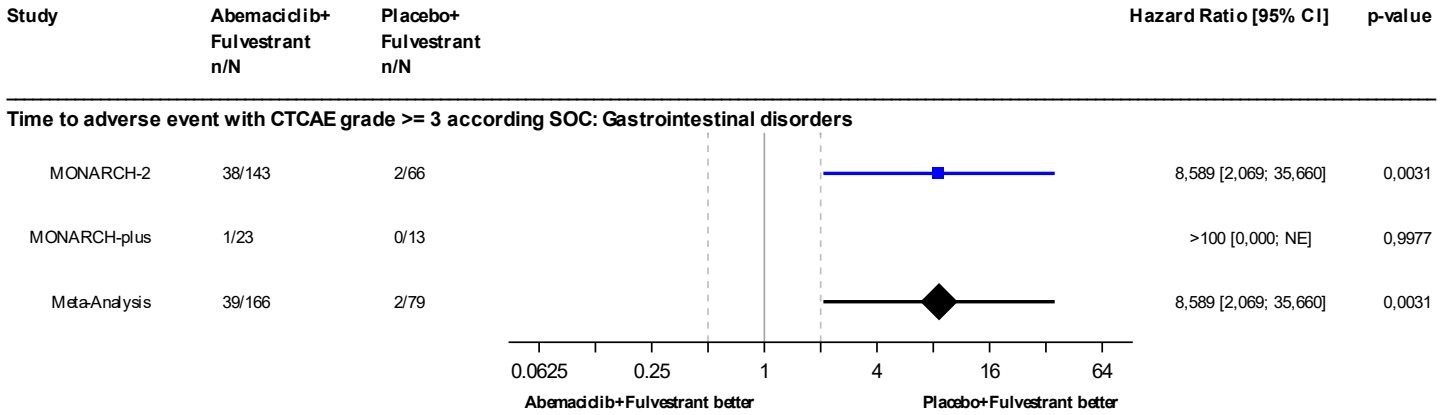
Figure 1327: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3s002_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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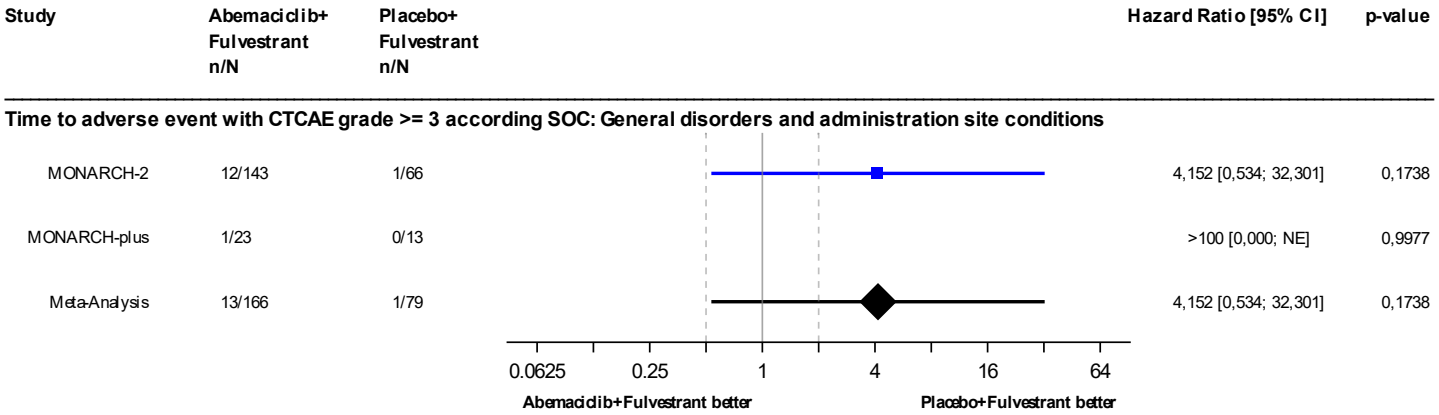
Figure 1328: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - General disorders and administration site conditions
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9979, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3s003_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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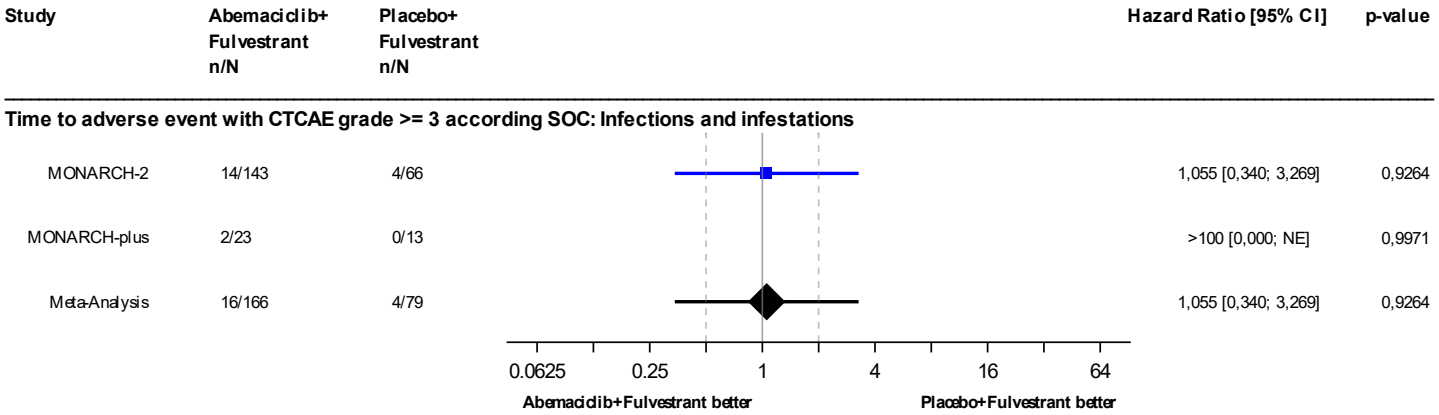
Figure 1329: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Infections and infestations
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9971, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3s004_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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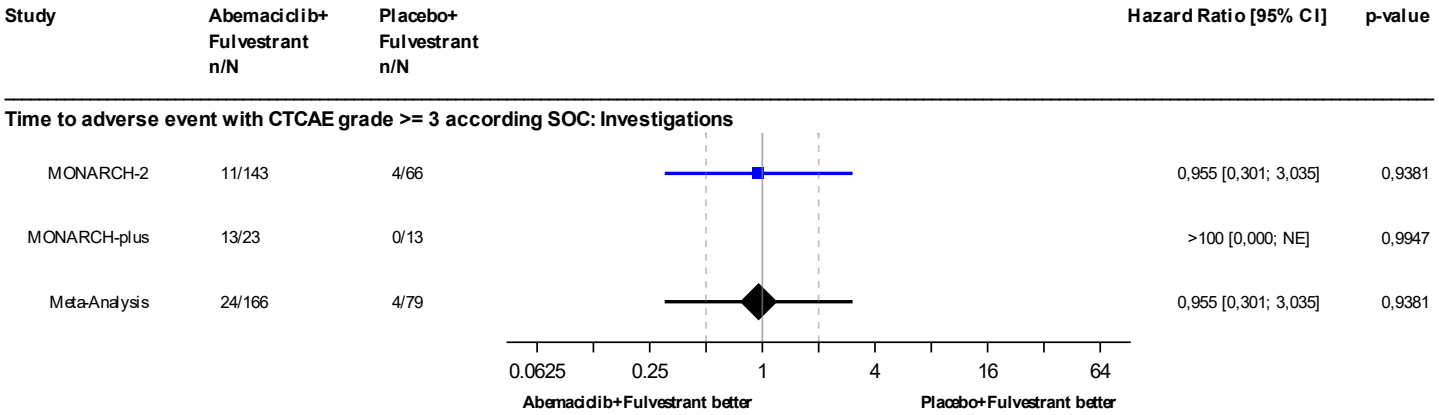
Figure 1330: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9947, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3s005_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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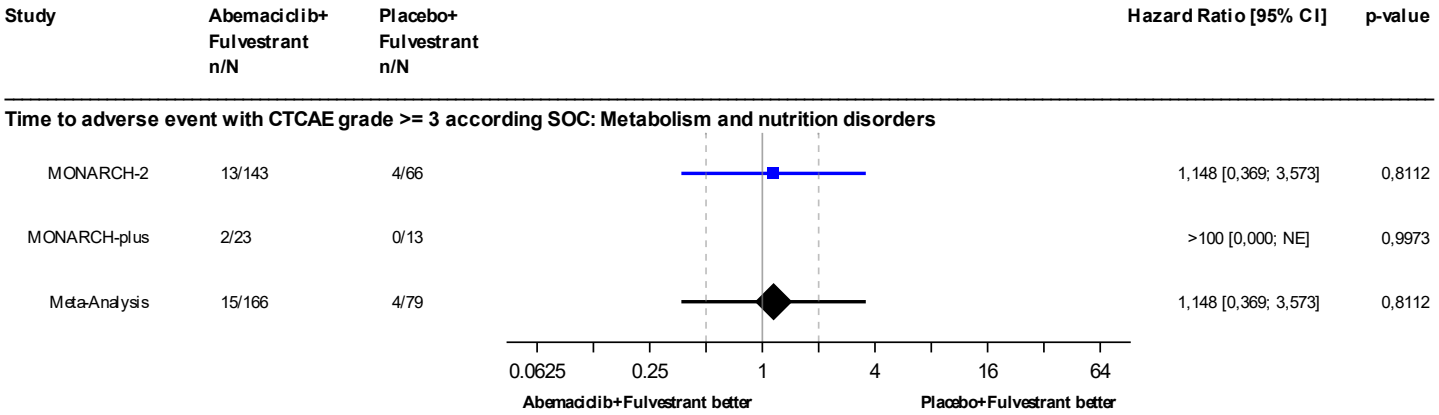
Figure 1331: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Metabolism and nutrition disorders
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9973, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3s006_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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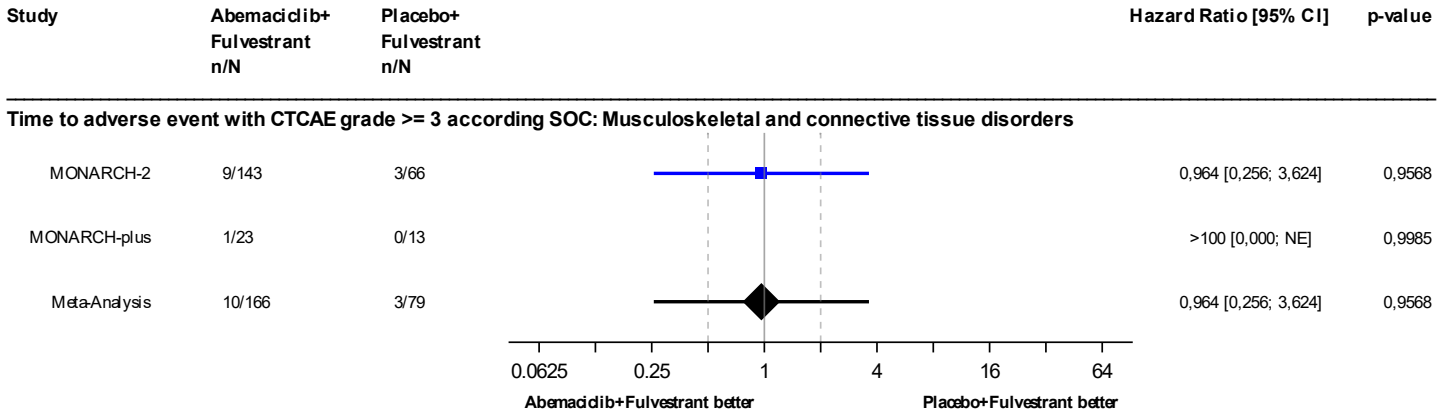
Figure 1332: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Musculoskeletal and connective tissue disorders
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3s007_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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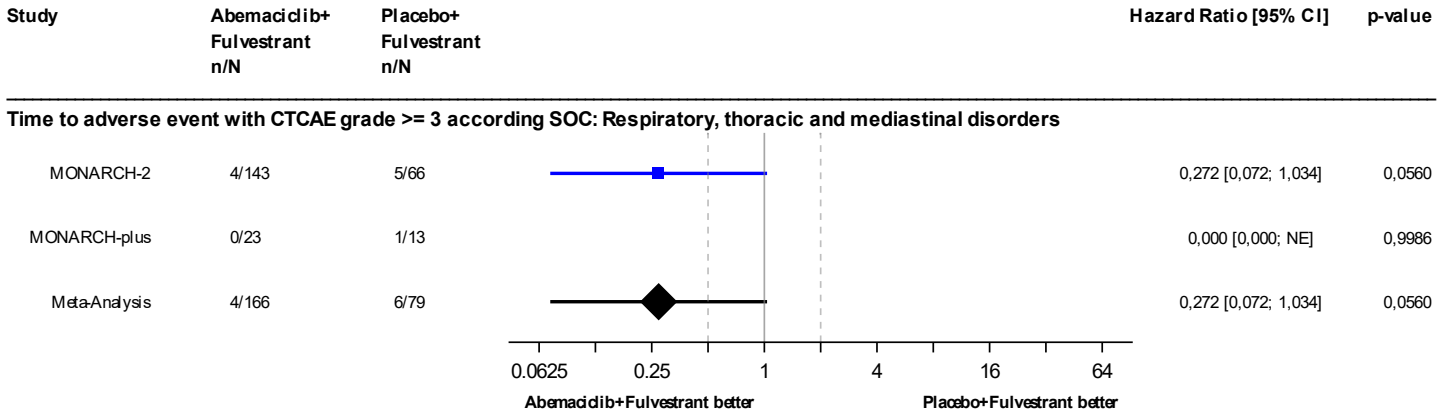
Figure 1333: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Respiratory, thoracic and mediastinal disorders
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3s008_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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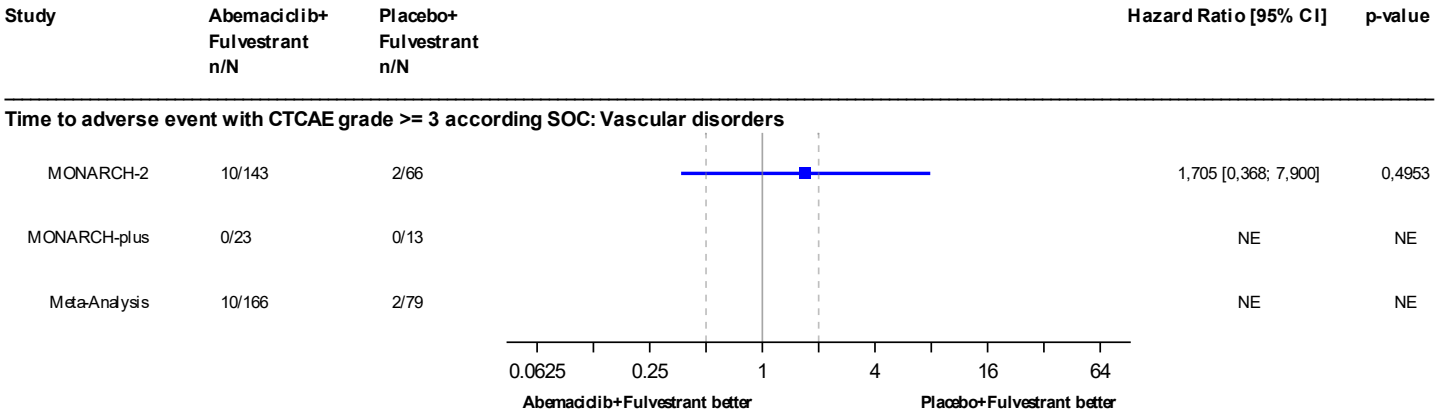
Figure 1334: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Vascular disorders
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE.
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttirgr3s009_popa2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam
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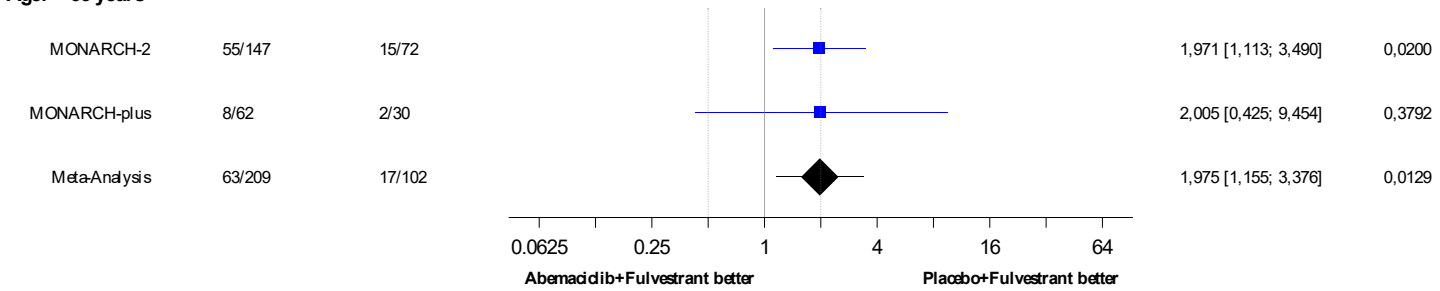
Anhang 4-G3.4: Subgruppenanalysen der Metaanalyse

Abbildung 159 (Anhang): Ergebnisse der Subgruppenanalyse von häufigen unerwünschten Ereignissen (Metaanalyse der Studien MONARCH-2 und MONARCH-plus)

Figure 1102.1.1.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0004, p-value=0,9836, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep002_popa1_agegr1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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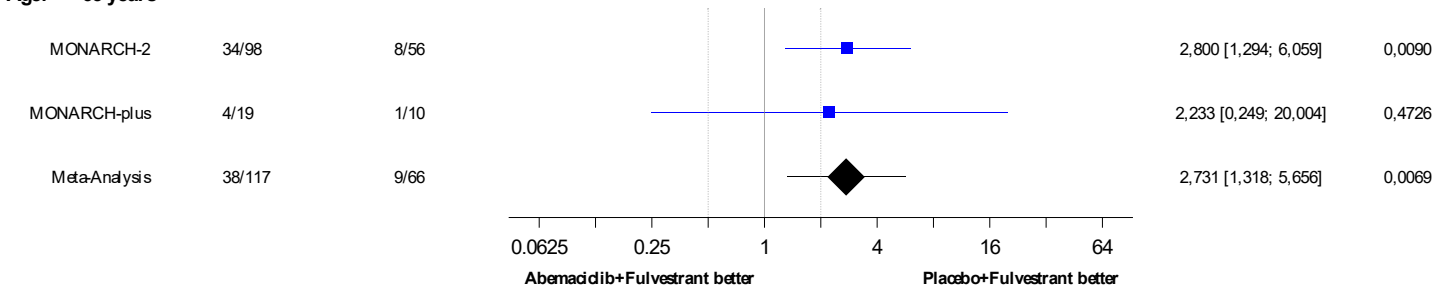
Figure 1102.1.1.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0363, p-value=0,8488, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep002_popa1_agegr1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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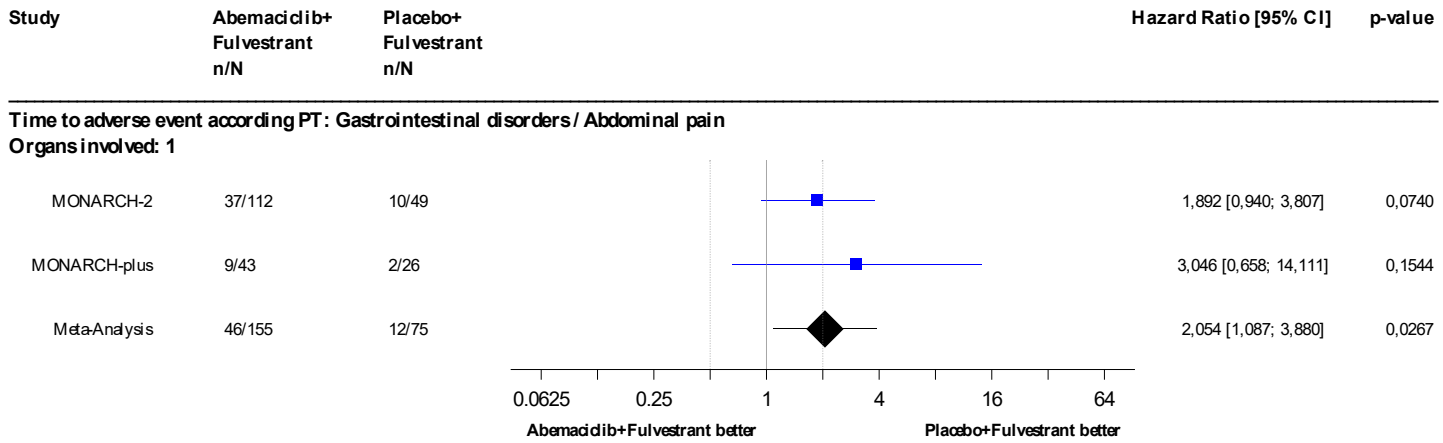
**Figure 1102.1.2.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,3071, p-value=0,5794, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep002_popa1_norggr_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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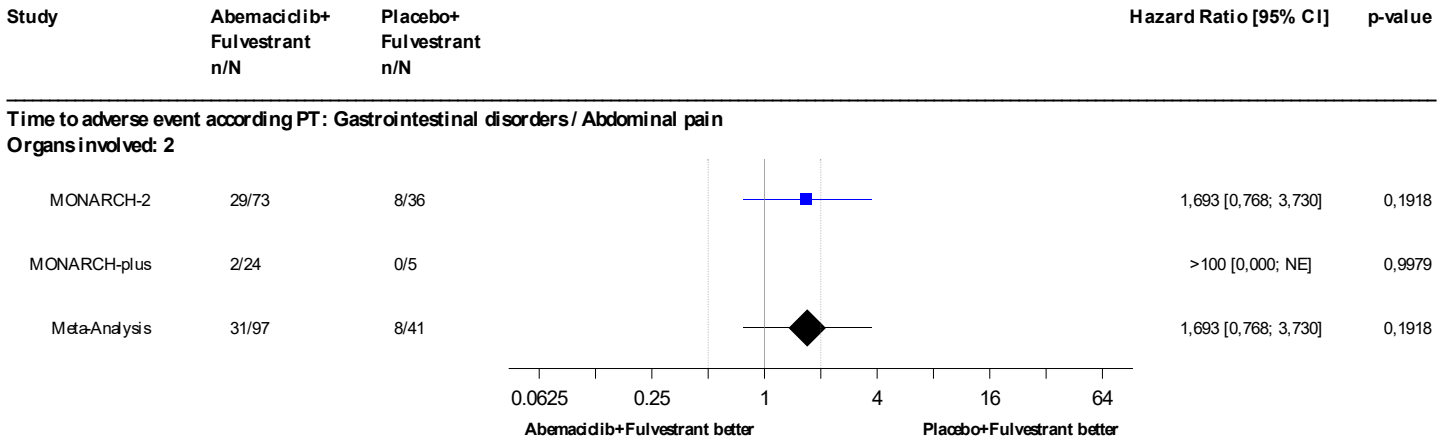
**Figure 1102.1.2.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep002_popa1_norggr_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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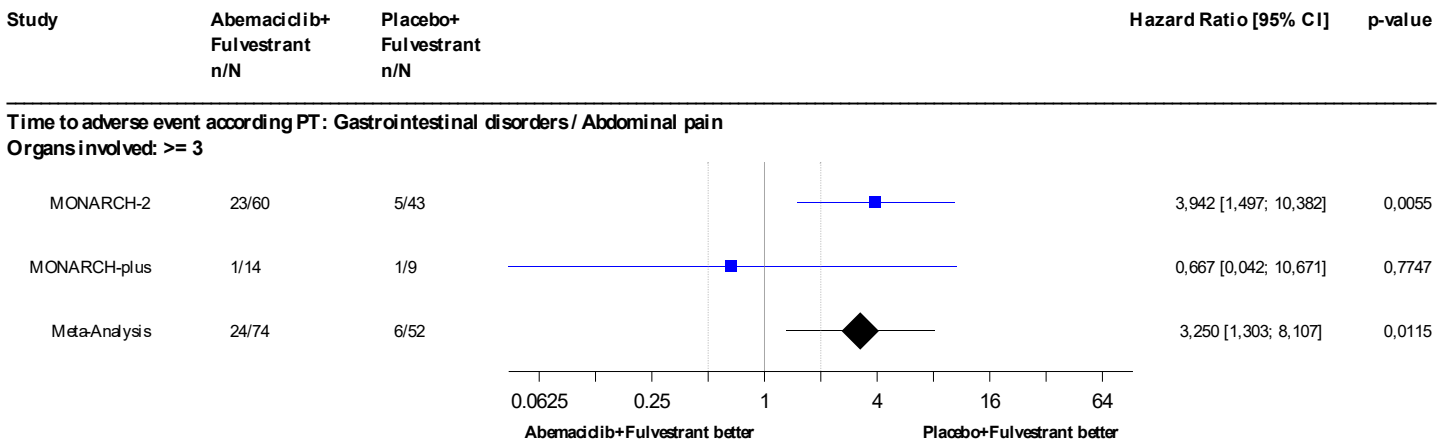
Figure 1102.1.2.3: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,4059, p-value=0,2357, I2 index=28,9%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep002_popa1_norggr_3.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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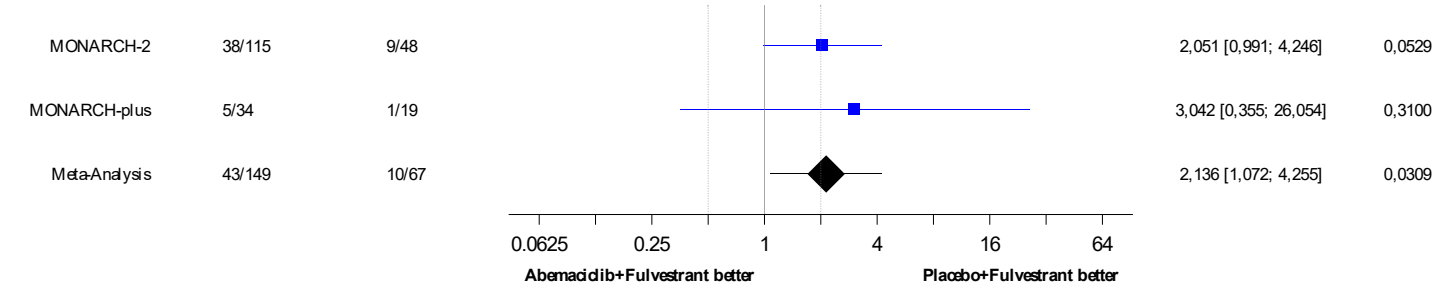
Figure 1102.1.3.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1160, p-value=0,7334, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep002_popa1_natdis2_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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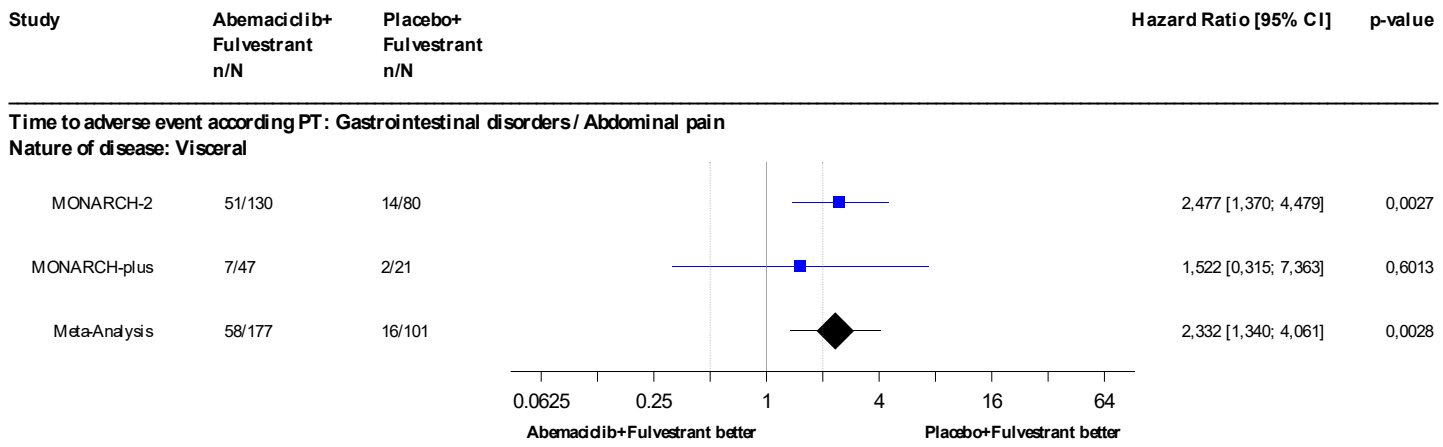
Figure 1102.1.3.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3212, p-value=0,5709, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep002_popa1_natdis2_2.rtf
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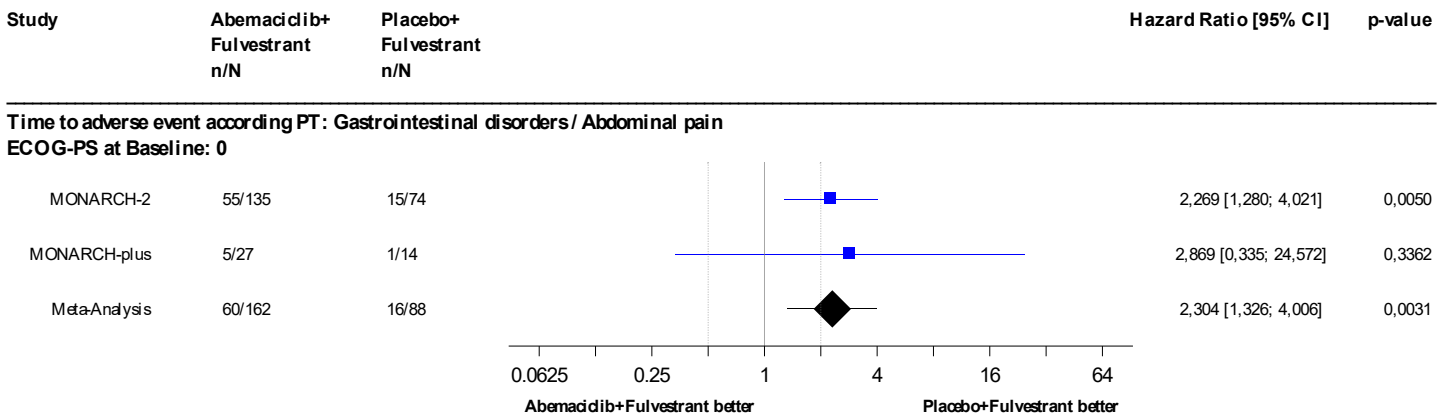
Figure 1102.1.4.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0428, p-value=0,8361, I2 index=0%

Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep002_popa1_ecogbl_1.rtf

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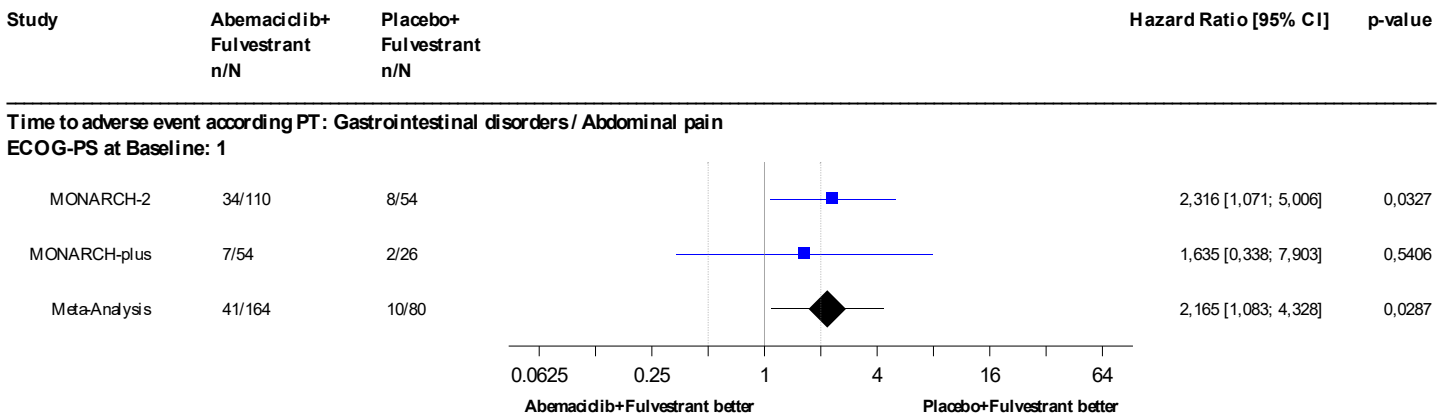
Figure 1102.1.4.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1512, p-value=0,6973, I2 index=0%

Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep002_popa1_ecogbl_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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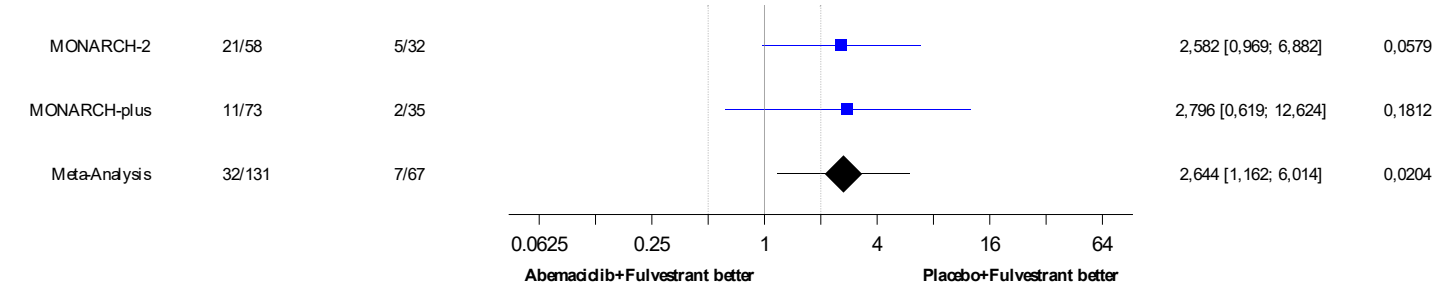
Figure 1102.1.5.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0076, p-value=0,9307, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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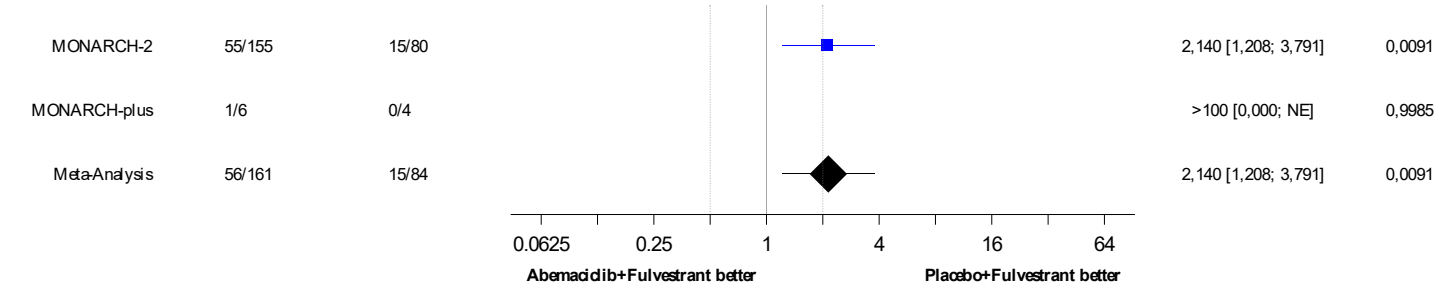
Figure 1102.1.5.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep002_popa1_racegr1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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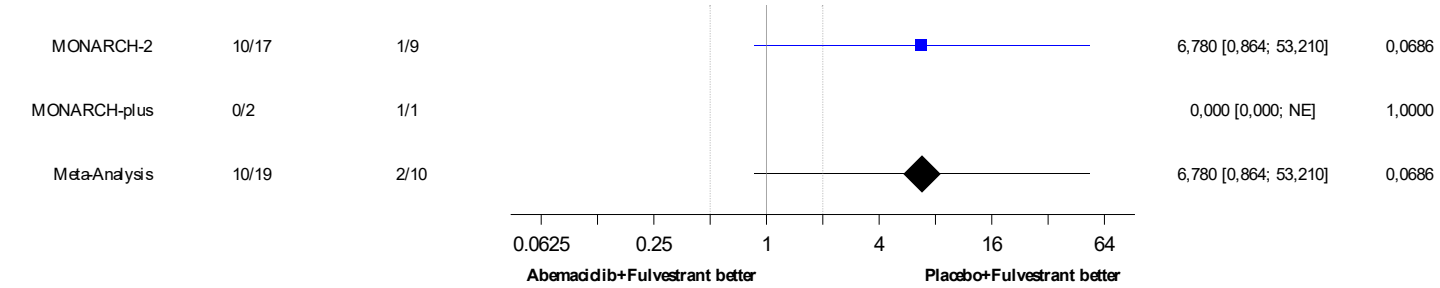
Figure 1102.1.5.3: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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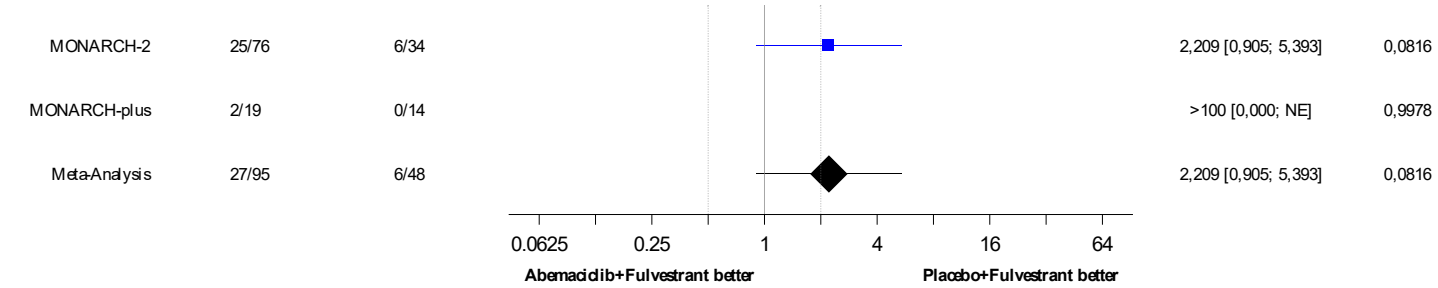
Figure 1102.1.6.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9979, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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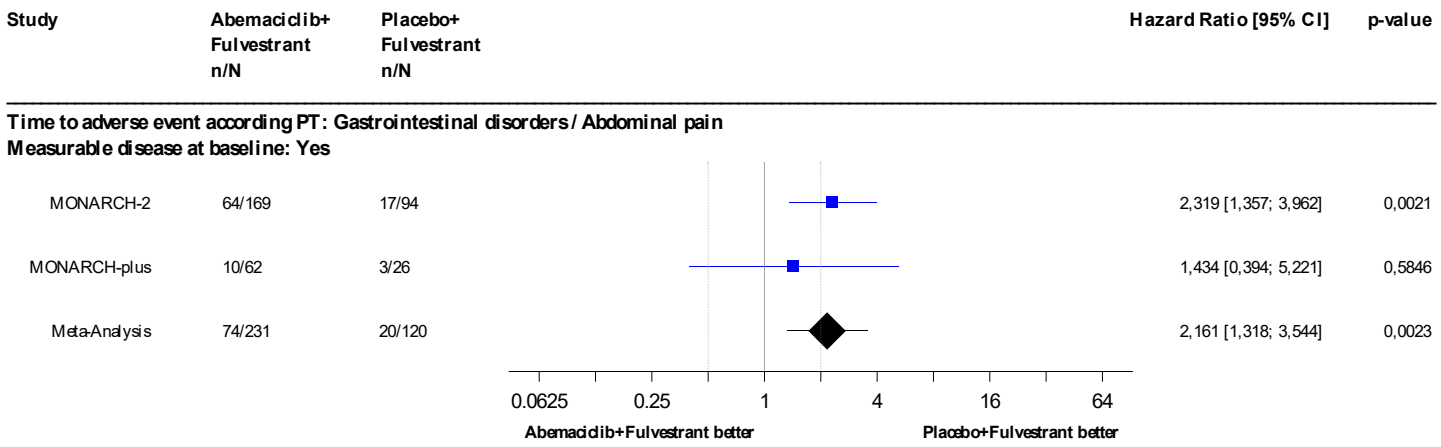
Figure 1102.1.6.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4535, p-value=0,5007, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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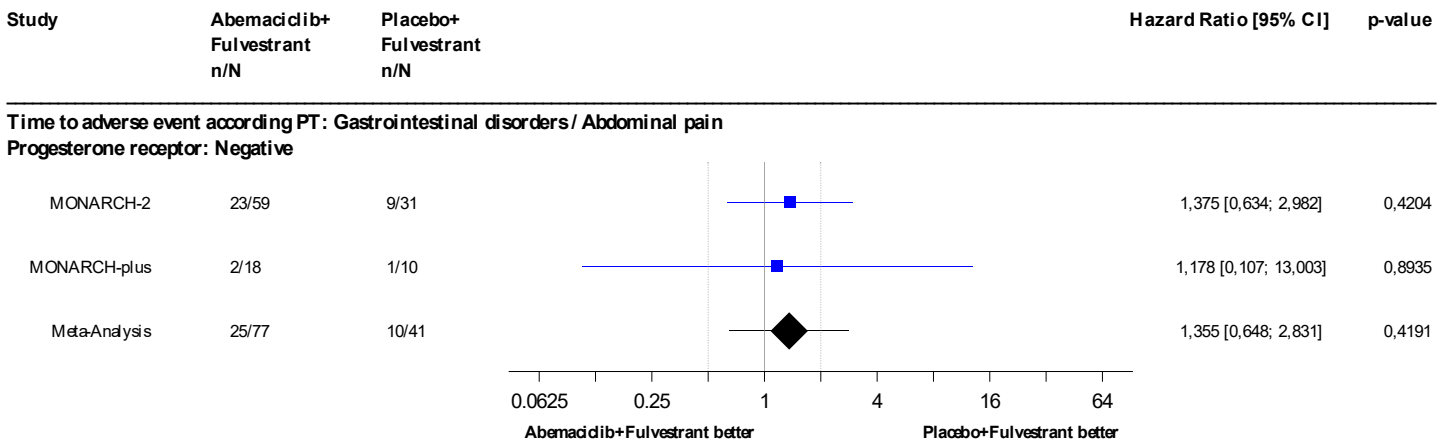
Figure 1102.1.7.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0144, p-value=0,9046, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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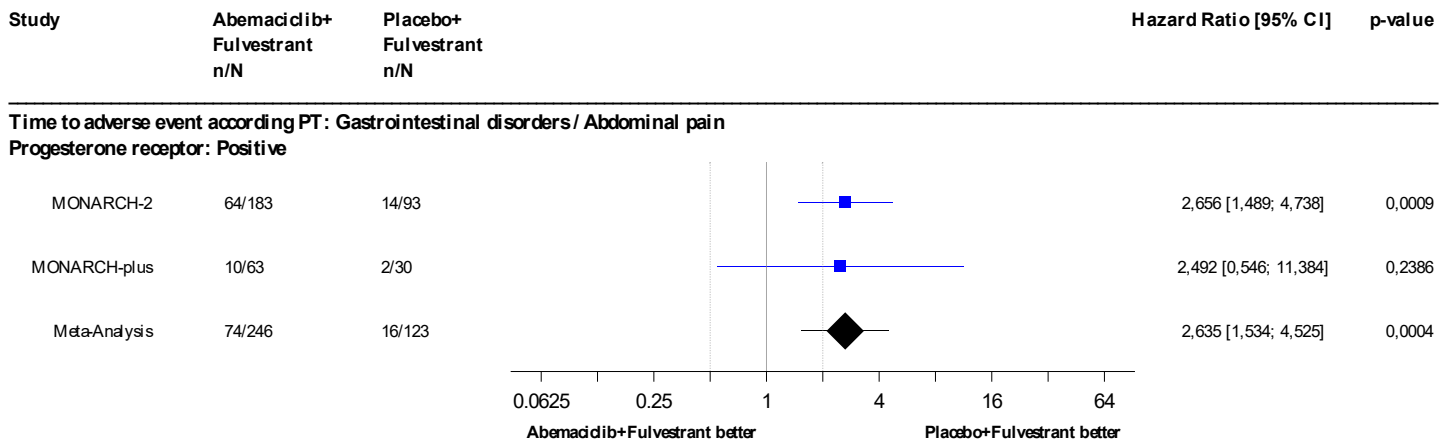
Figure 1102.1.7.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0059, p-value=0,9389, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep002_popa1_pgrstat_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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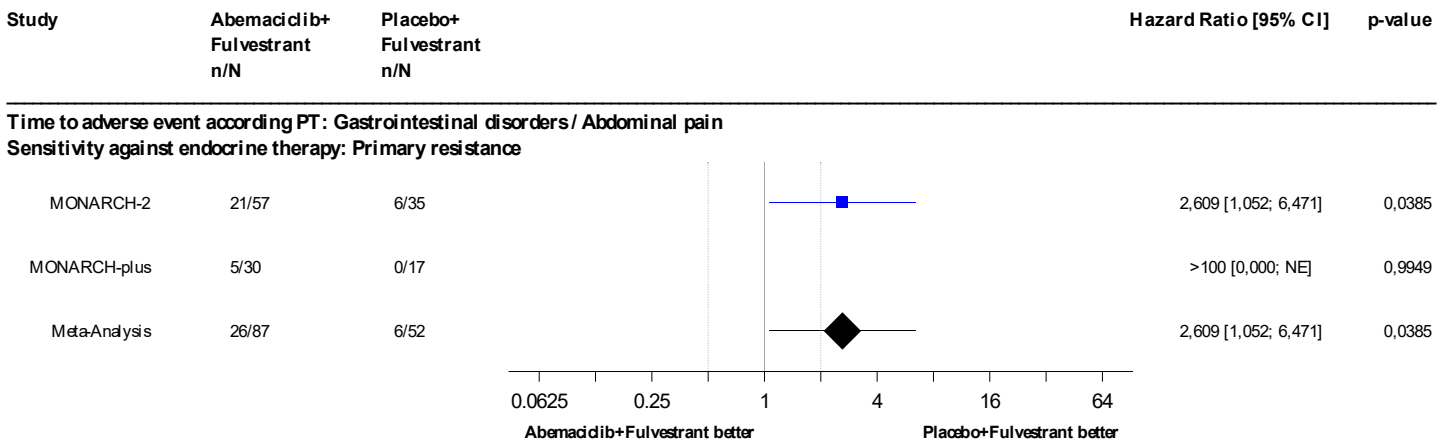
Figure 1102.1.8.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9952, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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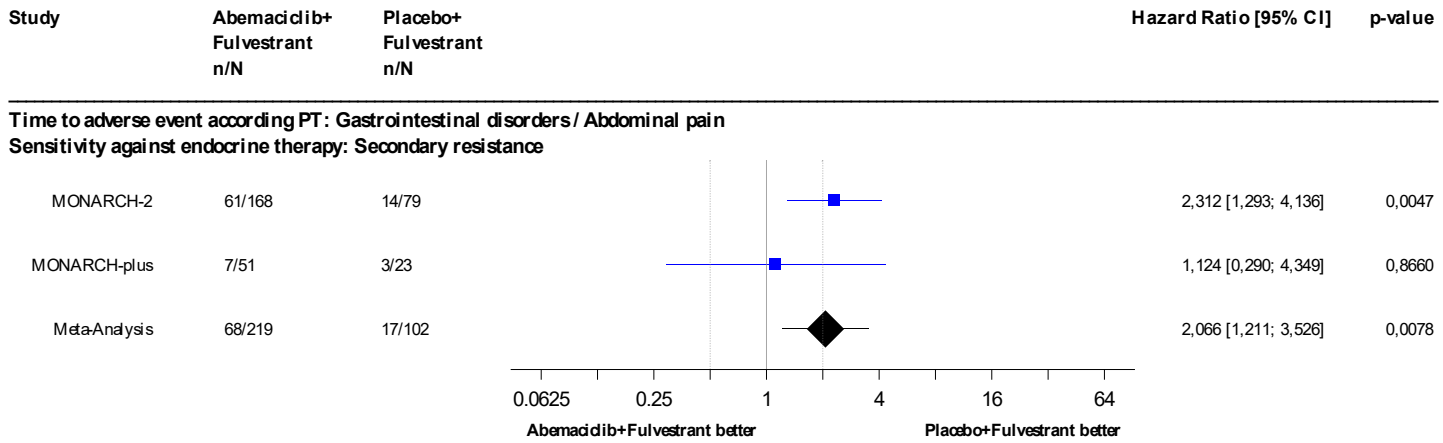
Figure 1102.1.8.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,9223, p-value=0,3369, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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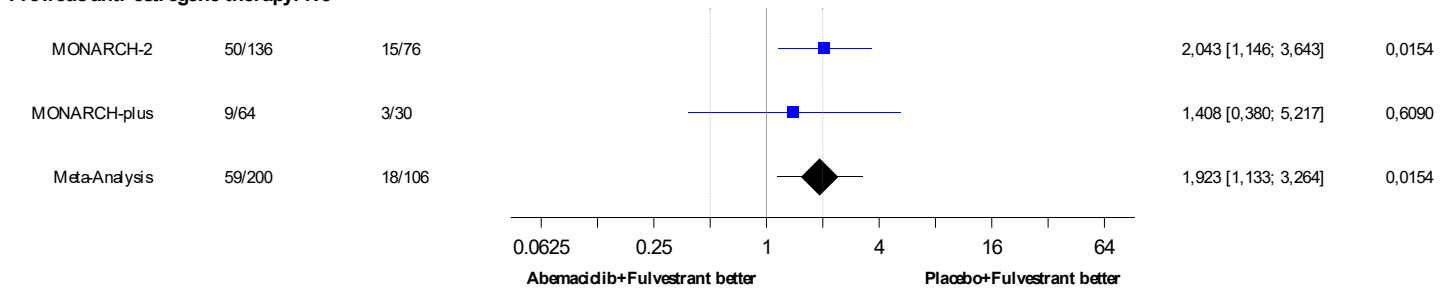
Figure 1102.1.9.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2603, p-value=0,6099, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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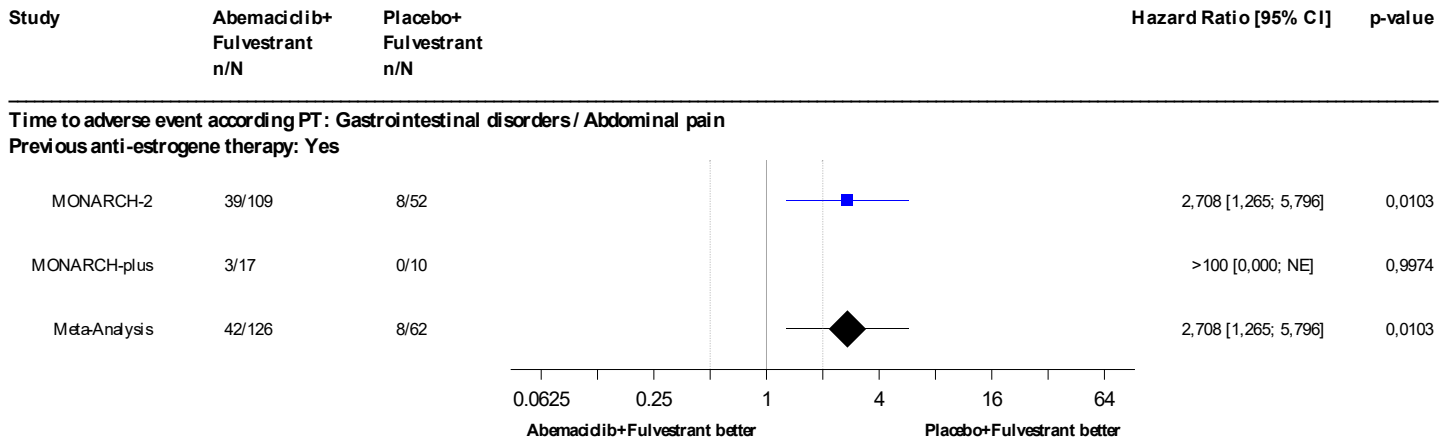
Figure 1102.1.9.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9975, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep002_popa1_paet_2.rtf
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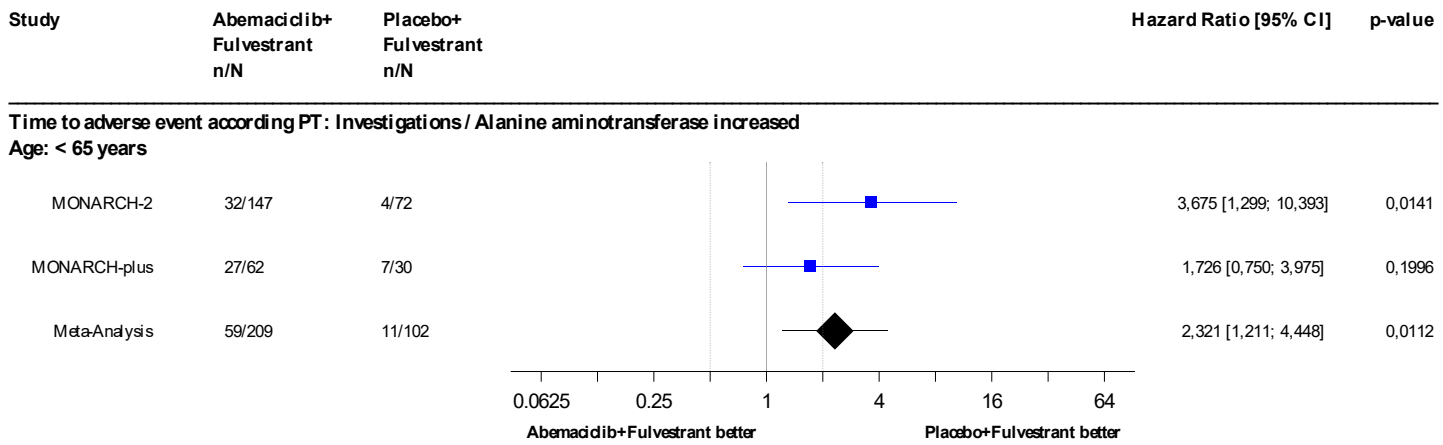
Figure 1103.1.1.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,2343, p-value=0,2666, I2 index=19,0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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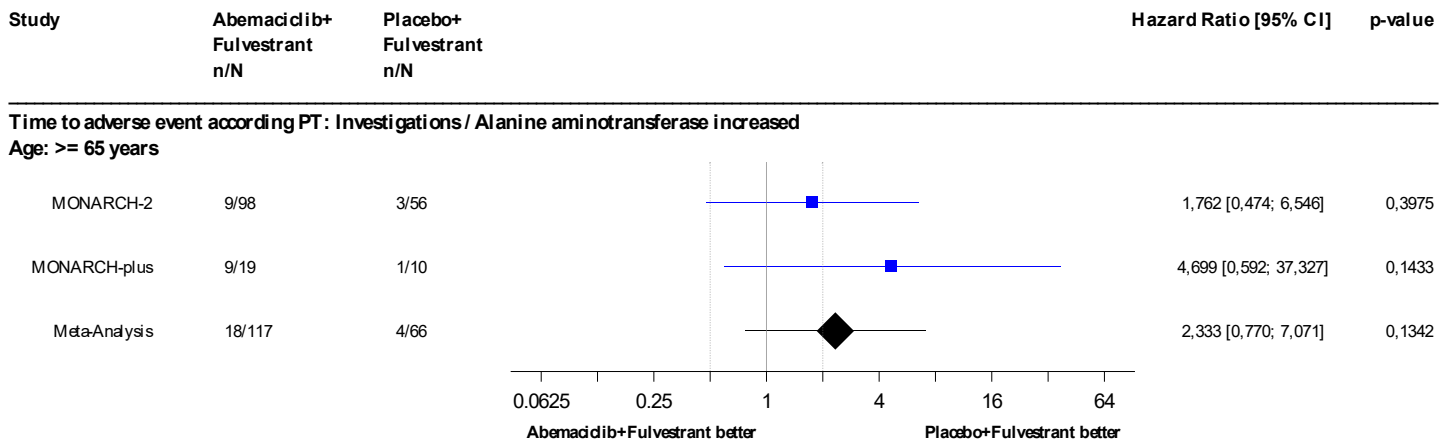
Figure 1103.1.1.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6142, p-value=0,4332, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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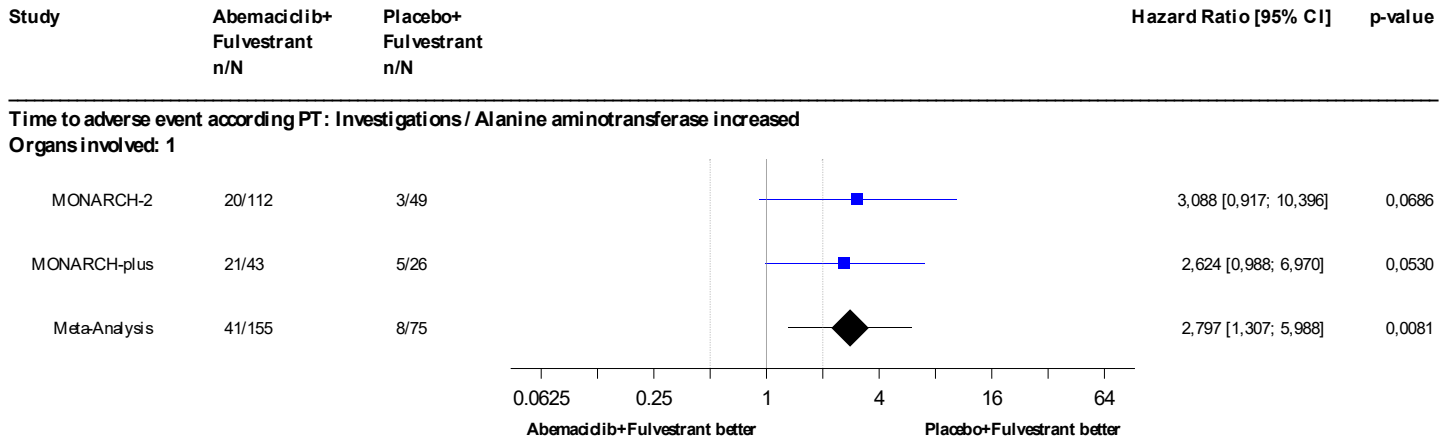
**Figure 1103.1.2.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0420, p-value=0,8376, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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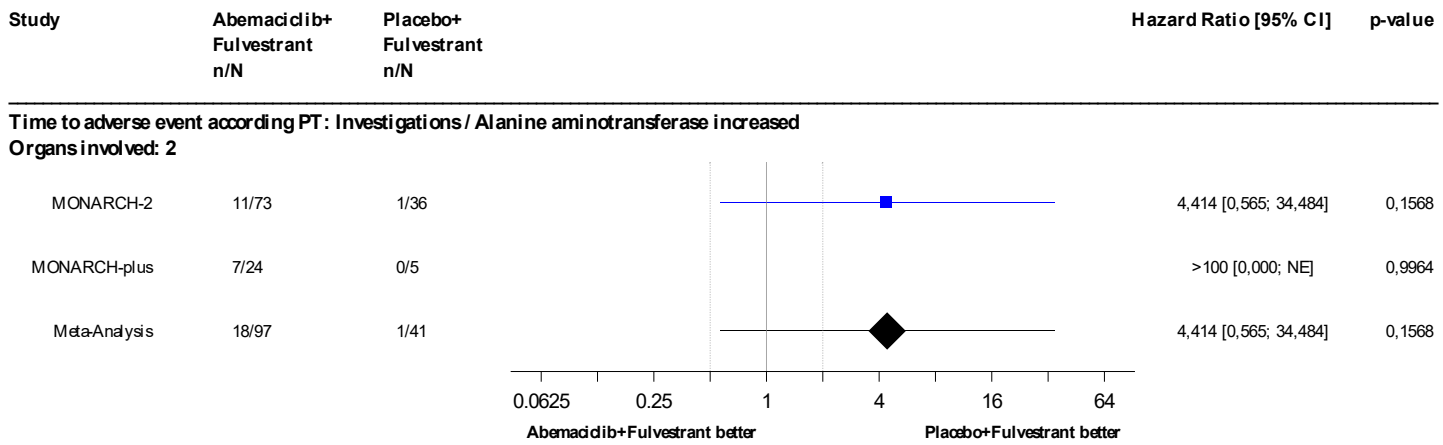
Figure 1103.1.2.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9967, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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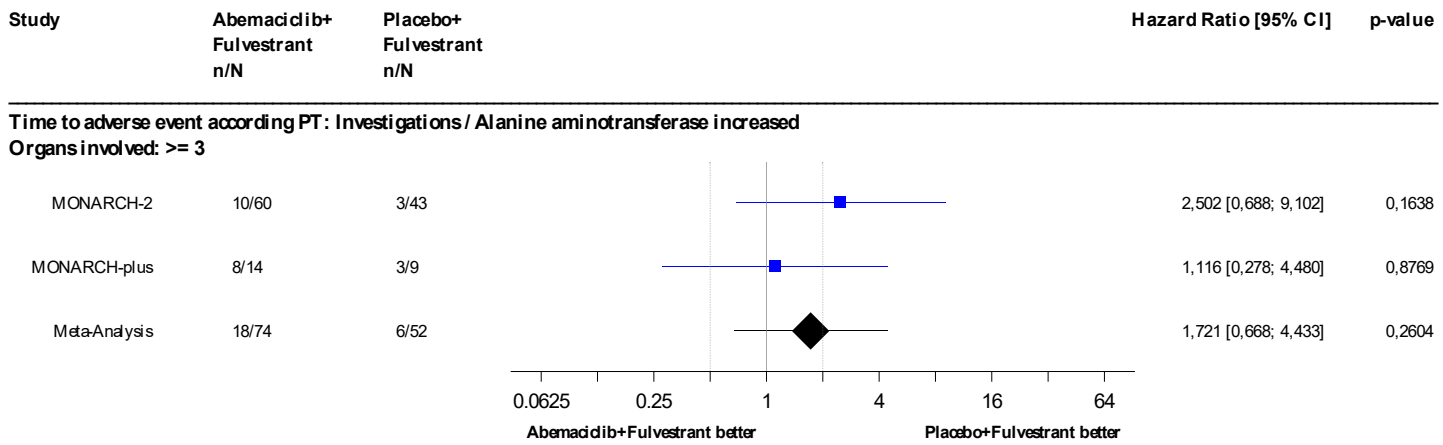
Figure 1103.1.2.3: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6958, p-value=0,4042, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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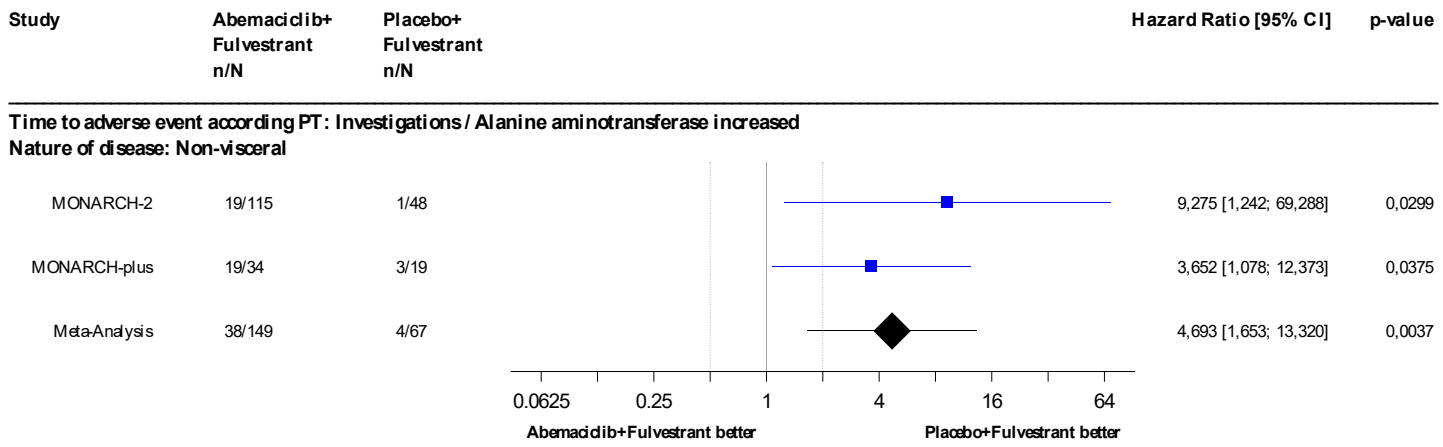
Figure 1103.1.3.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6031, p-value=0,4374, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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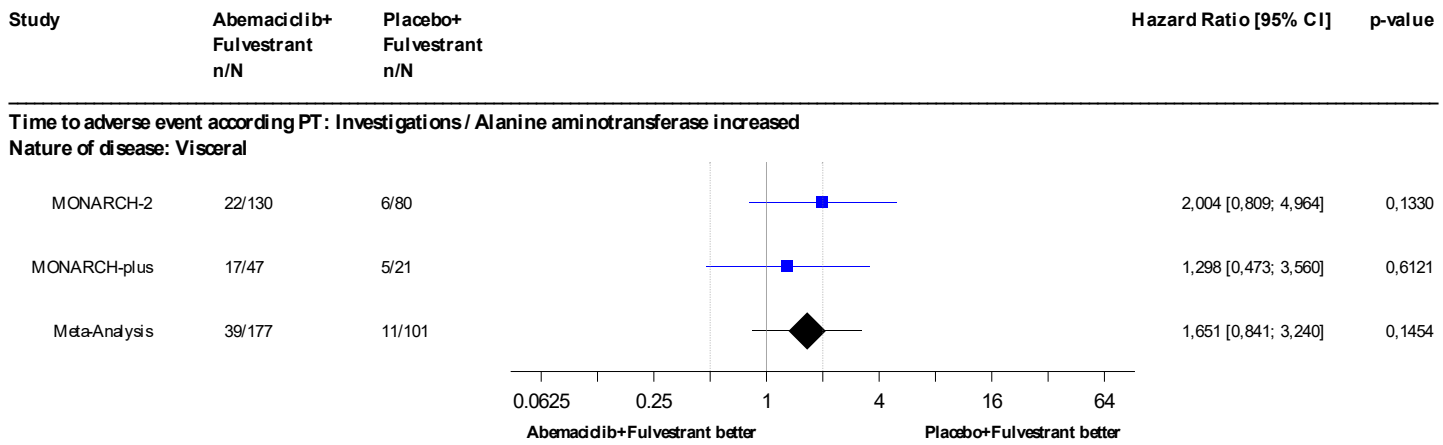
Figure 1103.1.3.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3934, p-value=0,5305, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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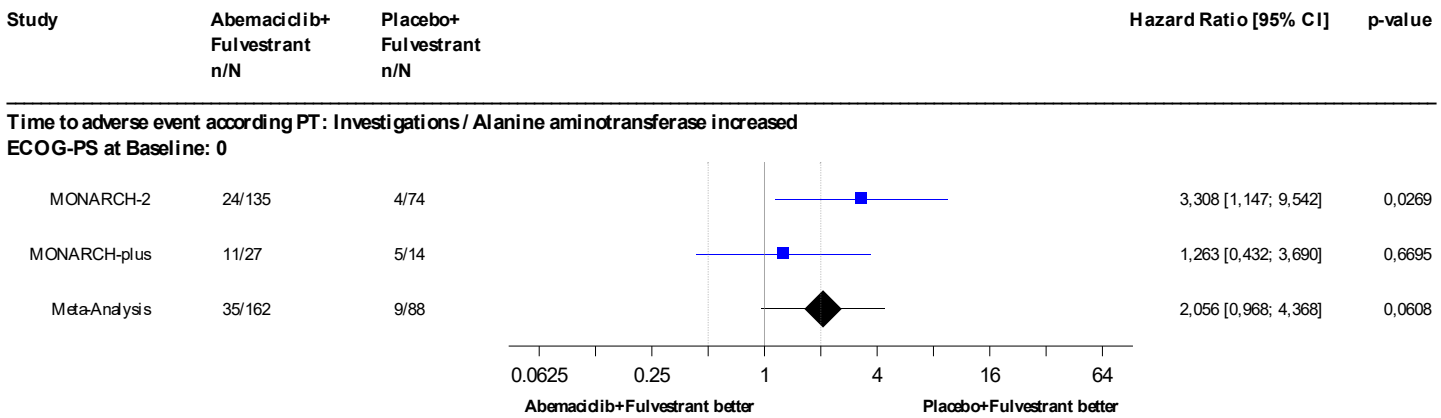
Figure 1103.1.4.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,5676, p-value=0,2105, I2 index=36,2%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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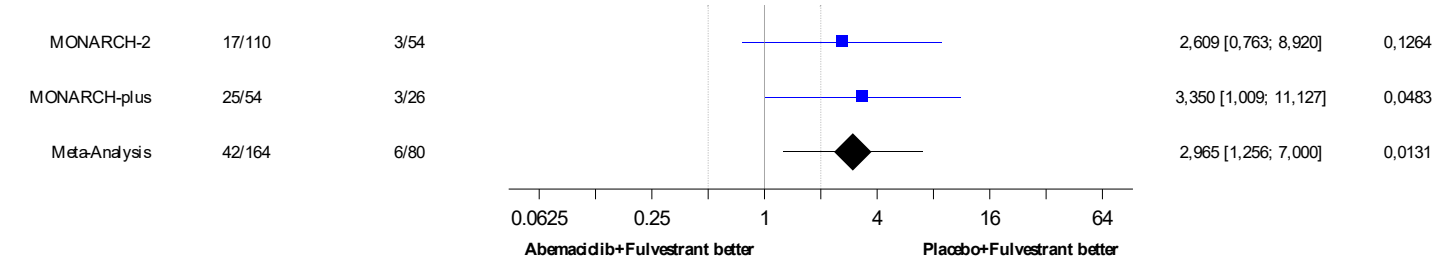
**Figure 1103.1.4.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0815, p-value=0,7753, I2 index=0%

Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep003_popa1_ecogbl_2.rtf

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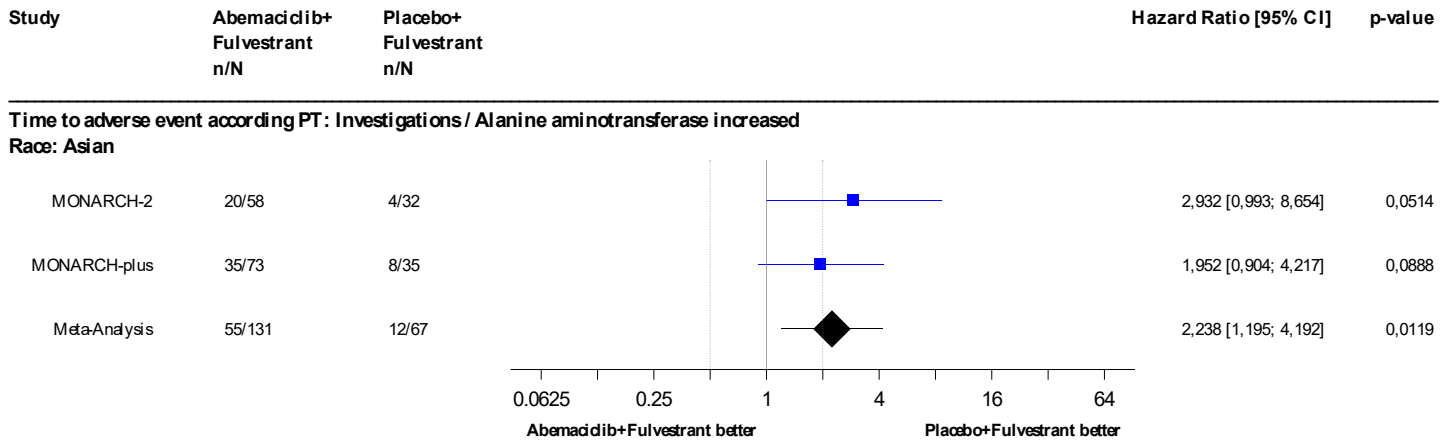
Figure 1103.1.5.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3604, p-value=0,5483, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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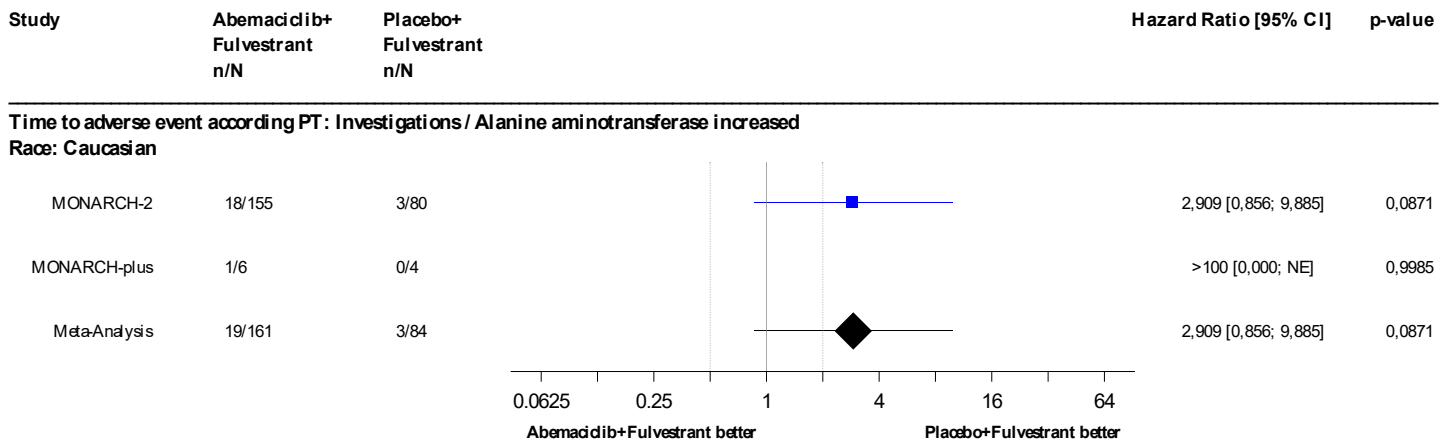
Figure 1103.1.5.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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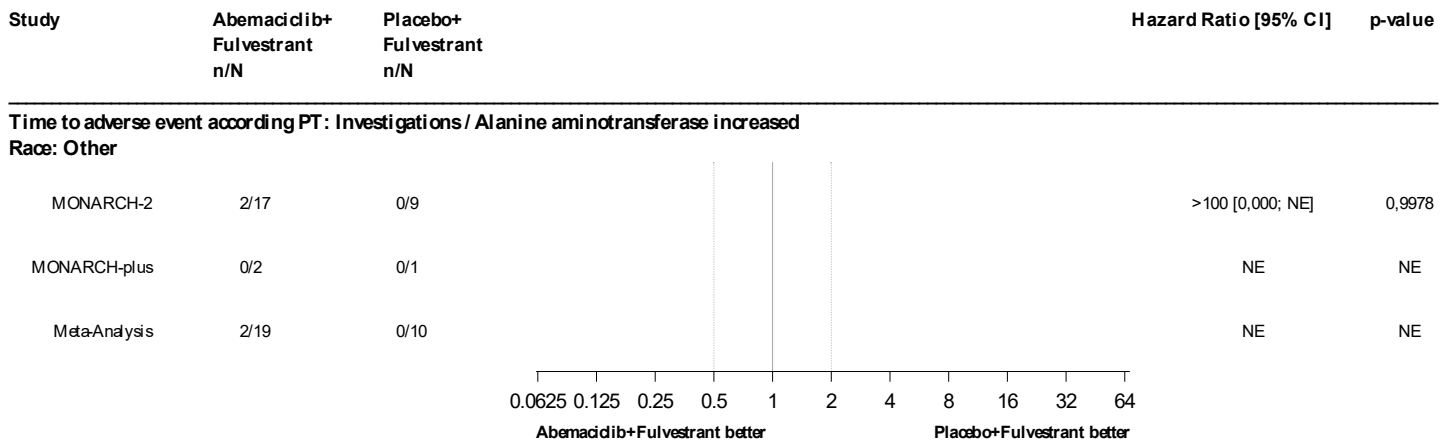
Figure 1103.1.5.3: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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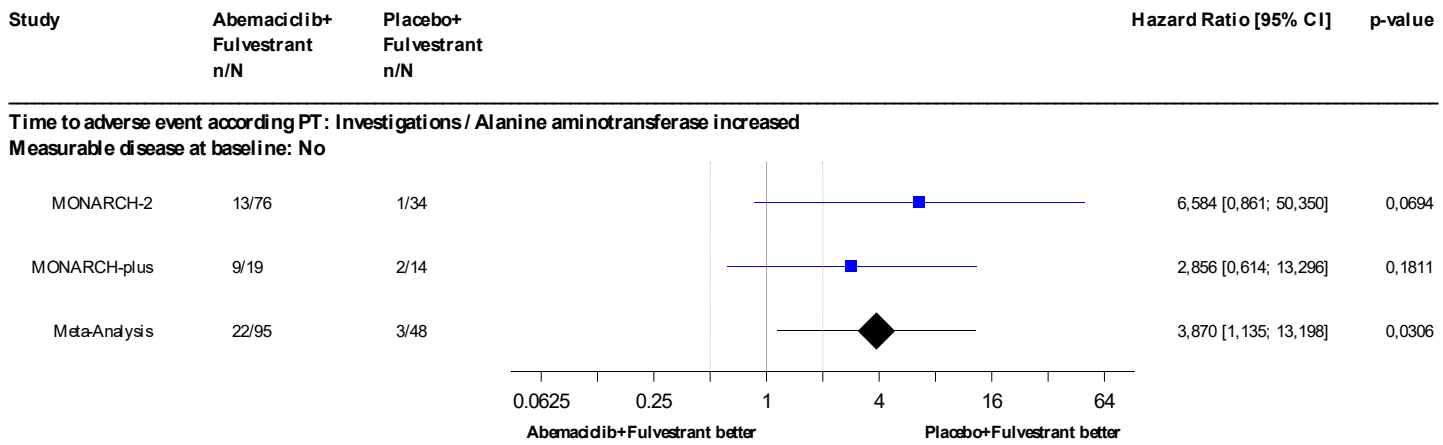
Figure 1103.1.6.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4119, p-value=0,5210, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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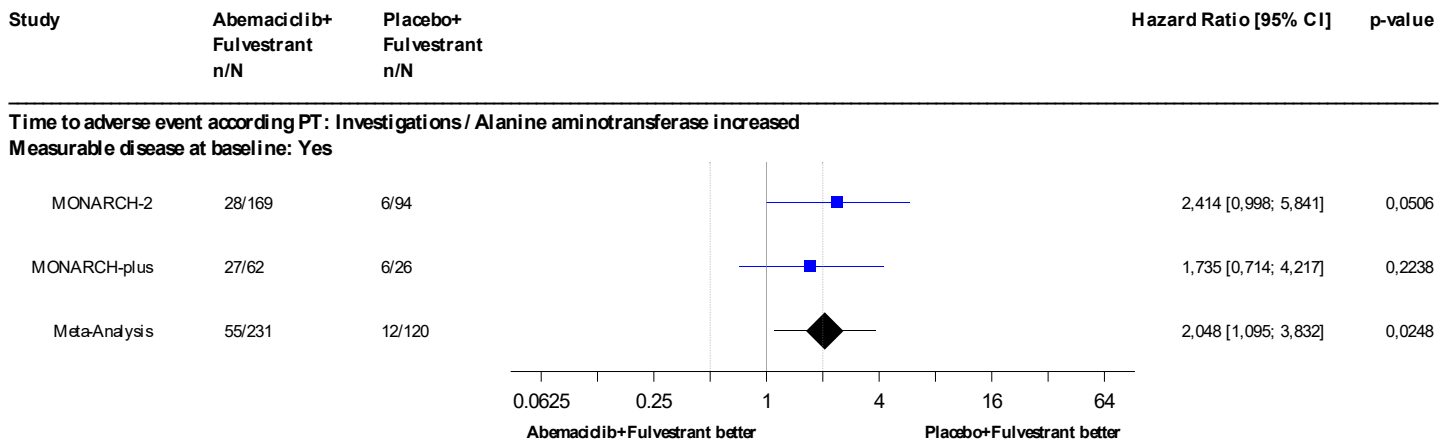
**Figure 1103.1.6.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,2670, p-value=0,6054, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep003_popa1_measdis_2.rtf
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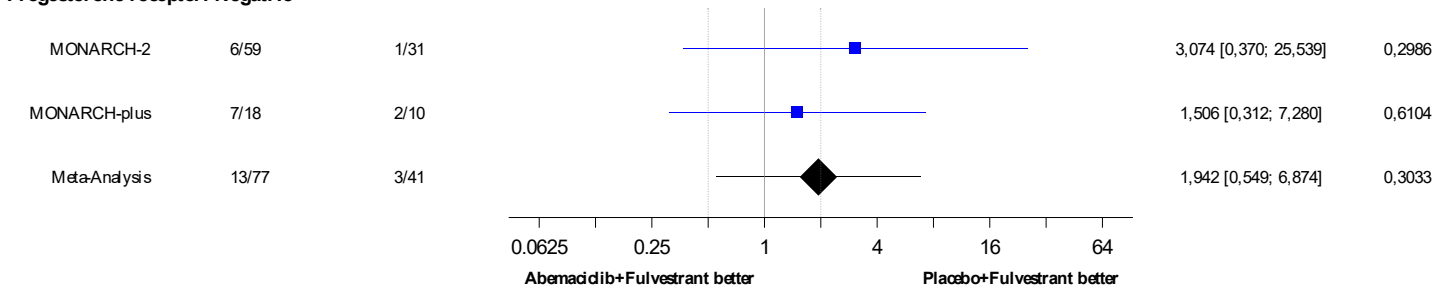
Figure 1103.1.7.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2806, p-value=0,5963, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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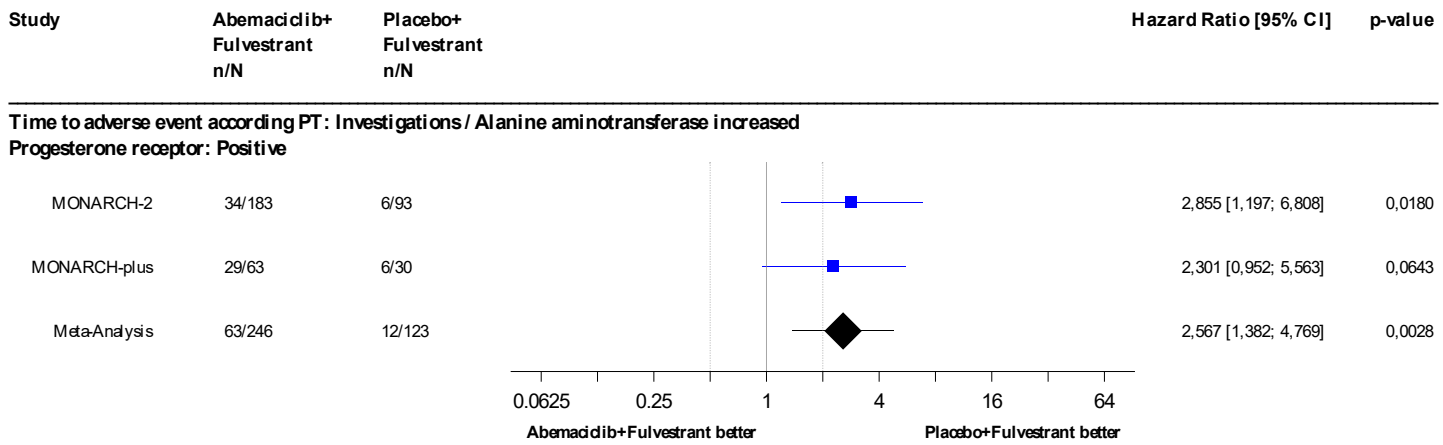
Figure 1103.1.7.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1165, p-value=0,7329, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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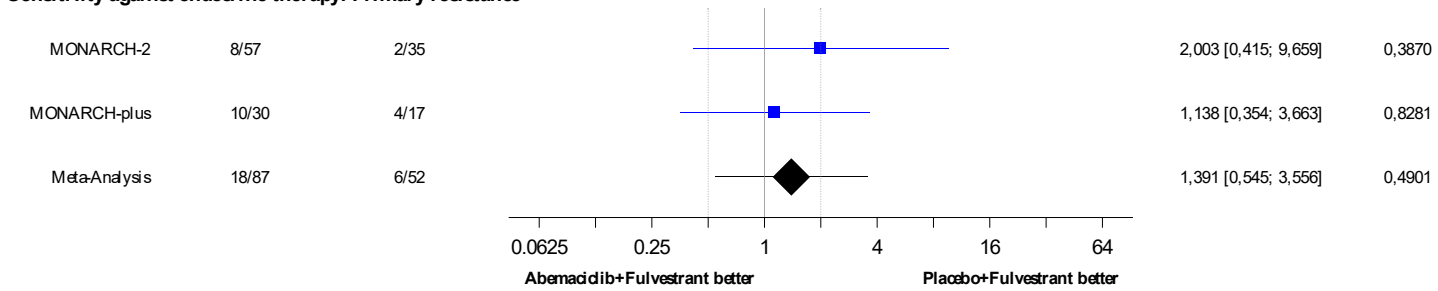
**Figure 1103.1.8.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,3193, p-value=0,5720, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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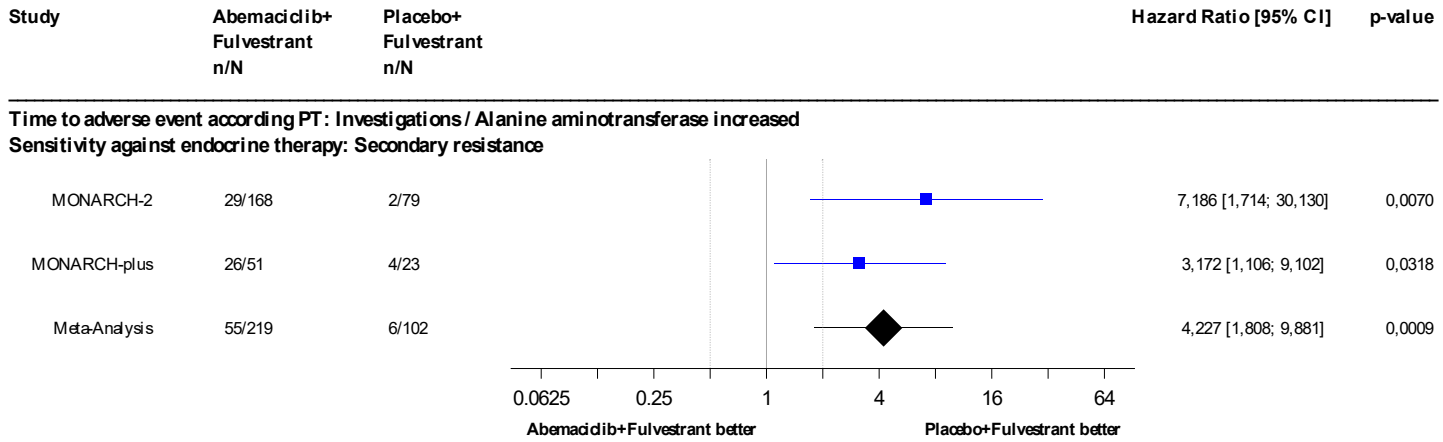
Figure 1103.1.8.2: Metaanalysis results for adverse events according PT[1] - Investigations / Alanine aminotransferase increased
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,8114, p-value=0,3677, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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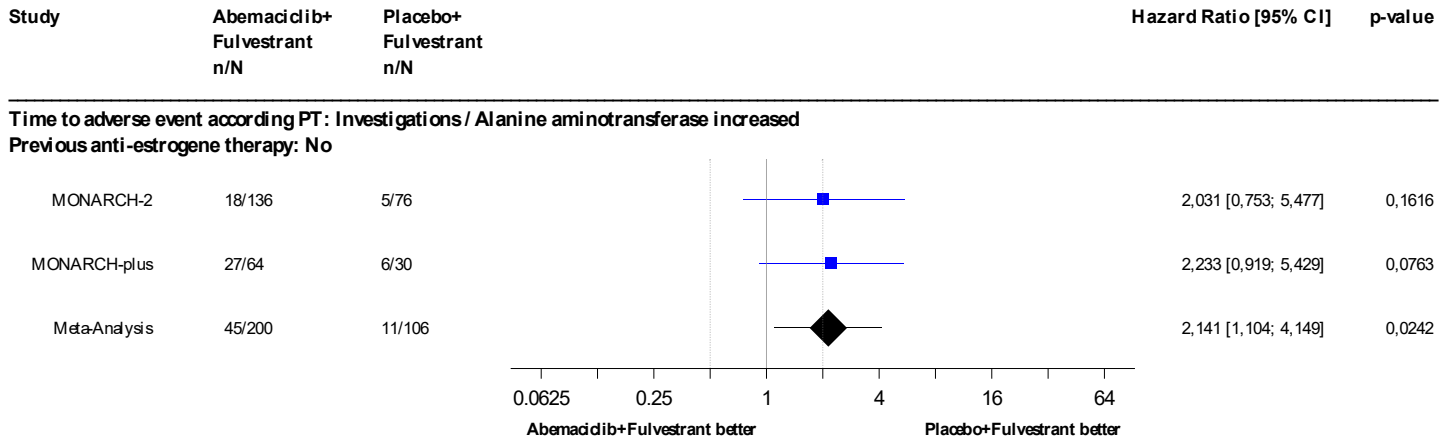
**Figure 1103.1.9.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0195, p-value=0,8890, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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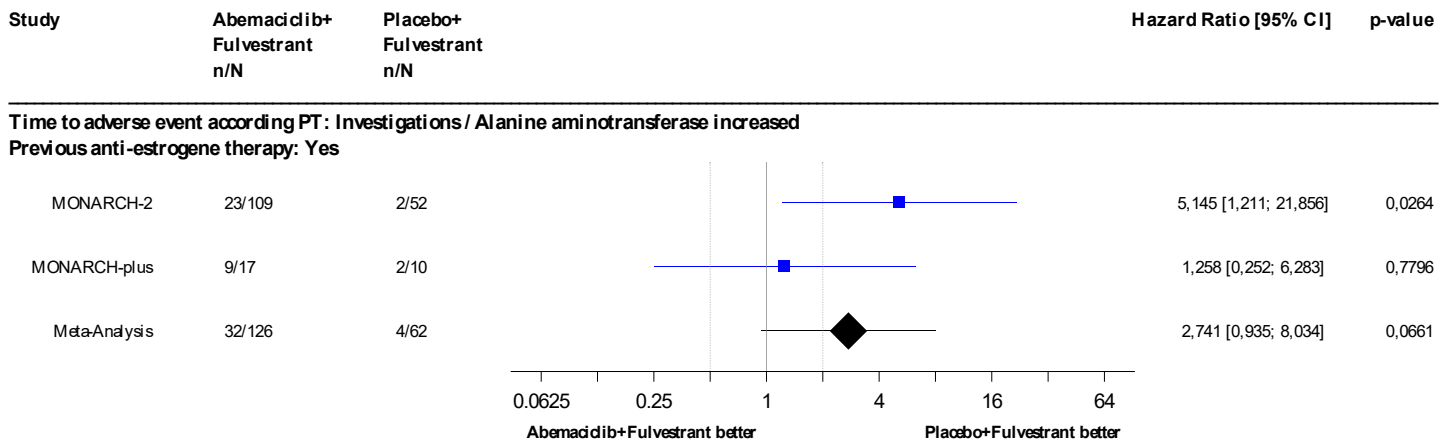
**Figure 1103.1.9.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Alanine aminotransferase increased
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=1,6289, p-value=0,2019, I2 index=38,6%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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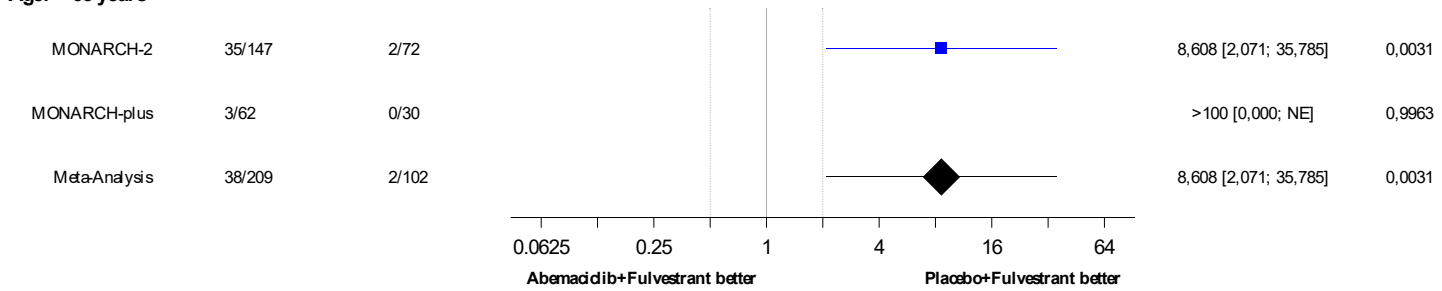
Figure 1104.1.1.1: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9968, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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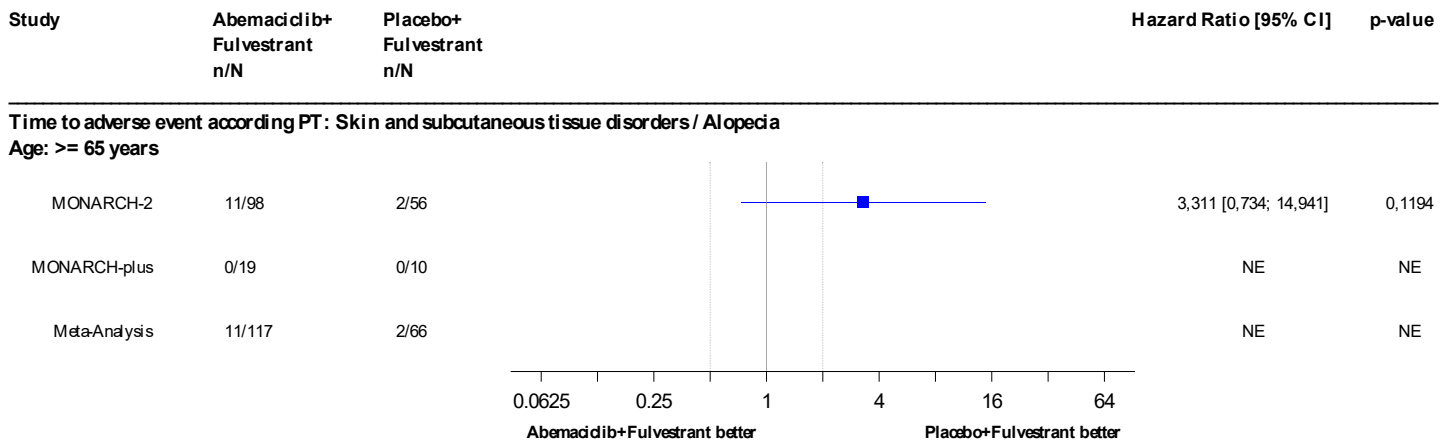
Figure 1104.1.1.2: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep004_popa1_agegr1_2.rtf
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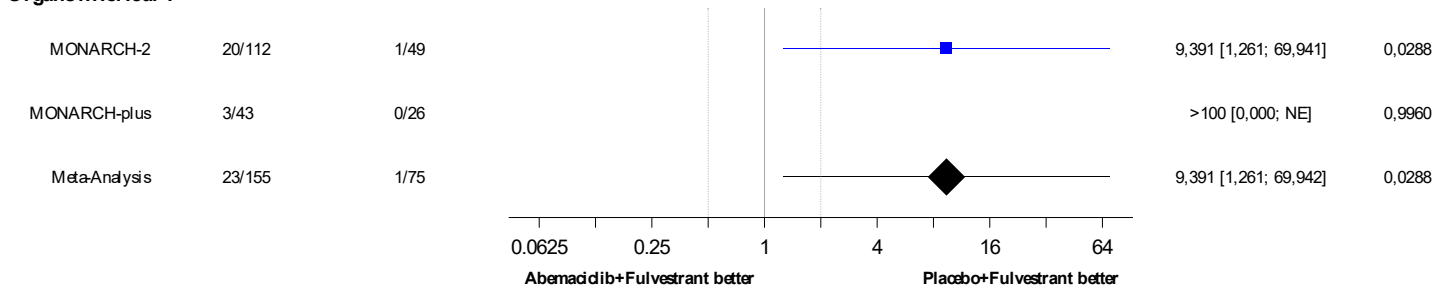
Figure 1104.1.2.1: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9965, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep004_popa1_norggr_1.rtf
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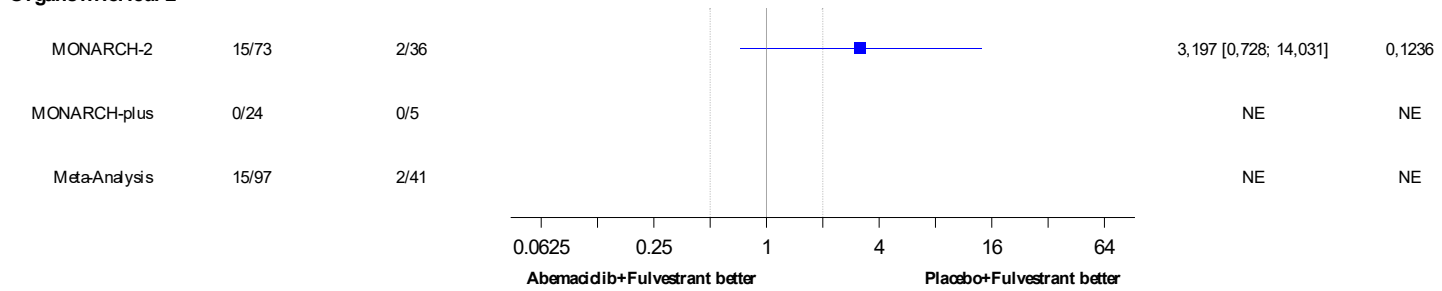
Figure 1104.1.2.2: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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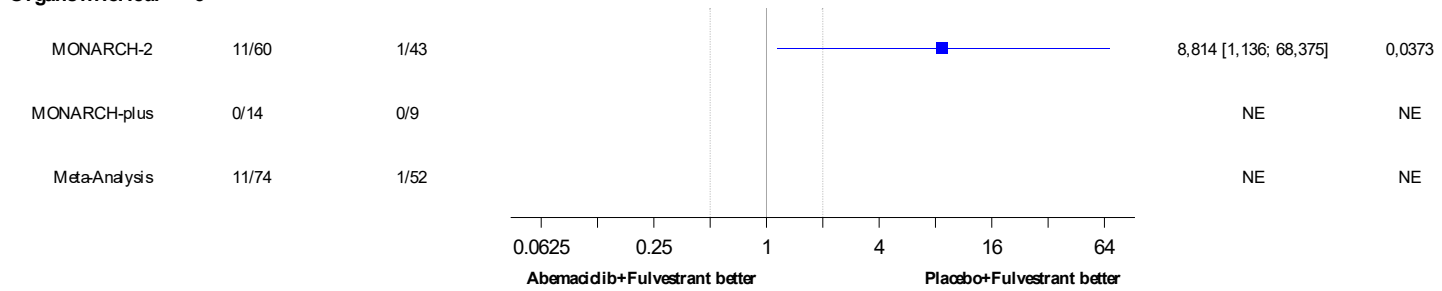
Figure 1104.1.2.3: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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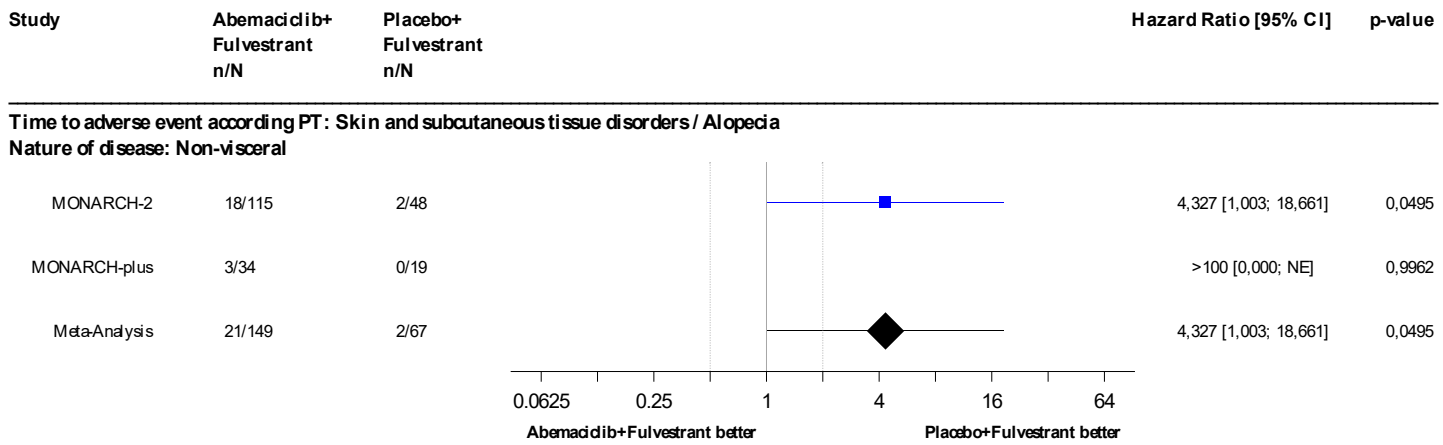
Figure 1104.1.3.1: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9965, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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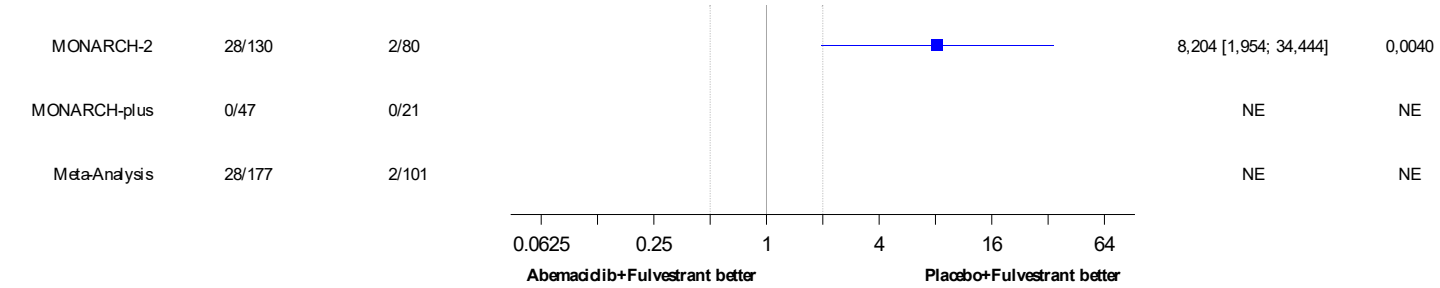
Figure 1104.1.3.2: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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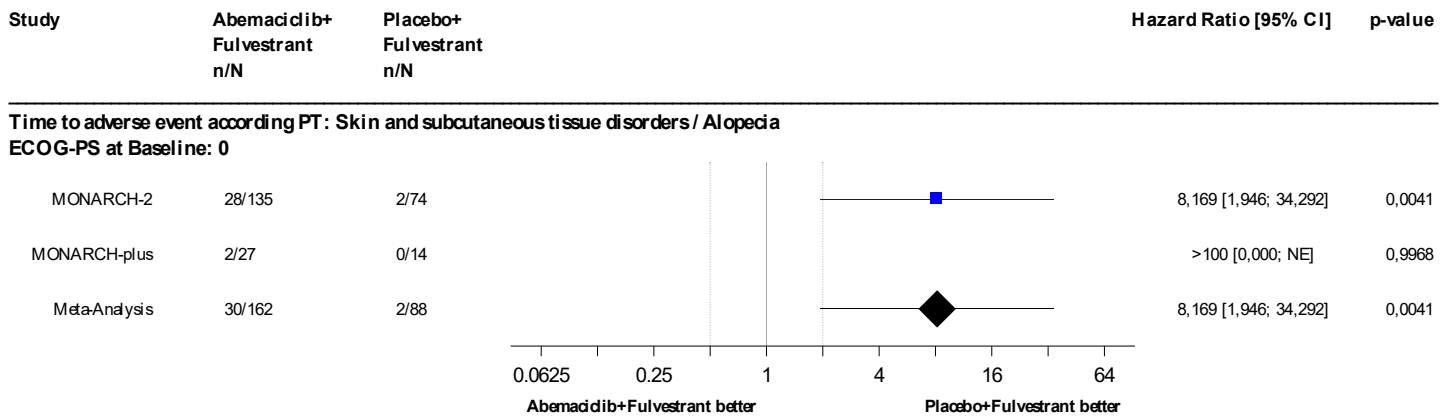
Figure 1104.1.4.1: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9972, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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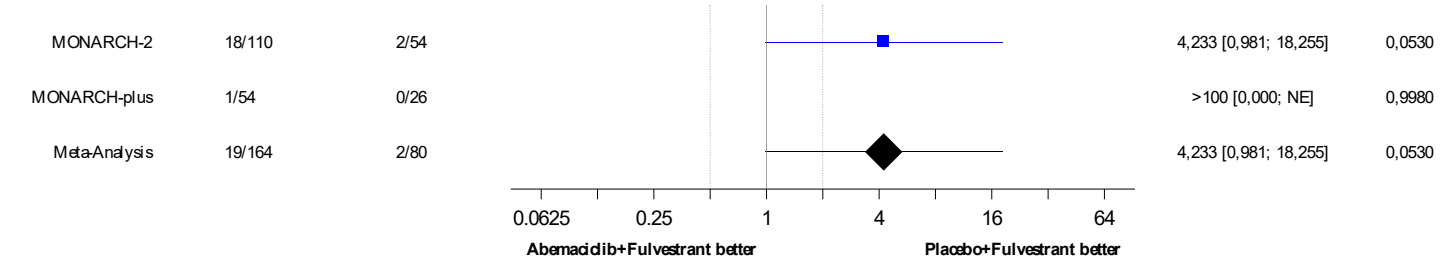
Figure 1104.1.4.2: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9982, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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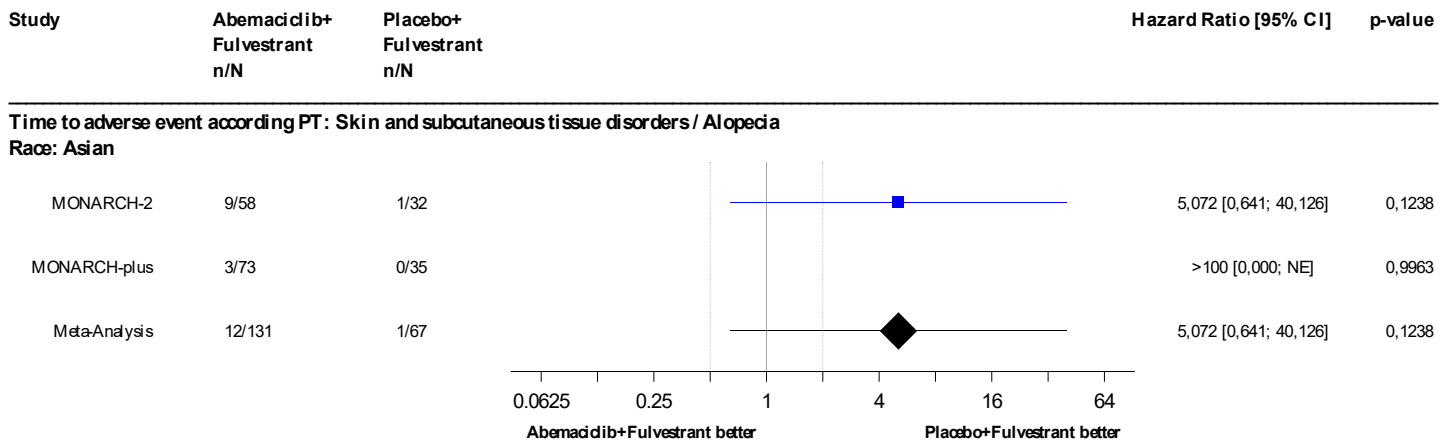
Figure 1104.1.5.1: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9967, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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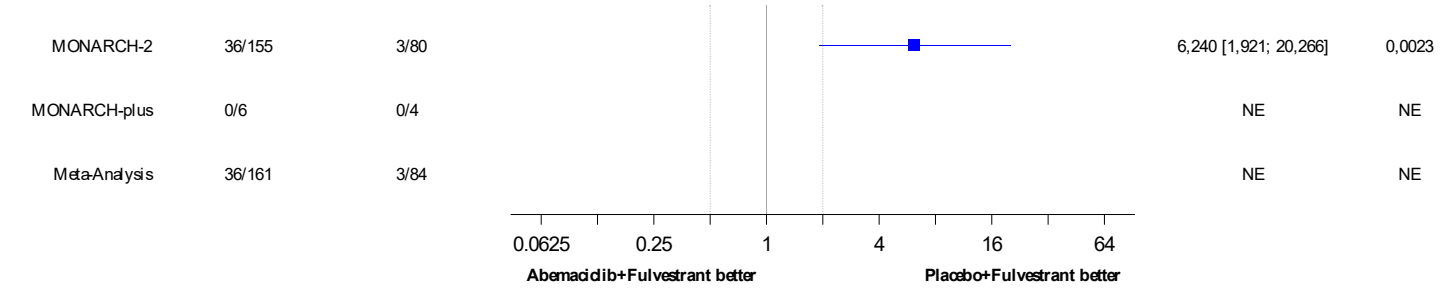
Figure 1104.1.5.2: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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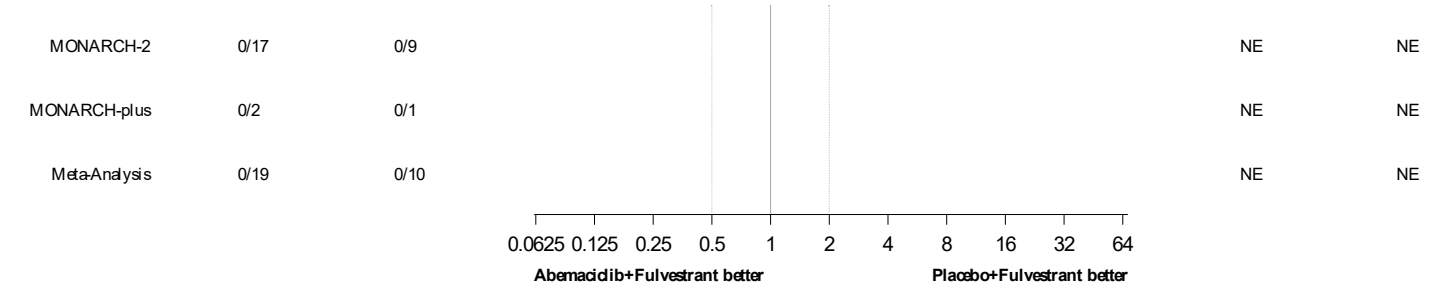
Figure 1104.1.5.3: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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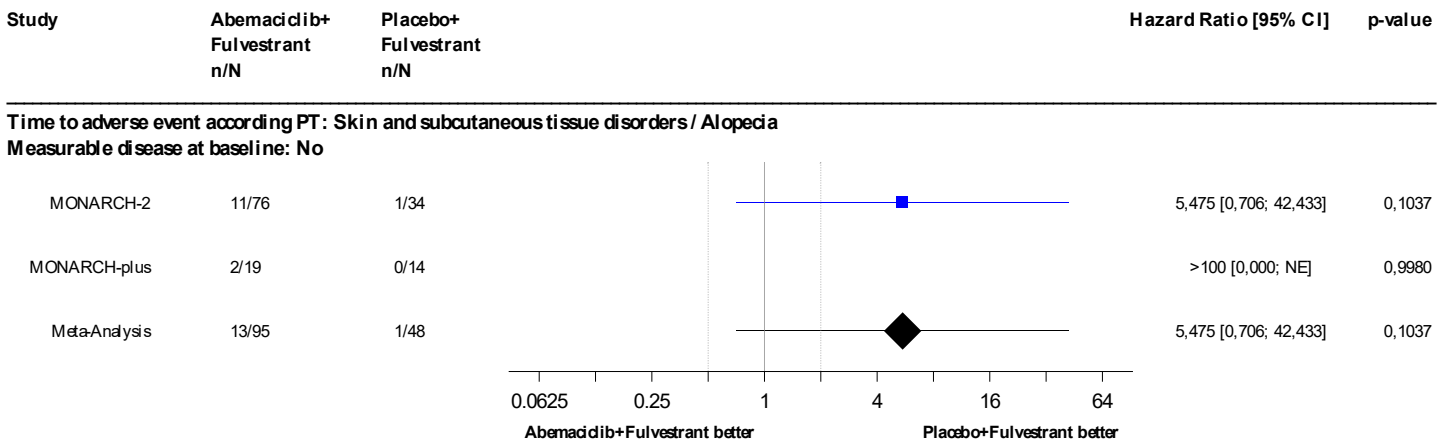
Figure 1104.1.6.1: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9982, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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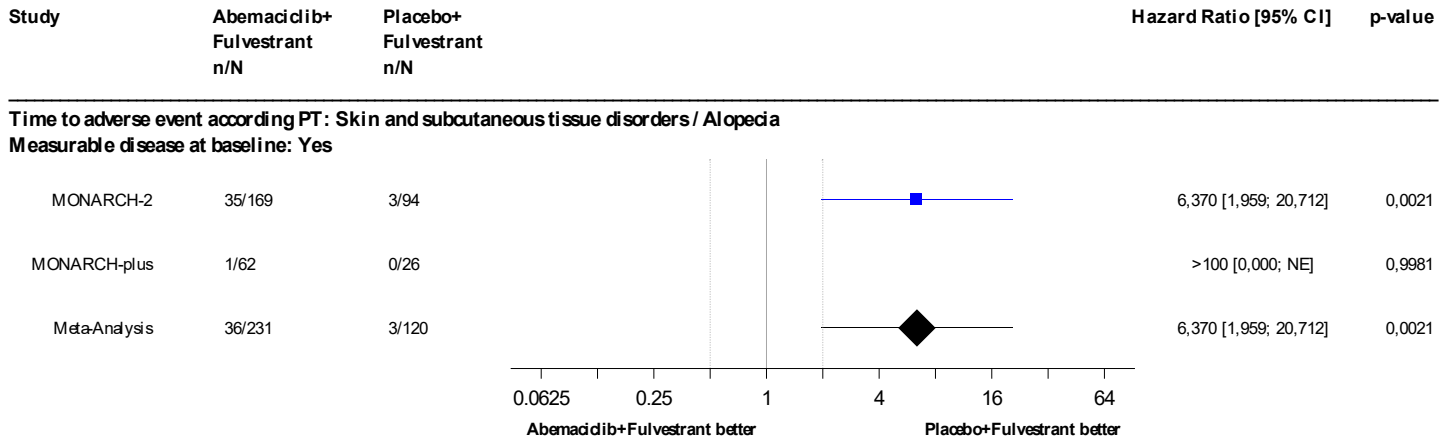
Figure 1104.1.6.2: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9983, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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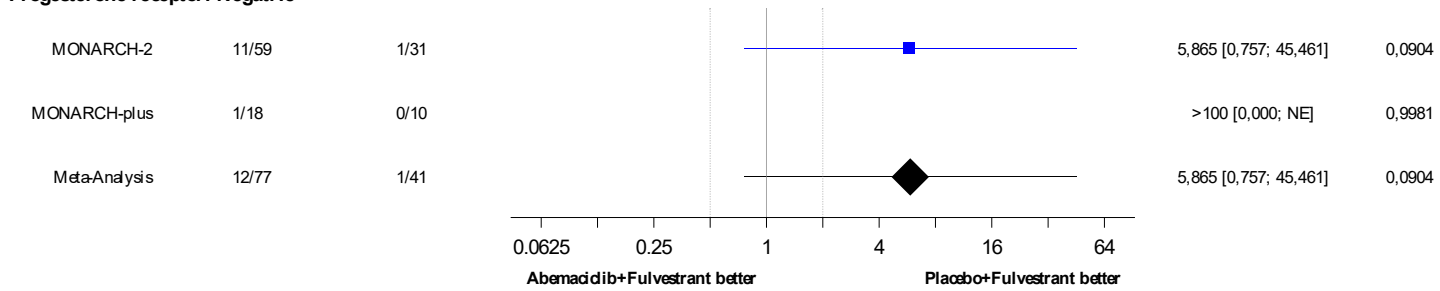
Figure 1104.1.7.1: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9983, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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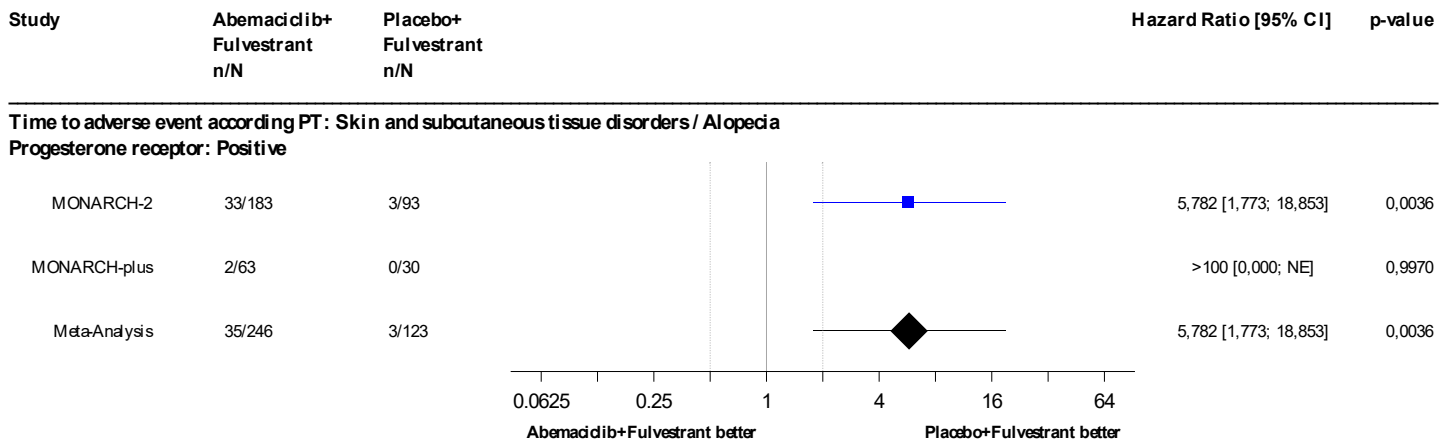
Figure 1104.1.7.2: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9973, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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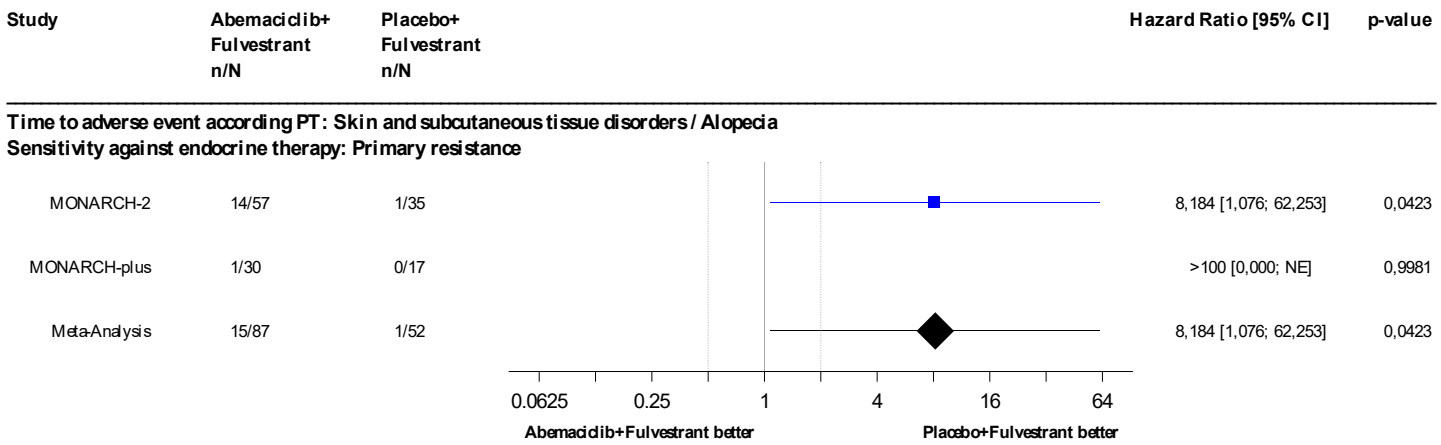
Figure 1104.1.8.1: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9983, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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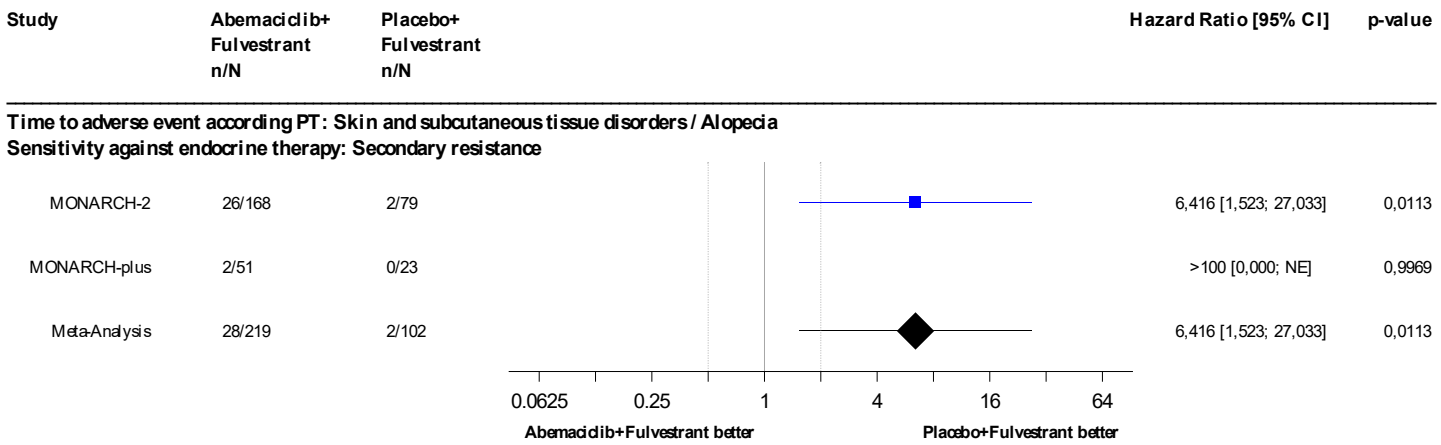
Figure 1104.1.8.2: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9973, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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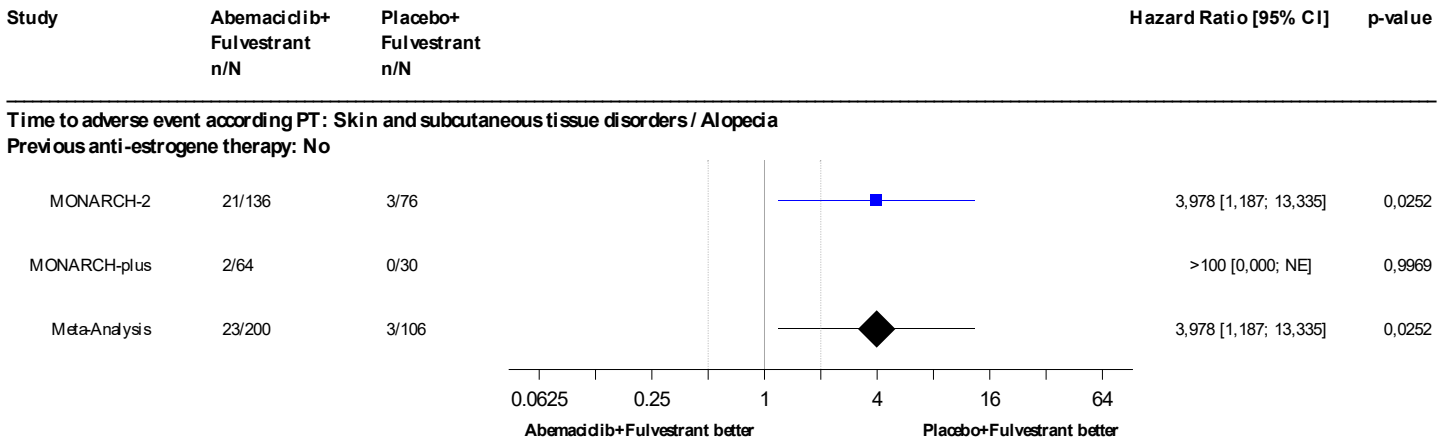
Figure 1104.1.9.1: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9972, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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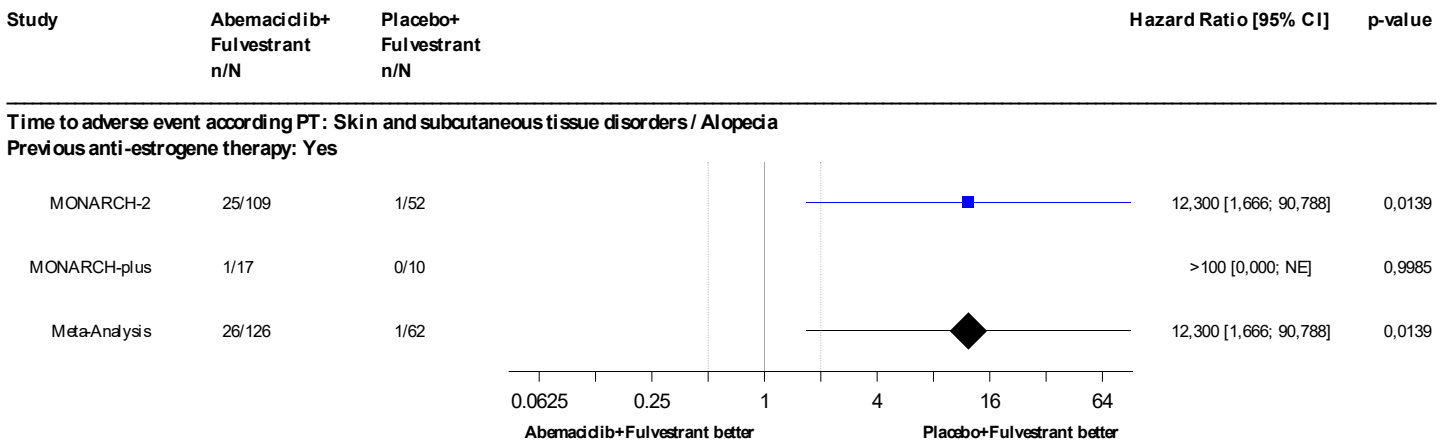
Figure 1104.1.9.2: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9987, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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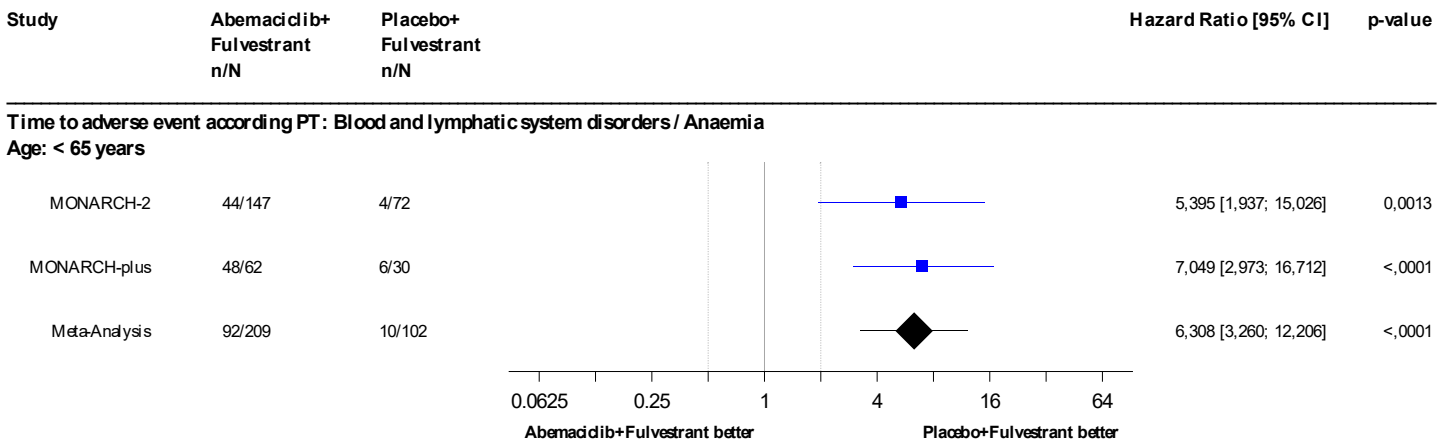
Figure 1105.1.1.1: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1532, p-value=0,6955, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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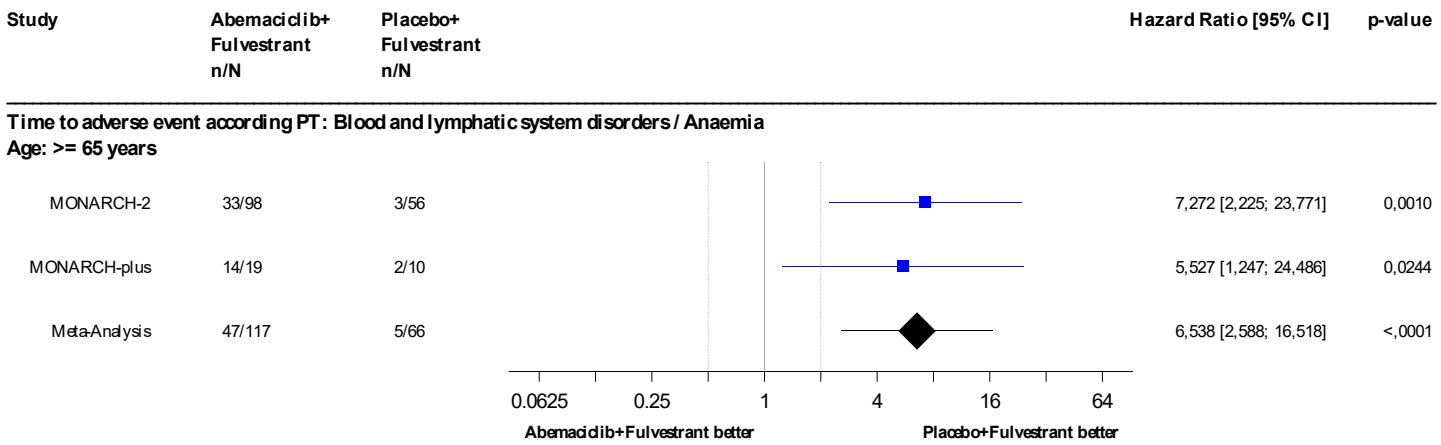
Figure 1105.1.1.2: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0800, p-value=0,7774, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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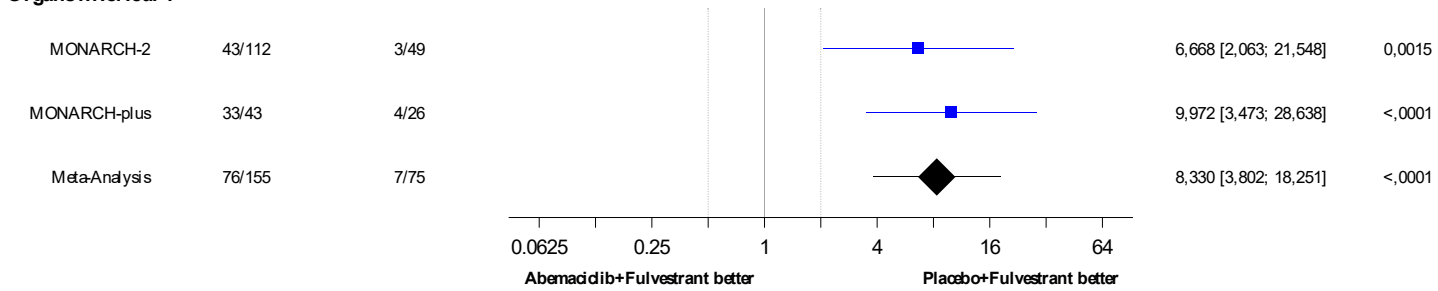
Figure 1105.1.2.1: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2501, p-value=0,6170, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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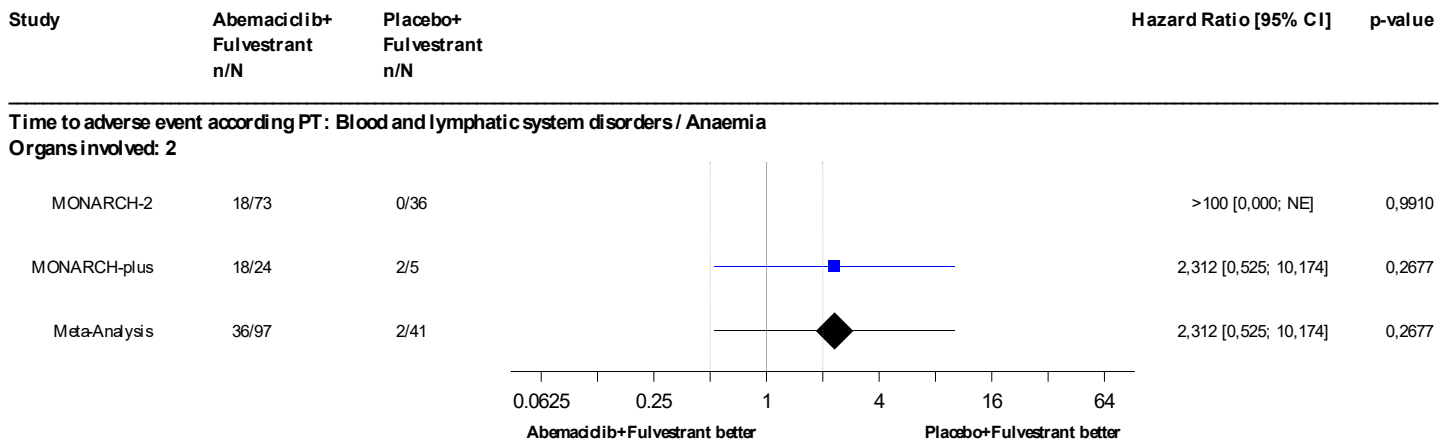
Figure 1105.1.2.2: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9915, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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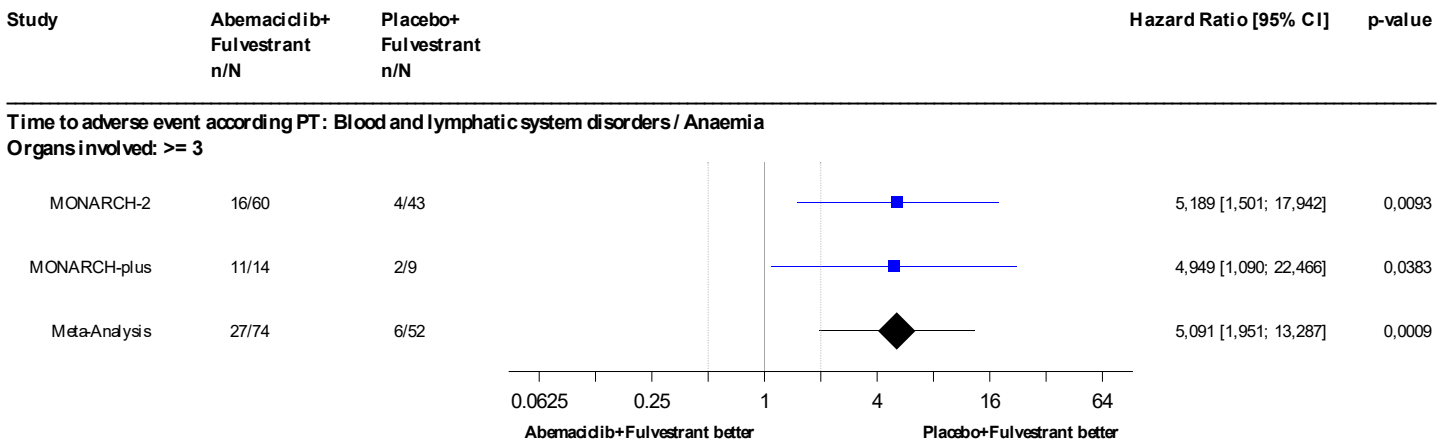
Figure 1105.1.2.3: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0022, p-value=0,9622, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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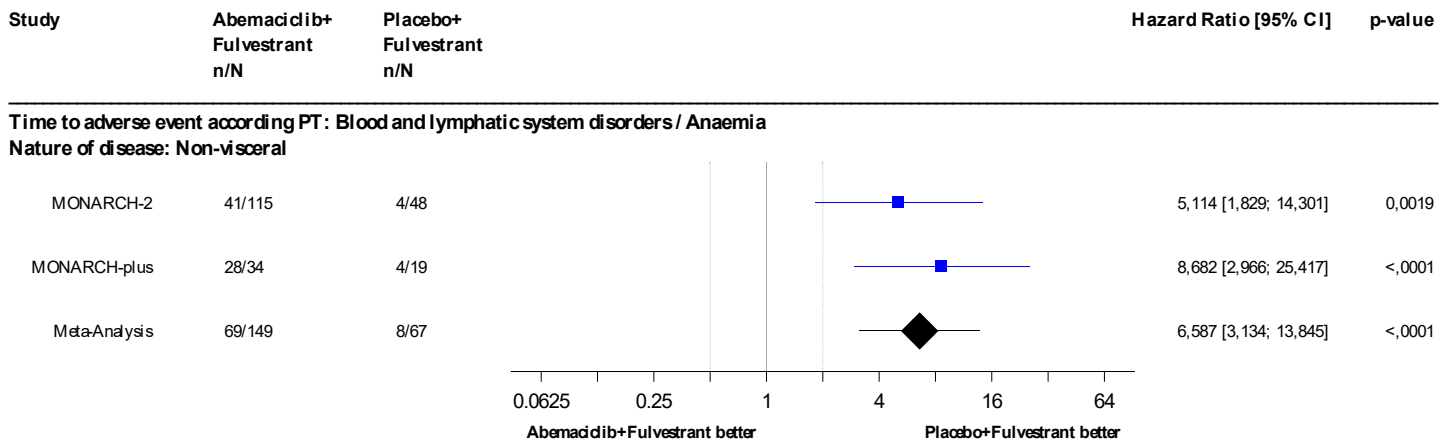
Figure 1105.1.3.1: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4867, p-value=0,4854, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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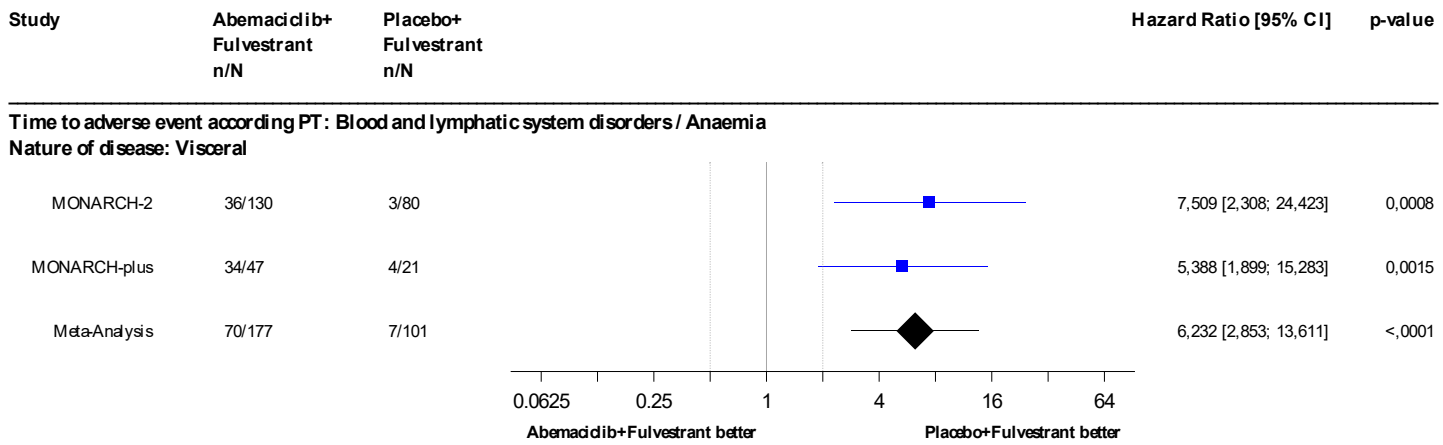
Figure 1105.1.3.2: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1708, p-value=0,6794, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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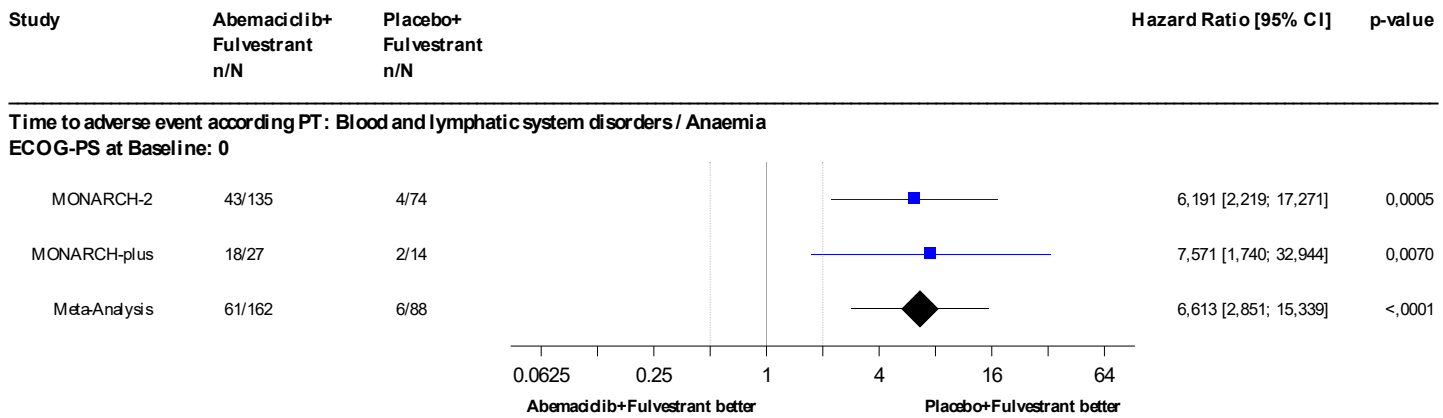
Figure 1105.1.4.1: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0484, p-value=0,8258, I2 index=0%

Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

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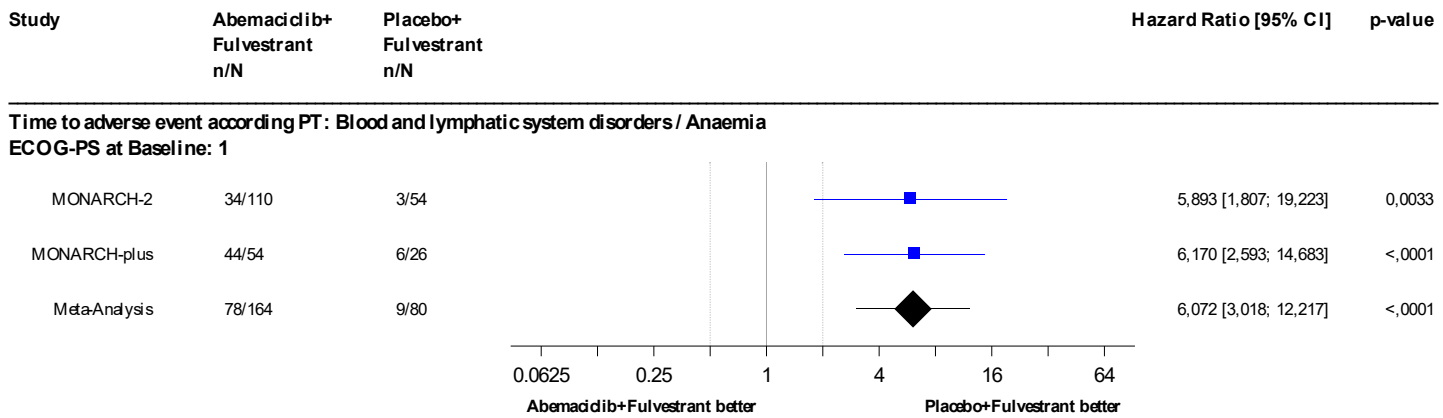
Figure 1105.1.4.2: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0038, p-value=0,9510, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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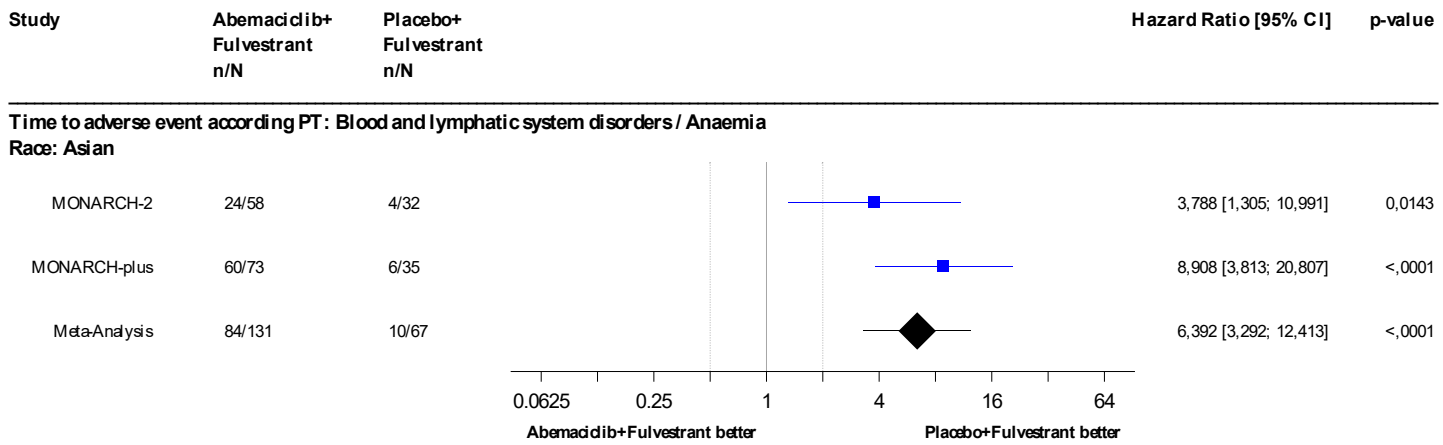
Figure 1105.1.5.1: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,5147, p-value=0,2184, I2 index=34,0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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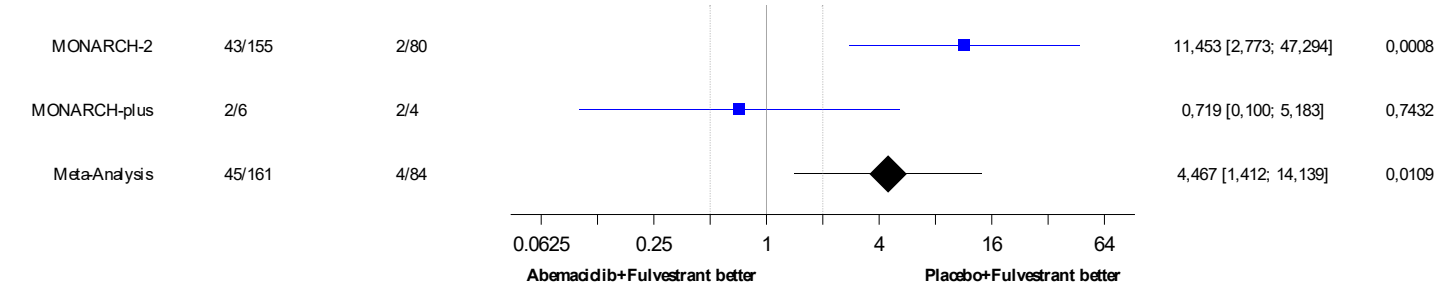
Figure 1105.1.5.2: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=4,9780, p-value=0,0257, I2 index=79,9%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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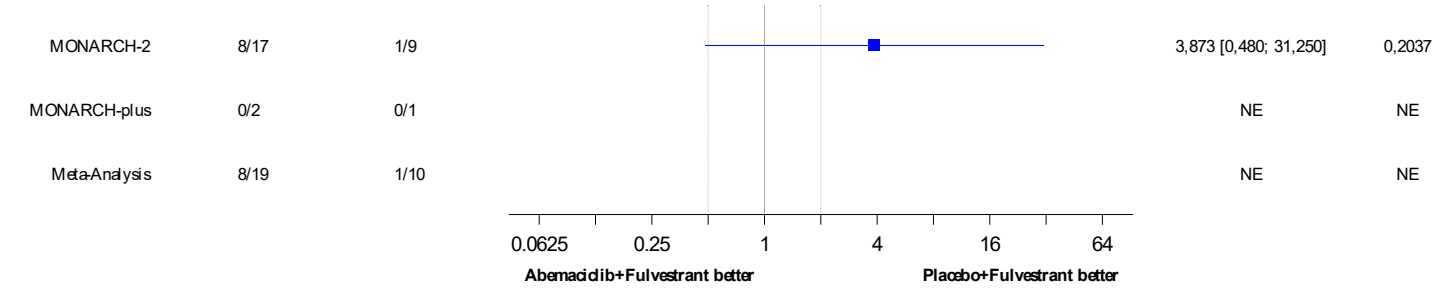
Figure 1105.1.5.3: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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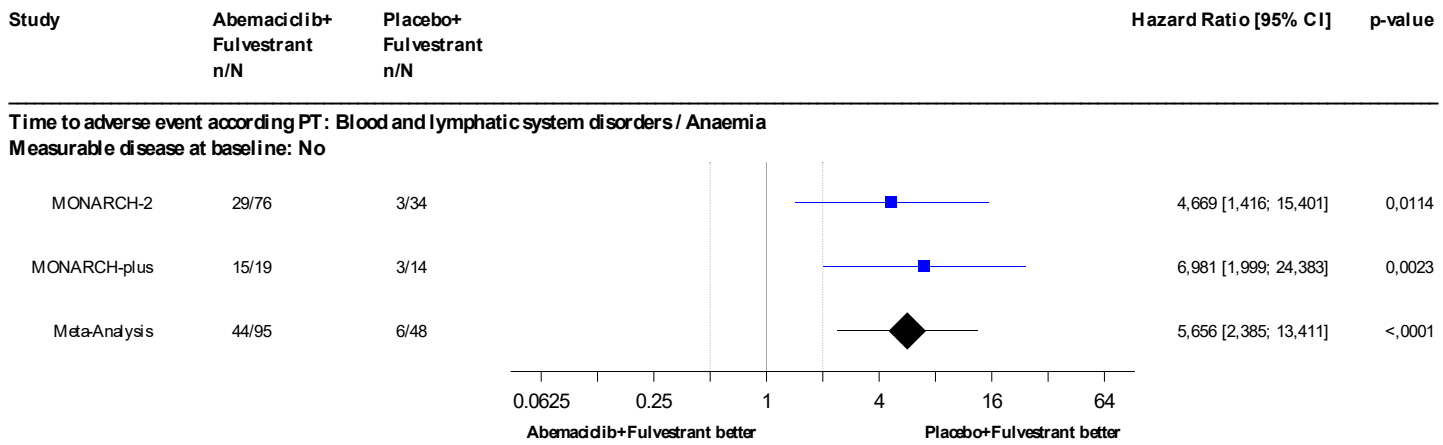
Figure 1105.1.6.1: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2080, p-value=0,6484, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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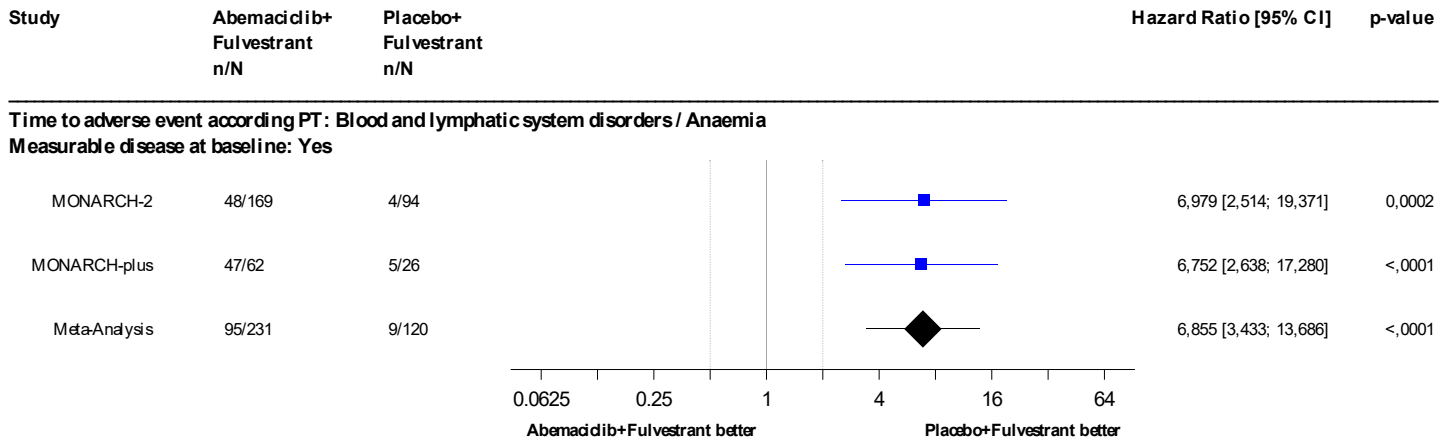
Figure 1105.1.6.2: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0022, p-value=0,9627, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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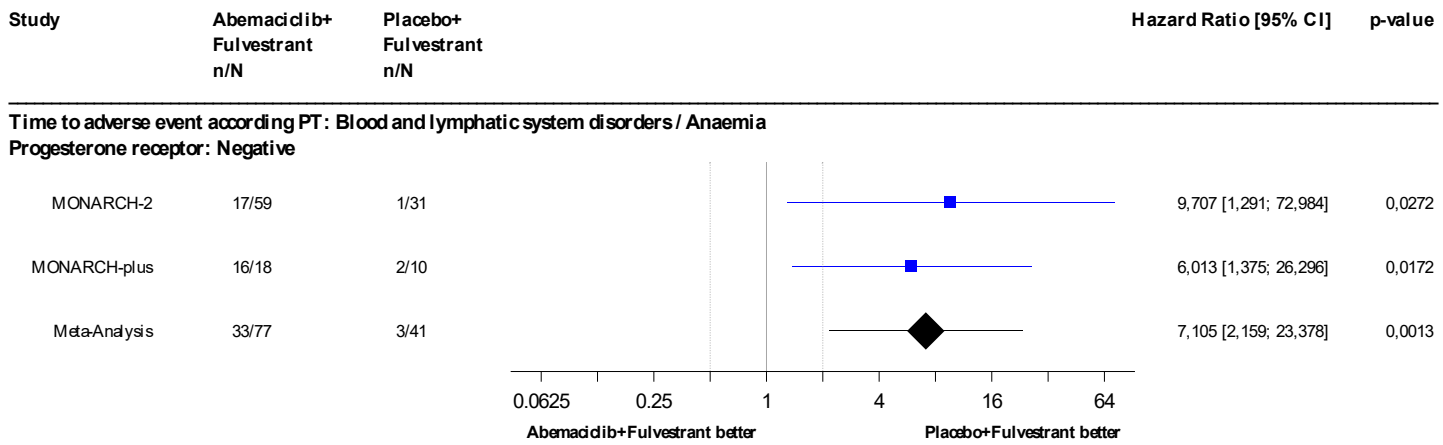
Figure 1105.1.7.1: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1411, p-value=0,7072, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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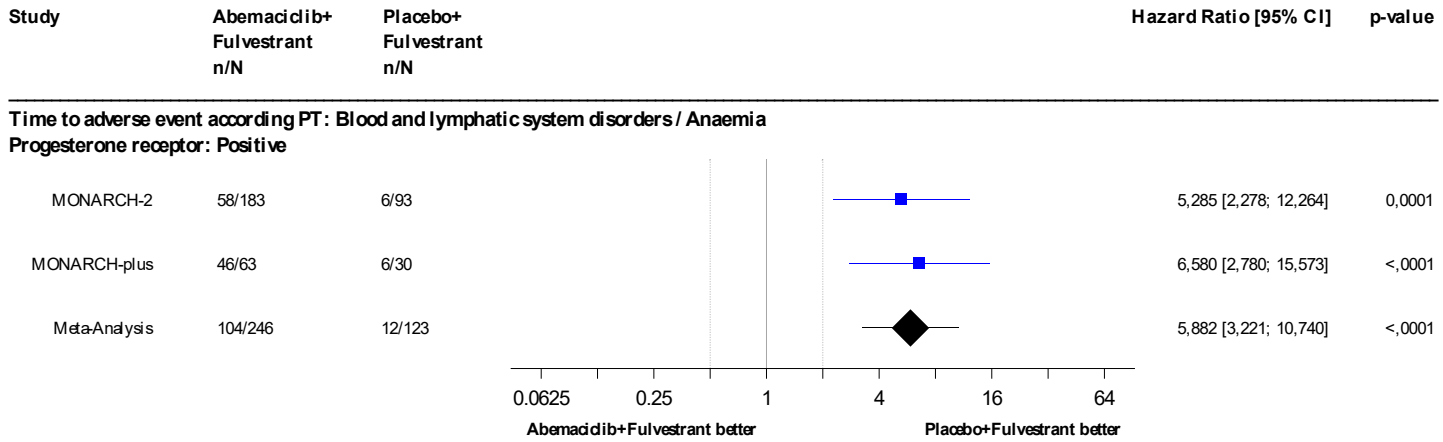
Figure 1105.1.7.2: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1270, p-value=0,7215, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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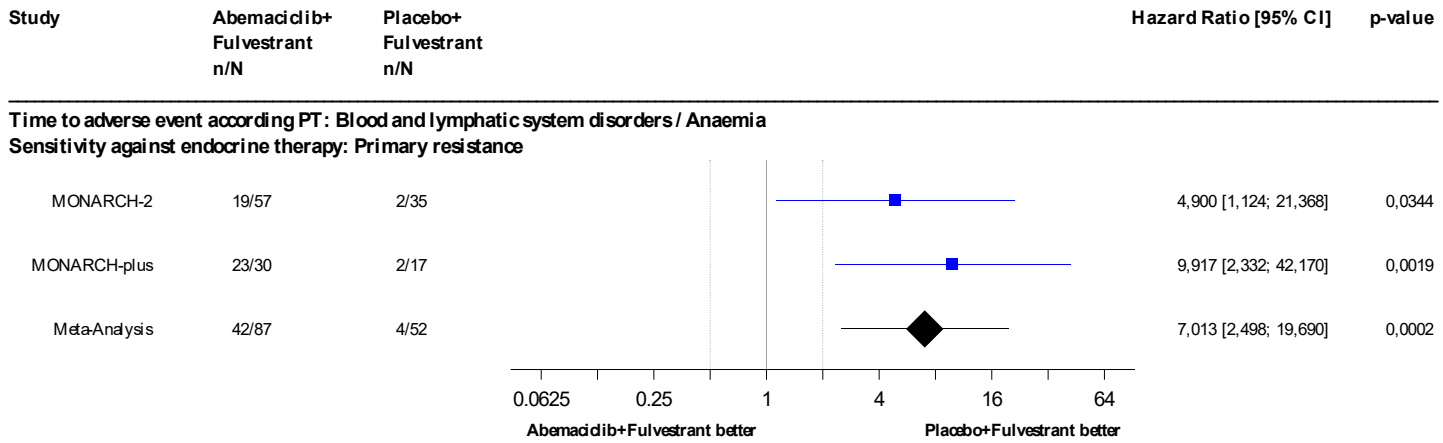
Figure 1105.1.8.1: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4477, p-value=0,5034, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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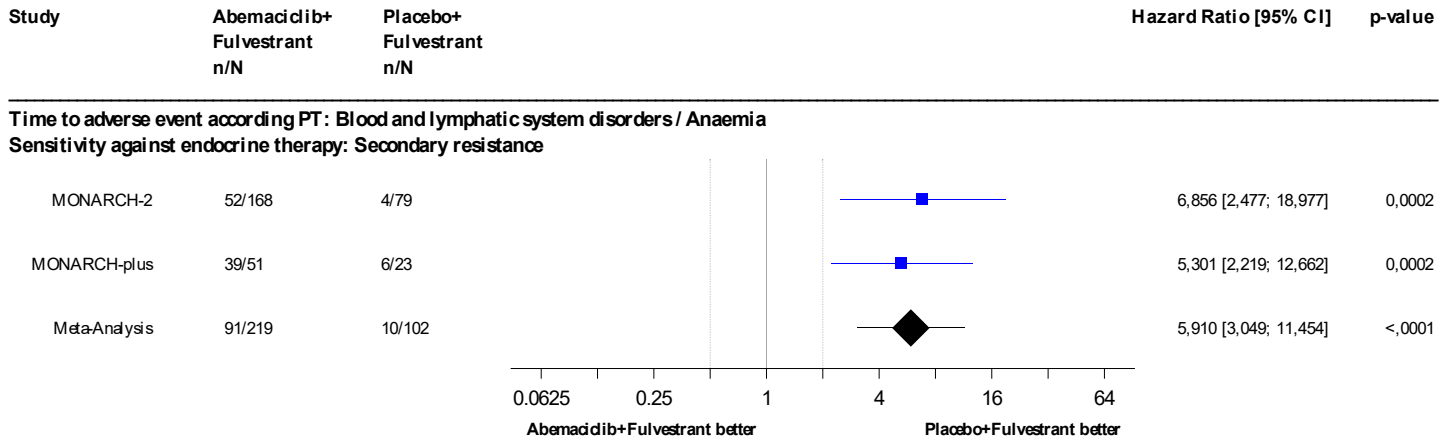
**Figure 1105.1.8.2: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,1416, p-value=0,7067, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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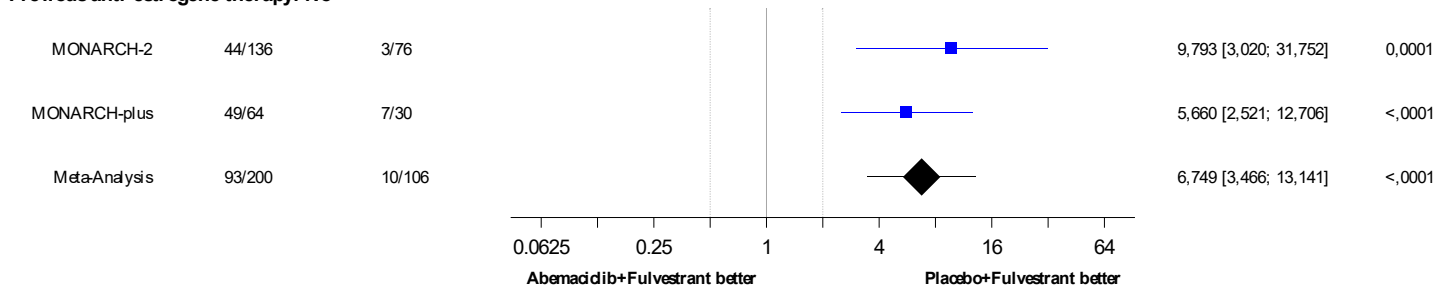
Figure 1105.1.9.1: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5668, p-value=0,4515, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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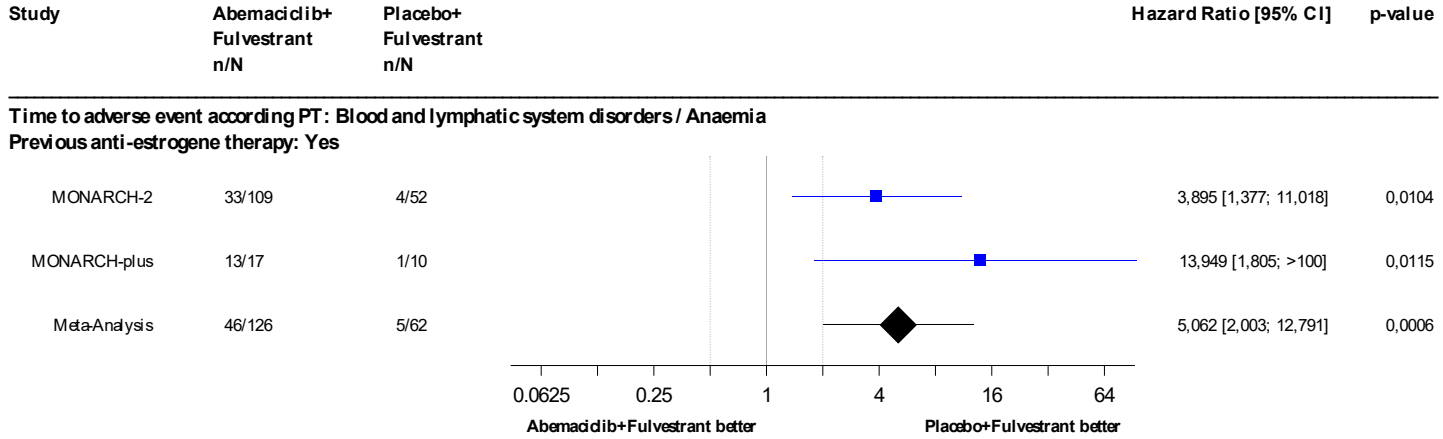
Figure 1105.1.9.2: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,1884, p-value=0,2757, I2 index=15,8%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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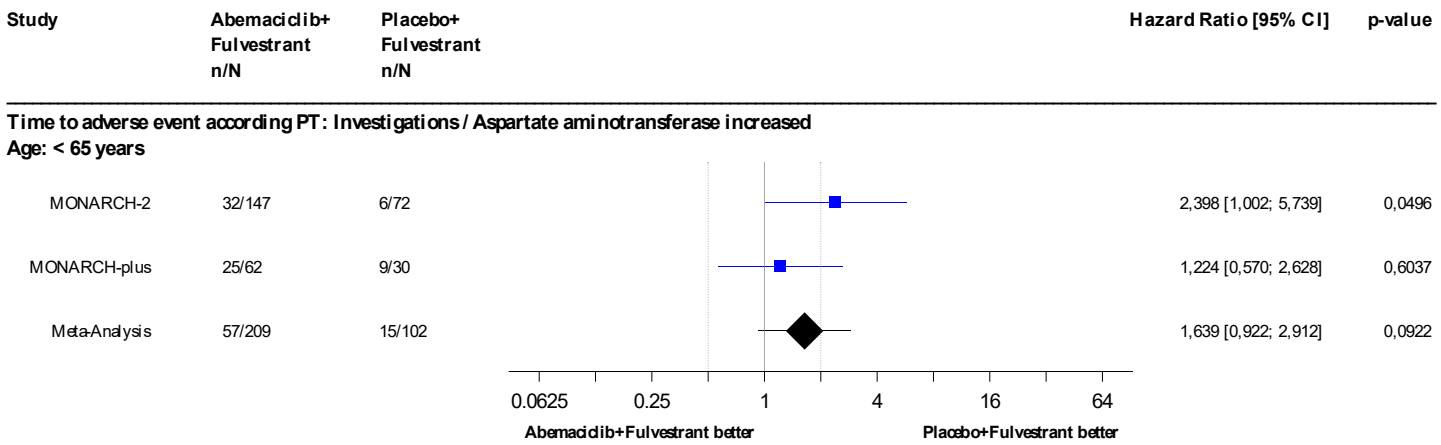
Figure 1108.1.1.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Aspartate aminotransferase increased
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,2901, p-value=0,2560, I2 index=22,5%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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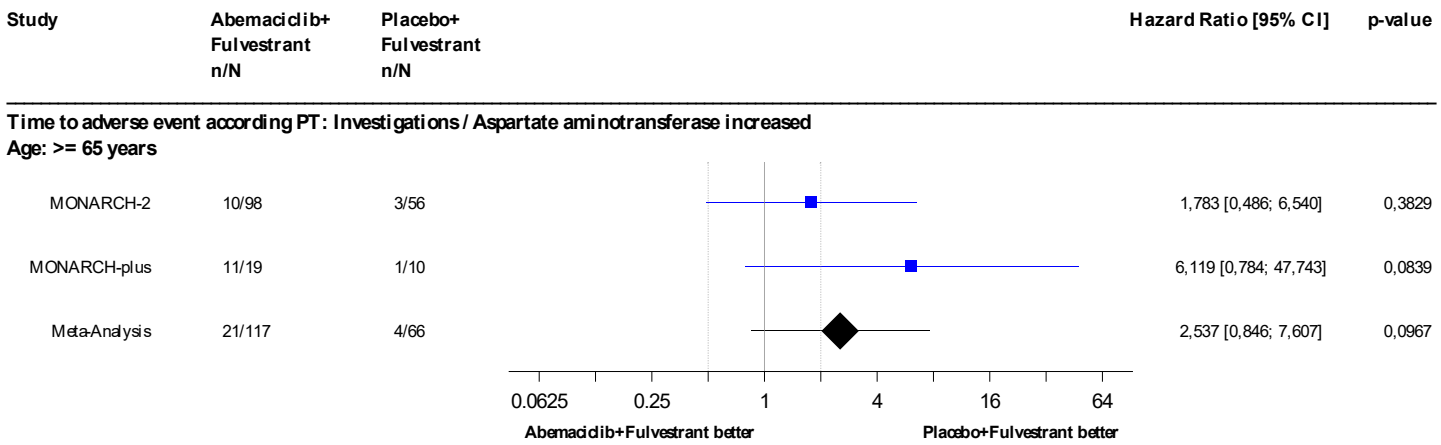
Figure 1108.1.1.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Aspartate aminotransferase increased
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,9884, p-value=0,3201, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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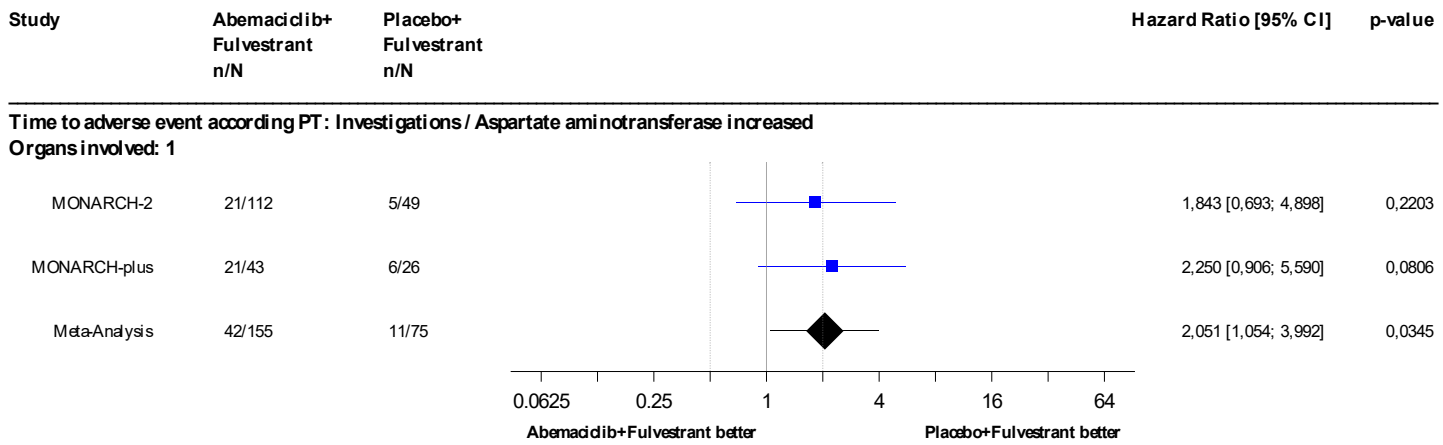
Figure 1108.1.2.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Aspartate aminotransferase increased
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0860, p-value=0,7694, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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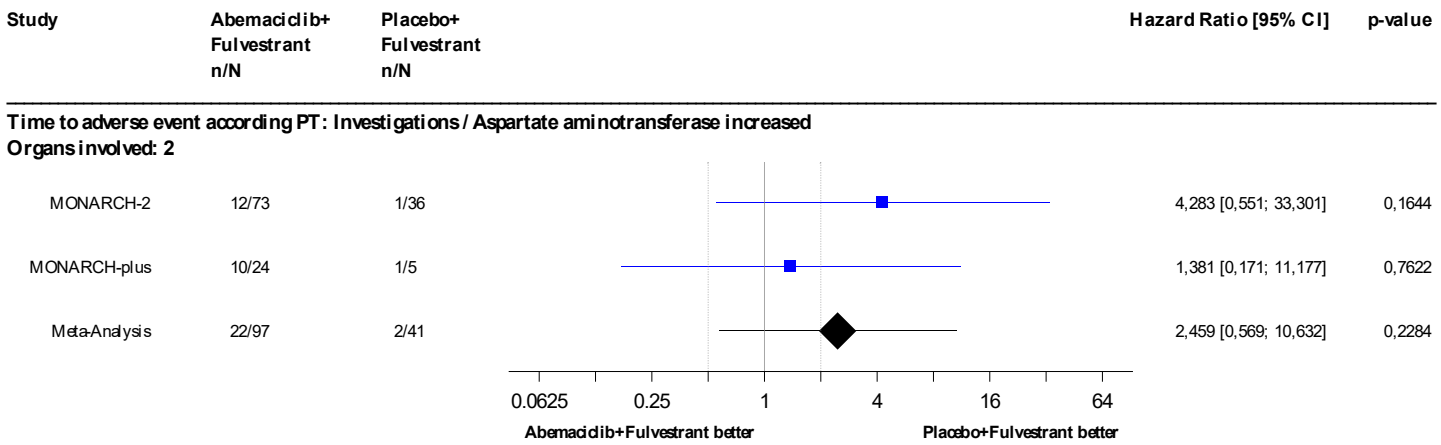
Figure 1108.1.2.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Aspartate aminotransferase increased
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5737, p-value=0,4488, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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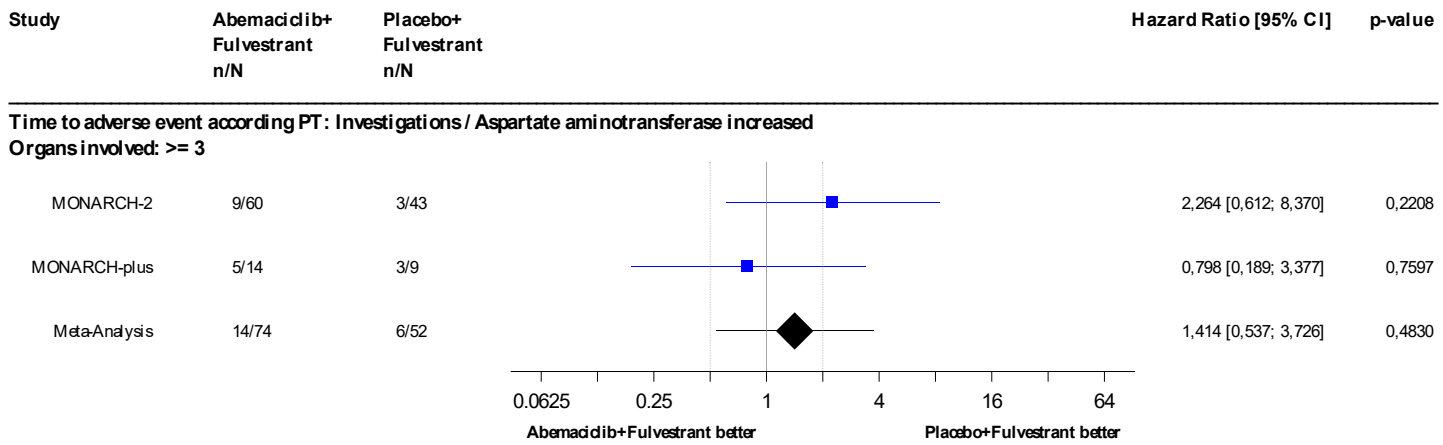
Figure 1108.1.2.3: Metaanalysis results for adverse events according PT[1] -
Investigations / Aspartate aminotransferase increased
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,1008, p-value=0,2941, I2 index=9,2%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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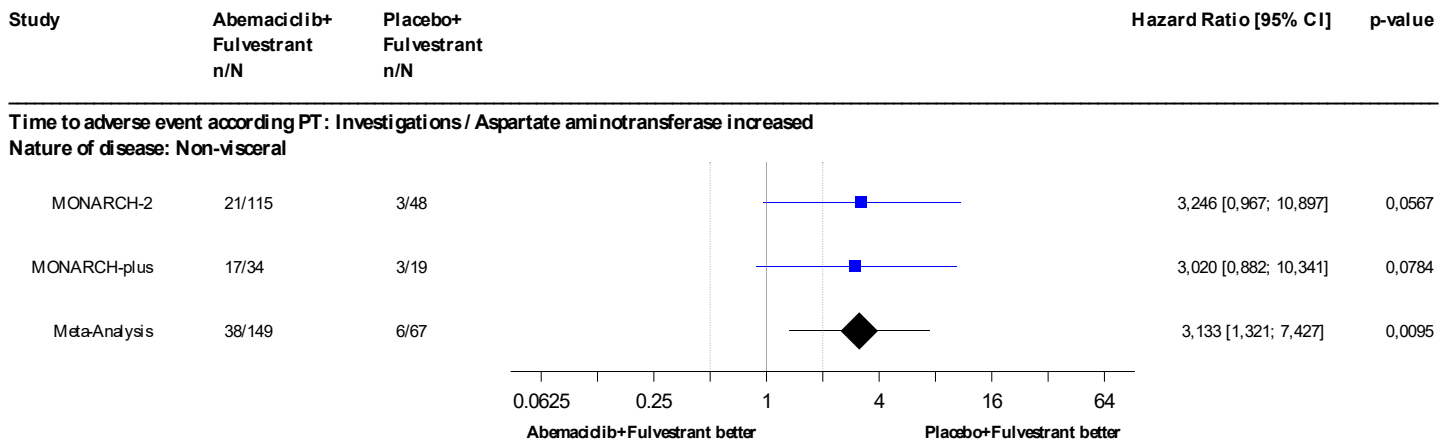
Figure 1108.1.3.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Aspartate aminotransferase increased
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0067, p-value=0,9348, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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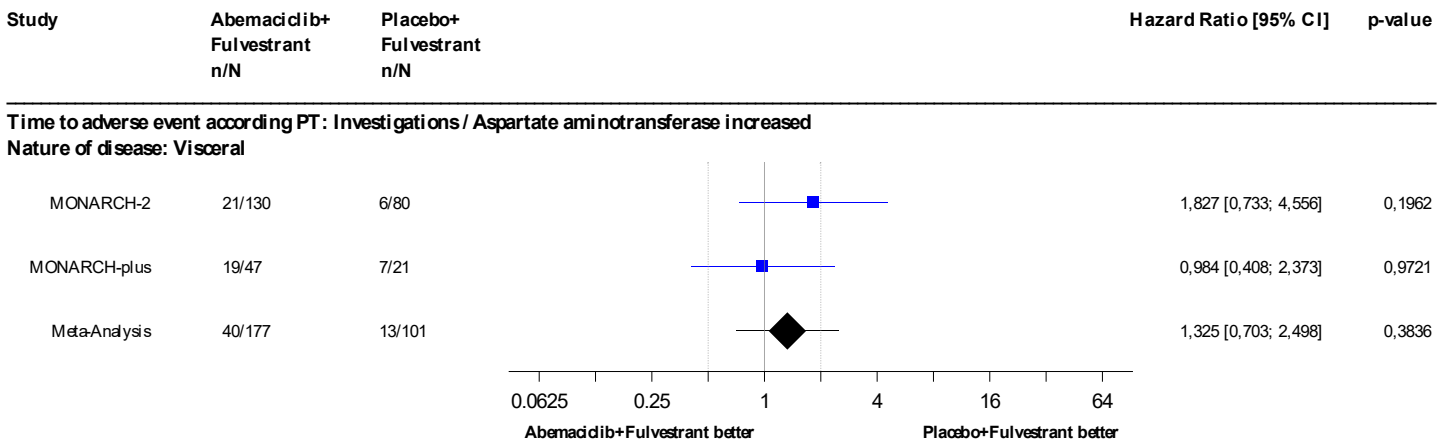
Figure 1108.1.3.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Aspartate aminotransferase increased
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,9126, p-value=0,3394, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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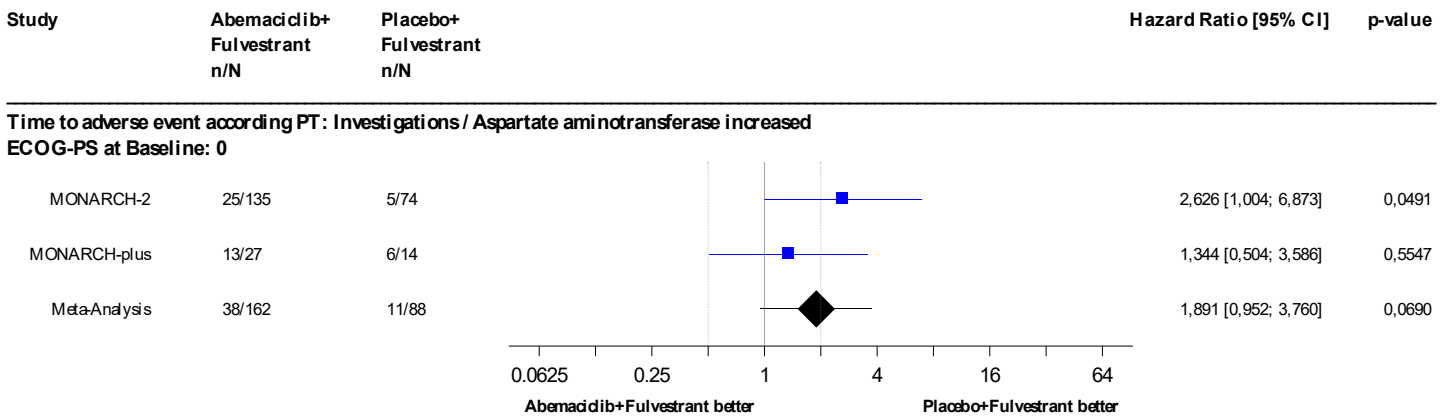
Figure 1108.1.4.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Aspartate aminotransferase increased
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,9127, p-value=0,3394, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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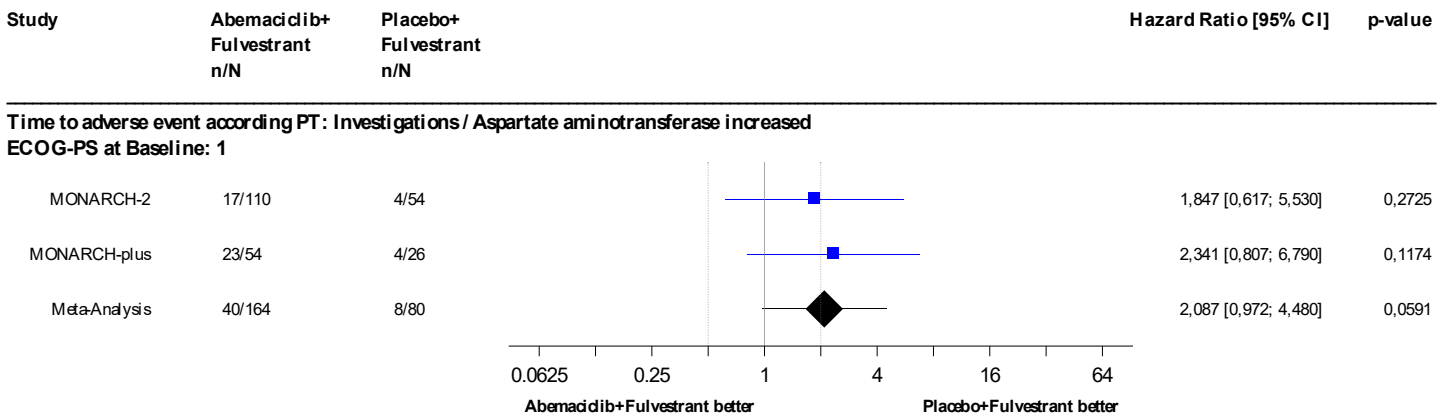
Figure 1108.1.4.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Aspartate aminotransferase increased
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0923, p-value=0,7613, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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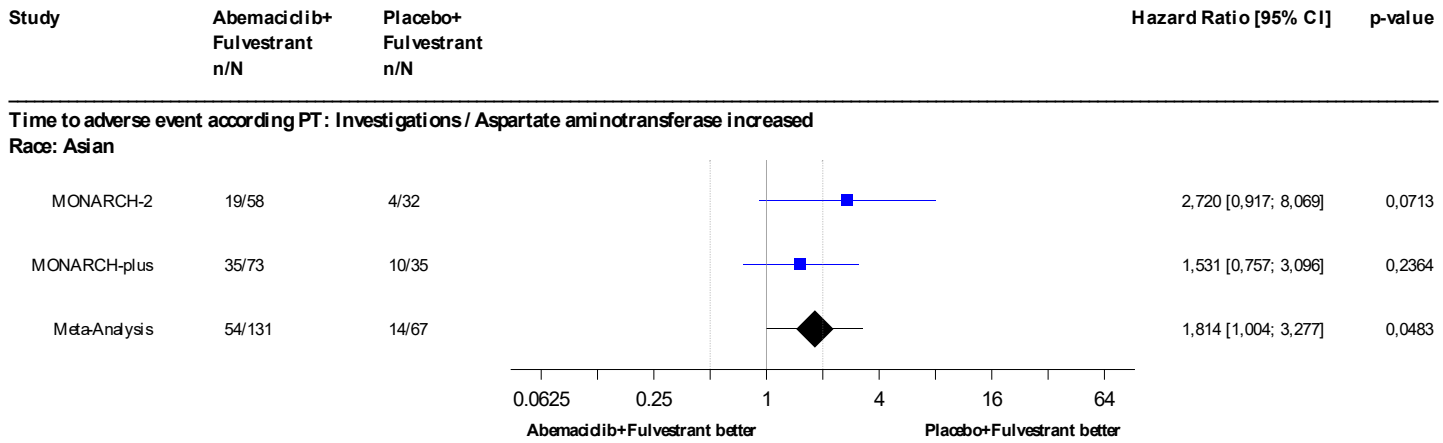
Figure 1108.1.5.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Aspartate aminotransferase increased
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,7566, p-value=0,3844, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep008_popa1_racegr1_1.rtf
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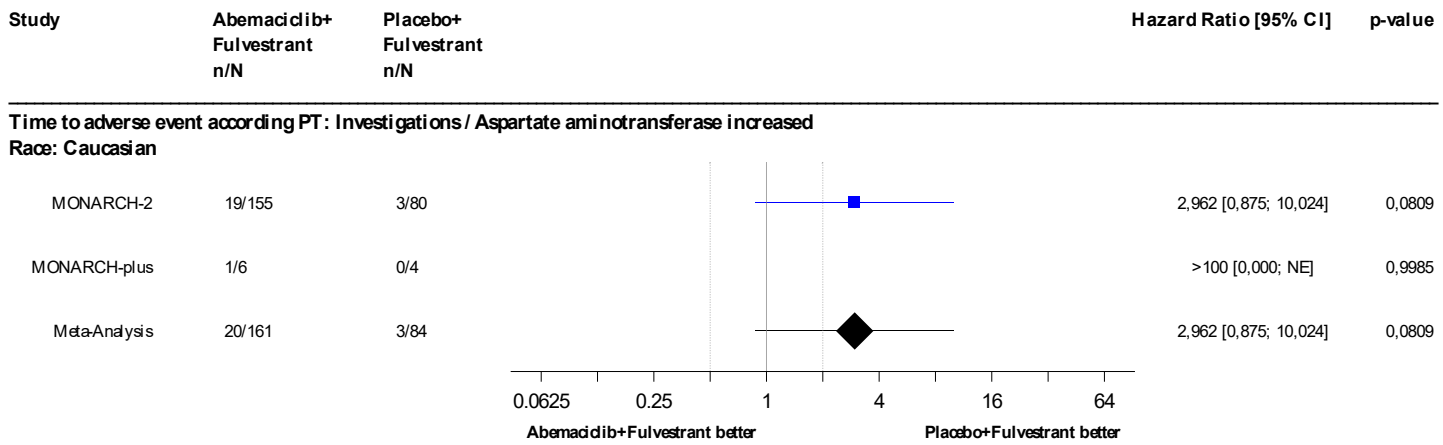
Figure 1108.1.5.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Aspartate aminotransferase increased
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep008_popa1_racegr1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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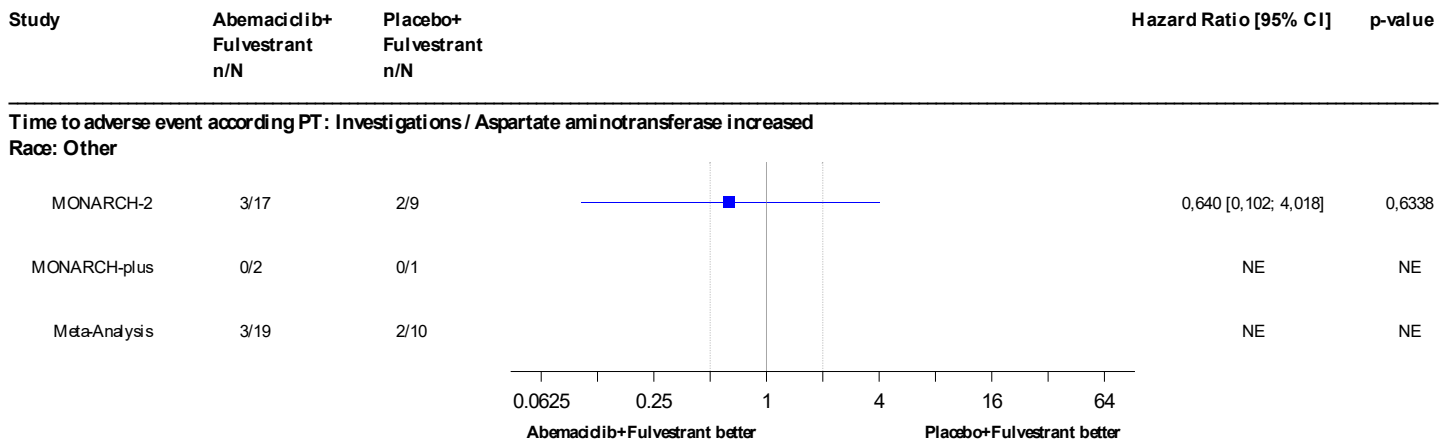
Figure 1108.1.5.3: Metaanalysis results for adverse events according PT[1] -
Investigations / Aspartate aminotransferase increased
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep008_popa1_racegr1_3.rtf
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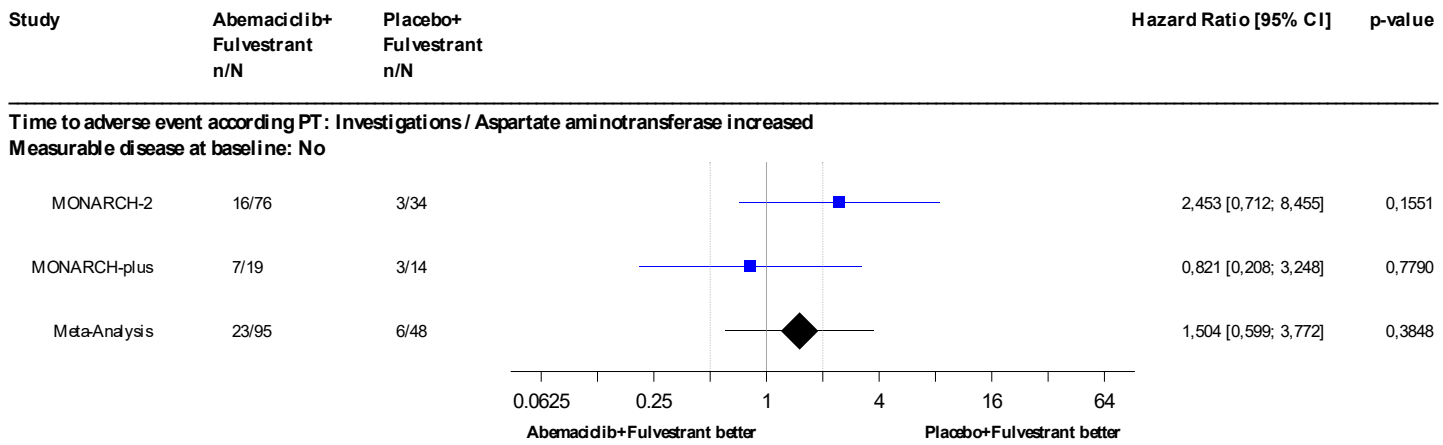
**Figure 1108.1.6.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Aspartate aminotransferase increased
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=1,3446, p-value=0,2462, I2 index=25,6%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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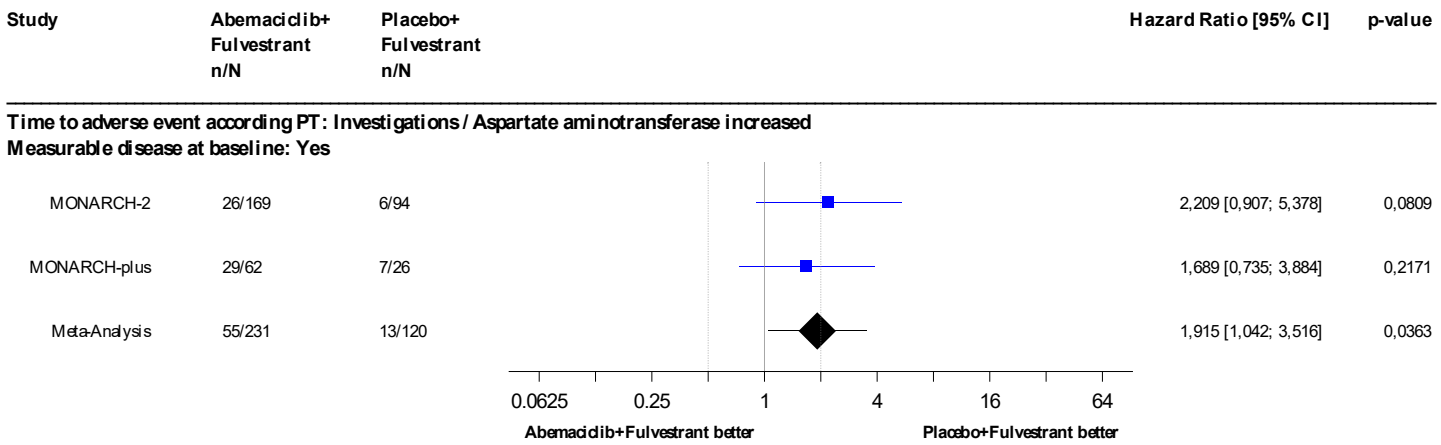
Figure 1108.1.6.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Aspartate aminotransferase increased
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1861, p-value=0,6662, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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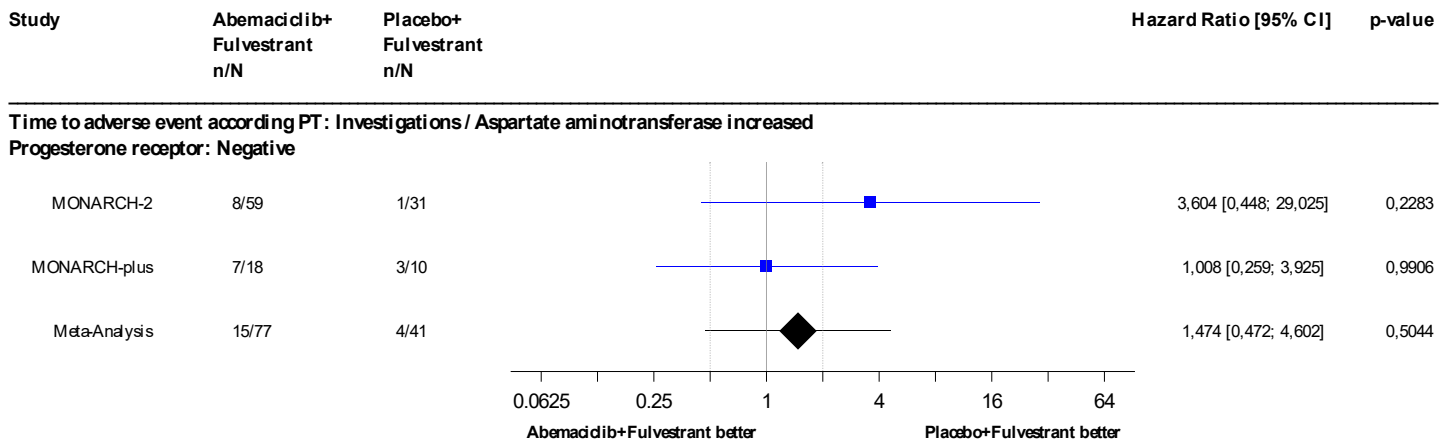
Figure 1108.1.7.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Aspartate aminotransferase increased
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,0059, p-value=0,3159, I2 index=0,6%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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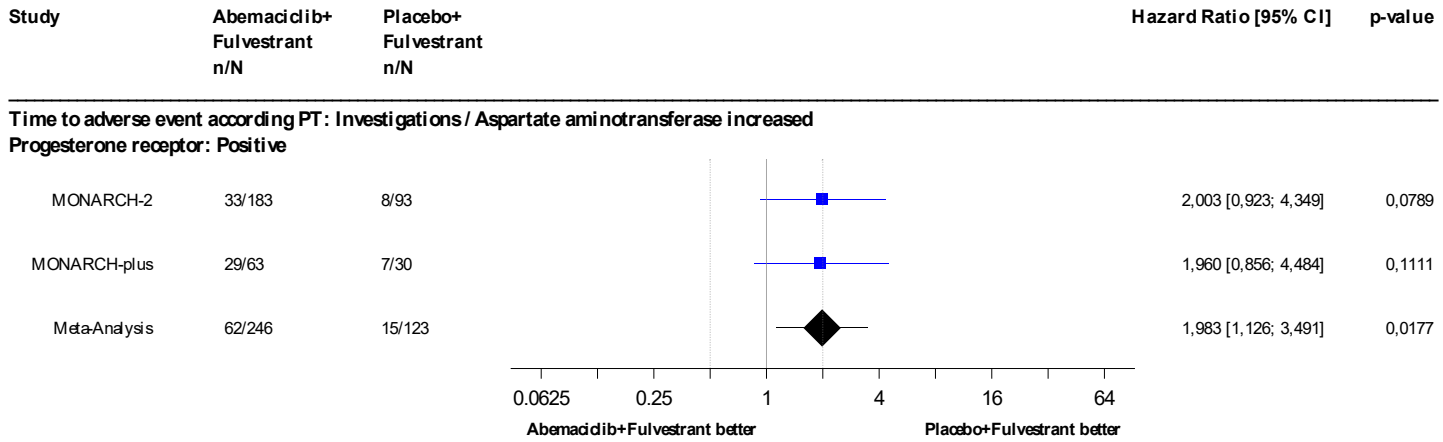
**Figure 1108.1.7.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Aspartate aminotransferase increased
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0015, p-value=0,9695, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep008_popa1_pgrstat_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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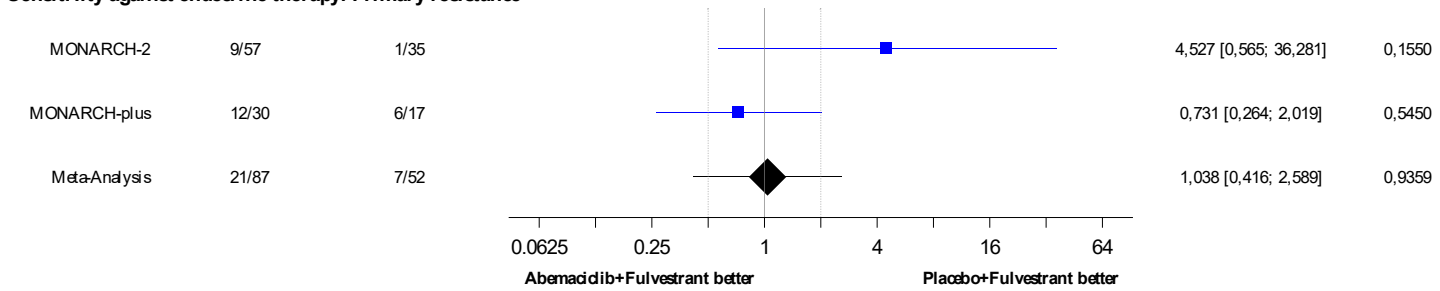
Figure 1108.1.8.1: Metaanalysis results for adverse events according PT[1] - Investigations / Aspartate aminotransferase increased Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,3826, p-value=0,1227, I2 index=58,0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep008_popa1_snthr_1.rtf
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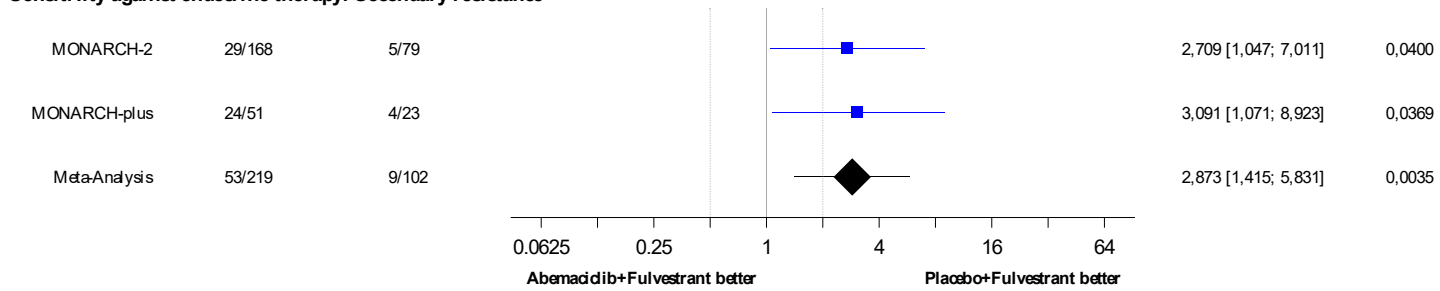
Figure 1108.1.8.2: Metaanalysis results for adverse events according PT[1] - Investigations / Aspartate aminotransferase increased Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0330, p-value=0,8559, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep008_popa1_snthr_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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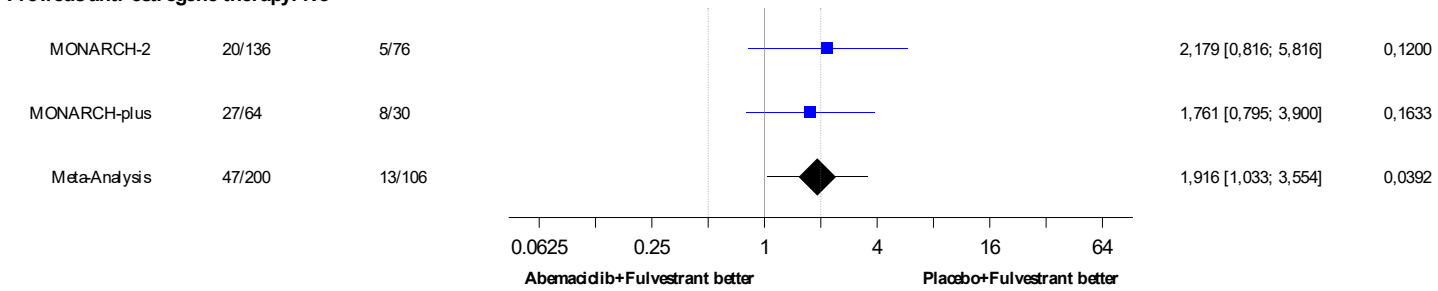
Figure 1108.1.9.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Aspartate aminotransferase increased
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1094, p-value=0,7408, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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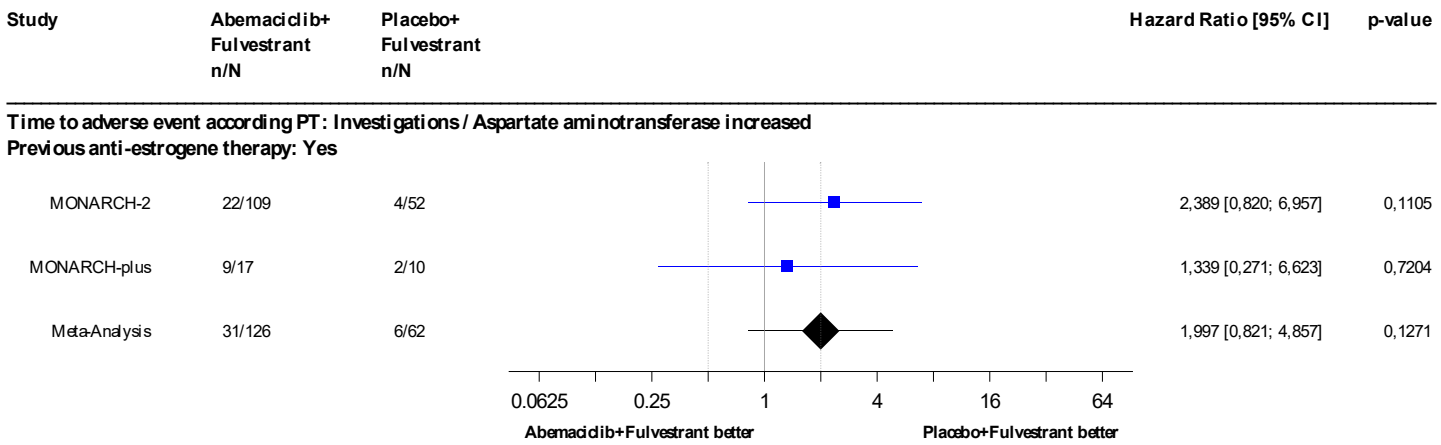
**Figure 1108.1.9.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Aspartate aminotransferase increased
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,3479, p-value=0,5553, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep008_popa1_paet_2.rtf
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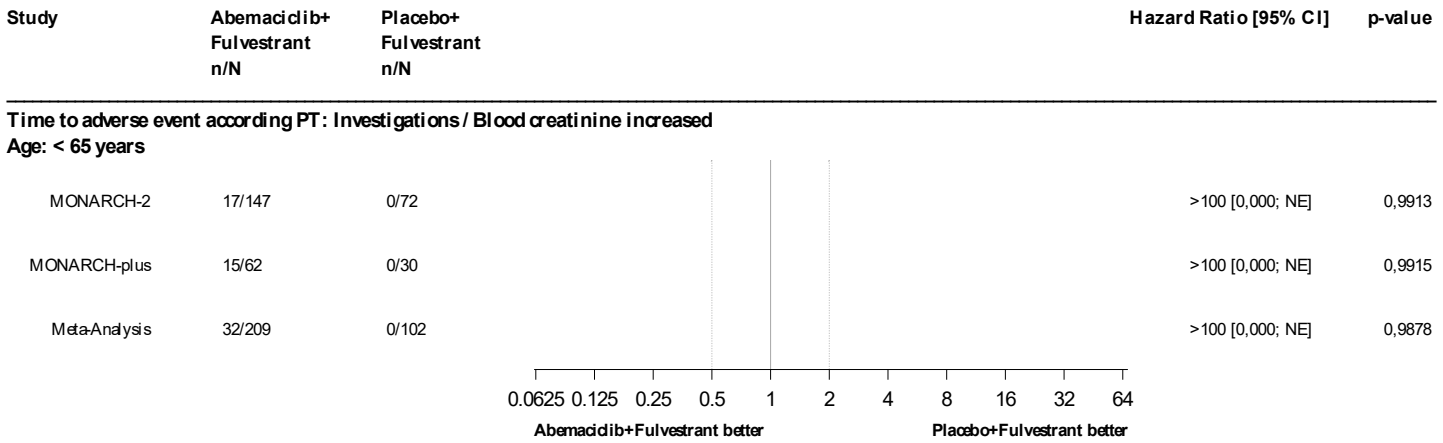
Figure 1111.1.1.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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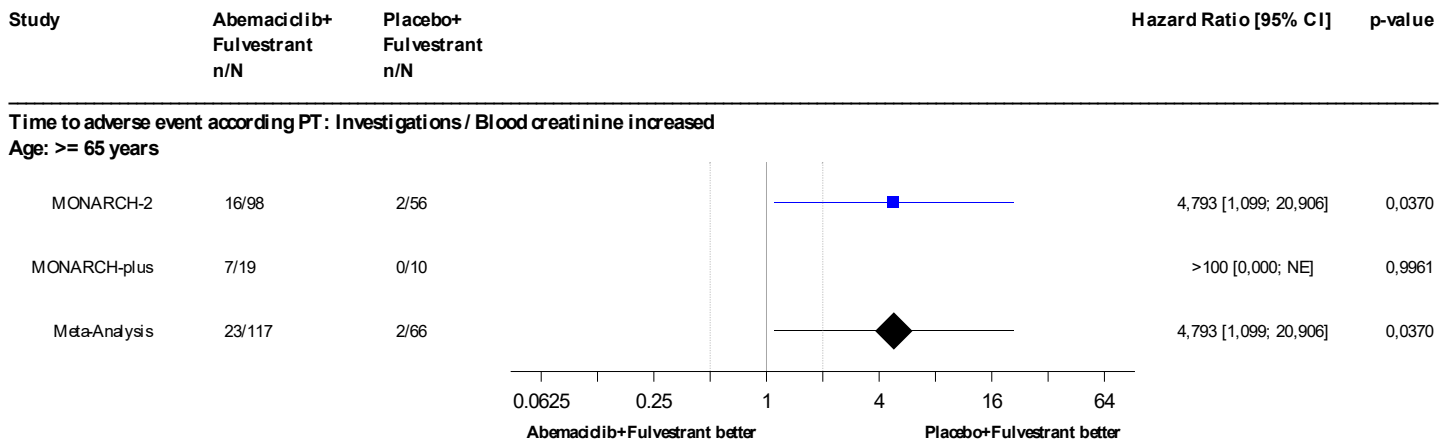
Figure 1111.1.1.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9964, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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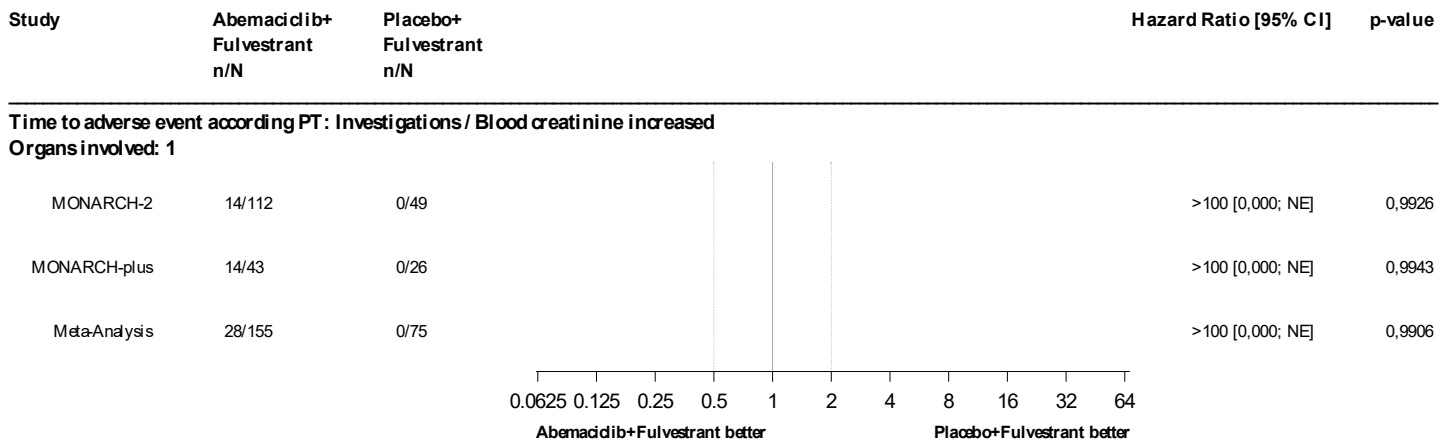
Figure 1111.1.2.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9997, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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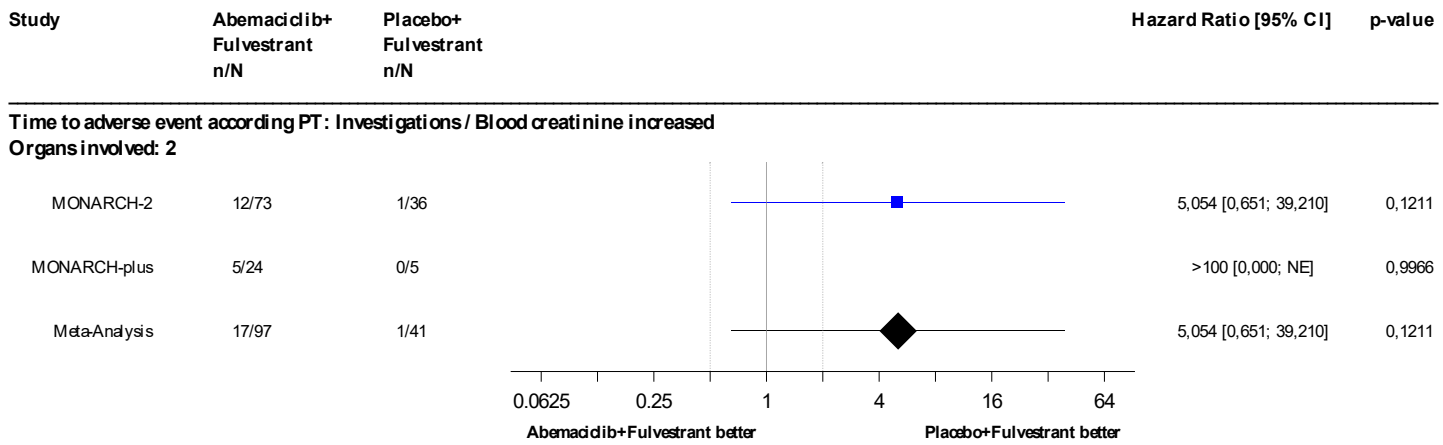
**Figure 1111.1.2.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9969, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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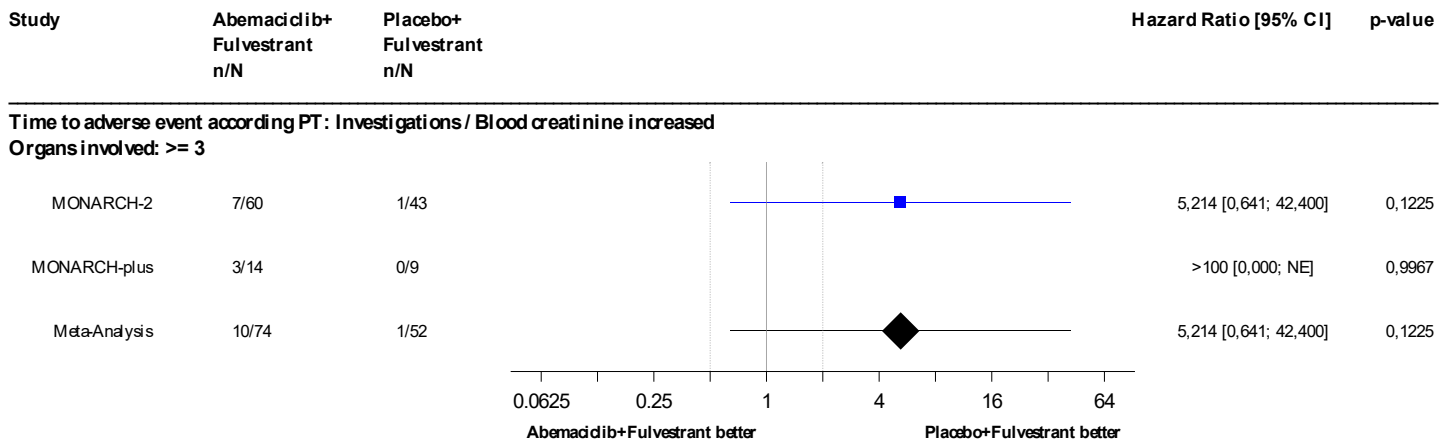
Figure 1111.1.2.3: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9971, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep011_popa1_norggr_3.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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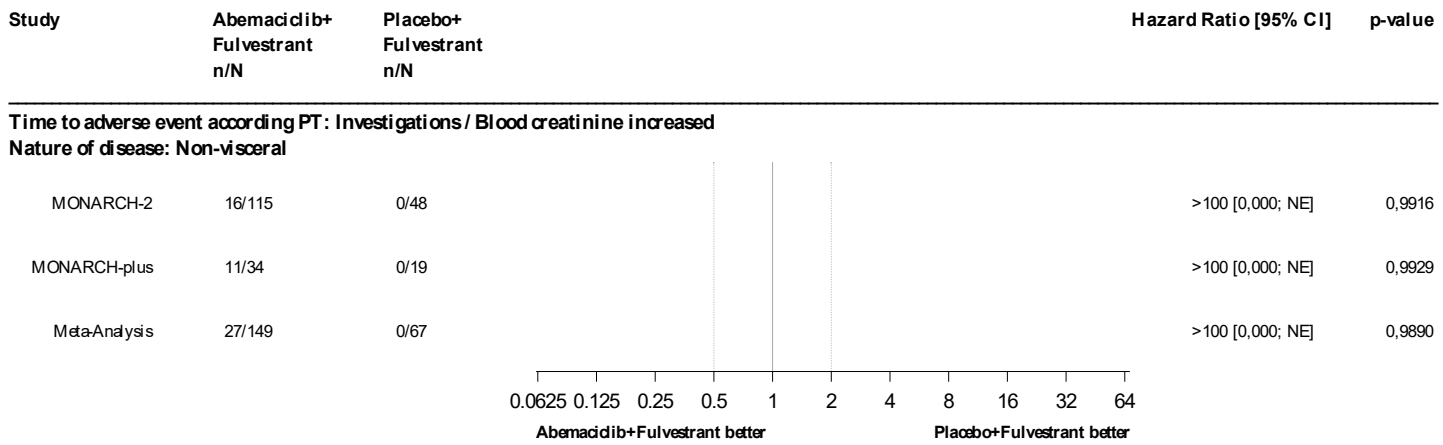
Figure 1111.1.3.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep011_popa1_natdis2_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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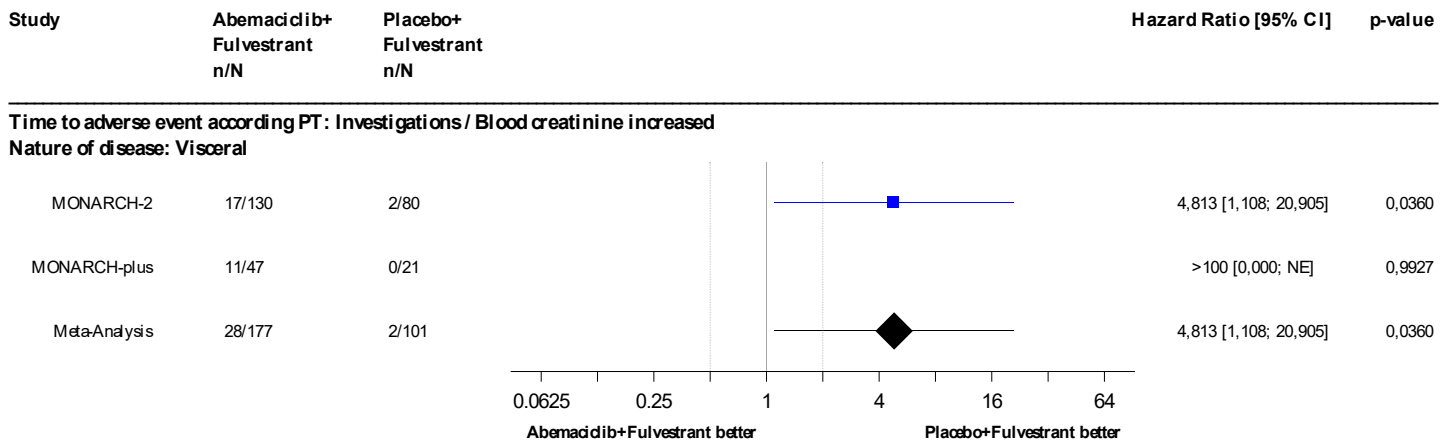
Figure 1111.1.3.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9934, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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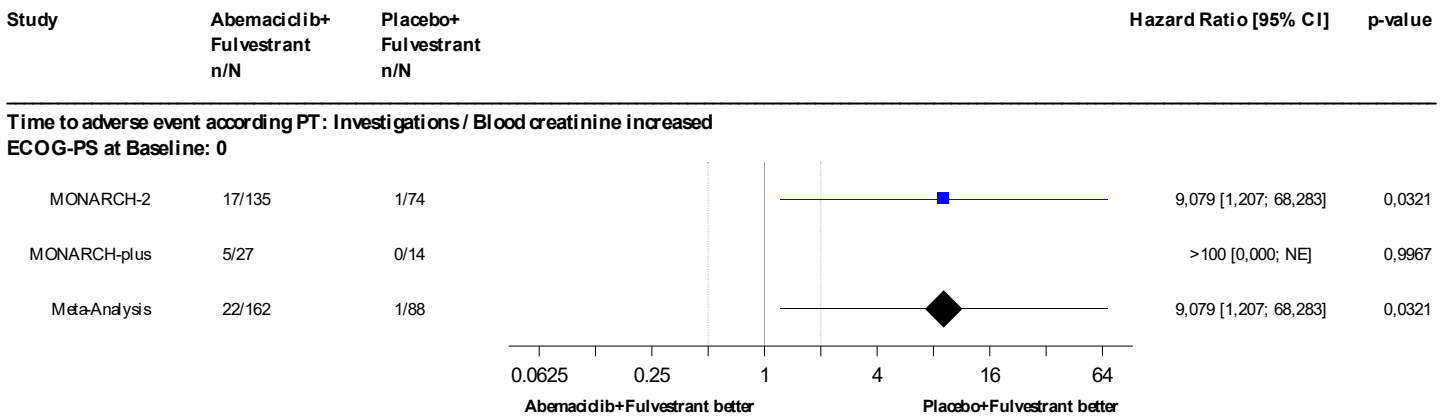
Figure 1111.1.4.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9971, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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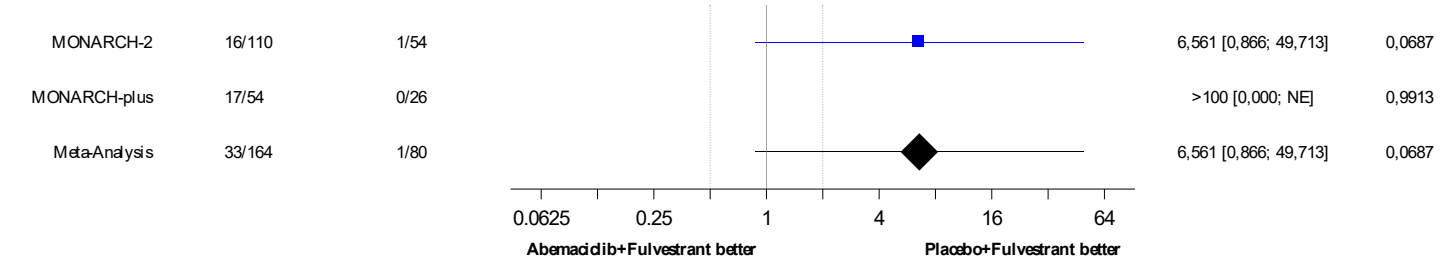
Figure 1111.1.4.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9923, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep011_popa1_ecogbl_2.rtf
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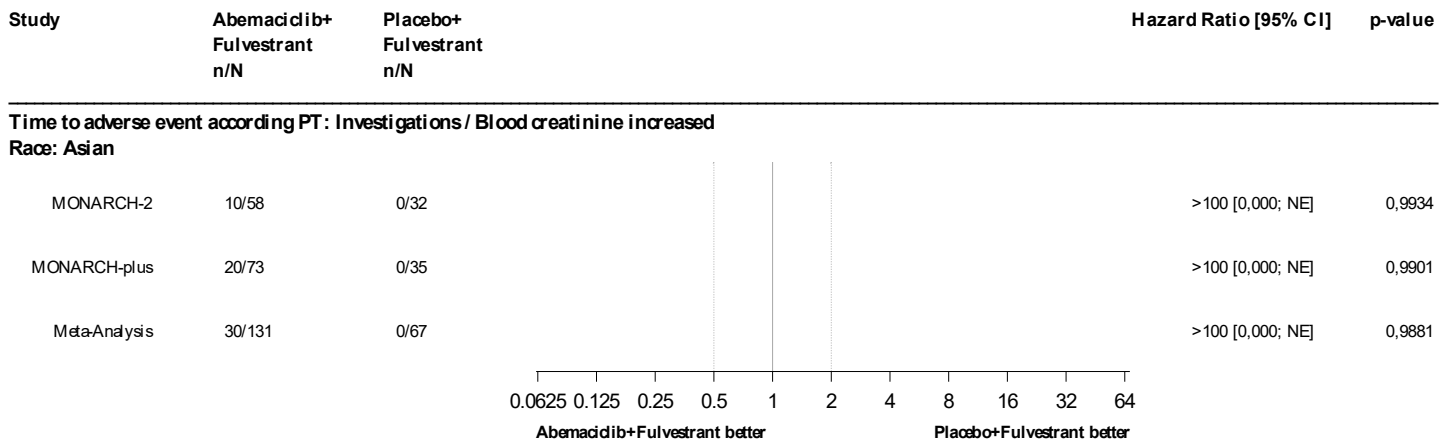
Figure 1111.1.5.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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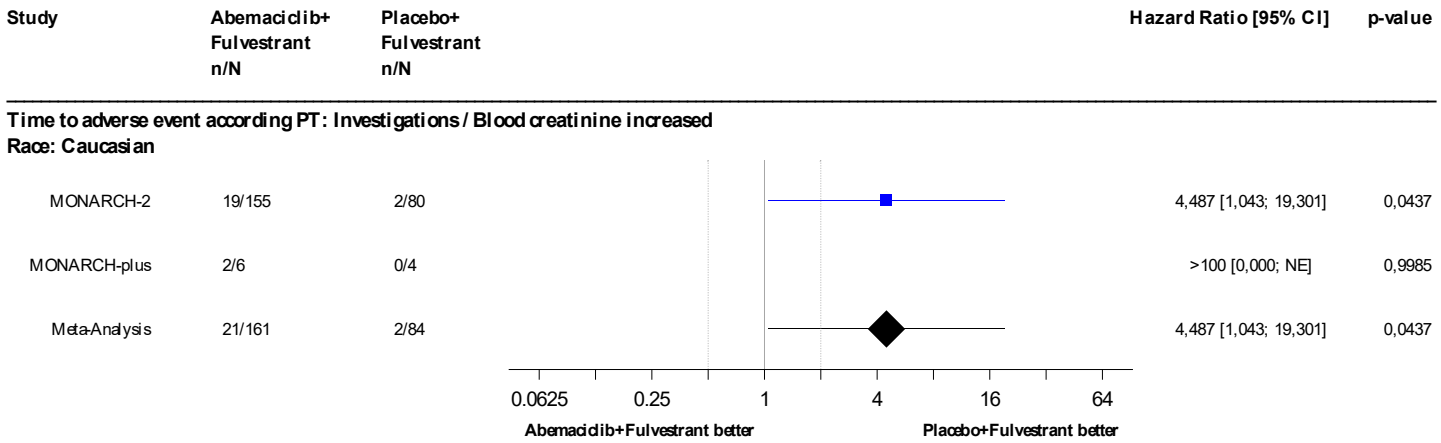
Figure 1111.1.5.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep011_popa1_racegr1_2.rtf
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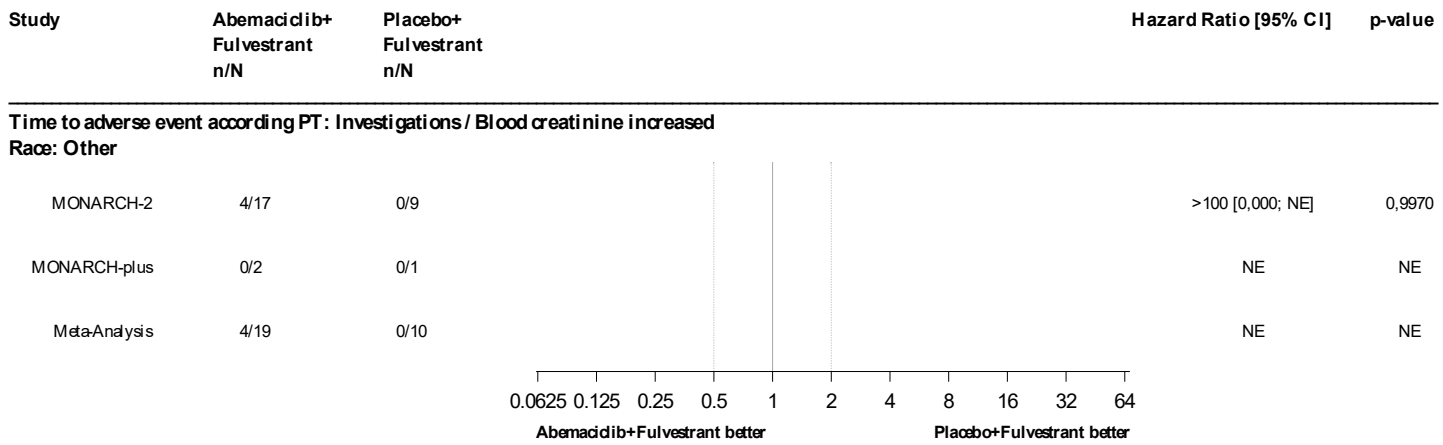
Figure 1111.1.5.3: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep011_popa1_racegr1_3.rtf
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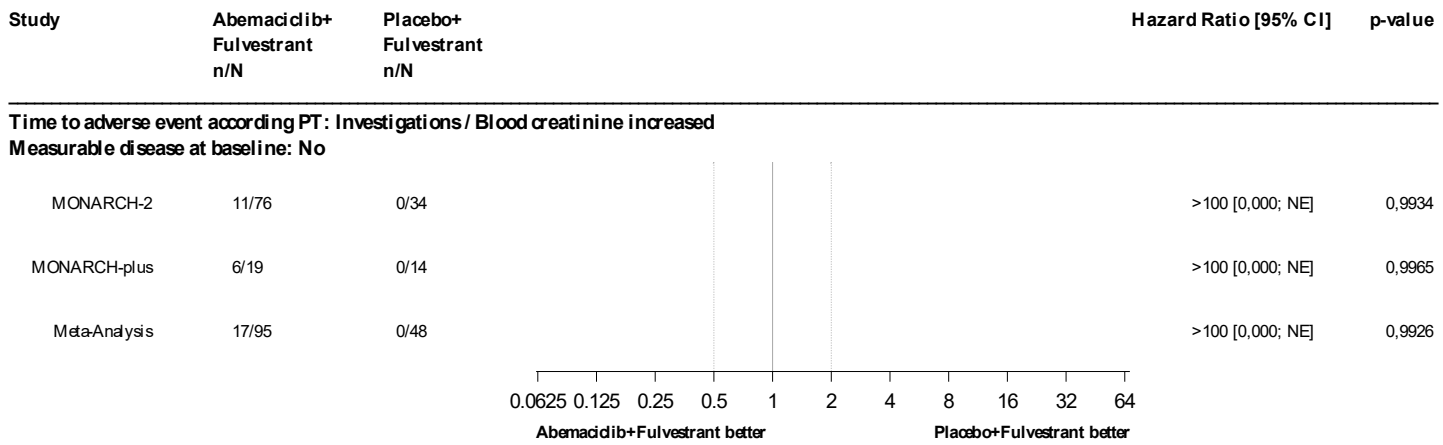
Figure 1111.1.6.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9998, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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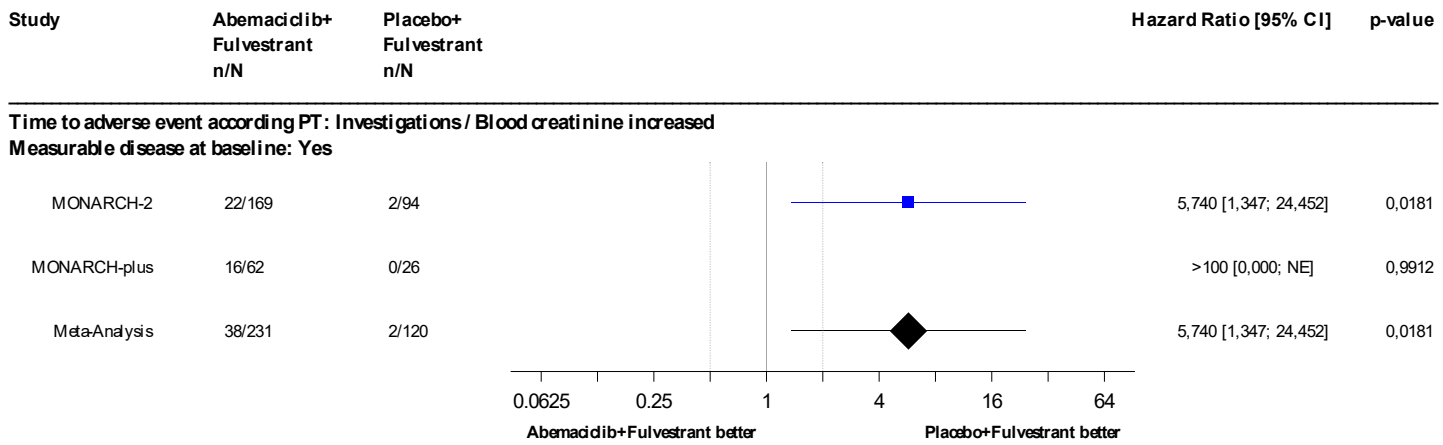
Figure 1111.1.6.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9922, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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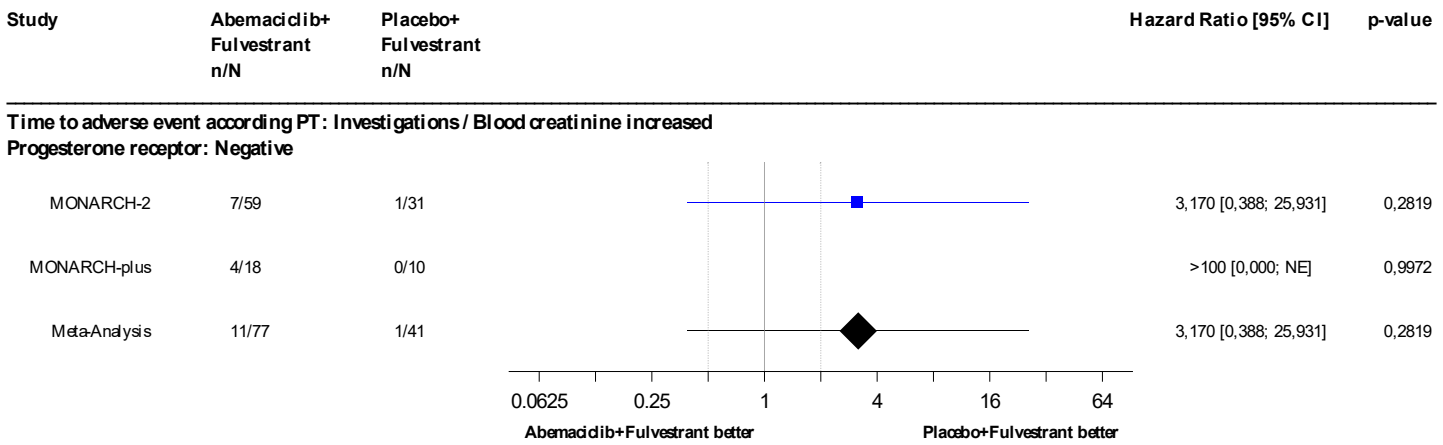
Figure 1111.1.7.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9974, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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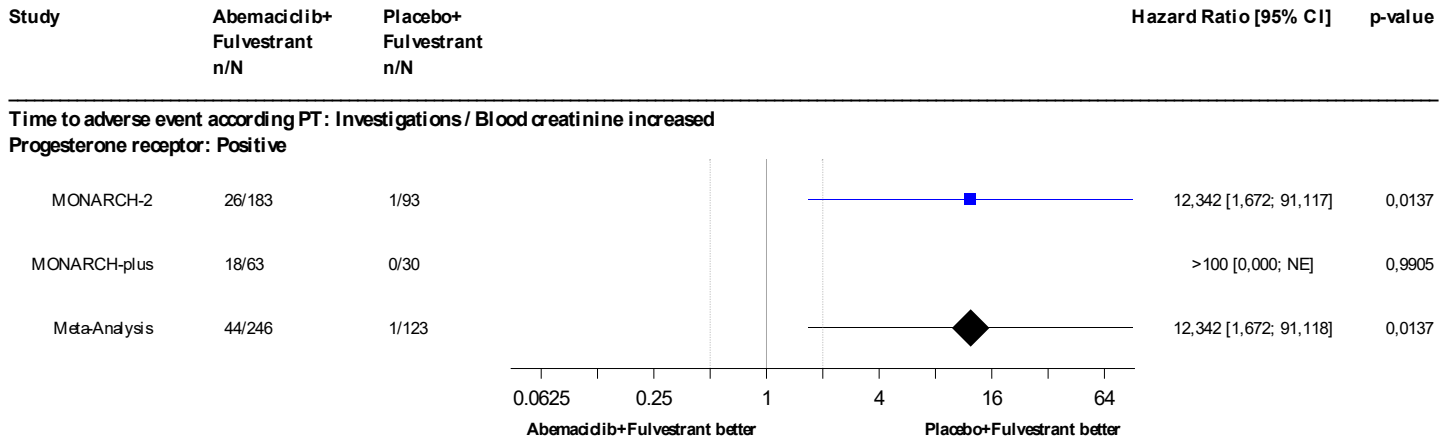
Figure 1111.1.7.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9920, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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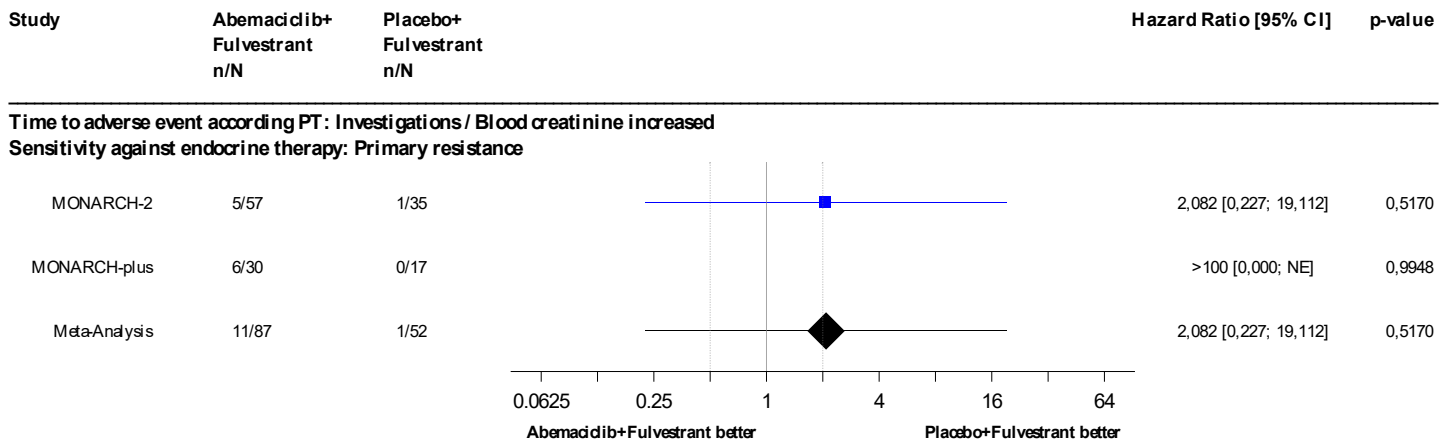
Figure 1111.1.8.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9951, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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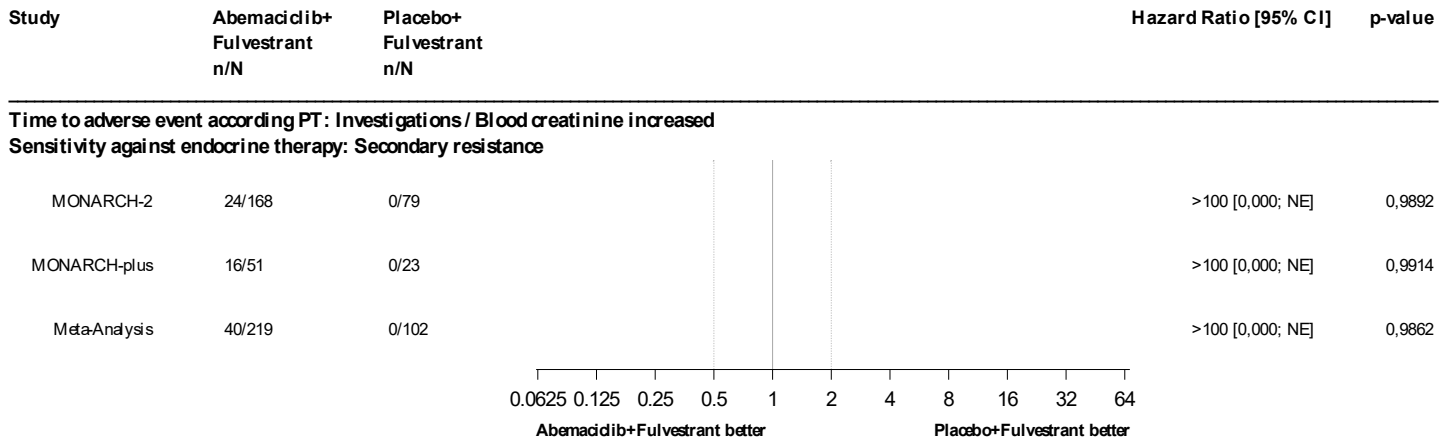
Figure 1111.1.8.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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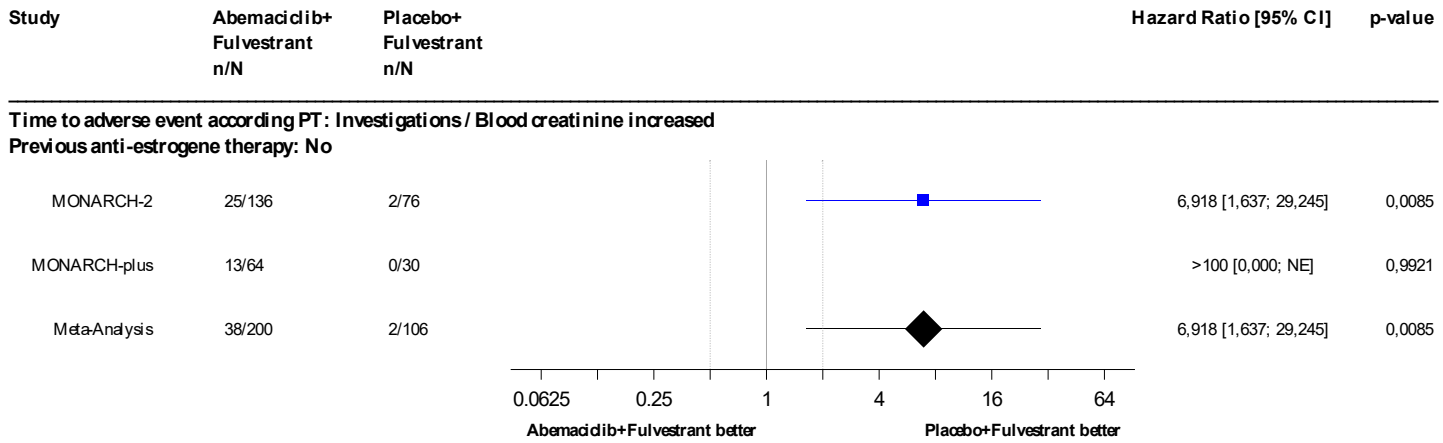
**Figure 1111.1.9.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9930, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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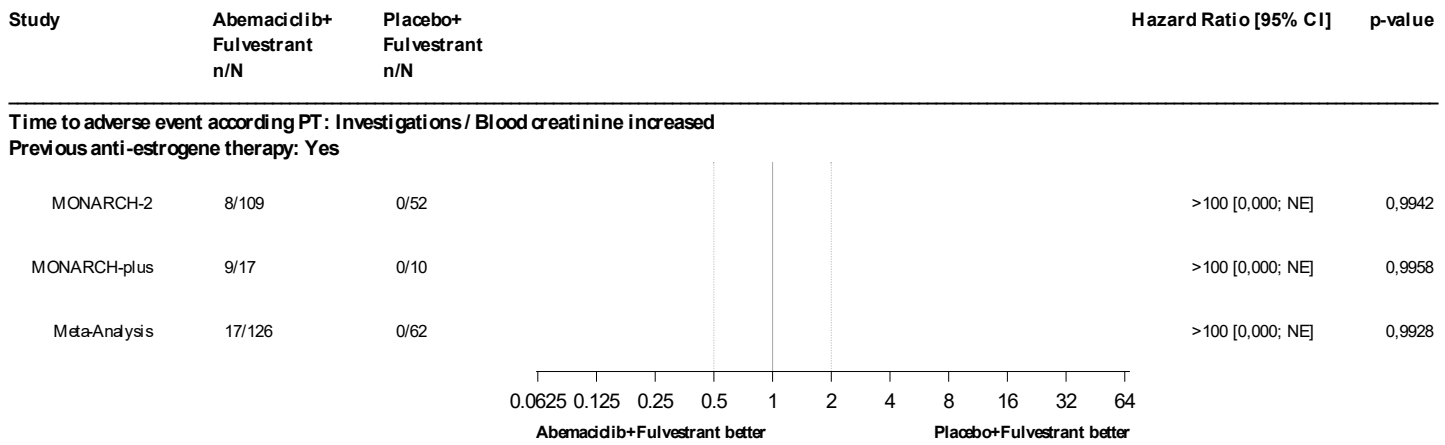
Figure 1111.1.9.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Blood creatinine increased
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9998, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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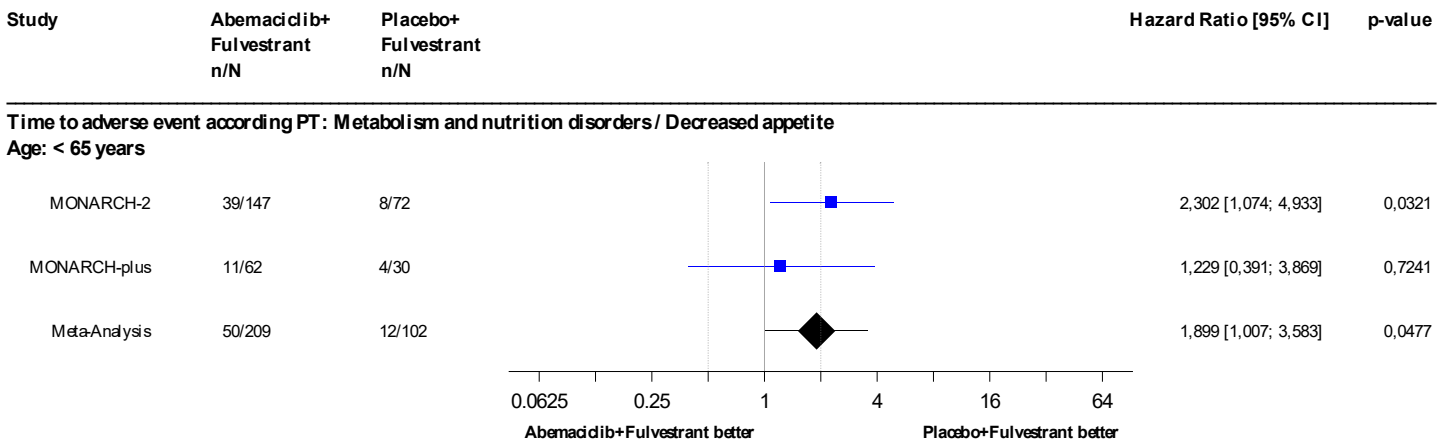
Figure 1119.1.1.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,7969, p-value=0,3720, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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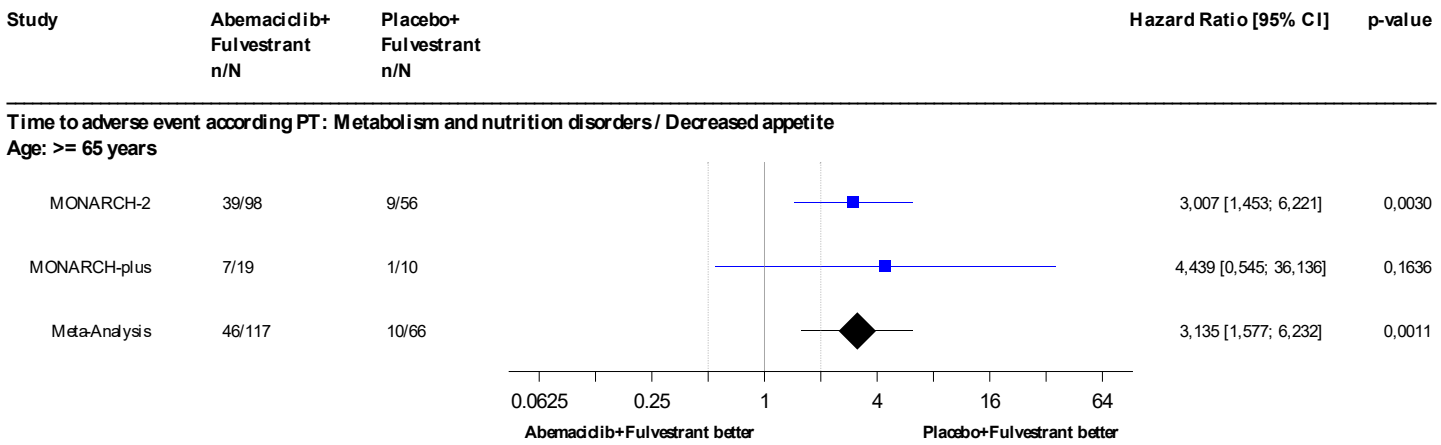
Figure 1119.1.1.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1183, p-value=0,7309, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep019_popa1_agegr1_2.rtf
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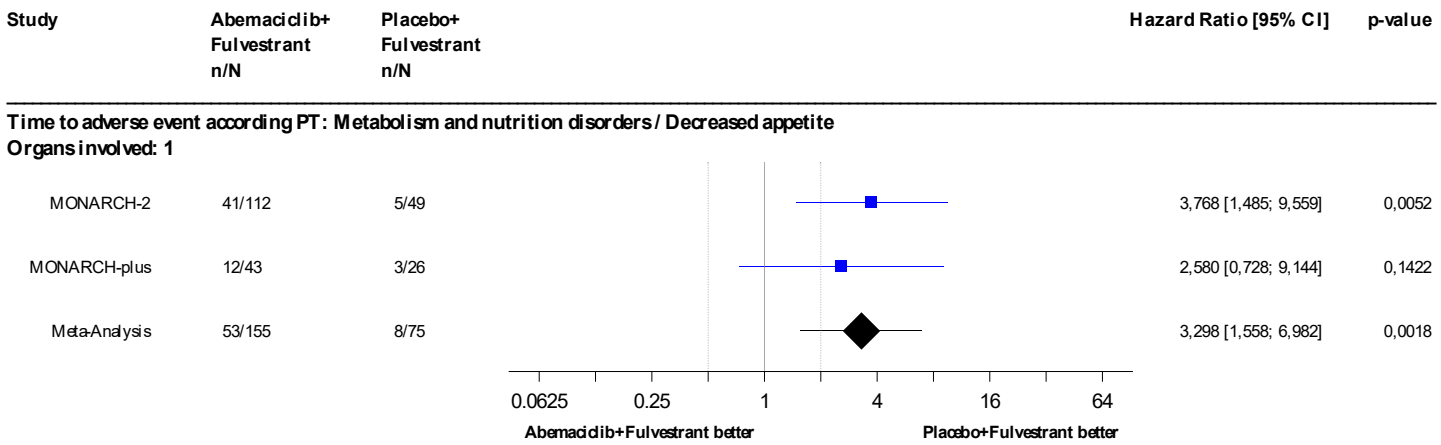
Figure 1119.1.2.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2234, p-value=0,6364, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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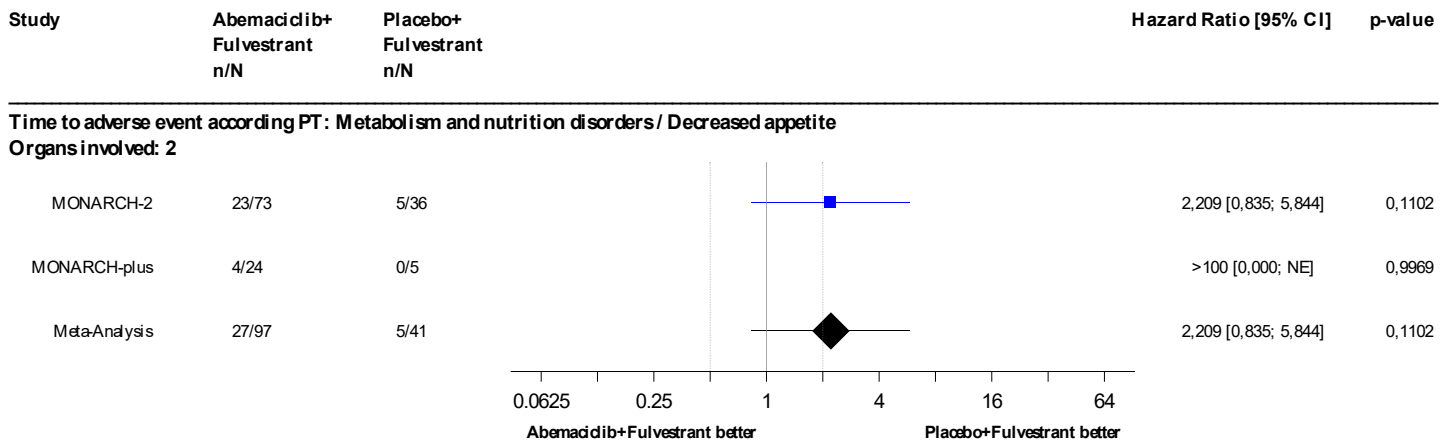
Figure 1119.1.2.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9971, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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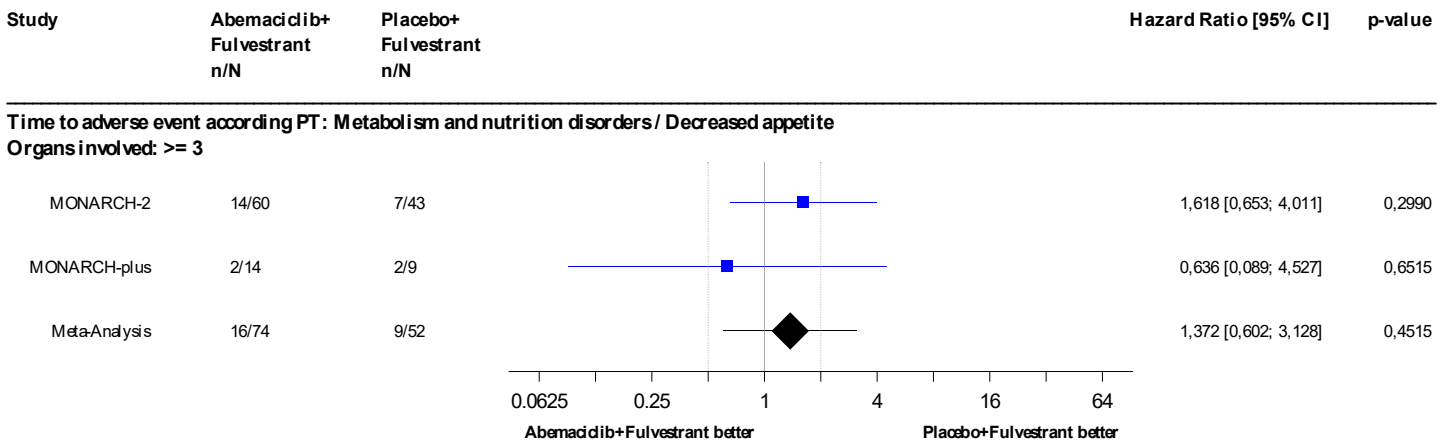
Figure 1119.1.2.3: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,7157, p-value=0,3976, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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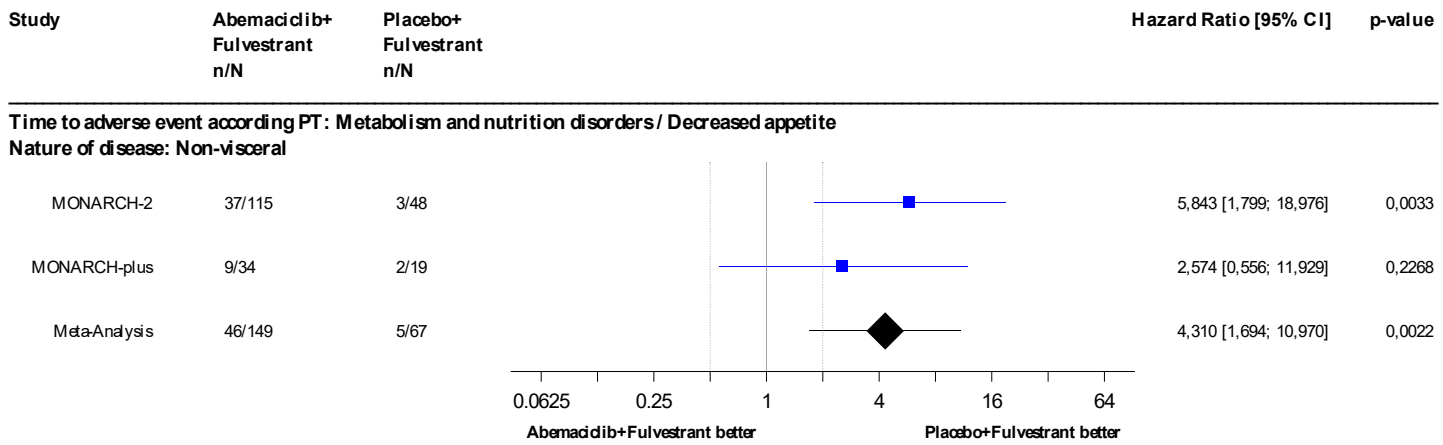
Figure 1119.1.3.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6902, p-value=0,4061, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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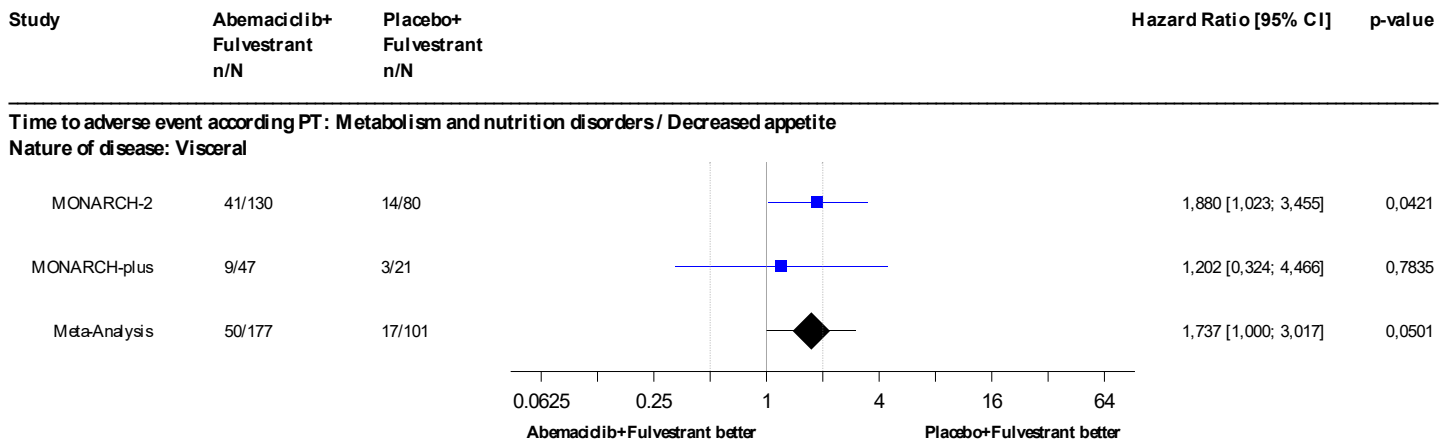
Figure 1119.1.3.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3670, p-value=0,5446, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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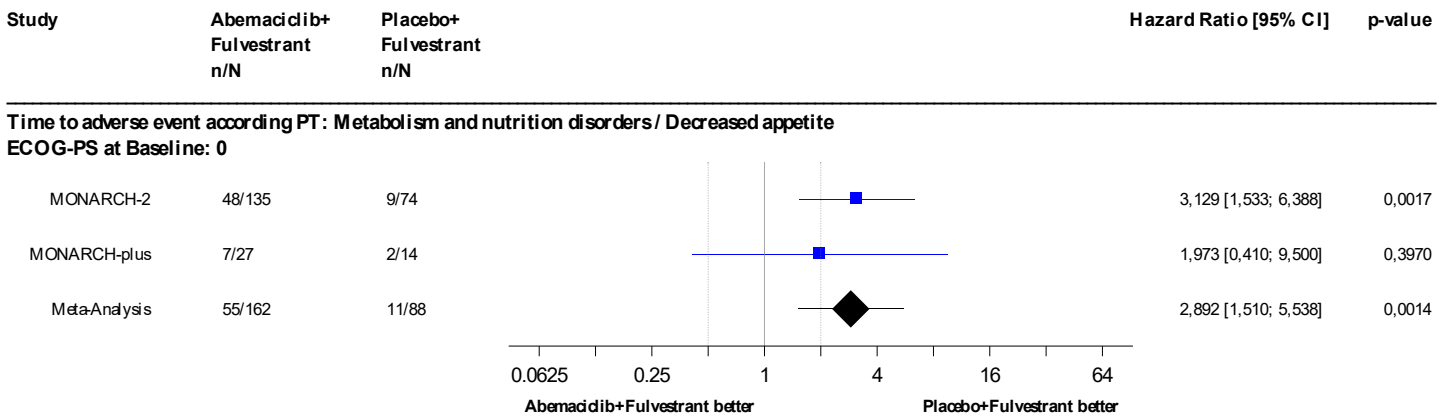
Figure 1119.1.4.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2745, p-value=0,6003, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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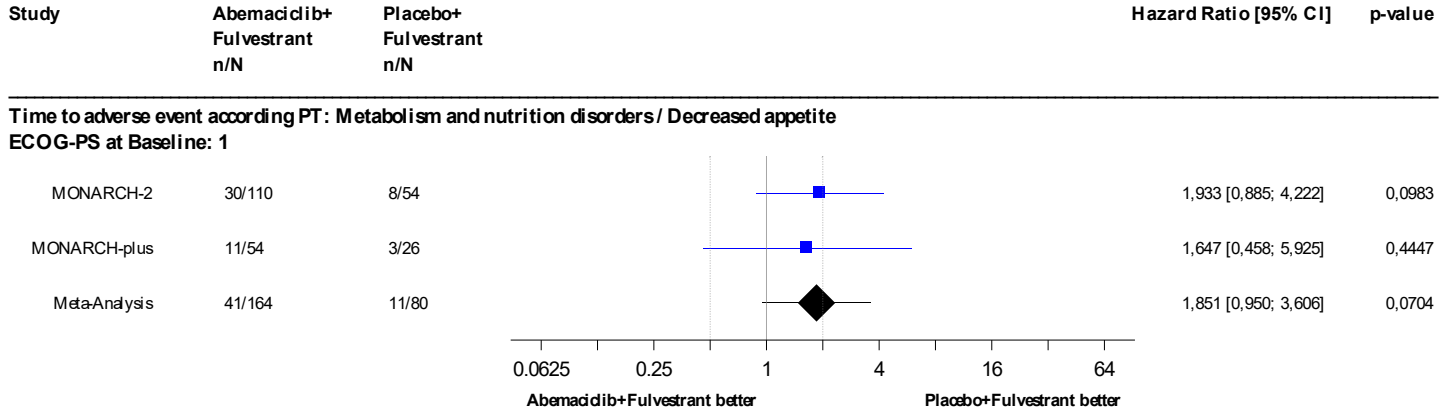
Figure 1119.1.4.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0437, p-value=0,8345, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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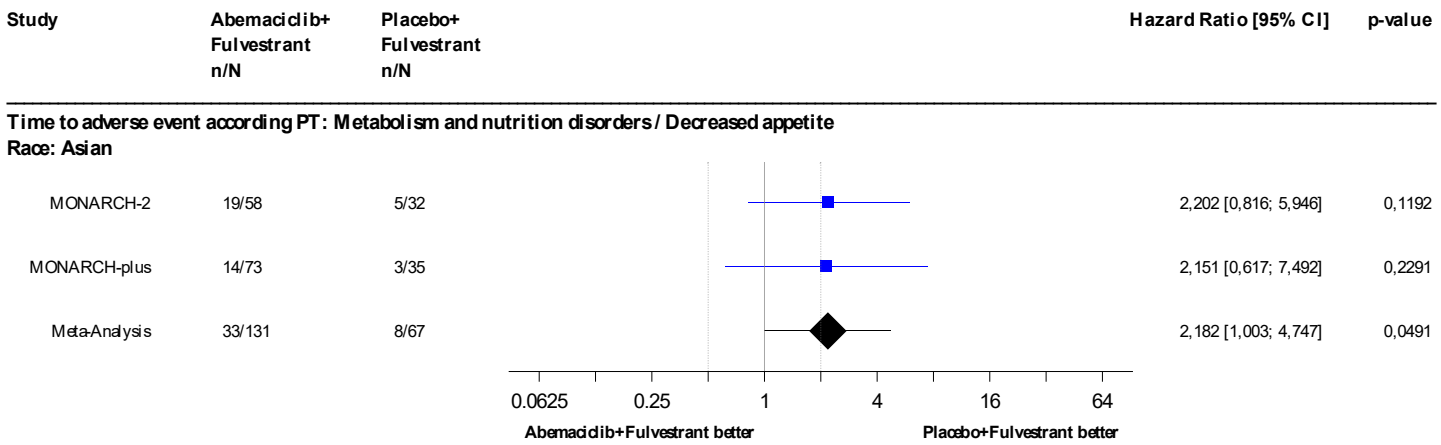
Figure 1119.1.5.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0008, p-value=0,9768, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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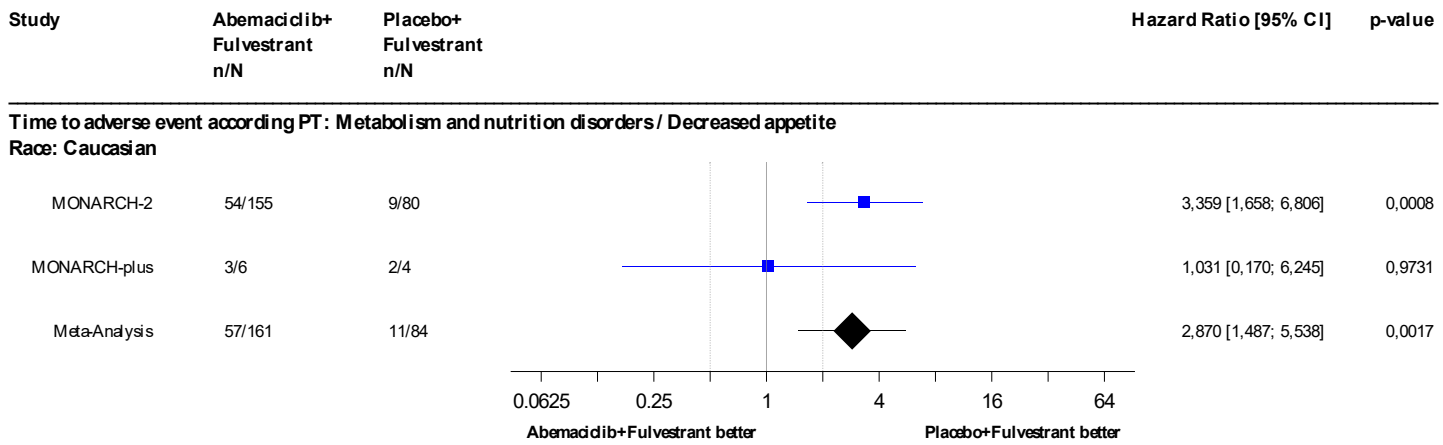
Figure 1119.1.5.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,4310, p-value=0,2316, I2 index=30,1%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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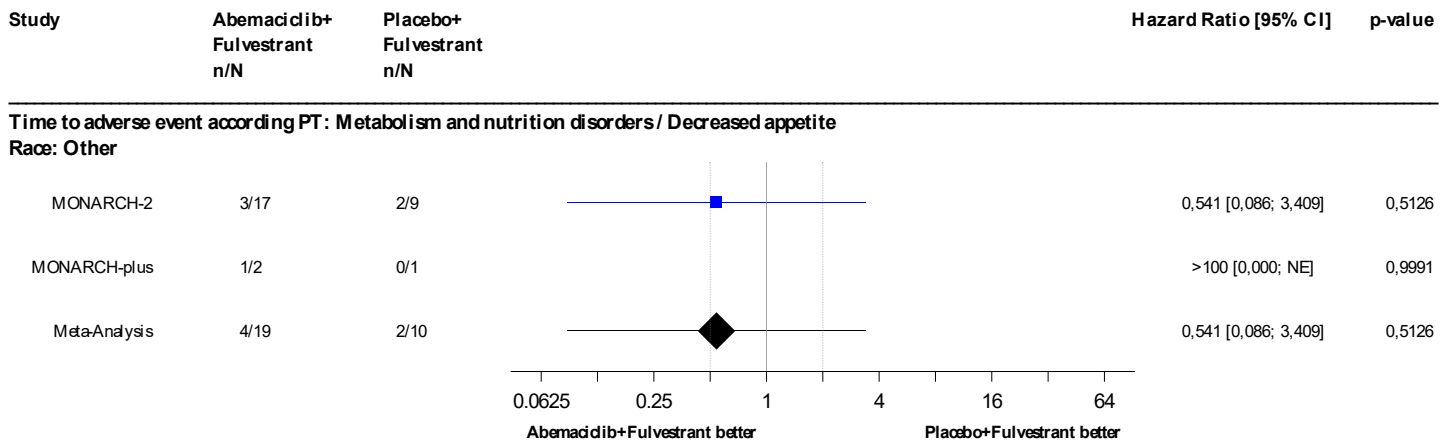
Figure 1119.1.5.3: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9990, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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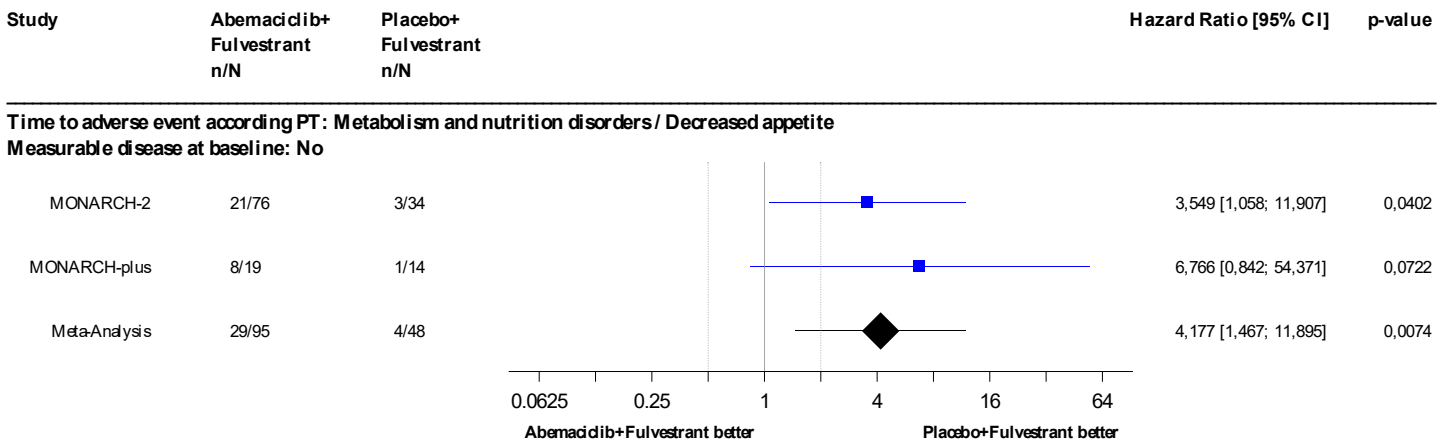
Figure 1119.1.6.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2752, p-value=0,5998, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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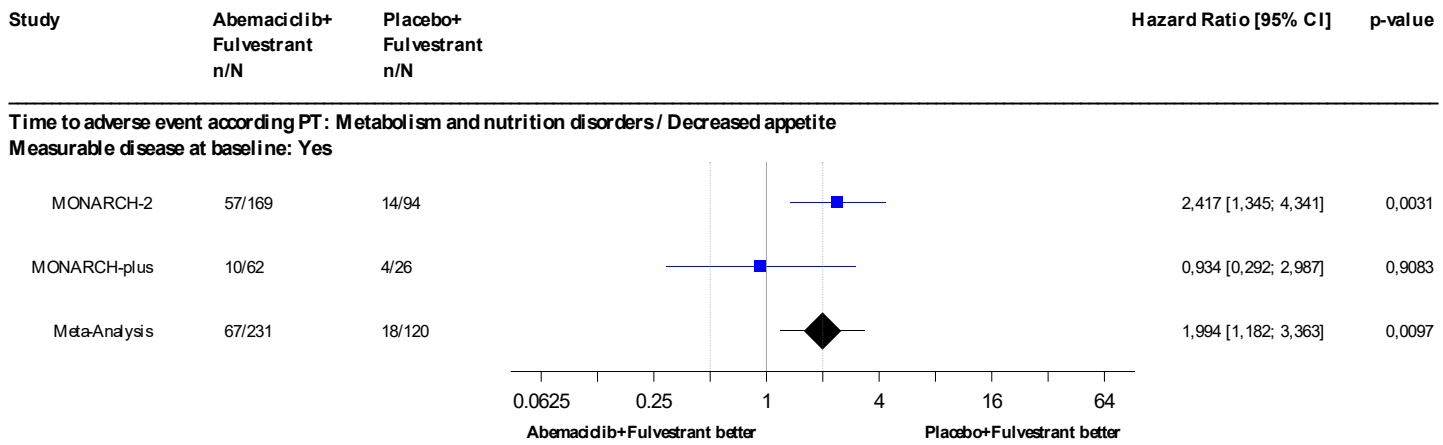
Figure 1119.1.6.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,0493, p-value=0,1523, I2 index=51,2%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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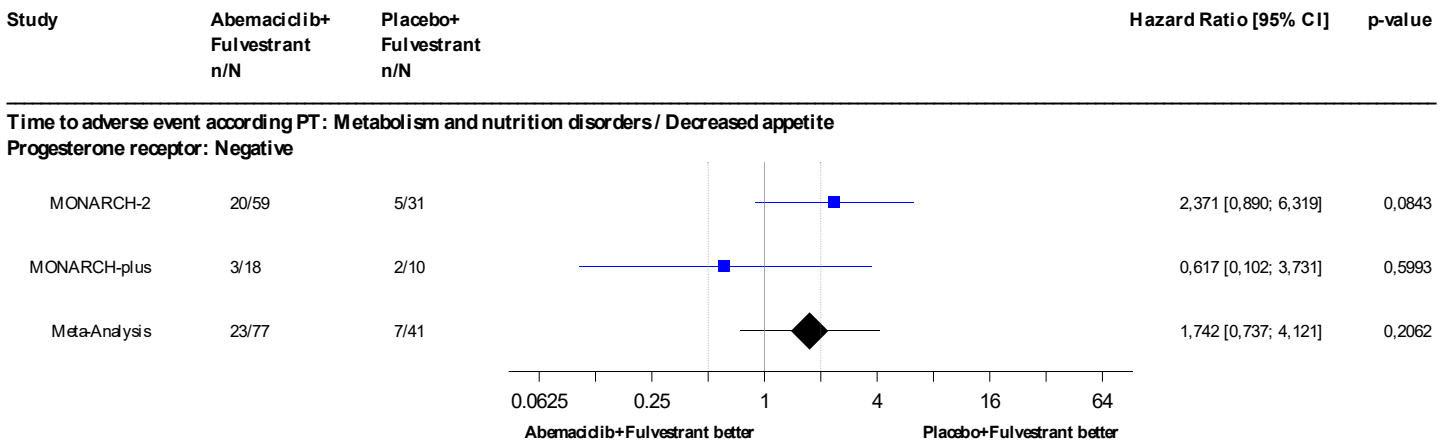
Figure 1119.1.7.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,6569, p-value=0,1980, I2 index=39,6%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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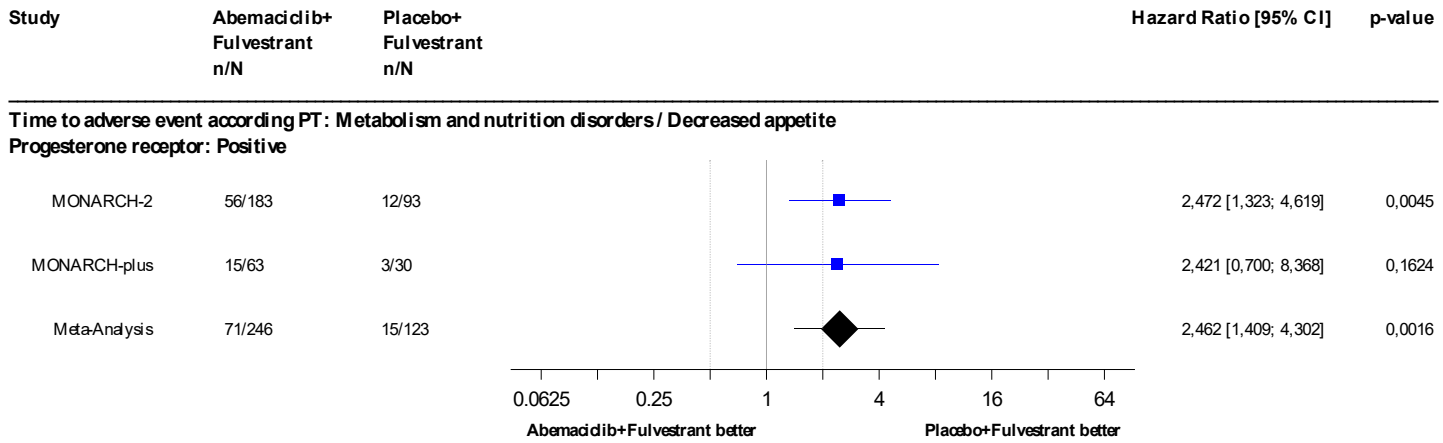
Figure 1119.1.7.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0009, p-value=0,9762, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep019_popa1_pgrstat_2.rtf
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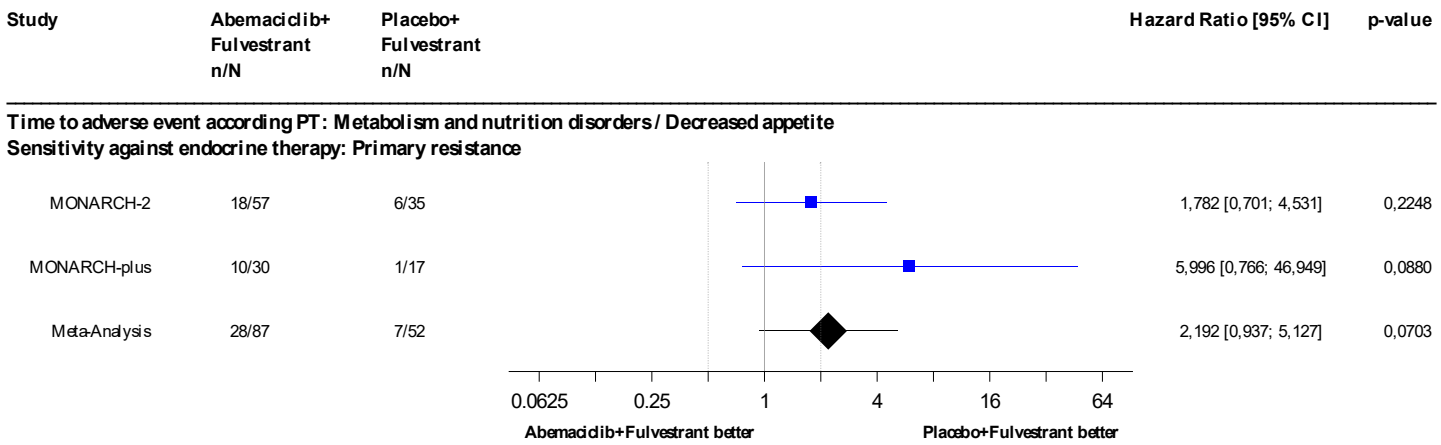
Figure 1119.1.8.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,1076, p-value=0,2926, I2 index=9,7%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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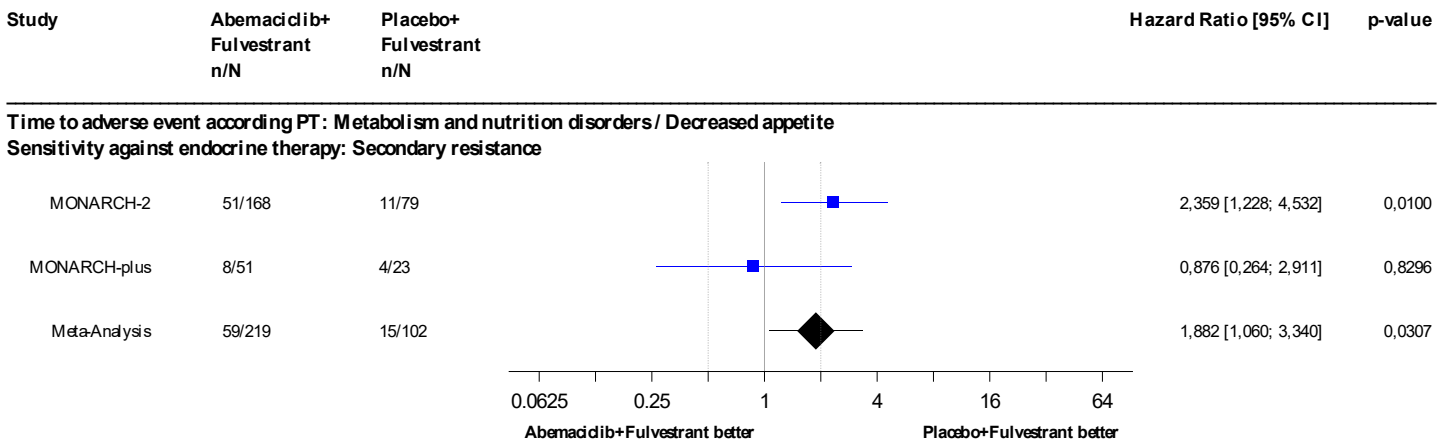
Figure 1119.1.8.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,0167, p-value=0,1556, I2 index=50,4%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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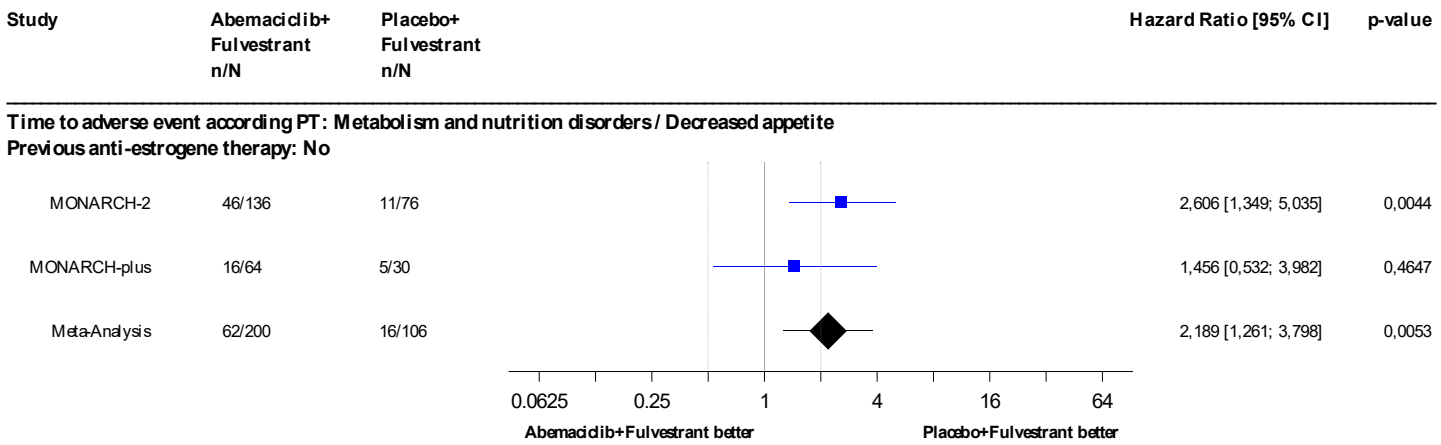
Figure 1119.1.9.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,9011, p-value=0,3425, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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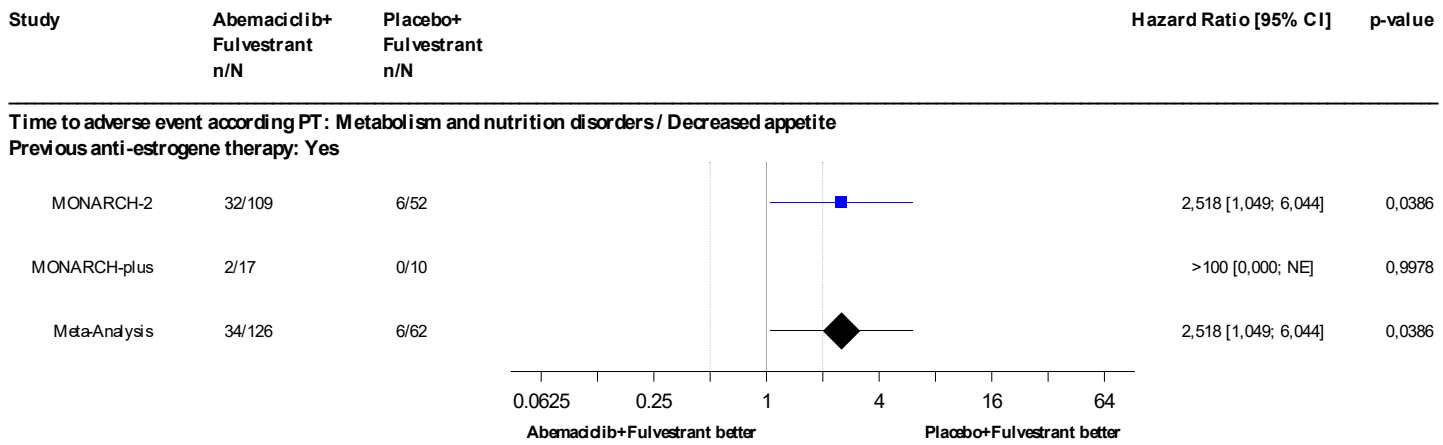
Figure 1119.1.9.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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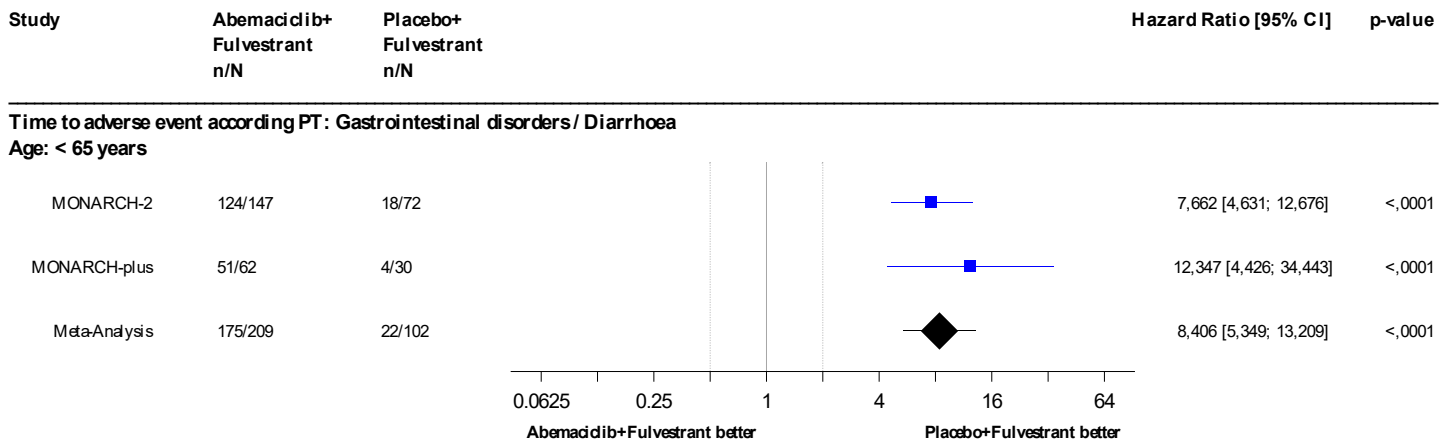
Figure 1123.1.1.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6697, p-value=0,4132, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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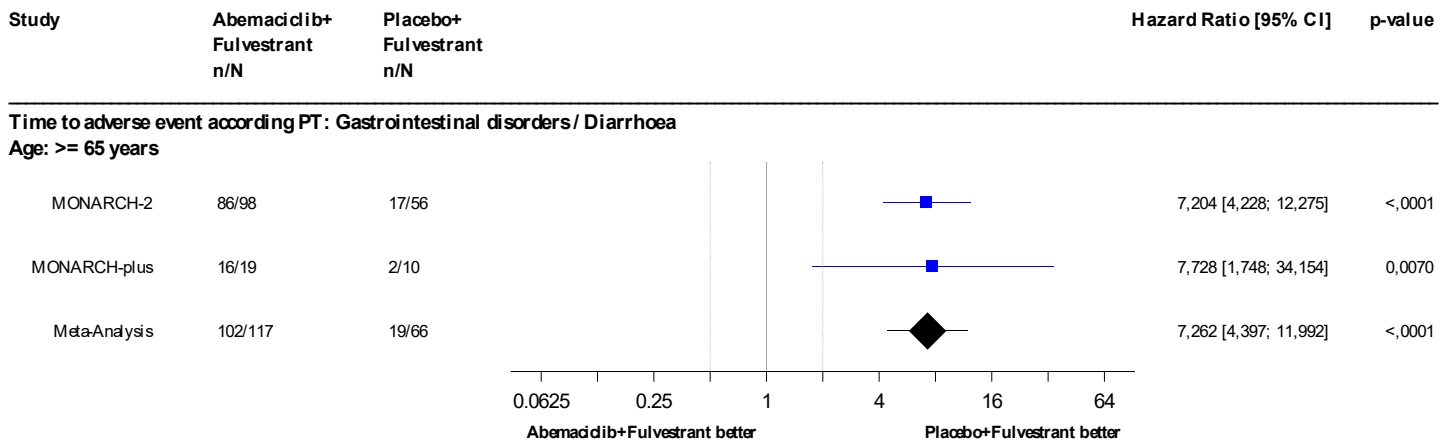
Figure 1123.1.1.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0076, p-value=0,9306, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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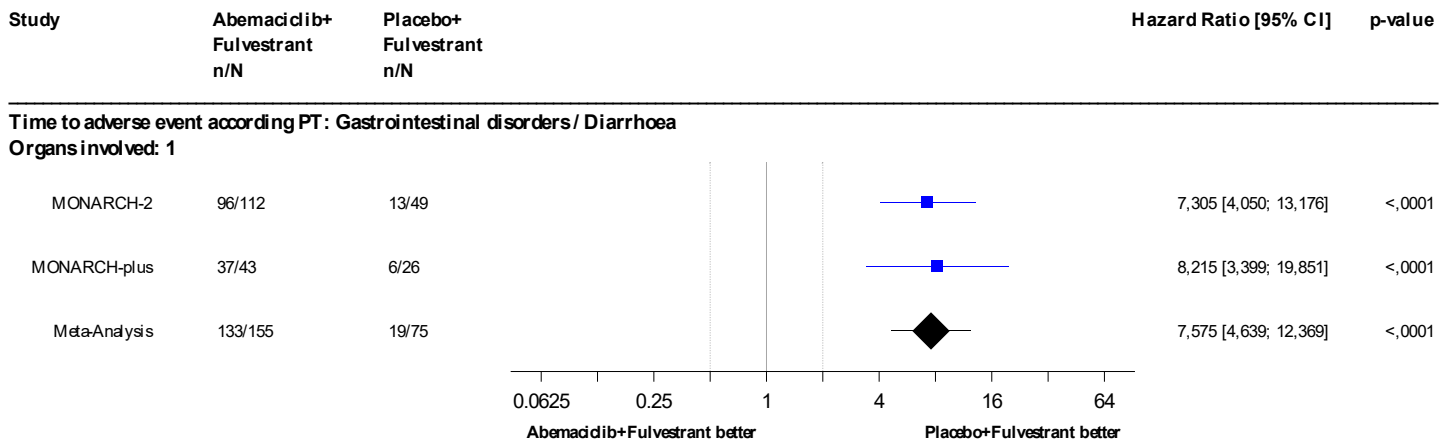
Figure 1123.1.2.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0469, p-value=0,8285, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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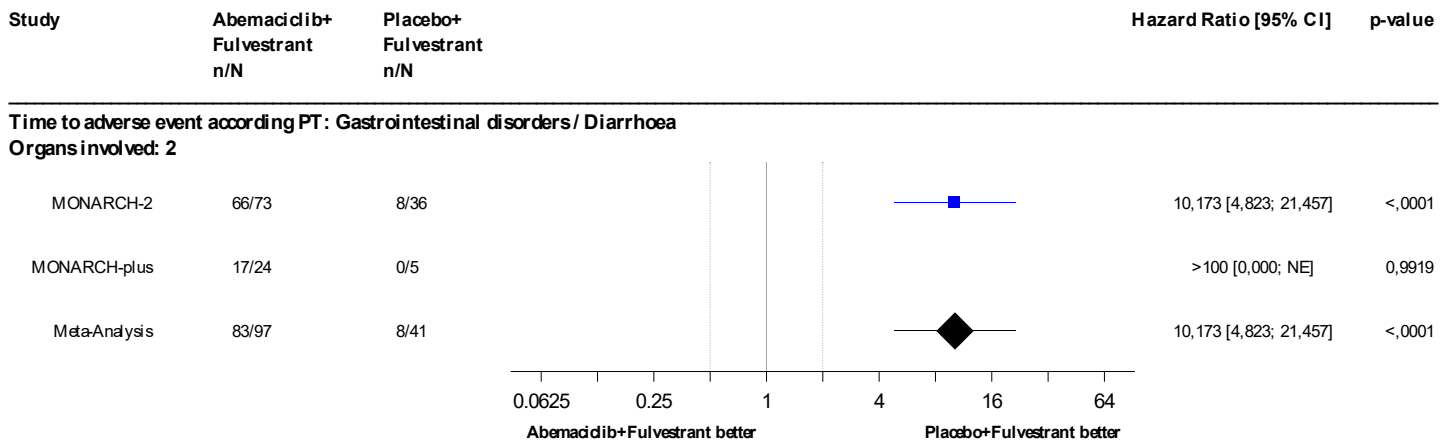
Figure 1123.1.2.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9930, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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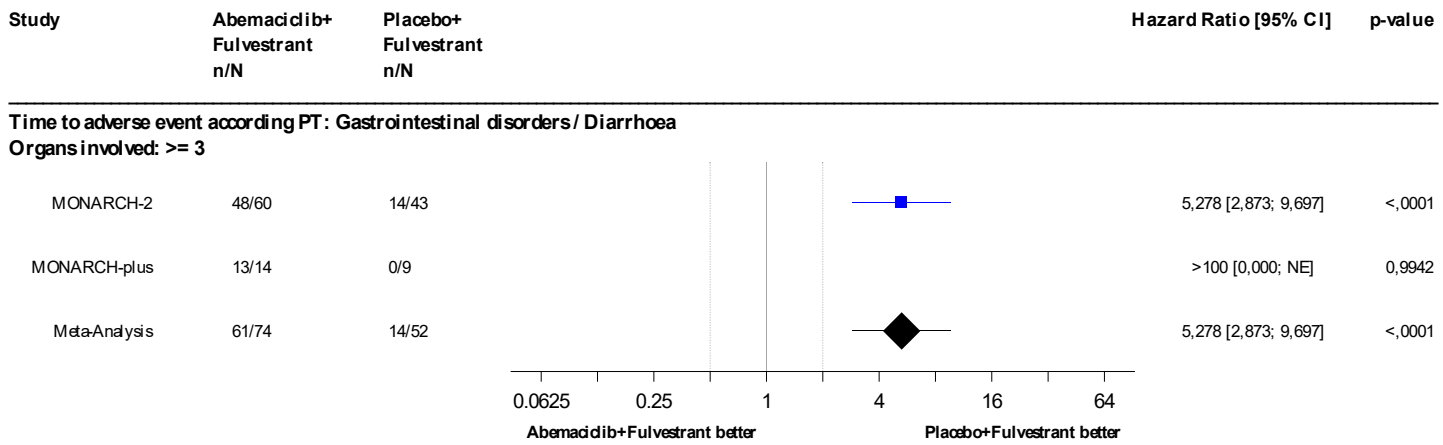
Figure 1123.1.2.3: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9947, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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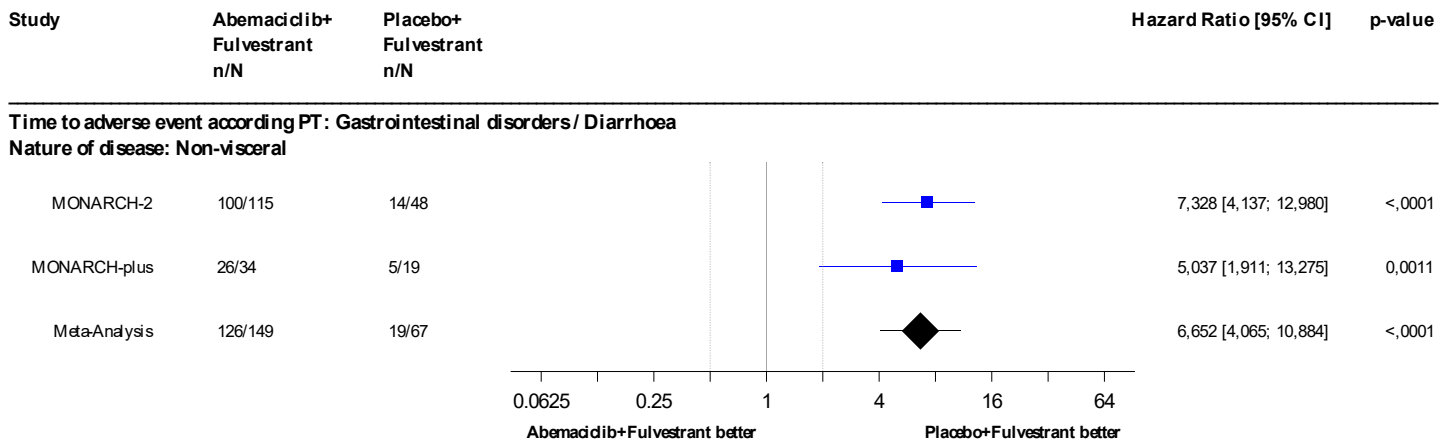
Figure 1123.1.3.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4264, p-value=0,5137, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep023_popa1_natdis2_1.rtf
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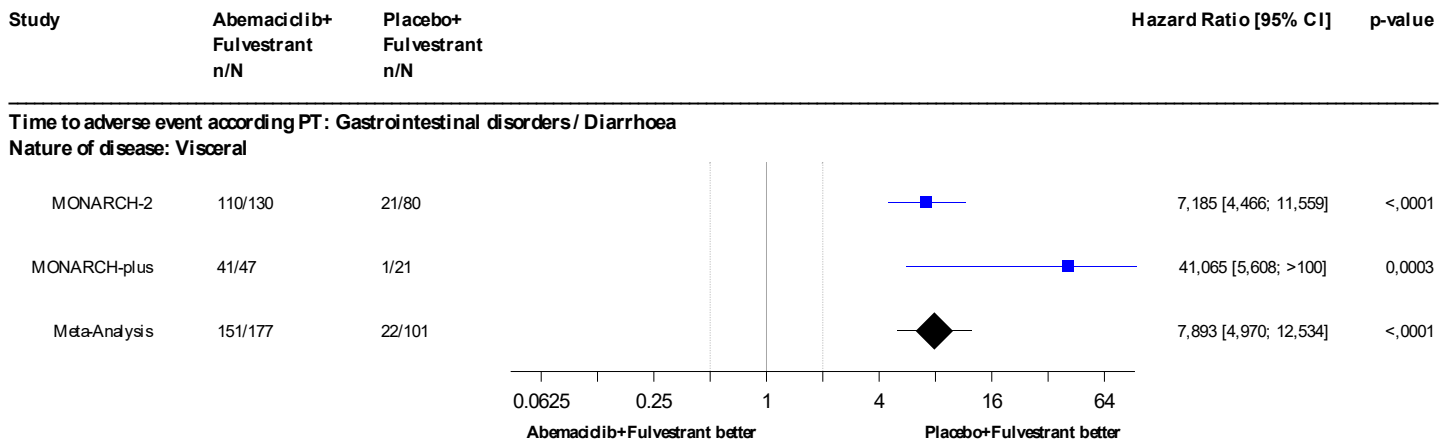
Figure 1123.1.3.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,7862, p-value=0,0951, I2 index=64,1%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep023_popa1_natdis2_2.rtf
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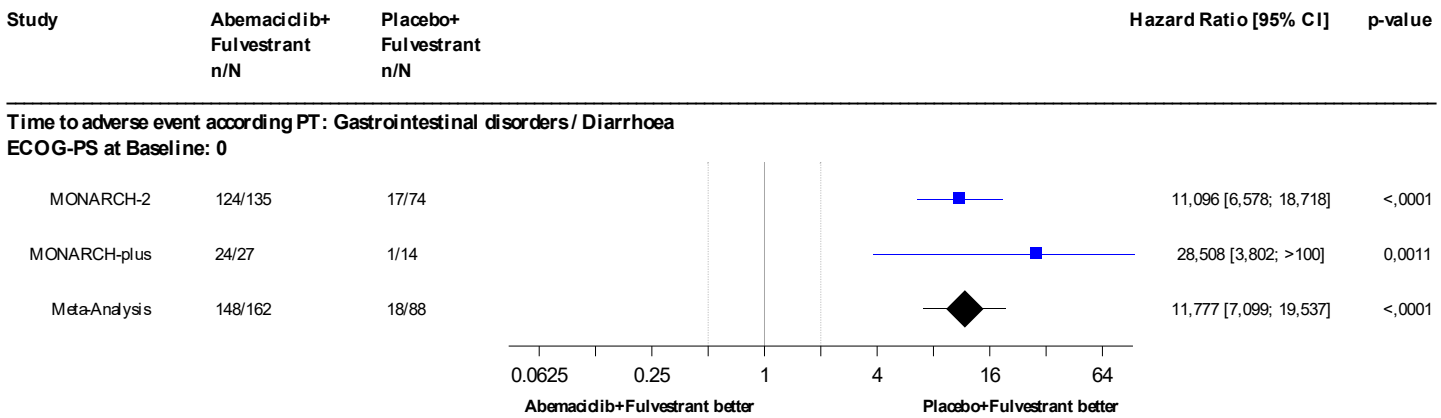
Figure 1123.1.4.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,7895, p-value=0,3742, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep023_popa1_ecogbl_1.rtf
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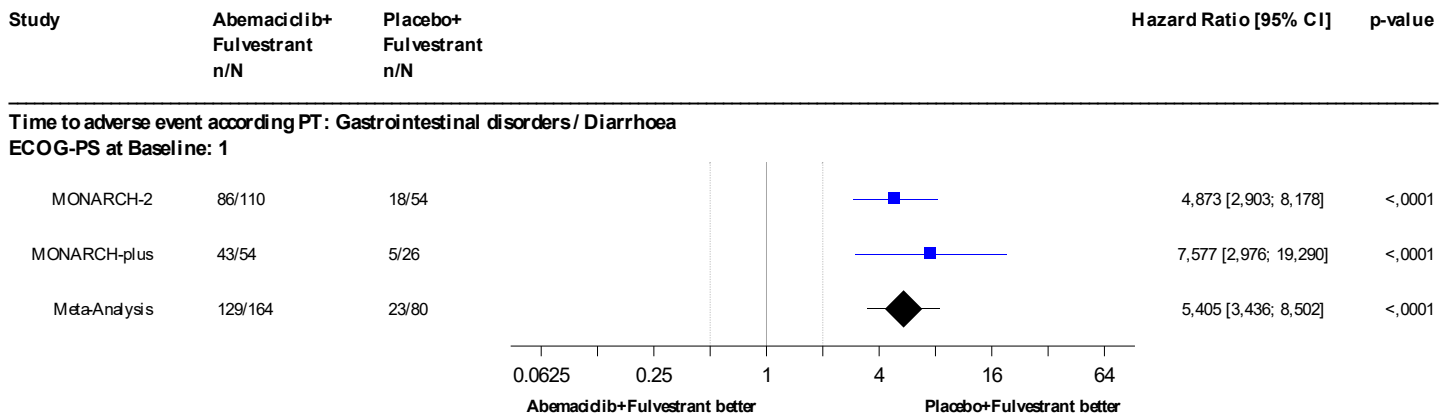
Figure 1123.1.4.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6561, p-value=0,4179, I2 index=0%

Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep023_popa1_ecogbl_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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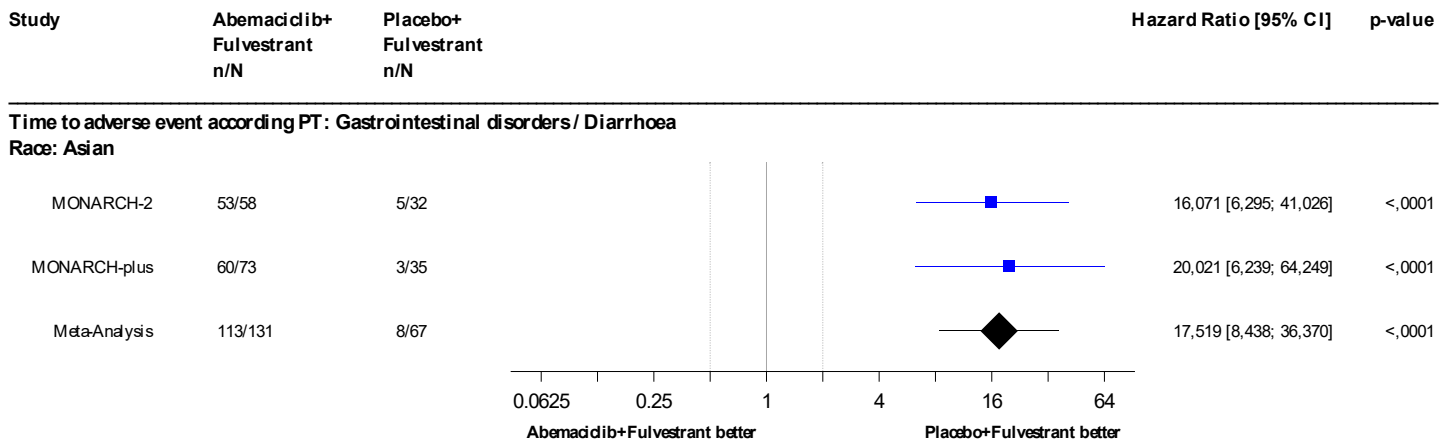
Figure 1123.1.5.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0829, p-value=0,7734, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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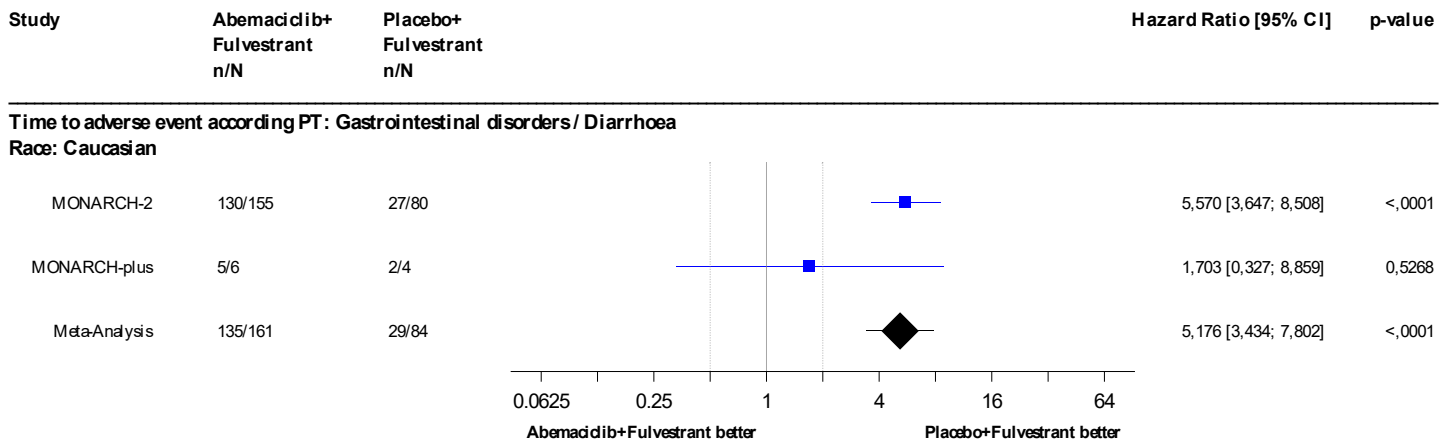
Figure 1123.1.5.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,8610, p-value=0,1725, I2 index=46,3%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep023_popa1_racegr1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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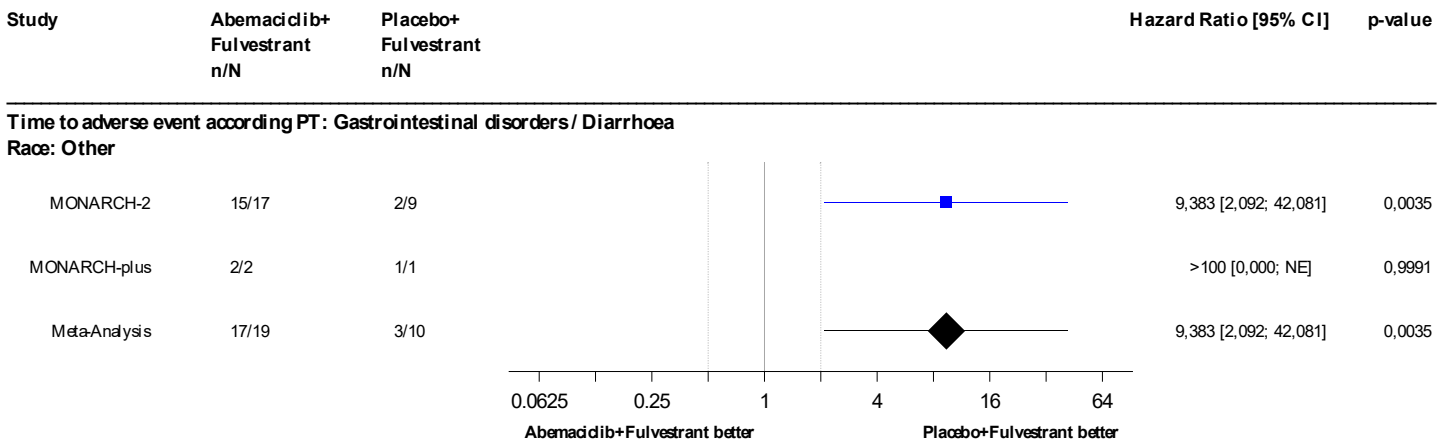
Figure 1123.1.5.3: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9992, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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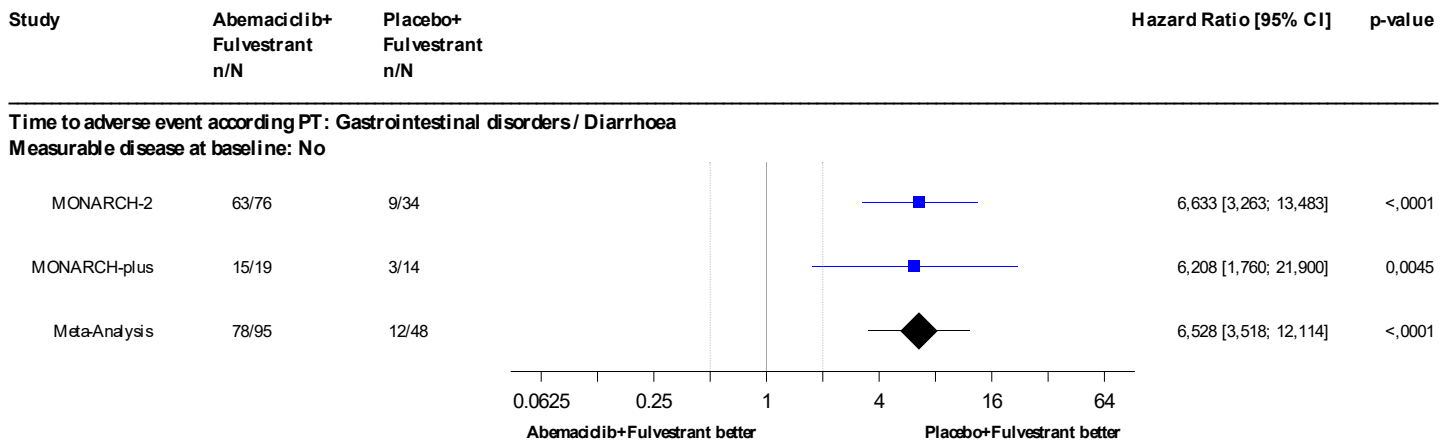
Figure 1123.1.6.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0081, p-value=0,9285, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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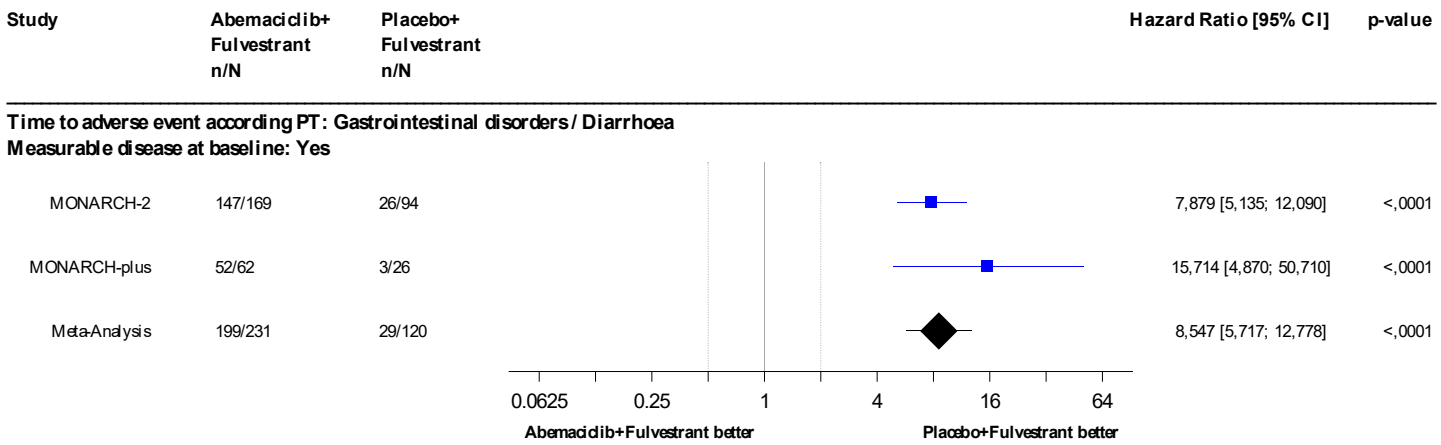
Figure 1123.1.6.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,1769, p-value=0,2780, I2 index=15,0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep023_popa1_measdis_2.rtf
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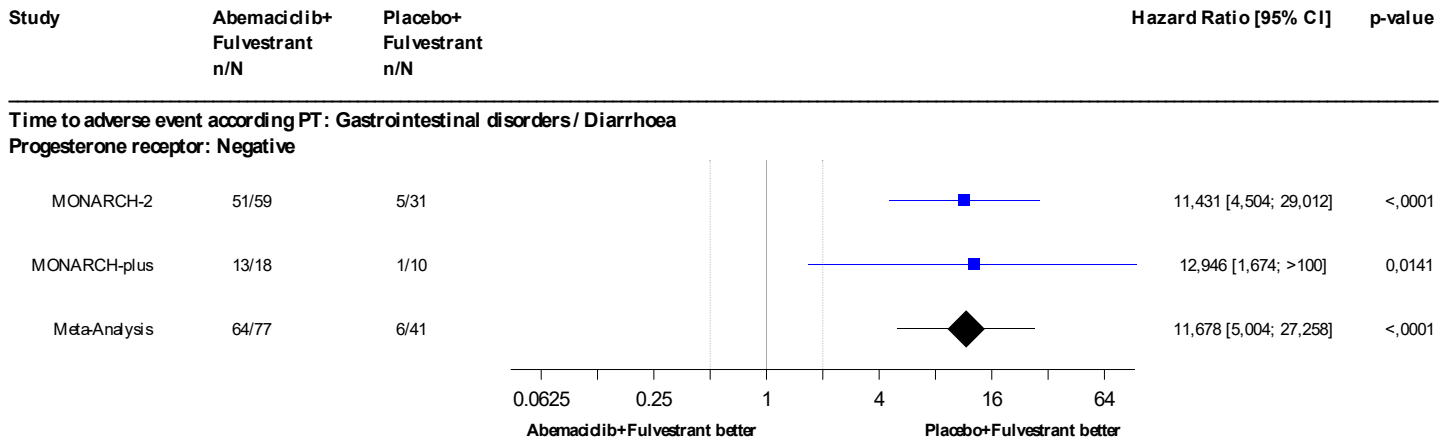
Figure 1123.1.7.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0118, p-value=0,9136, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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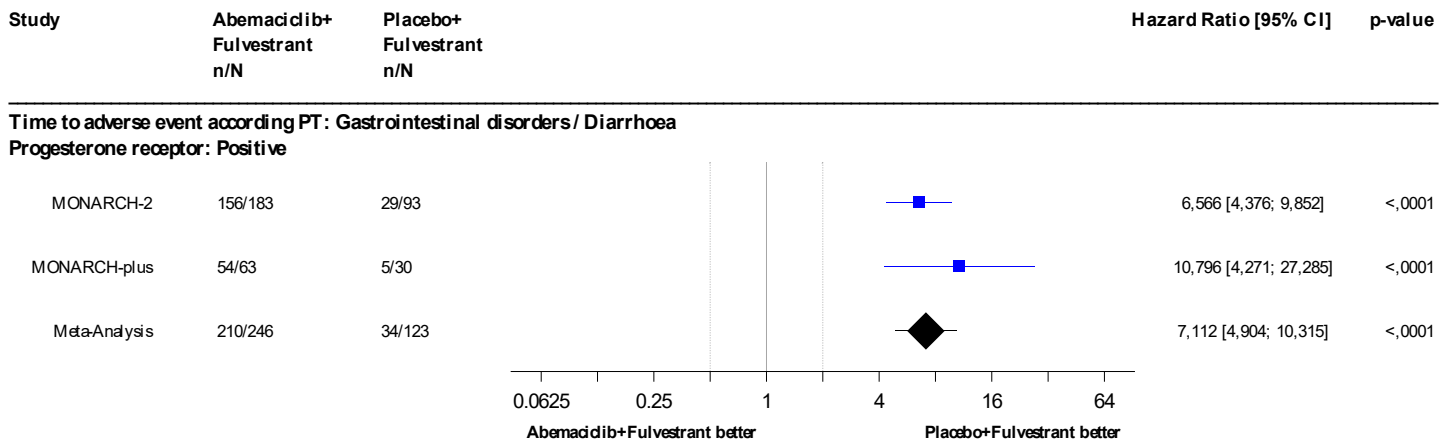
Figure 1123.1.7.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,9273, p-value=0,3356, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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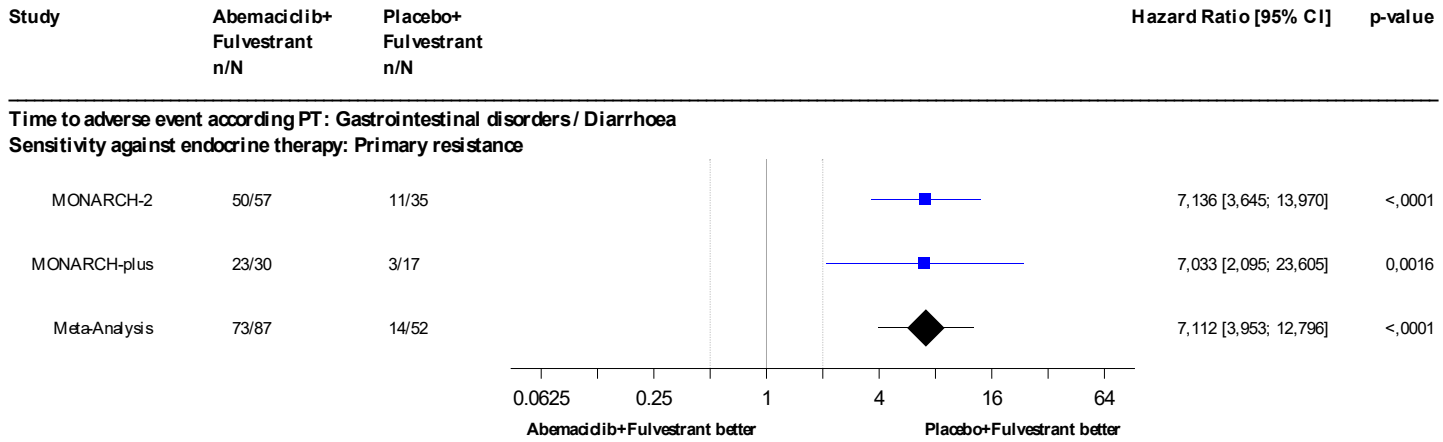
Figure 1123.1.8.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0004, p-value=0,9835, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep023_popa1_snthr_1.rtf
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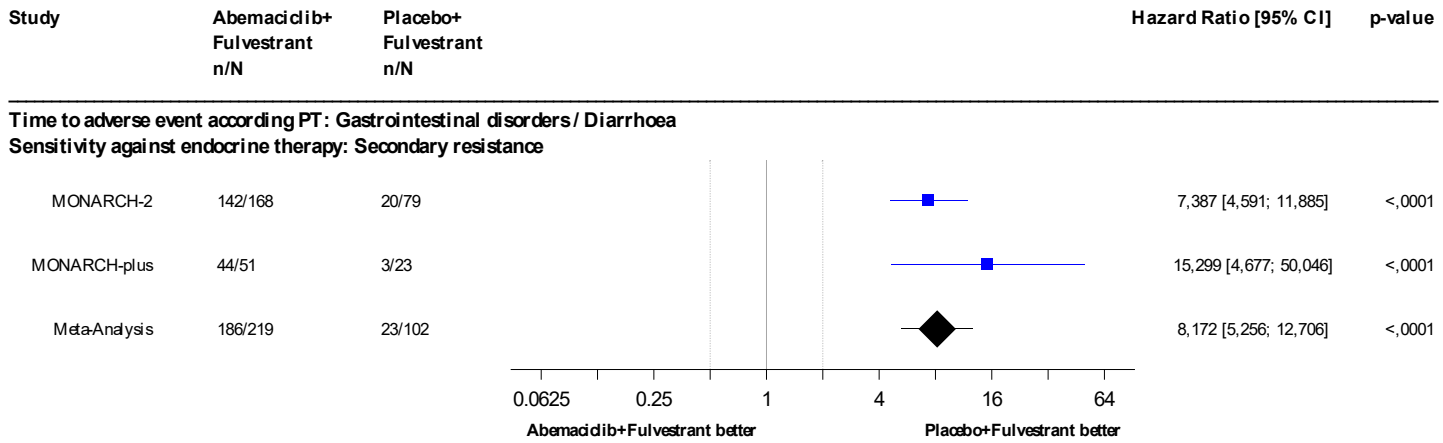
Figure 1123.1.8.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,2488, p-value=0,2638, I2 index=19,9%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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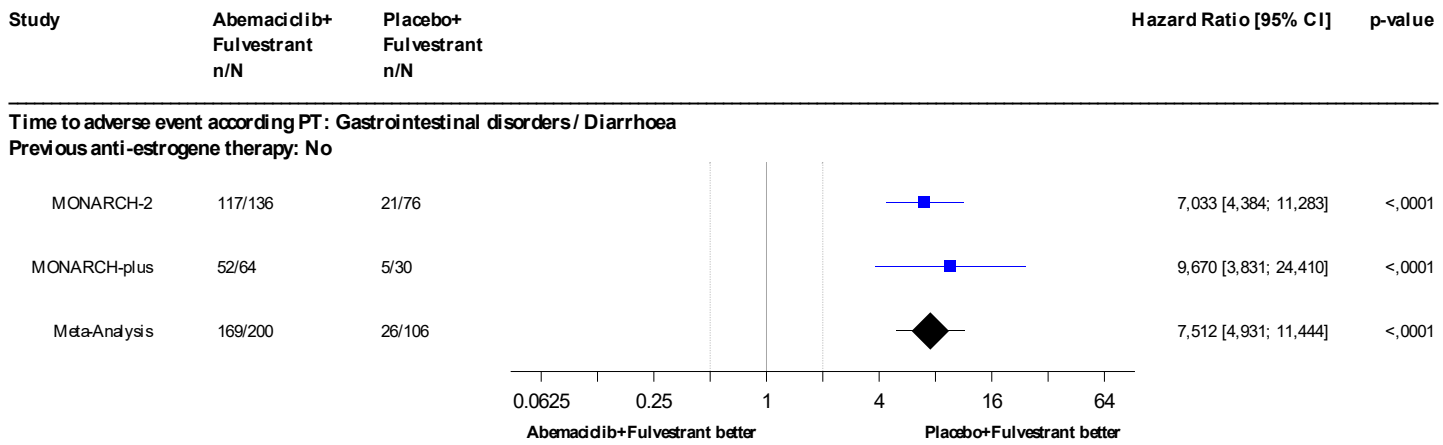
Figure 1123.1.9.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3604, p-value=0,5483, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep023_popa1_paet_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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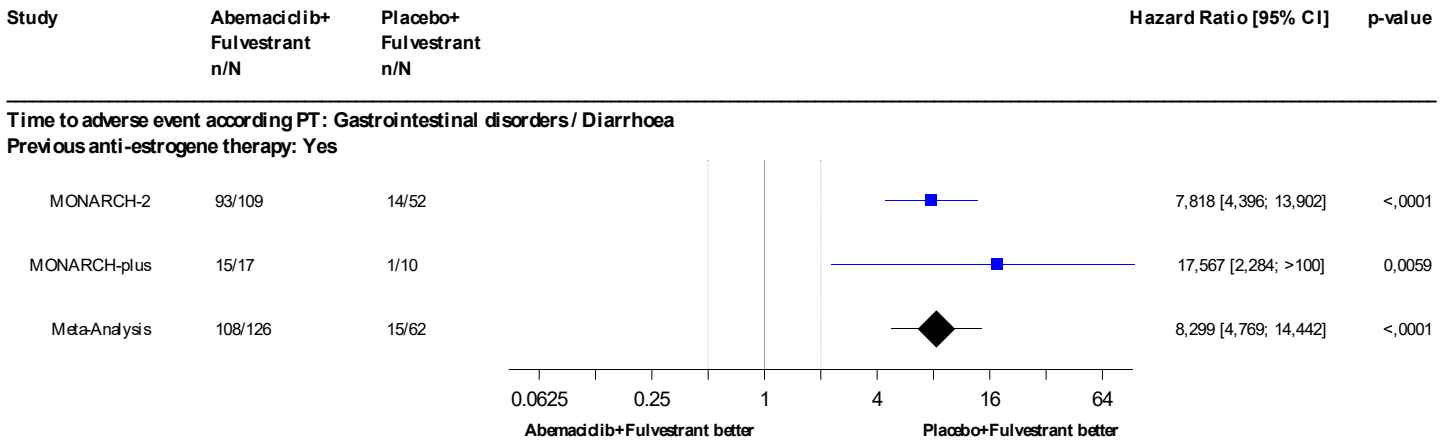
Figure 1123.1.9.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5604, p-value=0,4541, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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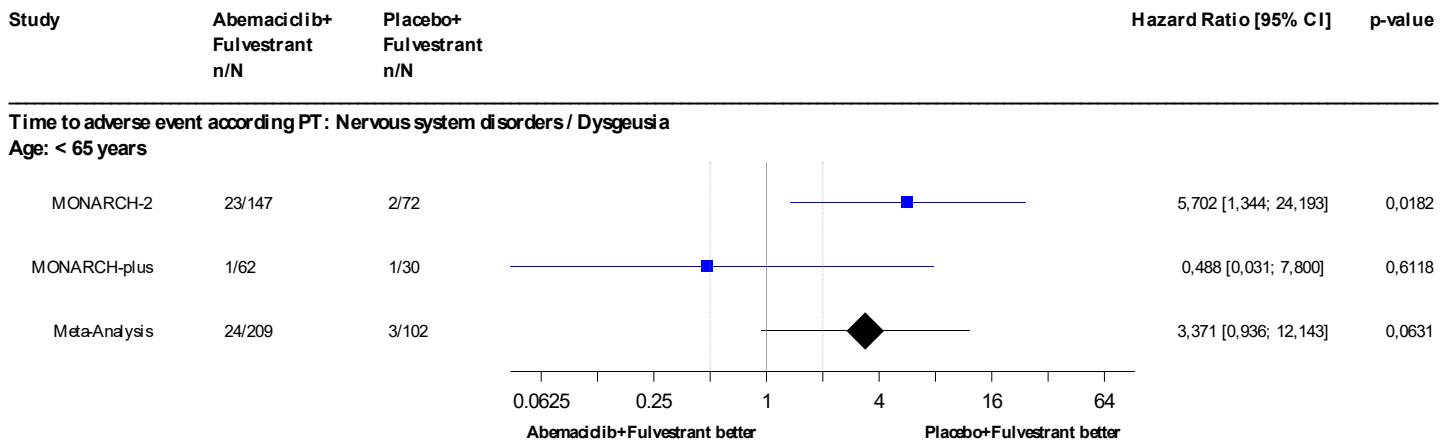
Figure 1127.1.1.1: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,3761, p-value=0,1232, I2 index=57,9%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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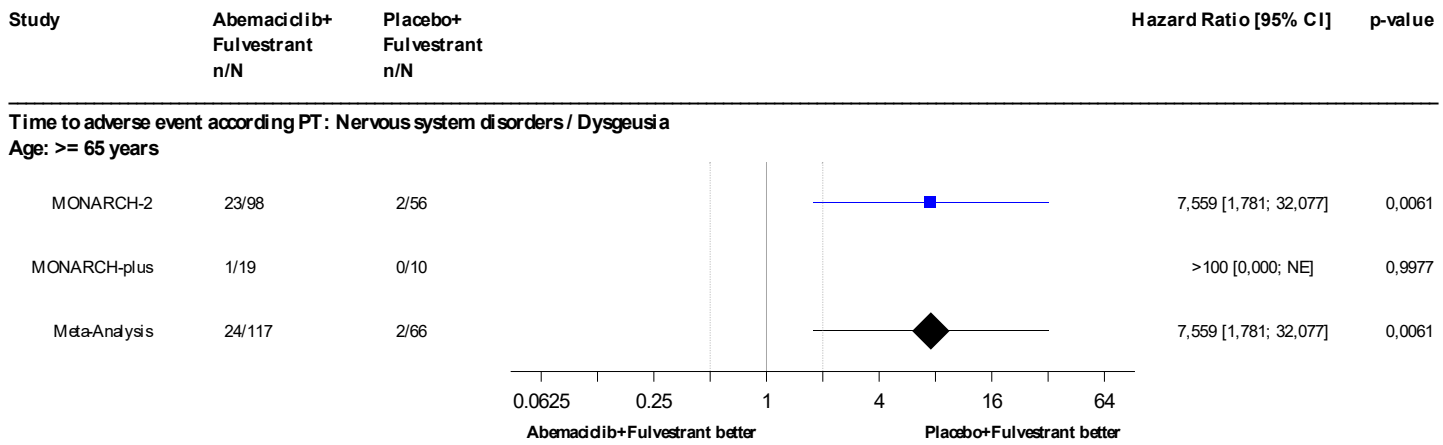
Figure 1127.1.1.2: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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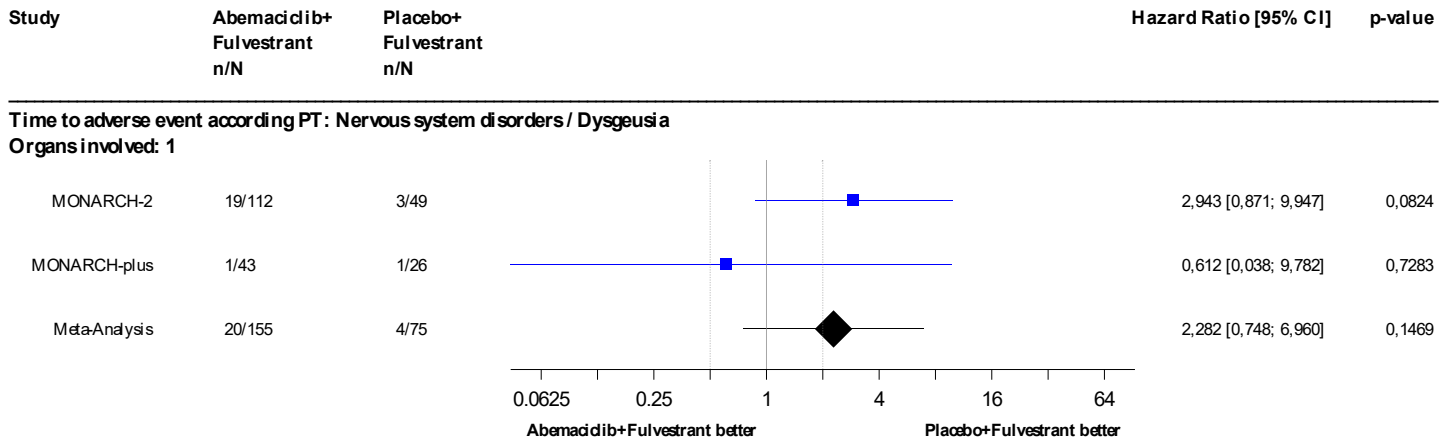
Figure 1127.1.2.1: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,0339, p-value=0,3092, I2 index=3,3%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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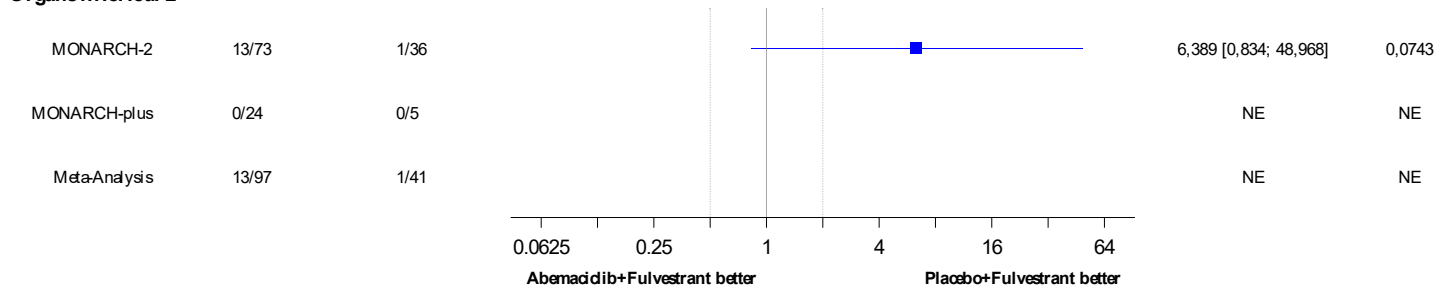
Figure 1127.1.2.2: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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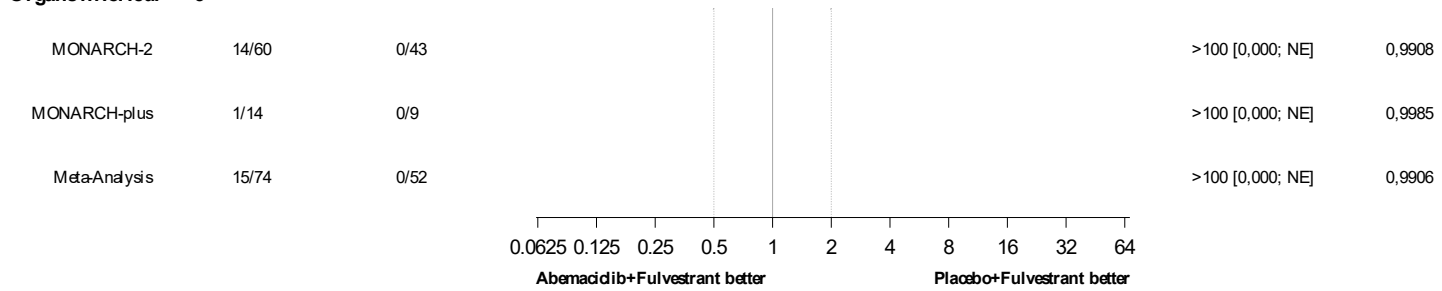
Figure 1127.1.2.3: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9999, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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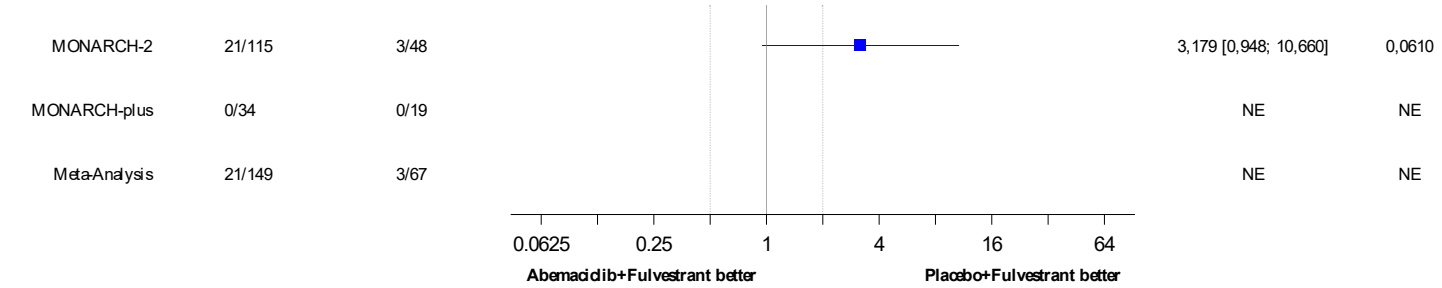
Figure 1127.1.3.1: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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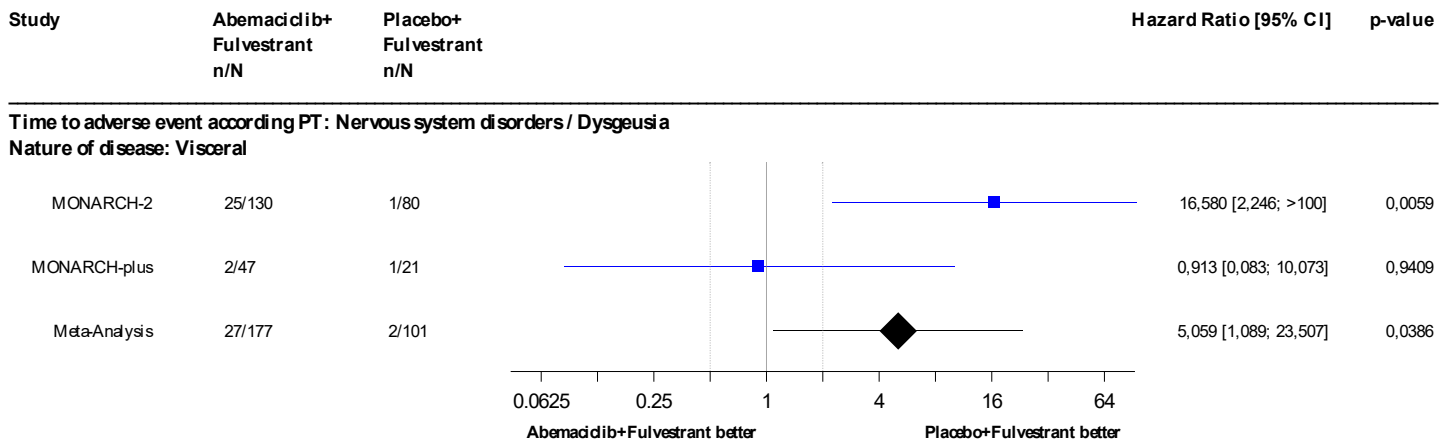
Figure 1127.1.3.2: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=3,3084, p-value=0,0689, I2 index=69,8%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep027_popa1_natdis2_2.rtf
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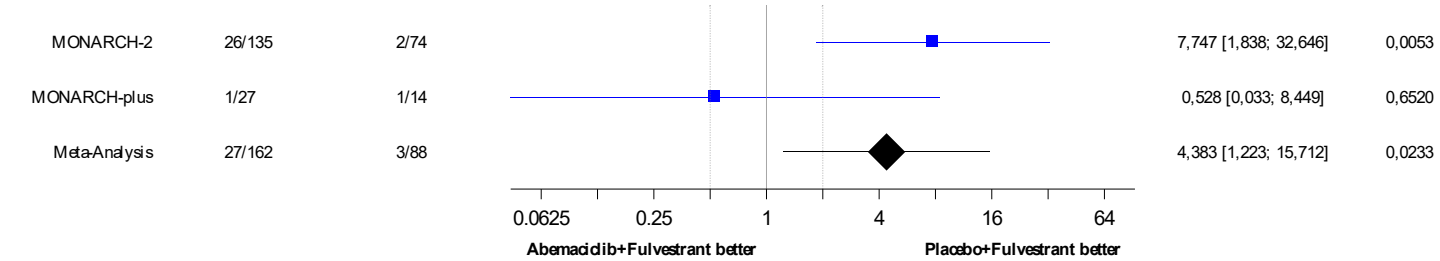
Figure 1127.1.4.1: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,8401, p-value=0,0919, I2 index=64,8%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep027_popa1_ecogbl_1.rtf
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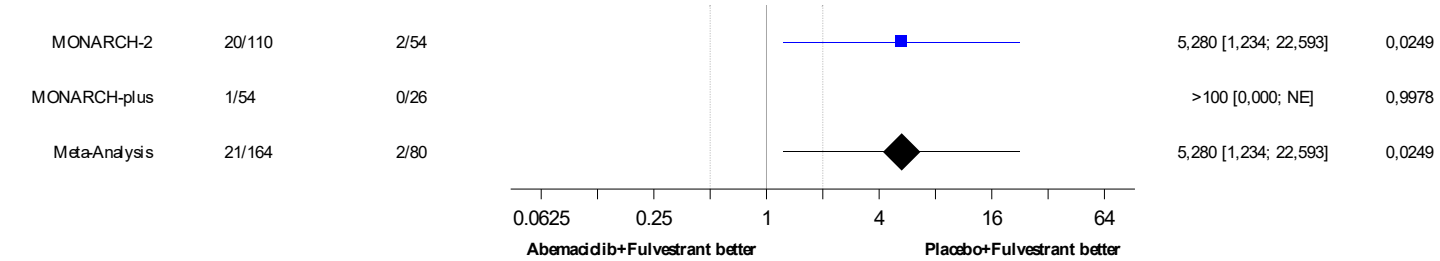
Figure 1127.1.4.2: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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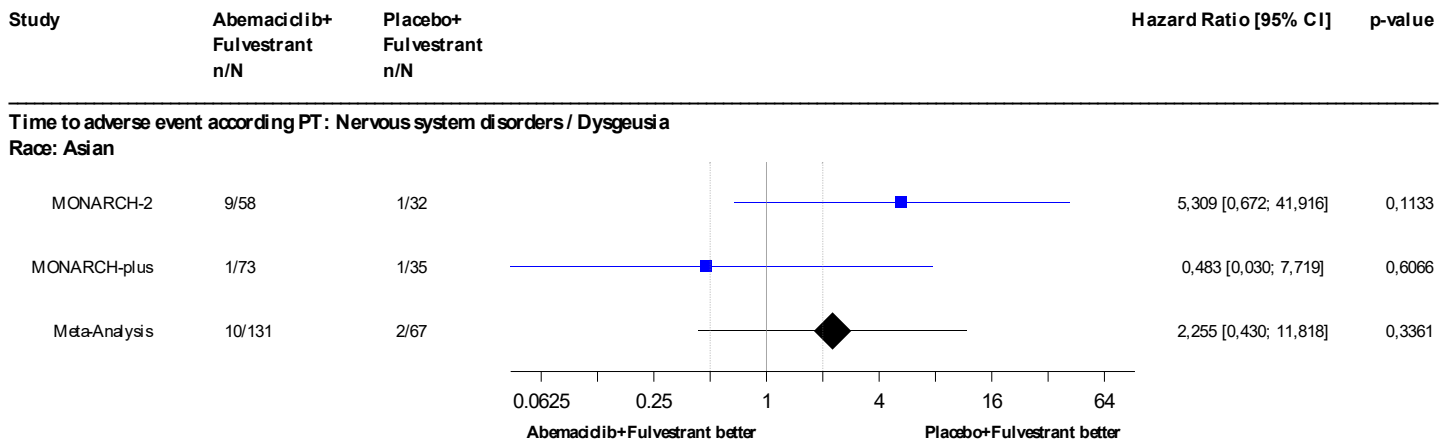
Figure 1127.1.5.1: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,8476, p-value=0,1741, I2 index=45,9%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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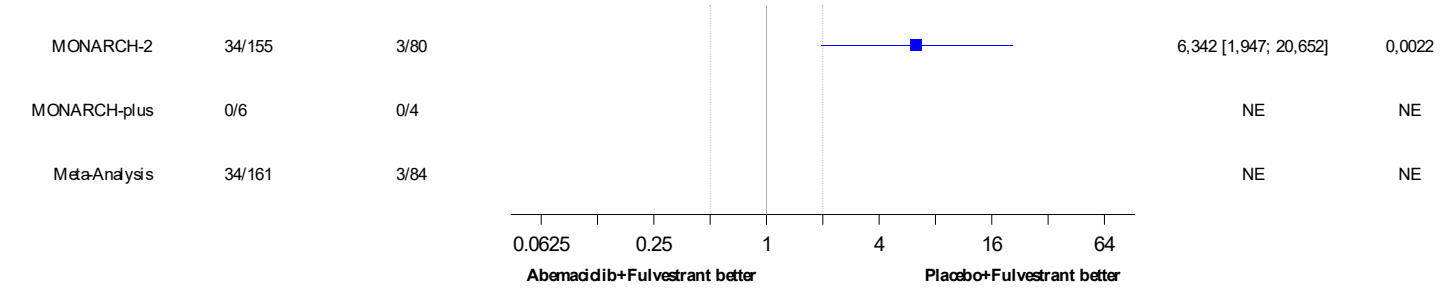
Figure 1127.1.5.2: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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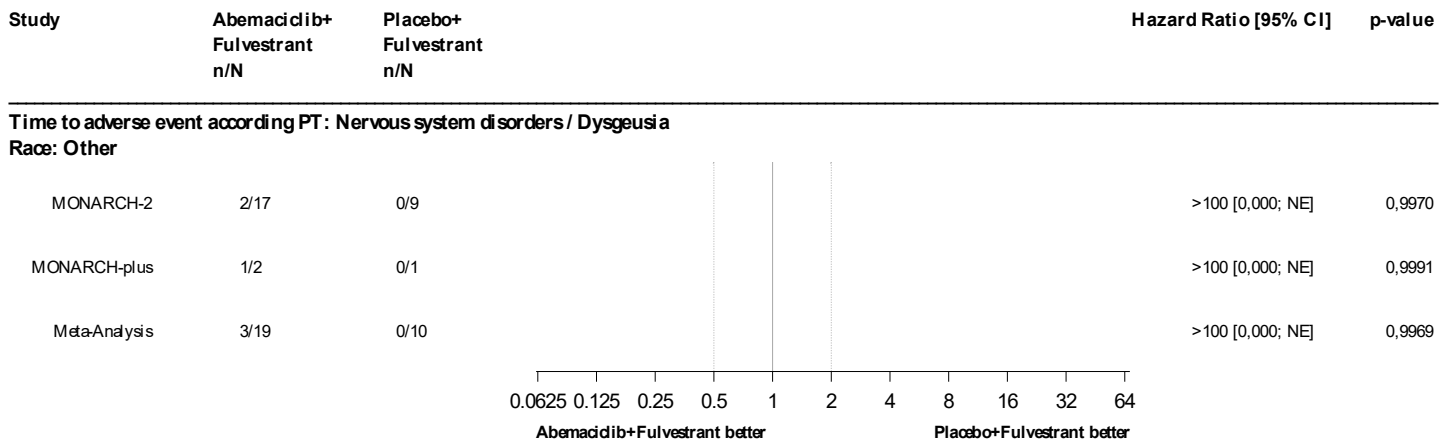
Figure 1127.1.5.3: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9999, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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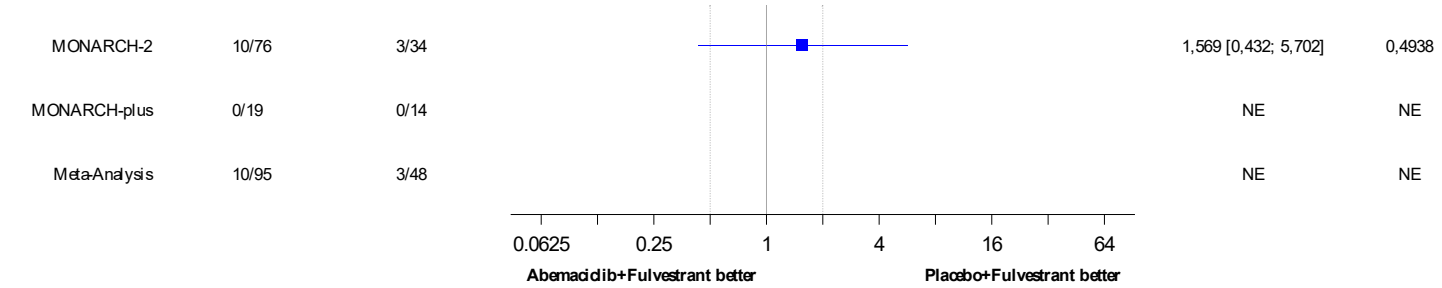
Figure 1127.1.6.1: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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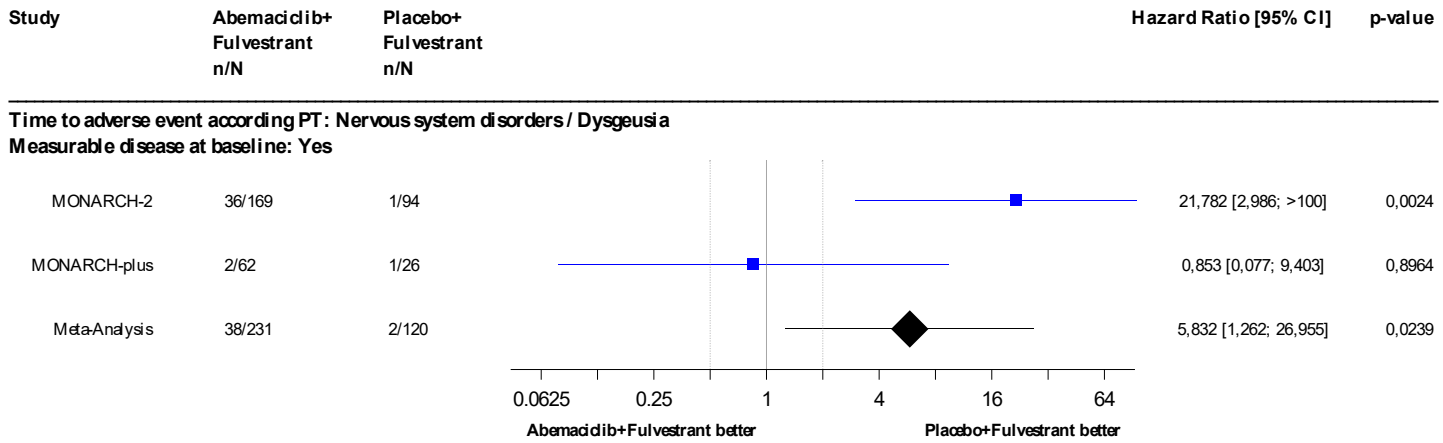
Figure 1127.1.6.2: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=4,1542, p-value=0,0415, I2 index=75,9%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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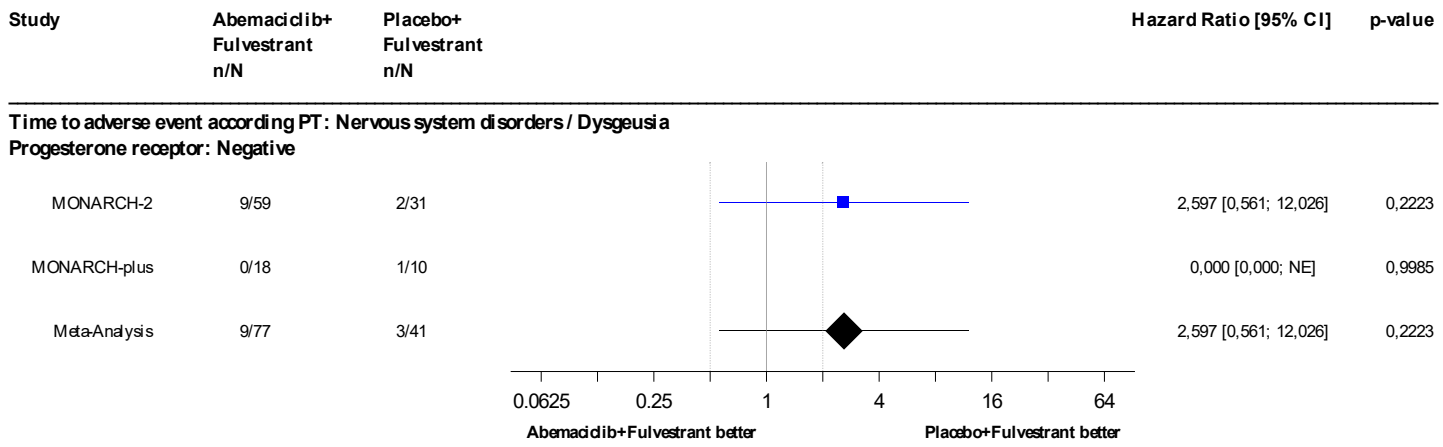
Figure 1127.1.7.1: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9984, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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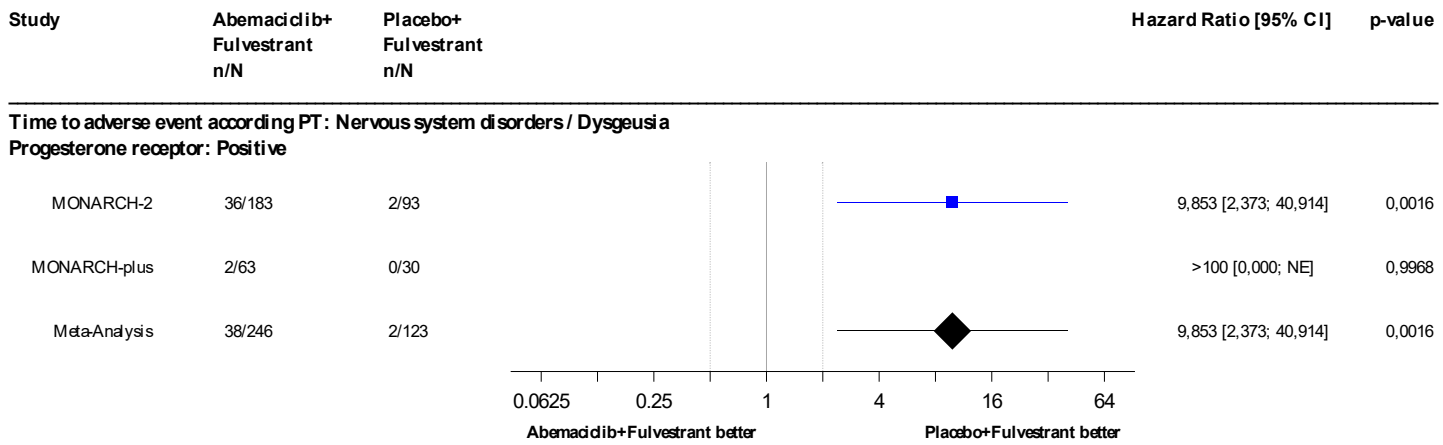
Figure 1127.1.7.2: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9973, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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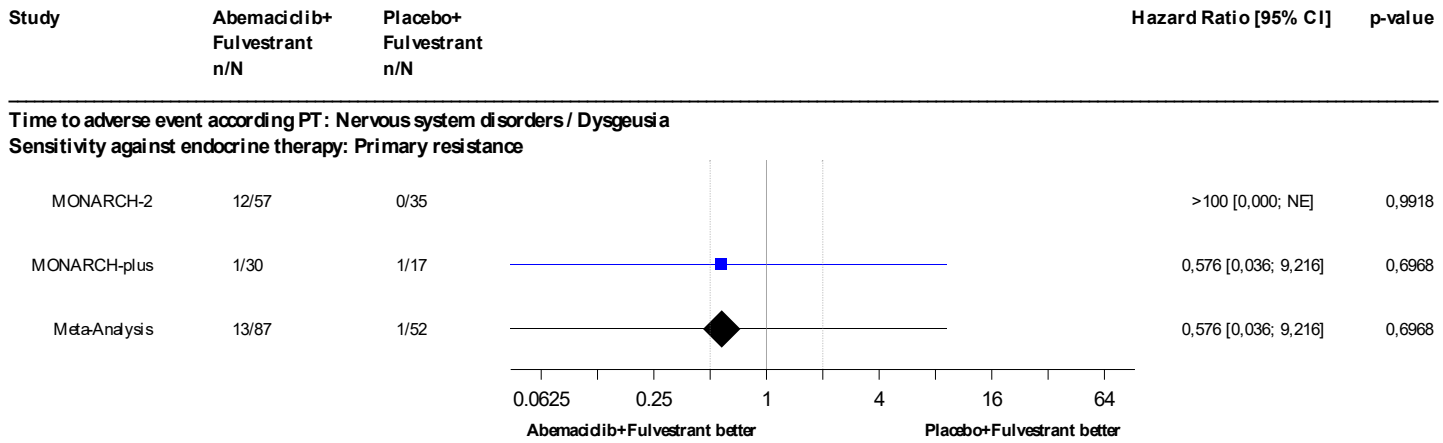
Figure 1127.1.8.1: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9915, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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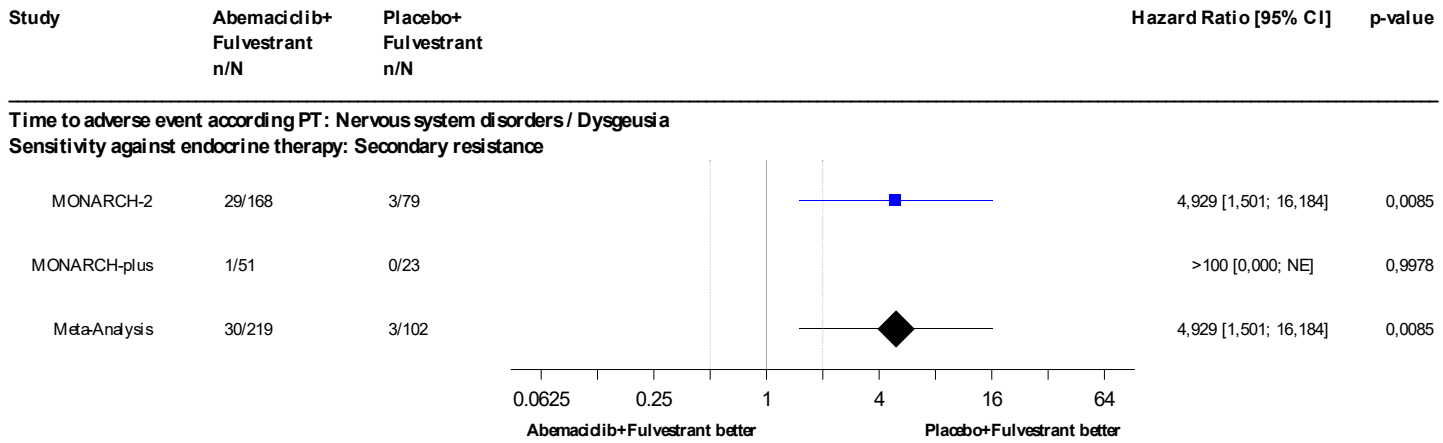
Figure 1127.1.8.2: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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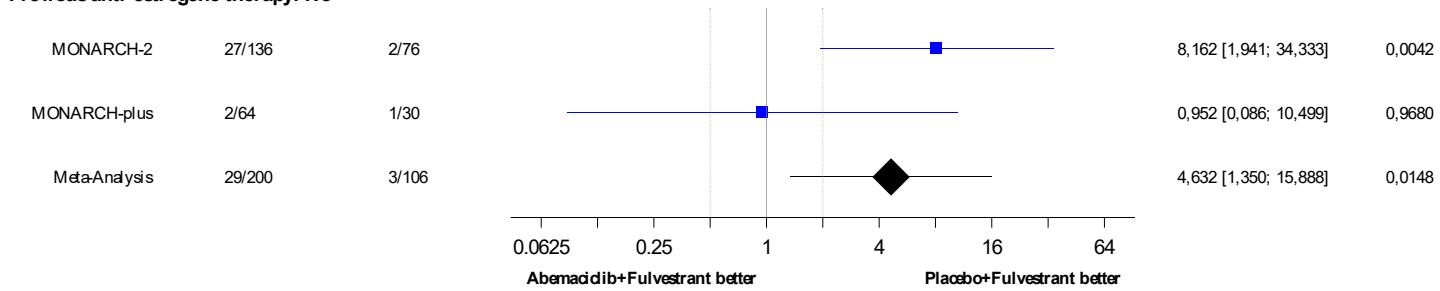
Figure 1127.1.9.1: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,2663, p-value=0,1322, I2 index=55,9%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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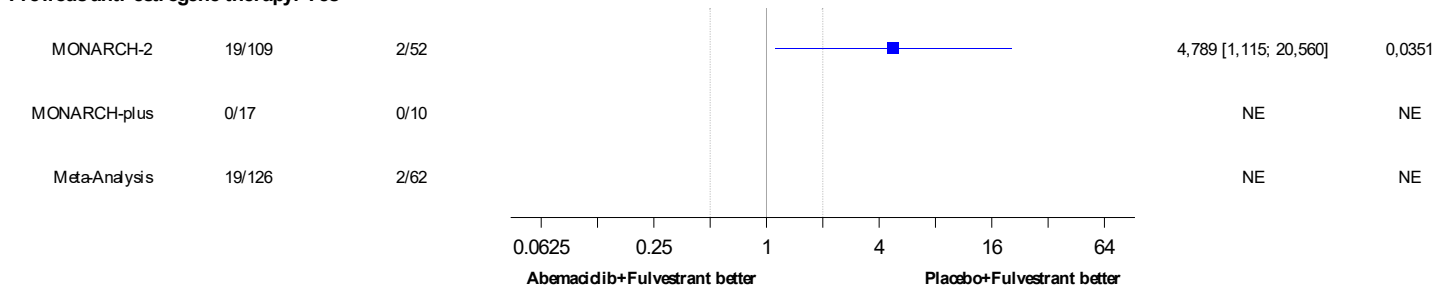
Figure 1127.1.9.2: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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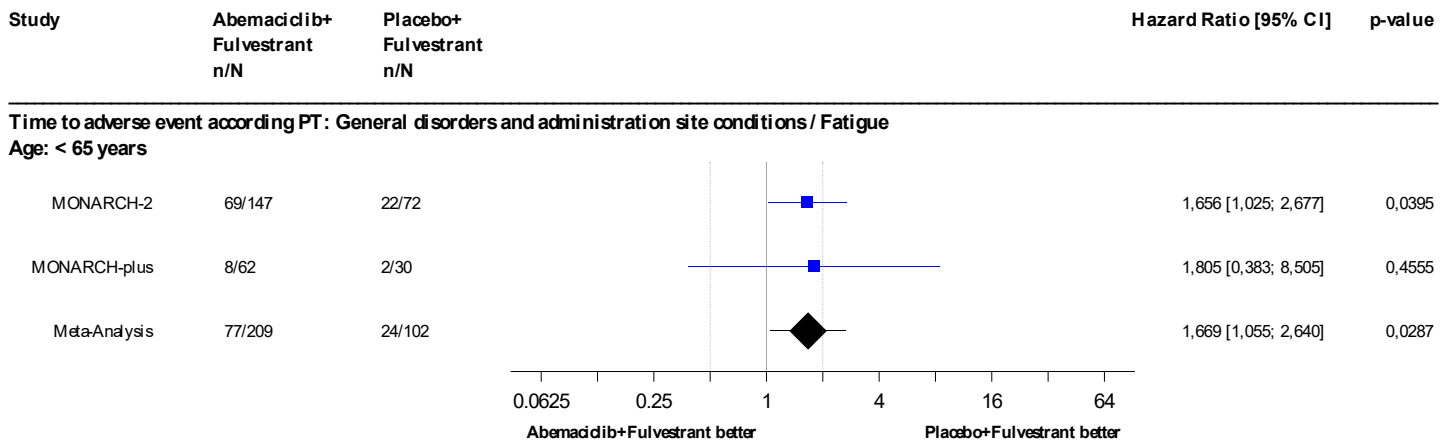
Figure 1133.1.1.1: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0107, p-value=0,9175, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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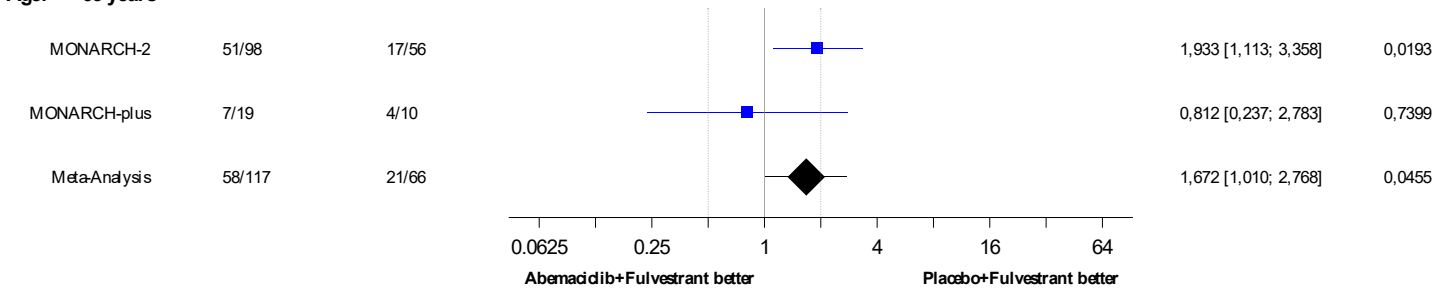
Figure 1133.1.1.2: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,5871, p-value=0,2077, I2 index=37,0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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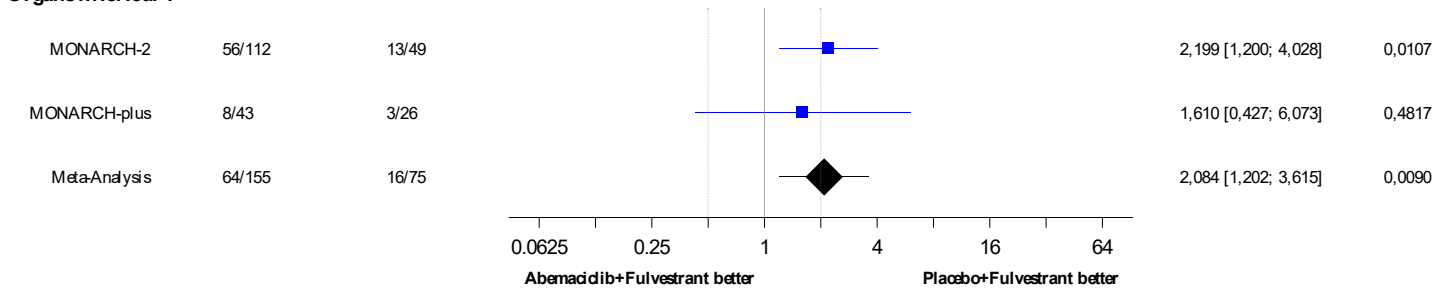
Figure 1133.1.2.1: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1752, p-value=0,6756, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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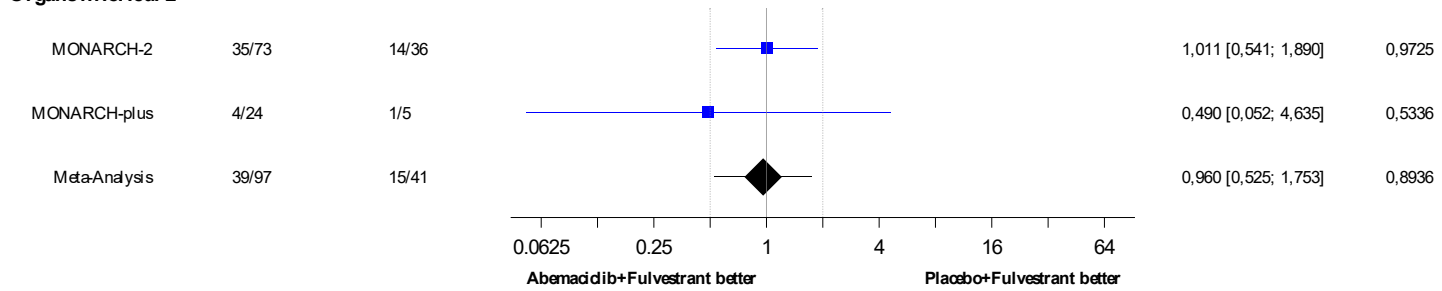
Figure 1133.1.2.2: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3709, p-value=0,5425, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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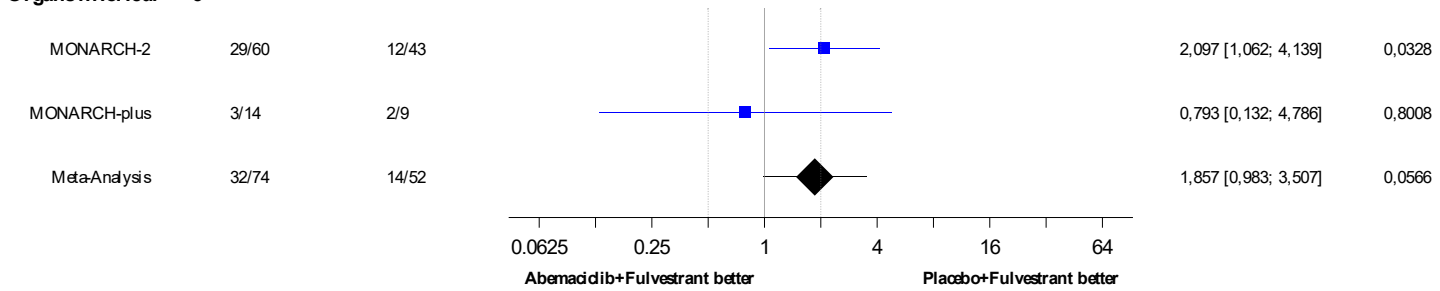
Figure 1133.1.2.3: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,9826, p-value=0,3216, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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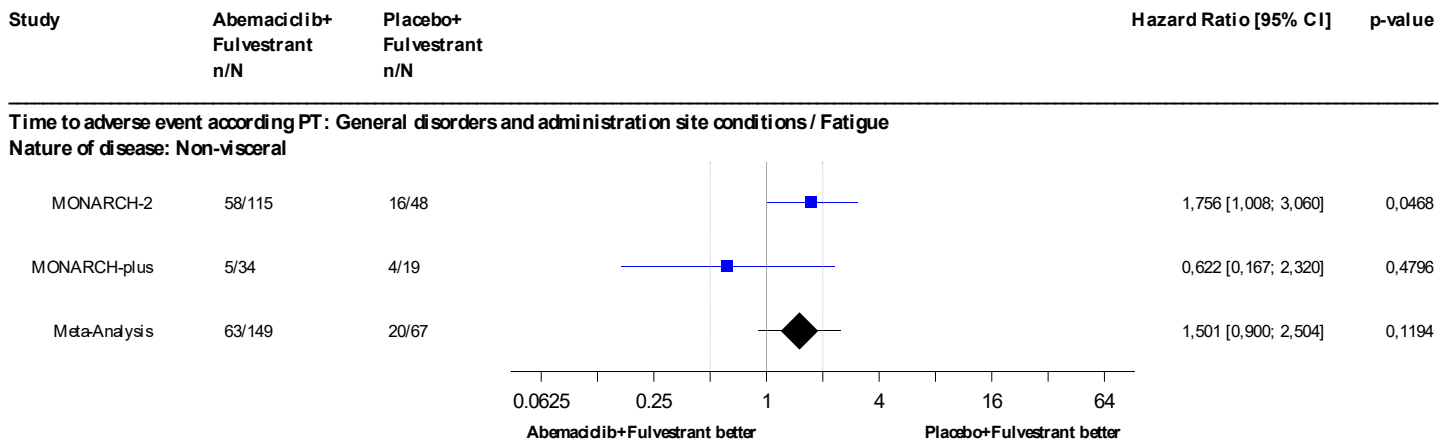
**Figure 1133.1.3.1: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=2,0275, p-value=0,1545, I2 index=50,7%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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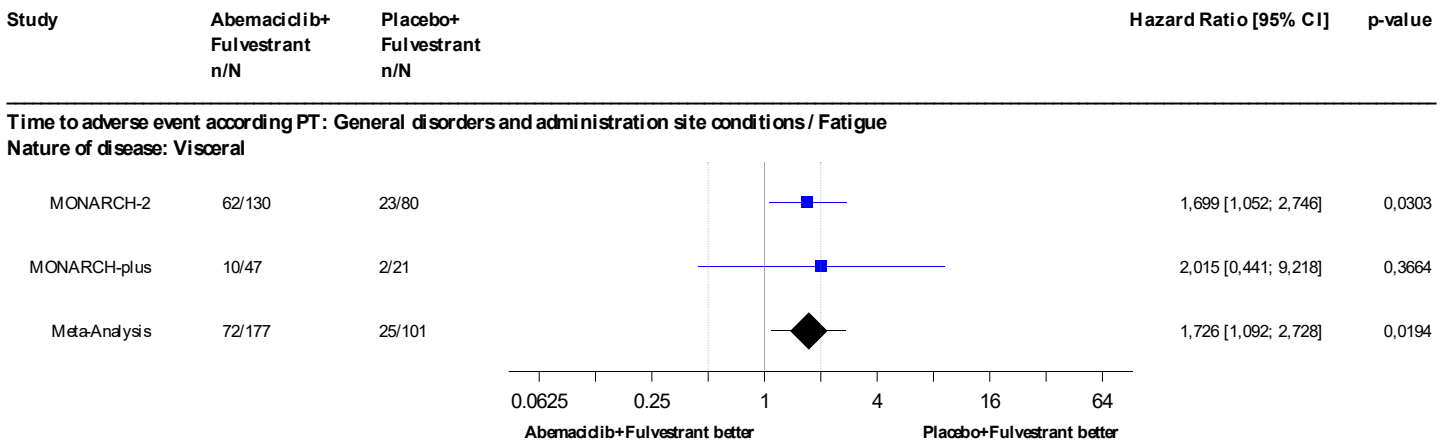
Figure 1133.1.3.2: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0439, p-value=0,8341, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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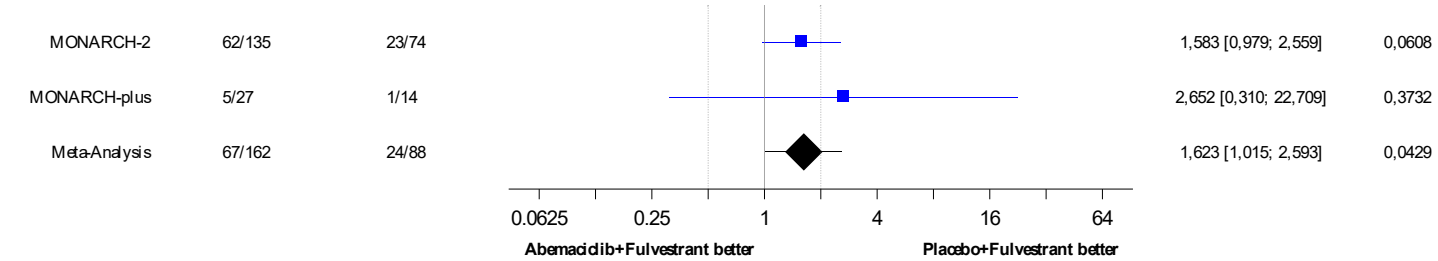
Figure 1133.1.4.1: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2113, p-value=0,6457, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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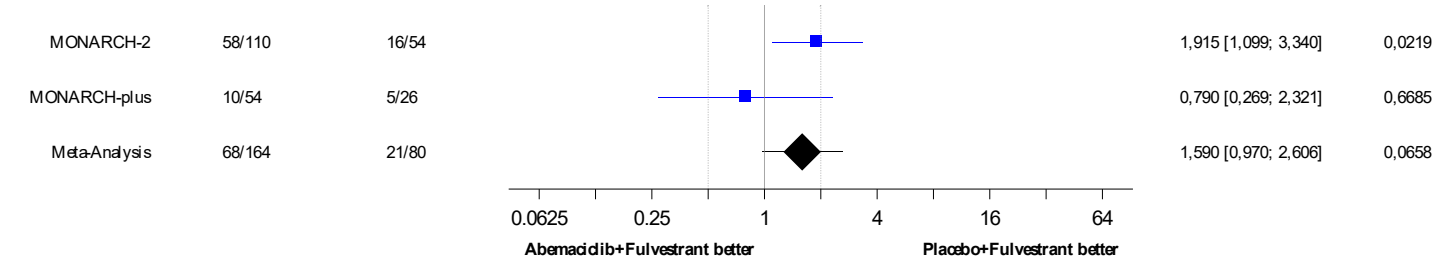
Figure 1133.1.4.2: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,0486, p-value=0,1523, I2 index=51,2%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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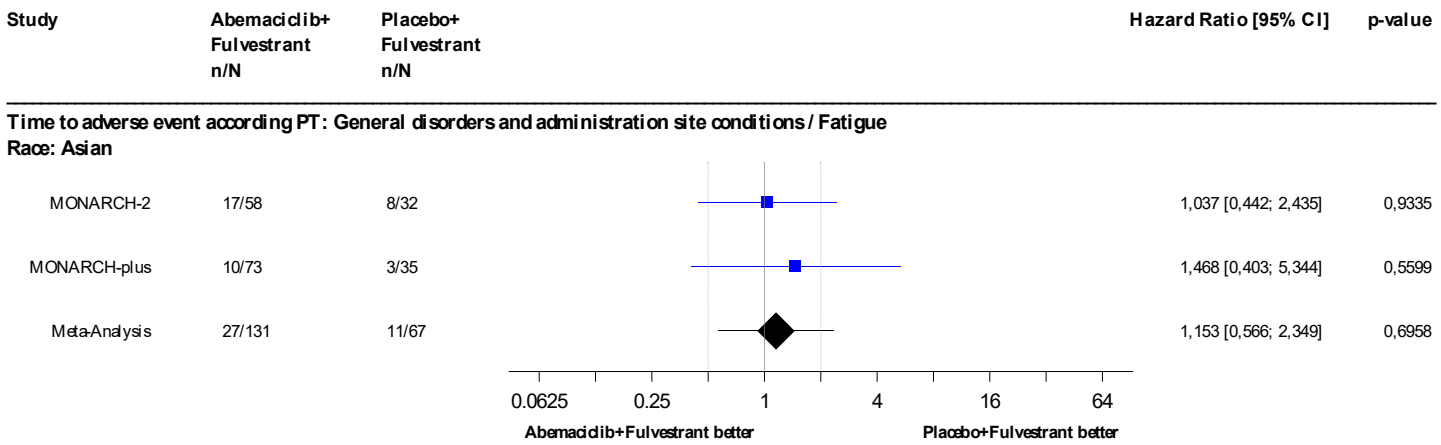
Figure 1133.1.5.1: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1939, p-value=0,6597, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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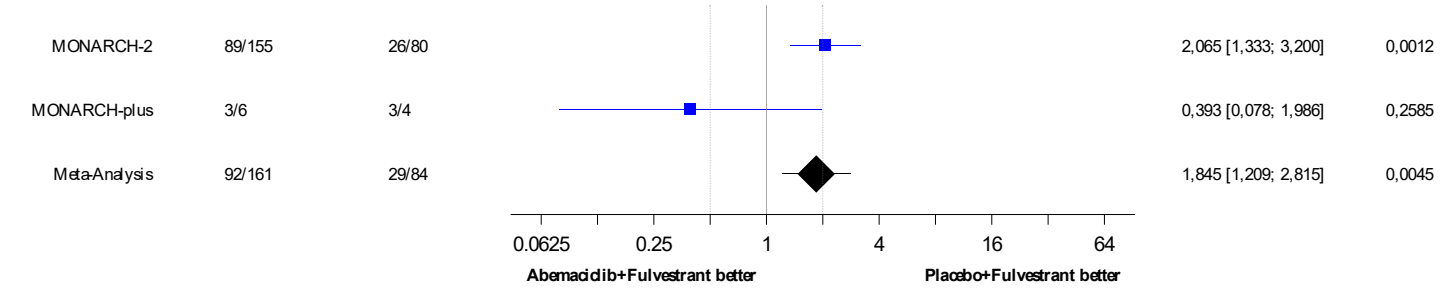
Figure 1133.1.5.2: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=3,7559, p-value=0,0526, I2 index=73,4%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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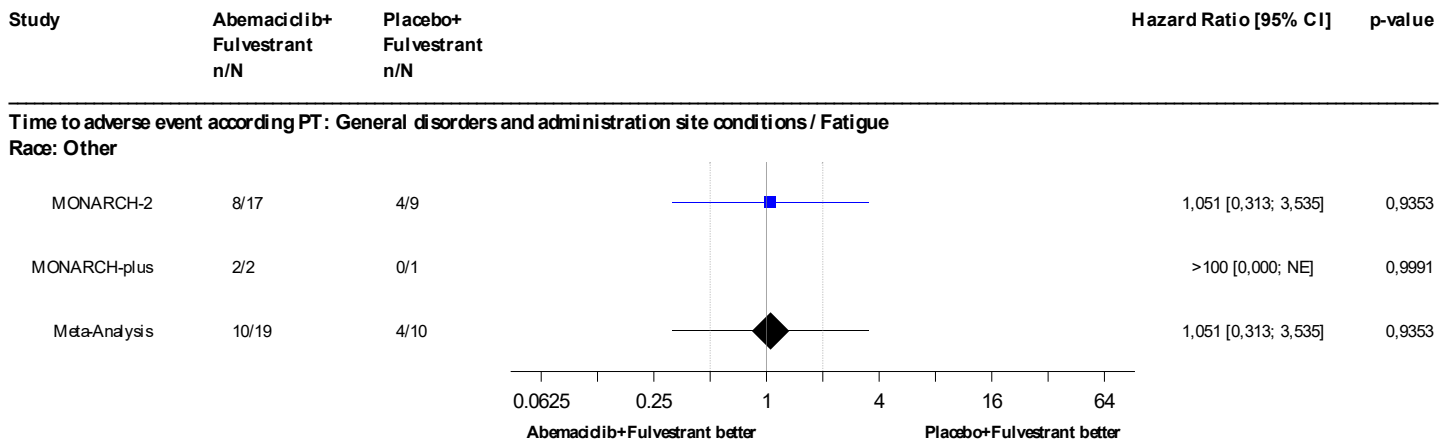
**Figure 1133.1.5.3: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9991, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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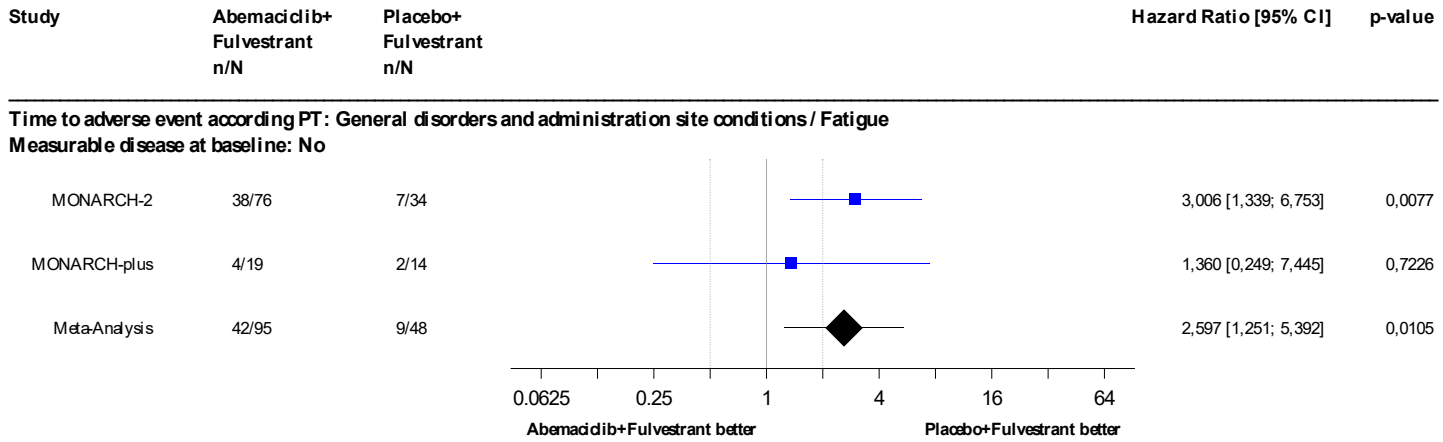
**Figure 1133.1.6.1: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,6816, p-value=0,4090, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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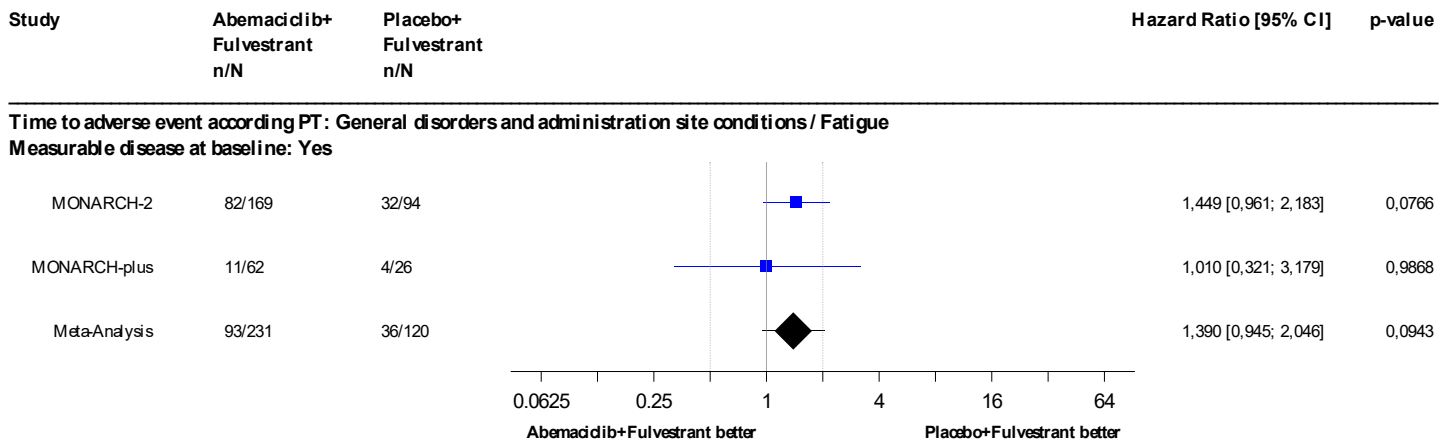
**Figure 1133.1.6.2: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,3372, p-value=0,5614, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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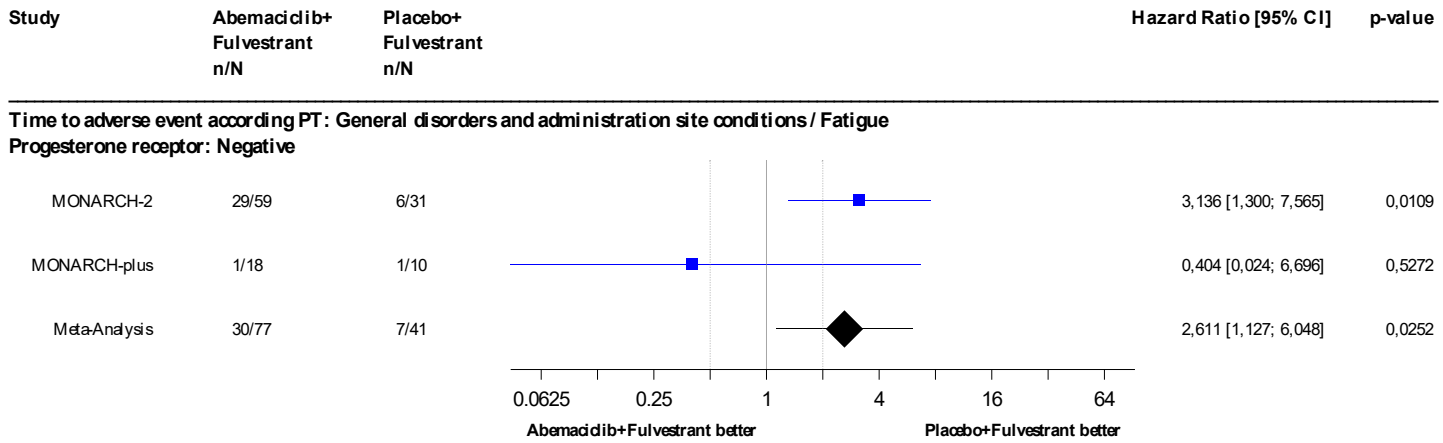
**Figure 1133.1.7.1: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=1,8629, p-value=0,1723, I2 index=46,3%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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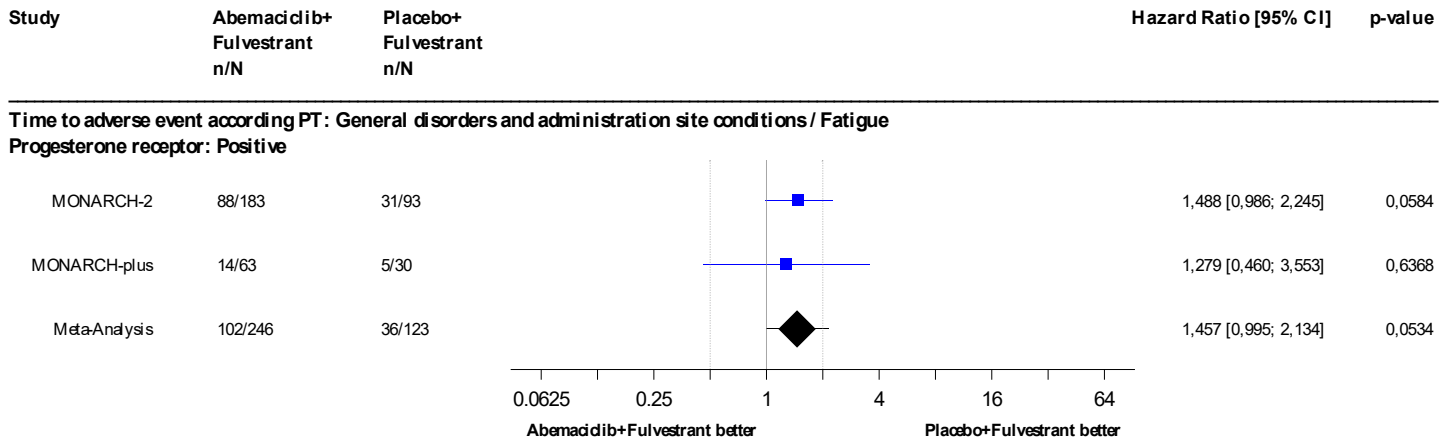
**Figure 1133.1.7.2: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0724, p-value=0,7878, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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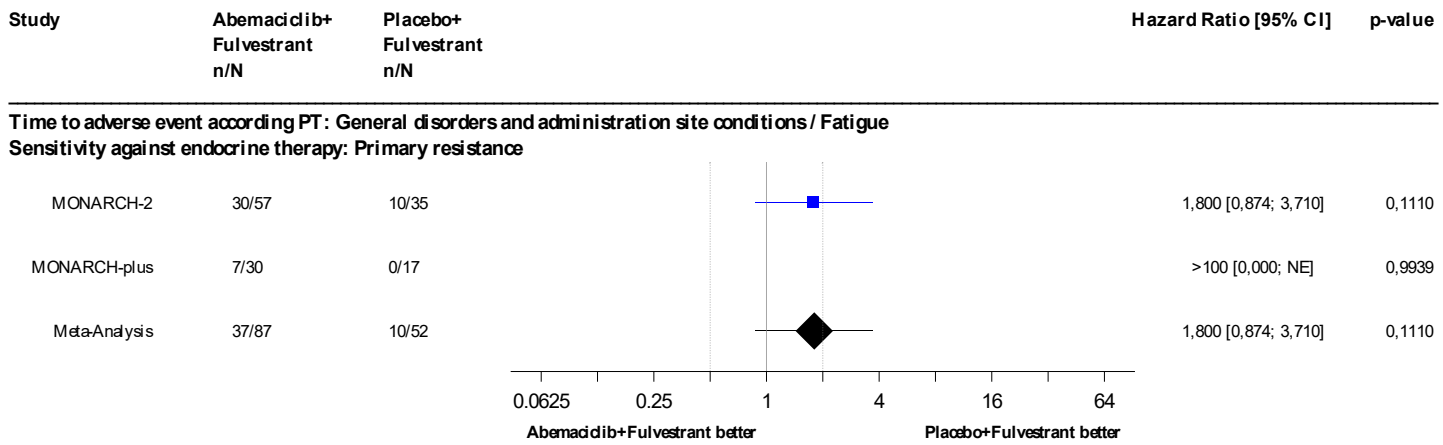
**Figure 1133.1.8.1: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9941, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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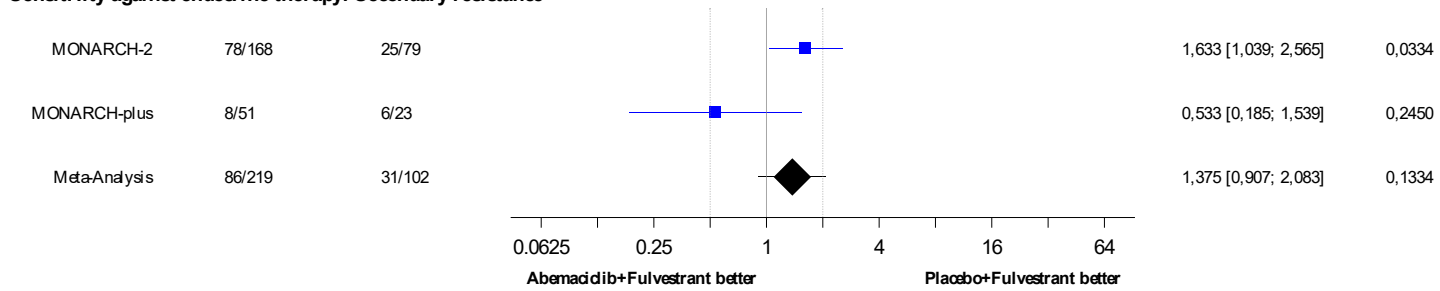
**Figure 1133.1.8.2: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=3,6243, p-value=0,0569, I2 index=72,4%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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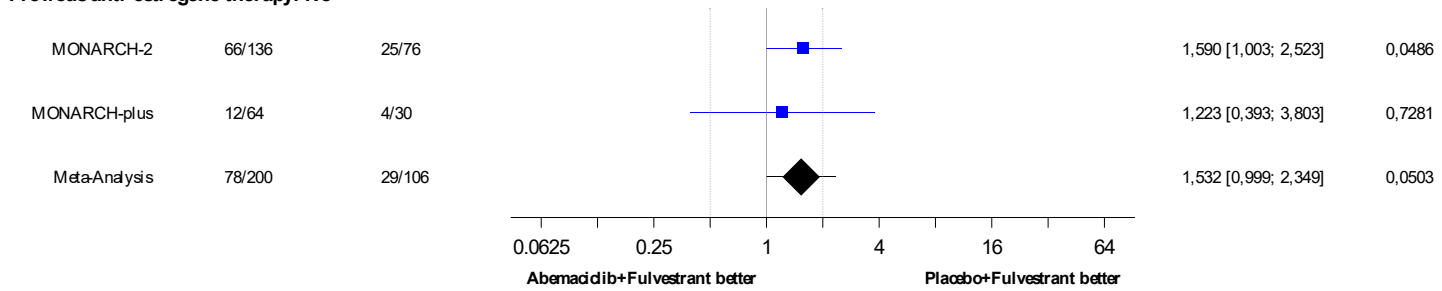
**Figure 1133.1.9.1: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,1768, p-value=0,6741, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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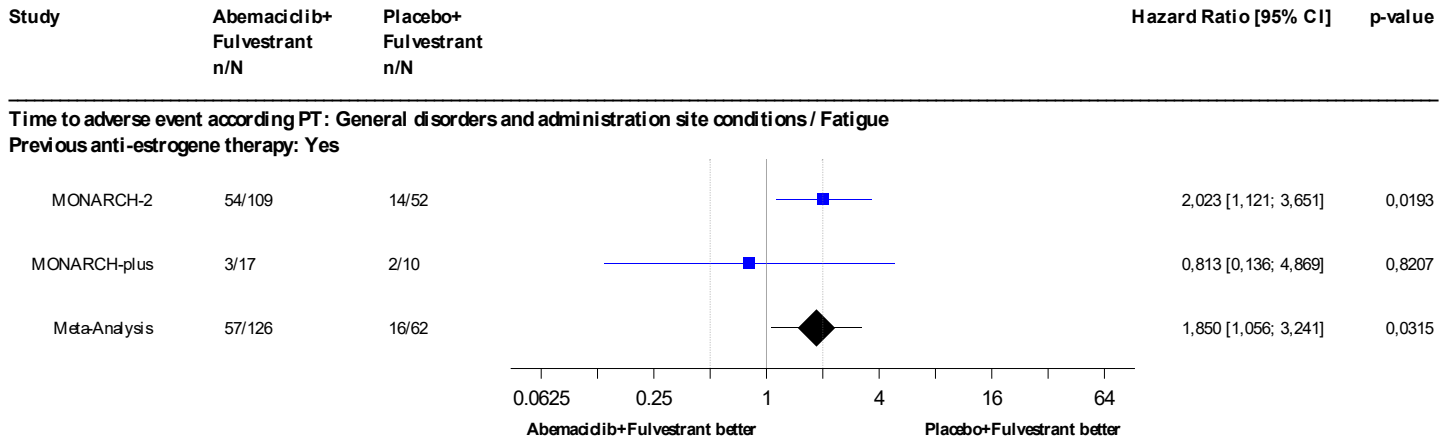
**Figure 1133.1.9.2: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,8989, p-value=0,3431, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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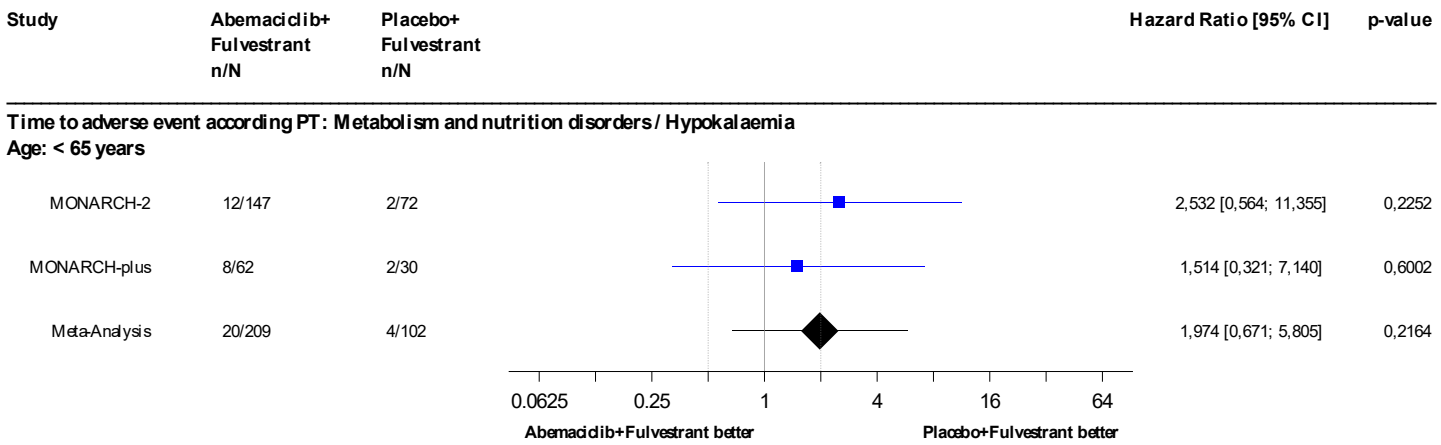
Figure 1149.1.1.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2179, p-value=0,6406, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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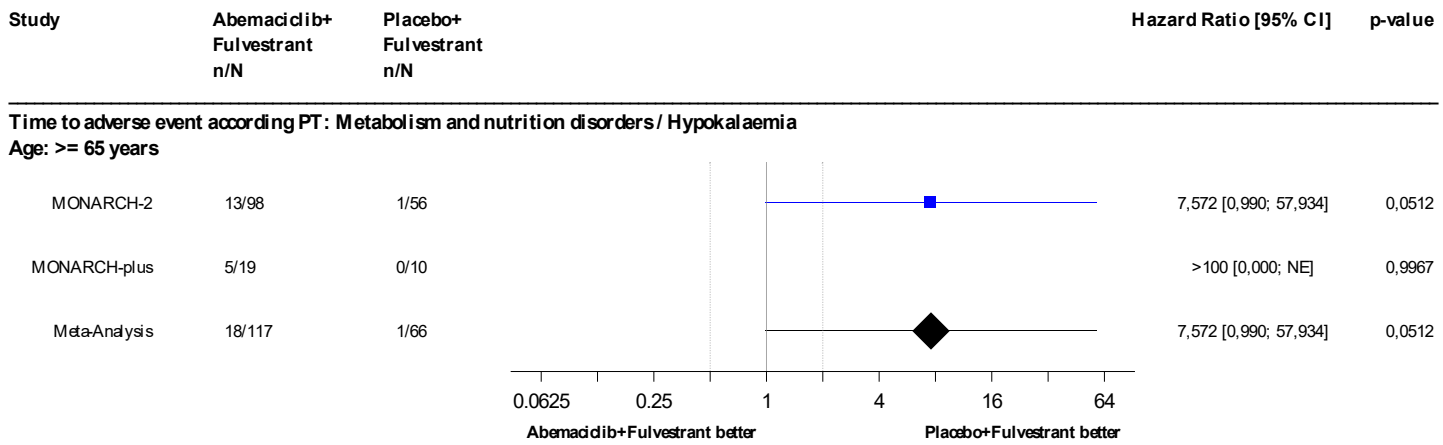
Figure 1149.1.1.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9971, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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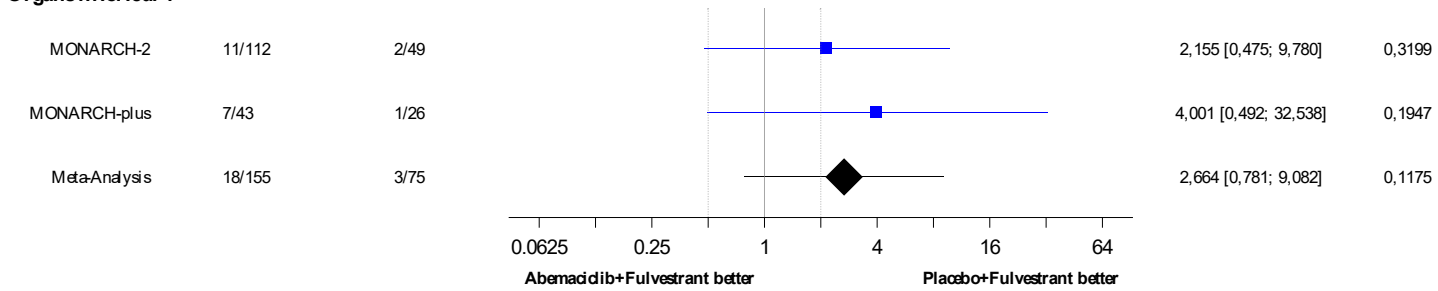
Figure 1149.1.2.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2203, p-value=0,6388, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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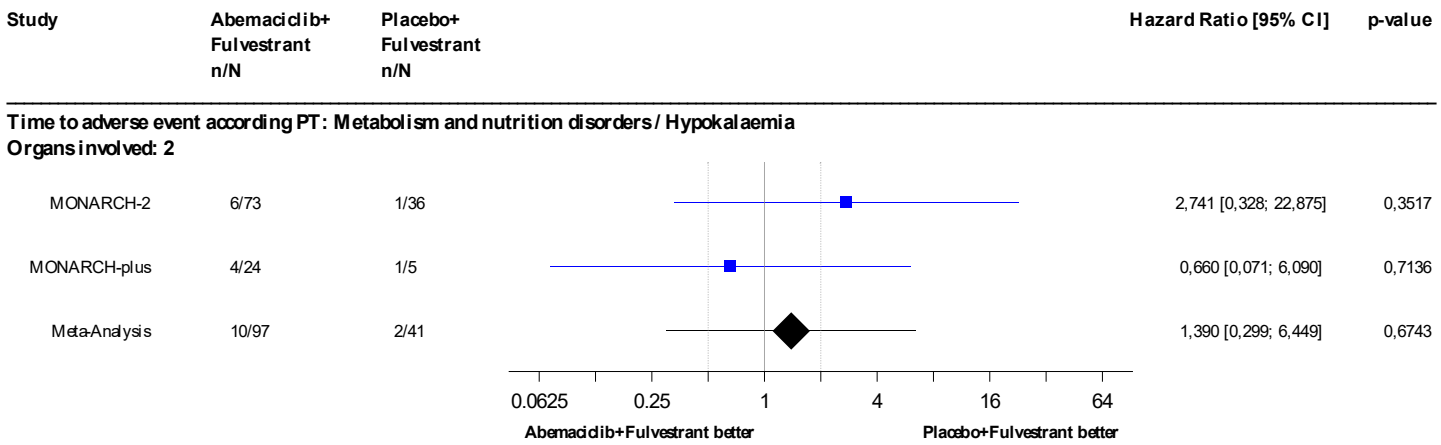
Figure 1149.1.2.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,8255, p-value=0,3636, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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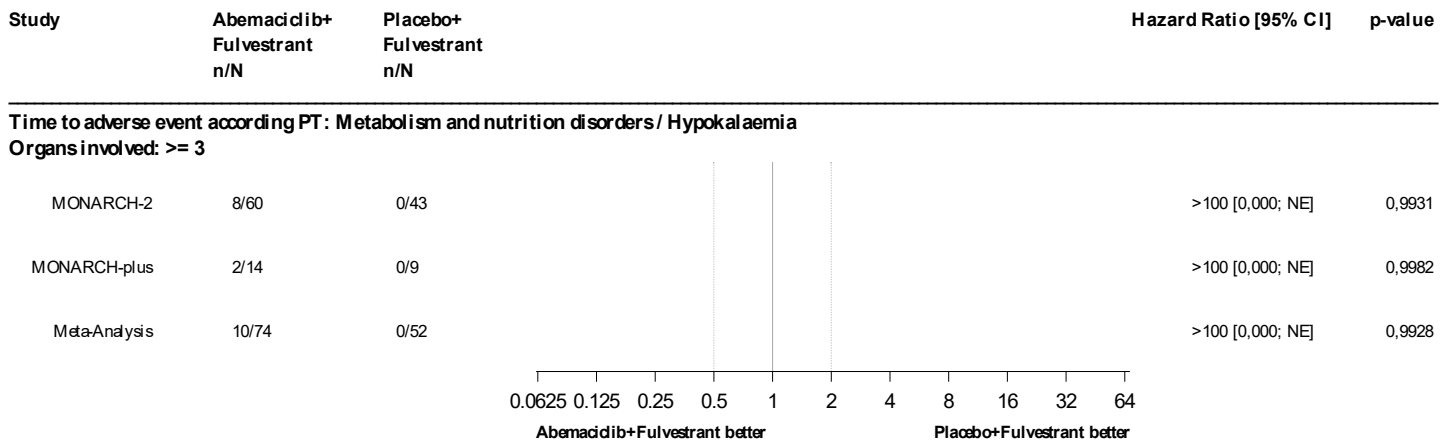
Figure 1149.1.2.3: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9999, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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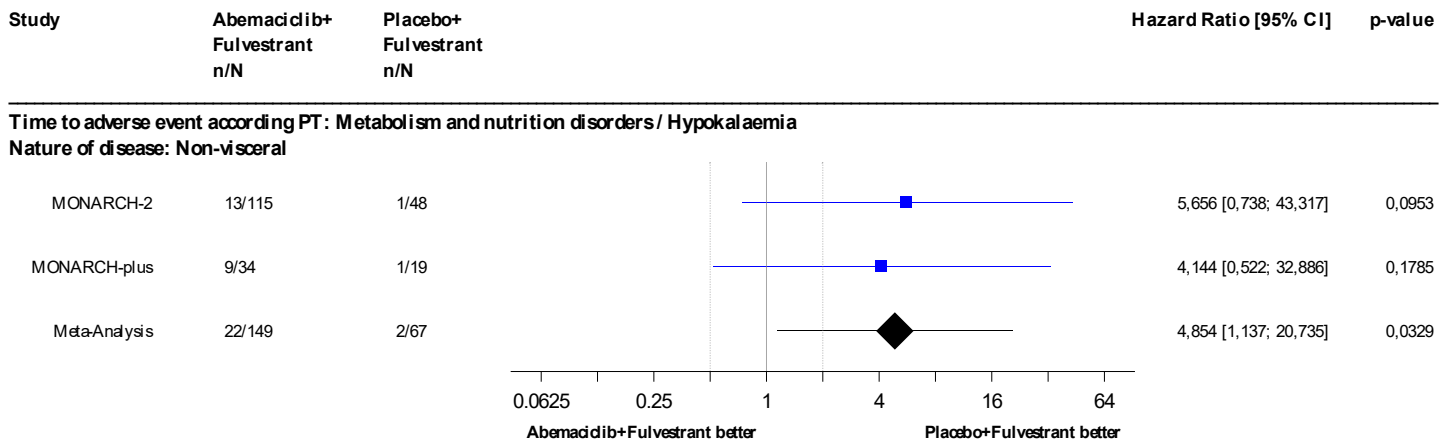
Figure 1149.1.3.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0440, p-value=0,8338, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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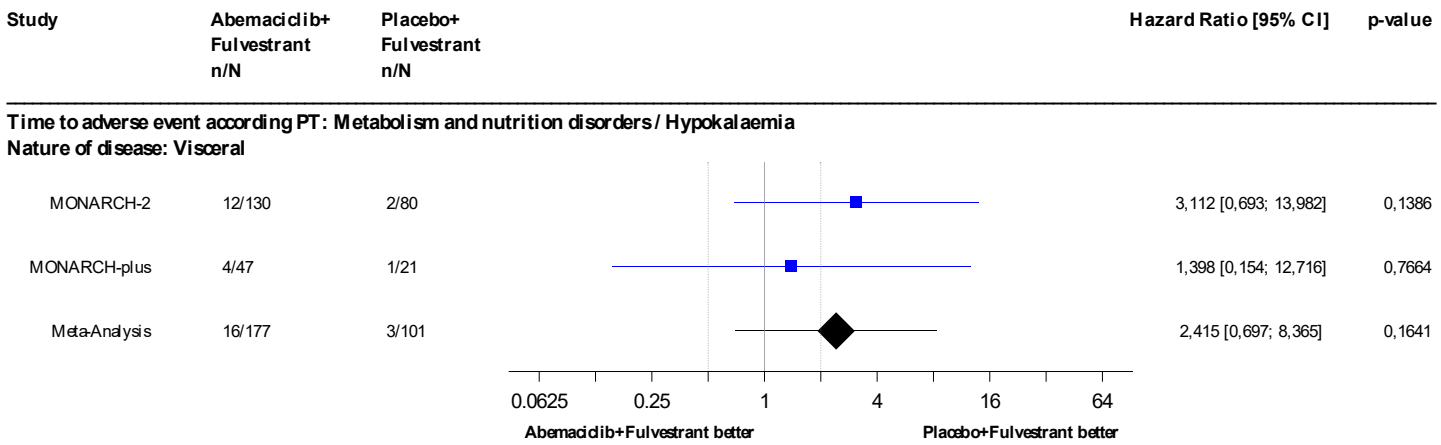
Figure 1149.1.3.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3451, p-value=0,5569, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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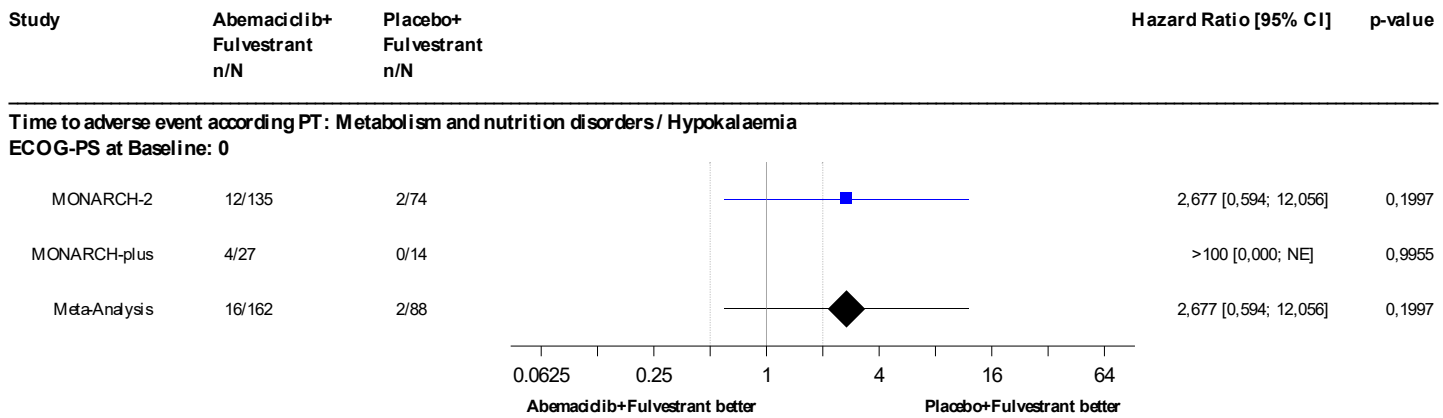
Figure 1149.1.4.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9958, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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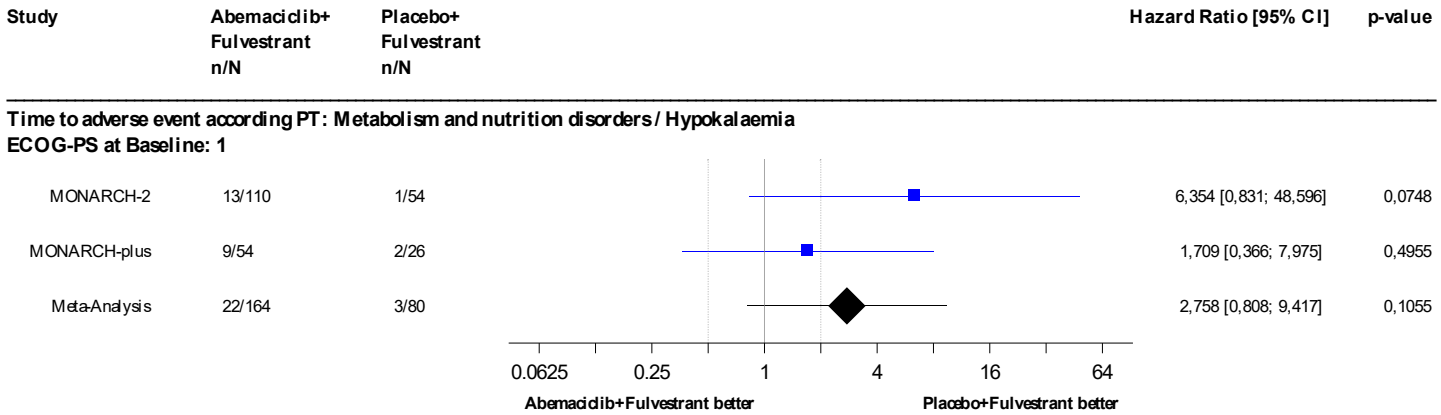
Figure 1149.1.4.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,0177, p-value=0,3131, I2 index=1,7%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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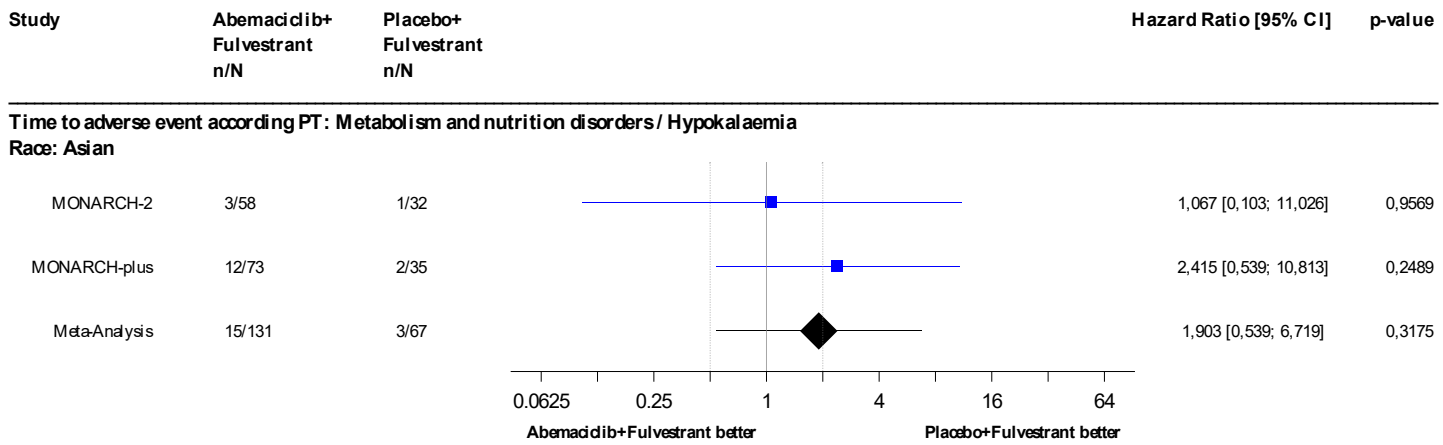
Figure 1149.1.5.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3332, p-value=0,5638, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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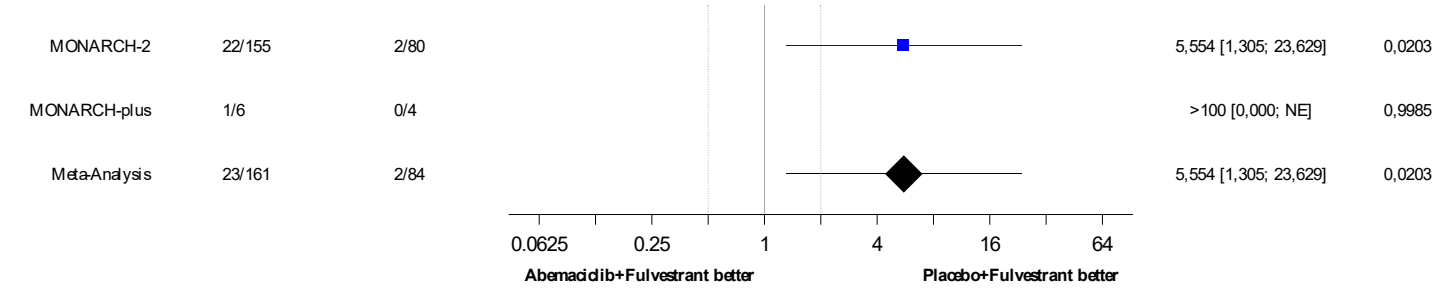
Figure 1149.1.5.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep049_popa1_racegr1_2.rtf
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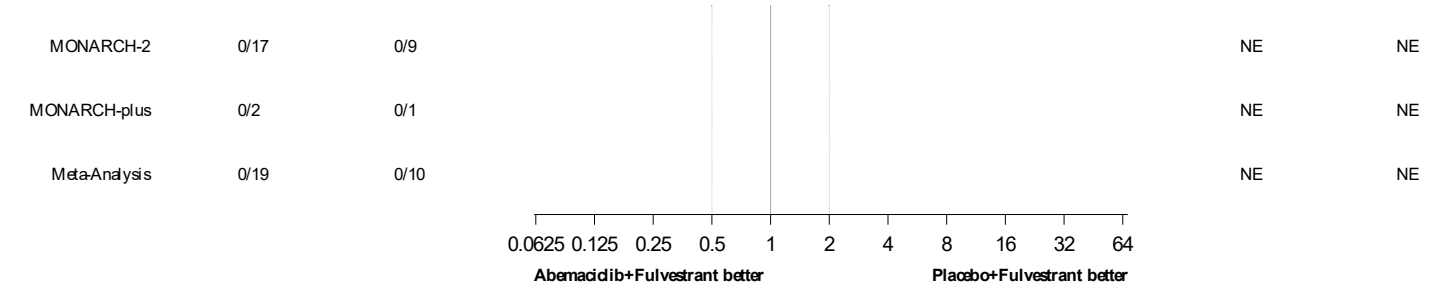
Figure 1149.1.5.3: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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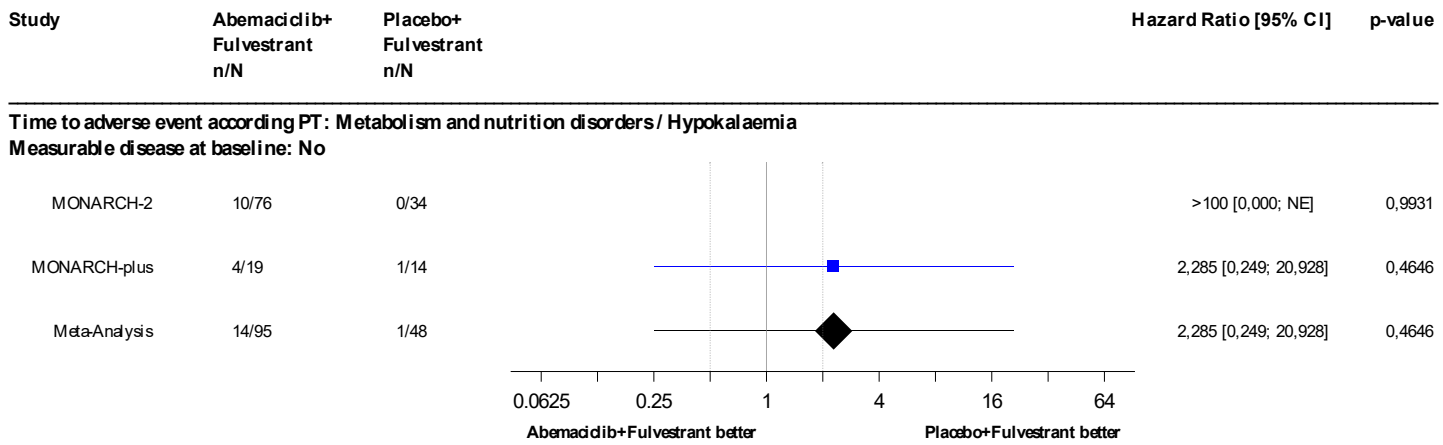
Figure 1149.1.6.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9934, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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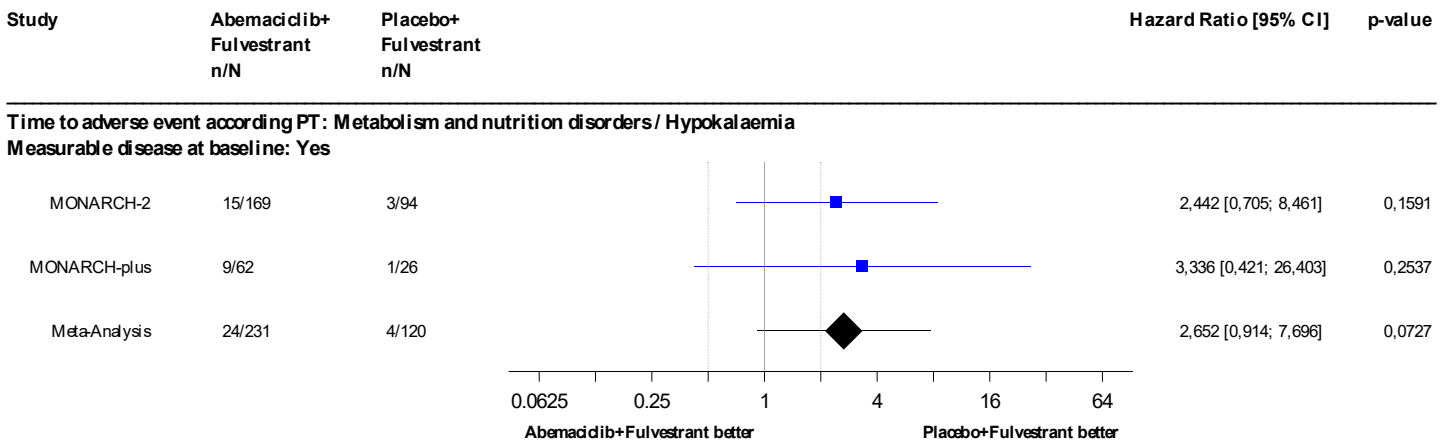
Figure 1149.1.6.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0642, p-value=0,8000, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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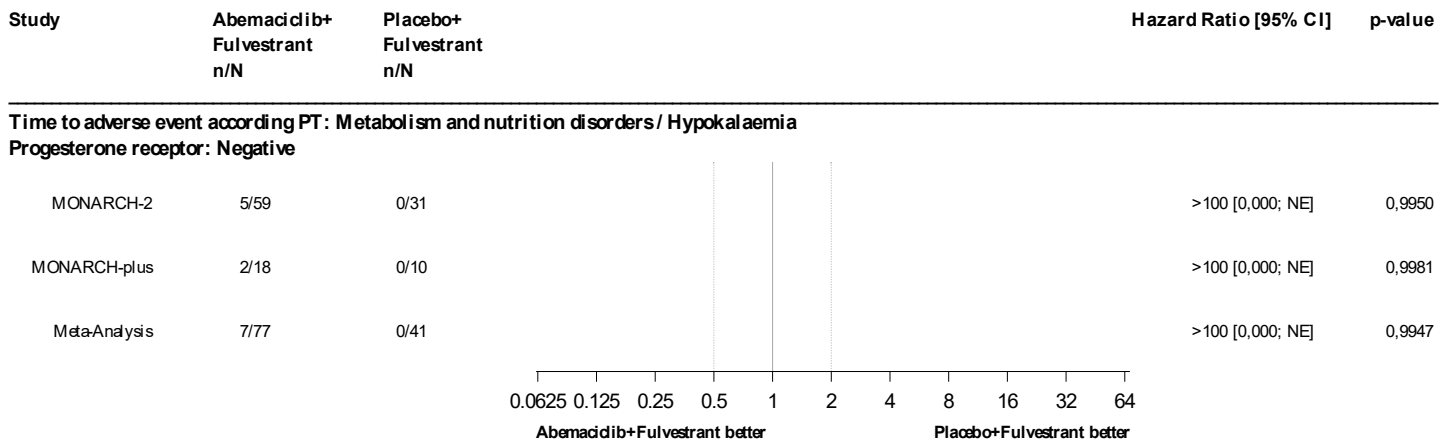
Figure 1149.1.7.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9999, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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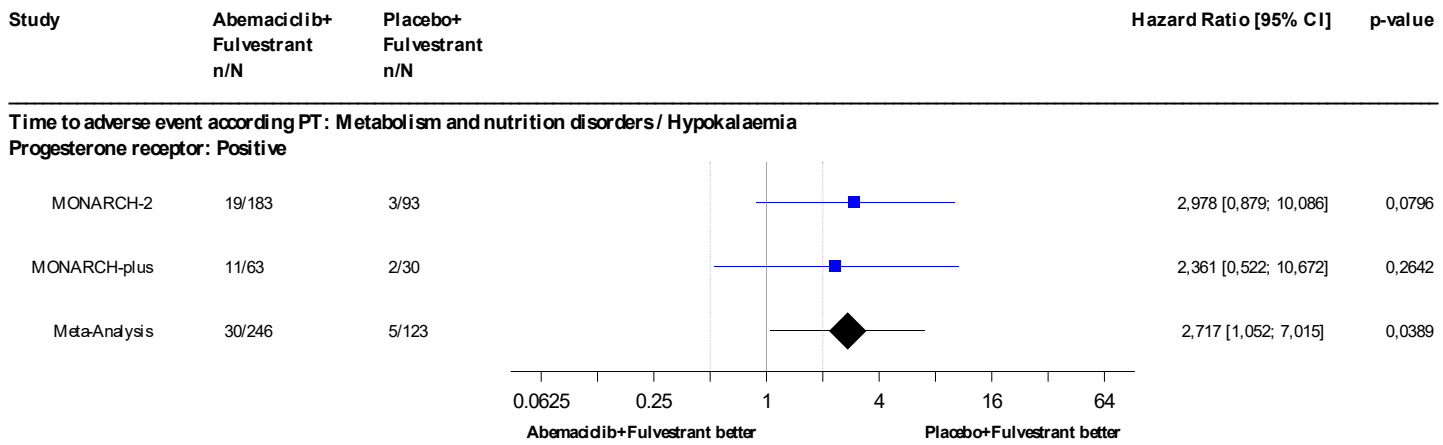
Figure 1149.1.7.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0549, p-value=0,8147, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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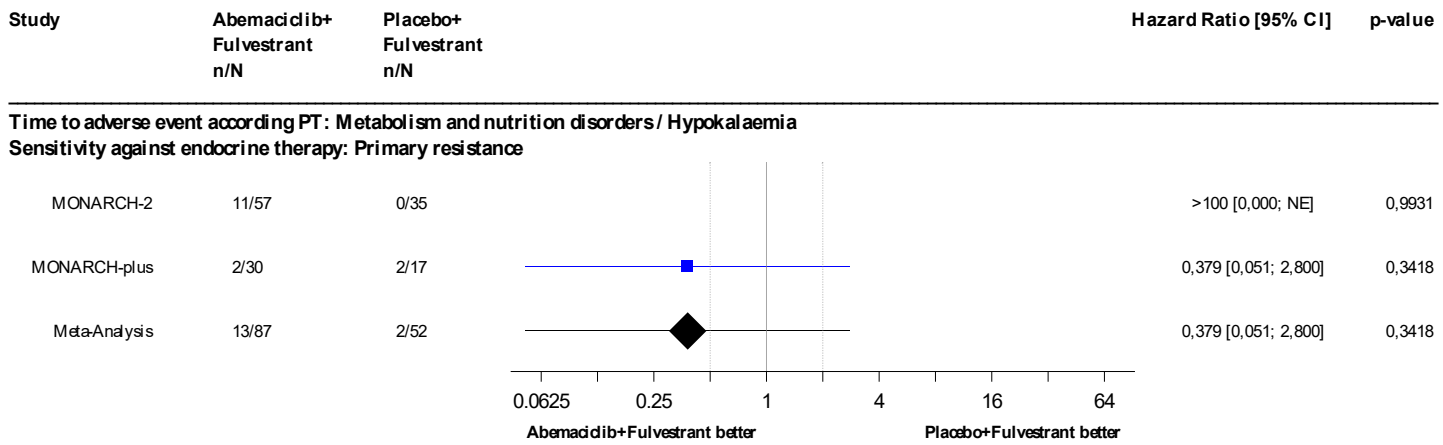
Figure 1149.1.8.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9927, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep049_popa1_snthr_1.rtf
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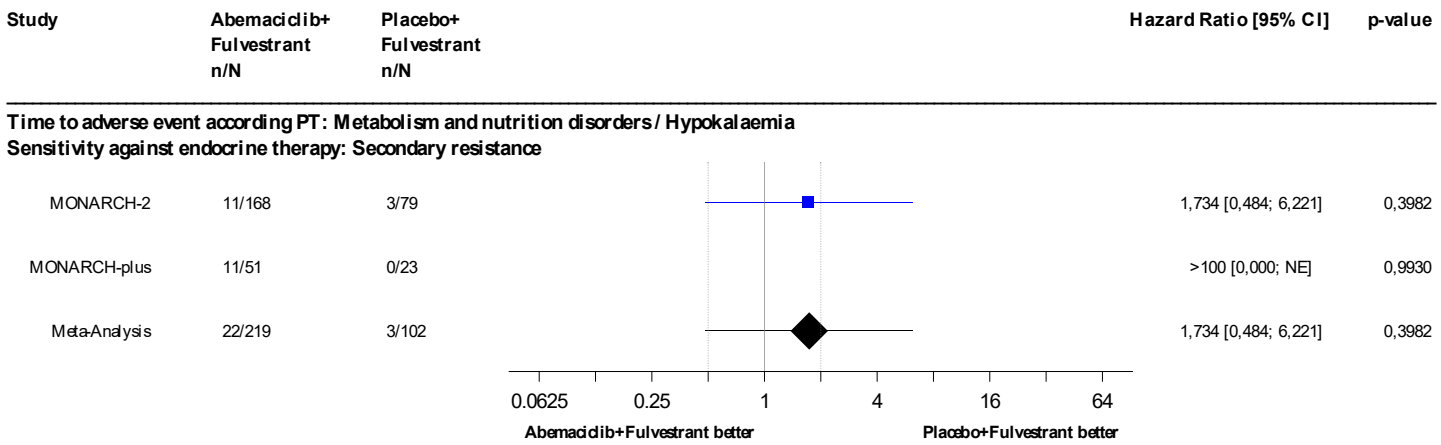
Figure 1149.1.8.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9932, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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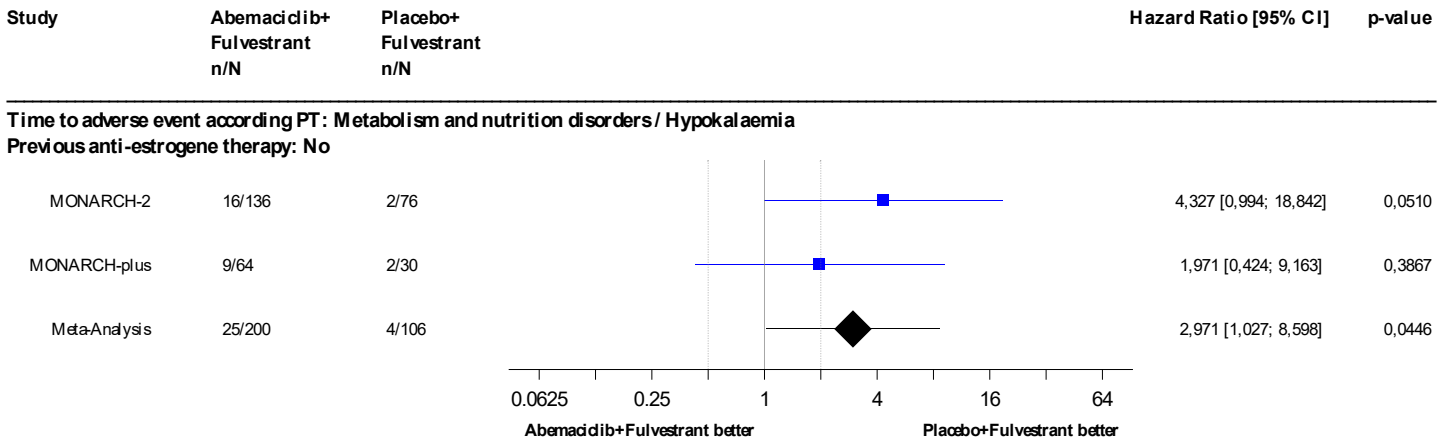
Figure 1149.1.9.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5249, p-value=0,4688, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep049_popa1_paet_1.rtf
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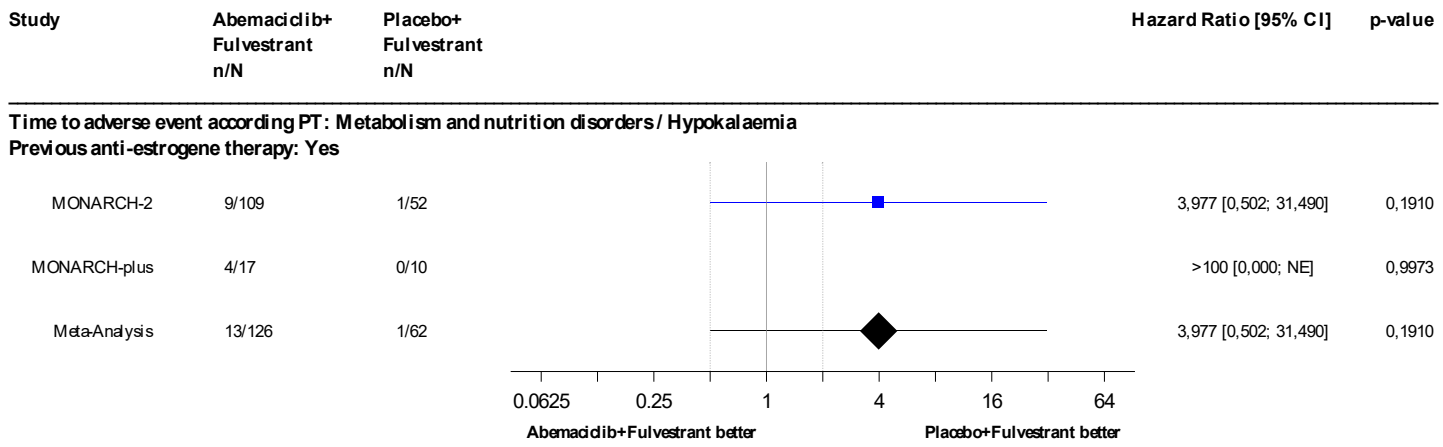
Figure 1149.1.9.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Hypokalaemia
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9975, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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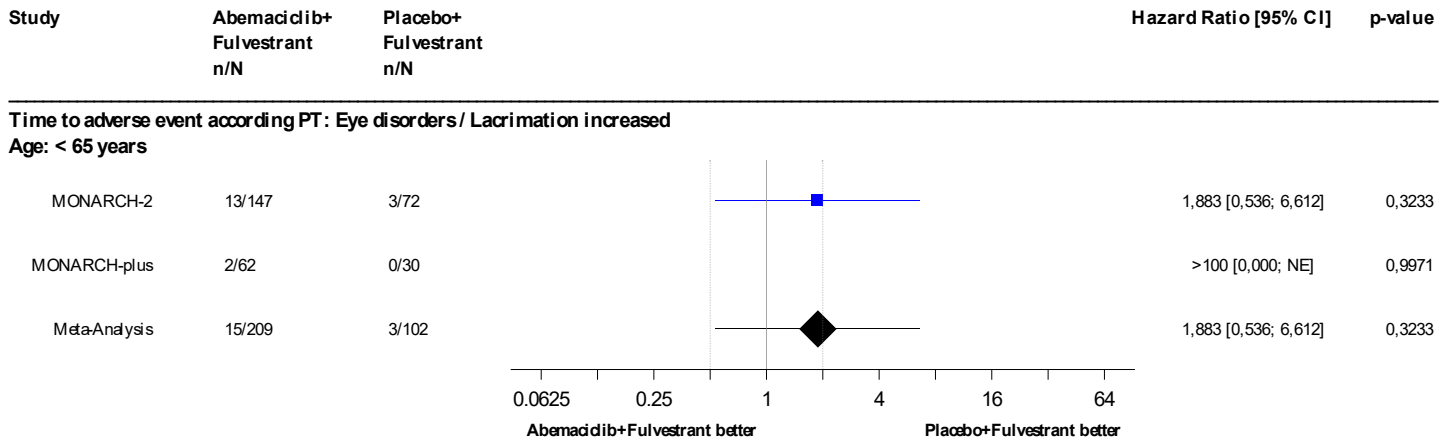
Figure 1154.1.1.1: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9972, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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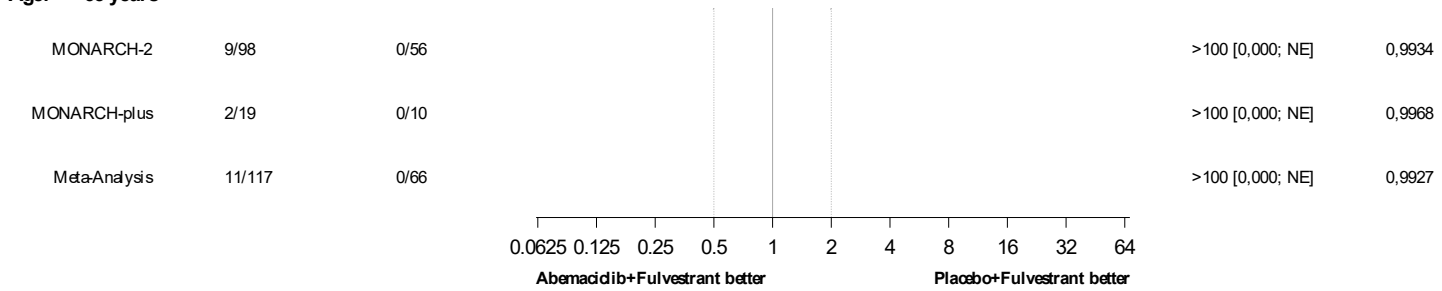
Figure 1154.1.1.2: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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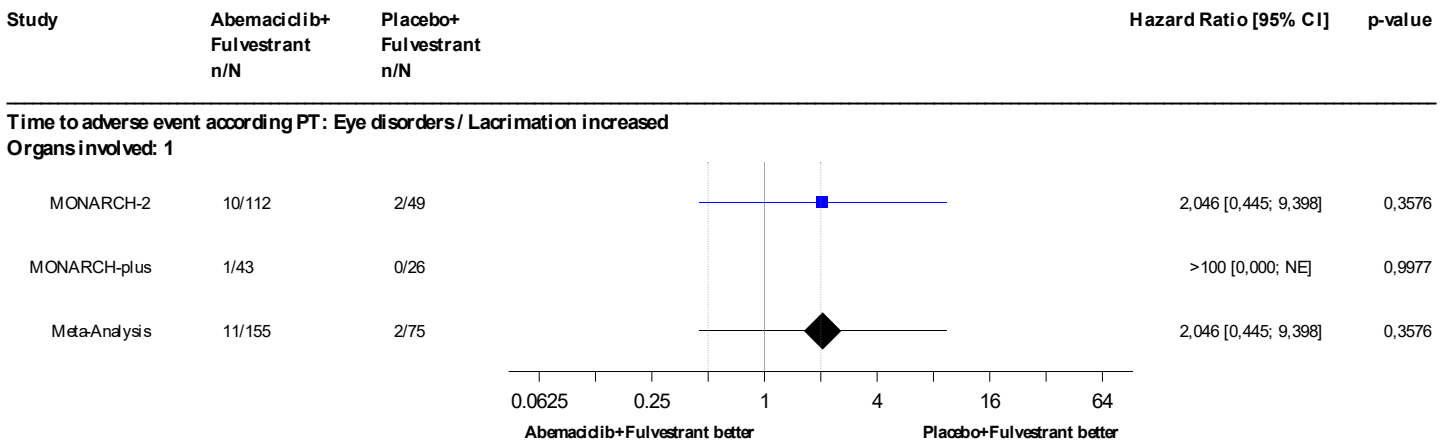
Figure 1154.1.2.1: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9978, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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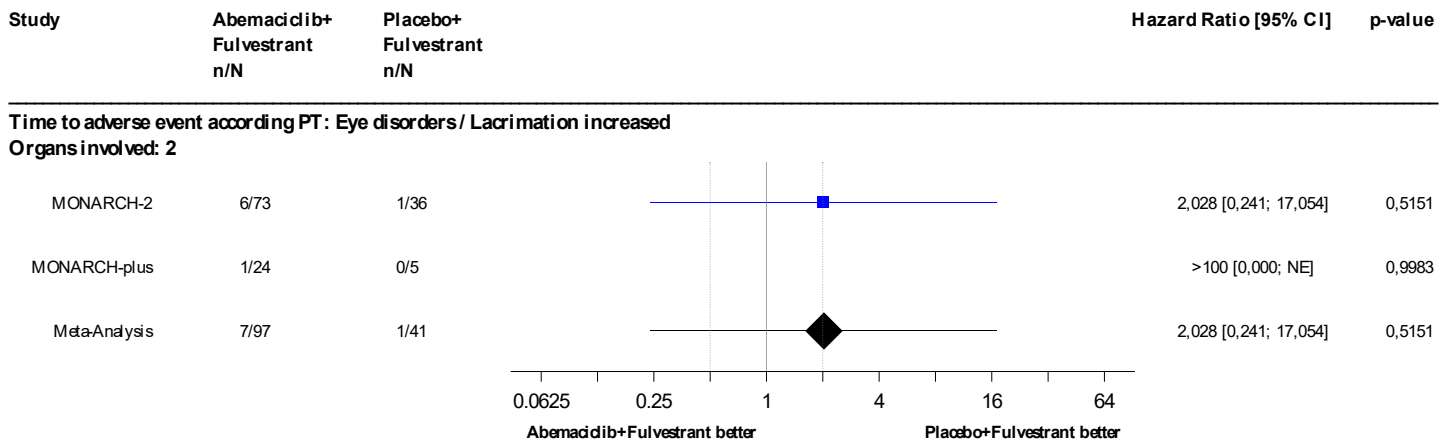
Figure 1154.1.2.2: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9984, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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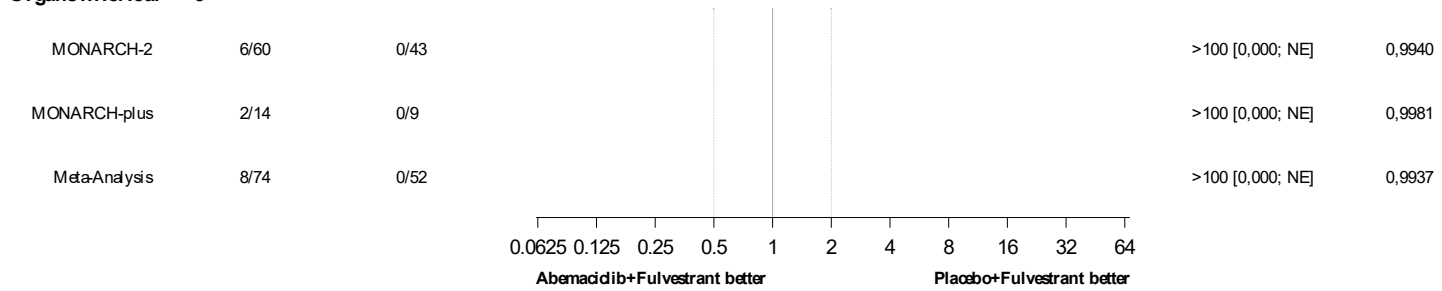
Figure 1154.1.2.3: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9999, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep054_popa1_norggr_3.rtf
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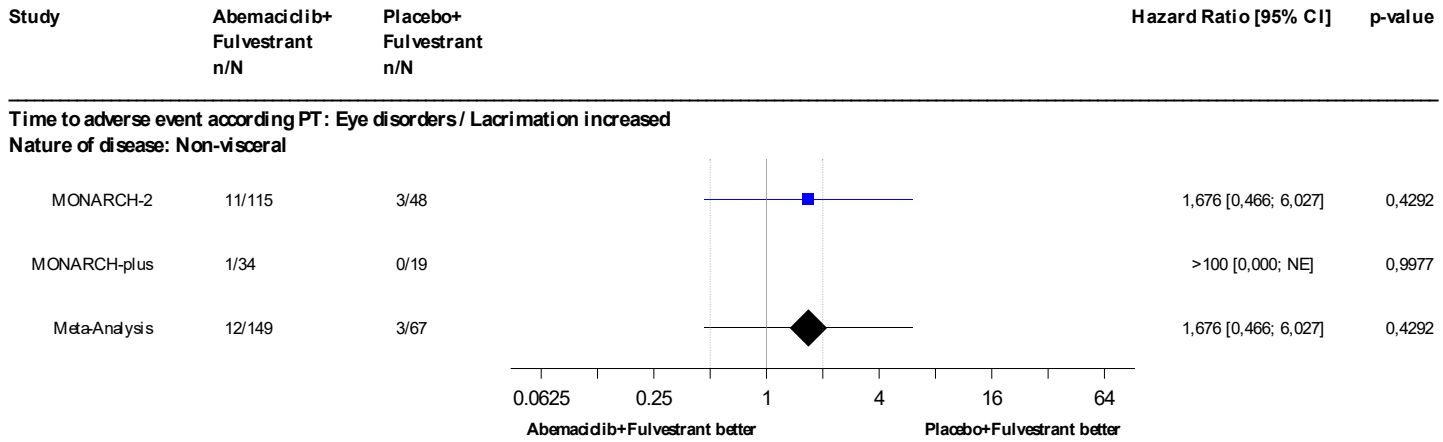
Figure 1154.1.3.1: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9978, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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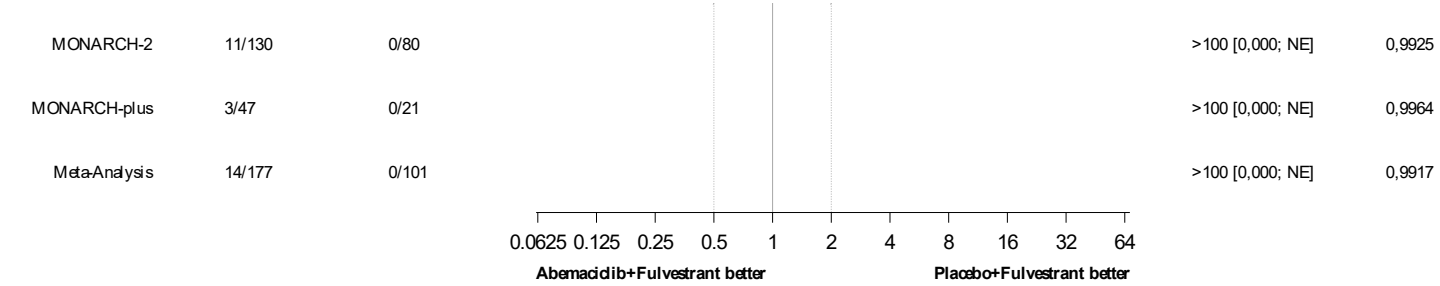
Figure 1154.1.3.2: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep054_popa1_natdis2_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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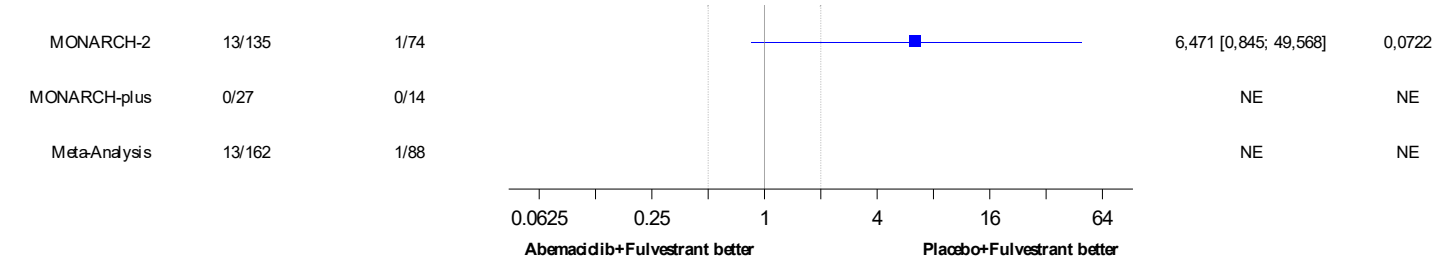
Figure 1154.1.4.1: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep054_popa1_ecogbl_1.rtf
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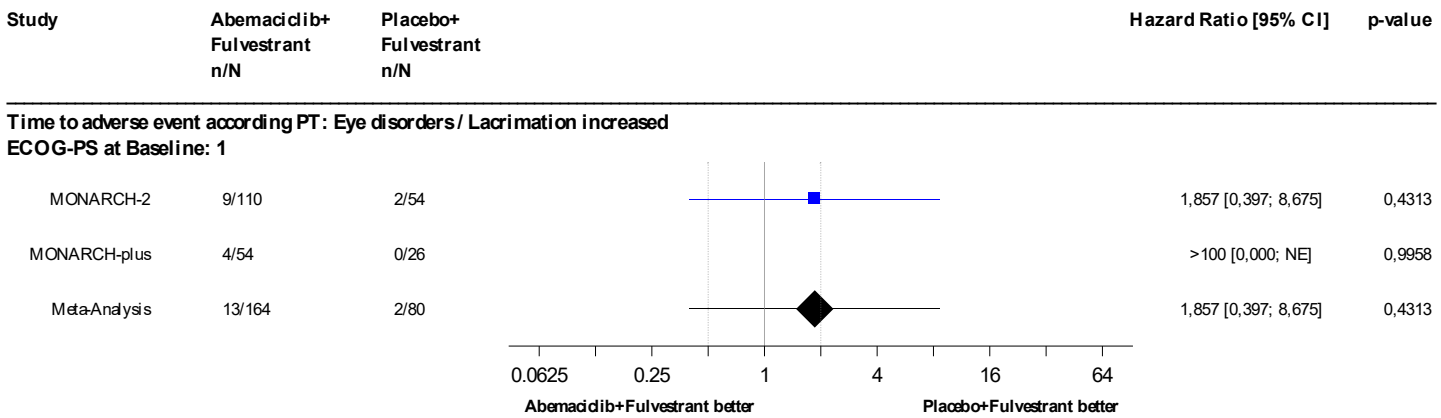
Figure 1154.1.4.2: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9959, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep054_popa1_ecogbl_2.rtf
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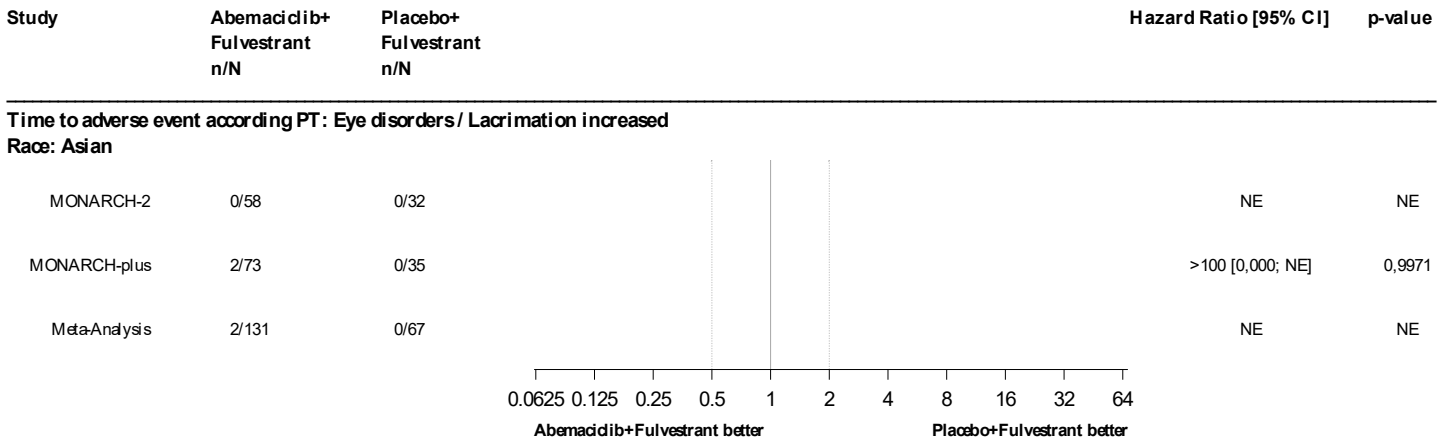
Figure 1154.1.5.1: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep054_popa1_racegr1_1.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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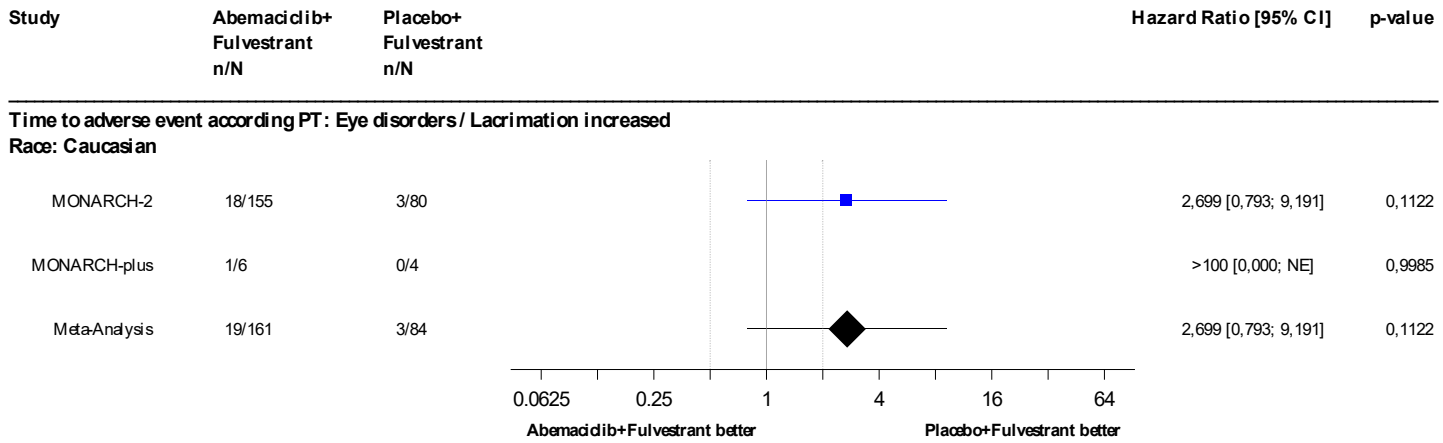
Figure 1154.1.5.2: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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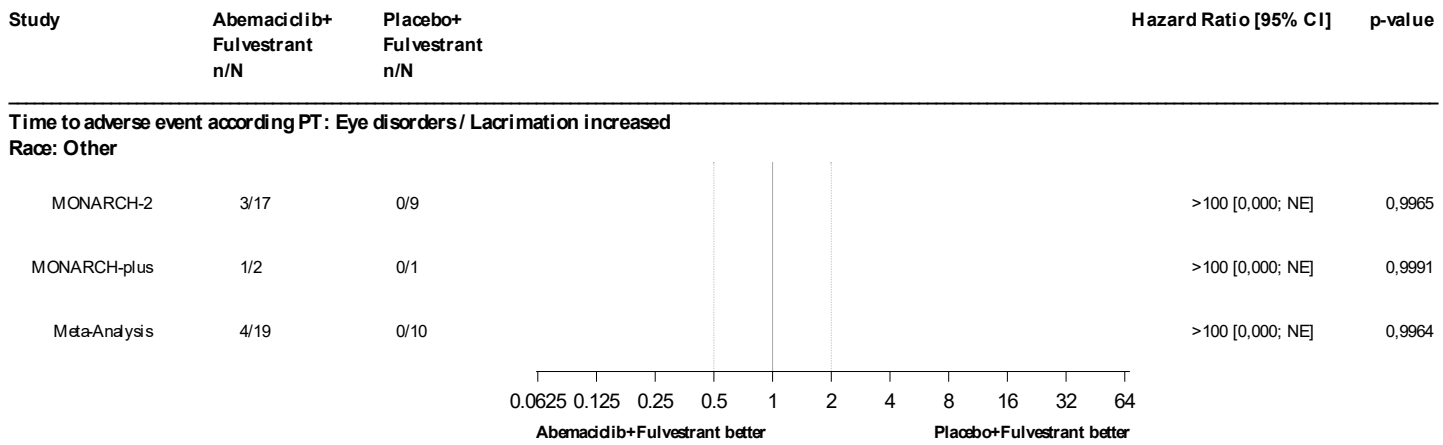
Figure 1154.1.5.3: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9999, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep054_popa1_racegr1_3.rtf
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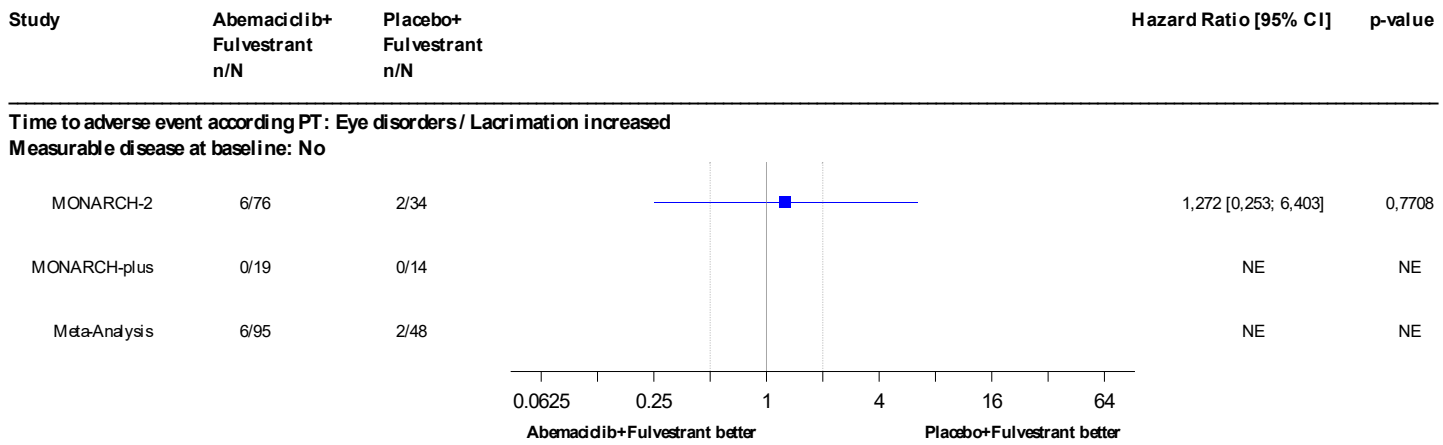
Figure 1154.1.6.1: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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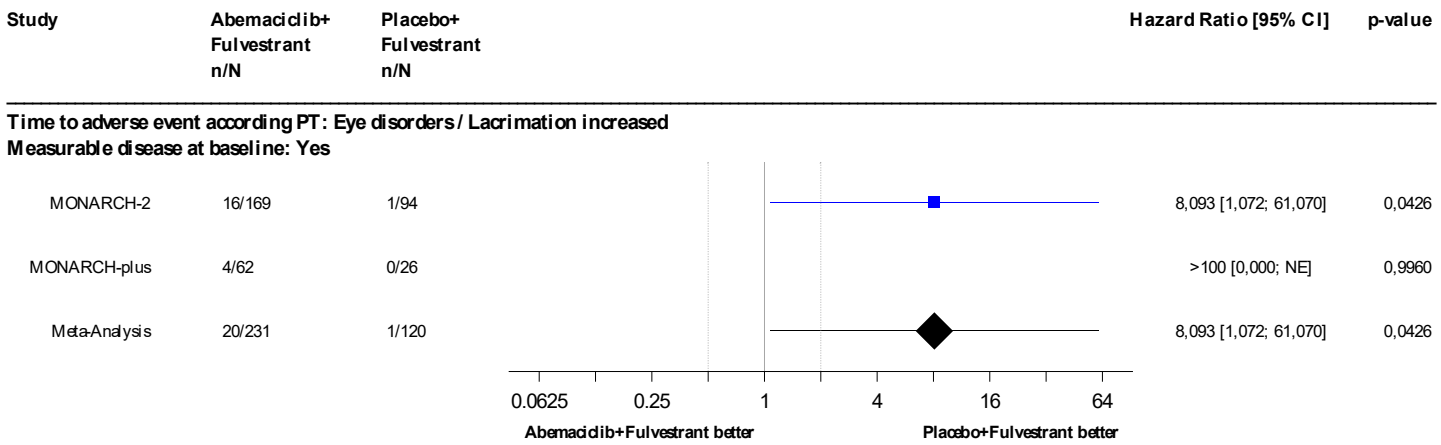
Figure 1154.1.6.2: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9965, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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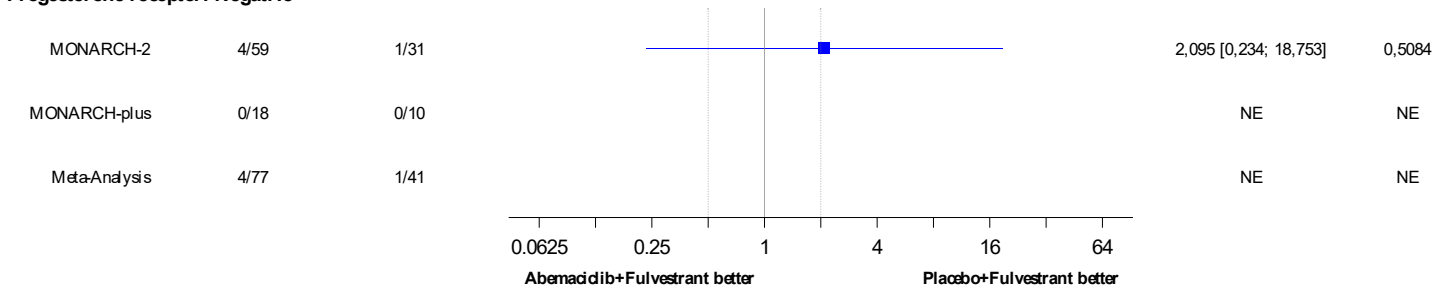
Figure 1154.1.7.1: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep054_popa1_pgrstat_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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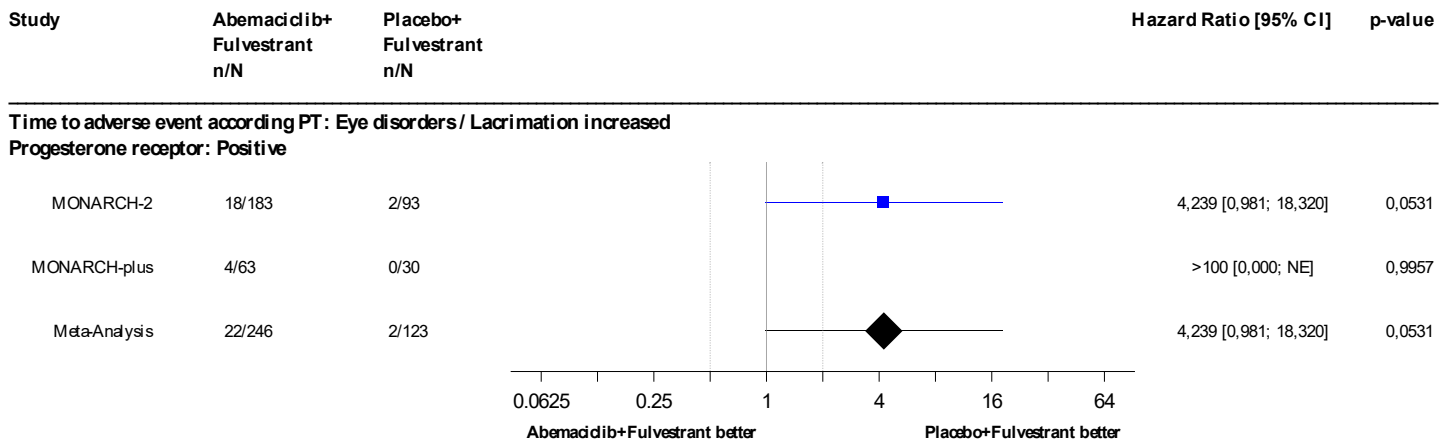
Figure 1154.1.7.2: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9960, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep054_popa1_pgrstat_2.rtf
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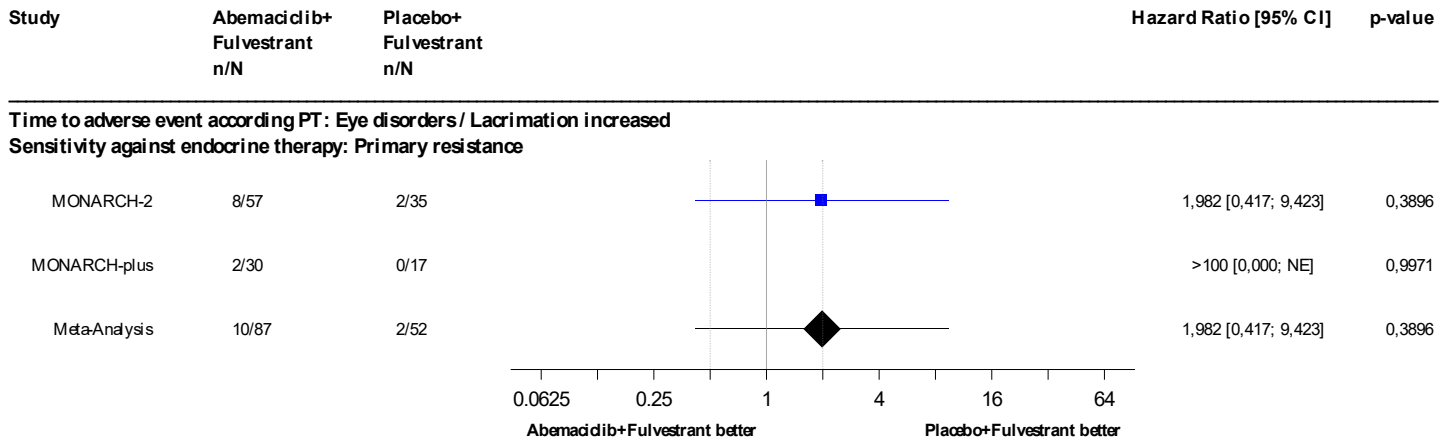
Figure 1154.1.8.1: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9972, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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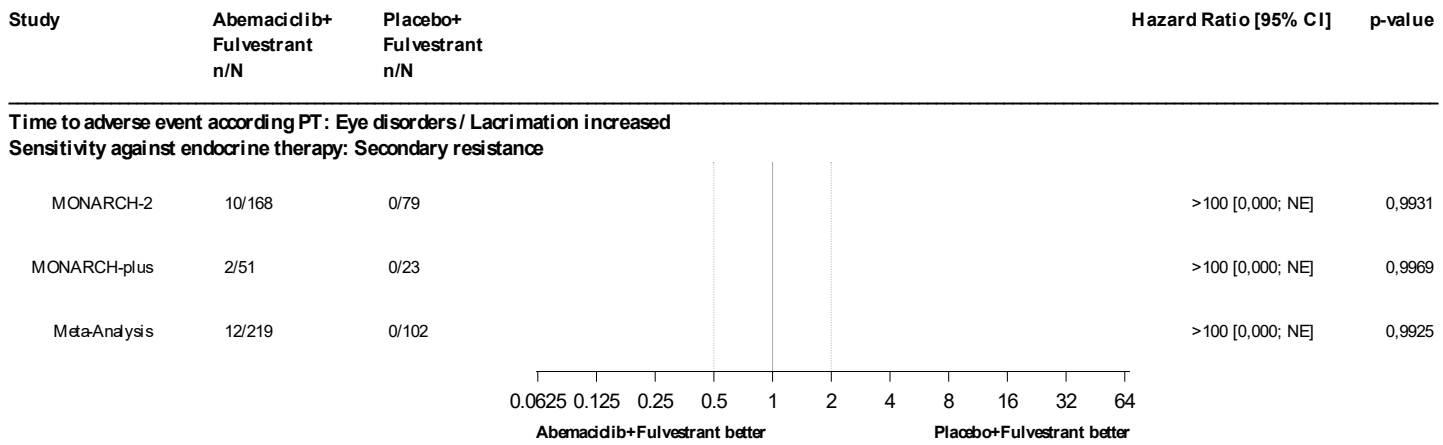
Figure 1154.1.8.2: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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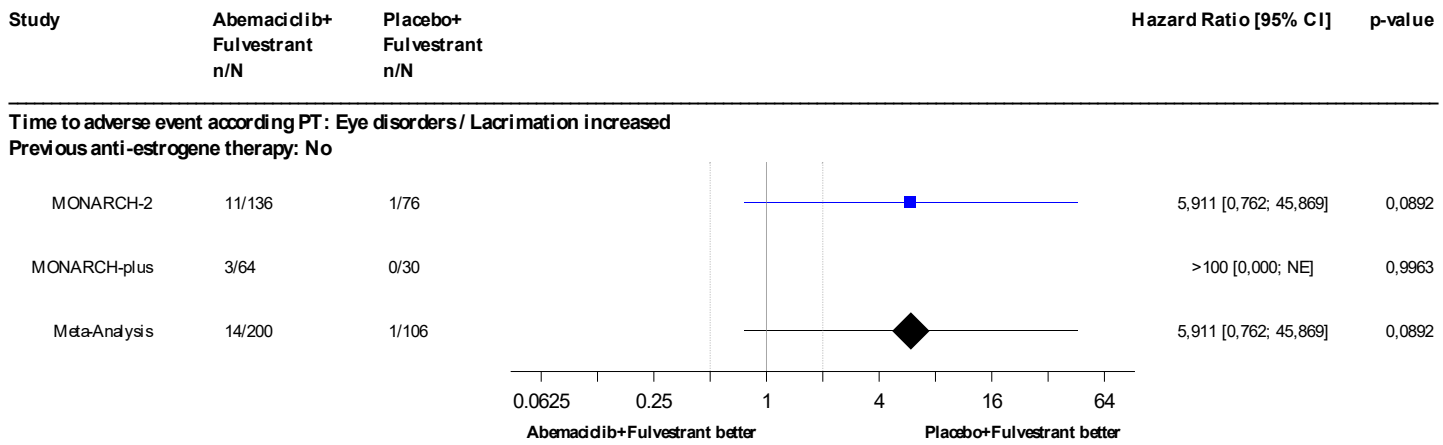
Figure 1154.1.9.1: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9967, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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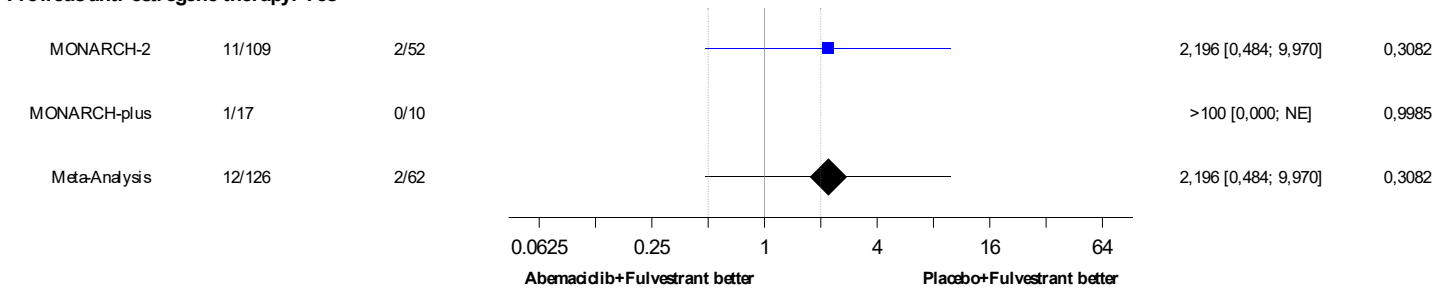
Figure 1154.1.9.2: Metaanalysis results for adverse events according PT[1] -
Eye disorders / Lacrimation increased
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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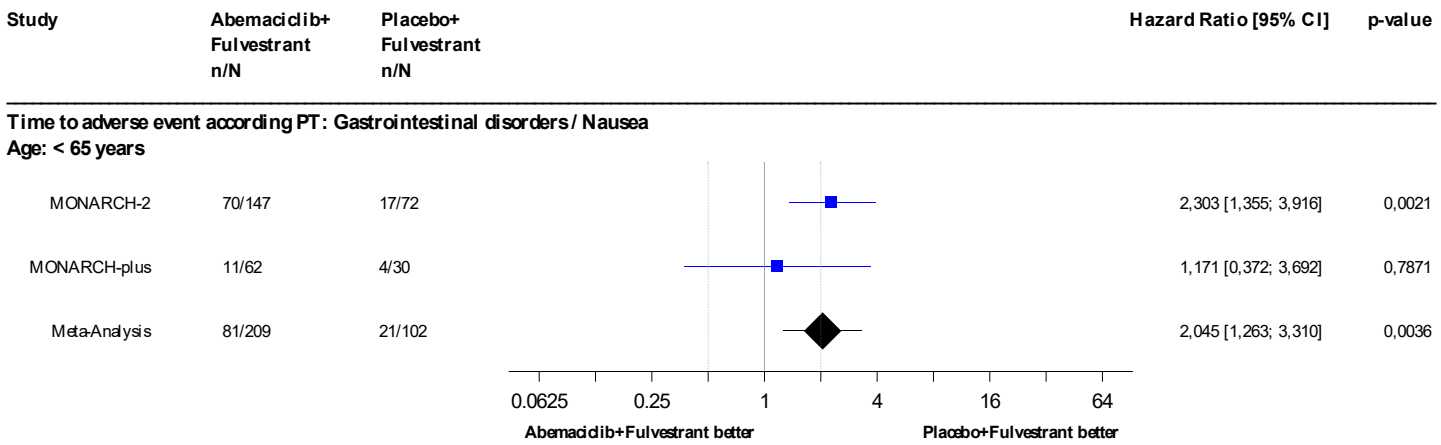
Figure 1165.1.1.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,0985, p-value=0,2946, I2 index=9,0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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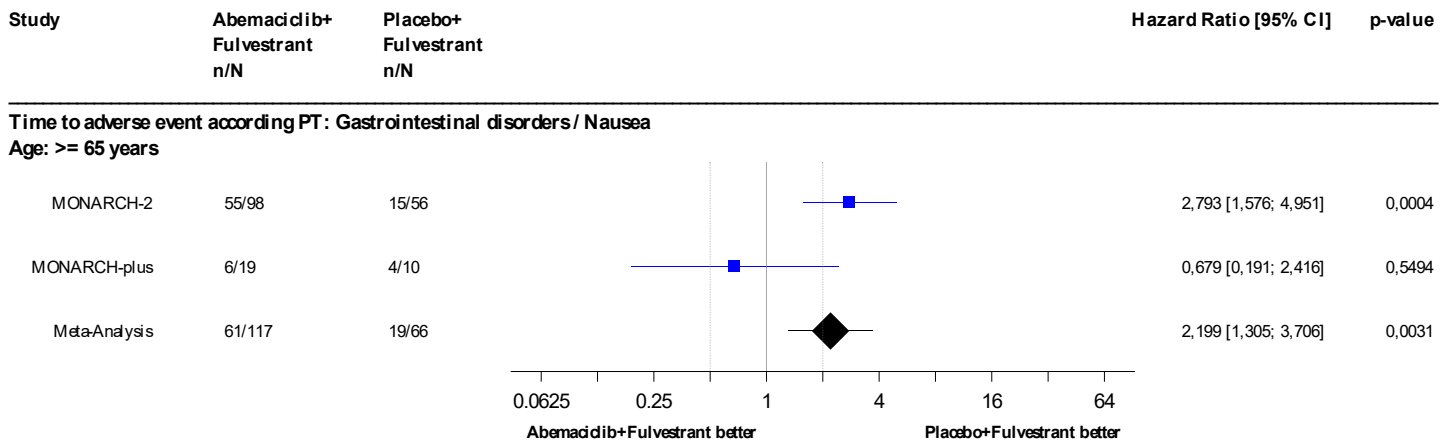
Figure 1165.1.1.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=3,9645, p-value=0,0465, I2 index=74,8%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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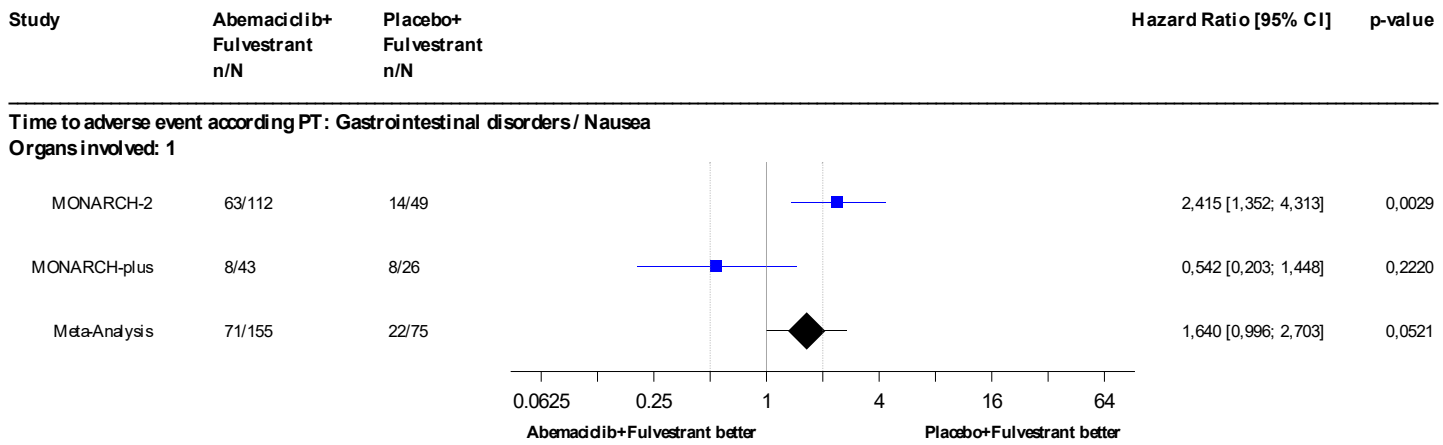
Figure 1165.1.2.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=6,5887, p-value=0,0103, I2 index=84,8%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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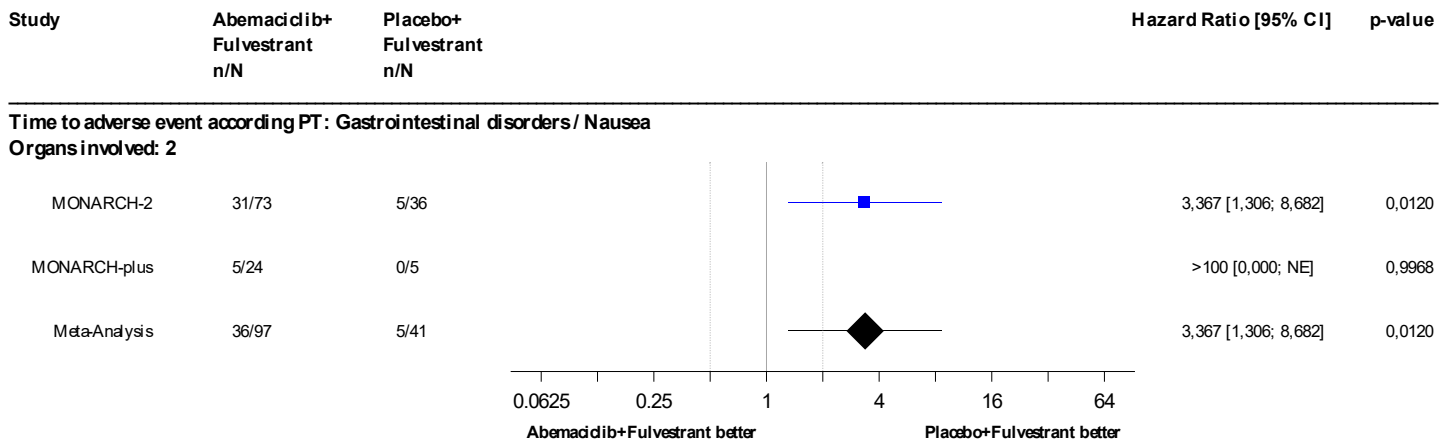
Figure 1165.1.2.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9970, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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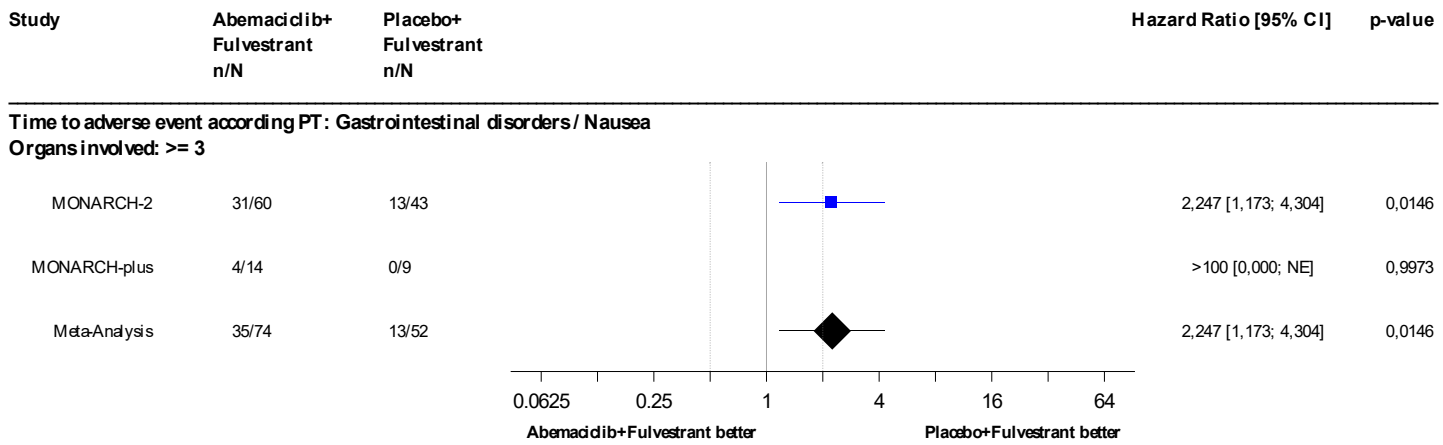
Figure 1165.1.2.3: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9974, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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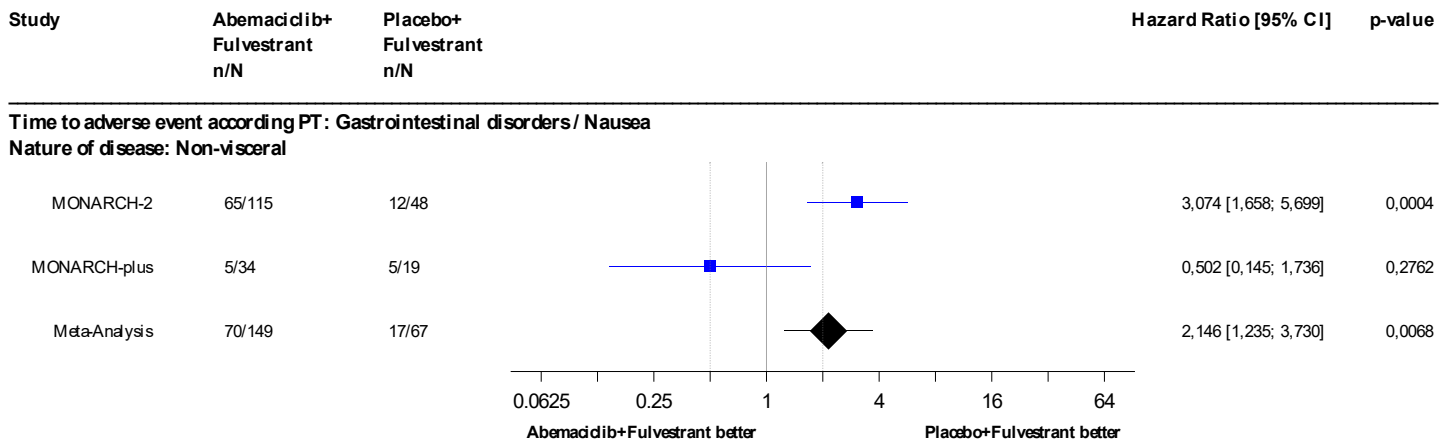
Figure 1165.1.3.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=6,5641, p-value=0,0104, I2 index=84,8%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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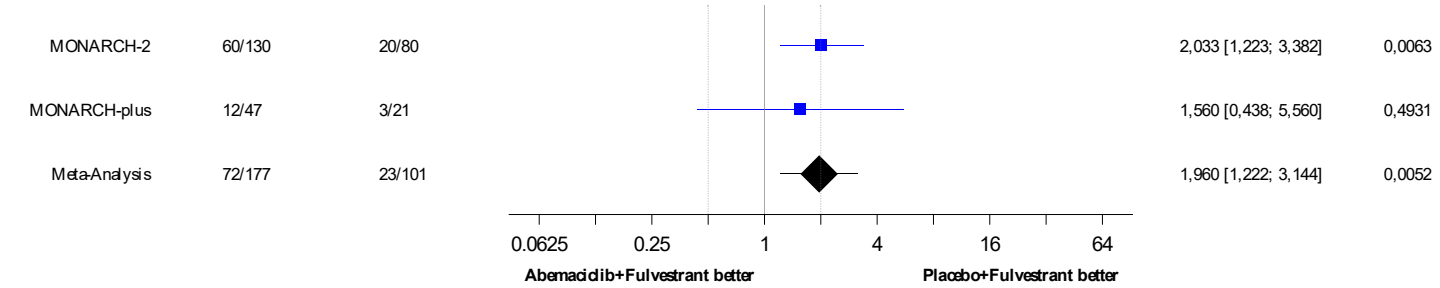
Figure 1165.1.3.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1442, p-value=0,7042, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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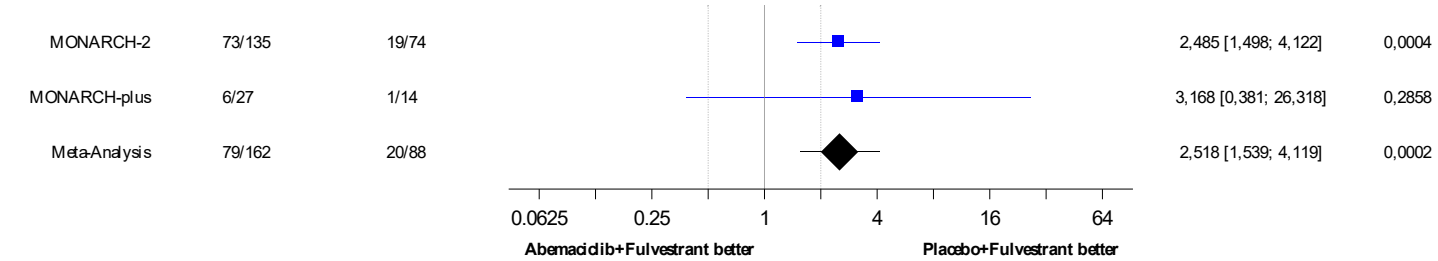
Figure 1165.1.4.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0478, p-value=0,8270, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep065_popa1_ecogbl_1.rtf
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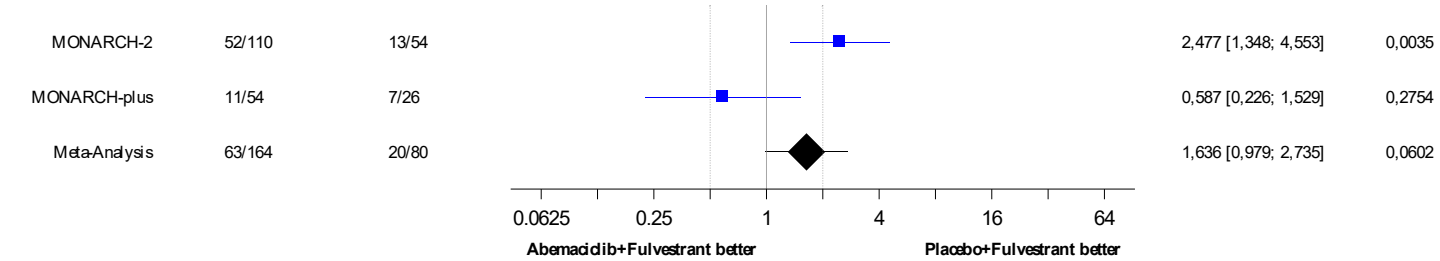
Figure 1165.1.4.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=6,1898, p-value=0,0128, I2 index=83,8%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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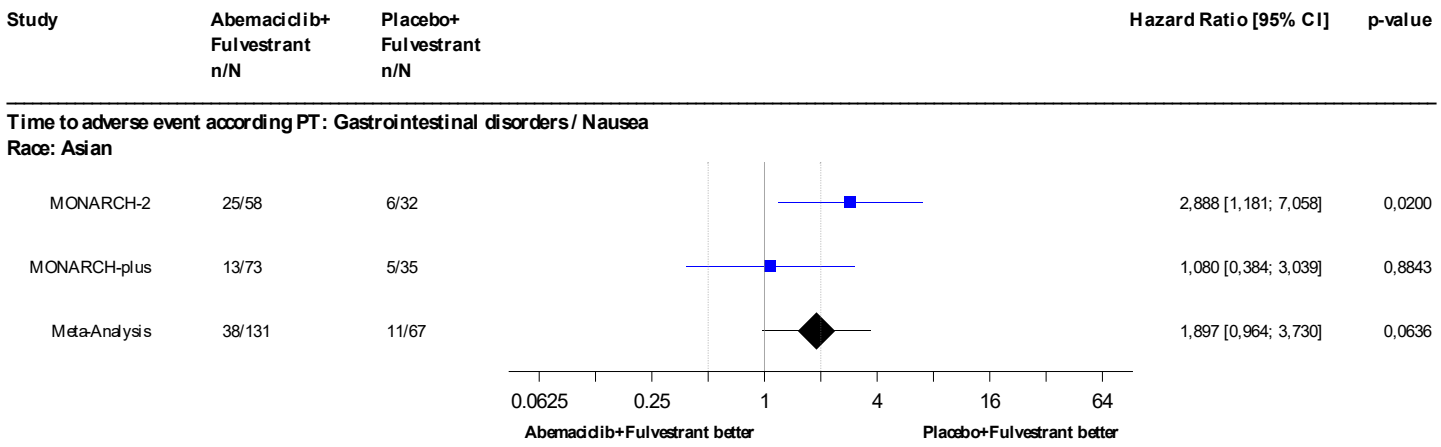
Figure 1165.1.5.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,9885, p-value=0,1585, I2 index=49,7%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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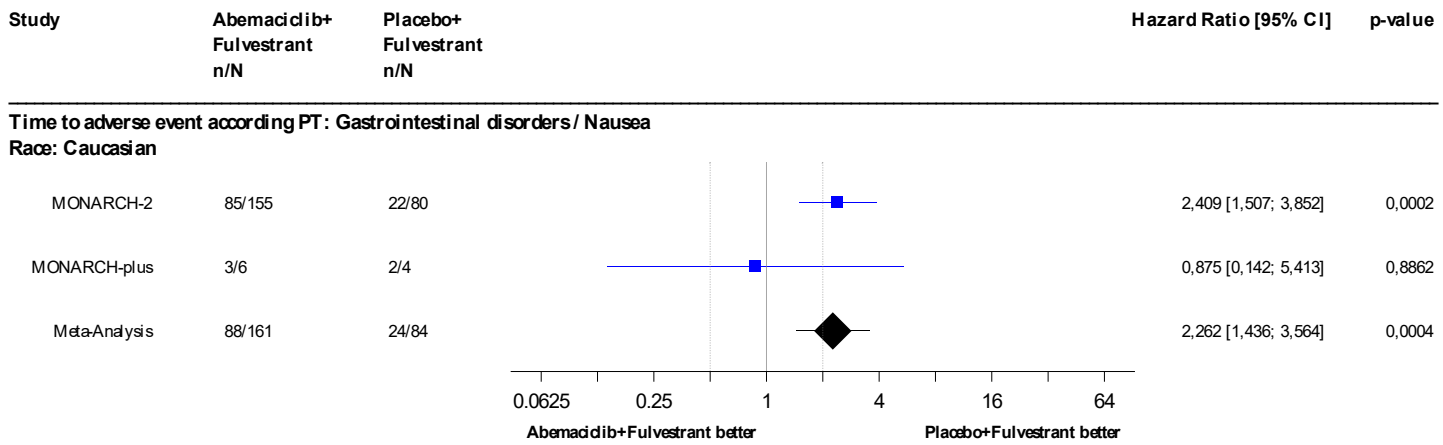
Figure 1165.1.5.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,1122, p-value=0,2916, I2 index=10,1%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep065_popa1_racegr1_2.rtf
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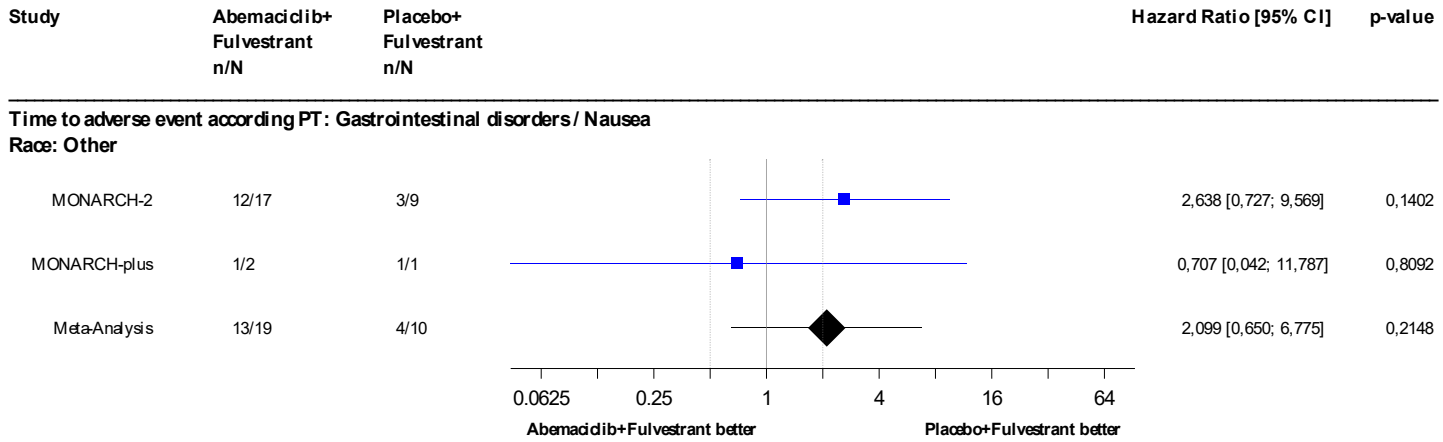
Figure 1165.1.5.3: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6951, p-value=0,4044, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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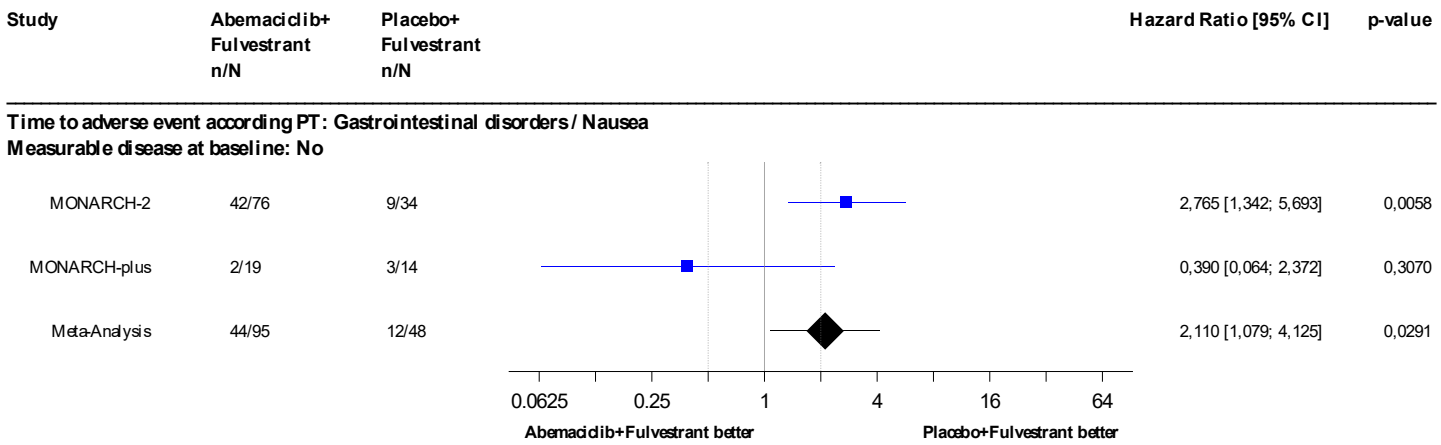
Figure 1165.1.6.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=3,8962, p-value=0,0484, I2 index=74,3%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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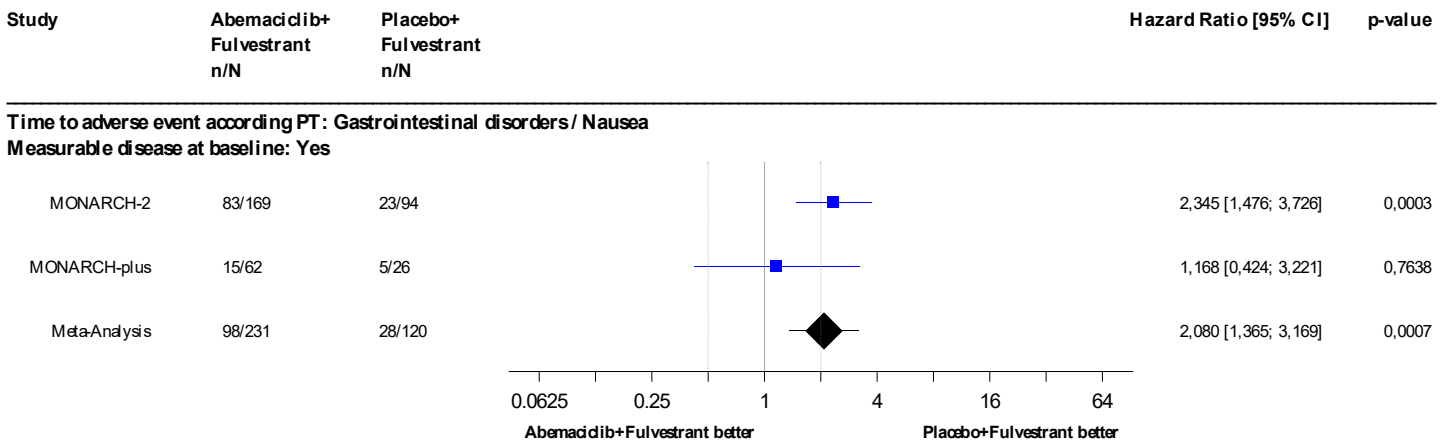
Figure 1165.1.6.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,5010, p-value=0,2205, I2 index=33,4%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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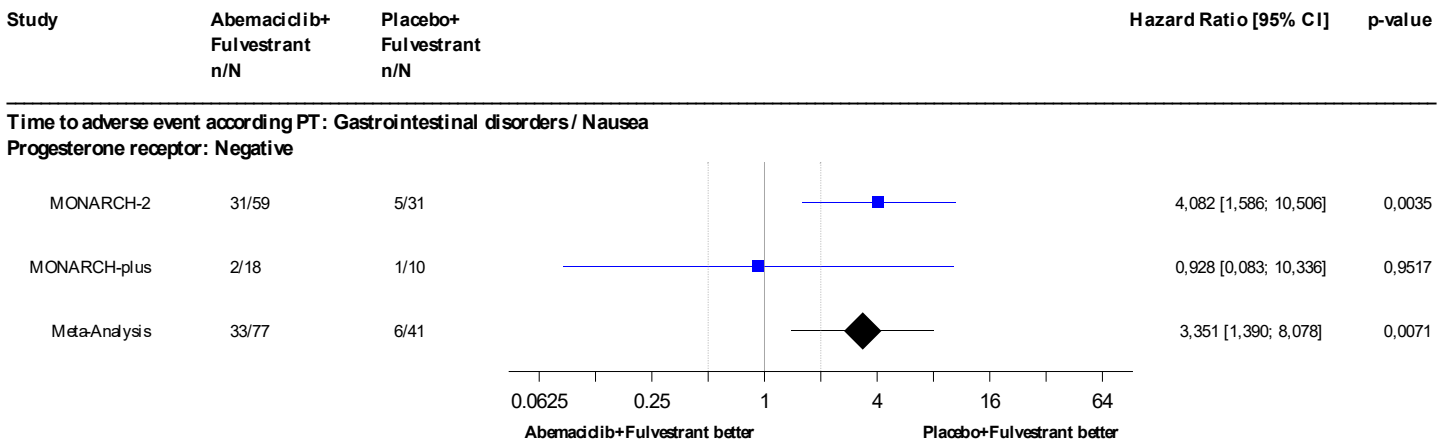
Figure 1165.1.7.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,2574, p-value=0,2621, I2 index=20,5%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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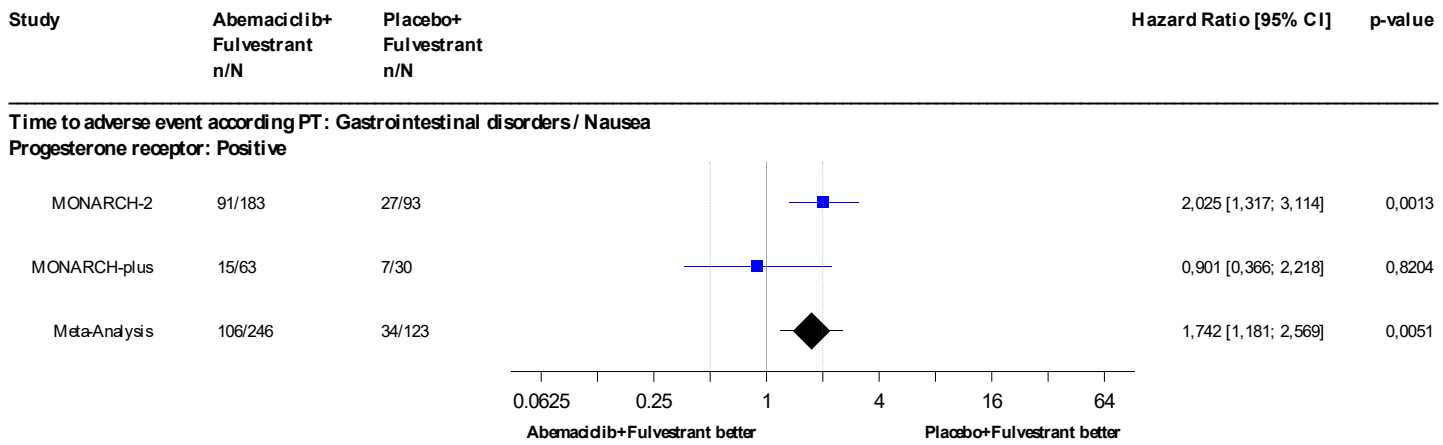
Figure 1165.1.7.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,5288, p-value=0,1118, I2 index=60,5%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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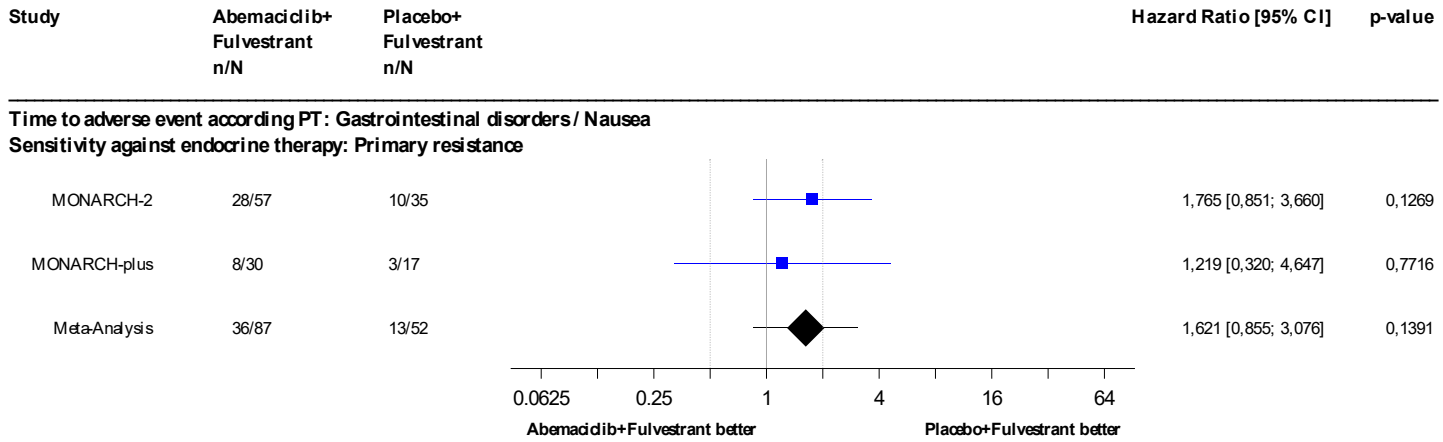
Figure 1165.1.8.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2263, p-value=0,6343, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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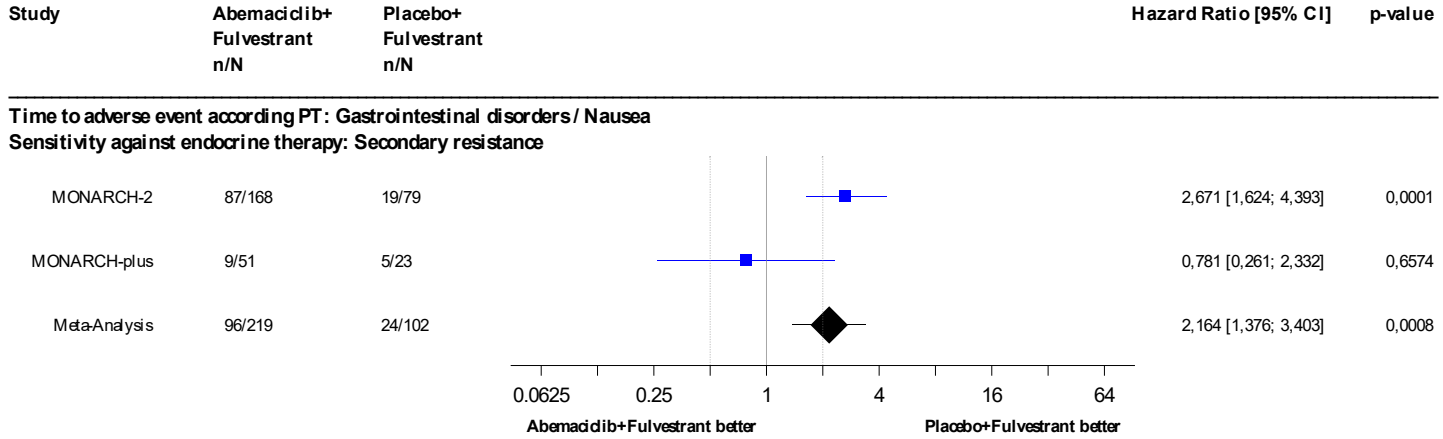
Figure 1165.1.8.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=4,0212, p-value=0,0449, I2 index=75,1%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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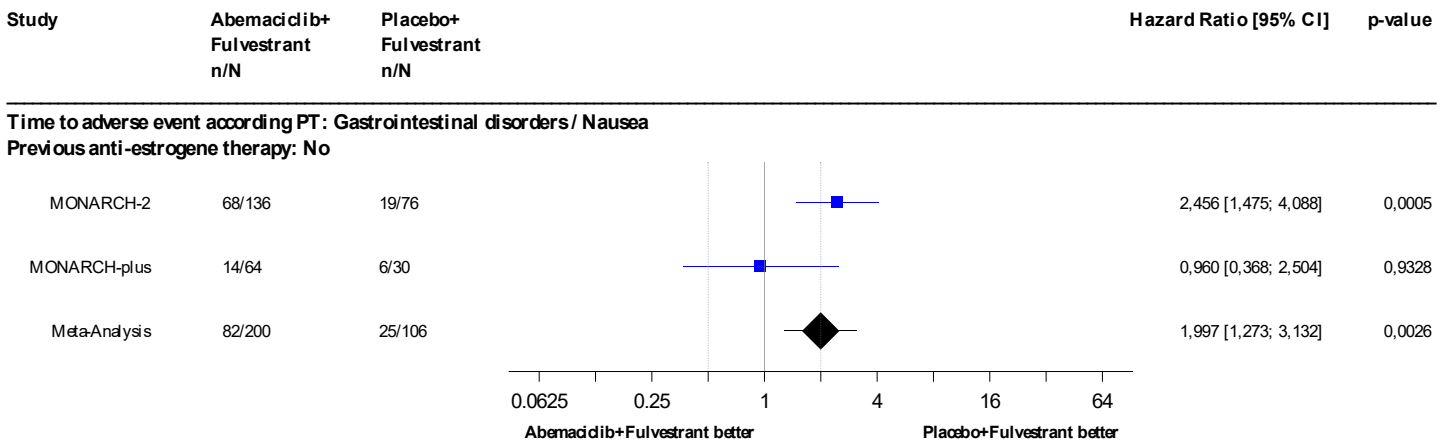
Figure 1165.1.9.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,8755, p-value=0,0899, I2 index=65,2%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep065_popa1_paet_1.rtf
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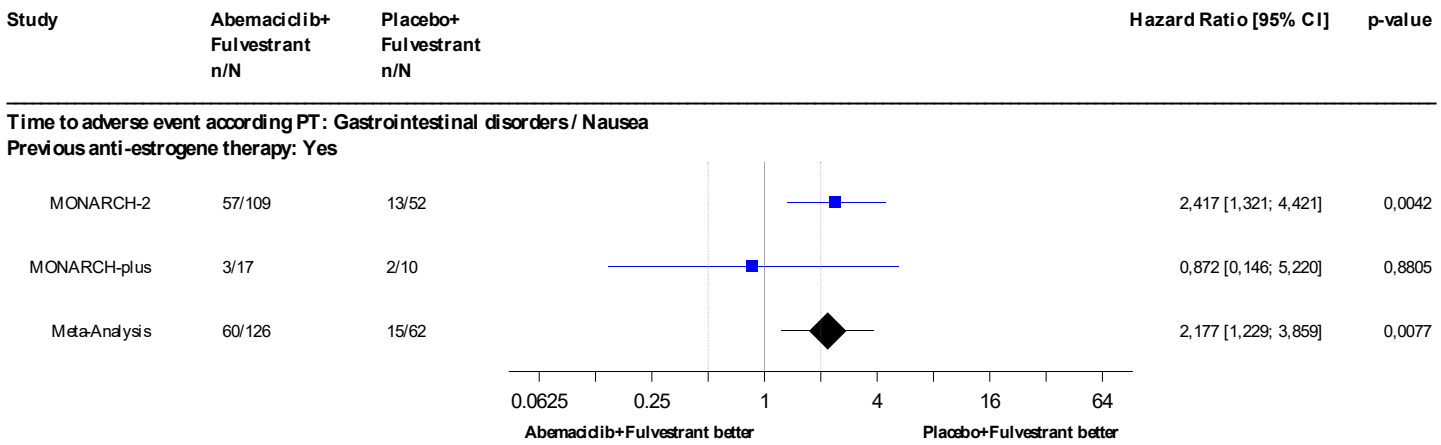
Figure 1165.1.9.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,1193, p-value=0,2901, I2 index=10,7%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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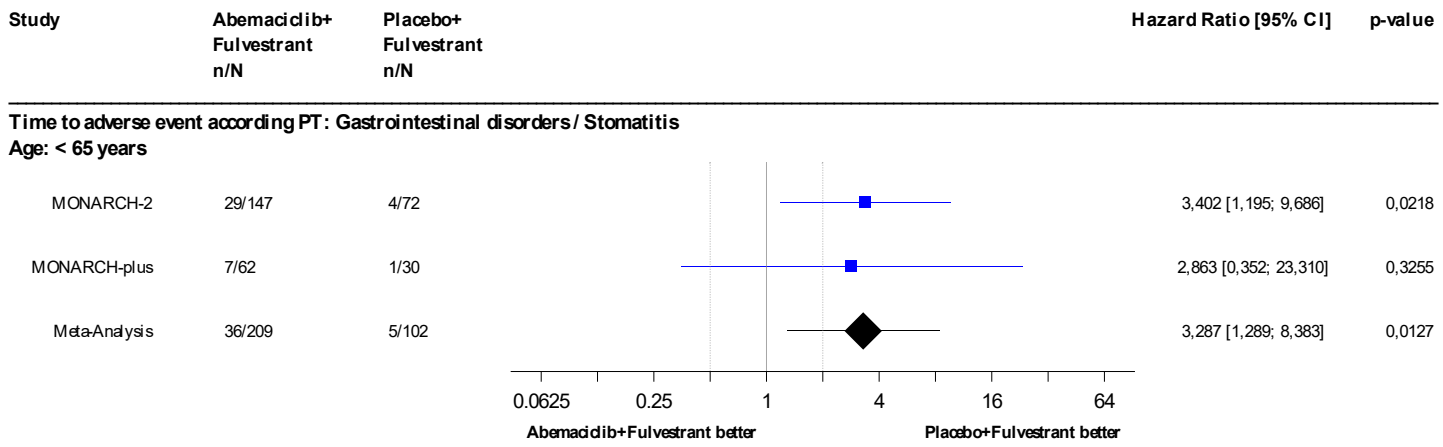
Figure 1186.1.1.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0208, p-value=0,8853, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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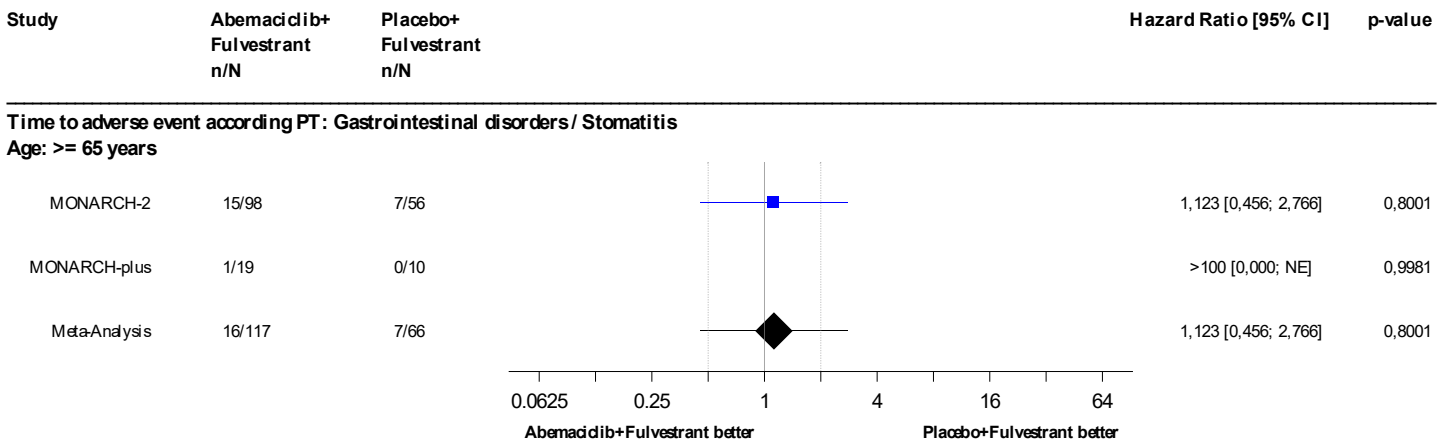
Figure 1186.1.1.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9981, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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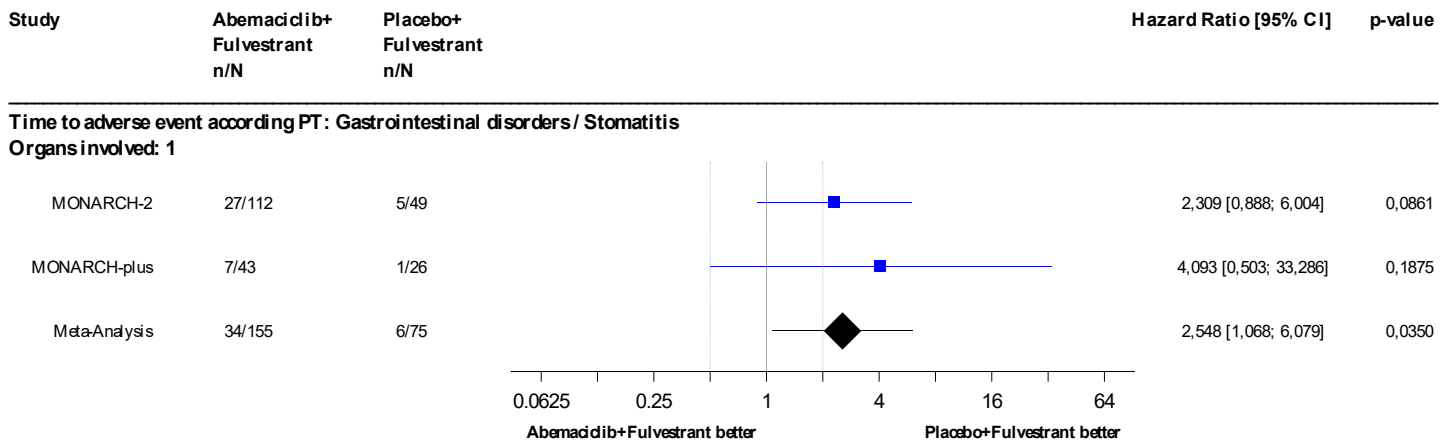
Figure 1186.1.2.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2374, p-value=0,6261, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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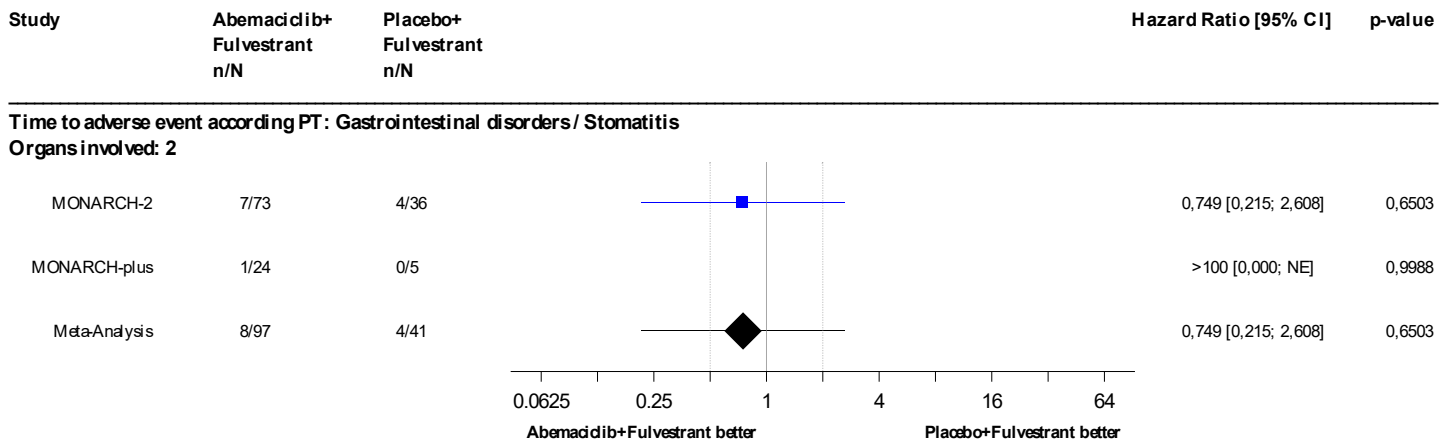
Figure 1186.1.2.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9988, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep086_popa1_norggr_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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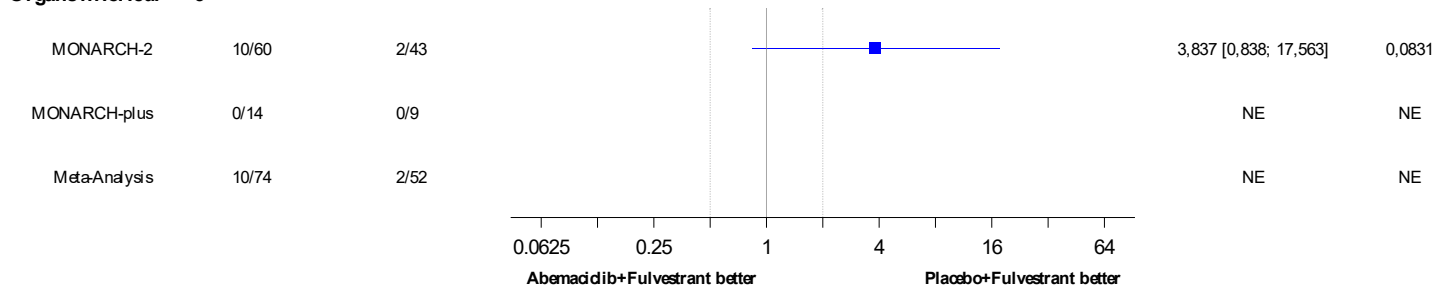
Figure 1186.1.2.3: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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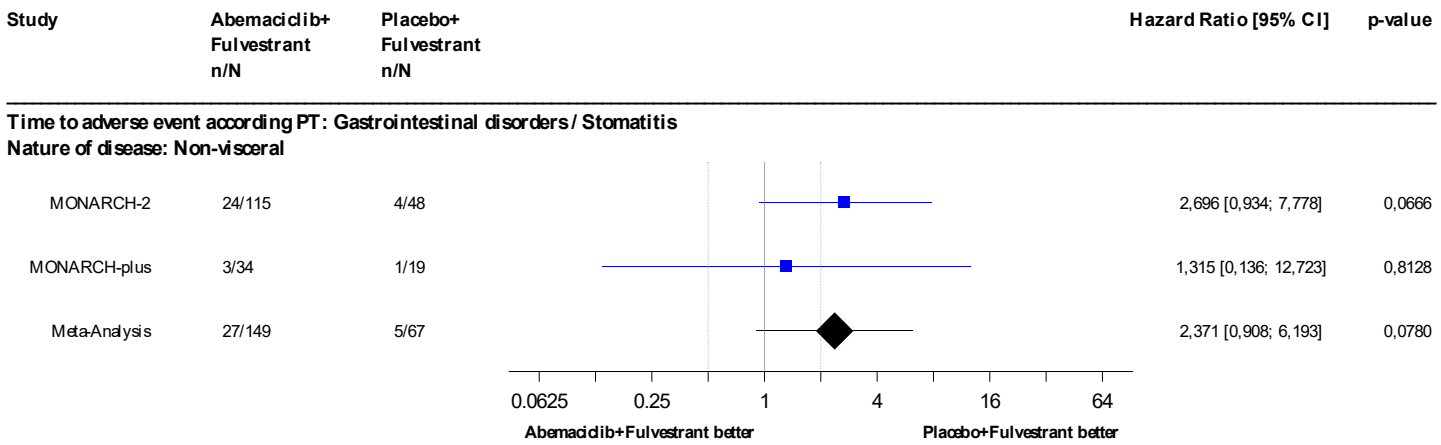
Figure 1186.1.3.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3154, p-value=0,5744, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep086_popa1_natdis2_1.rtf
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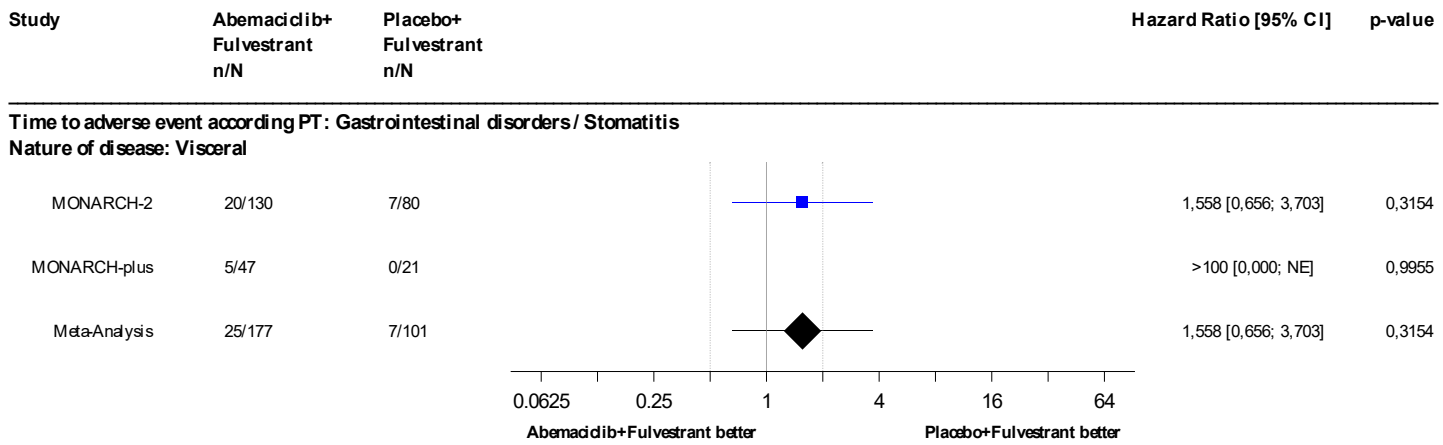
Figure 1186.1.3.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9956, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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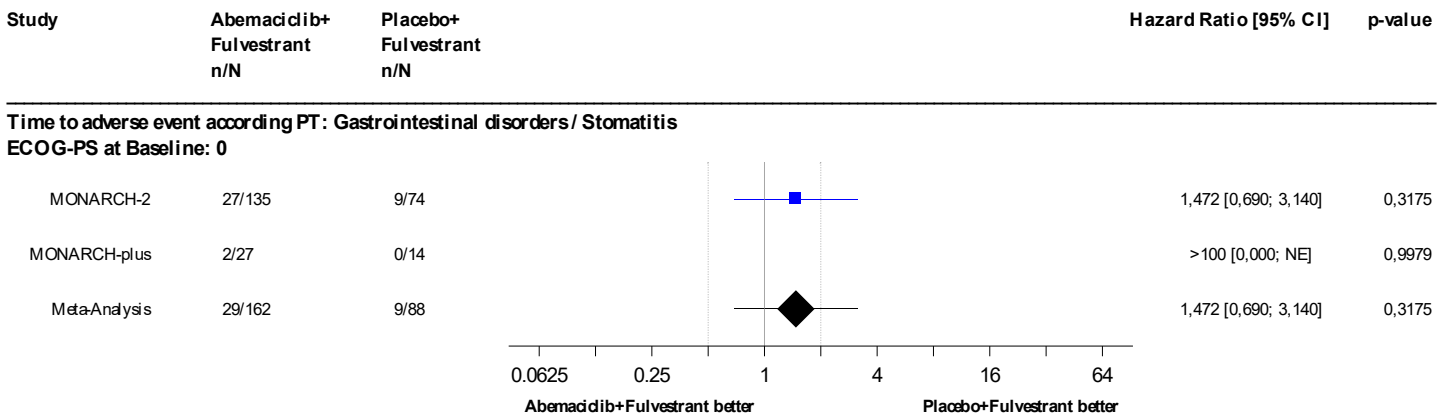
Figure 1186.1.4.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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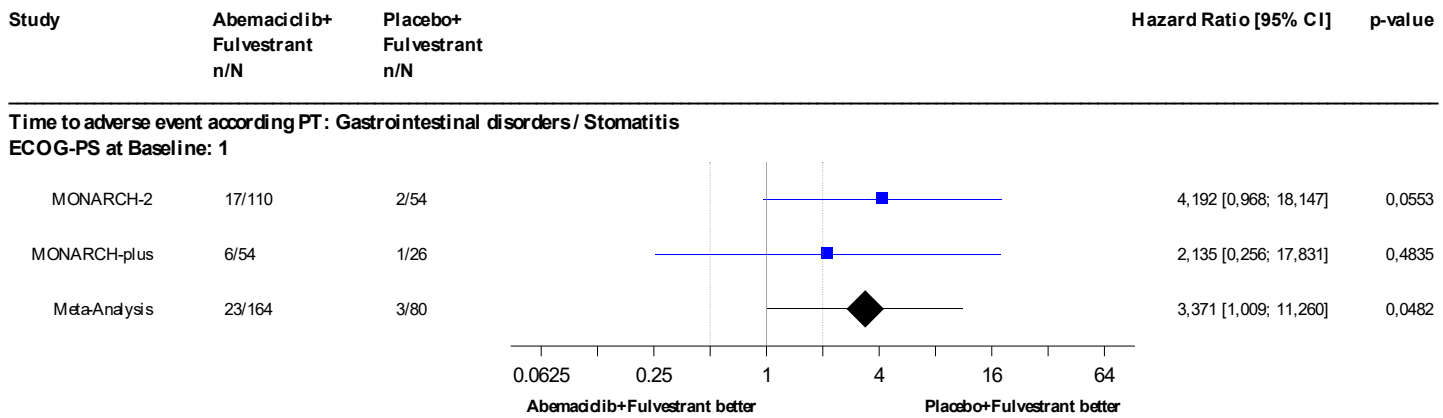
Figure 1186.1.4.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2627, p-value=0,6083, I2 index=0%

Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep086_popa1_ecogbl_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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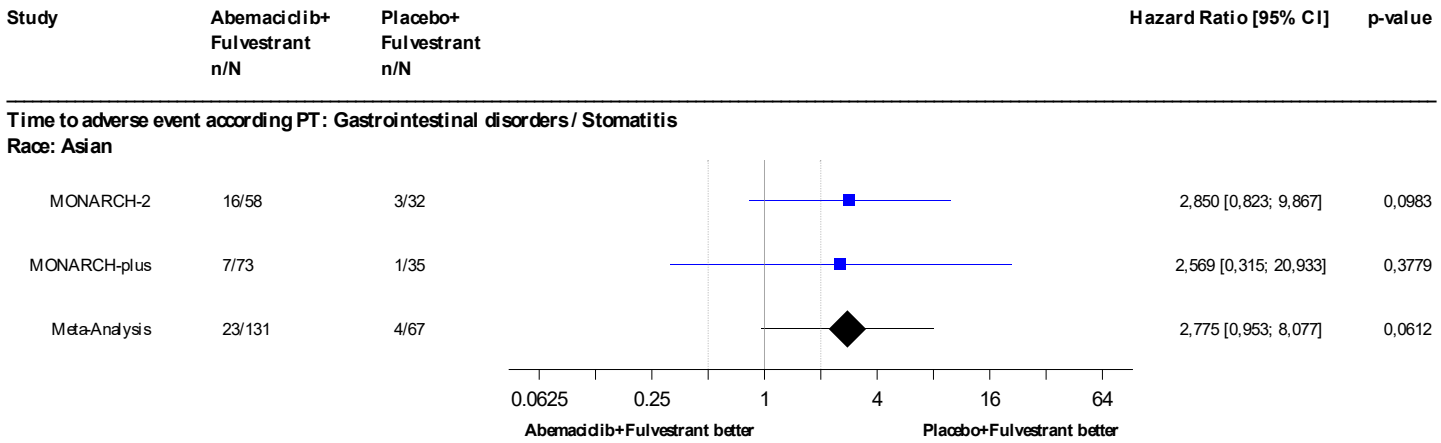
Figure 1186.1.5.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0070, p-value=0,9335, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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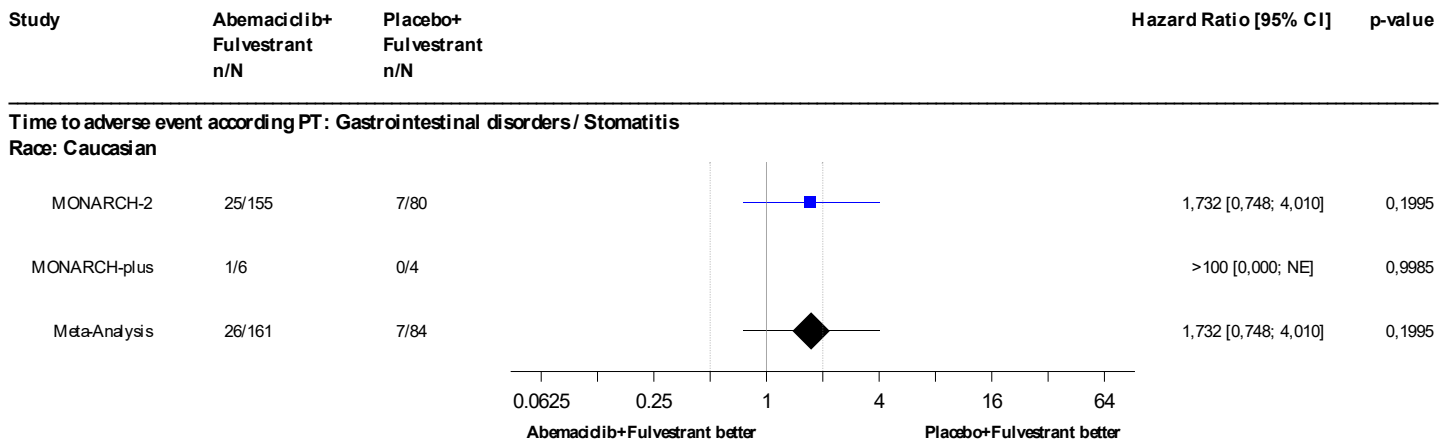
Figure 1186.1.5.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep086_popa1_racegr1_2.rtf
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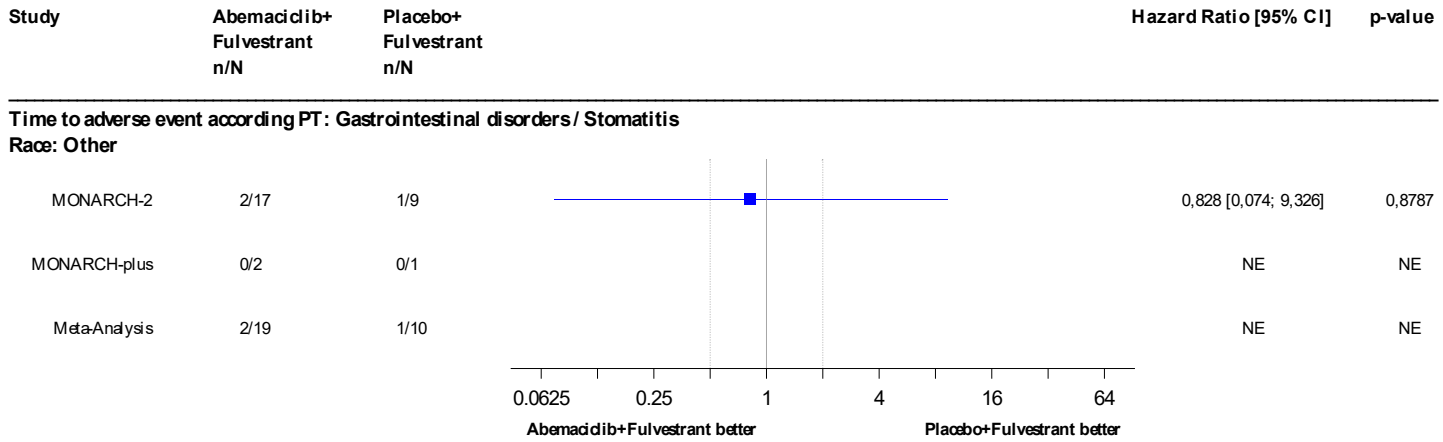
Figure 1186.1.5.3: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep086_popa1_racegr1_3.rtf
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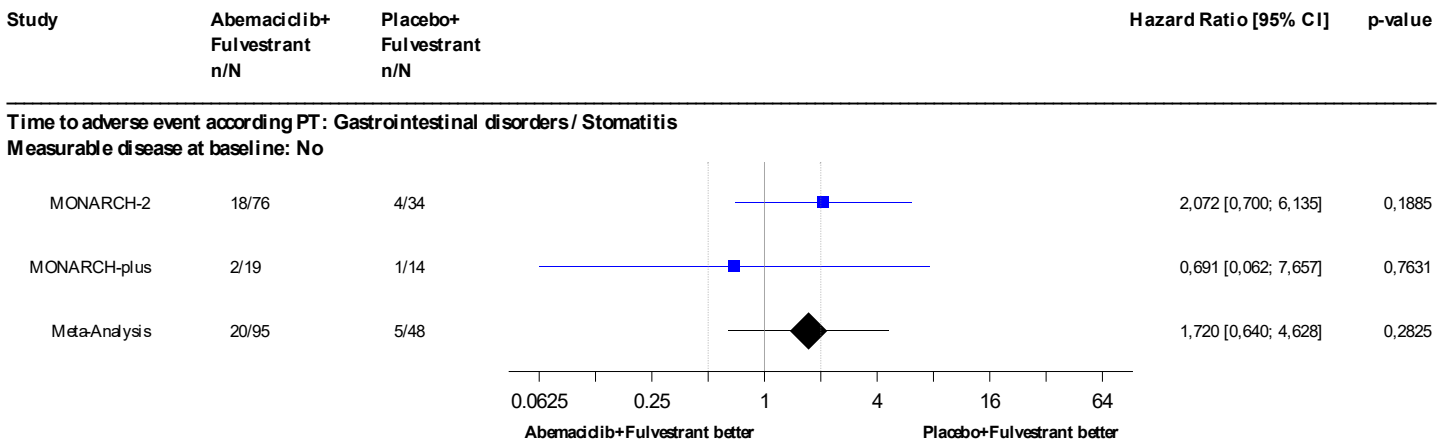
Figure 1186.1.6.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6653, p-value=0,4147, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep086_popa1_measdis_1.rtf
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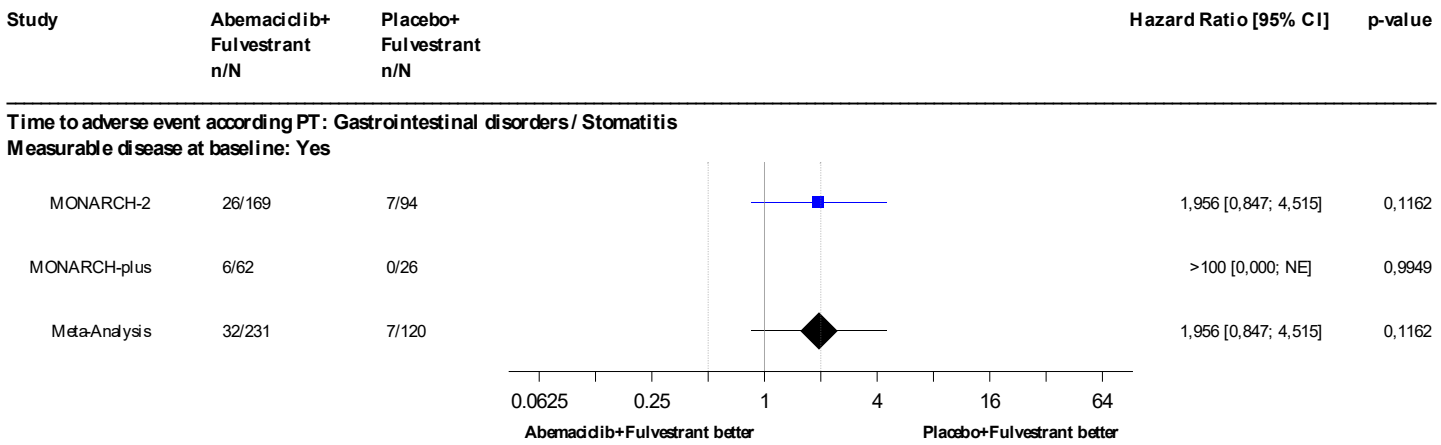
Figure 1186.1.6.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9952, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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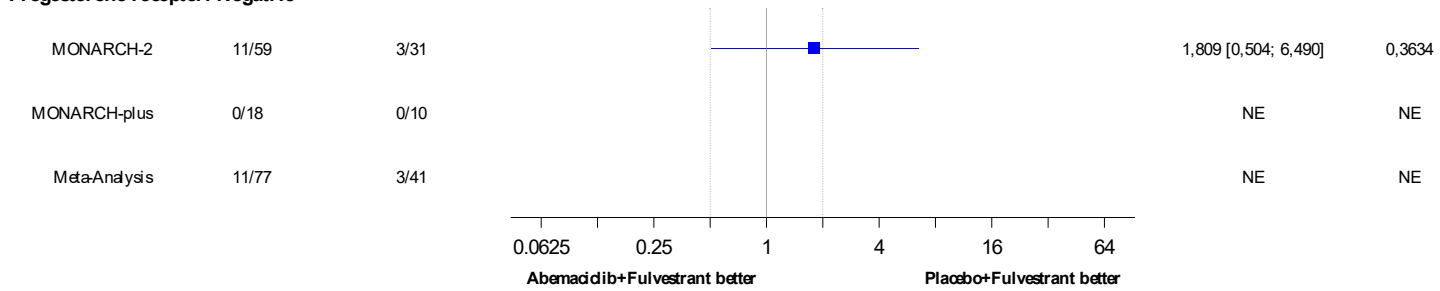
Figure 1186.1.7.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep086_popa1_pgrstat_1.rtf
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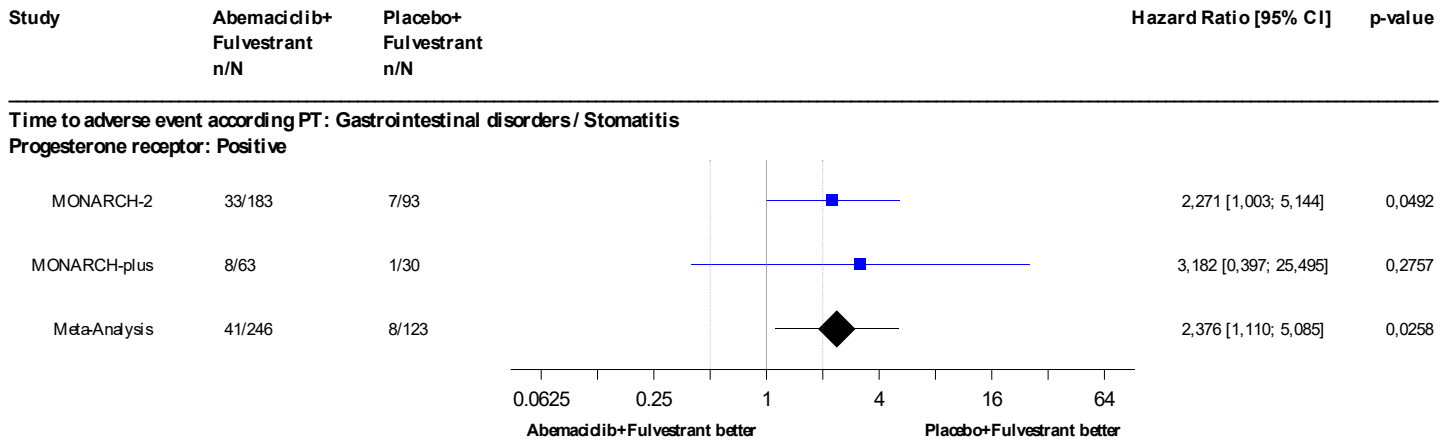
Figure 1186.1.7.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0873, p-value=0,7677, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep086_popa1_pgrstat_2.rtf
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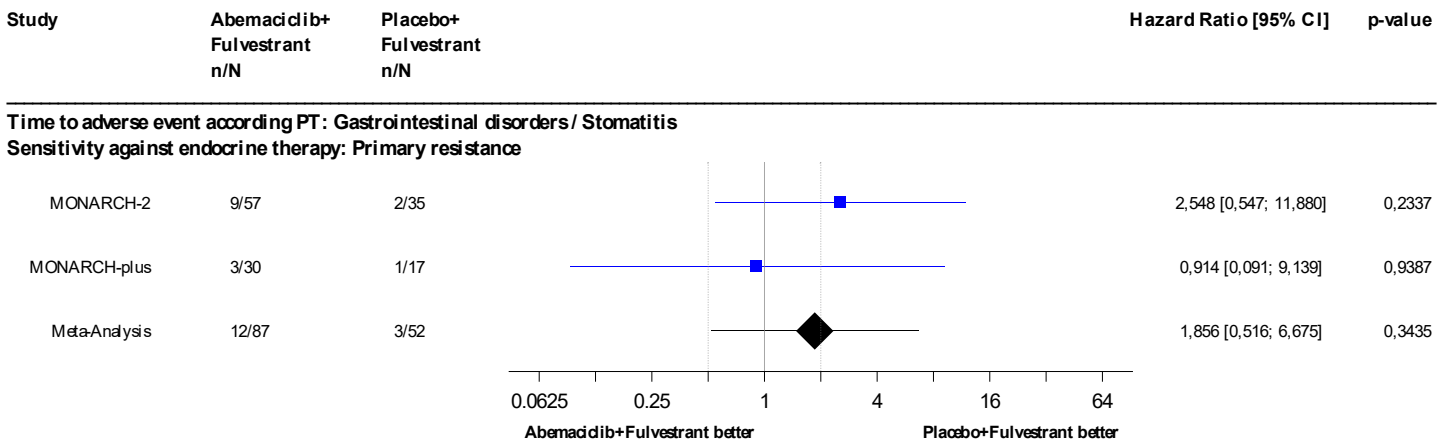
Figure 1186.1.8.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5267, p-value=0,4680, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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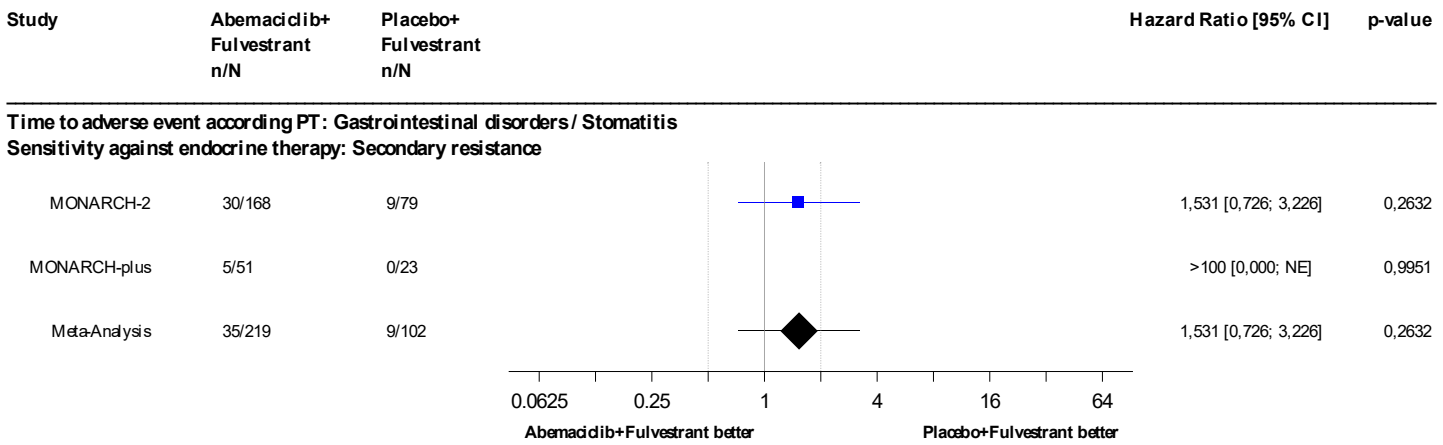
Figure 1186.1.8.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9952, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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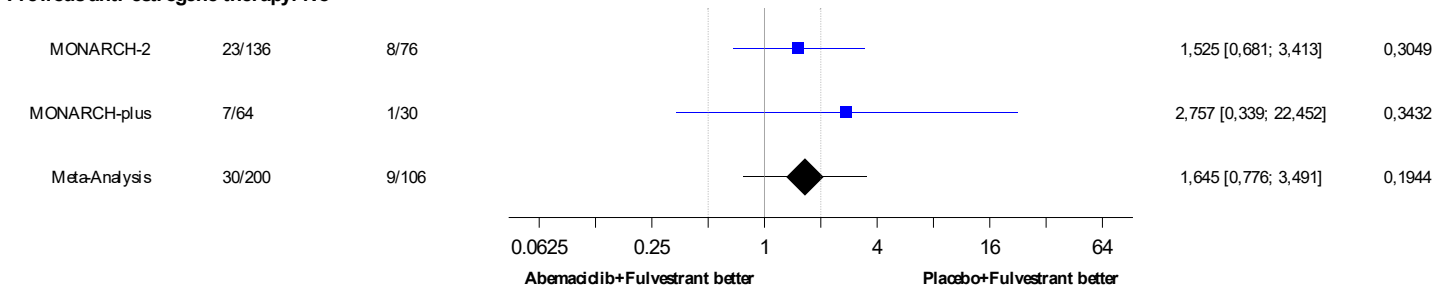
Figure 1186.1.9.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2670, p-value=0,6054, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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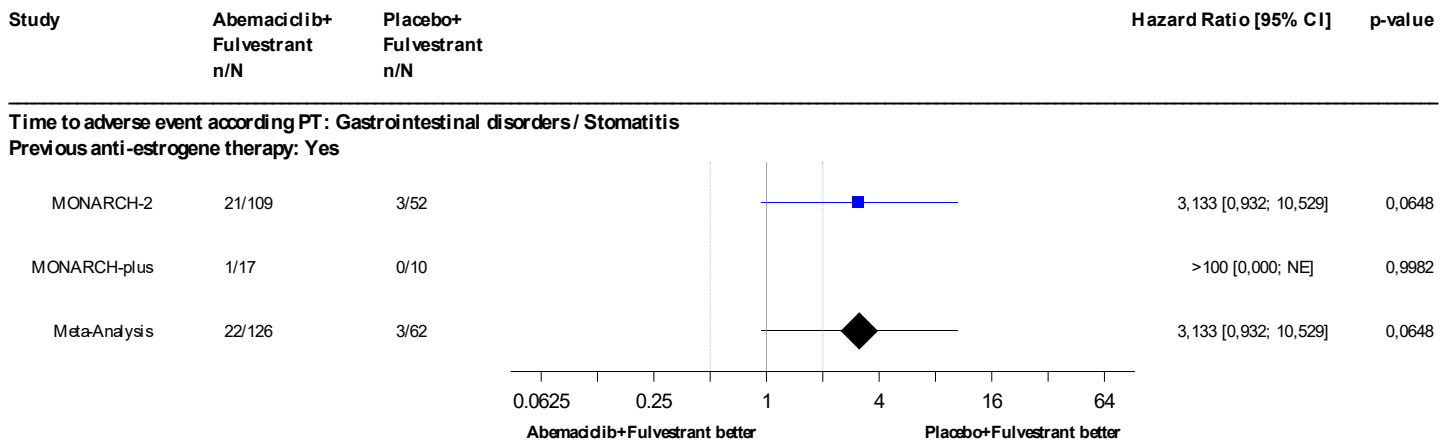
Figure 1186.1.9.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Stomatitis
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9984, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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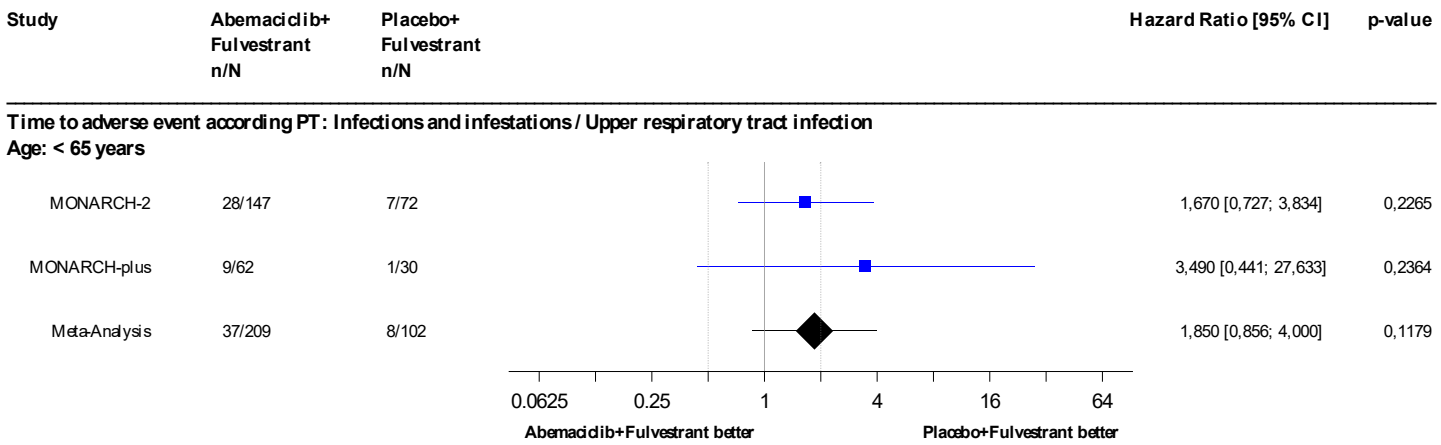
Figure 1188.1.1.1: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4198, p-value=0,5170, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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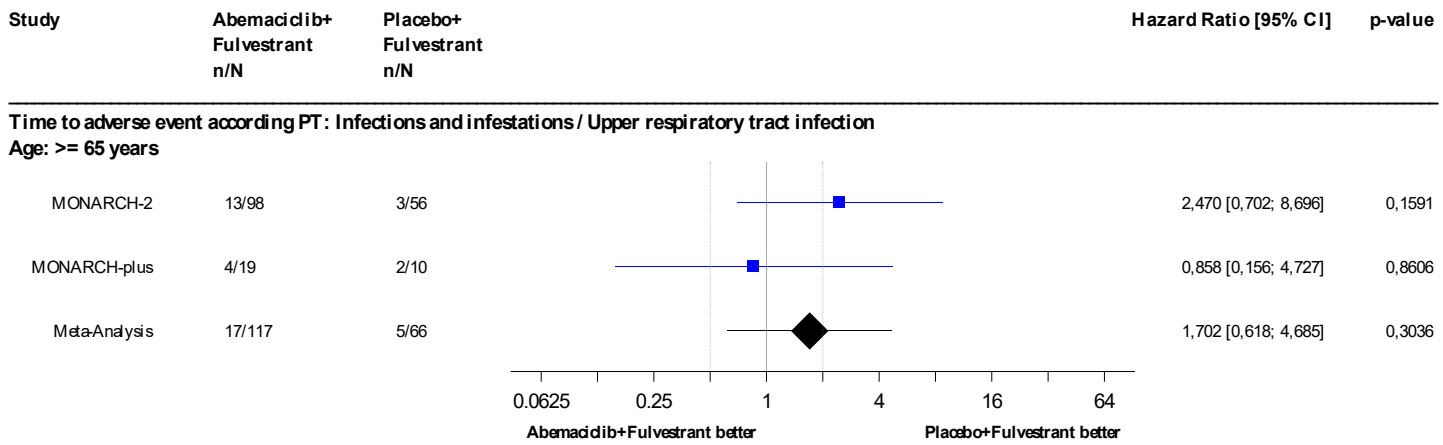
Figure 1188.1.1.2: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,9549, p-value=0,3285, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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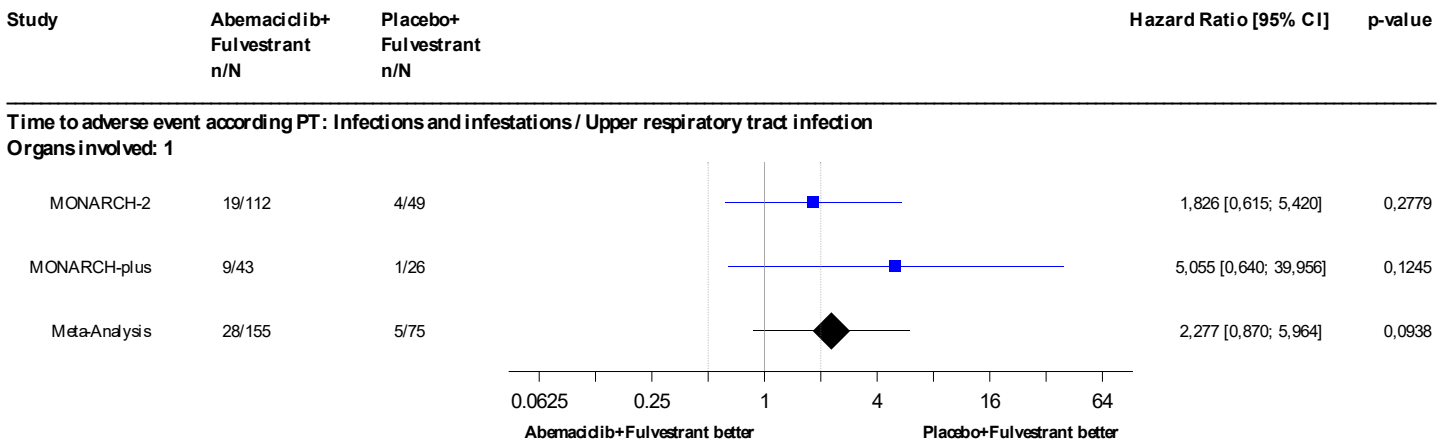
Figure 1188.1.2.1: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,7296, p-value=0,3930, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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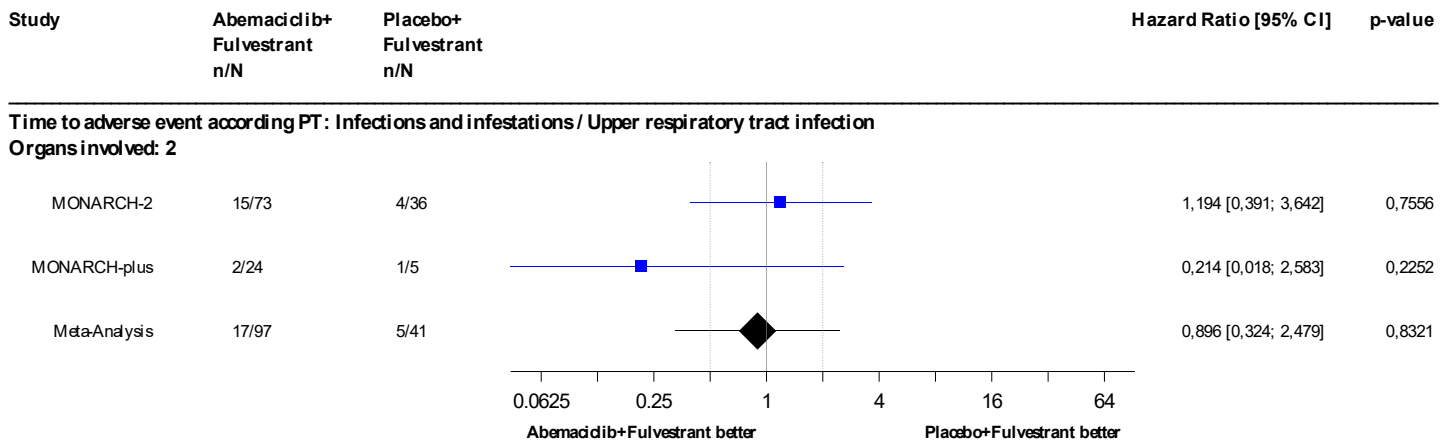
Figure 1188.1.2.2: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,5227, p-value=0,2172, I2 index=34,3%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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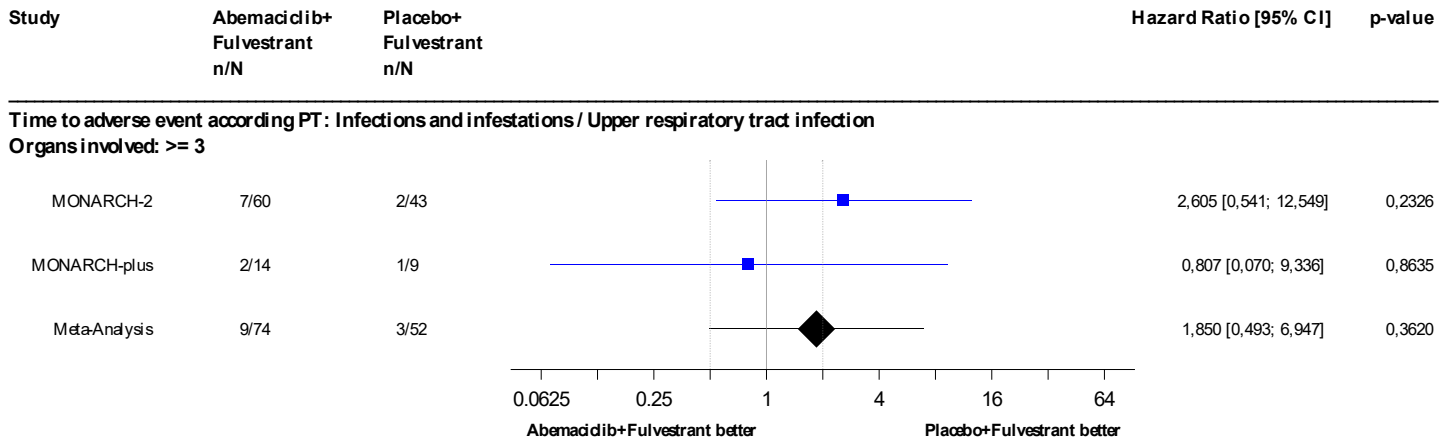
Figure 1188.1.2.3: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6234, p-value=0,4298, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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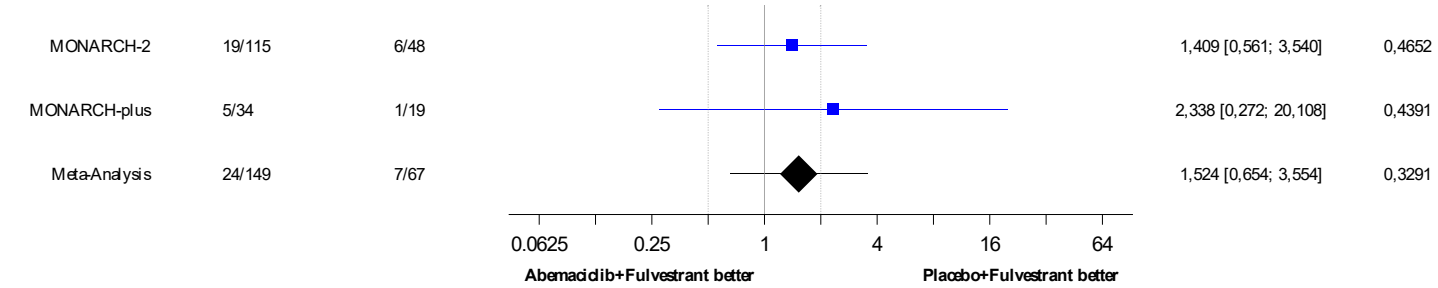
Figure 1188.1.3.1: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1798, p-value=0,6716, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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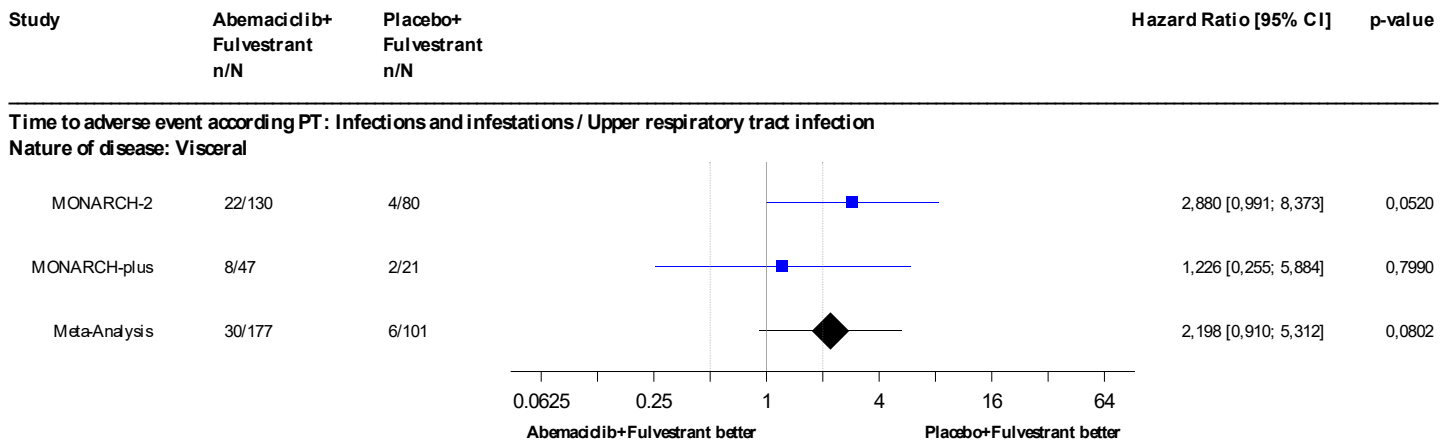
Figure 1188.1.3.2: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,7787, p-value=0,3775, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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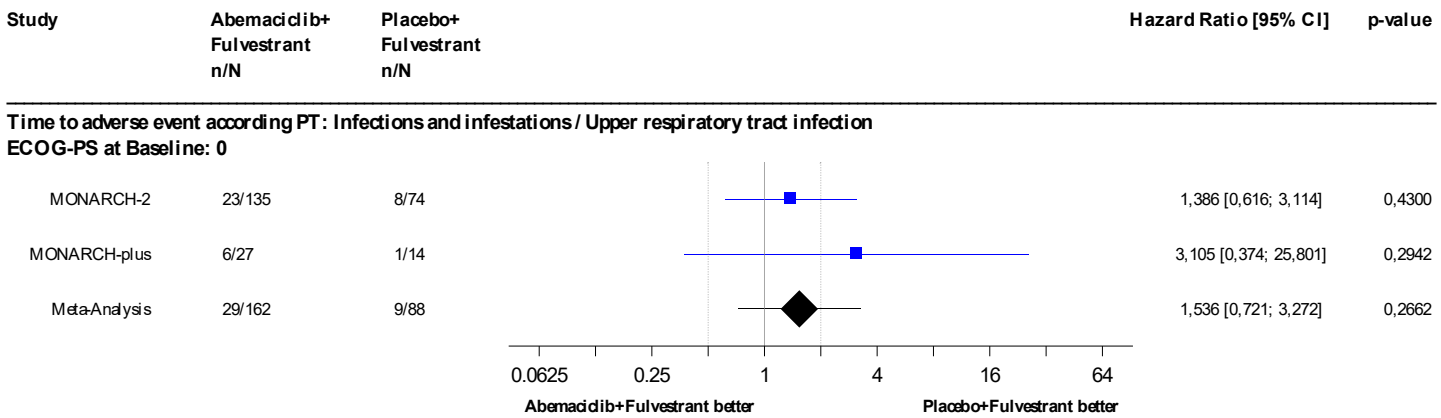
Figure 1188.1.4.1: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4869, p-value=0,4853, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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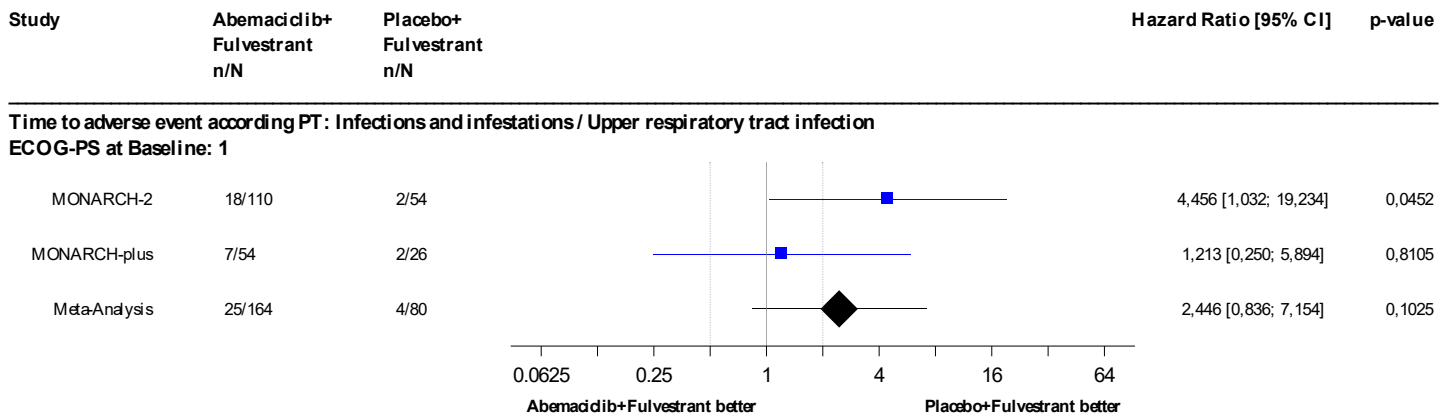
Figure 1188.1.4.2: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,4022, p-value=0,2364, I2 index=28,7%

Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

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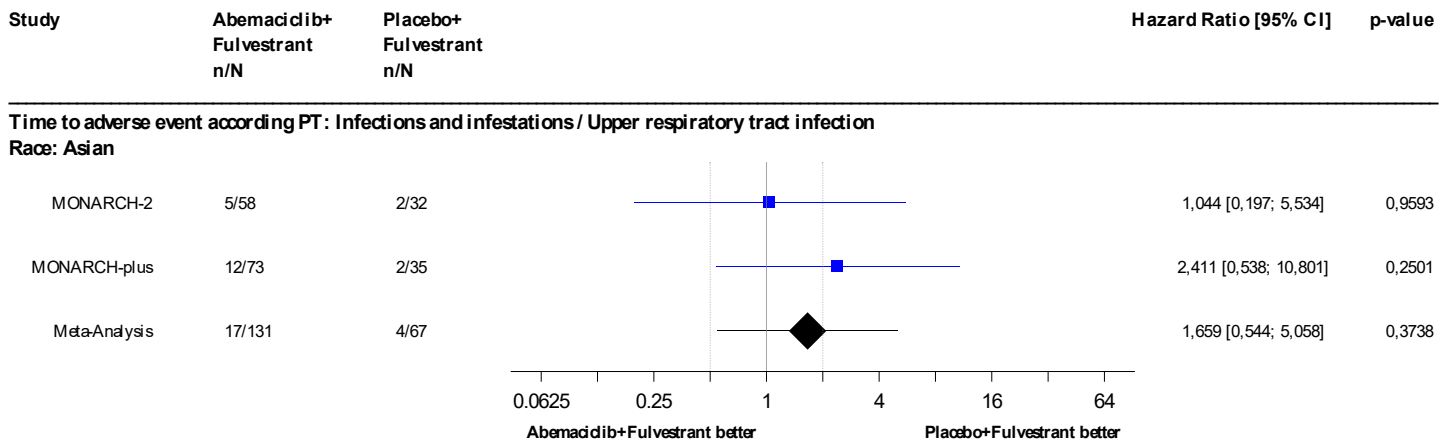
Figure 1188.1.5.1: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5346, p-value=0,4647, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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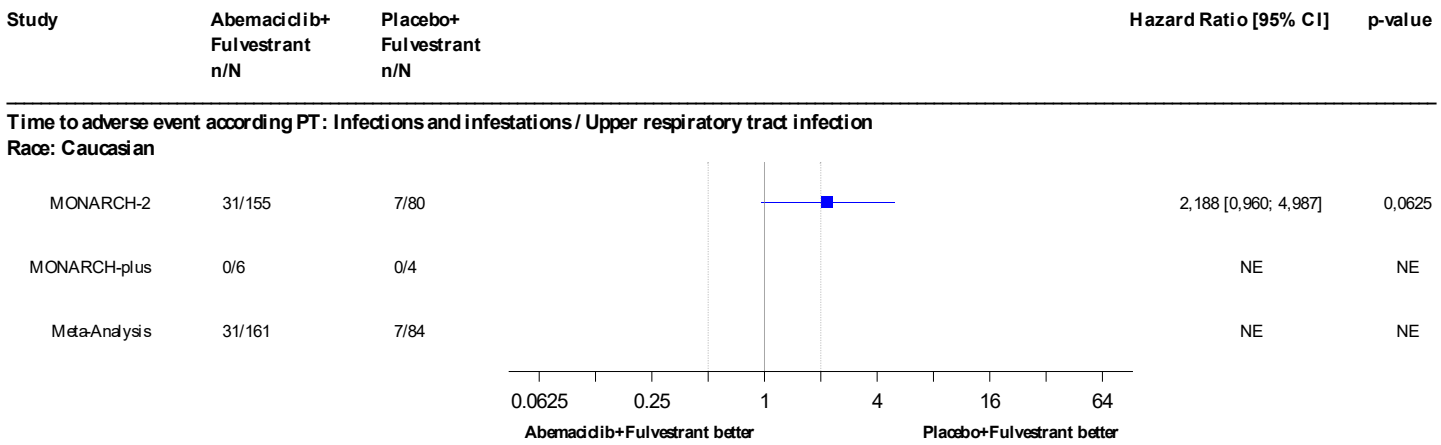
Figure 1188.1.5.2: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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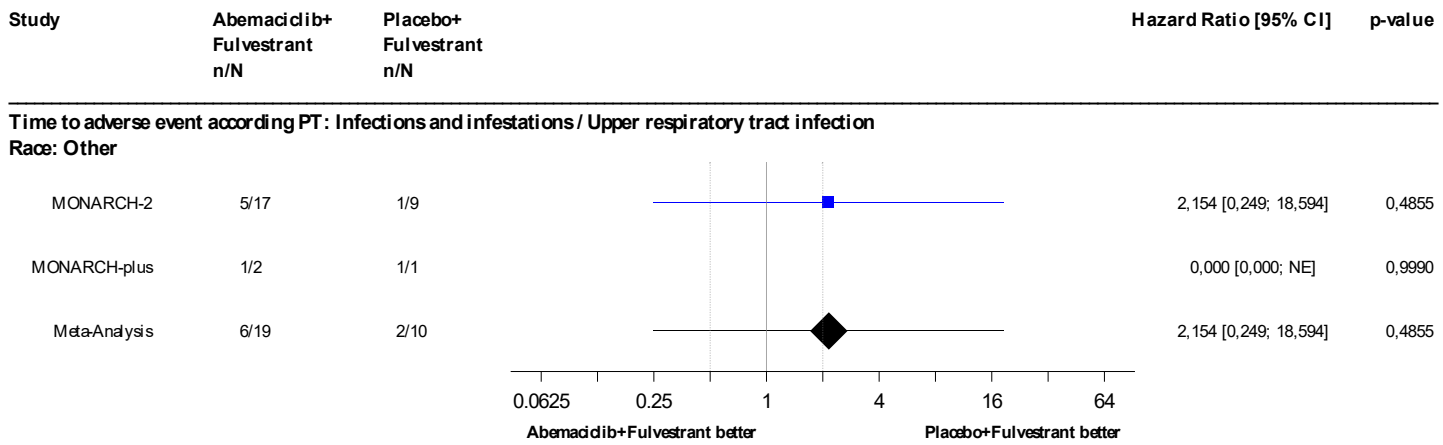
Figure 1188.1.5.3: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9990, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep088_popa1_racegr1_3.rtf
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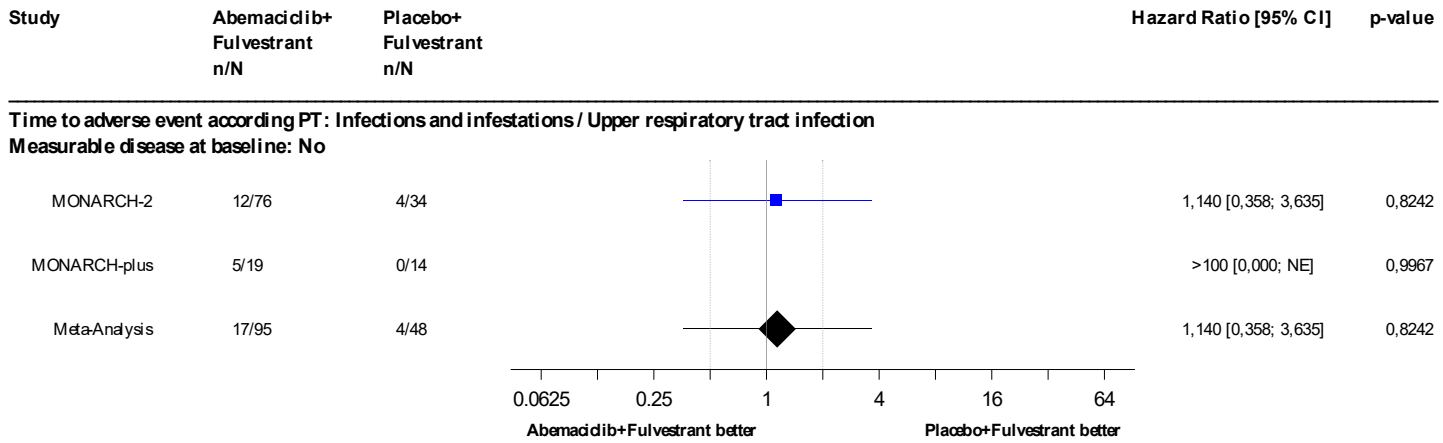
**Figure 1188.1.6.1: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9968, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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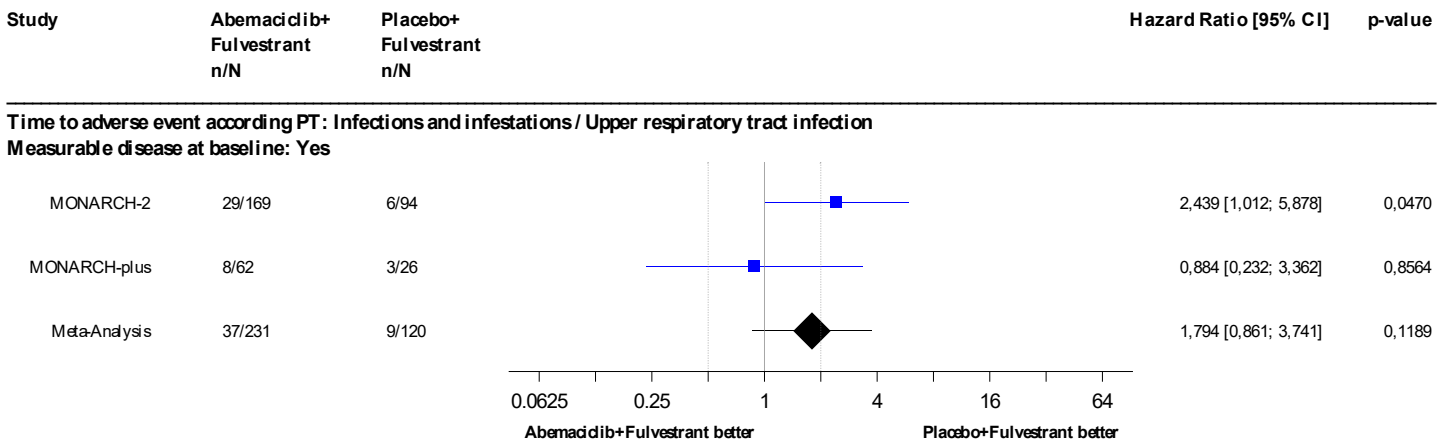
Figure 1188.1.6.2: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,5465, p-value=0,2137, I2 index=35,3%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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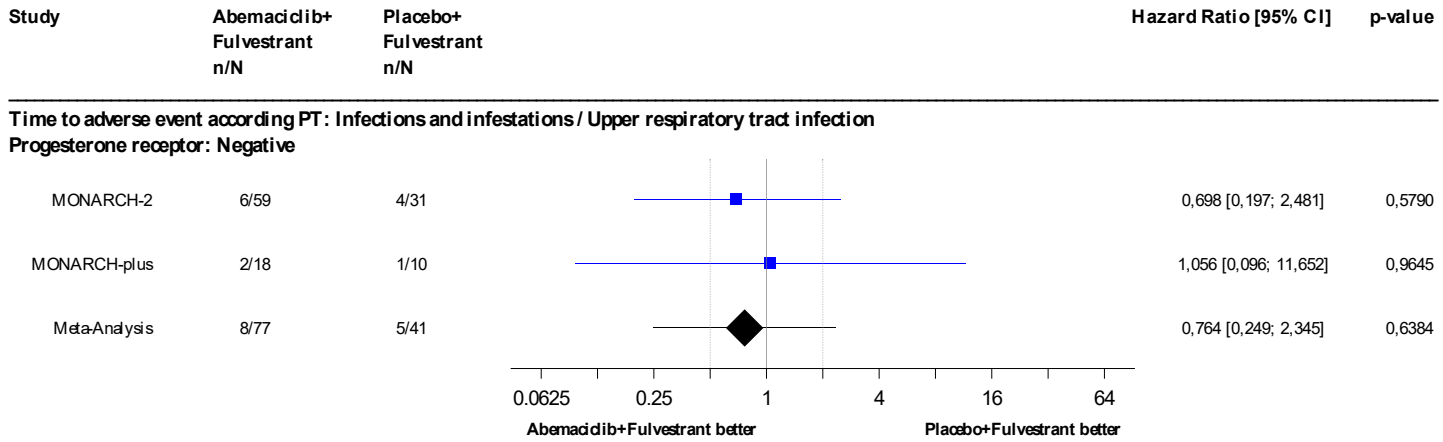
Figure 1188.1.7.1: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0890, p-value=0,7654, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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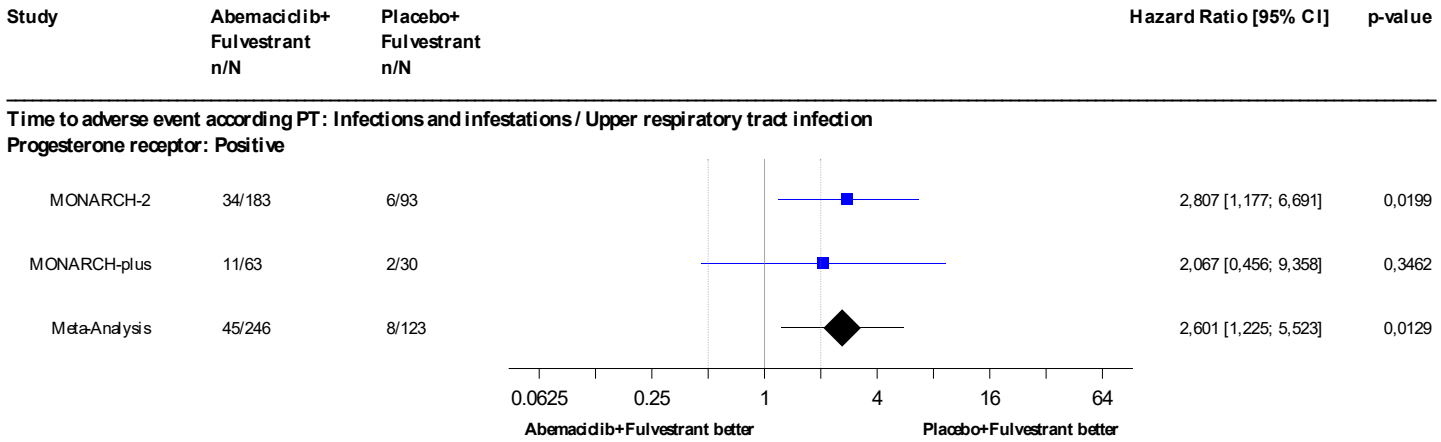
Figure 1188.1.7.2: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1185, p-value=0,7306, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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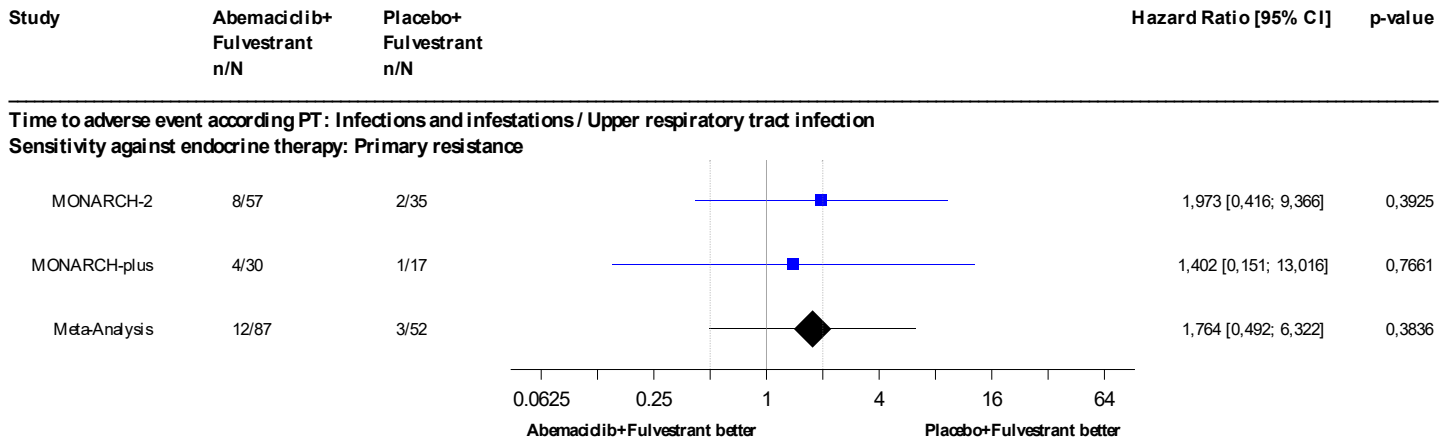
Figure 1188.1.8.1: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0606, p-value=0,8056, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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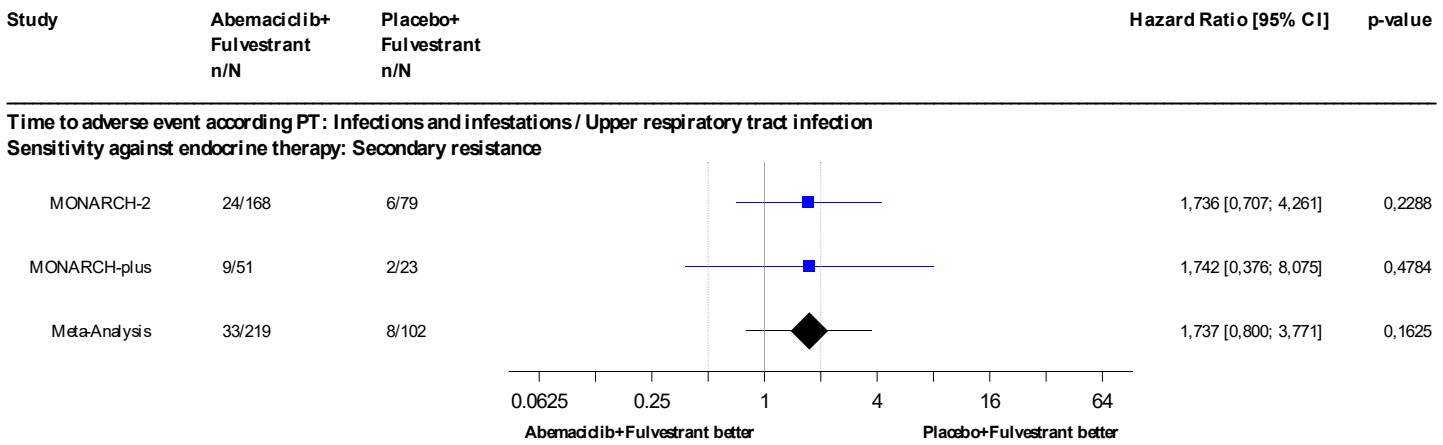
Figure 1188.1.8.2: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9970, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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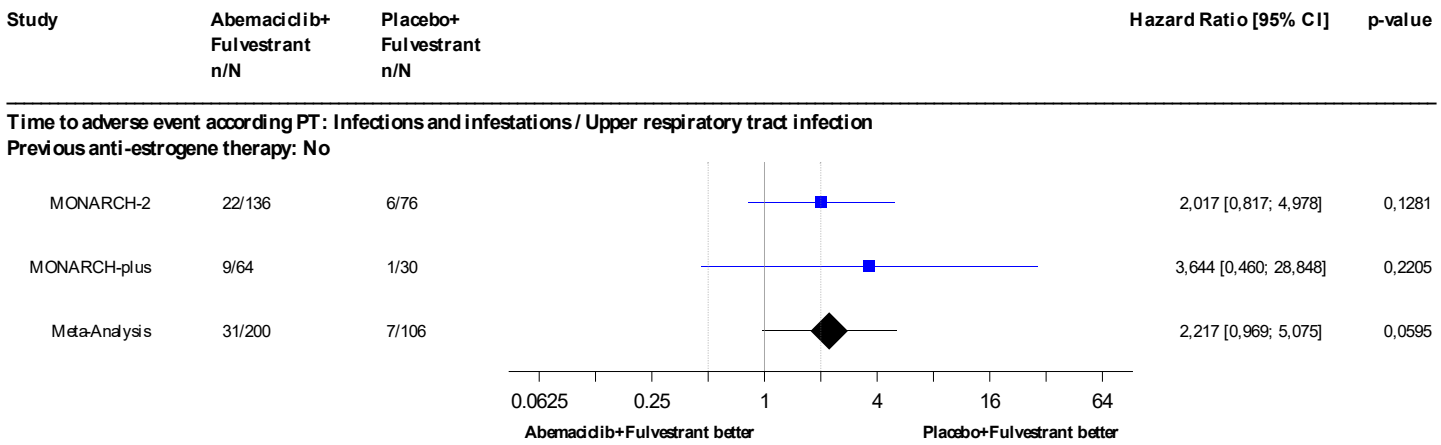
Figure 1188.1.9.1: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2639, p-value=0,6074, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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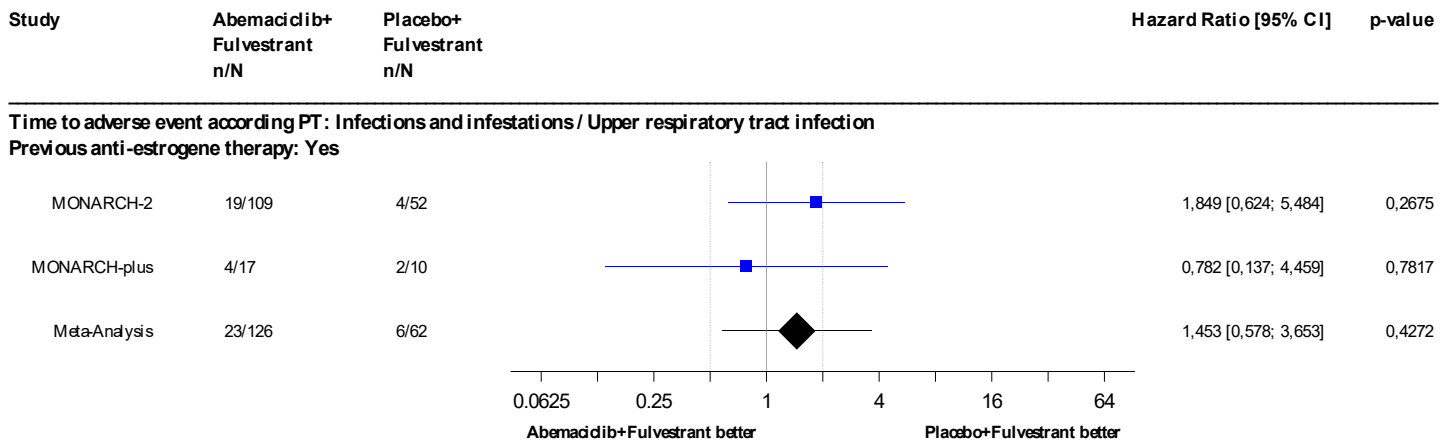
Figure 1188.1.9.2: Metaanalysis results for adverse events according PT[1] -
Infections and infestations / Upper respiratory tract infection
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6761, p-value=0,4109, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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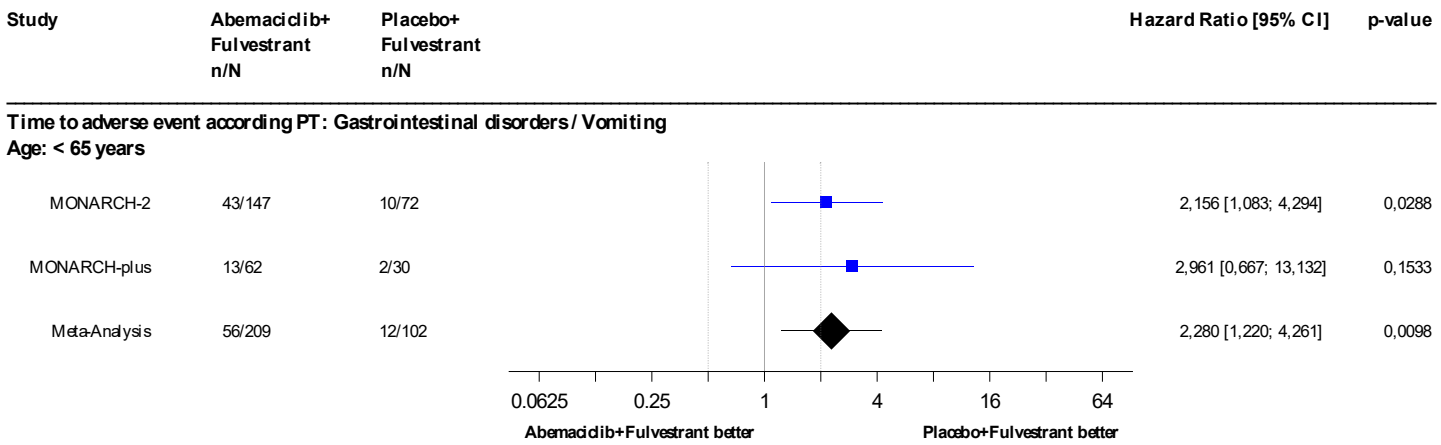
Figure 1191.1.1.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1434, p-value=0,7050, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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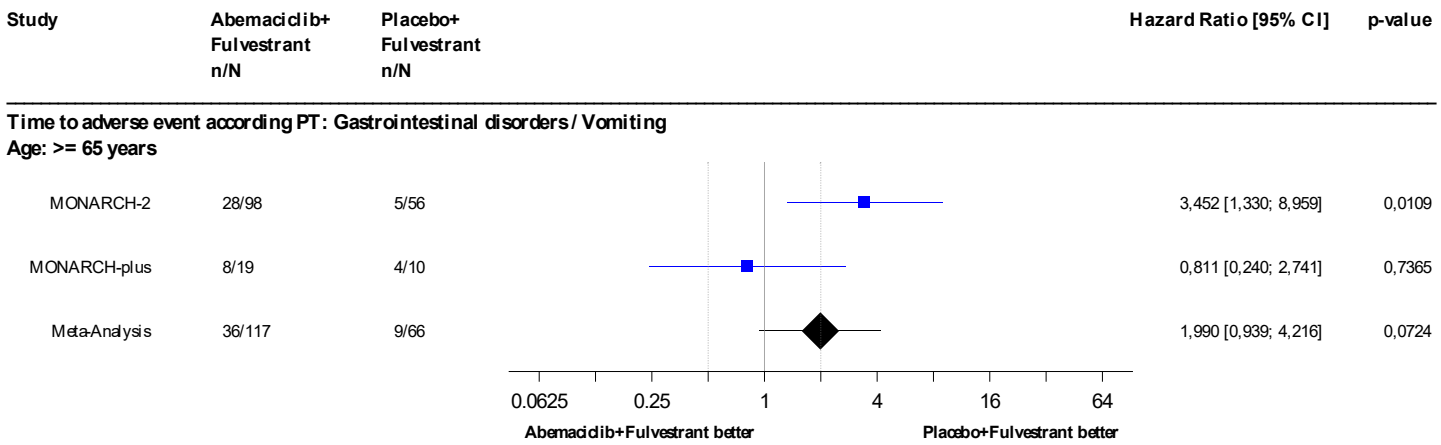
Figure 1191.1.1.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=3,3684, p-value=0,0665, I2 index=70,3%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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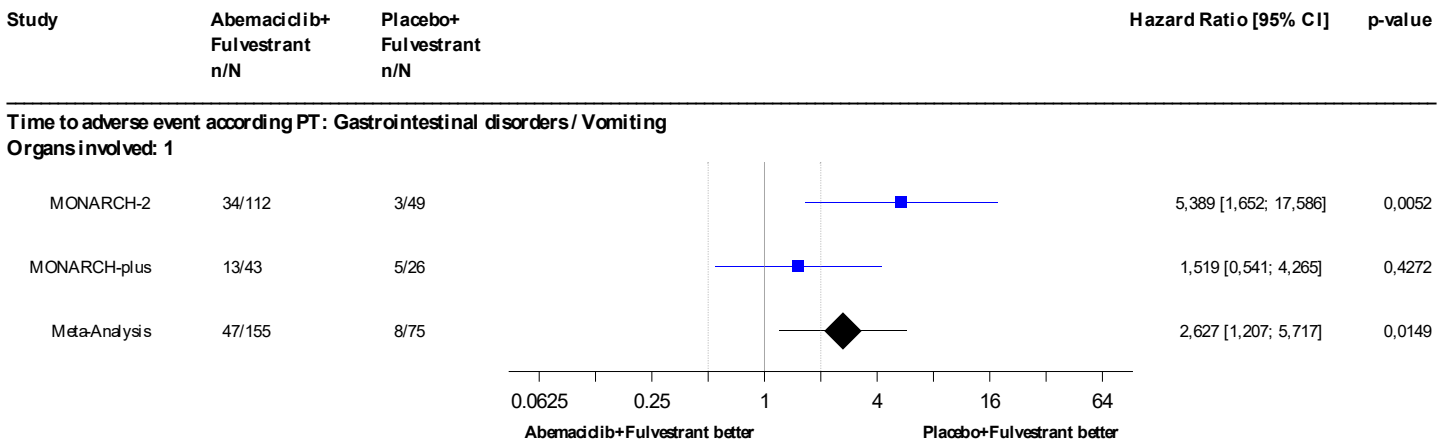
Figure 1191.1.2.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,4994, p-value=0,1139, I2 index=60,0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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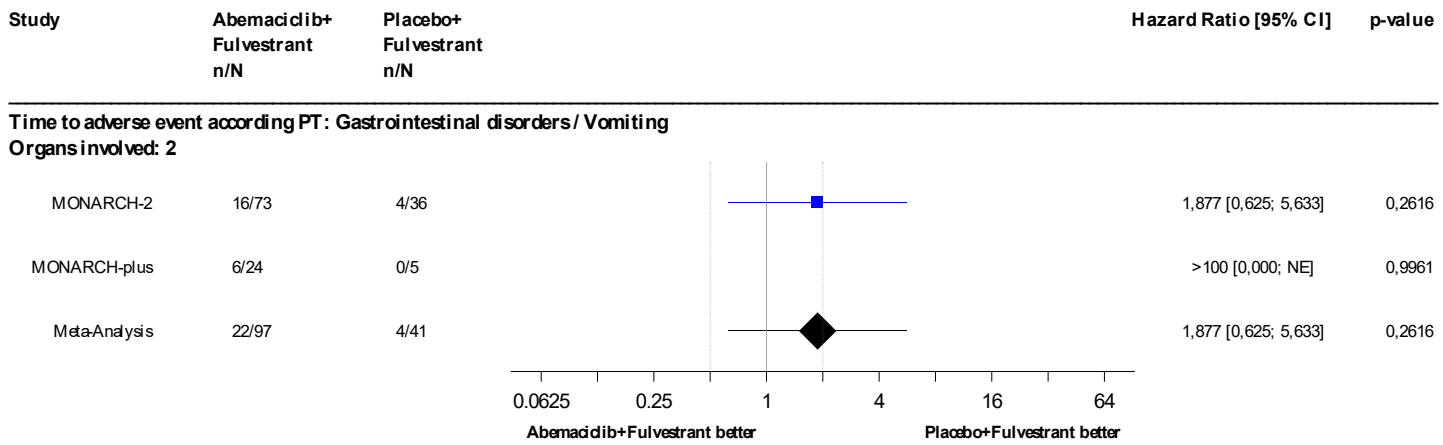
Figure 1191.1.2.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9962, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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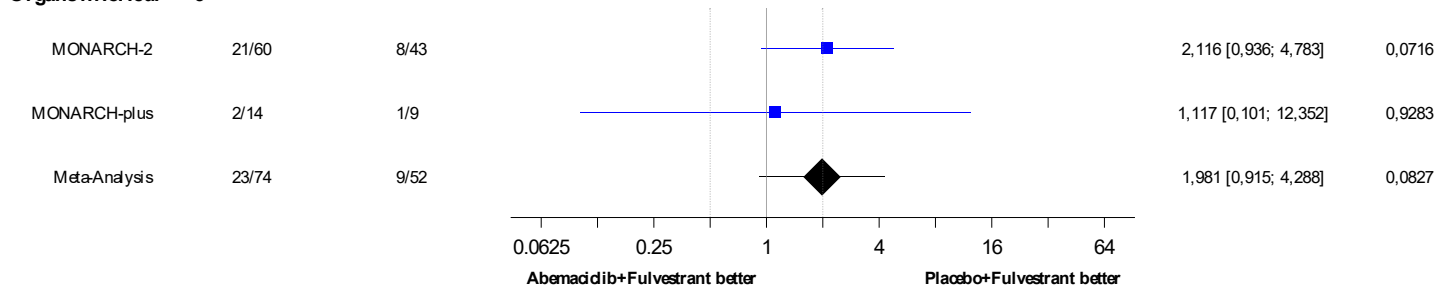
Figure 1191.1.2.3: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2438, p-value=0,6215, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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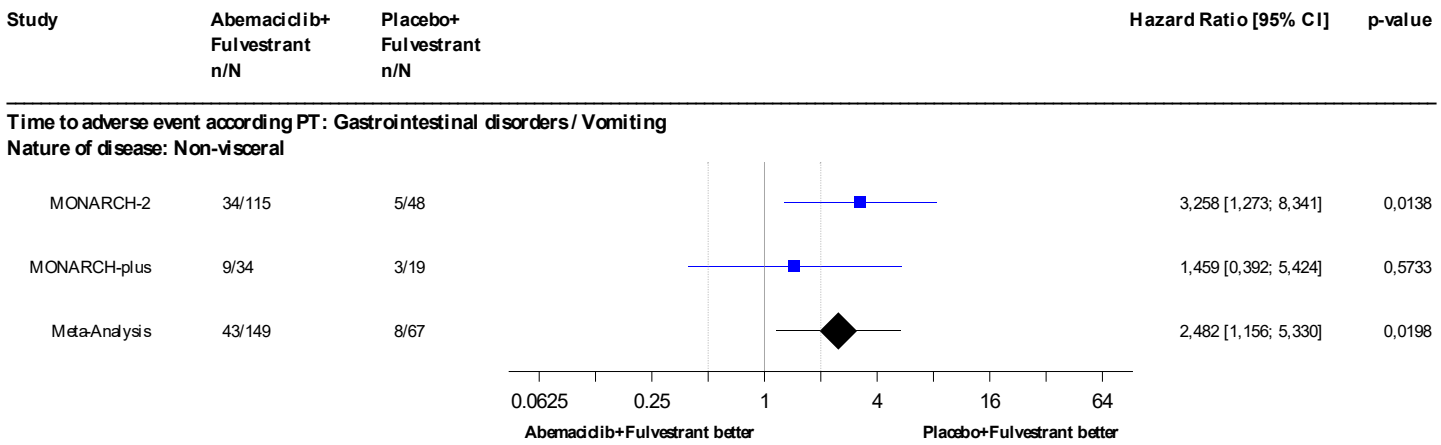
Figure 1191.1.3.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,9513, p-value=0,3294, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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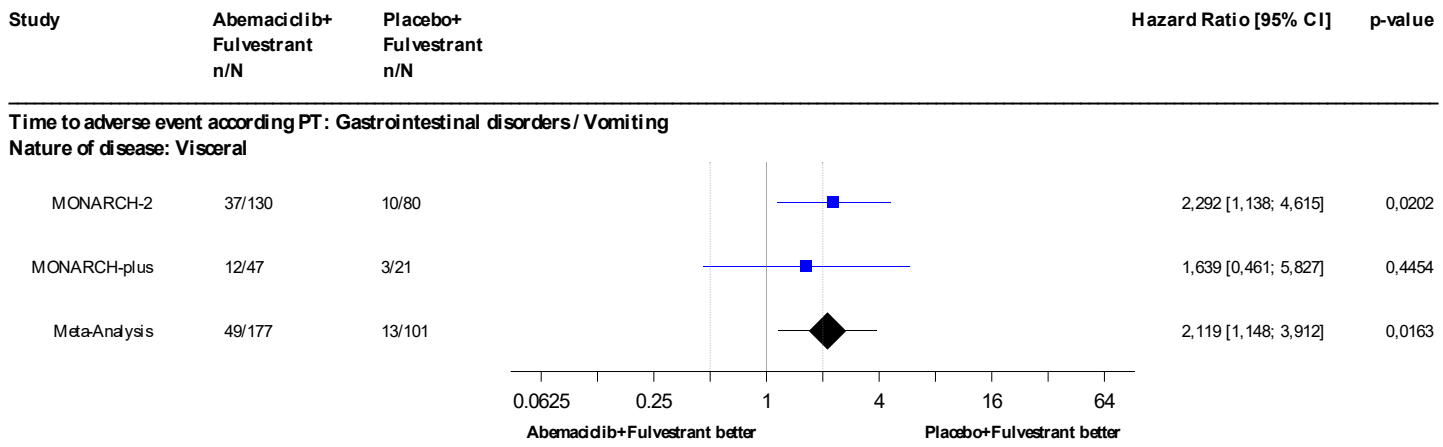
Figure 1191.1.3.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2058, p-value=0,6501, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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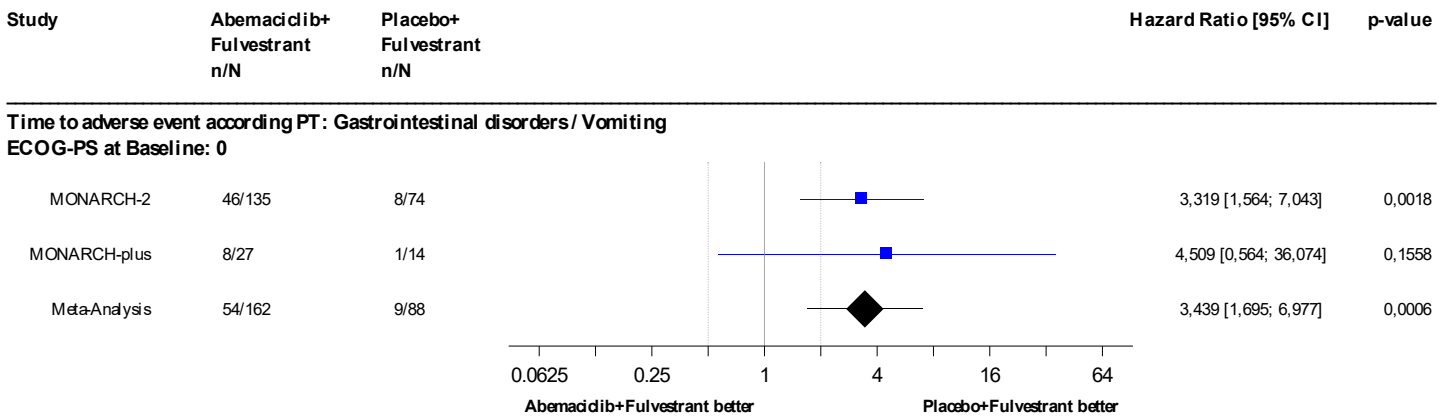
Figure 1191.1.4.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0738, p-value=0,7860, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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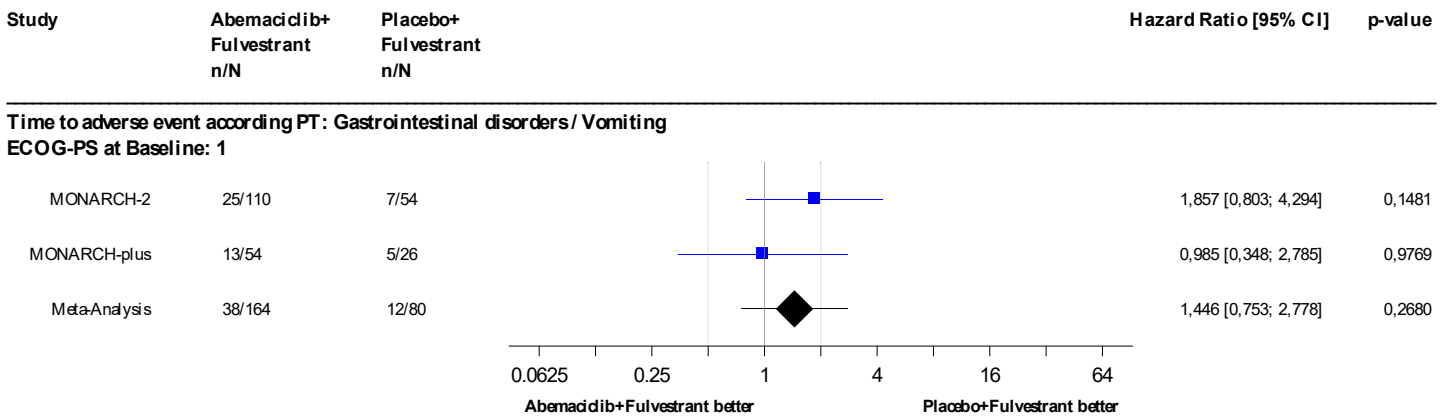
Figure 1191.1.4.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,8660, p-value=0,3521, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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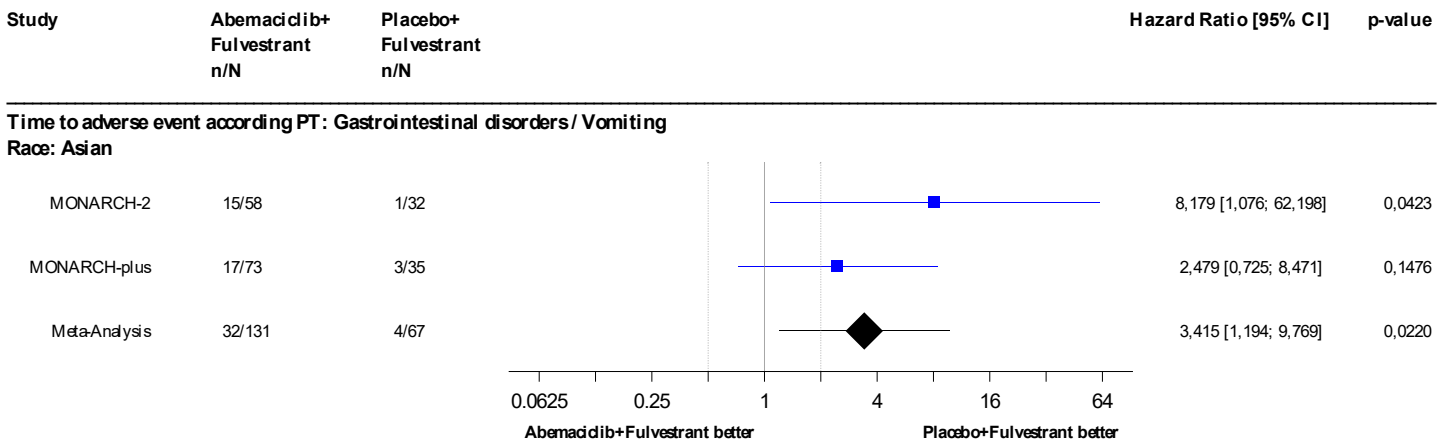
Figure 1191.1.5.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,9732, p-value=0,3239, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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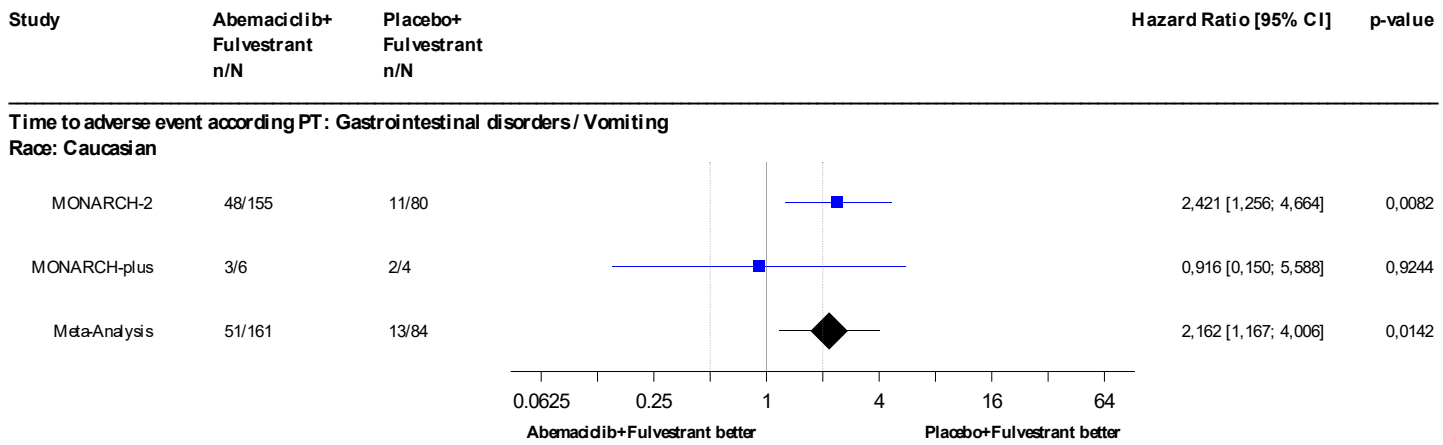
Figure 1191.1.5.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,9803, p-value=0,3221, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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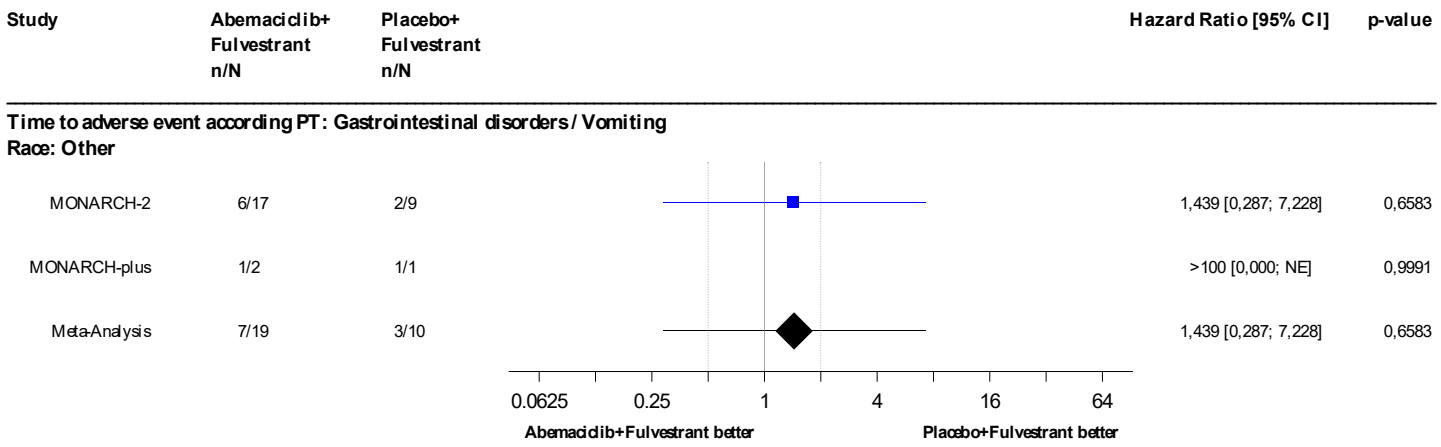
Figure 1191.1.5.3: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9991, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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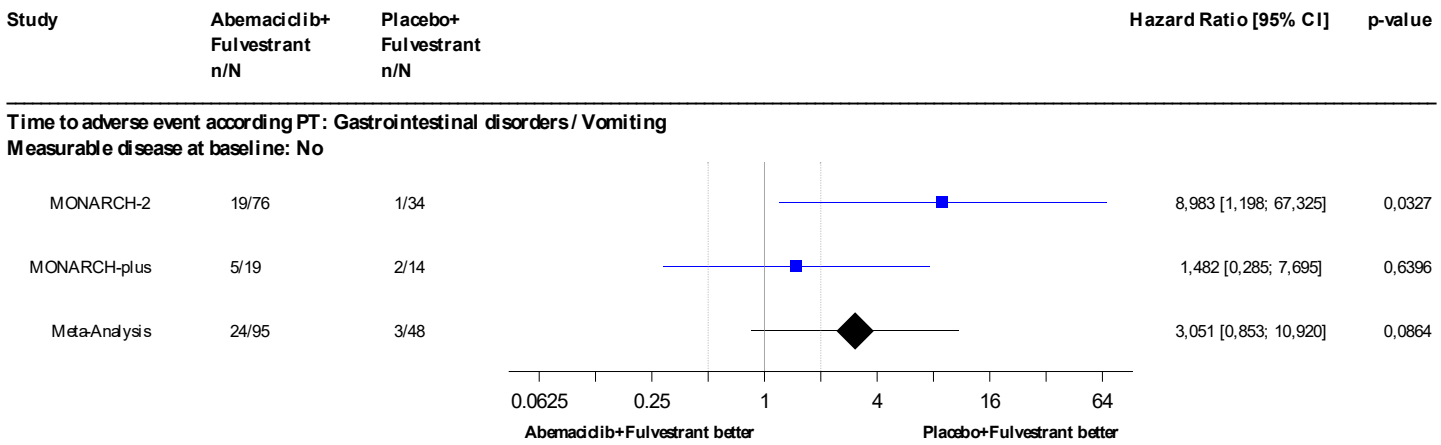
Figure 1191.1.6.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,8422, p-value=0,1747, I2 index=45,7%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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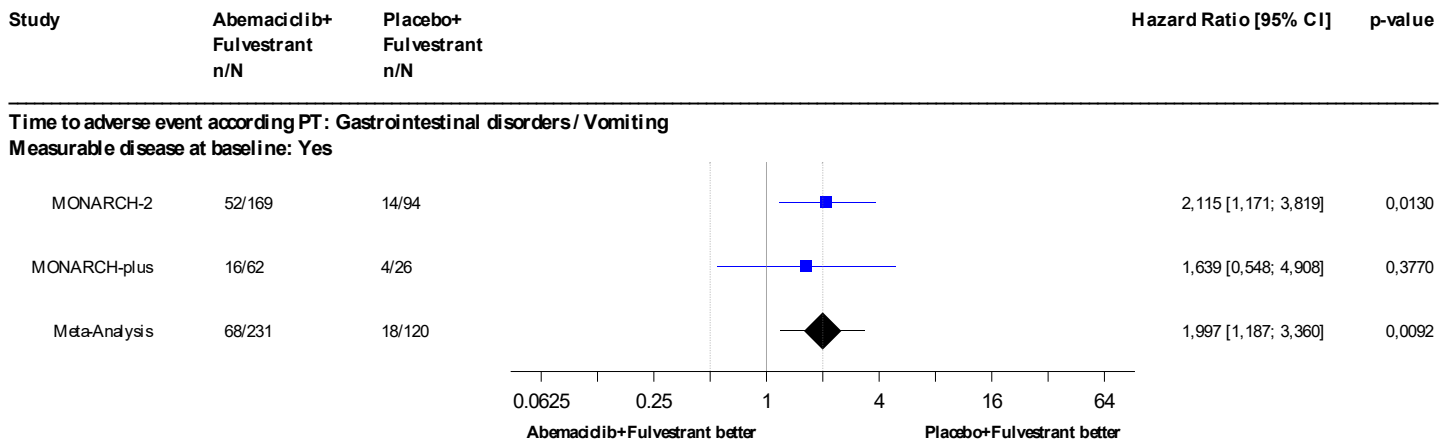
Figure 1191.1.6.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1606, p-value=0,6886, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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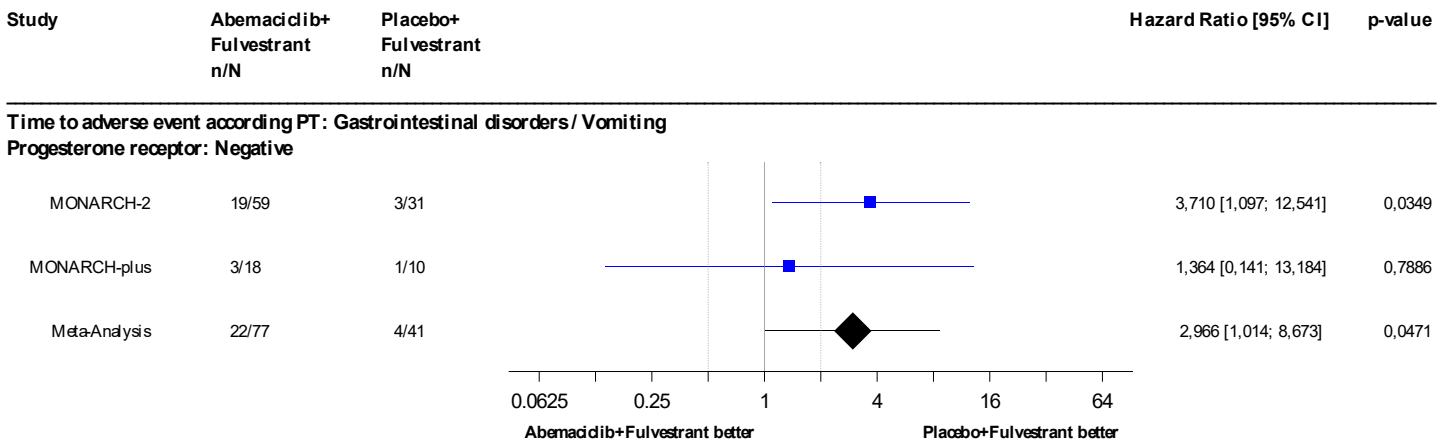
Figure 1191.1.7.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5800, p-value=0,4463, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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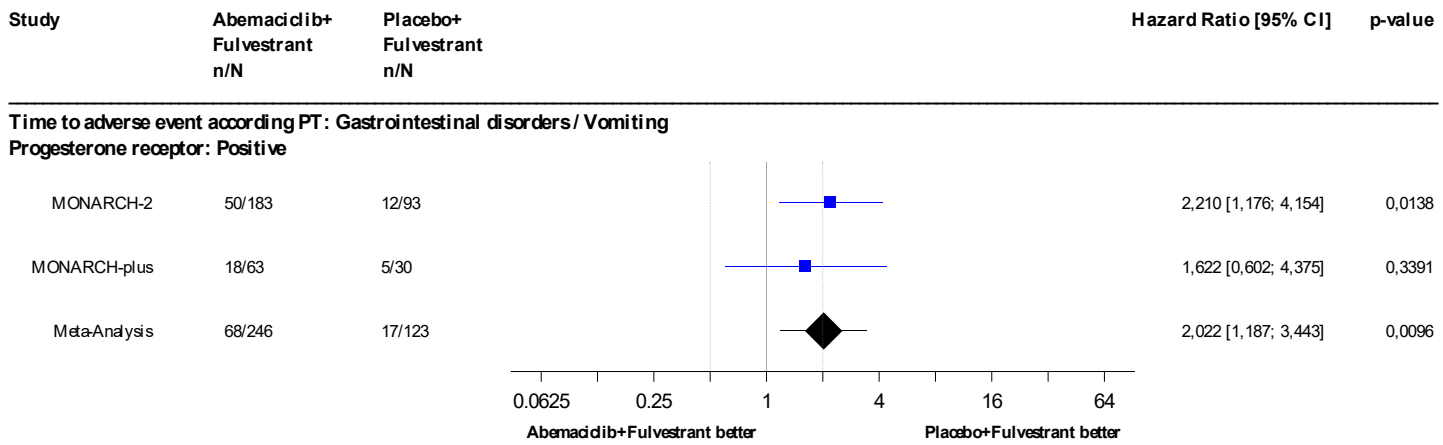
Figure 1191.1.7.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2656, p-value=0,6063, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep091_popa1_pgrstat_2.rtf
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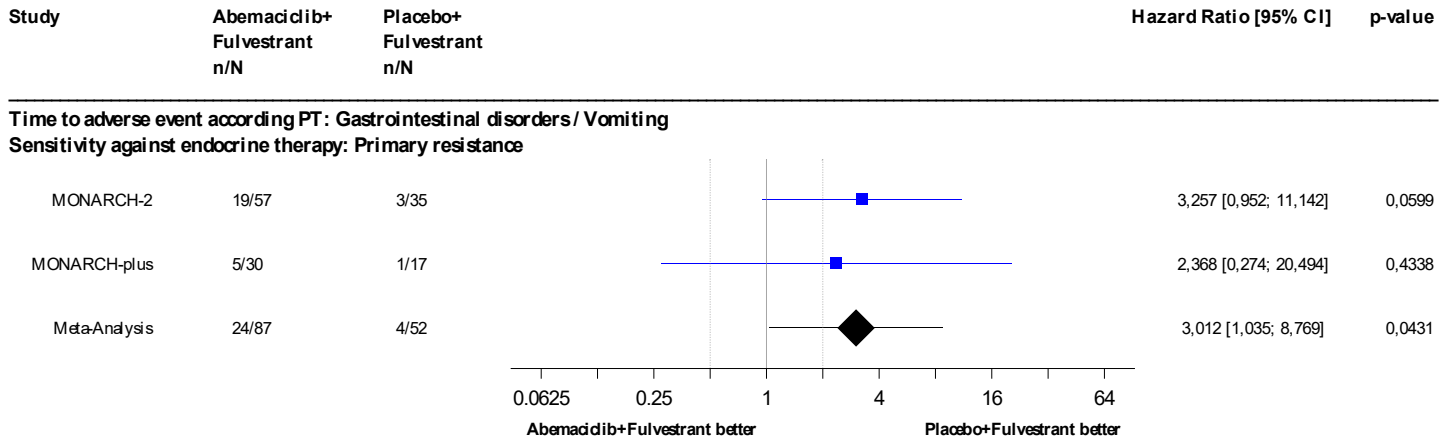
Figure 1191.1.8.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0633, p-value=0,8013, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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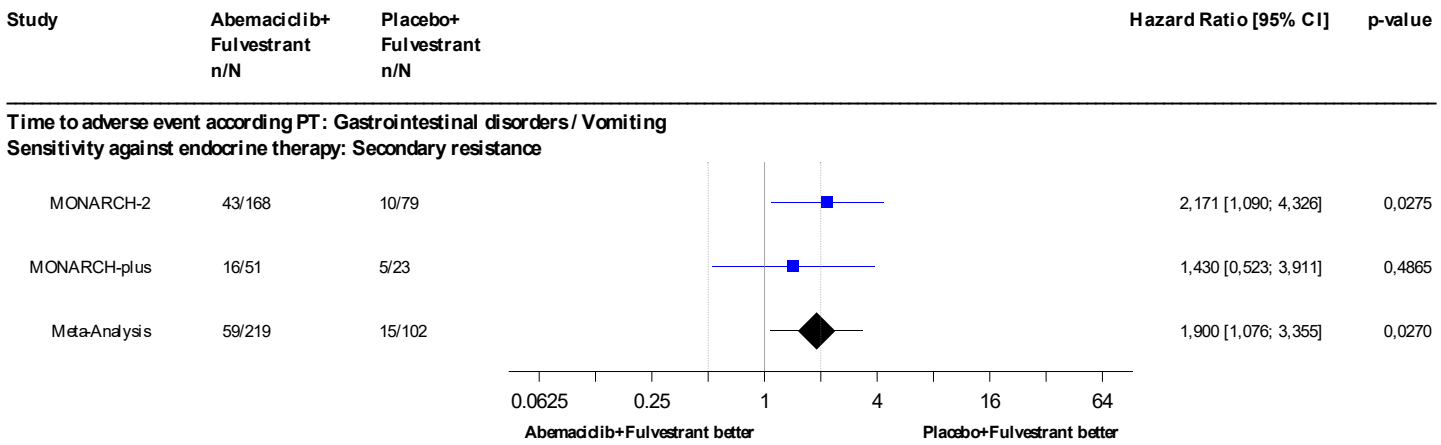
Figure 1191.1.8.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4508, p-value=0,5019, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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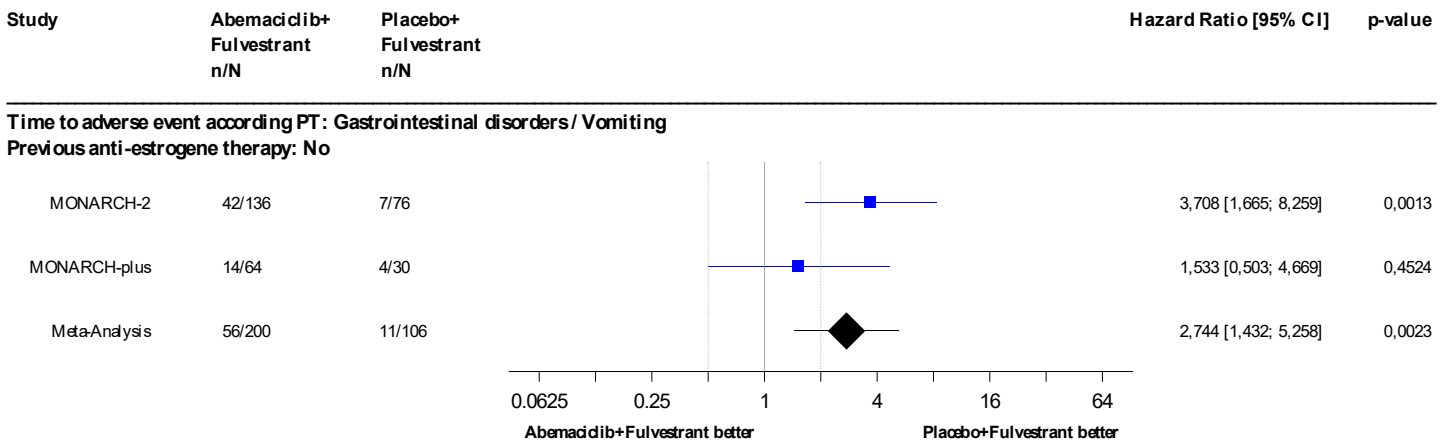
Figure 1191.1.9.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,5933, p-value=0,2069, I2 index=37,2%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep091_popa1_paet_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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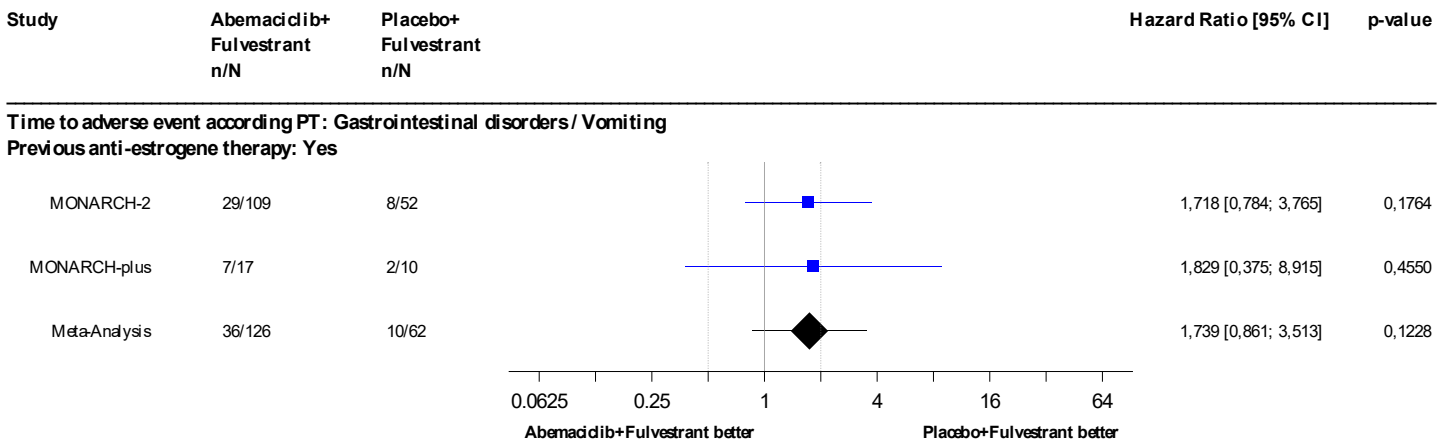
Figure 1191.1.9.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0048, p-value=0,9446, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep091_popa1_paet_2.rtf
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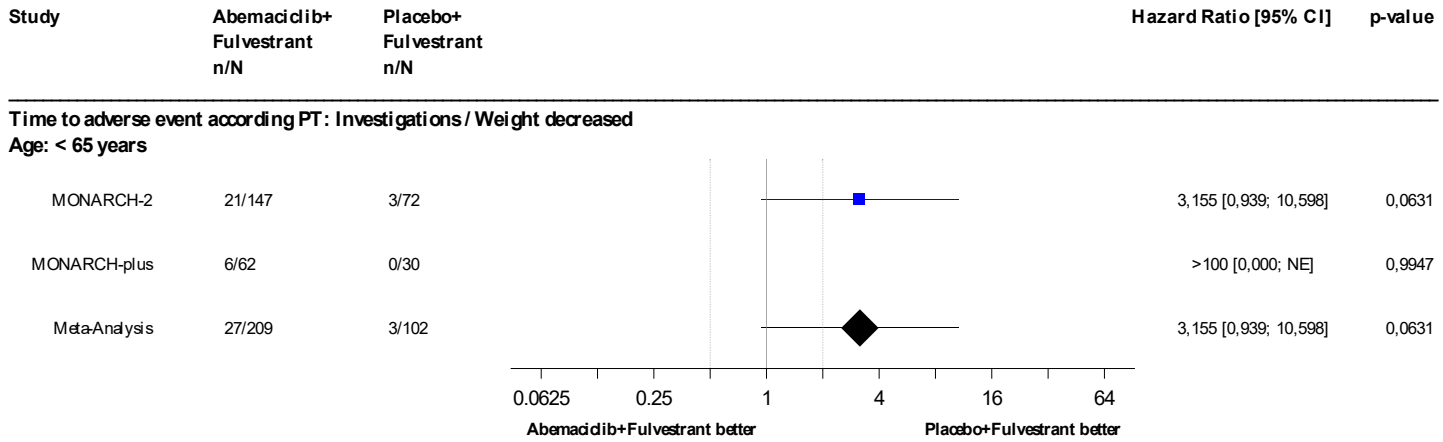
Figure 1192.1.1.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Weight decreased
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9951, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep092_popa1_agegr1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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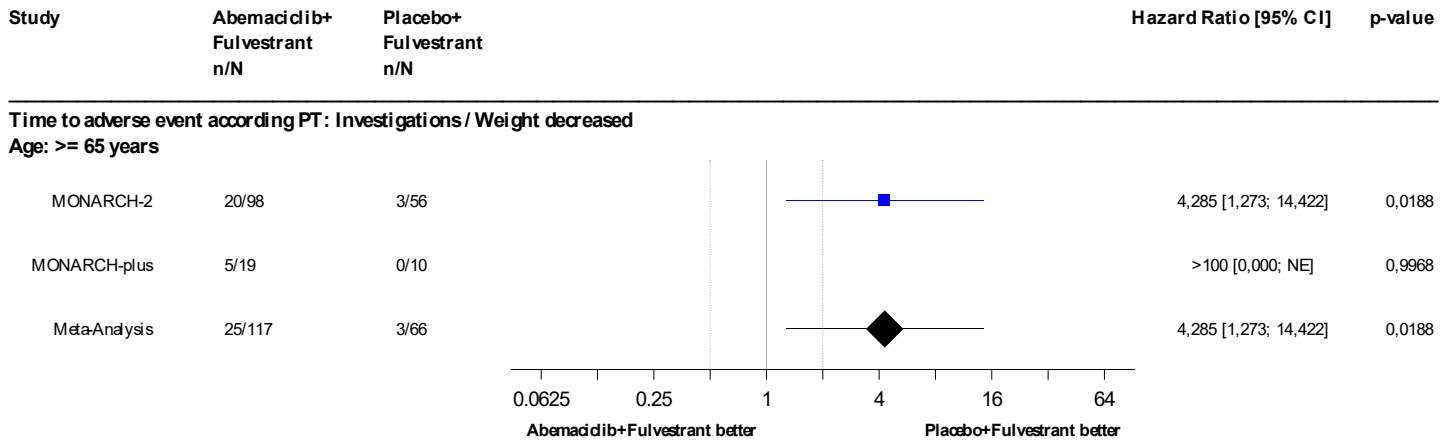
Figure 1192.1.1.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Weight decreased
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9970, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep092_popa1_agegr1_2.rtf
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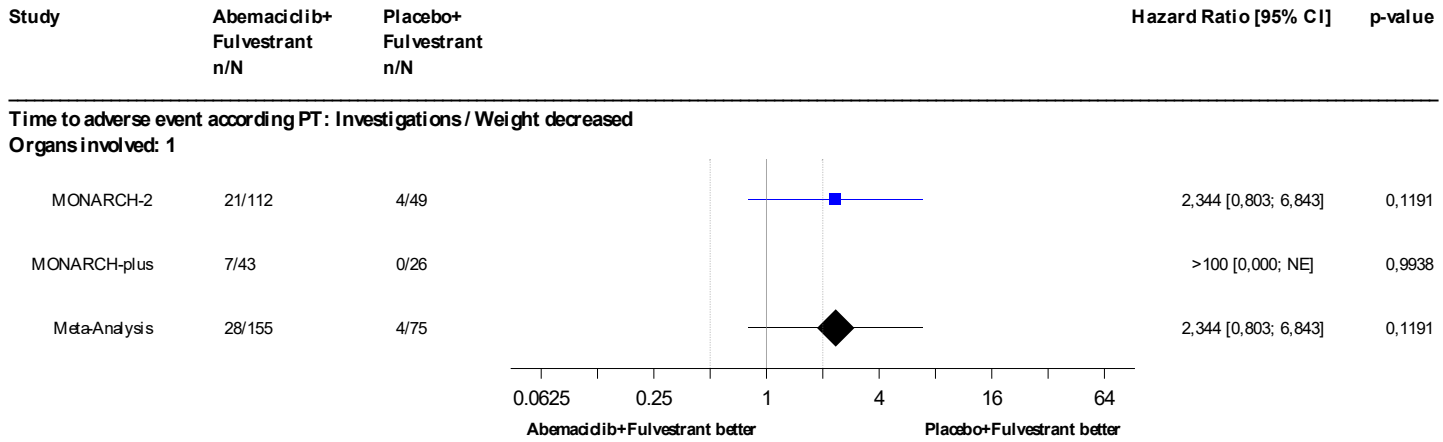
Figure 1192.1.2.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Weight decreased
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9942, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep092_popa1_norggr_1.rtf
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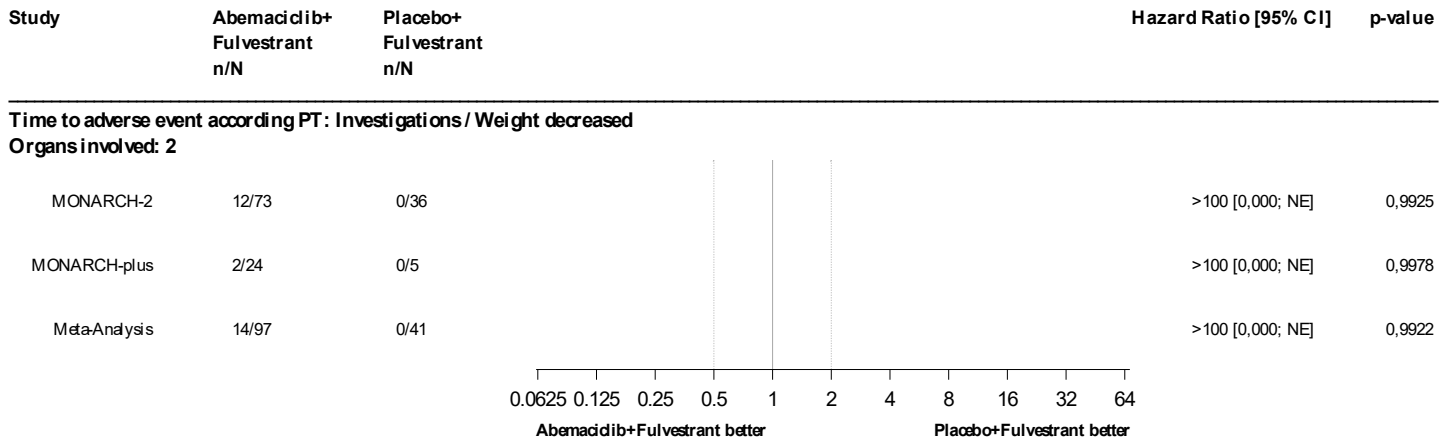
Figure 1192.1.2.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Weight decreased
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep092_popa1_norggr_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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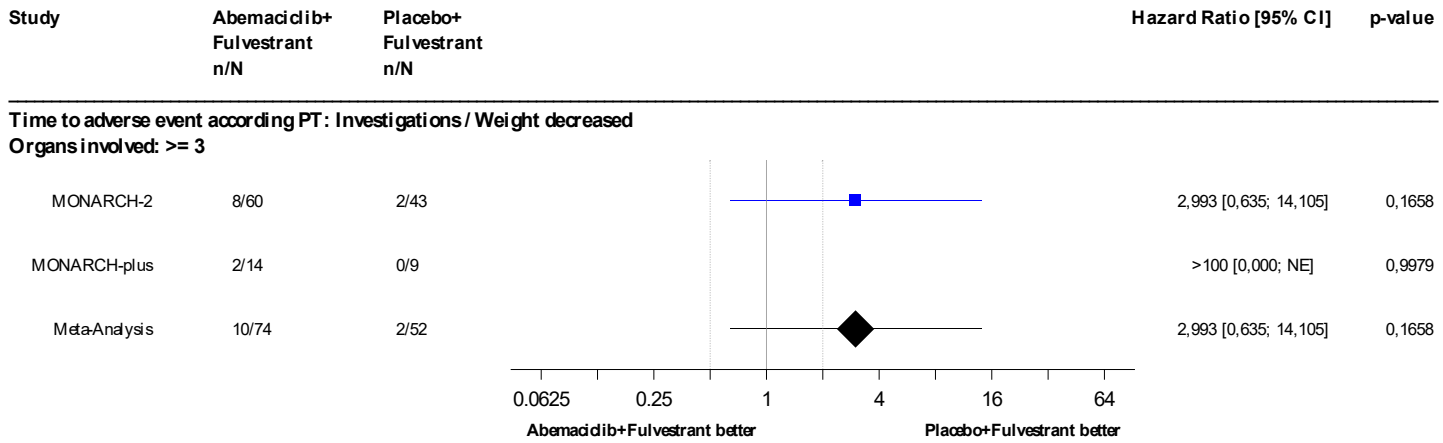
Figure 1192.1.2.3: Metaanalysis results for adverse events according PT[1] -
Investigations / Weight decreased
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep092_popa1_norggr_3.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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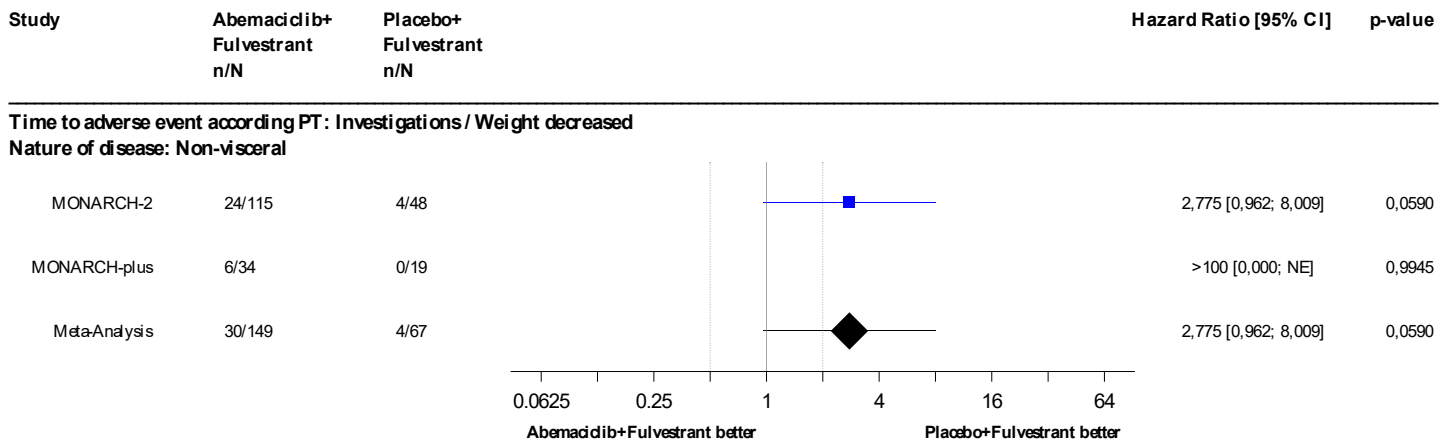
Figure 1192.1.3.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Weight decreased
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9948, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep092_popa1_natdis2_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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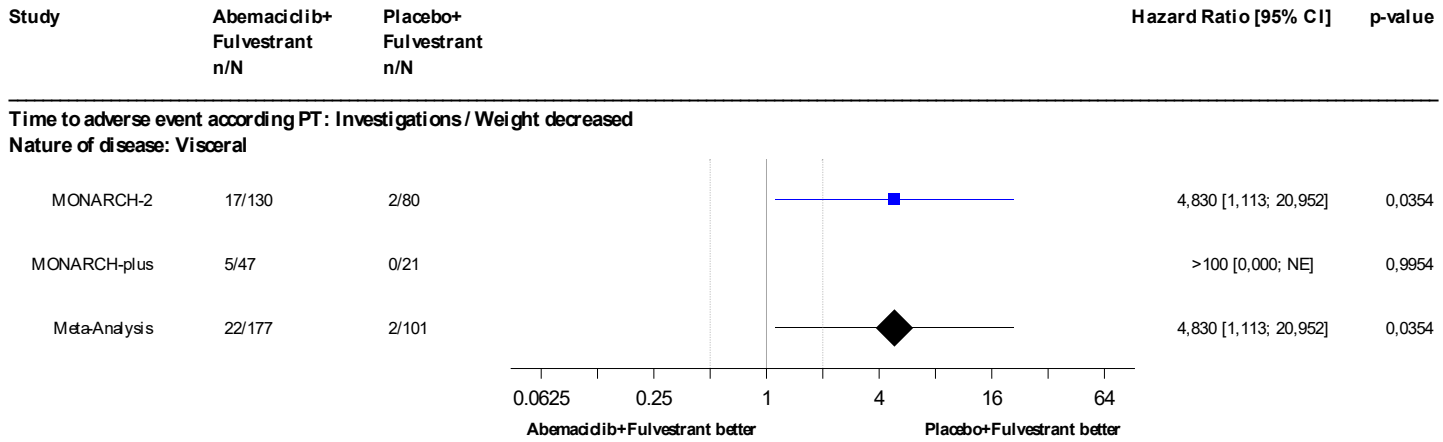
Figure 1192.1.3.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Weight decreased
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9958, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep092_popa1_natdis2_2.rtf
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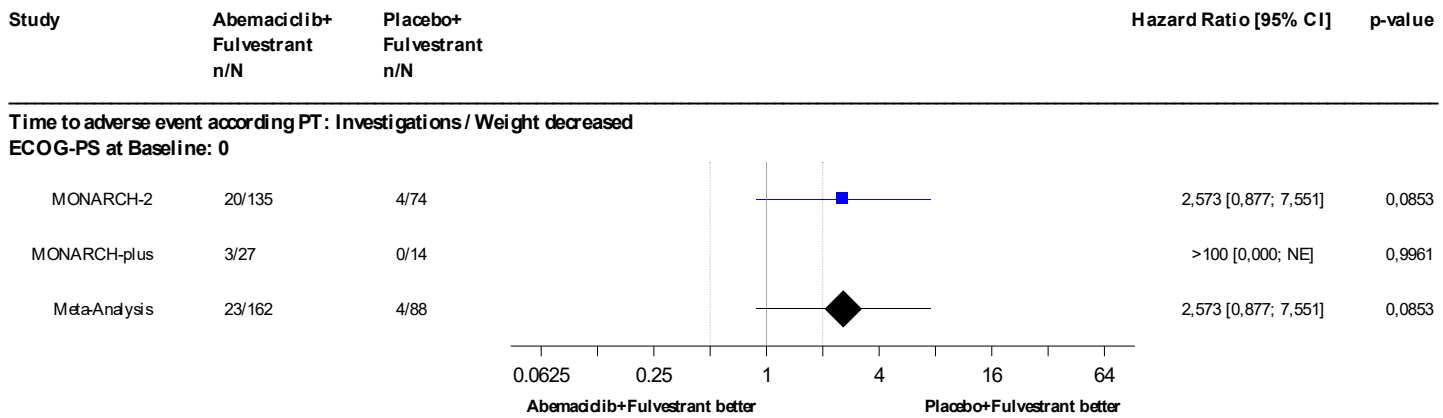
Figure 1192.1.4.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Weight decreased
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9963, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep092_popa1_ecogbl_1.rtf
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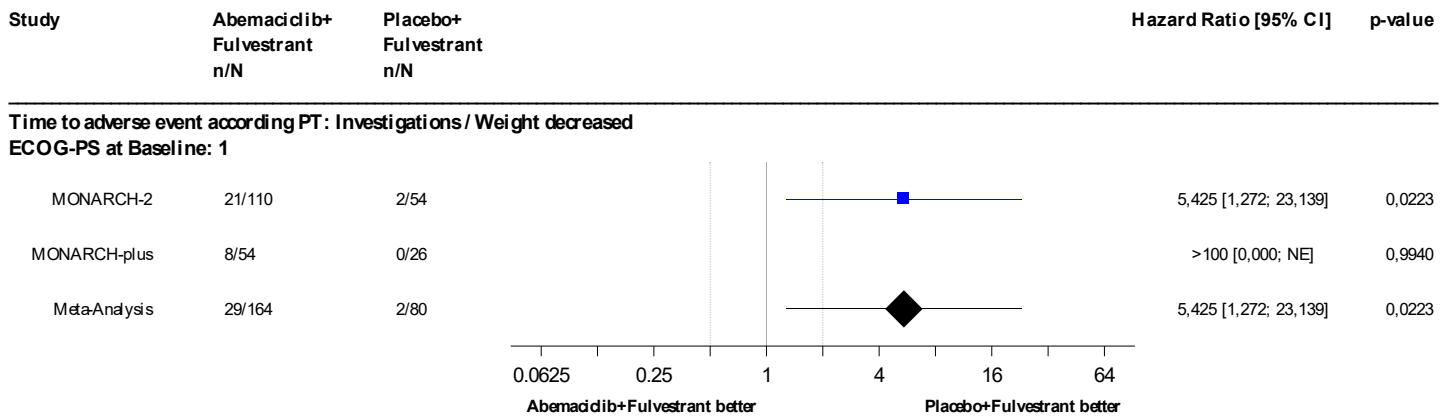
Figure 1192.1.4.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Weight decreased
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9946, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep092_popa1_ecogbl_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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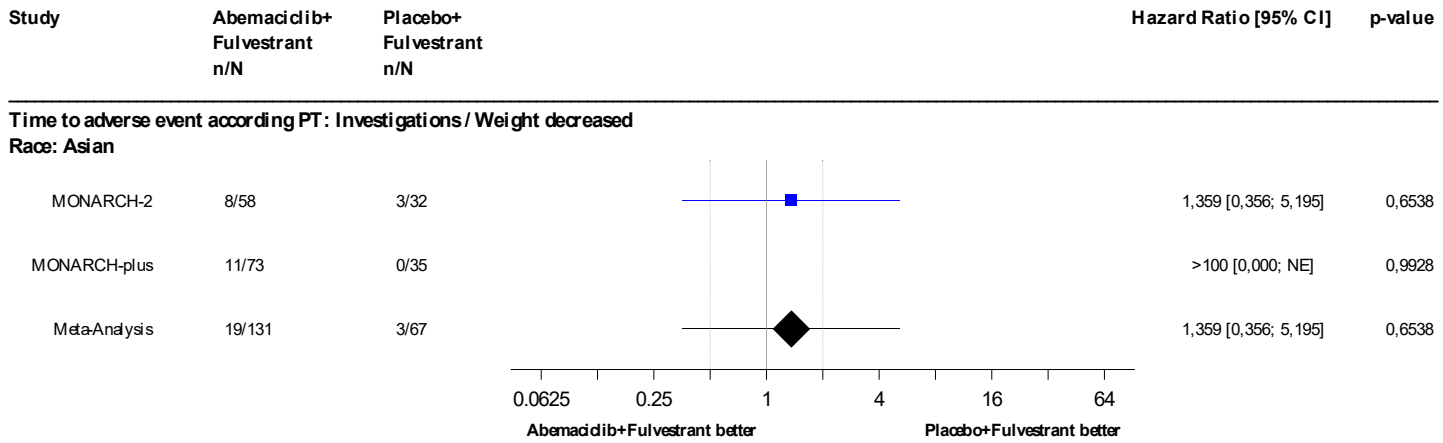
Figure 1192.1.5.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Weight decreased
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9930, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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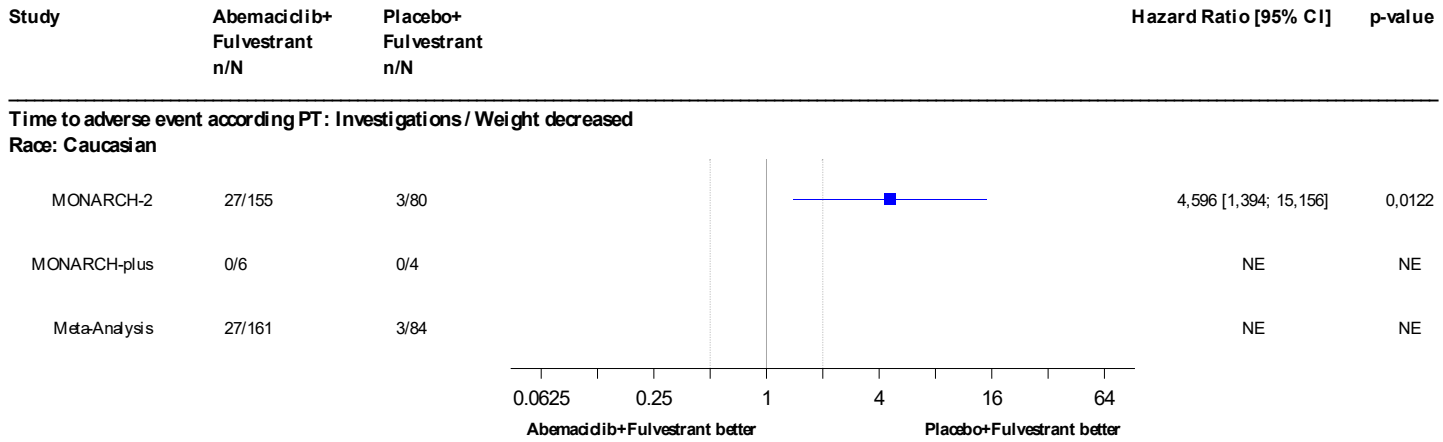
**Figure 1192.1.5.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Weight decreased
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep092_popa1_racegr1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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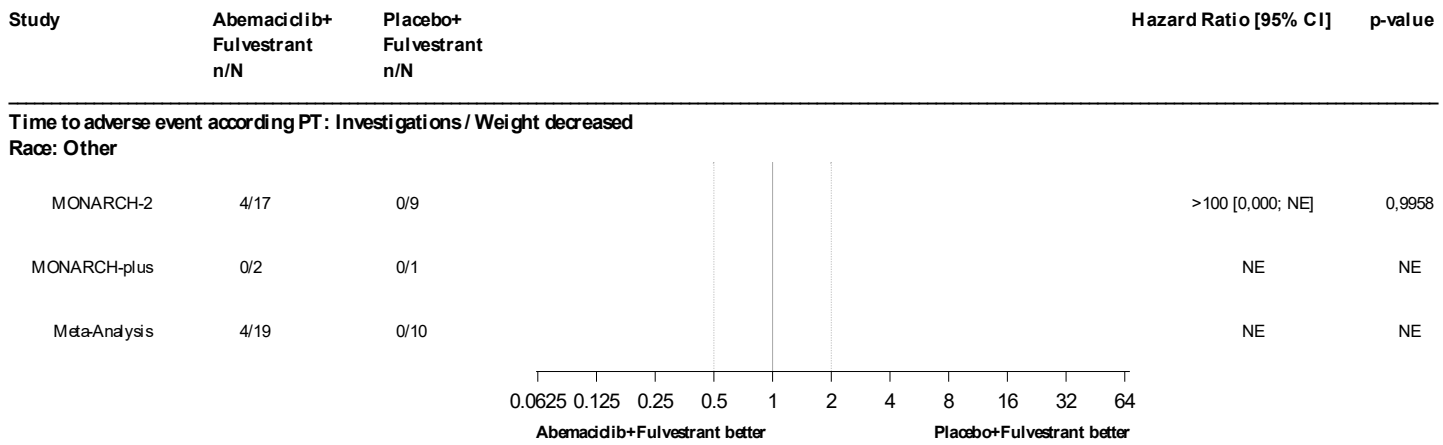
Figure 1192.1.5.3: Metaanalysis results for adverse events according PT[1] -
Investigations / Weight decreased
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep092_popa1_racegr1_3.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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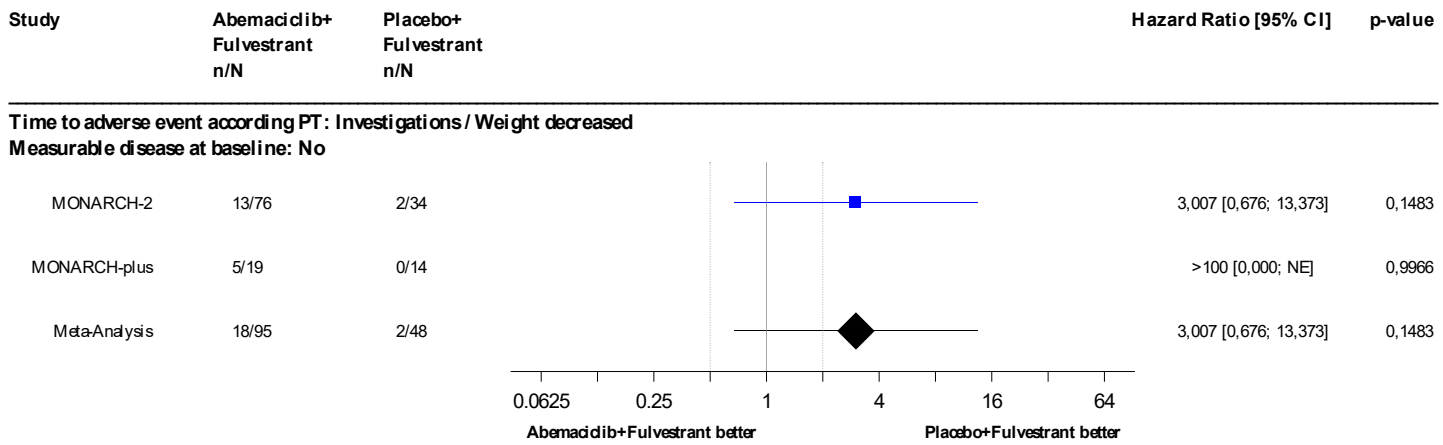
Figure 1192.1.6.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Weight decreased
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9968, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep092_popa1_measdis_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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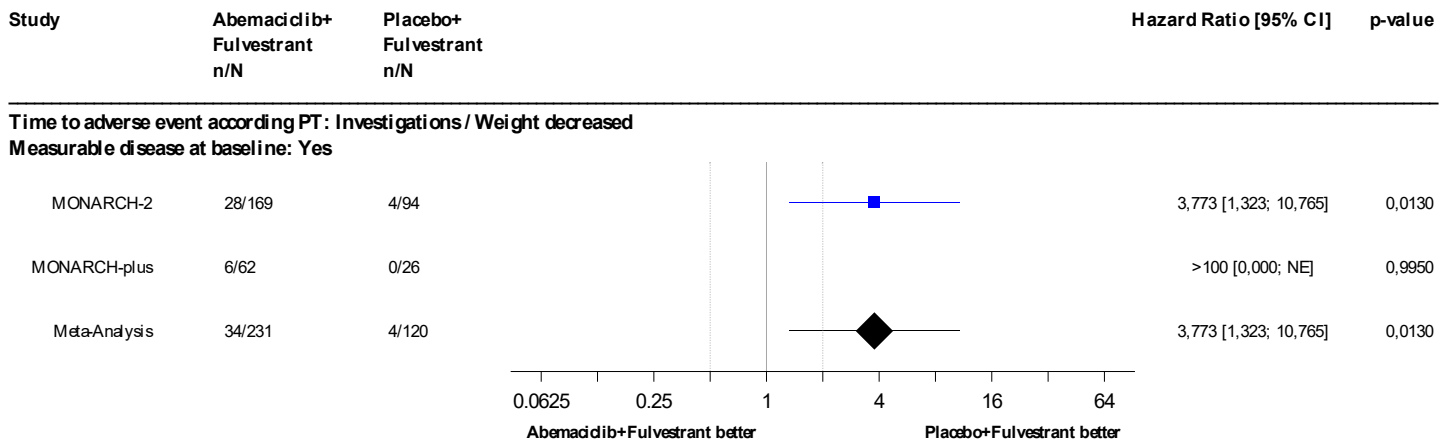
Figure 1192.1.6.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Weight decreased
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9954, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep092_popa1_measdis_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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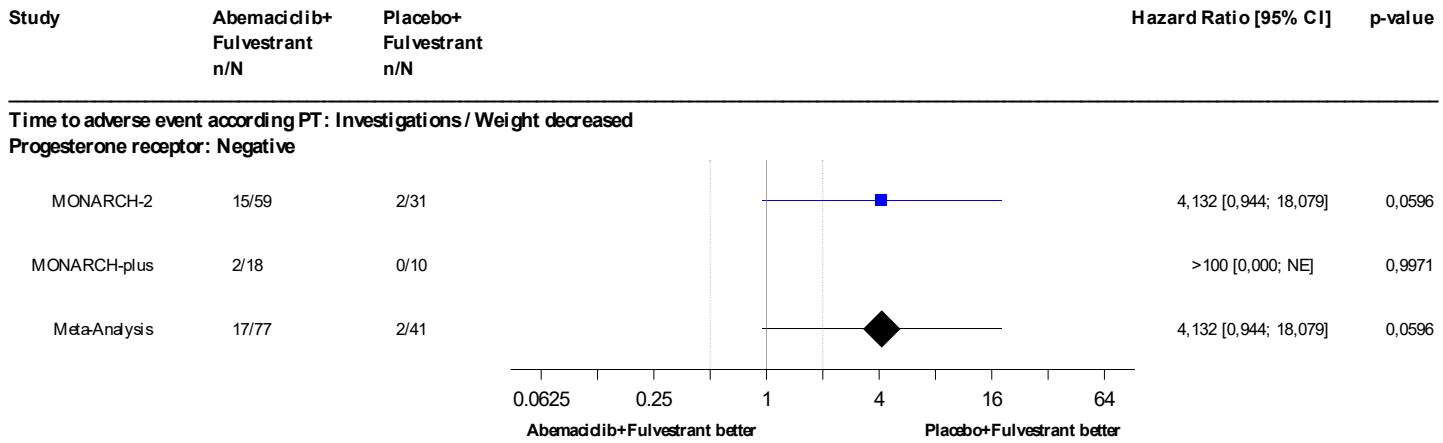
Figure 1192.1.7.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Weight decreased
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9973, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep092_popa1_pgrstat_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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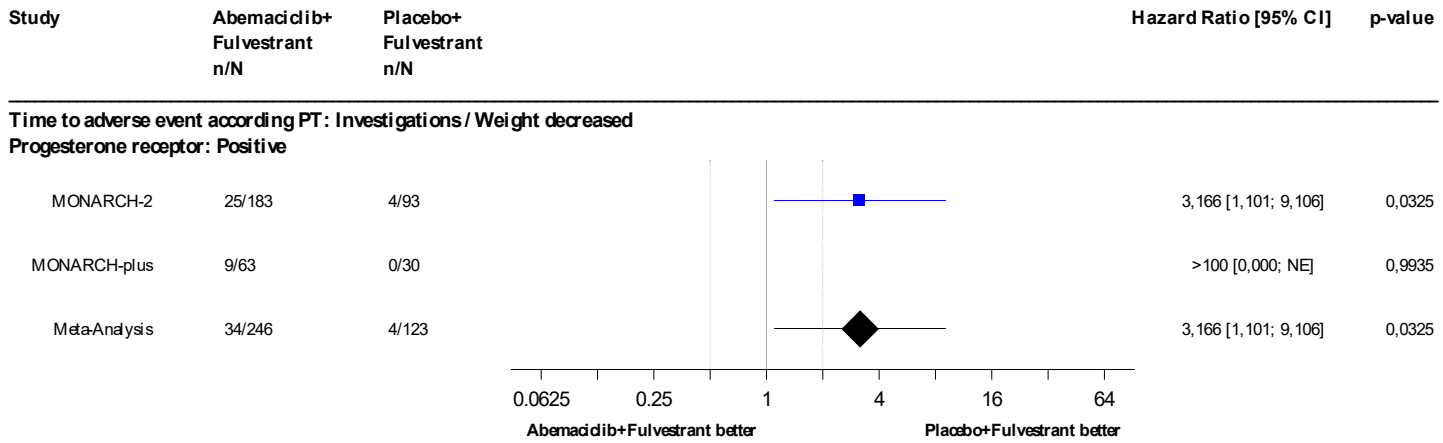
Figure 1192.1.7.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Weight decreased
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9939, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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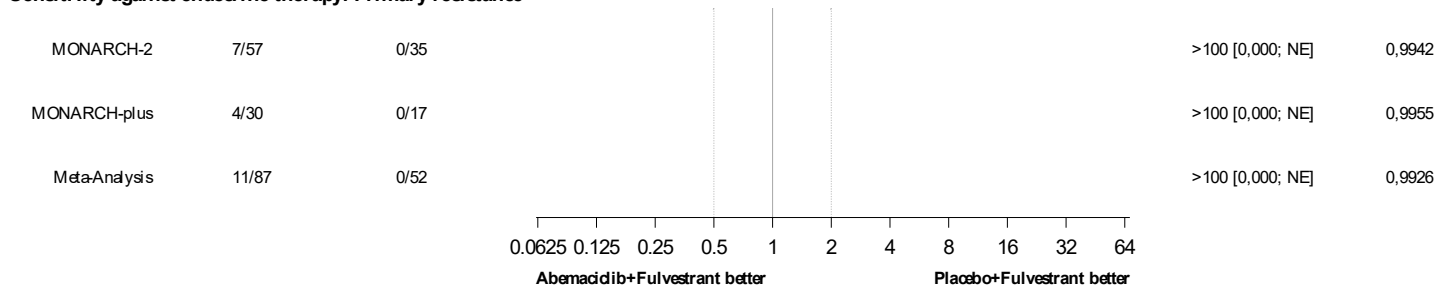
Figure 1192.1.8.1: Metaanalysis results for adverse events according PT[1] - Investigations / Weight decreased
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep092_popa1_snthr_1.rtf
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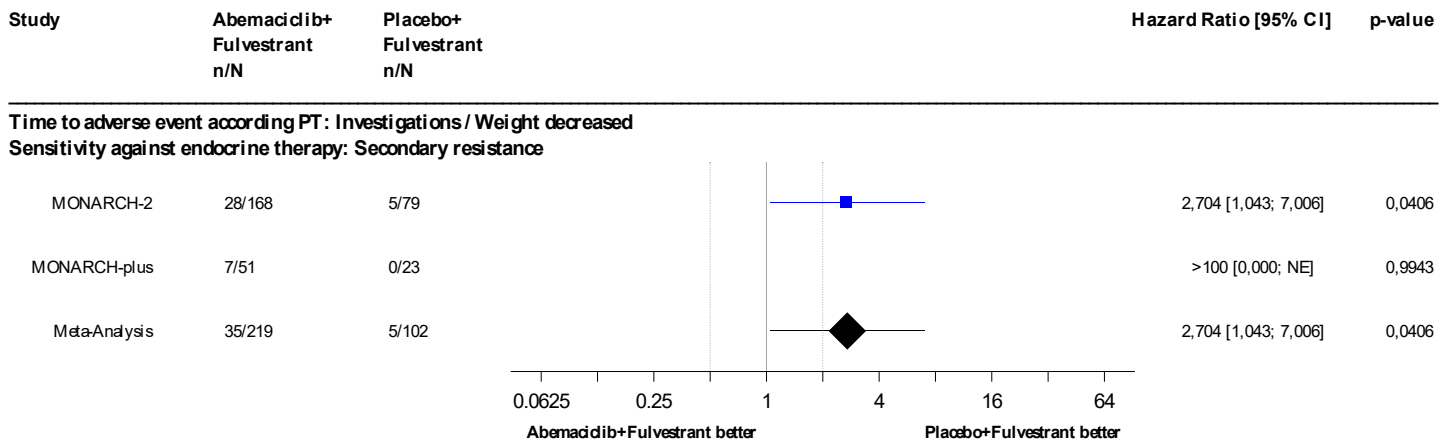
Figure 1192.1.8.2: Metaanalysis results for adverse events according PT[1] - Investigations / Weight decreased
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9947, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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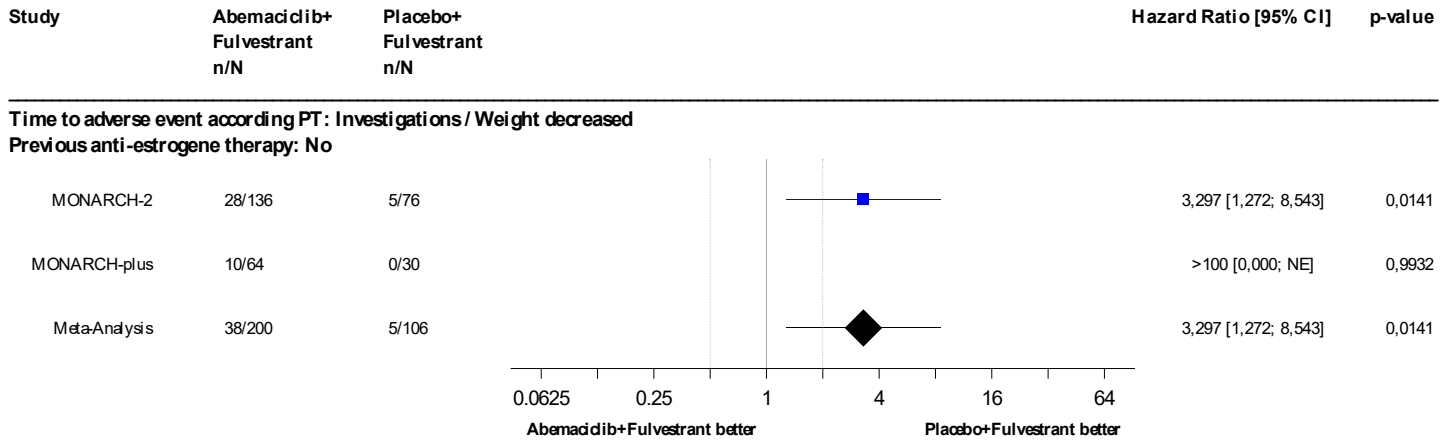
**Figure 1192.1.9.1: Metaanalysis results for adverse events according PT[1] -
Investigations / Weight decreased
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9937, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep092_popa1_paet_1.rtf
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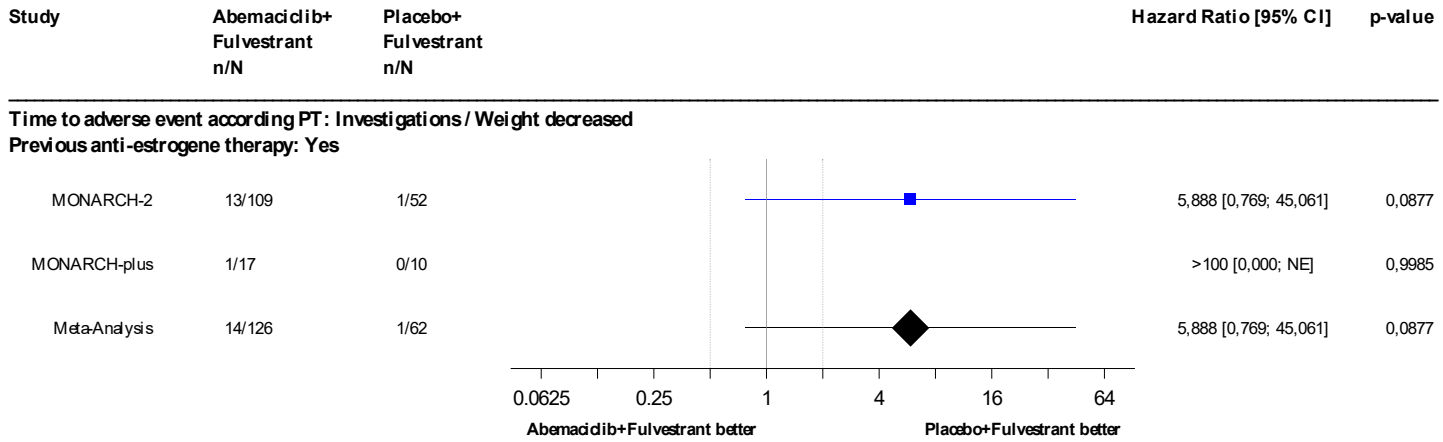
**Figure 1192.1.9.2: Metaanalysis results for adverse events according PT[1] -
Investigations / Weight decreased
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep092_popa1_paet_2.rtf
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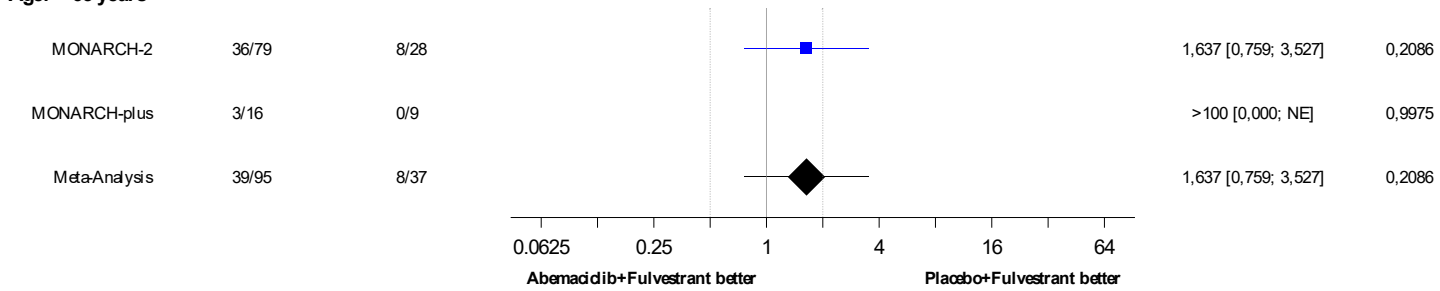
Figure 1195.2.1.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9975, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep002_popa2_agegr1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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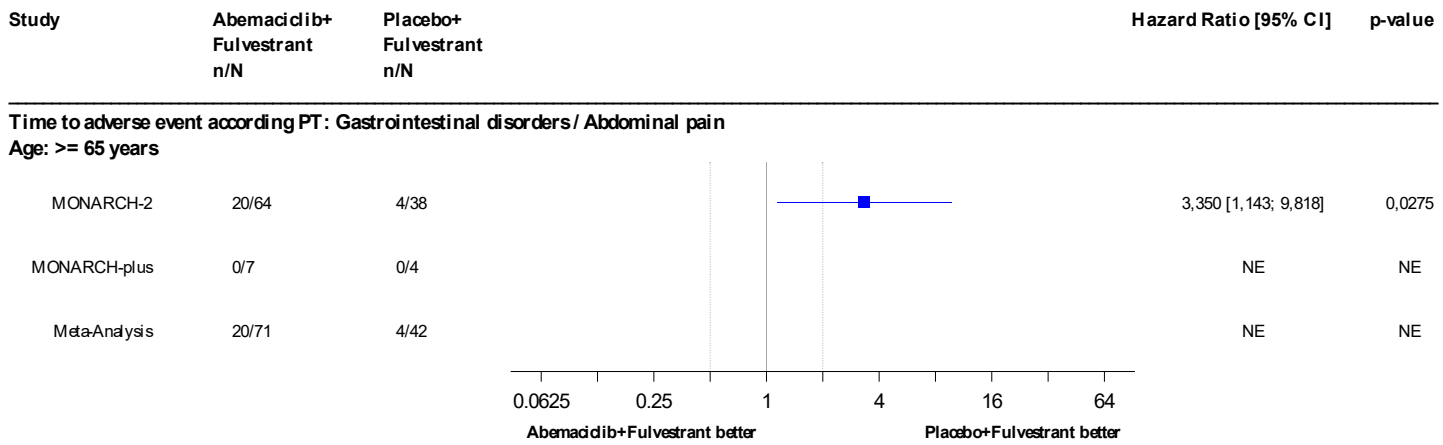
Figure 1195.2.1.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep002_popa2_agegr1_2.rtf
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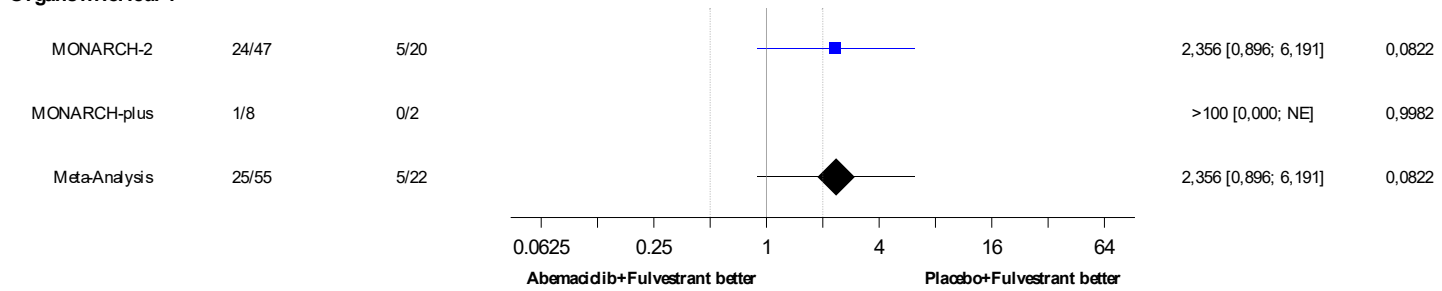
Figure 1195.2.2.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9983, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep002_popa2_norggr_1.rtf
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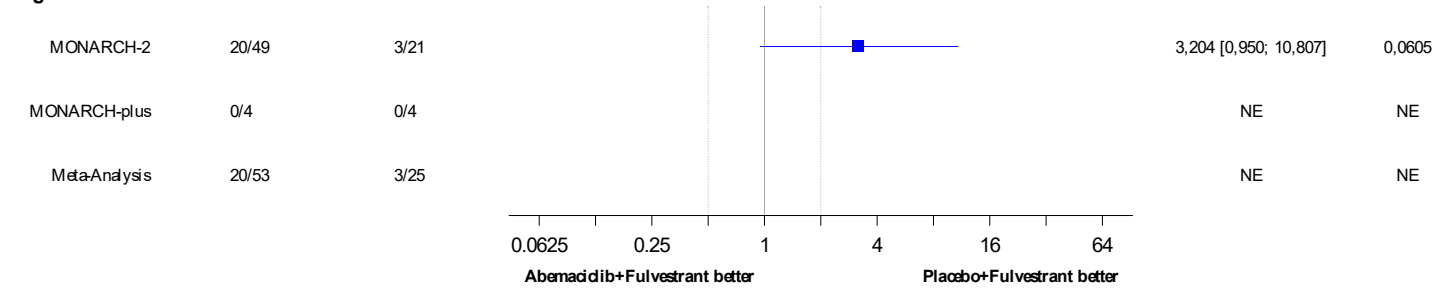
**Figure 1195.2.2.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep002_popa2_norggr_2.rtf
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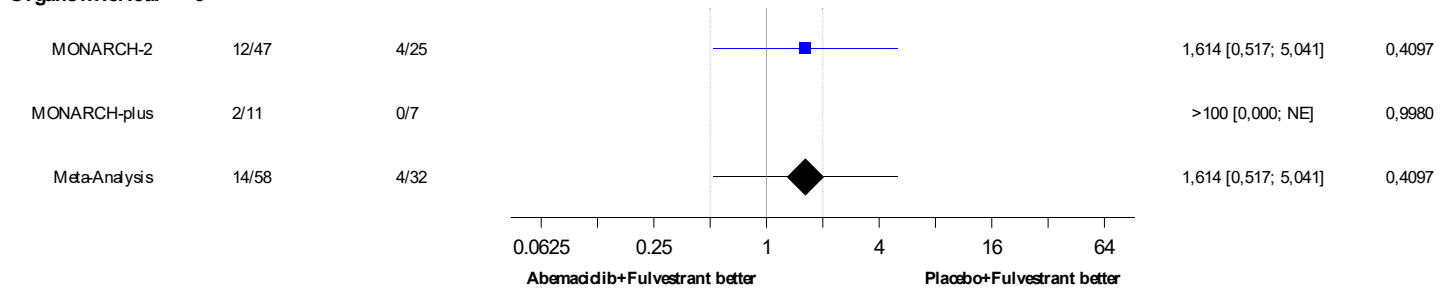
Figure 1195.2.2.3: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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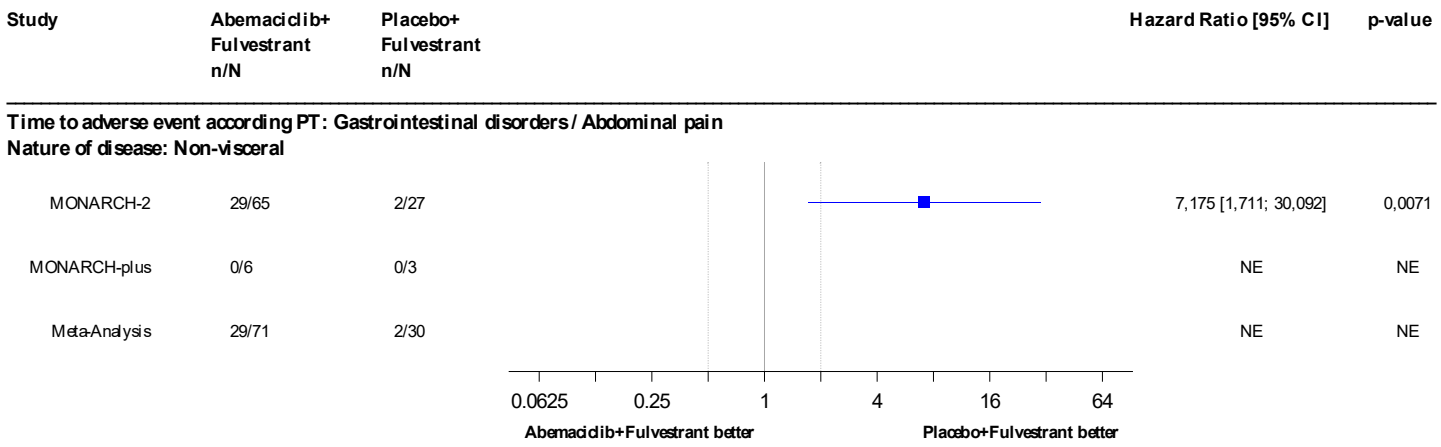
Figure 1195.2.3.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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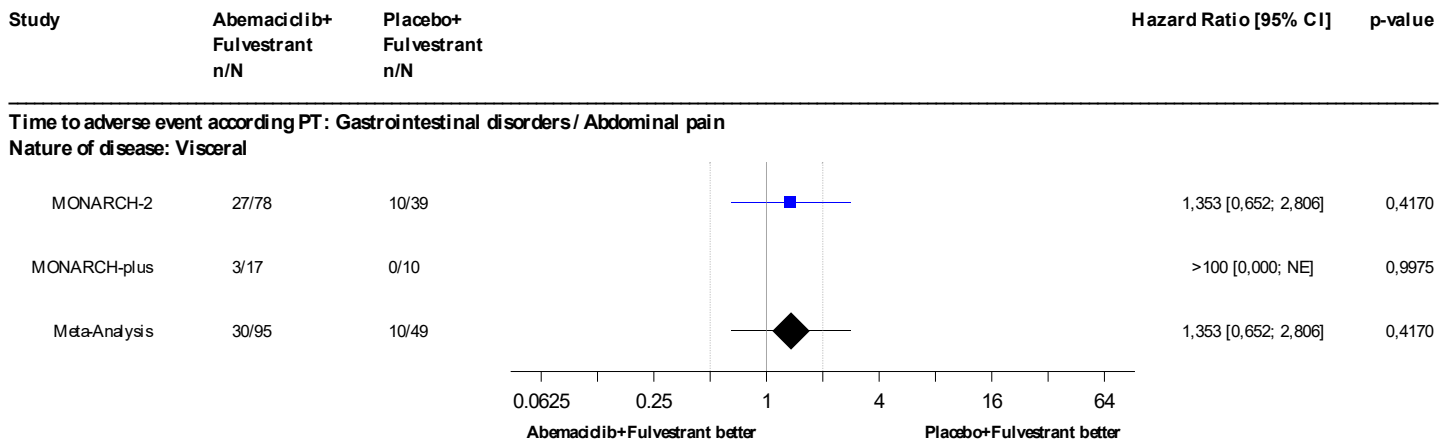
Figure 1195.2.3.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9975, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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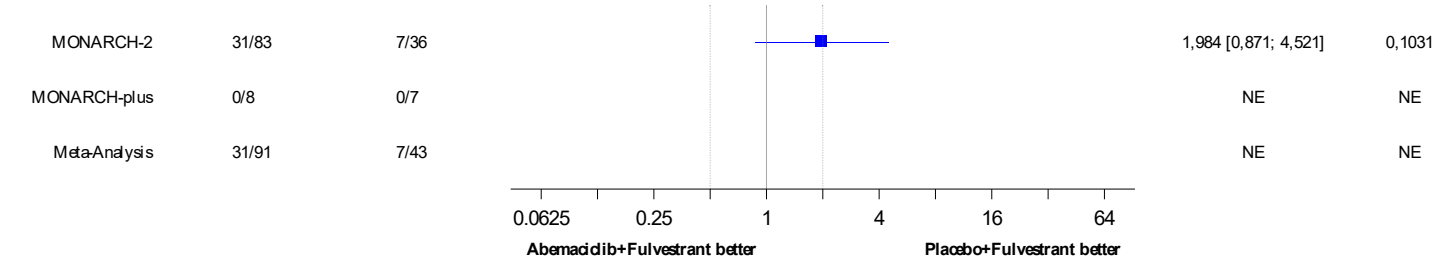
**Figure 1195.2.4.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE

Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep002_popa2_ecogbl_1.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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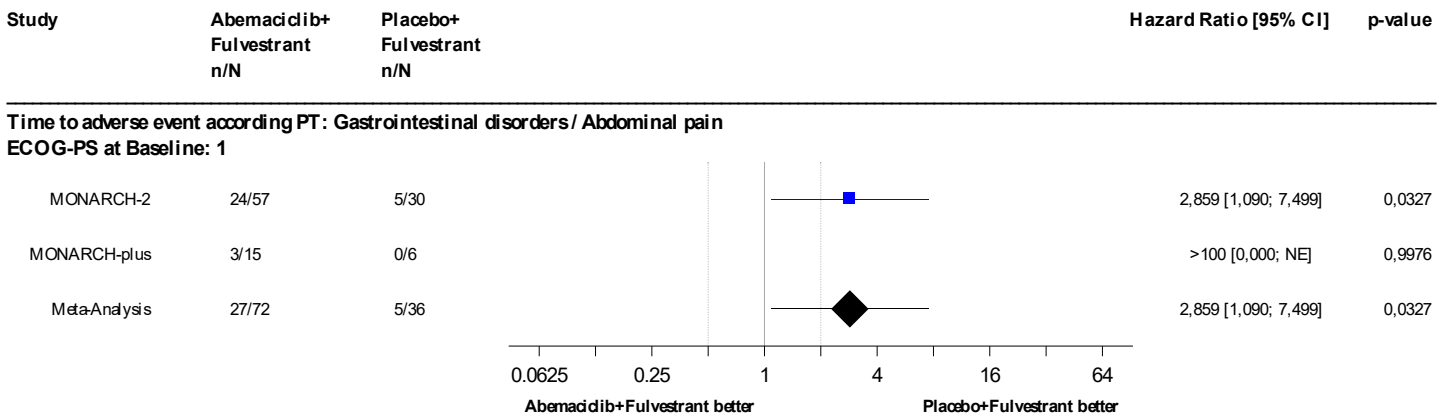
**Figure 1195.2.4.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9978, I2 index=0%

Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep002_popa2_ecogbl_2.rtf

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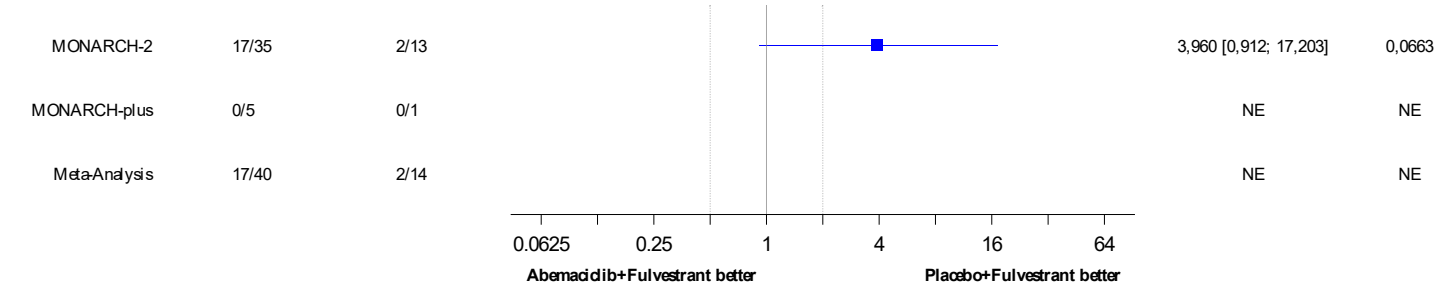
Figure 1195.2.6.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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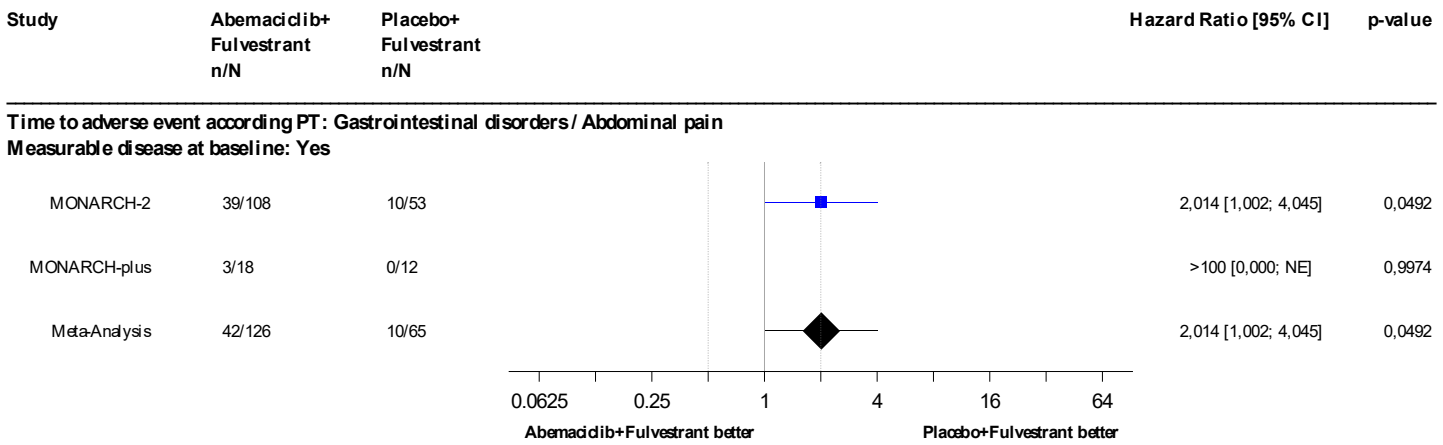
Figure 1195.2.6.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9975, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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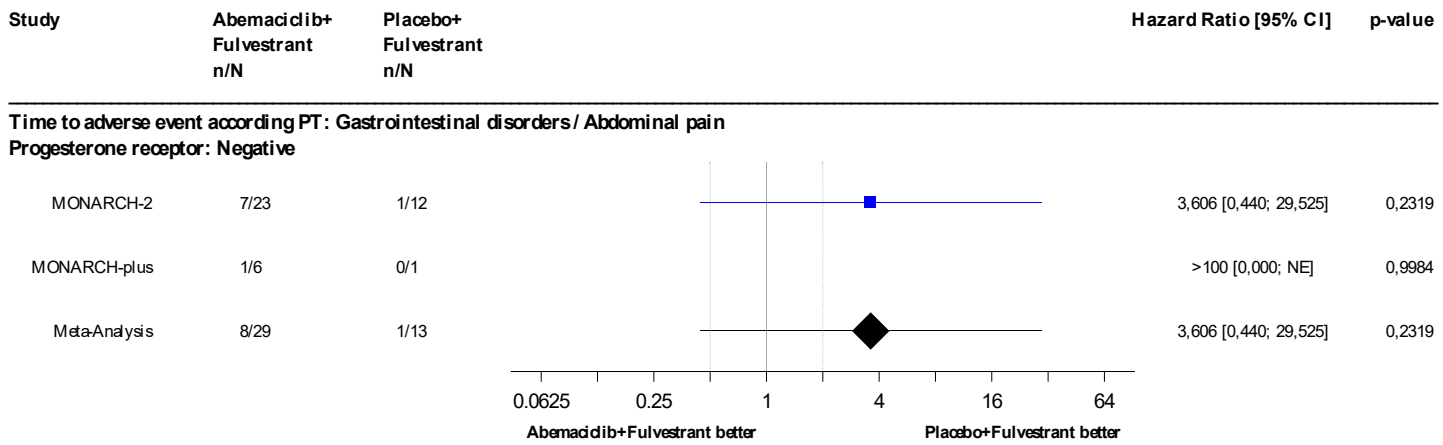
Figure 1195.2.7.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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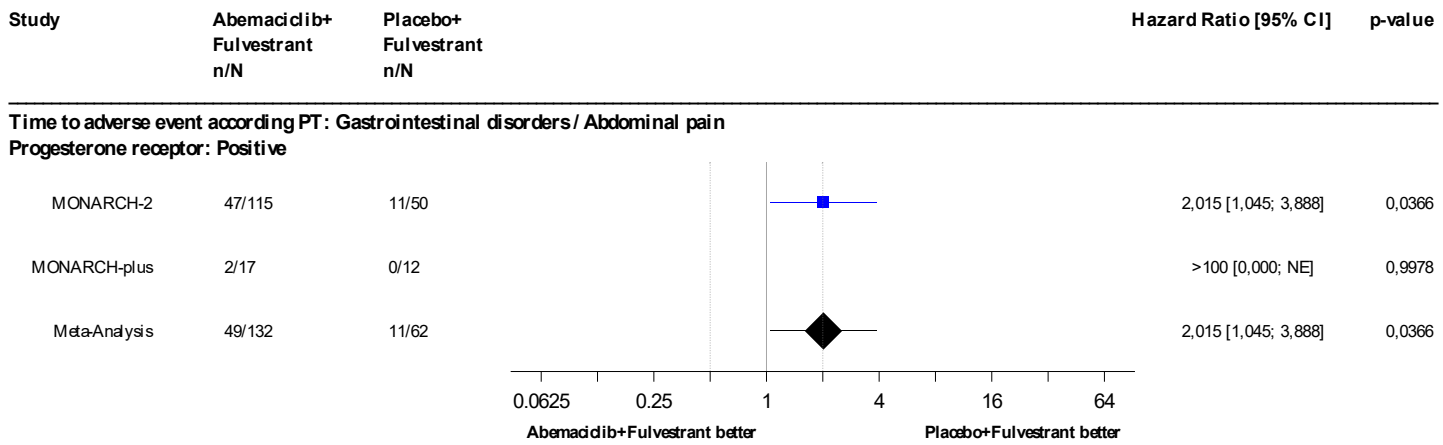
Figure 1195.2.7.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9979, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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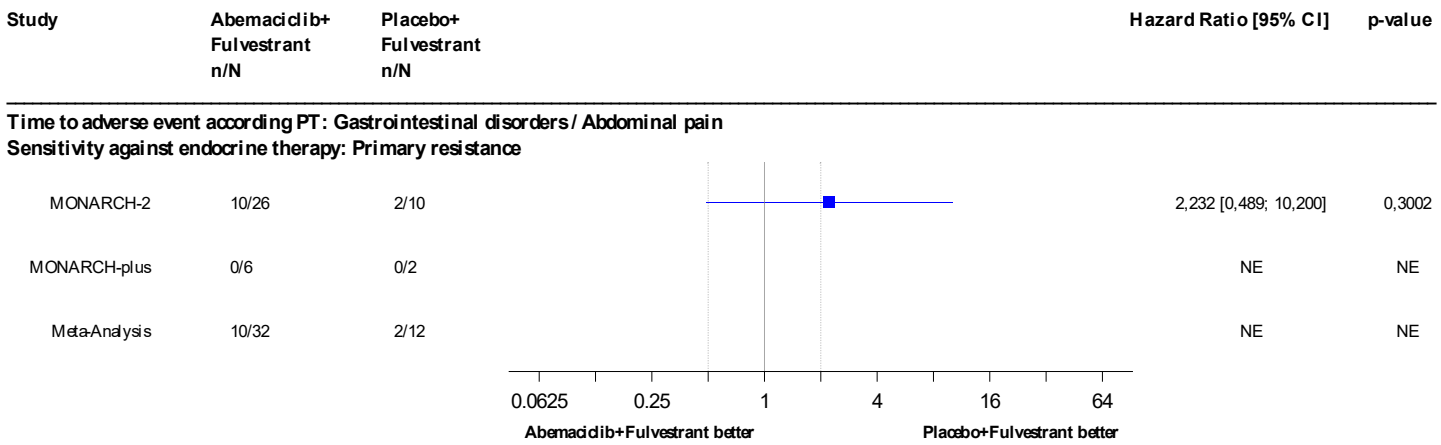
Figure 1195.2.8.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep002_popa2_snthr_1.rtf
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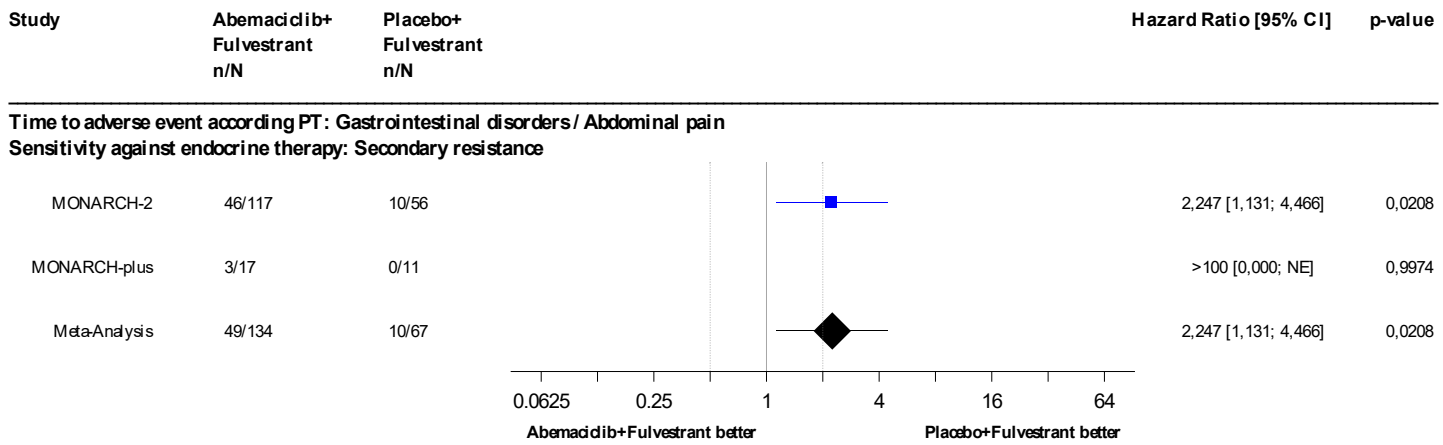
Figure 1195.2.8.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9975, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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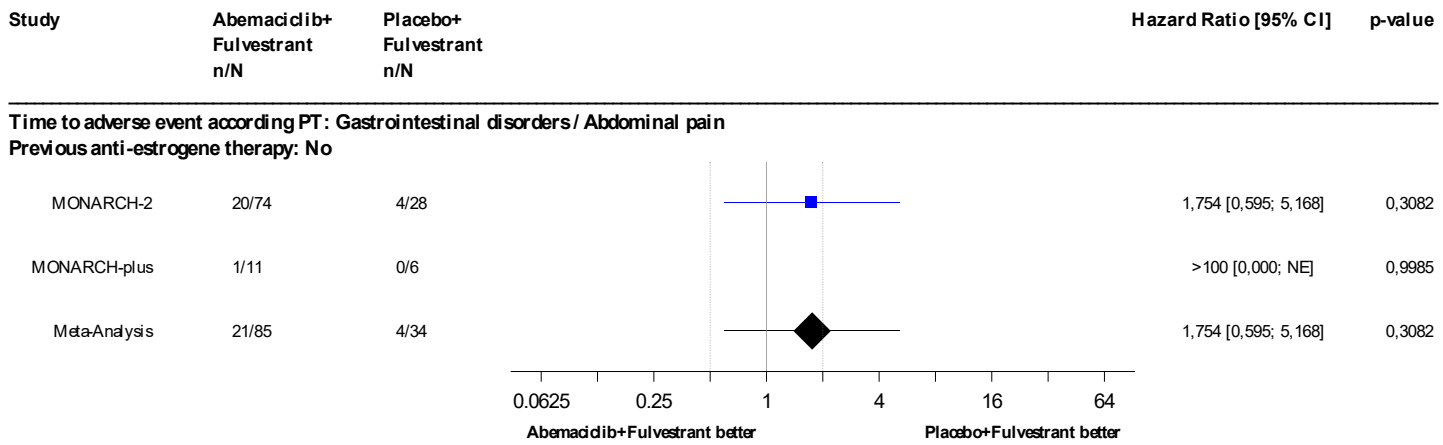
Figure 1195.2.9.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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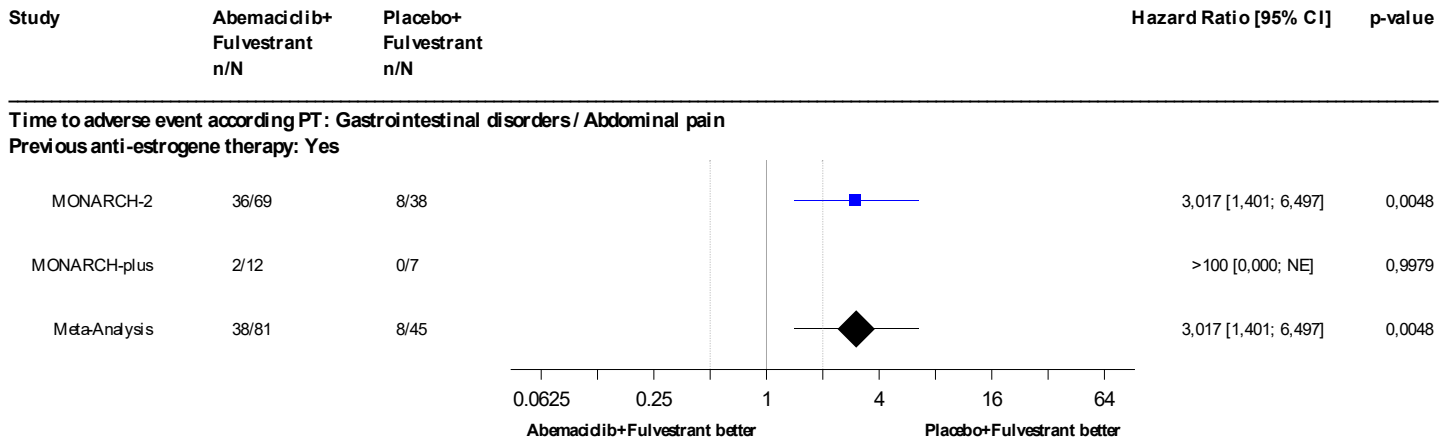
Figure 1195.2.9.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Abdominal pain
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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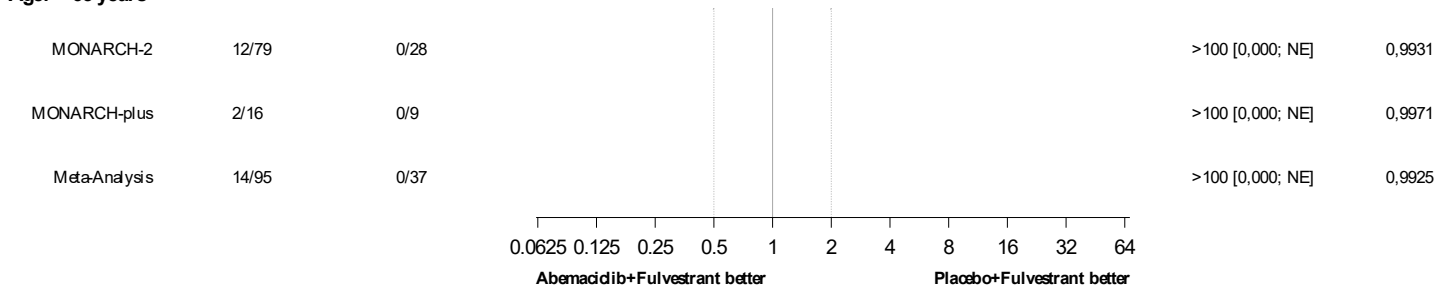
Figure 1197.2.1.1: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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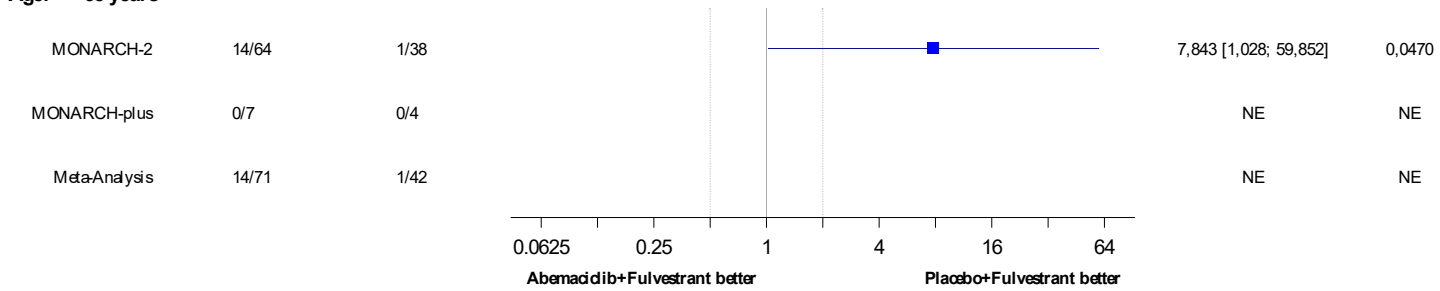
Figure 1197.2.1.2: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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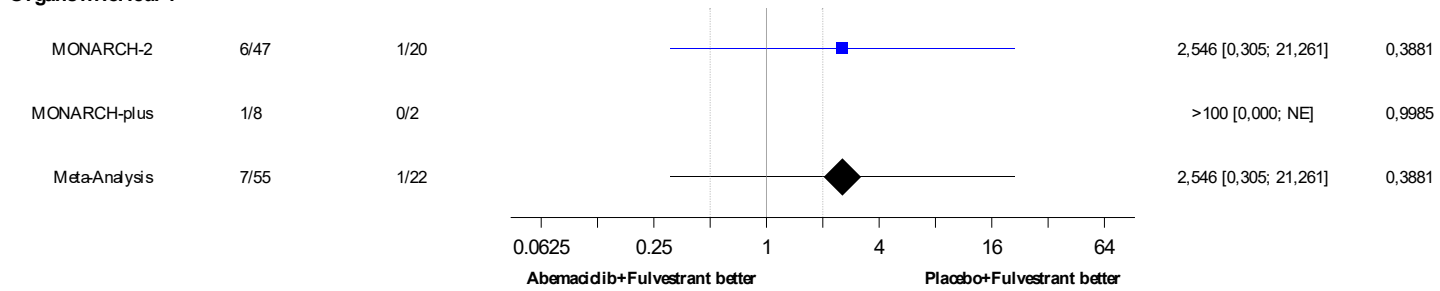
Figure 1197.2.2.1: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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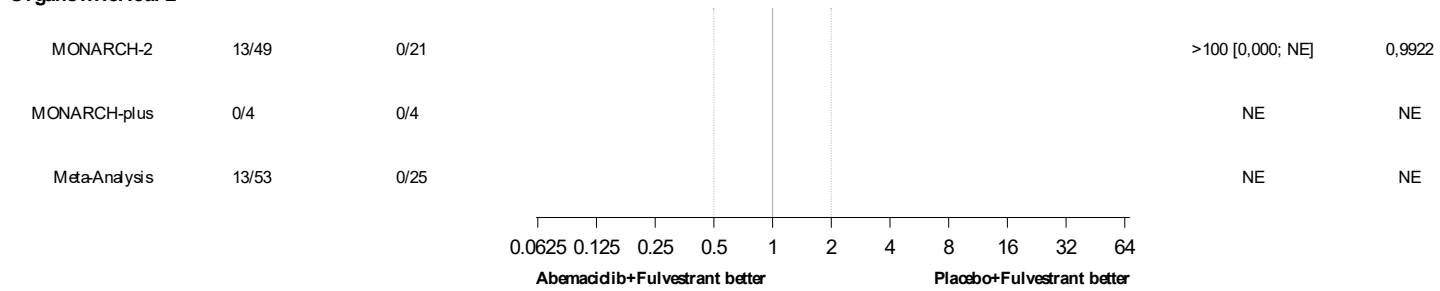
Figure 1197.2.2.2: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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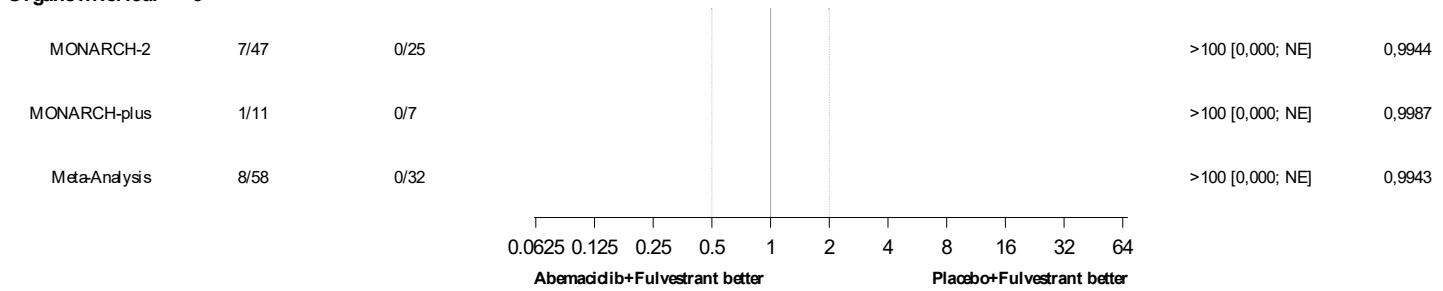
Figure 1197.2.2.3: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9999, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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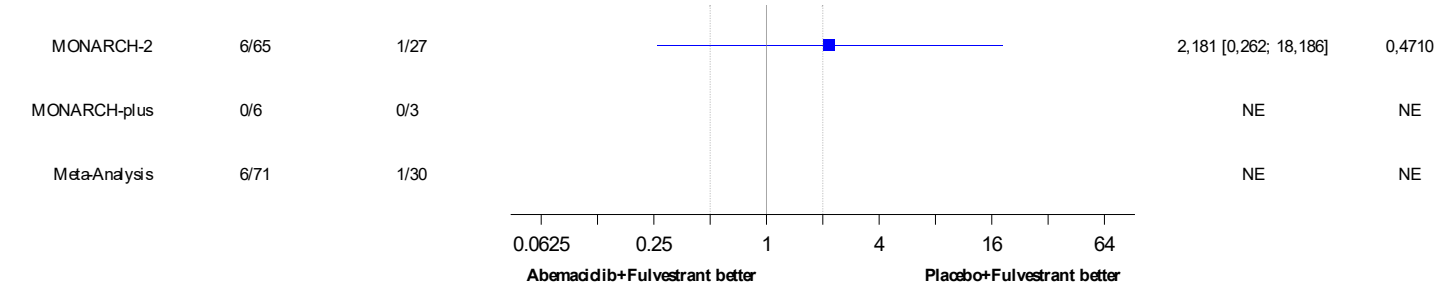
Figure 1197.2.3.1: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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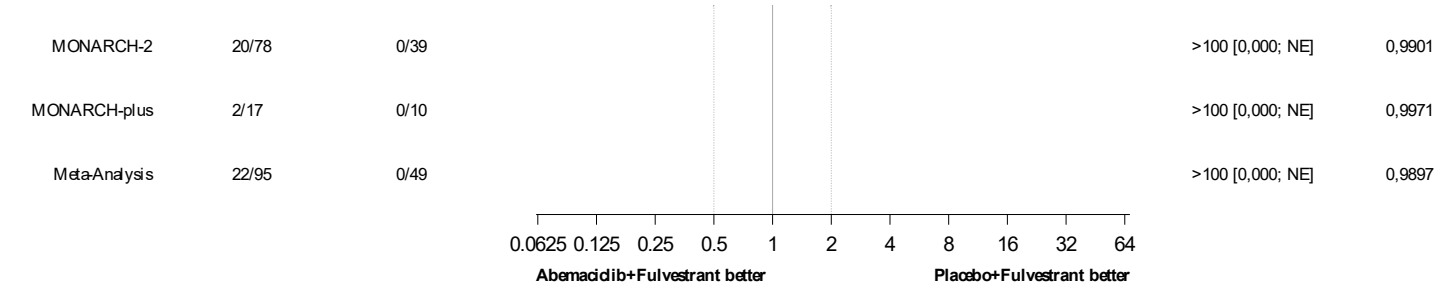
Figure 1197.2.3.2: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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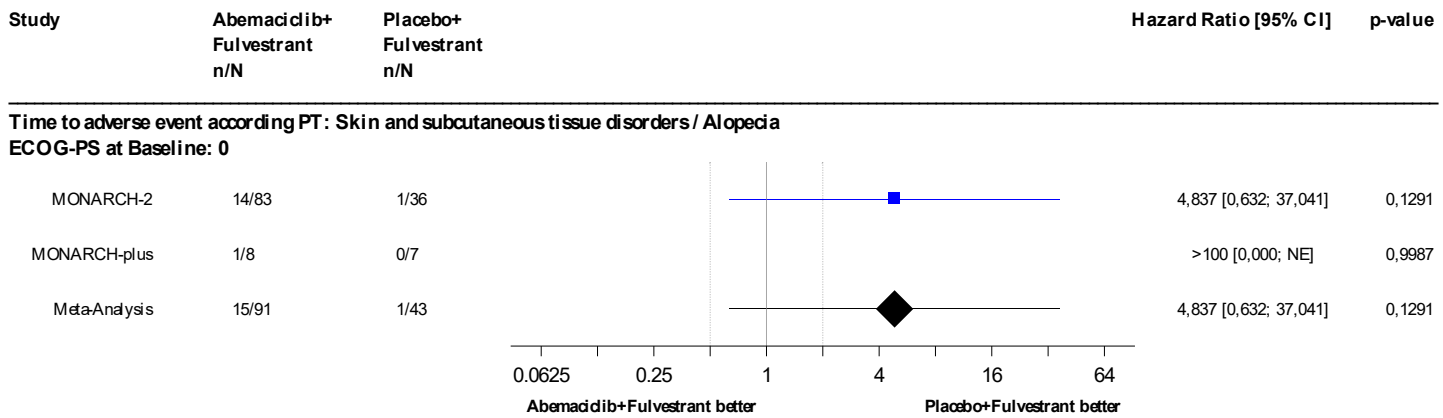
Figure 1197.2.4.1: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9988, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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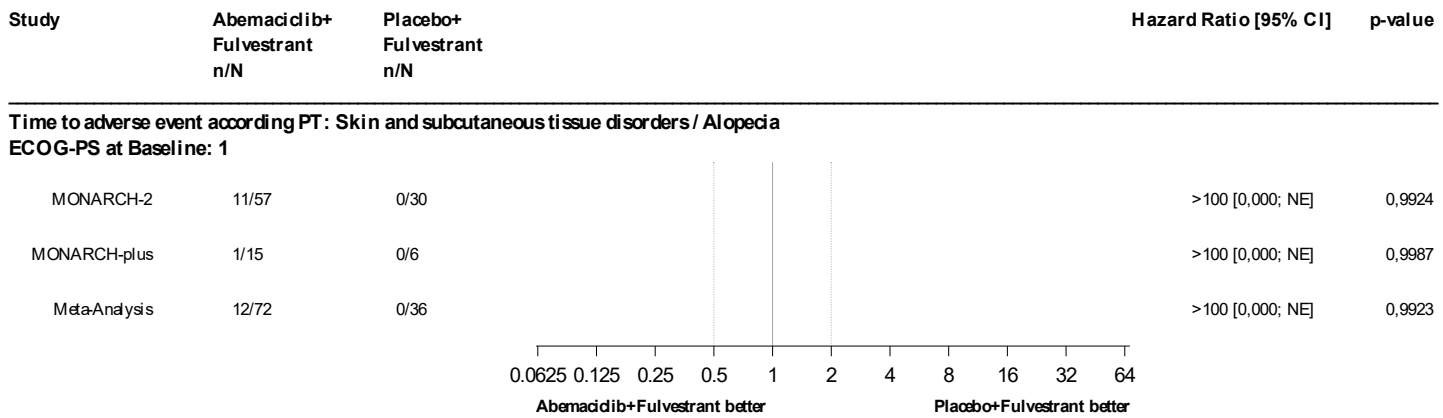
Figure 1197.2.4.2: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9999, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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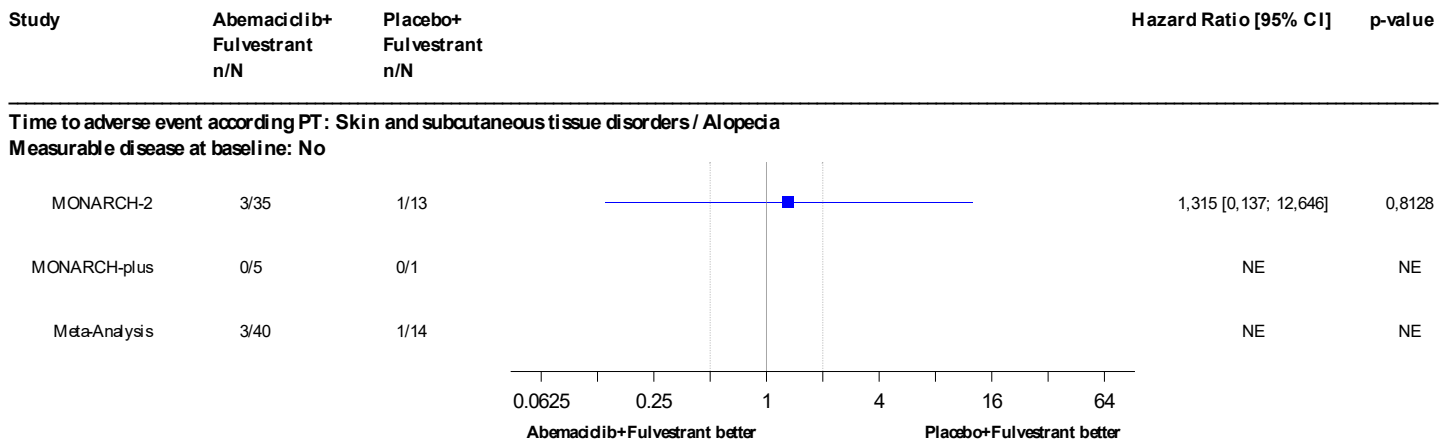
Figure 1197.2.6.1: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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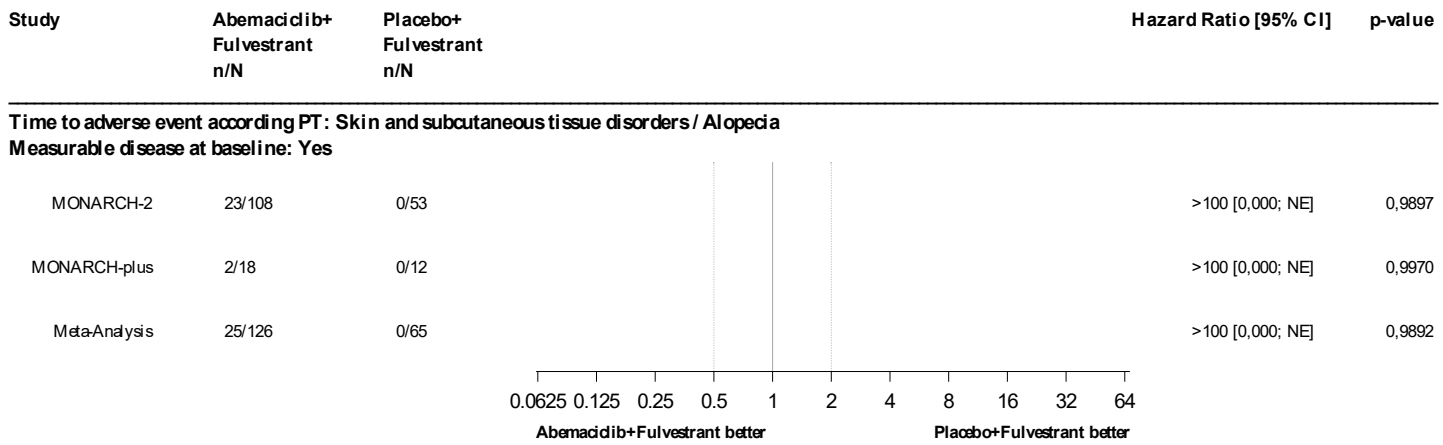
Figure 1197.2.6.2: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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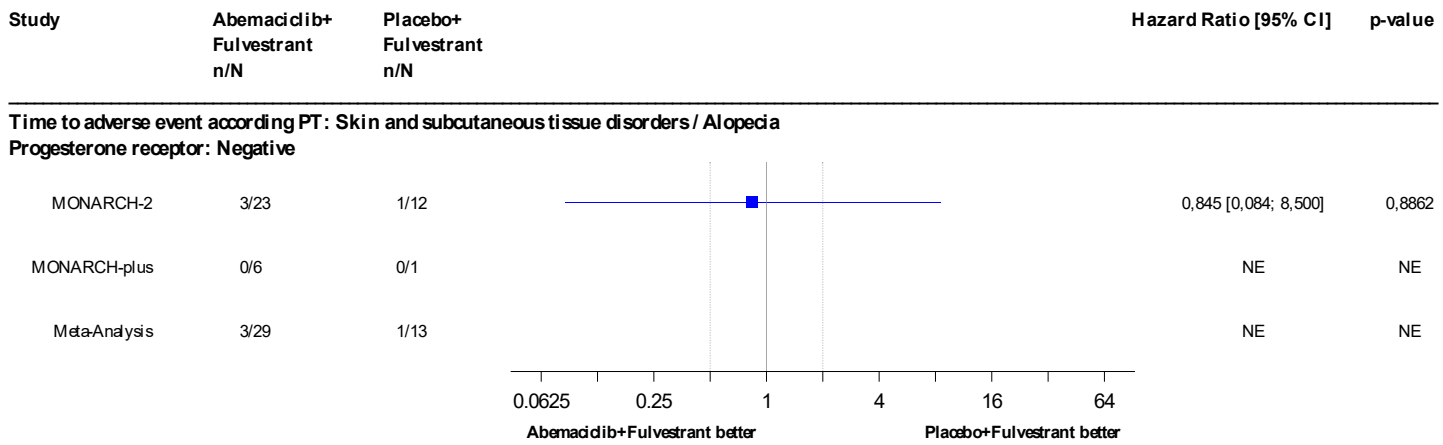
Figure 1197.2.7.1: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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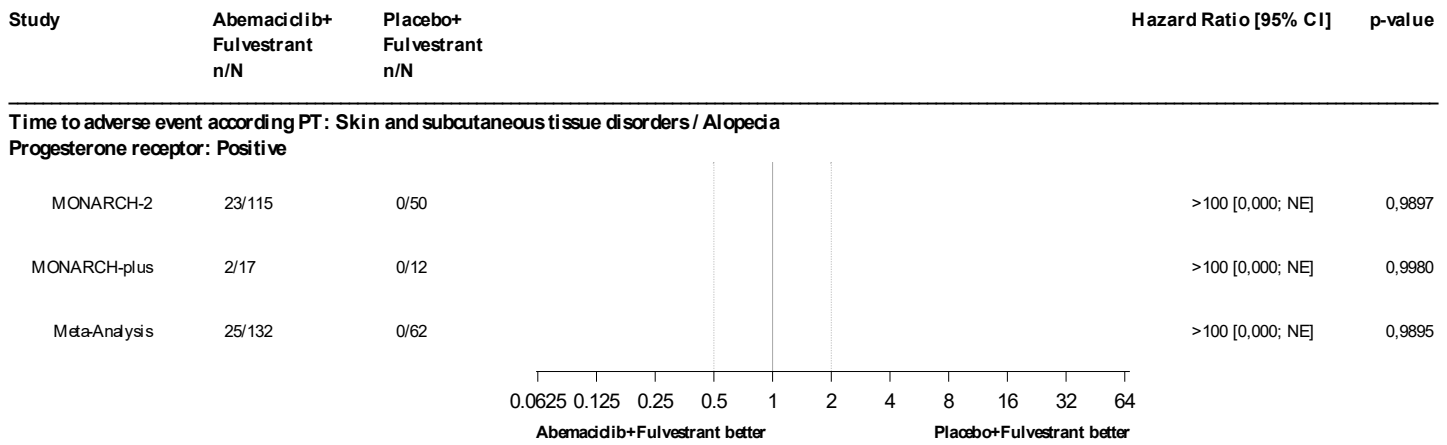
Figure 1197.2.7.2: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9999, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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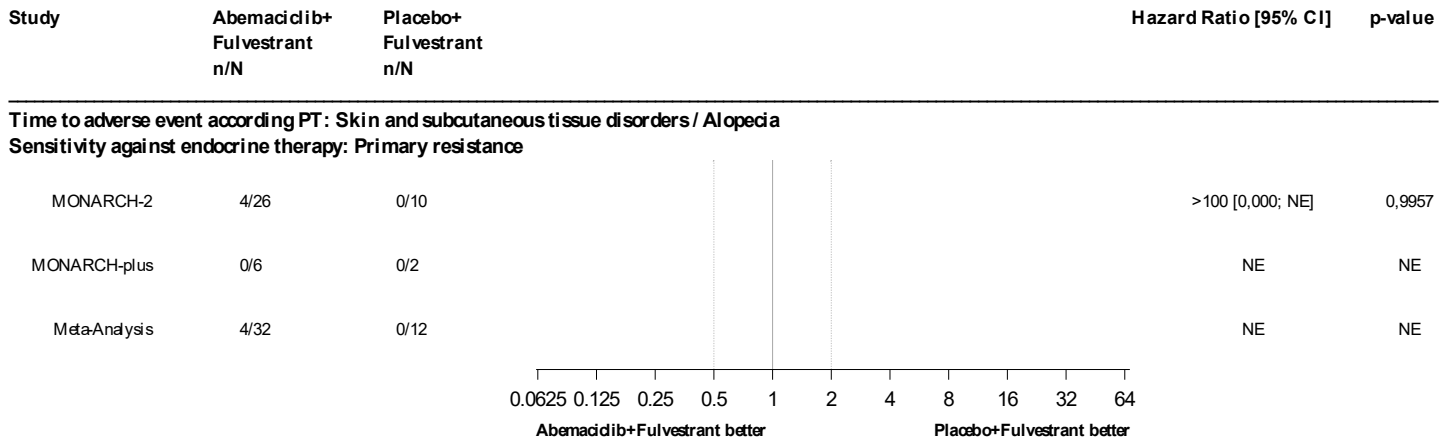
Figure 1197.2.8.1: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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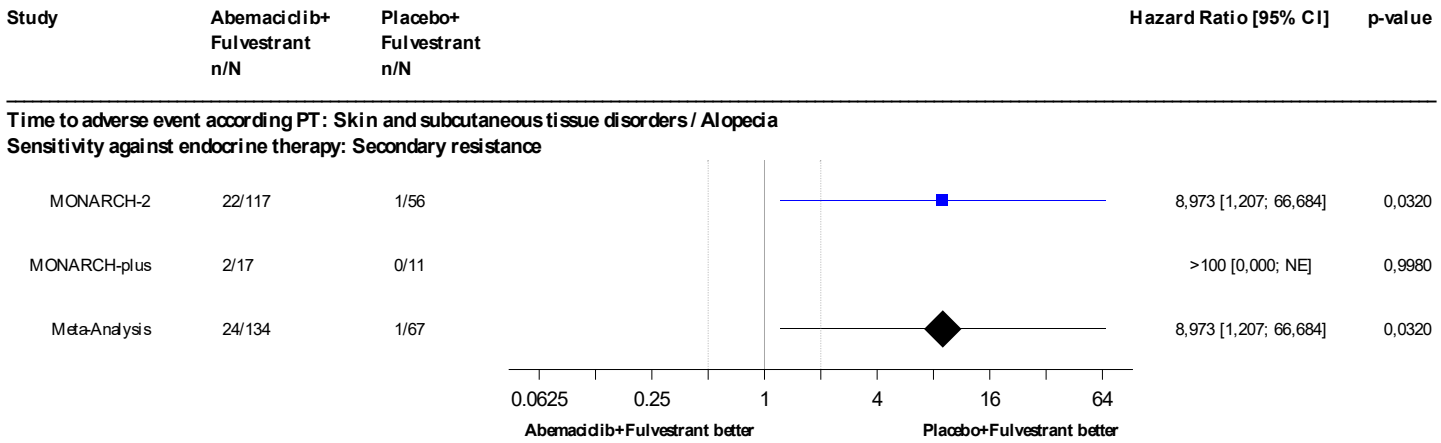
**Figure 1197.2.8.2: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9983, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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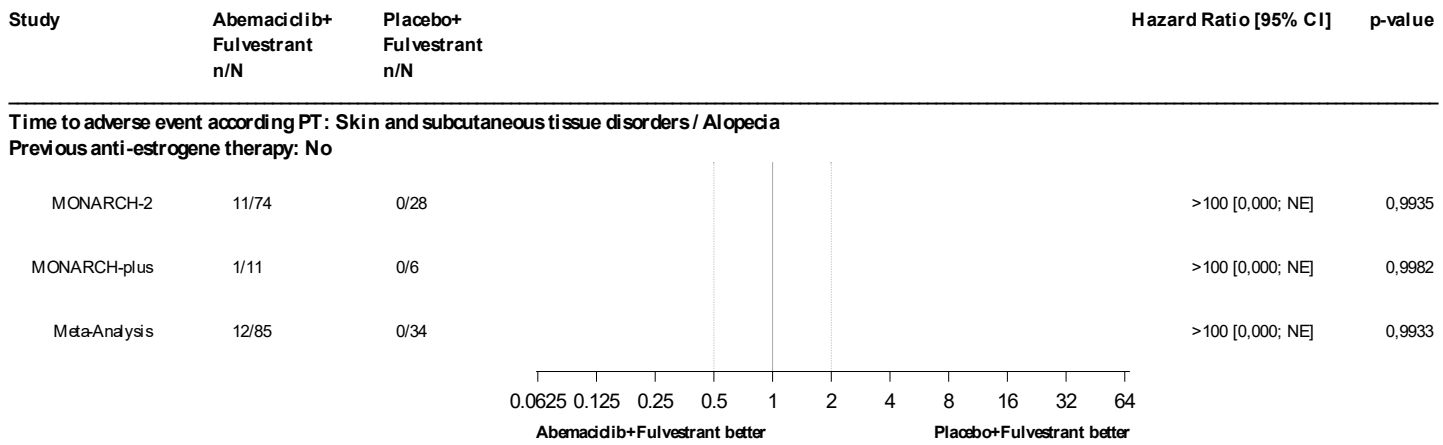
Figure 1197.2.9.1: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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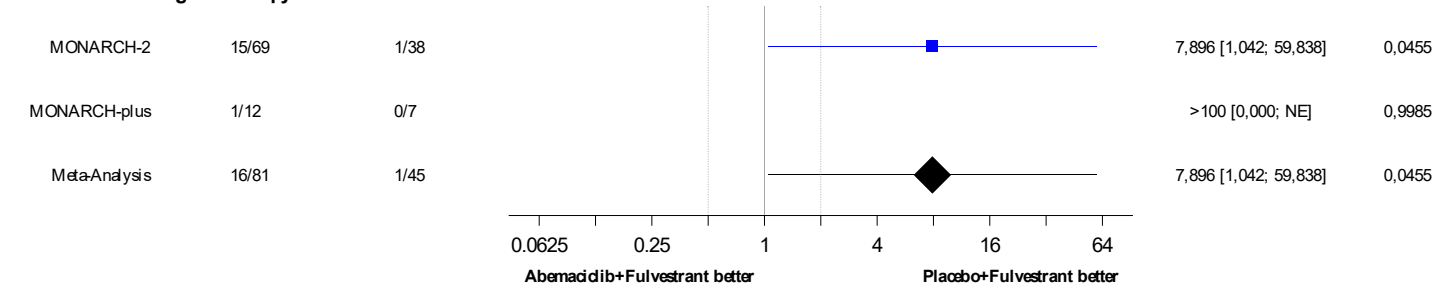
Figure 1197.2.9.2: Metaanalysis results for adverse events according PT[1] -
Skin and subcutaneous tissue disorders / Alopecia
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9987, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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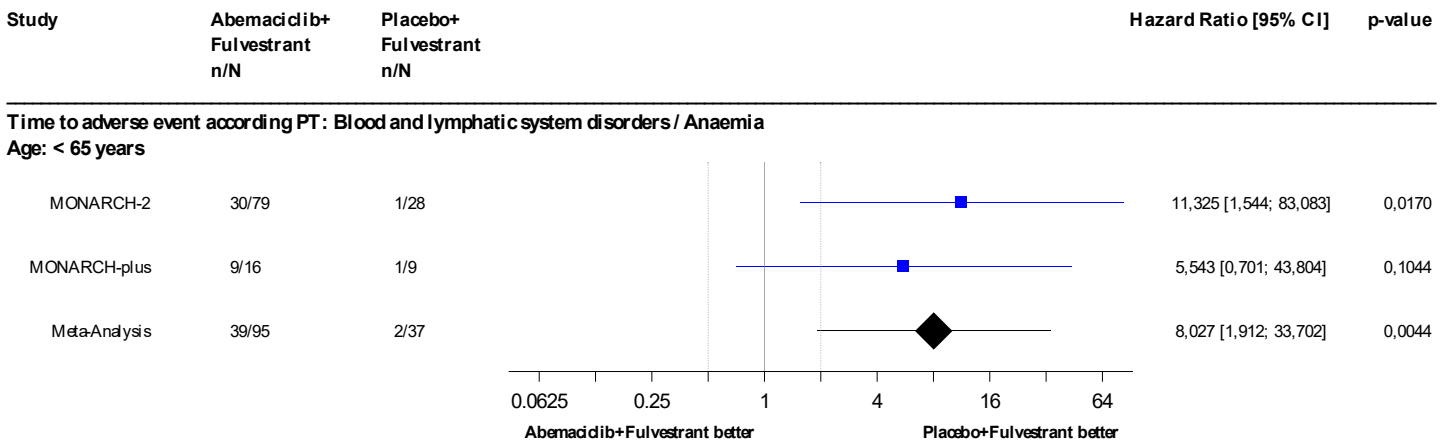
Figure 1198.2.1.1: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2379, p-value=0,6258, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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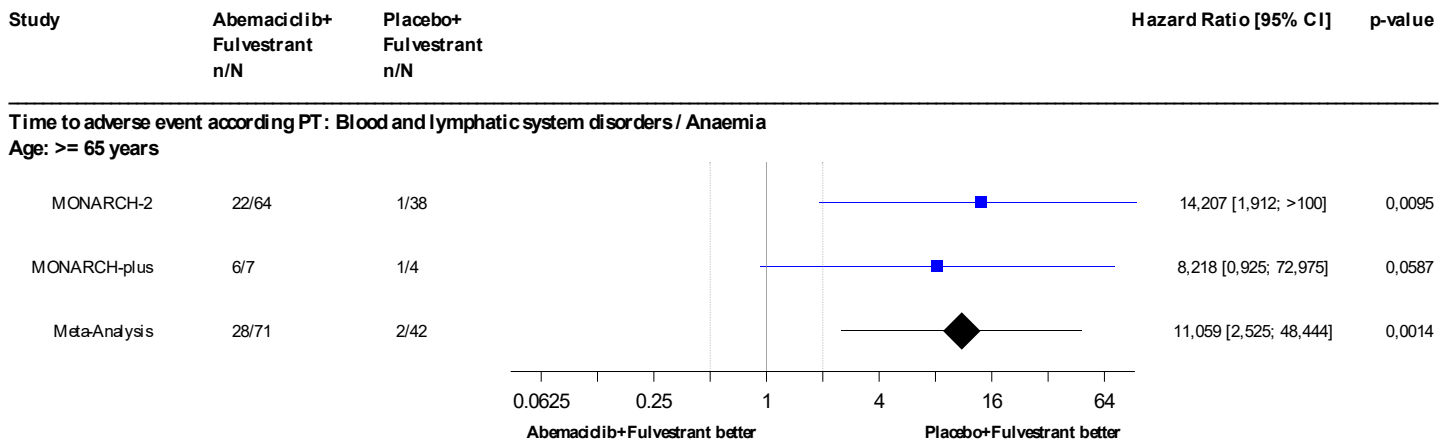
Figure 1198.2.1.2: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1310, p-value=0,7174, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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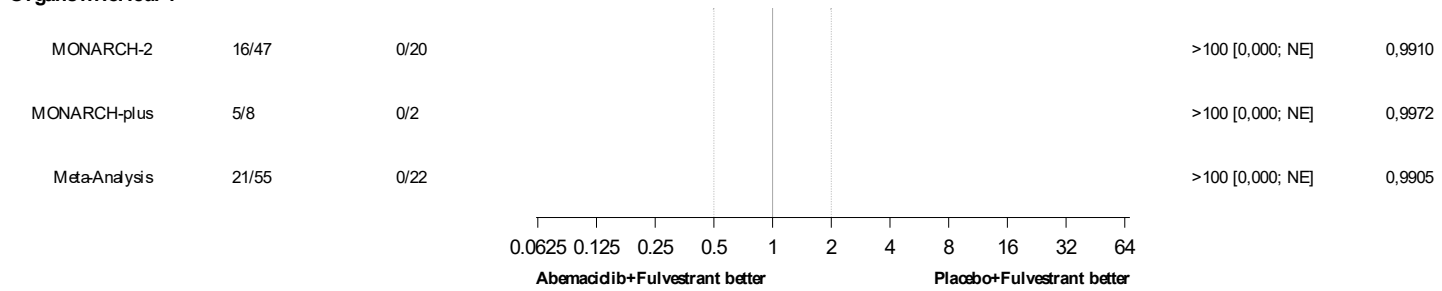
Figure 1198.2.2.1: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9999, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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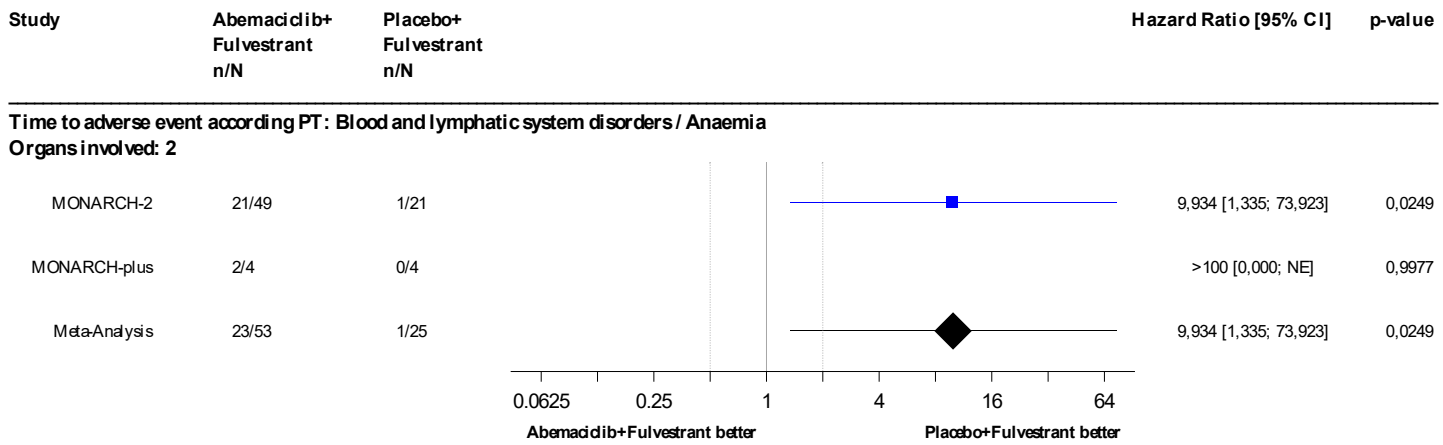
Figure 1198.2.2.2: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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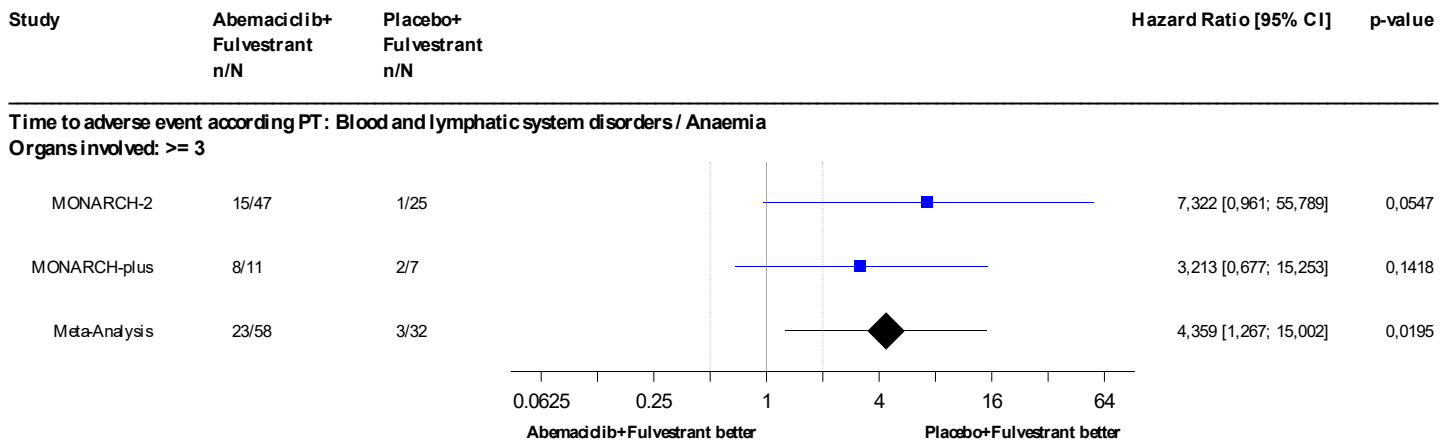
Figure 1198.2.2.3: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3978, p-value=0,5282, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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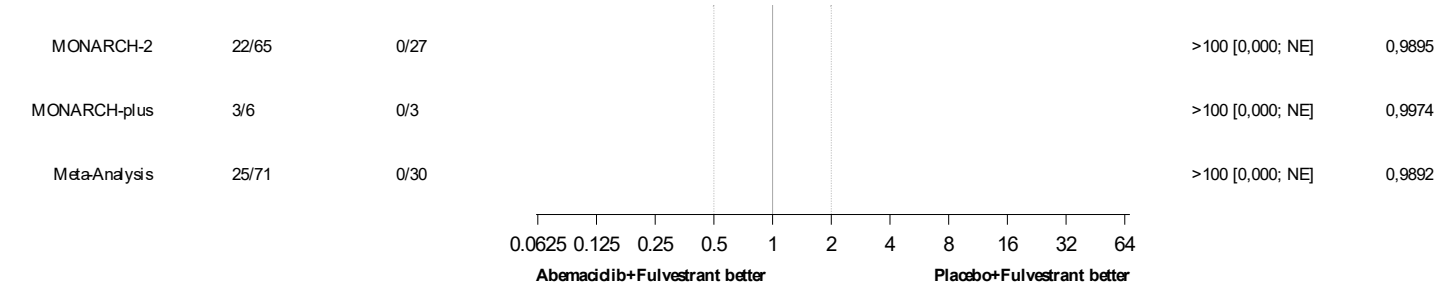
Figure 1198.2.3.1: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9998, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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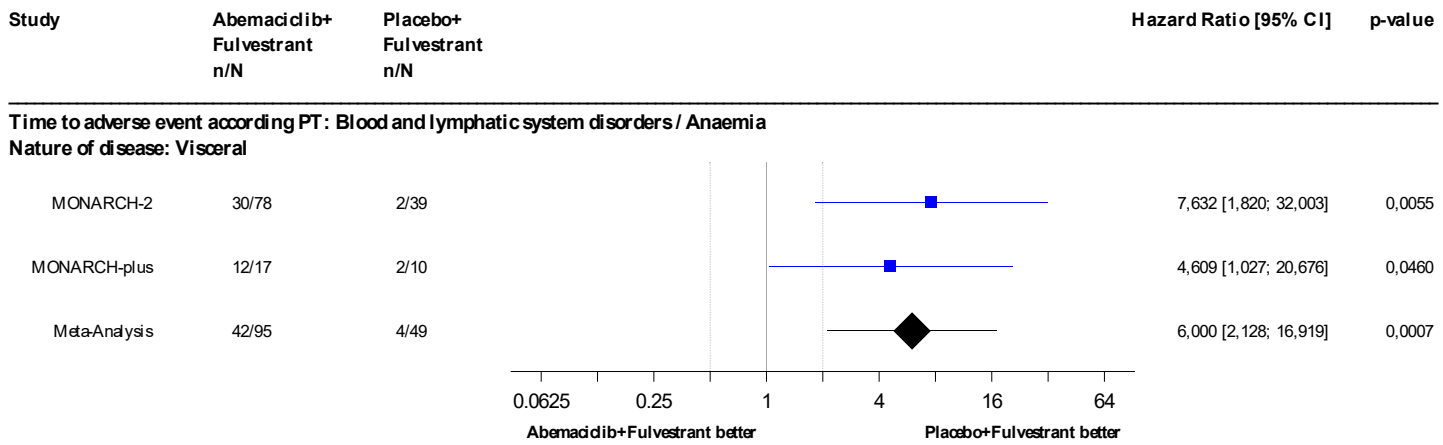
Figure 1198.2.3.2: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2268, p-value=0,6339, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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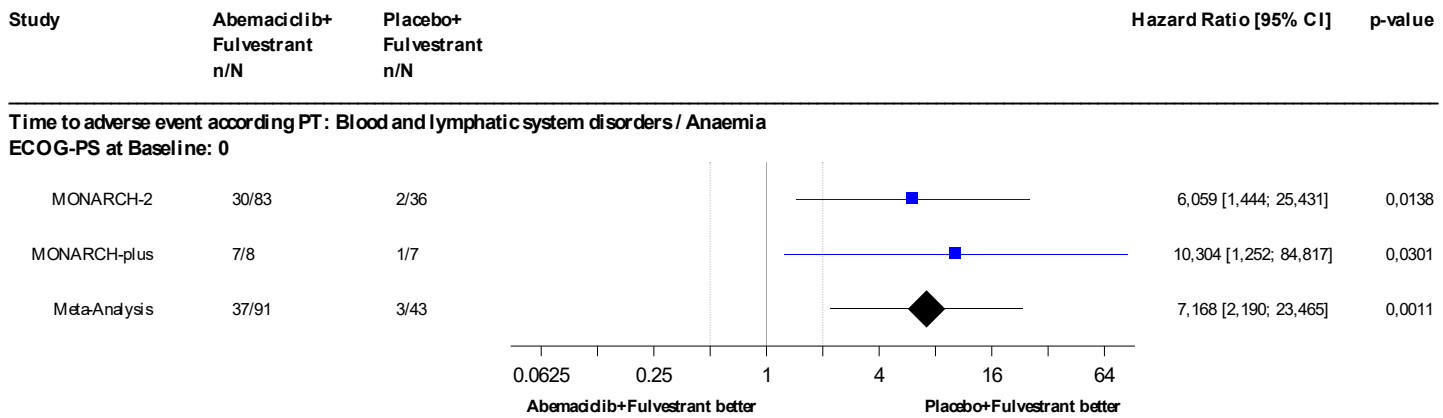
Figure 1198.2.4.1: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1666, p-value=0,6831, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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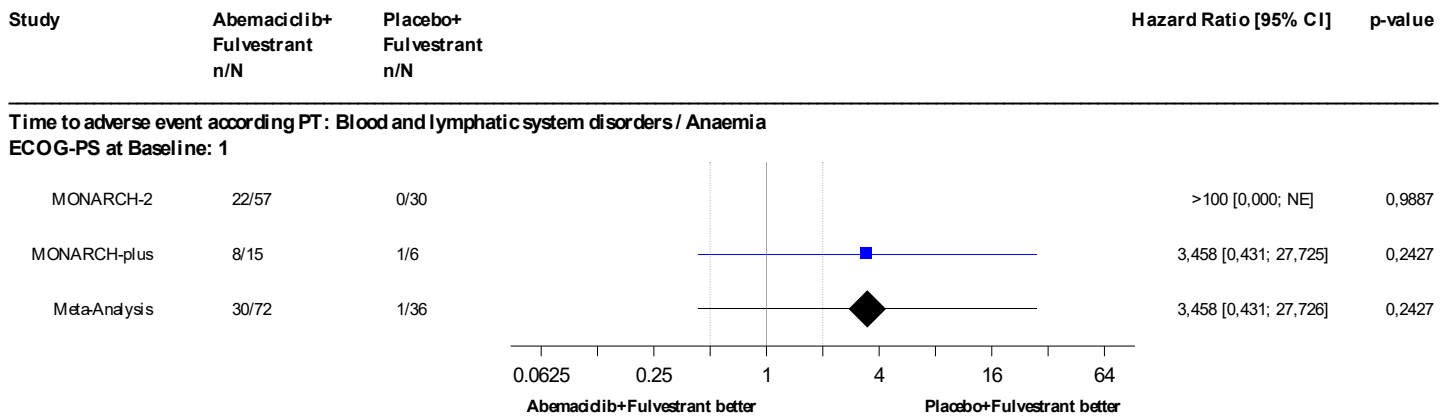
Figure 1198.2.4.2: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0002, p-value=0,9896, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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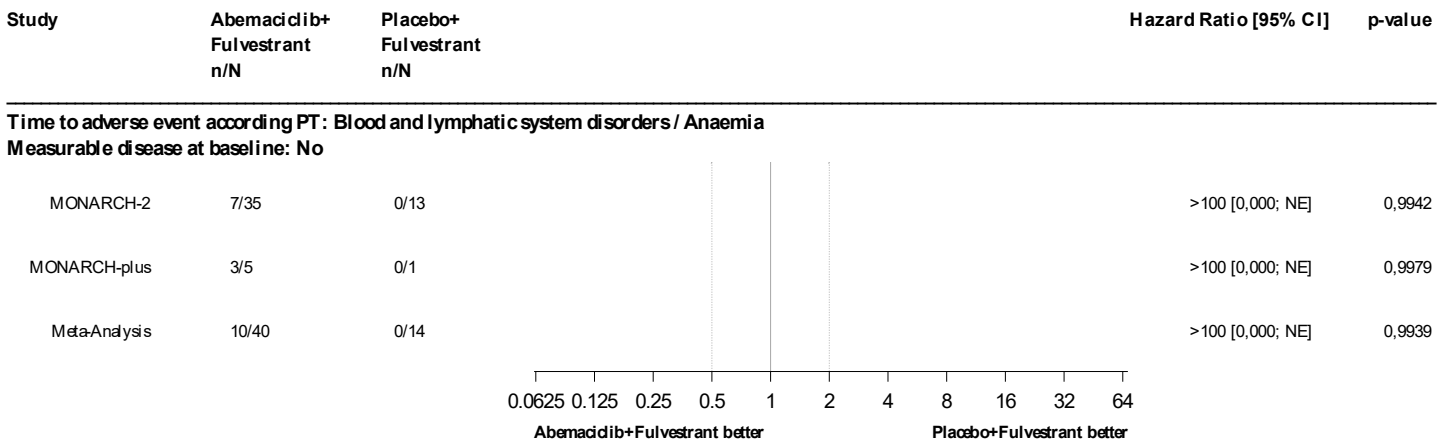
Figure 1198.2.6.1: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9999, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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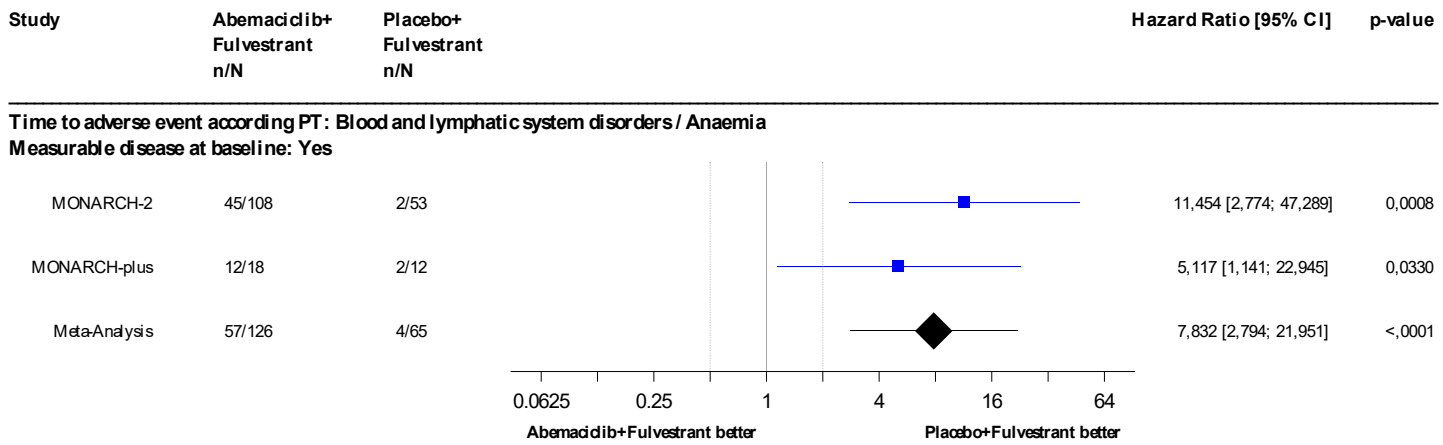
Figure 1198.2.6.2: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5851, p-value=0,4443, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep005_popa2_measdis_2.rtf
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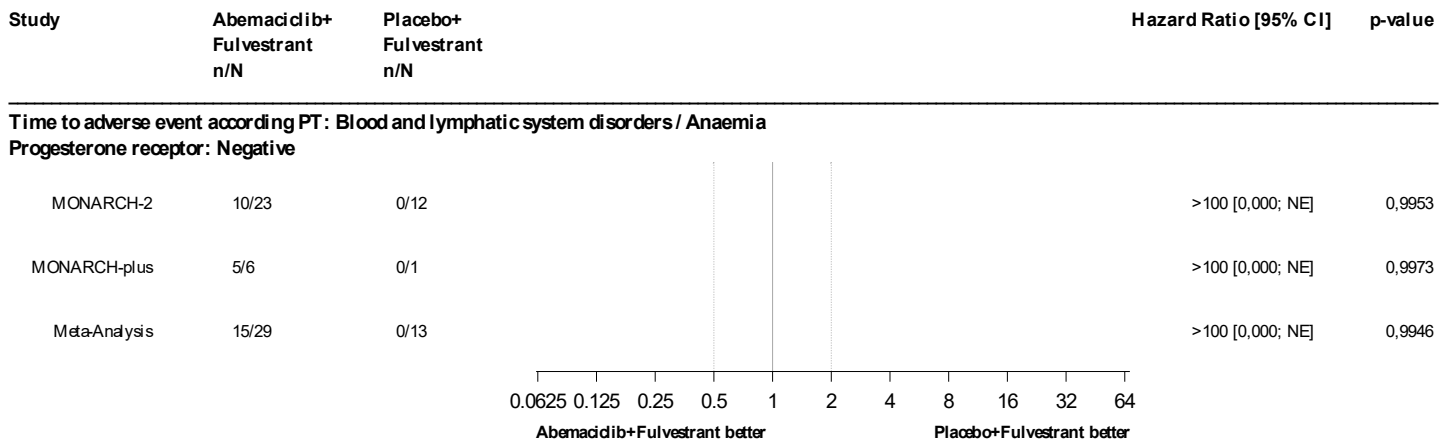
Figure 1198.2.7.1: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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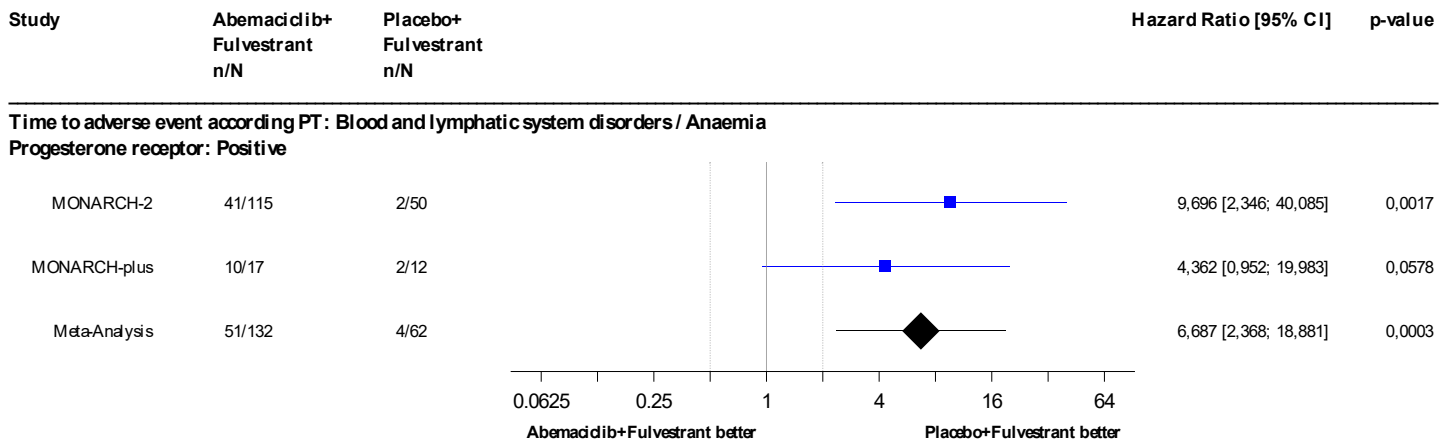
Figure 1198.2.7.2: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5660, p-value=0,4518, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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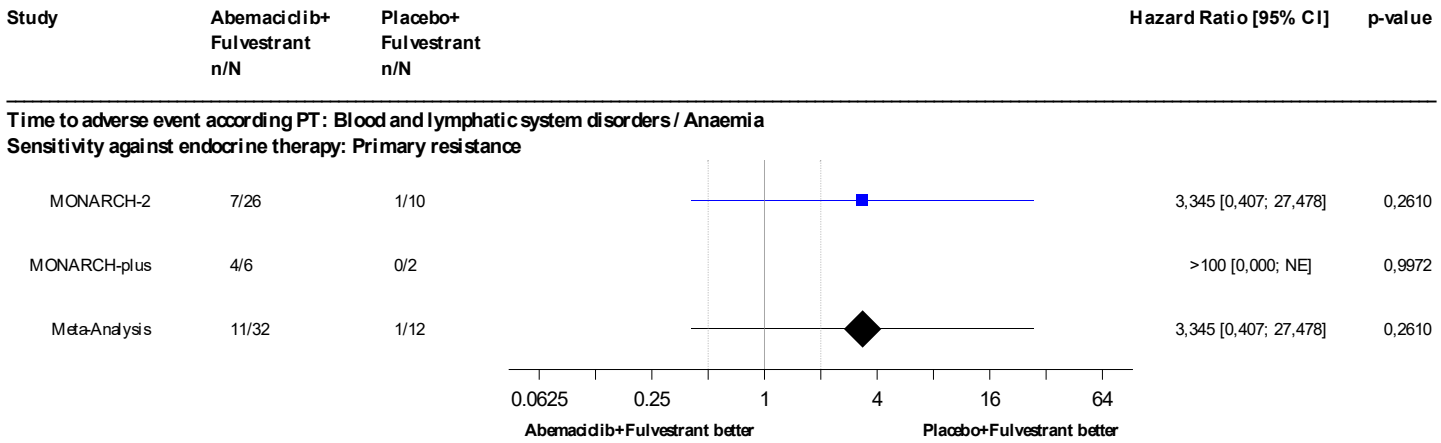
Figure 1198.2.8.1: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9974, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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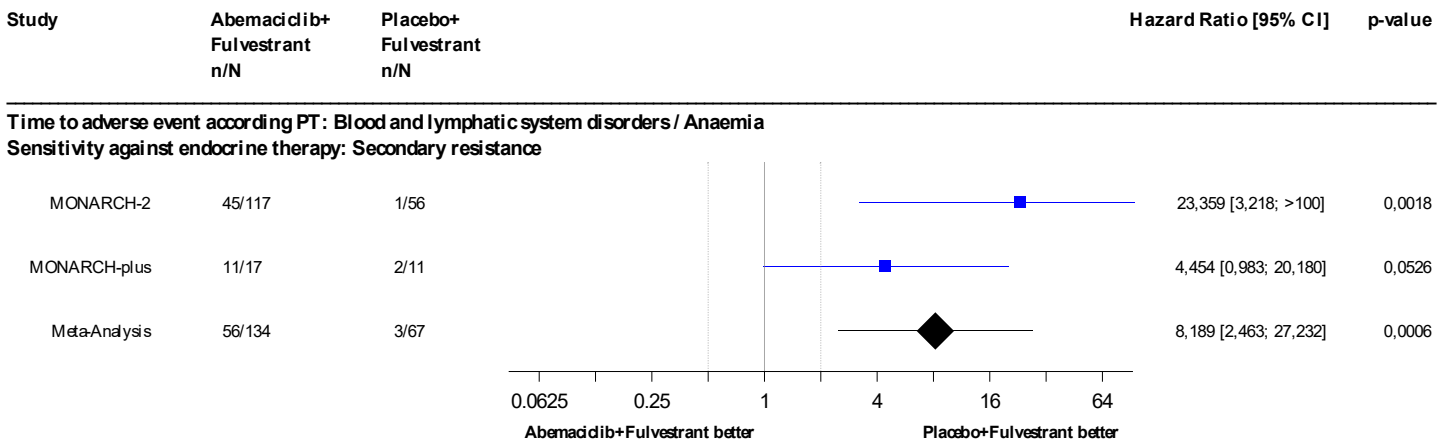
Figure 1198.2.8.2: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,6984, p-value=0,1925, I2 index=41,1%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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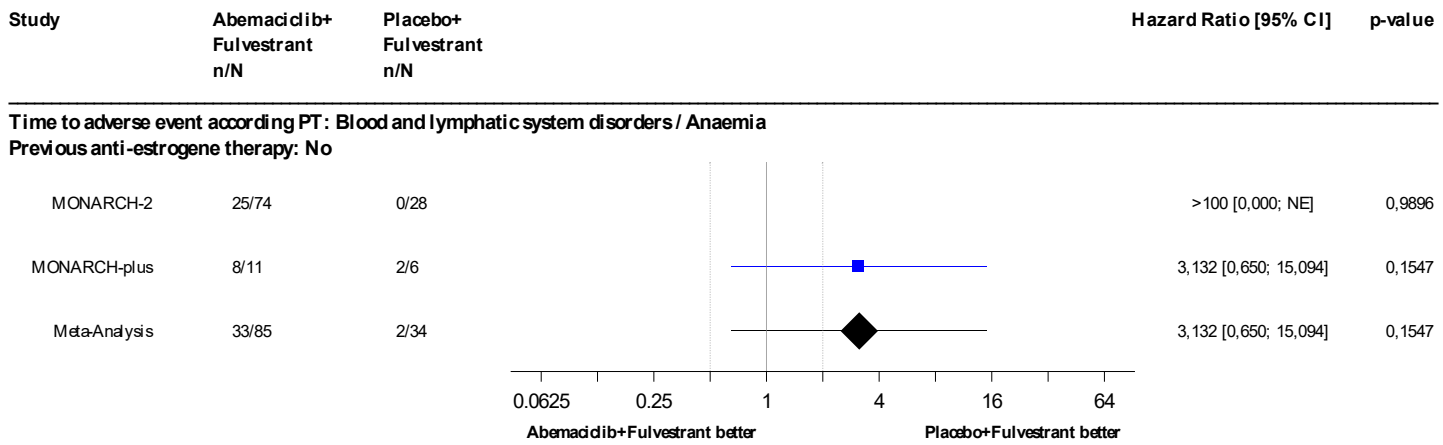
Figure 1198.2.9.1: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9903, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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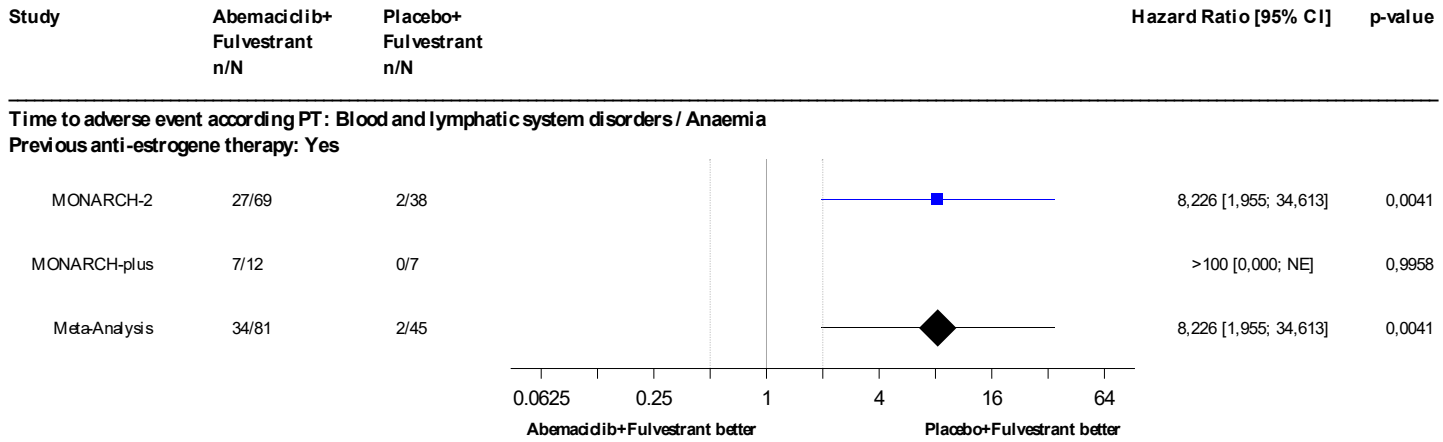
Figure 1198.2.9.2: Metaanalysis results for adverse events according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9963, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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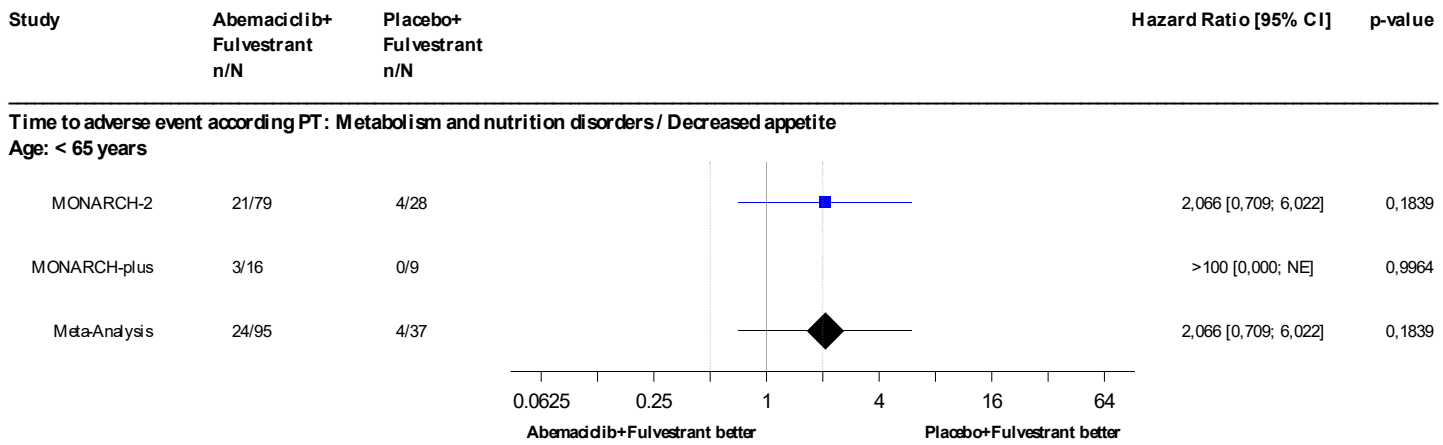
Figure 1207.2.1.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9966, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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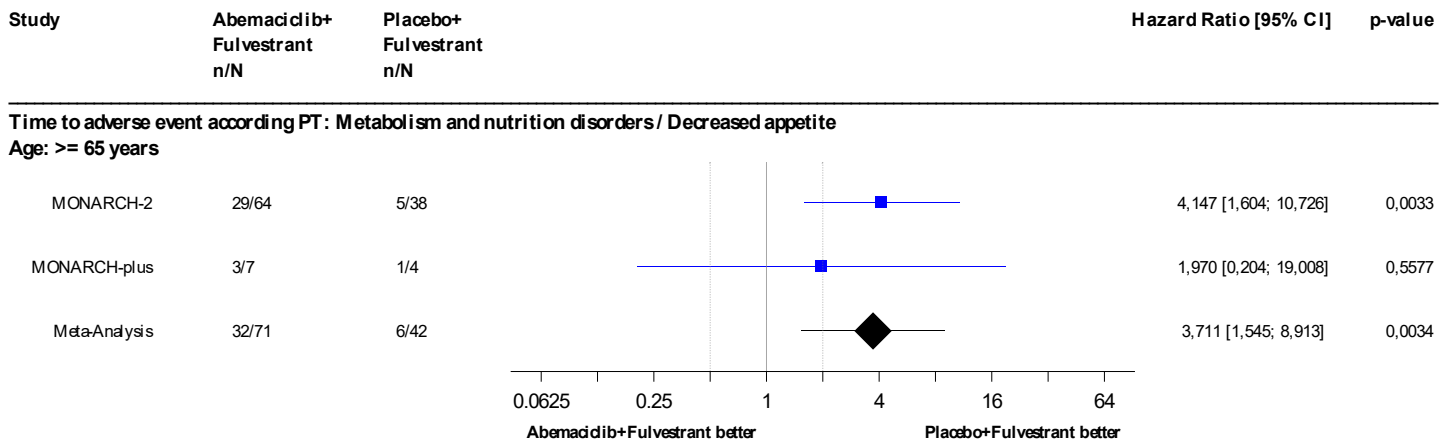
Figure 1207.2.1.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3525, p-value=0,5527, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep014_popa2_agegr1_2.rtf
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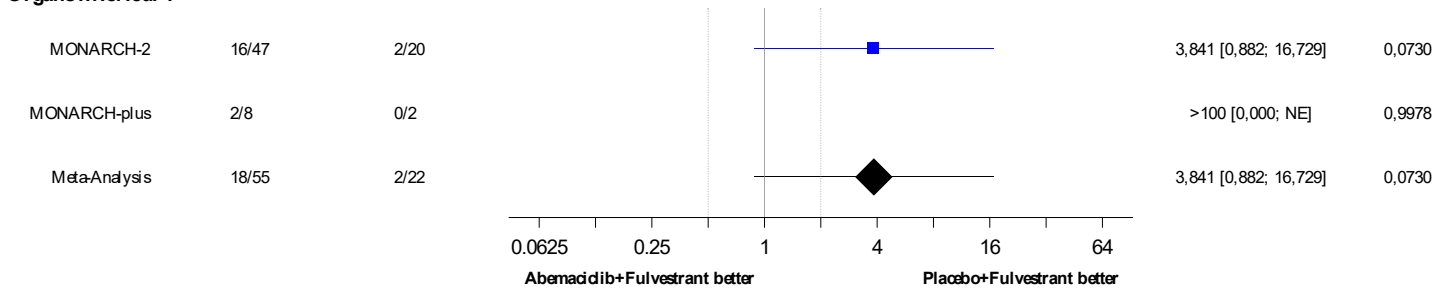
Figure 1207.2.2.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9979, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep014_popa2_norggr_1.rtf
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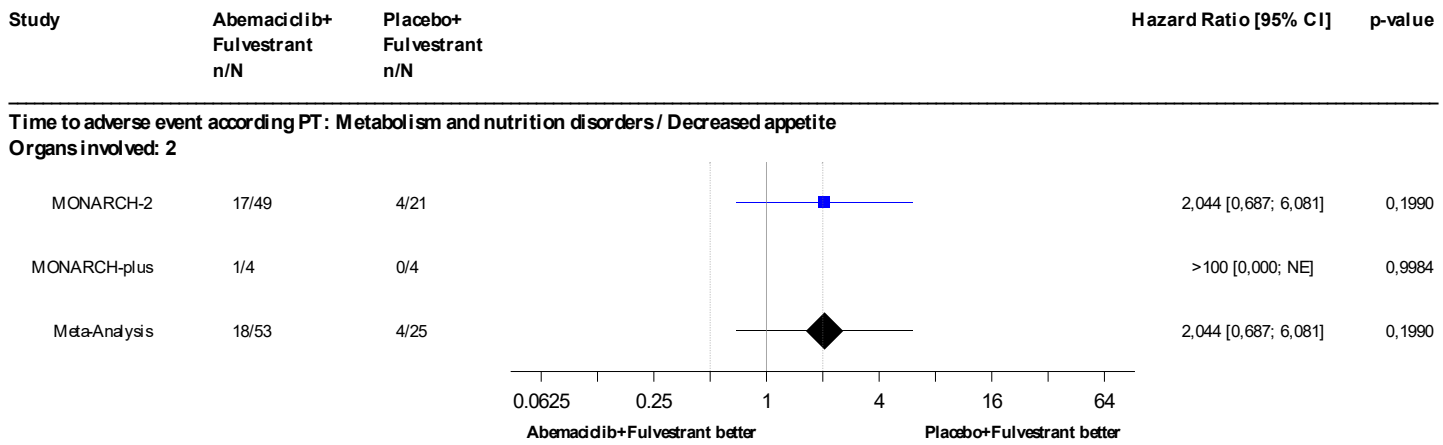
Figure 1207.2.2.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9984, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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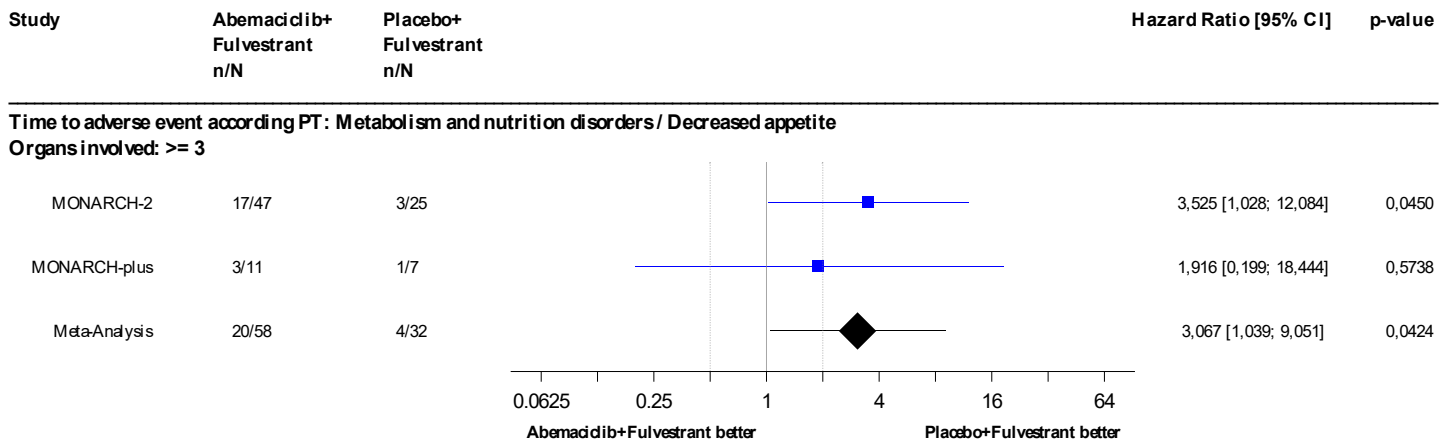
Figure 1207.2.2.3: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2150, p-value=0,6429, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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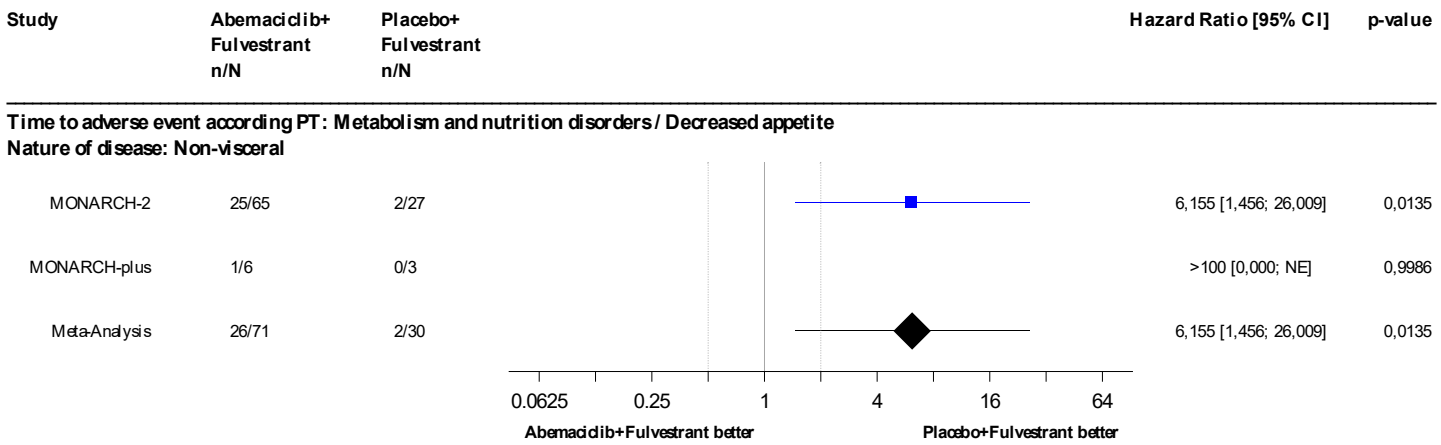
Figure 1207.2.3.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9988, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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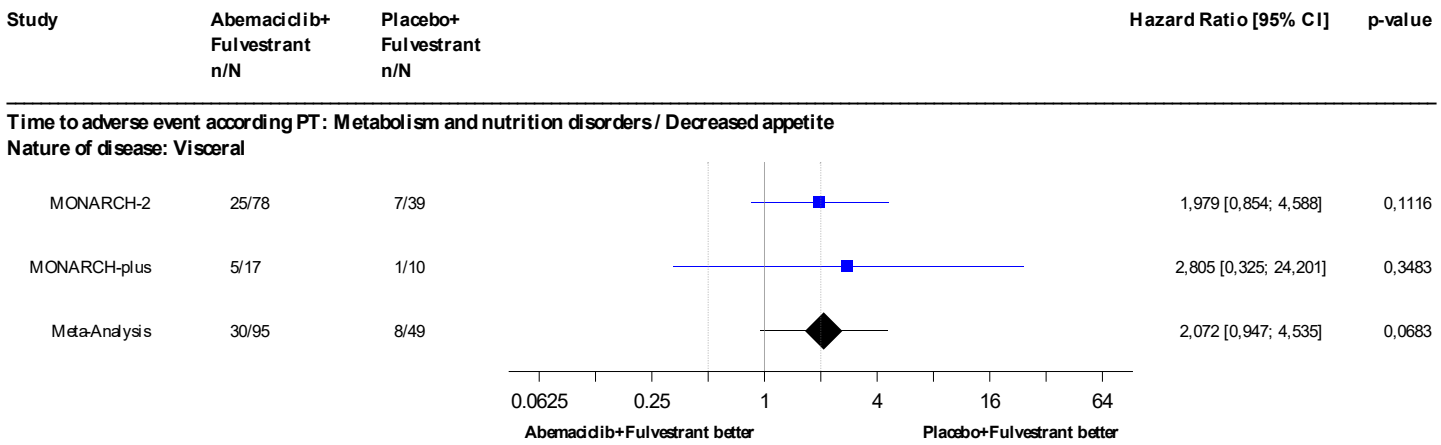
Figure 1207.2.3.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0873, p-value=0,7676, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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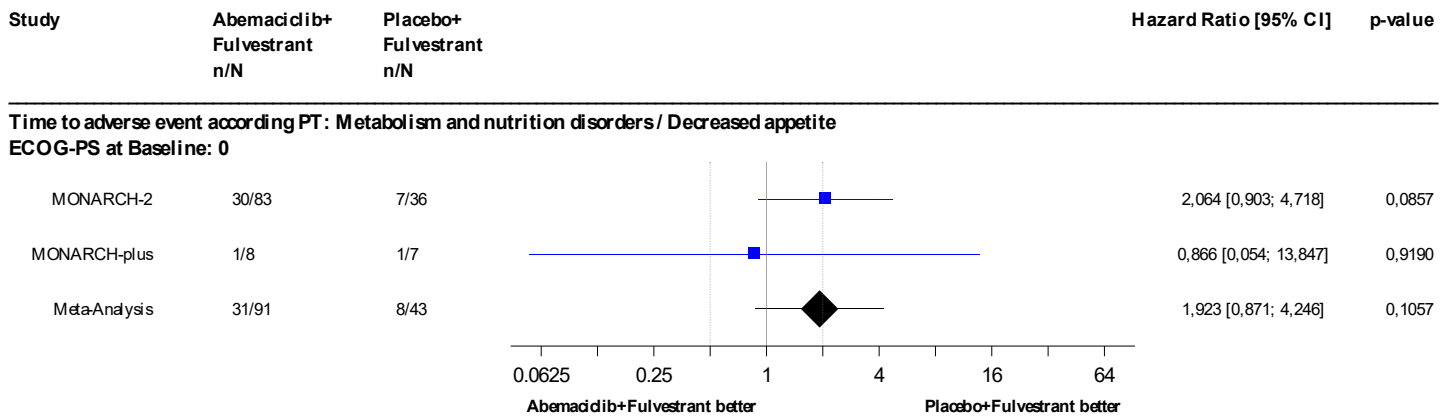
Figure 1207.2.4.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3464, p-value=0,5561, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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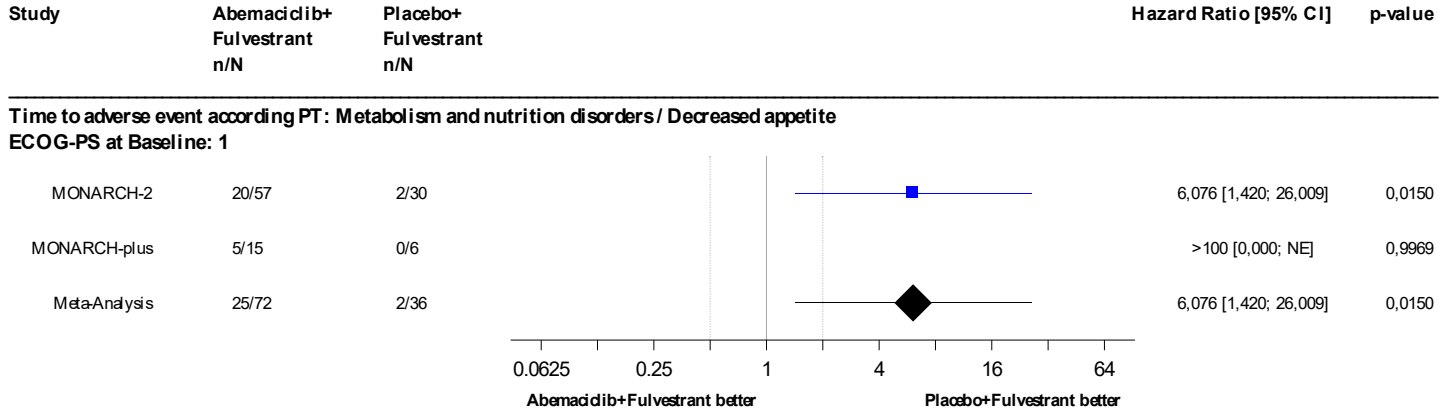
Figure 1207.2.4.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9972, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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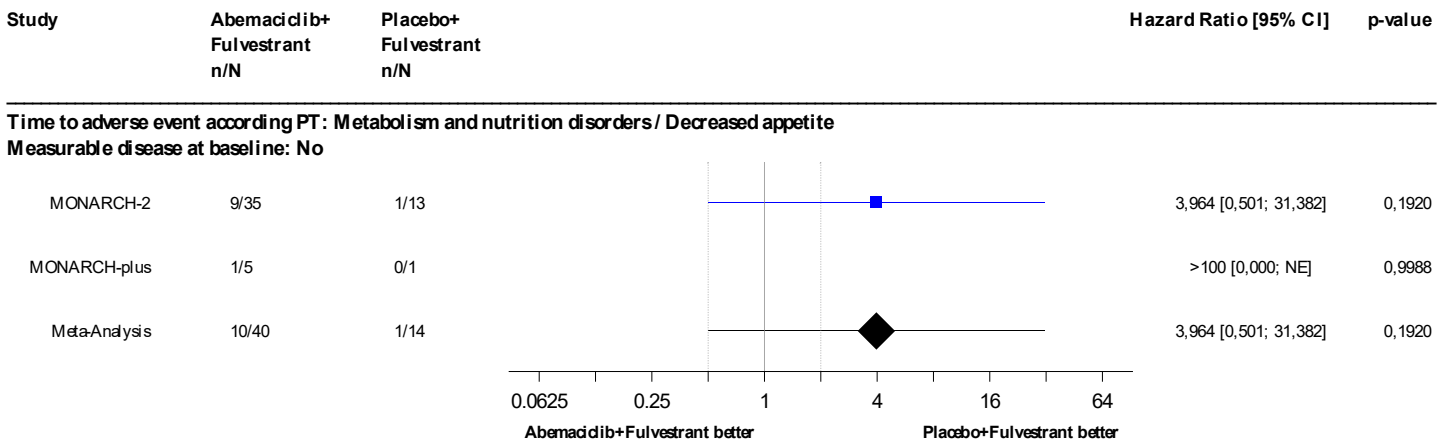
Figure 1207.2.6.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9989, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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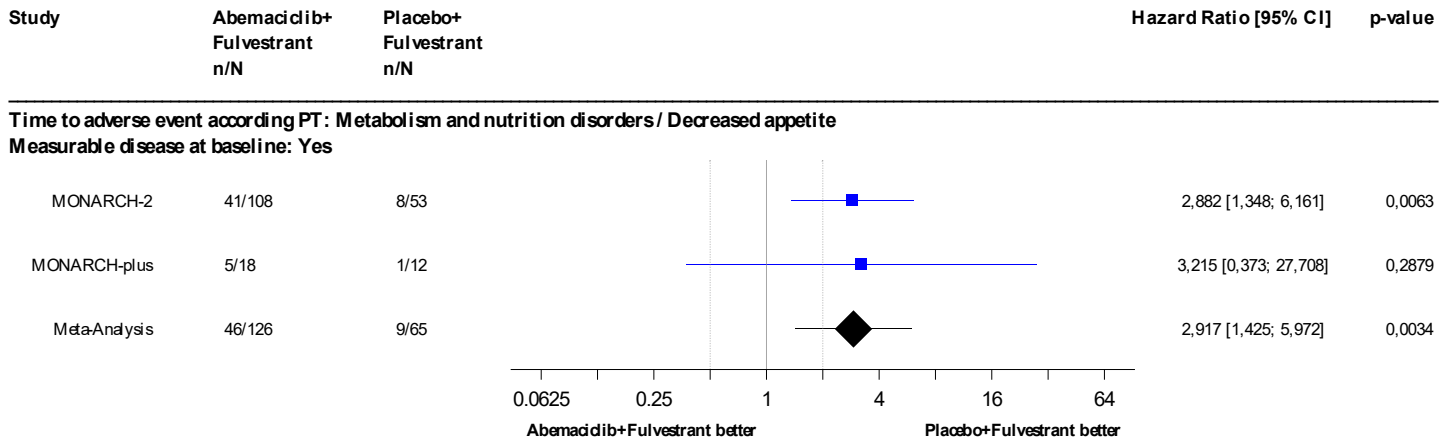
Figure 1207.2.6.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0088, p-value=0,9253, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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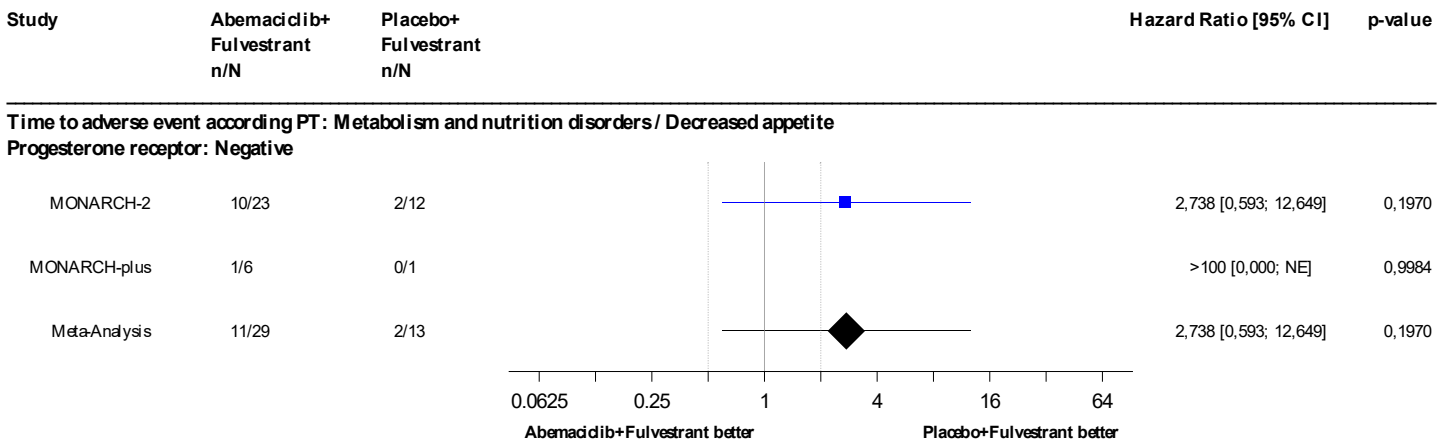
Figure 1207.2.7.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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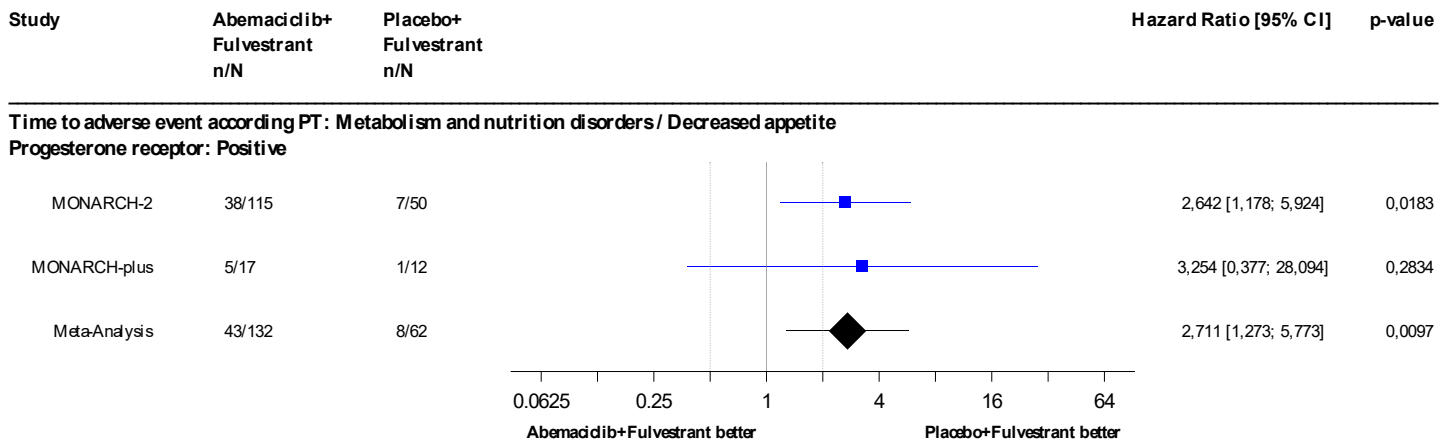
Figure 1207.2.7.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0315, p-value=0,8592, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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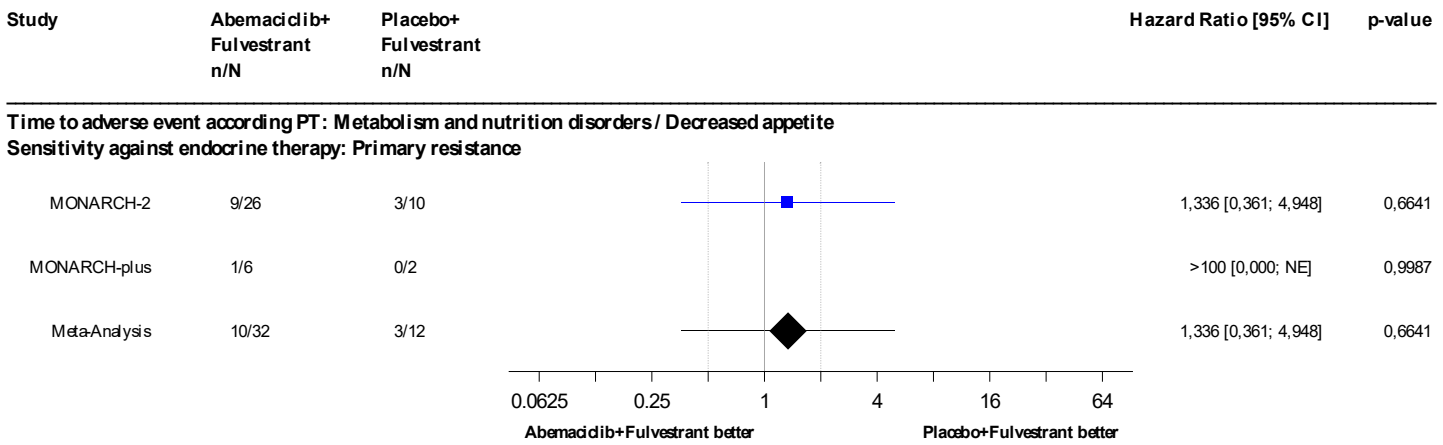
Figure 1207.2.8.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9987, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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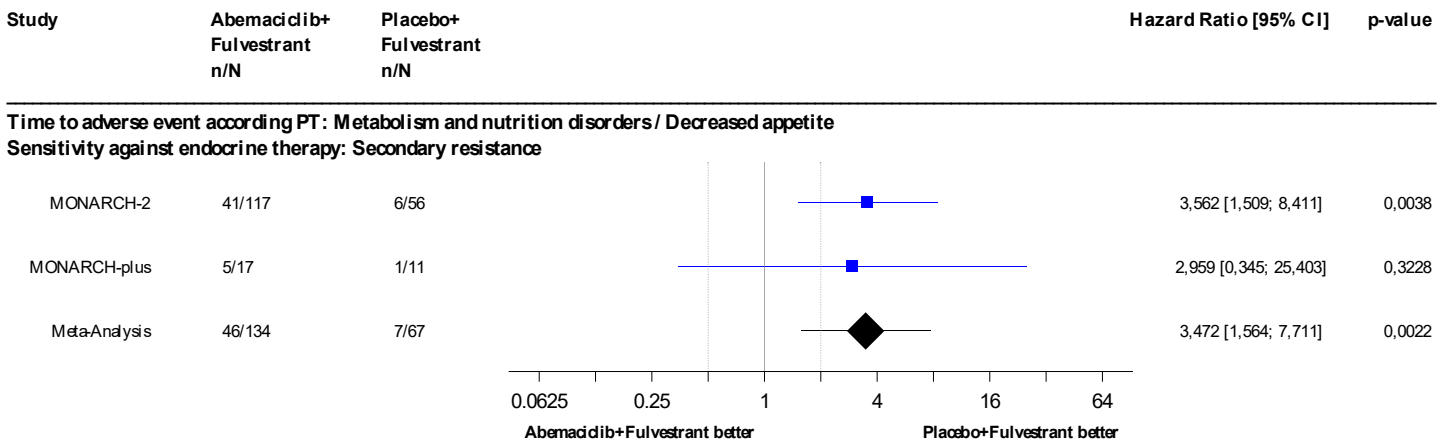
Figure 1207.2.8.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0247, p-value=0,8751, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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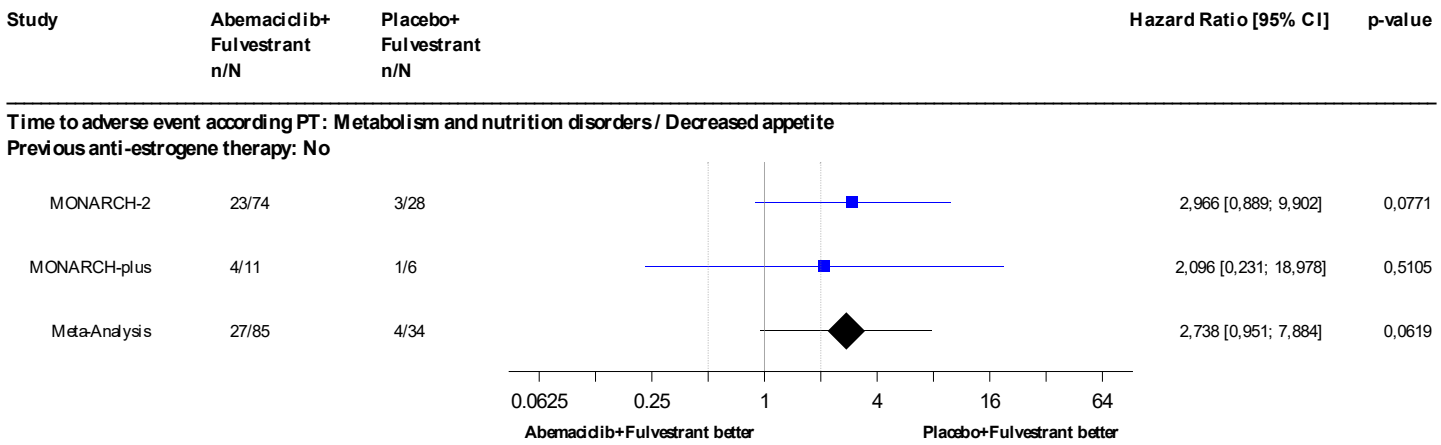
Figure 1207.2.9.1: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0735, p-value=0,7863, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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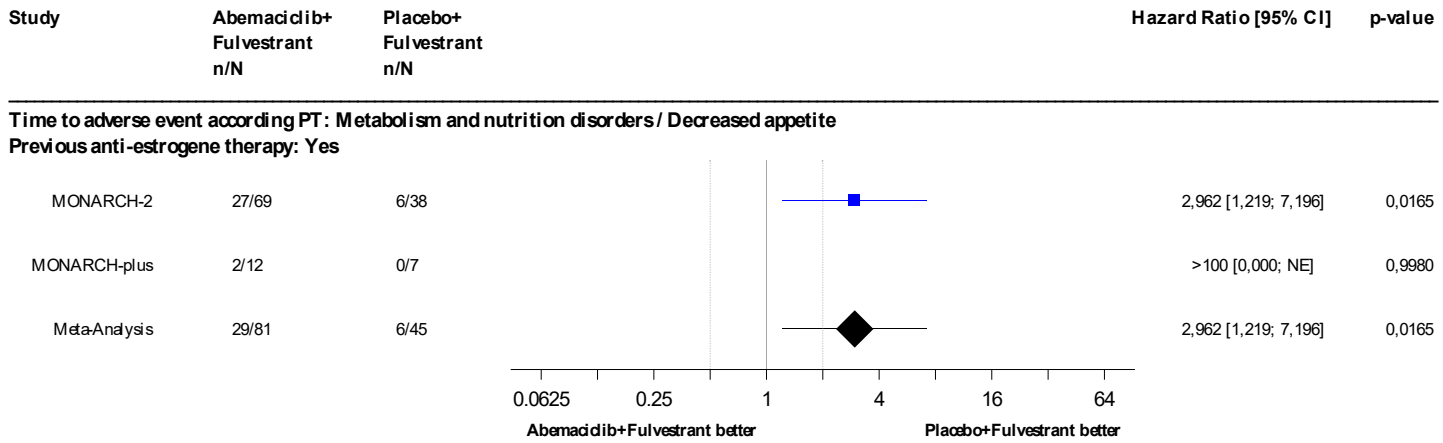
Figure 1207.2.9.2: Metaanalysis results for adverse events according PT[1] -
Metabolism and nutrition disorders / Decreased appetite
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9981, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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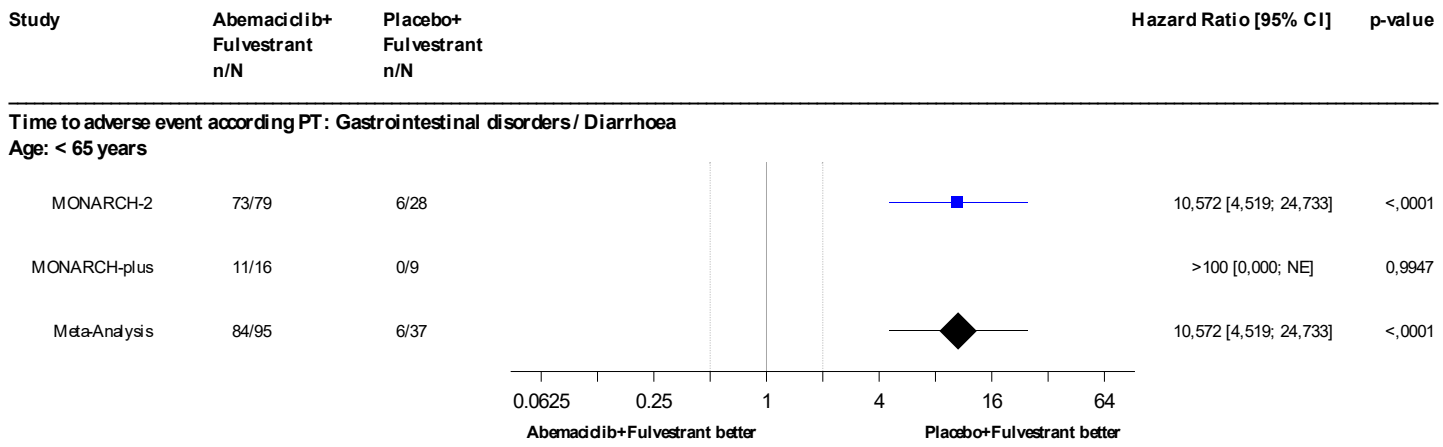
Figure 1208.2.1.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9954, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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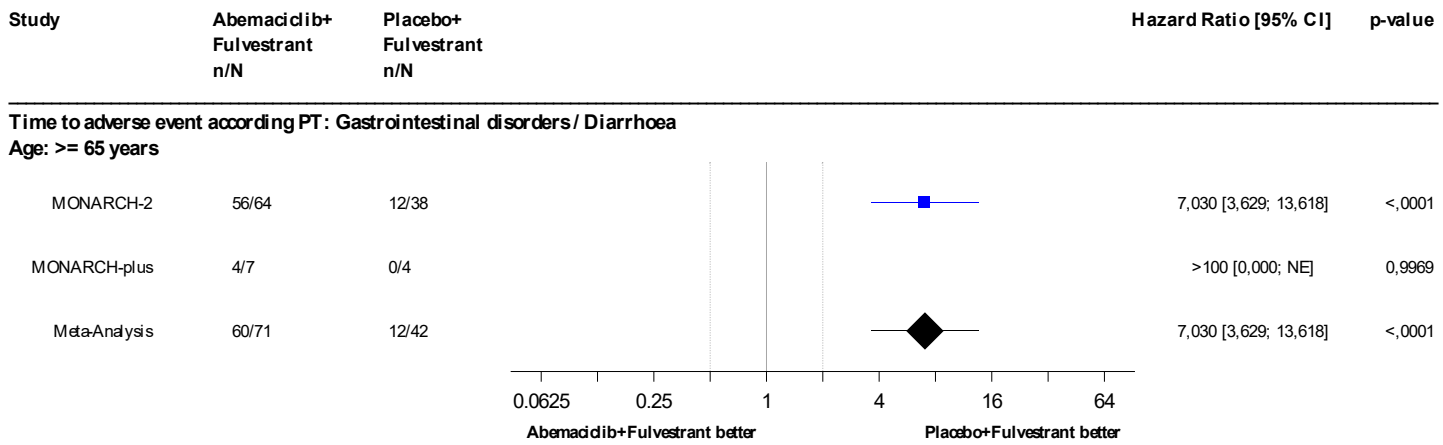
Figure 1208.2.1.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9972, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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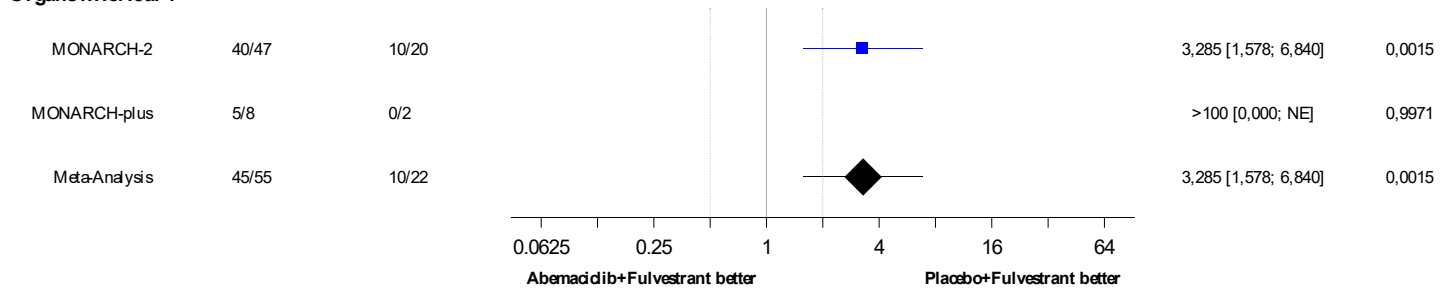
Figure 1208.2.2.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9973, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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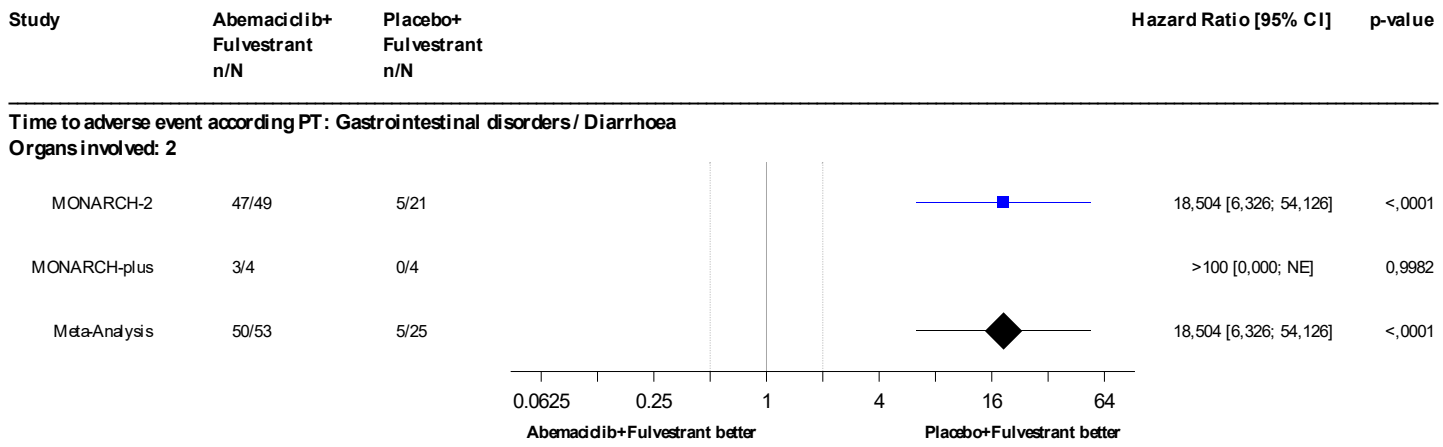
Figure 1208.2.2.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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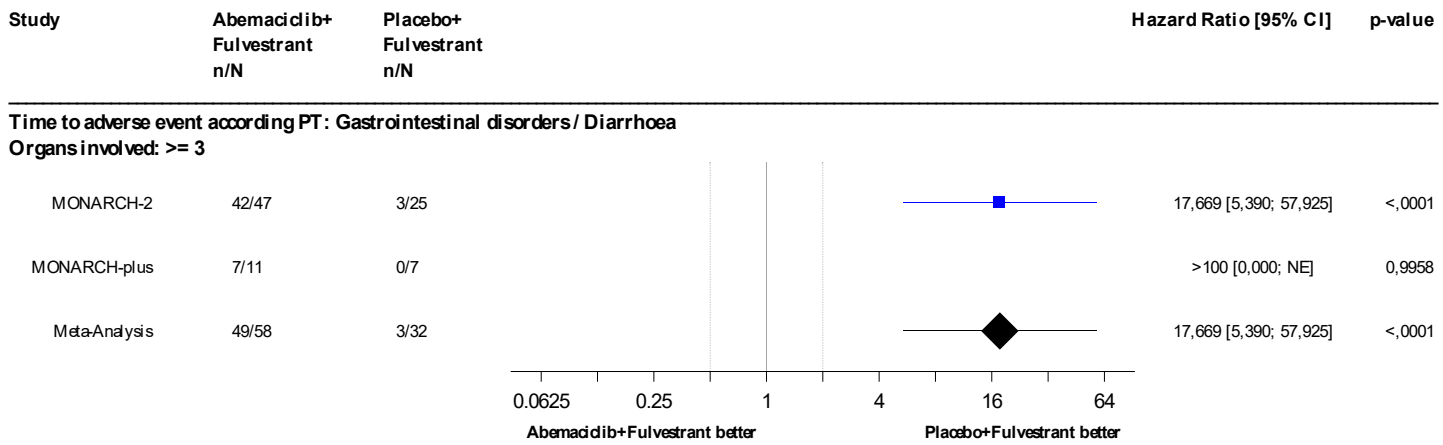
Figure 1208.2.2.3: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9964, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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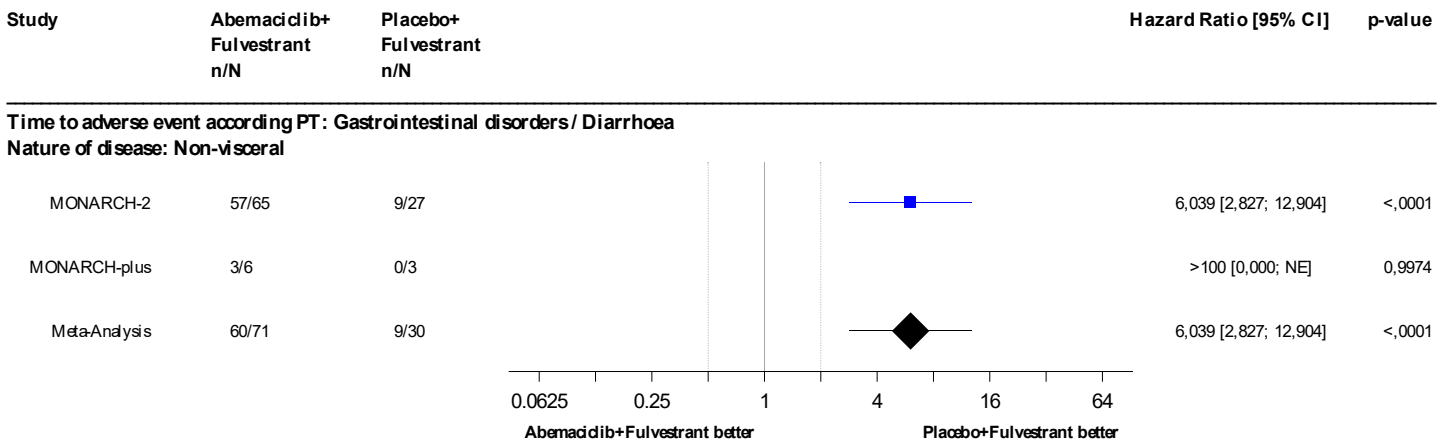
Figure 1208.2.3.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9976, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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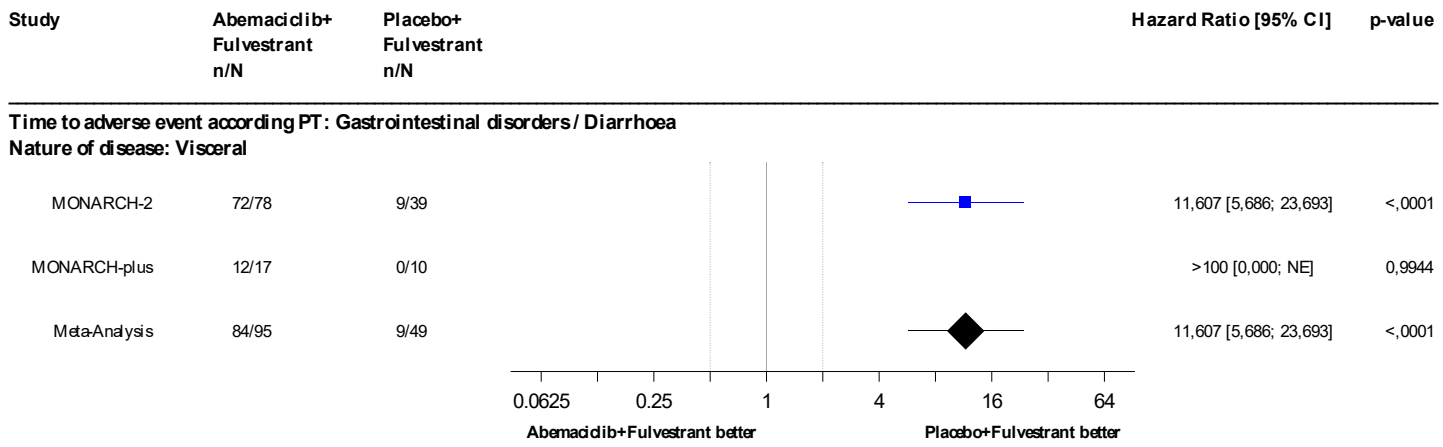
Figure 1208.2.3.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9952, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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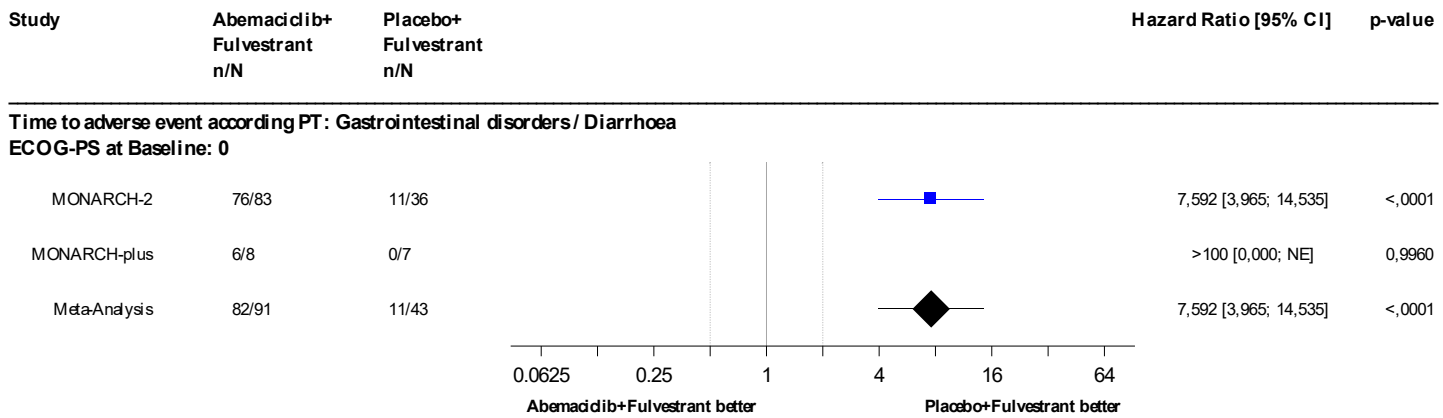
Figure 1208.2.4.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9965, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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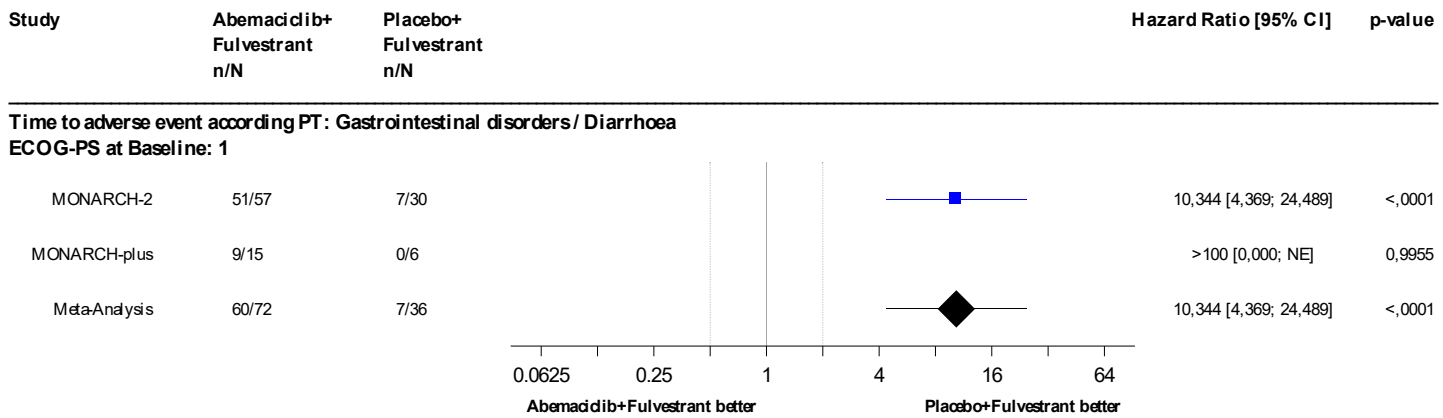
Figure 1208.2.4.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9961, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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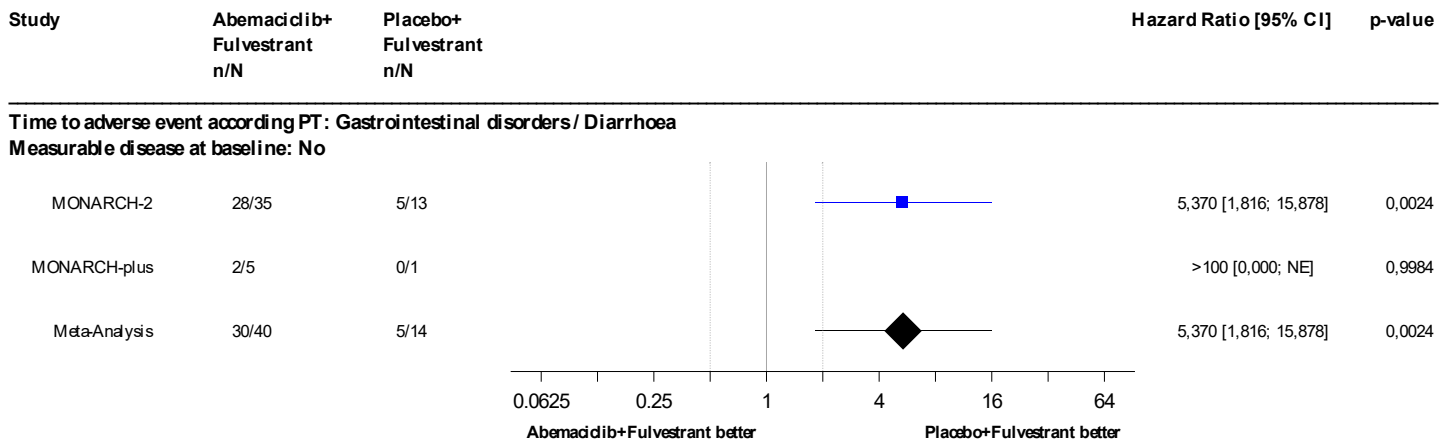
Figure 1208.2.6.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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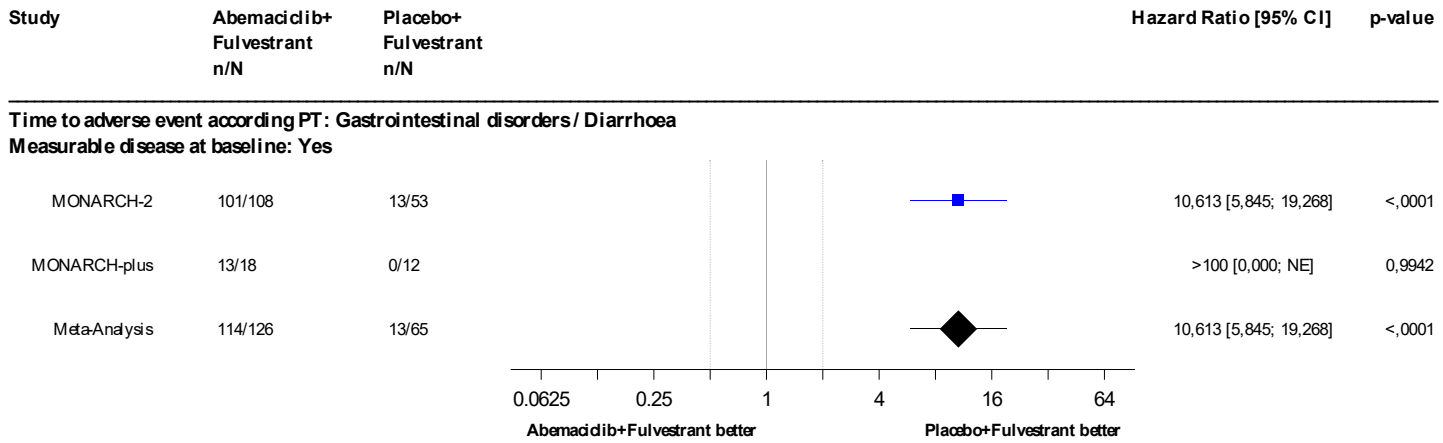
Figure 1208.2.6.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9949, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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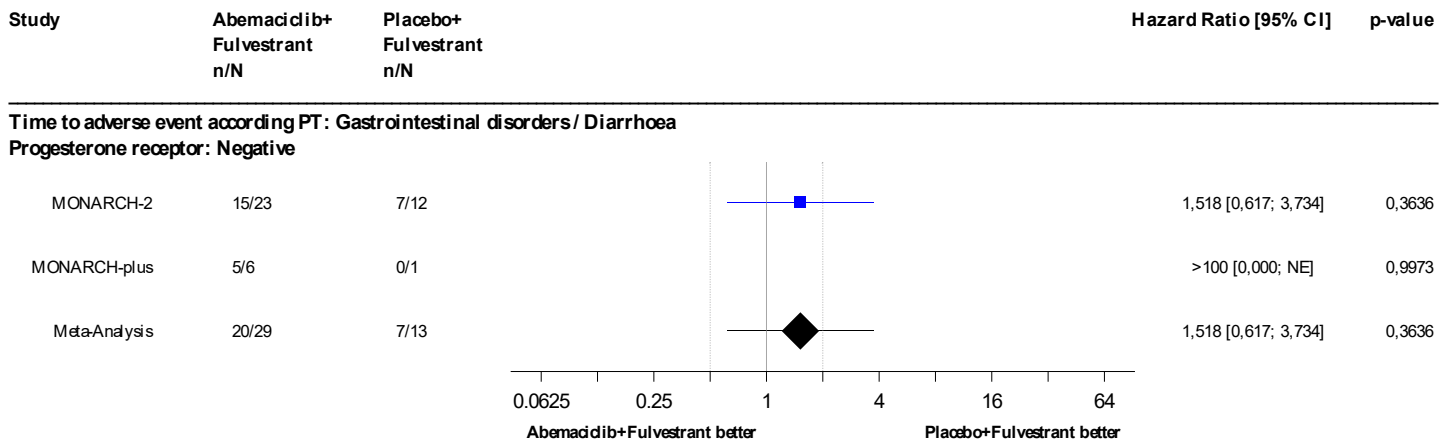
Figure 1208.2.7.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9973, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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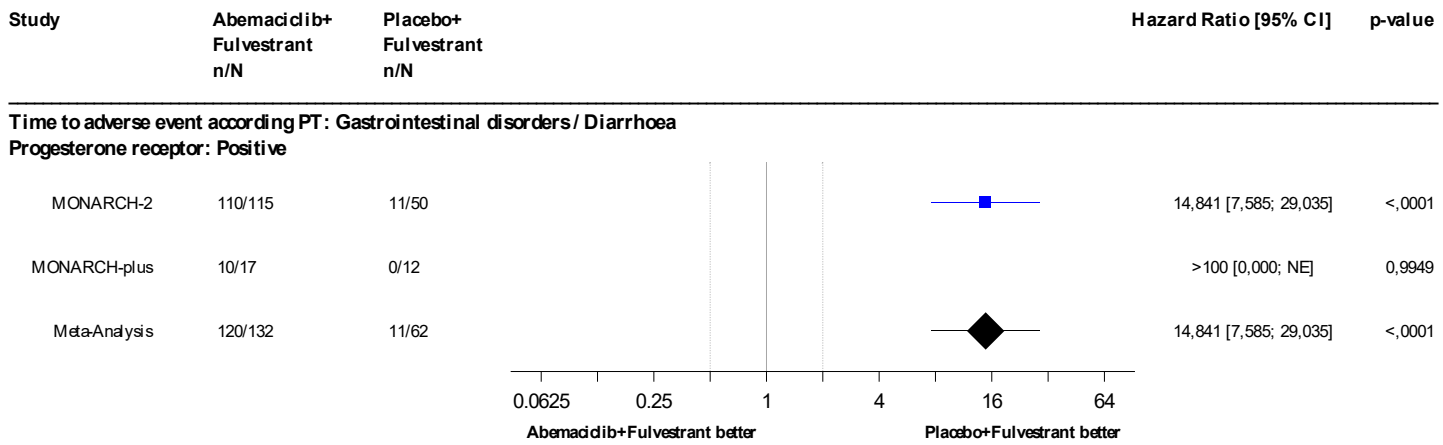
Figure 1208.2.7.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9956, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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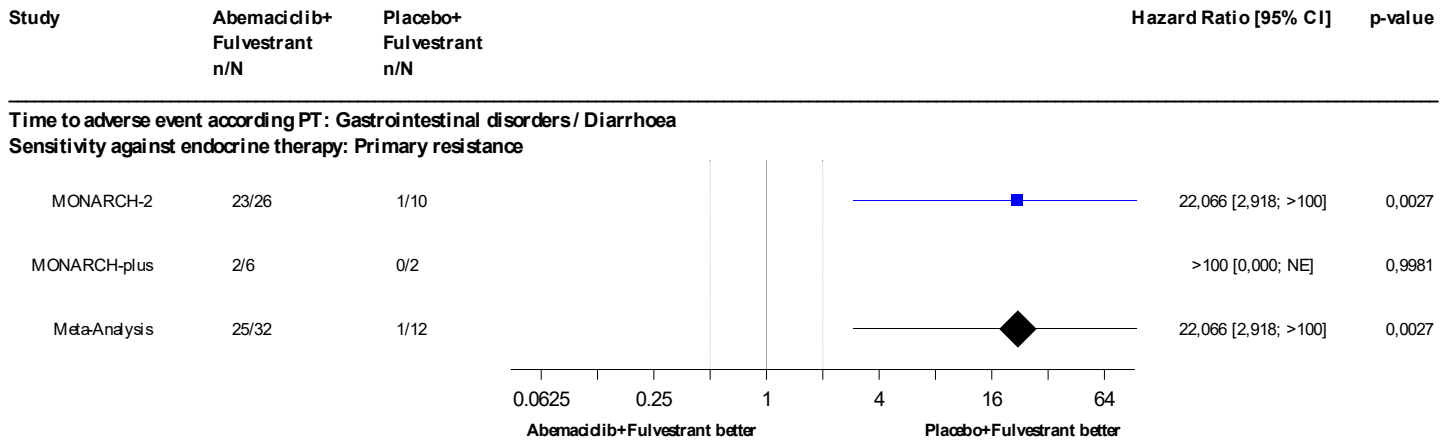
Figure 1208.2.8.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9984, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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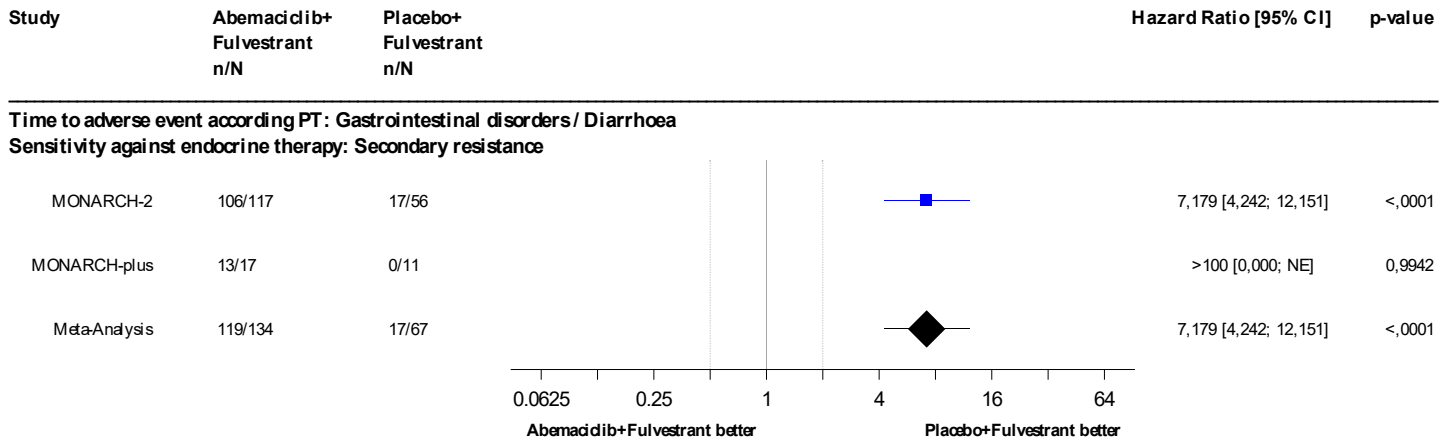
Figure 1208.2.8.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9948, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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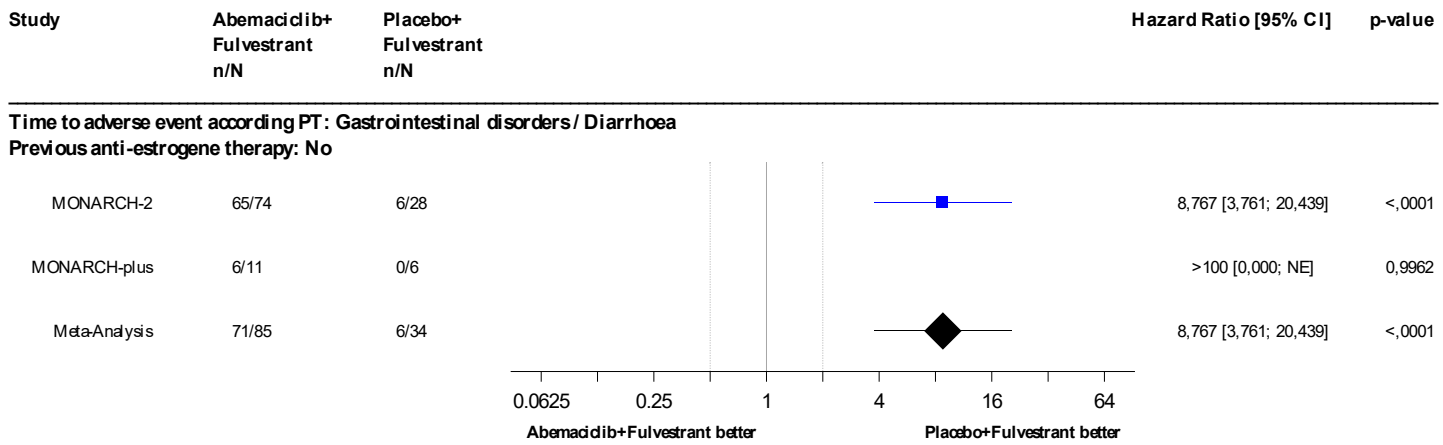
Figure 1208.2.9.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9966, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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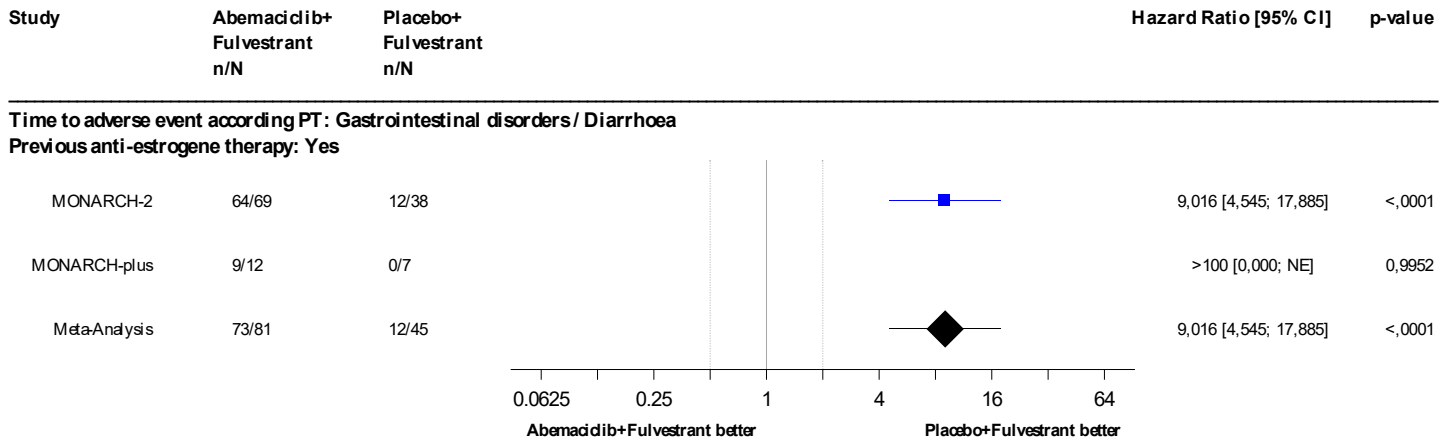
Figure 1208.2.9.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9958, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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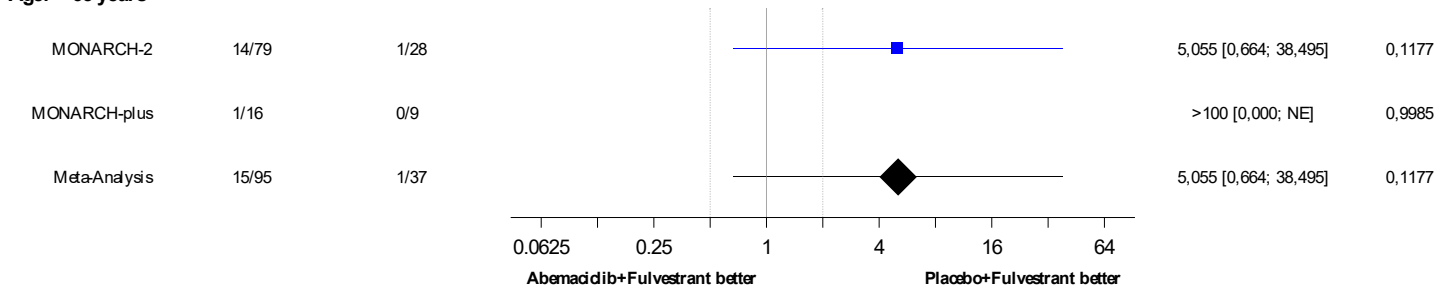
Figure 1212.2.1.1: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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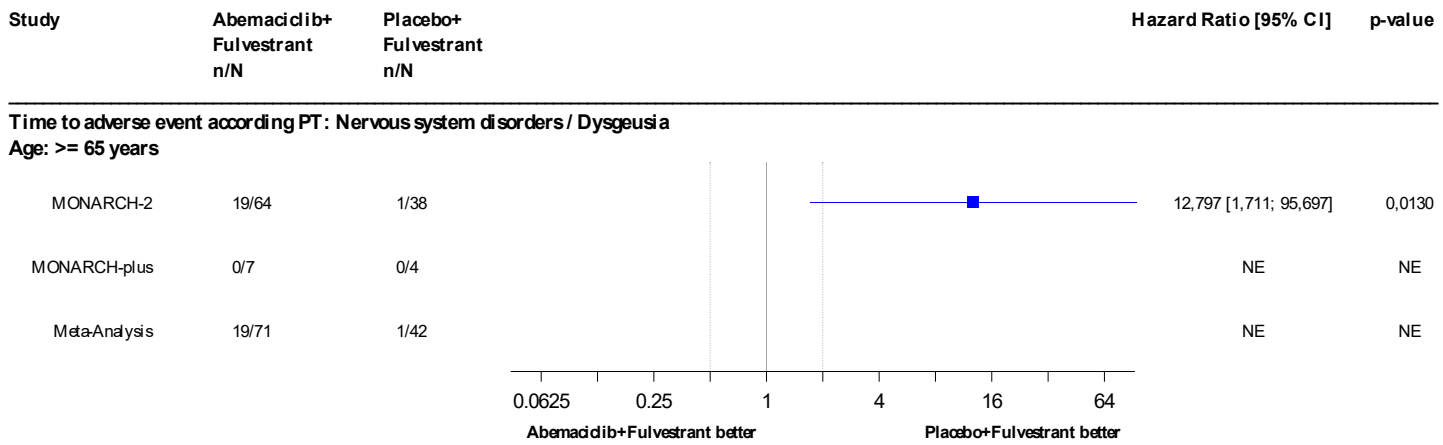
Figure 1212.2.1.2: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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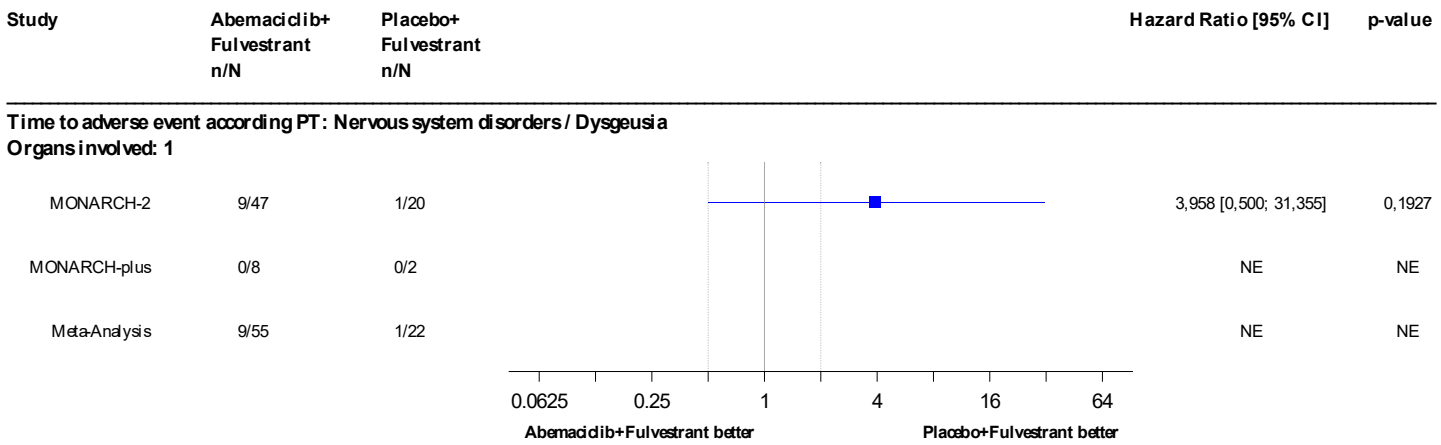
Figure 1212.2.2.1: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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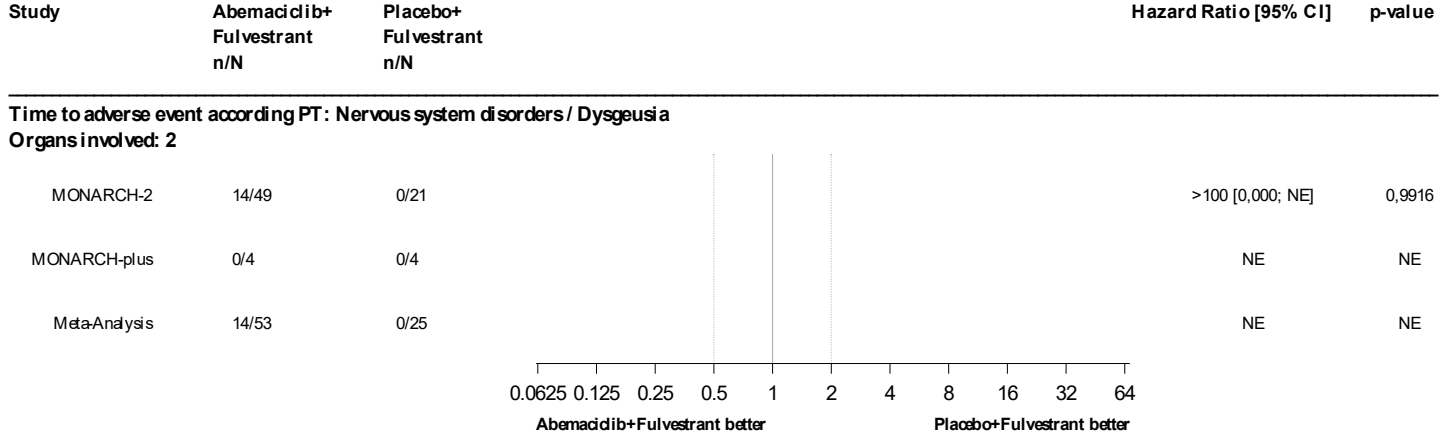
Figure 1212.2.2.2: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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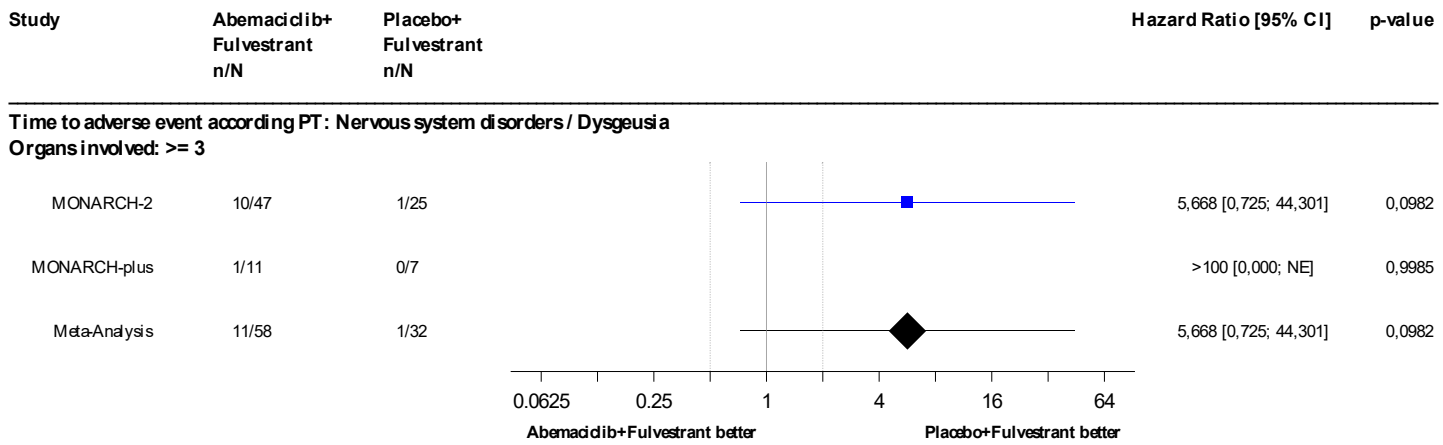
Figure 1212.2.2.3: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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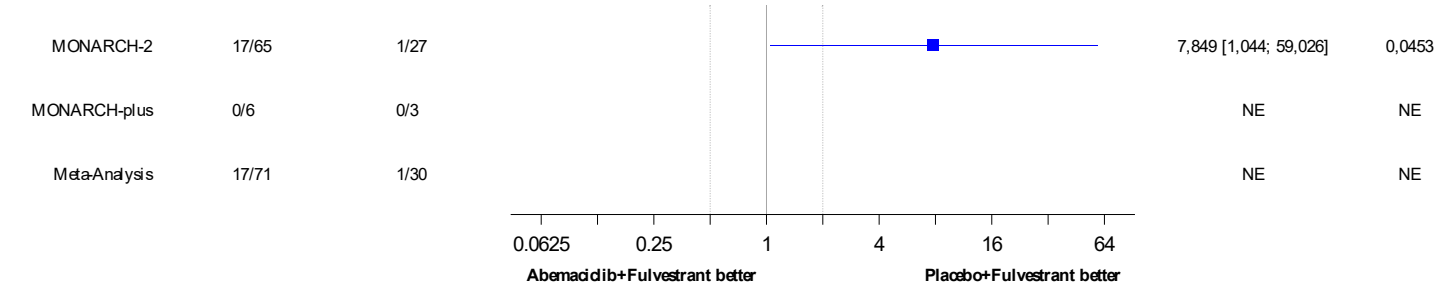
Figure 1212.2.3.1: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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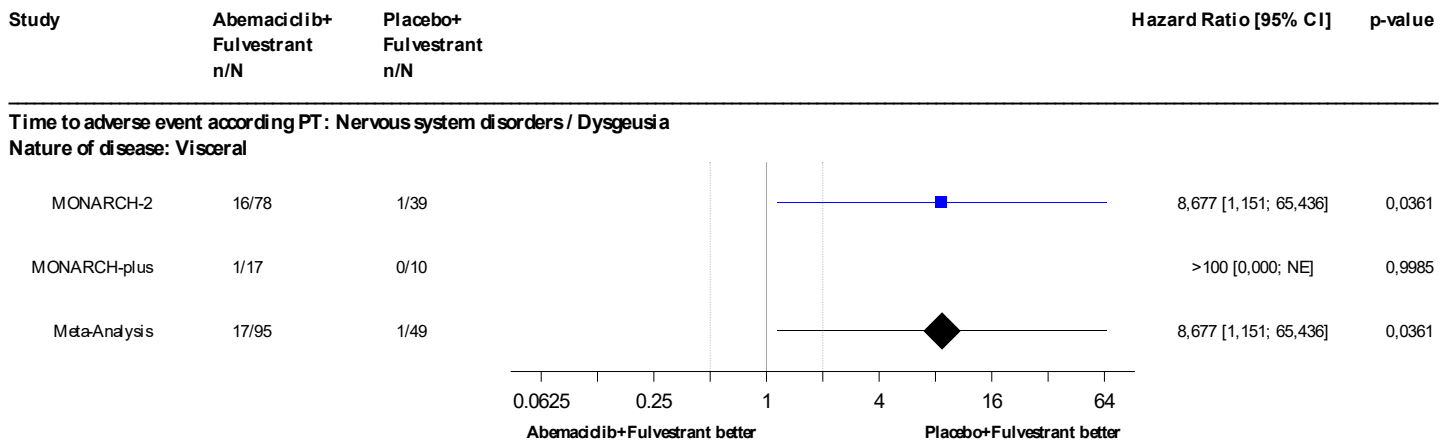
Figure 1212.2.3.2: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9987, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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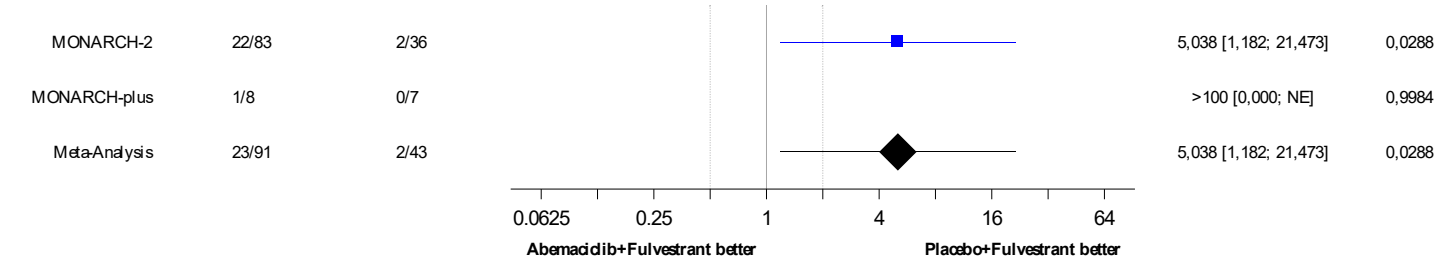
Figure 1212.2.4.1: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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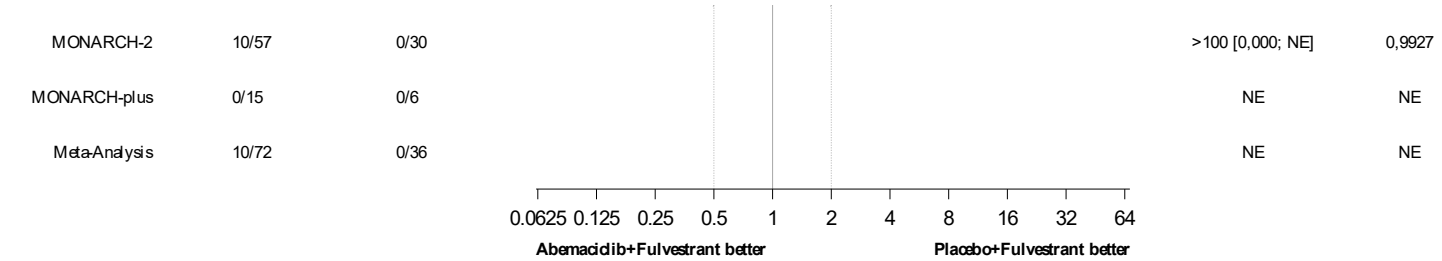
Figure 1212.2.4.2: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE

Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

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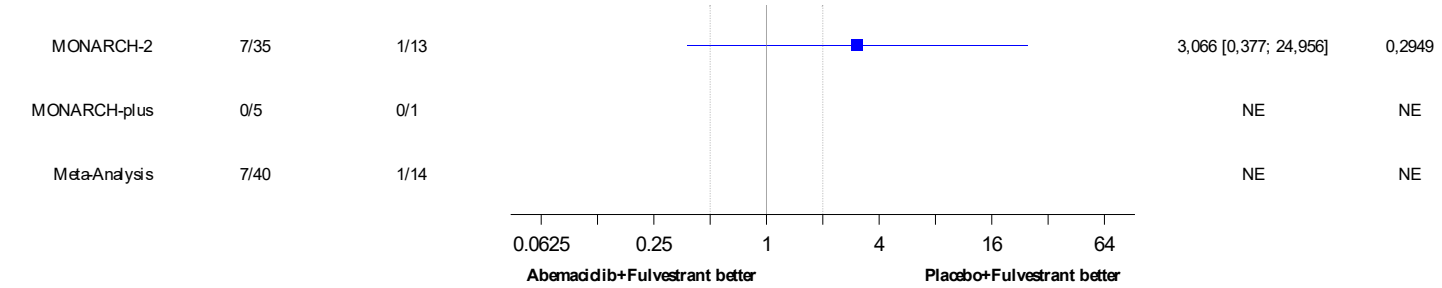
Figure 1212.2.6.1: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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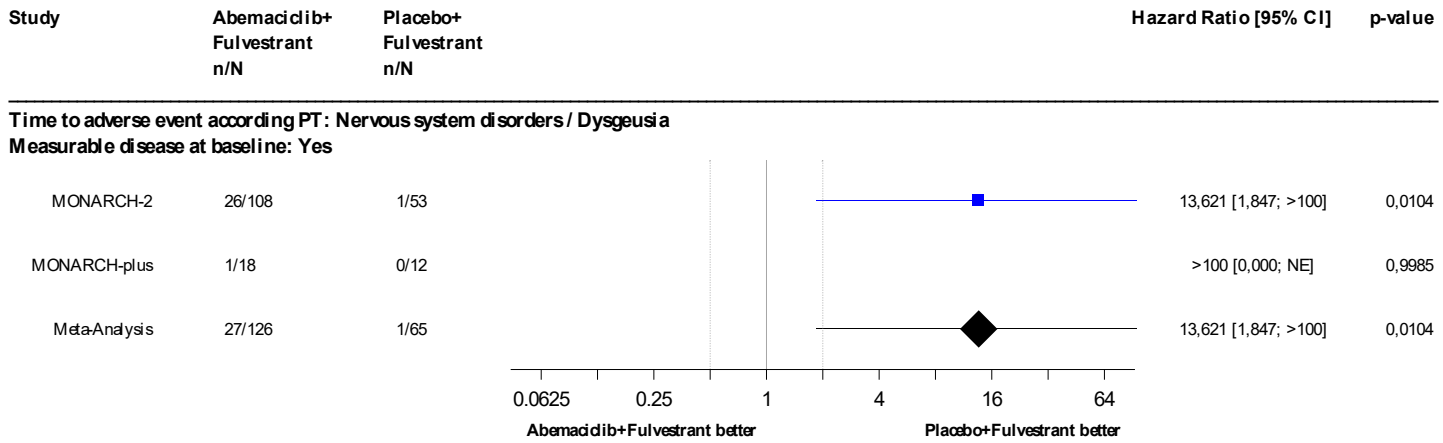
Figure 1212.2.6.2: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9987, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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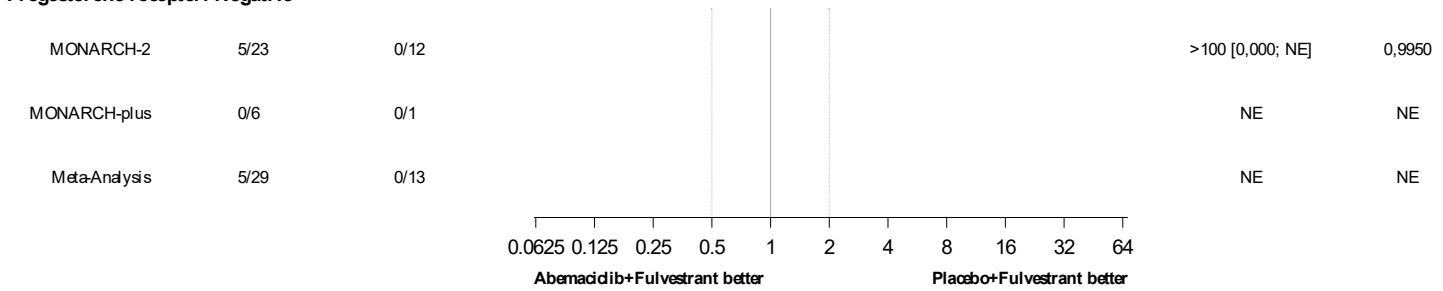
Figure 1212.2.7.1: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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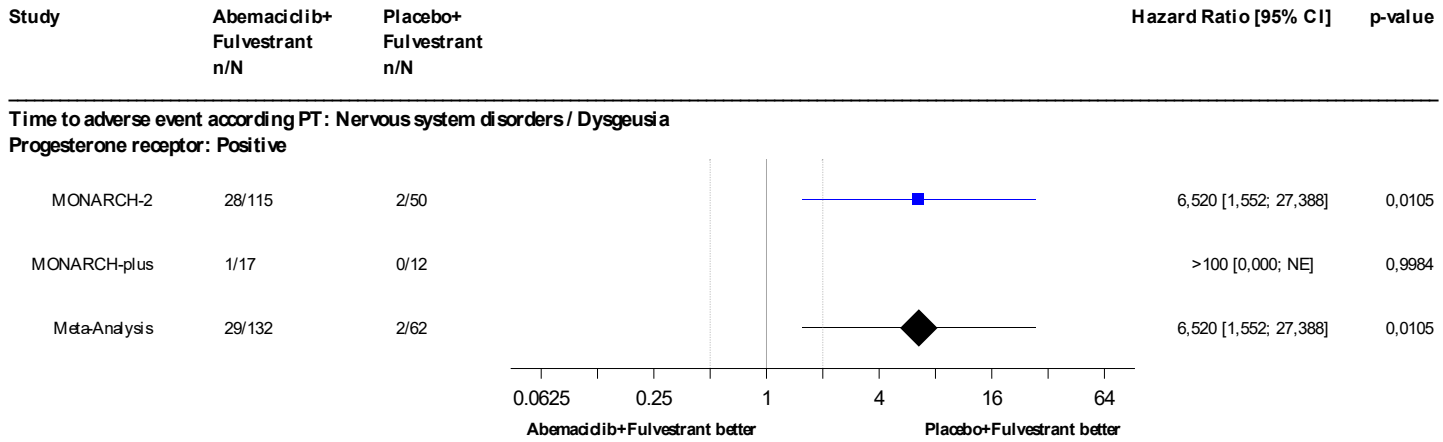
Figure 1212.2.7.2: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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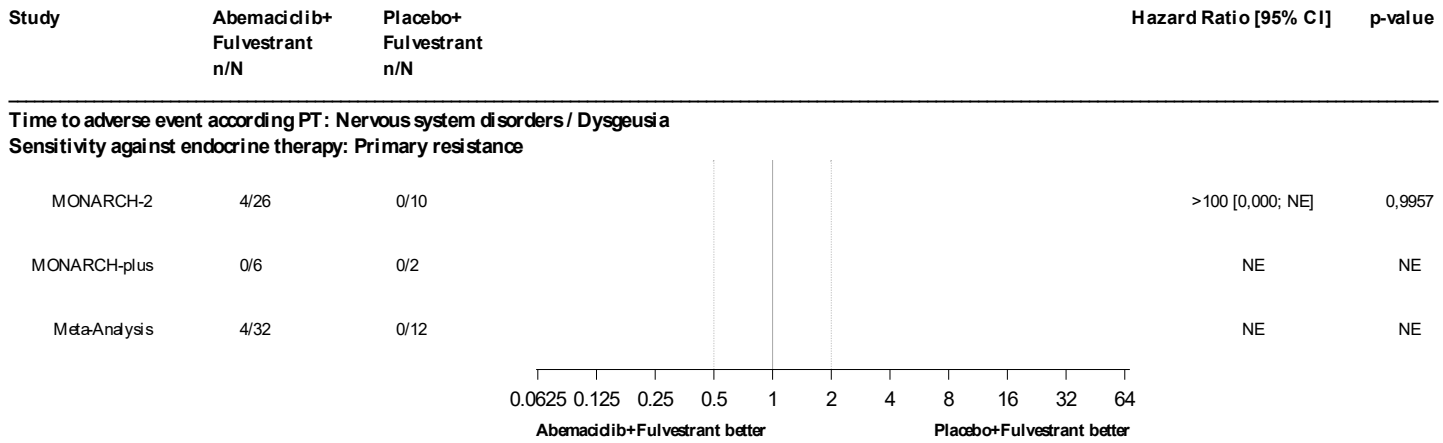
Figure 1212.2.8.1: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep019_popa2_snthr_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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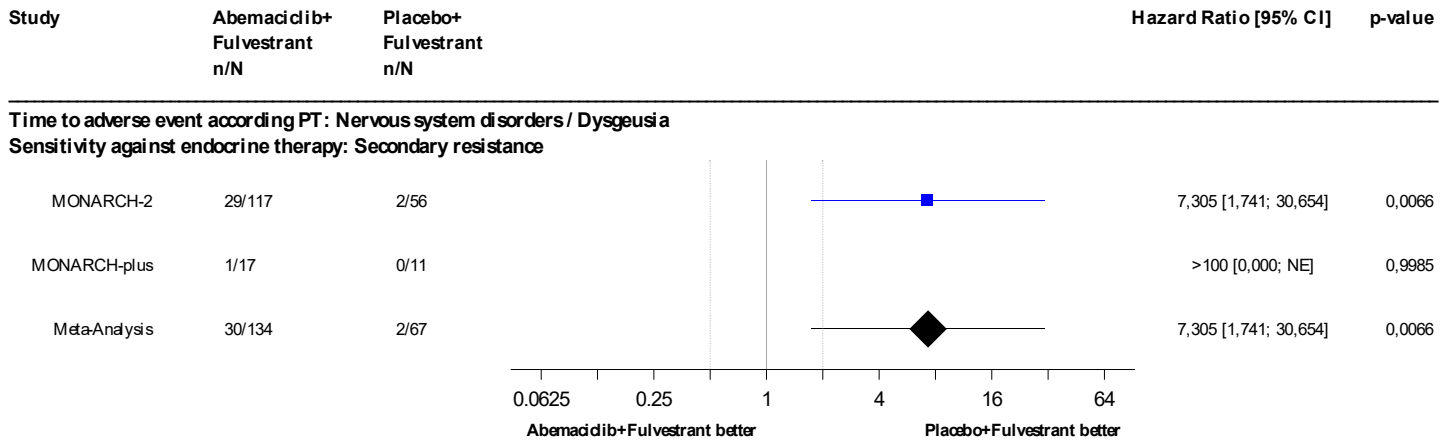
Figure 1212.2.8.2: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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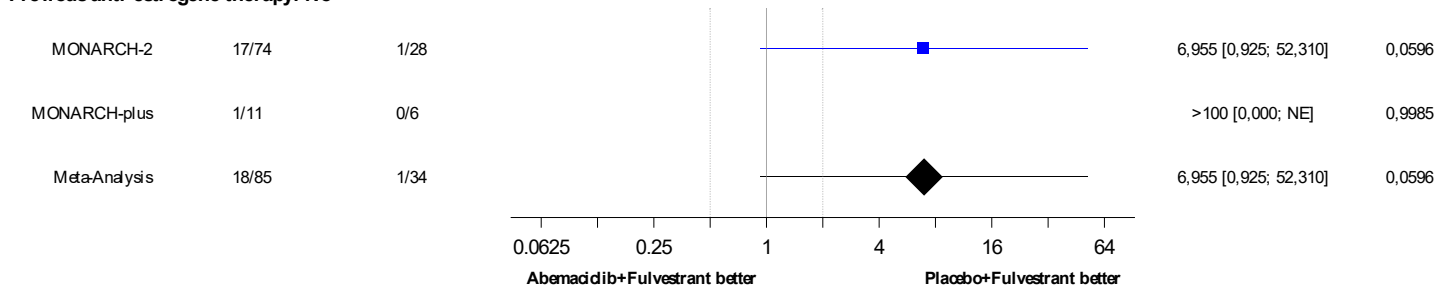
Figure 1212.2.9.1: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9987, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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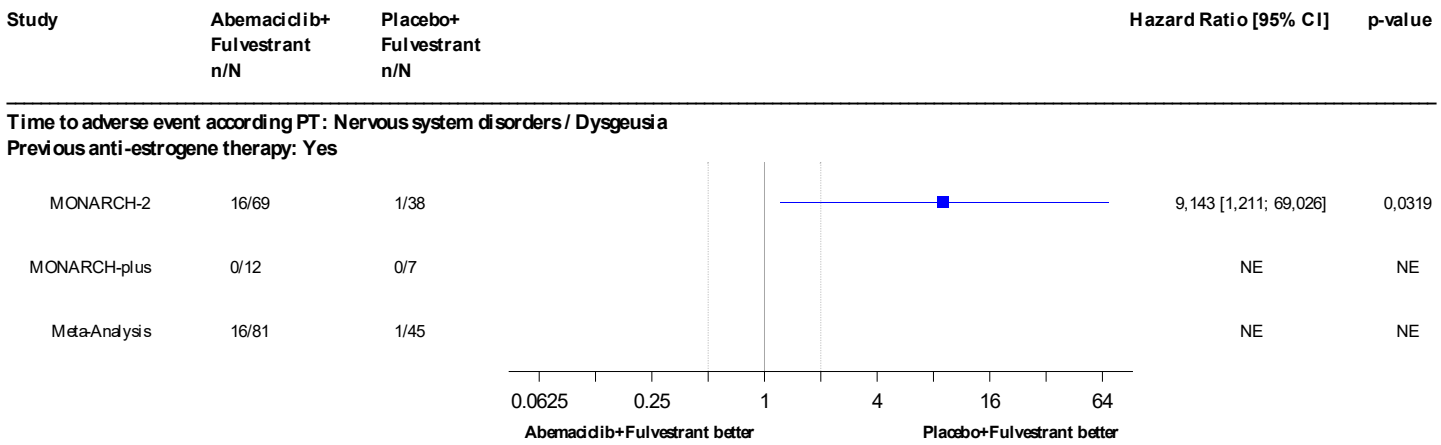
Figure 1212.2.9.2: Metaanalysis results for adverse events according PT[1] -
Nervous system disorders / Dysgeusia
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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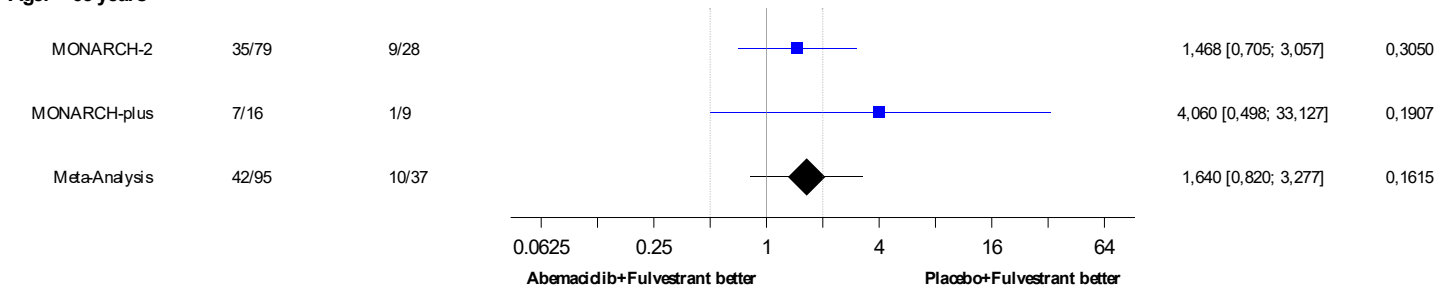
Figure 1216.2.1.1: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,8043, p-value=0,3698, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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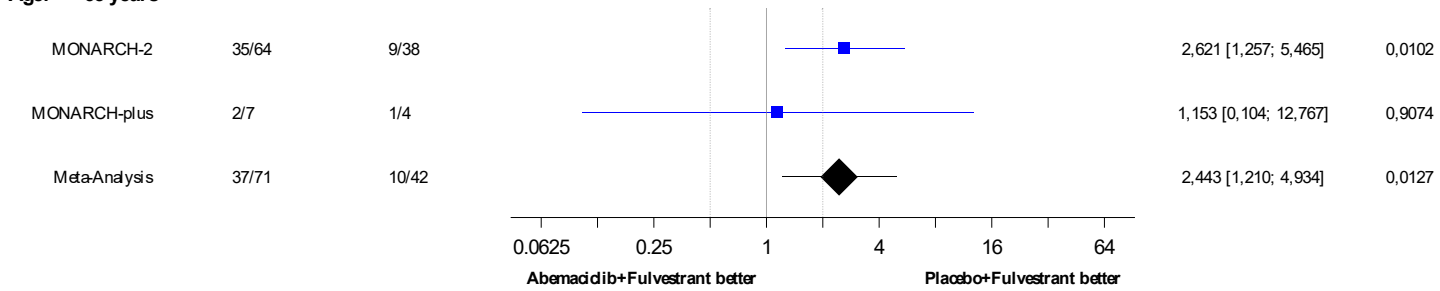
Figure 1216.2.1.2: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4096, p-value=0,5222, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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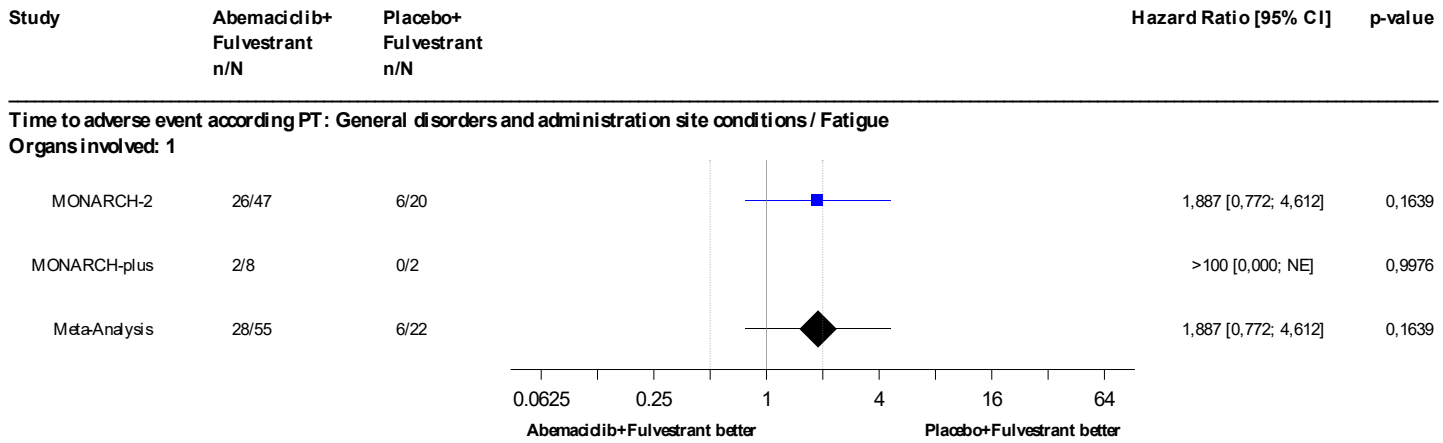
**Figure 1216.2.2.1: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9977, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep023_popa2_norggr_1.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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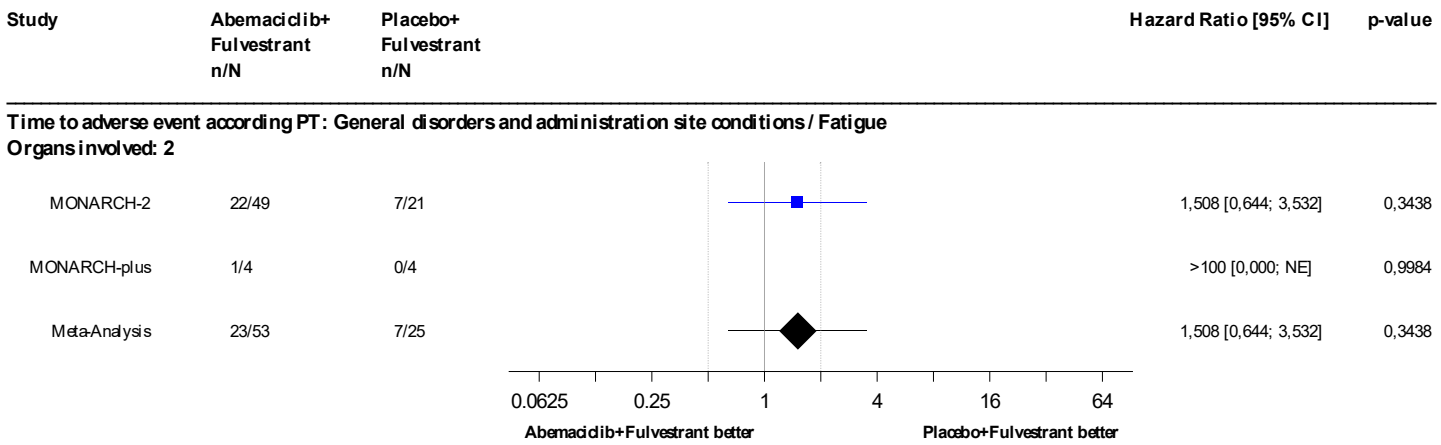
**Figure 1216.2.2.2: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9984, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep023_popa2_norggr_2.rtf

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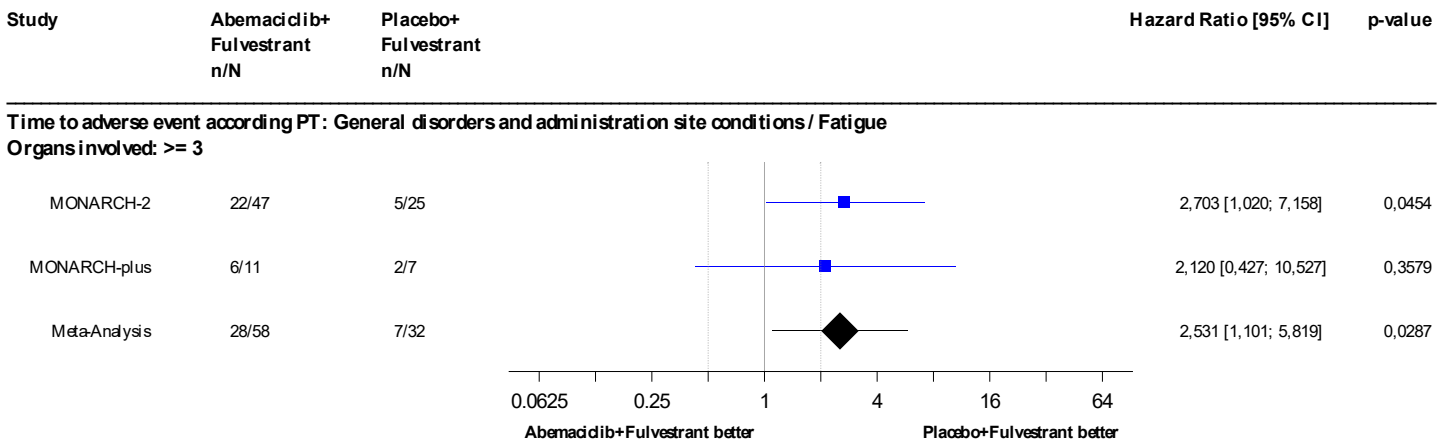
Figure 1216.2.2.3: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0643, p-value=0,7998, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep023_popa2_norggr_3.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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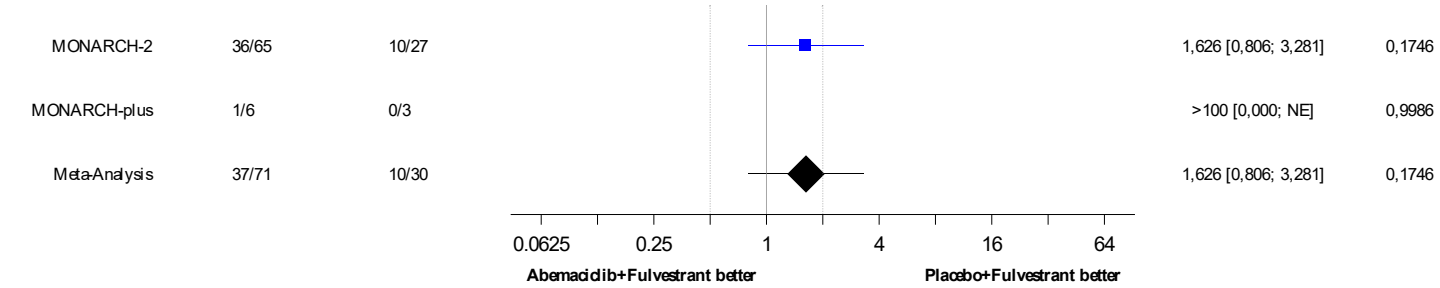
**Figure 1216.2.3.1: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9987, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep023_popa2_natdis2_1.rtf
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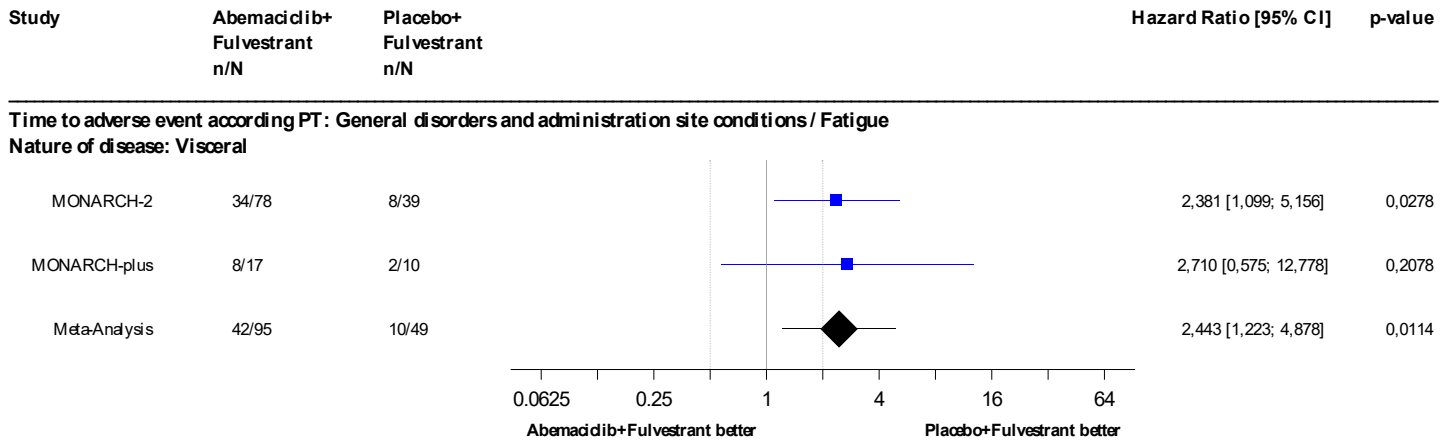
**Figure 1216.2.3.2: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0215, p-value=0,8835, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep023_popa2_natdis2_2.rtf
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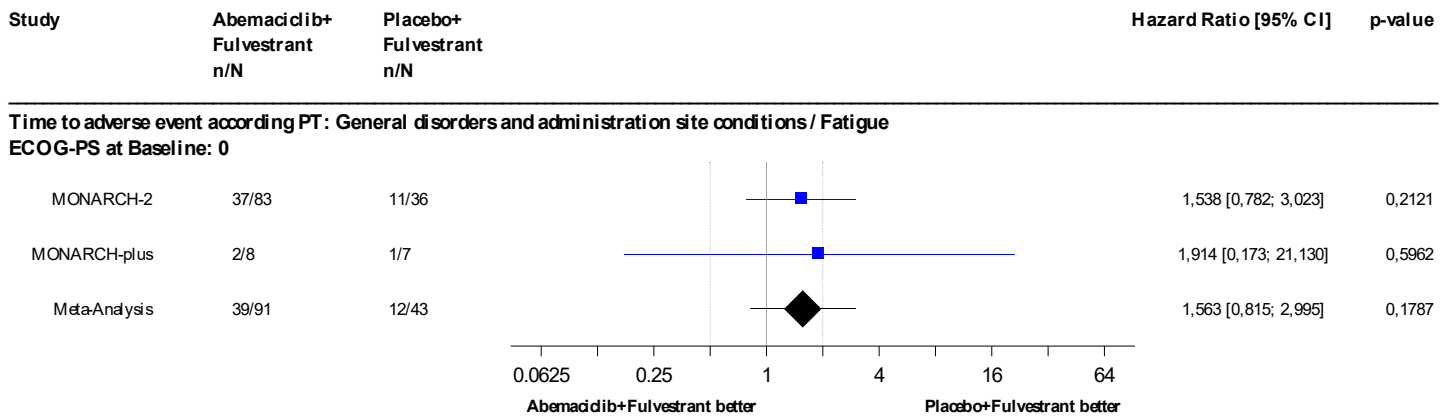
Figure 1216.2.4.1: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0296, p-value=0,8635, I2 index=0%

Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep023_popa2_ecogbl_1.rtf

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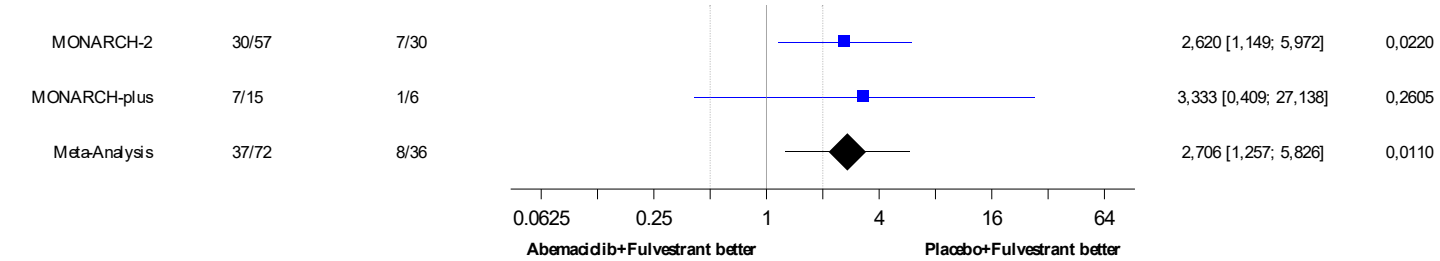
**Figure 1216.2.4.2: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0438, p-value=0,8341, I2 index=0%

Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep023_popa2_ecogbl_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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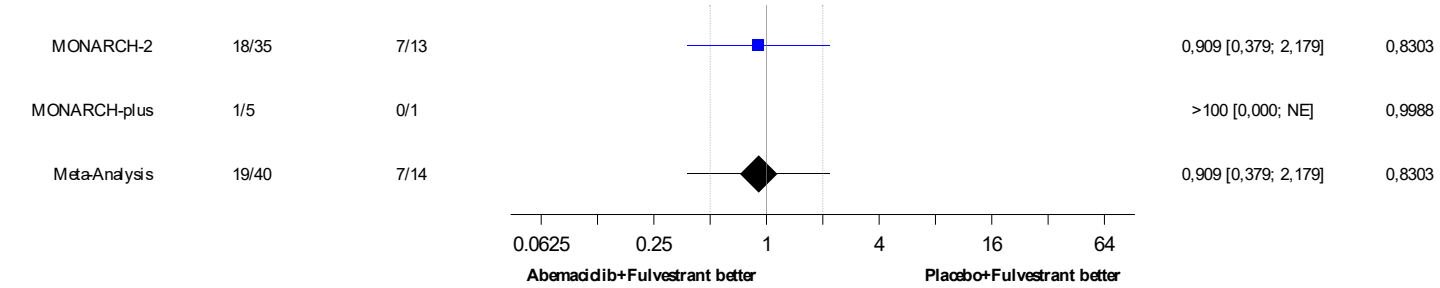
**Figure 1216.2.6.1: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9988, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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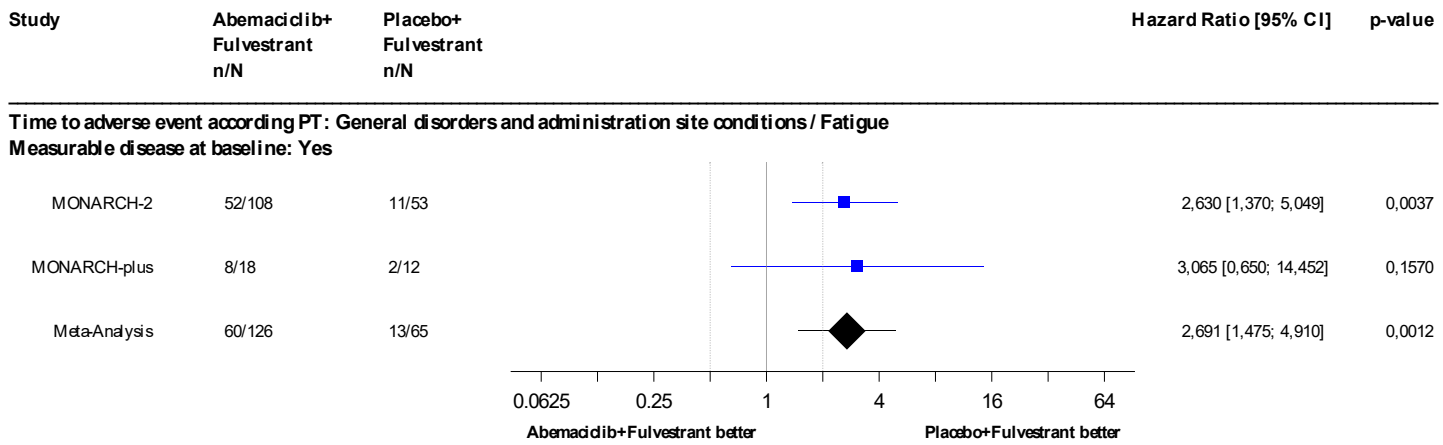
**Figure 1216.2.6.2: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0317, p-value=0,8587, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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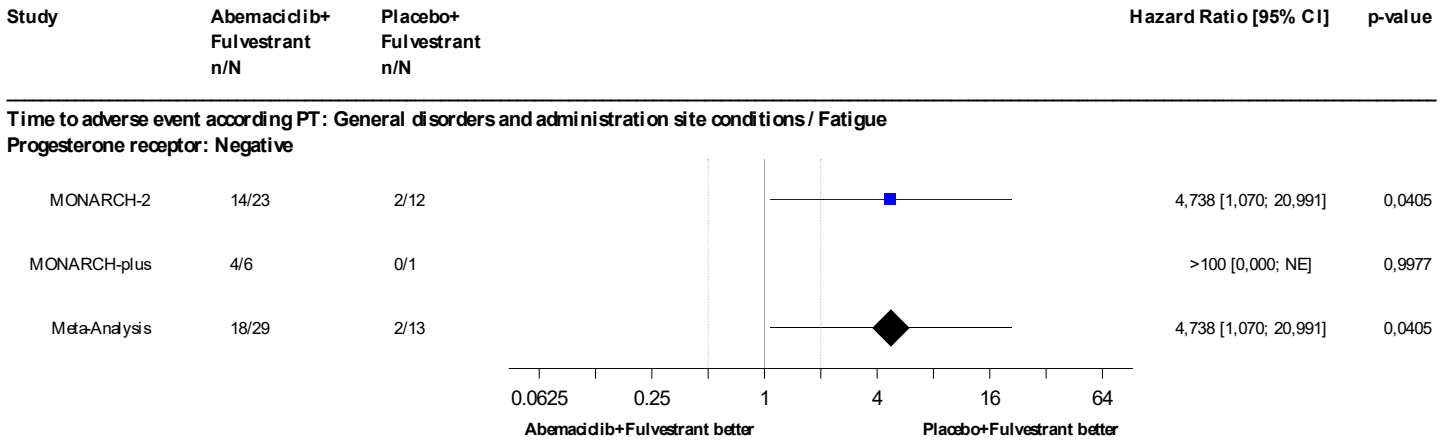
**Figure 1216.2.7.1: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9979, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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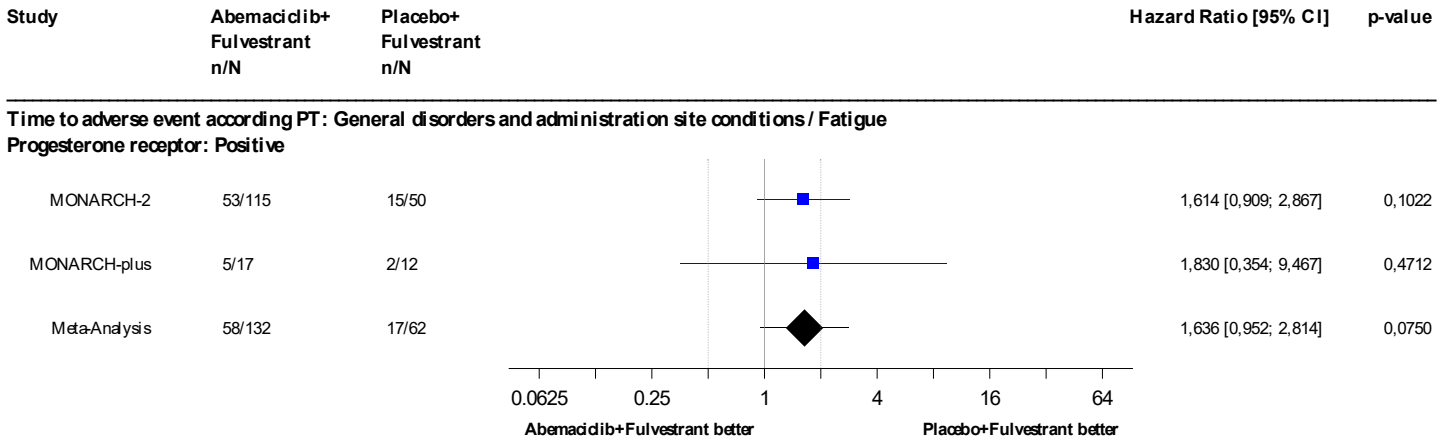
**Figure 1216.2.7.2: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0199, p-value=0,8879, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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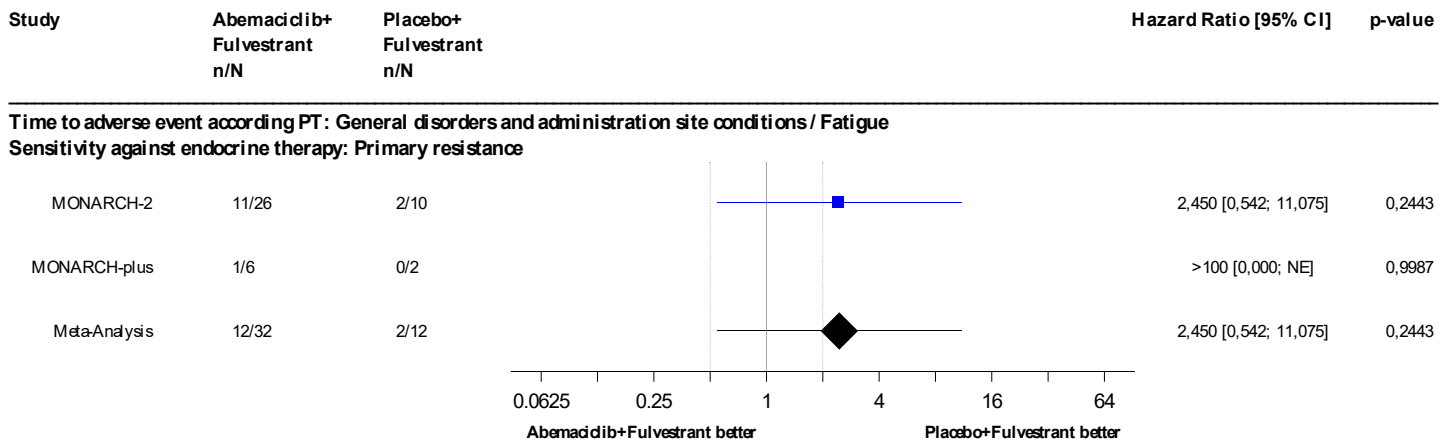
**Figure 1216.2.8.1: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9988, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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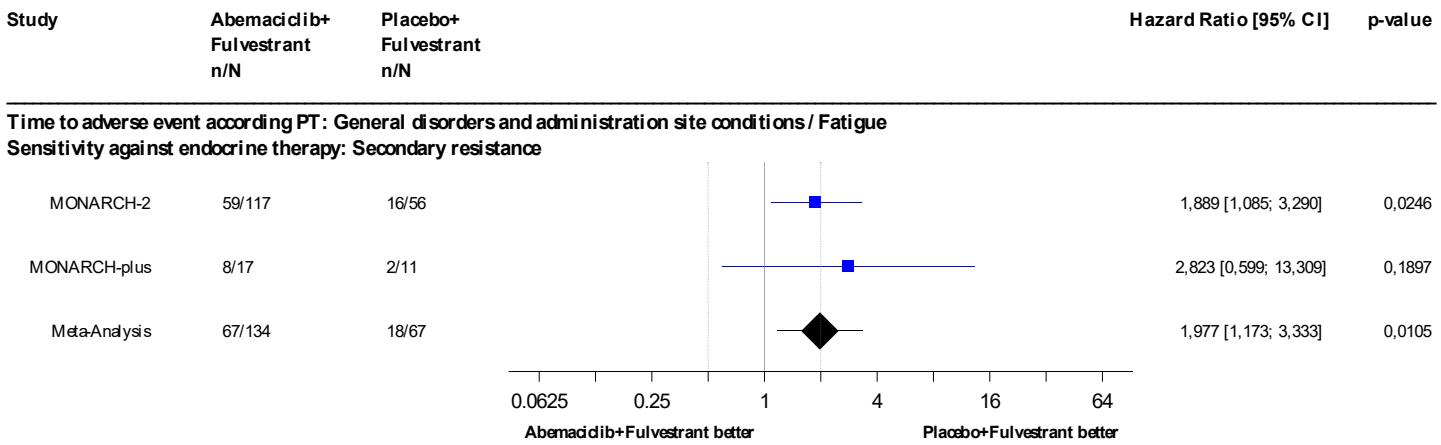
**Figure 1216.2.8.2: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,2283, p-value=0,6328, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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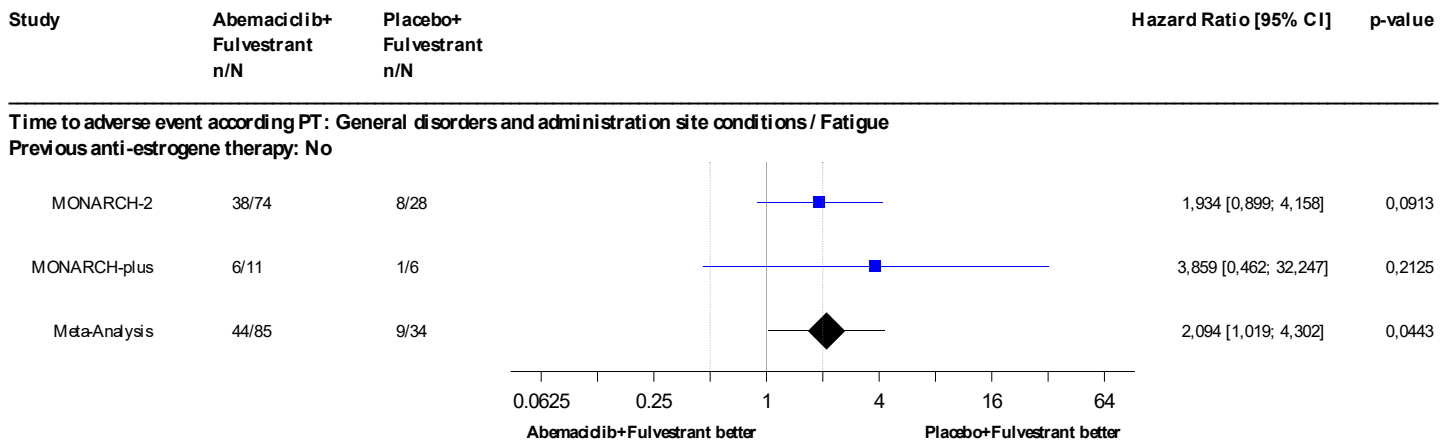
**Figure 1216.2.9.1: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,3602, p-value=0,5484, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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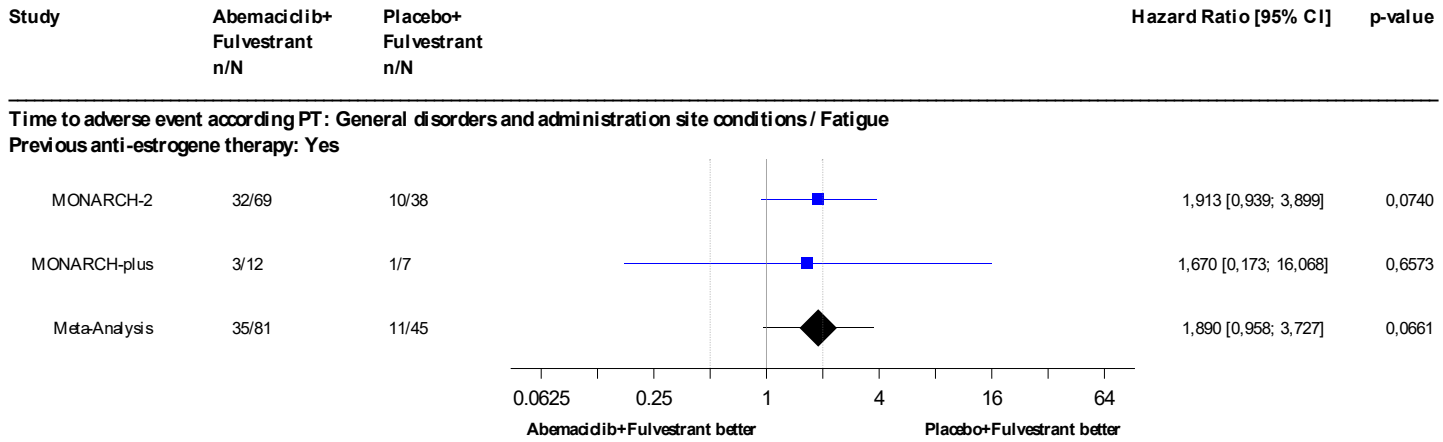
**Figure 1216.2.9.2: Metaanalysis results for adverse events according PT[1] -
General disorders and administration site conditions / Fatigue
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0127, p-value=0,9104, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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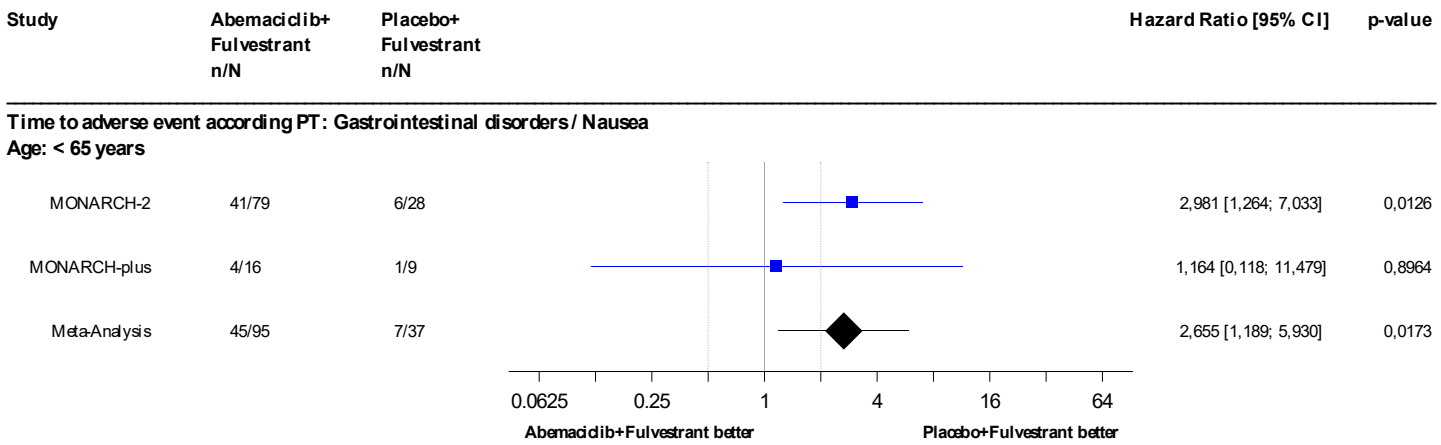
Figure 1229.2.1.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5685, p-value=0,4508, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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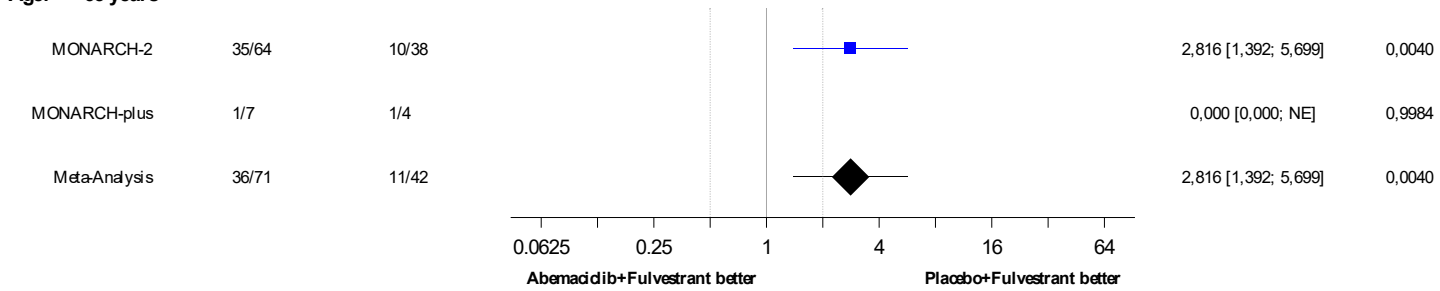
Figure 1229.2.1.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9983, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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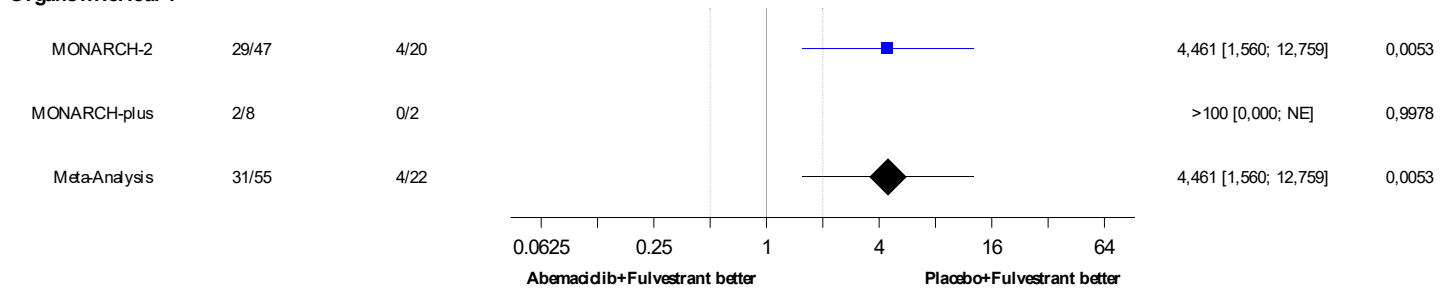
Figure 1229.2.2.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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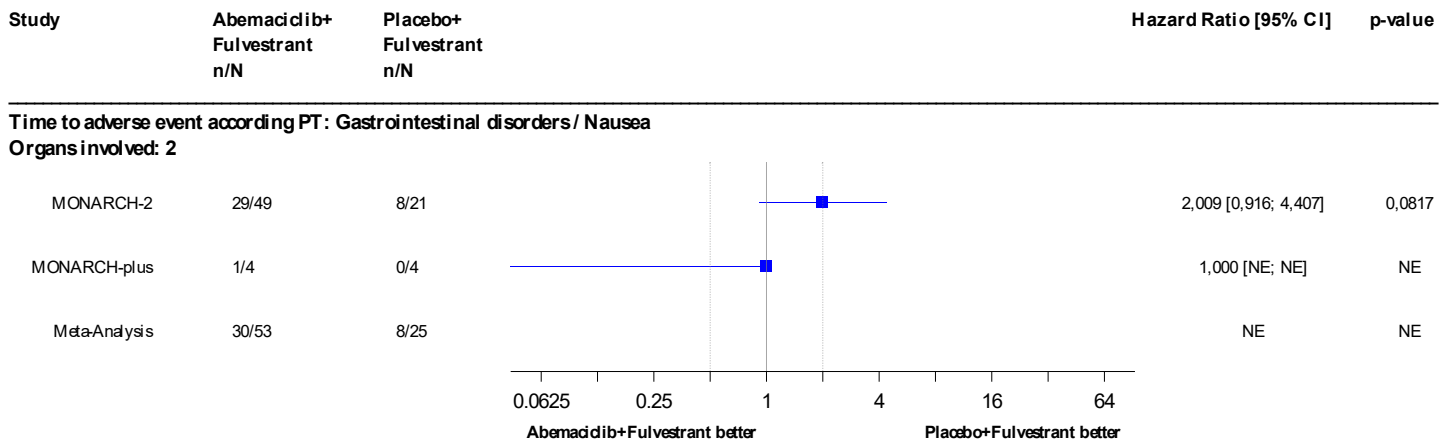
Figure 1229.2.2.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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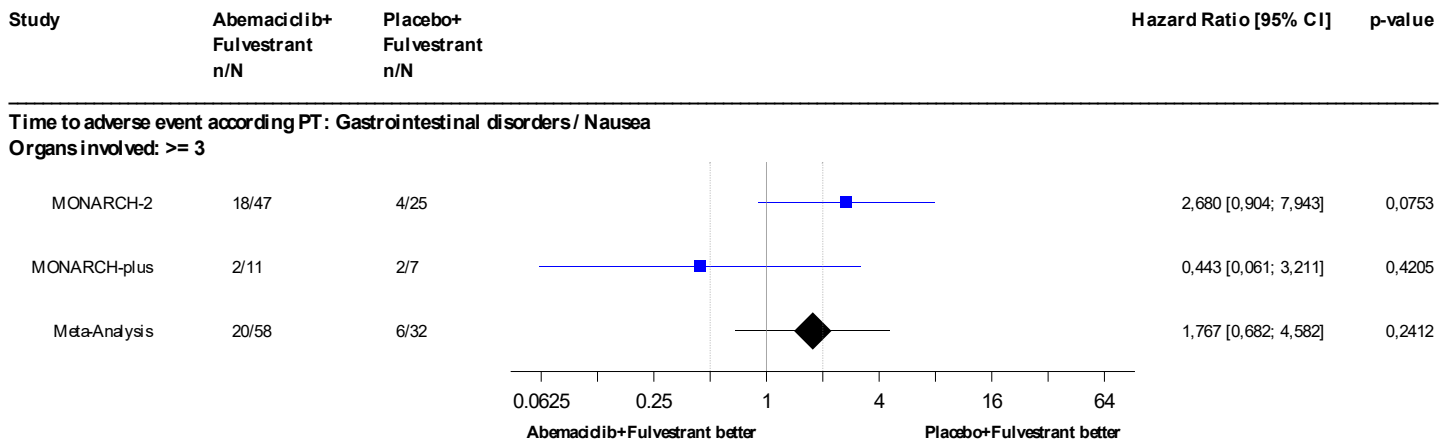
Figure 1229.2.2.3: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,4384, p-value=0,1184, I2 index=59,0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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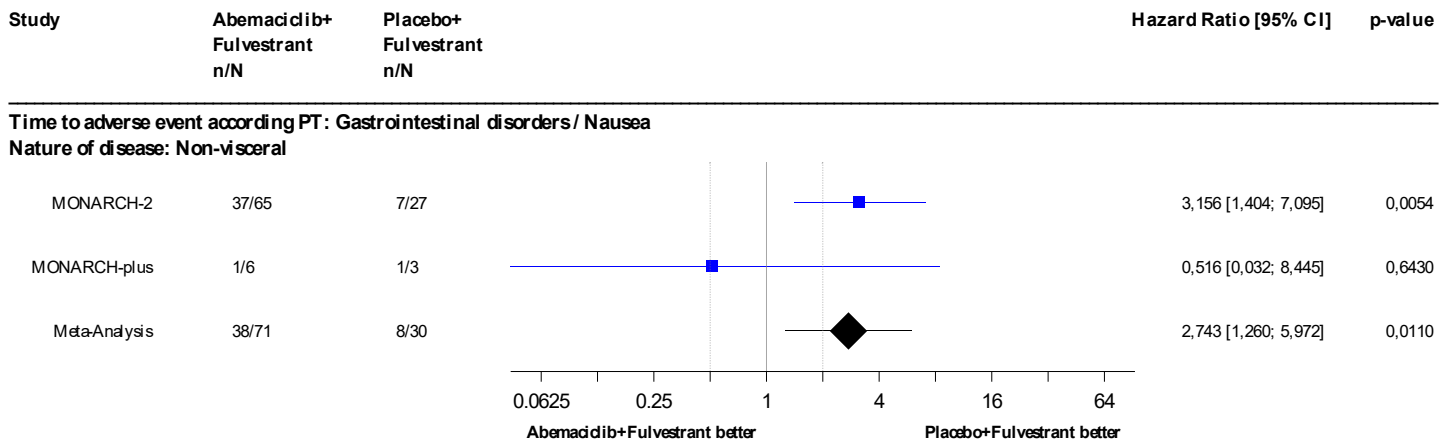
Figure 1229.2.3.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,4872, p-value=0,2227, I2 index=32,8%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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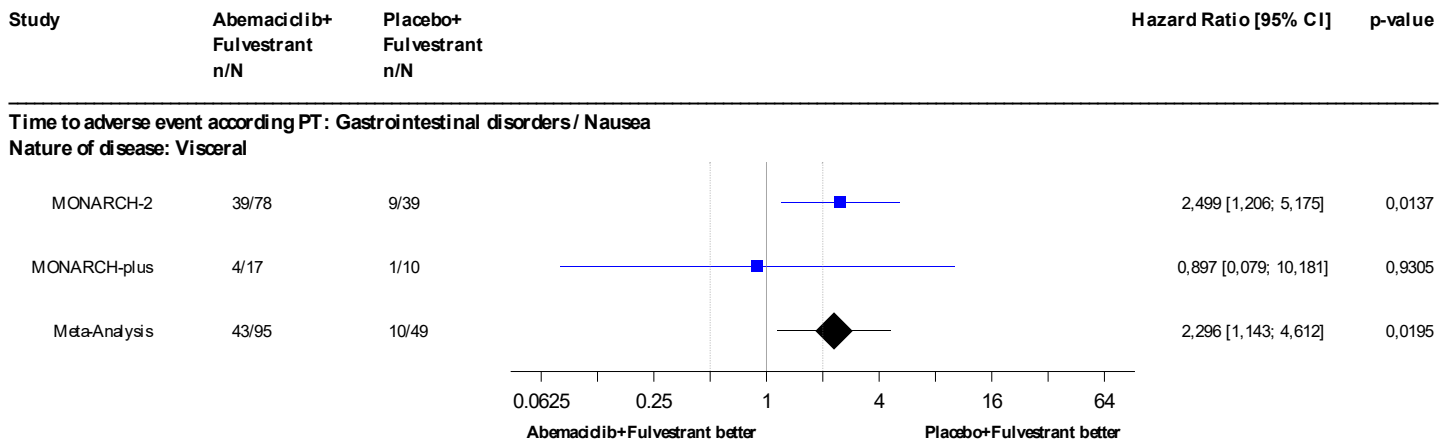
Figure 1229.2.3.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6265, p-value=0,4287, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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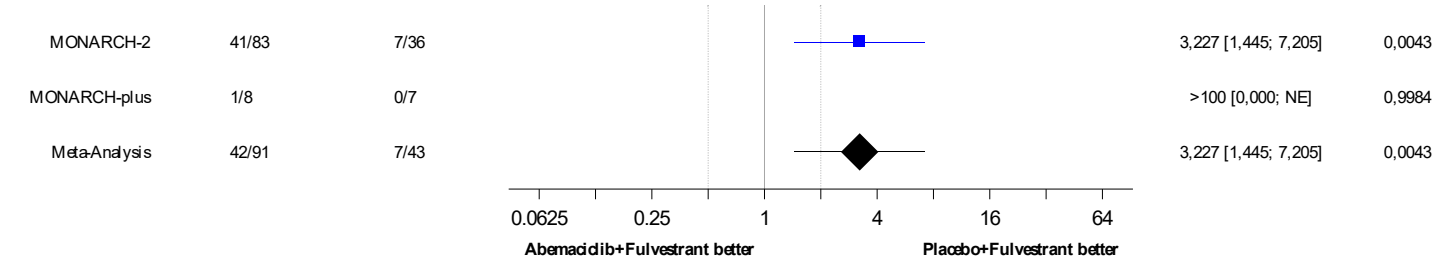
Figure 1229.2.4.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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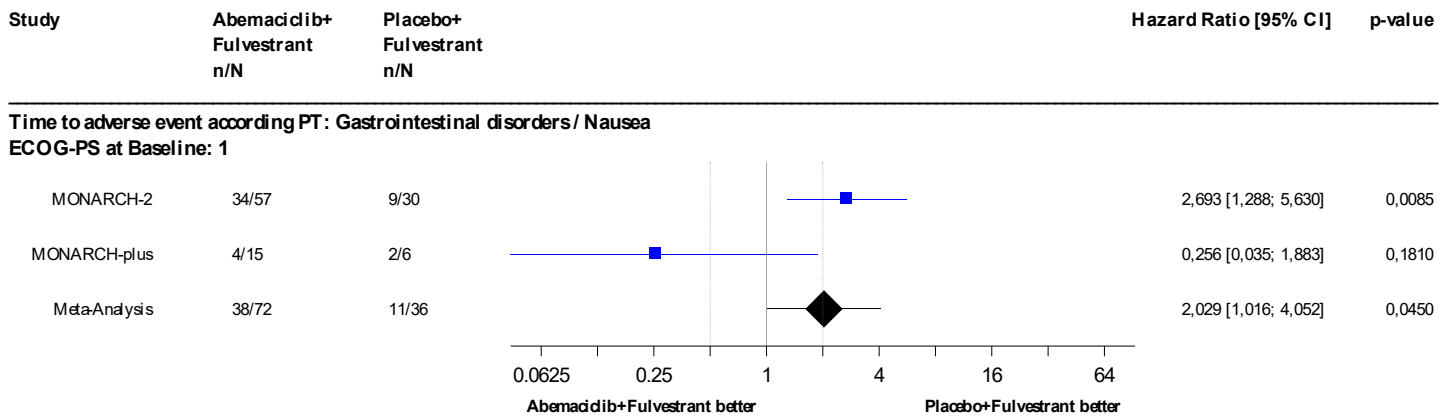
Figure 1229.2.4.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=4,6998, p-value=0,0302, I2 index=78,7%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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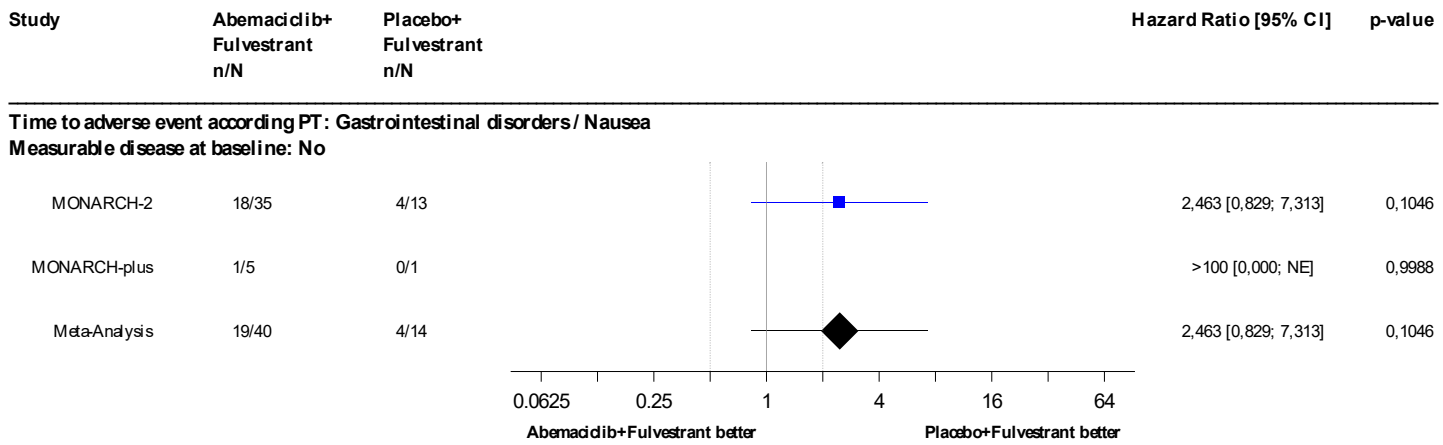
Figure 1229.2.6.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9989, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraep036_popa2_measdis_1.rtf
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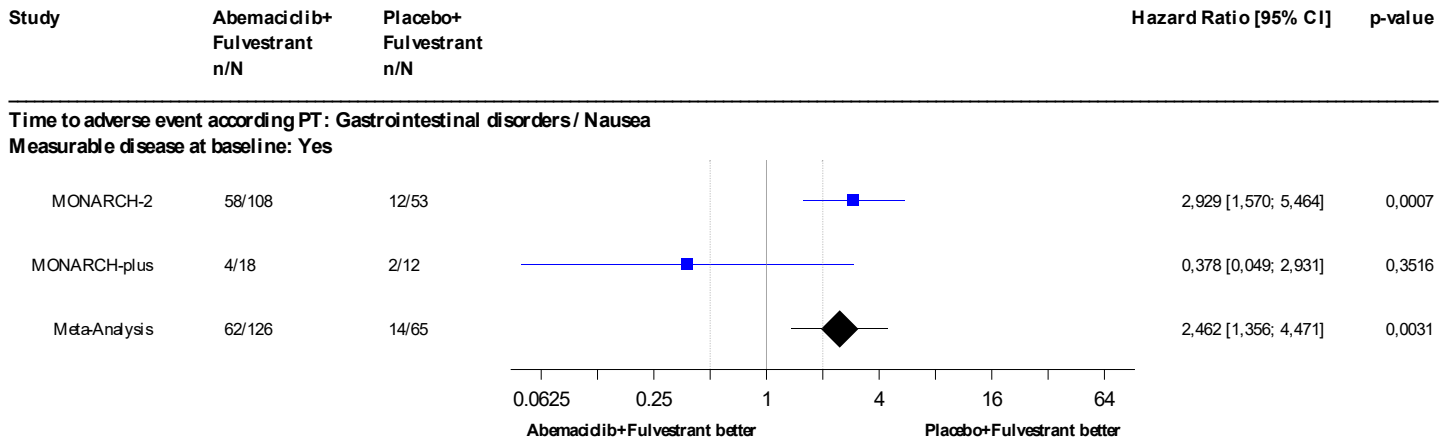
Figure 1229.2.6.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=3,5139, p-value=0,0609, I2 index=71,5%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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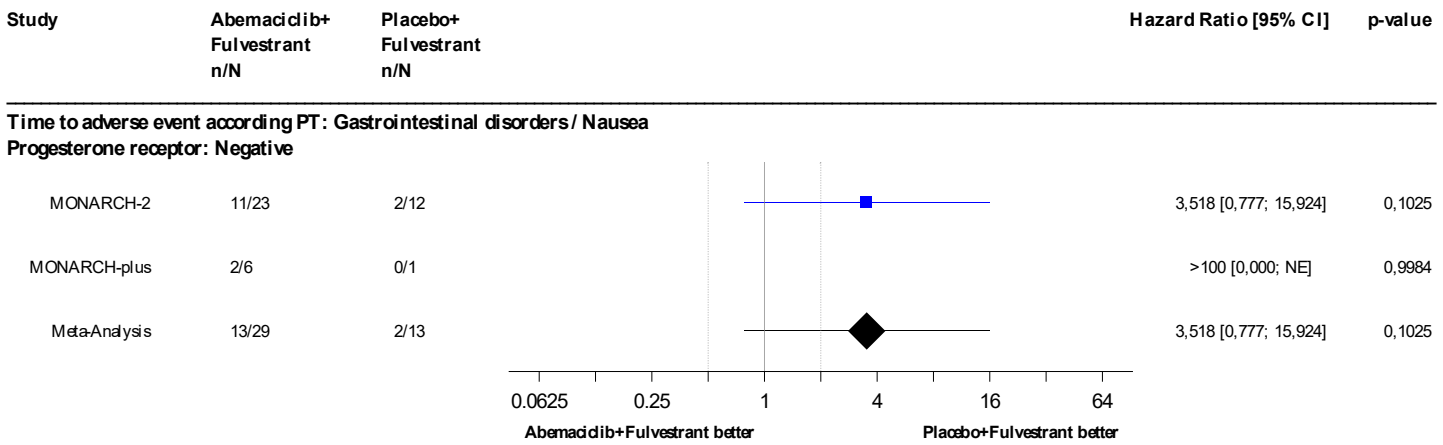
Figure 1229.2.7.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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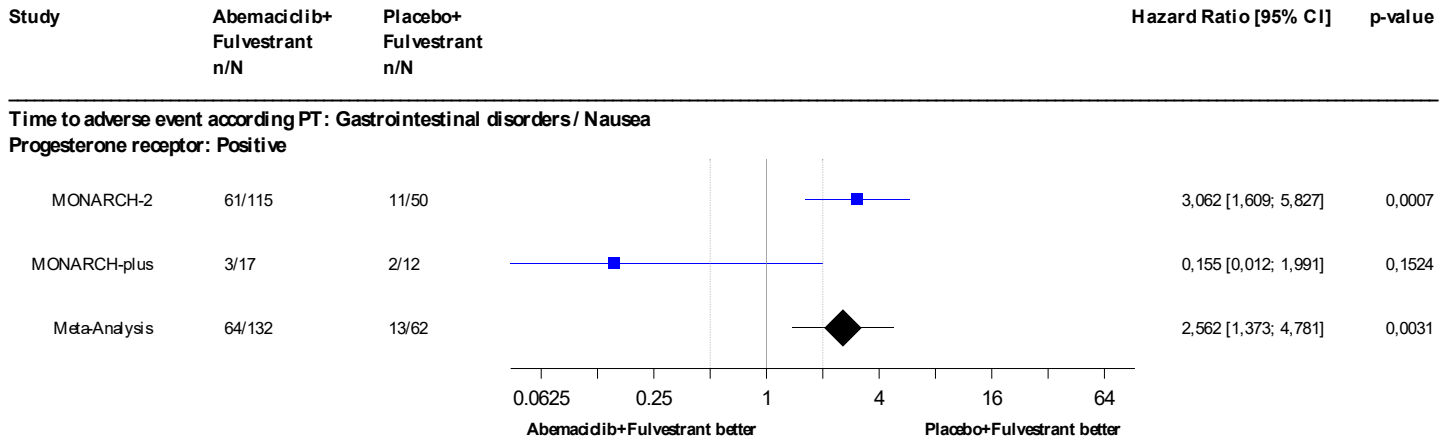
Figure 1229.2.7.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=4,9332, p-value=0,0263, I2 index=79,7%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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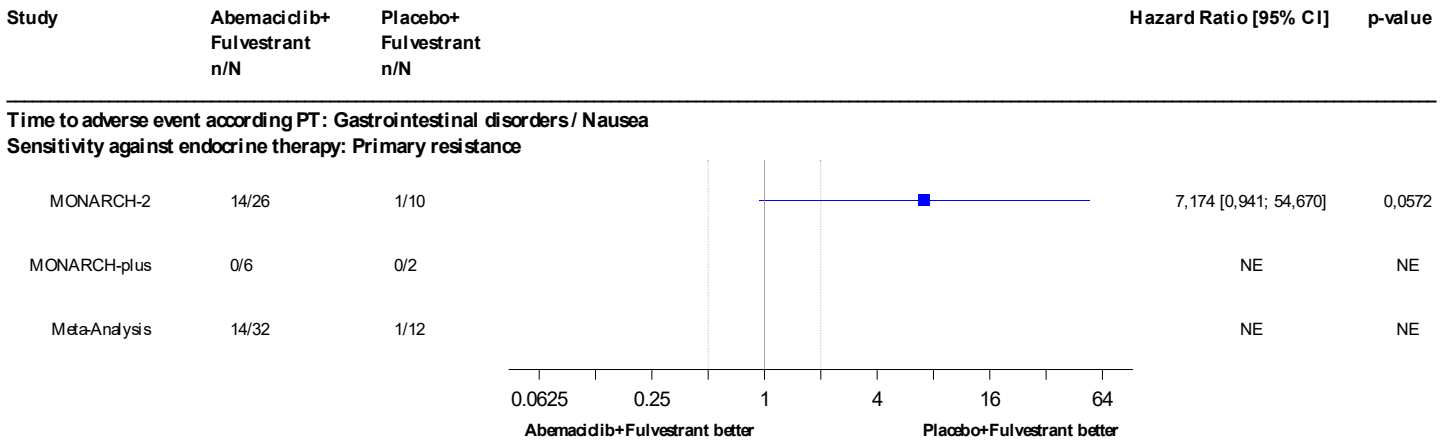
Figure 1229.2.8.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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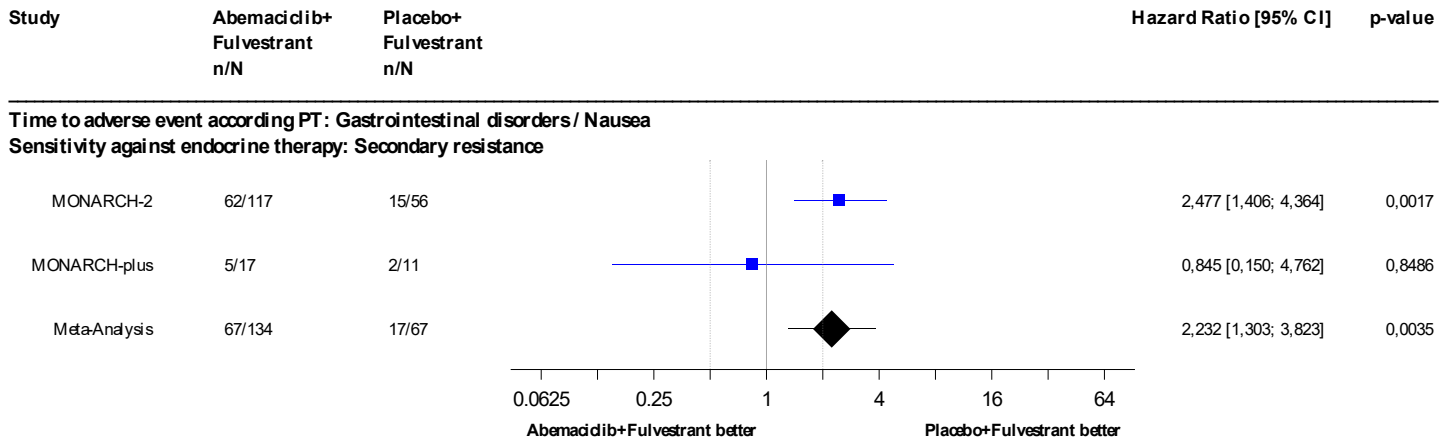
Figure 1229.2.8.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,3418, p-value=0,2467, I2 index=25,5%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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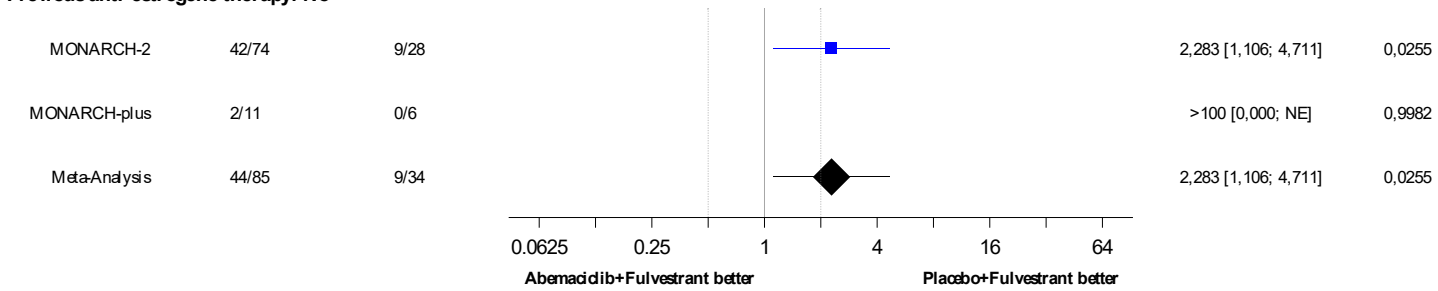
Figure 1229.2.9.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9983, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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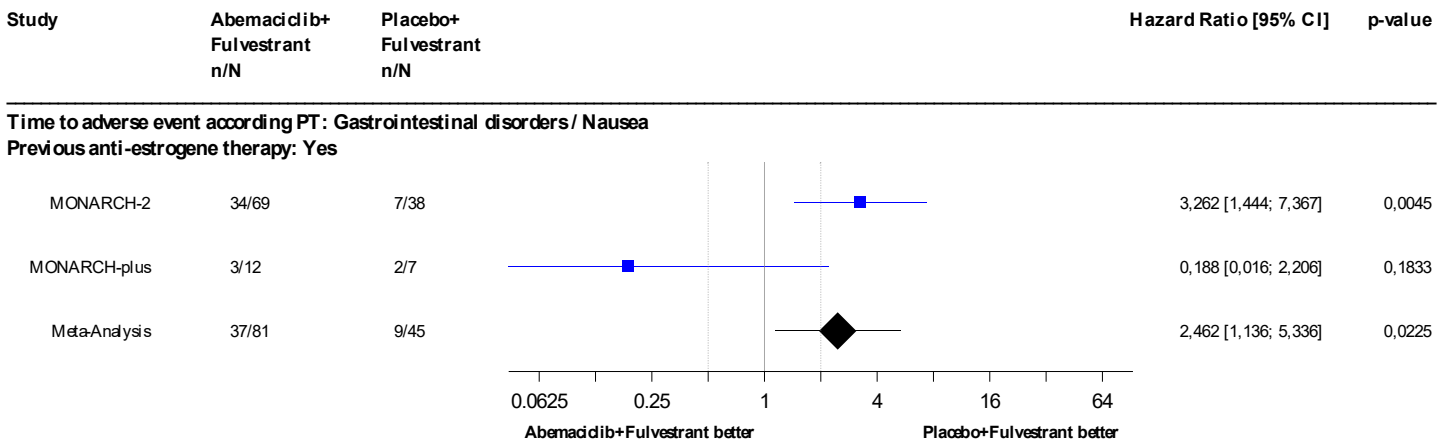
Figure 1229.2.9.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Nausea
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=4,6487, p-value=0,0311, I2 index=78,5%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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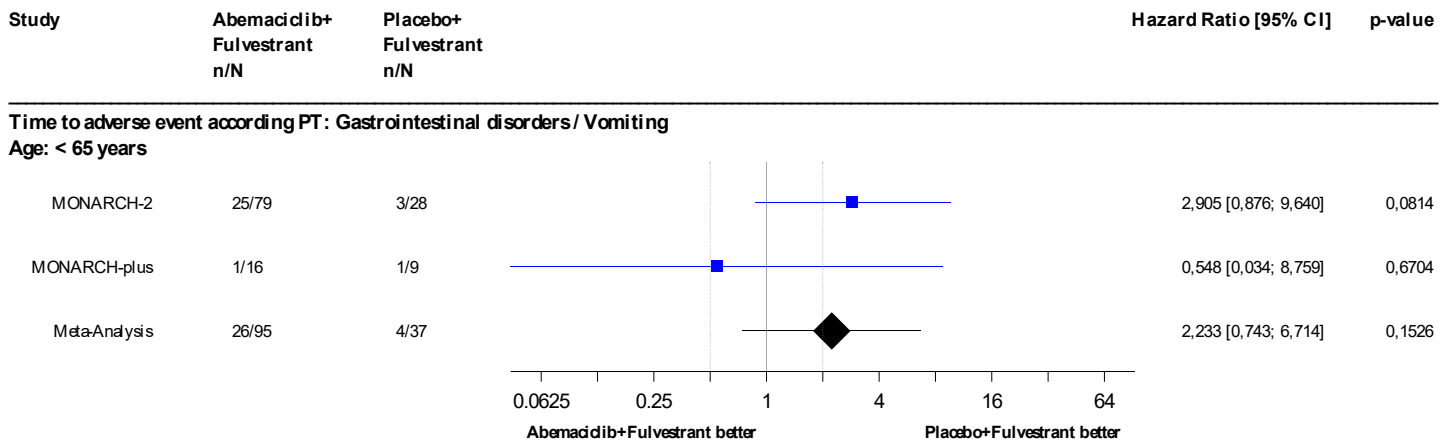
Figure 1248.2.1.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,1723, p-value=0,2789, I2 index=14,7%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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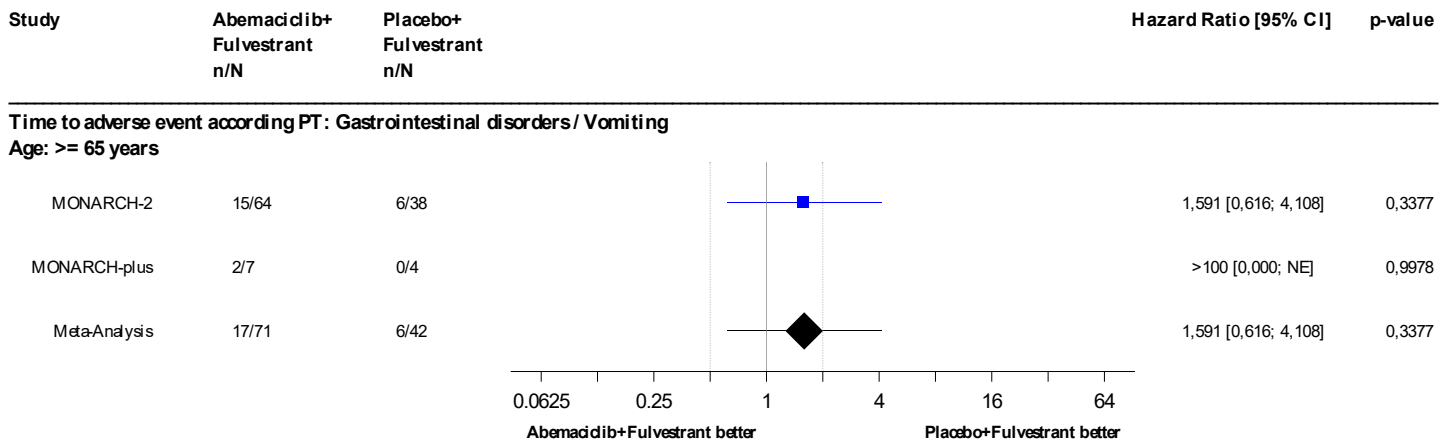
Figure 1248.2.1.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9979, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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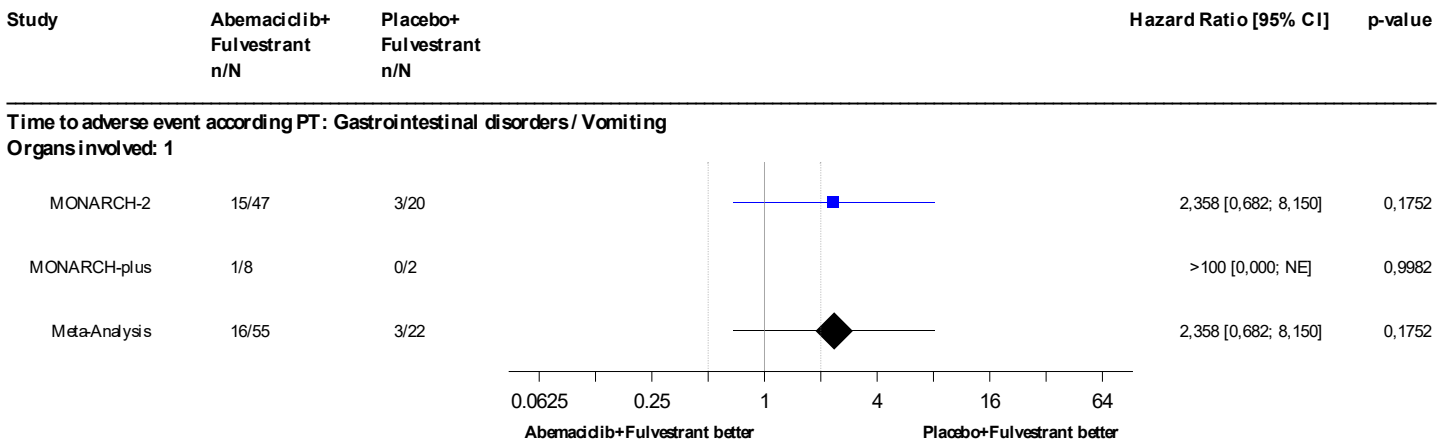
Figure 1248.2.2.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9983, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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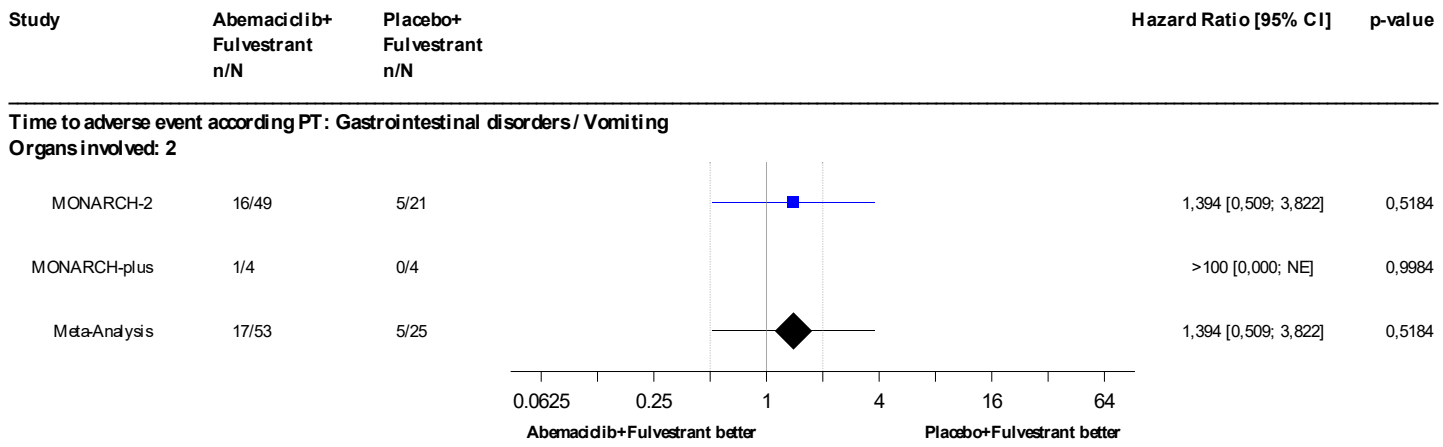
Figure 1248.2.2.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9984, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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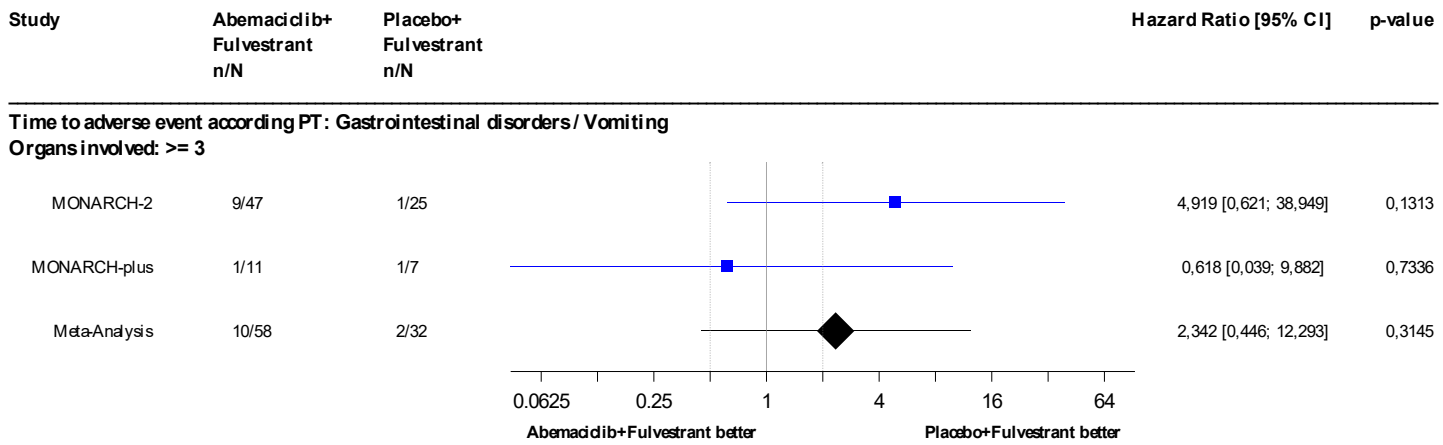
Figure 1248.2.2.3: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,3816, p-value=0,2398, I2 index=27,6%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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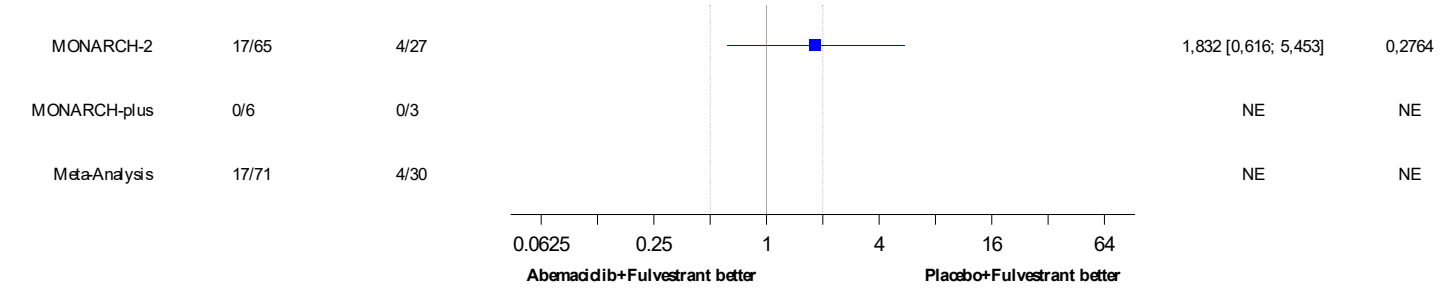
Figure 1248.2.3.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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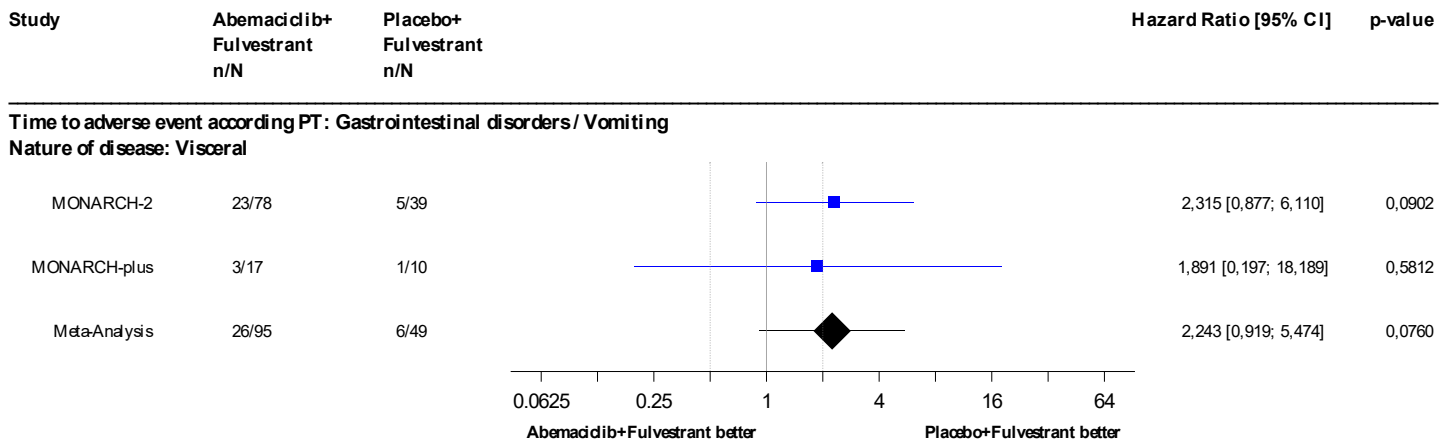
Figure 1248.2.3.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0259, p-value=0,8723, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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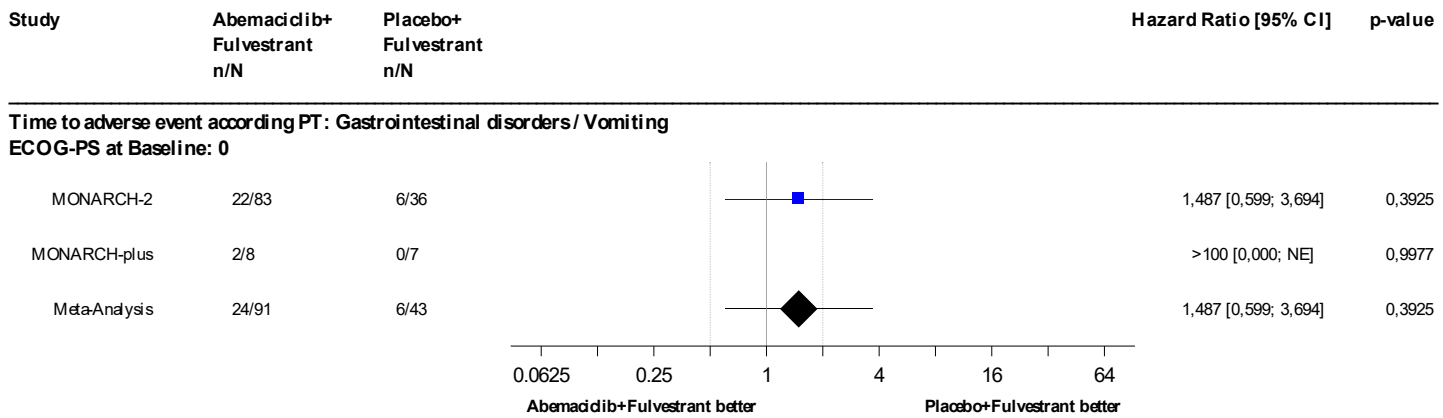
Figure 1248.2.4.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9978, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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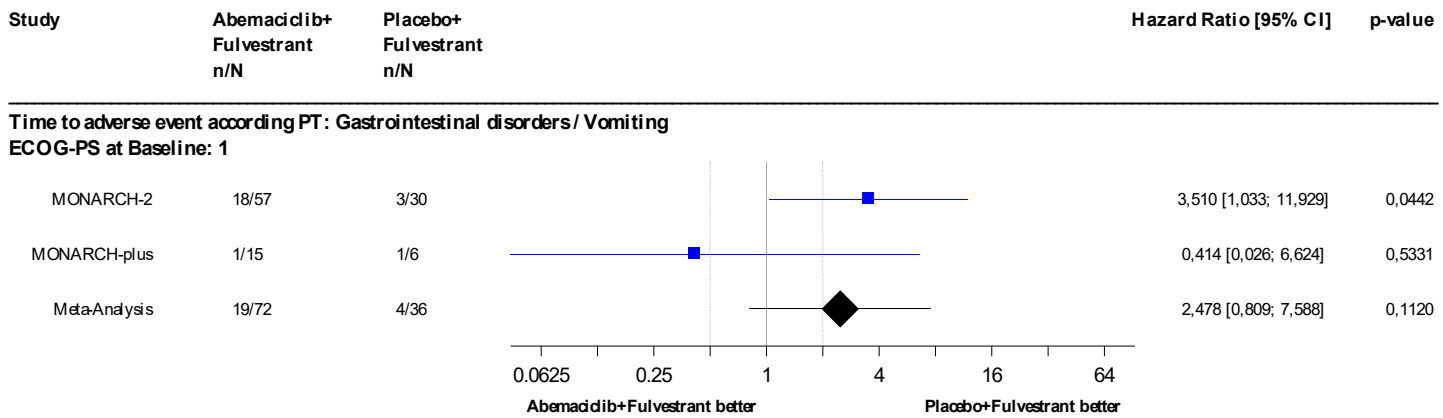
Figure 1248.2.4.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,9112, p-value=0,1668, I2 index=47,7%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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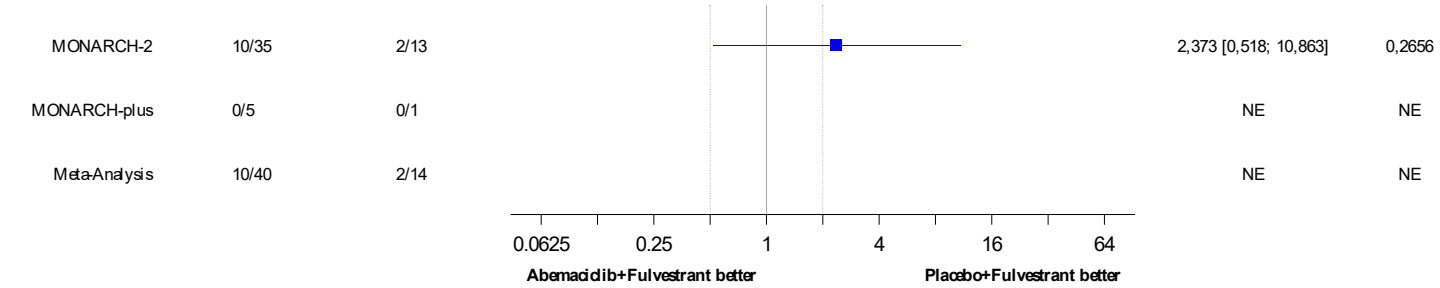
Figure 1248.2.6.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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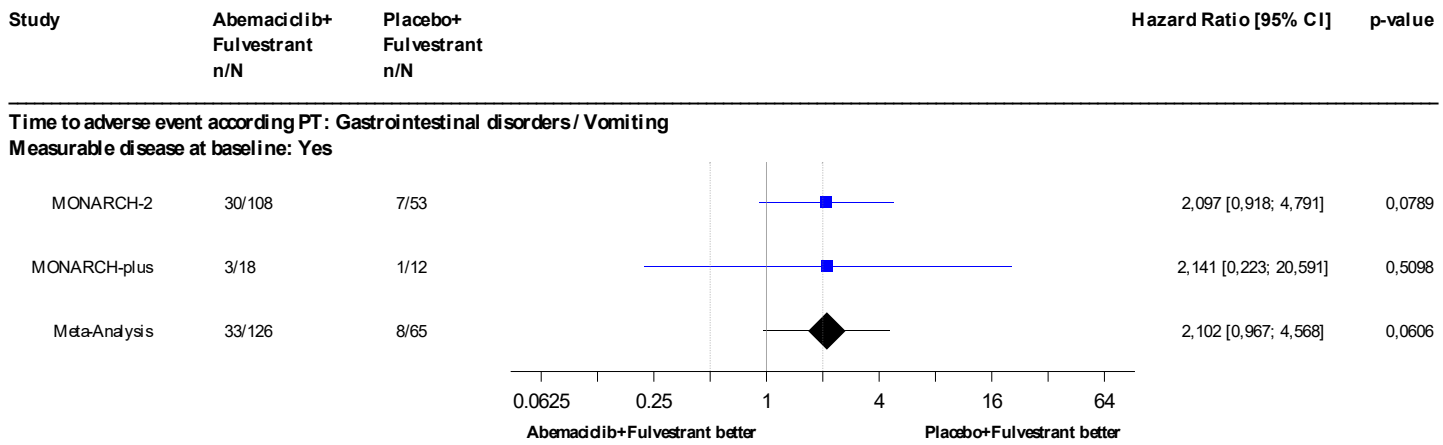
Figure 1248.2.6.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0003, p-value=0,9866, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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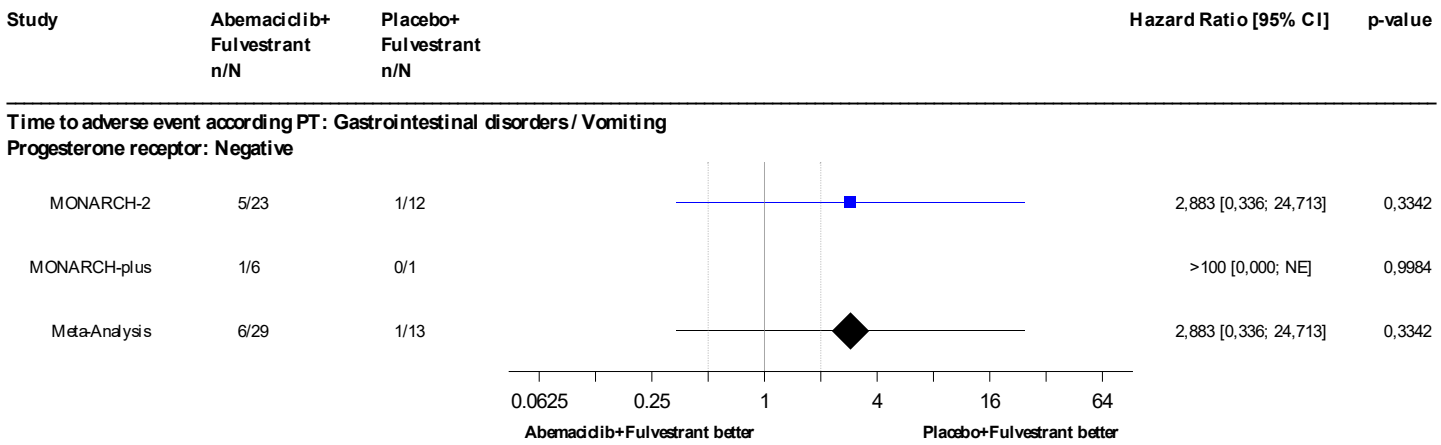
Figure 1248.2.7.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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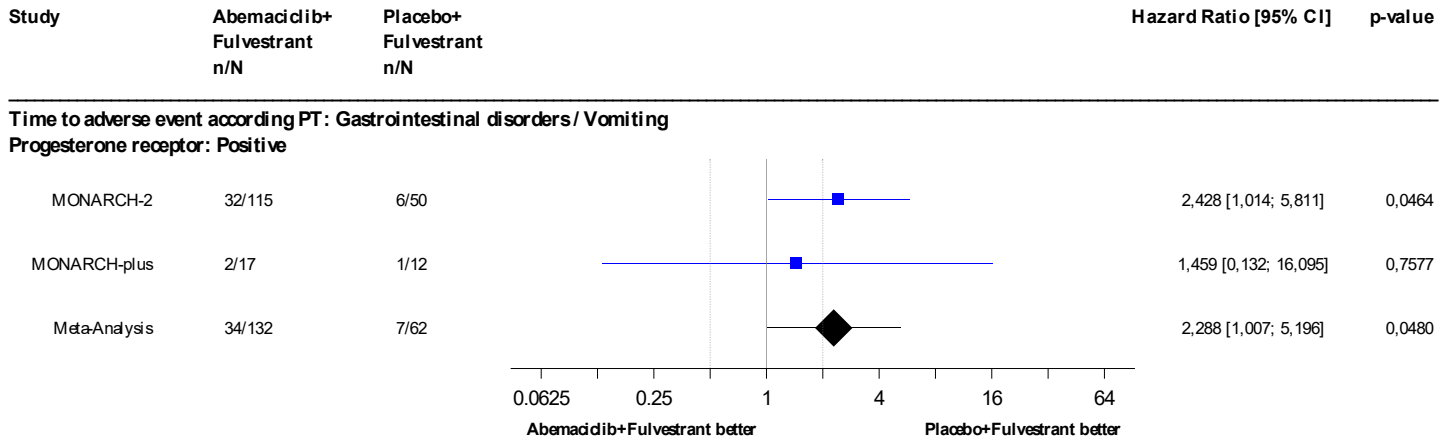
Figure 1248.2.7.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1526, p-value=0,6961, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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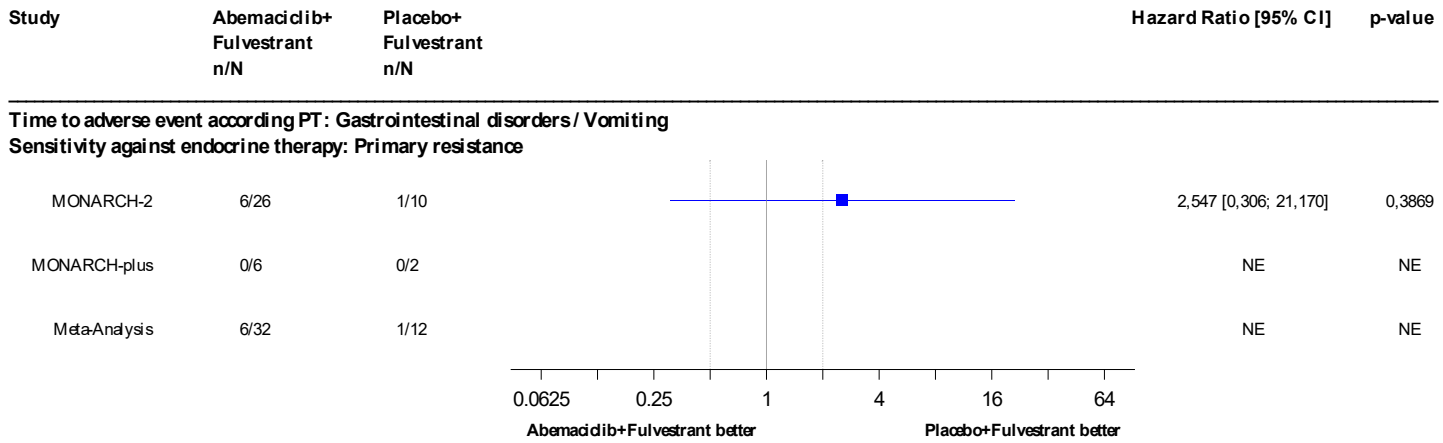
Figure 1248.2.8.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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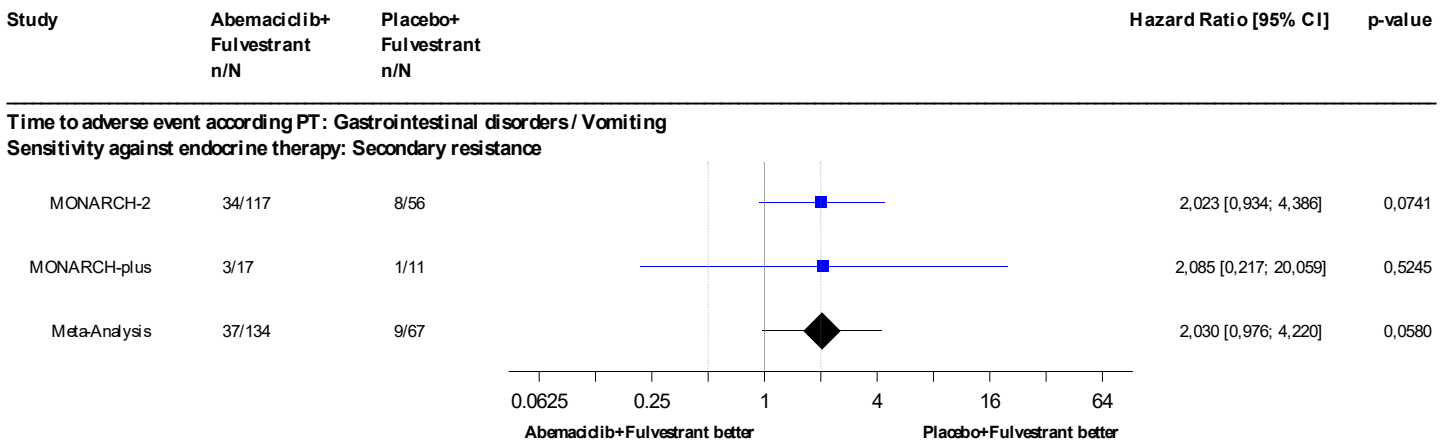
Figure 1248.2.8.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0006, p-value=0,9802, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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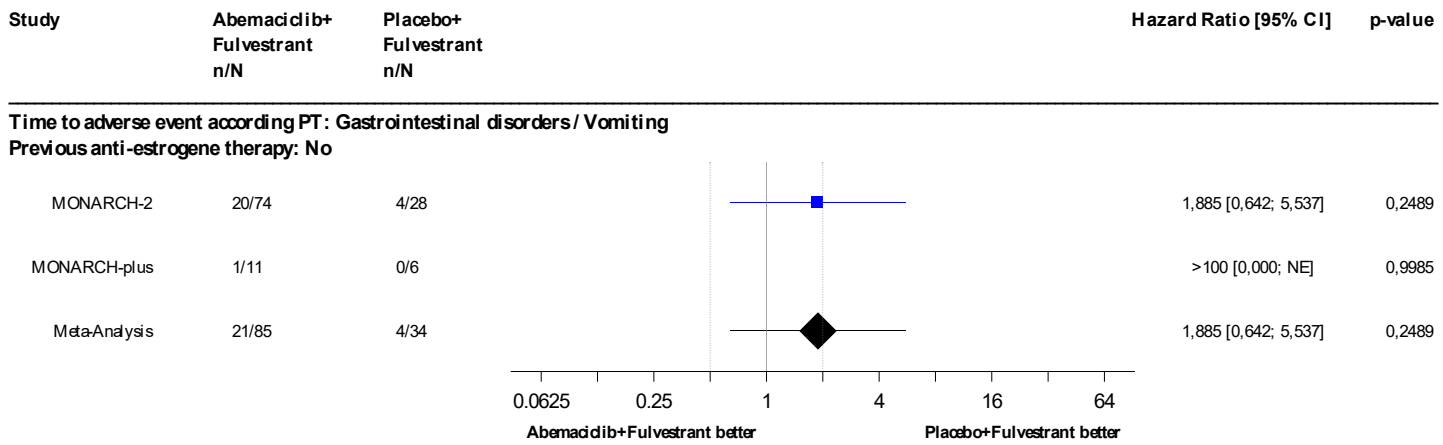
Figure 1248.2.9.1: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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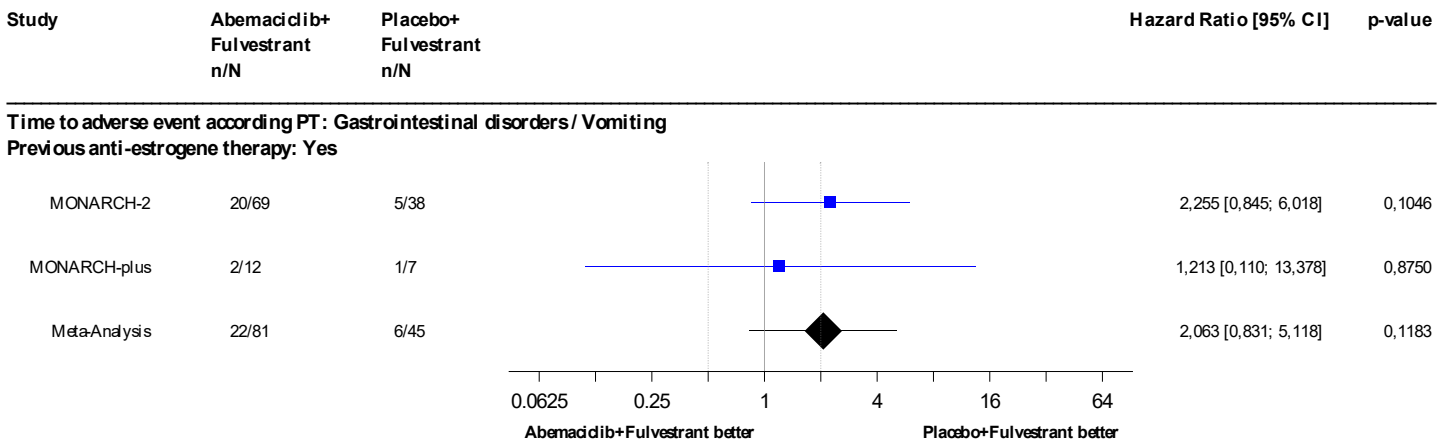
Figure 1248.2.9.2: Metaanalysis results for adverse events according PT[1] -
Gastrointestinal disorders / Vomiting
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2196, p-value=0,6393, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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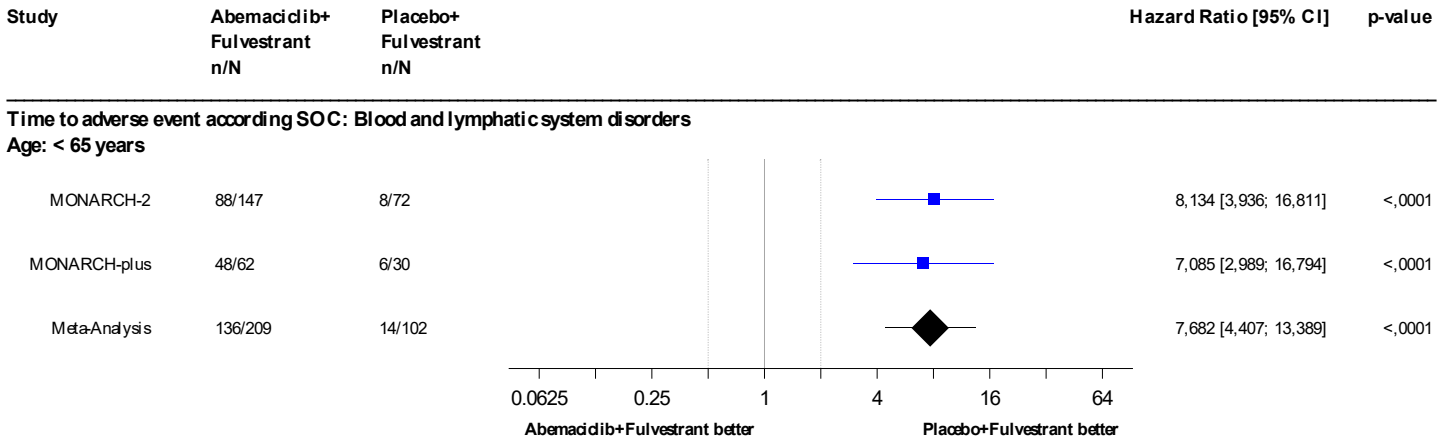
Figure 1251.1.1.1: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0576, p-value=0,8103, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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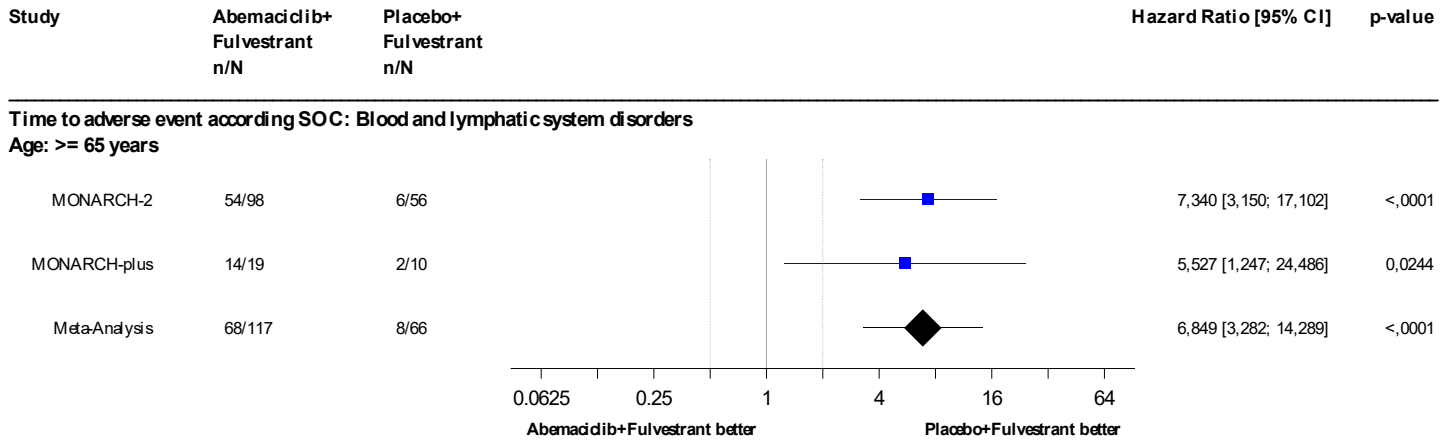
Figure 1251.1.1.2: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1055, p-value=0,7453, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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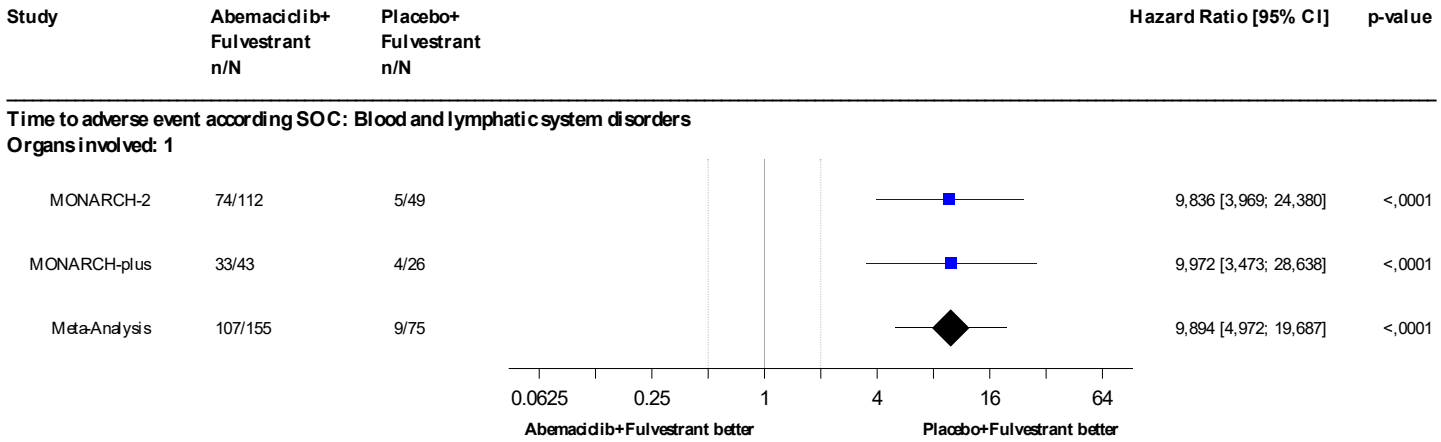
Figure 1251.1.2.1: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0004, p-value=0,9846, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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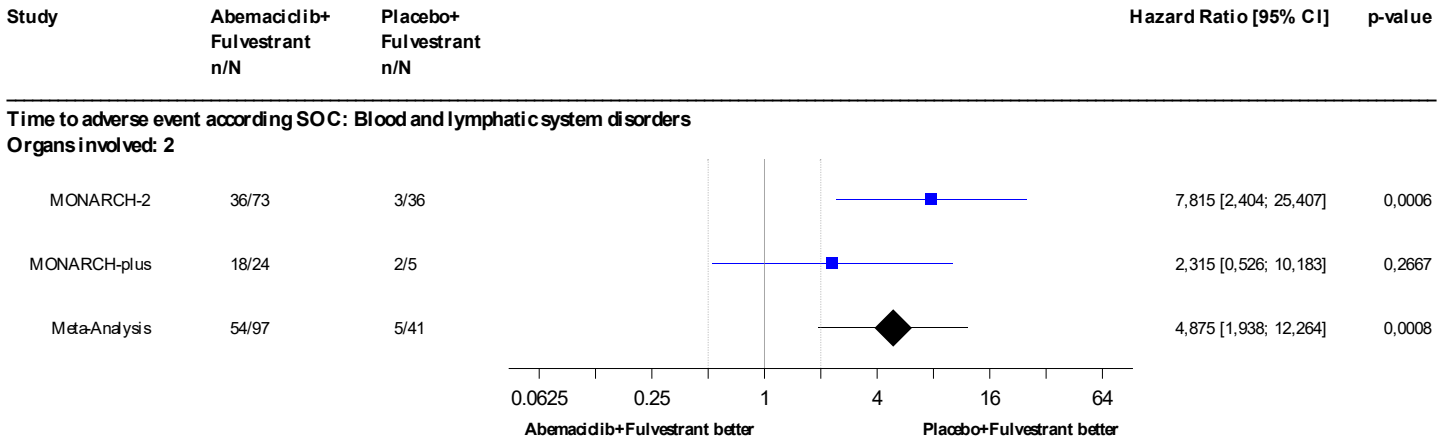
Figure 1251.1.2.2: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,5864, p-value=0,2078, I2 index=37,0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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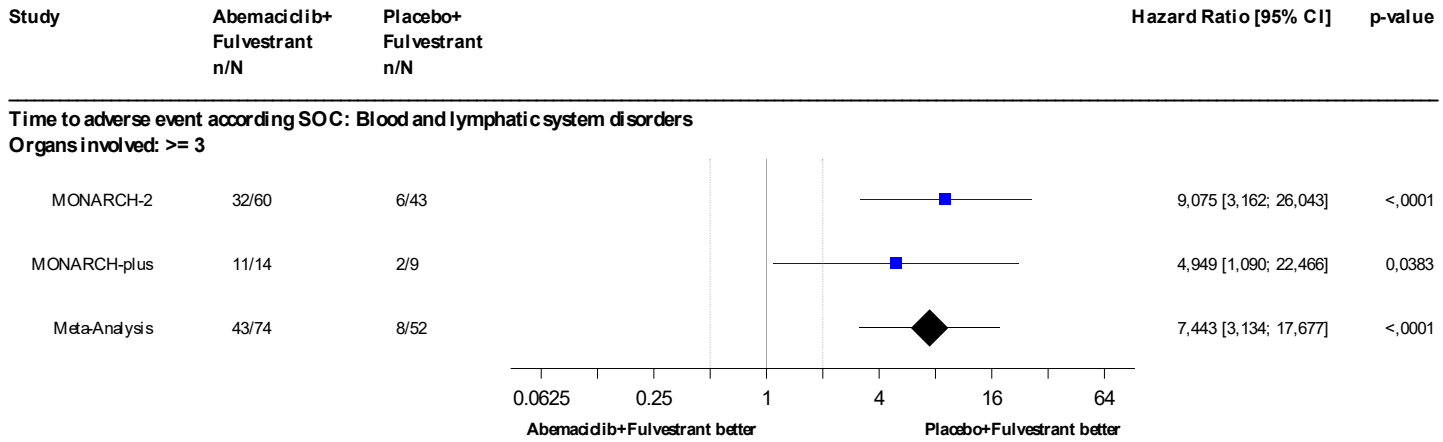
Figure 1251.1.2.3: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4154, p-value=0,5192, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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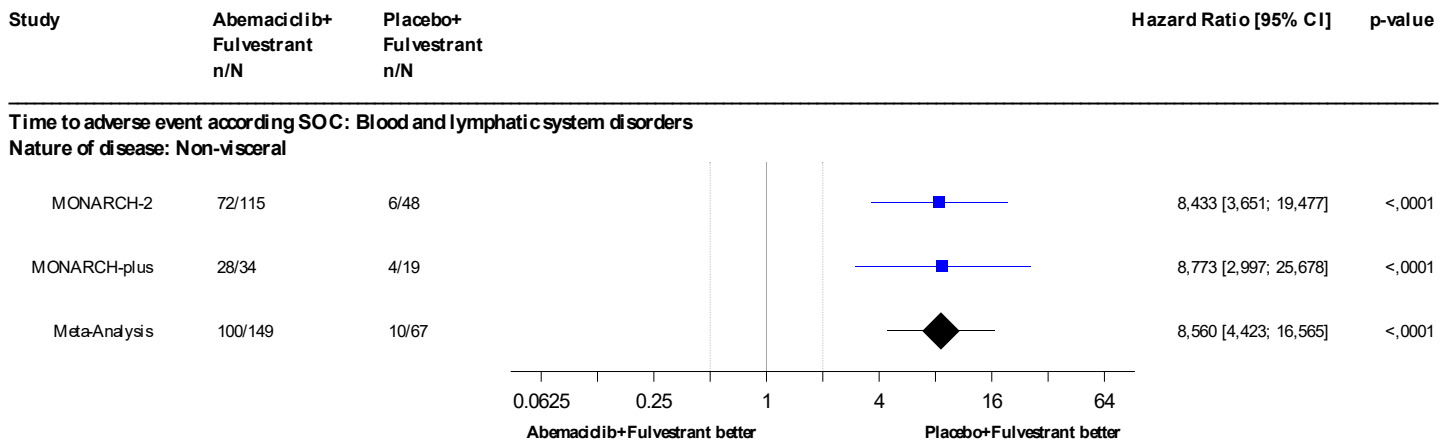
Figure 1251.1.3.1: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0032, p-value=0,9546, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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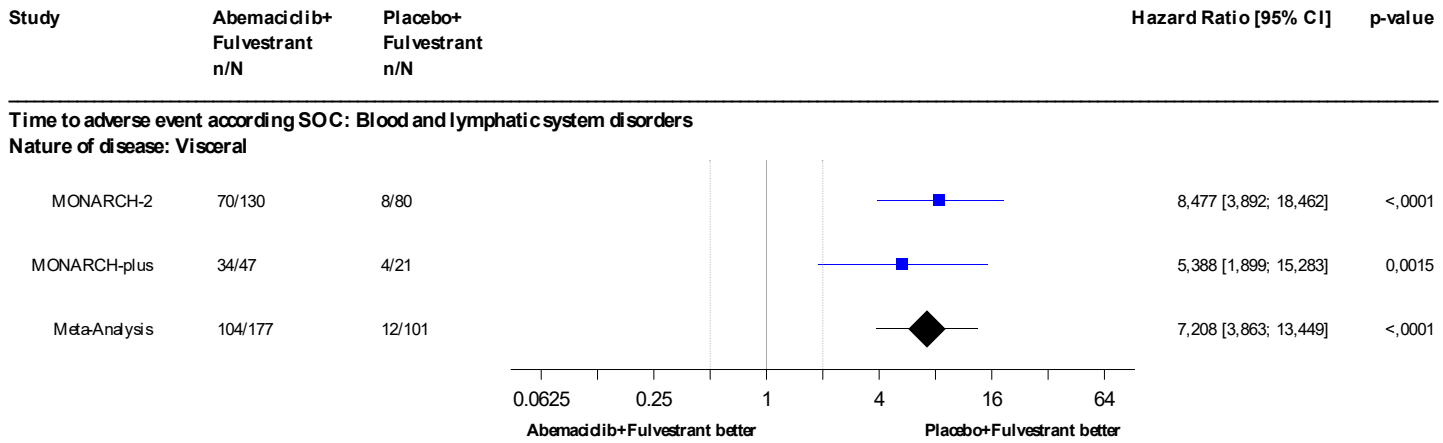
Figure 1251.1.3.2: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4662, p-value=0,4948, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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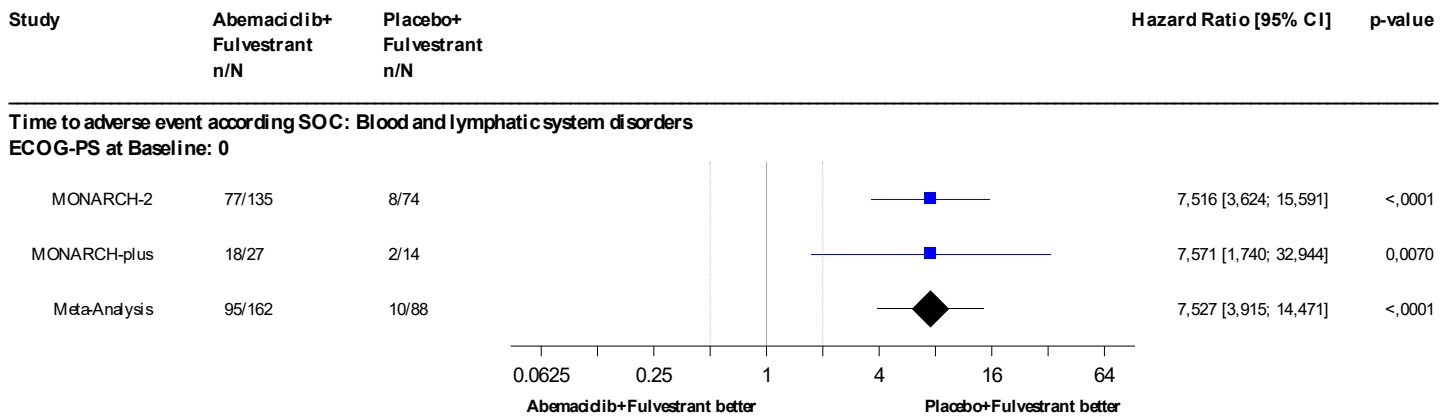
Figure 1251.1.4.1: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9931, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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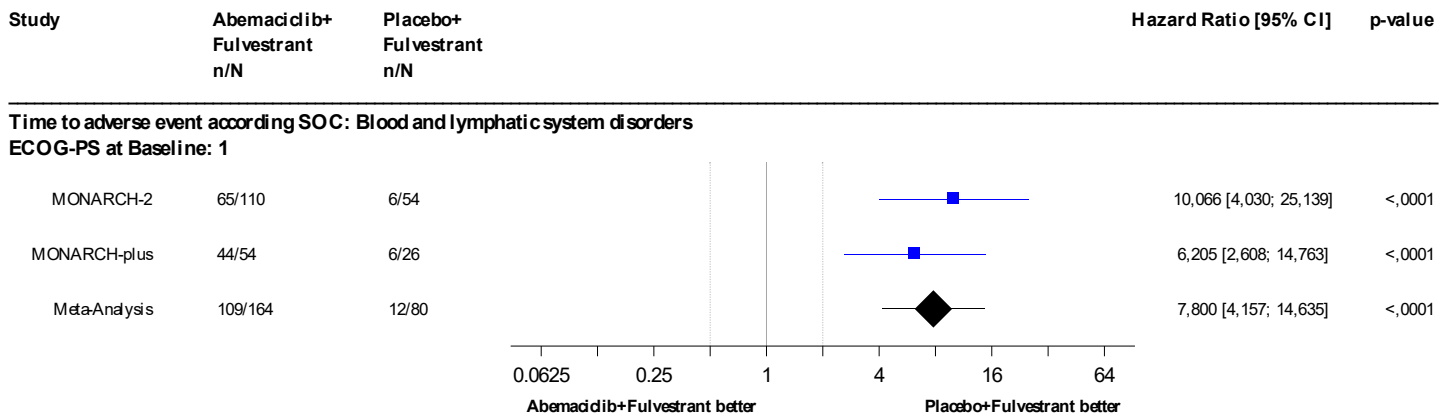
Figure 1251.1.4.2: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5658, p-value=0,4519, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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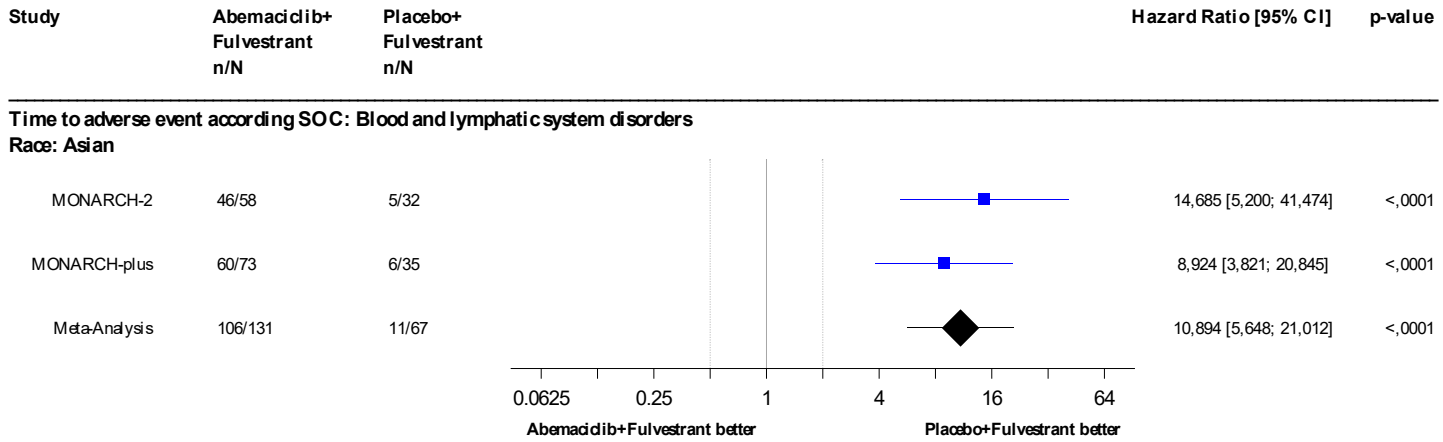
Figure 1251.1.5.1: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5302, p-value=0,4665, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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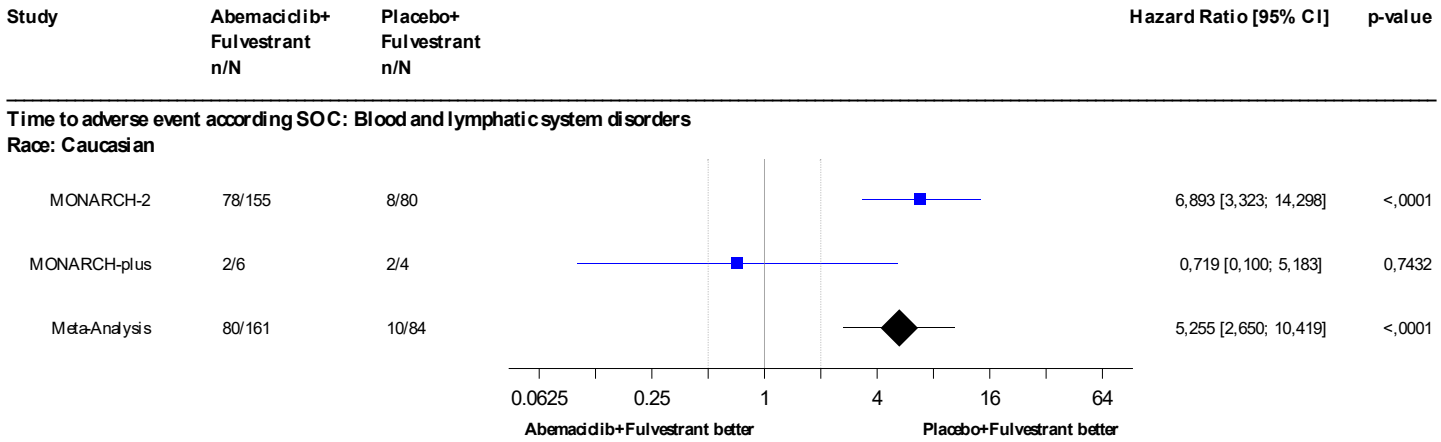
Figure 1251.1.5.2: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=4,4263, p-value=0,0354, I2 index=77,4%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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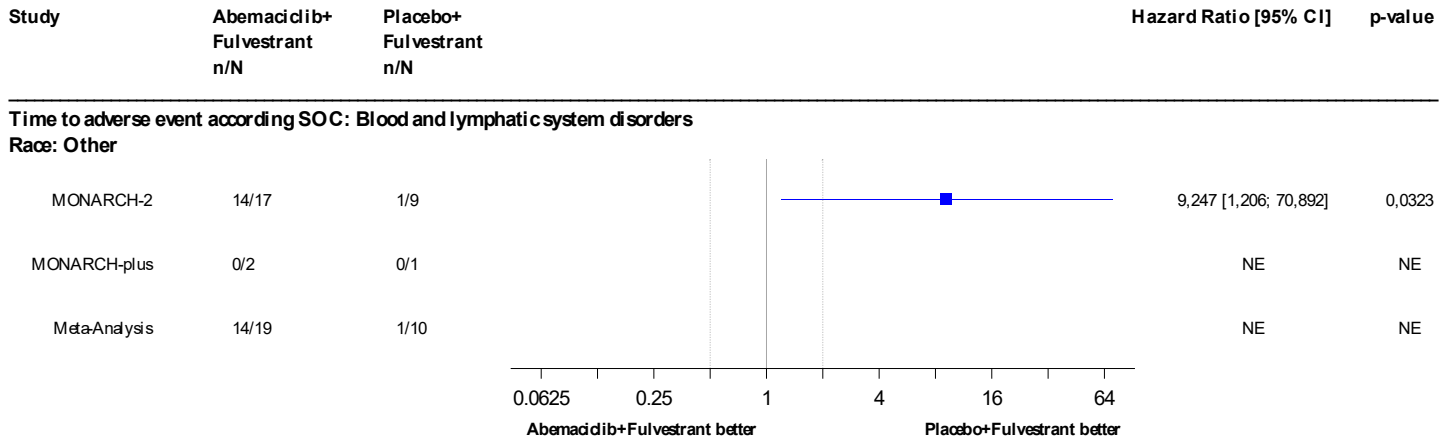
Figure 1251.1.5.3: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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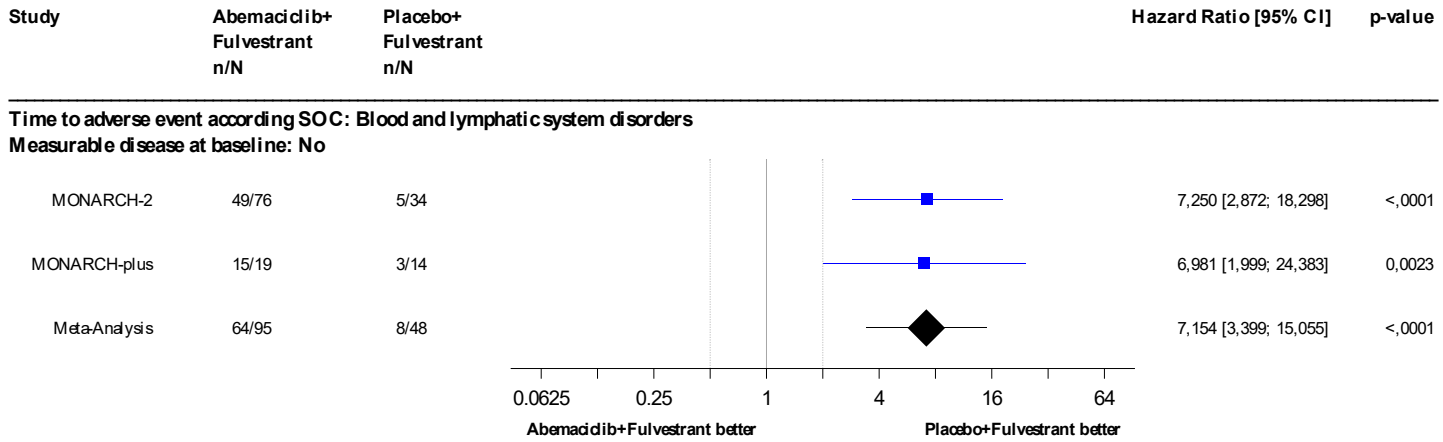
Figure 1251.1.6.1: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0023, p-value=0,9621, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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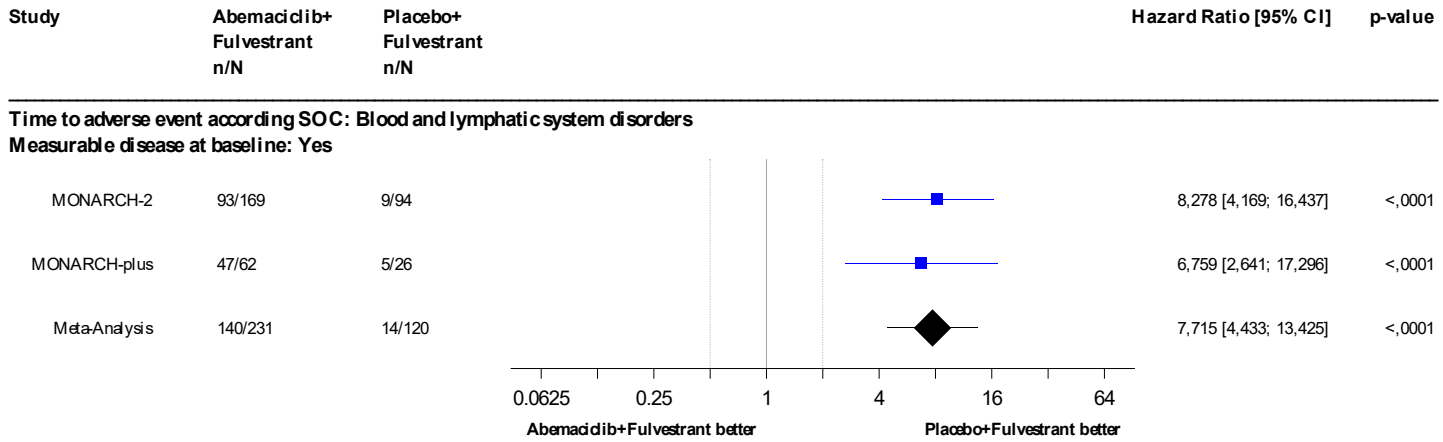
Figure 1251.1.6.2: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1166, p-value=0,7327, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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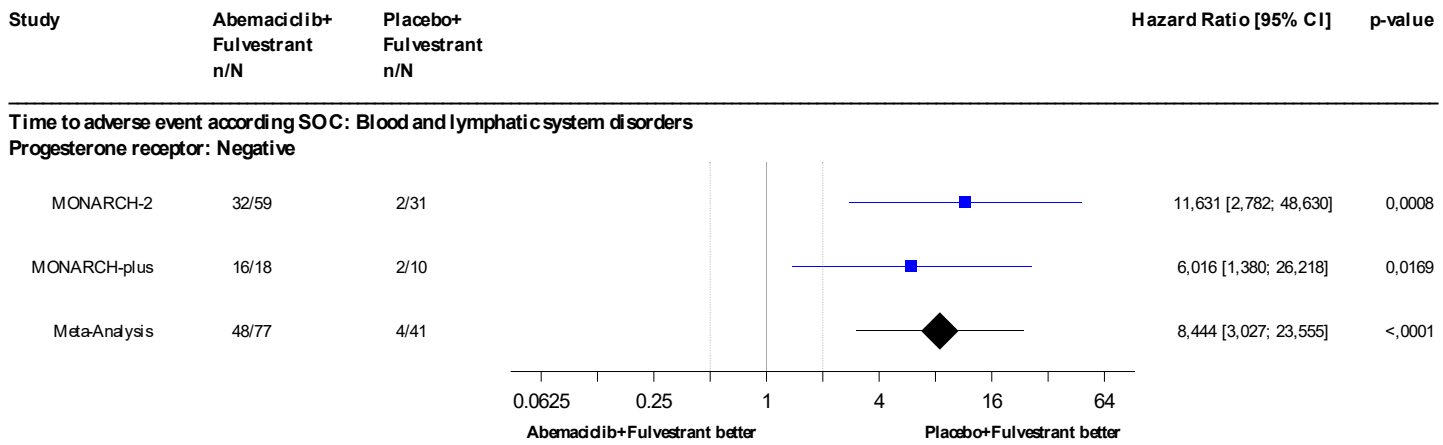
Figure 1251.1.7.1: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3962, p-value=0,5290, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes001_popa1_pgrstat_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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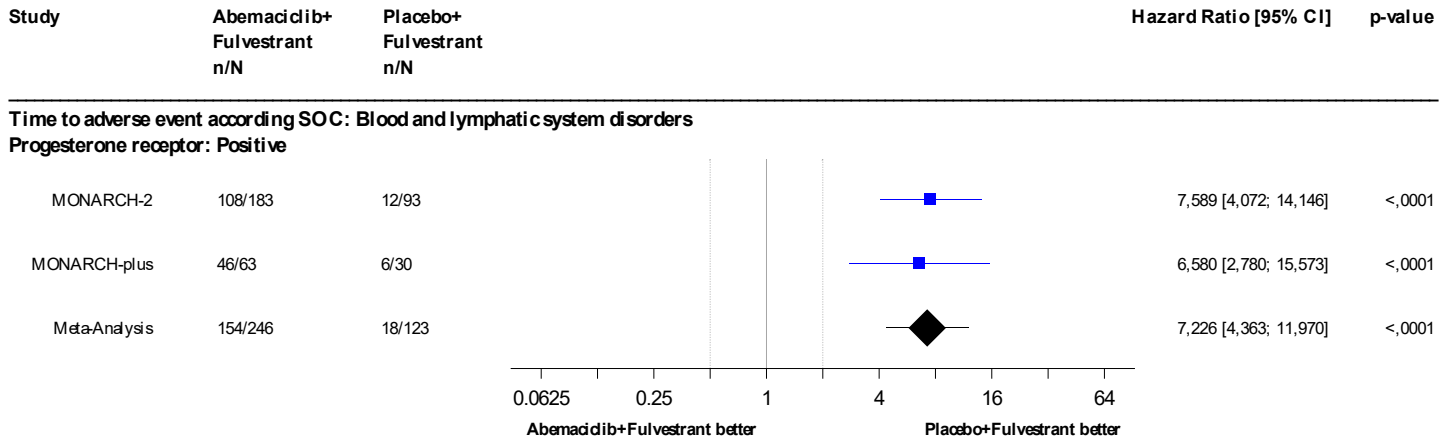
Figure 1251.1.7.2: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0693, p-value=0,7923, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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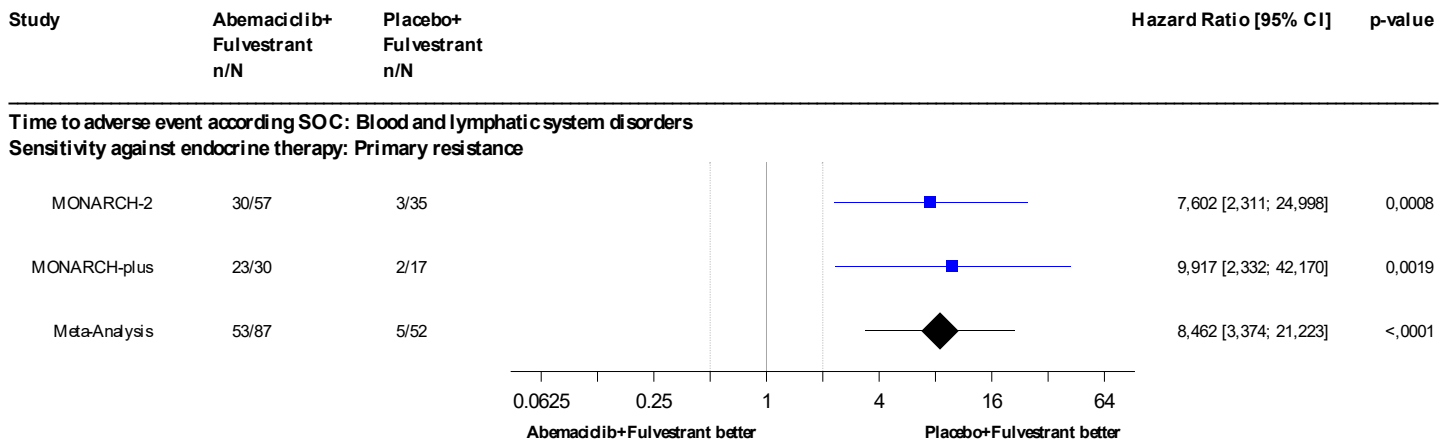
Figure 1251.1.8.1: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0773, p-value=0,7810, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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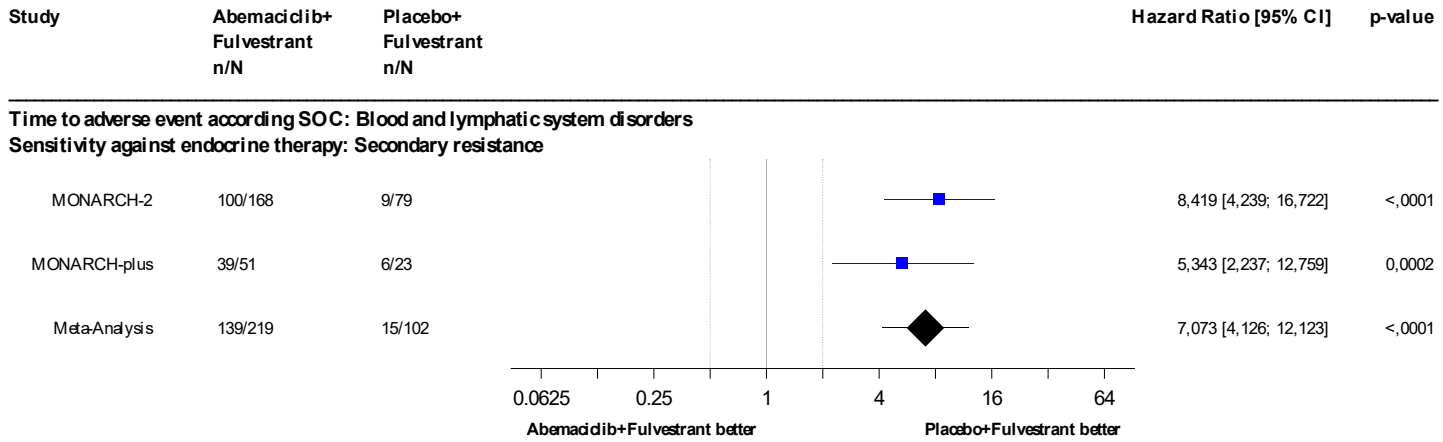
Figure 1251.1.8.2: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6467, p-value=0,4213, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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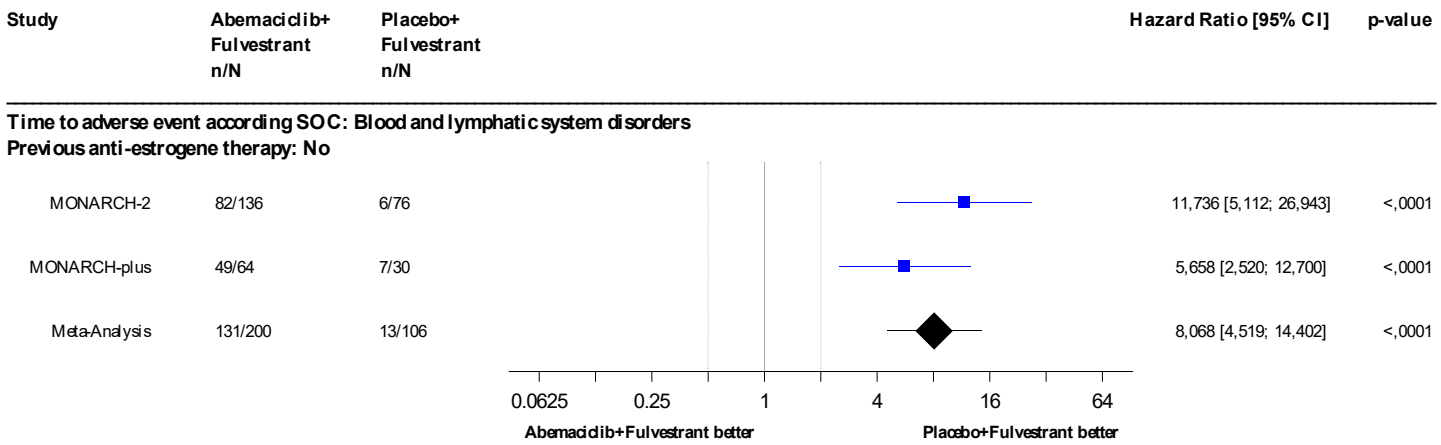
Figure 1251.1.9.1: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,5214, p-value=0,2174, I2 index=34,3%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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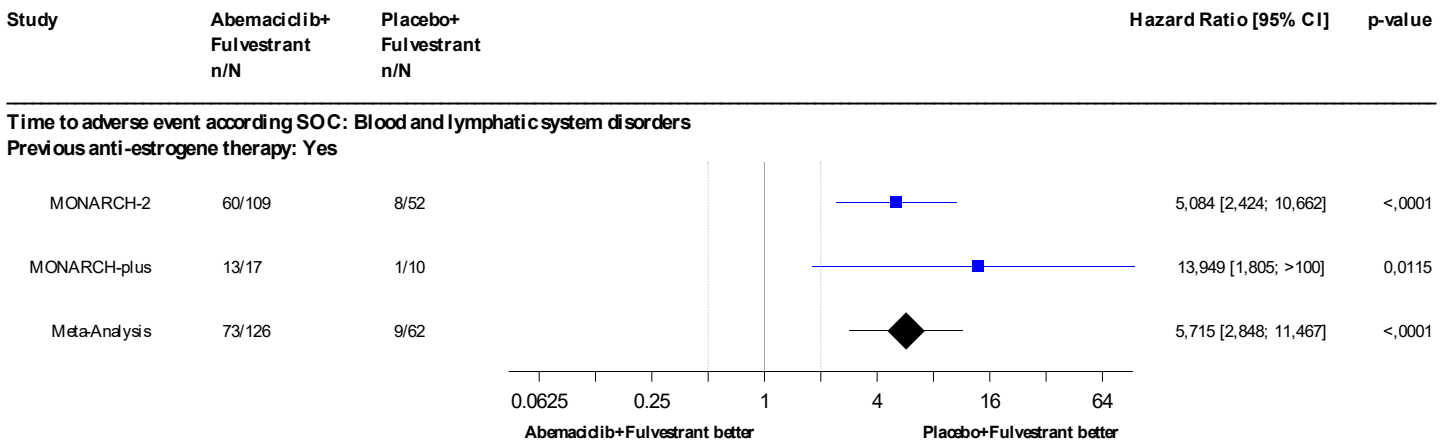
Figure 1251.1.9.2: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,8276, p-value=0,3630, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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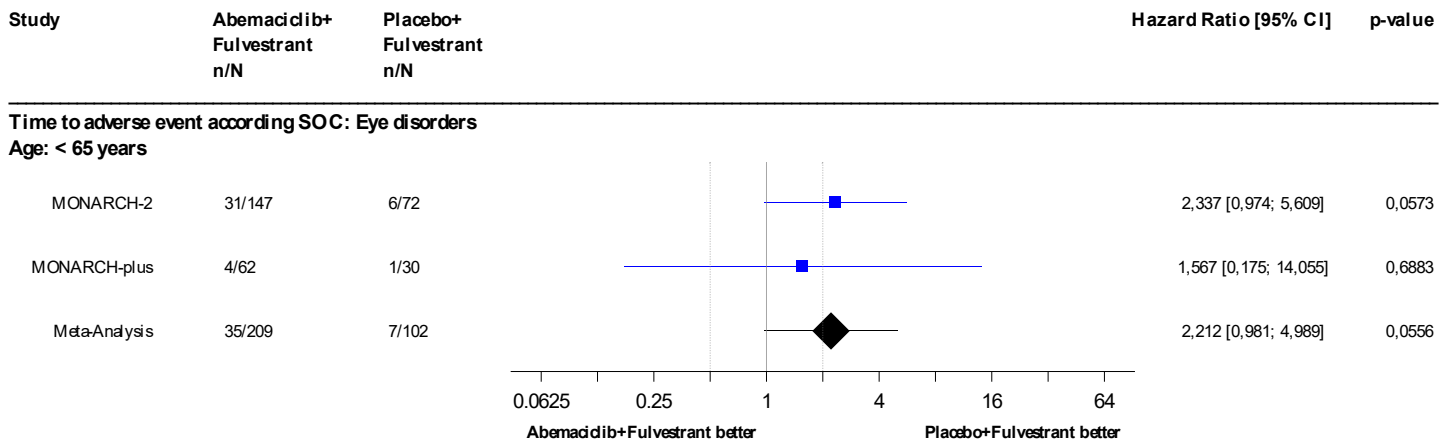
Figure 1254.1.1.1: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1102, p-value=0,7400, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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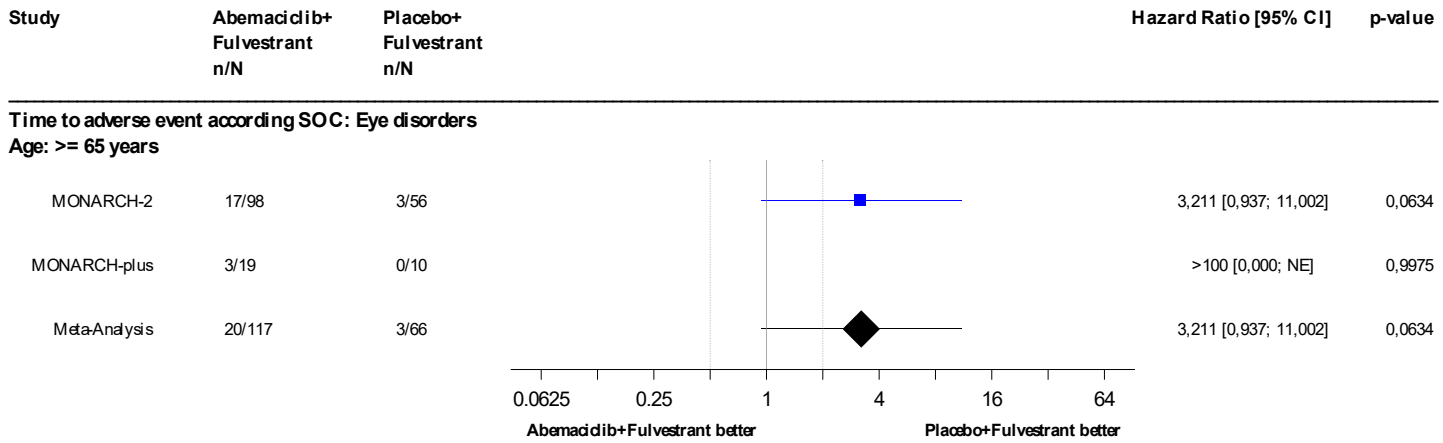
Figure 1254.1.1.2: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9976, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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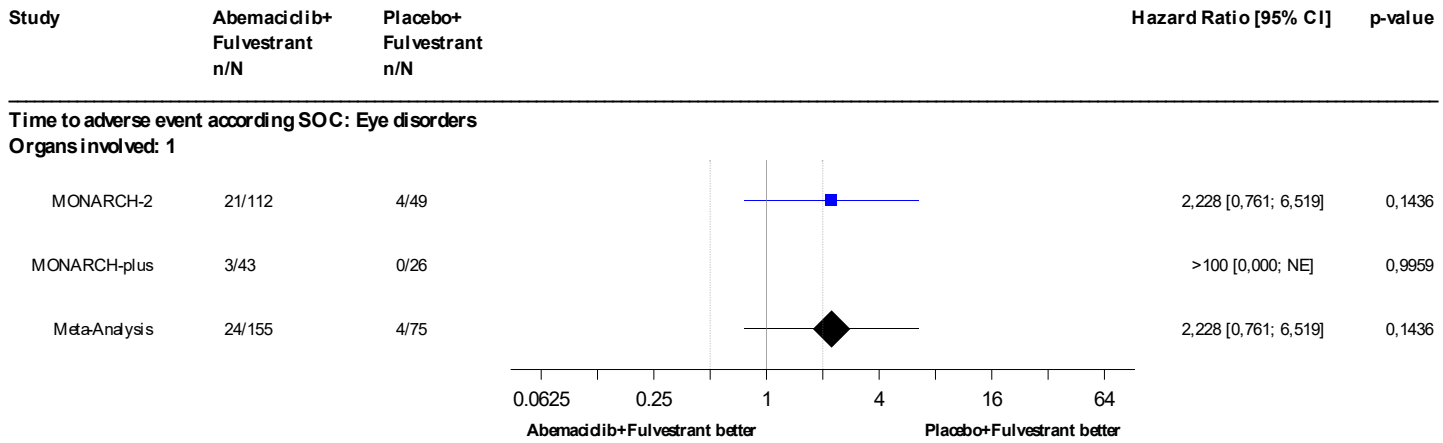
Figure 1254.1.2.1: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9961, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes004_popa1_norggr_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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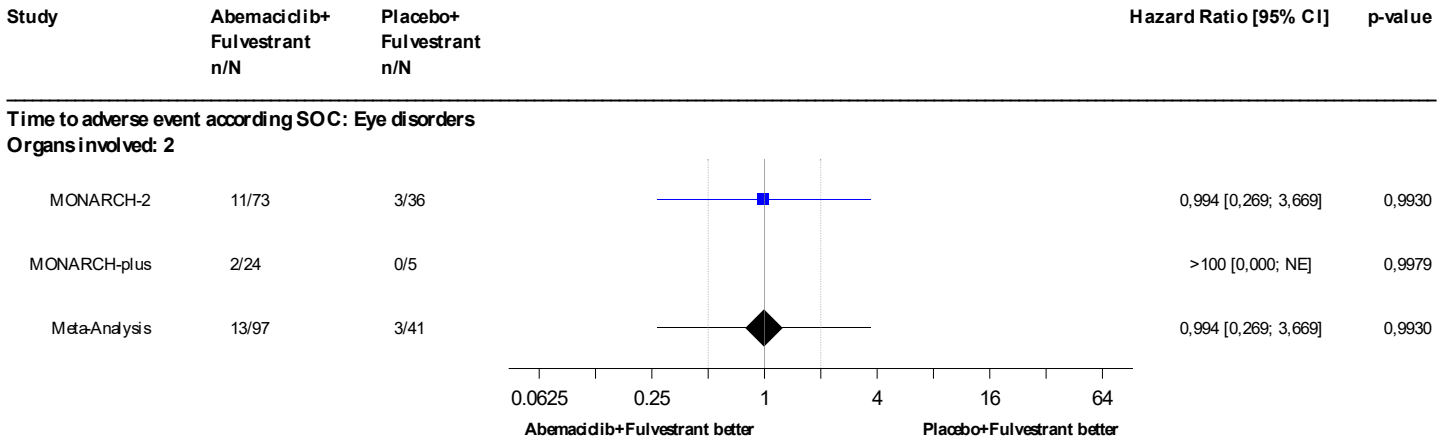
Figure 1254.1.2.2: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9979, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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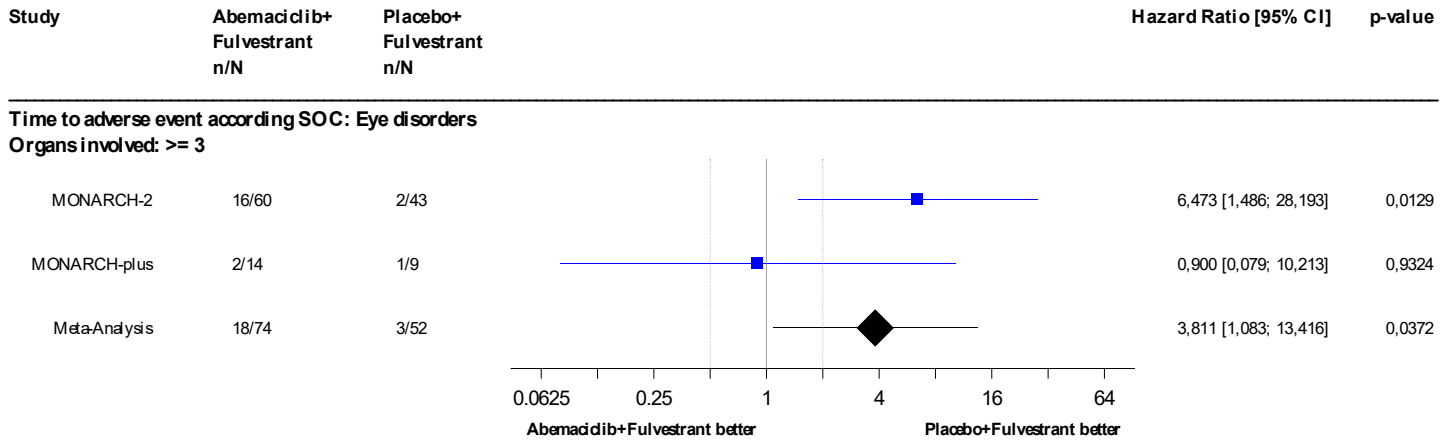
Figure 1254.1.2.3: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,8539, p-value=0,1733, I2 index=46,1%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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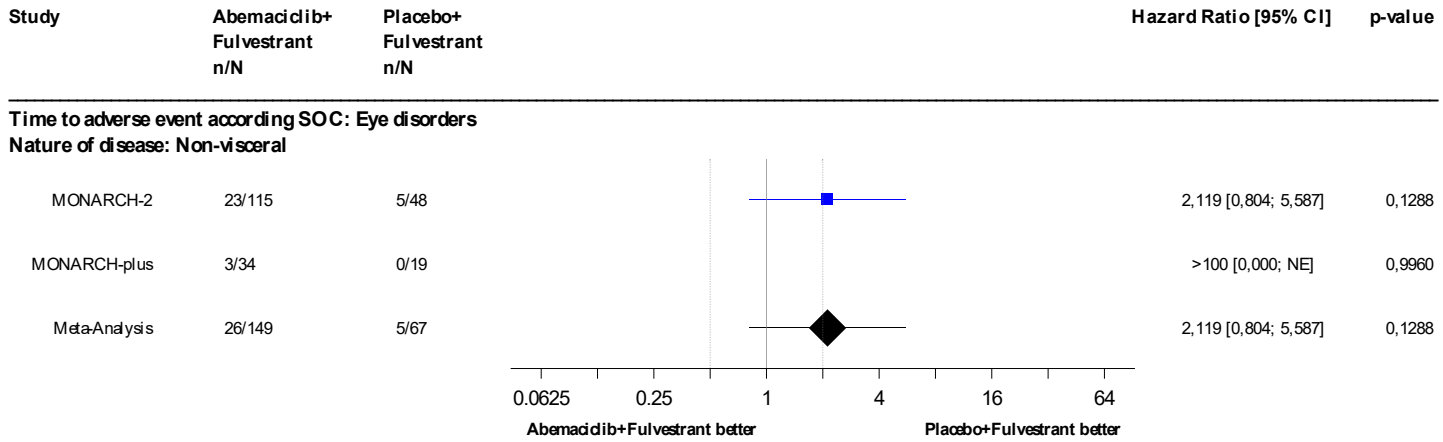
Figure 1254.1.3.1: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9962, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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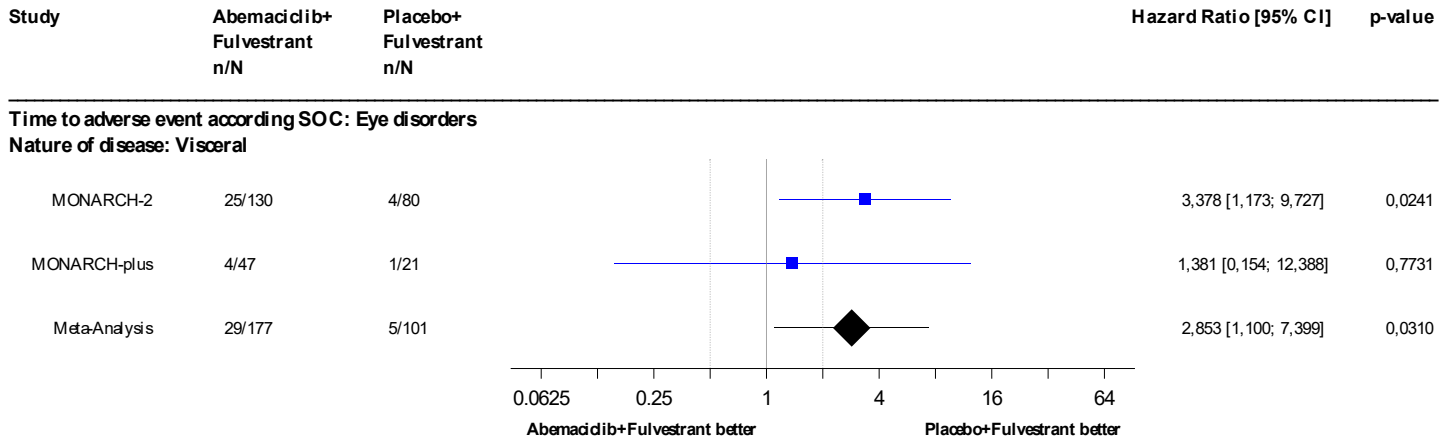
Figure 1254.1.3.2: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5182, p-value=0,4716, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes004_popa1_natdis2_2.rtf
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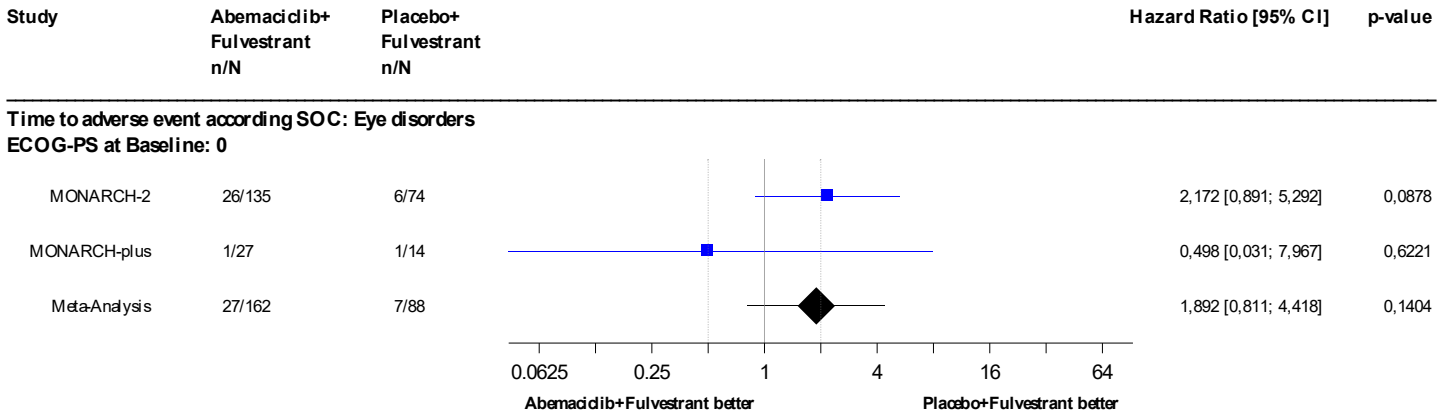
Figure 1254.1.4.1: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,9826, p-value=0,3216, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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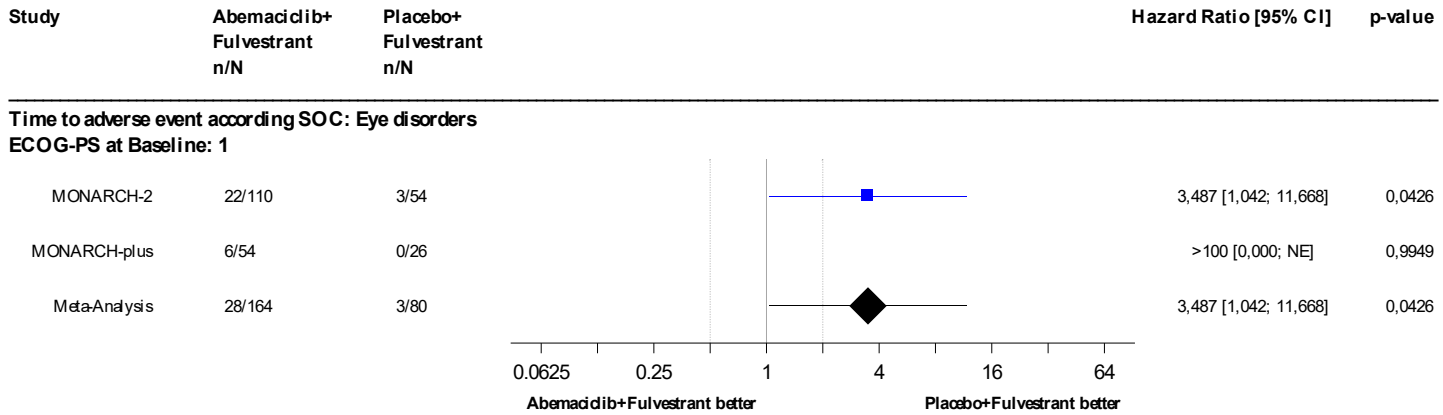
Figure 1254.1.4.2: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9953, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes004_popa1_ecogbl_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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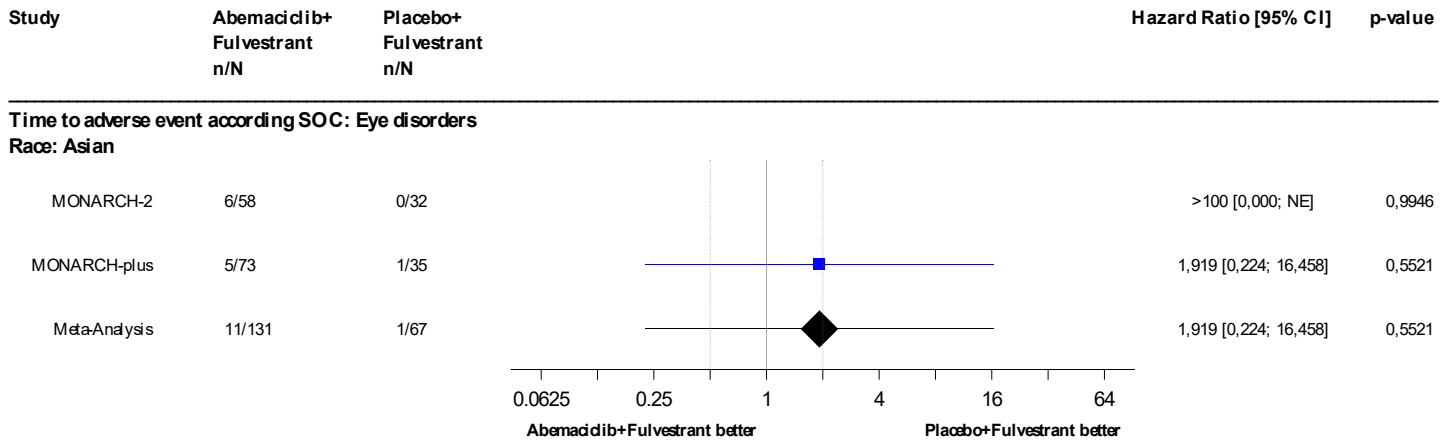
Figure 1254.1.5.1: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9948, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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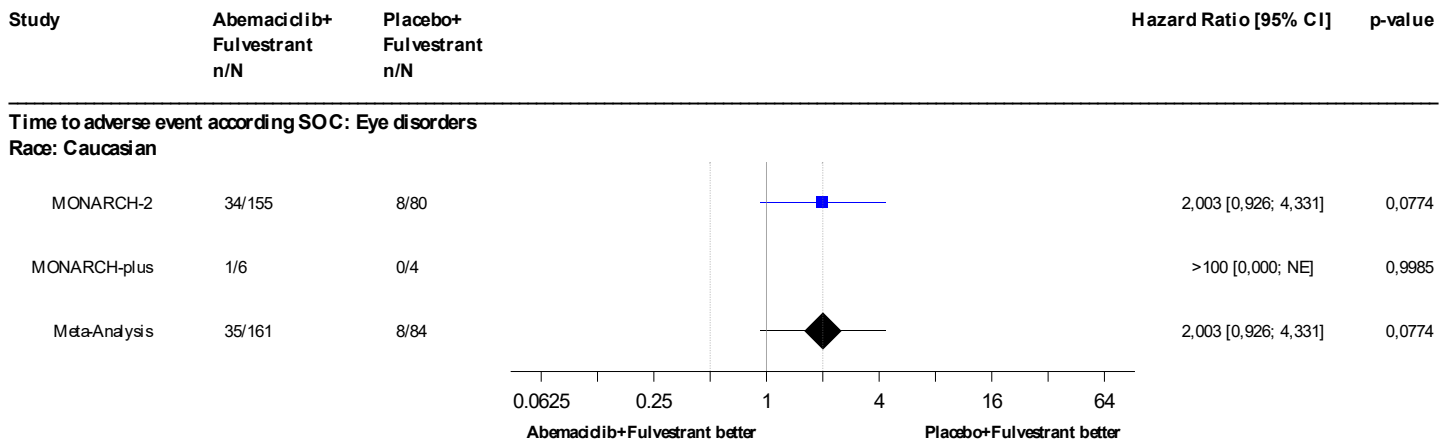
Figure 1254.1.5.2: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes004_popa1_racegr1_2.rtf
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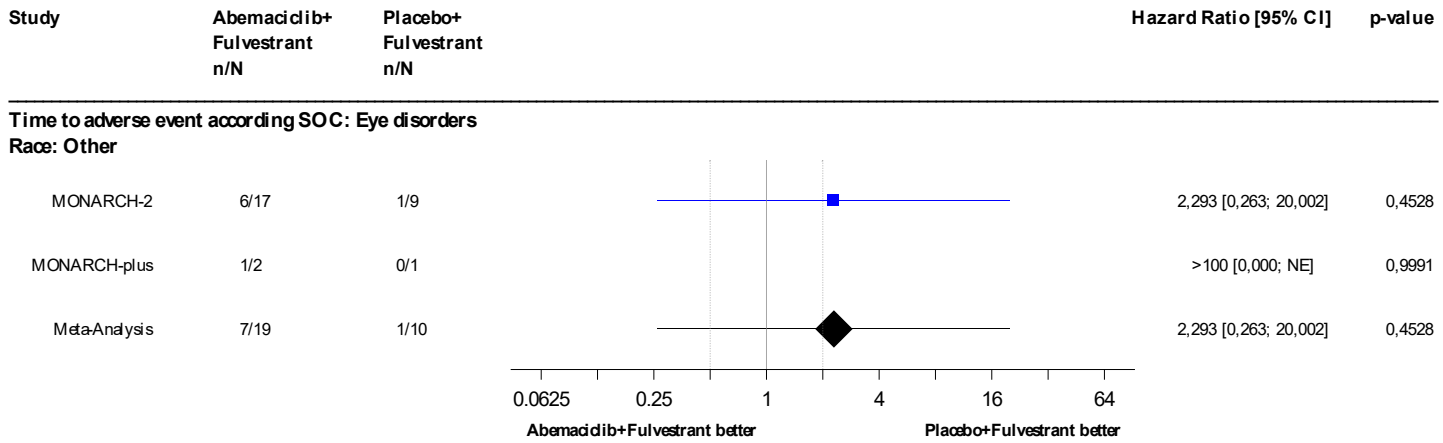
Figure 1254.1.5.3: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9991, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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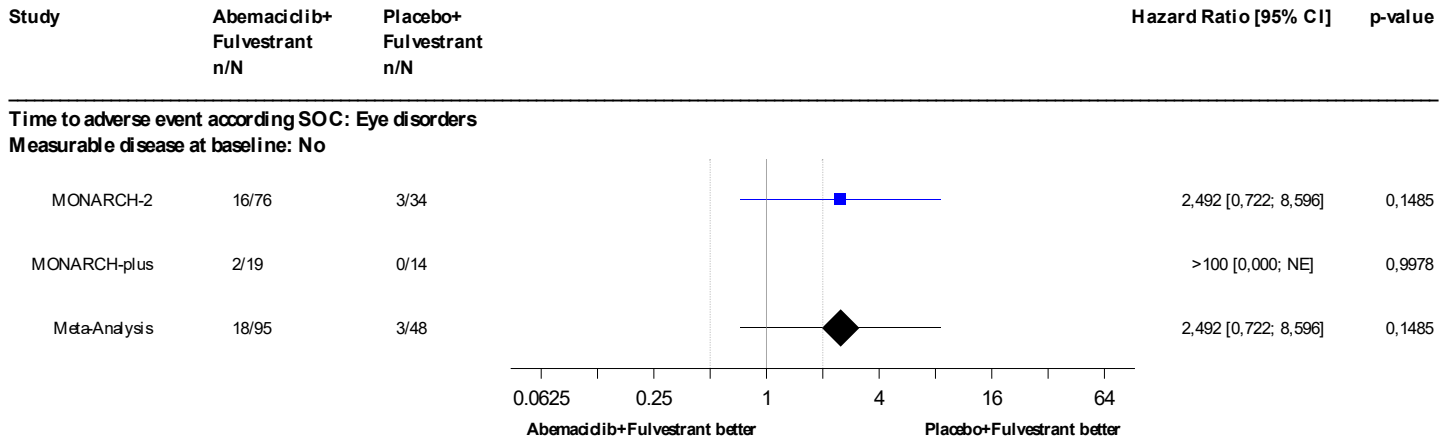
Figure 1254.1.6.1: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9979, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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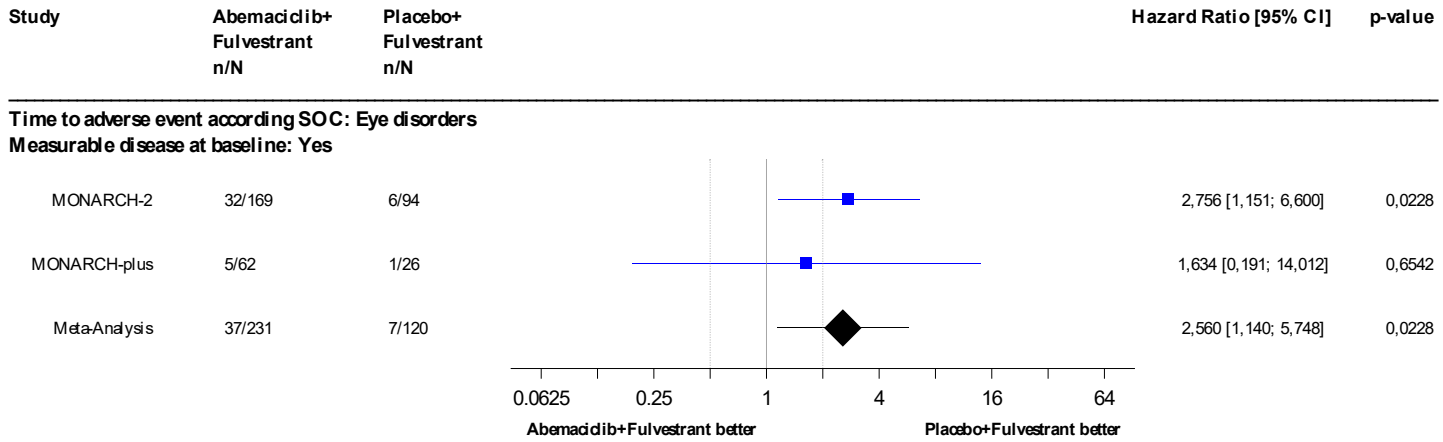
Figure 1254.1.6.2: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1952, p-value=0,6586, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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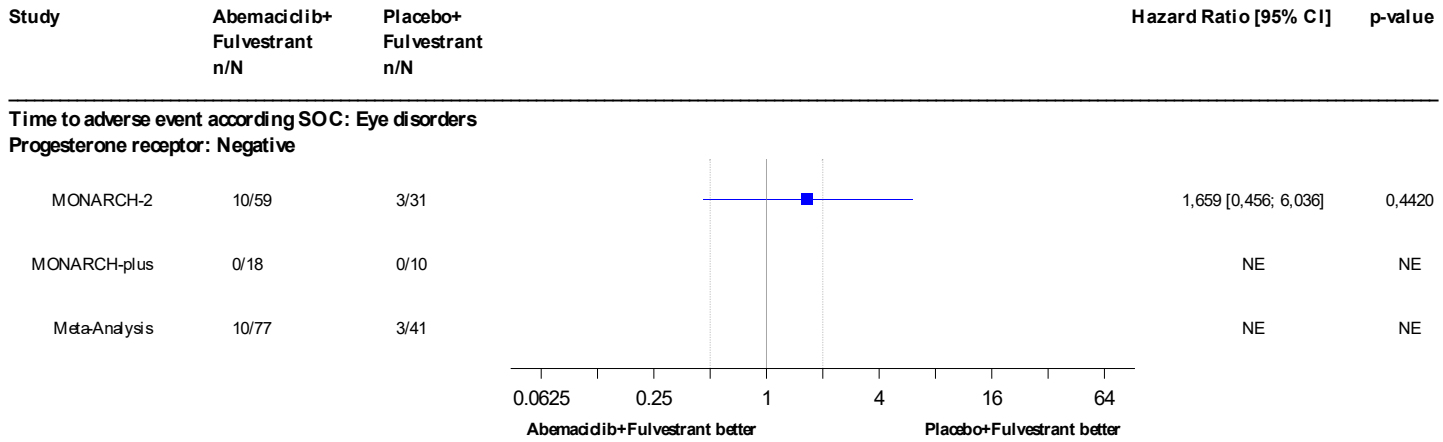
Figure 1254.1.7.1: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes004_popa1_pgrstat_1.rtf
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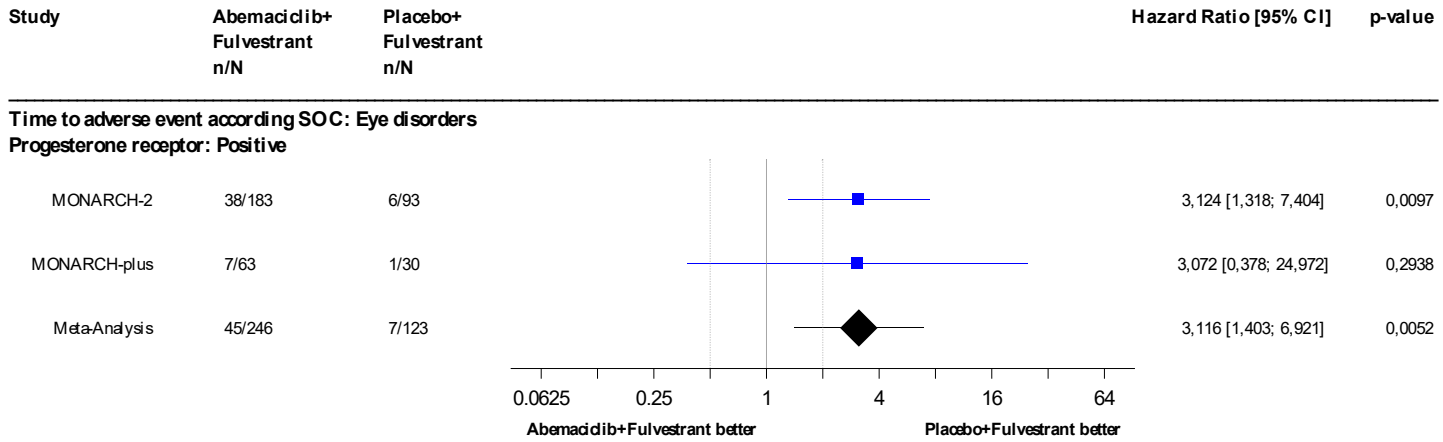
Figure 1254.1.7.2: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0002, p-value=0,9884, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes004_popa1_pgrstat_2.rtf
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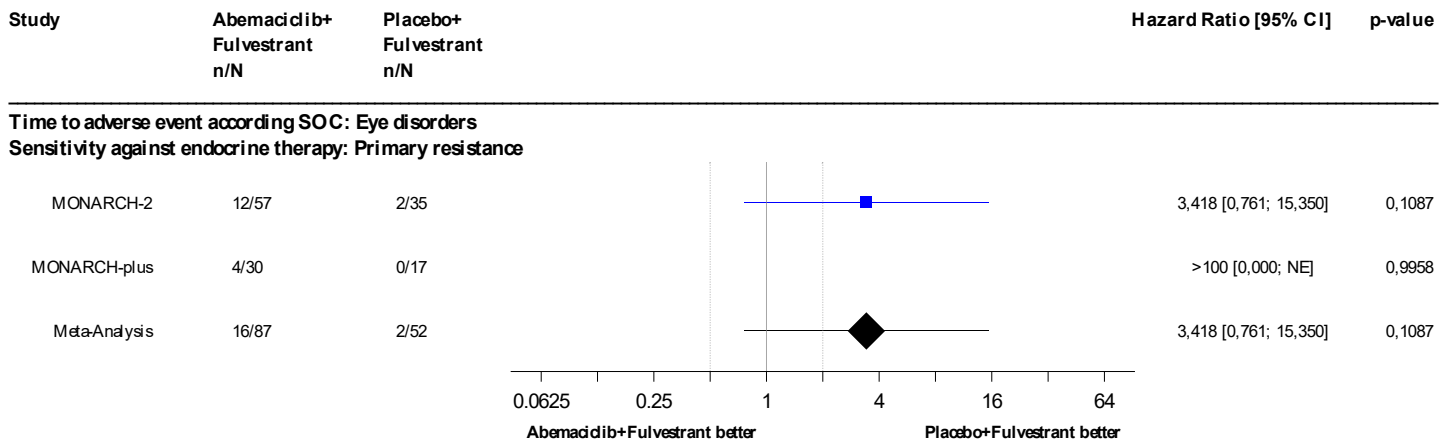
Figure 1254.1.8.1: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9961, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes004_popa1_snthr_1.rtf
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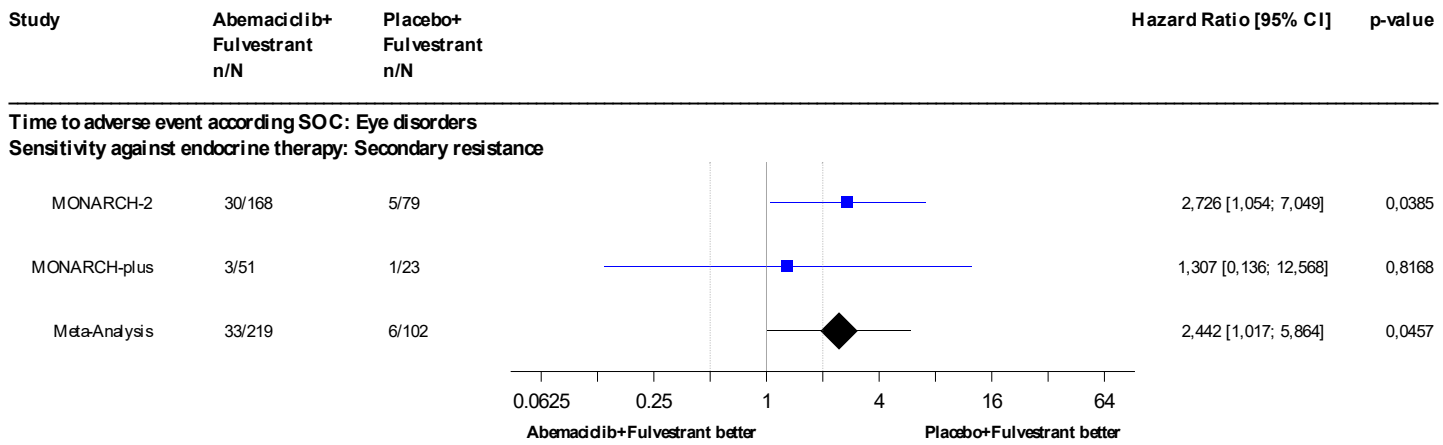
Figure 1254.1.8.2: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3447, p-value=0,5571, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes004_popa1_snthr_2.rtf
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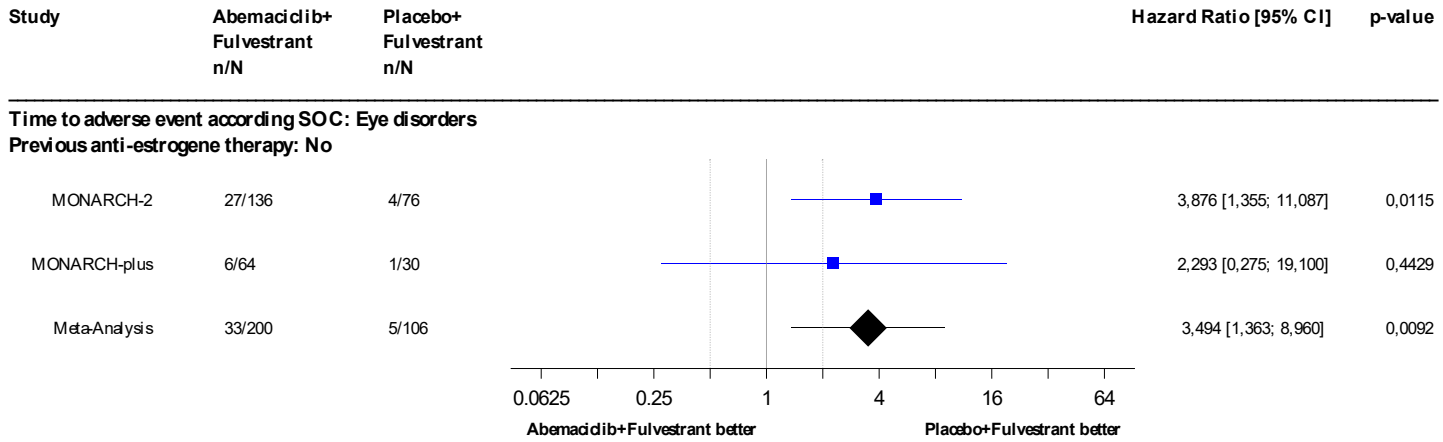
Figure 1254.1.9.1: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1890, p-value=0,6637, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes004_popa1_paet_1.rtf
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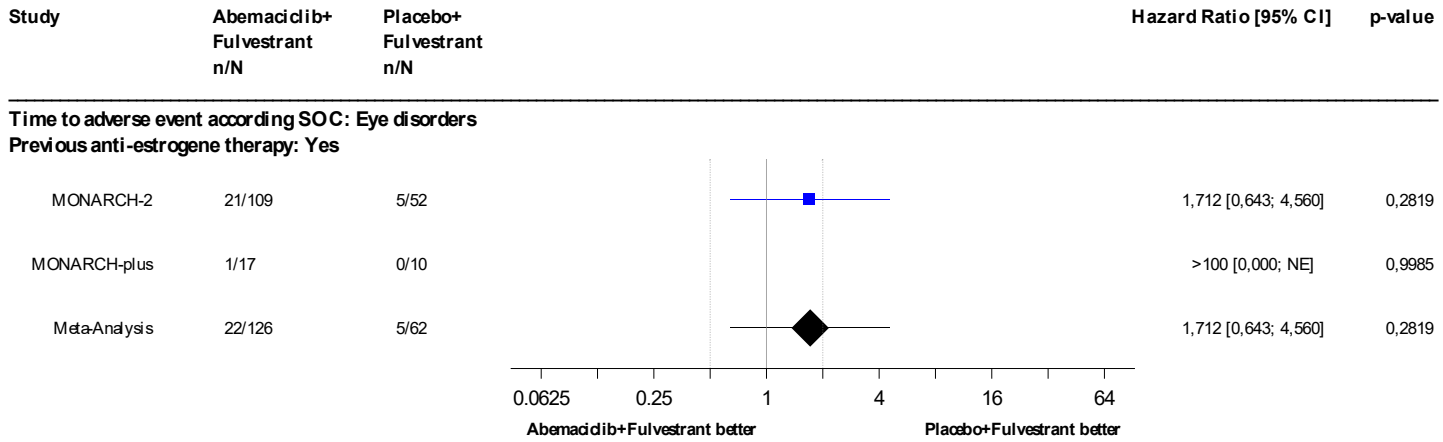
Figure 1254.1.9.2: Metaanalysis results for adverse events according SOC[1] -
Eye disorders
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes004_popa1_paet_2.rtf
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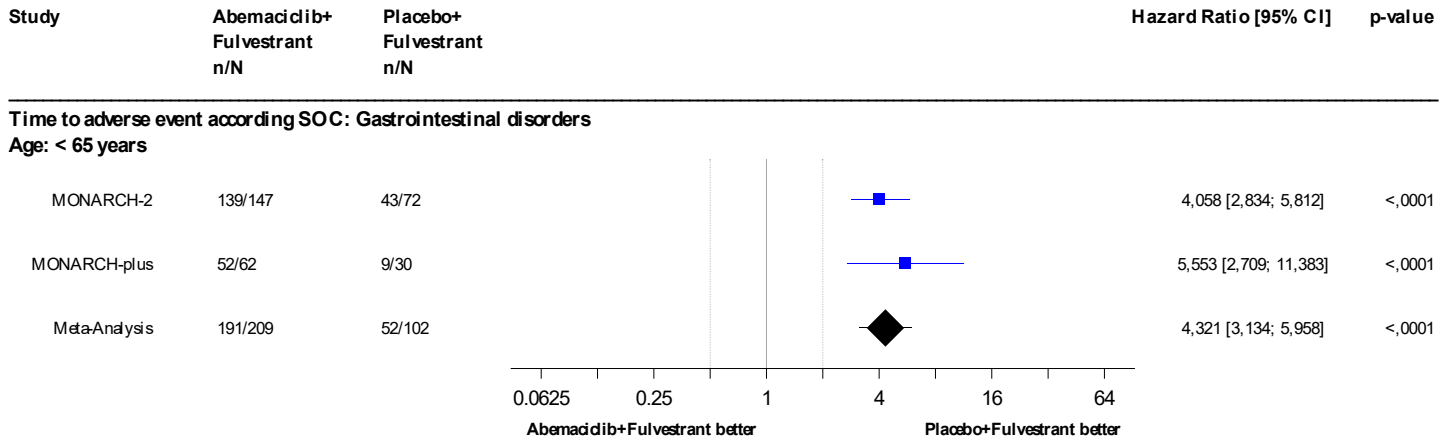
Figure 1255.1.1.1: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5865, p-value=0,4438, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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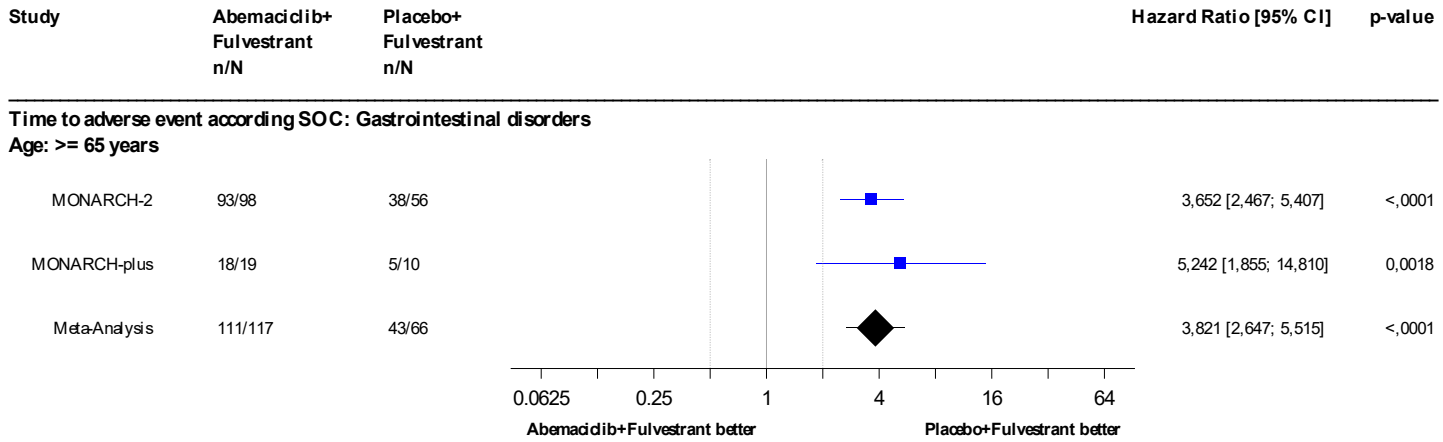
Figure 1255.1.1.2: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4068, p-value=0,5236, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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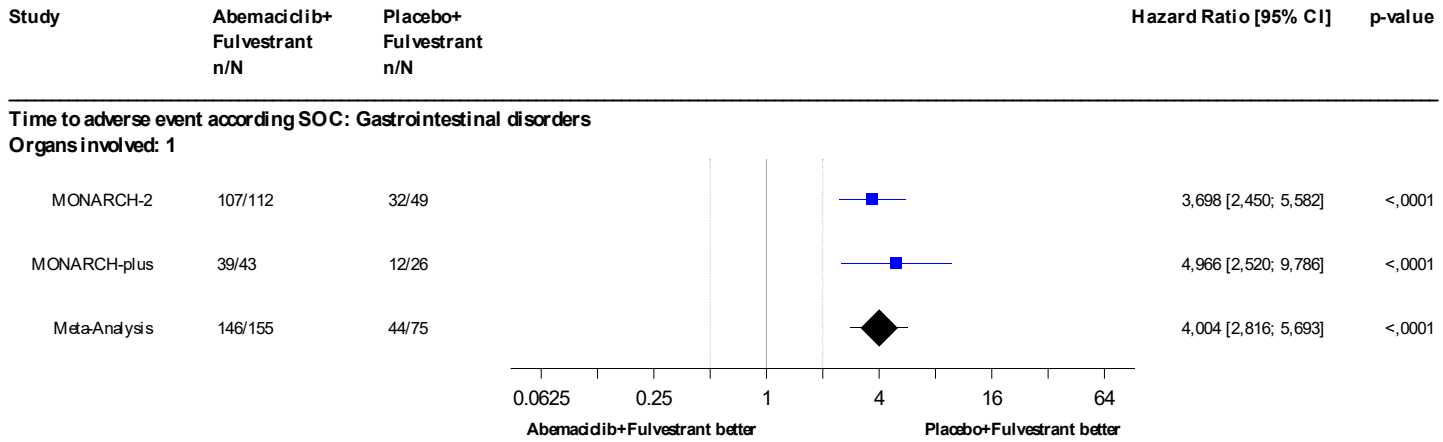
Figure 1255.1.2.1: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5305, p-value=0,4664, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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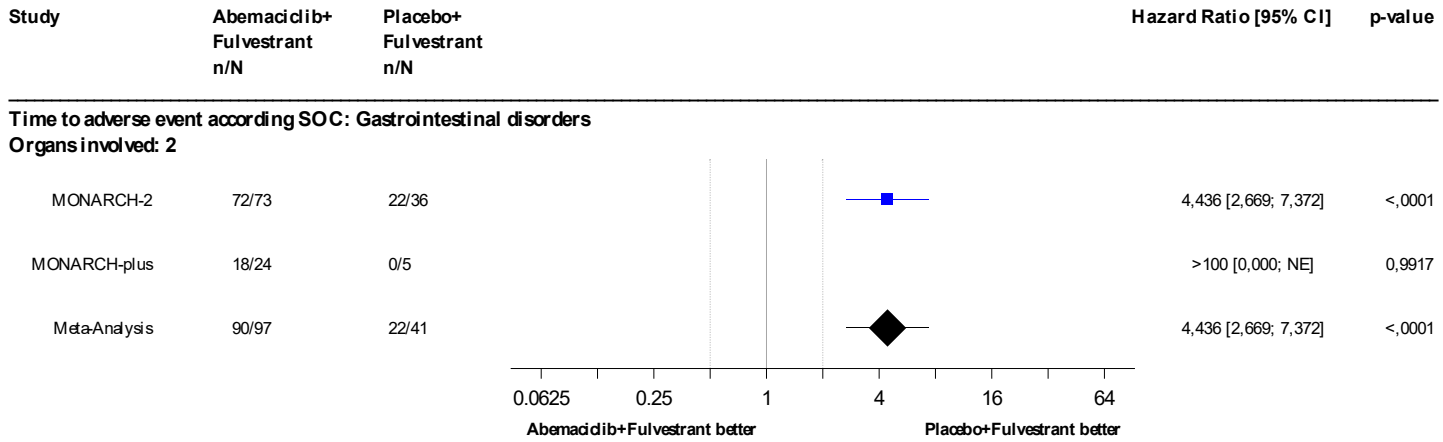
Figure 1255.1.2.2: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9924, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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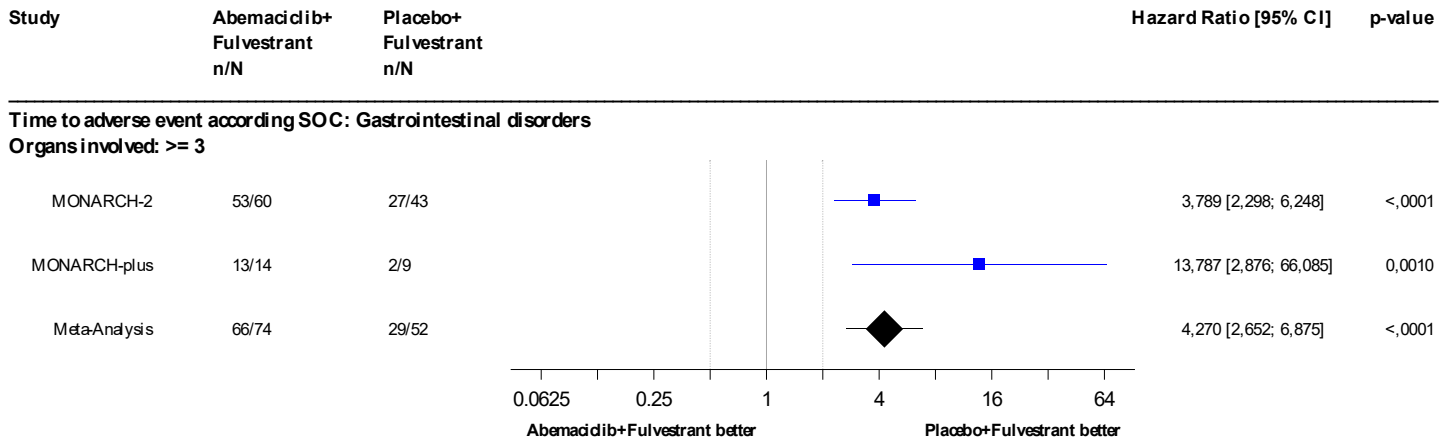
Figure 1255.1.2.3: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,3680, p-value=0,1238, I2 index=57,8%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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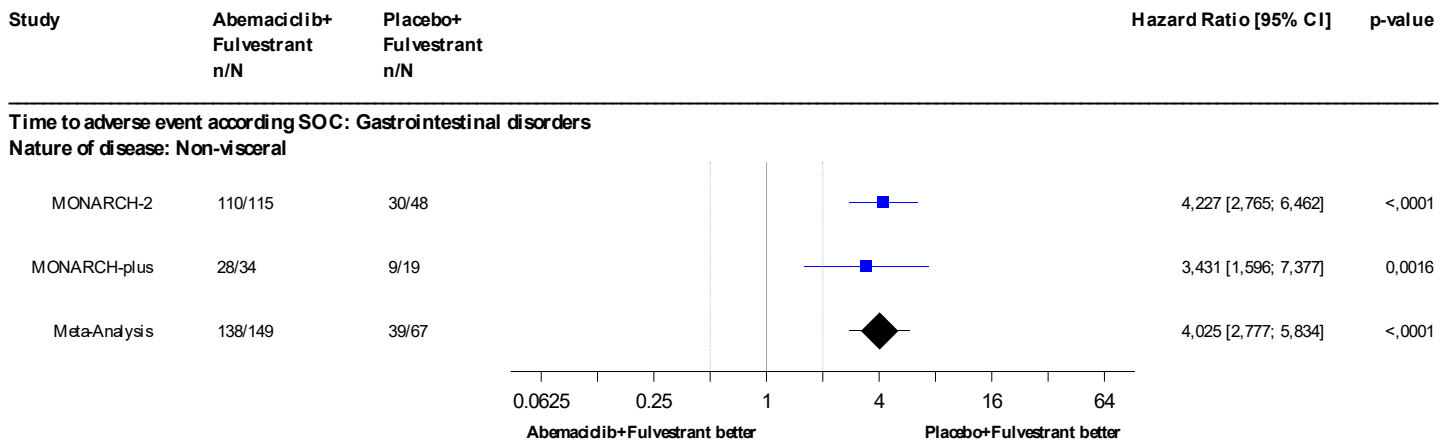
Figure 1255.1.3.1: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2183, p-value=0,6404, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes005_popa1_natdis2_1.rtf
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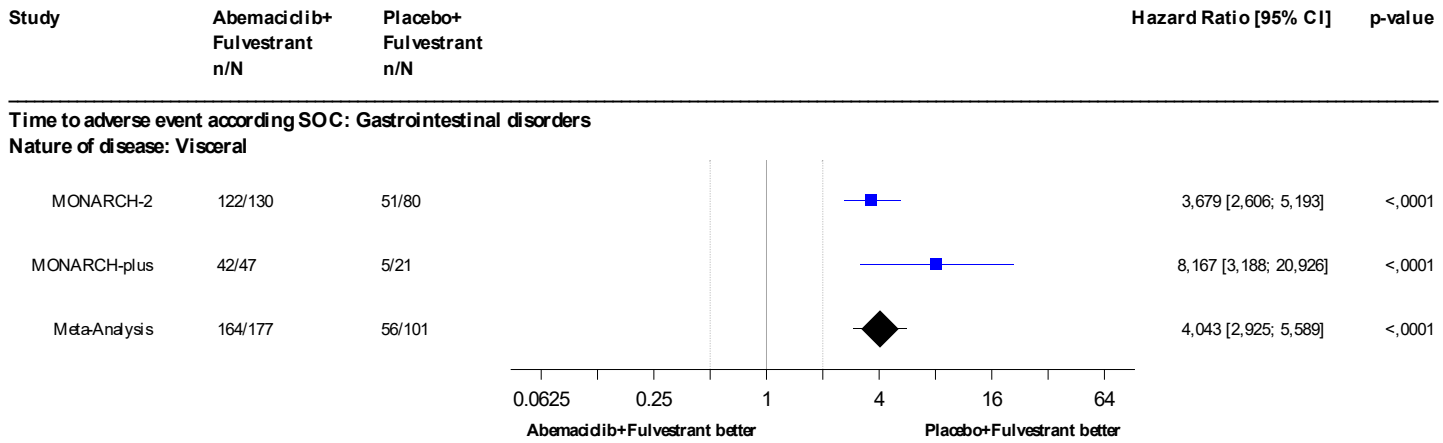
Figure 1255.1.3.2: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,4342, p-value=0,1187, I2 index=58,9%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes005_popa1_natdis2_2.rtf
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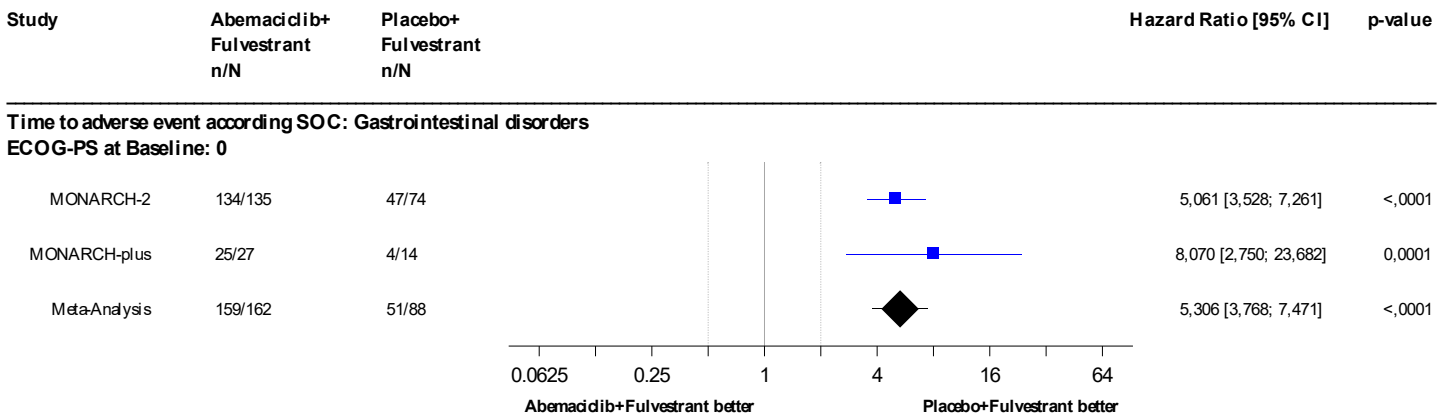
Figure 1255.1.4.1: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6484, p-value=0,4207, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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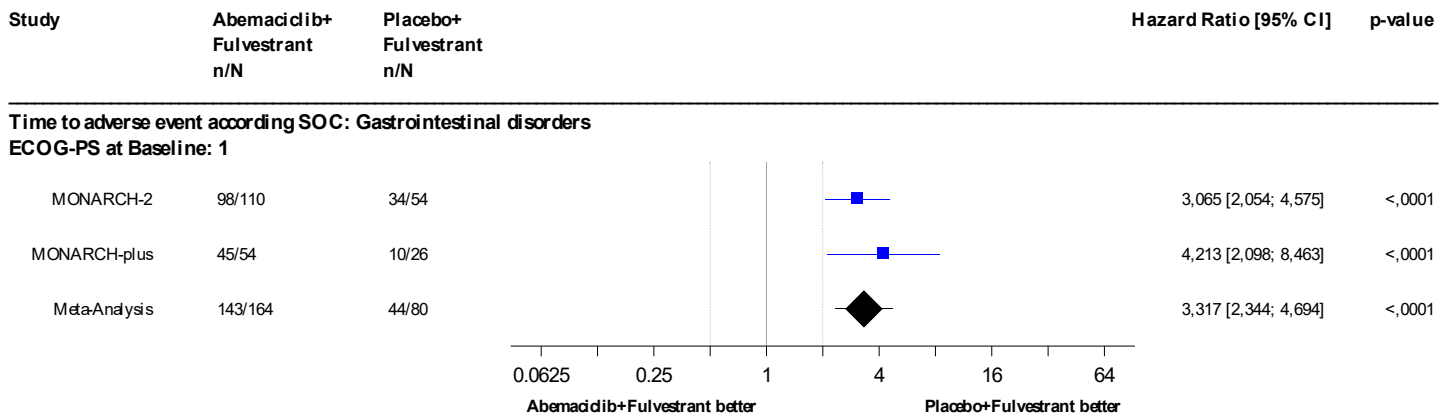
Figure 1255.1.4.2: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6010, p-value=0,4382, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes005_popa1_ecogbl_2.rtf
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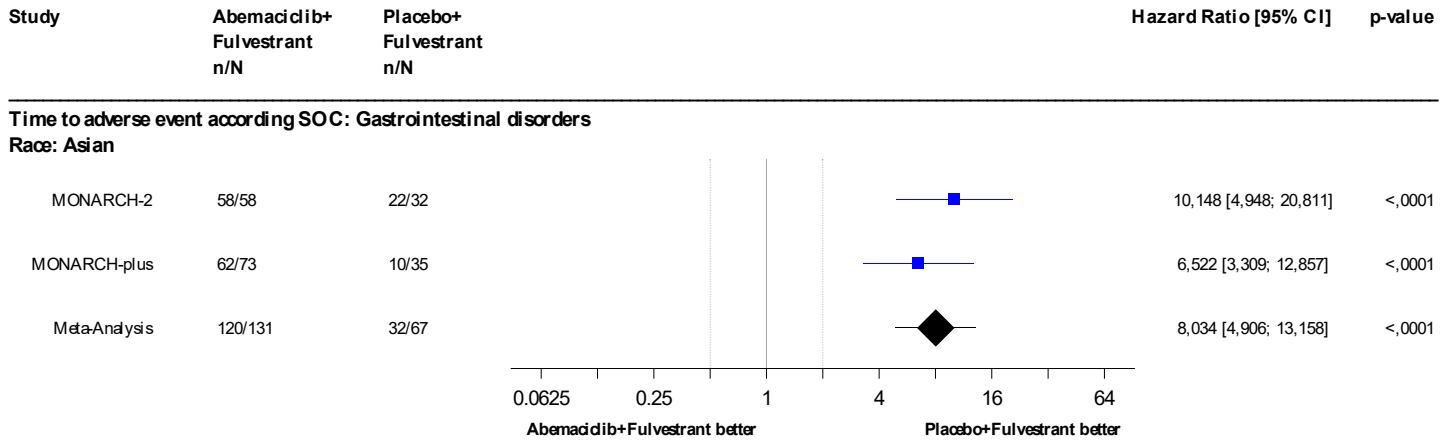
Figure 1255.1.5.1: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,7688, p-value=0,3806, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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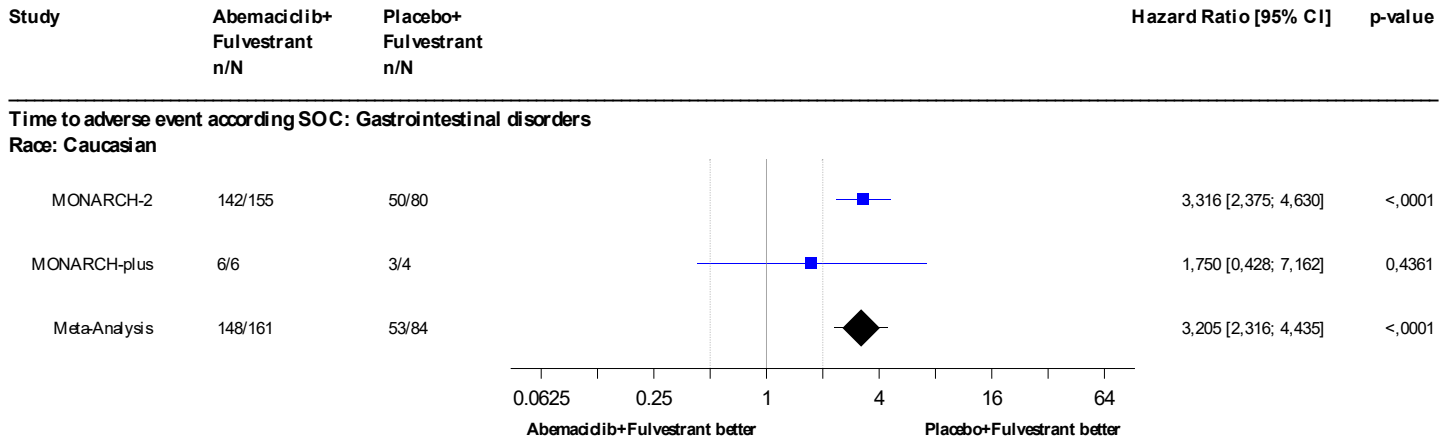
Figure 1255.1.5.2: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,7479, p-value=0,3871, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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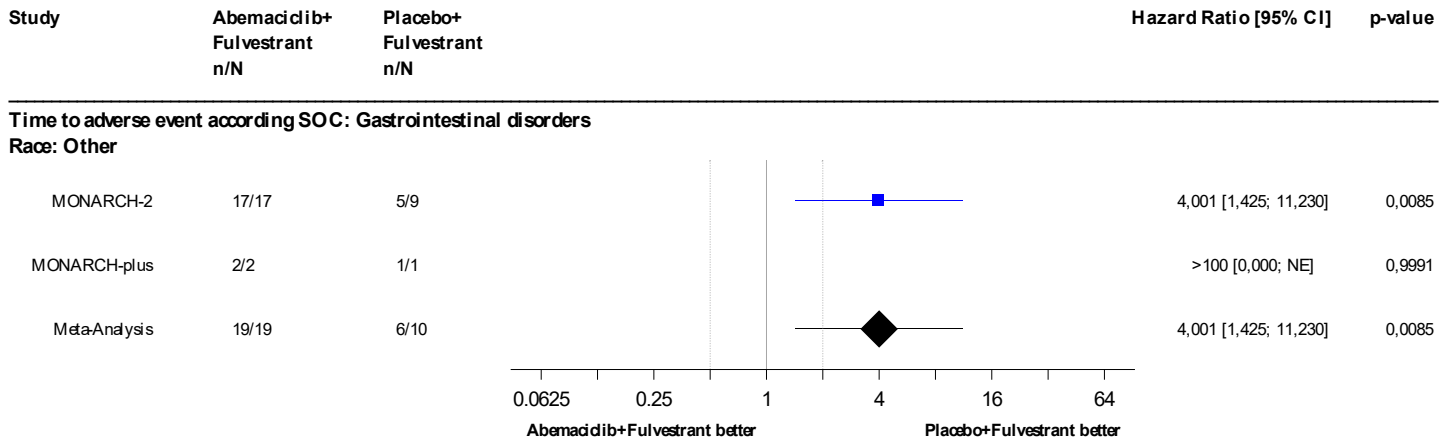
Figure 1255.1.5.3: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9992, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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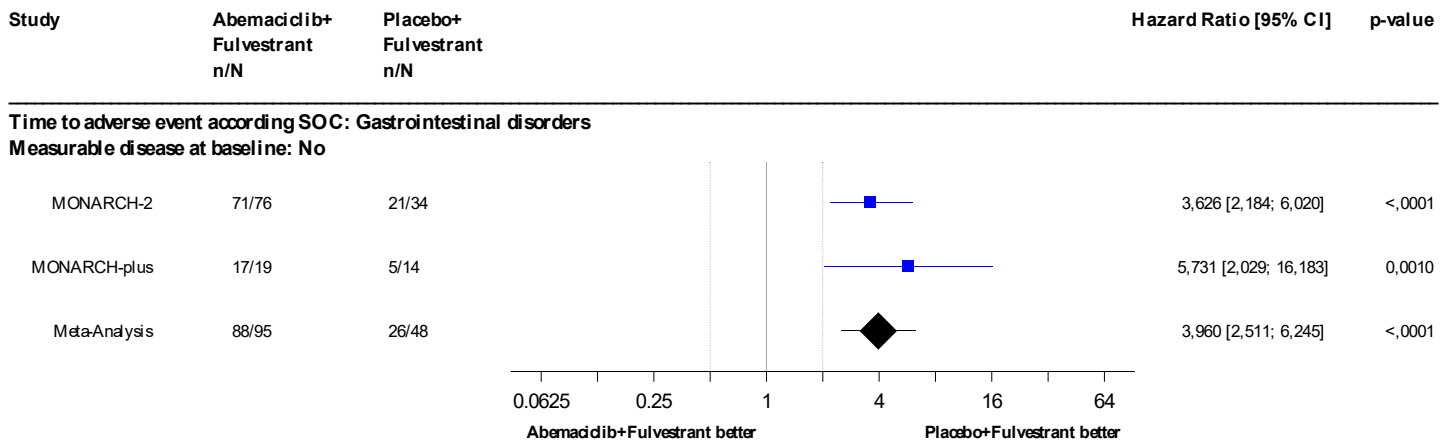
Figure 1255.1.6.1: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6029, p-value=0,4375, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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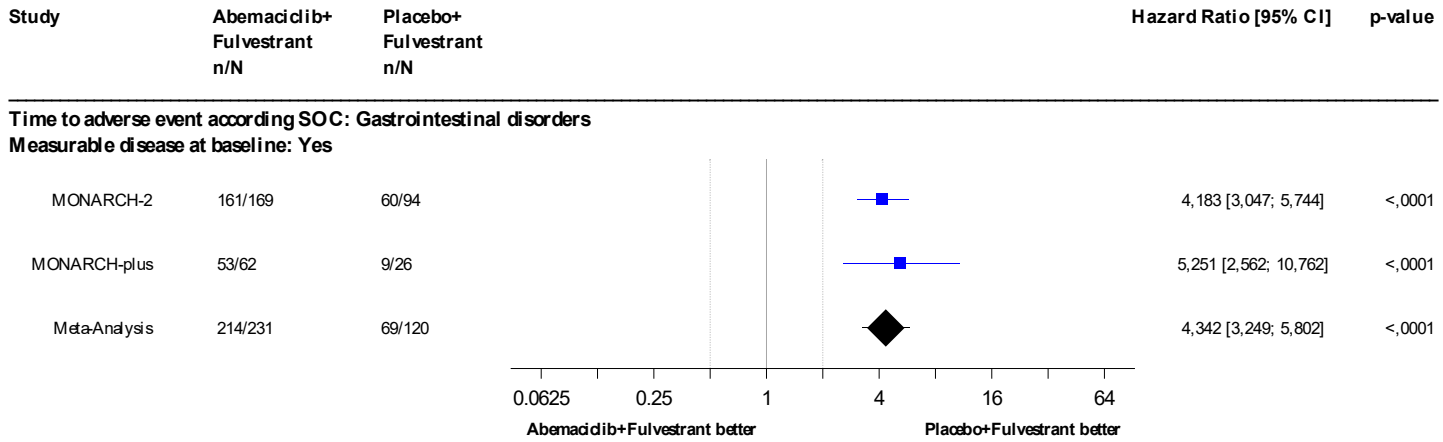
Figure 1255.1.6.2: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3222, p-value=0,5703, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes005_popa1_measdis_2.rtf
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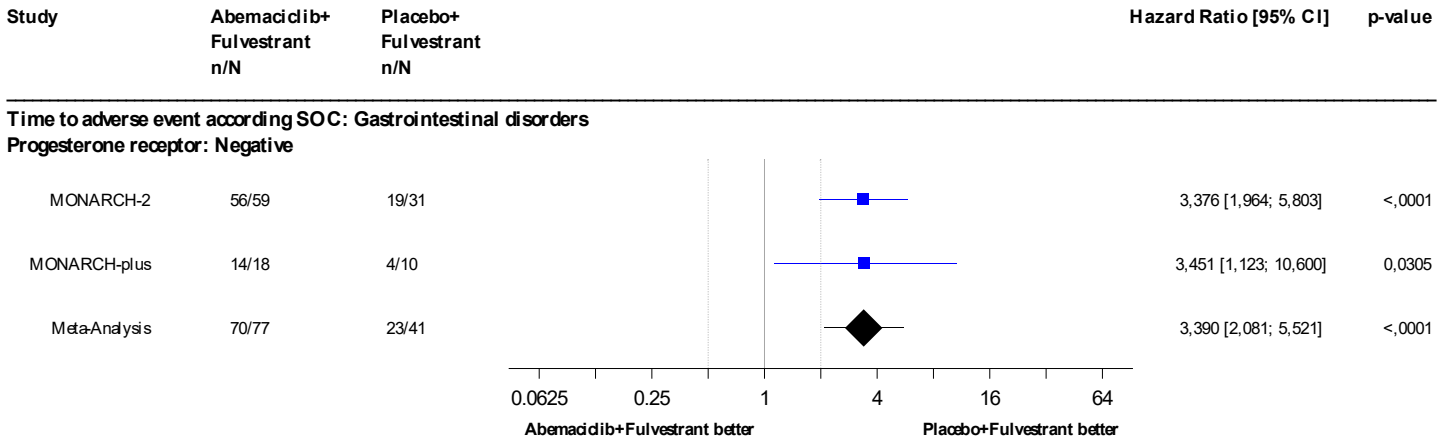
Figure 1255.1.7.1: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0012, p-value=0,9725, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes005_popa1_pgrstat_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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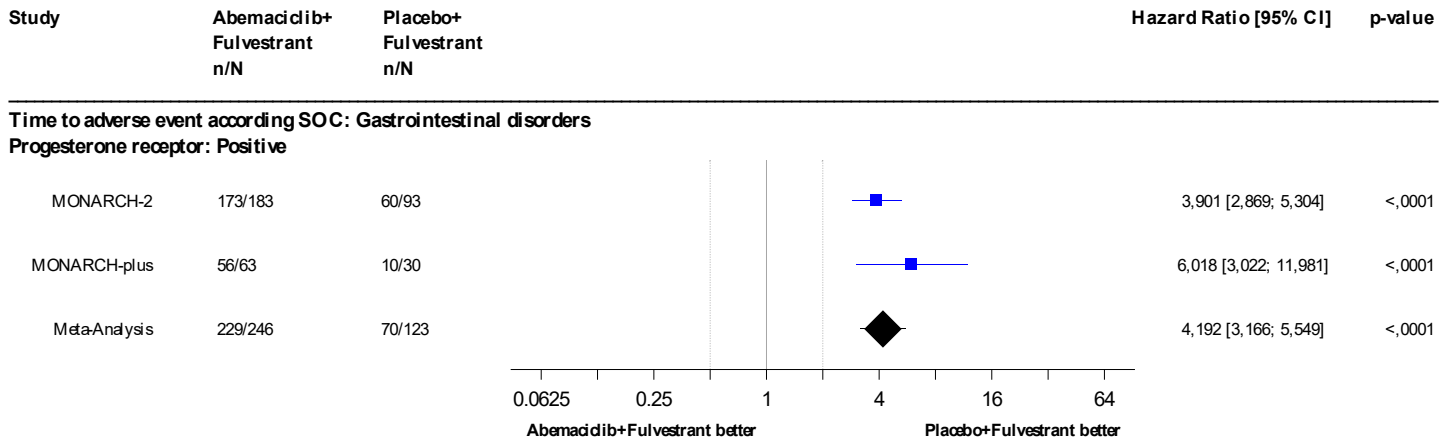
Figure 1255.1.7.2: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,2694, p-value=0,2599, I2 index=21,2%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes005_popa1_pgrstat_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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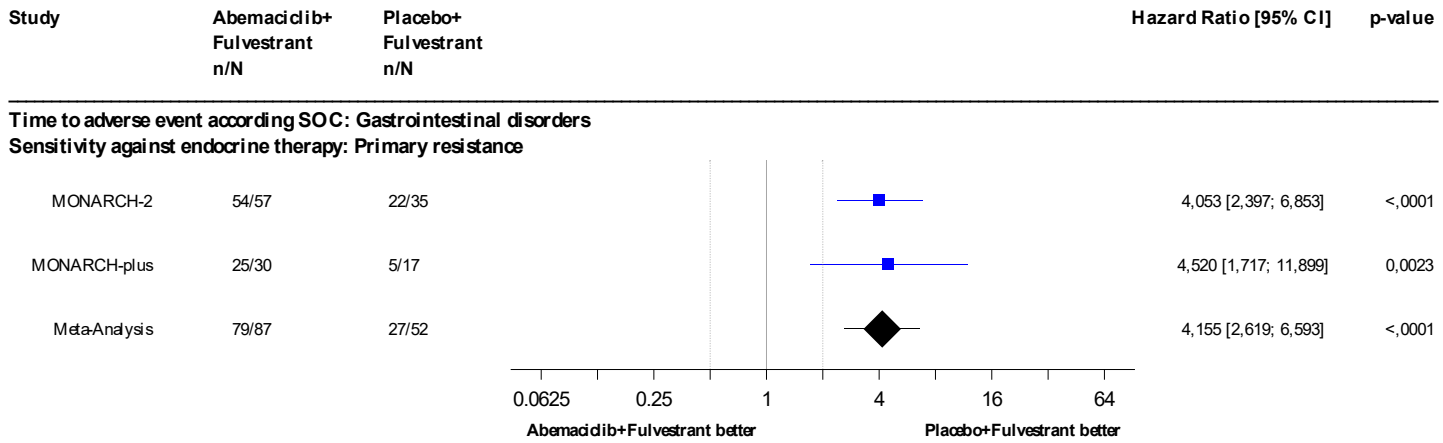
Figure 1255.1.8.1: Metaanalysis results for adverse events according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0377, p-value=0,8461, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes005_popa1_snthr_1.rtf
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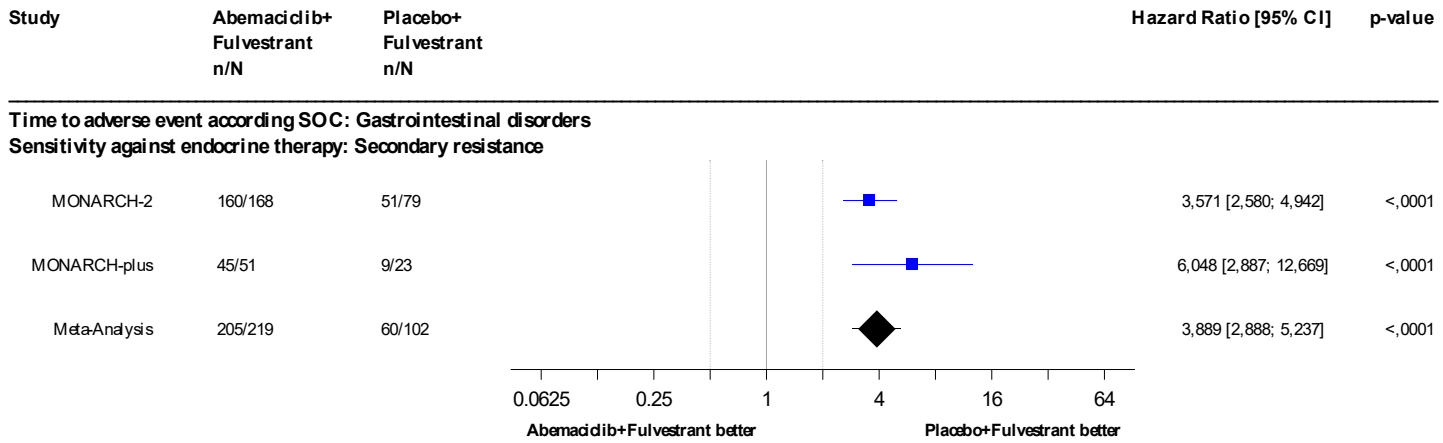
Figure 1255.1.8.2: Metaanalysis results for adverse events according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,6344, p-value=0,2011, I2 index=38,8%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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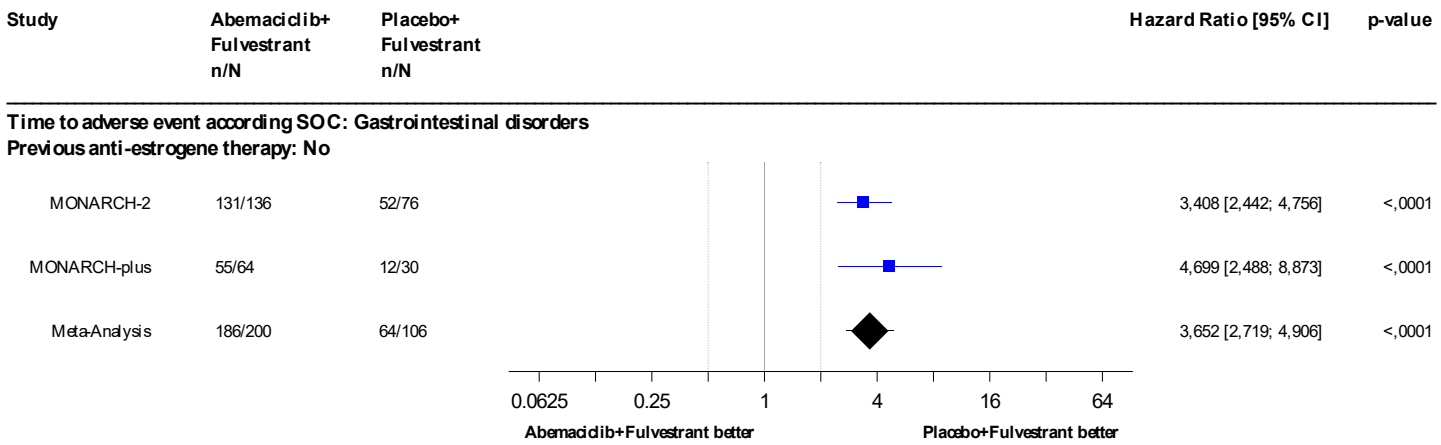
Figure 1255.1.9.1: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,7697, p-value=0,3803, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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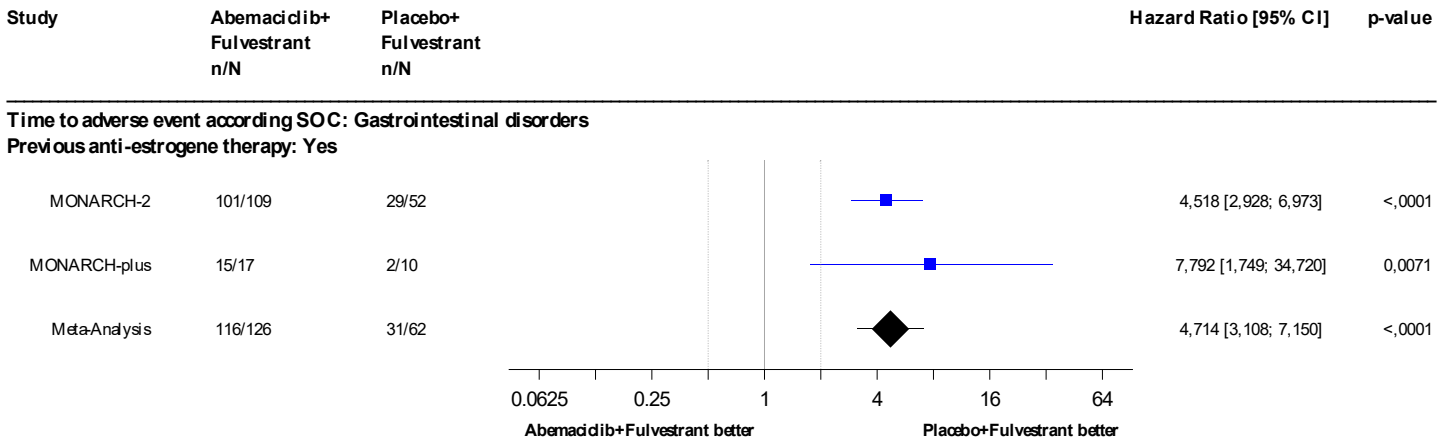
Figure 1255.1.9.2: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4712, p-value=0,4924, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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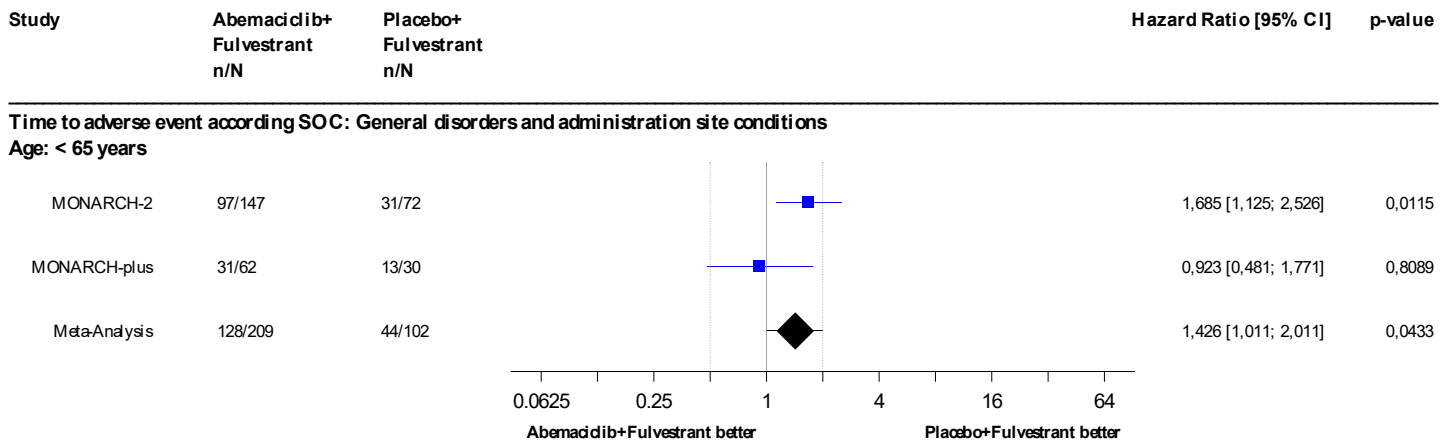
Figure 1256.1.1.1: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,3675, p-value=0,1239, I2 index=57,8%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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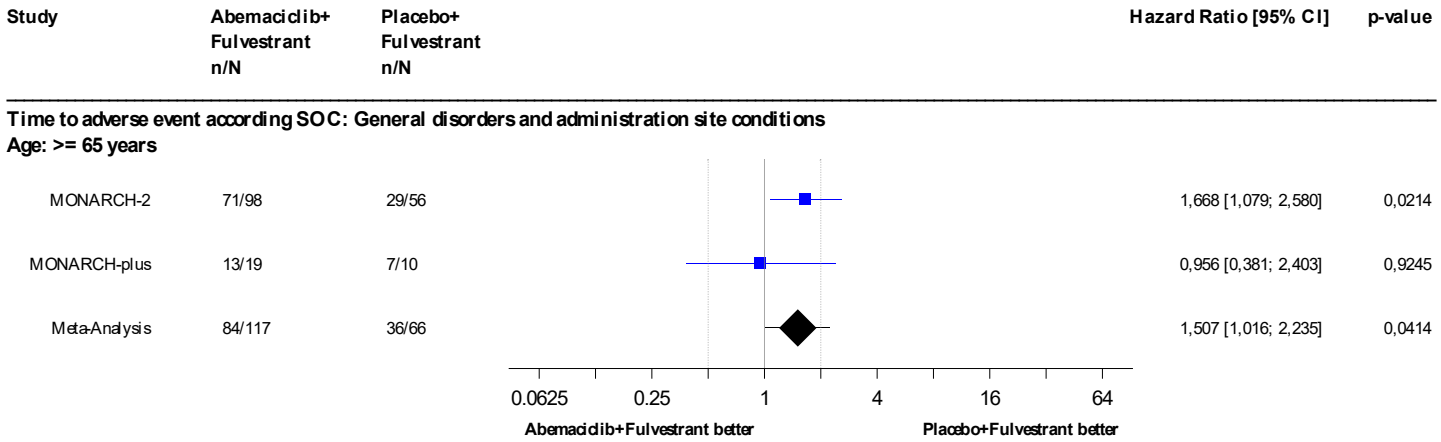
Figure 1256.1.1.2: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,1452, p-value=0,2846, I2 index=12,7%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes006_popa1_agegr1_2.rtf
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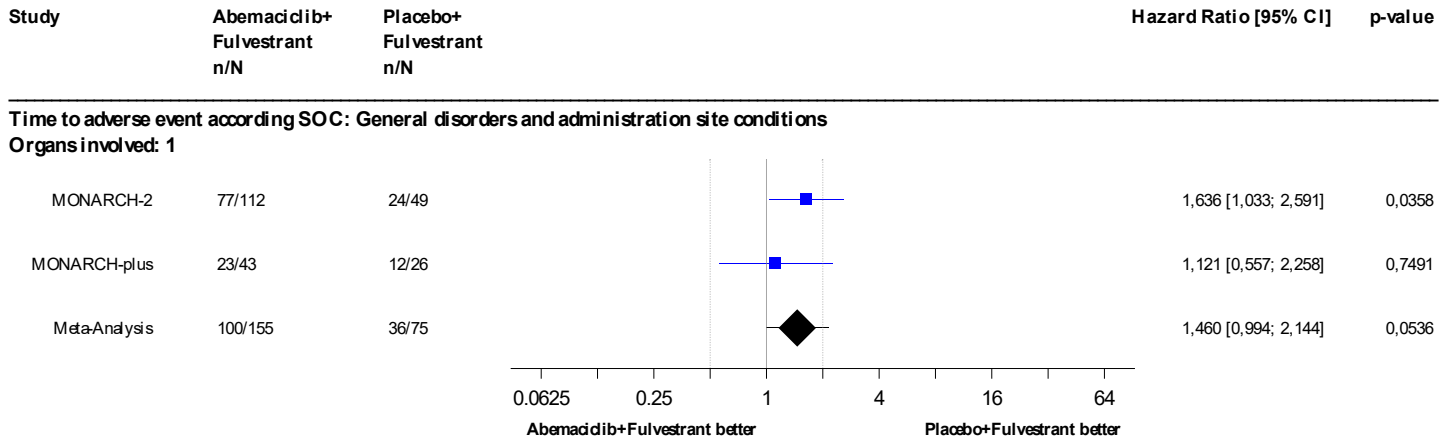
**Figure 1256.1.2.1: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,7831, p-value=0,3762, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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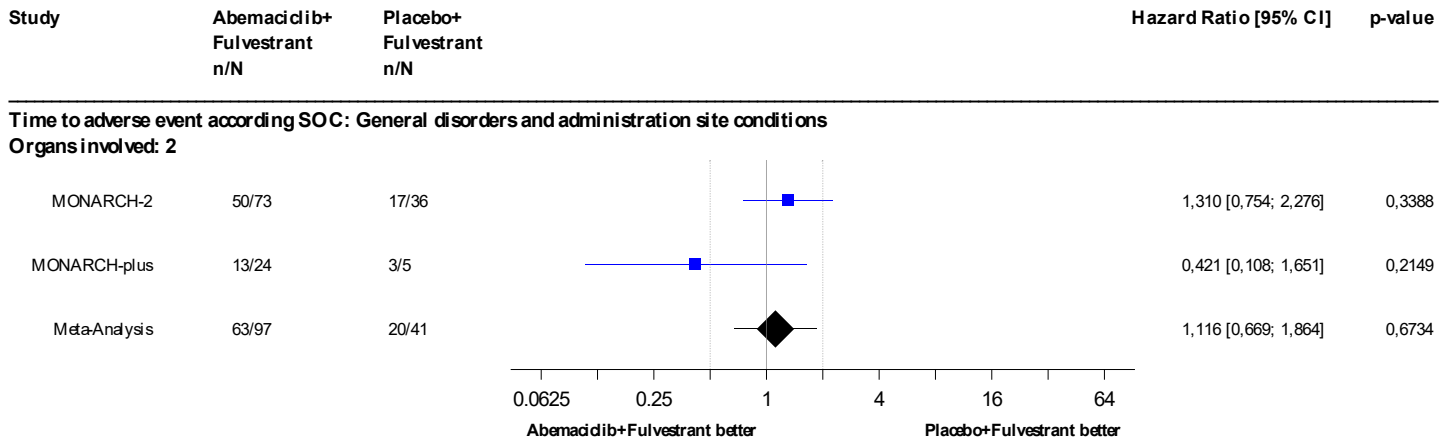
Figure 1256.1.2.2: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,2758, p-value=0,1314, I2 index=56,1%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes006_popa1_norggr_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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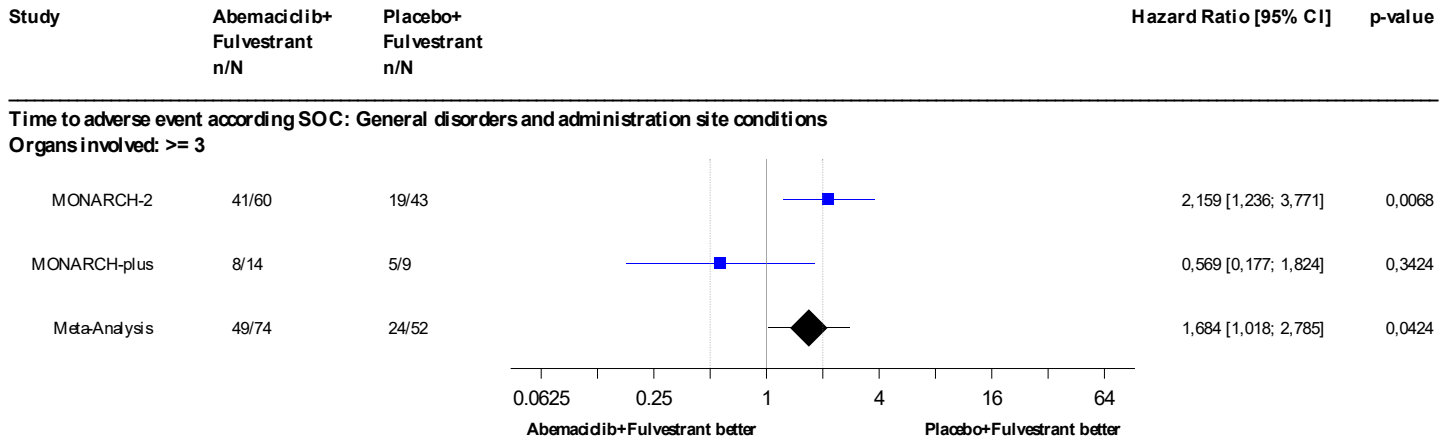
**Figure 1256.1.2.3: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=4,0958, p-value=0,0430, I2 index=75,6%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes006_popa1_norggr_3.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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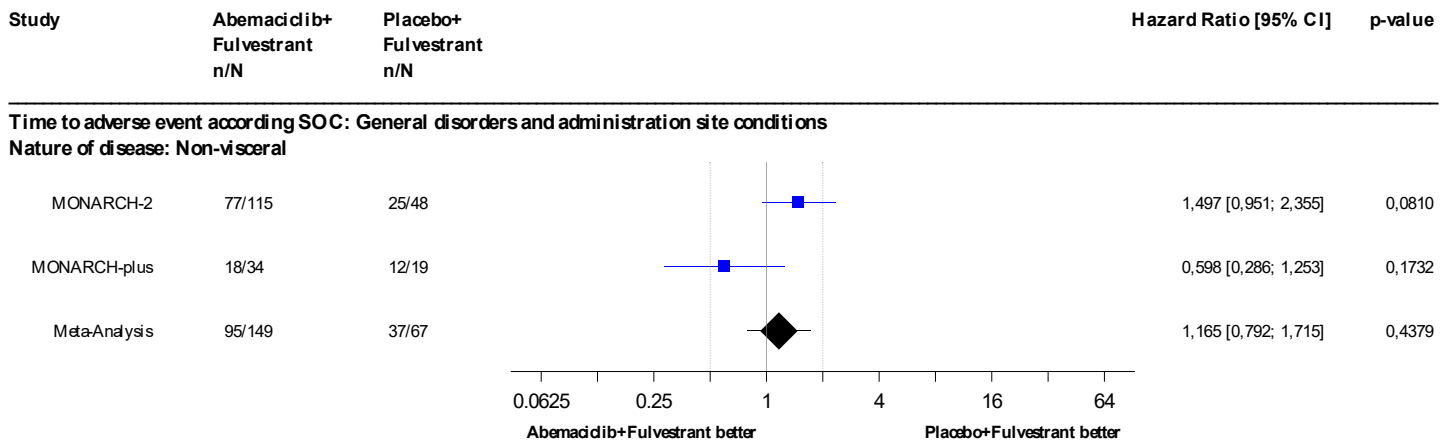
Figure 1256.1.3.1: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=4,2978, p-value=0,0382, I2 index=76,7%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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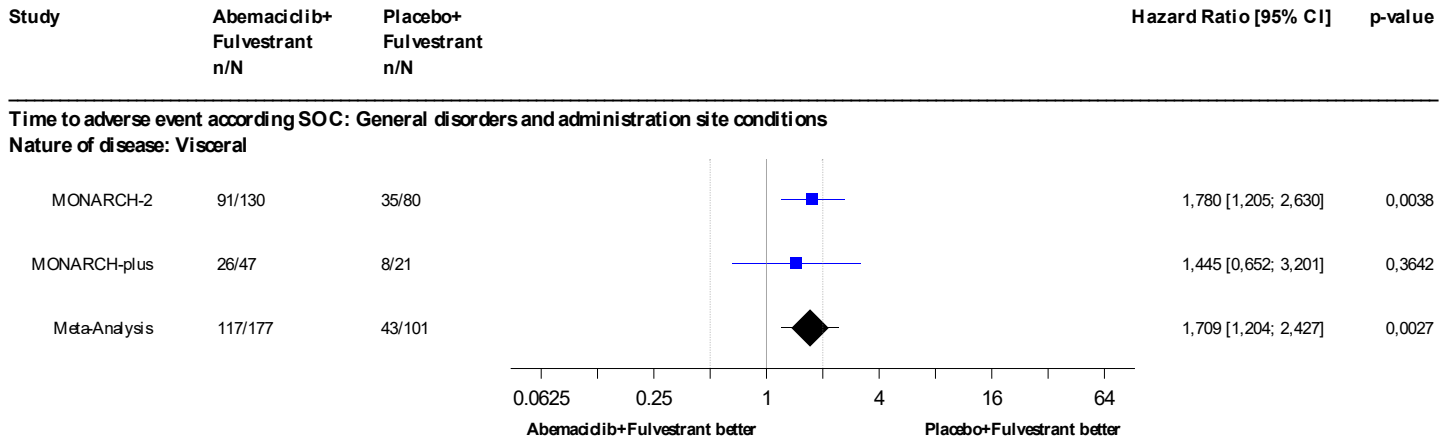
Figure 1256.1.3.2: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2126, p-value=0,6447, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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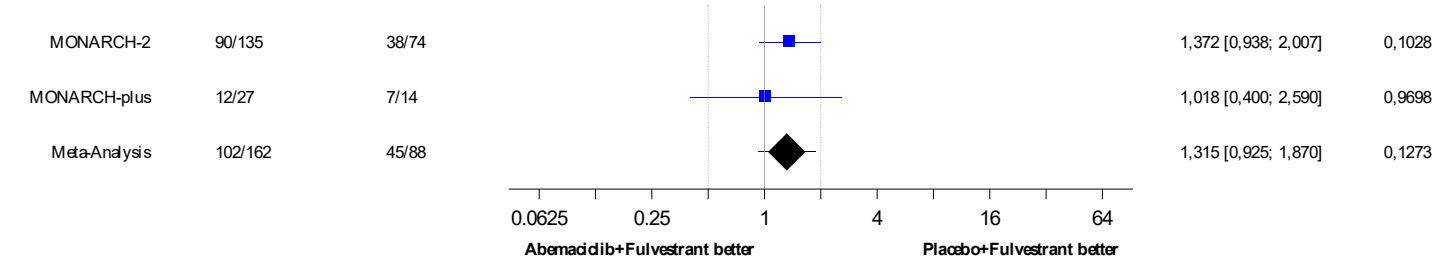
Figure 1256.1.4.1: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3367, p-value=0,5617, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes006_popa1_ecogbl_1.rtf
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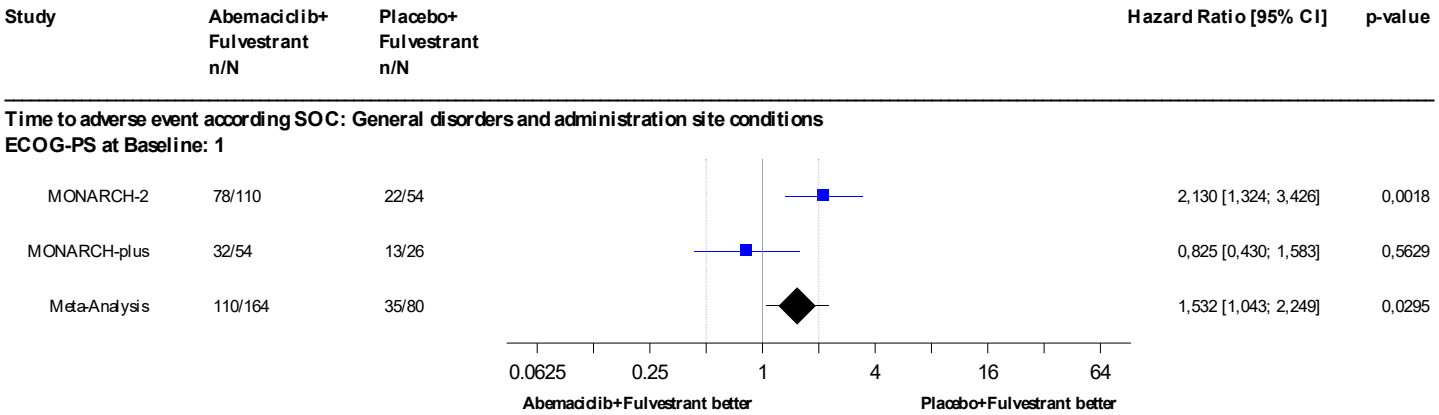
**Figure 1256.1.4.2: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=5,3108, p-value=0,0212, I2 index=81,2%

Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes006_popa1_ecogbl_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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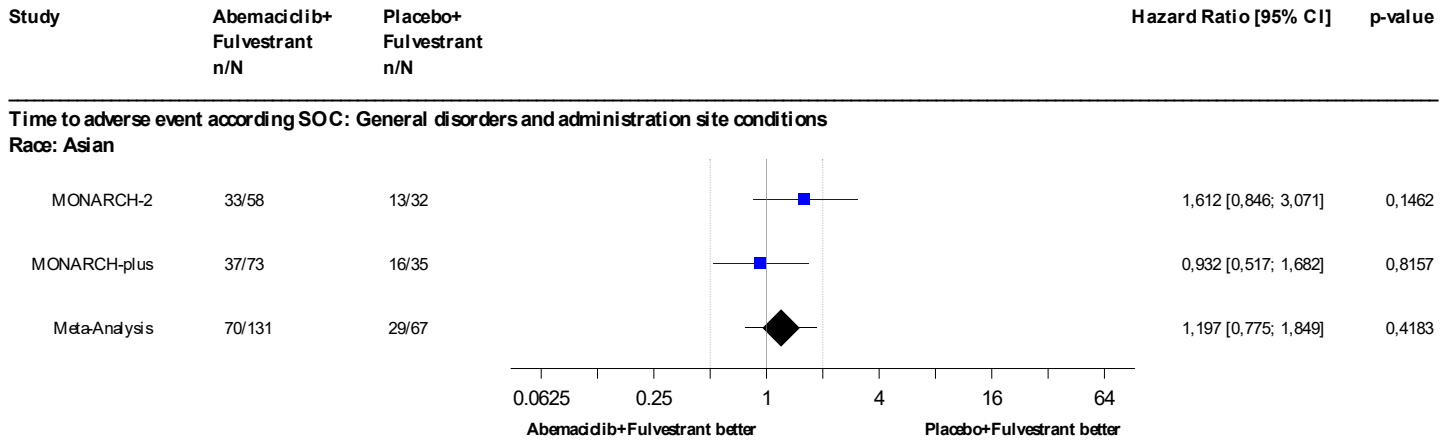
Figure 1256.1.5.1: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,5103, p-value=0,2191, I2 index=33,8%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes006_popa1_racegr1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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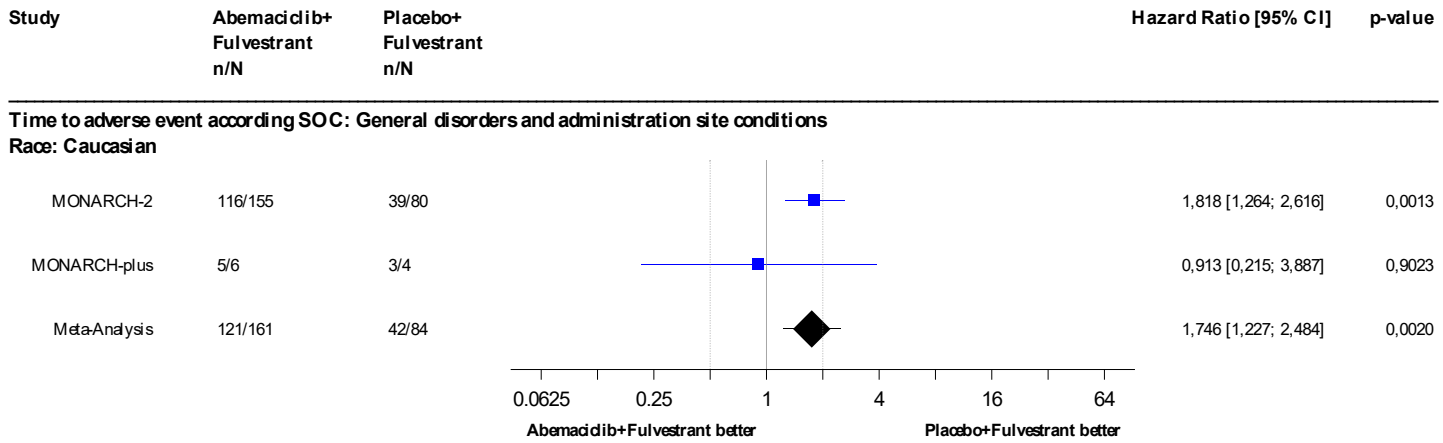
Figure 1256.1.5.2: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,8170, p-value=0,3661, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes006_popa1_racegr1_2.rtf
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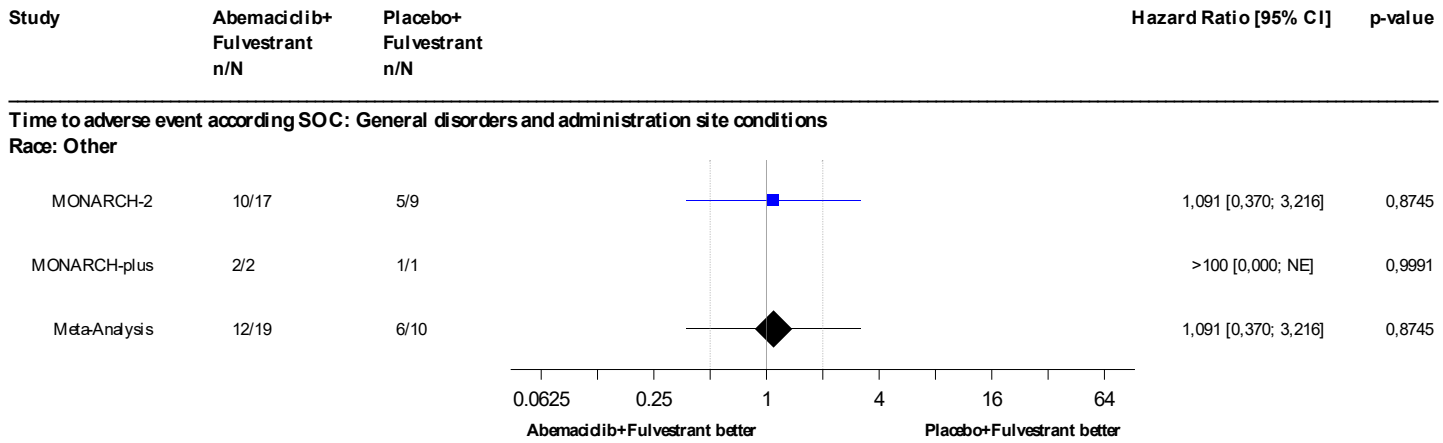
Figure 1256.1.5.3: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9991, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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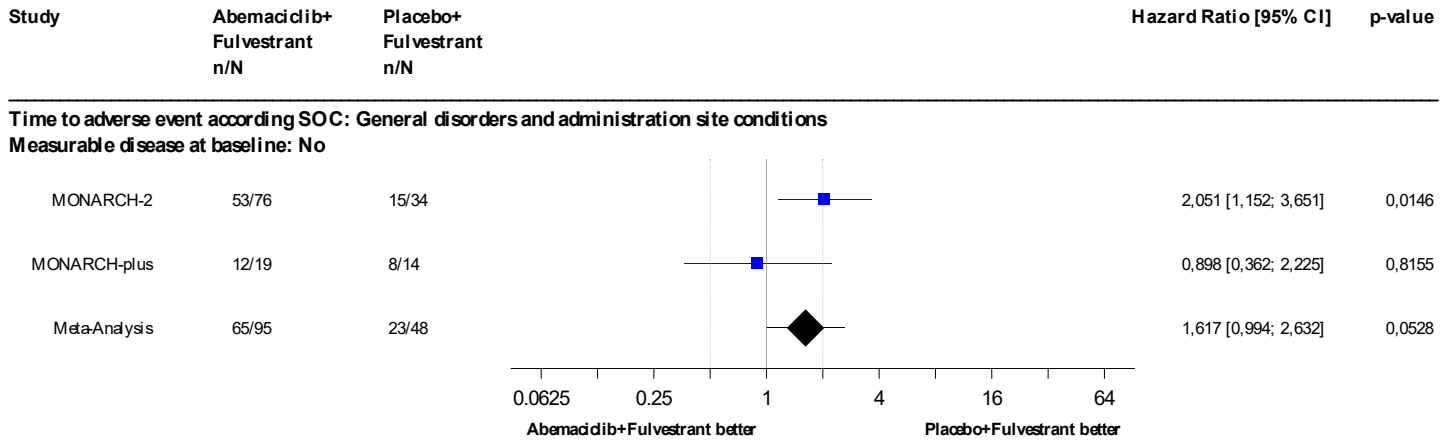
Figure 1256.1.6.1: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,2678, p-value=0,1321, I2 index=55,9%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes006_popa1_measdis_1.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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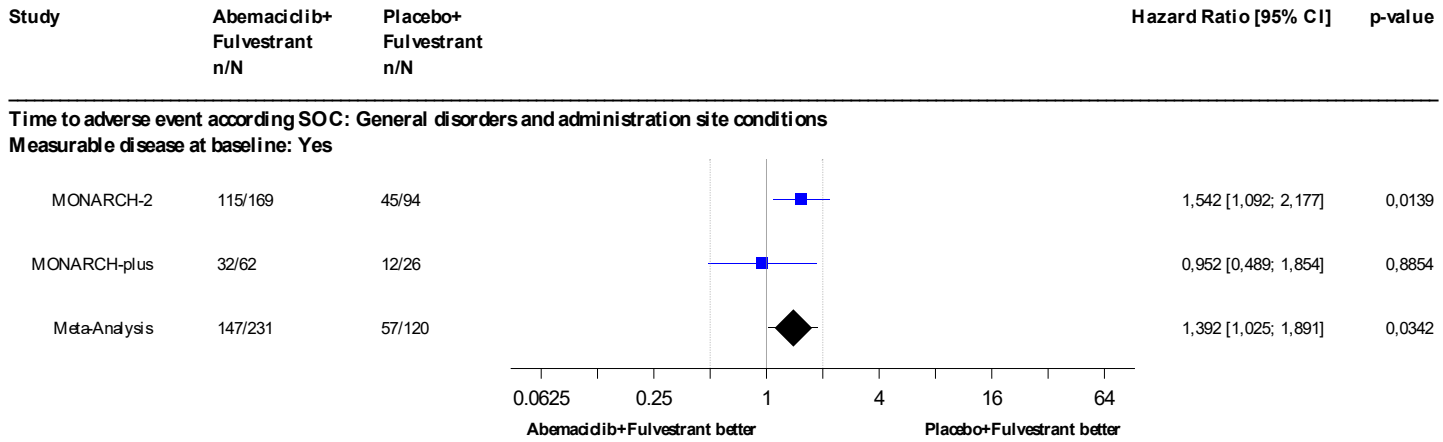
**Figure 1256.1.6.2: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=1,5844, p-value=0,2081, I2 index=36,9%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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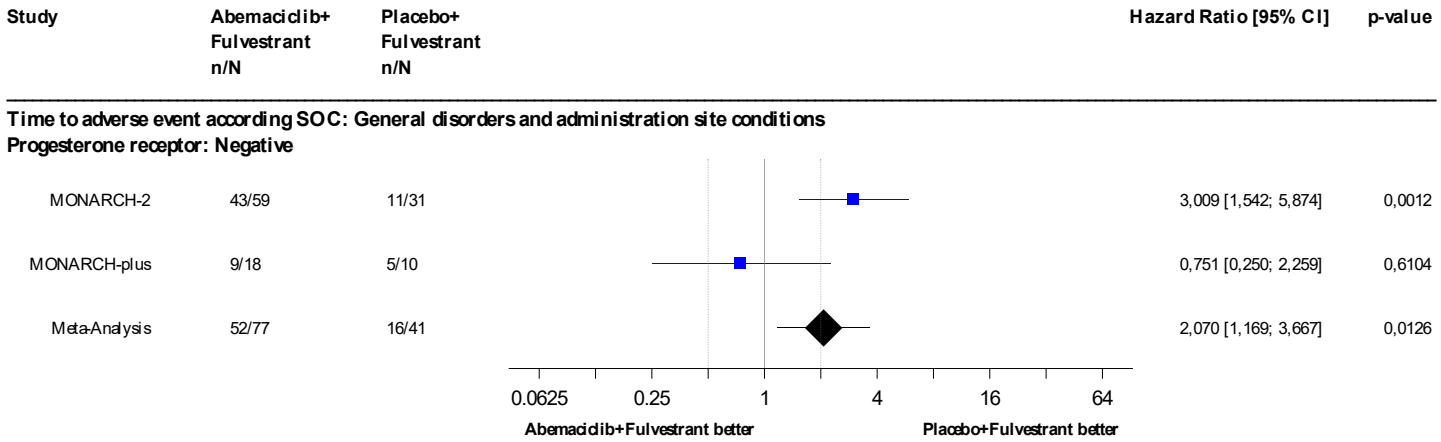
Figure 1256.1.7.1: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=4,4590, p-value=0,0347, I2 index=77,6%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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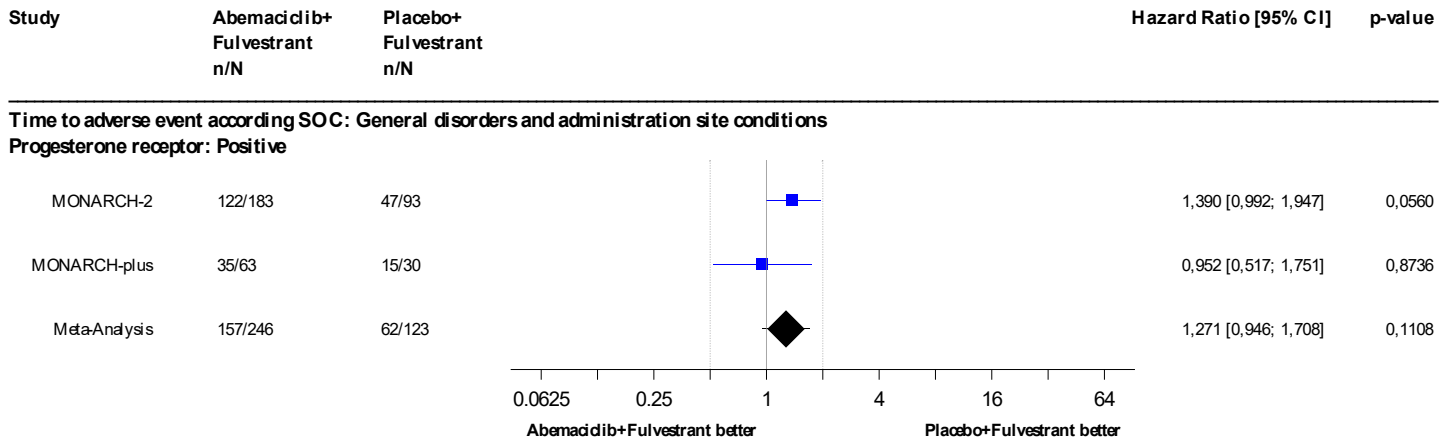
Figure 1256.1.7.2: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,1339, p-value=0,2870, I2 index=11,8%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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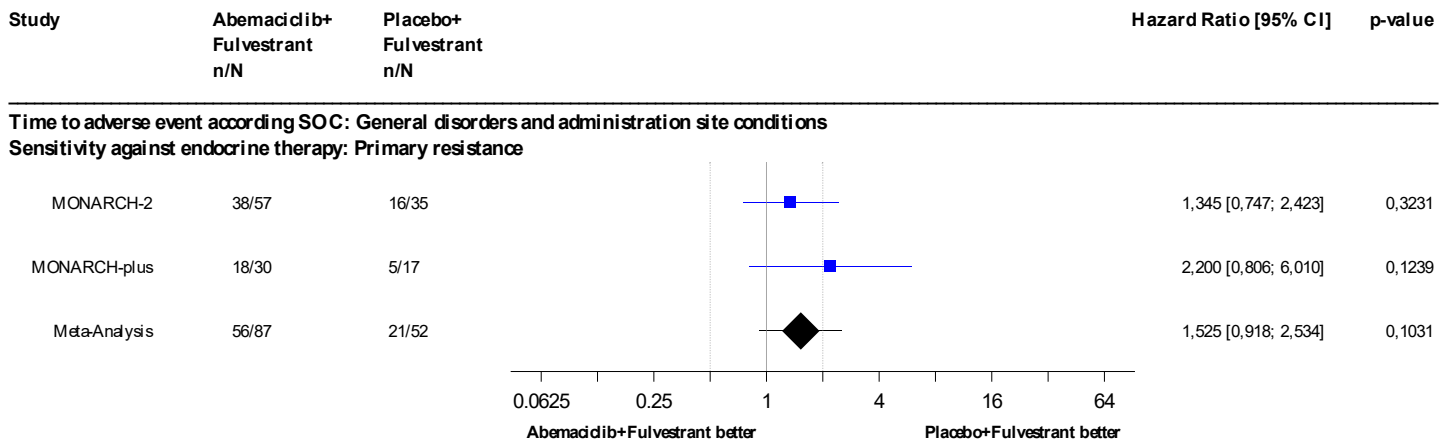
**Figure 1256.1.8.1: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,6861, p-value=0,4075, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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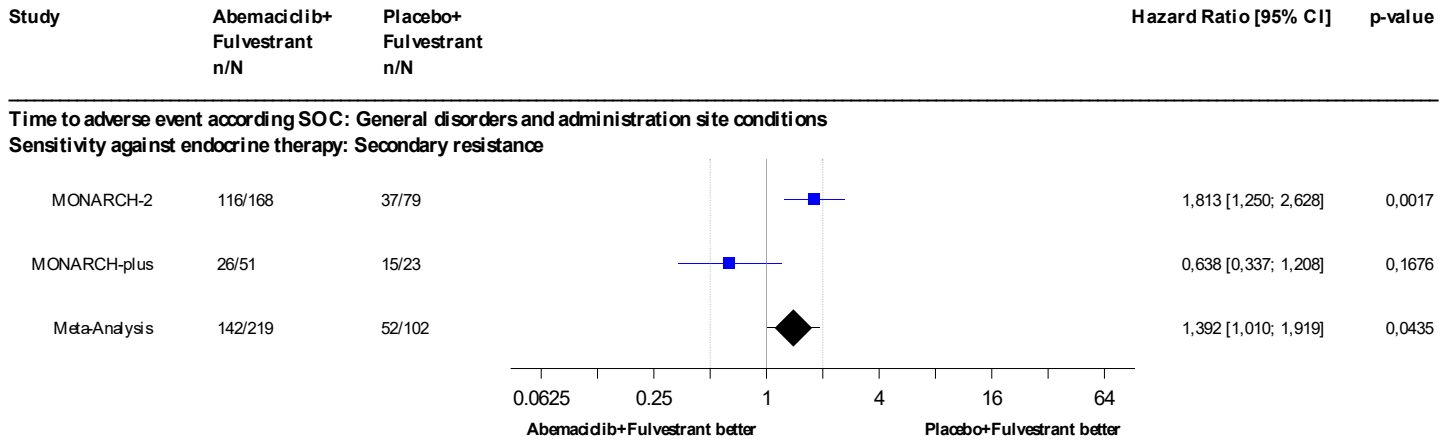
**Figure 1256.1.8.2: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=7,6801, p-value=0,0056, I2 index=87,0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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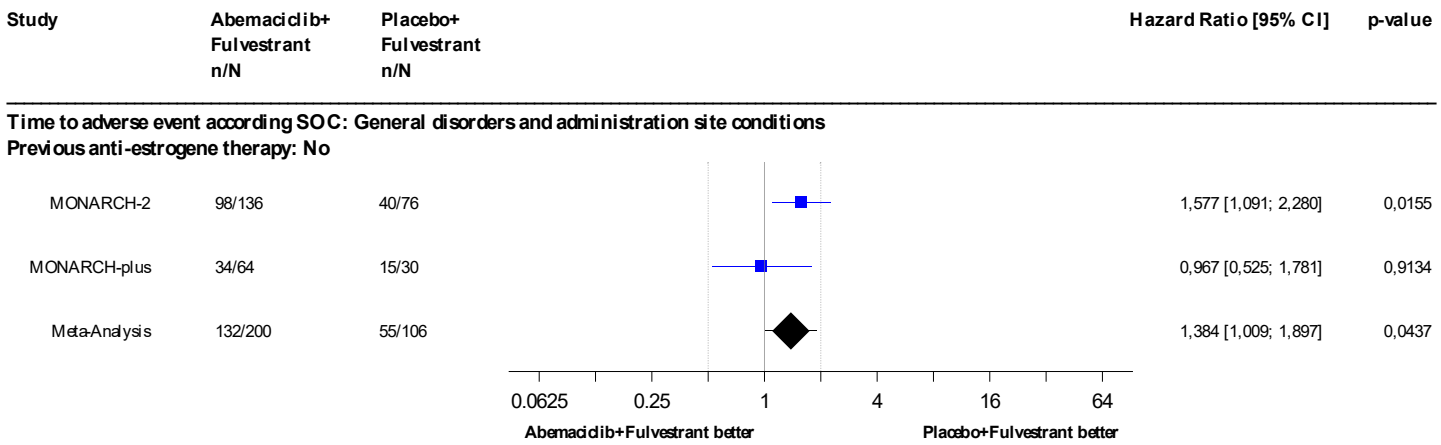
Figure 1256.1.9.1: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,8072, p-value=0,1788, I2 index=44,7%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes006_popa1_paet_1.rtf
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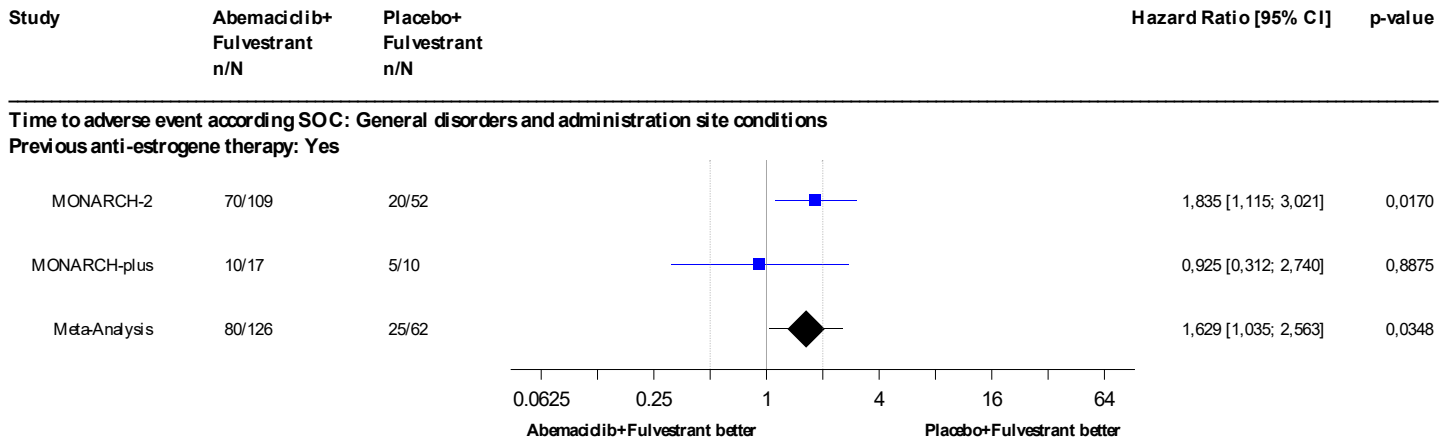
Figure 1256.1.9.2: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,2639, p-value=0,2609, I2 index=20,9%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes006_popa1_paet_2.rtf
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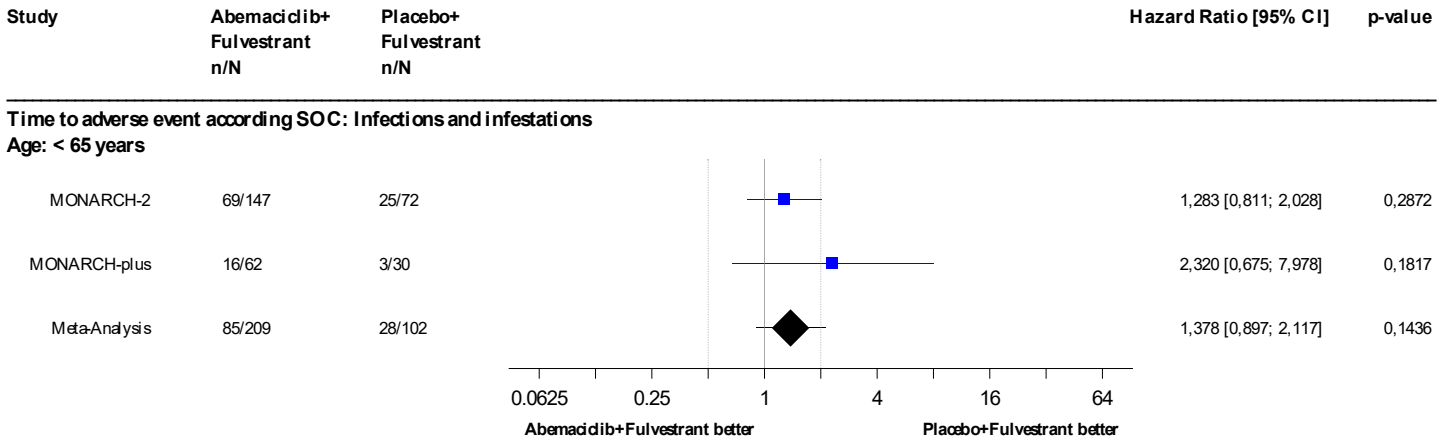
Figure 1259.1.1.1: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,7778, p-value=0,3778, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes009_popa1_agegr1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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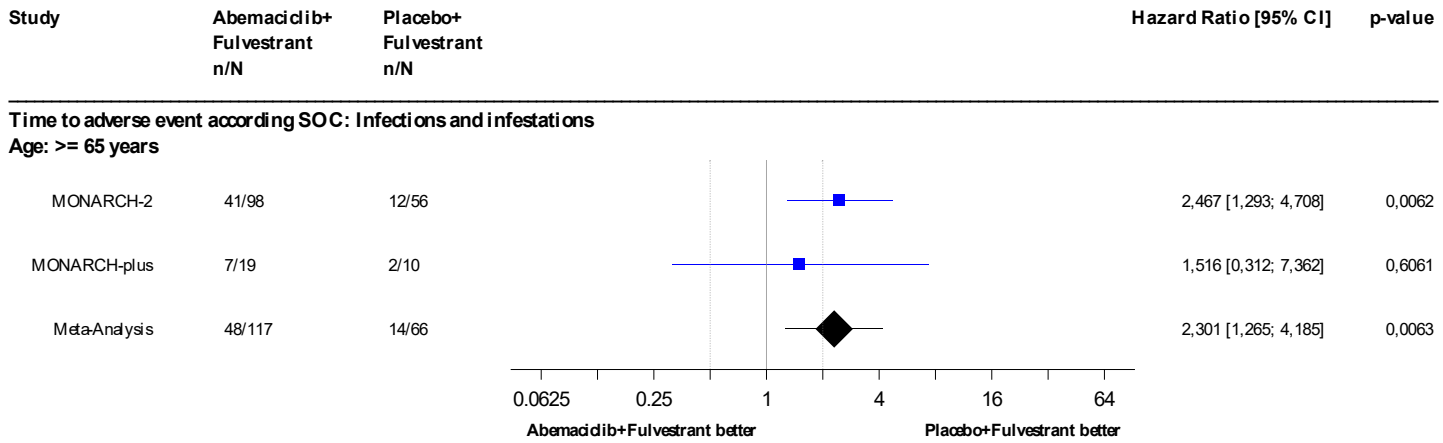
Figure 1259.1.1.2: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3127, p-value=0,5760, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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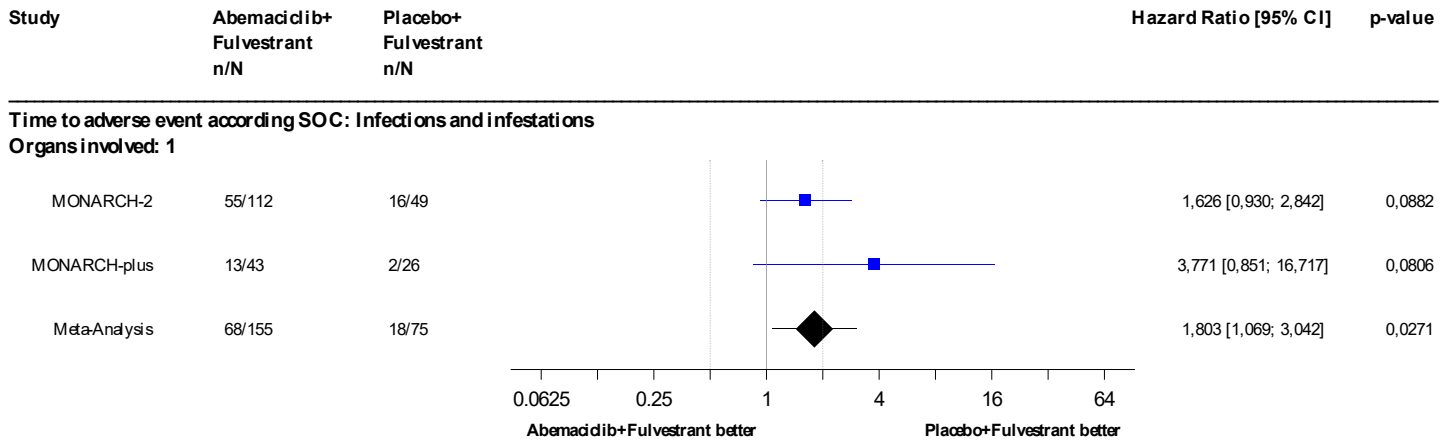
Figure 1259.1.2.1: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,0758, p-value=0,2996, I2 index=7,0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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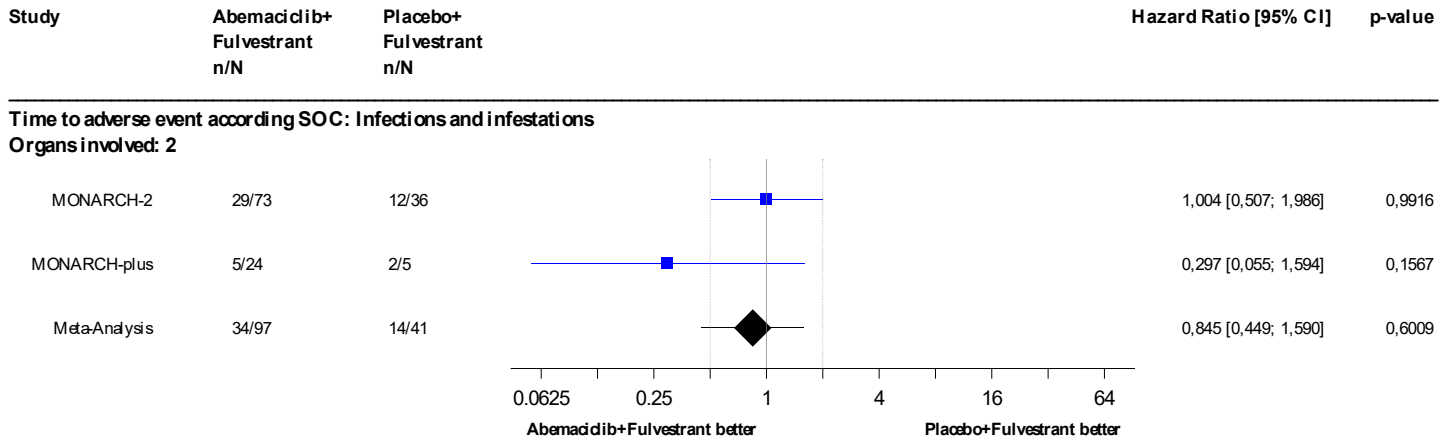
Figure 1259.1.2.2: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,7325, p-value=0,1881, I2 index=42,3%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes009_popa1_norggr_2.rtf
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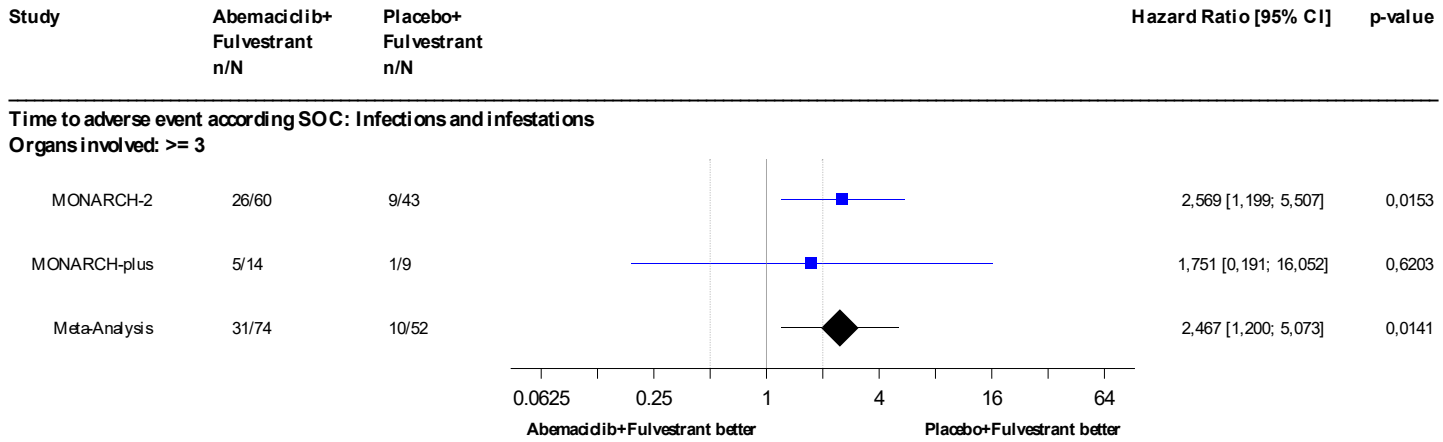
Figure 1259.1.2.3: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1029, p-value=0,7484, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes009_popa1_norggr_3.rtf
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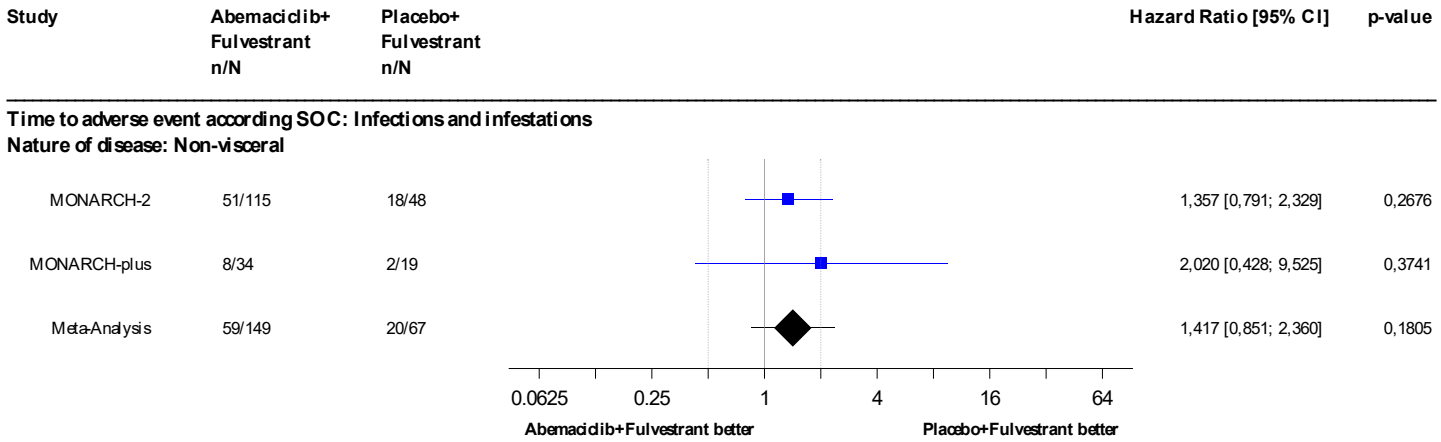
Figure 1259.1.3.1: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2253, p-value=0,6350, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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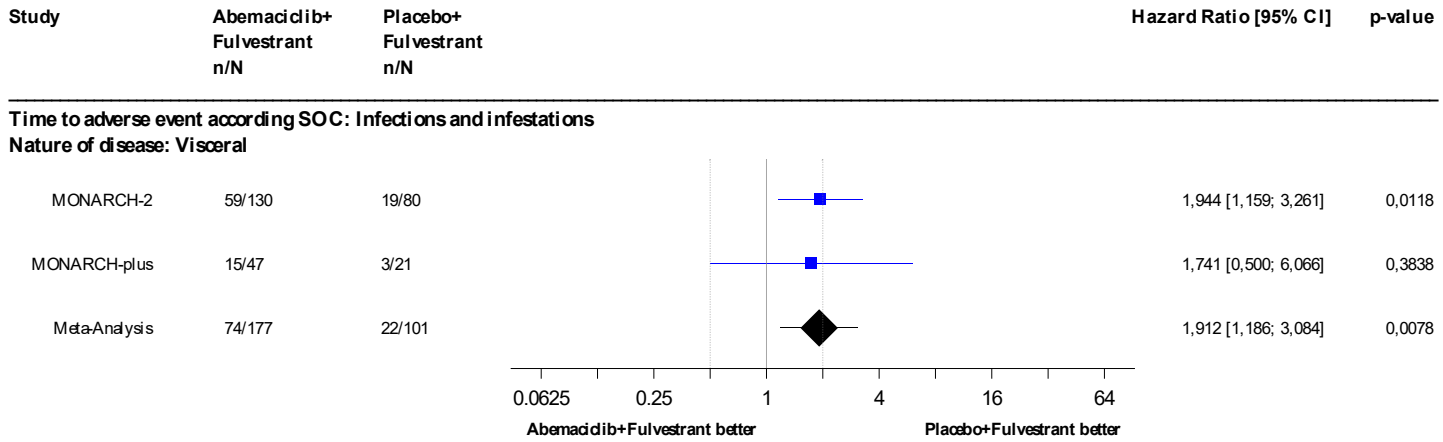
Figure 1259.1.3.2: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0255, p-value=0,8732, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes009_popa1_natdis2_2.rtf
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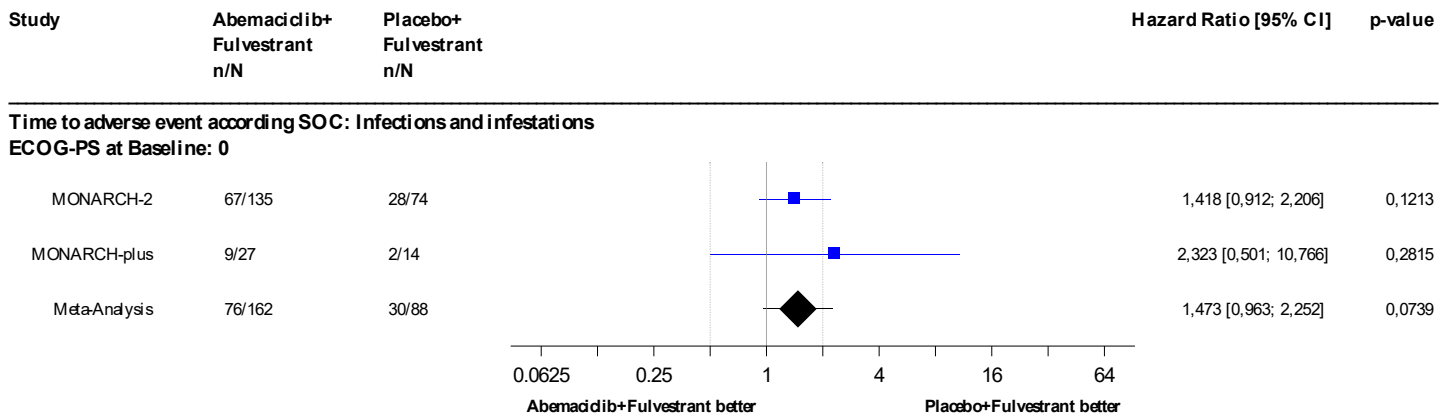
Figure 1259.1.4.1: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3672, p-value=0,5445, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes009_popa1_ecogbl_1.rtf
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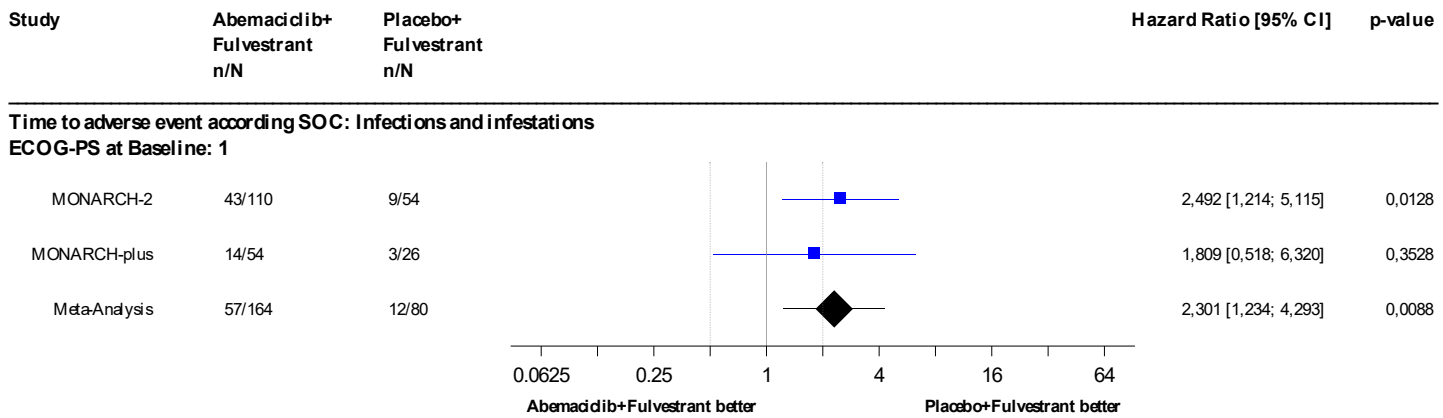
Figure 1259.1.4.2: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1890, p-value=0,6637, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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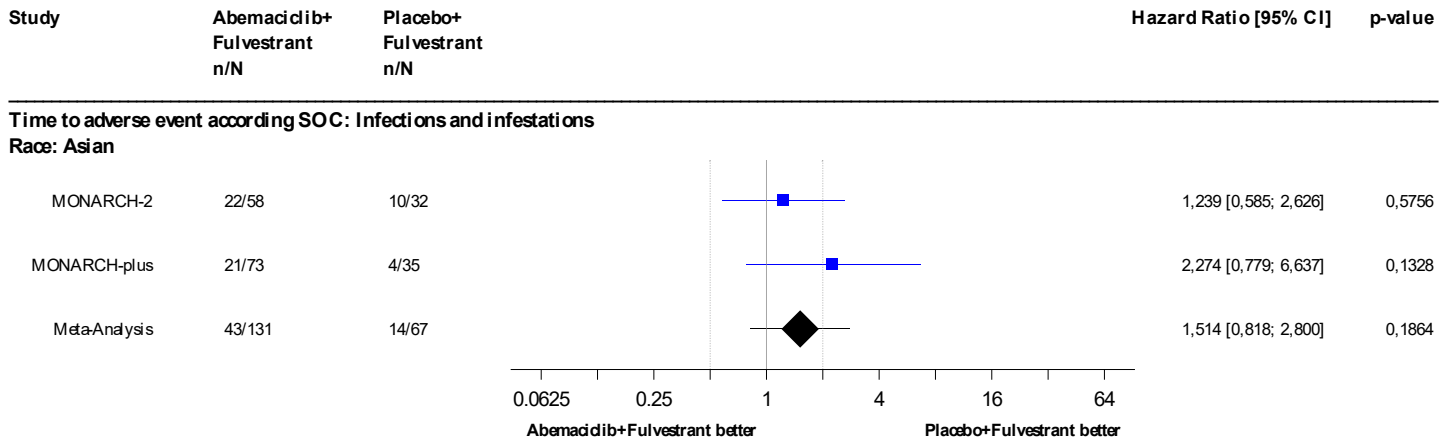
Figure 1259.1.5.1: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,8271, p-value=0,3631, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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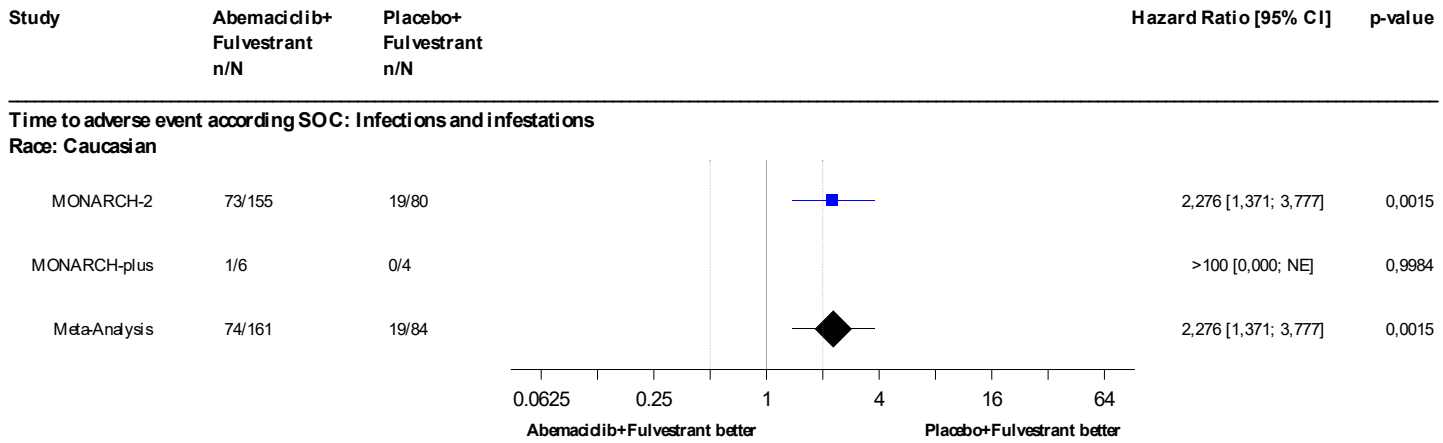
Figure 1259.1.5.2: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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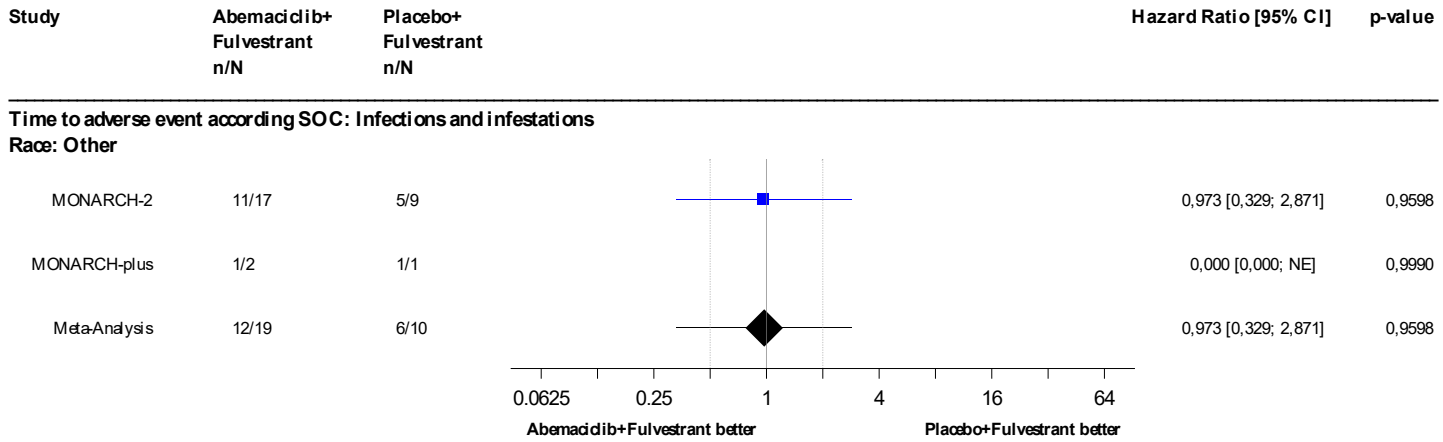
Figure 1259.1.5.3: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9990, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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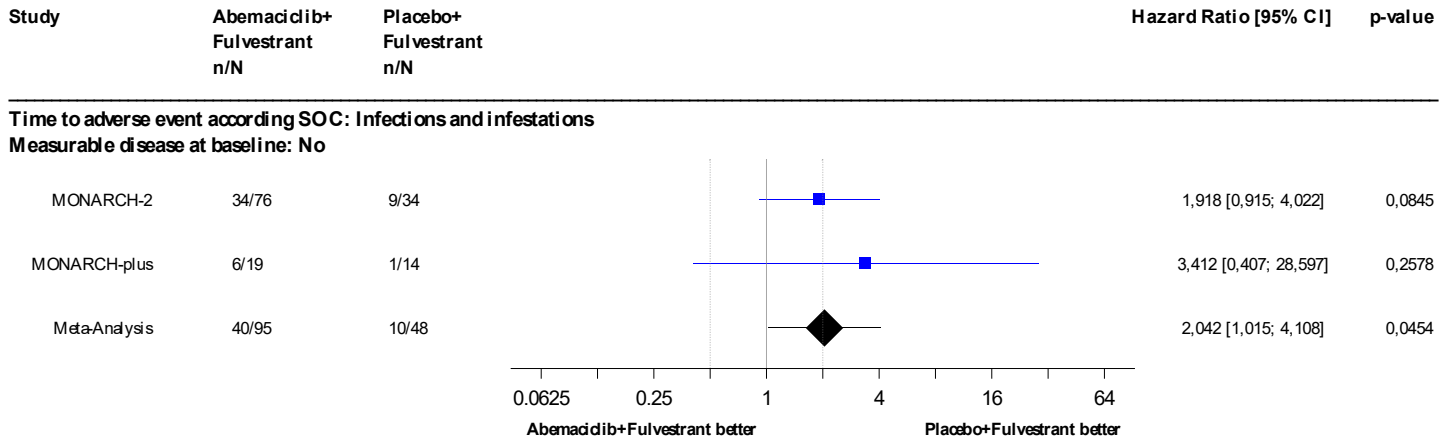
Figure 1259.1.6.1: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2514, p-value=0,6161, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes009_popa1_measdis_1.rtf
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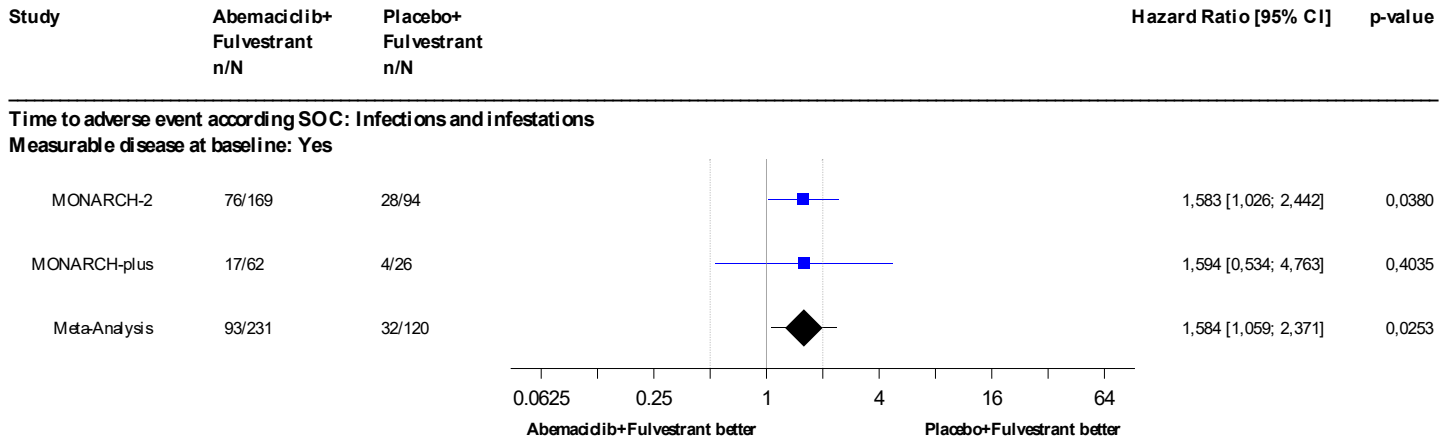
Figure 1259.1.6.2: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0002, p-value=0,9900, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes009_popa1_measdis_2.rtf
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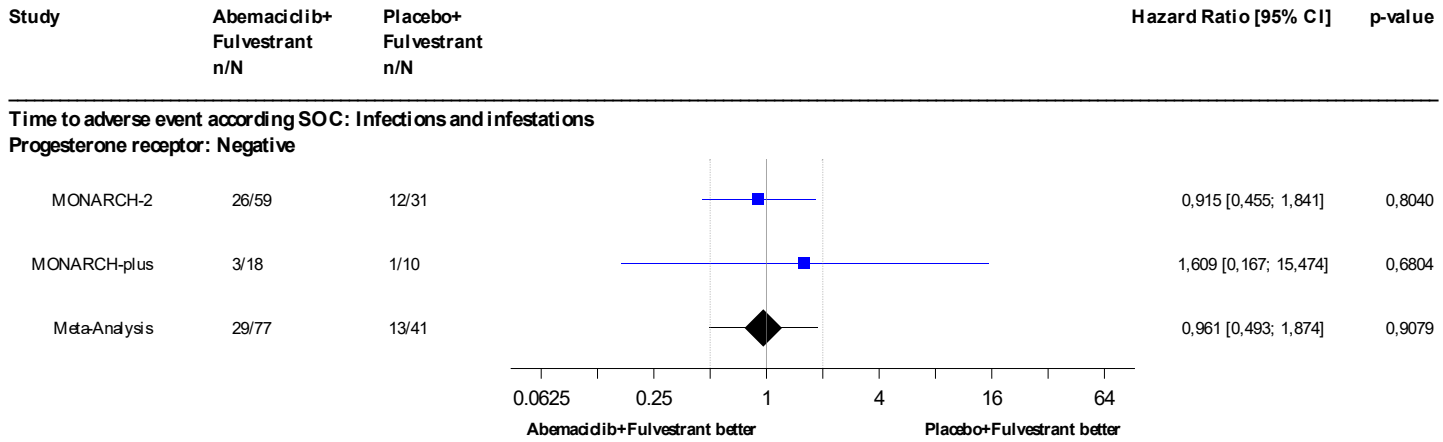
Figure 1259.1.7.1: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2179, p-value=0,6406, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes009_popa1_pgrstat_1.rtf
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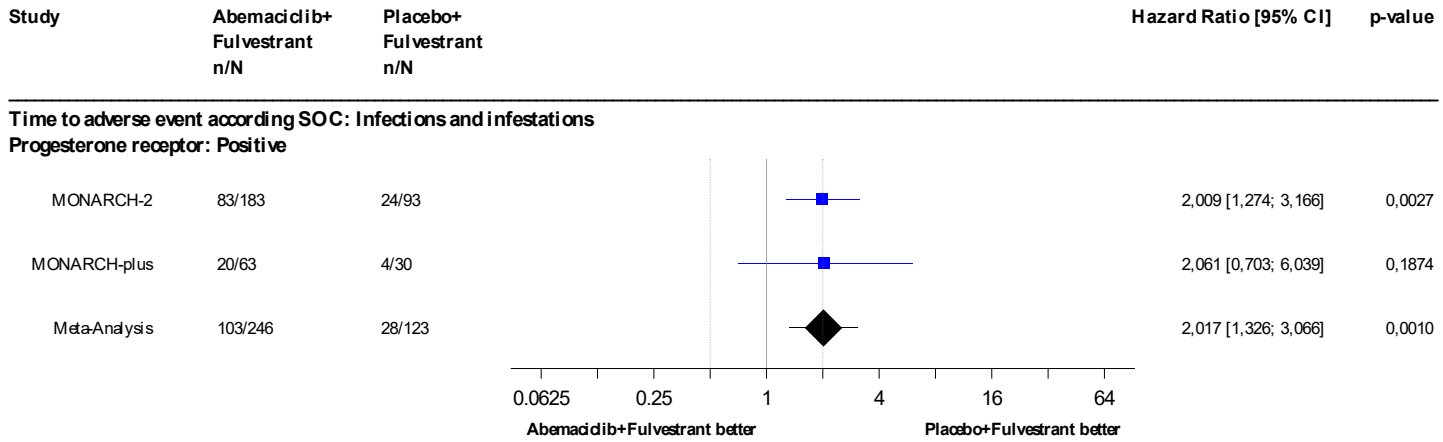
Figure 1259.1.7.2: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0018, p-value=0,9657, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes009_popa1_pgrstat_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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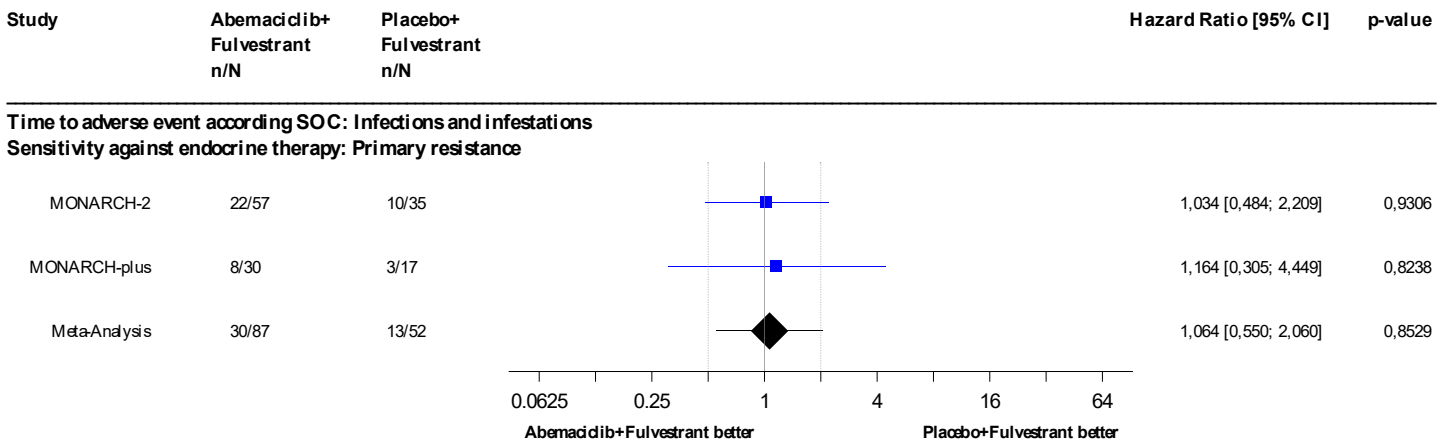
Figure 1259.1.8.1: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0228, p-value=0,8801, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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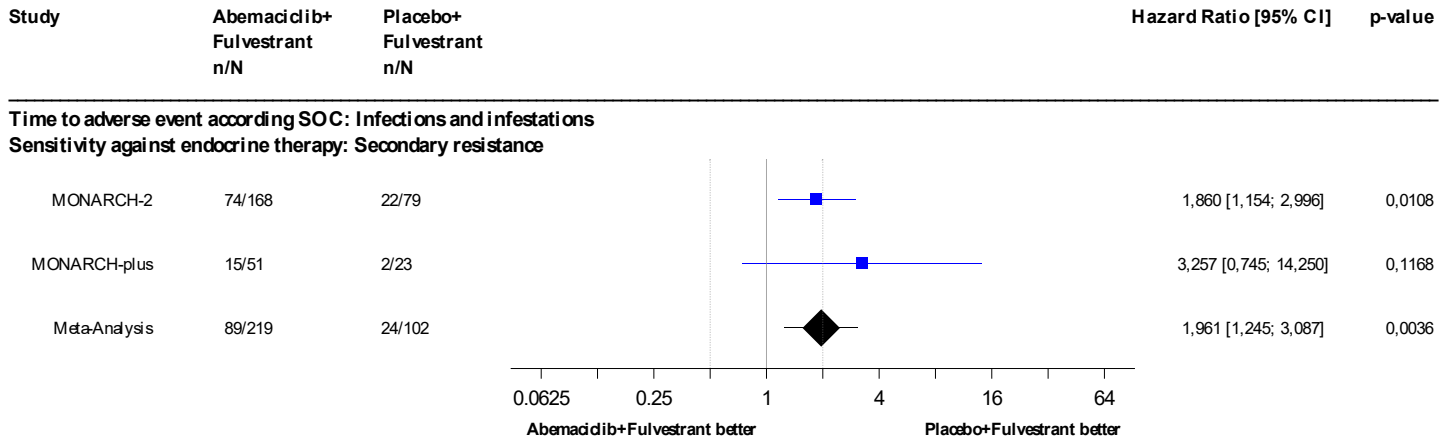
**Figure 1259.1.8.2: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,5017, p-value=0,4788, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes009_popa1_snthr_2.rtf
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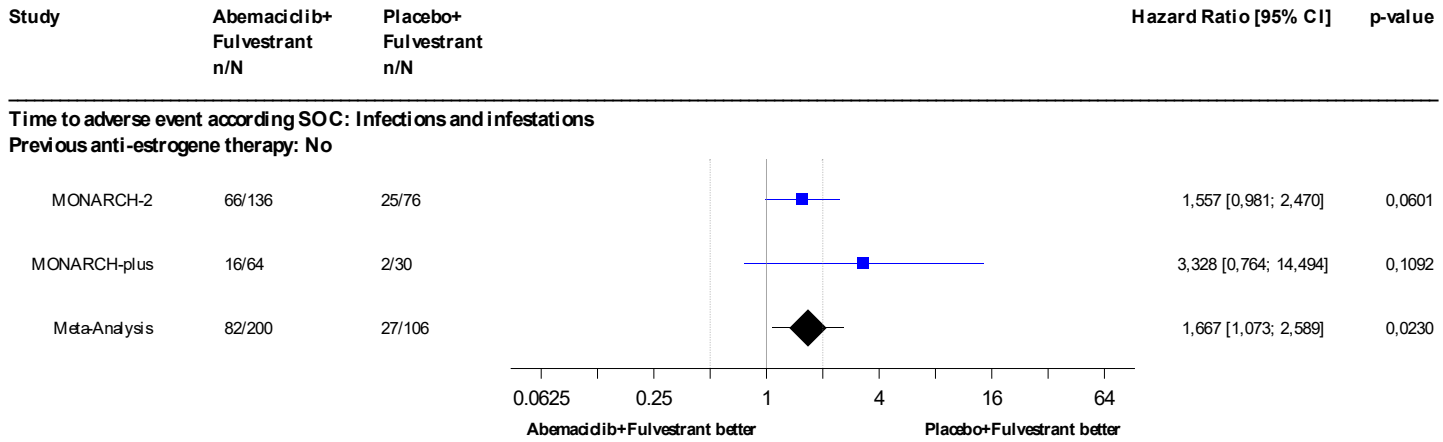
Figure 1259.1.9.1: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,9322, p-value=0,3343, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes009_popa1_paet_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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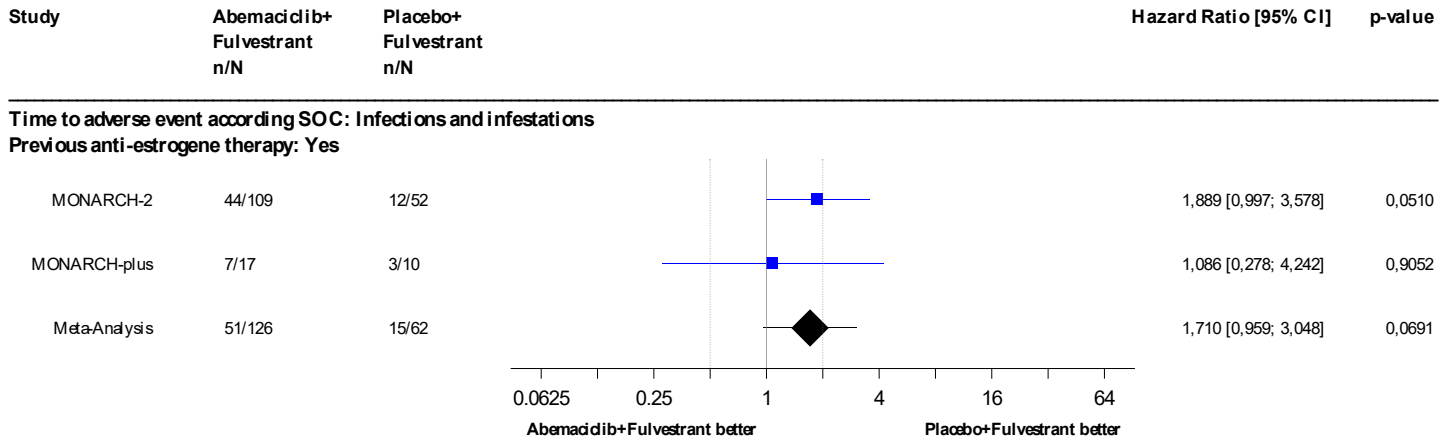
Figure 1259.1.9.2: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5193, p-value=0,4712, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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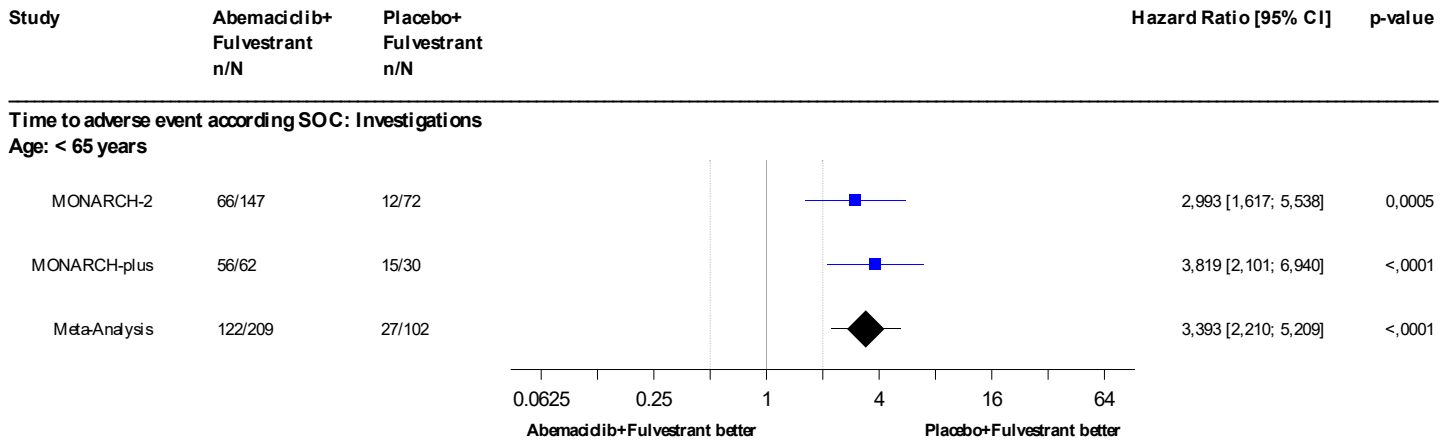
Figure 1261.1.1.1: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3101, p-value=0,5776, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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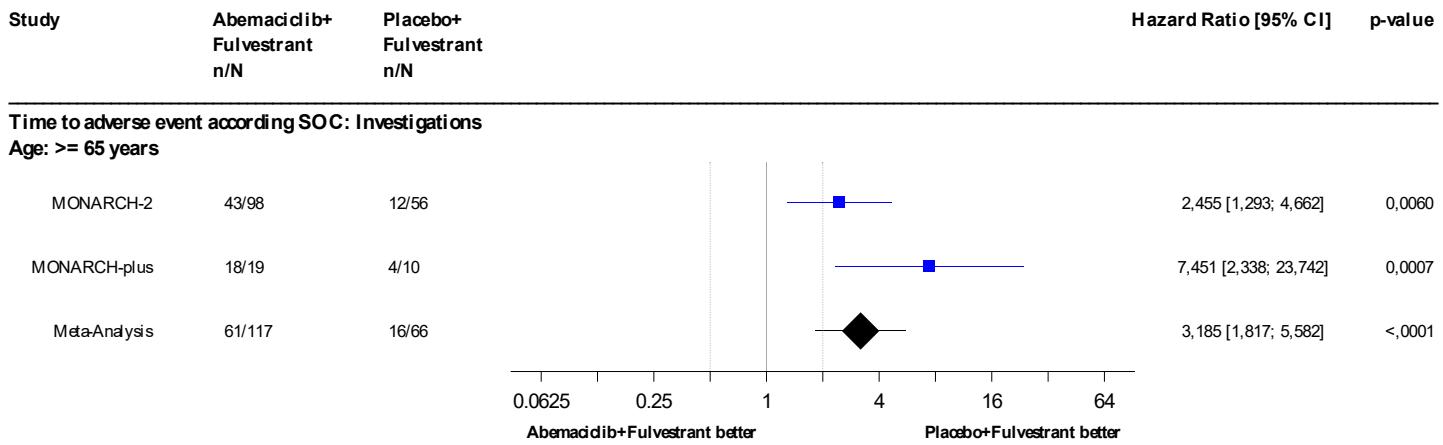
Figure 1261.1.1.2: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,6991, p-value=0,1004, I2 index=63,0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes011_popa1_agegr1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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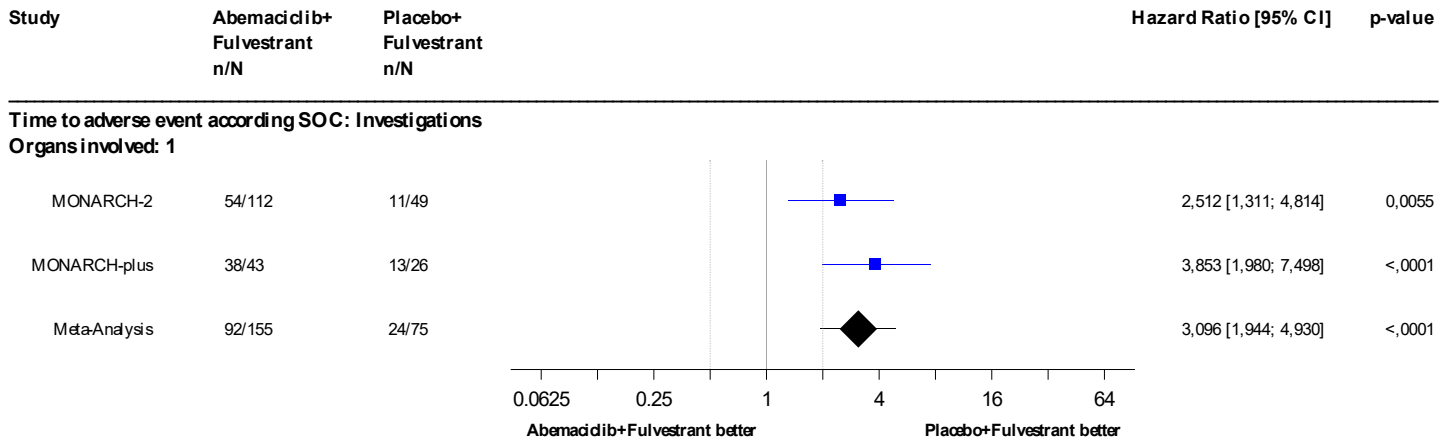
Figure 1261.1.2.1: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,8114, p-value=0,3677, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes011_popa1_norggr_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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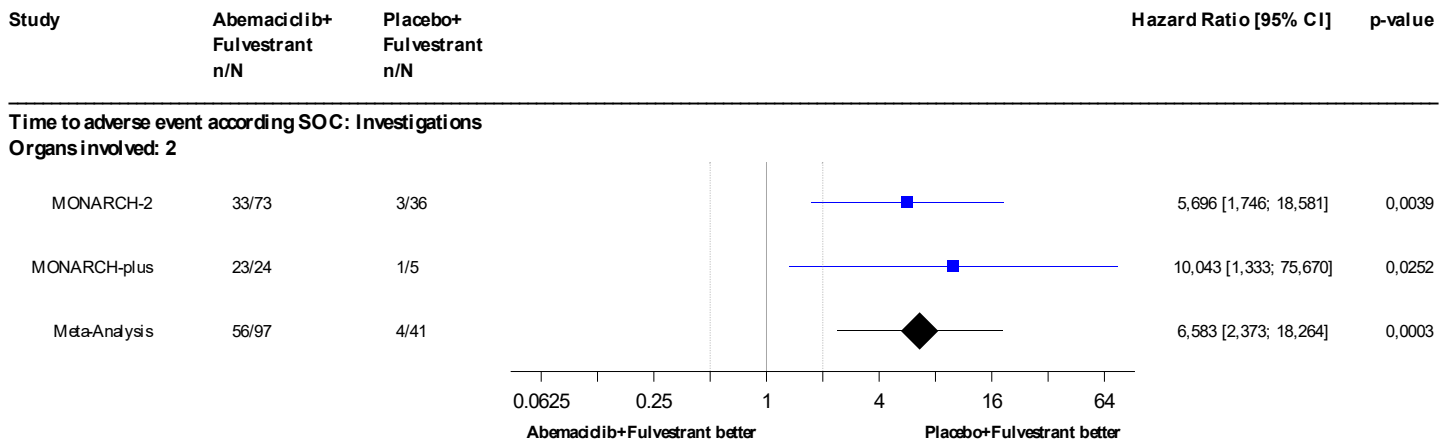
Figure 1261.1.2.2: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2256, p-value=0,6348, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes011_popa1_norggr_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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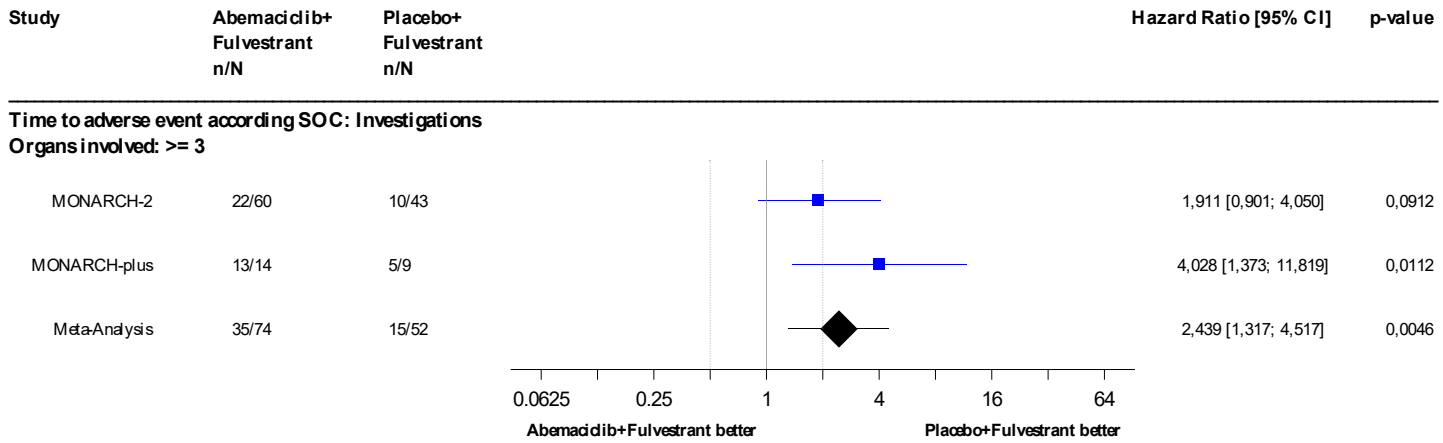
Figure 1261.1.2.3: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,2399, p-value=0,2655, I2 index=19,4%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes011_popa1_norggr_3.rtf
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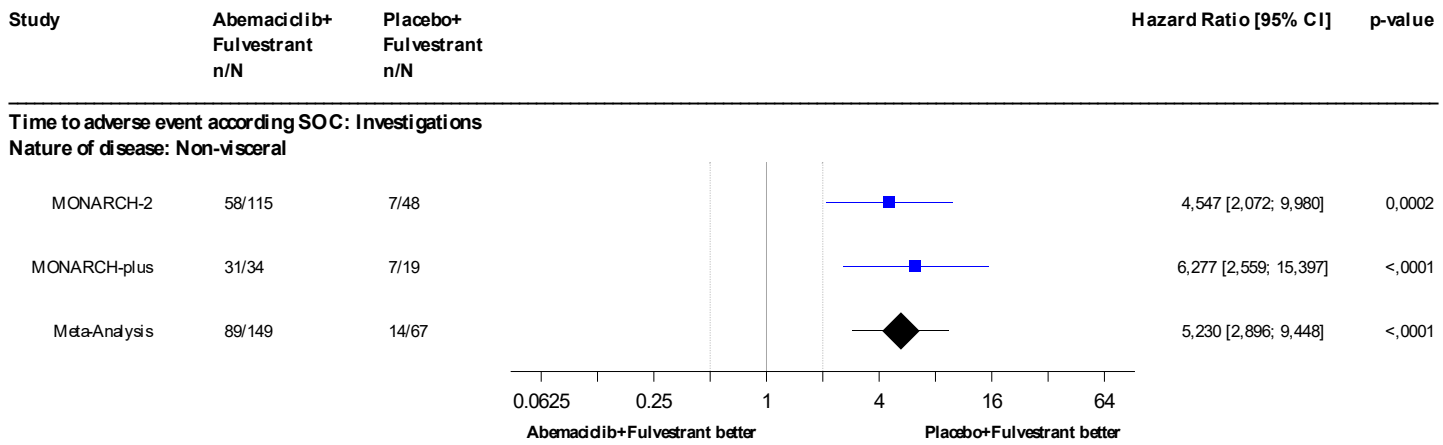
Figure 1261.1.3.1: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2804, p-value=0,5964, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes011_popa1_natdis2_1.rtf
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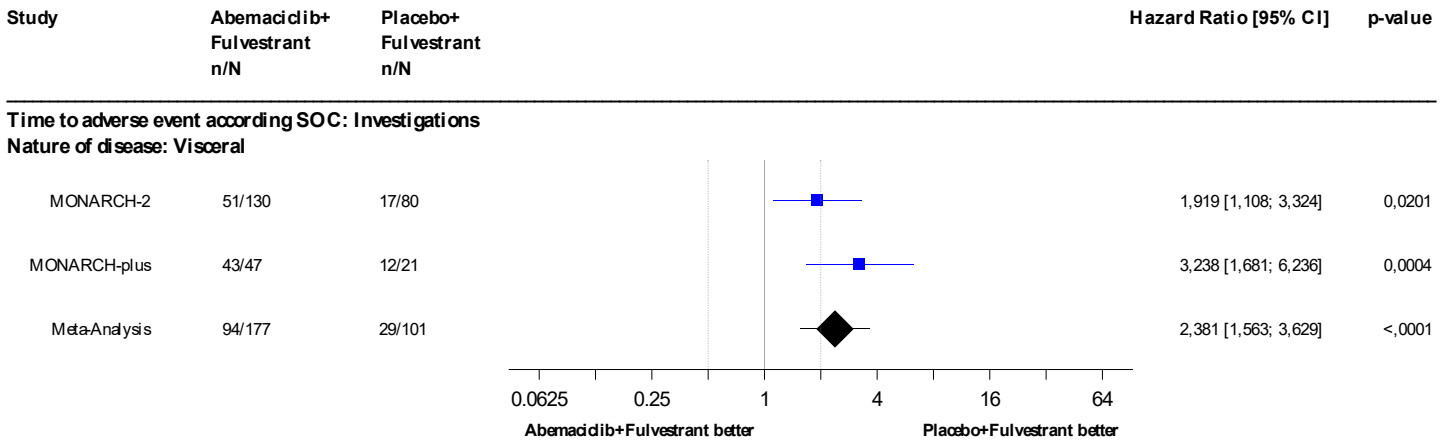
Figure 1261.1.3.2: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,4370, p-value=0,2306, I2 index=30,4%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes011_popa1_natdis2_2.rtf
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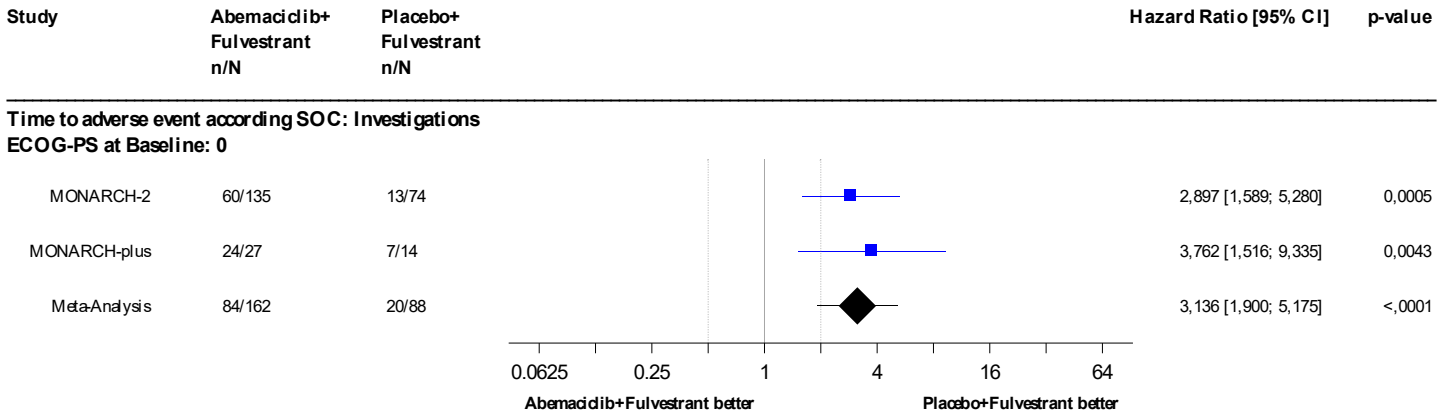
Figure 1261.1.4.1: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2213, p-value=0,6381, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes011_popa1_ecogbl_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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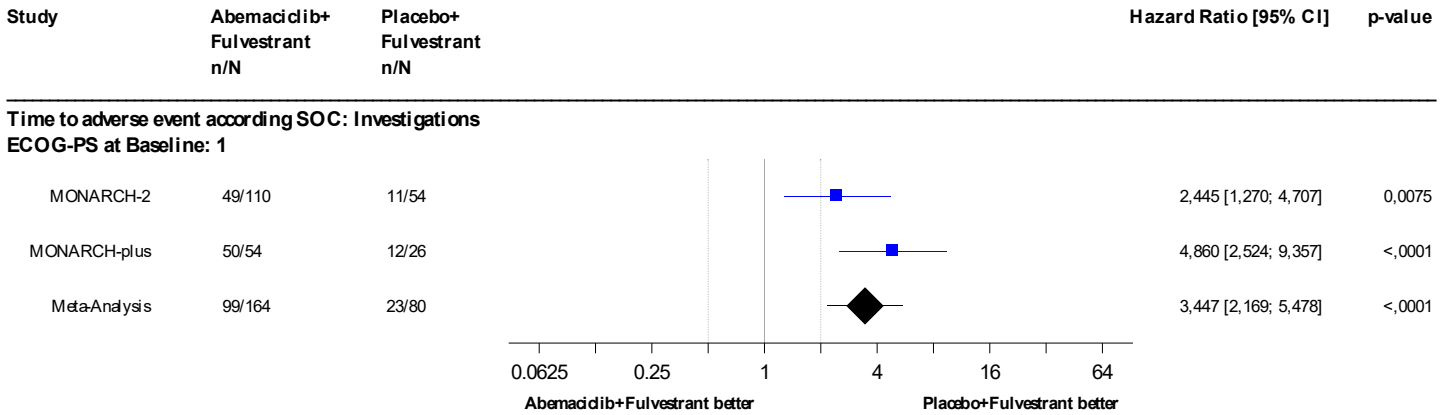
Figure 1261.1.4.2: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,1130, p-value=0,1460, I2 index=52,7%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes011_popa1_ecogbl_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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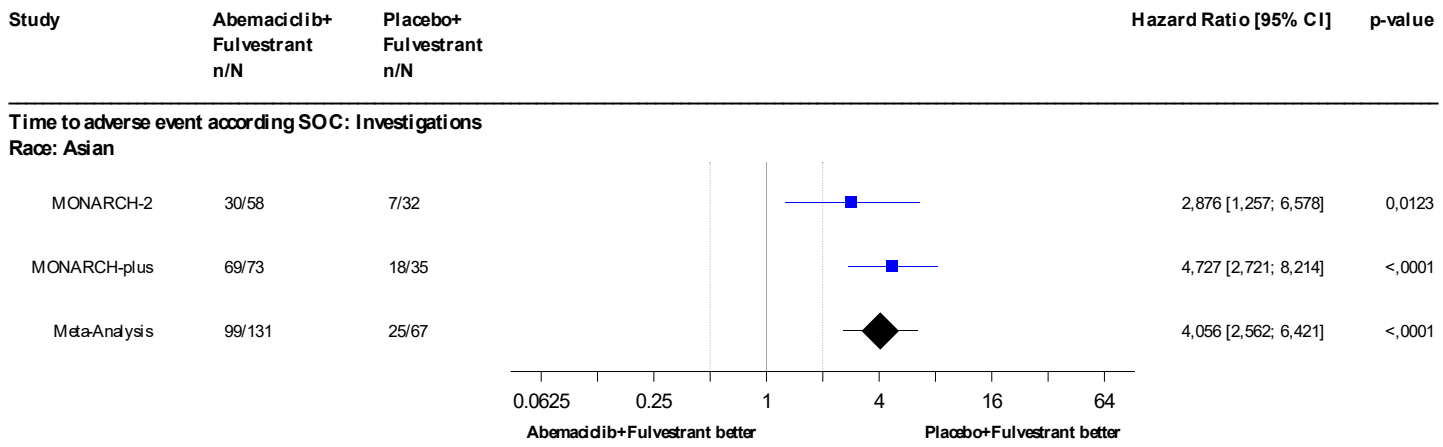
Figure 1261.1.5.1: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,9587, p-value=0,3275, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes011_popa1_racegr1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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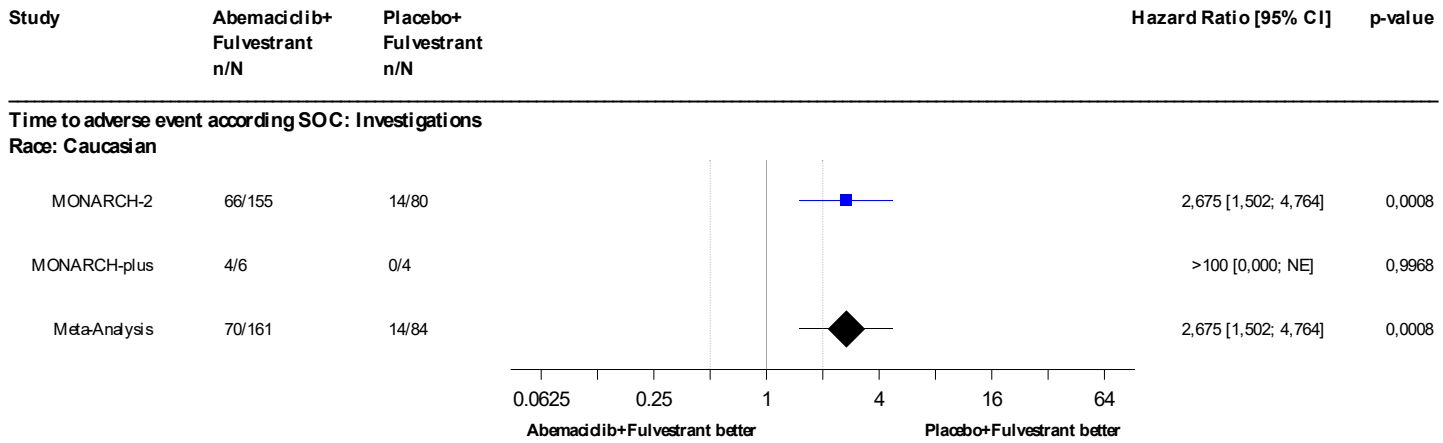
Figure 1261.1.5.2: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9970, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes011_popa1_racegr1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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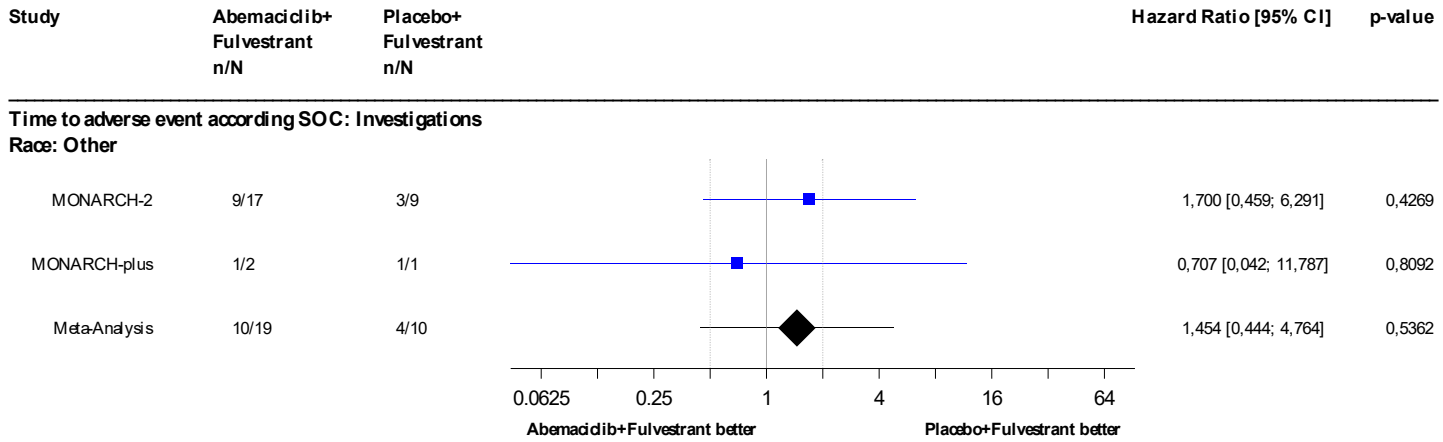
Figure 1261.1.5.3: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3069, p-value=0,5796, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes011_popa1_racegr1_3.rtf
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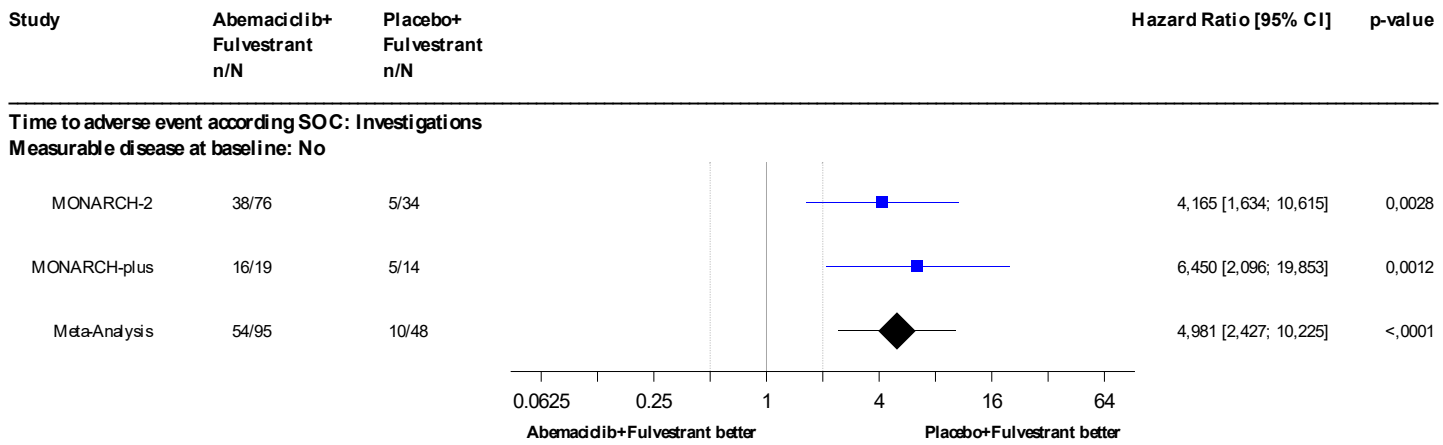
Figure 1261.1.6.1: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3437, p-value=0,5577, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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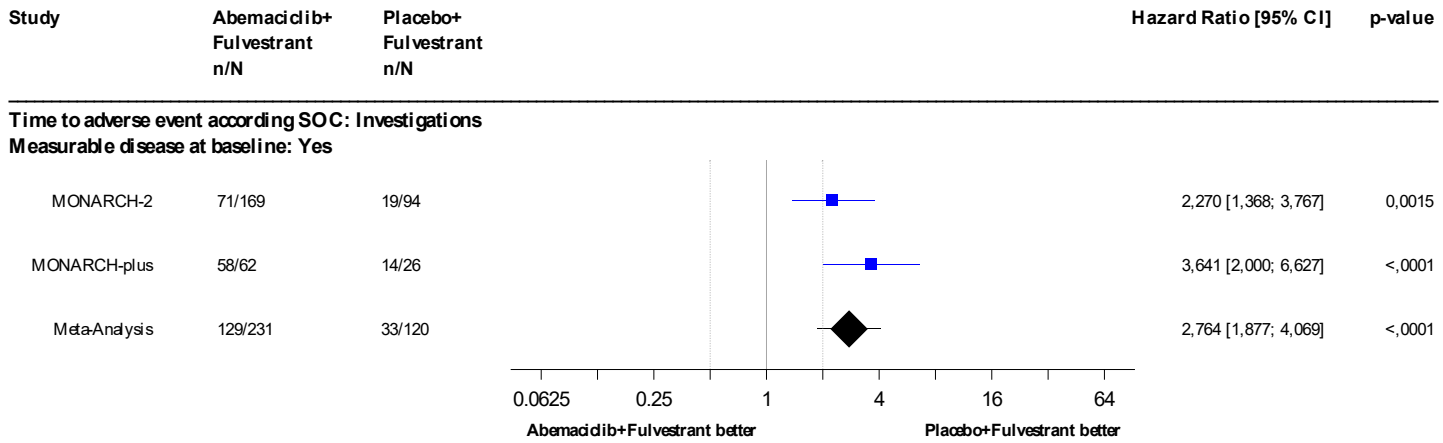
Figure 1261.1.6.2: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,3939, p-value=0,2377, I2 index=28,3%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes011_popa1_measdis_2.rtf
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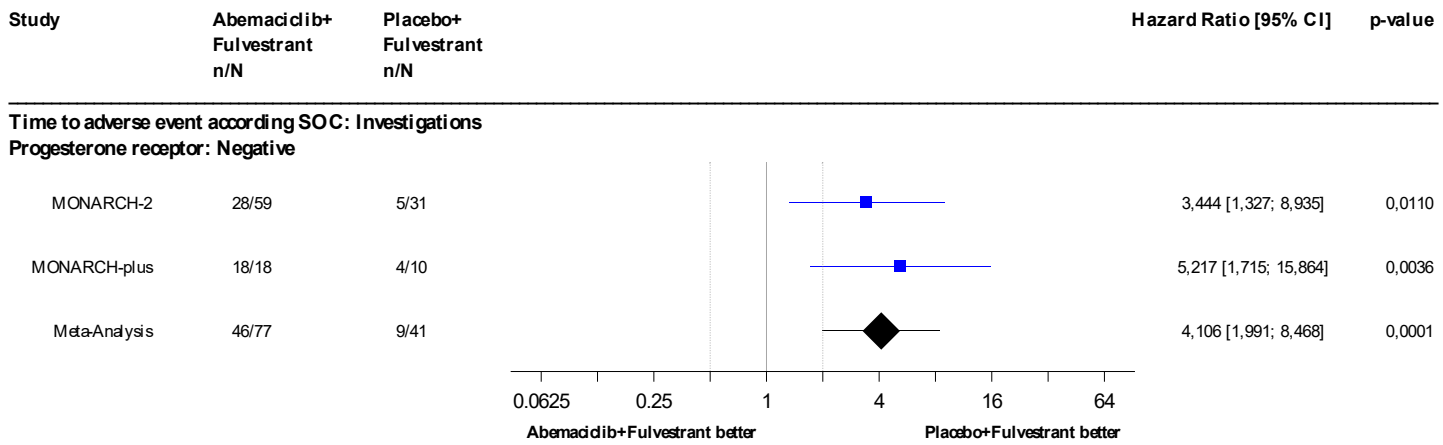
Figure 1261.1.7.1: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3089, p-value=0,5784, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes011_popa1_pgrstat_1.rtf
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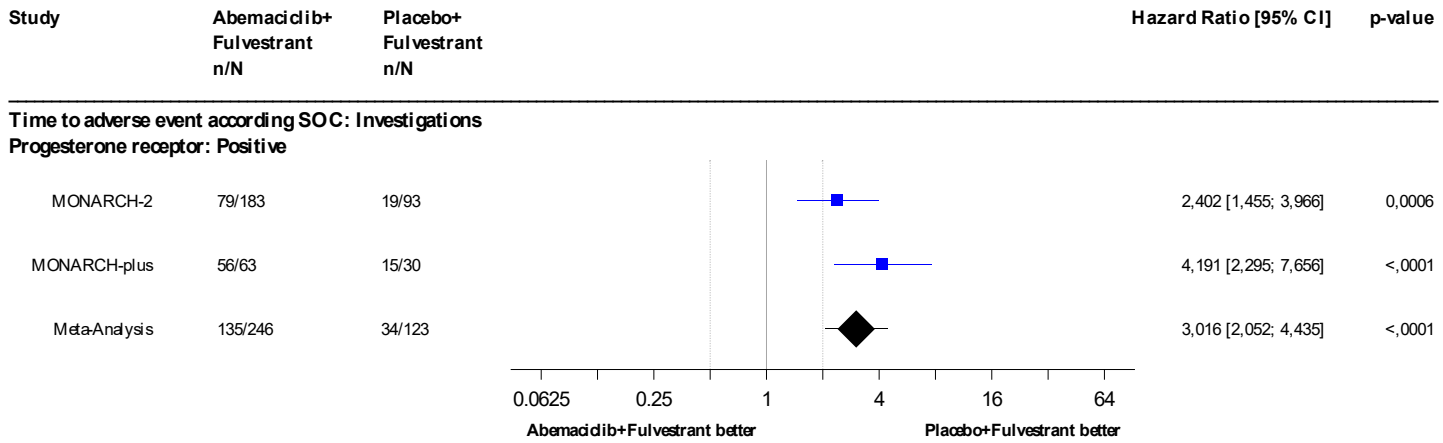
Figure 1261.1.7.2: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,9383, p-value=0,1639, I2 index=48,4%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes011_popa1_pgrstat_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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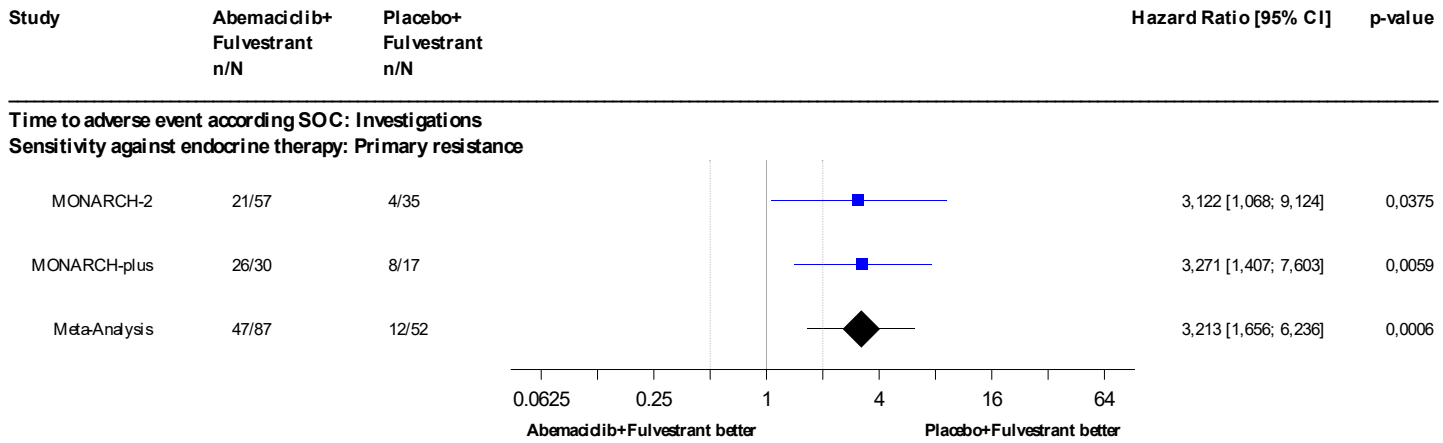
Figure 1261.1.8.1: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0045, p-value=0,9465, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes011_popa1_snthr_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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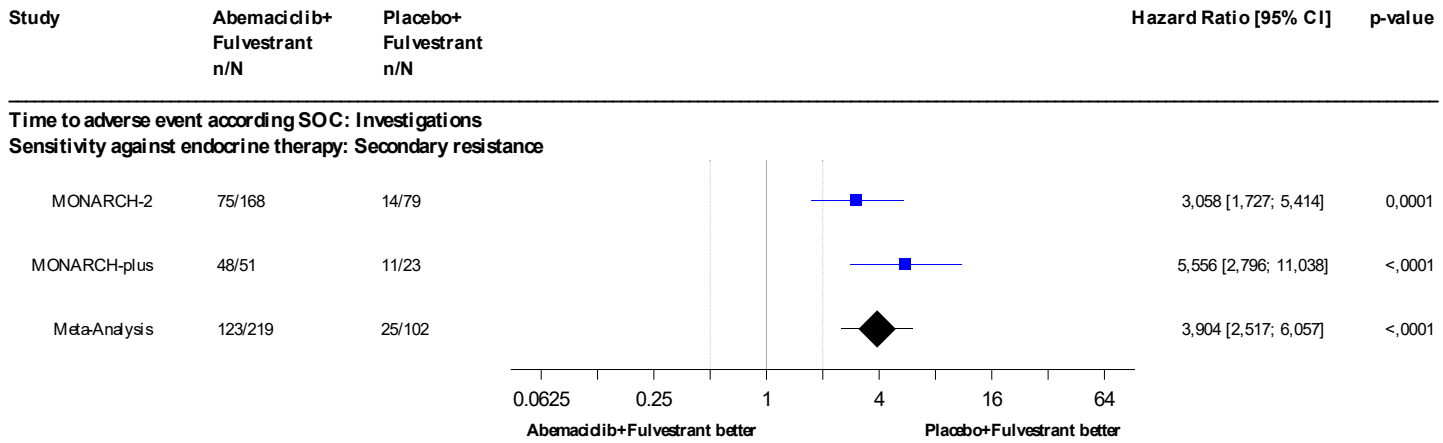
Figure 1261.1.8.2: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,7174, p-value=0,1900, I2 index=41,8%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes011_popa1_snthr_2.rtf
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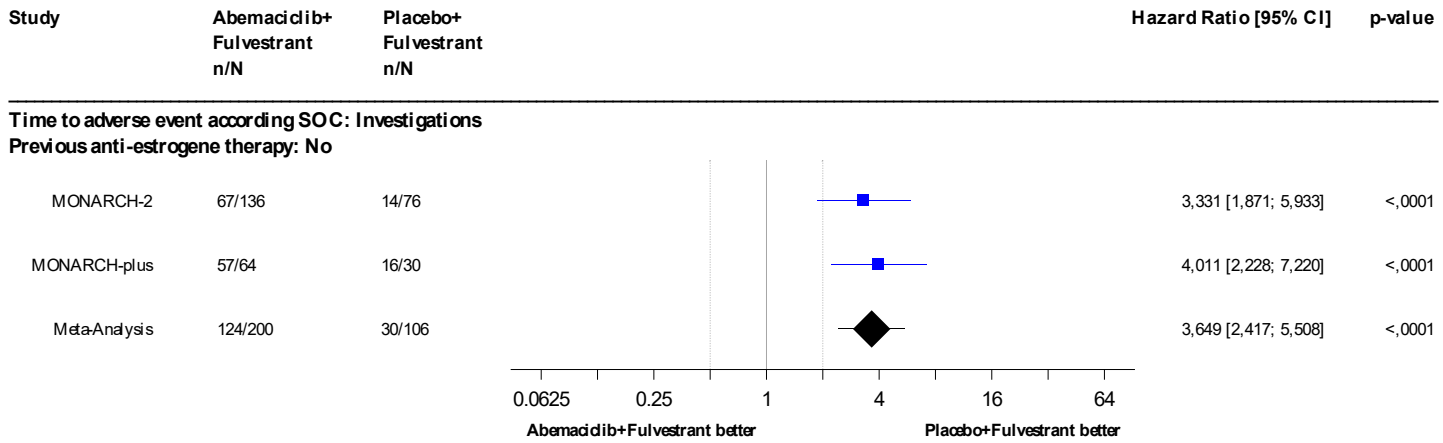
Figure 1261.1.9.1: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1951, p-value=0,6587, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes011_popa1_paet_1.rtf
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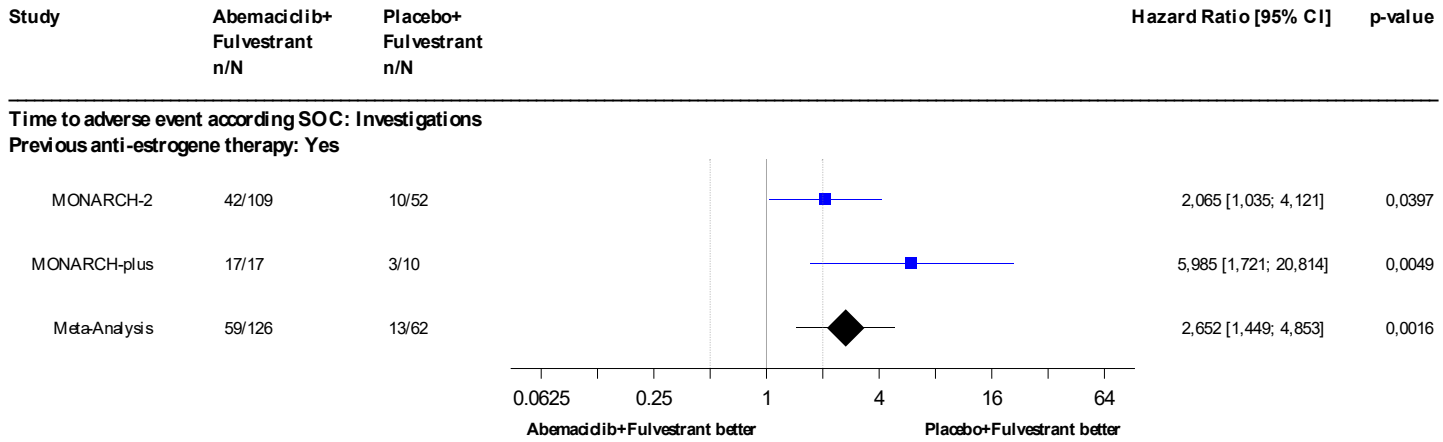
Figure 1261.1.9.2: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,1423, p-value=0,1433, I2 index=53,3%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes011_popa1_paet_2.rtf
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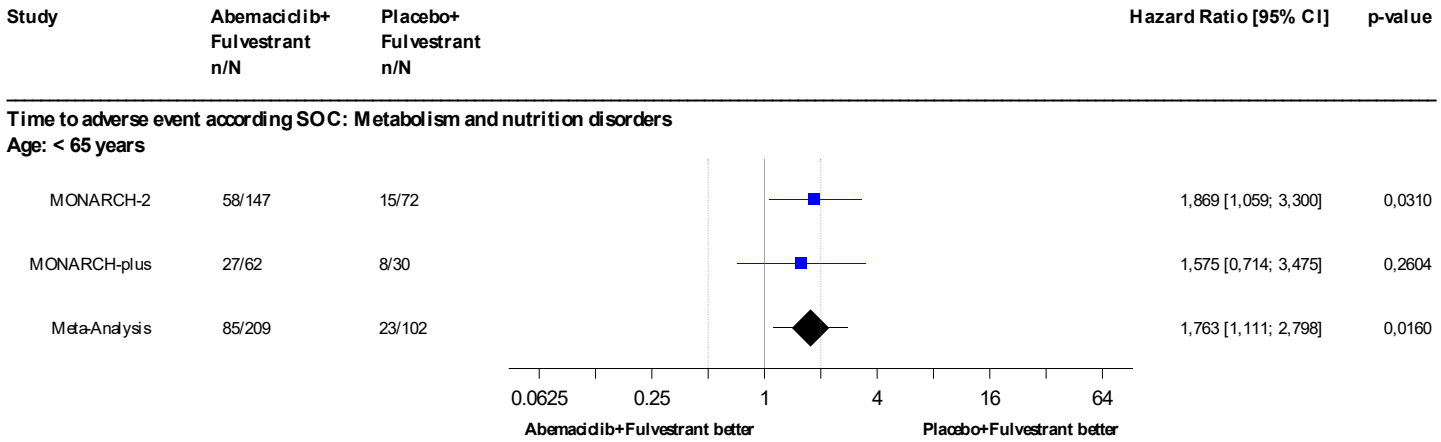
Figure 1262.1.1.1: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1187, p-value=0,7305, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes012_popa1_agegr1_1.rtf
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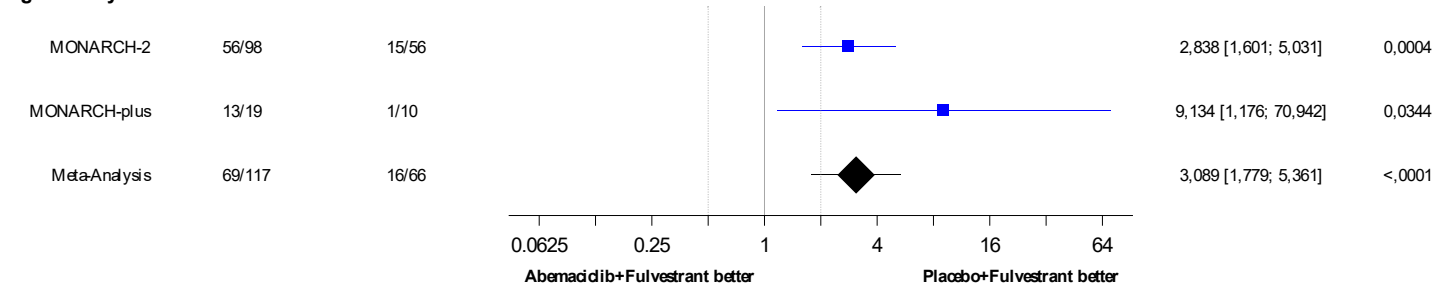
Figure 1262.1.1.2: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,1586, p-value=0,2818, I2 index=13,7%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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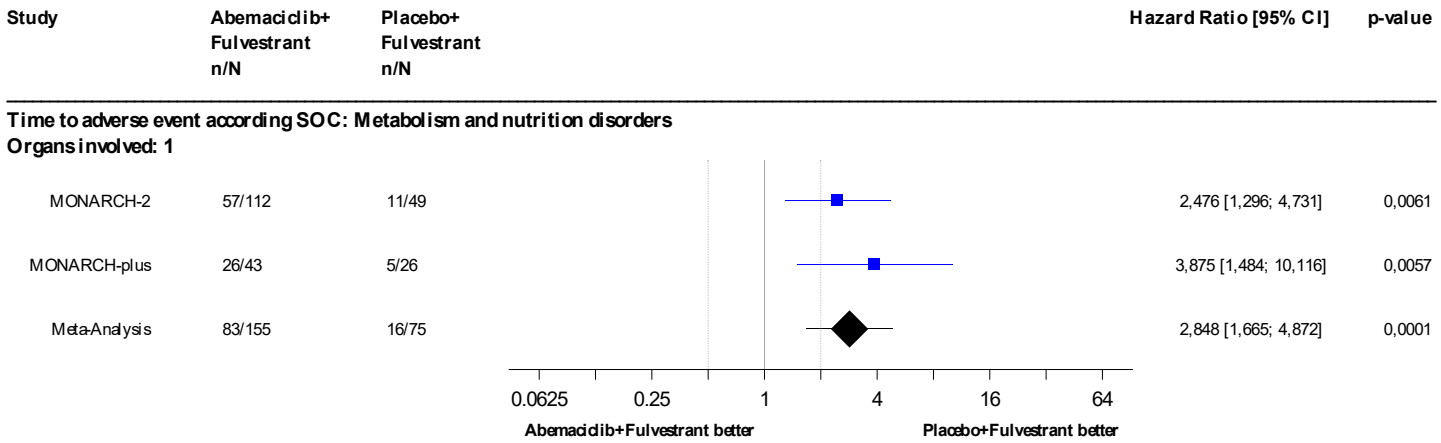
Figure 1262.1.2.1: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5748, p-value=0,4484, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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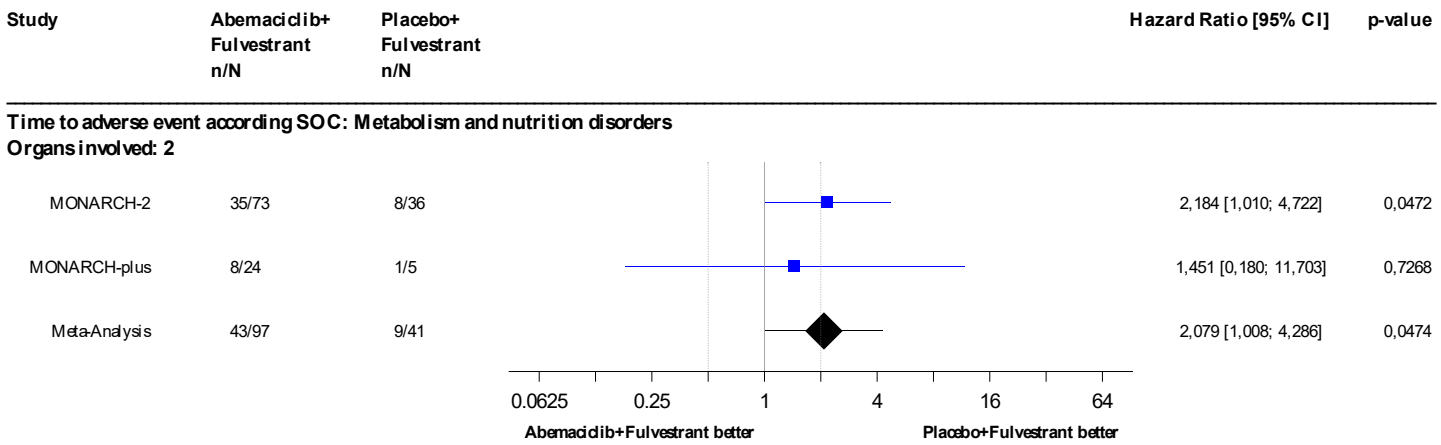
Figure 1262.1.2.2: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1296, p-value=0,7189, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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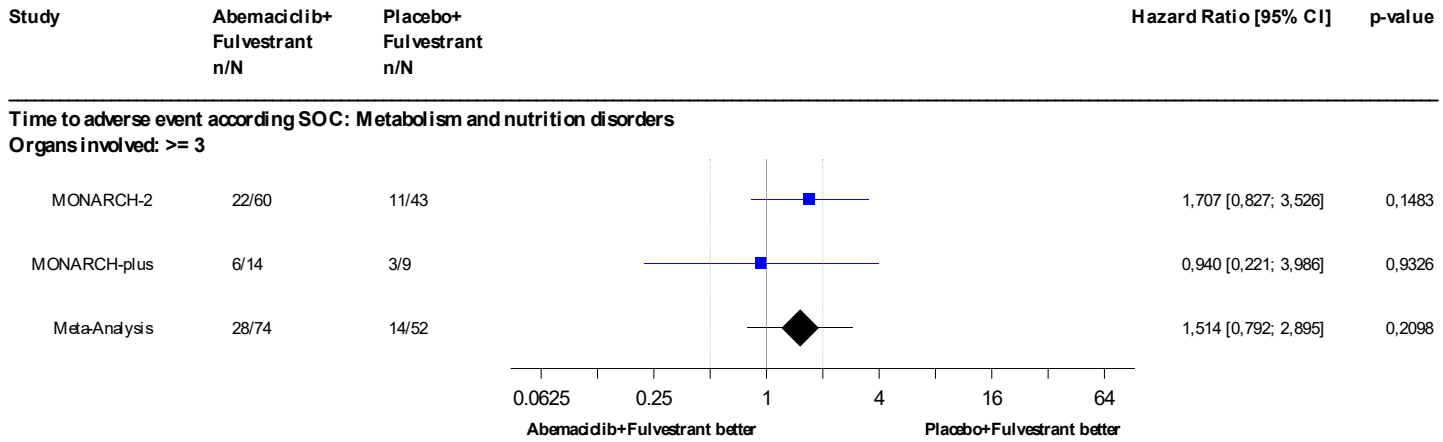
Figure 1262.1.2.3: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5243, p-value=0,4690, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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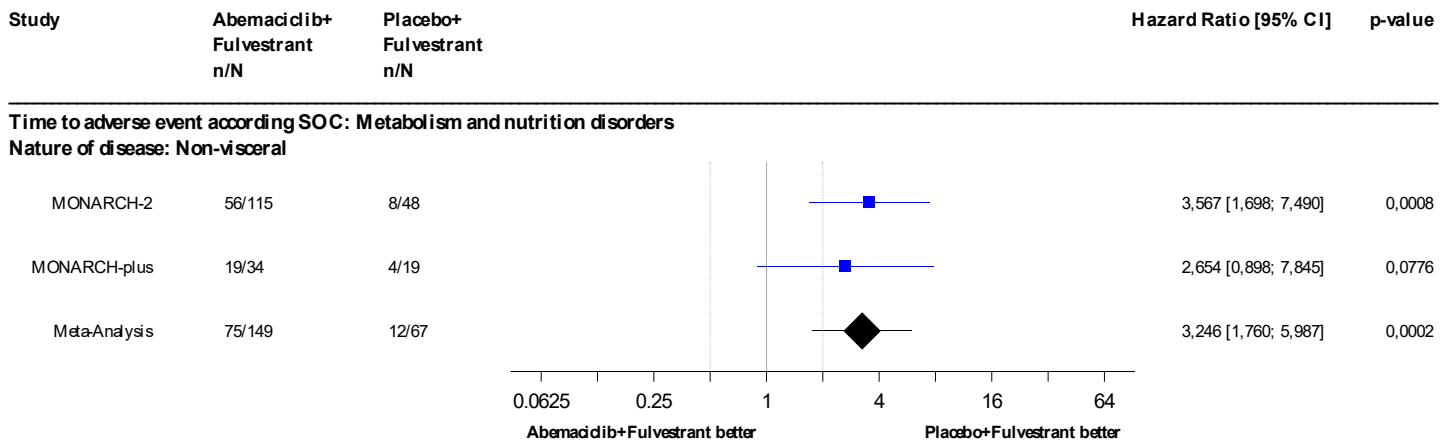
Figure 1262.1.3.1: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1948, p-value=0,6590, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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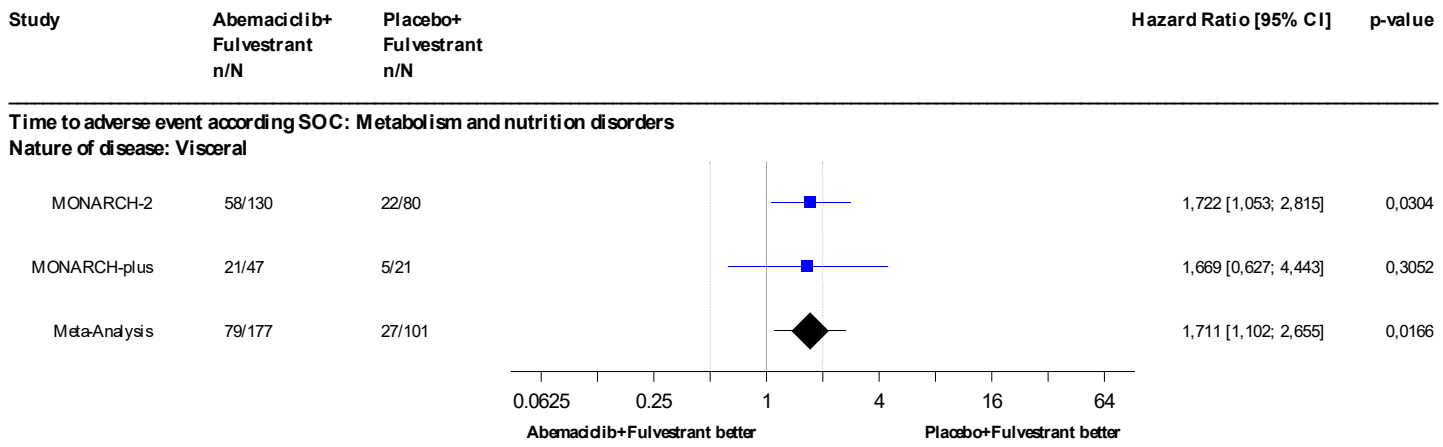
Figure 1262.1.3.2: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0031, p-value=0,9557, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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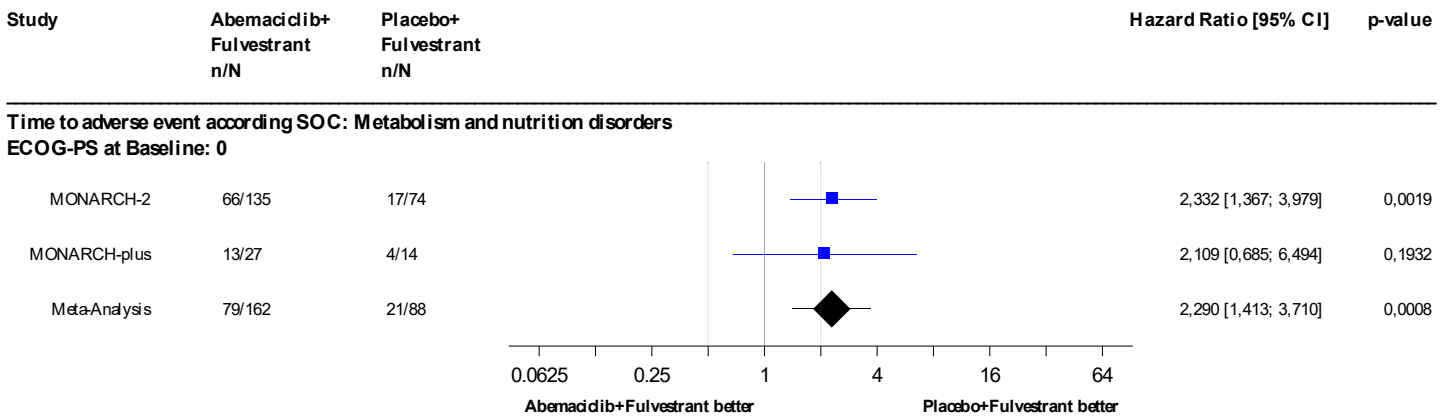
Figure 1262.1.4.1: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0250, p-value=0,8743, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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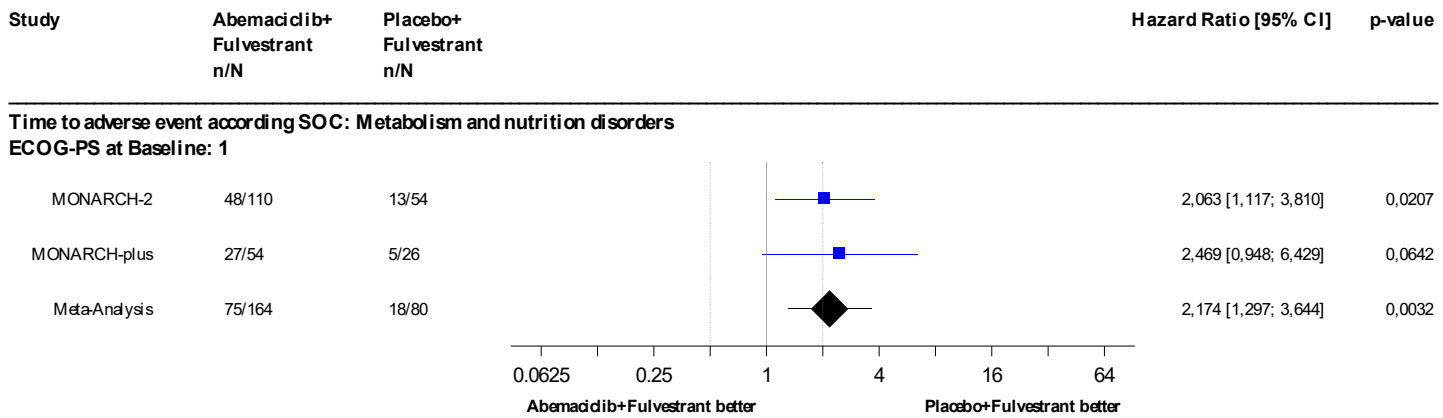
Figure 1262.1.4.2: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0958, p-value=0,7569, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes012_popa1_ecogbl_2.rtf
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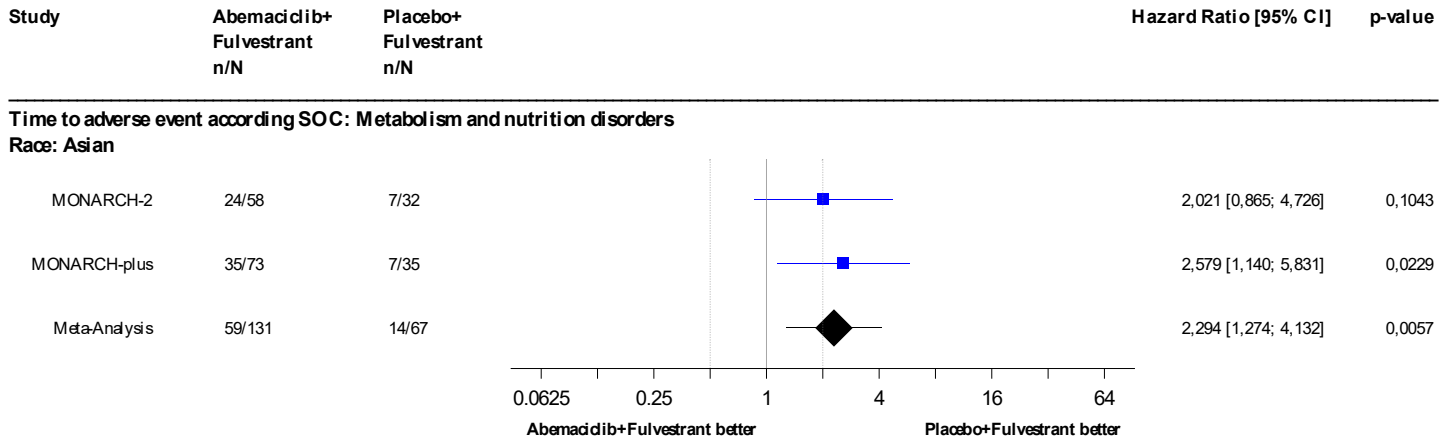
Figure 1262.1.5.1: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1642, p-value=0,6853, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes012_popa1_racegr1_1.rtf
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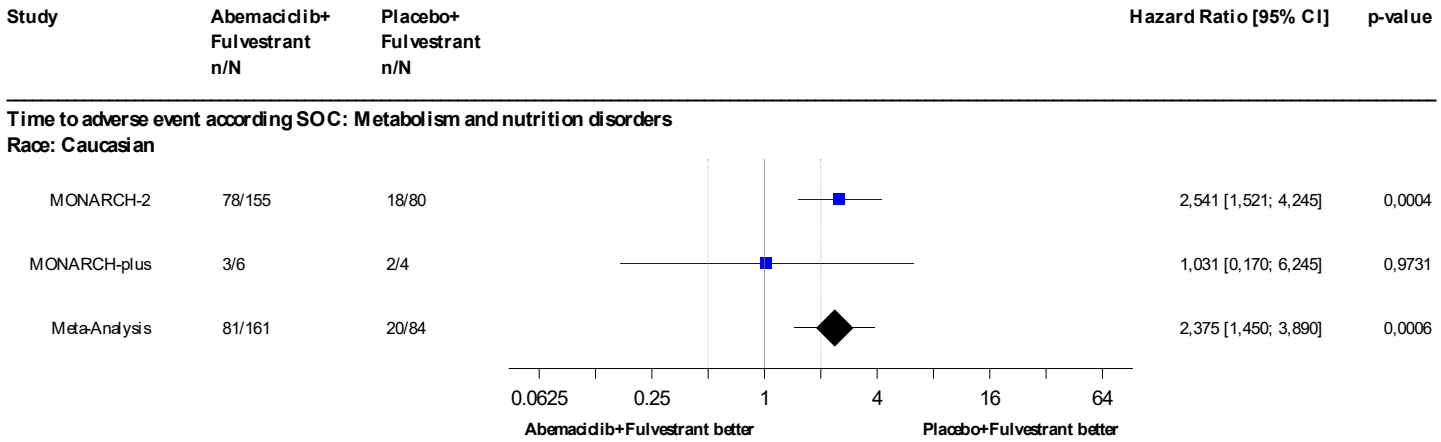
Figure 1262.1.5.2: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,8905, p-value=0,3453, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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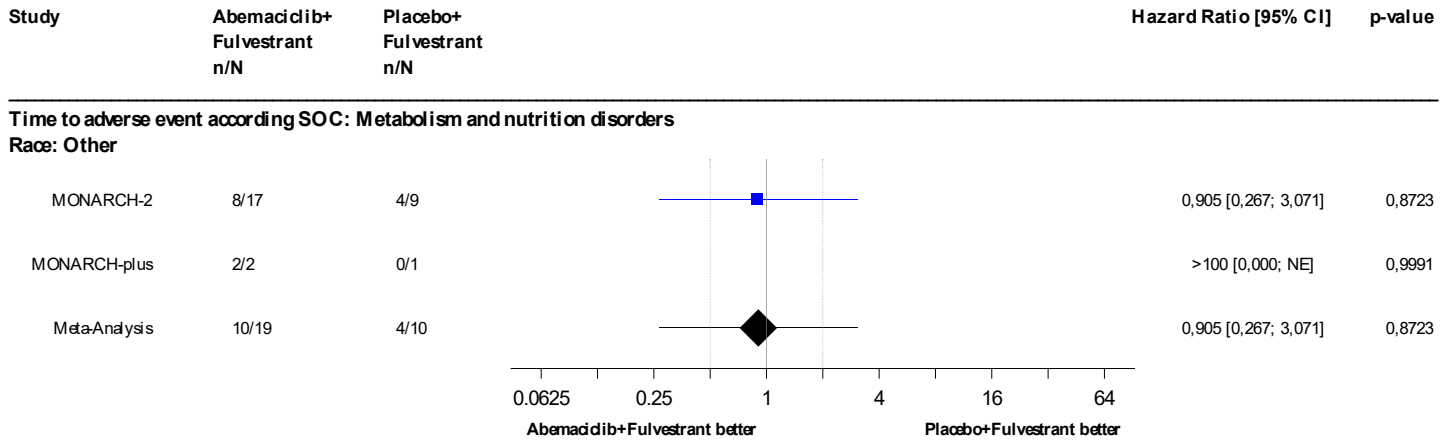
Figure 1262.1.5.3: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9991, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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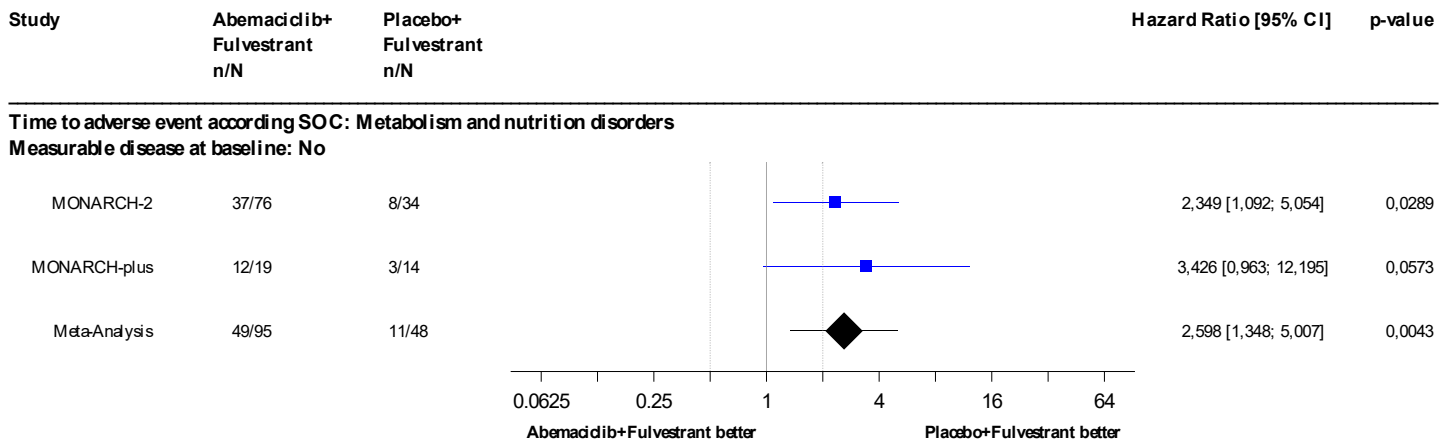
Figure 1262.1.6.1: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2487, p-value=0,6180, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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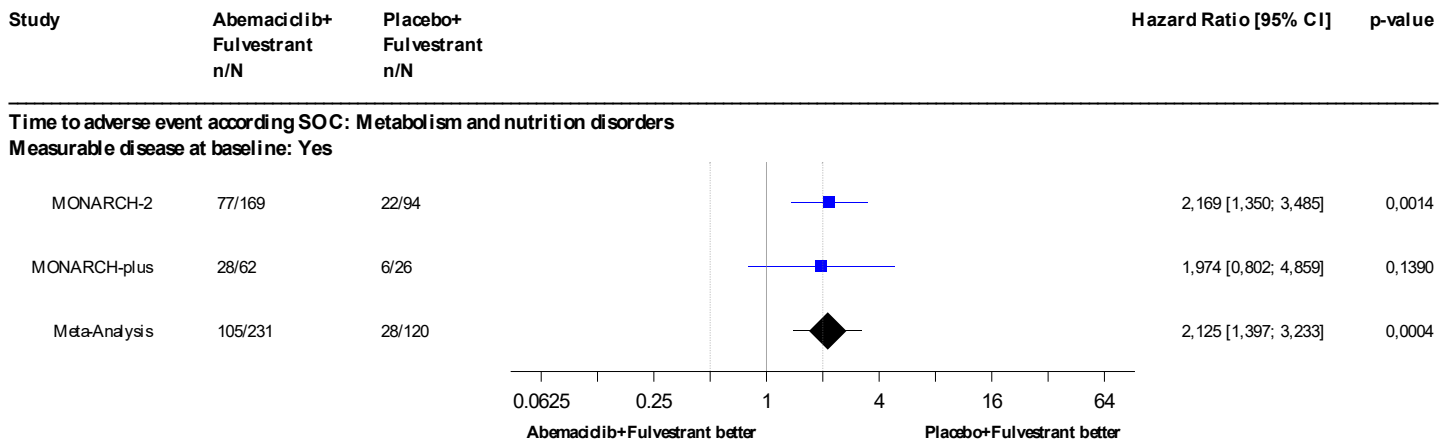
Figure 1262.1.6.2: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0329, p-value=0,8561, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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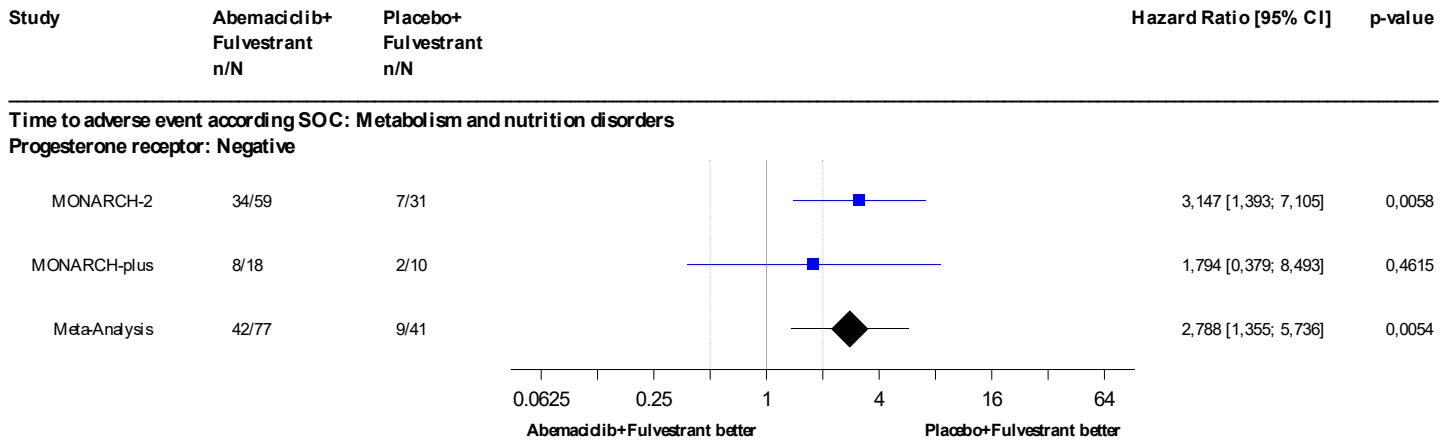
Figure 1262.1.7.1: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3938, p-value=0,5303, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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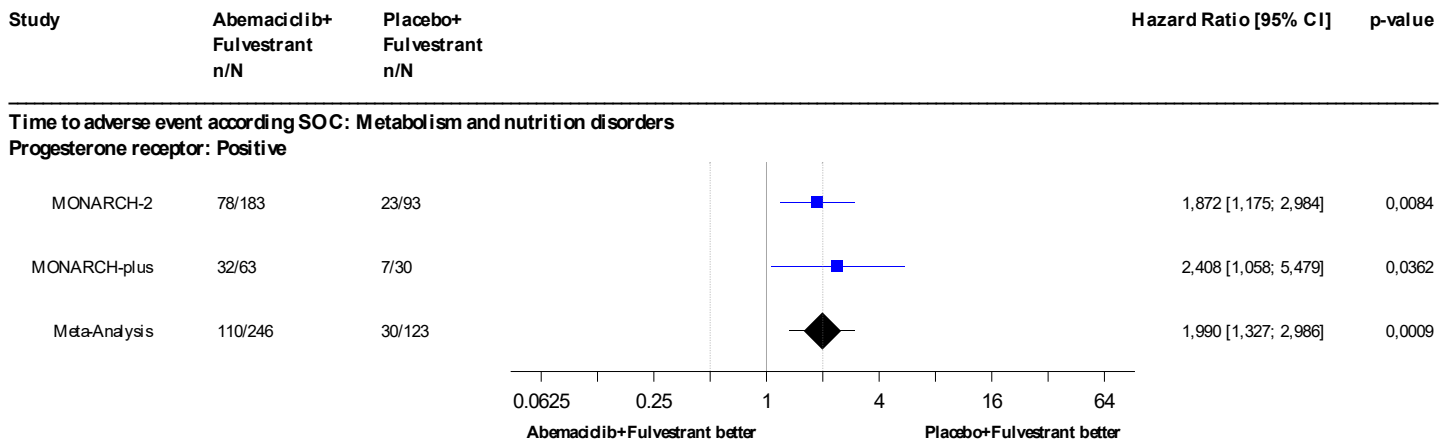
Figure 1262.1.7.2: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2722, p-value=0,6019, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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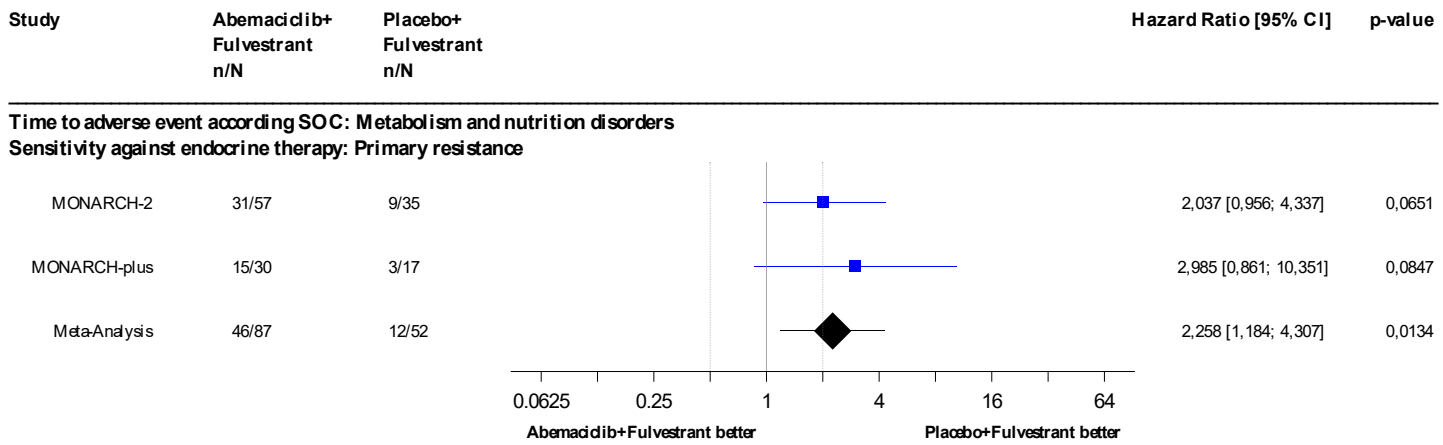
Figure 1262.1.8.1: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2652, p-value=0,6065, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes012_popa1_snthr_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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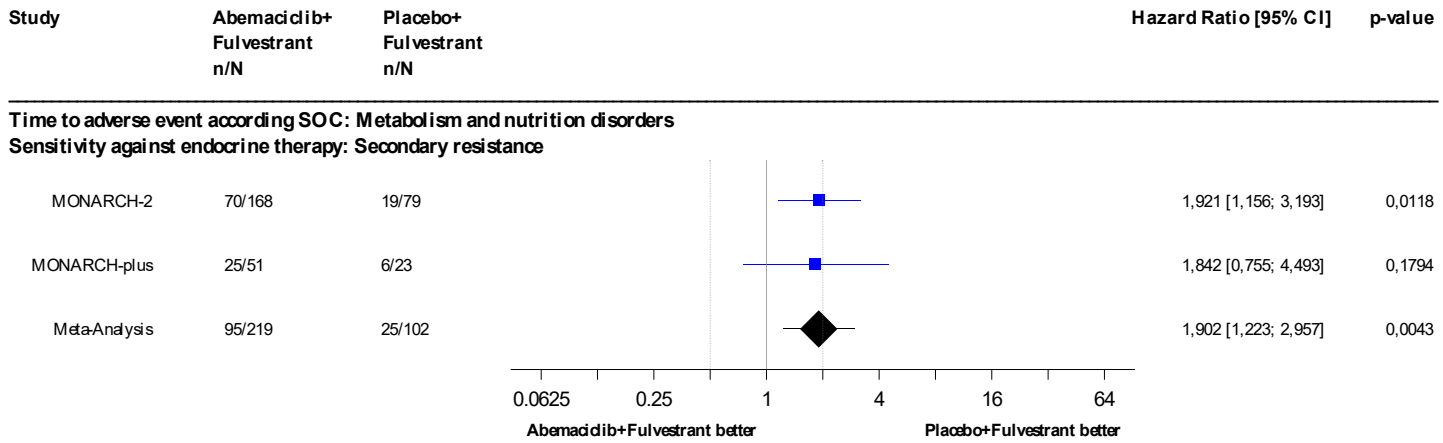
Figure 1262.1.8.2: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0065, p-value=0,9358, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes012_popa1_snthr_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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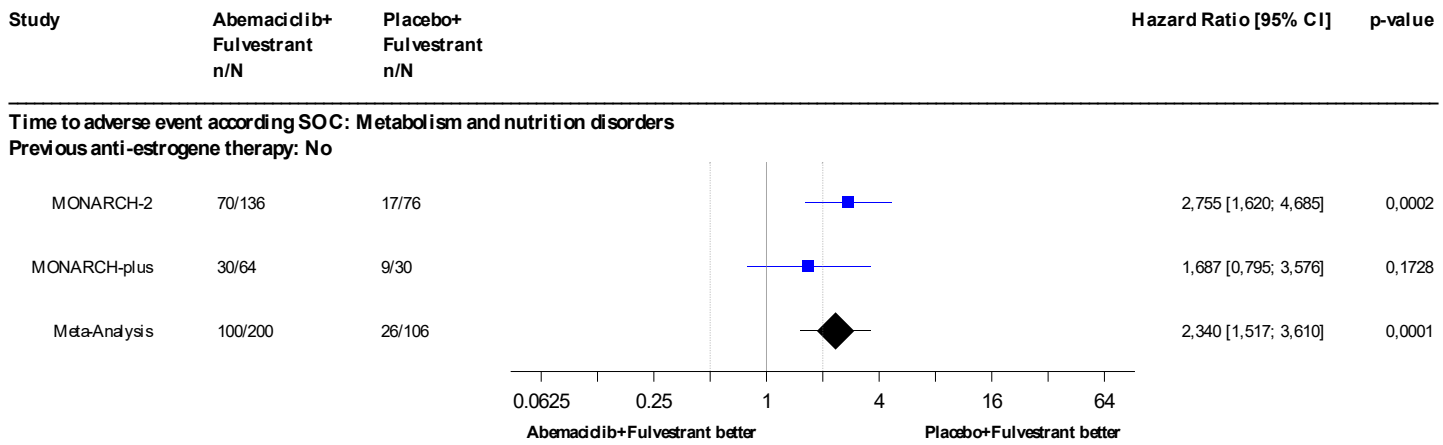
Figure 1262.1.9.1: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,0921, p-value=0,2960, I2 index=8,4%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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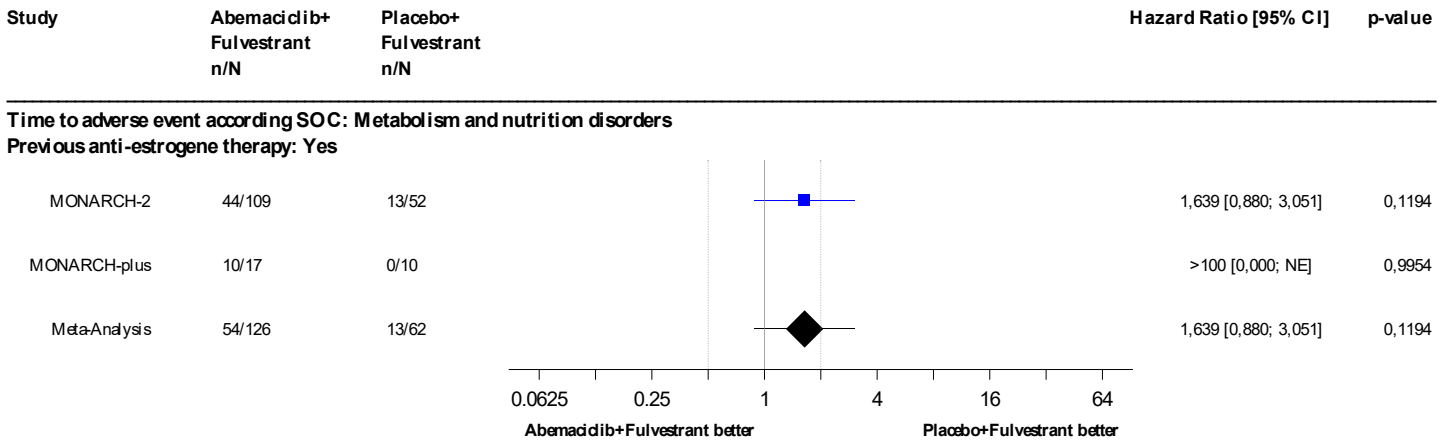
Figure 1262.1.9.2: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9955, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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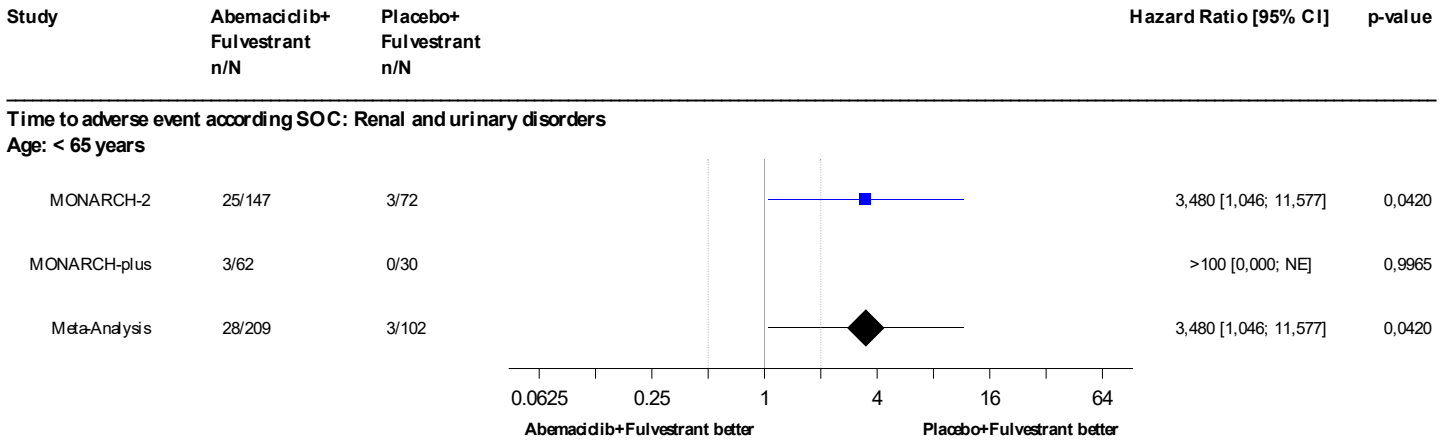
Figure 1267.1.1.1: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9968, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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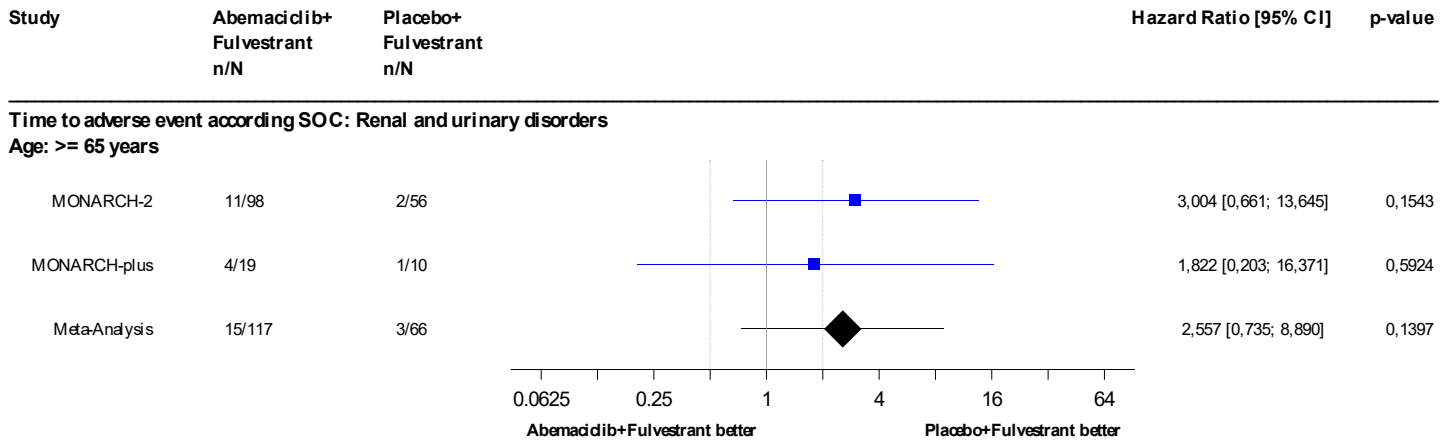
Figure 1267.1.1.2: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1351, p-value=0,7132, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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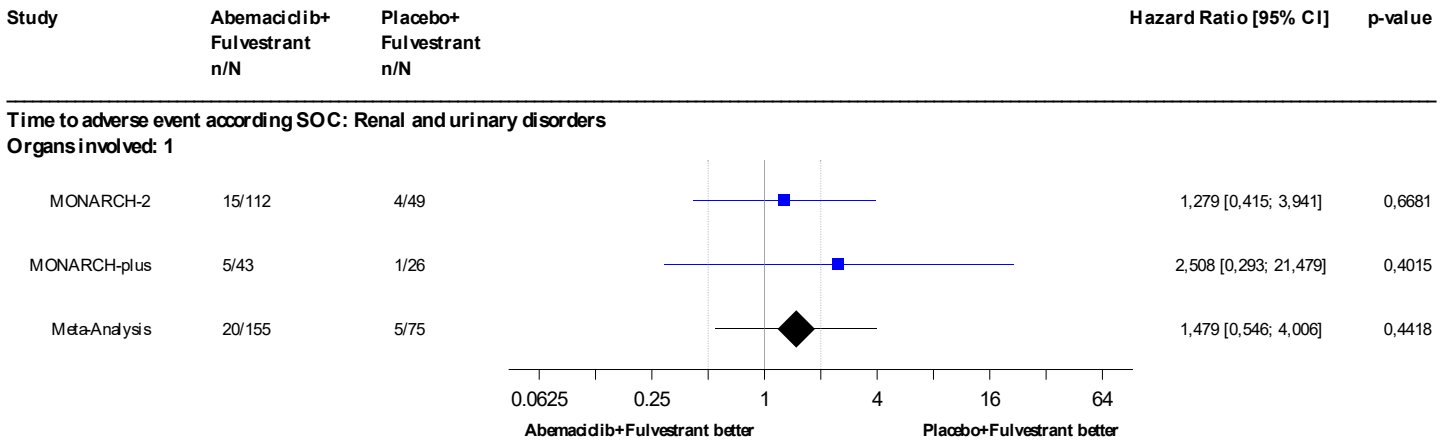
Figure 1267.1.2.1: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2961, p-value=0,5863, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes017_popa1_norggr_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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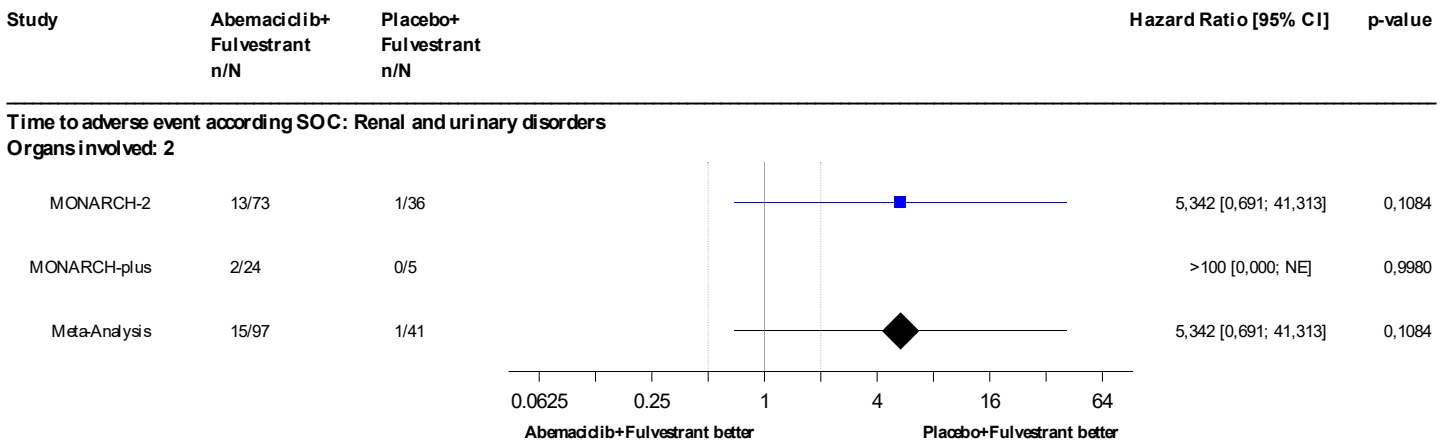
Figure 1267.1.2.2: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9982, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes017_popa1_norggr_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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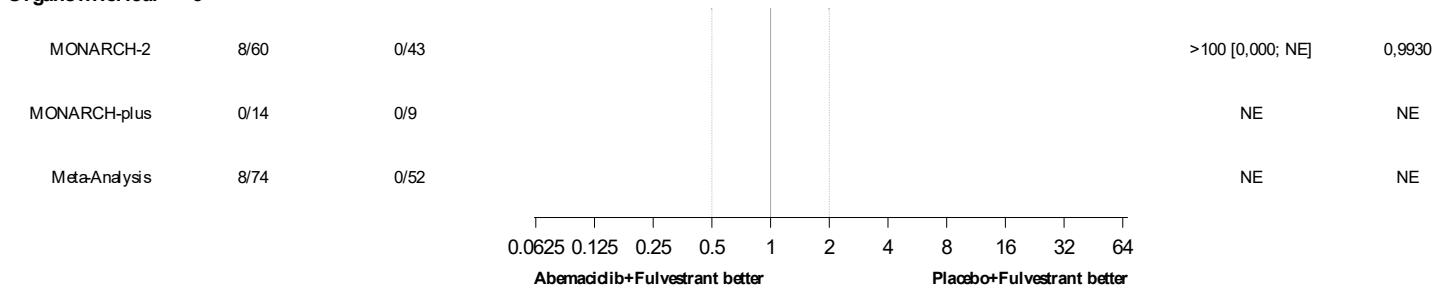
Figure 1267.1.2.3: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes017_popa1_norggr_3.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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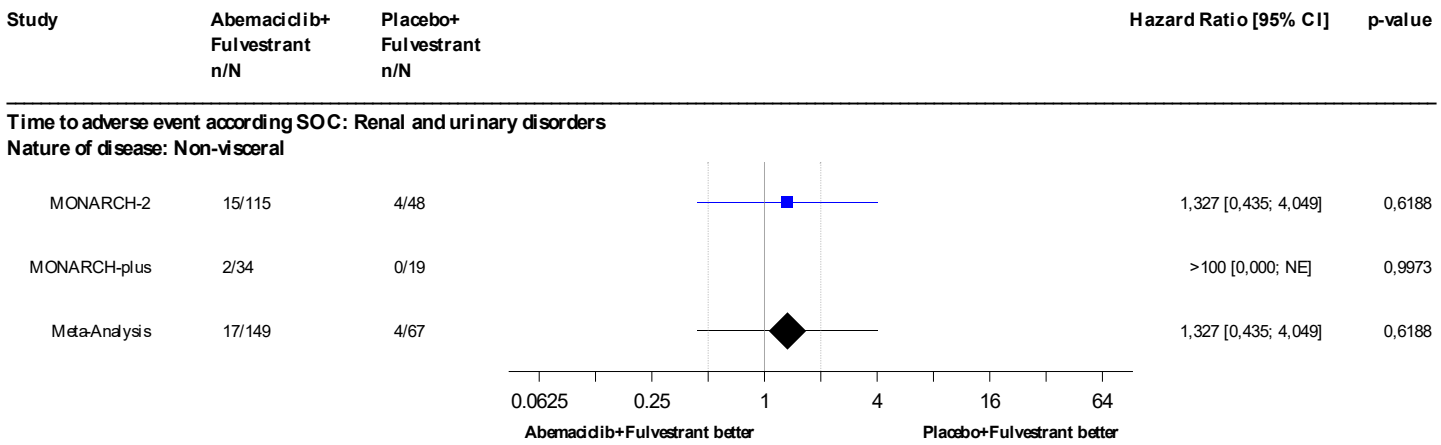
Figure 1267.1.3.1: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9974, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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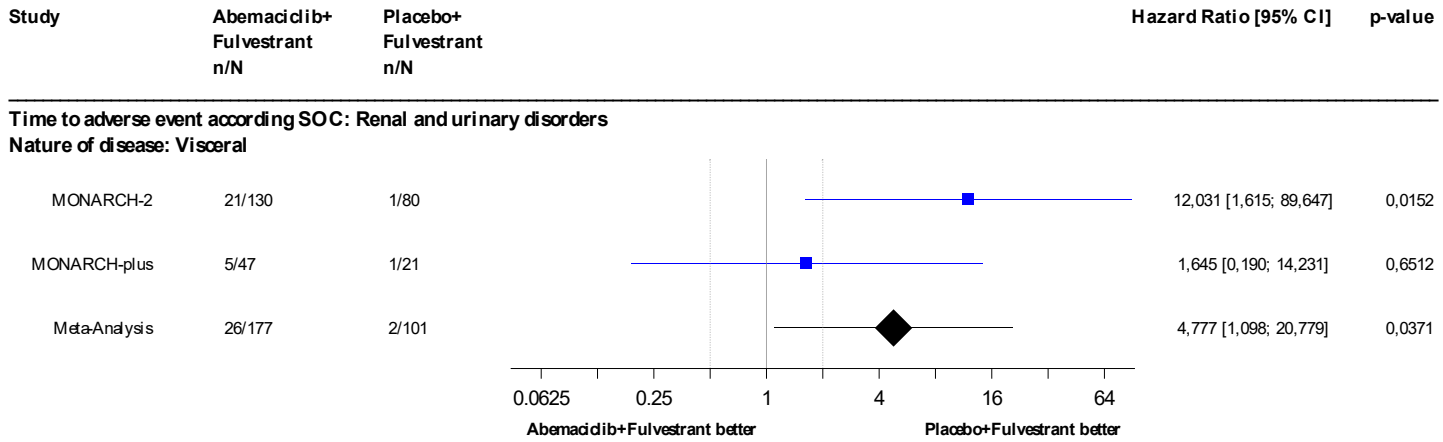
Figure 1267.1.3.2: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,7505, p-value=0,1858, I2 index=42,9%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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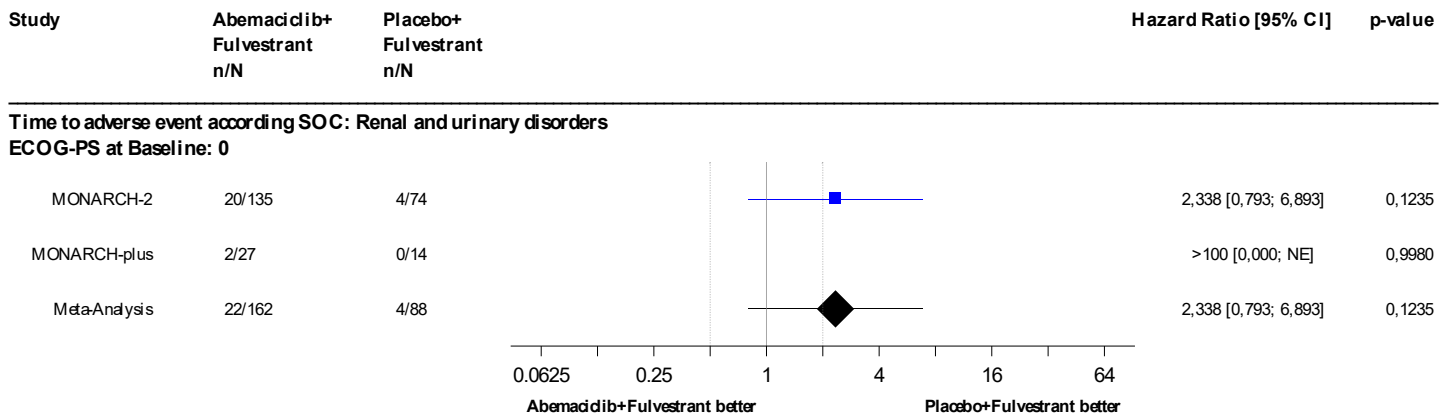
Figure 1267.1.4.1: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9981, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes017_popa1_ecogbl_1.rtf
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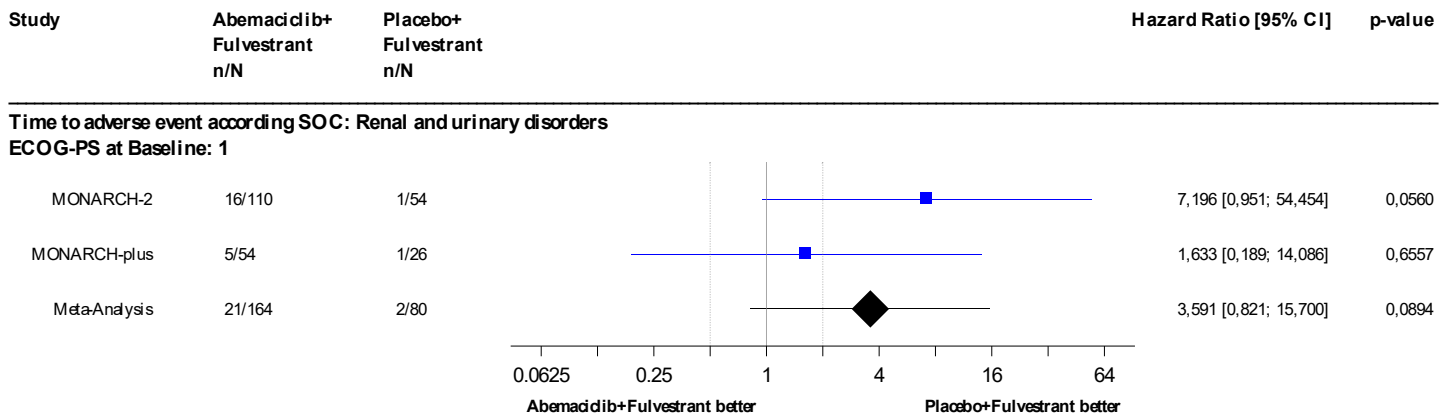
Figure 1267.1.4.2: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,9672, p-value=0,3254, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes017_popa1_ecogbl_2.rtf
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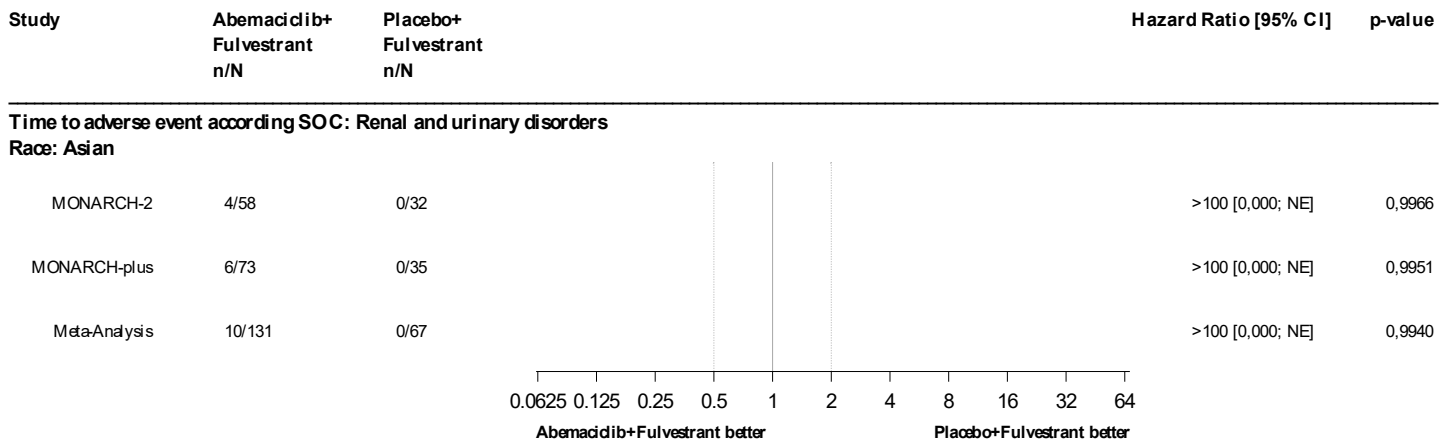
Figure 1267.1.5.1: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes017_popa1_racegr1_1.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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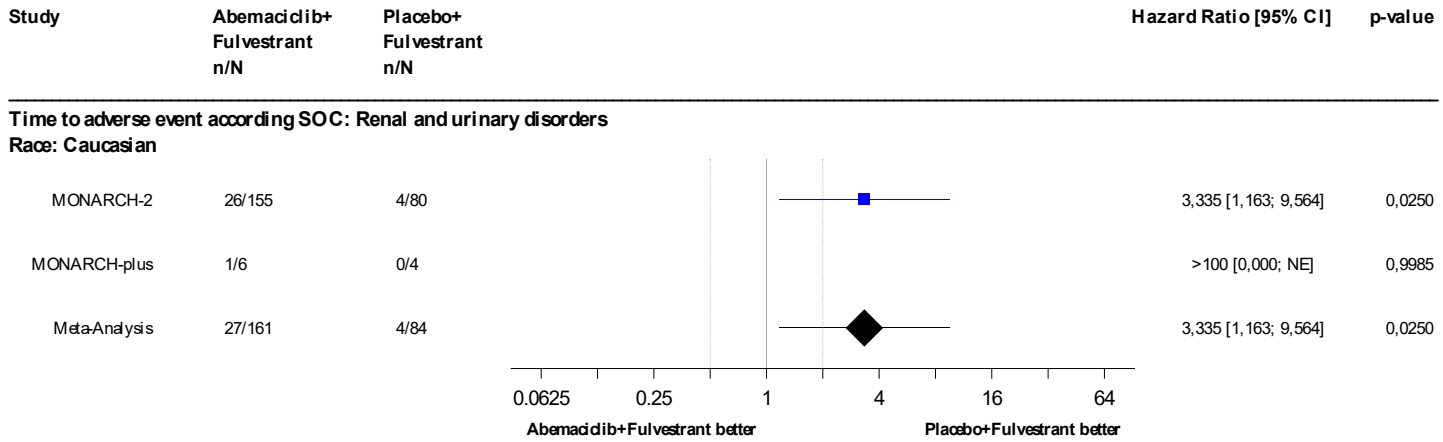
Figure 1267.1.5.2: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes017_popa1_racegr1_2.rtf
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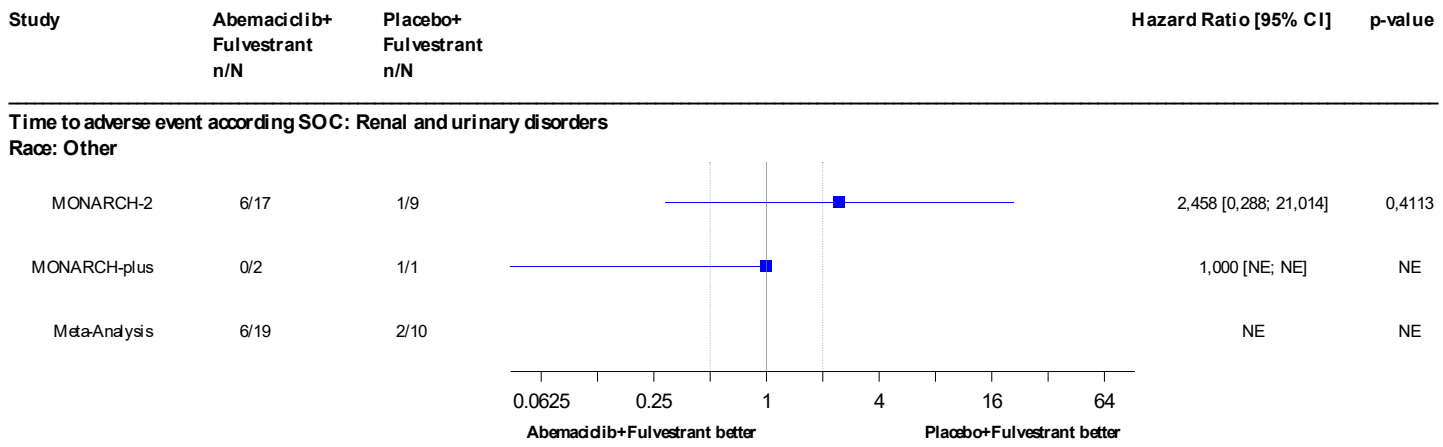
Figure 1267.1.5.3: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes017_popa1_racegr1_3.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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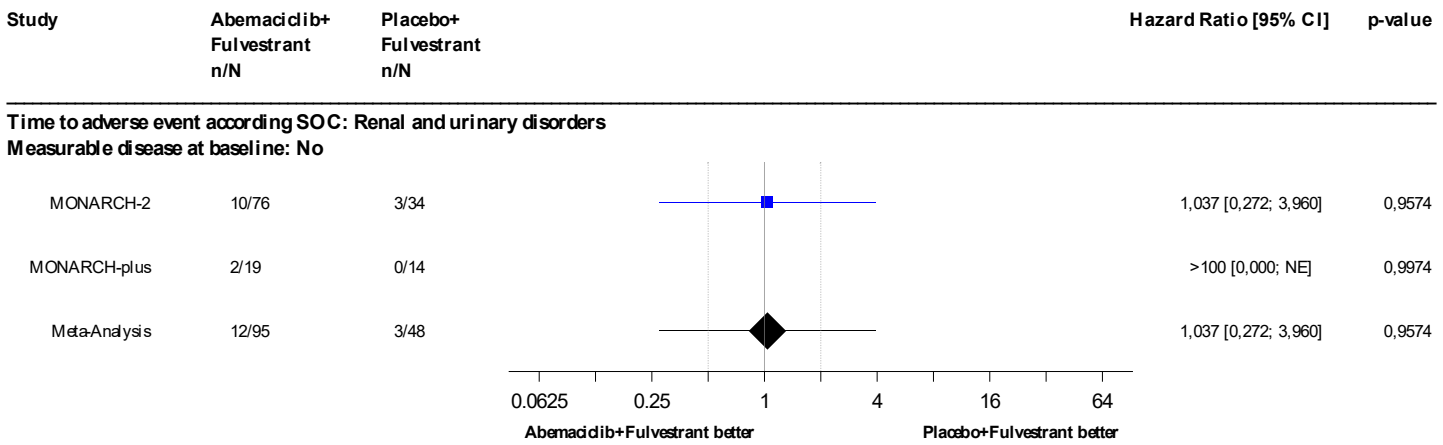
Figure 1267.1.6.1: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9975, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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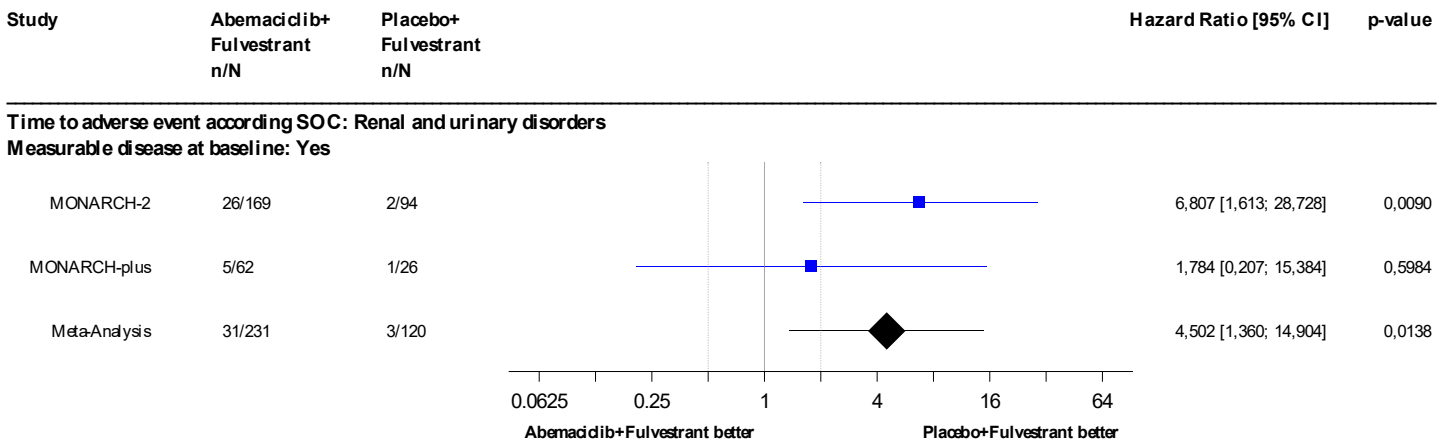
Figure 1267.1.6.2: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,0257, p-value=0,3112, I2 index=2,5%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes017_popa1_measdis_2.rtf
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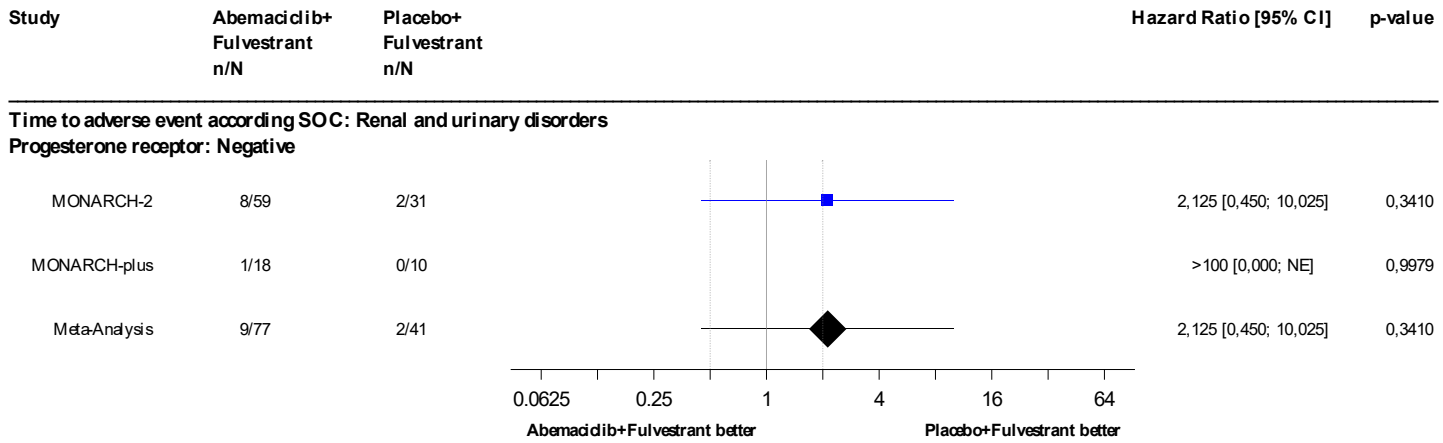
Figure 1267.1.7.1: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes017_popa1_pgrstat_1.rtf
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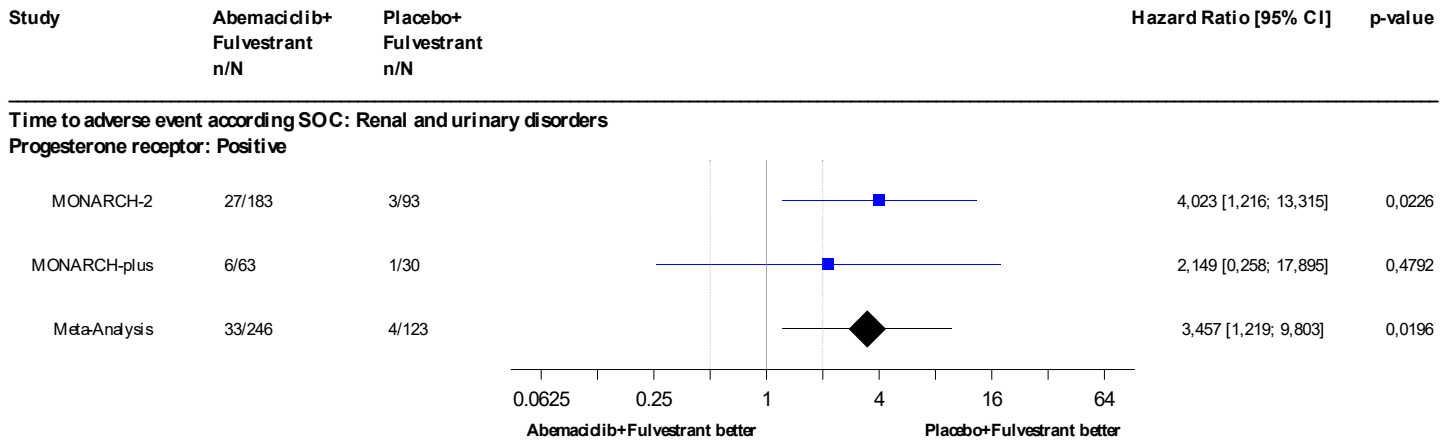
Figure 1267.1.7.2: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2549, p-value=0,6136, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes017_popa1_pgrstat_2.rtf
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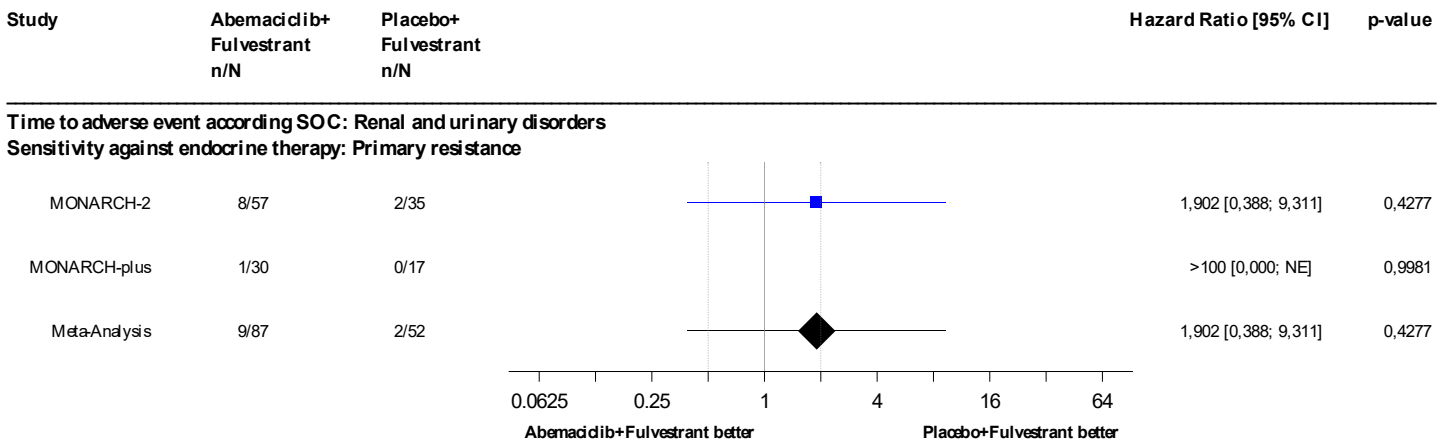
Figure 1267.1.8.1: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9981, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes017_popa1_snthr_1.rtf
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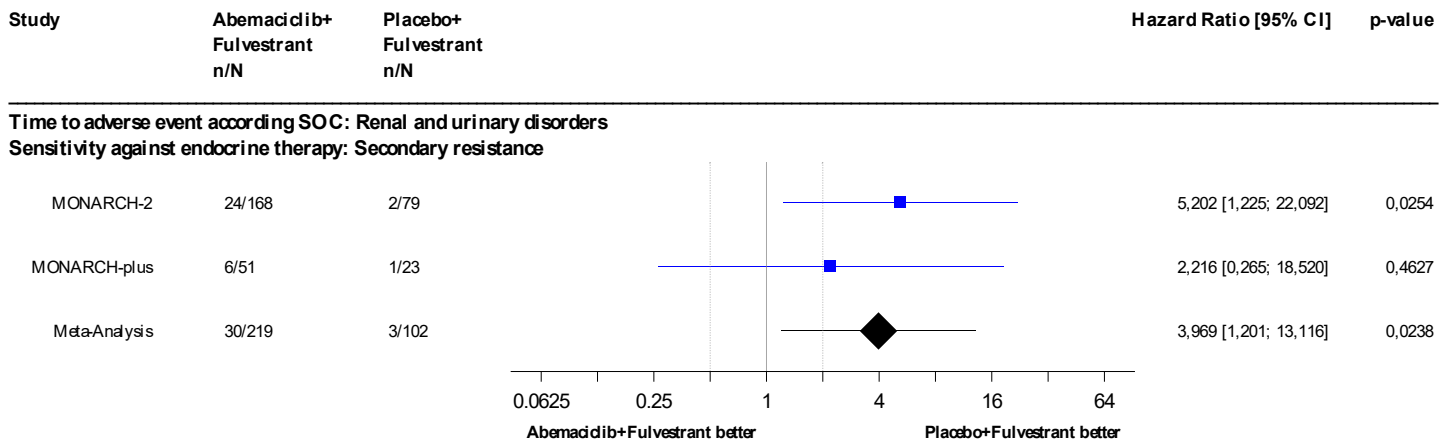
Figure 1267.1.8.2: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4240, p-value=0,5149, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes017_popa1_snthr_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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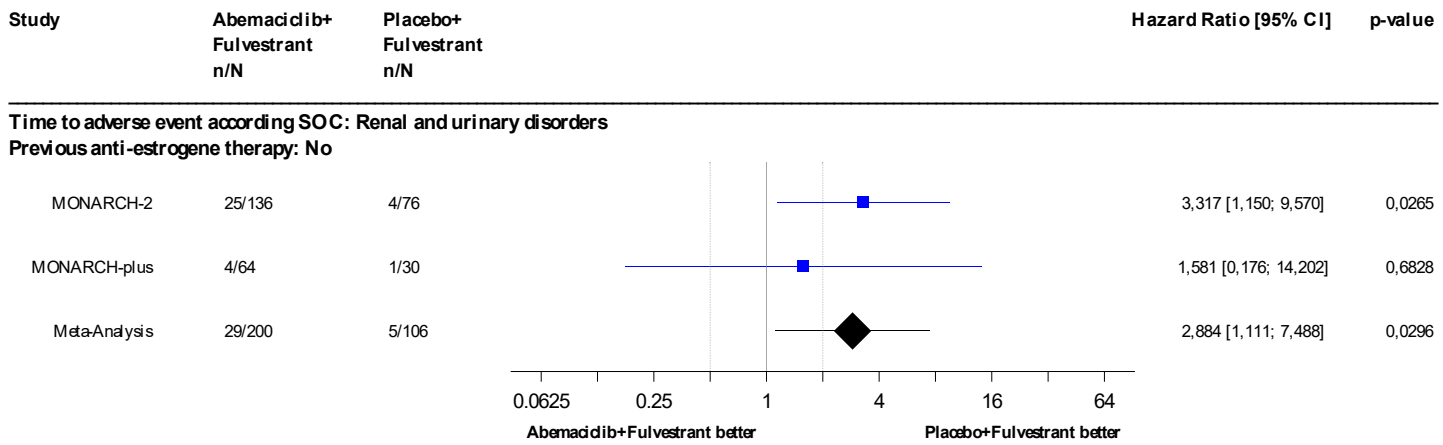
Figure 1267.1.9.1: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3553, p-value=0,5511, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes017_popa1_paet_1.rtf
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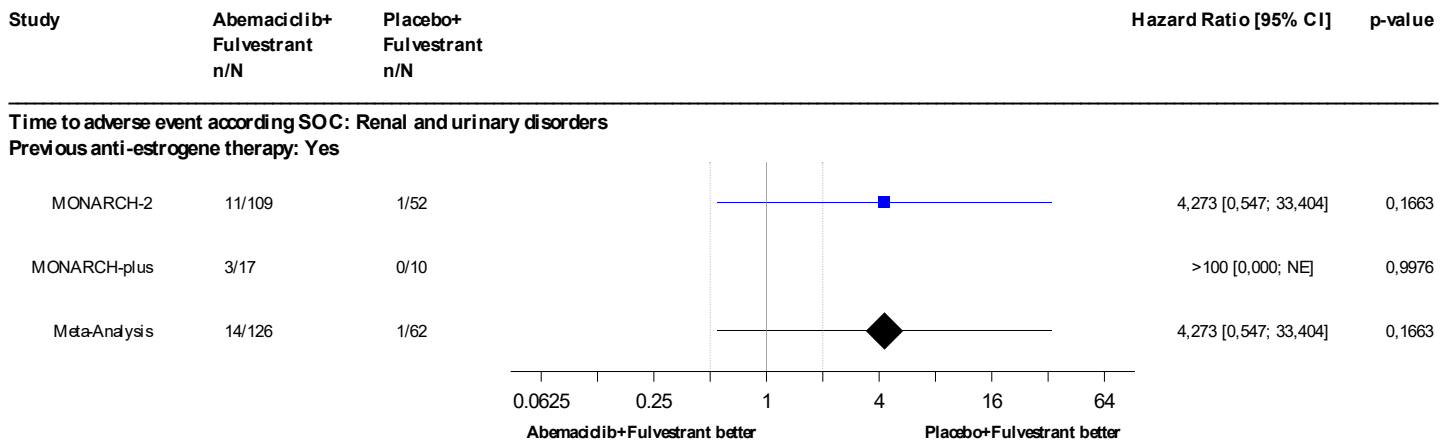
Figure 1267.1.9.2: Metaanalysis results for adverse events according SOC[1] -
Renal and urinary disorders
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9978, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes017_popa1_paet_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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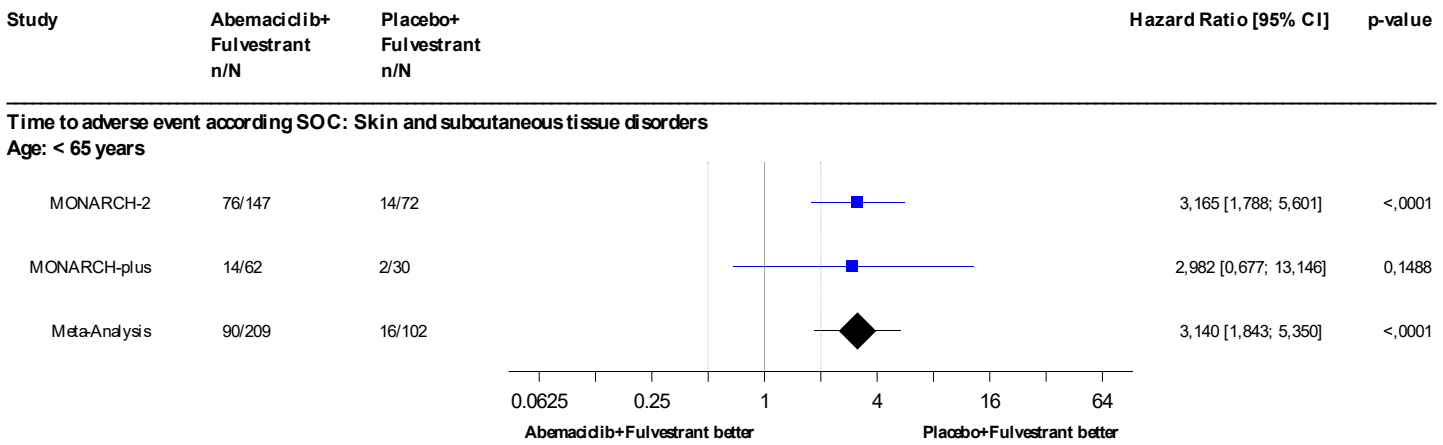
Figure 1270.1.1.1: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0053, p-value=0,9418, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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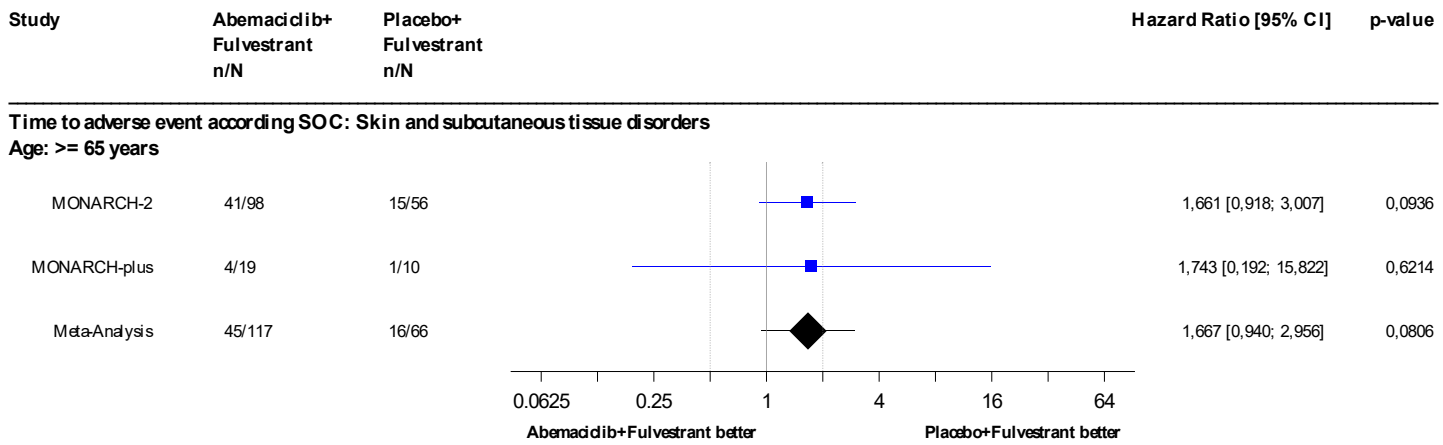
Figure 1270.1.1.2: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0017, p-value=0,9670, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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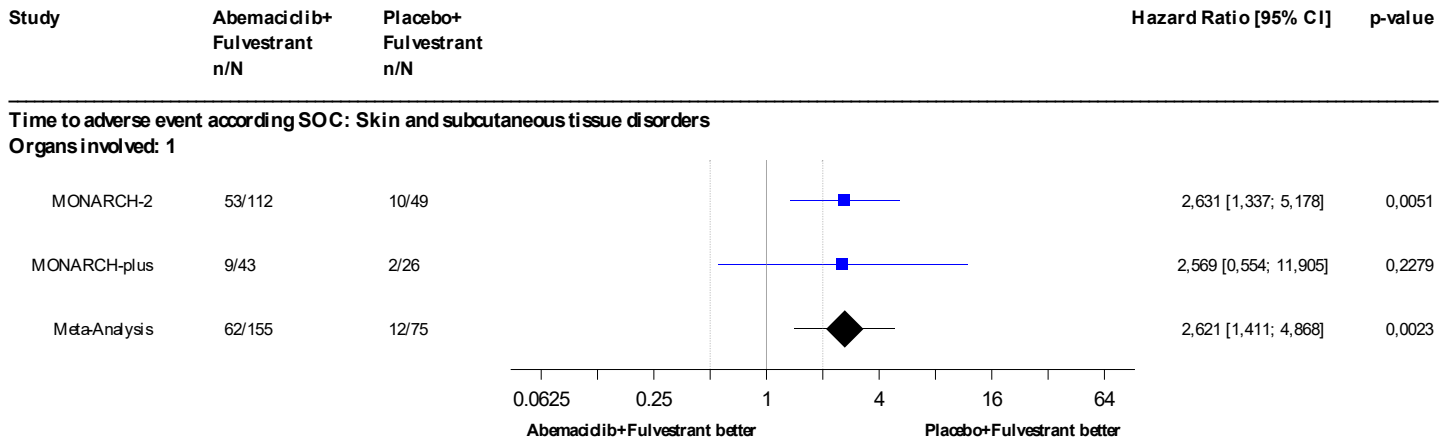
**Figure 1270.1.2.1: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0008, p-value=0,9775, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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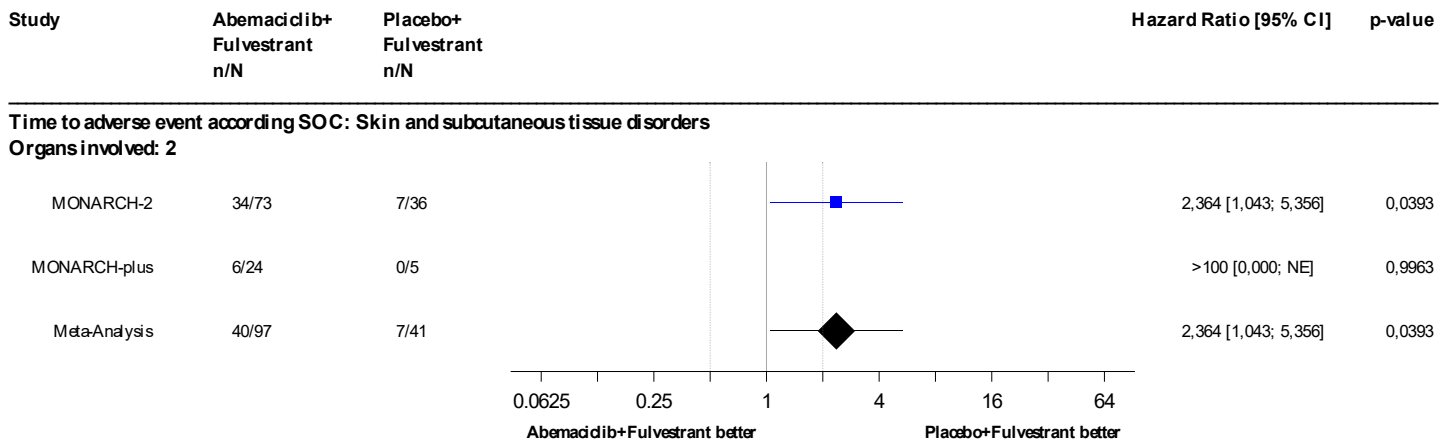
Figure 1270.1.2.2: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9965, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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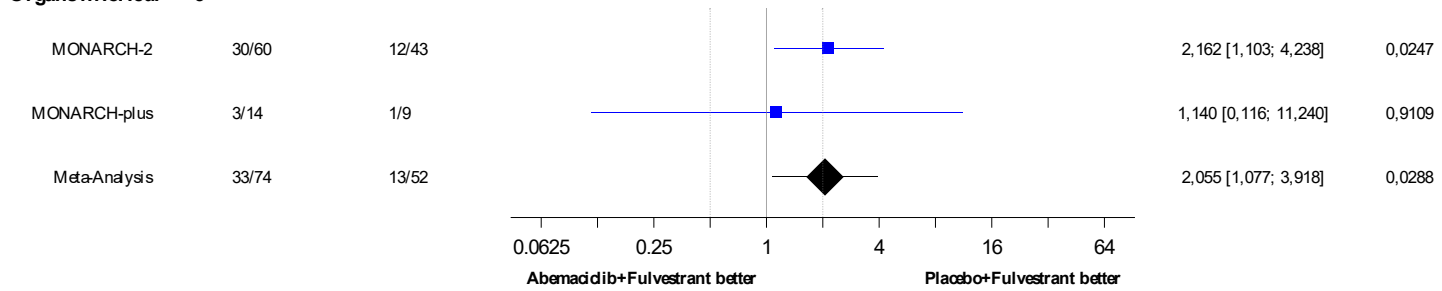
Figure 1270.1.2.3: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2768, p-value=0,5988, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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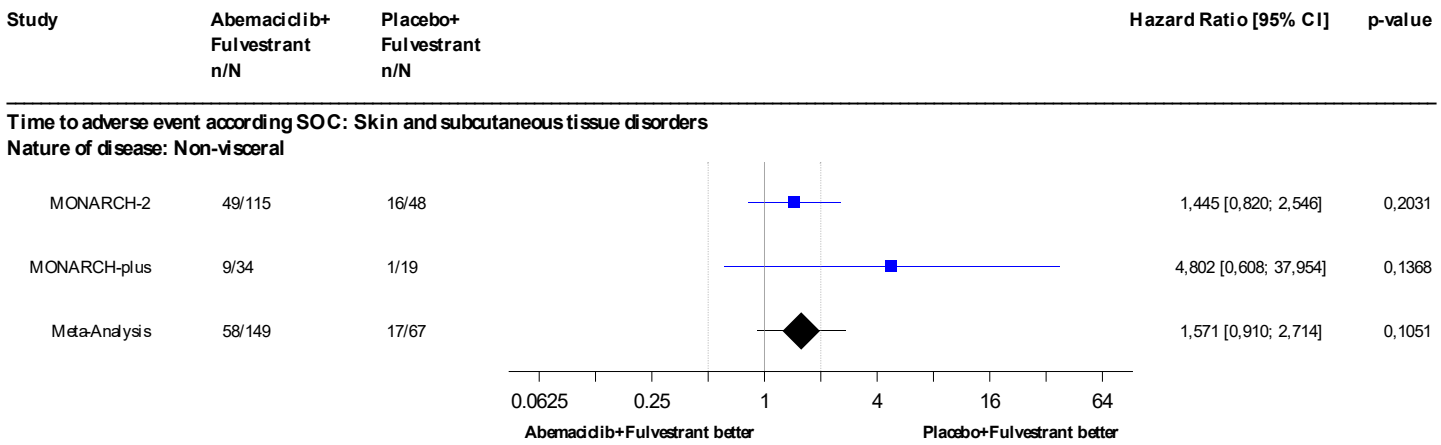
Figure 1270.1.3.1: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,2063, p-value=0,2721, I2 index=17,1%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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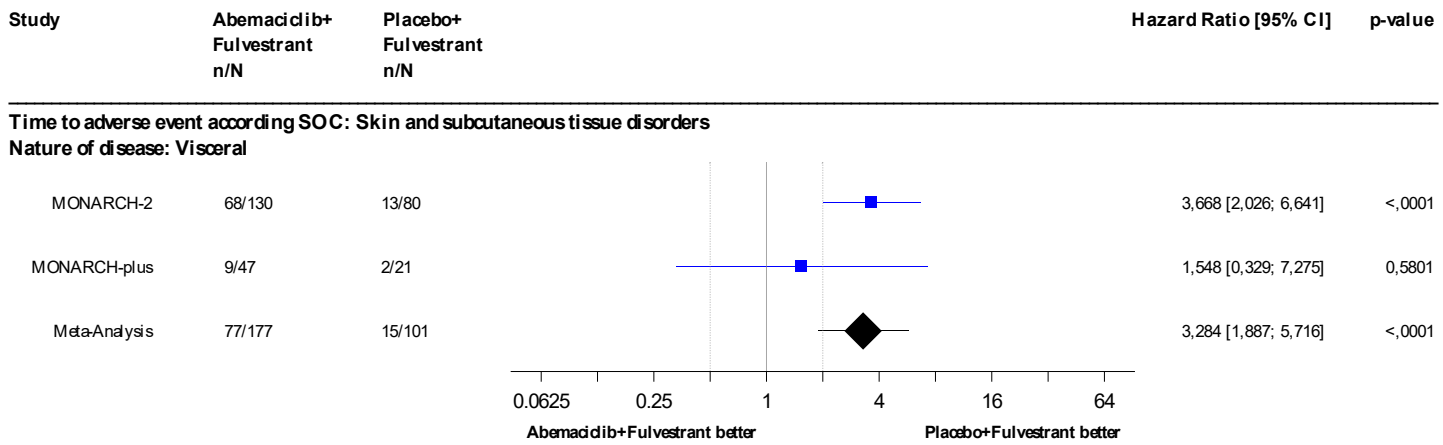
Figure 1270.1.3.2: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,0409, p-value=0,3076, I2 index=3,9%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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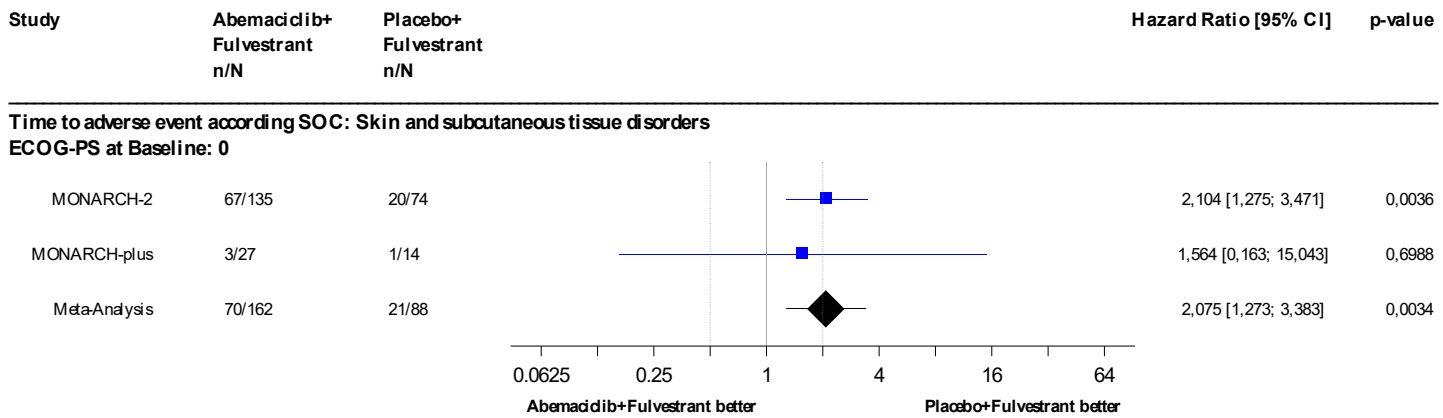
Figure 1270.1.4.1: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0630, p-value=0,8019, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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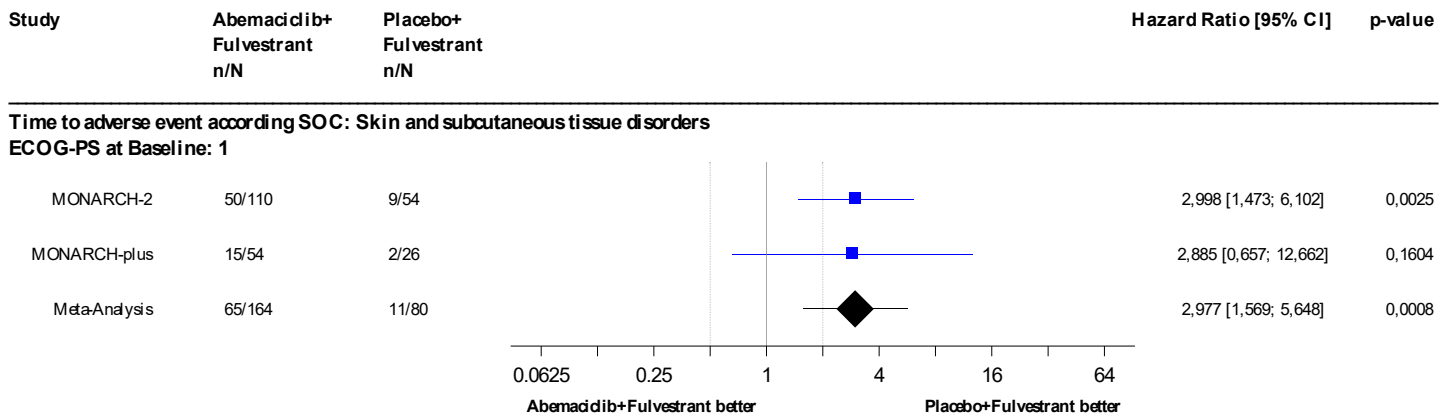
Figure 1270.1.4.2: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0021, p-value=0,9632, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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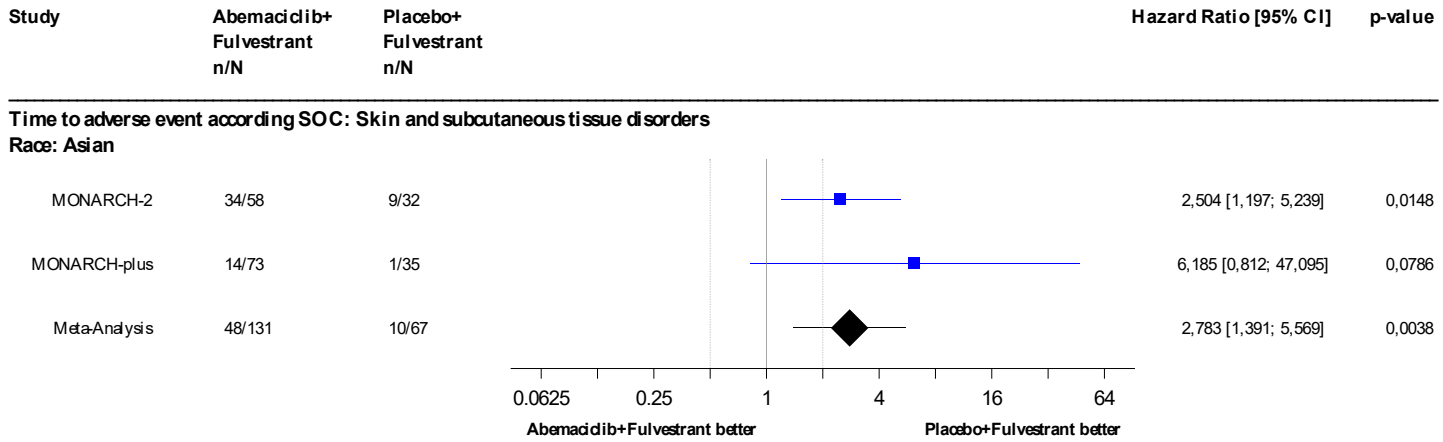
Figure 1270.1.5.1: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6730, p-value=0,4120, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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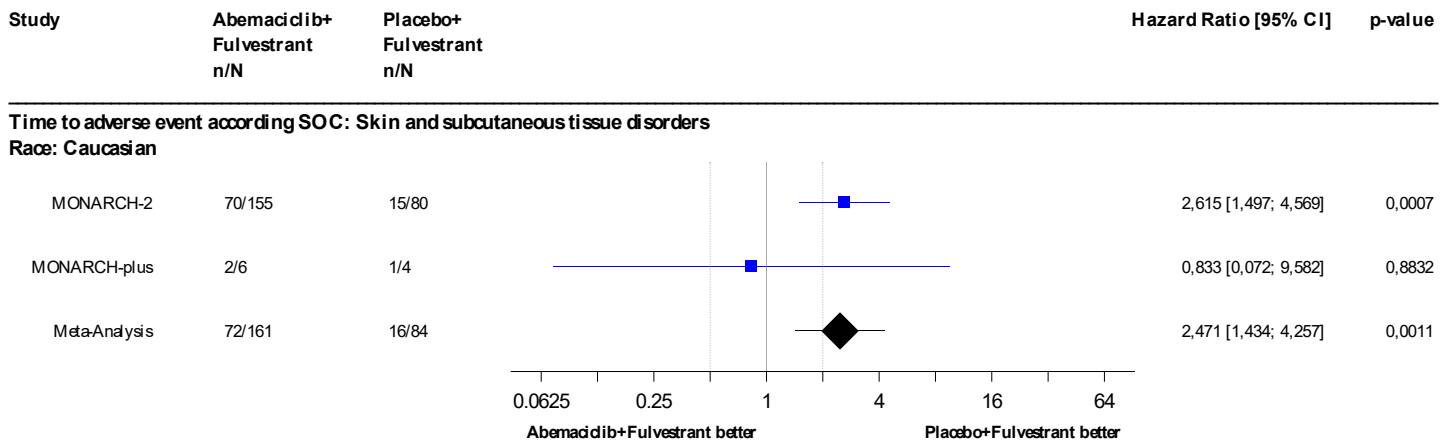
Figure 1270.1.5.2: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,8012, p-value=0,3707, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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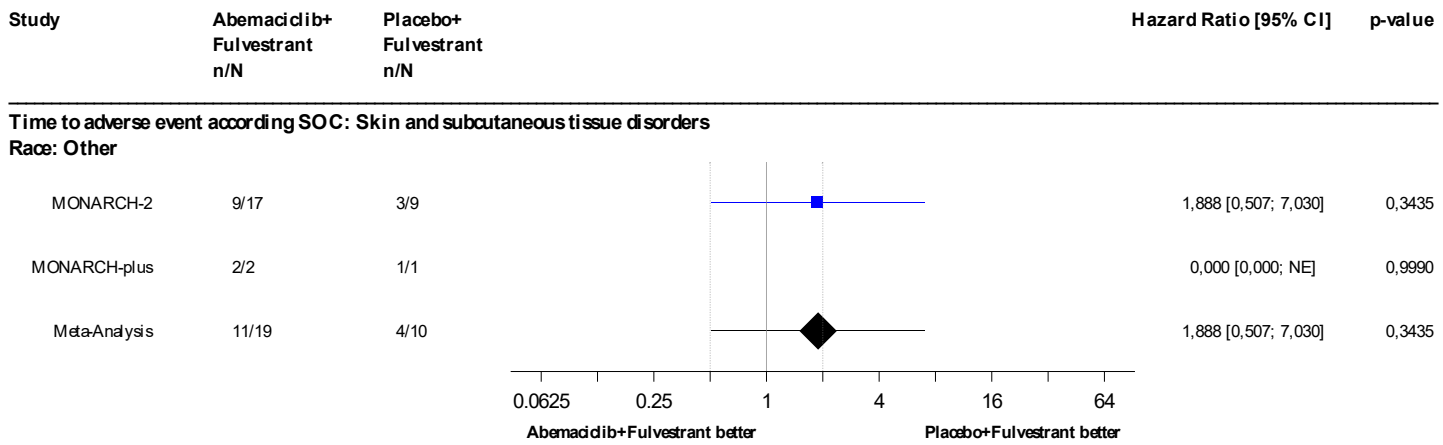
Figure 1270.1.5.3: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9990, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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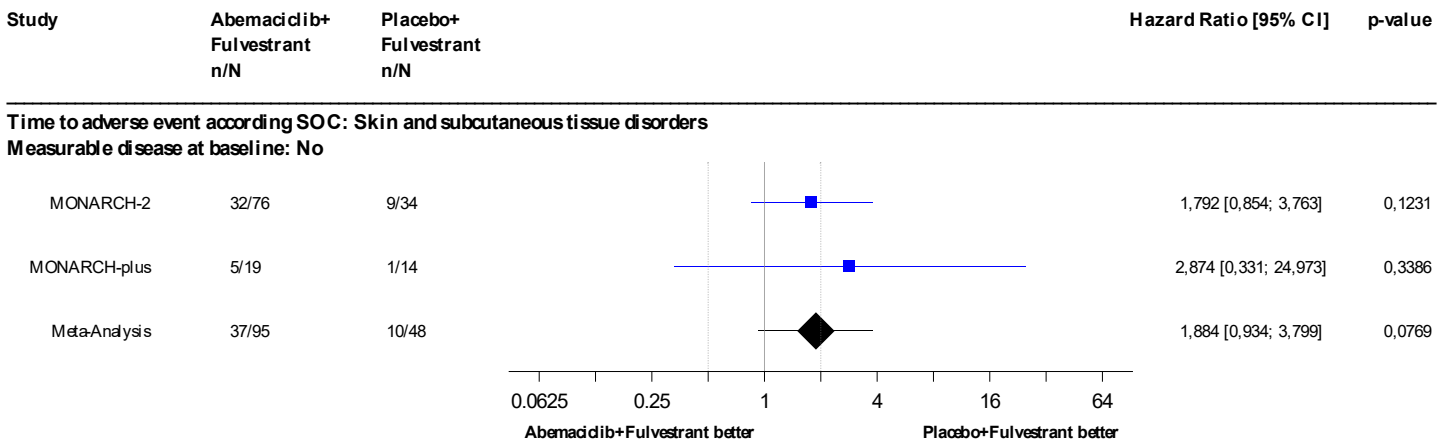
Figure 1270.1.6.1: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1639, p-value=0,6856, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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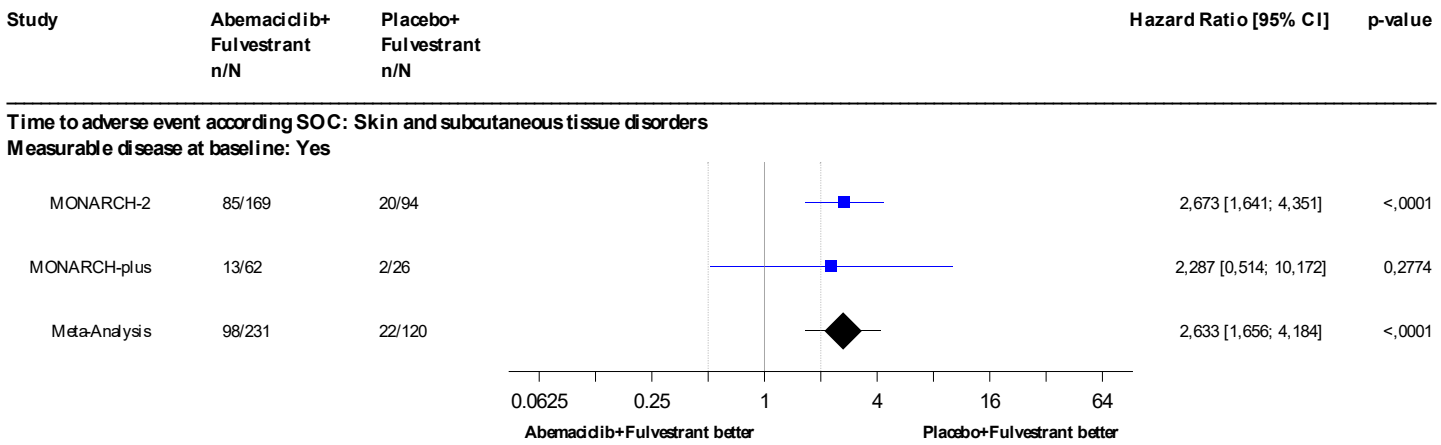
Figure 1270.1.6.2: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0379, p-value=0,8457, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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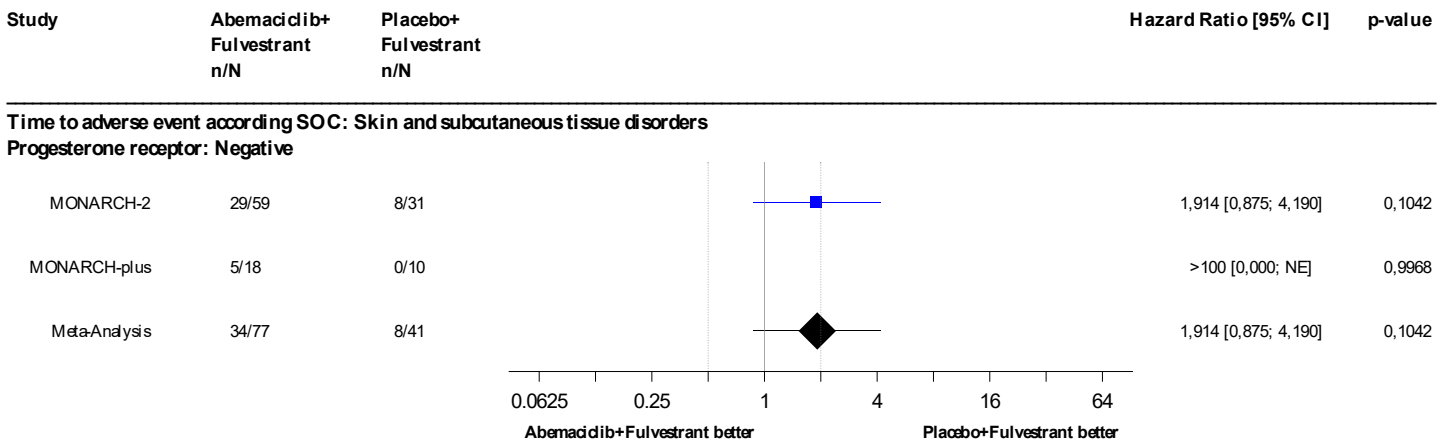
Figure 1270.1.7.1: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9969, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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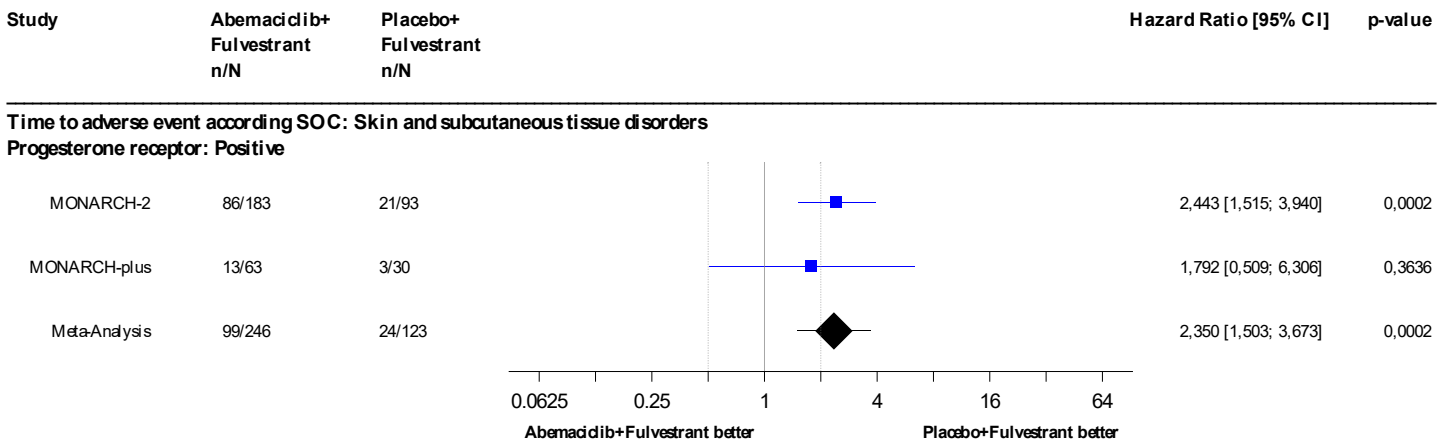
Figure 1270.1.7.2: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2040, p-value=0,6515, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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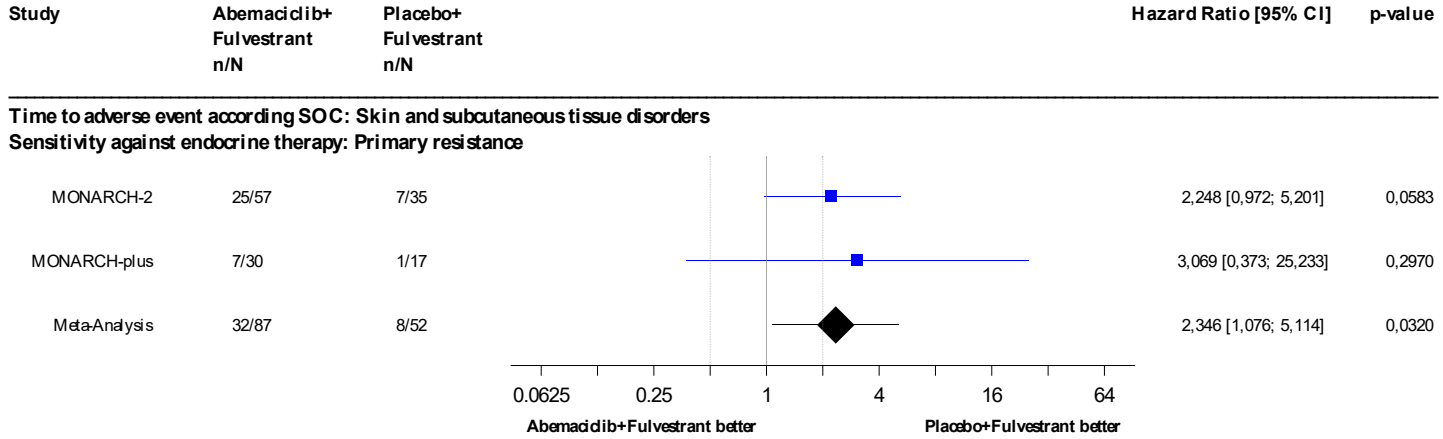
Figure 1270.1.8.1: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0723, p-value=0,7880, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes020_popa1_snthr_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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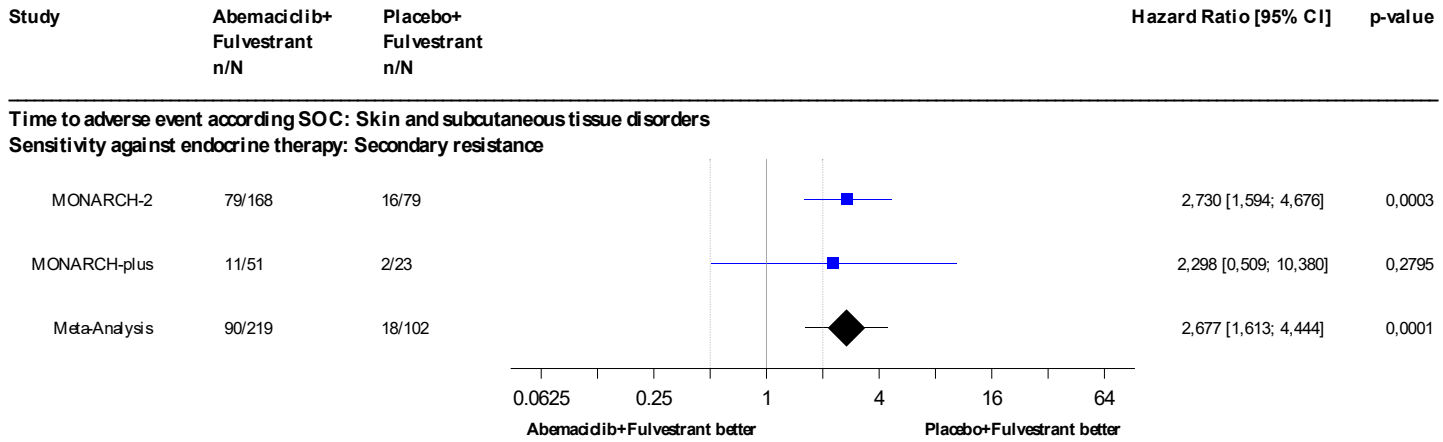
Figure 1270.1.8.2: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0445, p-value=0,8329, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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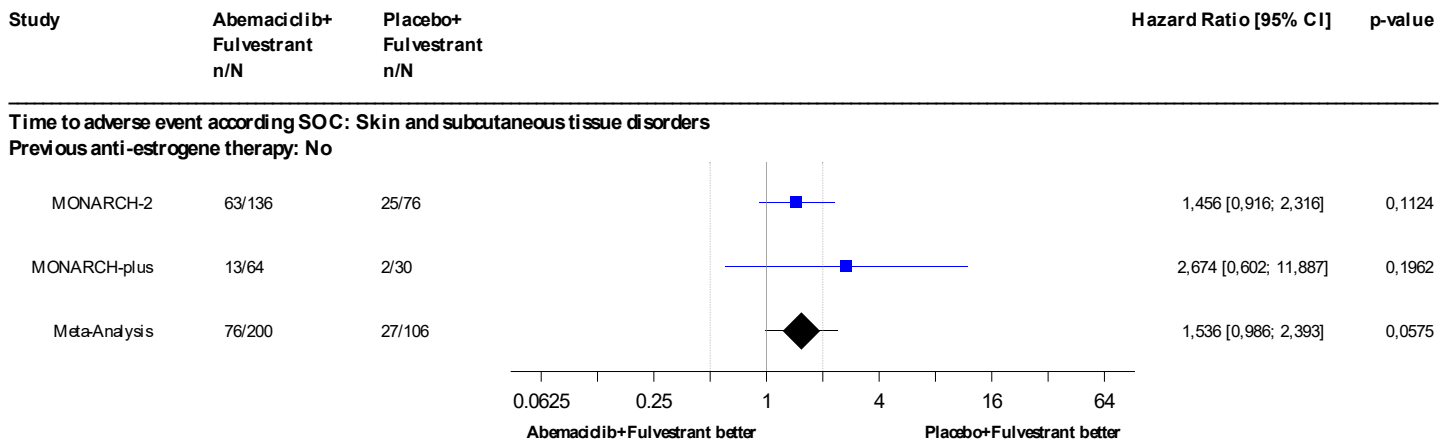
Figure 1270.1.9.1: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5814, p-value=0,4457, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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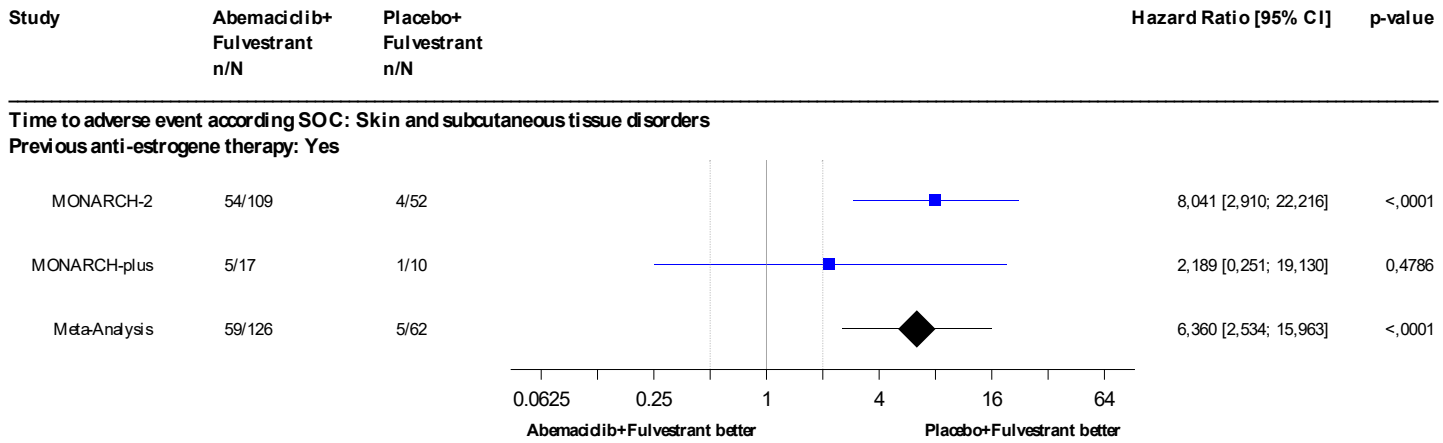
Figure 1270.1.9.2: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,1344, p-value=0,2868, I2 index=11,8%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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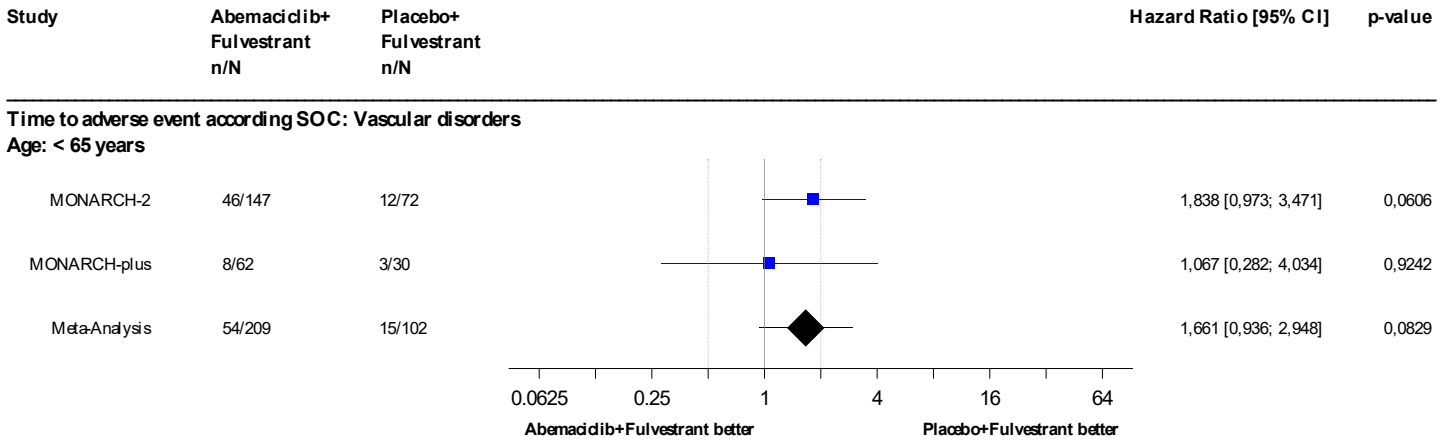
Figure 1272.1.1.1: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5232, p-value=0,4695, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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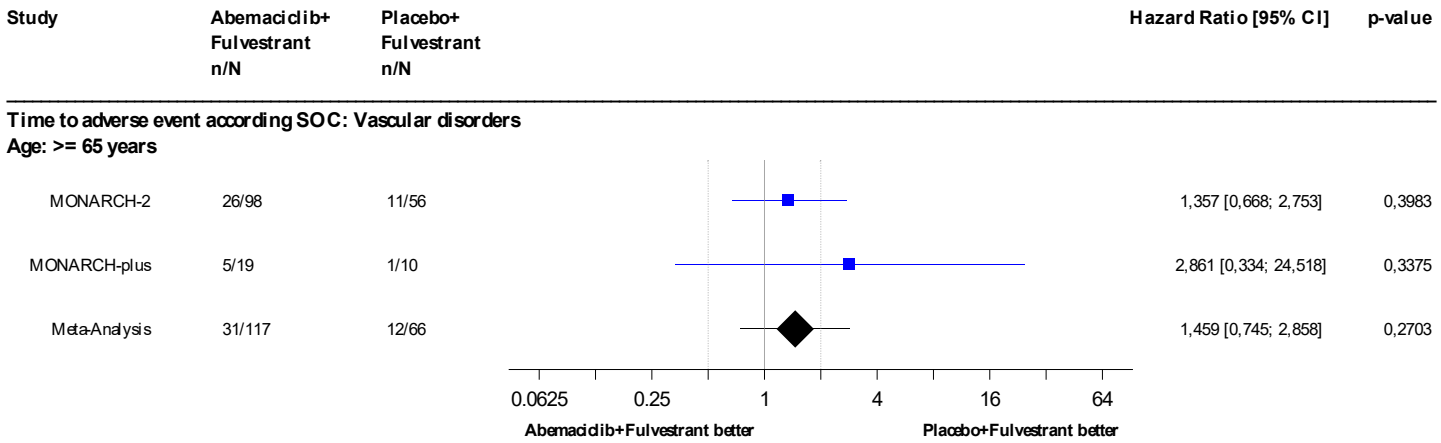
Figure 1272.1.1.2: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4181, p-value=0,5179, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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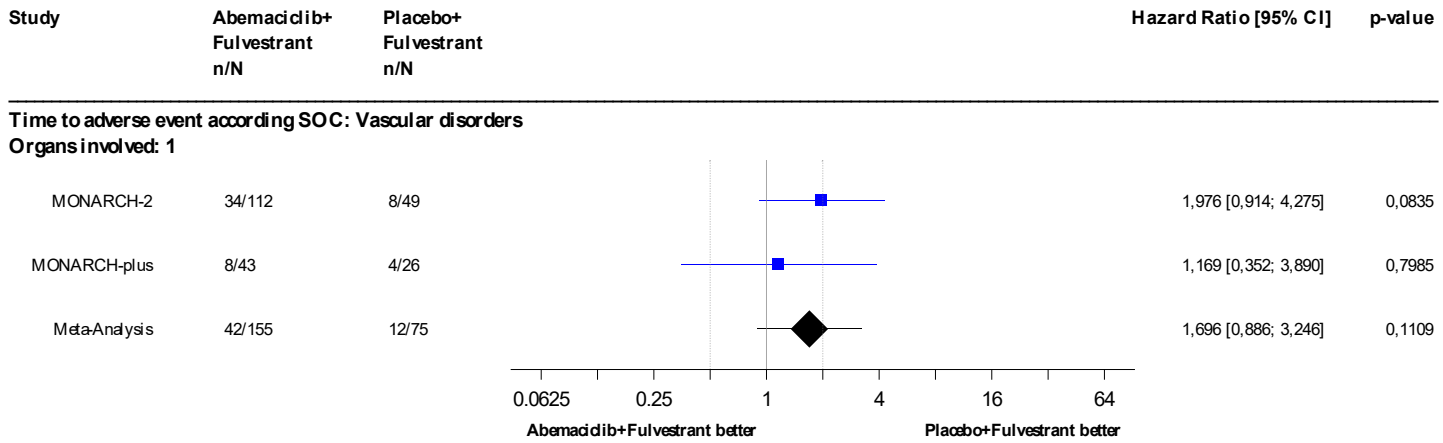
Figure 1272.1.2.1: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5185, p-value=0,4715, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes022_popa1_norggr_1.rtf
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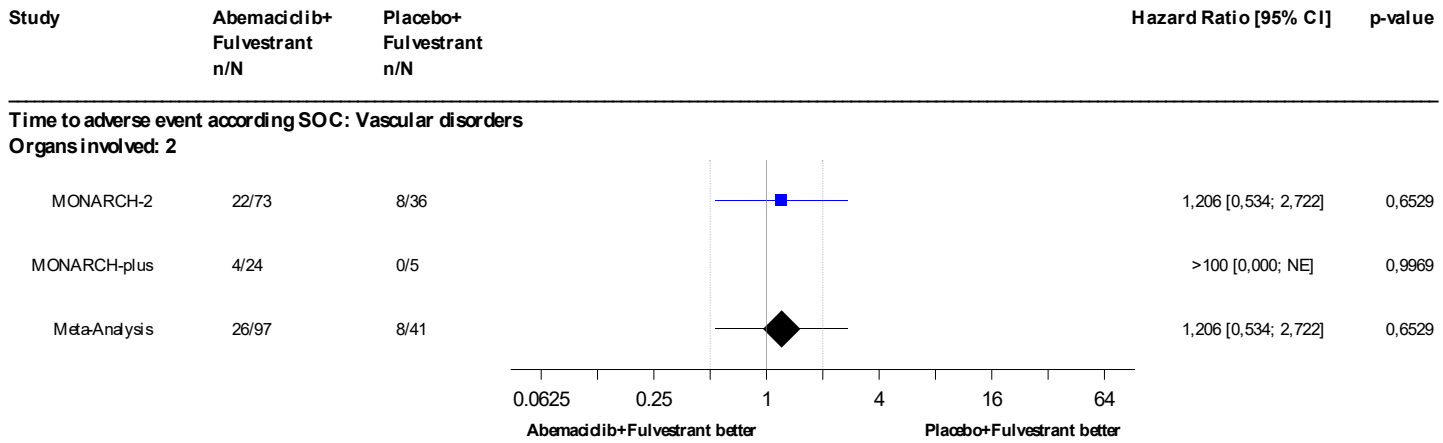
Figure 1272.1.2.2: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9970, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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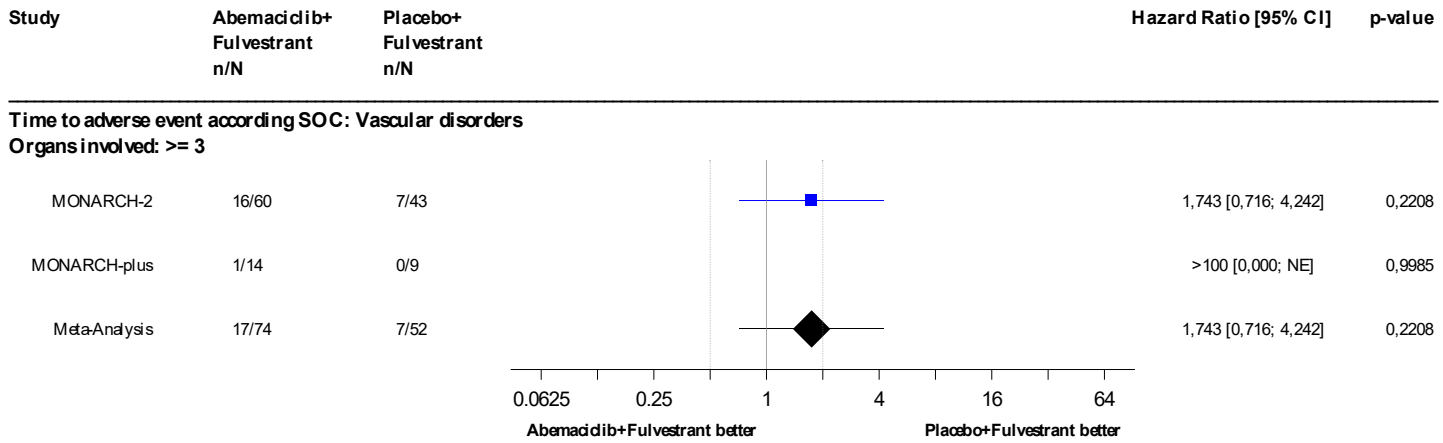
Figure 1272.1.2.3: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes022_popa1_norggr_3.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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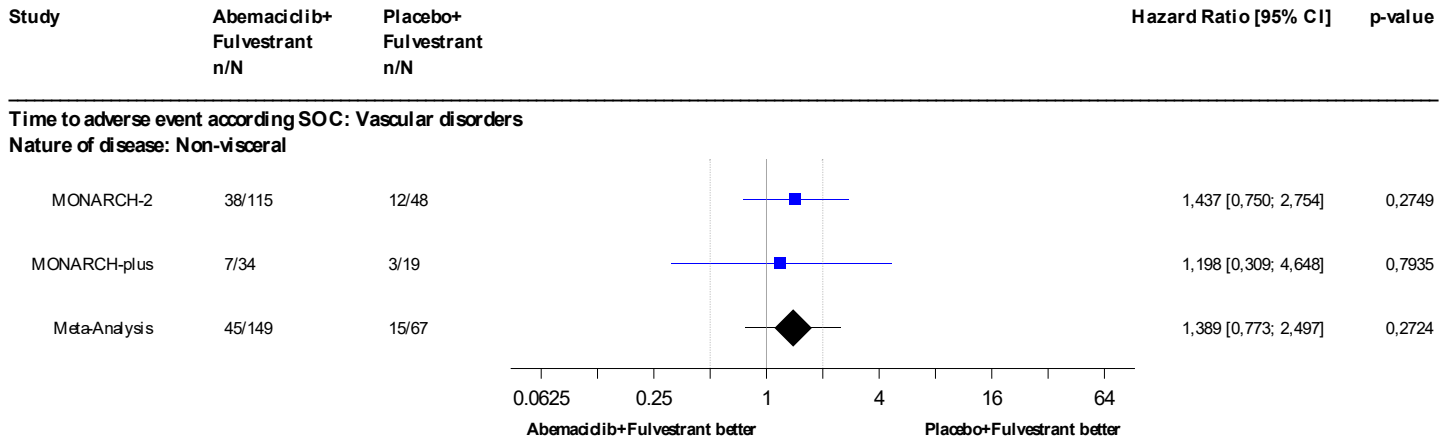
Figure 1272.1.3.1: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0559, p-value=0,8131, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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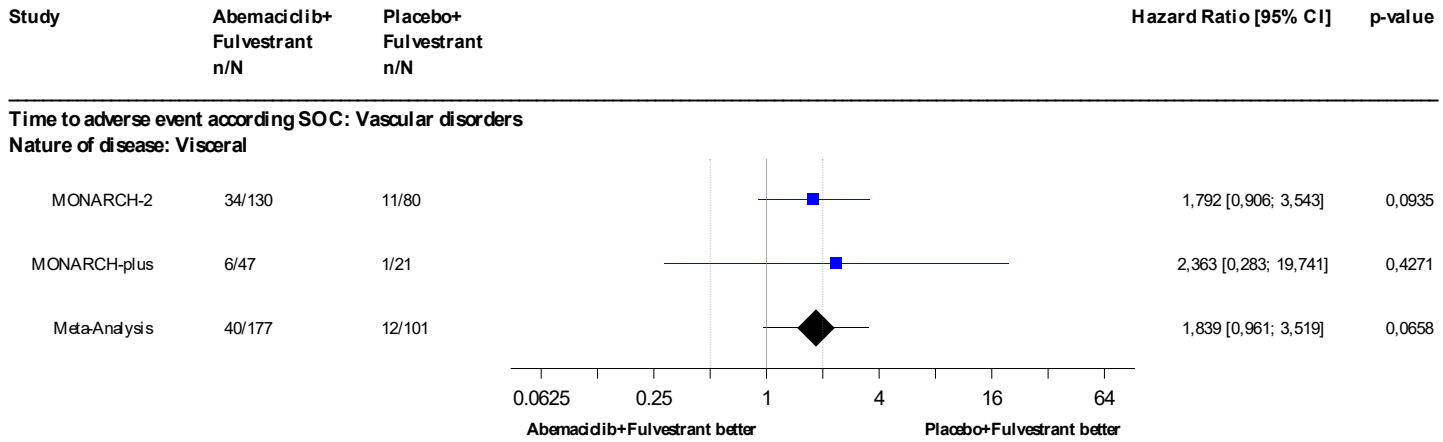
Figure 1272.1.3.2: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0592, p-value=0,8078, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes022_popa1_natdis2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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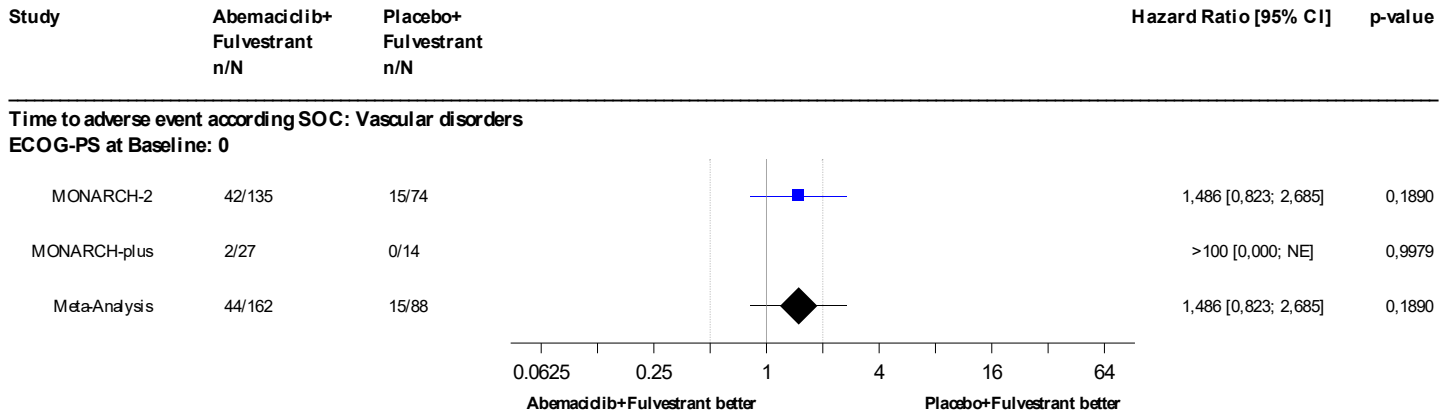
Figure 1272.1.4.1: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes022_popa1_ecogbl_1.rtf
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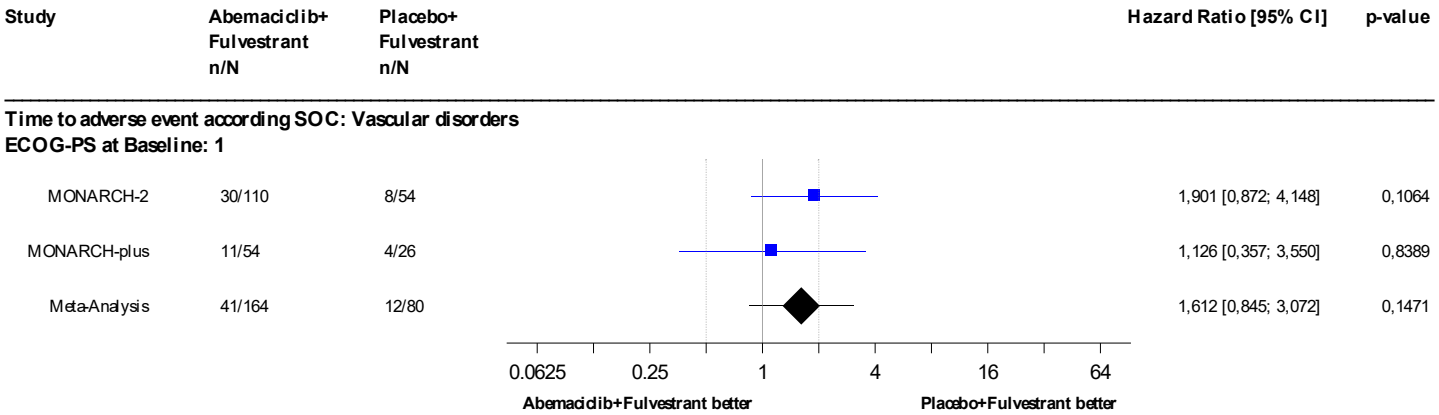
Figure 1272.1.4.2: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5467, p-value=0,4597, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes022_popa1_ecogbl_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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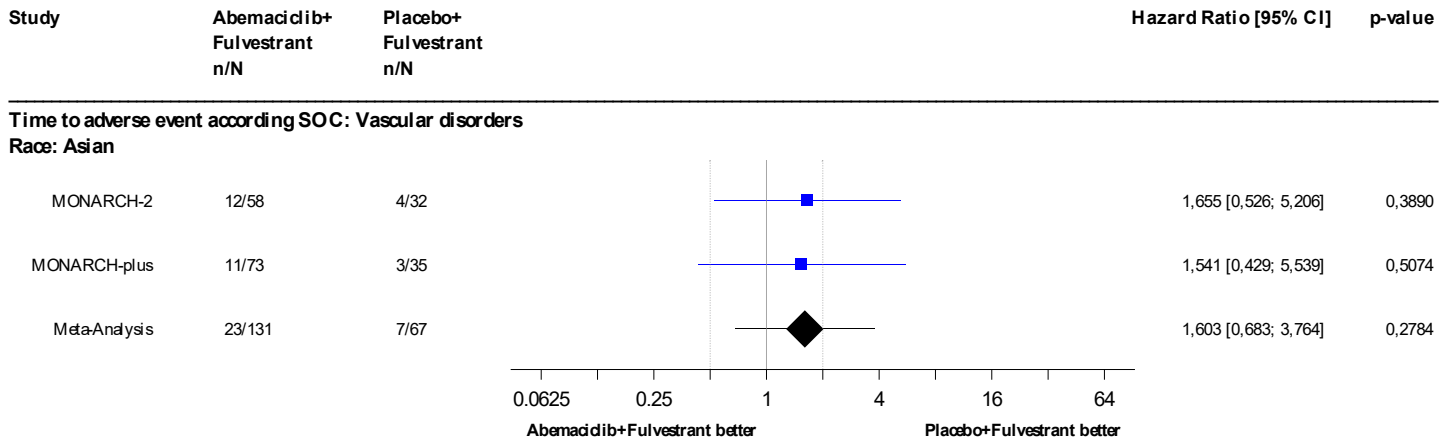
Figure 1272.1.5.1: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0066, p-value=0,9353, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes022_popa1_racegr1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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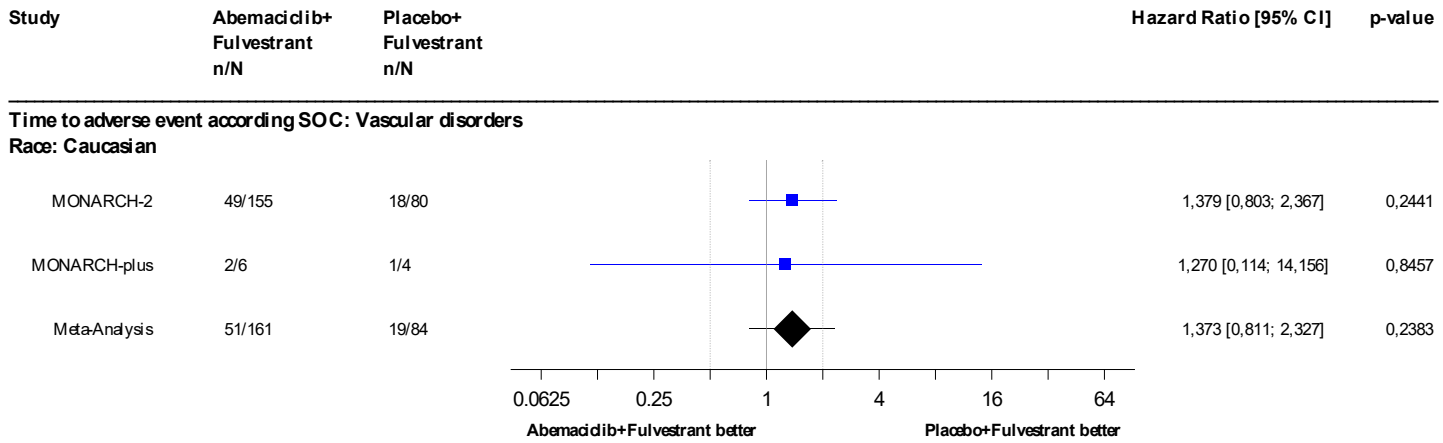
Figure 1272.1.5.2: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0042, p-value=0,9483, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes022_popa1_racegr1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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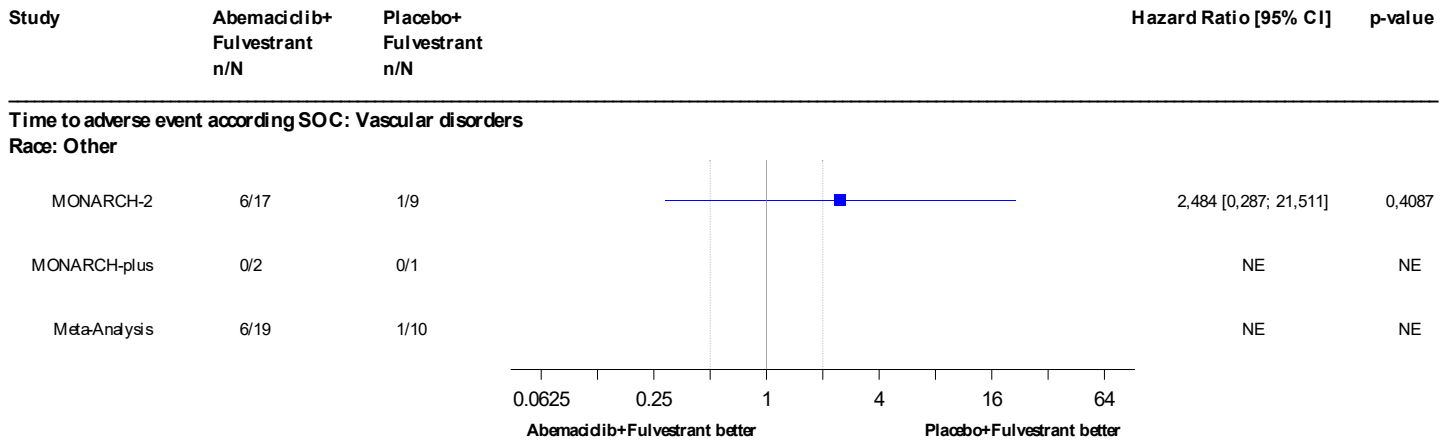
Figure 1272.1.5.3: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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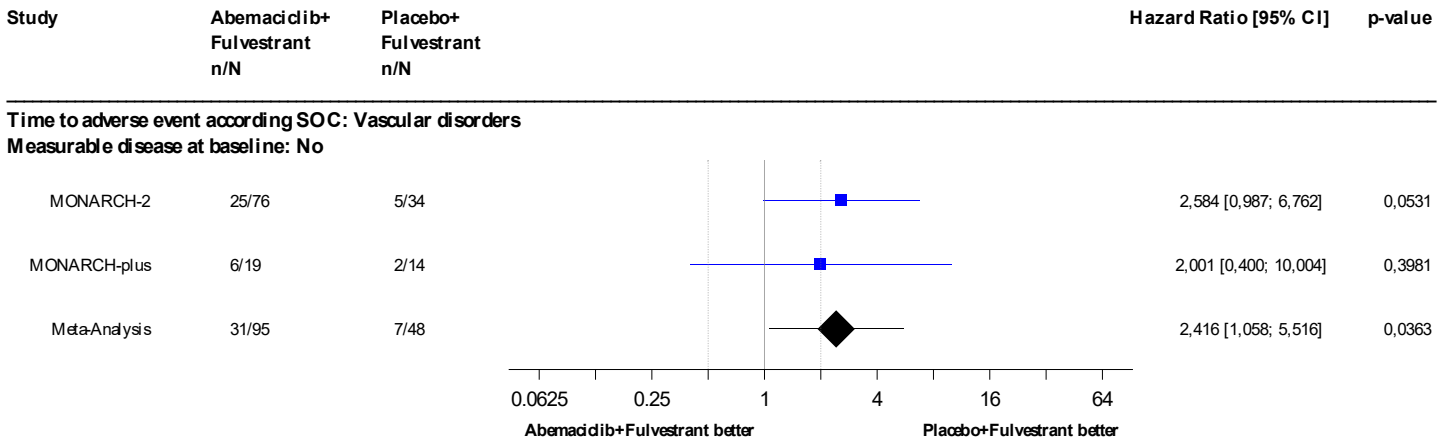
Figure 1272.1.6.1: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0714, p-value=0,7894, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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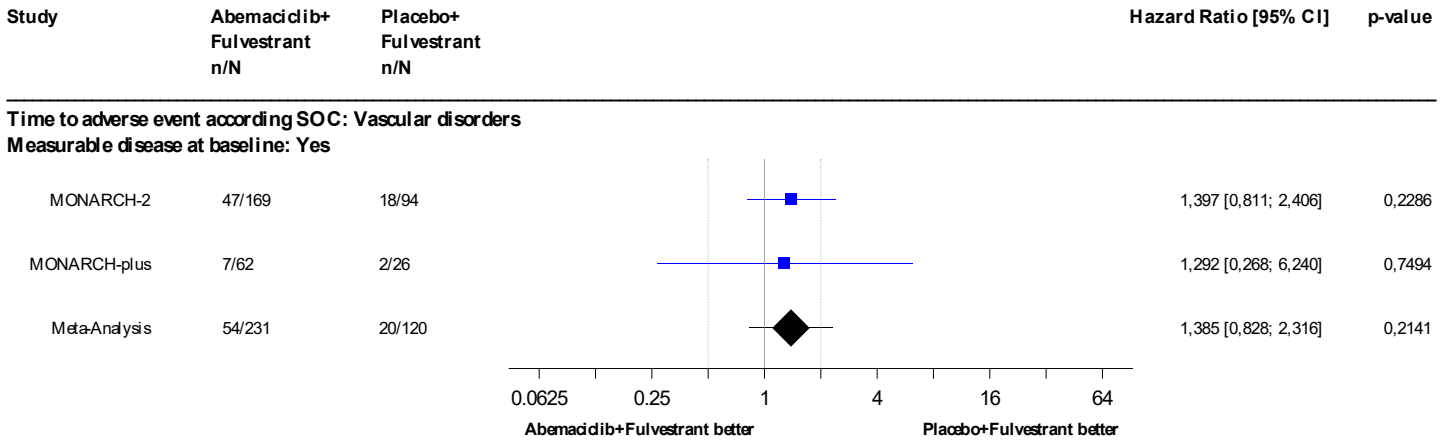
Figure 1272.1.6.2: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0083, p-value=0,9272, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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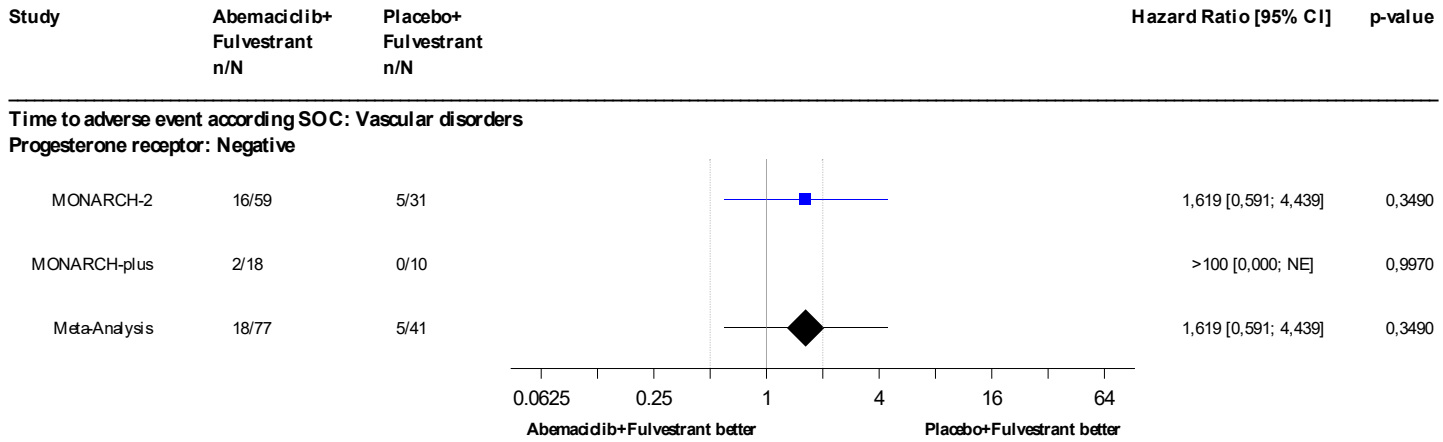
Figure 1272.1.7.1: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9970, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes022_popa1_pgrstat_1.rtf
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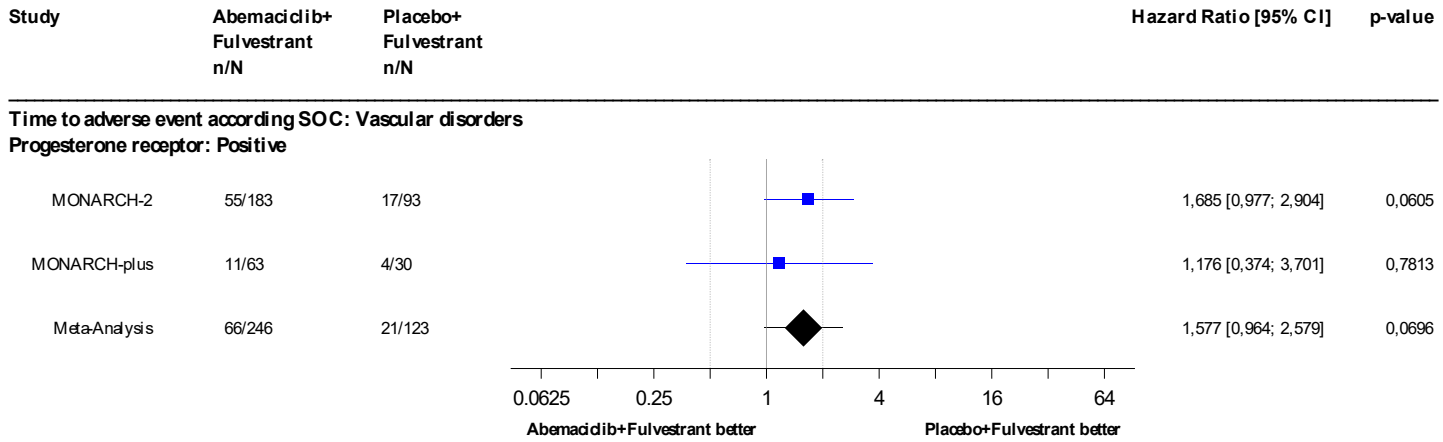
Figure 1272.1.7.2: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3078, p-value=0,5791, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes022_popa1_pgrstat_2.rtf
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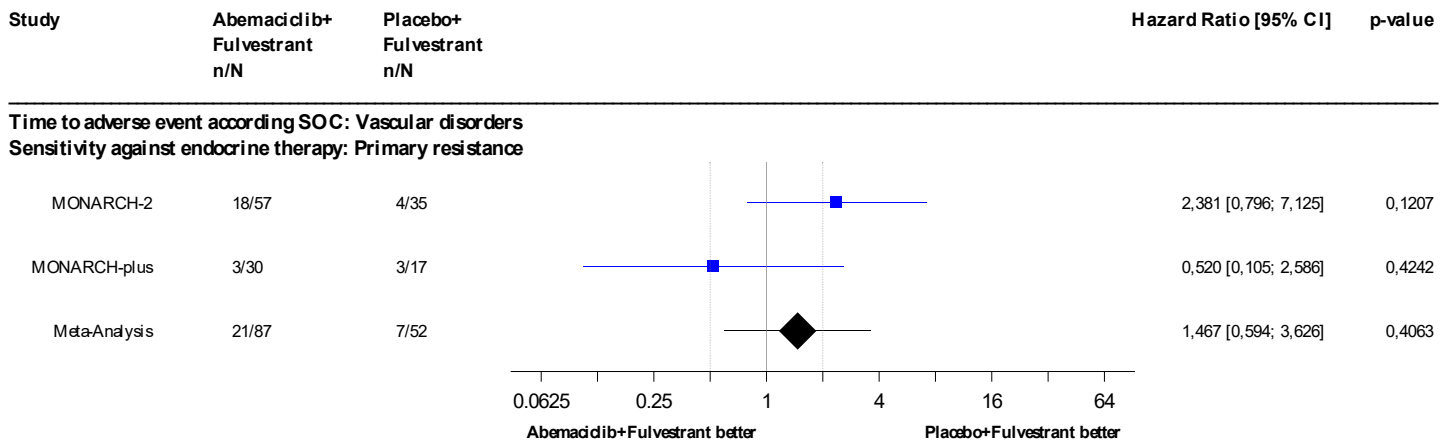
Figure 1272.1.8.1: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,3569, p-value=0,1247, I2 index=57,6%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes022_popa1_snthr_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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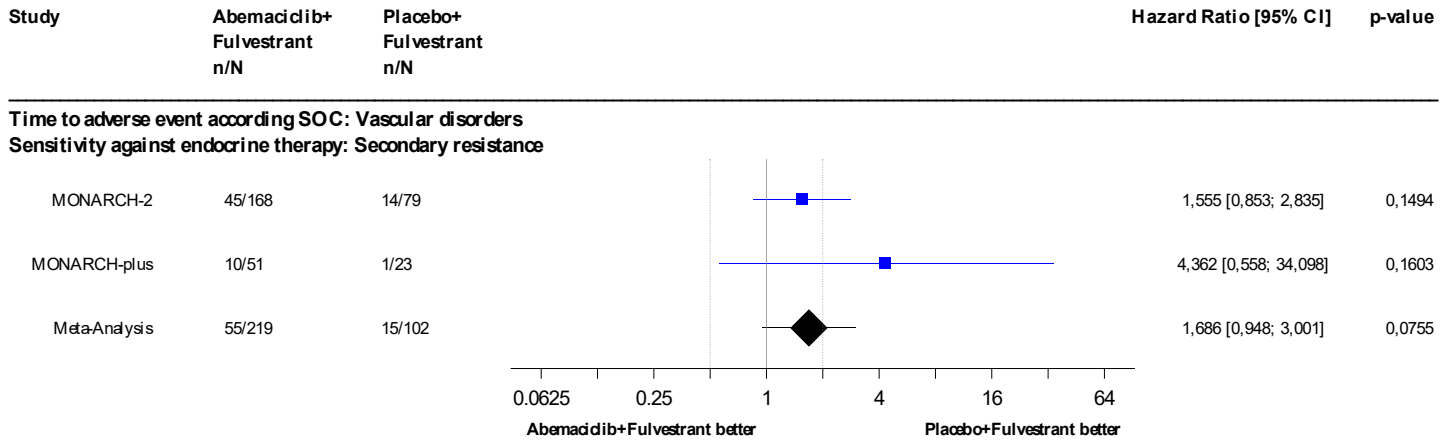
Figure 1272.1.8.2: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,8904, p-value=0,3454, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes022_popa1_snthr_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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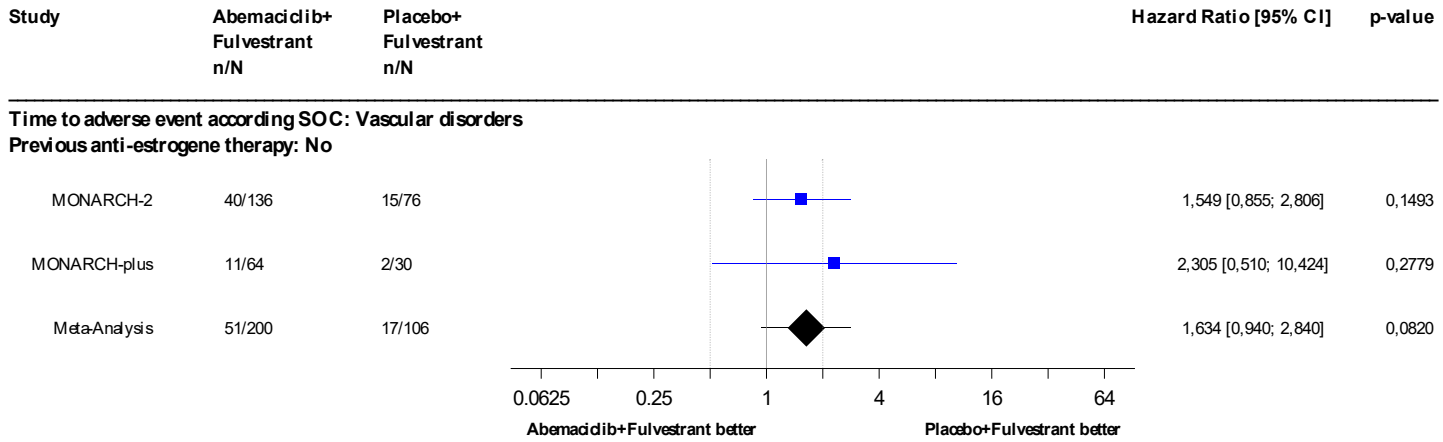
Figure 1272.1.9.1: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2312, p-value=0,6306, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes022_popa1_paet_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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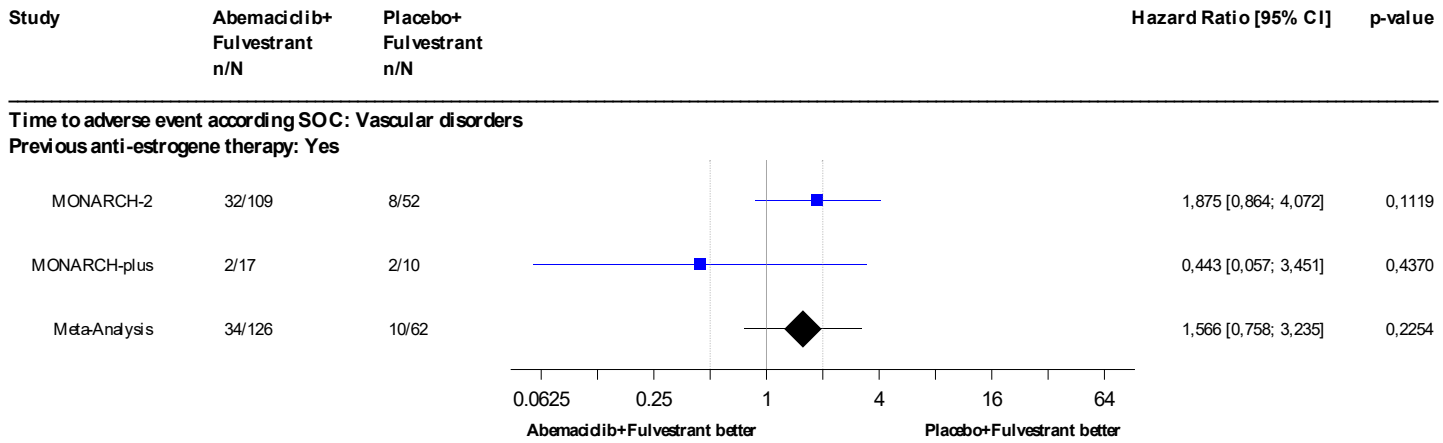
Figure 1272.1.9.2: Metaanalysis results for adverse events according SOC[1] -
Vascular disorders
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,6609, p-value=0,1975, I2 index=39,8%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes022_popa1_paet_2.rtf
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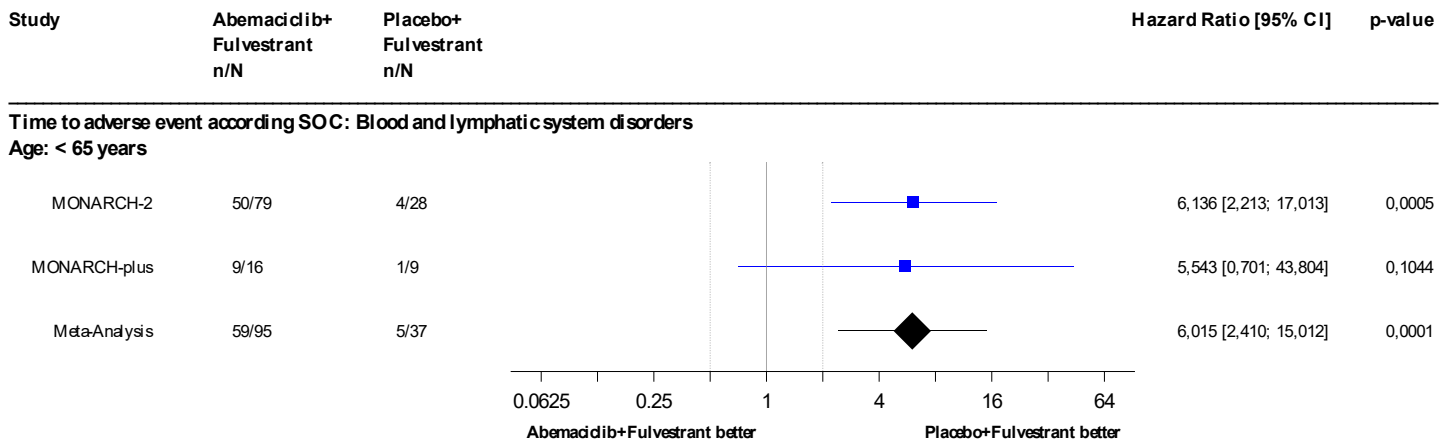
Figure 1273.2.1.1: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0075, p-value=0,9311, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes001_popa2_agegr1_1.rtf
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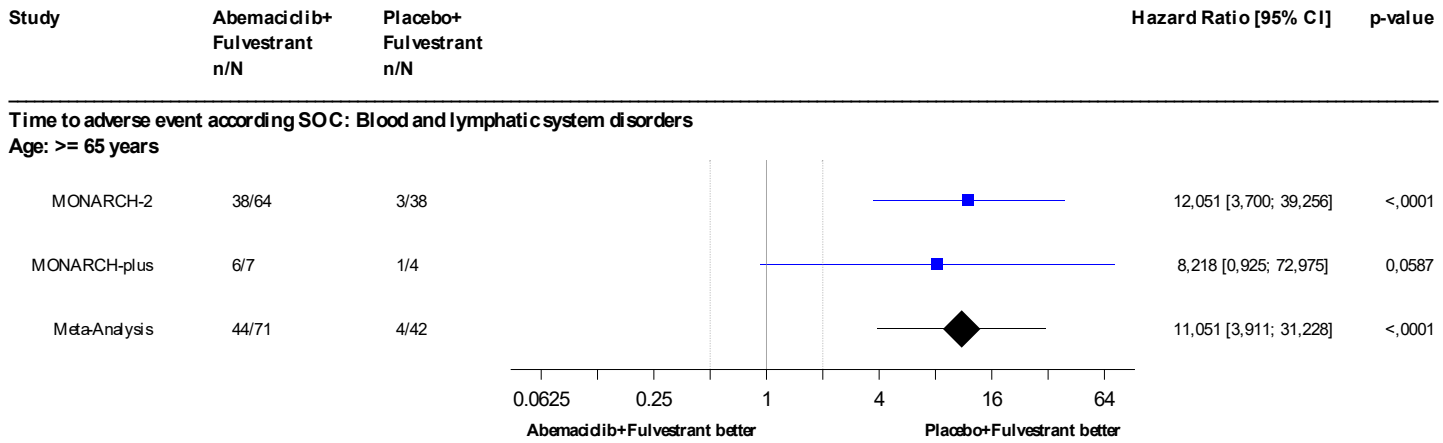
Figure 1273.2.1.2: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0914, p-value=0,7624, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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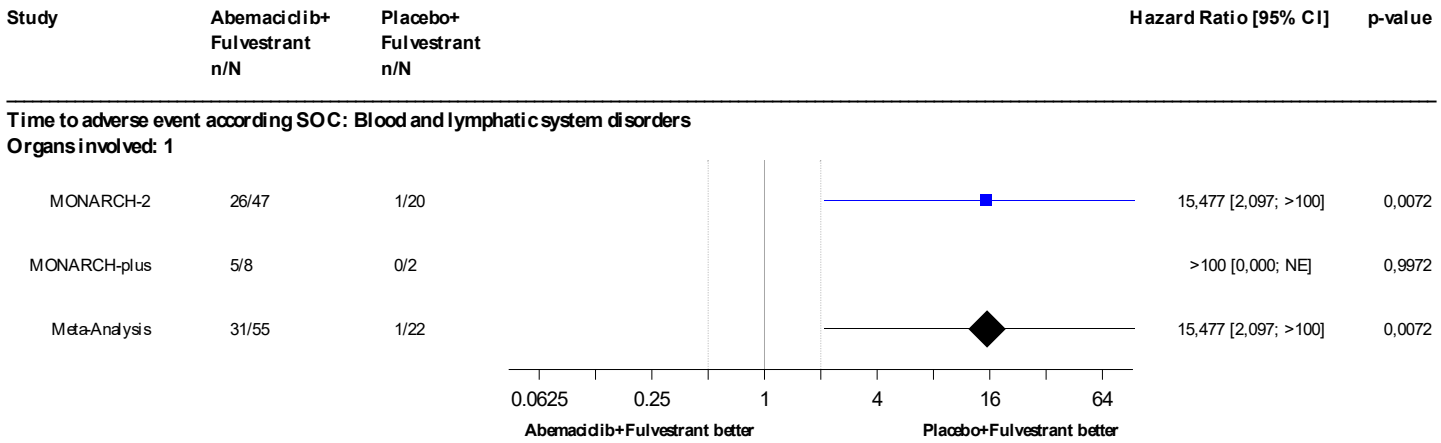
Figure 1273.2.2.1: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9976, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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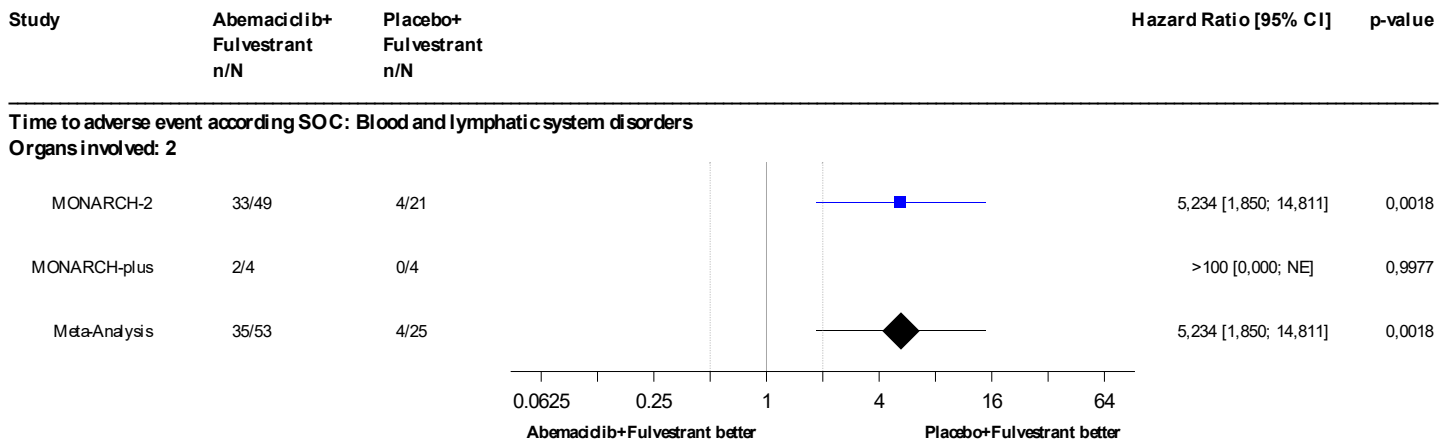
Figure 1273.2.2.2: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9979, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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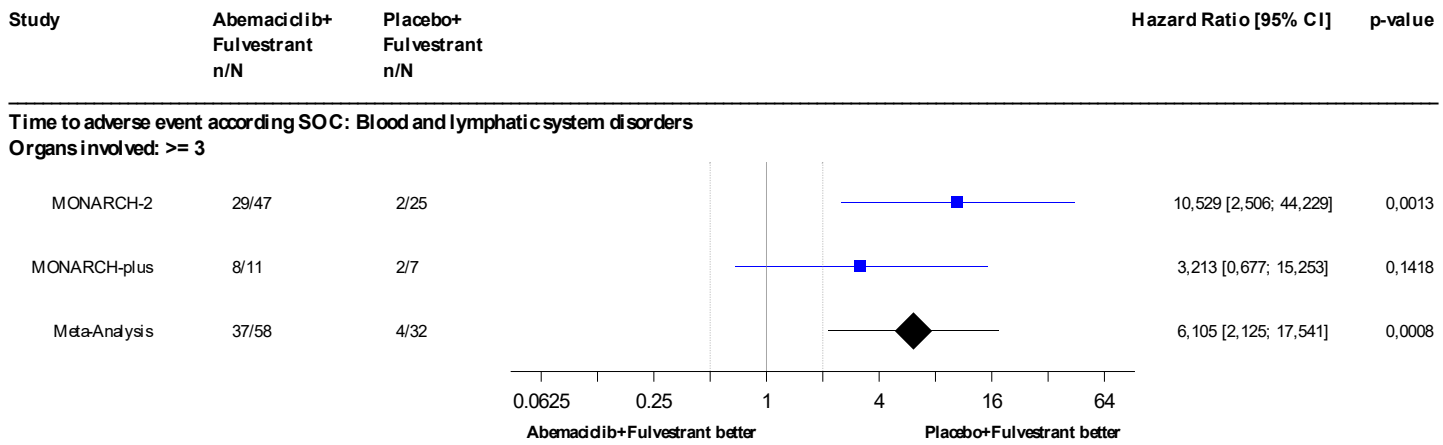
Figure 1273.2.2.3: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,2062, p-value=0,2721, I2 index=17,1%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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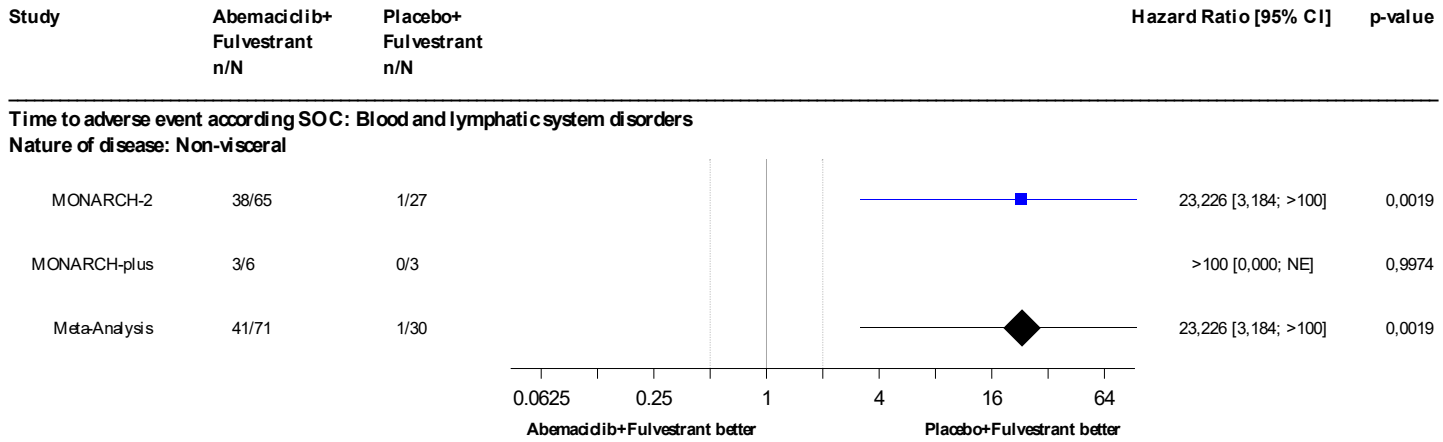
Figure 1273.2.3.1: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9978, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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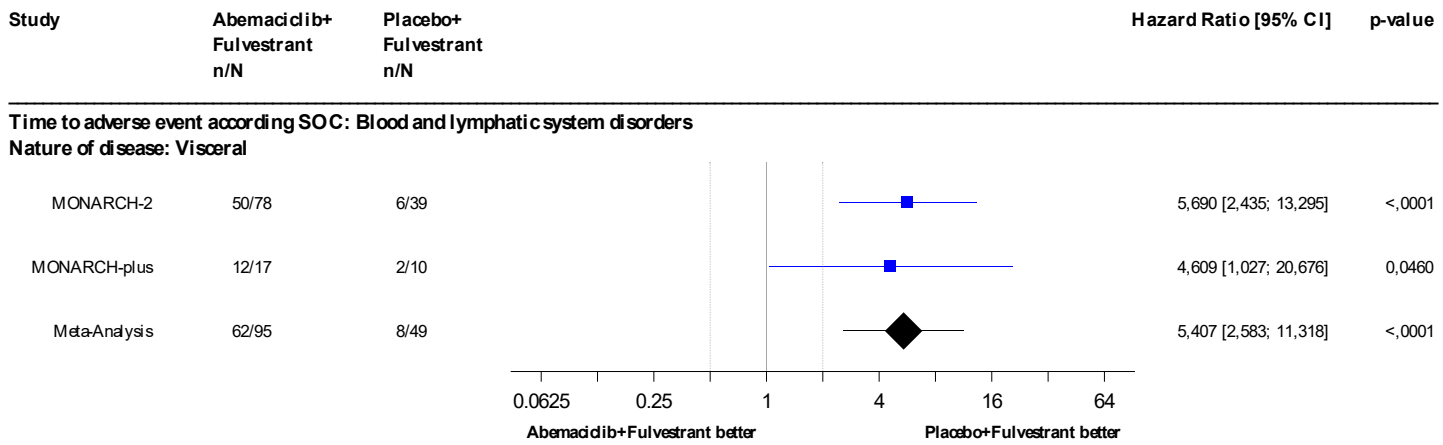
Figure 1273.2.3.2: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0574, p-value=0,8107, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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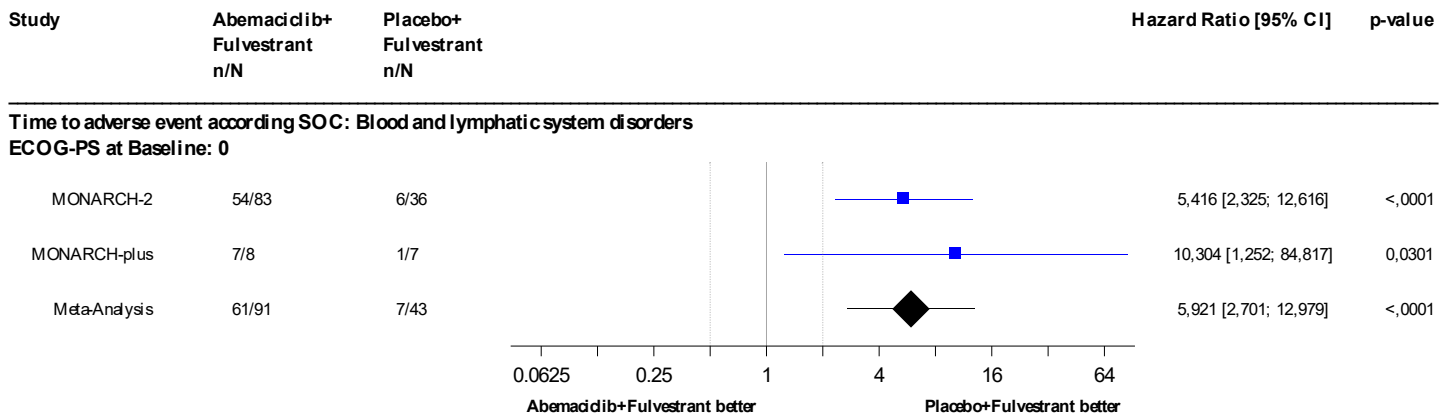
Figure 1273.2.4.1: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3081, p-value=0,5788, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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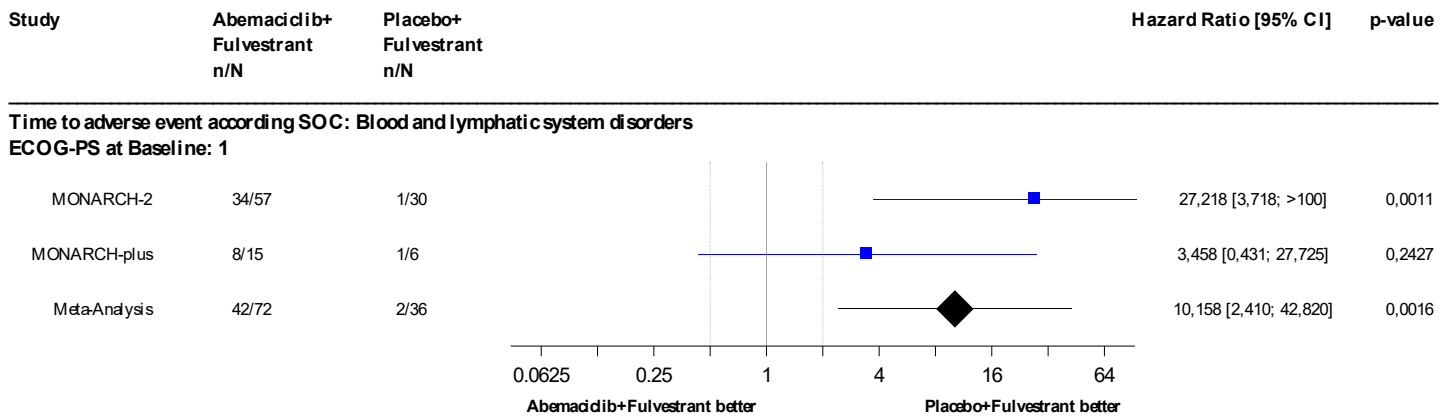
Figure 1273.2.4.2: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,9709, p-value=0,1604, I2 index=49,3%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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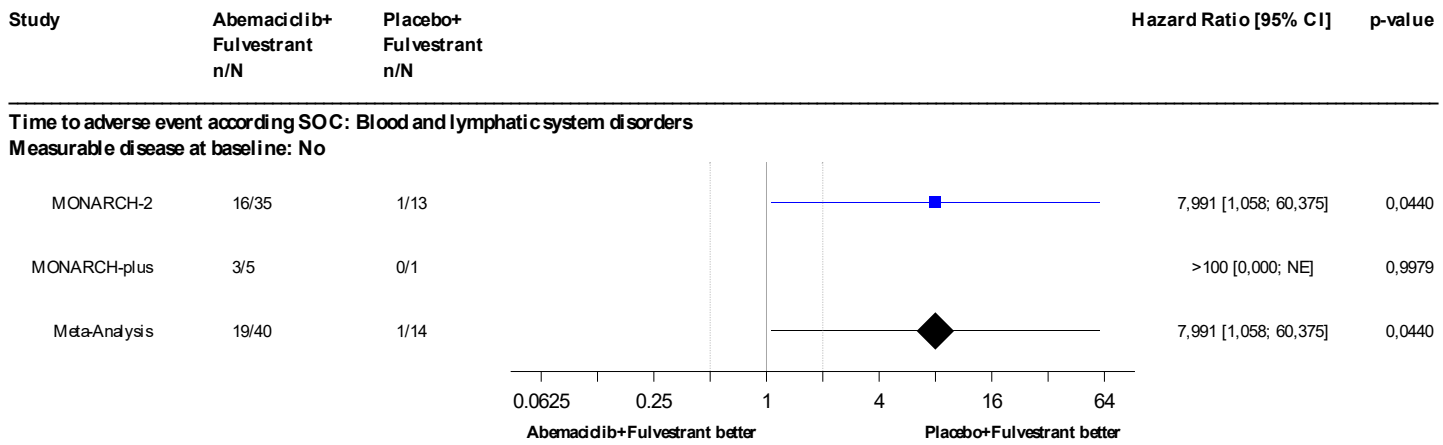
Figure 1273.2.6.1: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9982, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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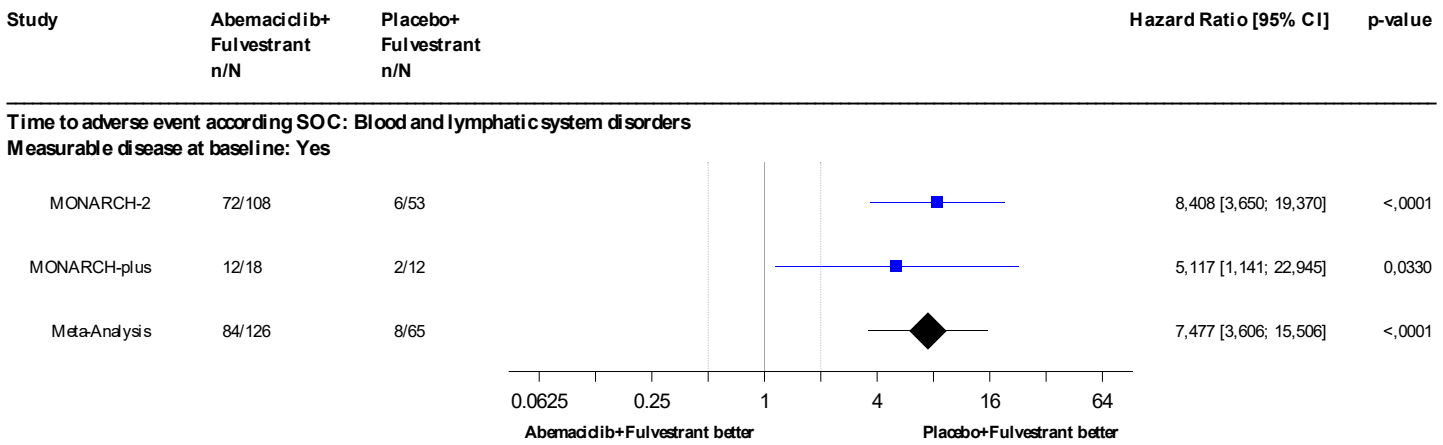
Figure 1273.2.6.2: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3214, p-value=0,5708, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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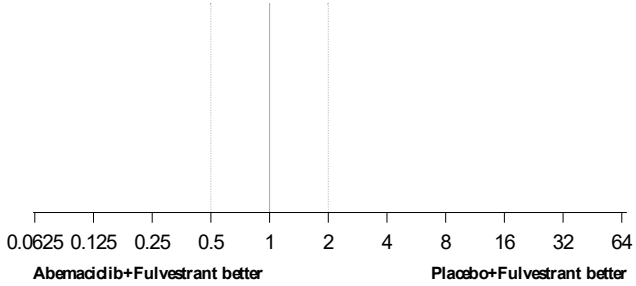
Figure 1273.2.7.1: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)

Study	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% CI]	p-value
Time to adverse event according SOC: Blood and lymphatic system disorders				
Progesterone receptor: Negative				
MONARCH-2	17/23	0/12	>100 [0,000; NE]	0,9934
MONARCH-plus	5/6	0/1	>100 [0,000; NE]	0,9973
Meta-Analysis	22/29	0/13	>100 [0,000; NE]	0,9929



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9999, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes001_popa2_pgrstat_1.rtf
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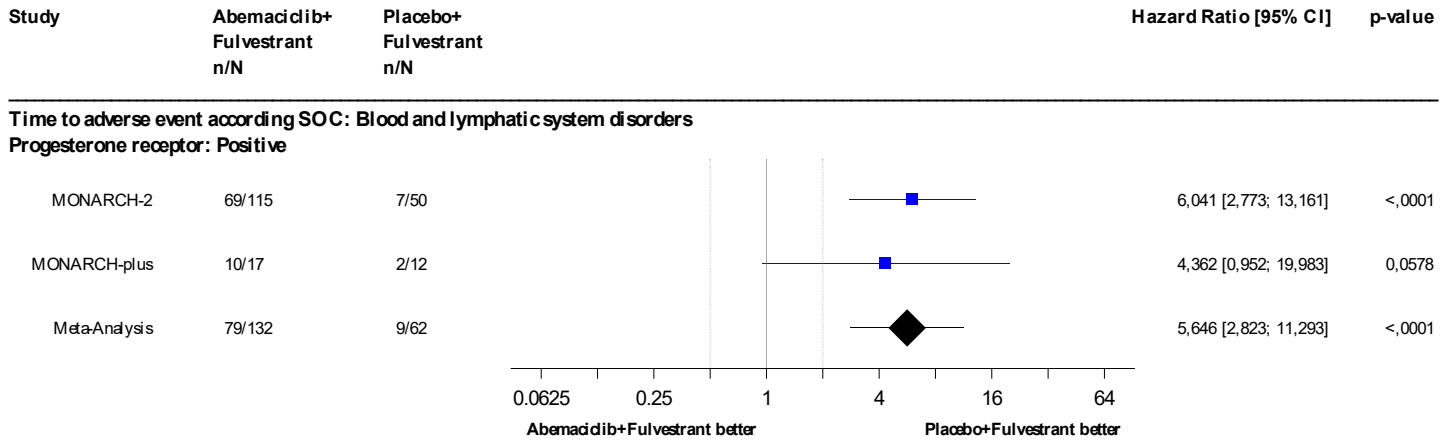
Figure 1273.2.7.2: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1393, p-value=0,7090, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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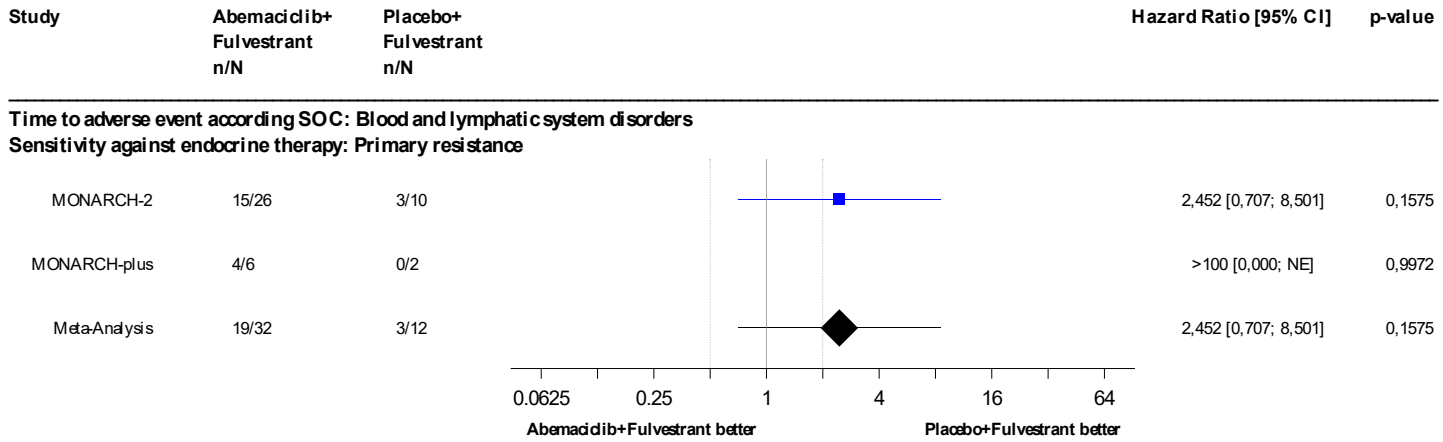
Figure 1273.2.8.1: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9973, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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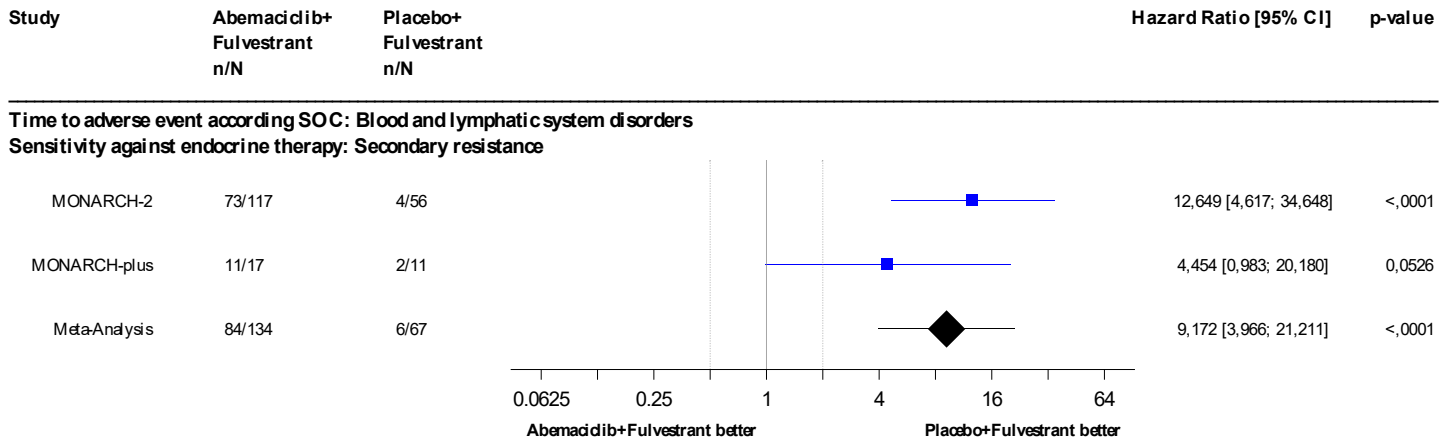
Figure 1273.2.8.2: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,2688, p-value=0,2600, I2 index=21,2%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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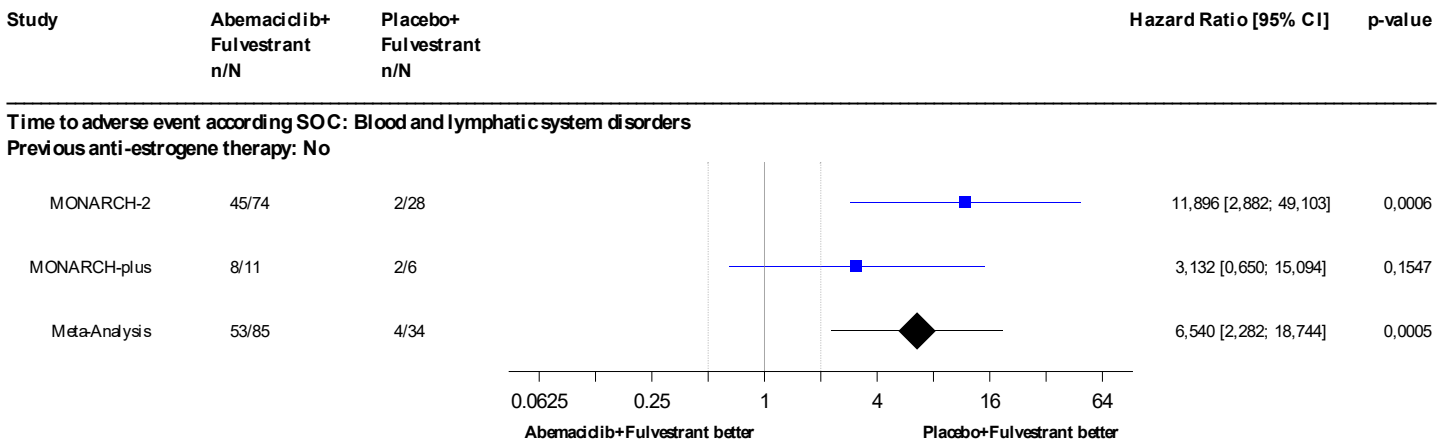
Figure 1273.2.9.1: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,5259, p-value=0,2167, I2 index=34,5%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes001_popa2_paet_1.rtf
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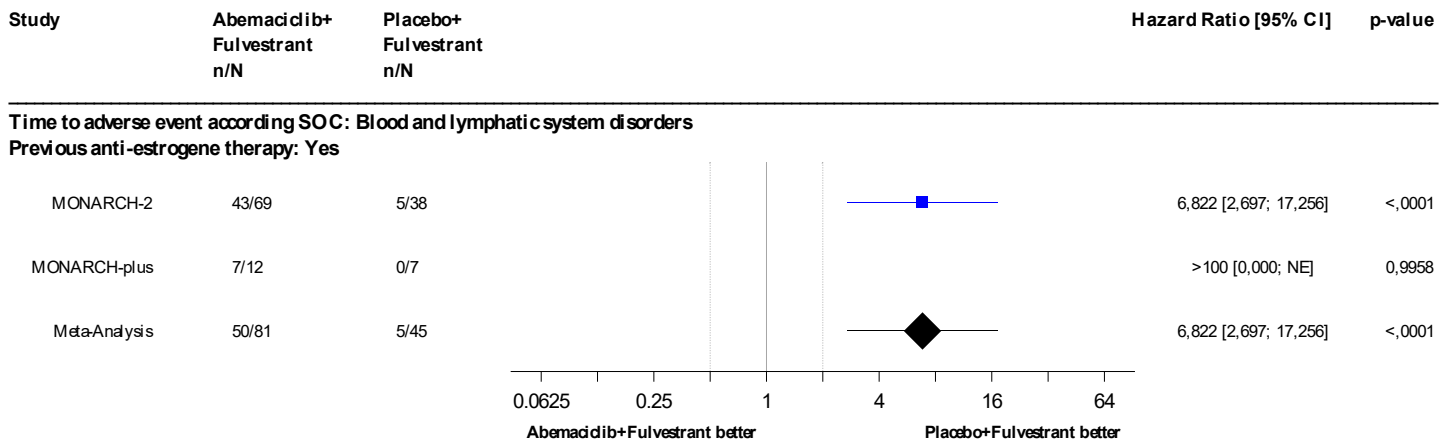
Figure 1273.2.9.2: Metaanalysis results for adverse events according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9963, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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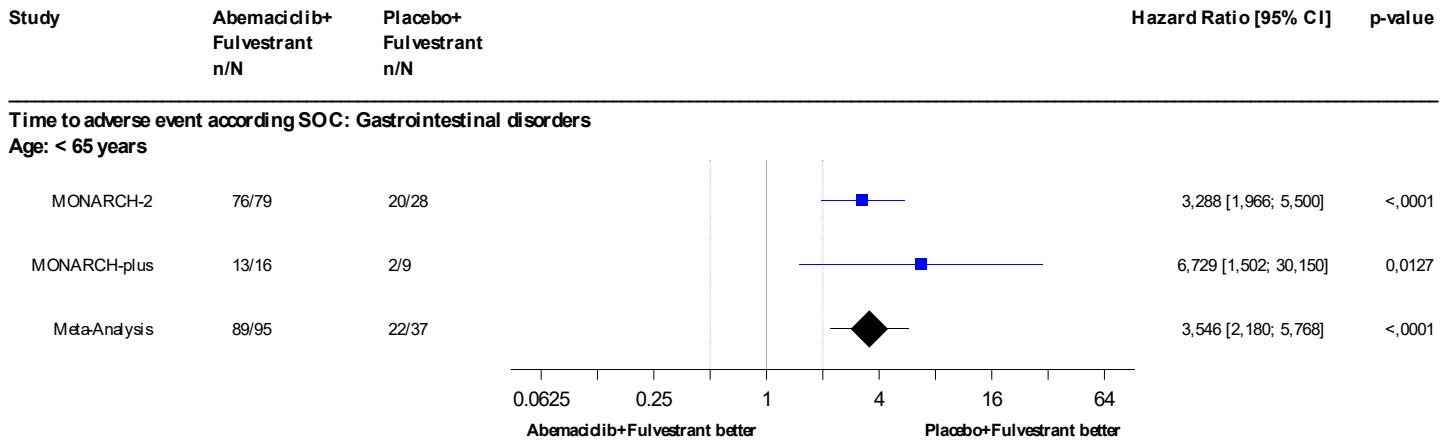
Figure 1276.2.1.1: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,7837, p-value=0,3760, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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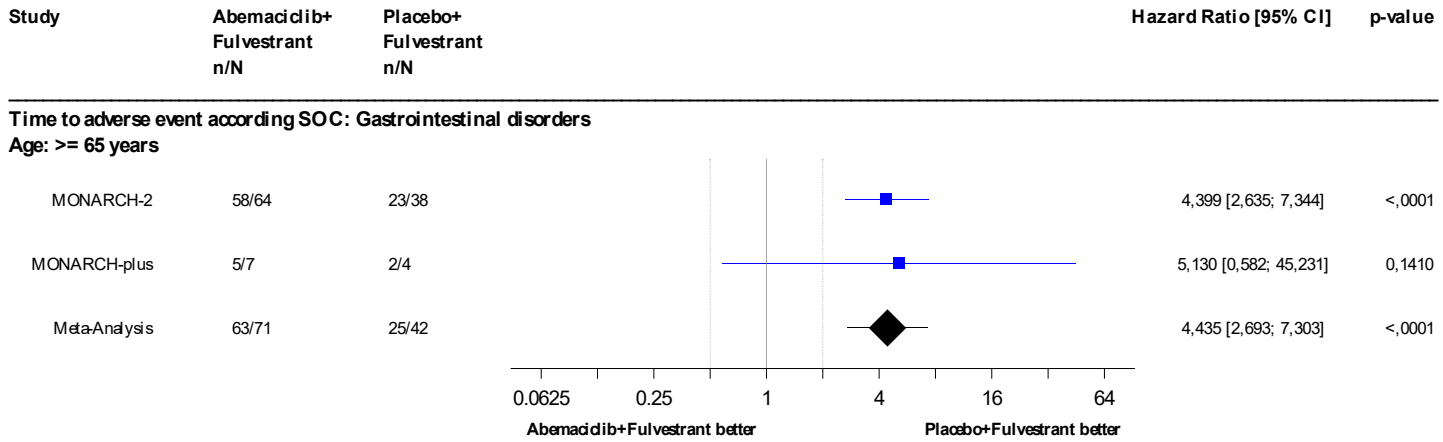
Figure 1276.2.1.2: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0181, p-value=0,8929, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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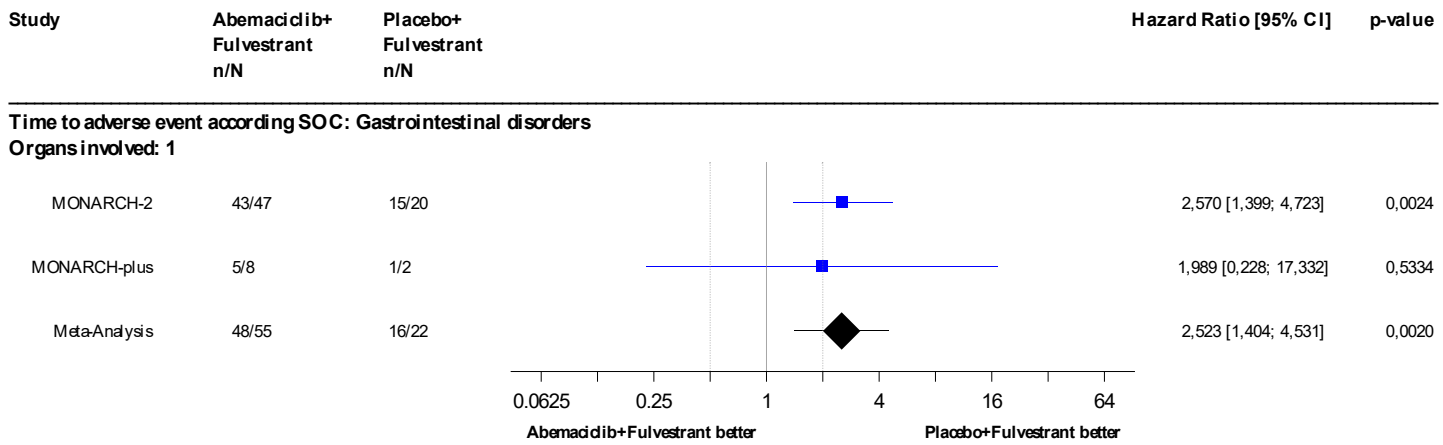
Figure 1276.2.2.1: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0499, p-value=0,8233, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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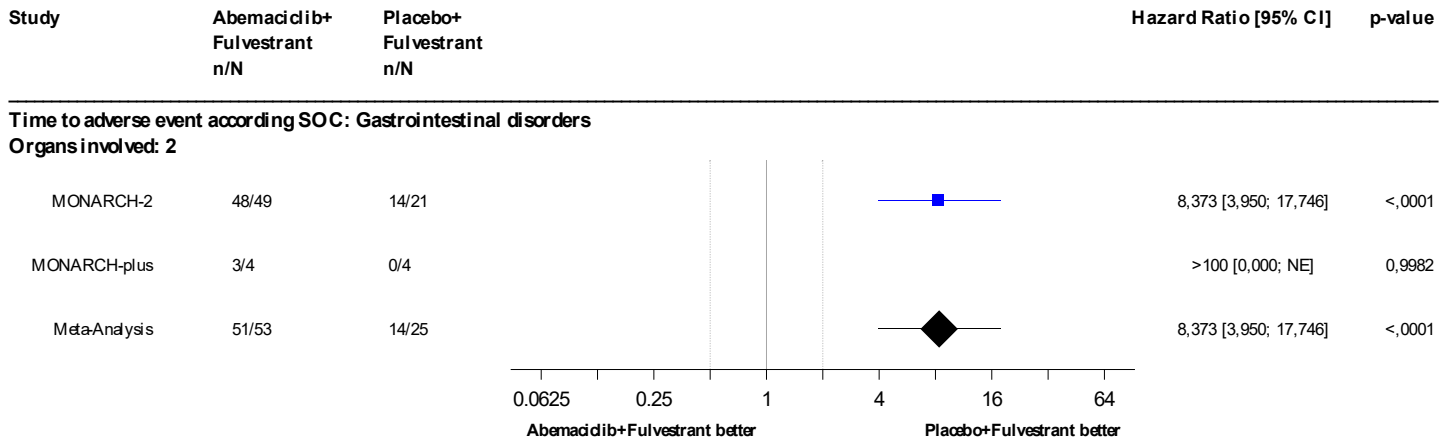
Figure 1276.2.2.2: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9984, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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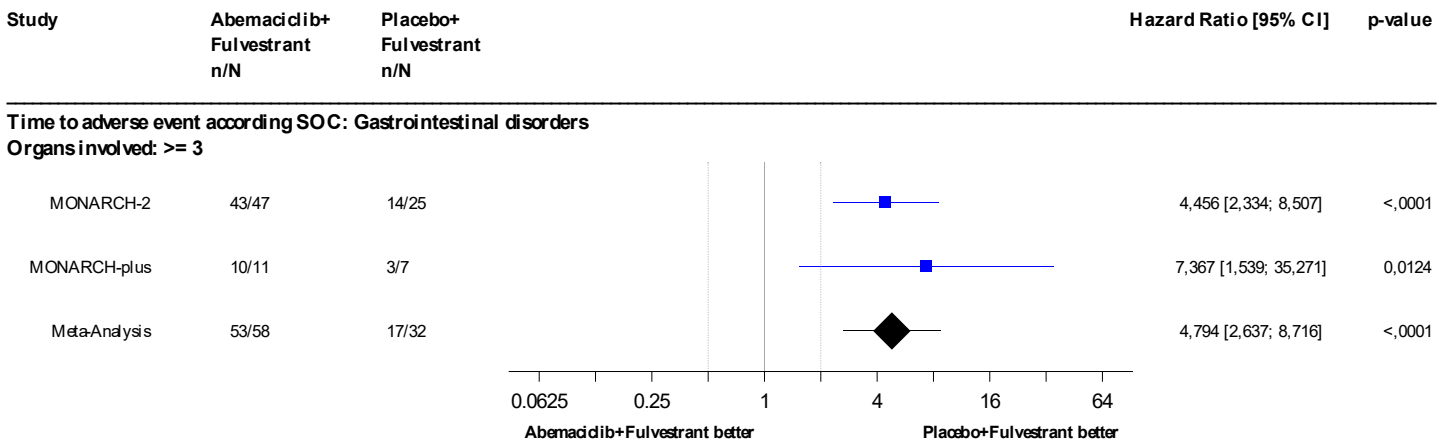
Figure 1276.2.2.3: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3385, p-value=0,5607, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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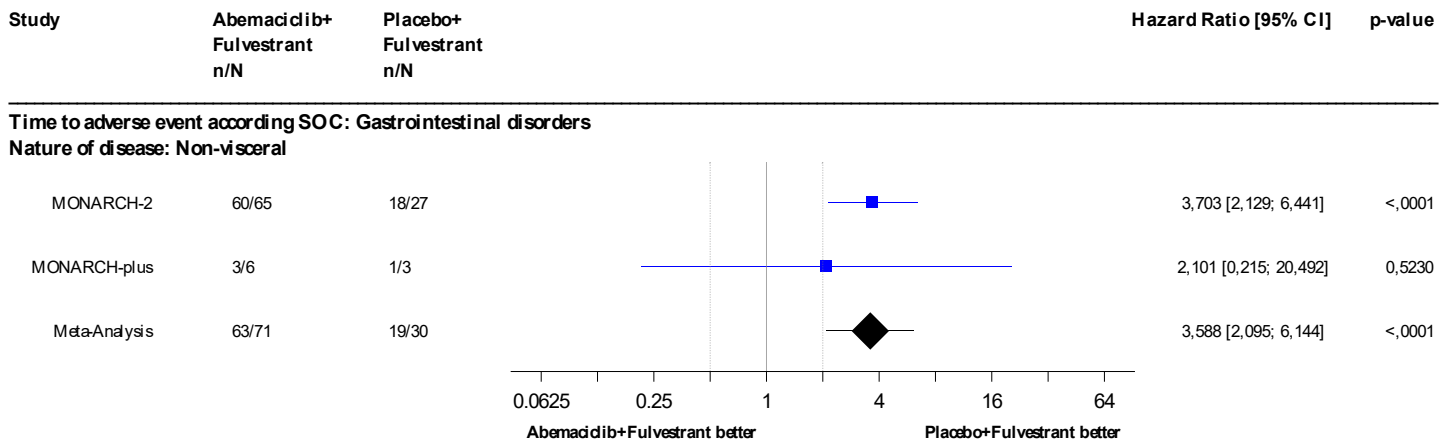
Figure 1276.2.3.1: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2246, p-value=0,6355, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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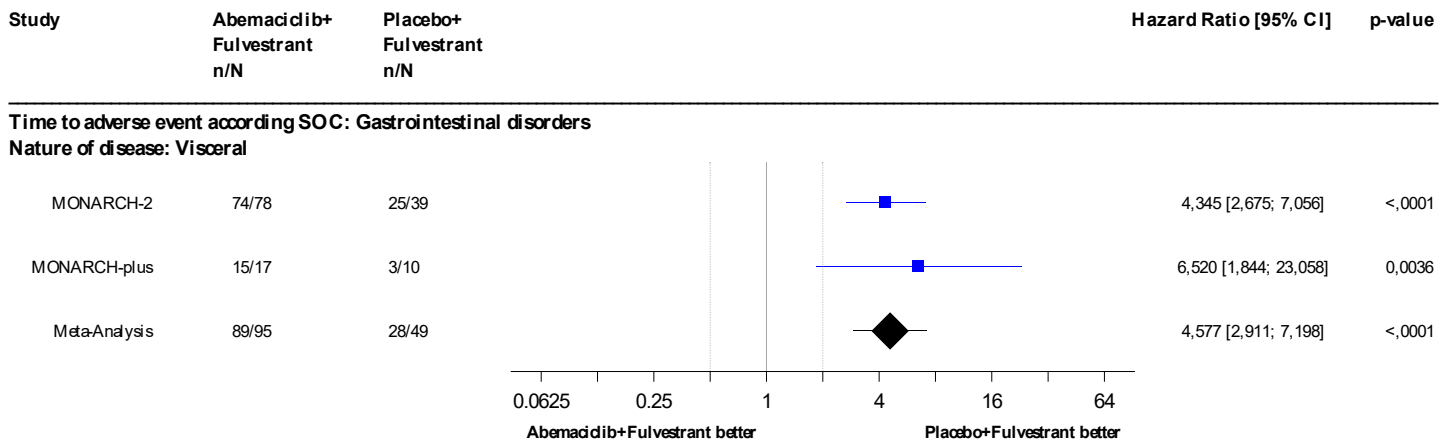
Figure 1276.2.3.2: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3460, p-value=0,5564, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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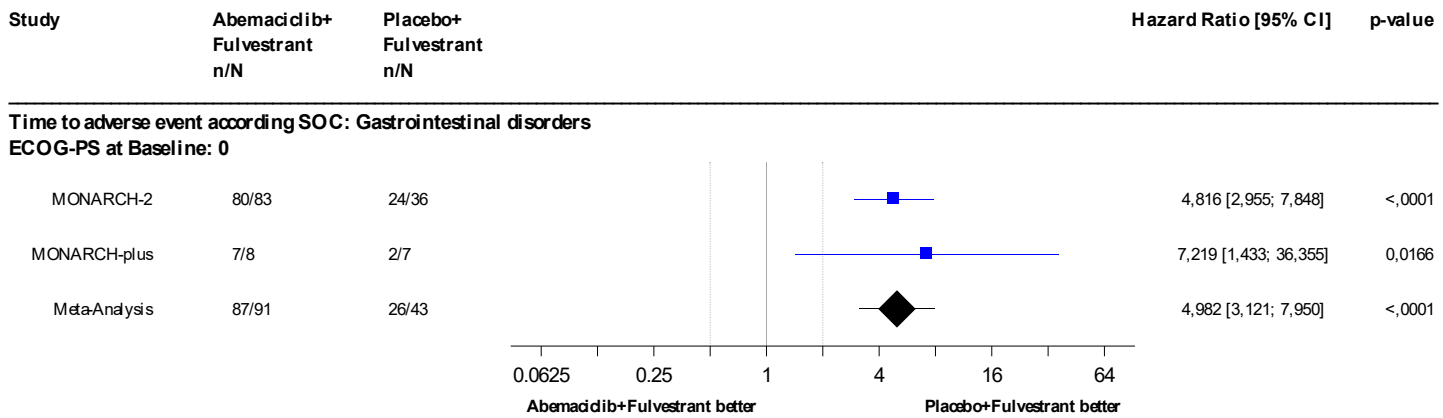
Figure 1276.2.4.1: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2207, p-value=0,6385, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes004_popa2_ecogbl_1.rtf
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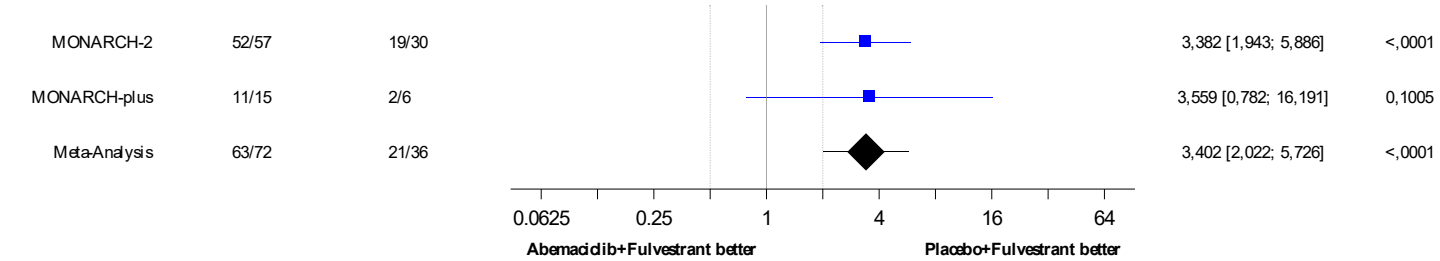
Figure 1276.2.4.2: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0039, p-value=0,9504, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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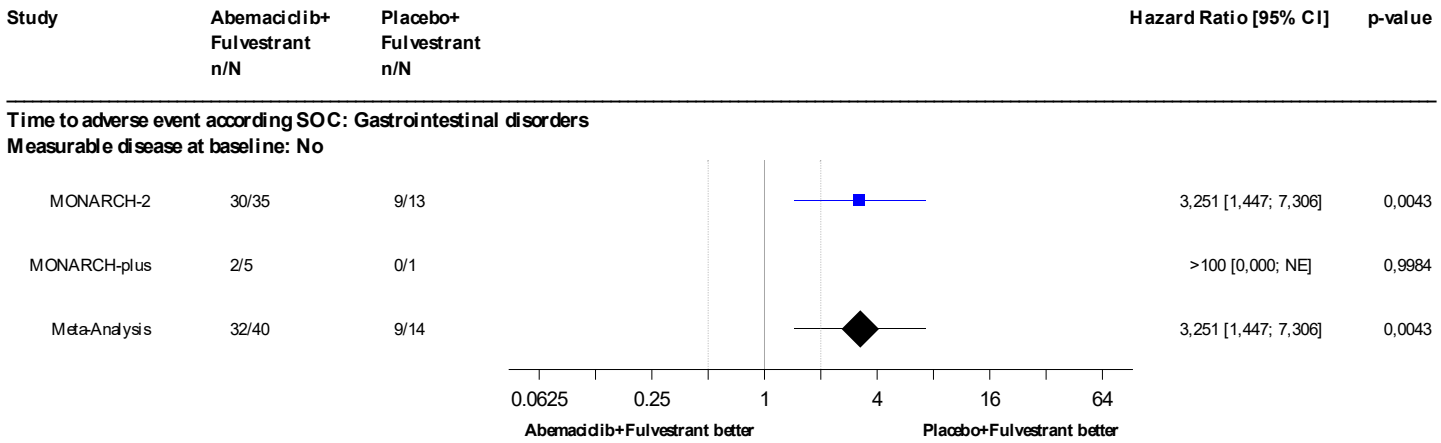
Figure 1276.2.6.1: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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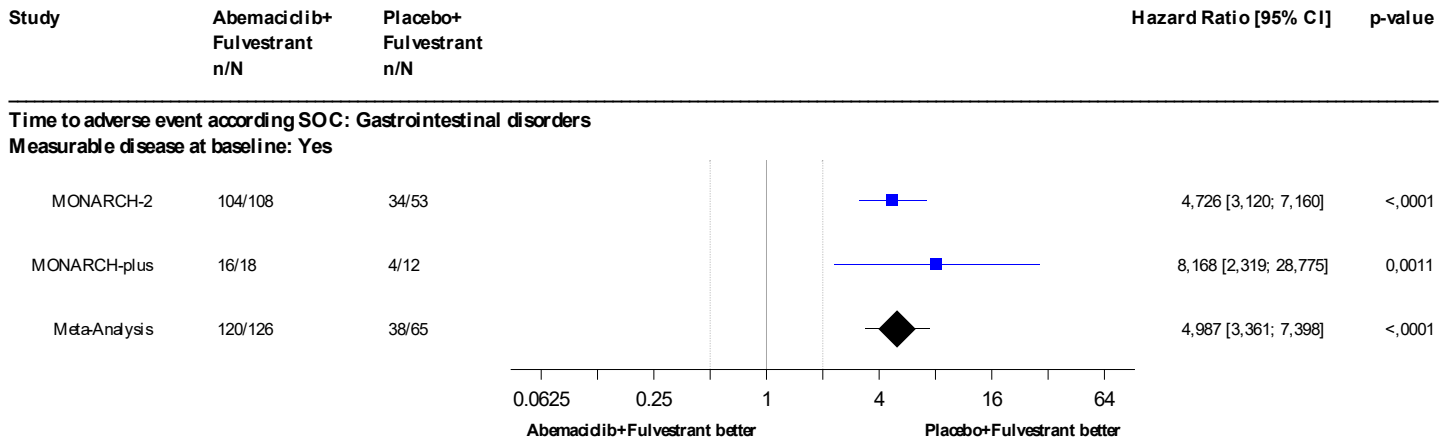
Figure 1276.2.6.2: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6540, p-value=0,4187, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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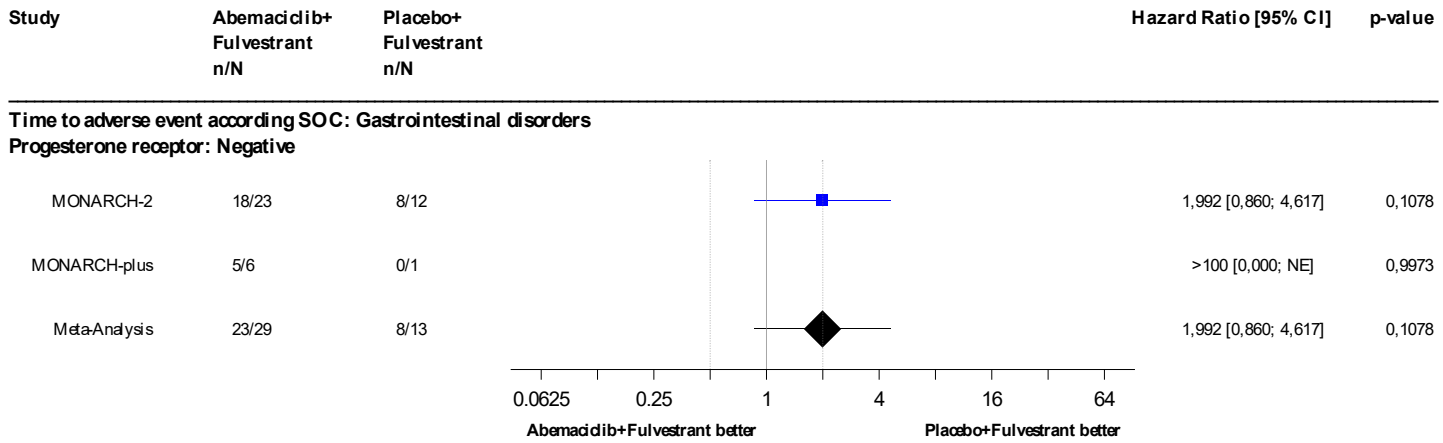
Figure 1276.2.7.1: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9974, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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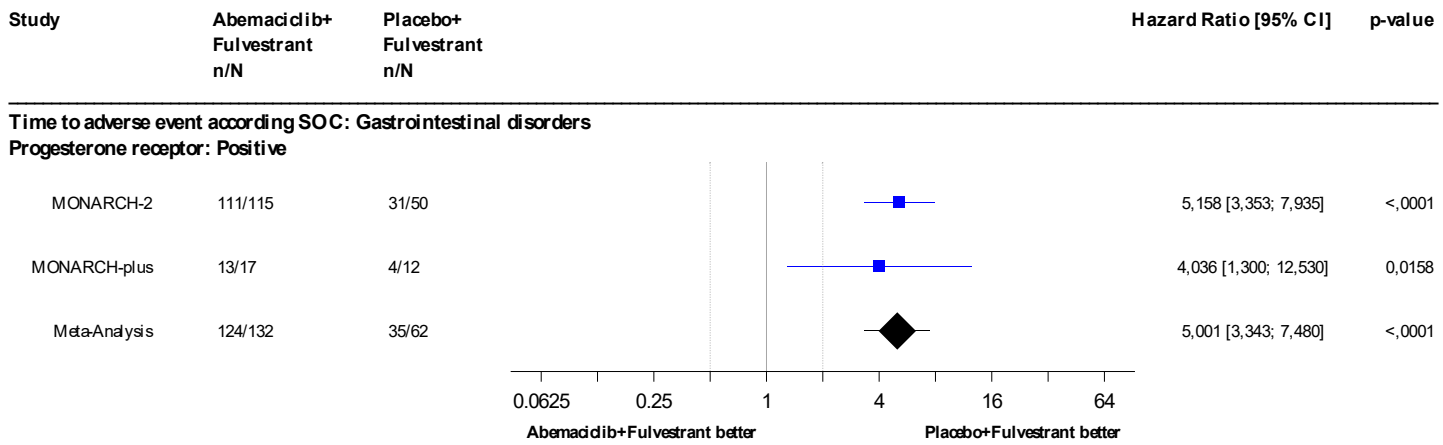
Figure 1276.2.7.2: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1572, p-value=0,6917, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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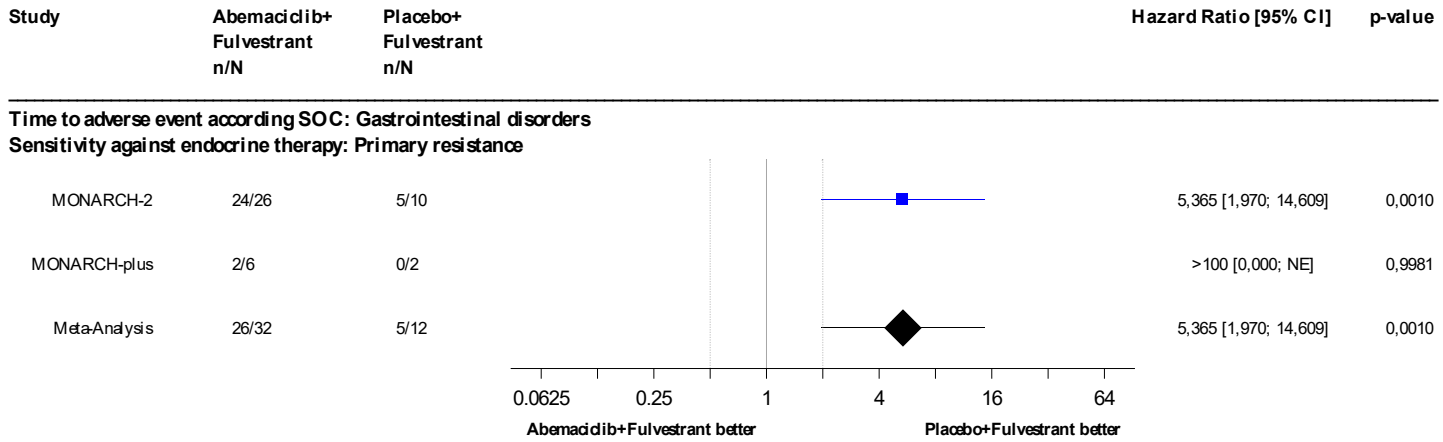
Figure 1276.2.8.1: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9983, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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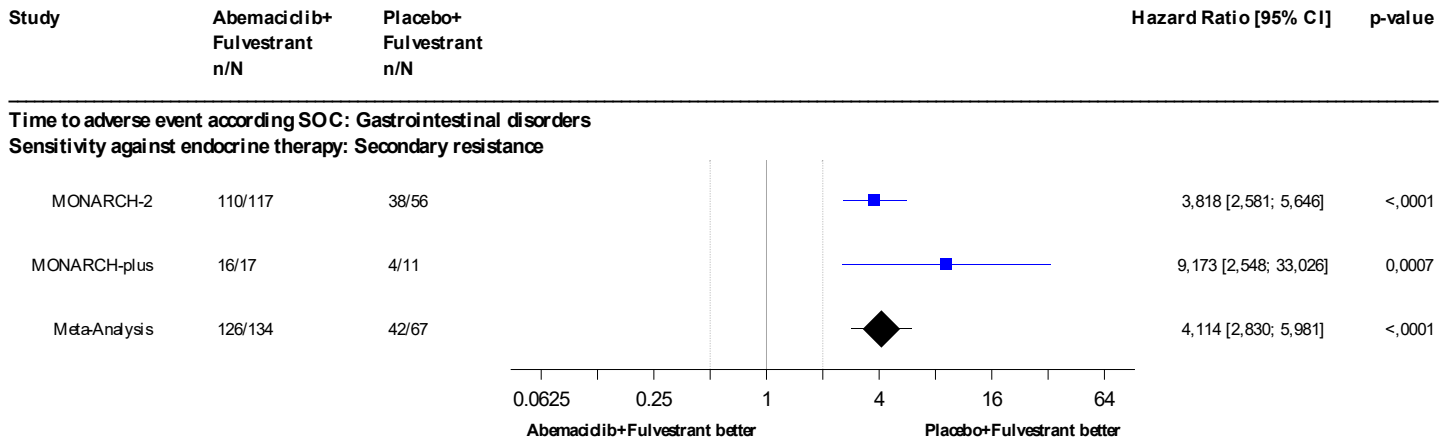
Figure 1276.2.8.2: Metaanalysis results for adverse events according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,6453, p-value=0,1996, I2 index=39,2%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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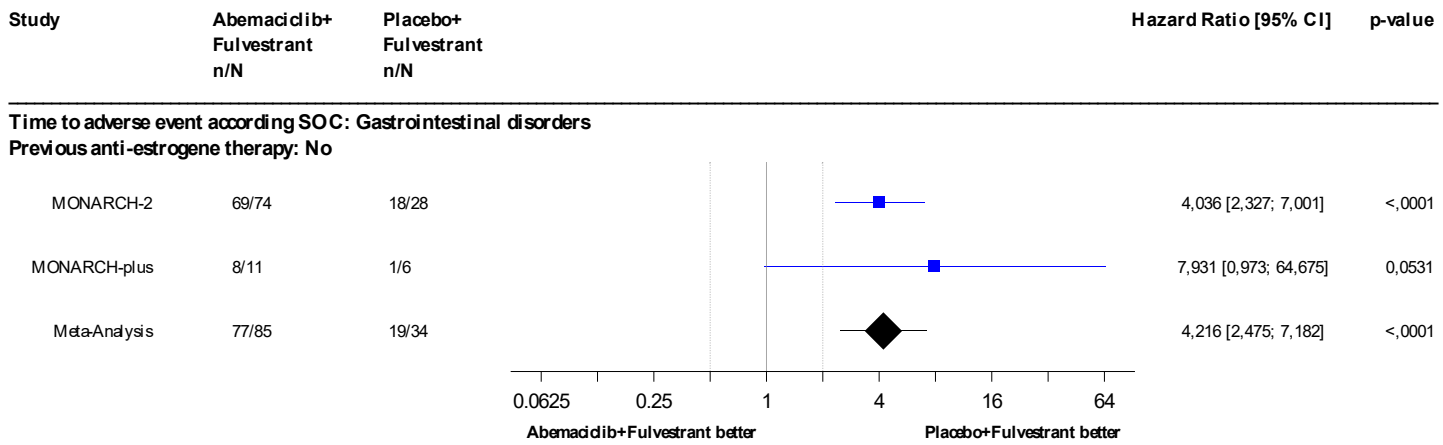
Figure 1276.2.9.1: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3723, p-value=0,5417, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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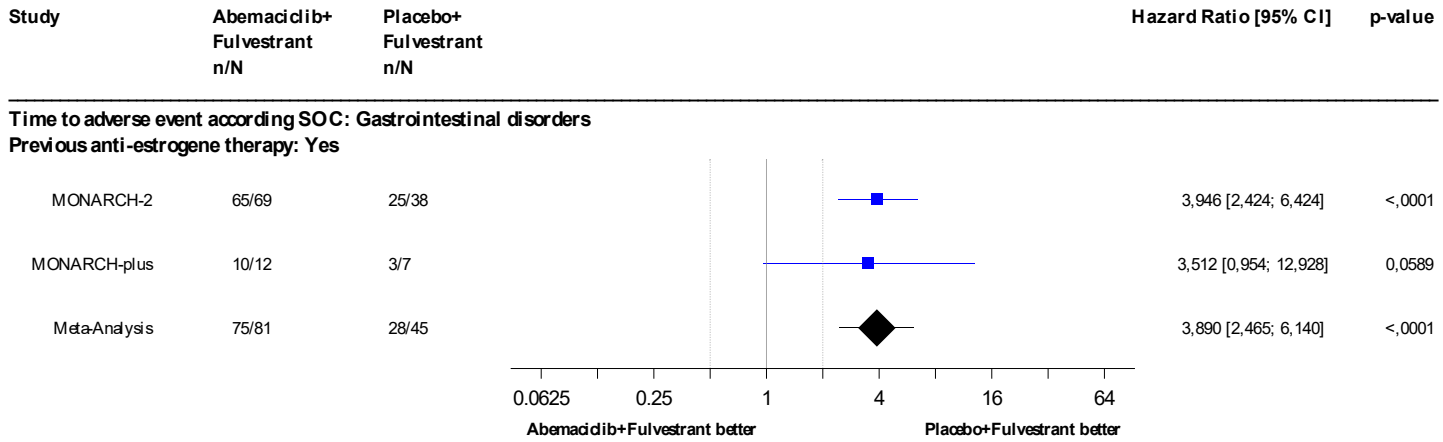
Figure 1276.2.9.2: Metaanalysis results for adverse events according SOC[1] -
Gastrointestinal disorders
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0270, p-value=0,8695, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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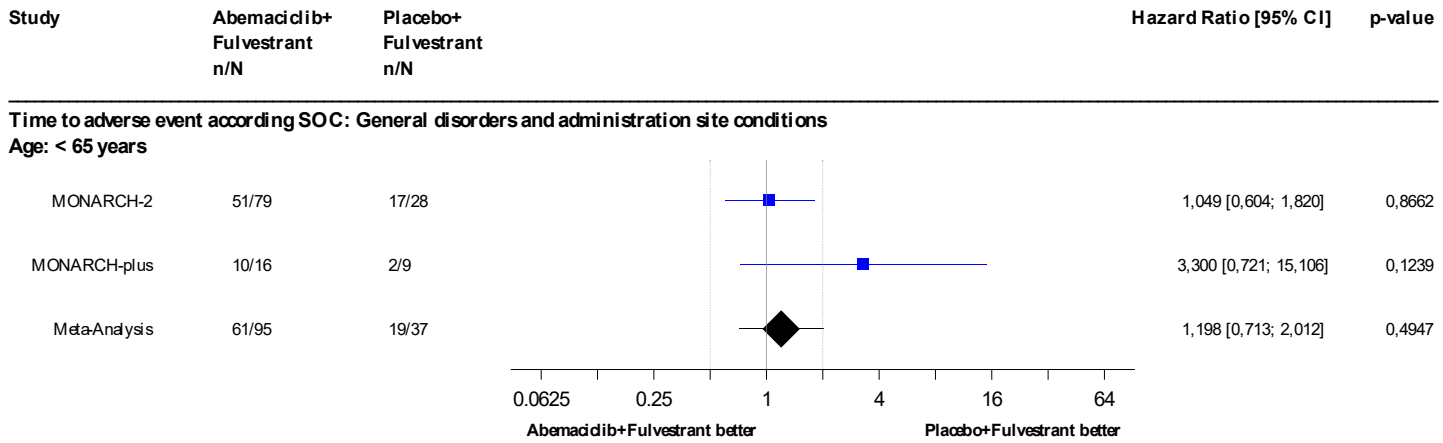
**Figure 1277.2.1.1: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=1,9296, p-value=0,1648, I2 index=48,2%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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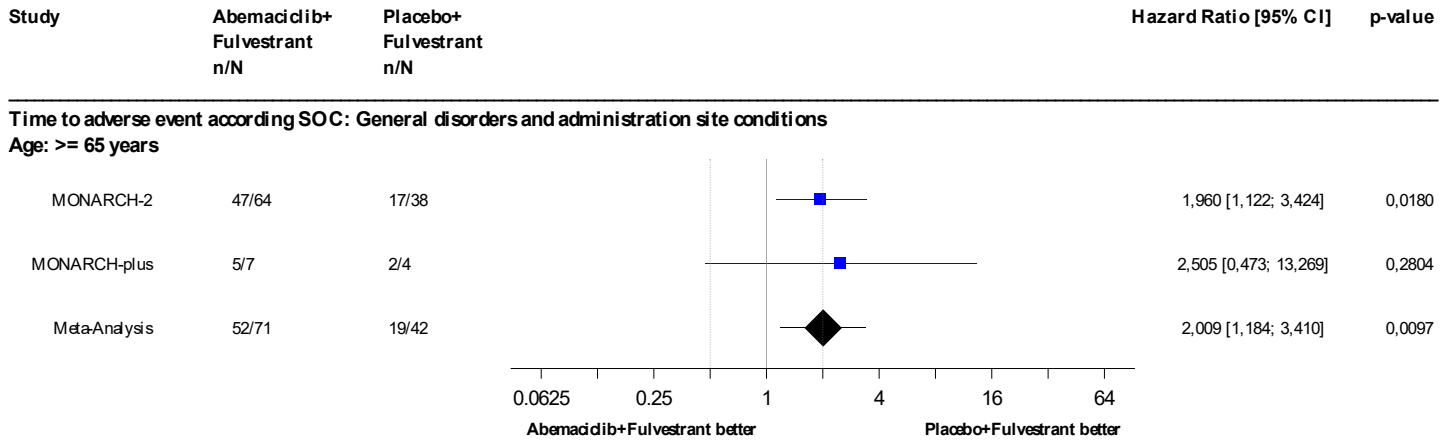
Figure 1277.2.1.2: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0747, p-value=0,7846, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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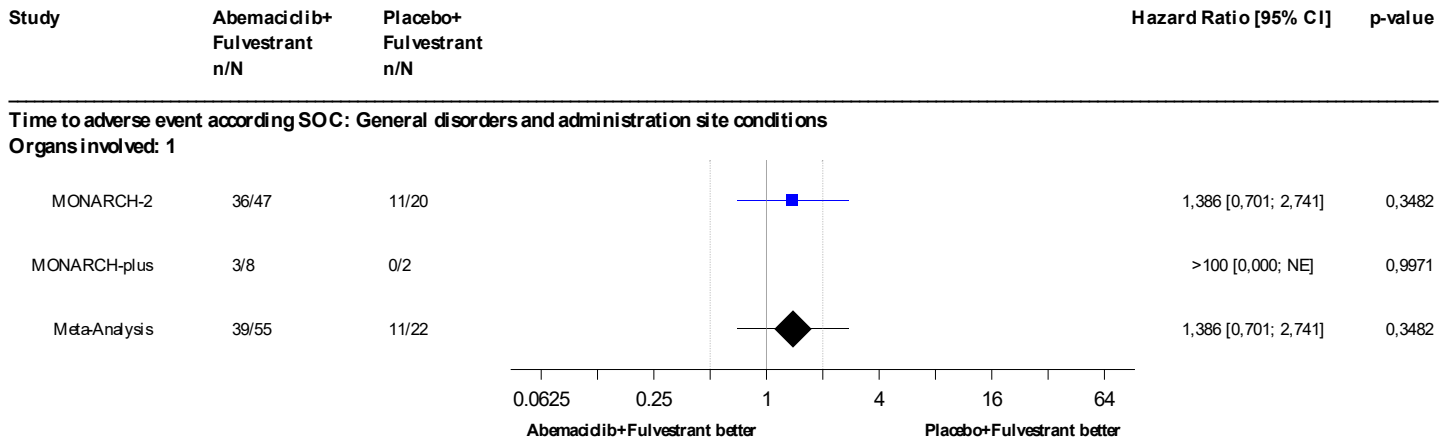
**Figure 1277.2.2.1: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9972, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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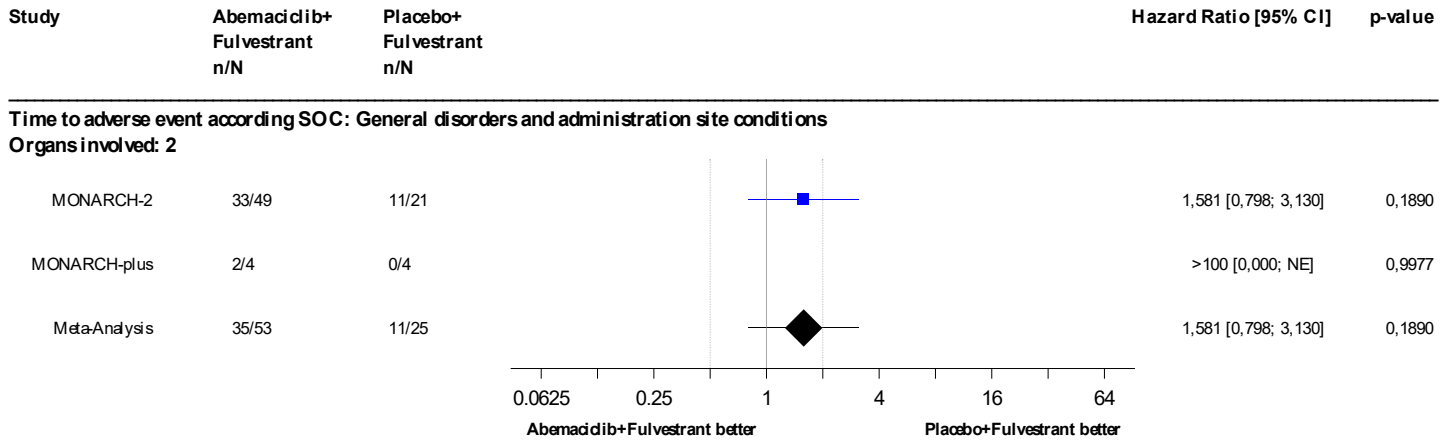
**Figure 1277.2.2.2: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9978, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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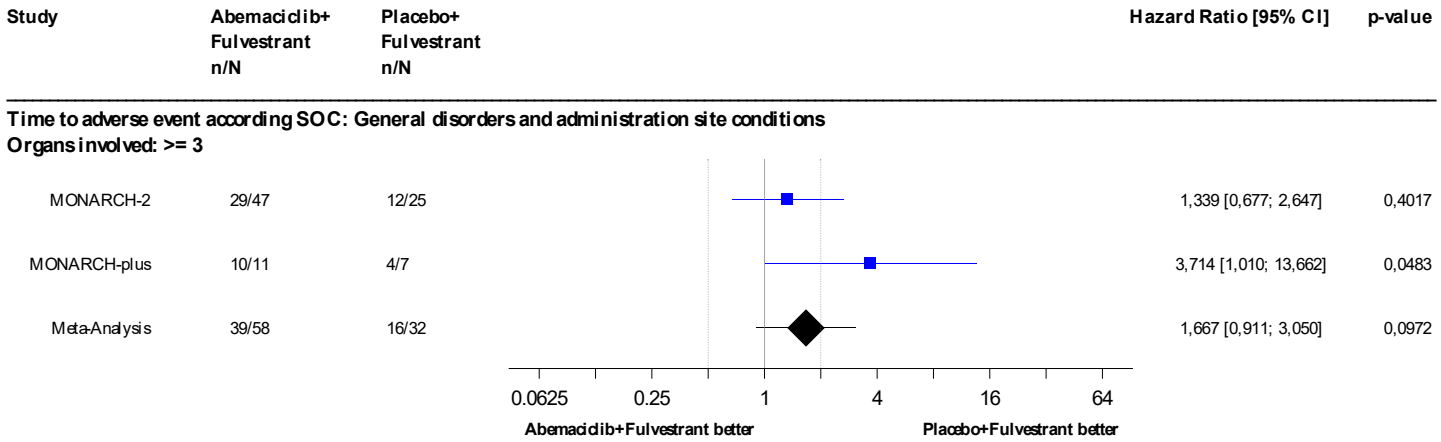
**Figure 1277.2.2.3: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=1,8505, p-value=0,1737, I2 index=46,0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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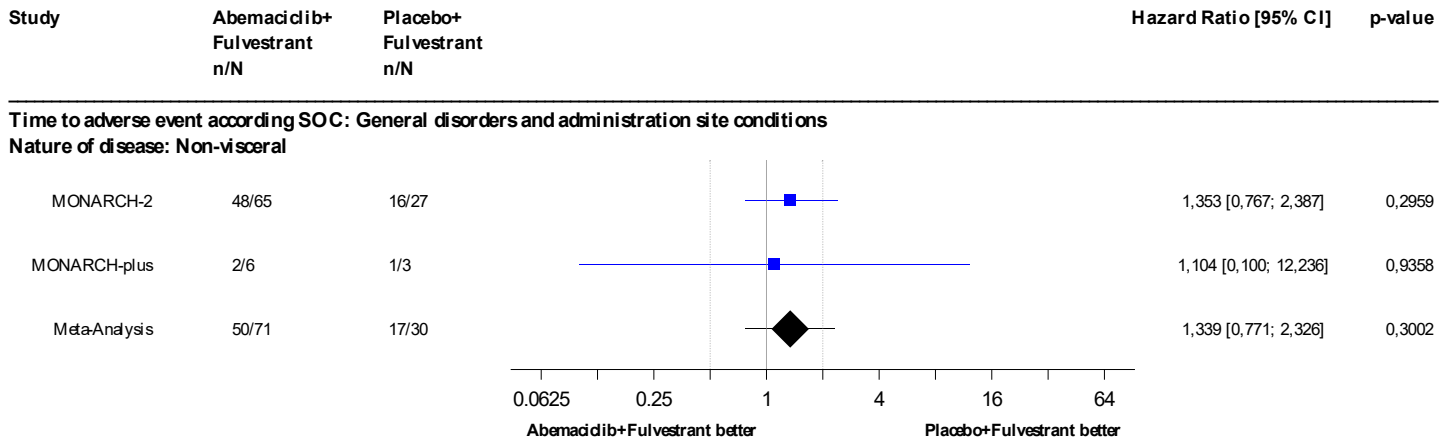
**Figure 1277.2.3.1: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0261, p-value=0,8716, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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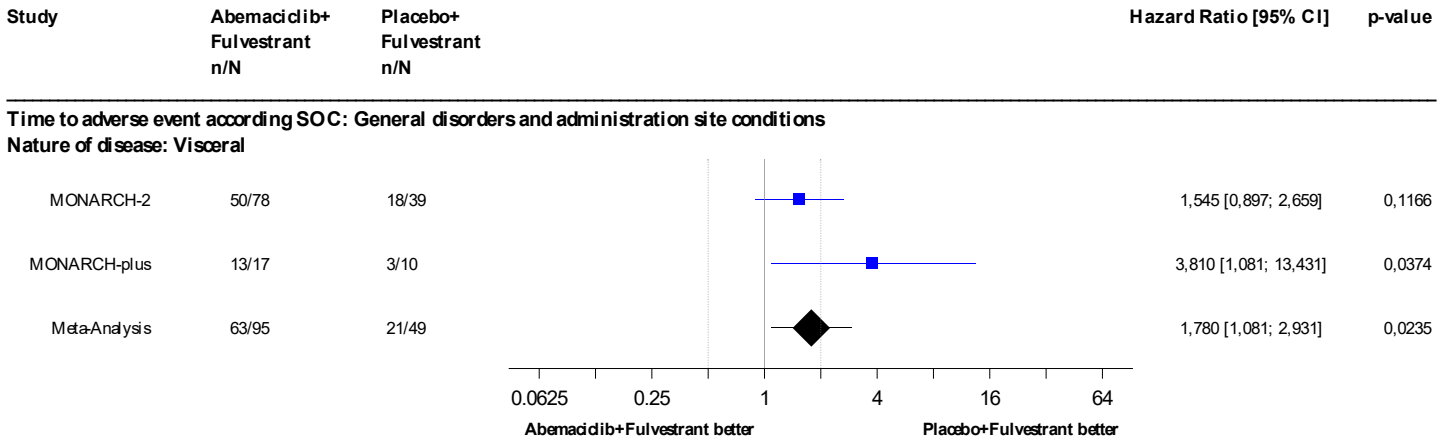
**Figure 1277.2.3.2: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=1,6637, p-value=0,1971, I2 index=39,9%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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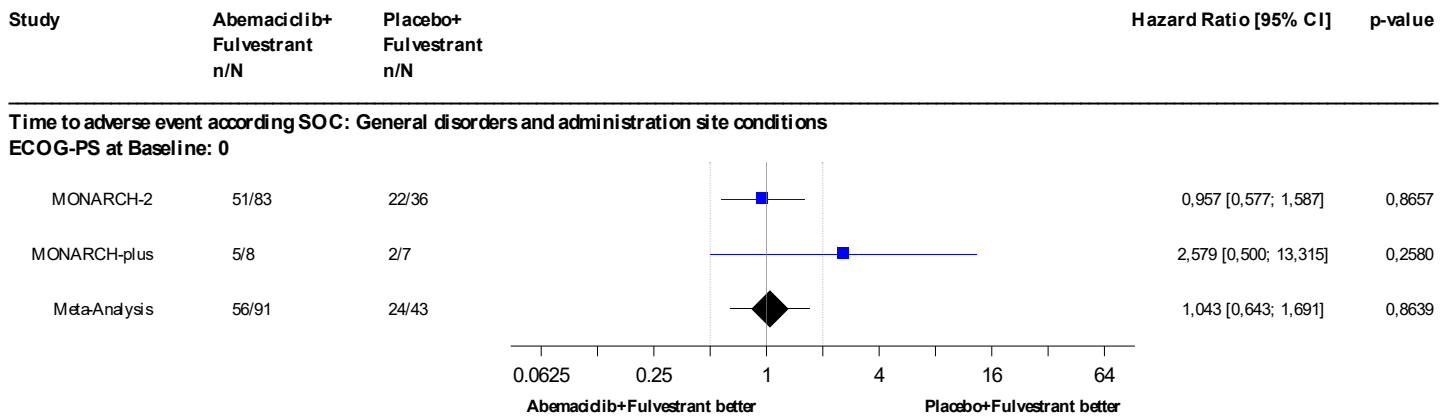
Figure 1277.2.4.1: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,2788, p-value=0,2581, I2 index=21,8%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes005_popa2_ecogbl_1.rtf
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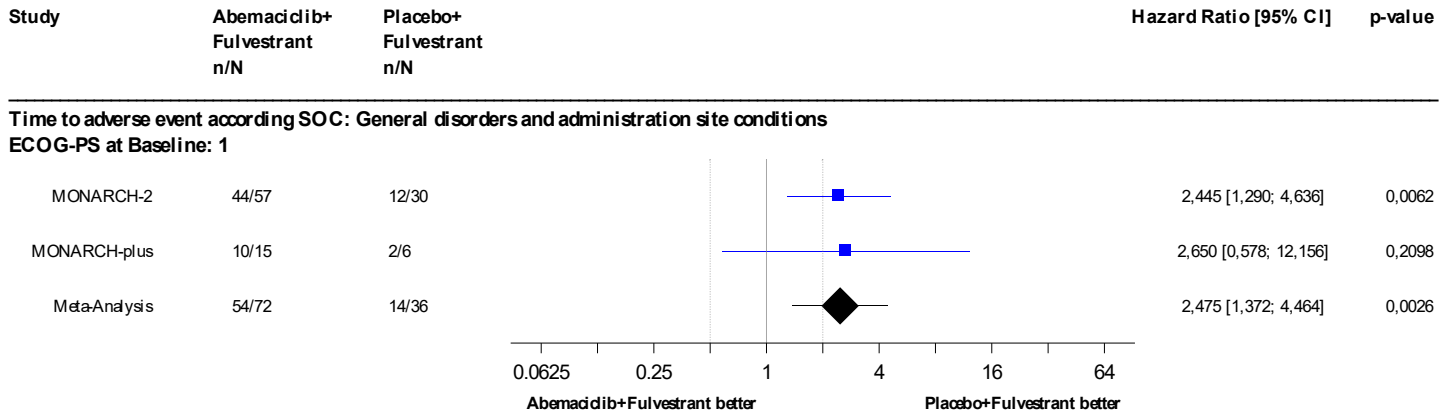
**Figure 1277.2.4.2: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0092, p-value=0,9238, I2 index=0%

Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes005_popa2_ecogbl_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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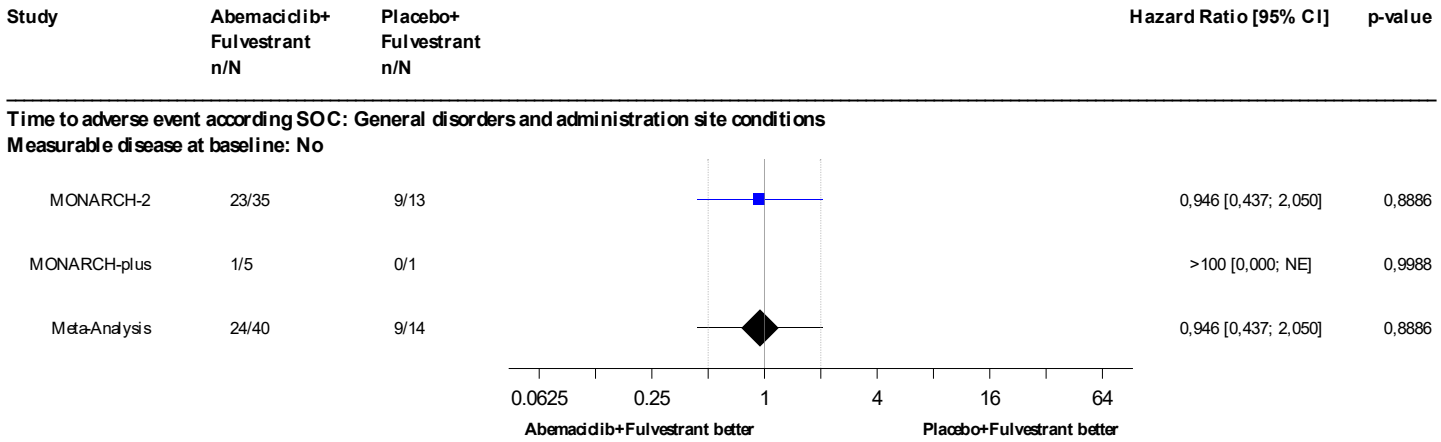
**Figure 1277.2.6.1: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9988, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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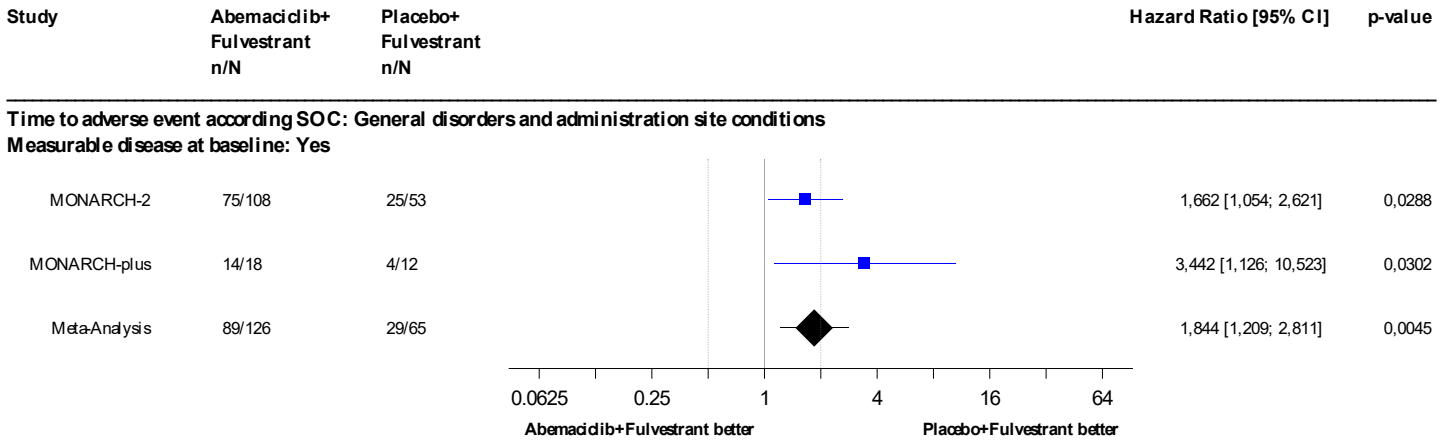
**Figure 1277.2.6.2: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=1,3983, p-value=0,2370, I2 index=28,5%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes005_popa2_measdis_2.rtf
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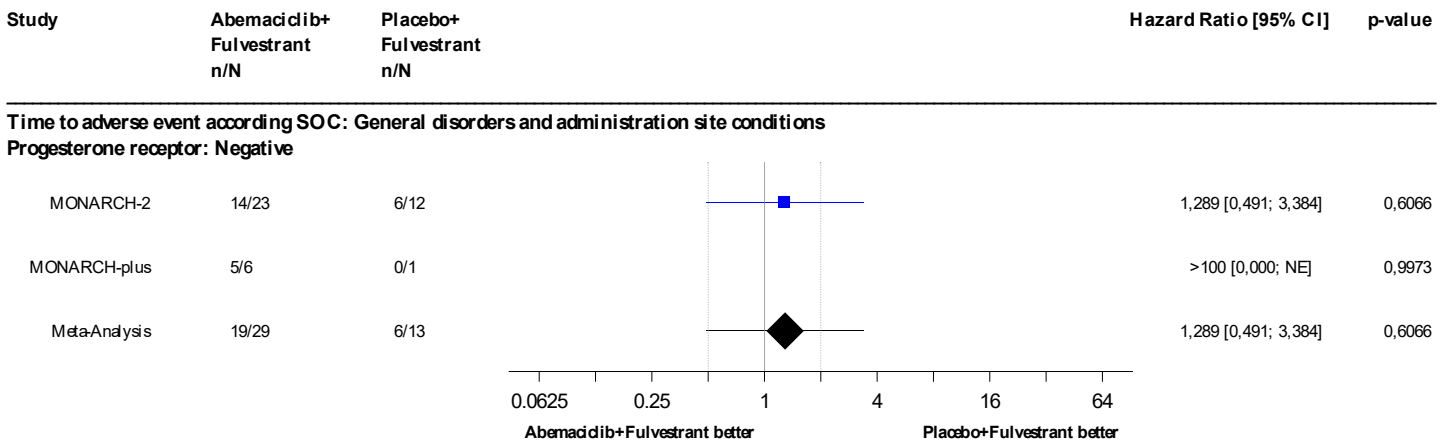
Figure 1277.2.7.1: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9973, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes005_popa2_pgrstat_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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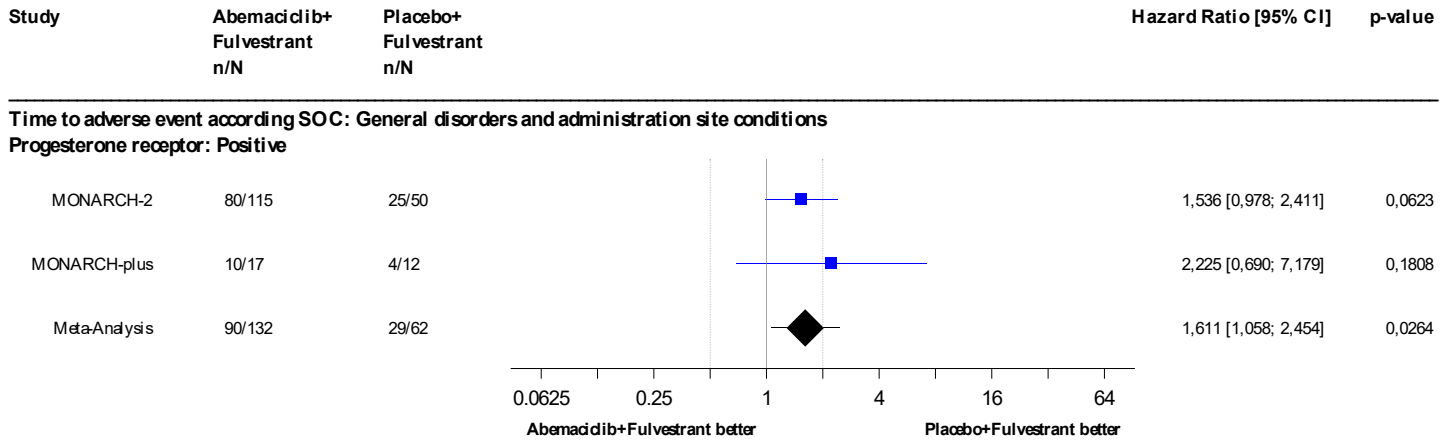
**Figure 1277.2.7.2: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,3354, p-value=0,5625, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes005_popa2_pgrstat_2.rtf
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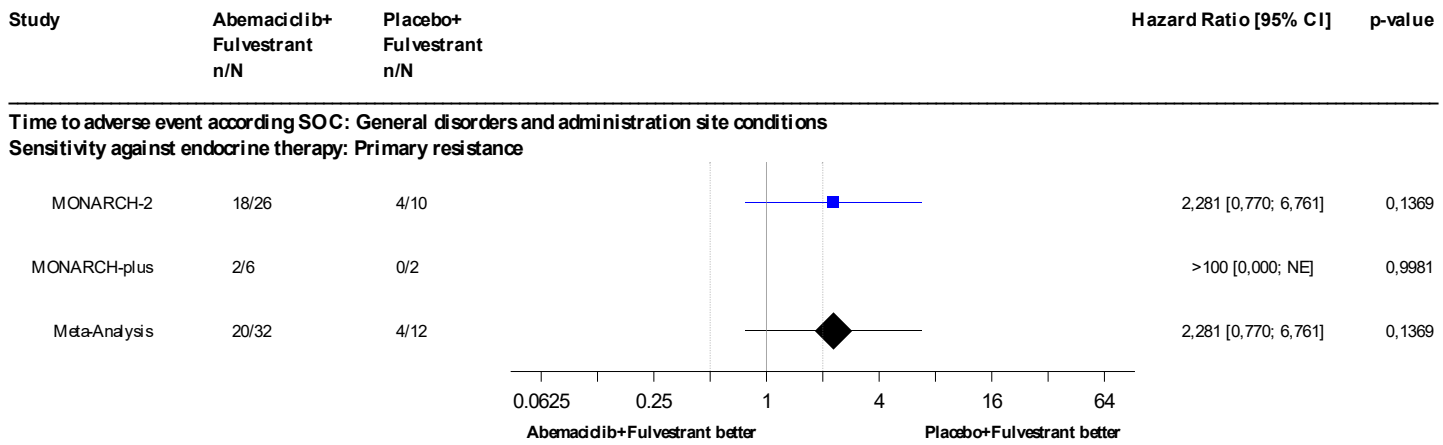
Figure 1277.2.8.1: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9982, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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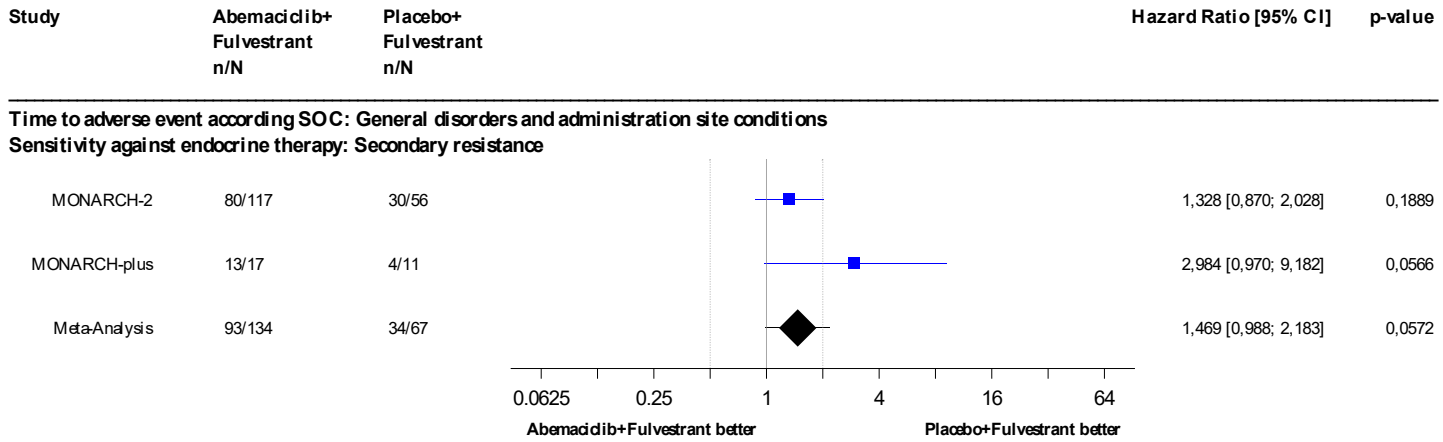
**Figure 1277.2.8.2: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=1,7450, p-value=0,1865, I2 index=42,7%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes005_popa2_snthr_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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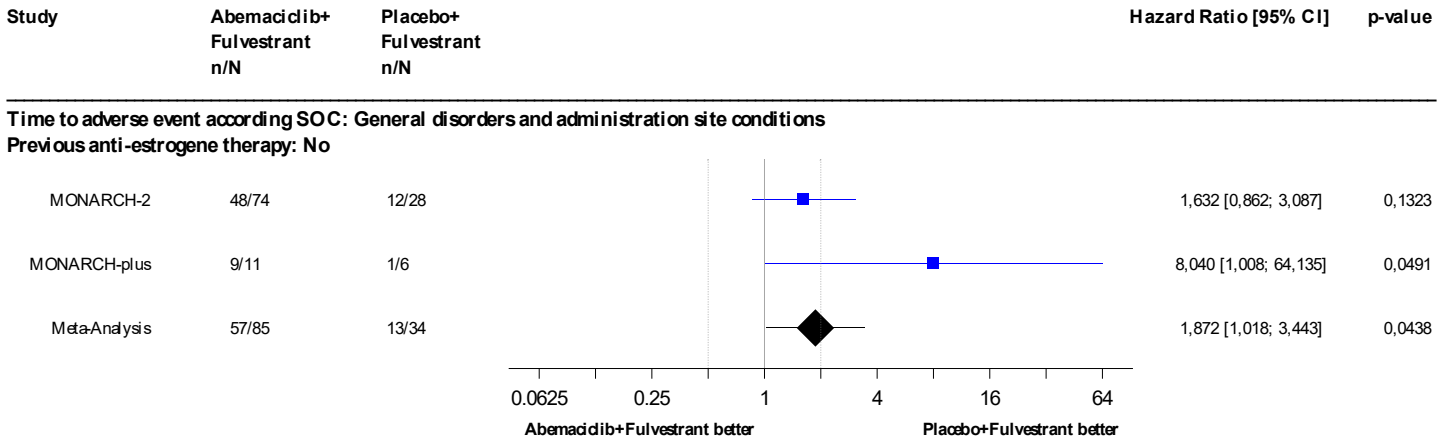
**Figure 1277.2.9.1: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=2,0712, p-value=0,1501, I2 index=51,7%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes005_popa2_paet_1.rtf
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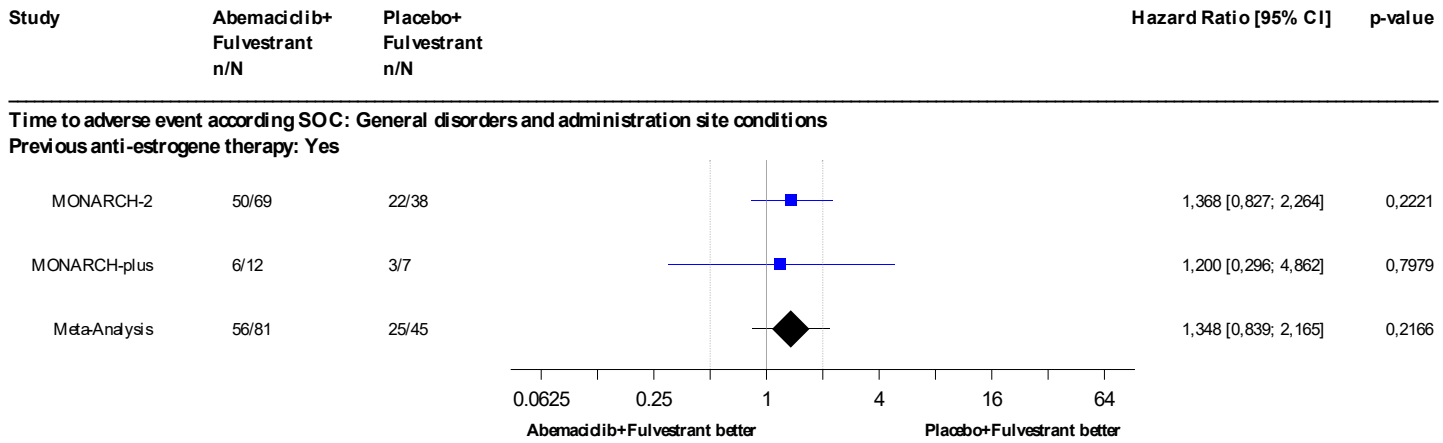
**Figure 1277.2.9.2: Metaanalysis results for adverse events according SOC[1] -
General disorders and administration site conditions
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0298, p-value=0,8629, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes005_popa2_paet_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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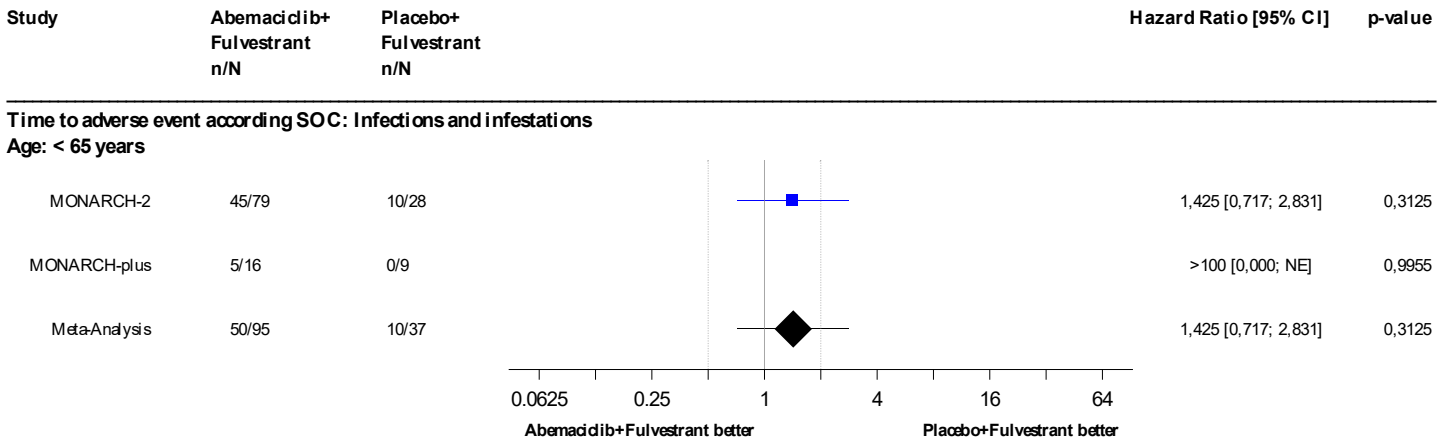
Figure 1278.2.1.1: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9956, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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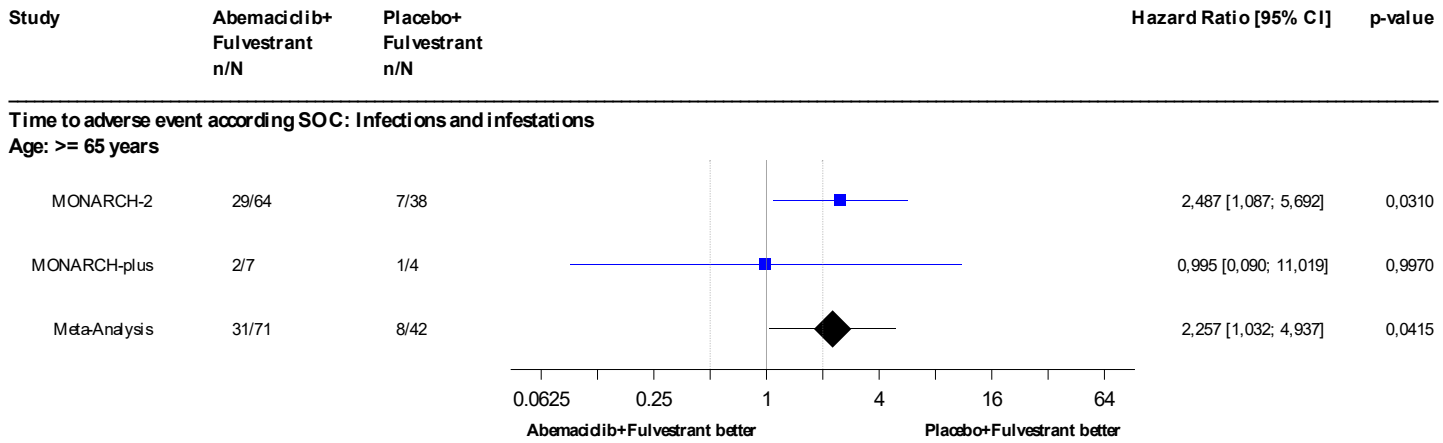
Figure 1278.2.1.2: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4982, p-value=0,4803, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes006_popa2_agegr1_2.rtf
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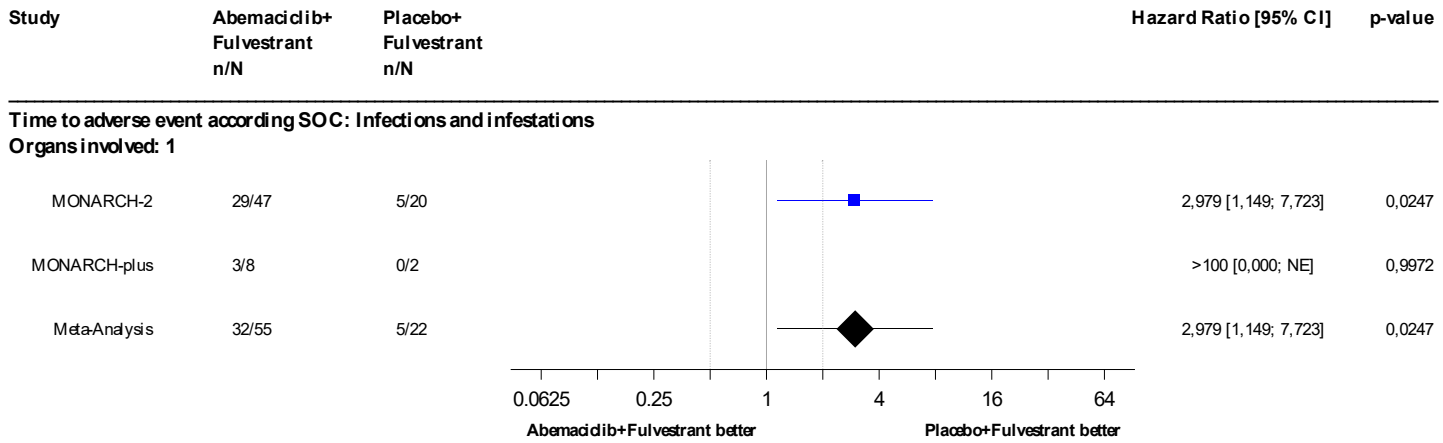
Figure 1278.2.2.1: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9974, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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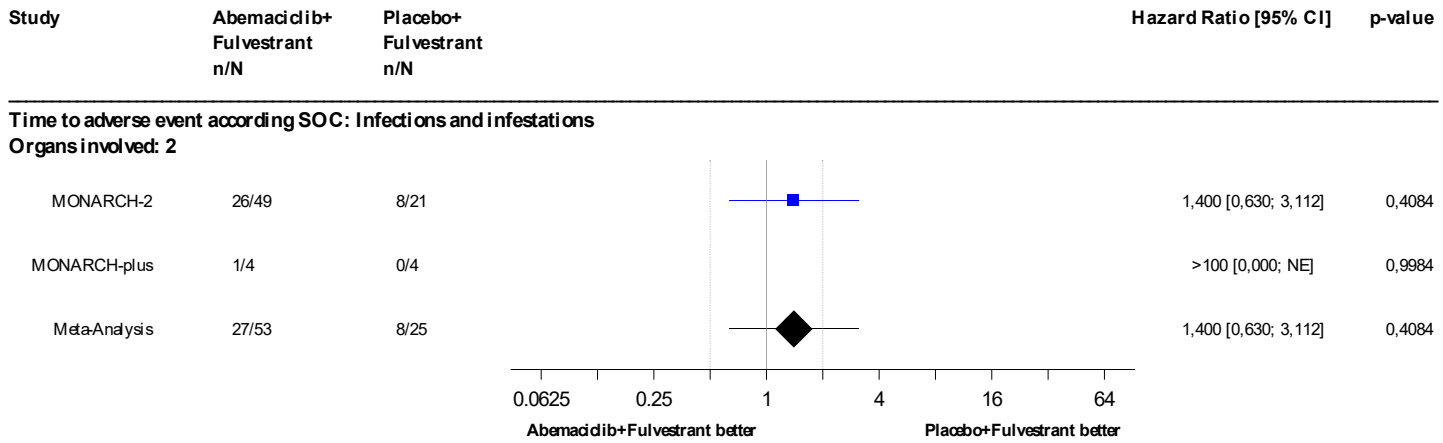
Figure 1278.2.2.2: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9984, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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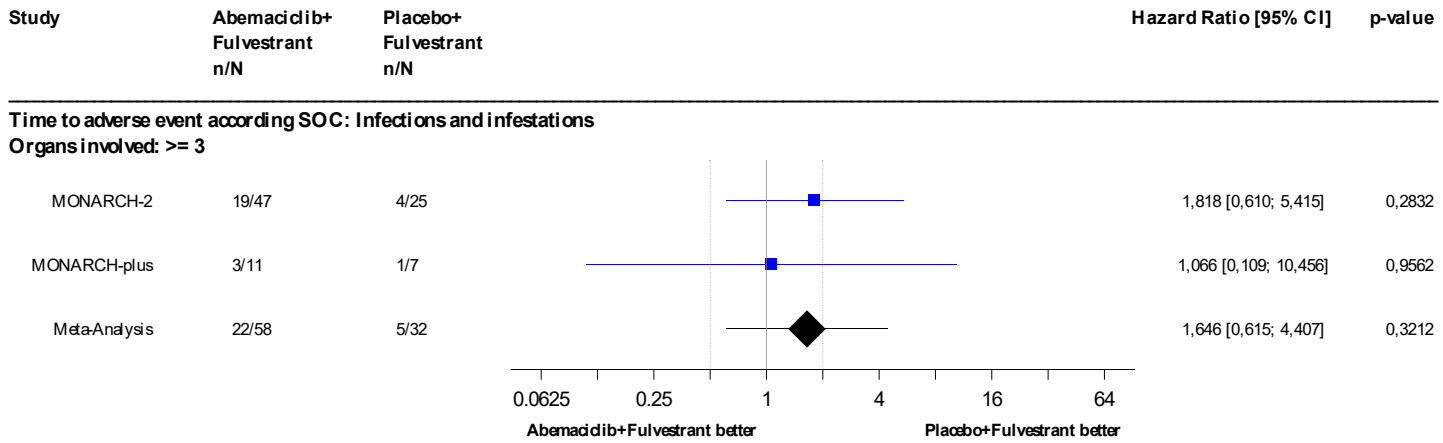
Figure 1278.2.2.3: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1708, p-value=0,6794, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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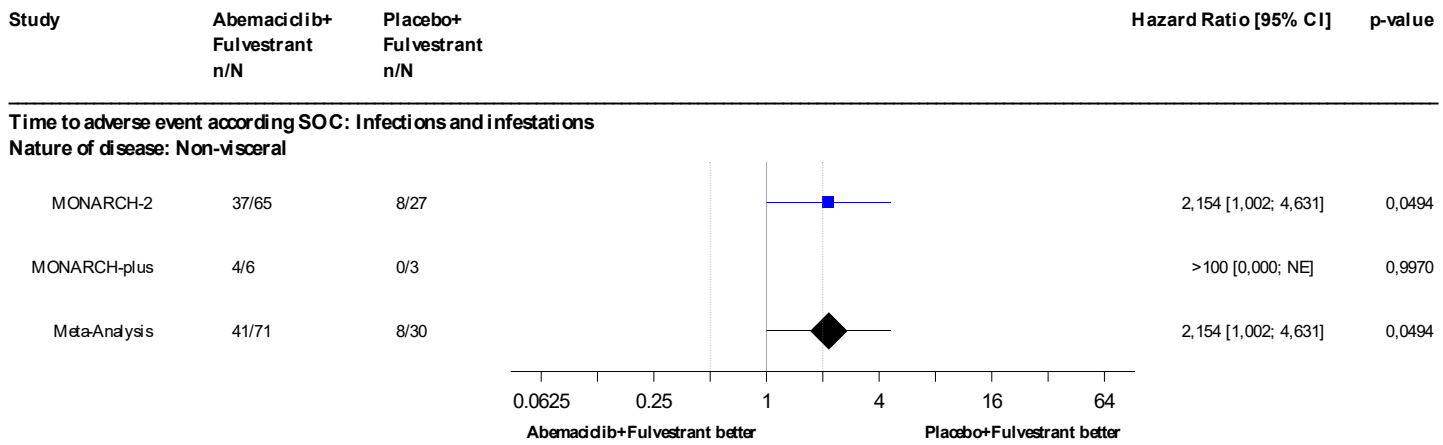
Figure 1278.2.3.1: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9971, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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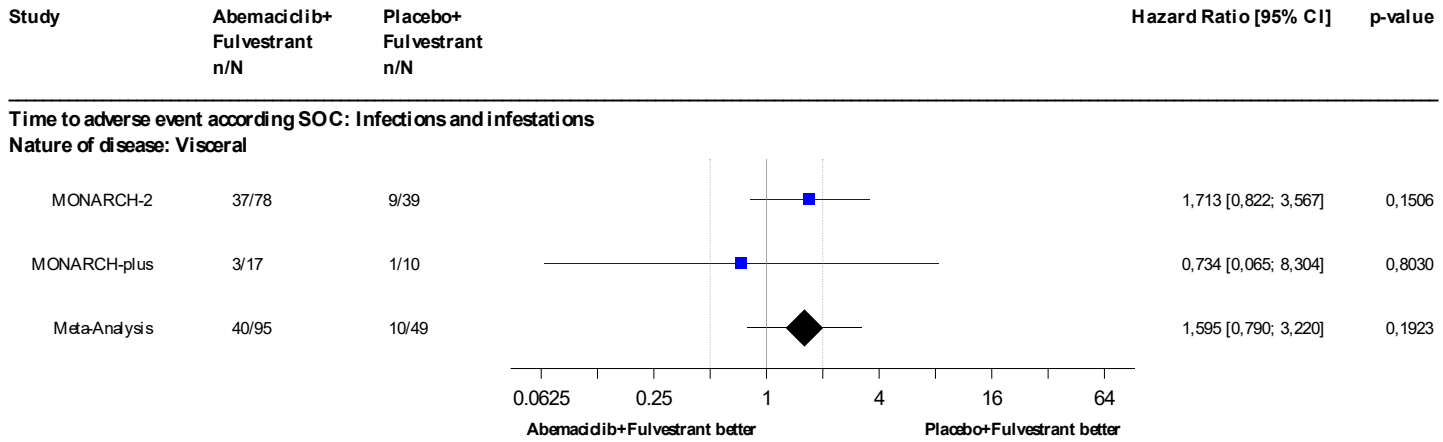
Figure 1278.2.3.2: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4289, p-value=0,5125, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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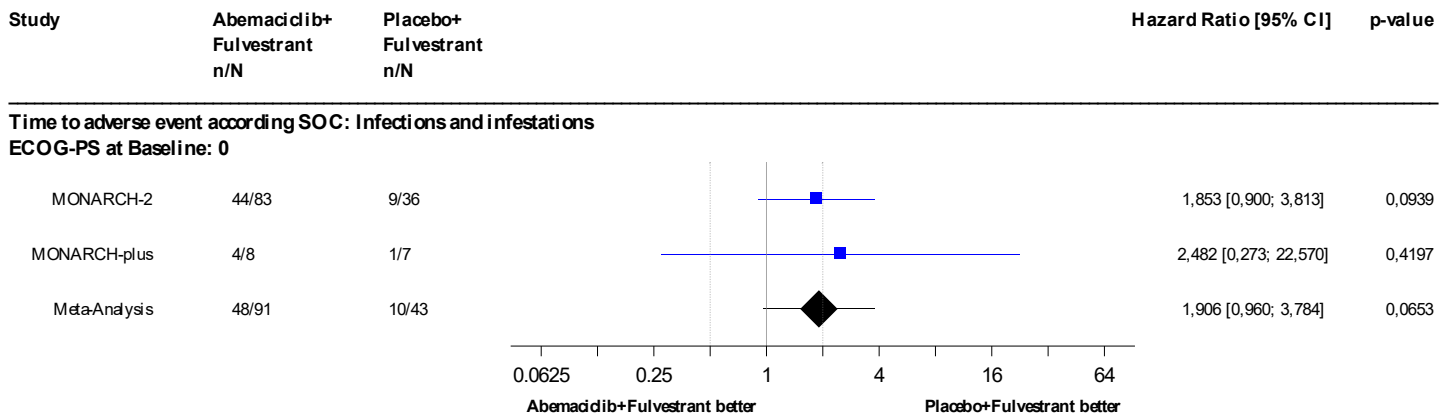
Figure 1278.2.4.1: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0608, p-value=0,8052, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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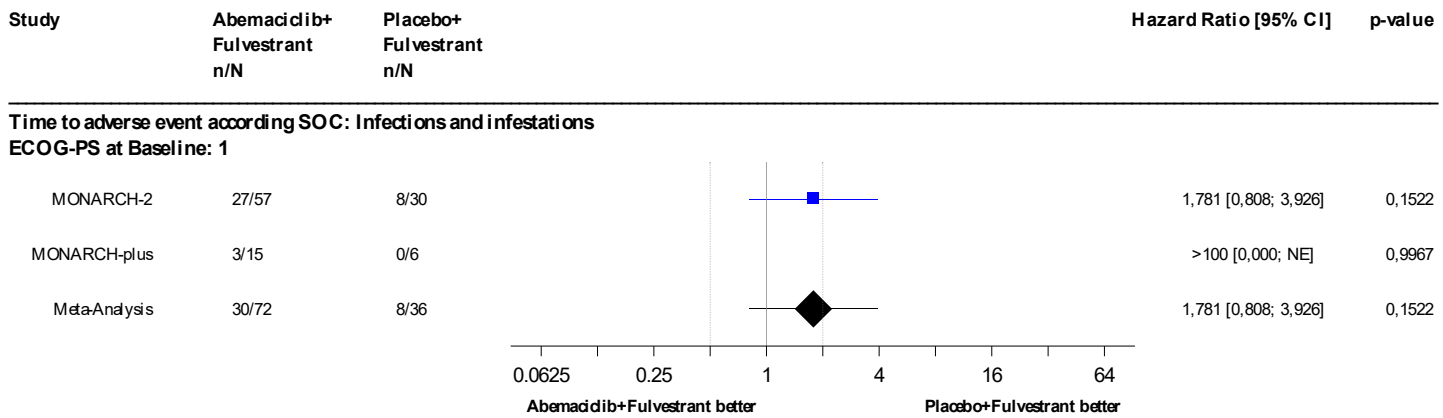
Figure 1278.2.4.2: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9968, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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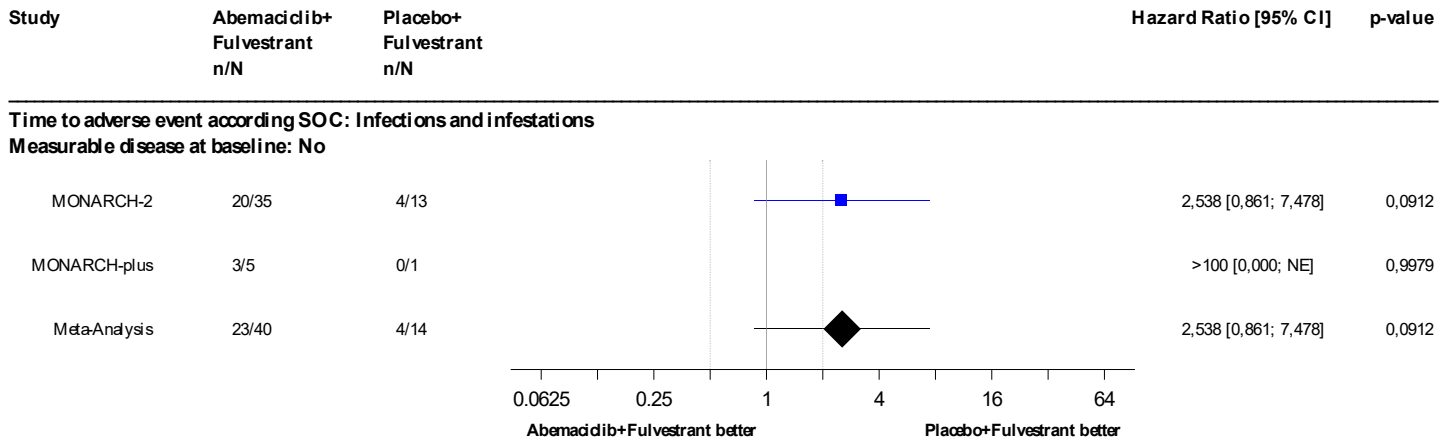
Figure 1278.2.6.1: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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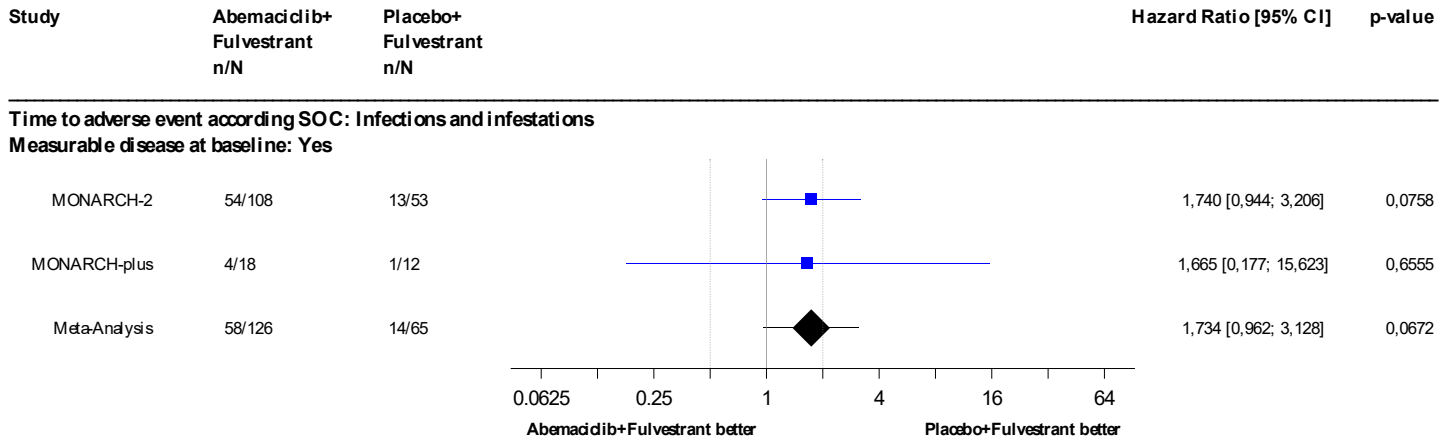
Figure 1278.2.6.2: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0014, p-value=0,9703, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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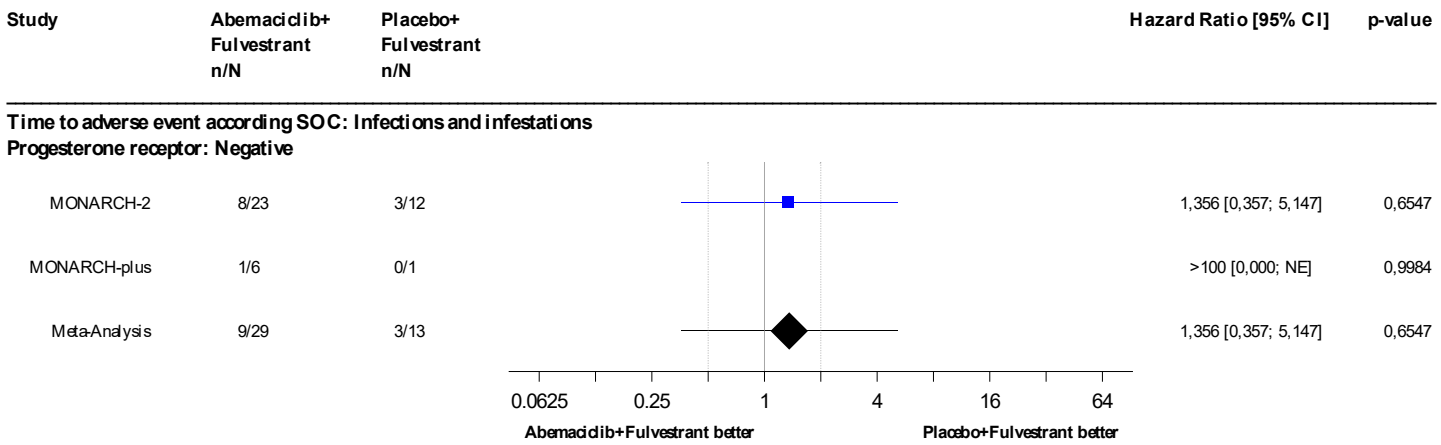
Figure 1278.2.7.1: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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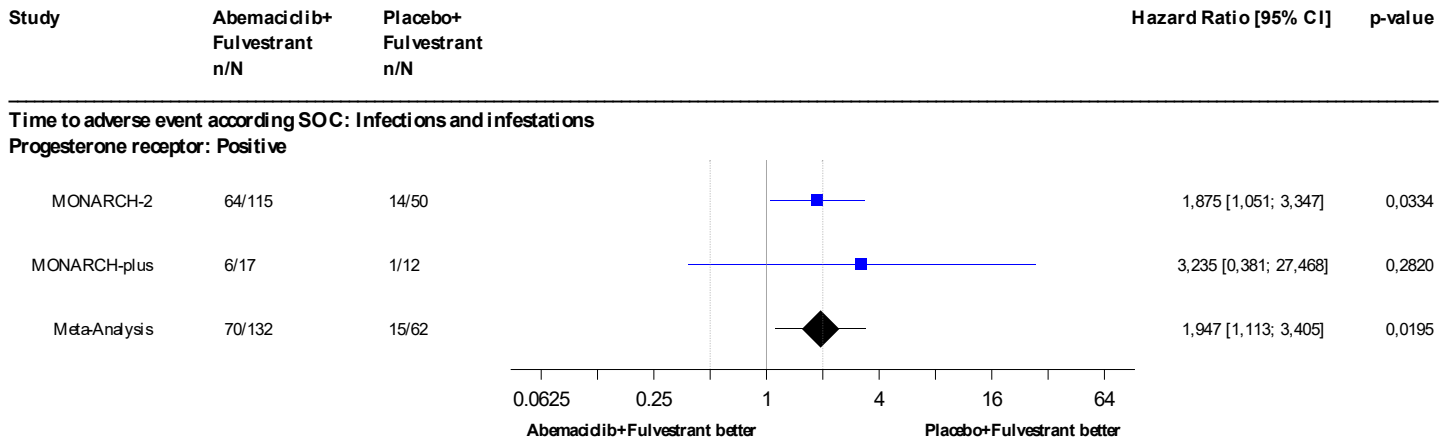
Figure 1278.2.7.2: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2325, p-value=0,6297, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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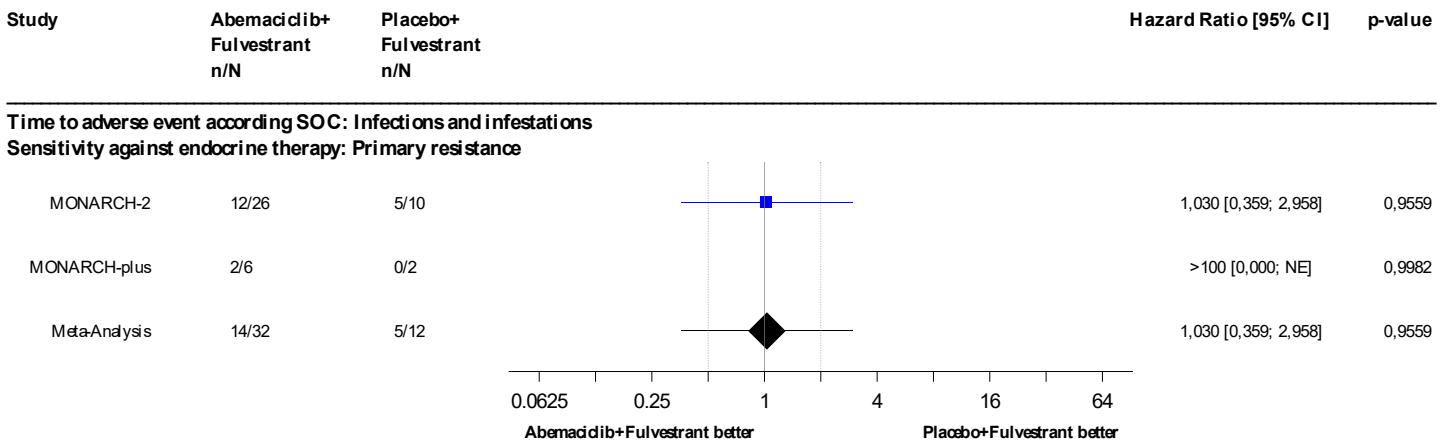
Figure 1278.2.8.1: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9983, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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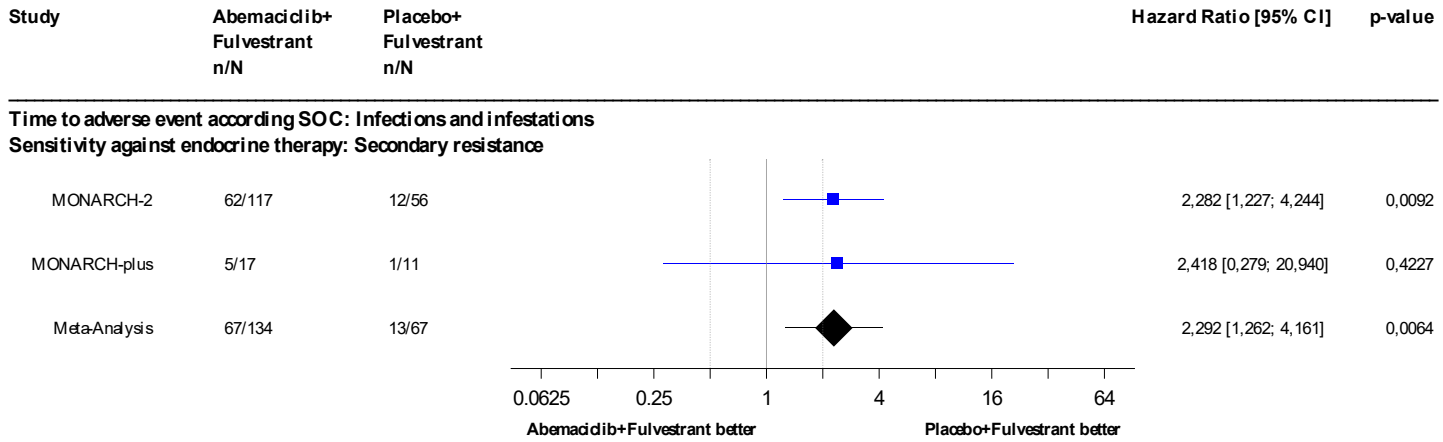
Figure 1278.2.8.2: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0026, p-value=0,9595, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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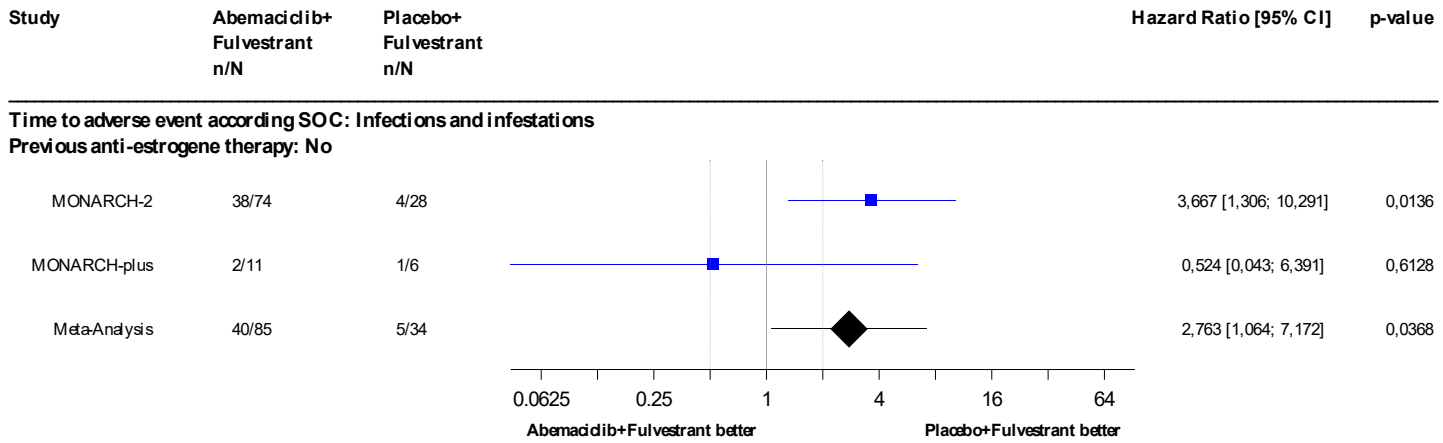
Figure 1278.2.9.1: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,9857, p-value=0,1588, I2 index=49,6%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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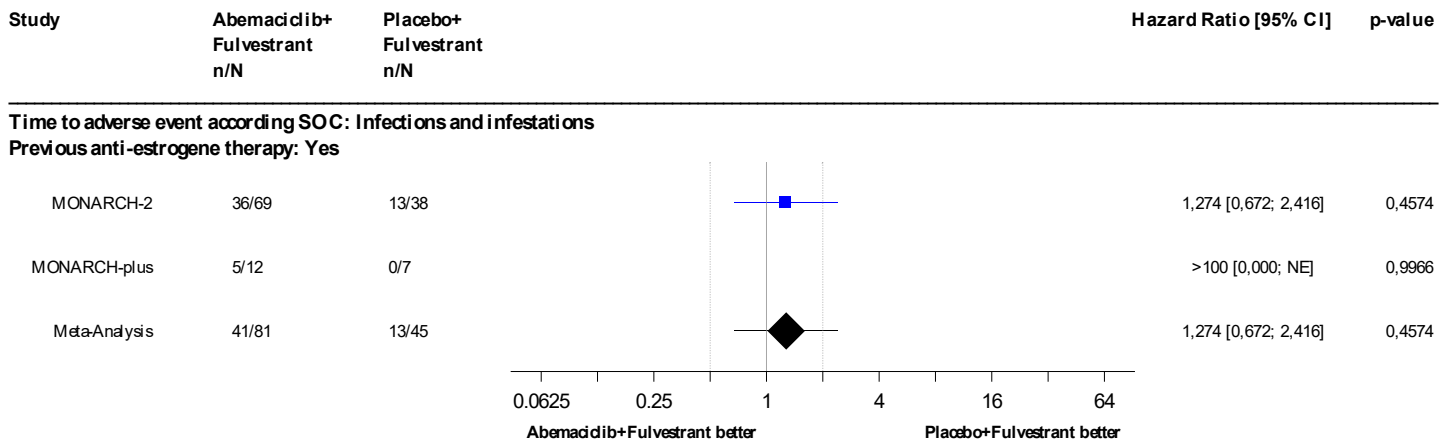
Figure 1278.2.9.2: Metaanalysis results for adverse events according SOC[1] -
Infections and infestations
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9967, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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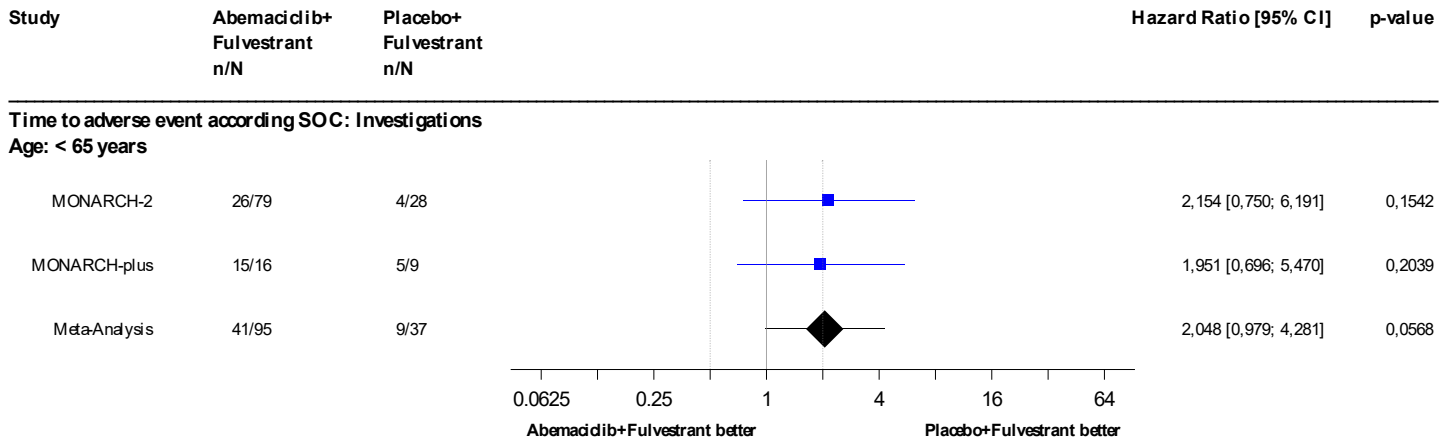
Figure 1280.2.1.1: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0173, p-value=0,8952, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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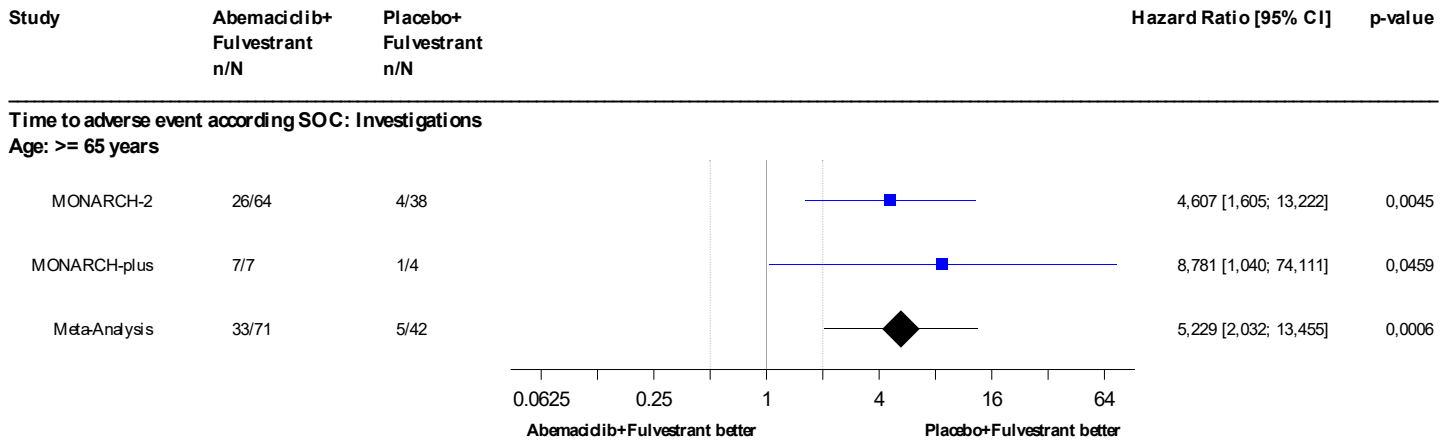
Figure 1280.2.1.2: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2824, p-value=0,5951, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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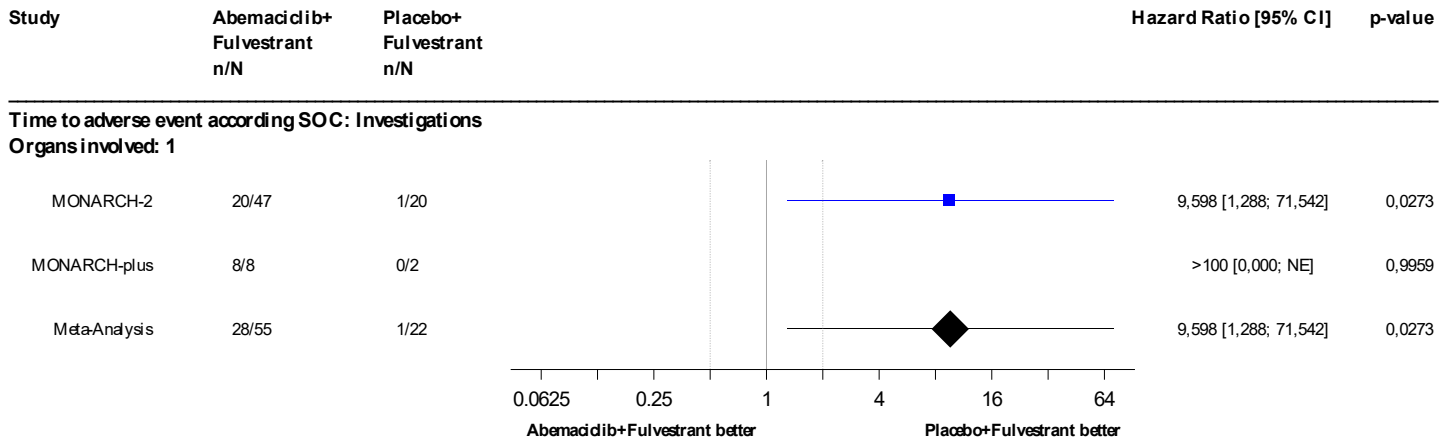
Figure 1280.2.2.1: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9964, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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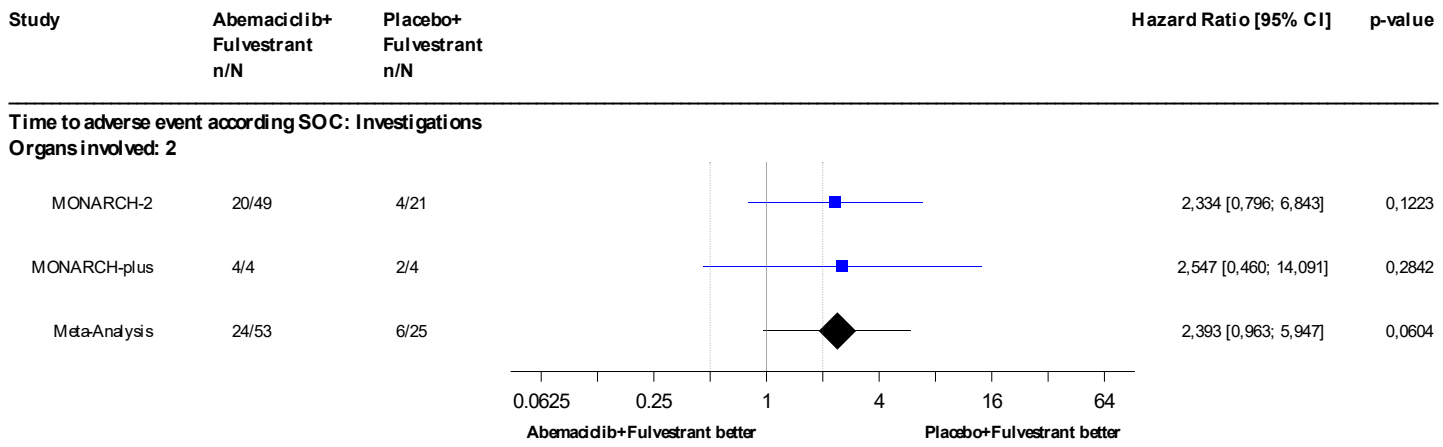
Figure 1280.2.2.2: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0071, p-value=0,9328, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes008_popa2_norggr_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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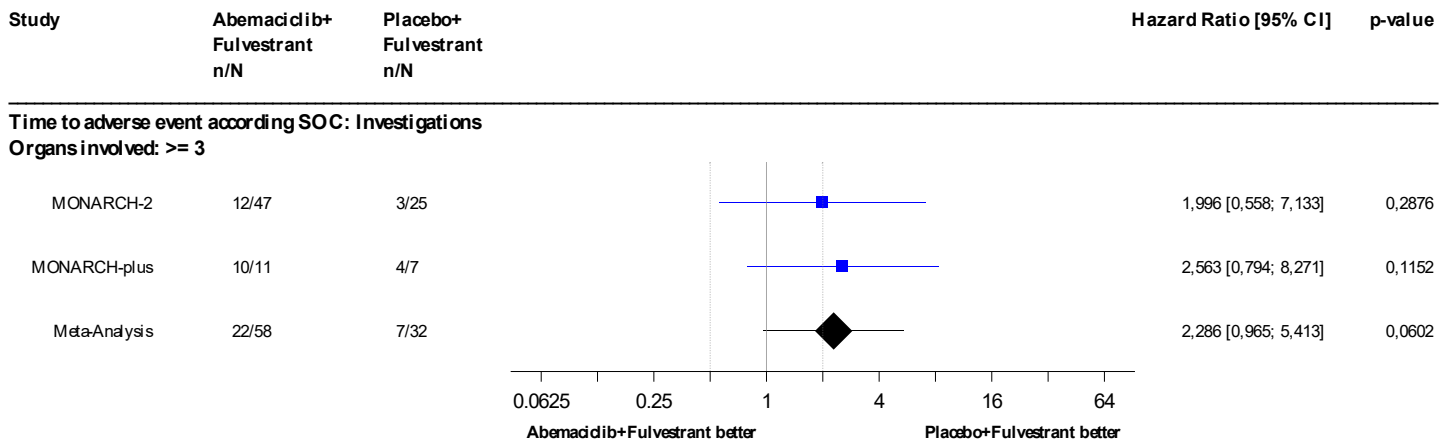
Figure 1280.2.2.3: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0804, p-value=0,7768, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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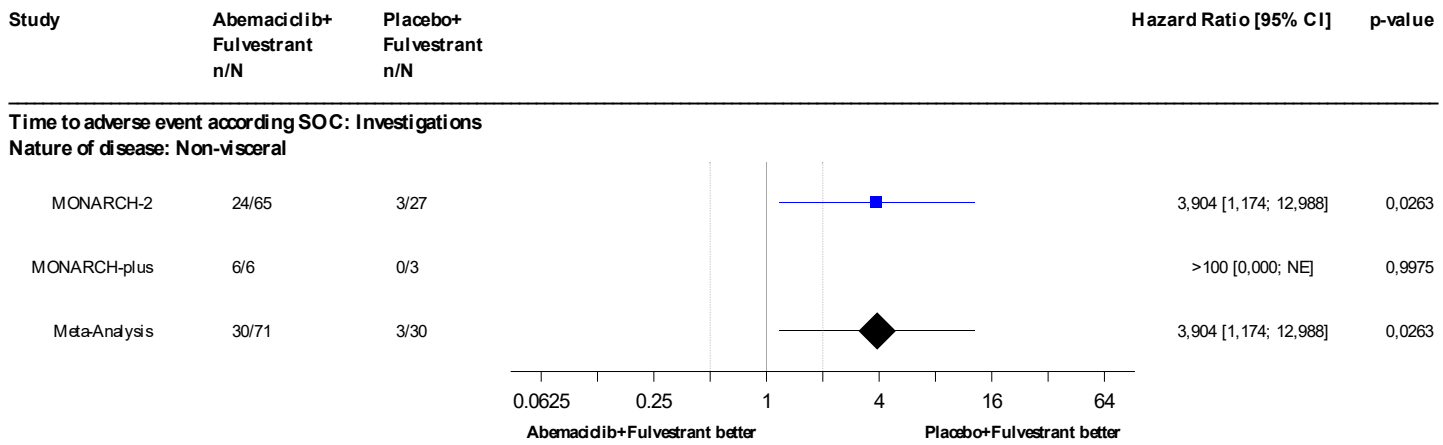
Figure 1280.2.3.1: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9977, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes008_popa2_natdis2_1.rtf
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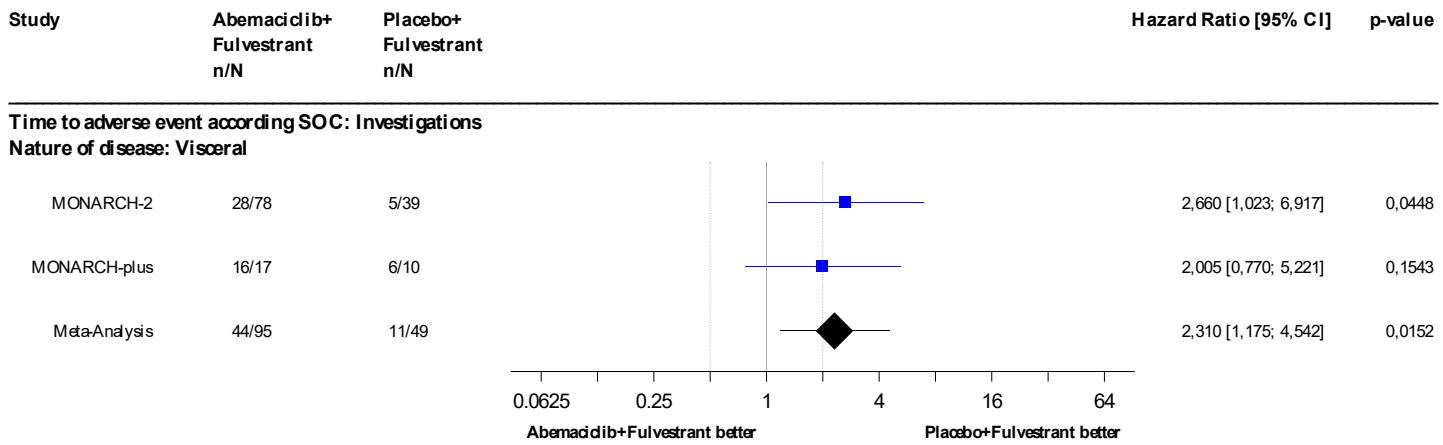
Figure 1280.2.3.2: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1679, p-value=0,6820, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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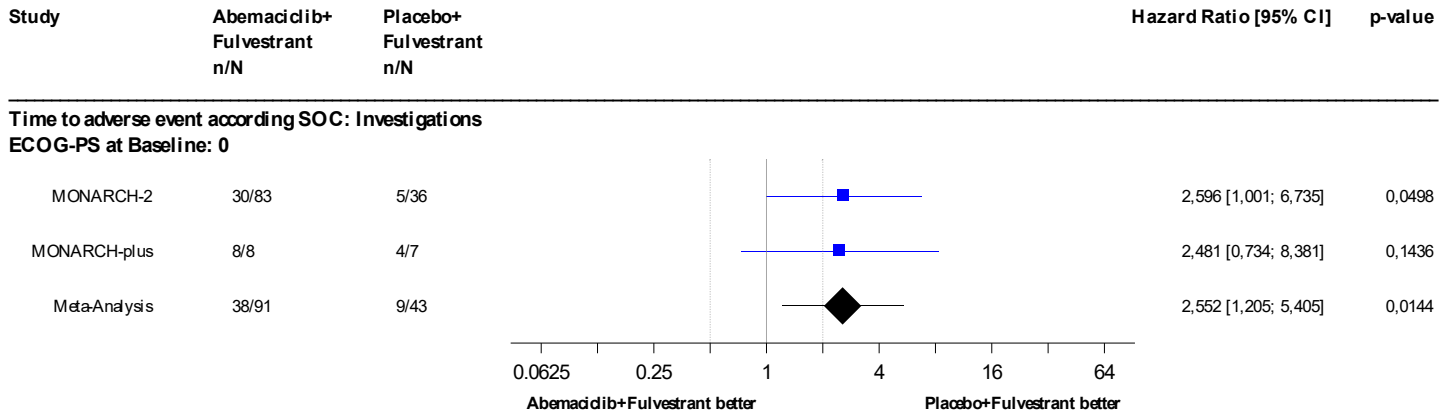
Figure 1280.2.4.1: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0033, p-value=0,9540, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes008_popa2_ecogbl_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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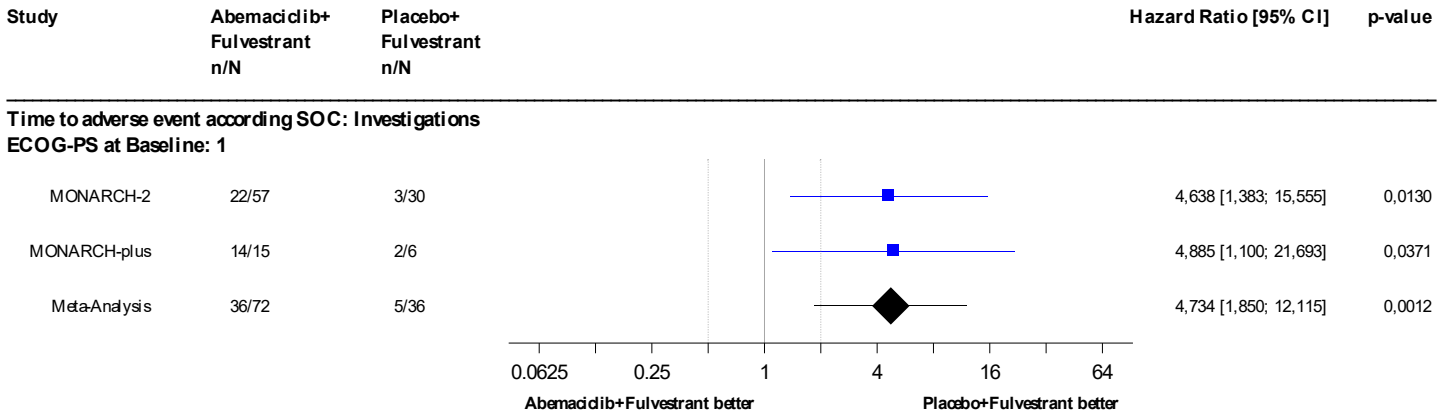
Figure 1280.2.4.2: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0028, p-value=0,9577, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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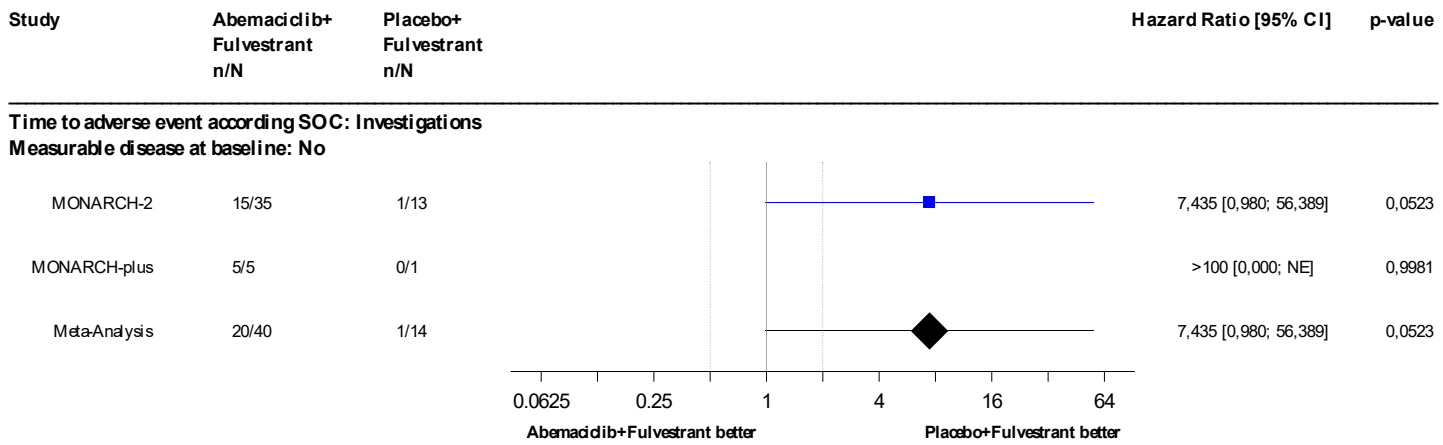
Figure 1280.2.6.1: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9983, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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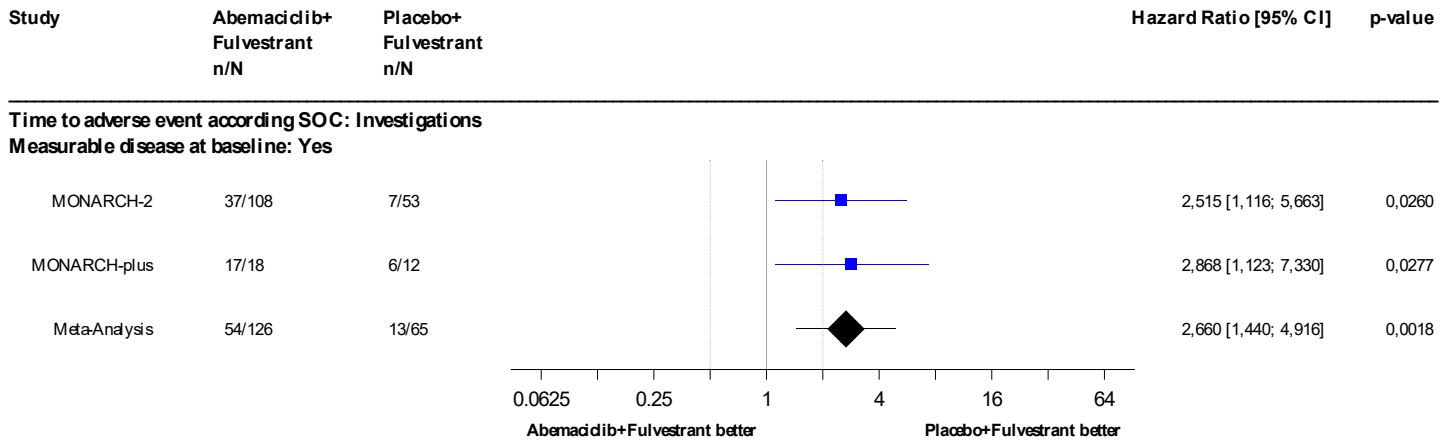
Figure 1280.2.6.2: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0433, p-value=0,8352, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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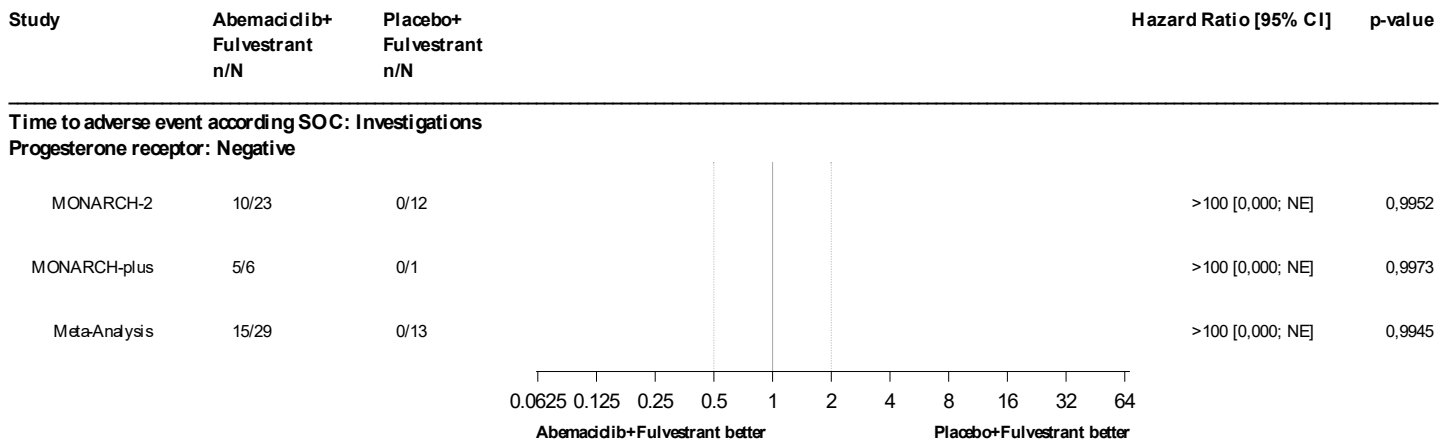
Figure 1280.2.7.1: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9999, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes008_popa2_pgrstat_1.rtf
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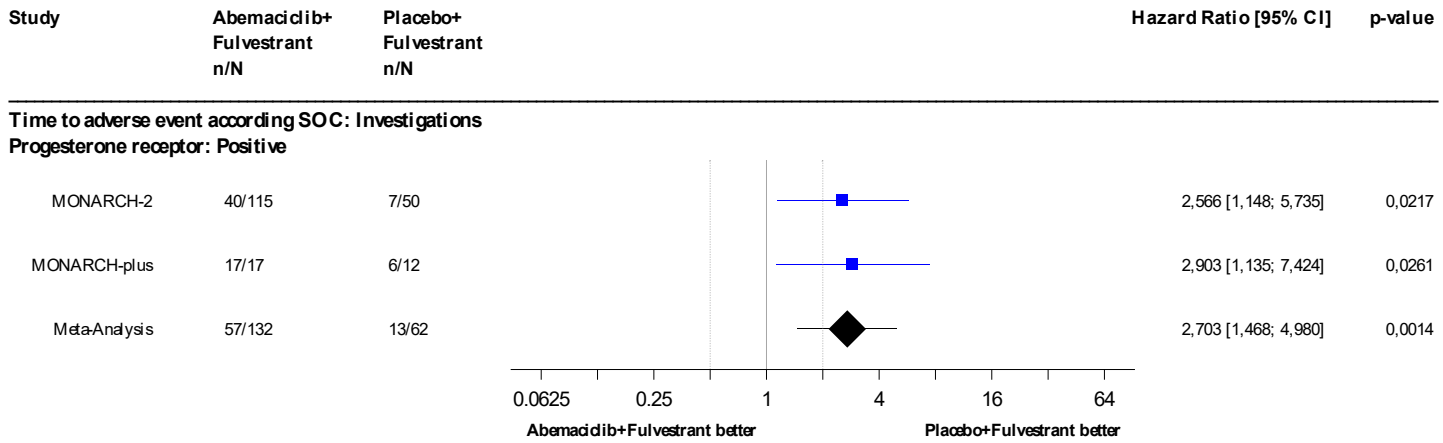
Figure 1280.2.7.2: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0383, p-value=0,8448, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes008_popa2_pgrstat_2.rtf
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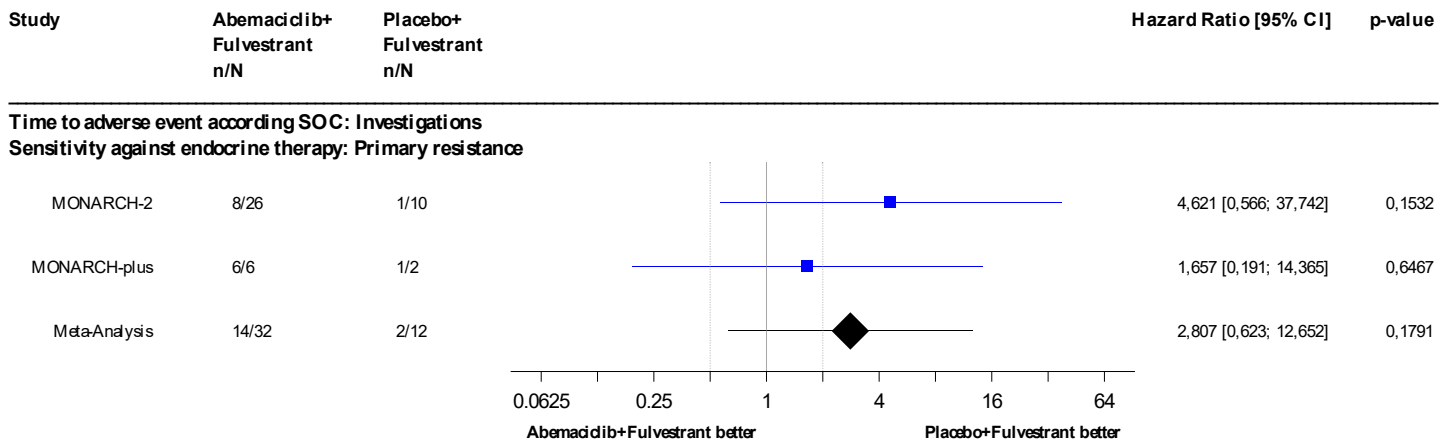
Figure 1280.2.8.1: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4452, p-value=0,5046, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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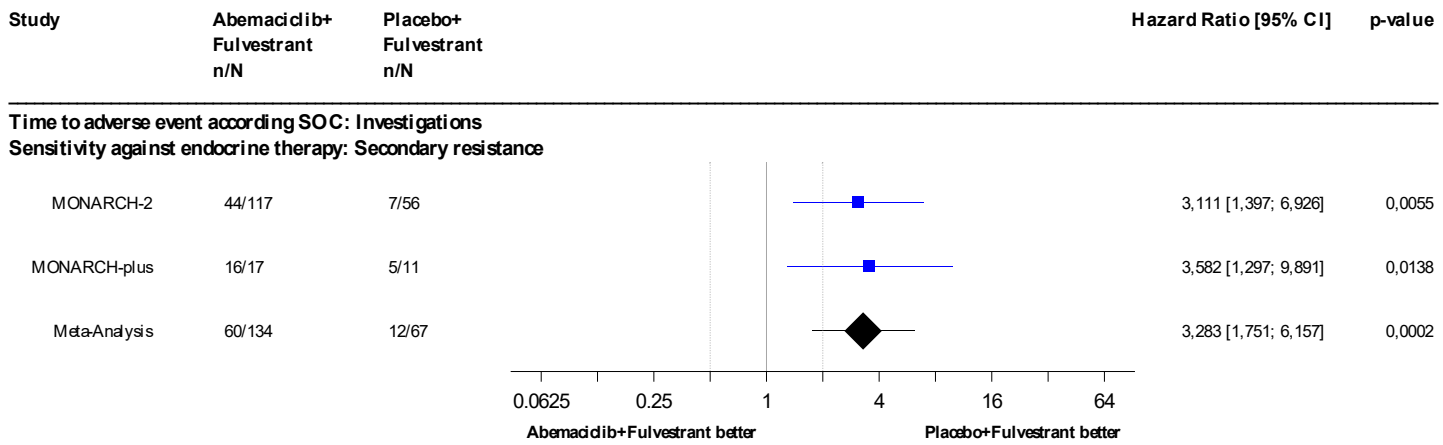
Figure 1280.2.8.2: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0458, p-value=0,8306, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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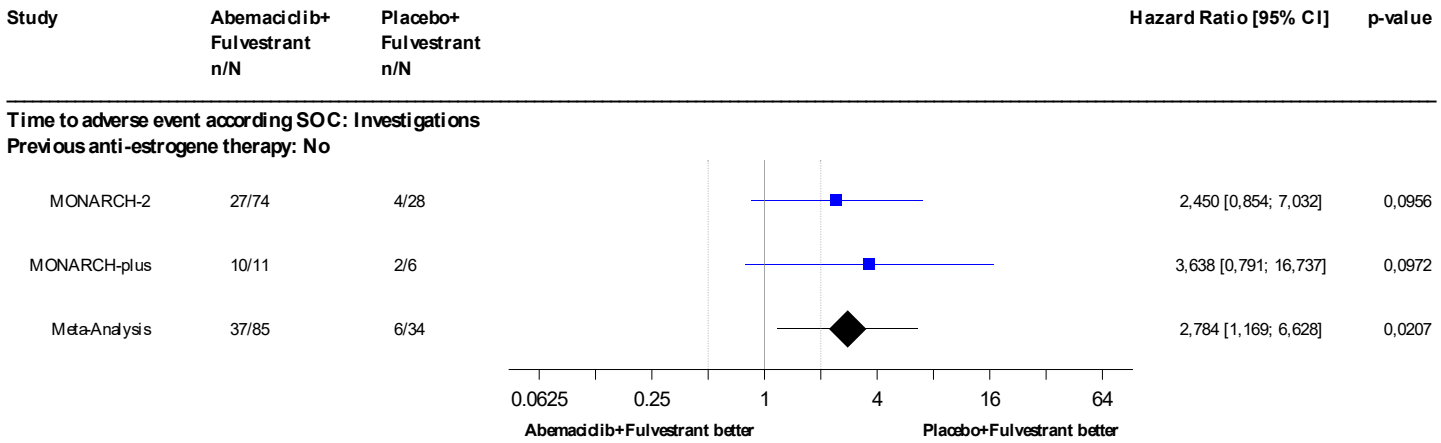
Figure 1280.2.9.1: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1743, p-value=0,6763, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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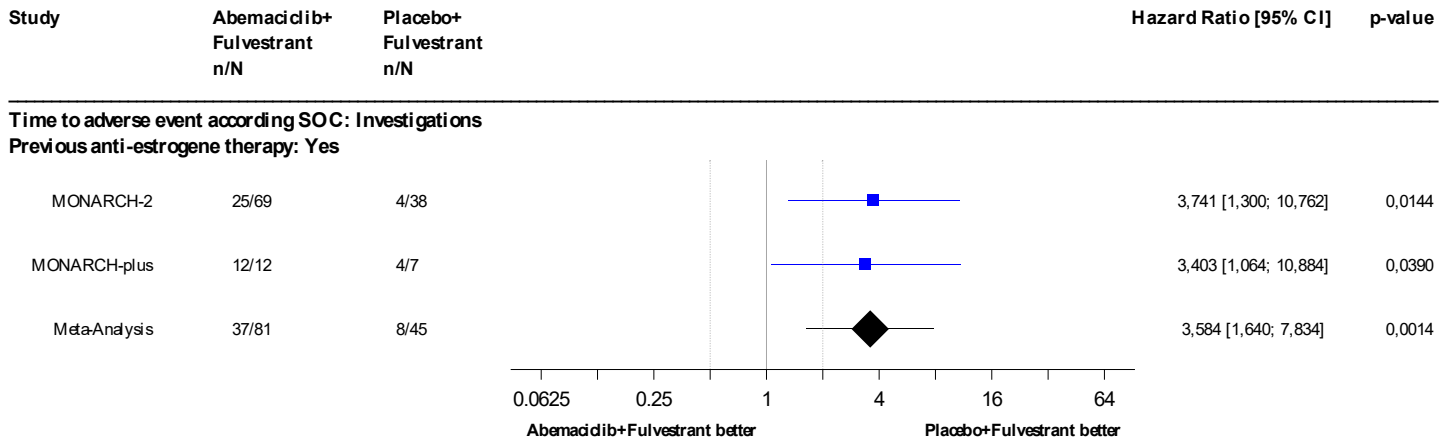
Figure 1280.2.9.2: Metaanalysis results for adverse events according SOC[1] - Investigations
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0139, p-value=0,9061, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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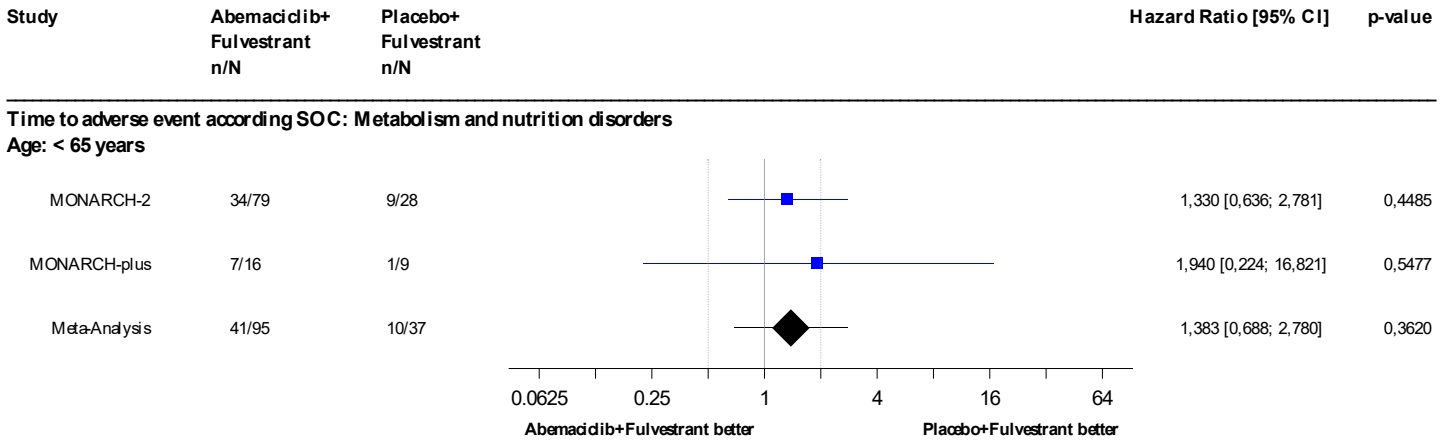
Figure 1281.2.1.1: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1050, p-value=0,7459, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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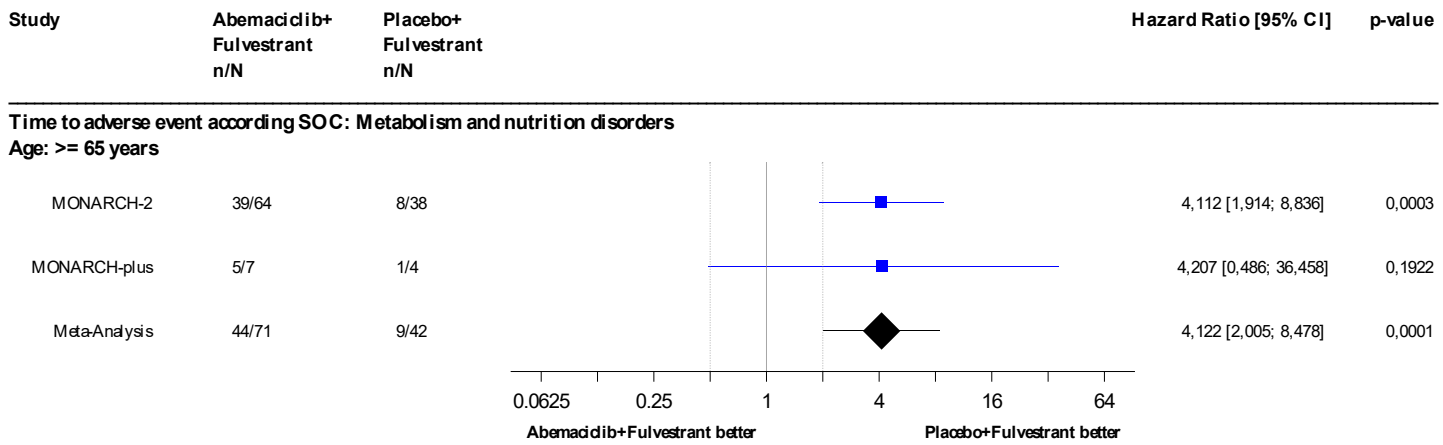
Figure 1281.2.1.2: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0004, p-value=0,9843, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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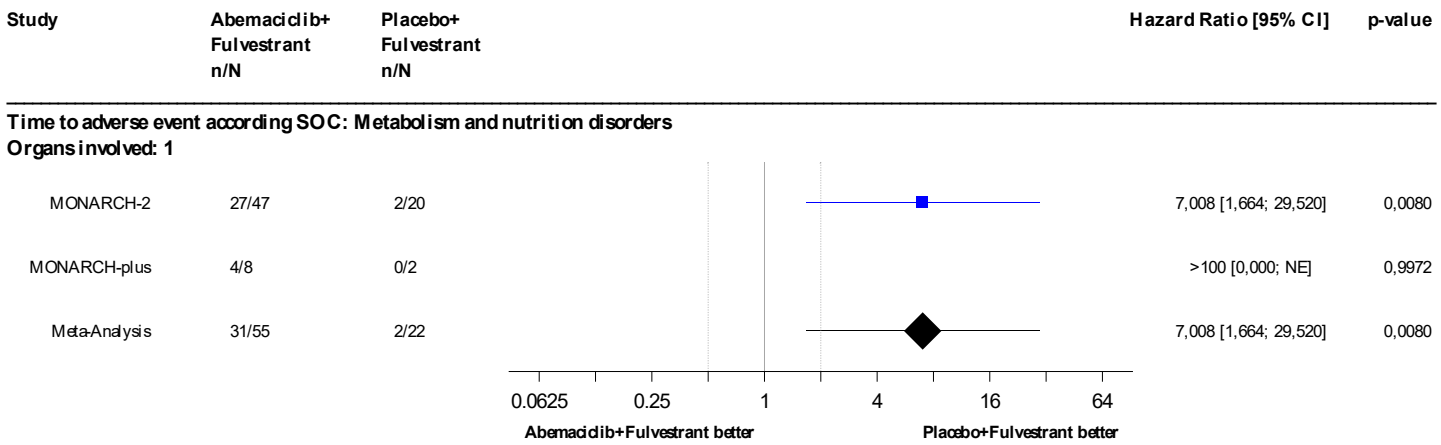
Figure 1281.2.2.1: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9975, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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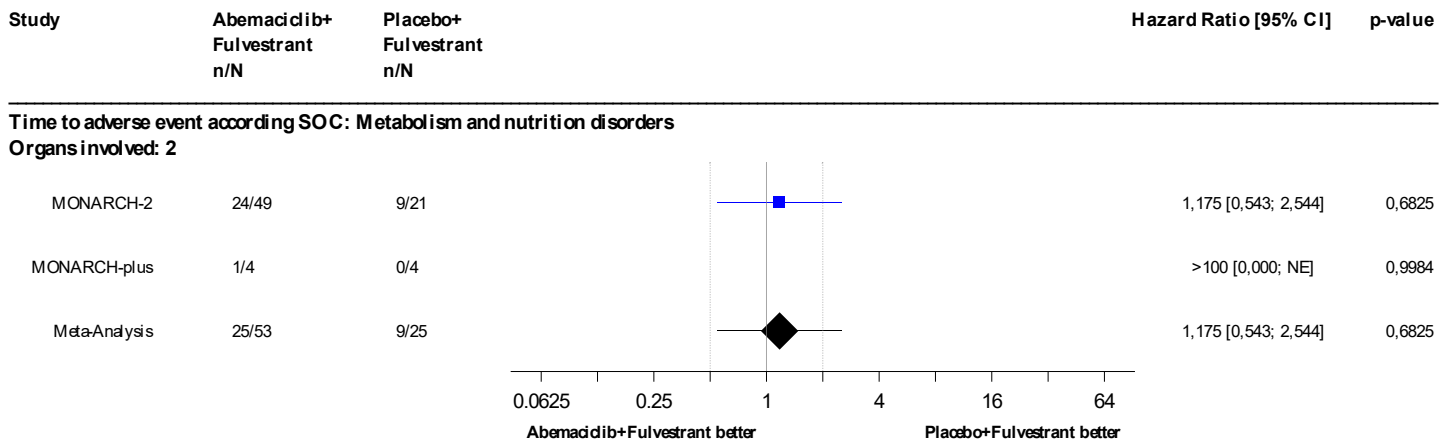
Figure 1281.2.2.2: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9984, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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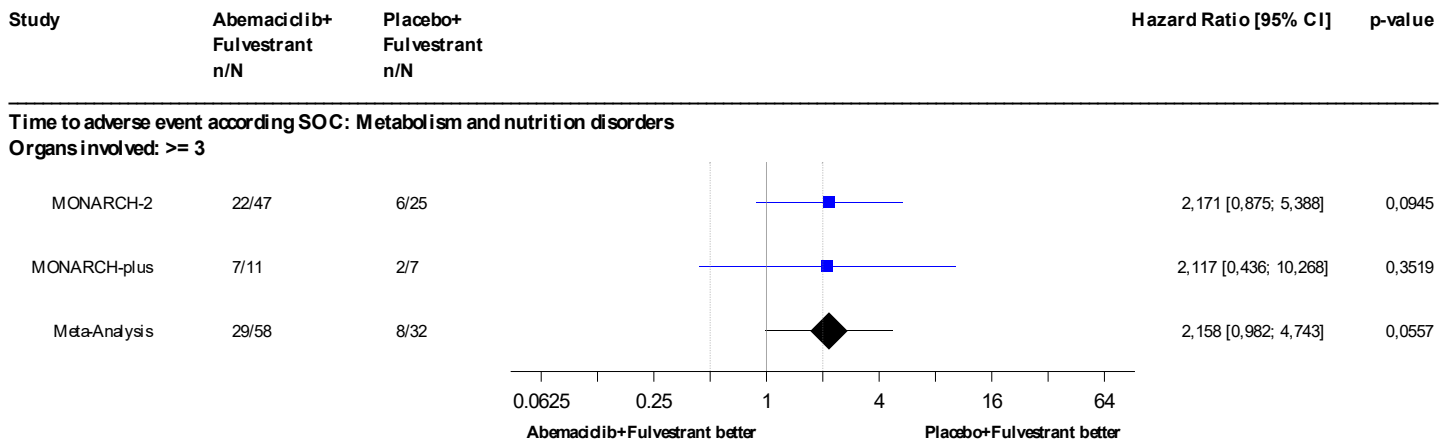
Figure 1281.2.2.3: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0007, p-value=0,9783, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes009_popa2_norggr_3.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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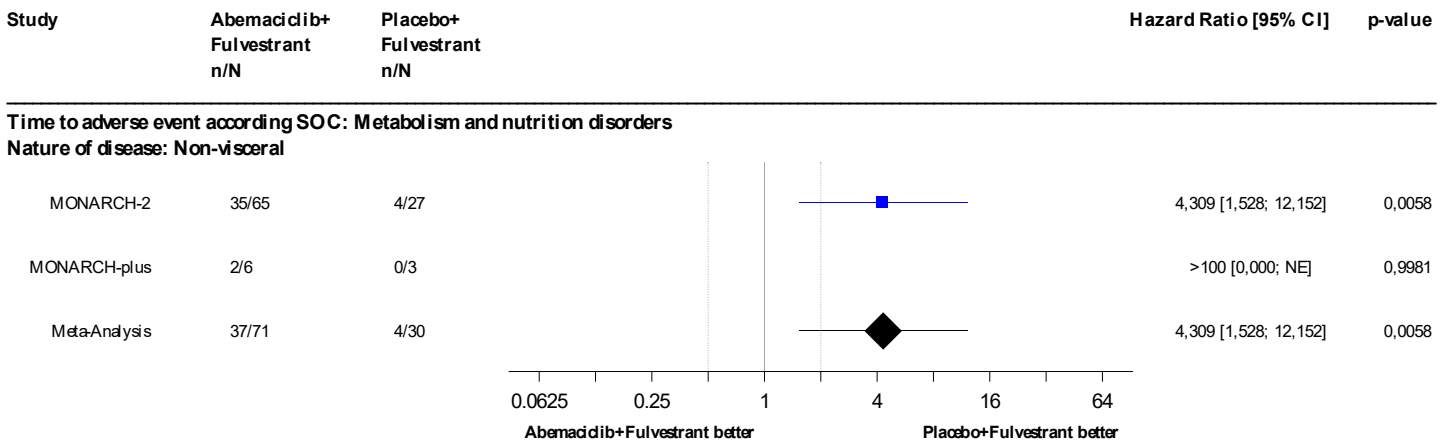
Figure 1281.2.3.1: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9983, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes009_popa2_natdis2_1.rtf
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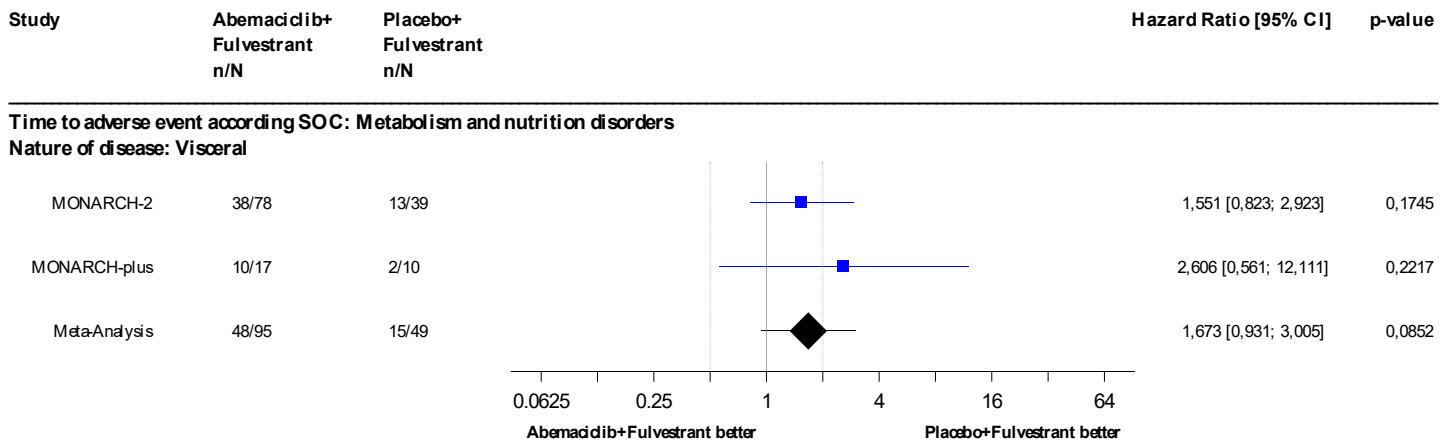
Figure 1281.2.3.2: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3744, p-value=0,5406, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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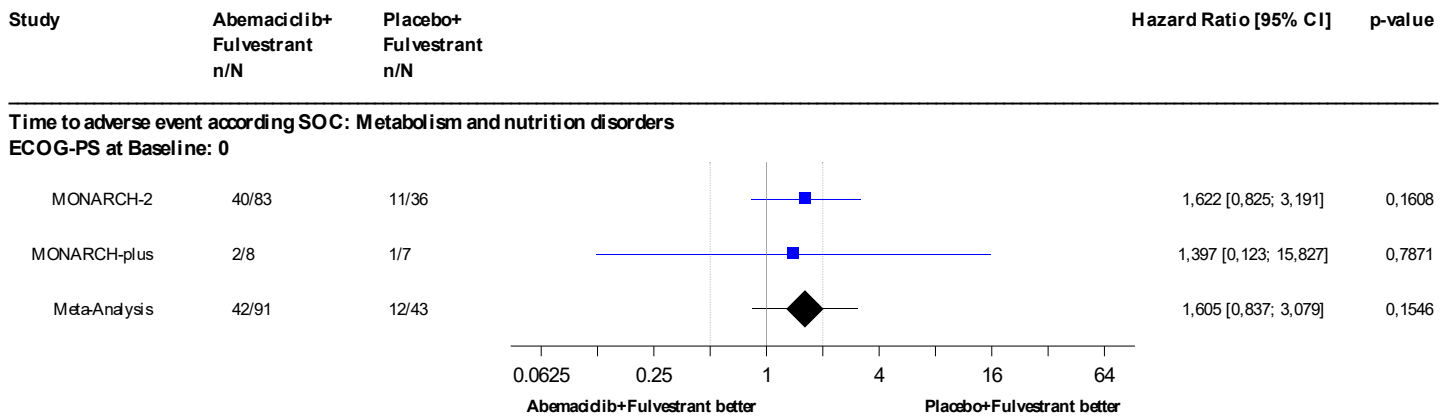
Figure 1281.2.4.1: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0135, p-value=0,9075, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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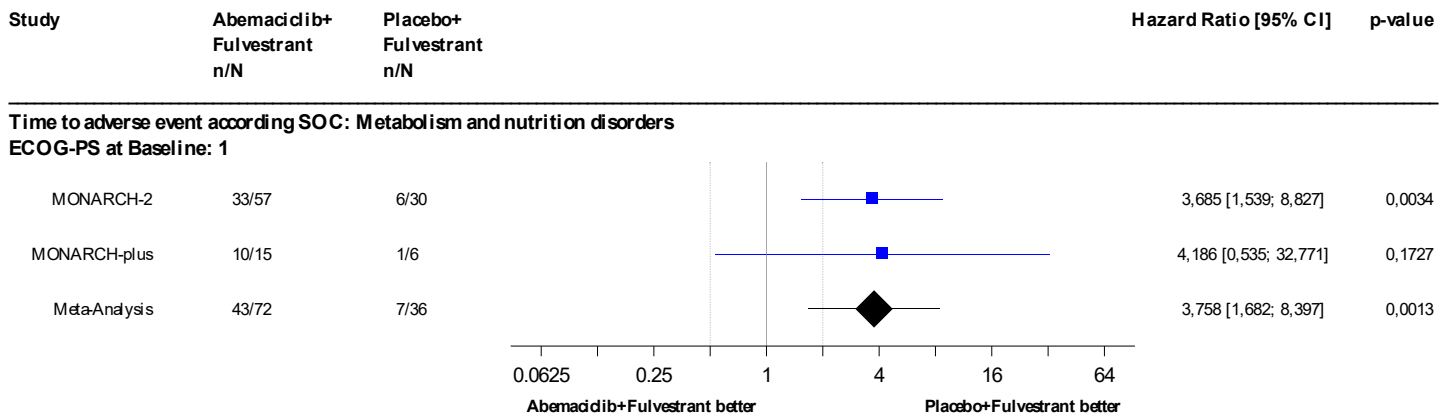
Figure 1281.2.4.2: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0125, p-value=0,9111, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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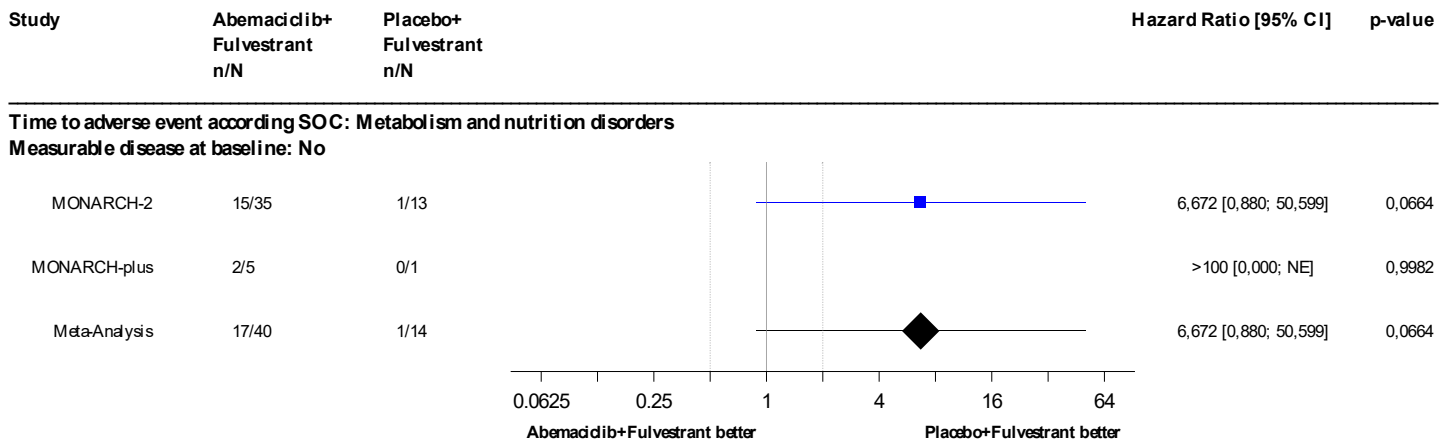
Figure 1281.2.6.1: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9984, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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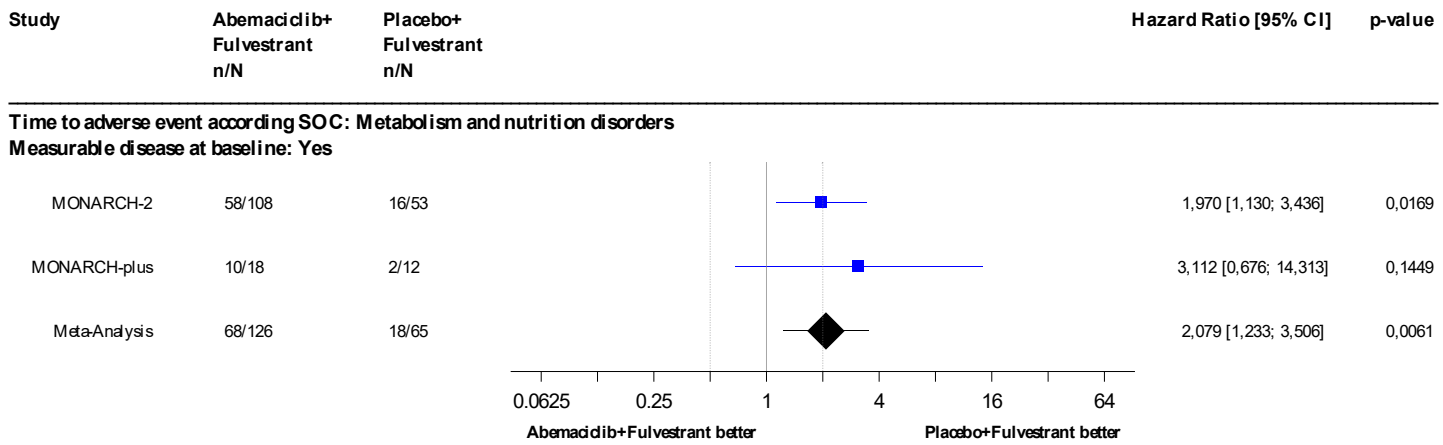
Figure 1281.2.6.2: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3041, p-value=0,5814, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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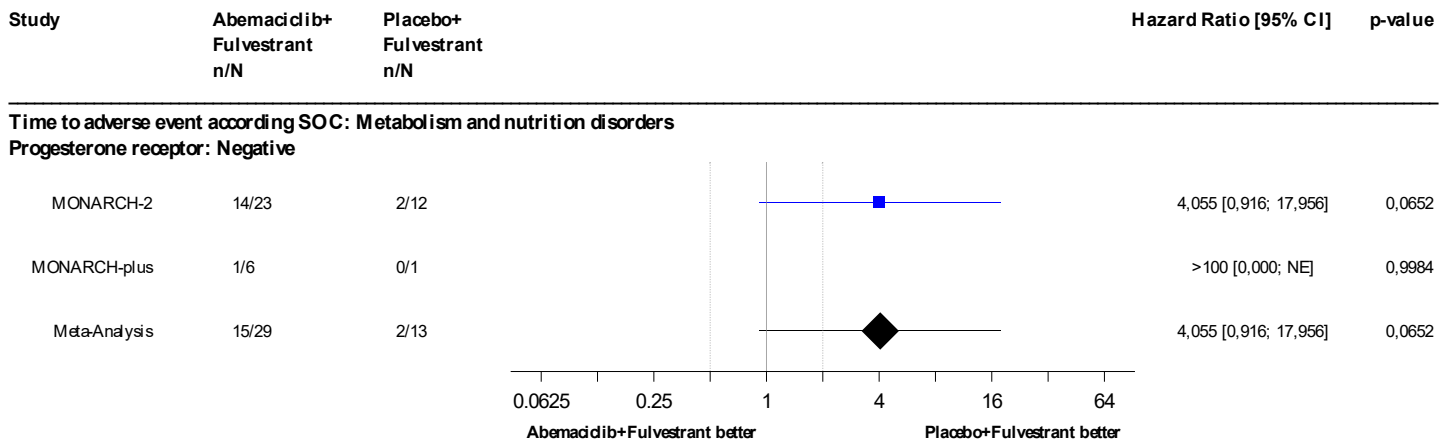
Figure 1281.2.7.1: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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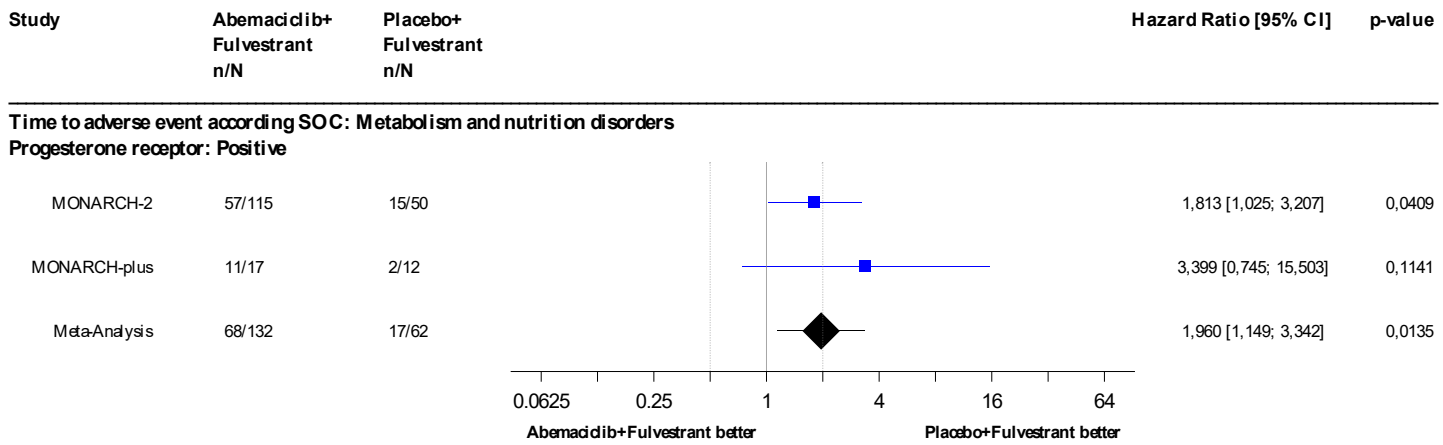
Figure 1281.2.7.2: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5775, p-value=0,4473, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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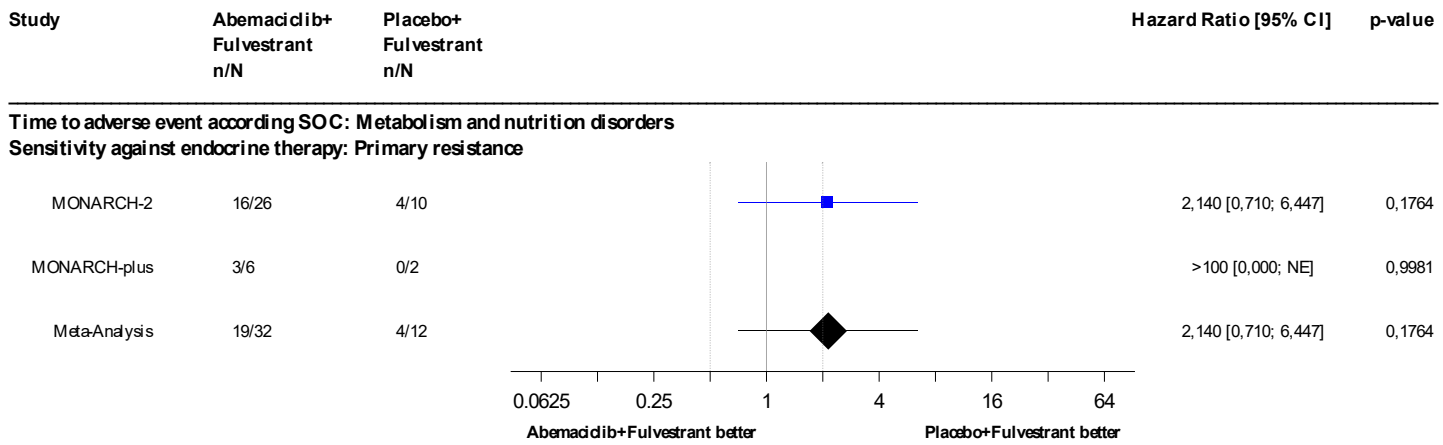
Figure 1281.2.8.1: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9982, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes009_popa2_snthr_1.rtf
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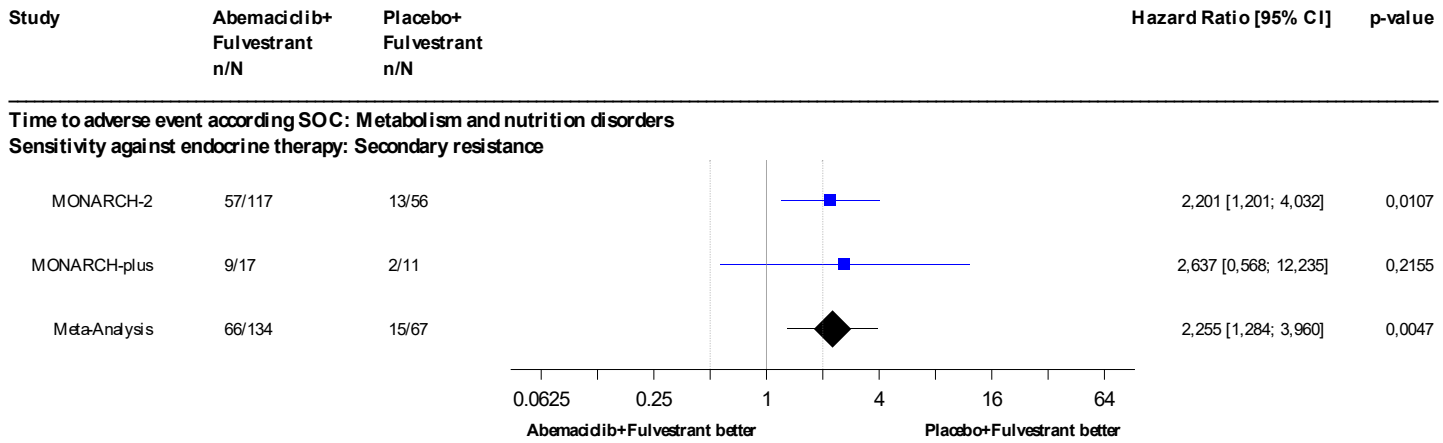
Figure 1281.2.8.2: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0463, p-value=0,8297, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes009_popa2_snthr_2.rtf
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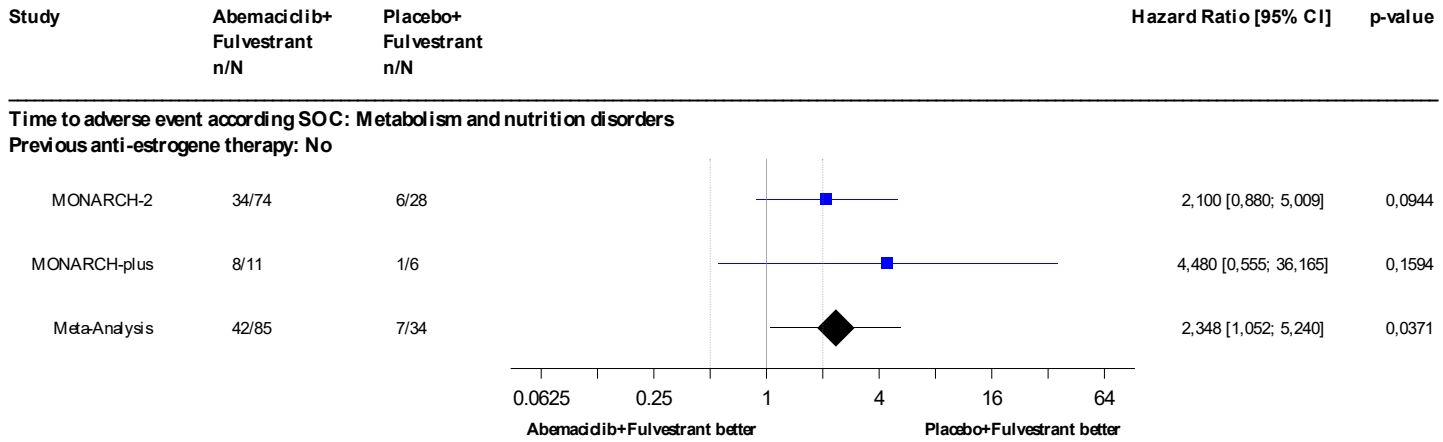
**Figure 1281.2.9.1: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,4309, p-value=0,5115, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes009_popa2_paet_1.rtf
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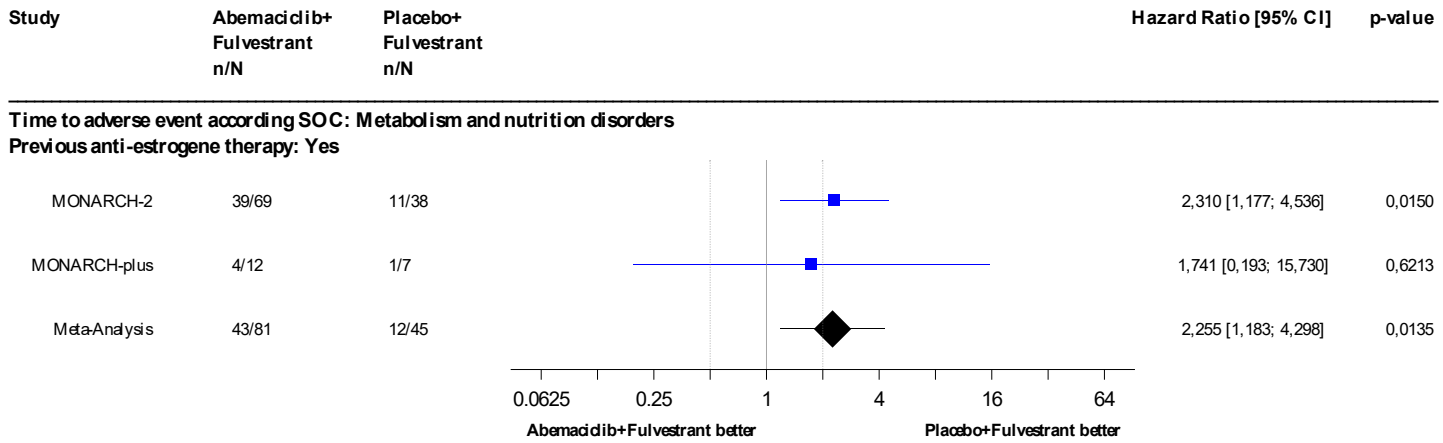
Figure 1281.2.9.2: Metaanalysis results for adverse events according SOC[1] -
Metabolism and nutrition disorders
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0579, p-value=0,8098, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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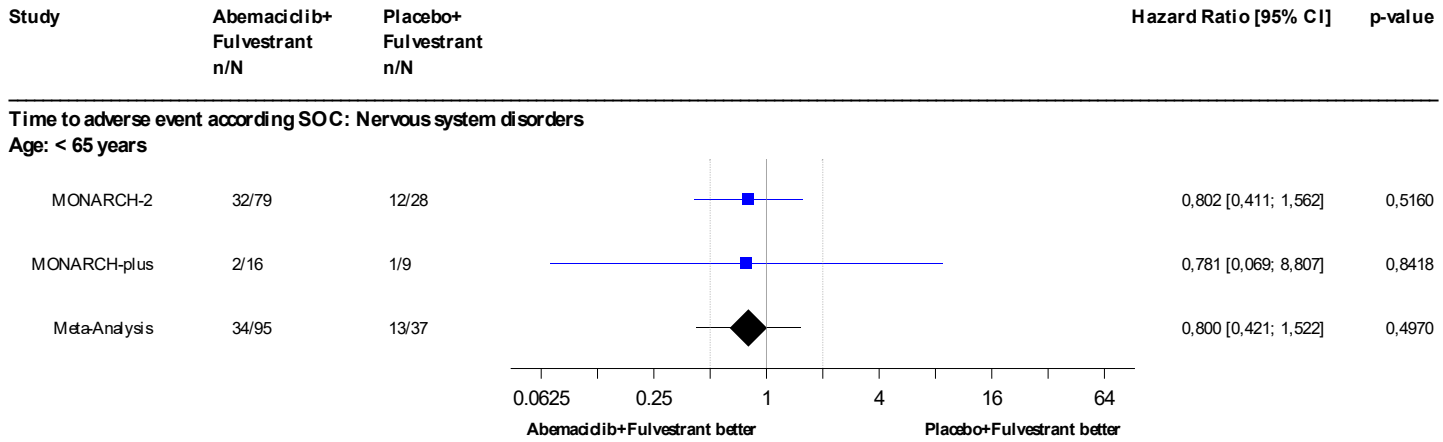
Figure 1284.2.1.1: Metaanalysis results for adverse events according SOC[1] -
Nervous system disorders
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0004, p-value=0,9840, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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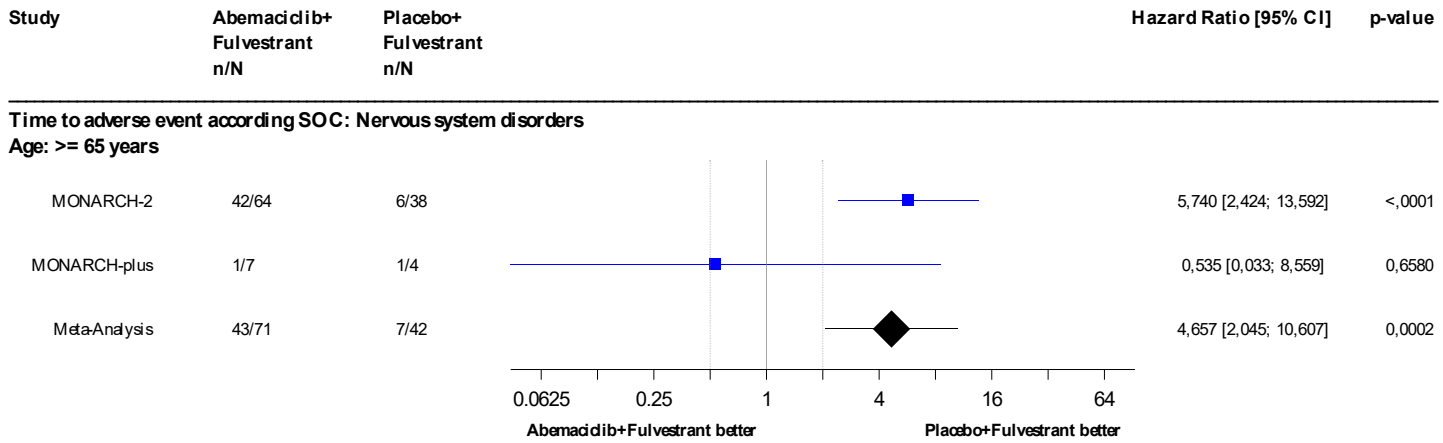
Figure 1284.2.1.2: Metaanalysis results for adverse events according SOC[1] -
Nervous system disorders
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,5666, p-value=0,1091, I2 index=61,0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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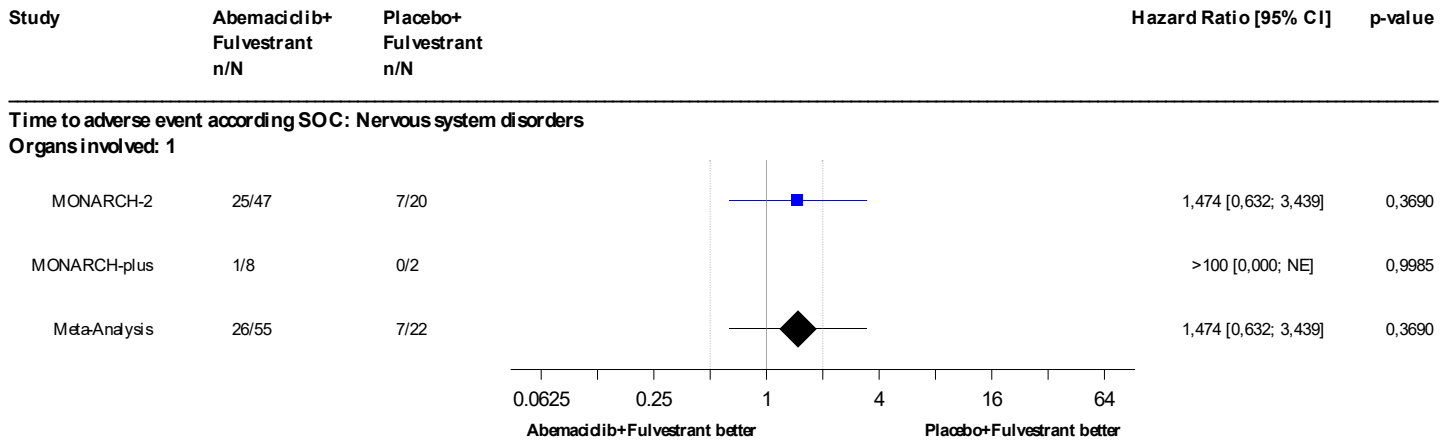
Figure 1284.2.2.1: Metaanalysis results for adverse events according SOC[1] -
Nervous system disorders
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes012_popa2_norggr_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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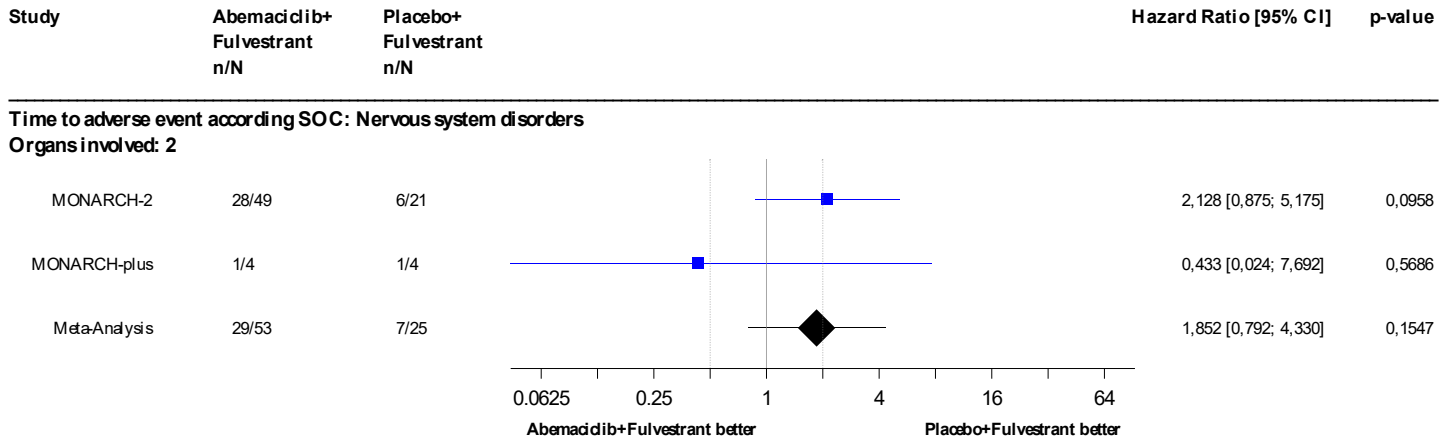
Figure 1284.2.2.2: Metaanalysis results for adverse events according SOC[1] -
Nervous system disorders
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,0739, p-value=0,3001, I2 index=6,9%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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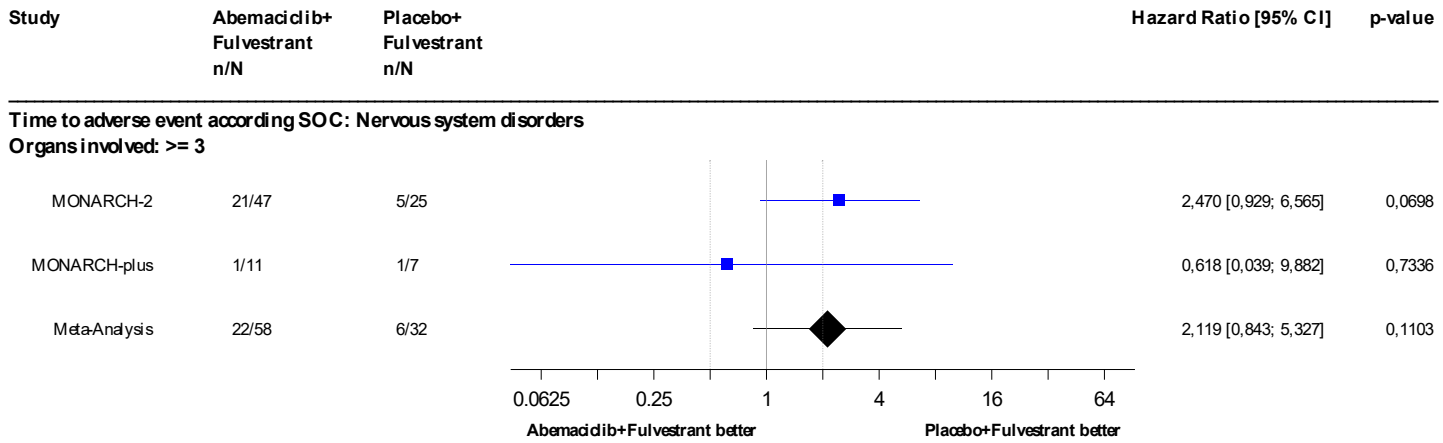
Figure 1284.2.2.3: Metaanalysis results for adverse events according SOC[1] -
Nervous system disorders
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,8537, p-value=0,3555, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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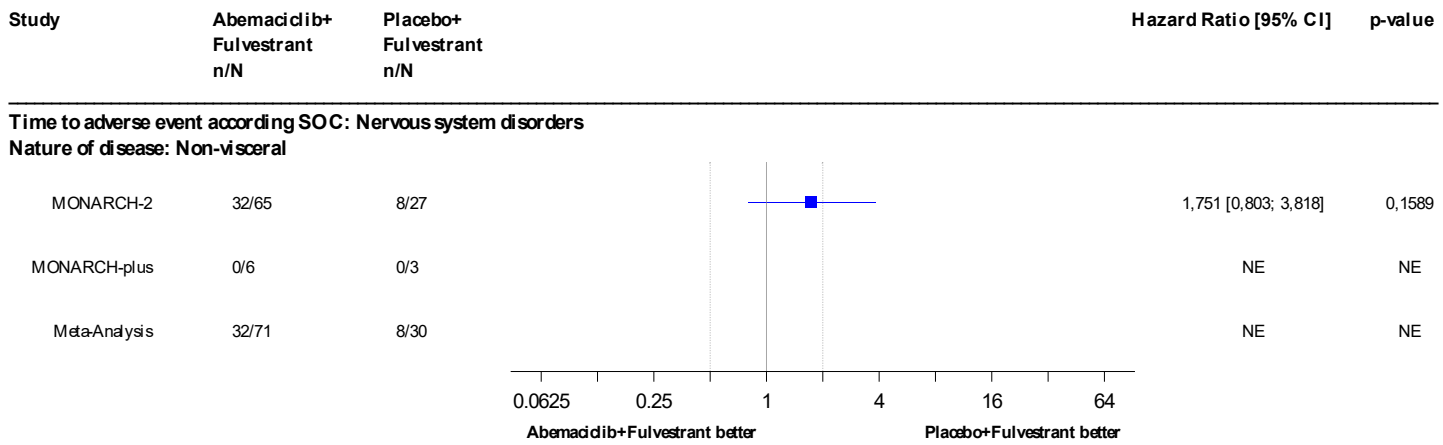
Figure 1284.2.3.1: Metaanalysis results for adverse events according SOC[1] -
Nervous system disorders
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes012_popa2_natdis2_1.rtf
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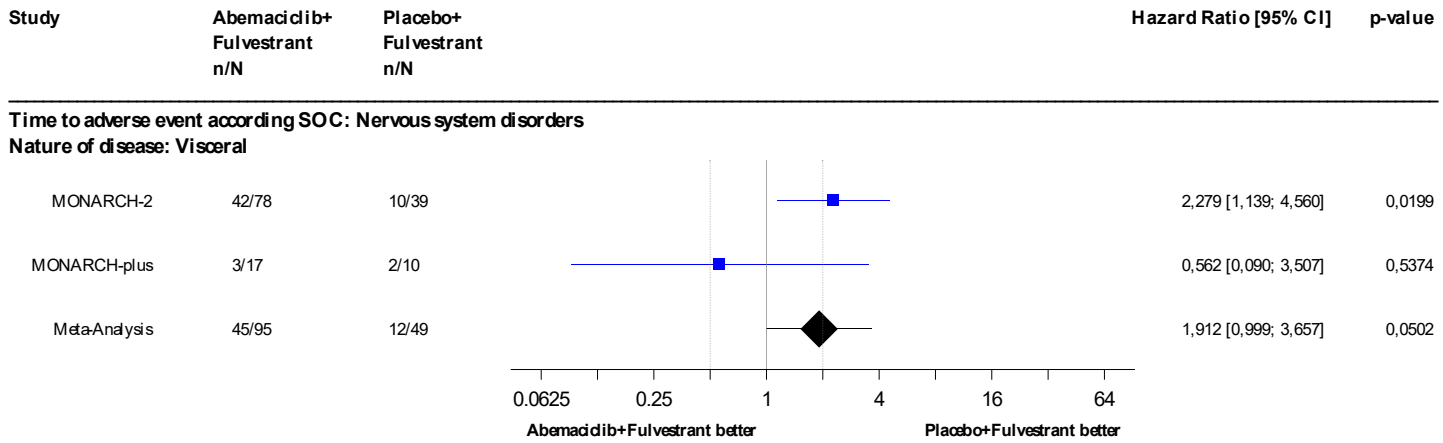
Figure 1284.2.3.2: Metaanalysis results for adverse events according SOC[1] -
Nervous system disorders
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,9638, p-value=0,1611, I2 index=49,1%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes012_popa2_natdis2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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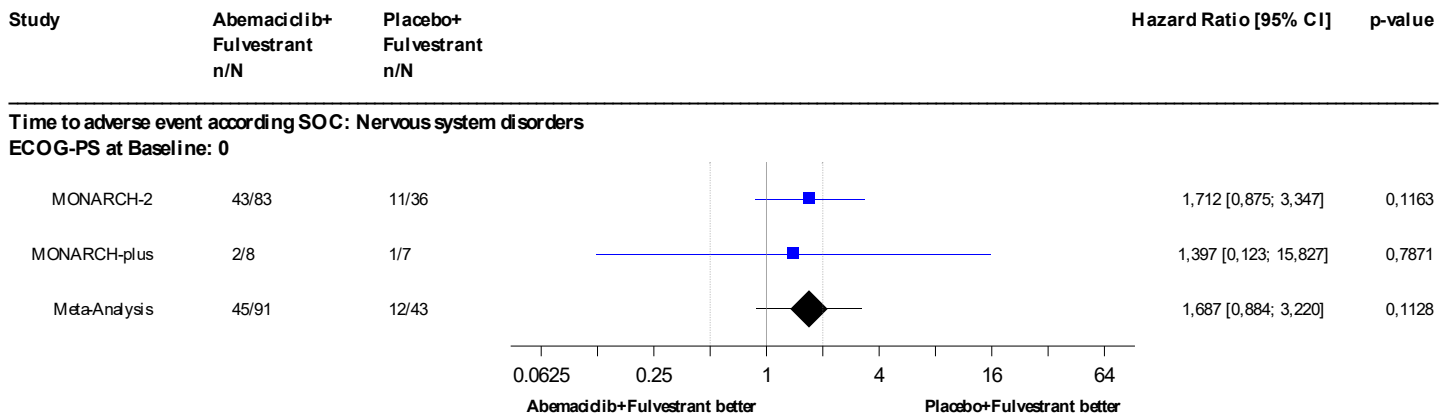
Figure 1284.2.4.1: Metaanalysis results for adverse events according SOC[1] -
Nervous system disorders
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0249, p-value=0,8745, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes012_popa2_ecogbl_1.rtf
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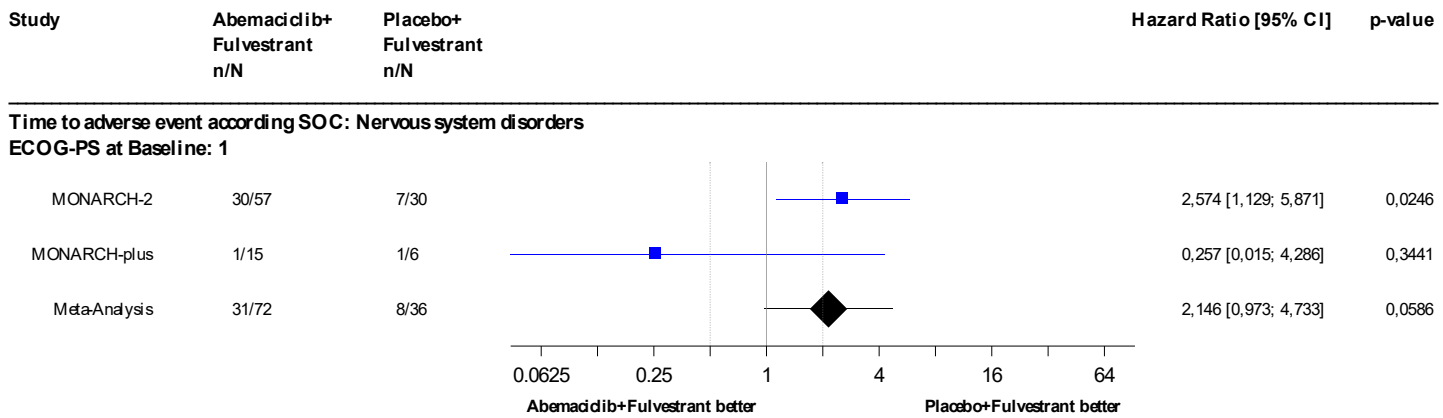
Figure 1284.2.4.2: Metaanalysis results for adverse events according SOC[1] -
Nervous system disorders
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,3719, p-value=0,1235, I2 index=57,8%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes012_popa2_ecogbl_2.rtf
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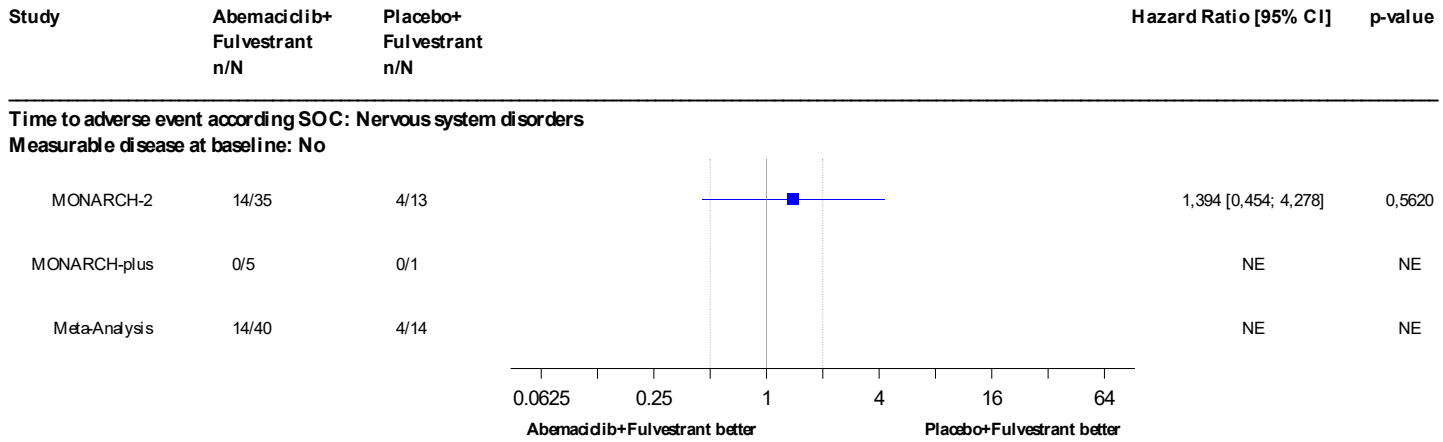
Figure 1284.2.6.1: Metaanalysis results for adverse events according SOC[1] -
Nervous system disorders
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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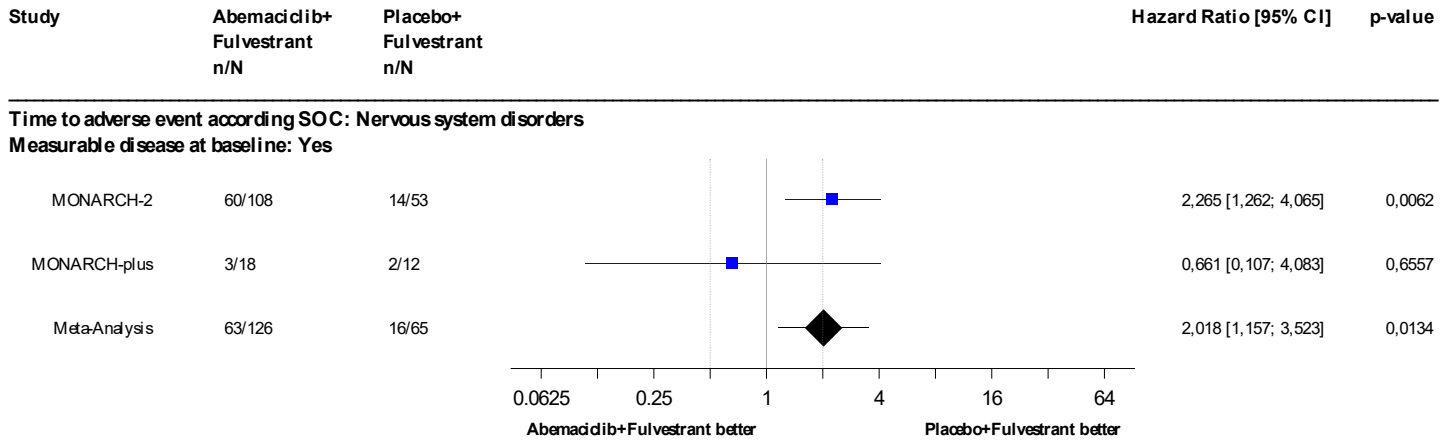
Figure 1284.2.6.2: Metaanalysis results for adverse events according SOC[1] -
Nervous system disorders
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,5932, p-value=0,2069, I2 index=37,2%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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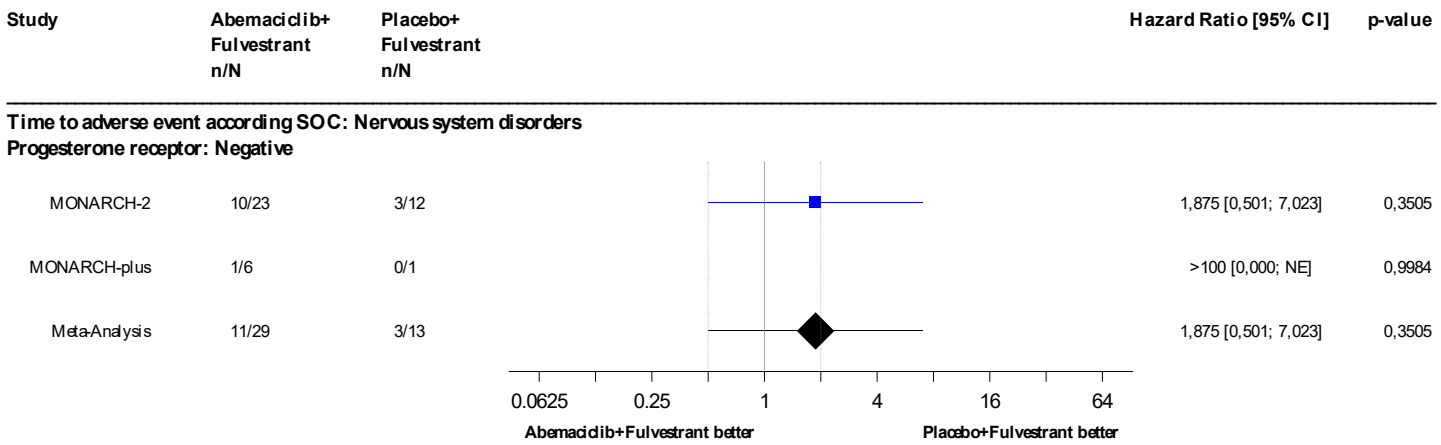
Figure 1284.2.7.1: Metaanalysis results for adverse events according SOC[1] -
Nervous system disorders
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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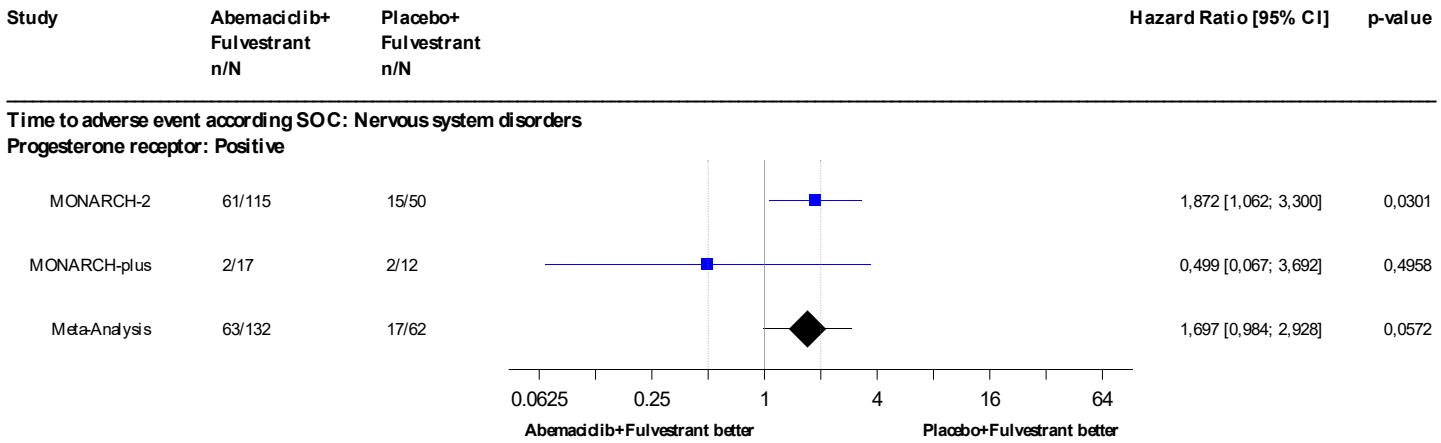
Figure 1284.2.7.2: Metaanalysis results for adverse events according SOC[1] -
Nervous system disorders
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,5530, p-value=0,2127, I2 index=35,6%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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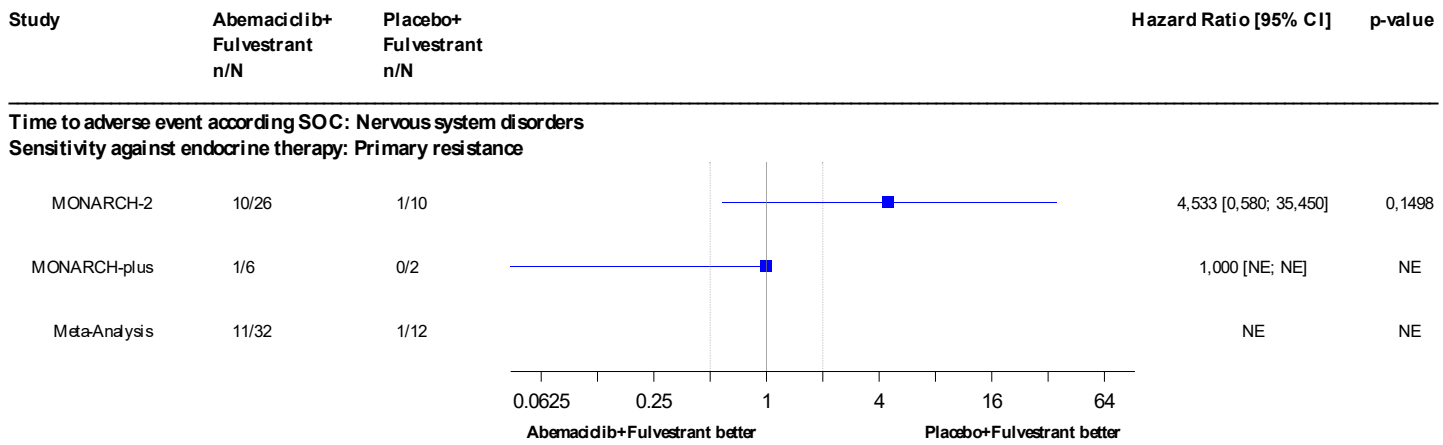
Figure 1284.2.8.1: Metaanalysis results for adverse events according SOC[1] -
Nervous system disorders
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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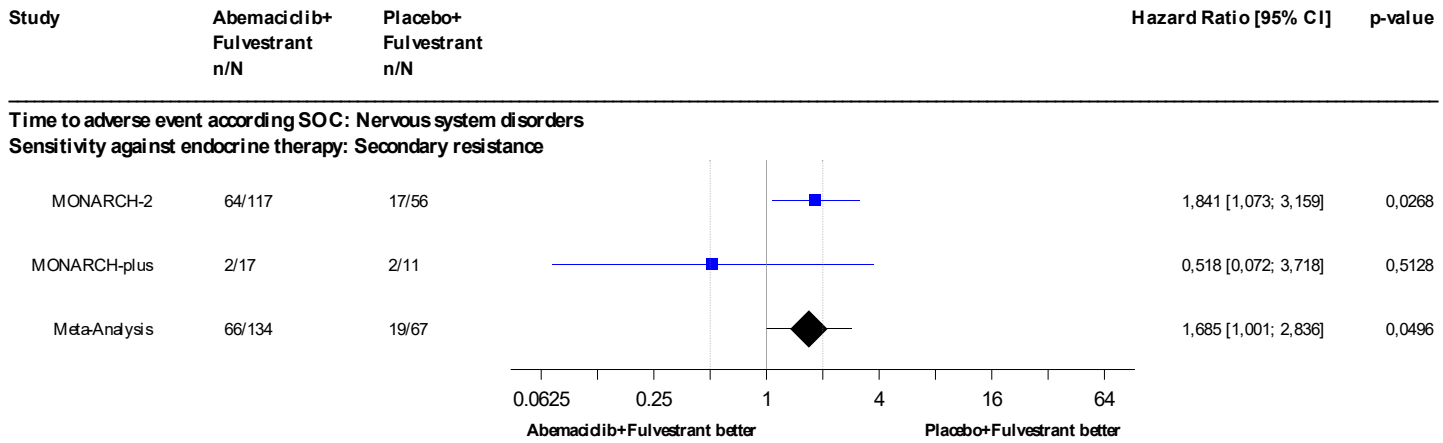
Figure 1284.2.8.2: Metaanalysis results for adverse events according SOC[1] -
Nervous system disorders
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,4794, p-value=0,2239, I2 index=32,4%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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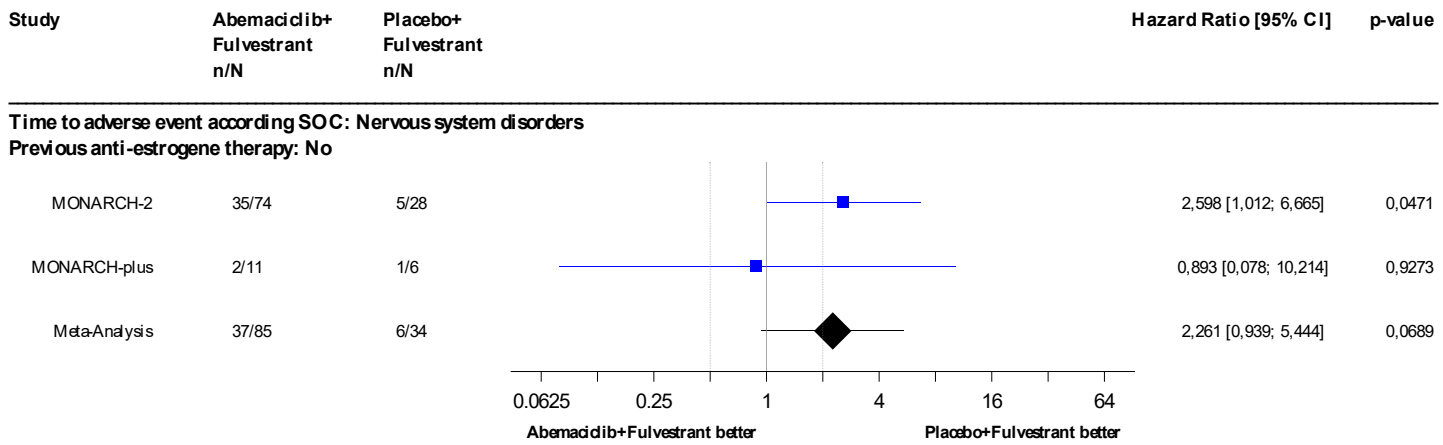
Figure 1284.2.9.1: Metaanalysis results for adverse events according SOC[1] -
Nervous system disorders
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6418, p-value=0,4231, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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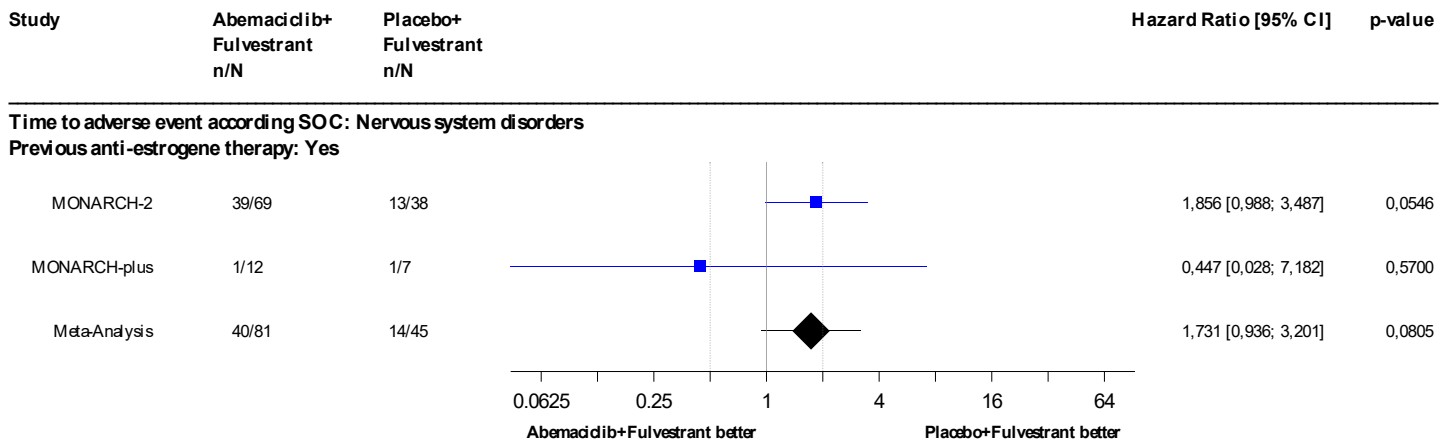
Figure 1284.2.9.2: Metaanalysis results for adverse events according SOC[1] -
Nervous system disorders
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,9597, p-value=0,3273, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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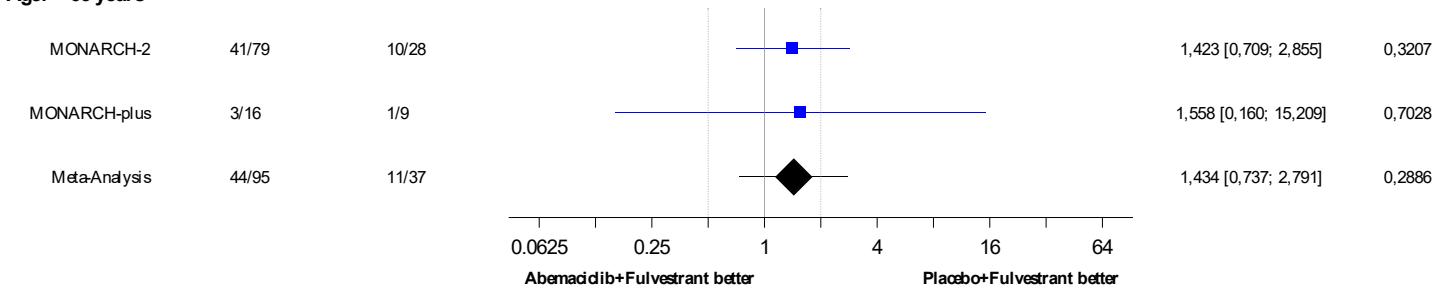
Figure 1289.2.1.1: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0056, p-value=0,9404, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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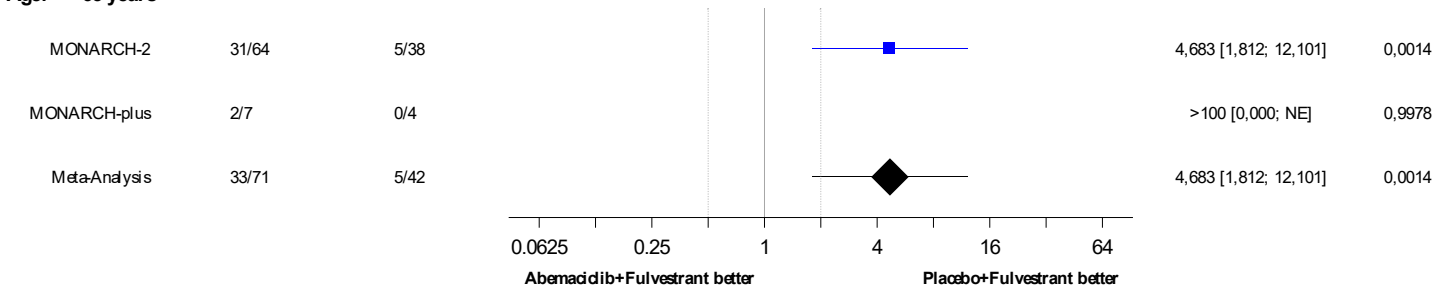
Figure 1289.2.1.2: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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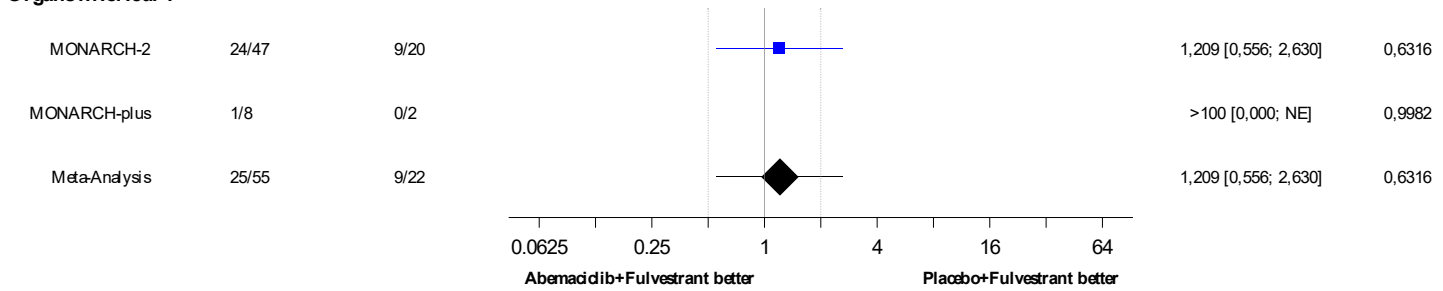
Figure 1289.2.2.1: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9982, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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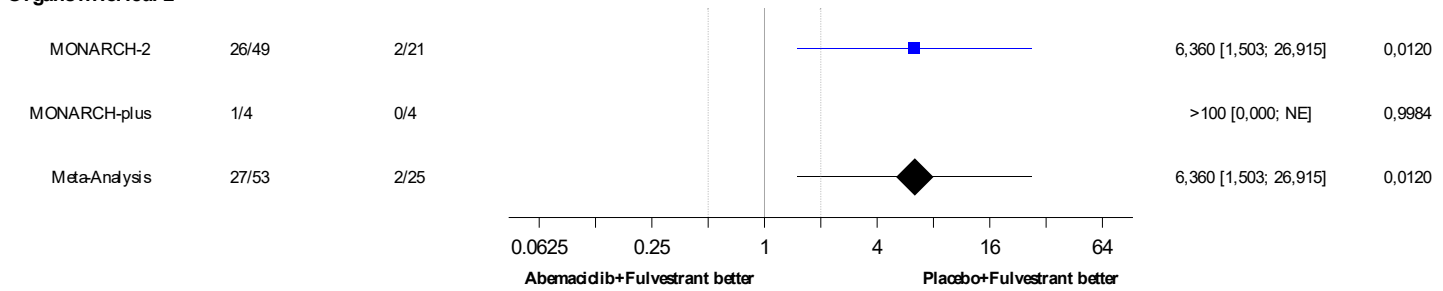
Figure 1289.2.2.2: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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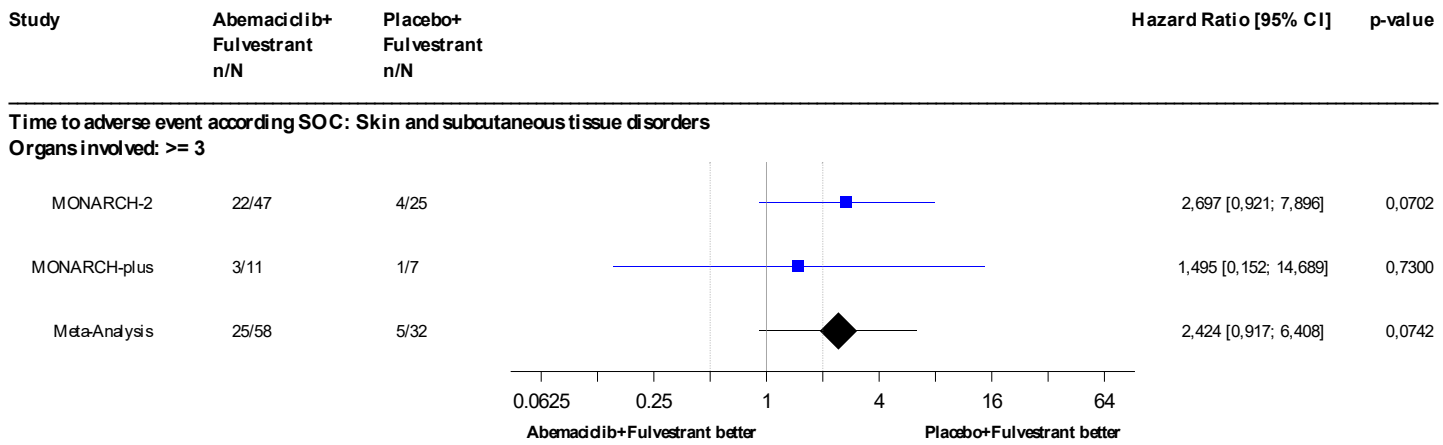
Figure 1289.2.2.3: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2097, p-value=0,6470, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttiraes017_popa2_norggr_3.rtf

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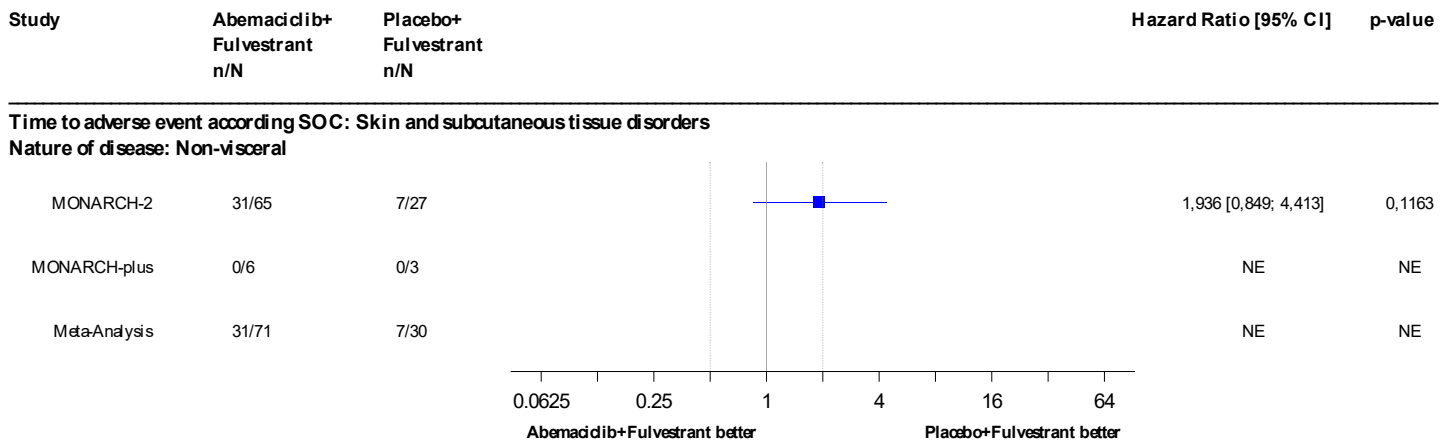
Figure 1289.2.3.1: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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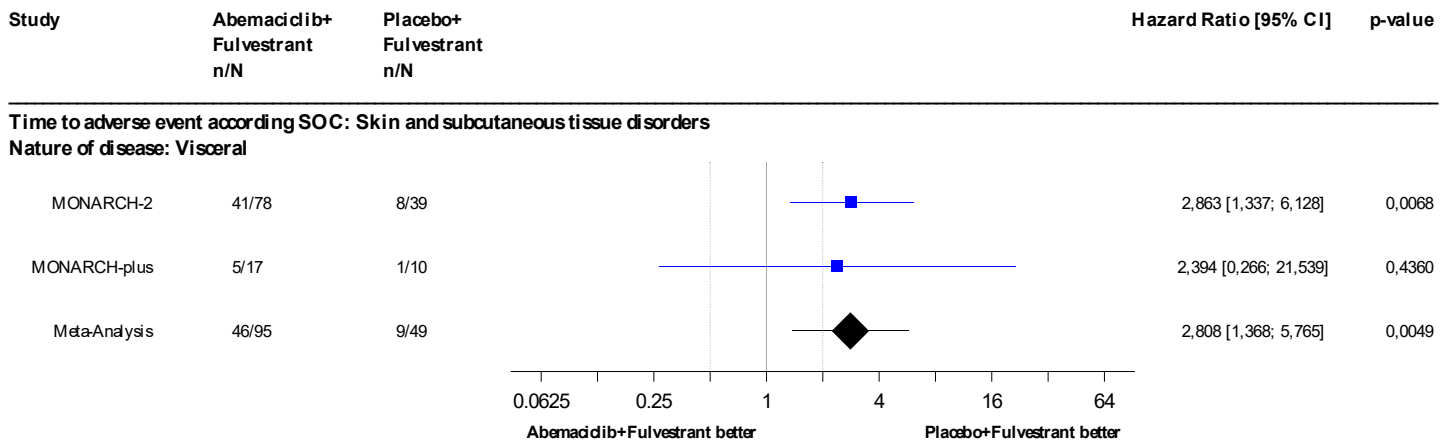
Figure 1289.2.3.2: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0227, p-value=0,8803, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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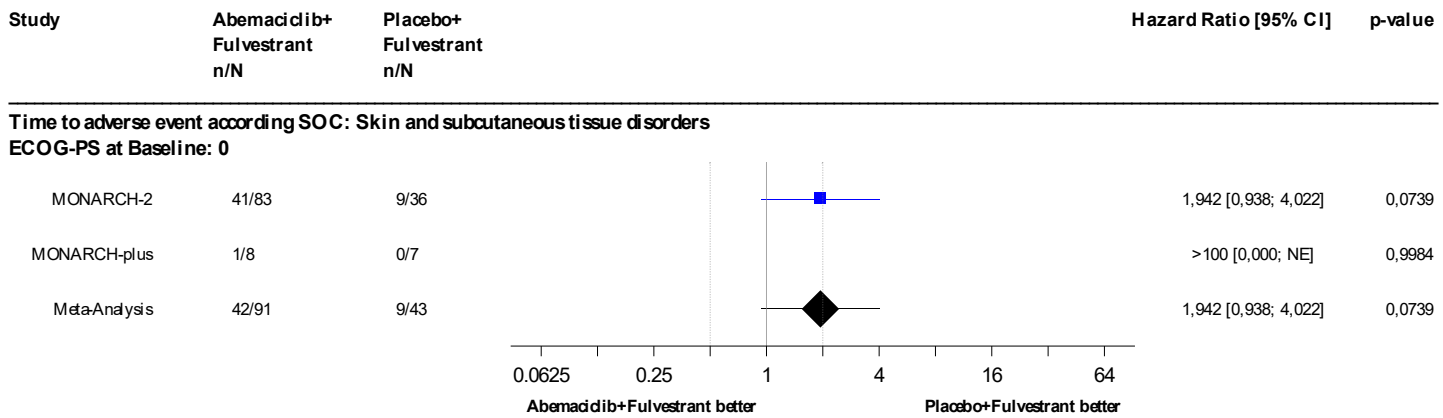
Figure 1289.2.4.1: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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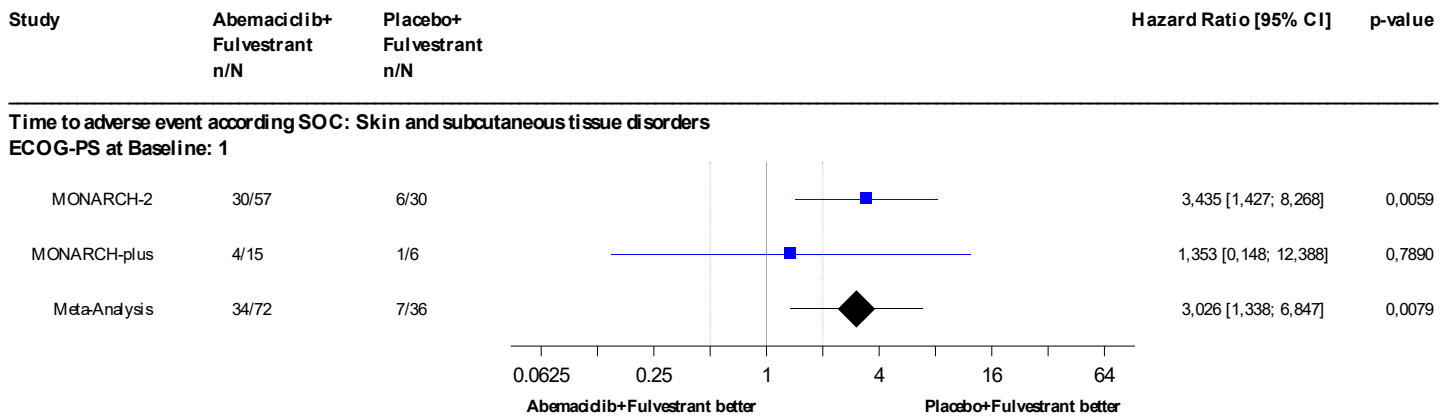
Figure 1289.2.4.2: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,5876, p-value=0,4433, I2 index=0%
Abbreviations: CI: Confidence Interval; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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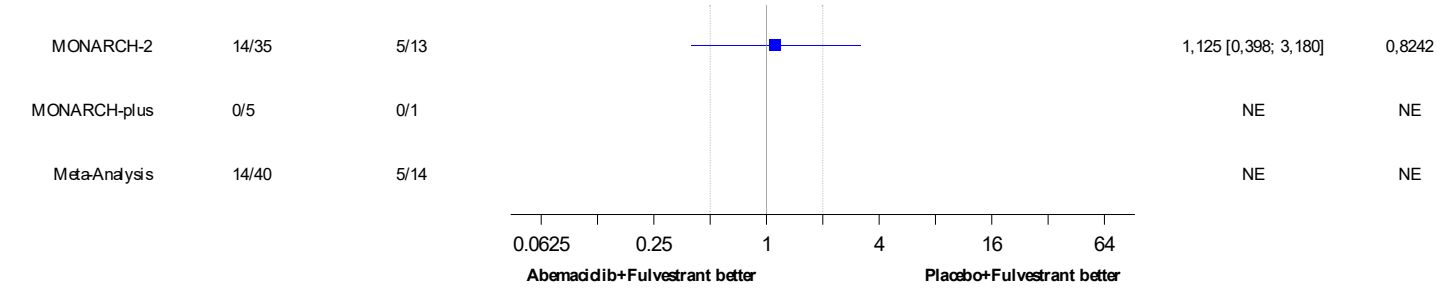
Figure 1289.2.6.1: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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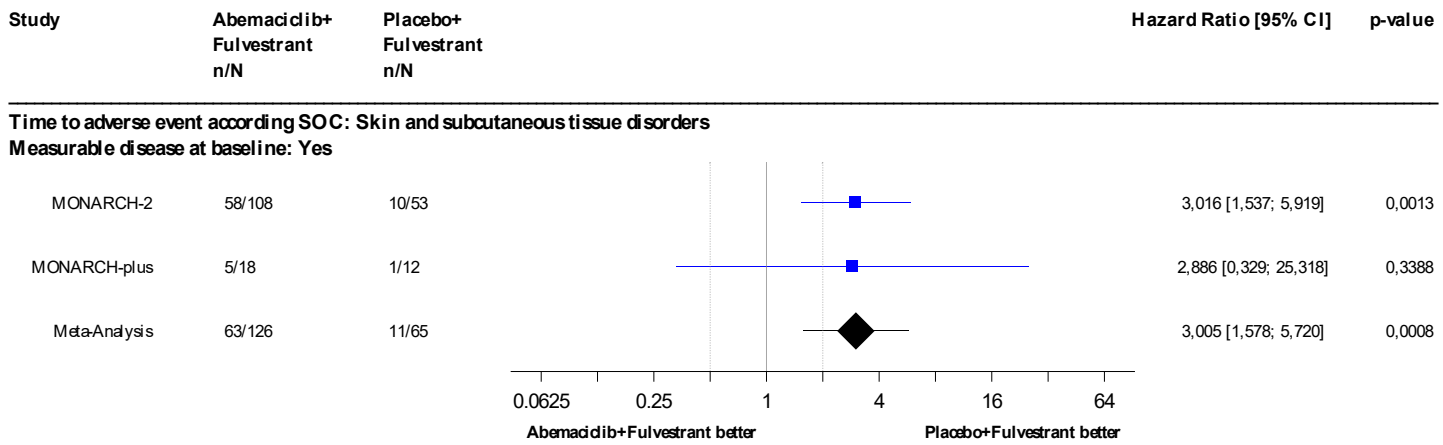
Figure 1289.2.6.2: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0015, p-value=0,9695, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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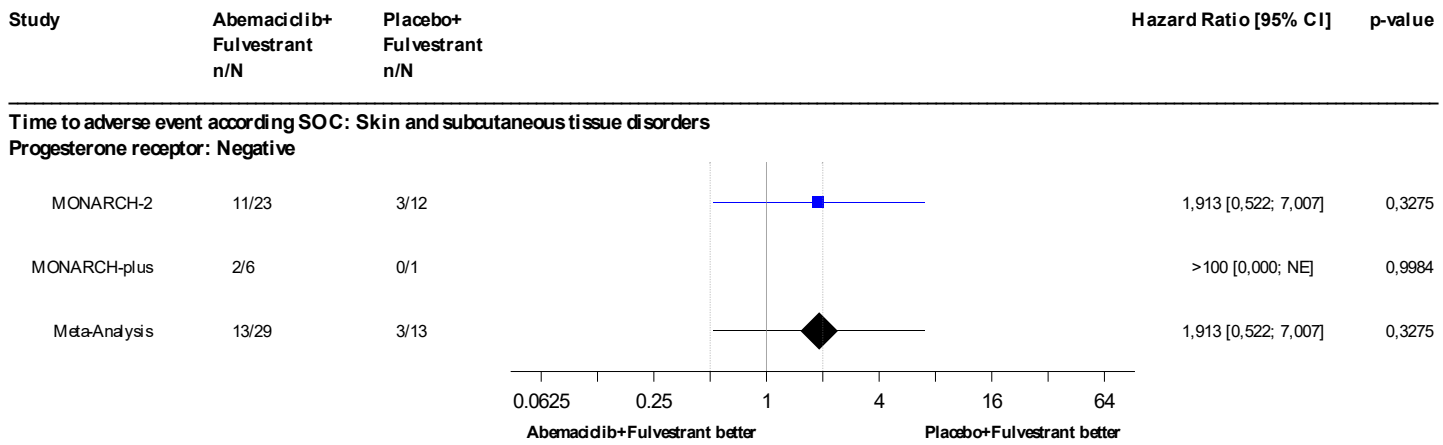
Figure 1289.2.7.1: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9984, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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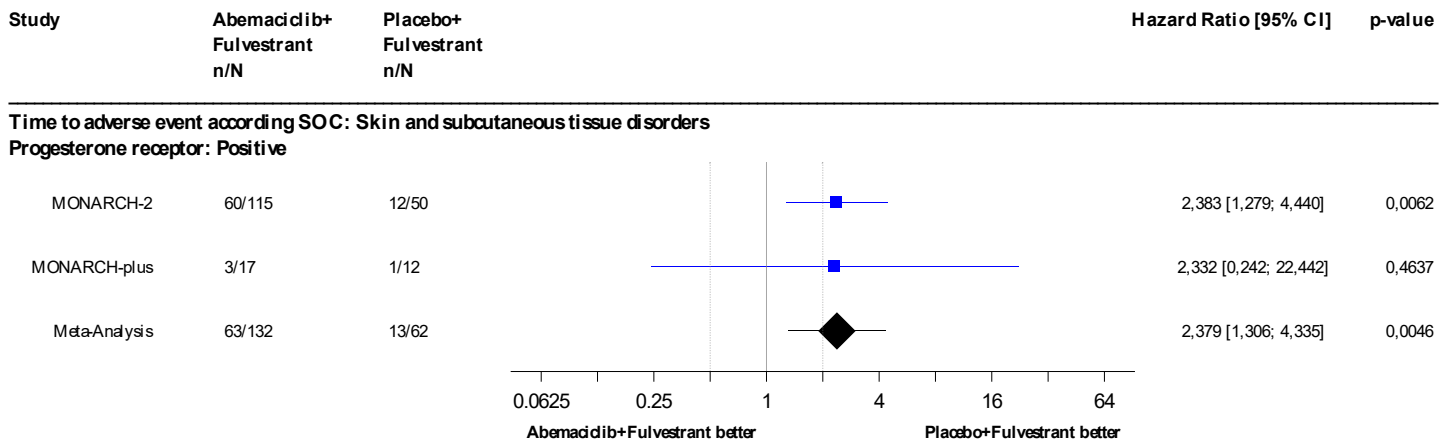
Figure 1289.2.7.2: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0003, p-value=0,9855, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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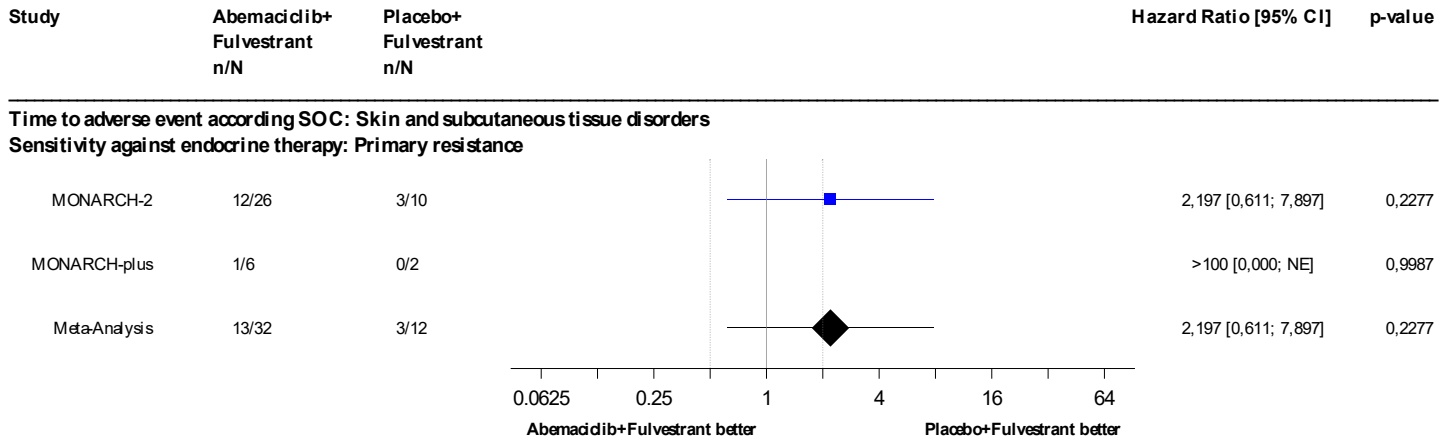
Figure 1289.2.8.1: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9988, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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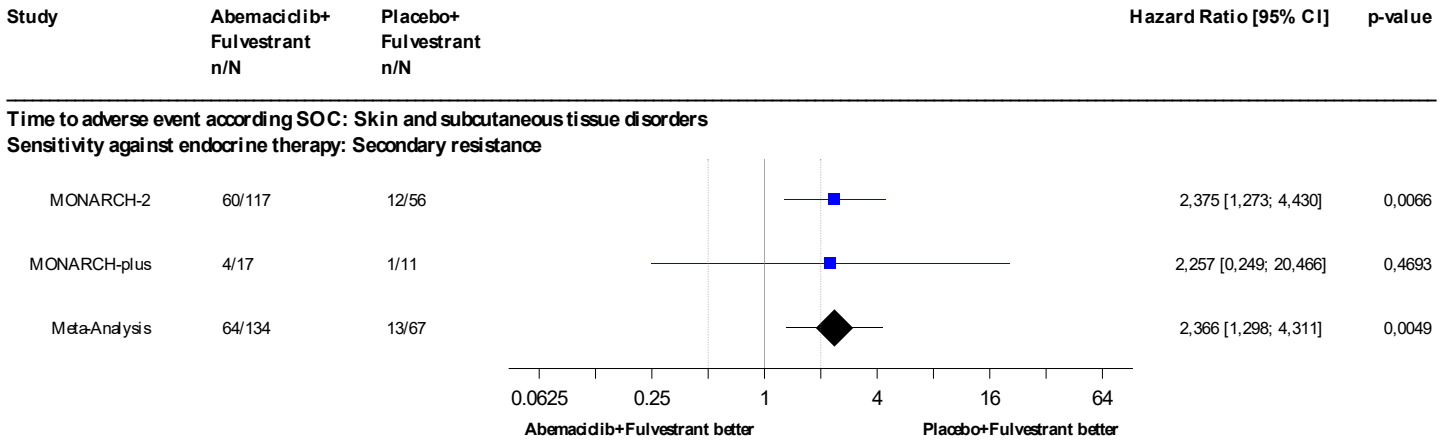
**Figure 1289.2.8.2: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)**



Heterogeneity: Cochran Q-test=0,0019, p-value=0,9653, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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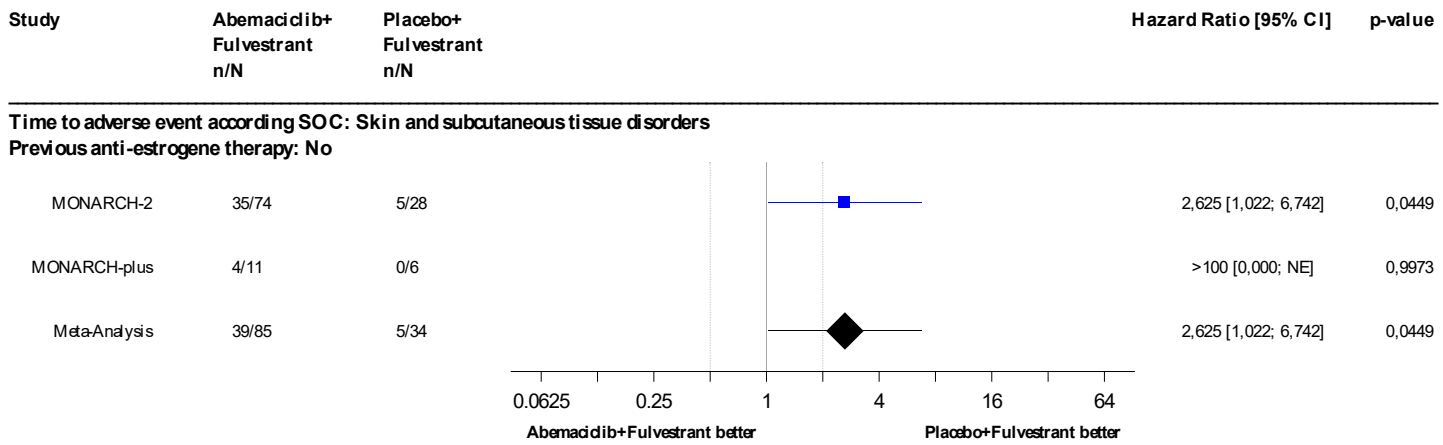
Figure 1289.2.9.1: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9974, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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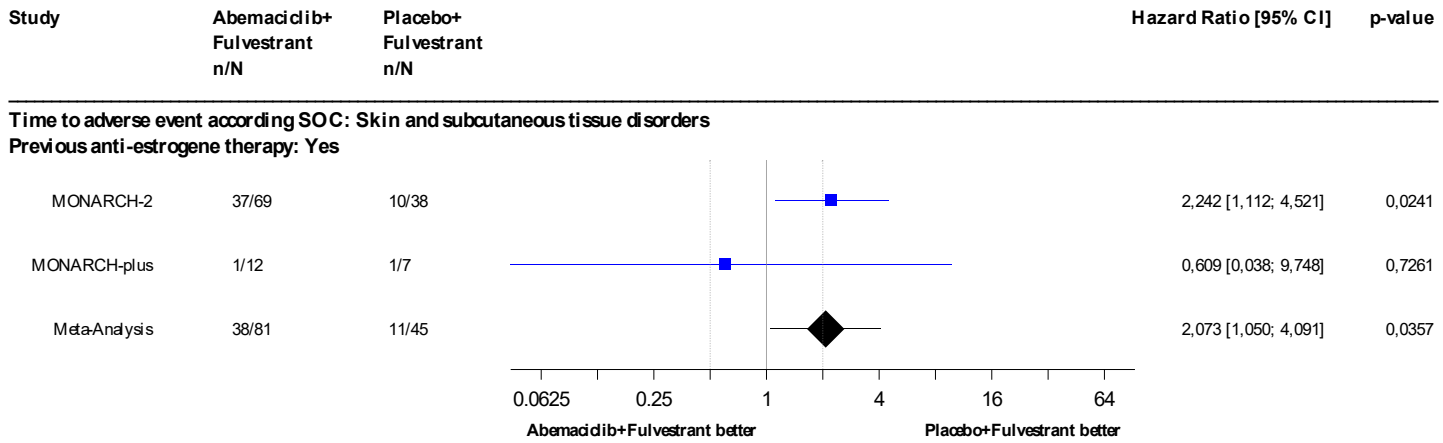
Figure 1289.2.9.2: Metaanalysis results for adverse events according SOC[1] -
Skin and subcutaneous tissue disorders
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,7971, p-value=0,3720, I2 index=0%
Abbreviations: CI: Confidence Interval; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events occurring in ≥10% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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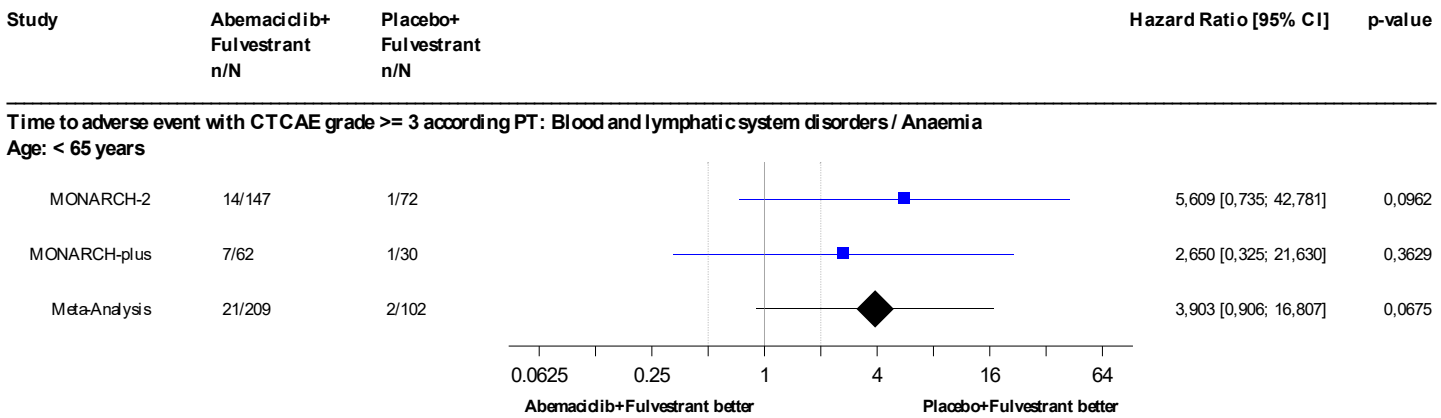
Figure 1299.1.1.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Blood and lymphatic system disorders / Anaemia Subgroup analysis for Age: < 65 years Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2531, p-value=0,6149, I2 index=0%

Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

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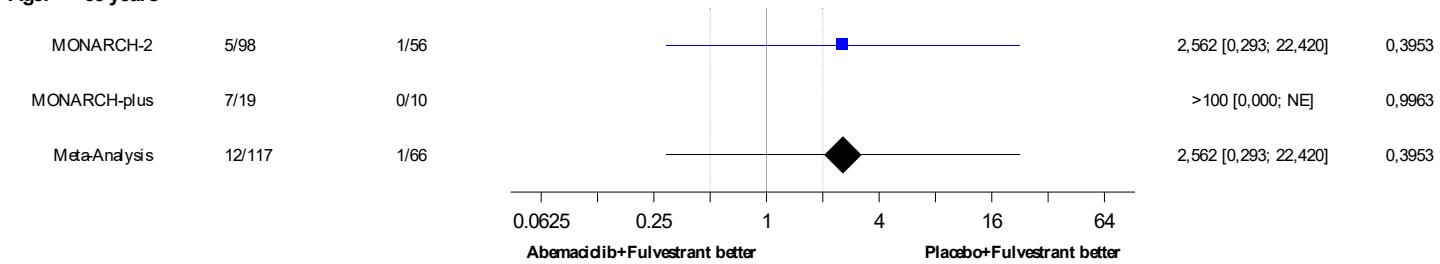
Figure 1299.1.1.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9965, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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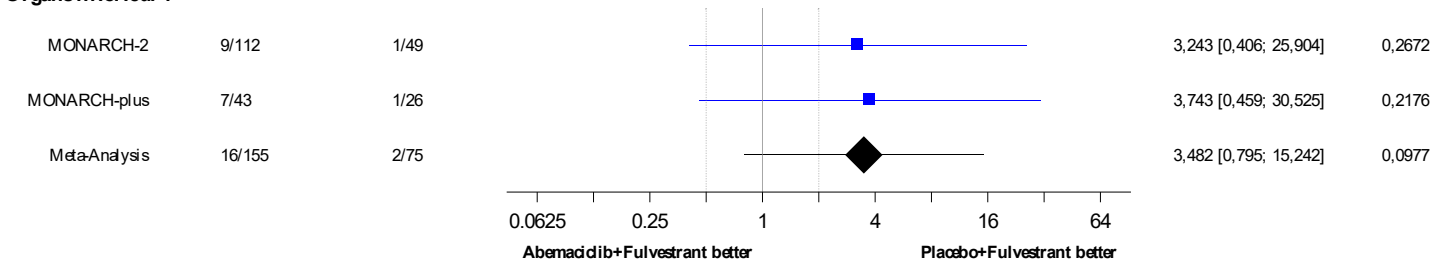
Figure 1299.1.2.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0091, p-value=0,9241, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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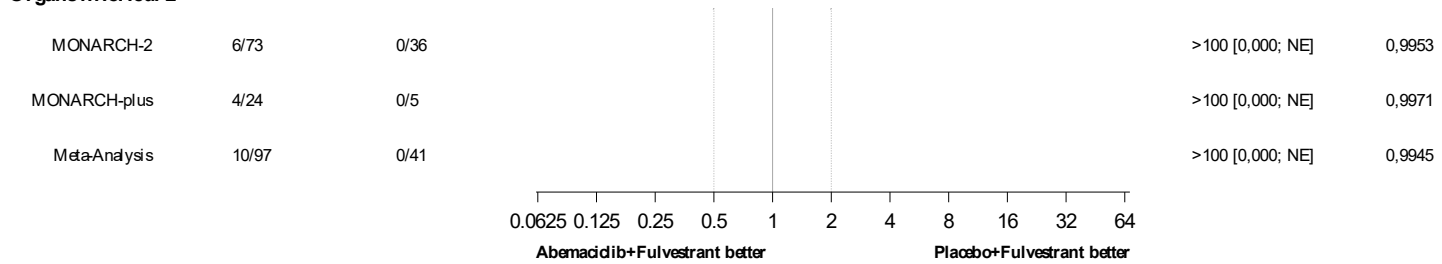
Figure 1299.1.2.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttirgr3p002_popa1_norggr_2.rtf

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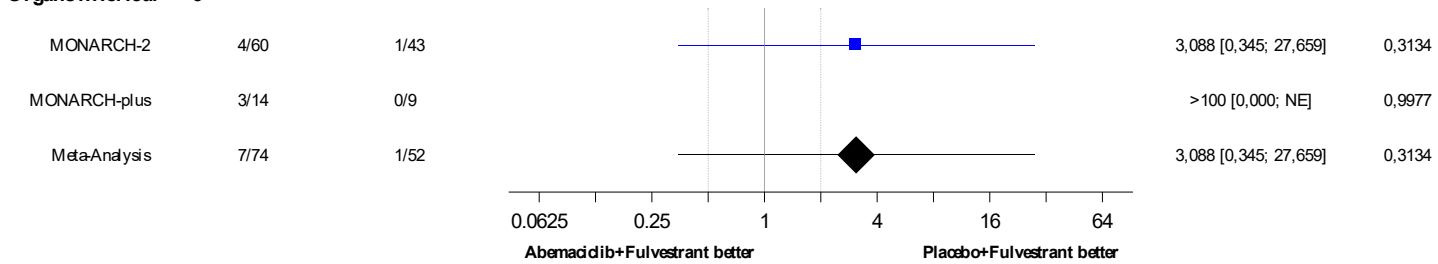
Figure 1299.1.2.3: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9979, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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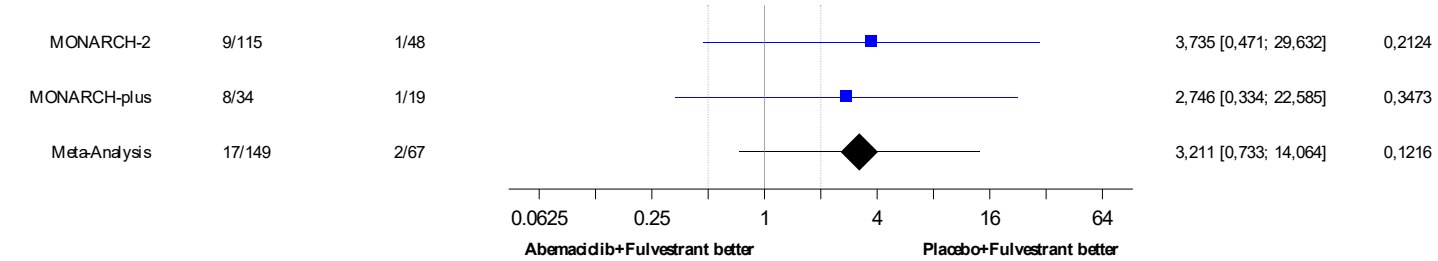
Figure 1299.1.3.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0416, p-value=0,8384, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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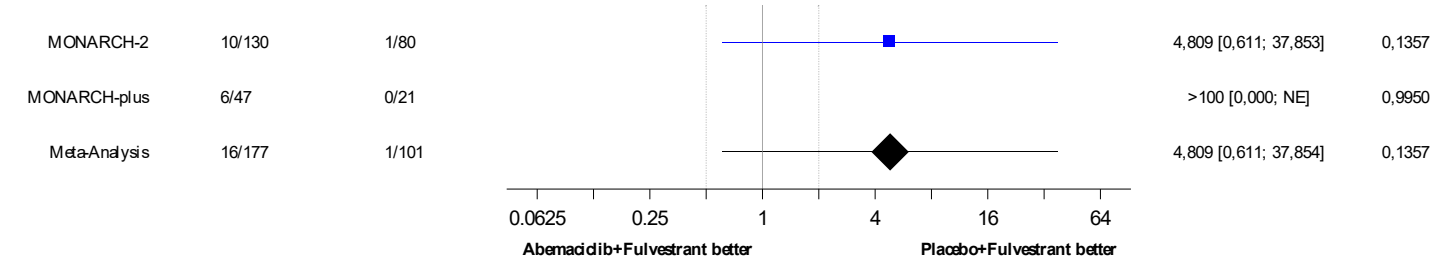
Figure 1299.1.3.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9955, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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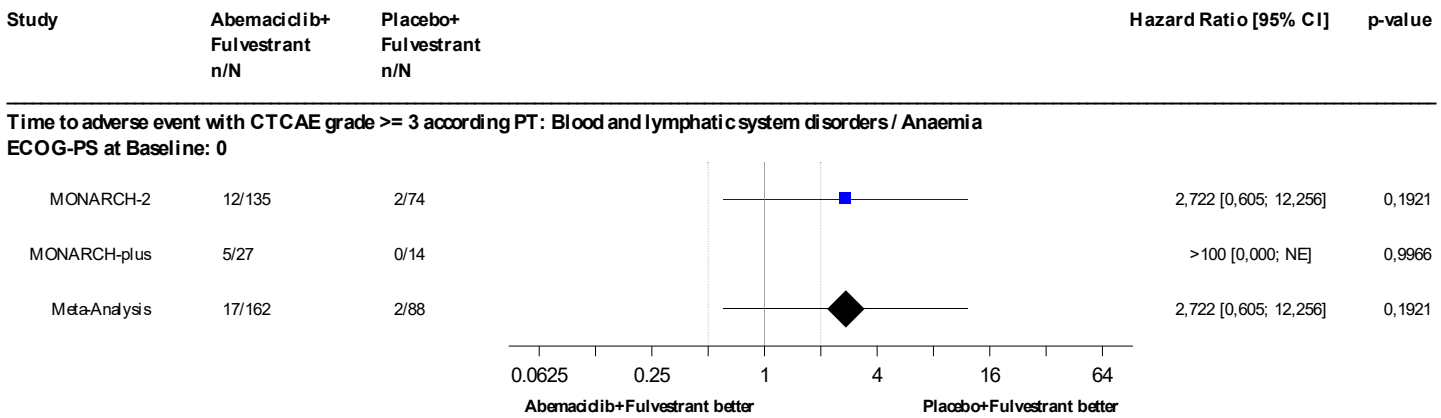
Figure 1299.1.4.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9968, I2 index=0%

Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttirgr3p002_popa1_ecogbl_1.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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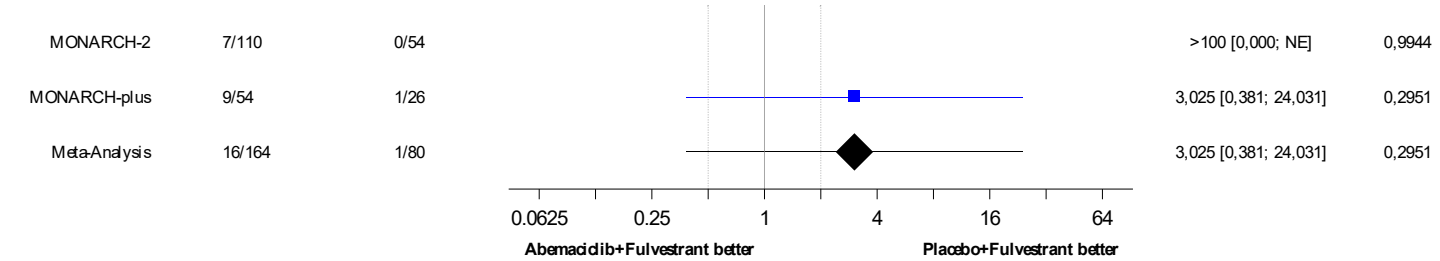
Figure 1299.1.4.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Blood and lymphatic system disorders / Anaemia Subgroup analysis for ECOG-PS at Baseline: 1 Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9948, I2 index=0%

Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

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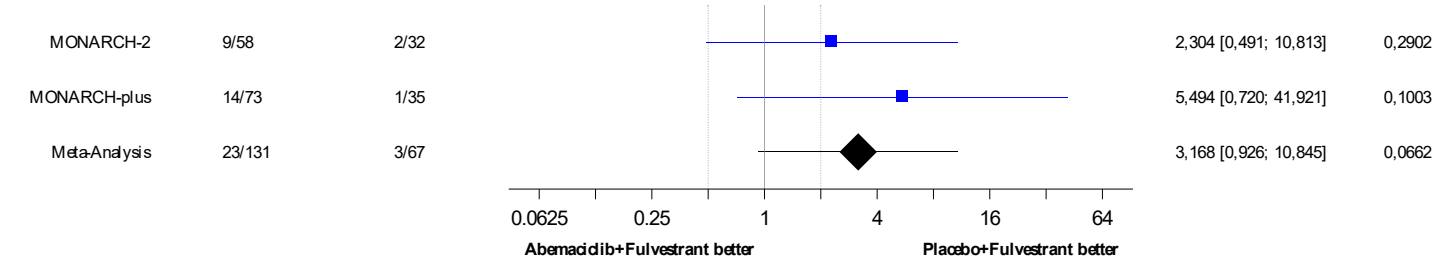
Figure 1299.1.5.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,4452, p-value=0,5046, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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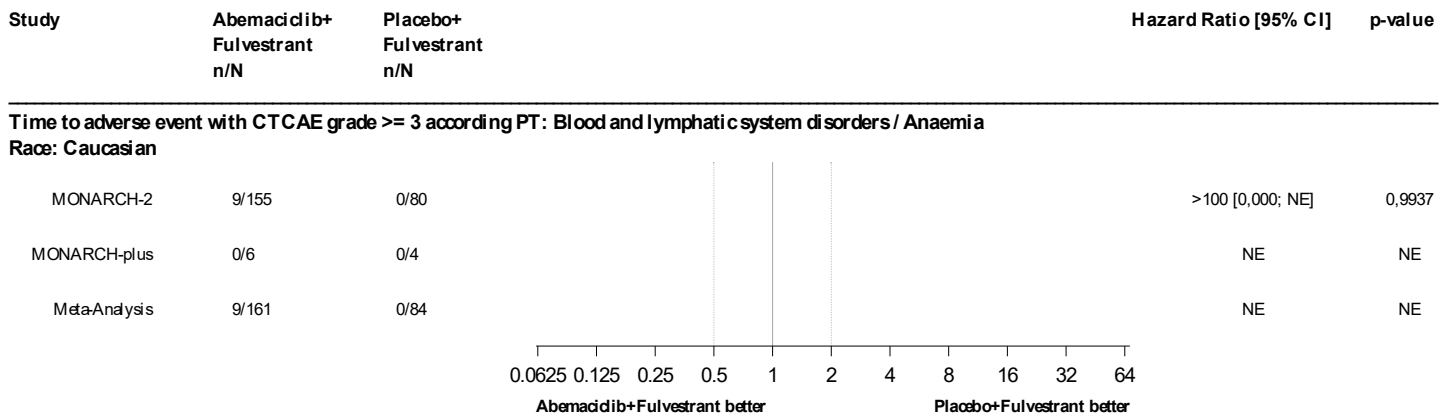
Figure 1299.1.5.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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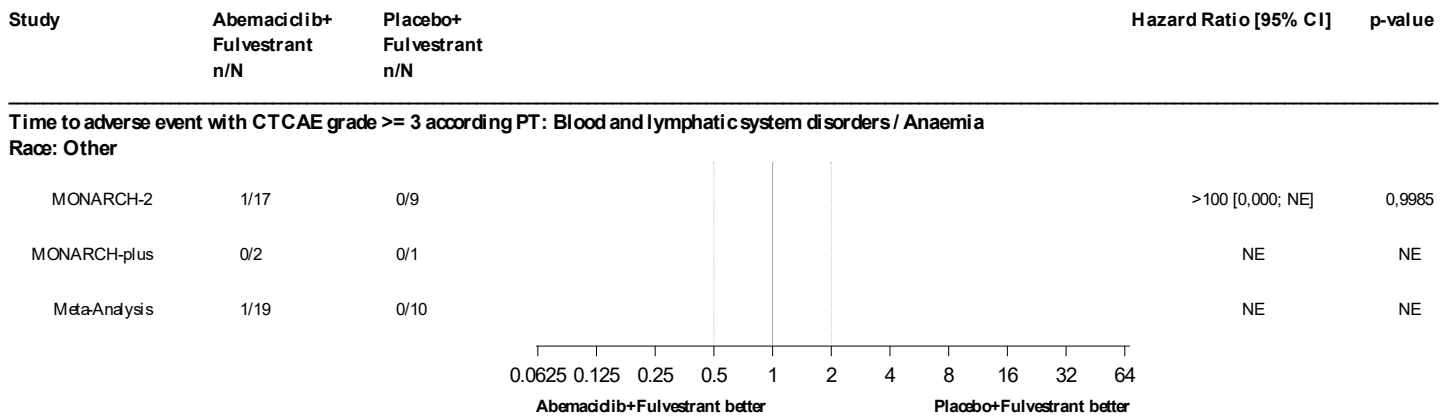
Figure 1299.1.5.3: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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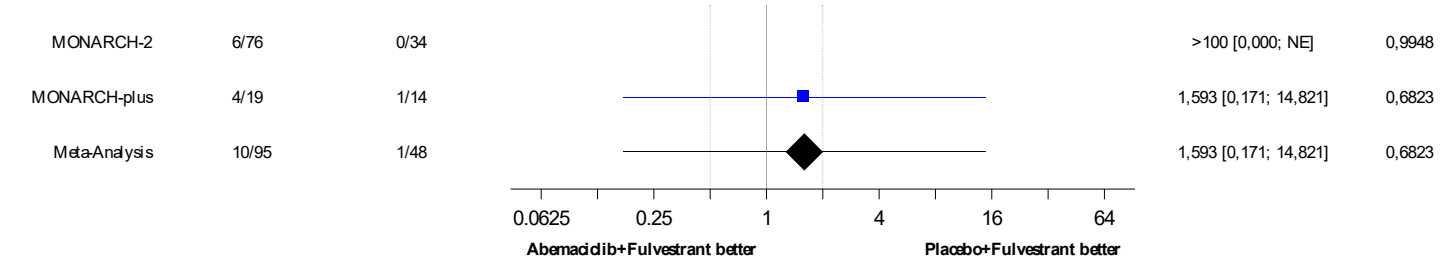
Figure 1299.1.6.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Blood and lymphatic system disorders / Anaemia Subgroup analysis for Measurable disease at baseline: No Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9950, I2 index=0%

Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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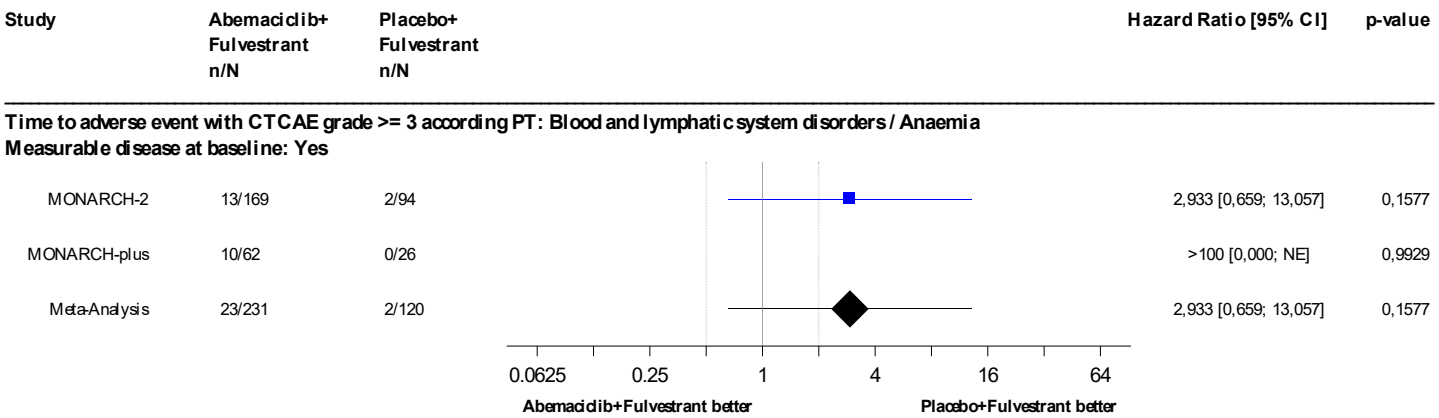
Figure 1299.1.6.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9934, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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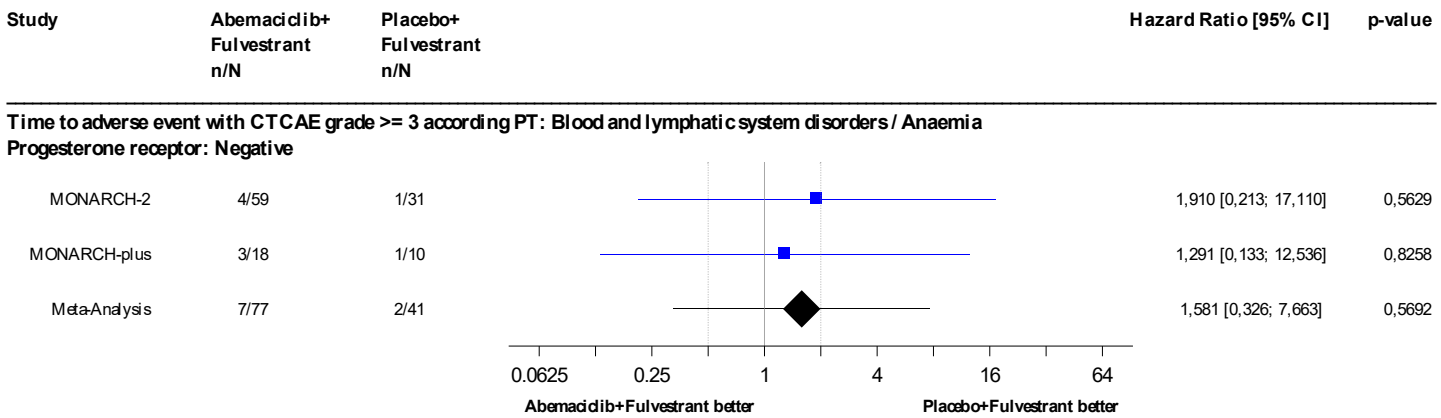
Figure 1299.1.7.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0591, p-value=0,8079, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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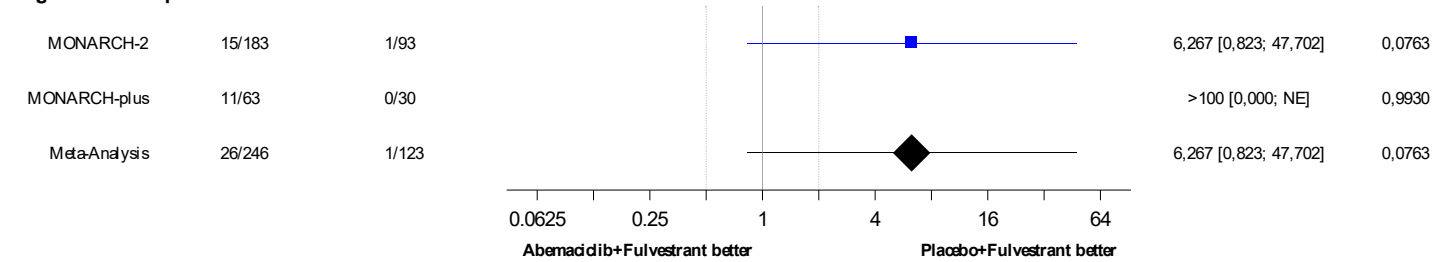
Figure 1299.1.7.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Blood and lymphatic system disorders / Anaemia Subgroup analysis for Progesterone receptor: Positive Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9938, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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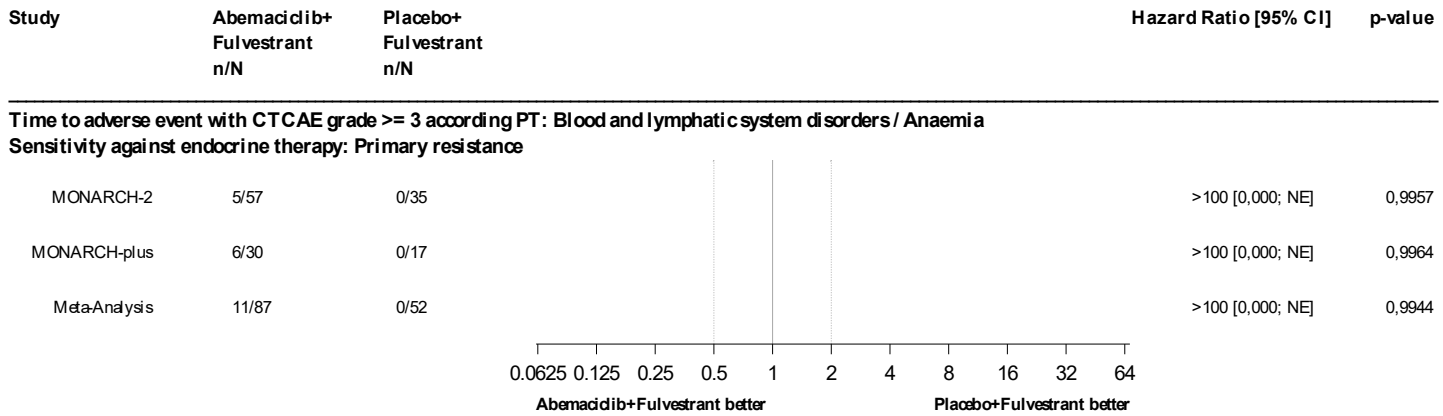
Figure 1299.1.8.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9998, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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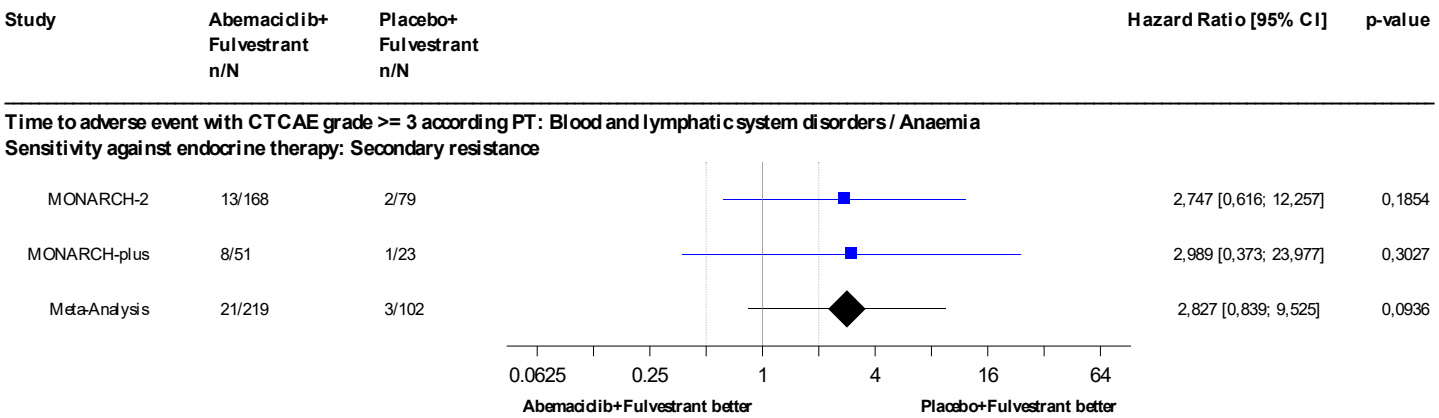
Figure 1299.1.8.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0042, p-value=0,9486, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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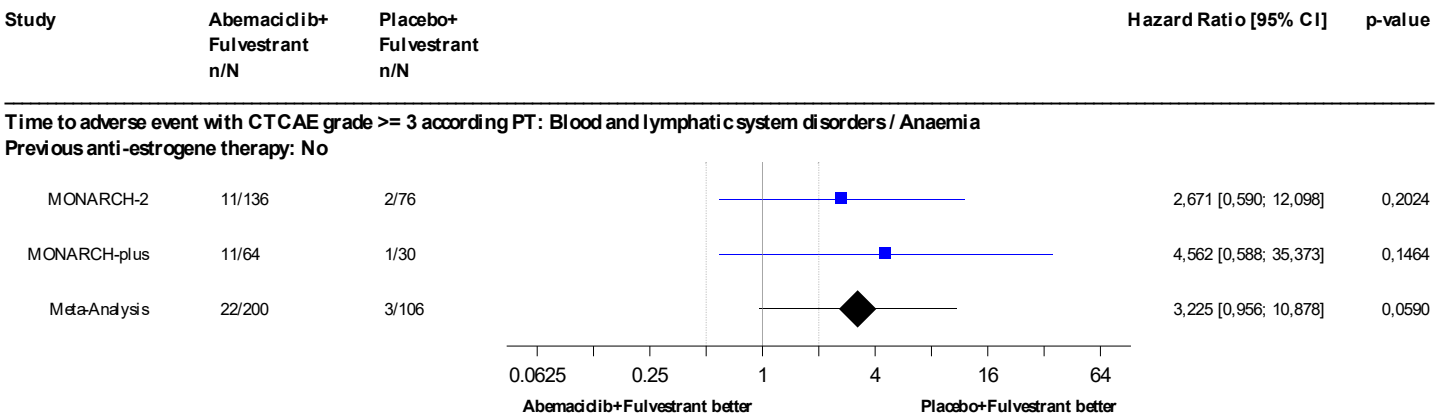
Figure 1299.1.9.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1700, p-value=0,6801, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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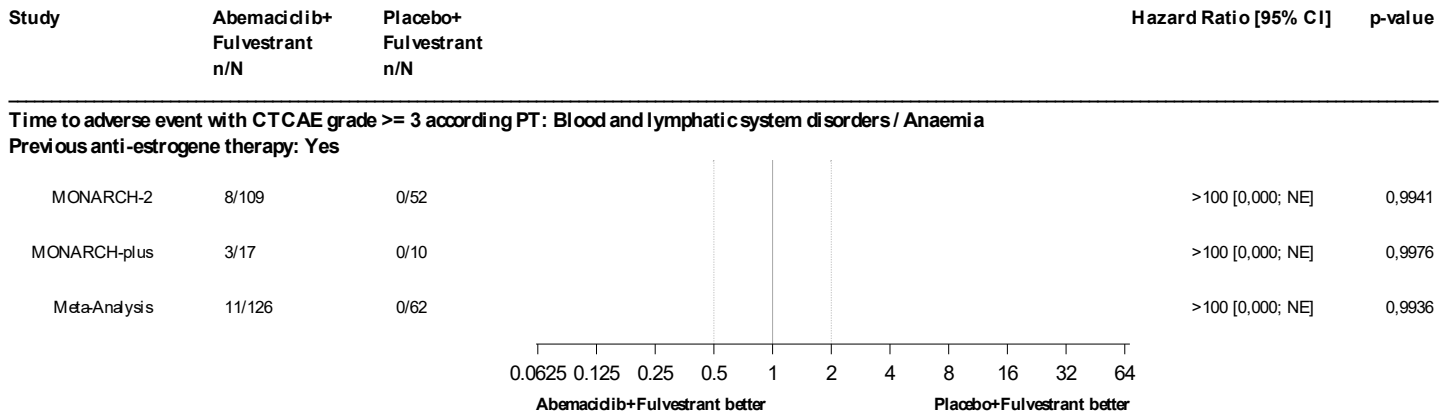
Figure 1299.1.9.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] -
Blood and lymphatic system disorders / Anaemia
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9999, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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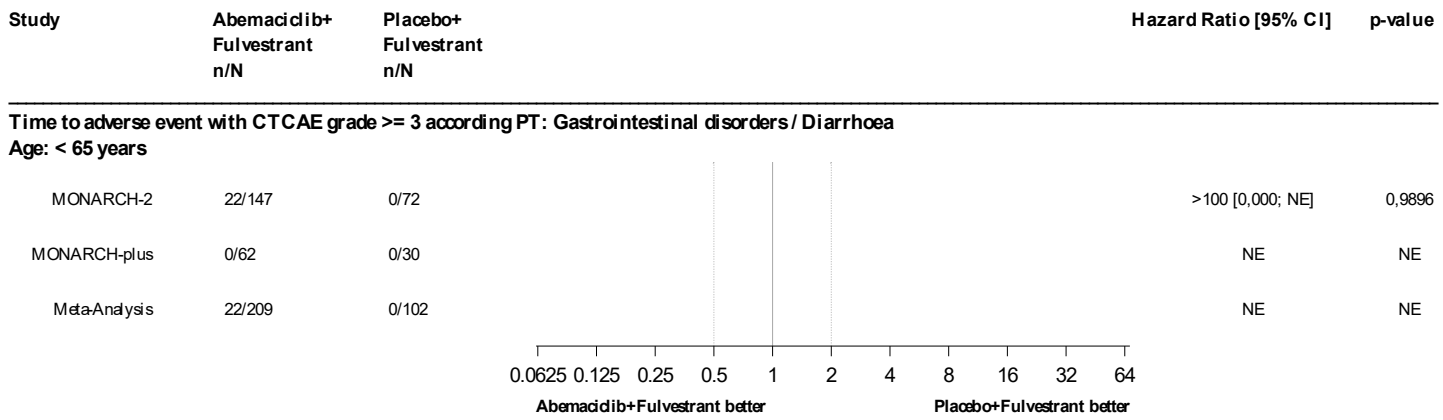
Figure 1301.1.1.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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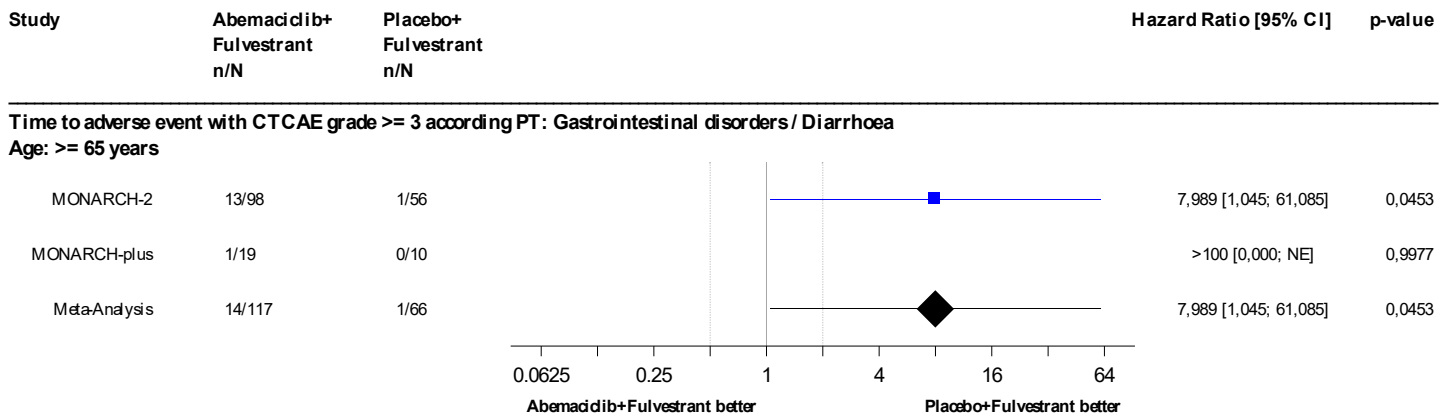
Figure 1301.1.1.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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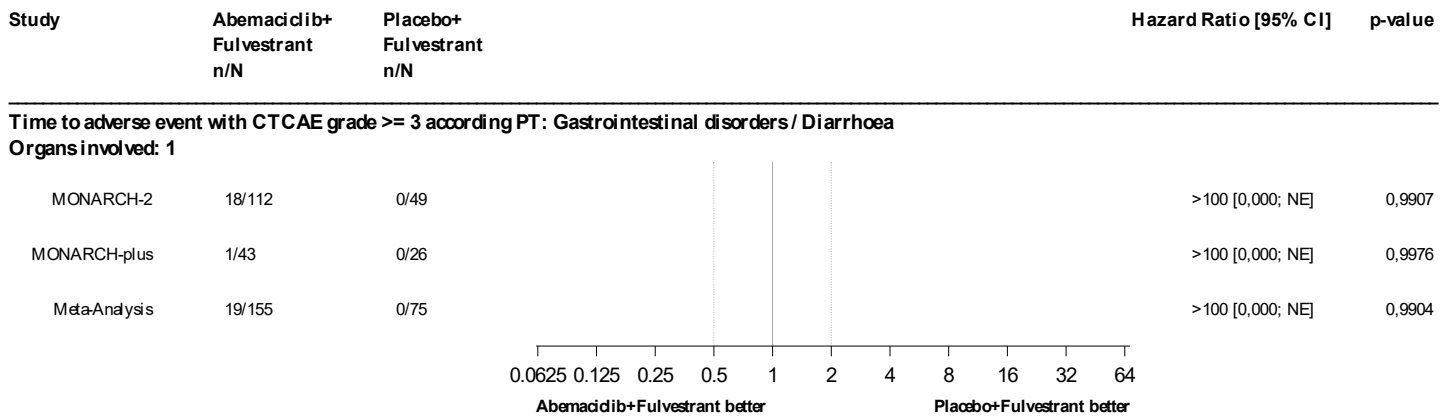
Figure 1301.1.2.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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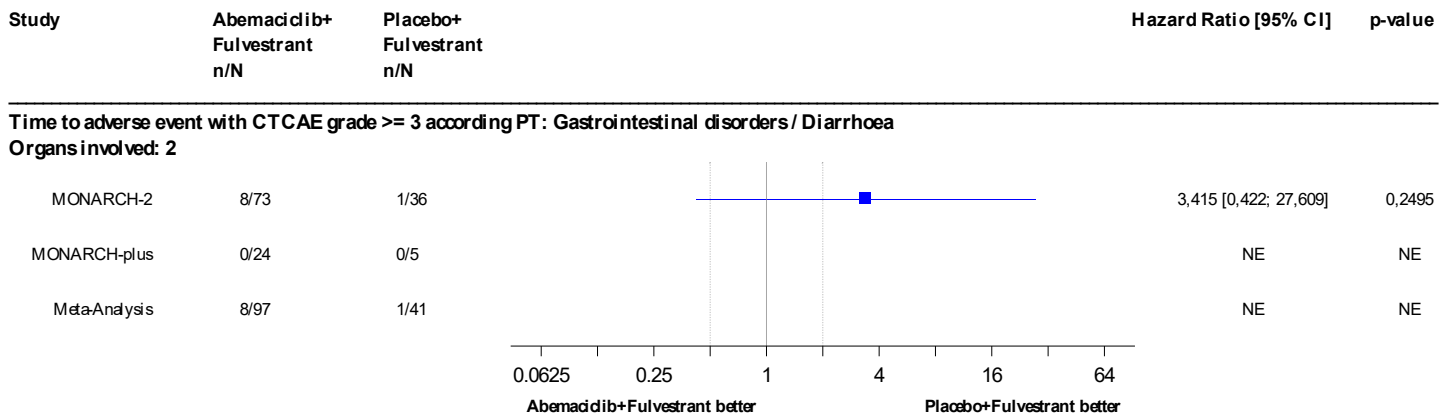
Figure 1301.1.2.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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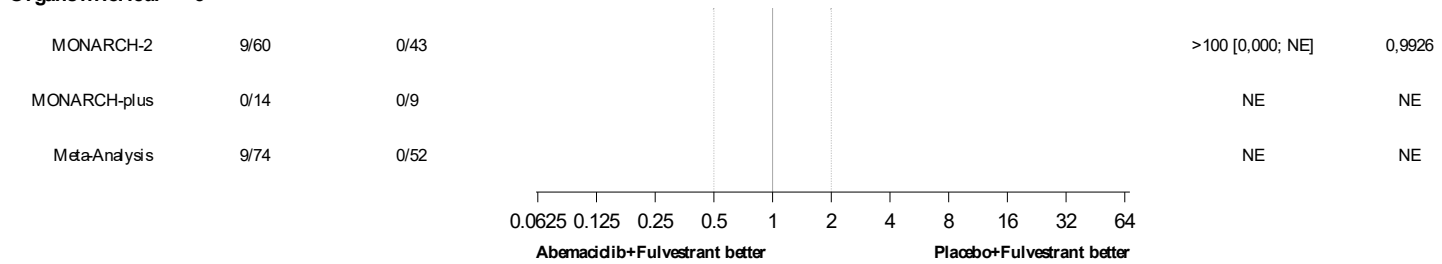
Figure 1301.1.2.3: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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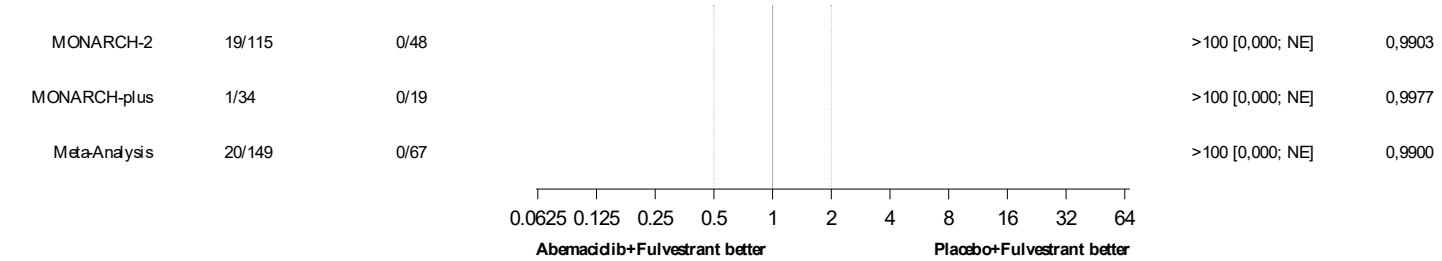
Figure 1301.1.3.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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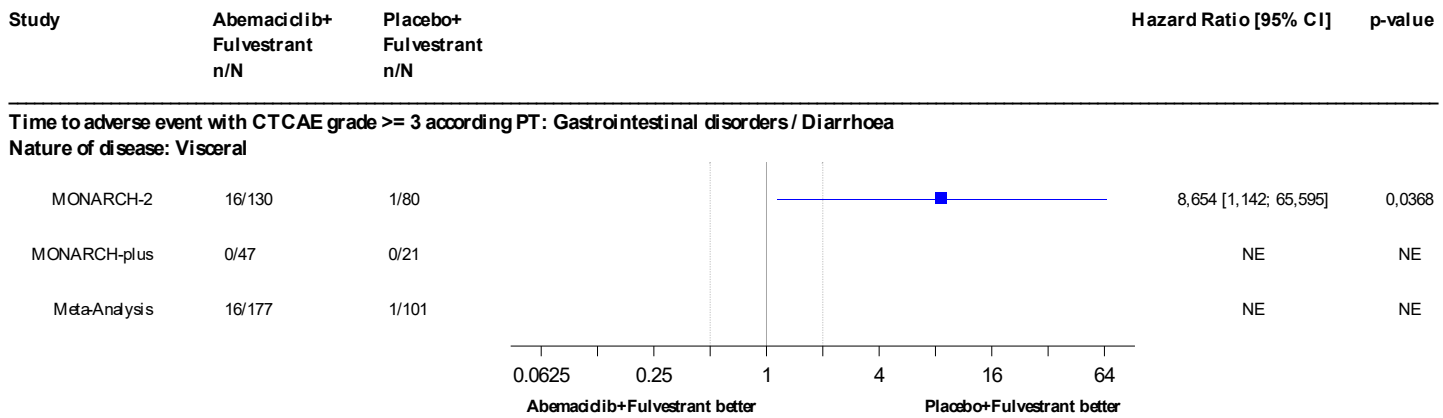
Figure 1301.1.3.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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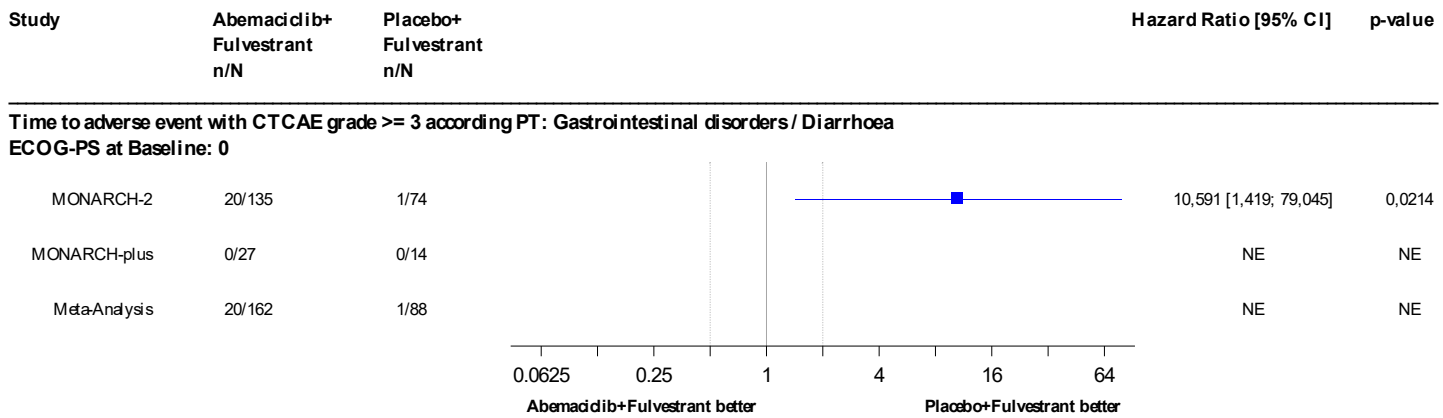
Figure 1301.1.4.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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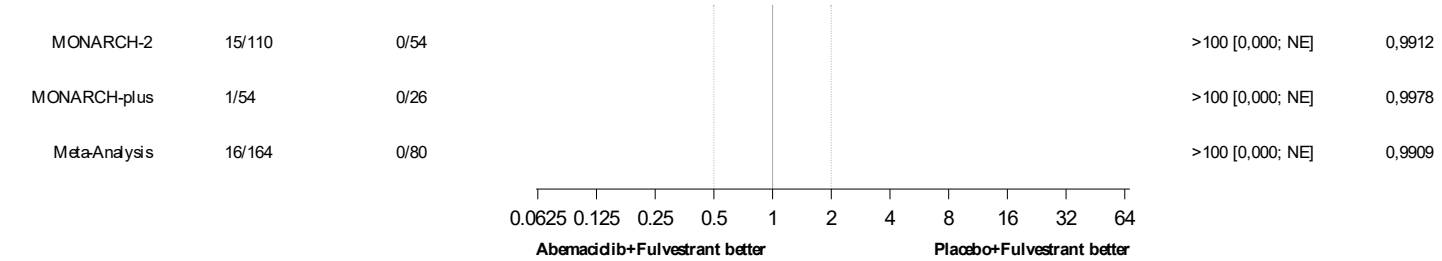
Figure 1301.1.4.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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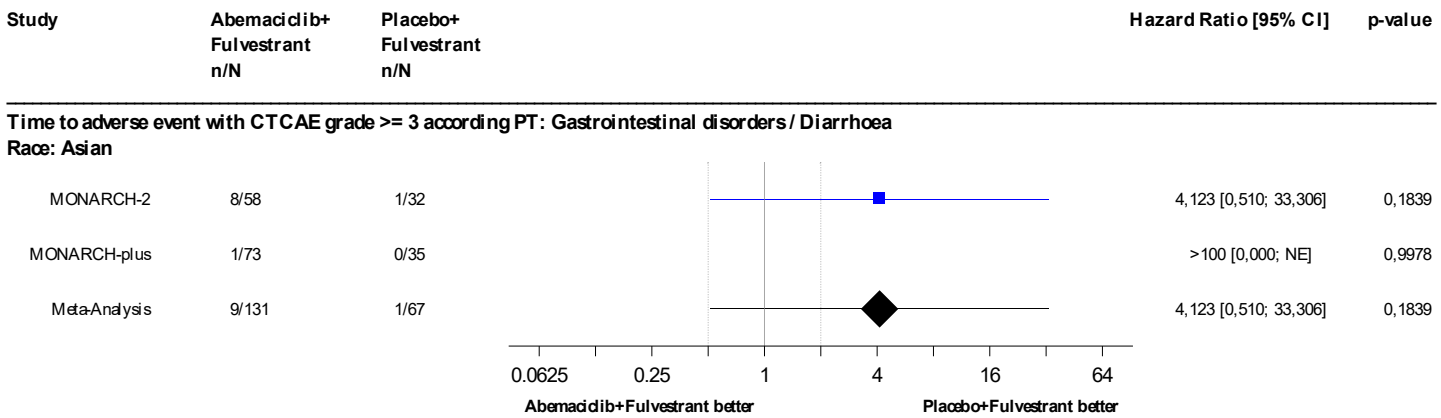
Figure 1301.1.5.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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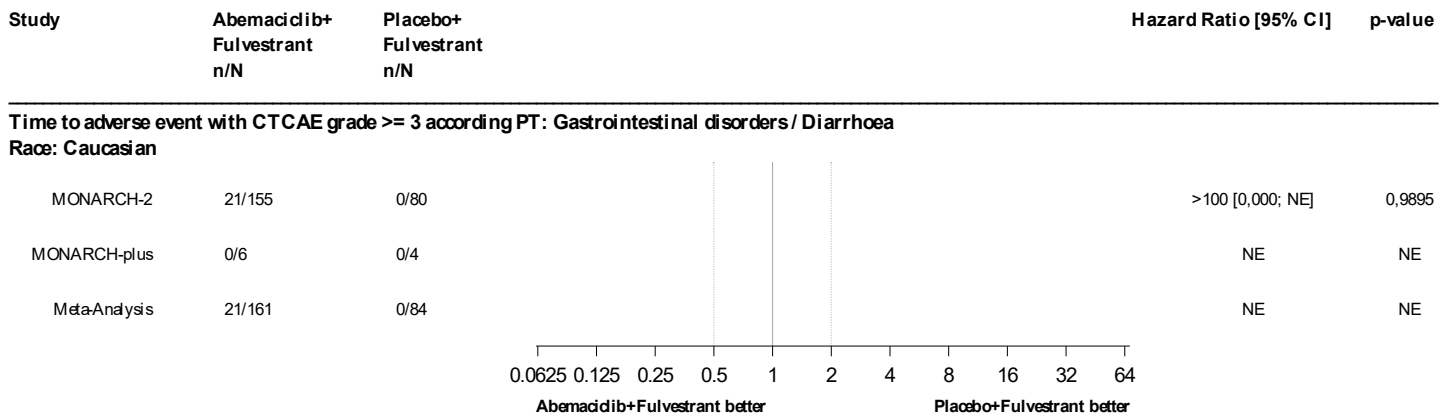
Figure 1301.1.5.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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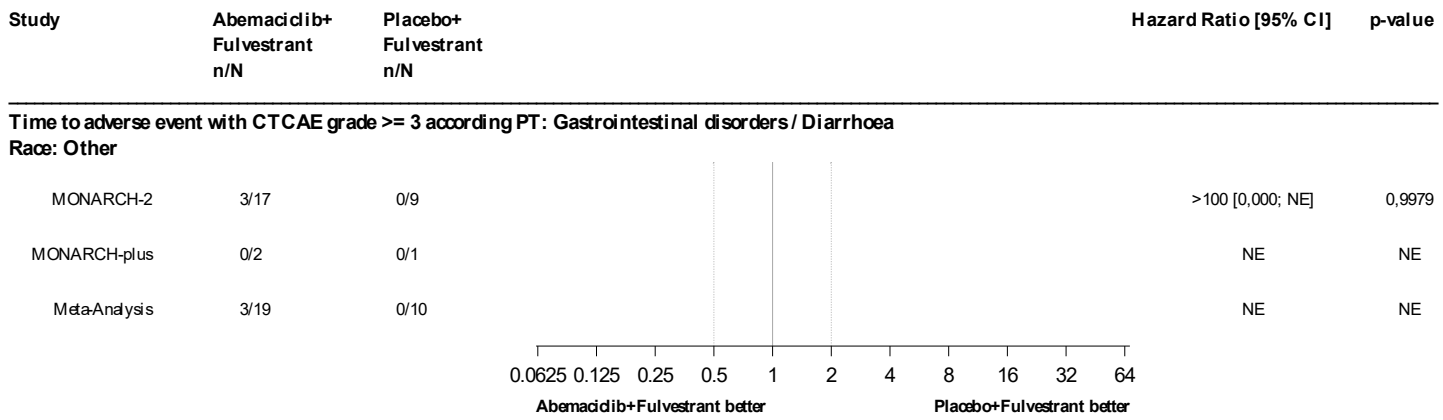
Figure 1301.1.5.3: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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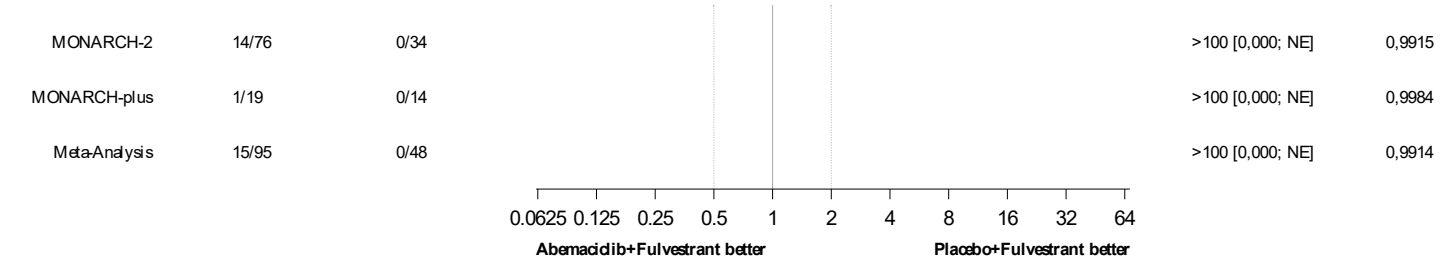
Figure 1301.1.6.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9999, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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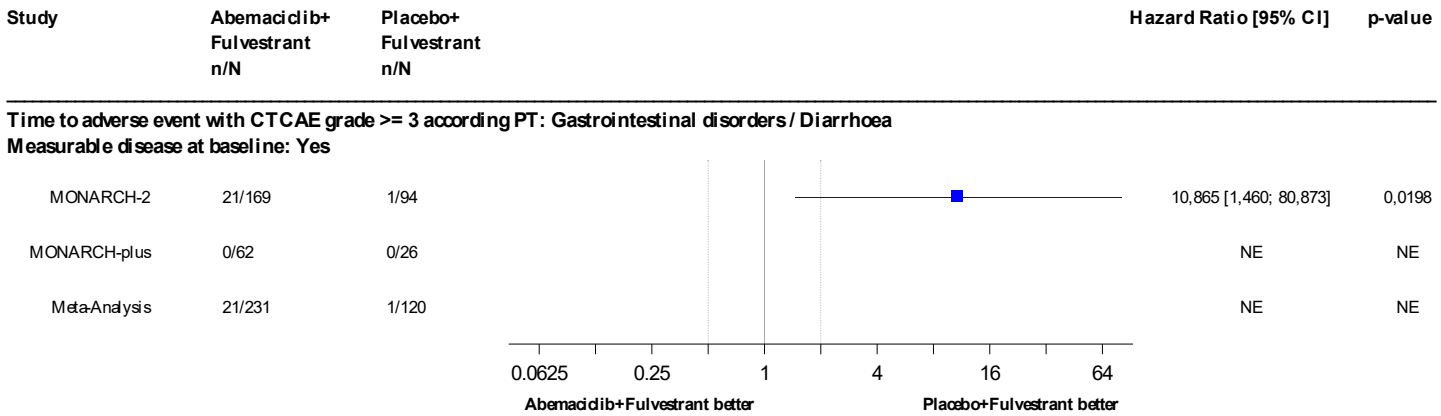
Figure 1301.1.6.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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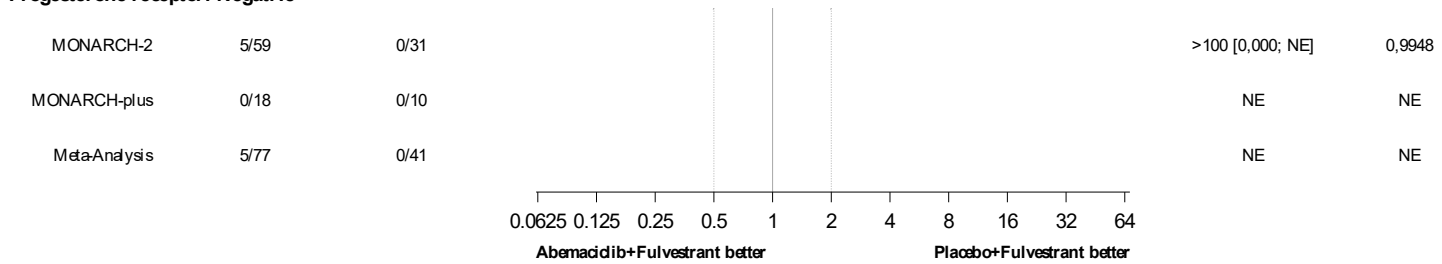
Figure 1301.1.7.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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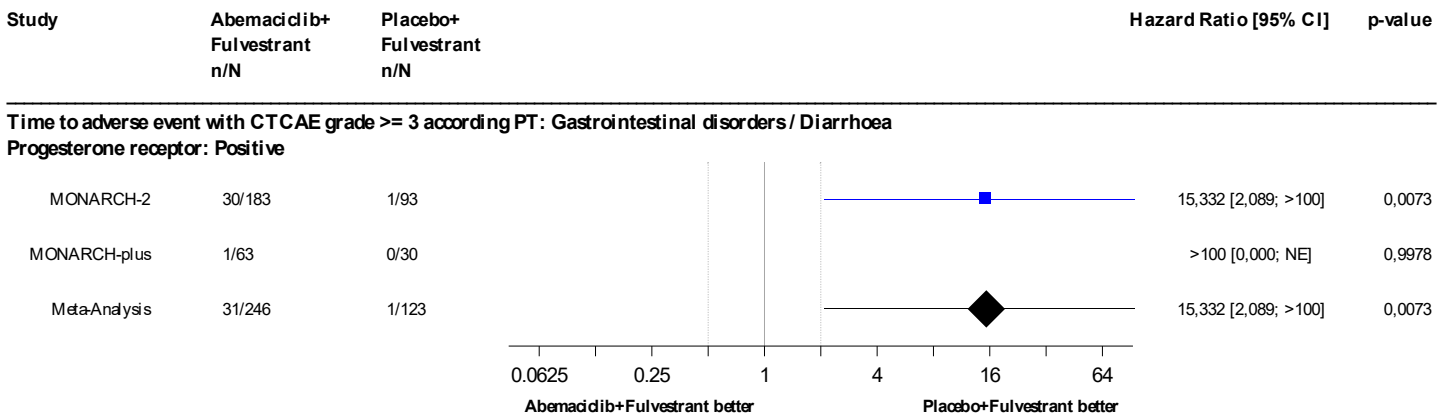
Figure 1301.1.7.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9981, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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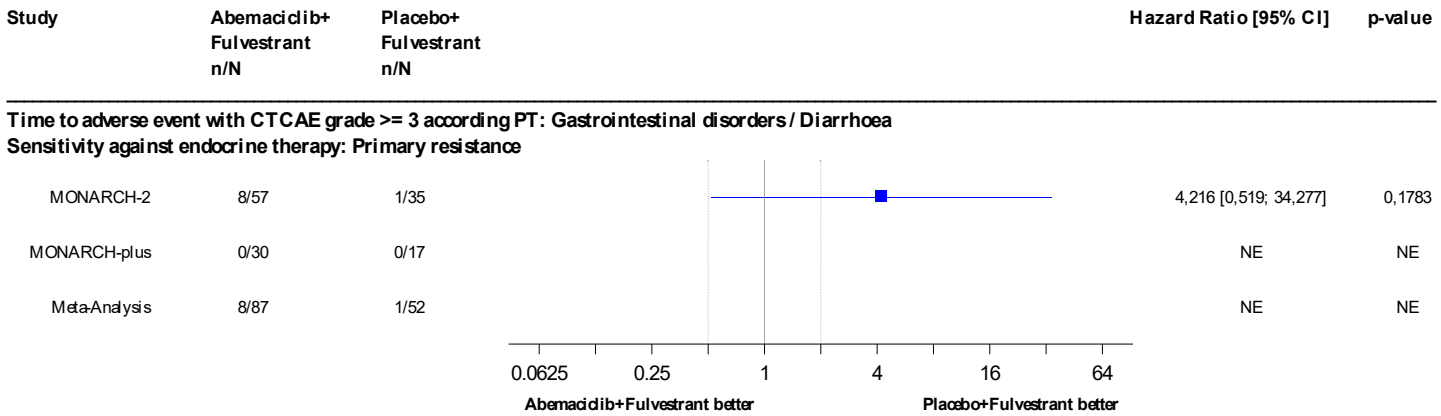
Figure 1301.1.8.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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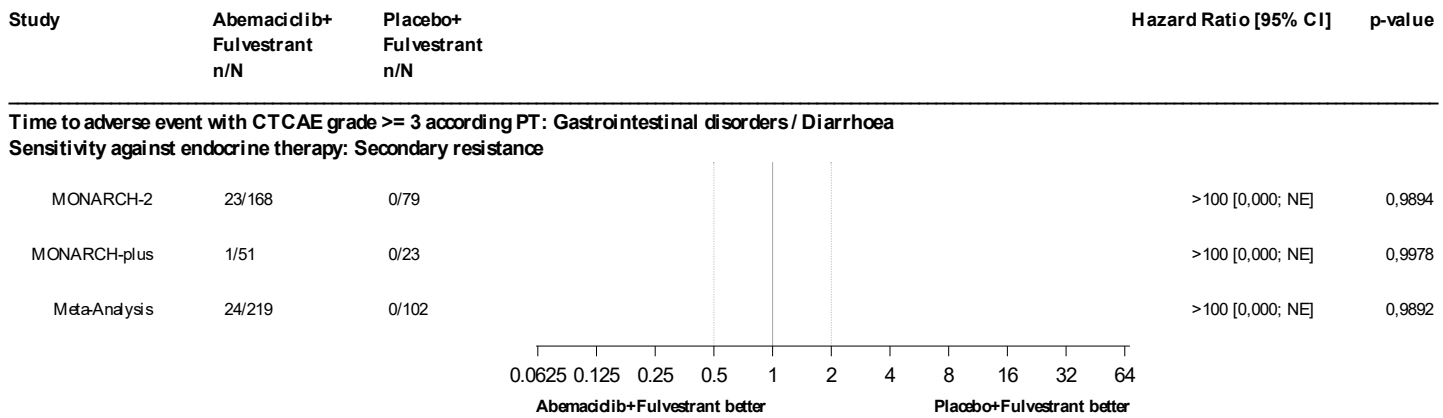
Figure 1301.1.8.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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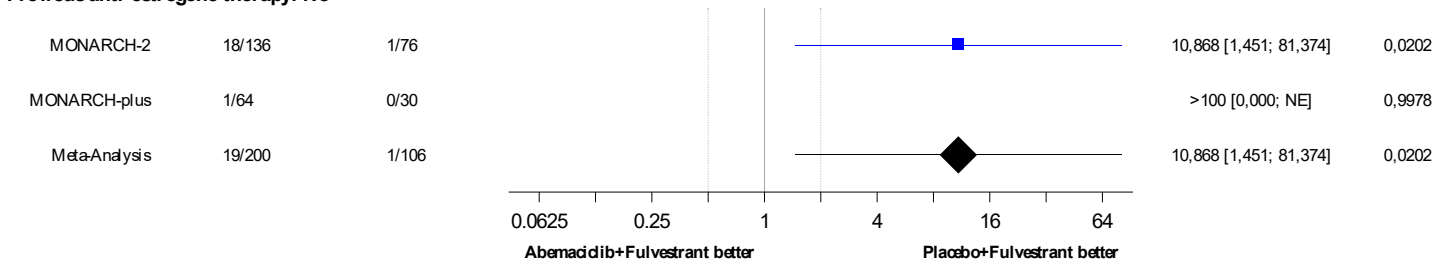
Figure 1301.1.9.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9981, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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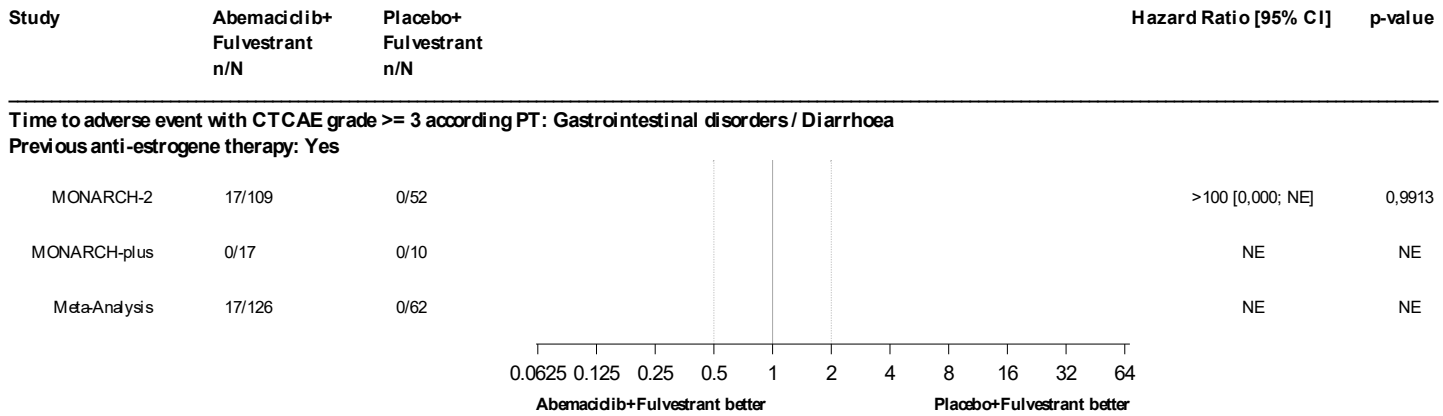
Figure 1301.1.9.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according PT[1] - Gastrointestinal disorders / Diarrhoea
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; PT: Preferred Term

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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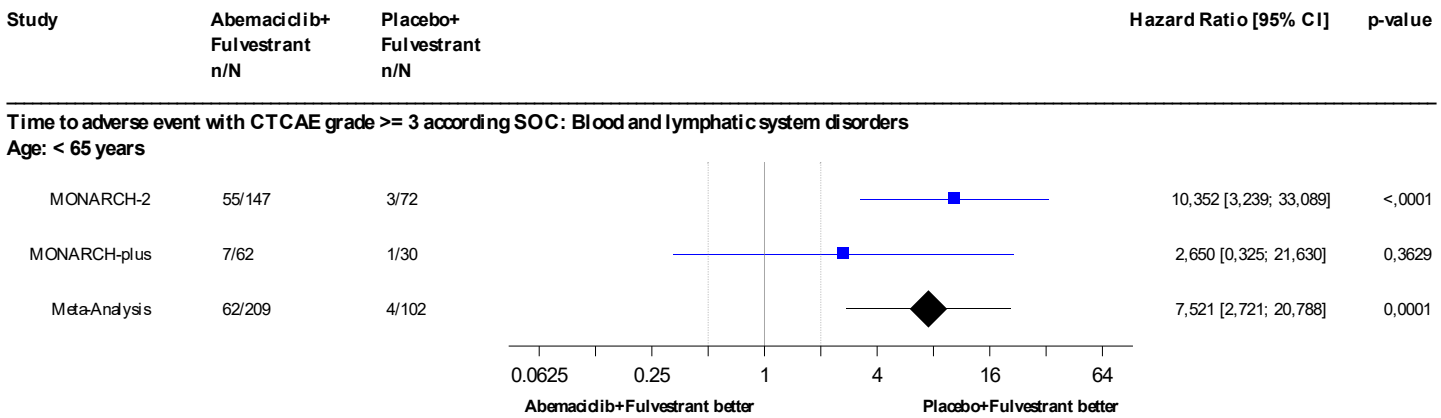
Figure 1316.1.1.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,2387, p-value=0,2657, I2 index=19,3%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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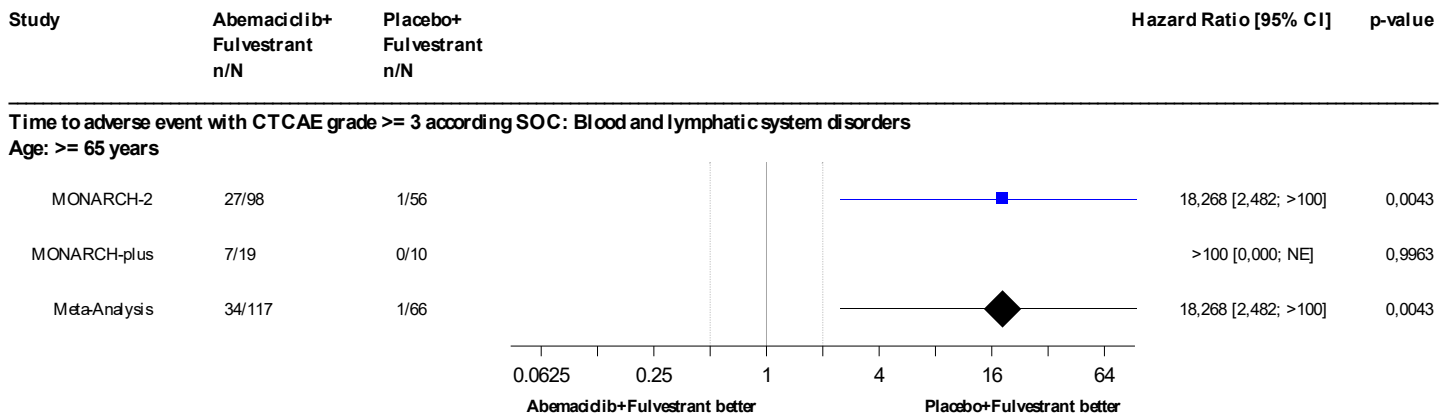
Figure 1316.1.1.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9969, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttirgr3s001_popa1_agegr1_2.rtf

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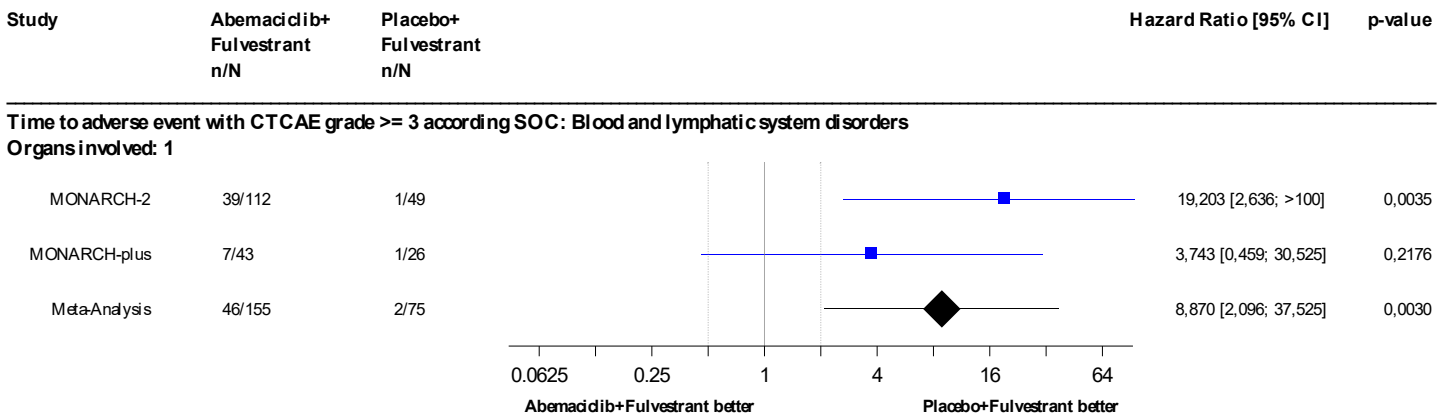
Figure 1316.1.2.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,2303, p-value=0,2673, I2 index=18,7%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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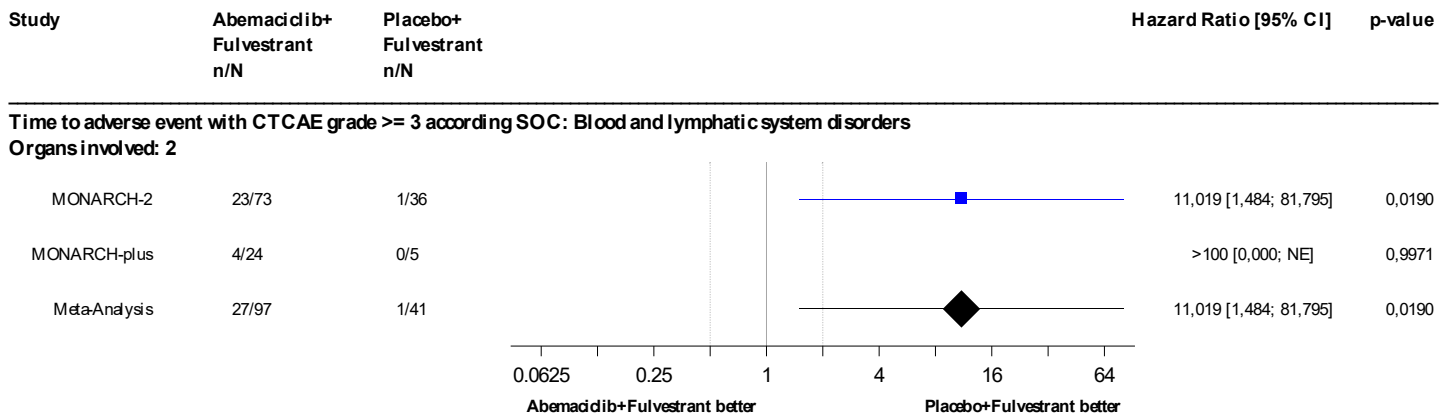
Figure 1316.1.2.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9975, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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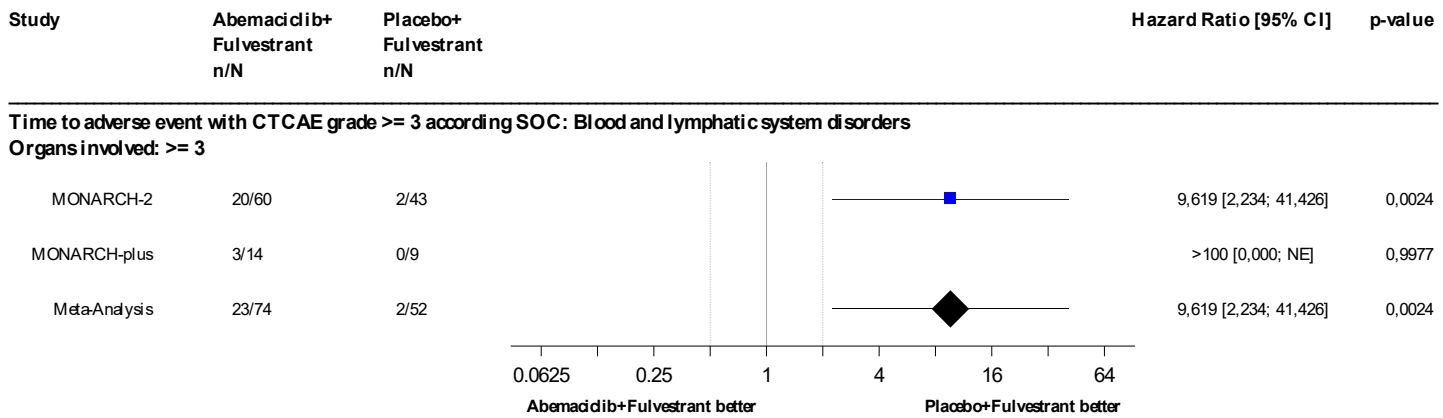
Figure 1316.1.2.3: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttirgr3s001_popa1_norggr_3.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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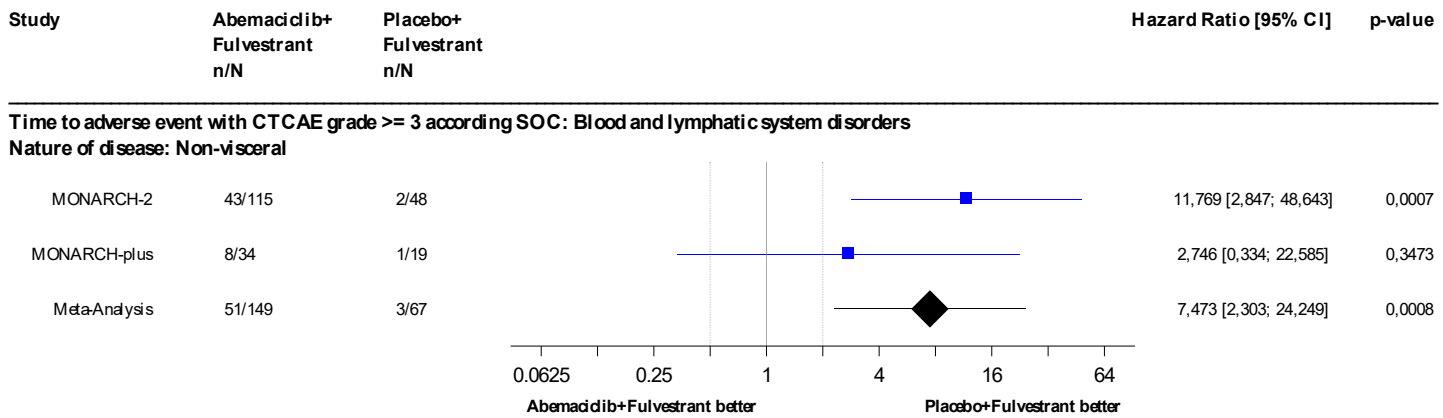
Figure 1316.1.3.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,2606, p-value=0,2615, I2 index=20,7%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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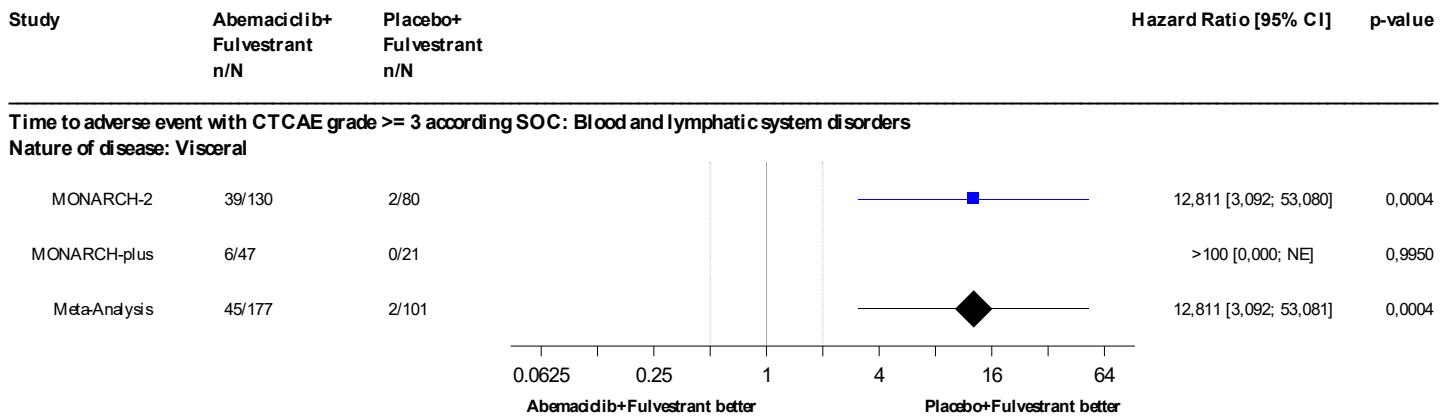
Figure 1316.1.3.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9958, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttirgr3s001_popa1_natdis2_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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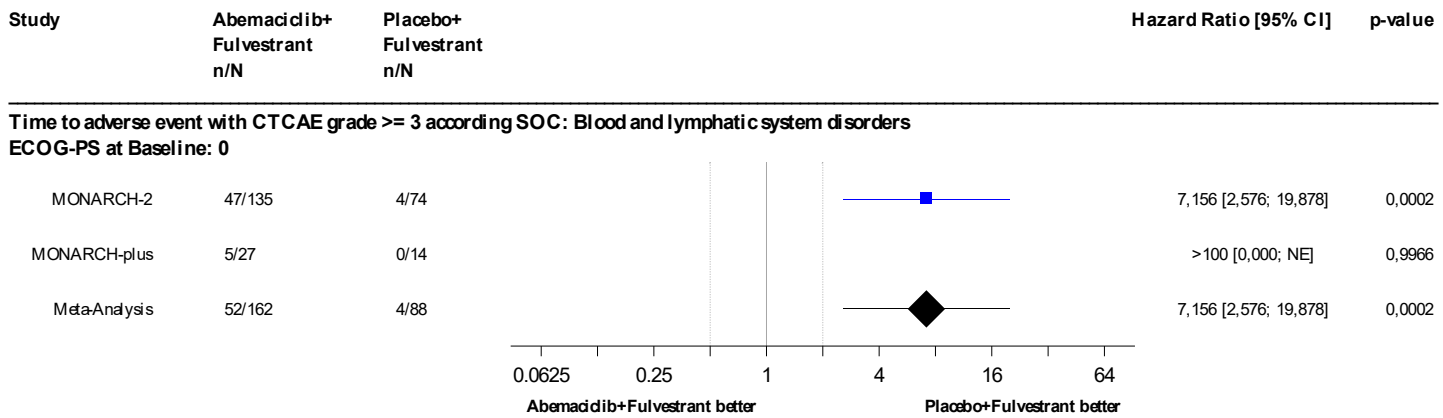
Figure 1316.1.4.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9970, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttirgr3s001_popa1_ecogbl_1.rtf

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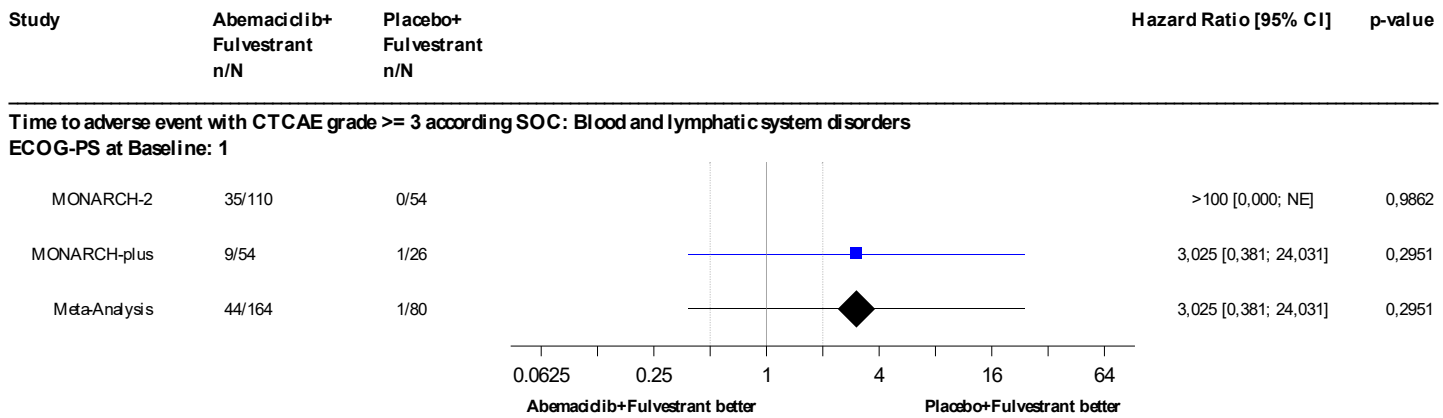
Figure 1316.1.4.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0003, p-value=0,9871, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

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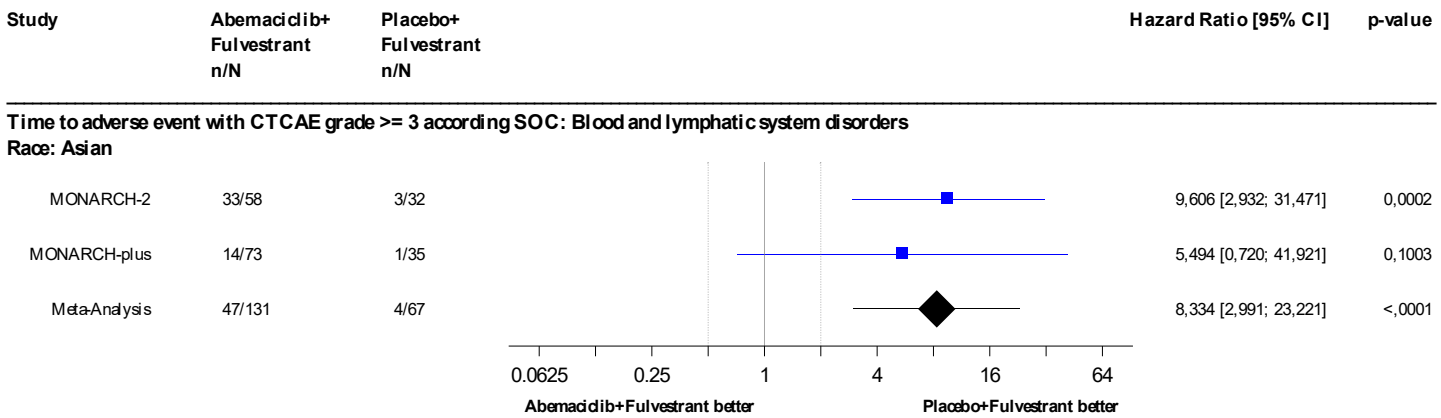
Figure 1316.1.5.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2165, p-value=0,6417, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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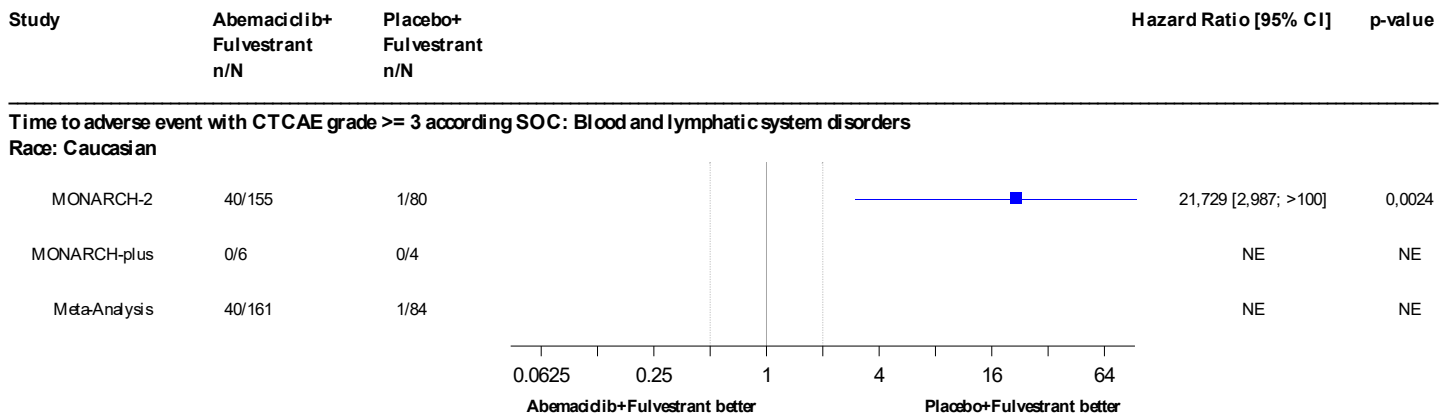
Figure 1316.1.5.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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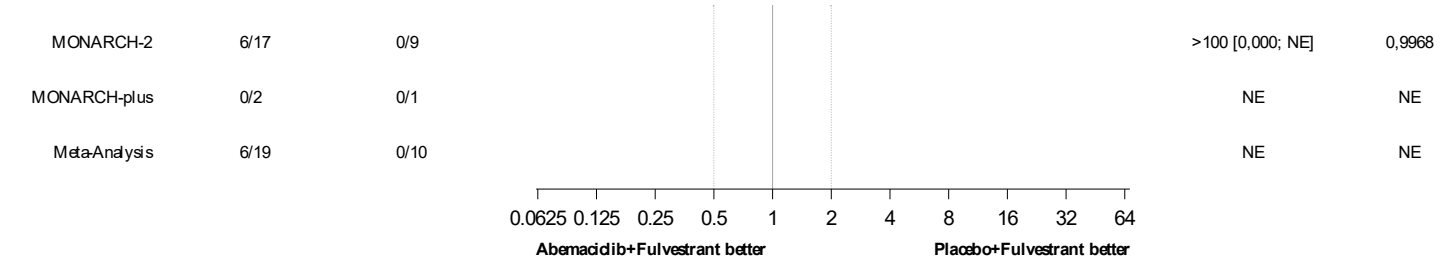
Figure 1316.1.5.3: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttirgr3s001_popa1_racegr1_3.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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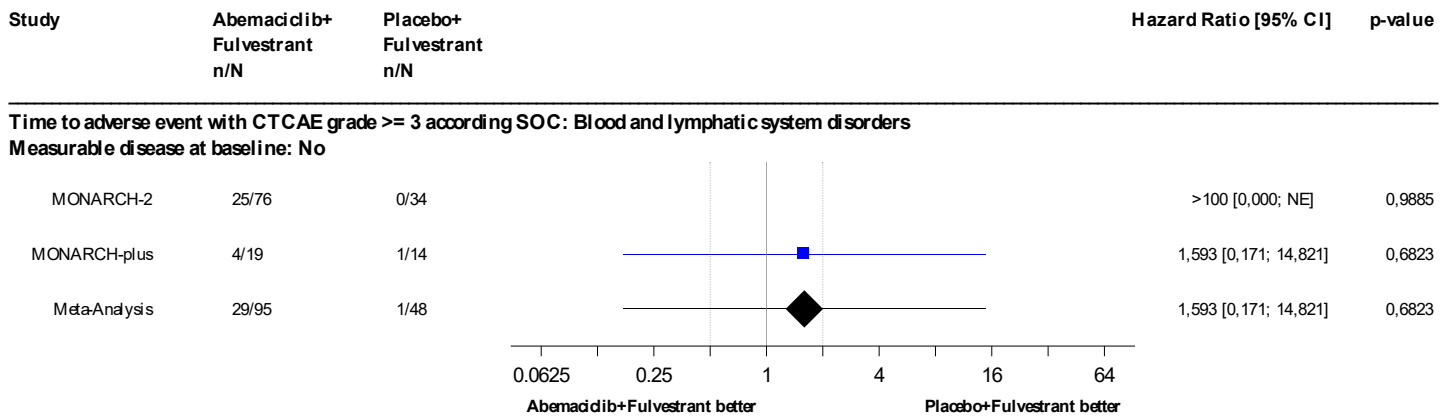
Figure 1316.1.6.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0002, p-value=0,9888, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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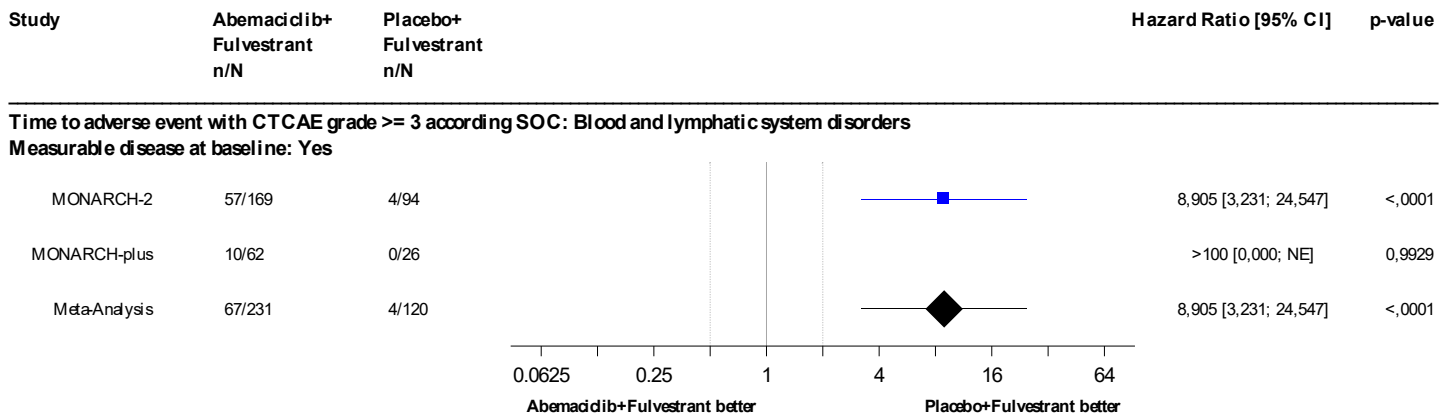
Figure 1316.1.6.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Blood and lymphatic system disorders
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9938, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttirgr3s001_popa1_measdis_2.rtf
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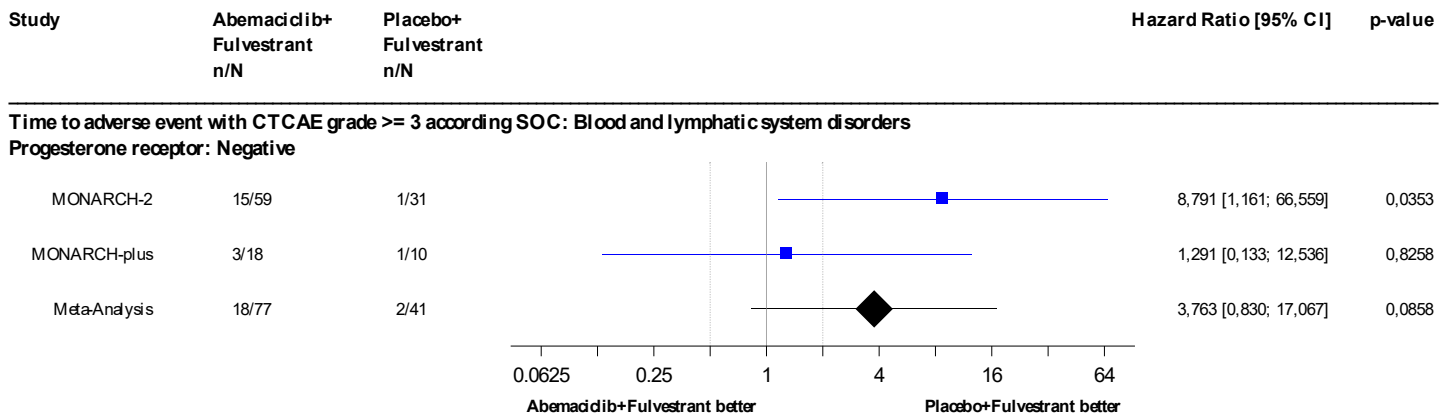
Figure 1316.1.7.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,5259, p-value=0,2167, I2 index=34,5%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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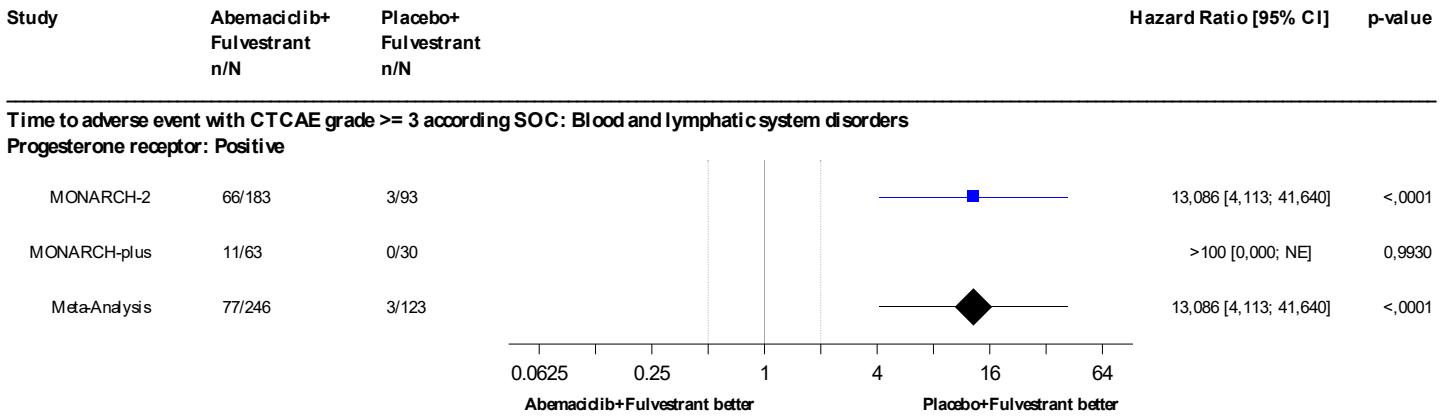
Figure 1316.1.7.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9941, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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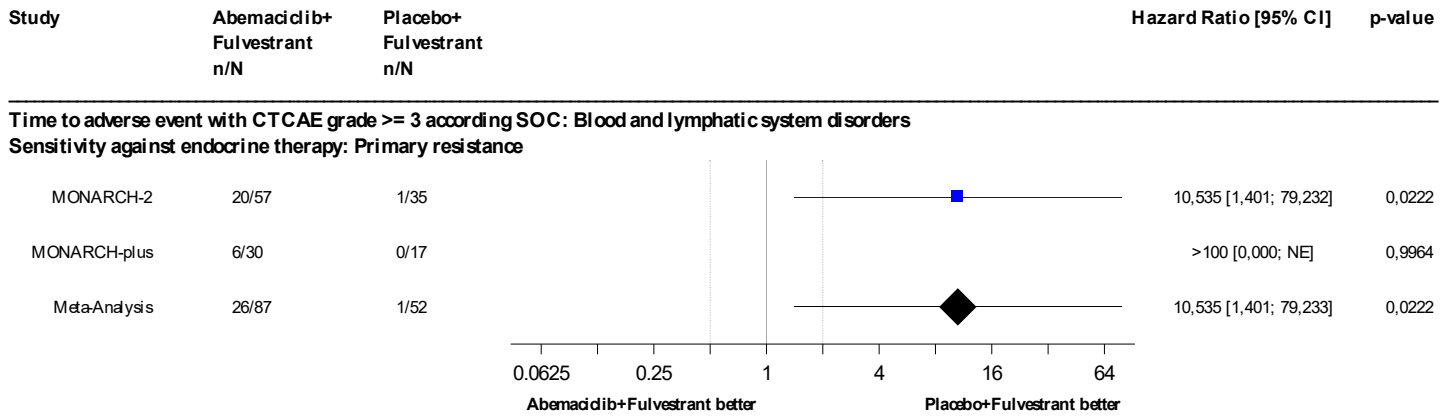
Figure 1316.1.8.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9969, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttirgr3s001_popa1_snthr_1.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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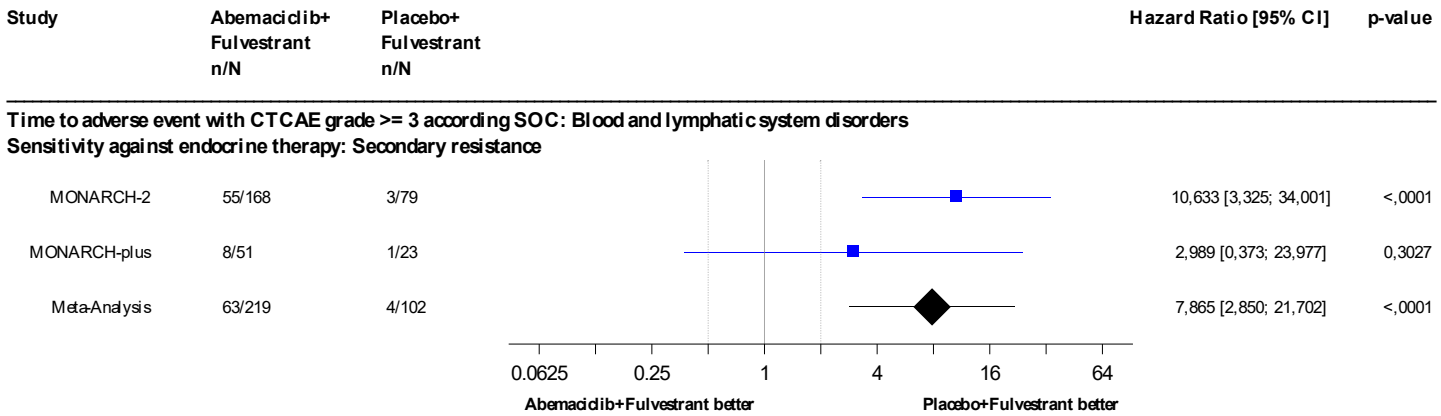
Figure 1316.1.8.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,0879, p-value=0,2969, I2 index=8,1%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttirgr3s001_popa1_snthr_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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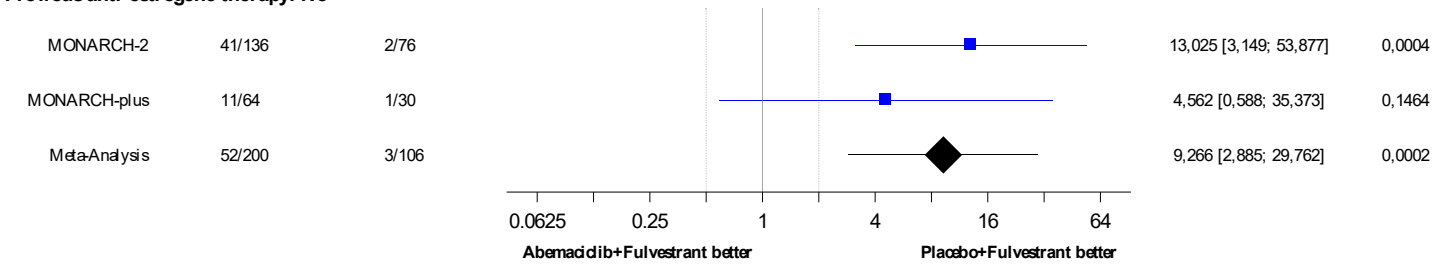
Figure 1316.1.9.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6807, p-value=0,4093, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttirgr3s001_popa1_paet_1.rtf

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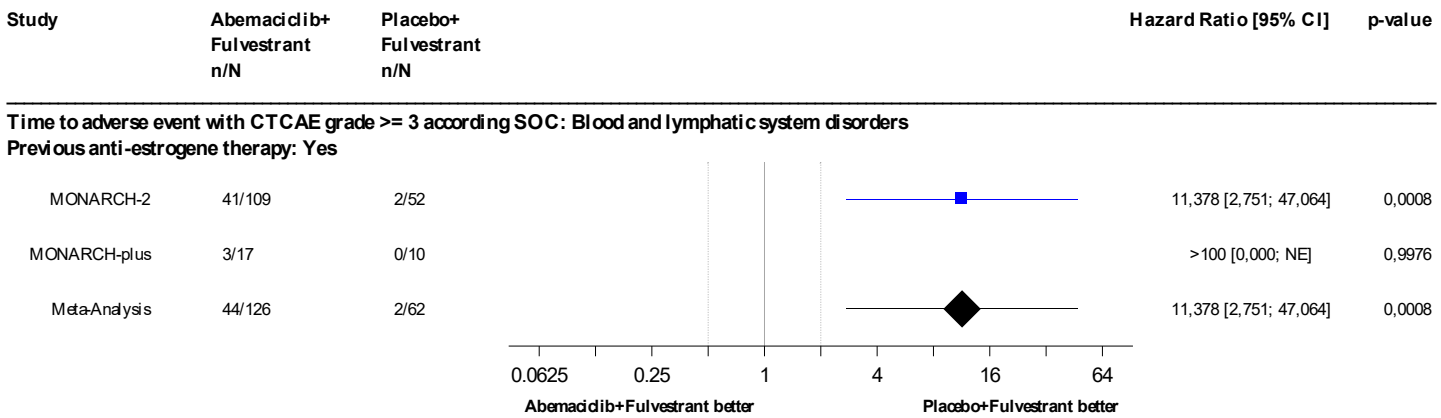
Figure 1316.1.9.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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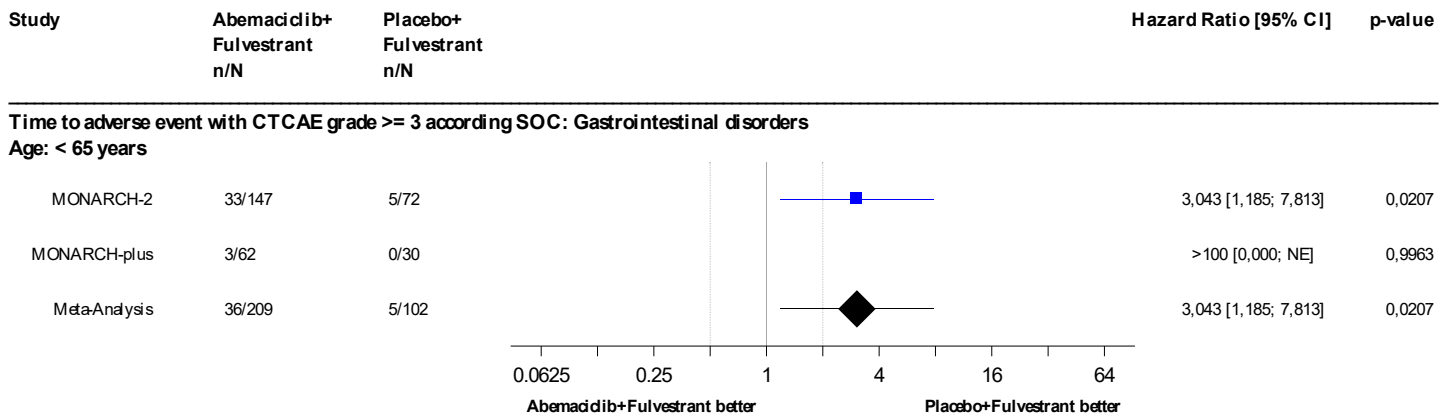
Figure 1317.1.1.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9966, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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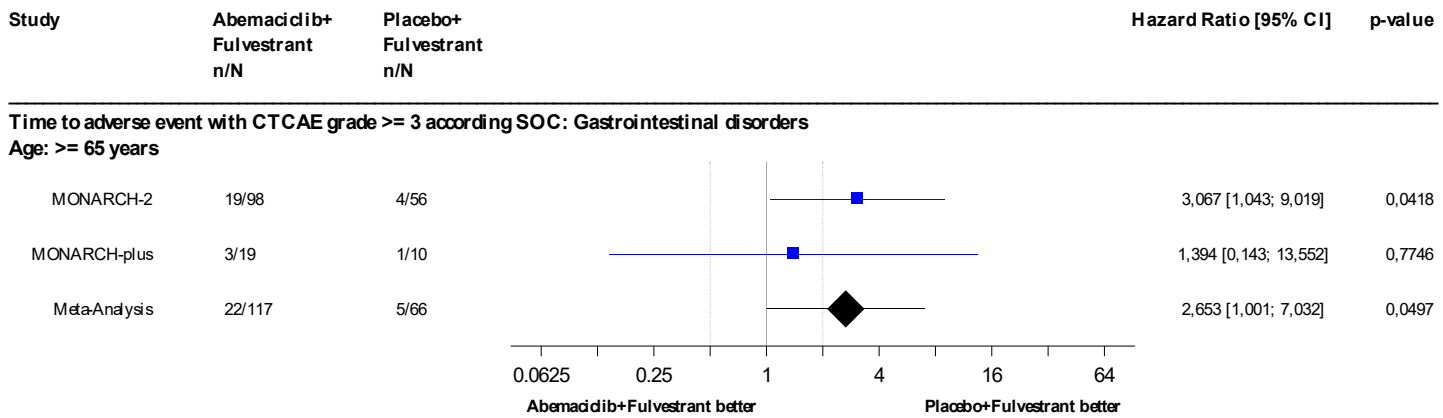
Figure 1317.1.1.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3768, p-value=0,5393, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttirgr3s002_popa1_agegr1_2.rtf
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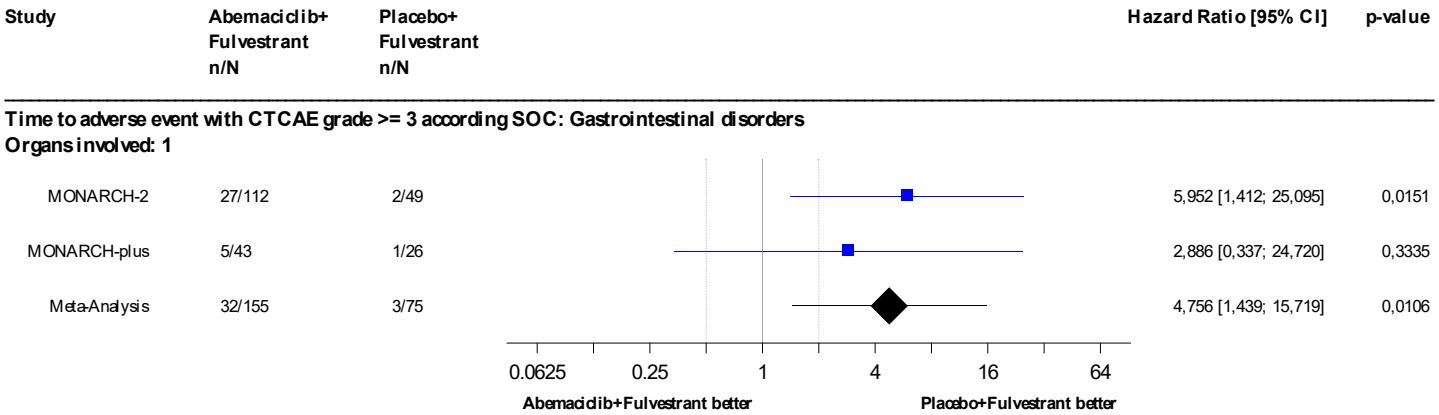
Figure 1317.1.2.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,3012, p-value=0,5831, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttirgr3s002_popa1_norggr_1.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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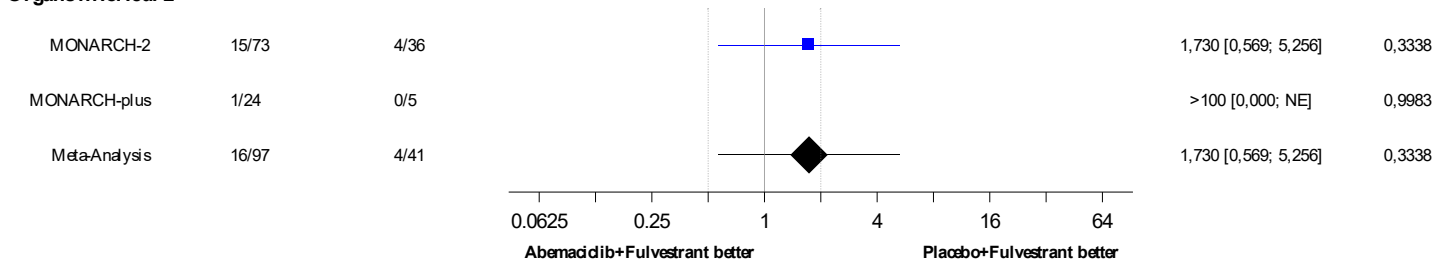
Figure 1317.1.2.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9983, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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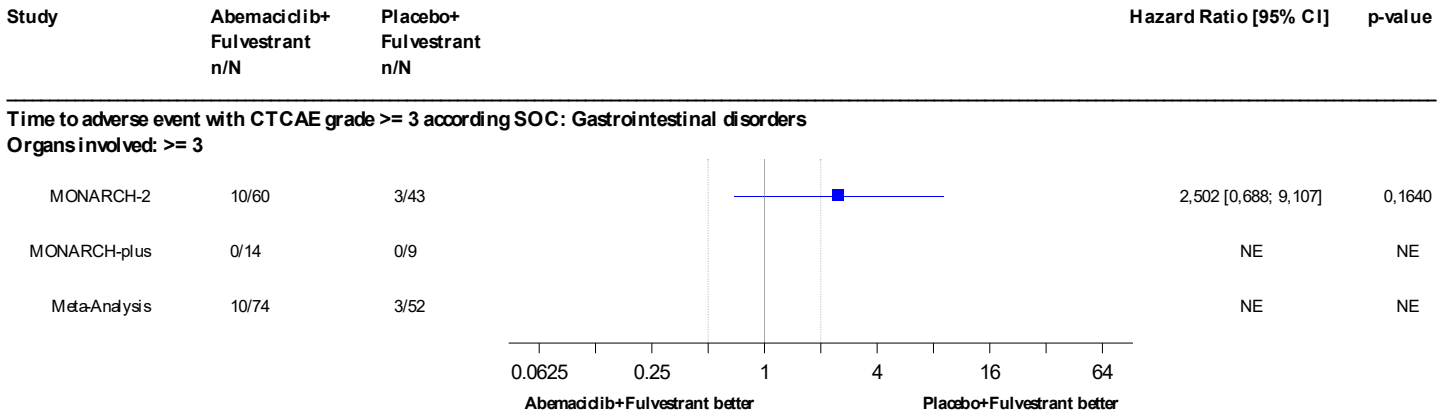
Figure 1317.1.2.3: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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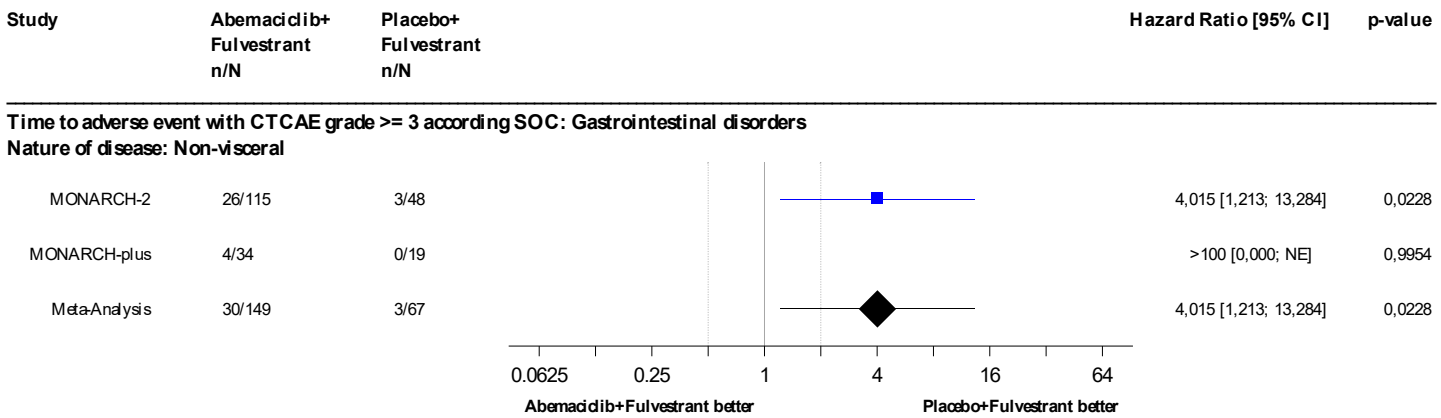
Figure 1317.1.3.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9958, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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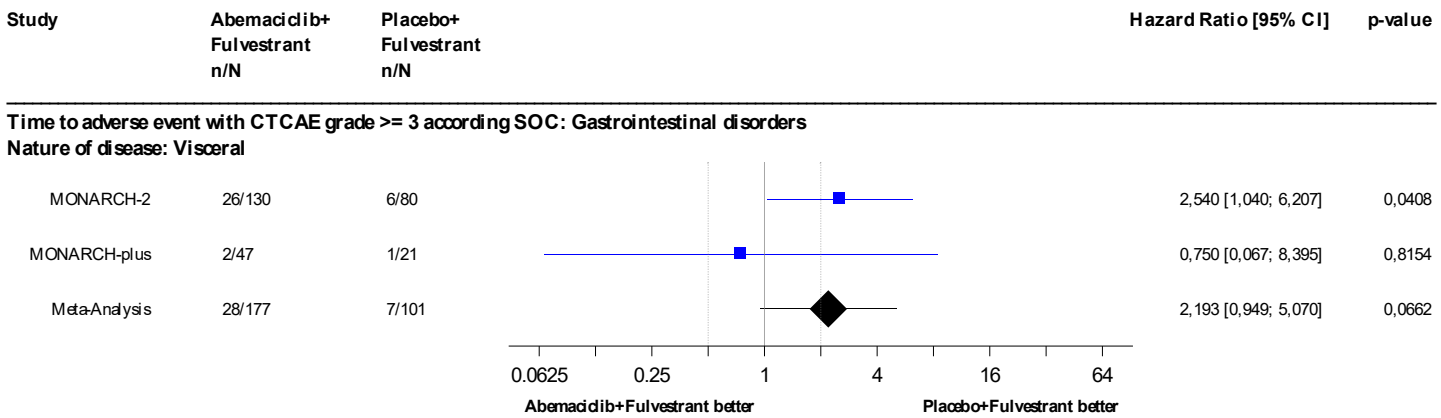
Figure 1317.1.3.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,8621, p-value=0,3532, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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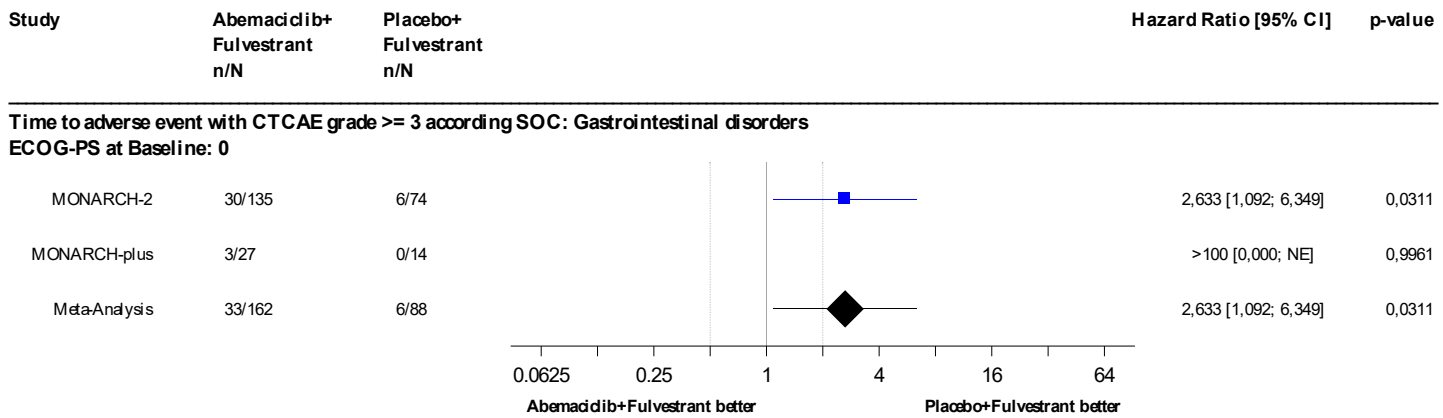
Figure 1317.1.4.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9963, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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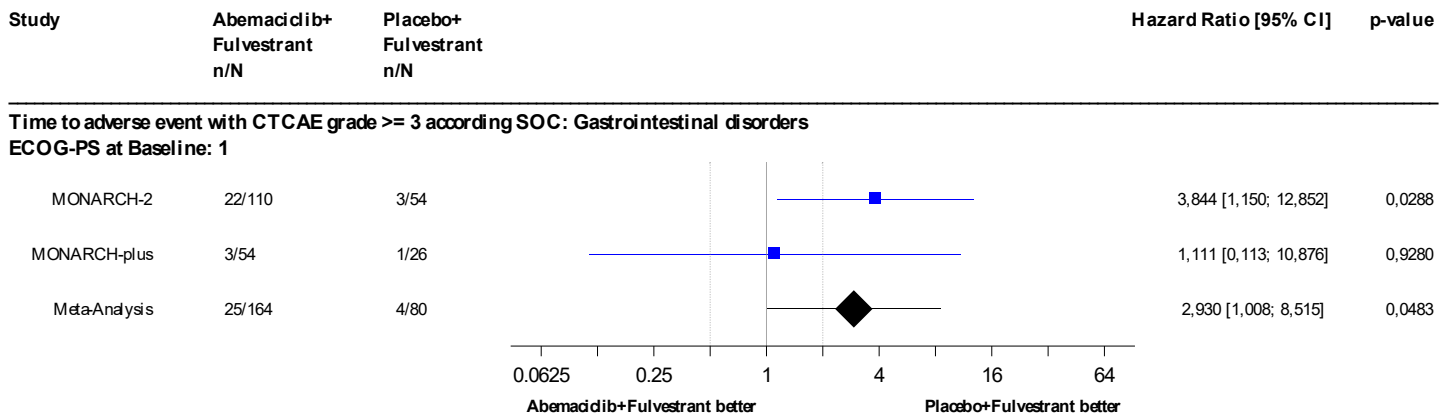
Figure 1317.1.4.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,8885, p-value=0,3459, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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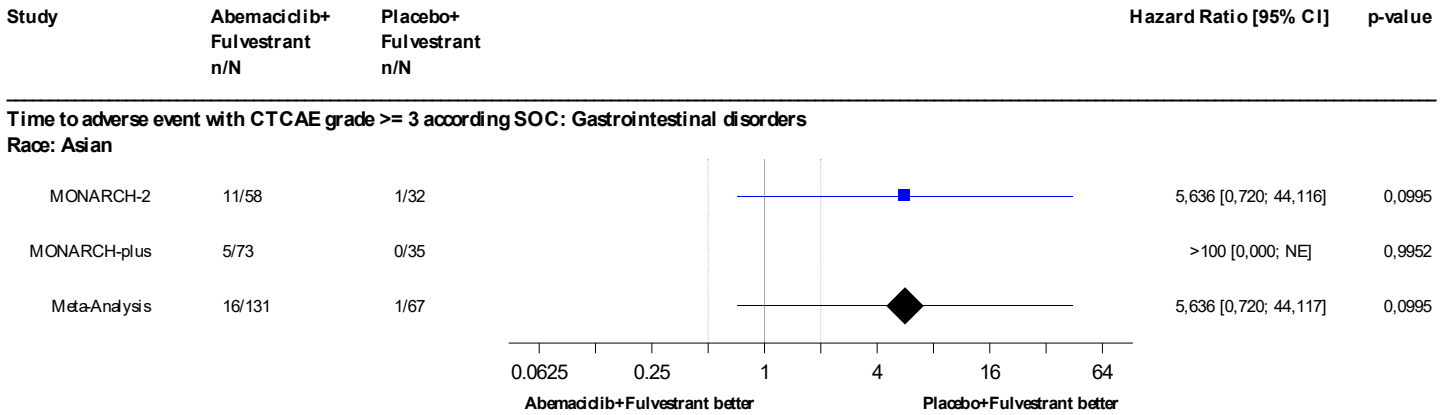
Figure 1317.1.5.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9957, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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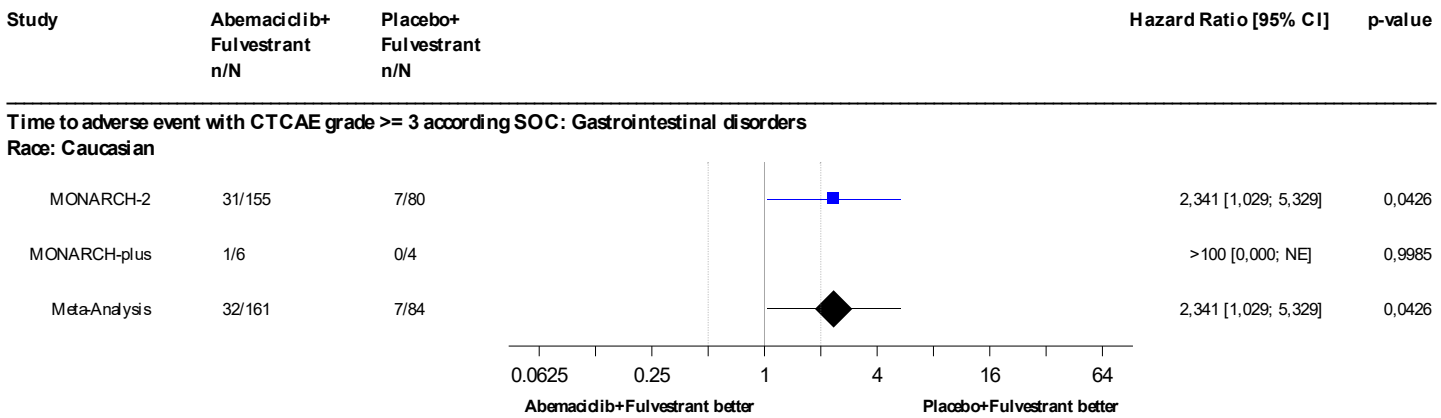
Figure 1317.1.5.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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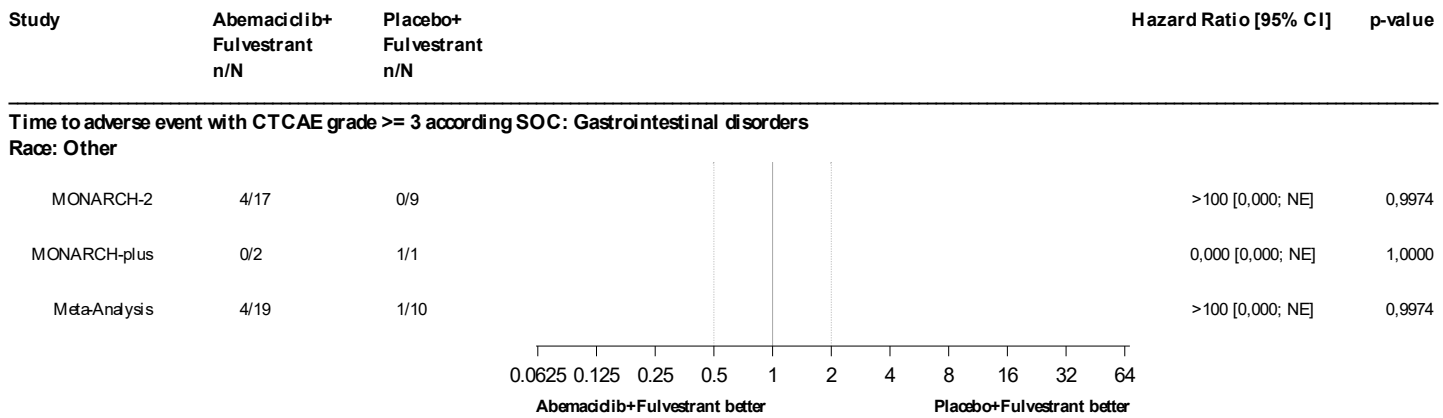
Figure 1317.1.5.3: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9999, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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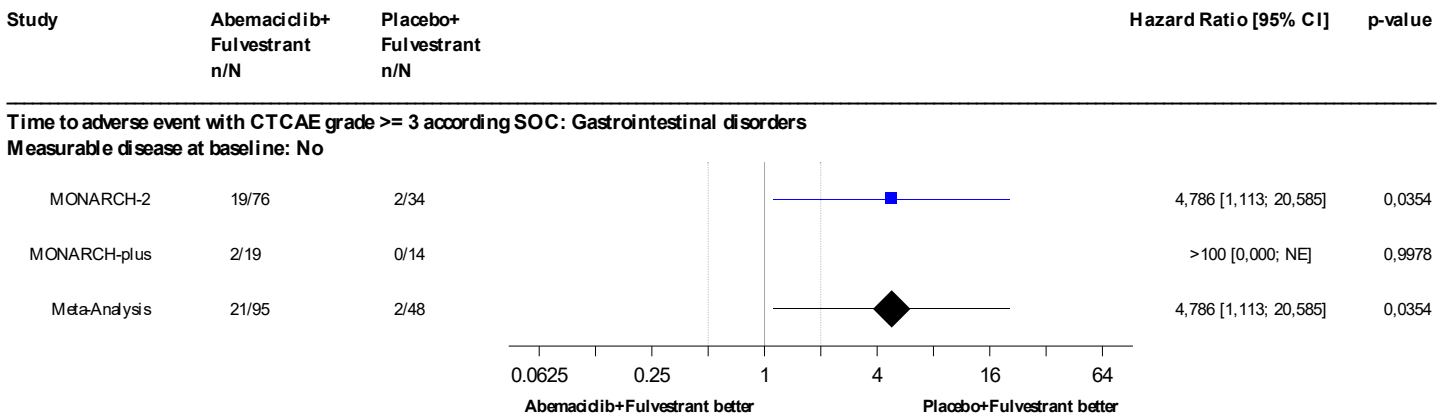
Figure 1317.1.6.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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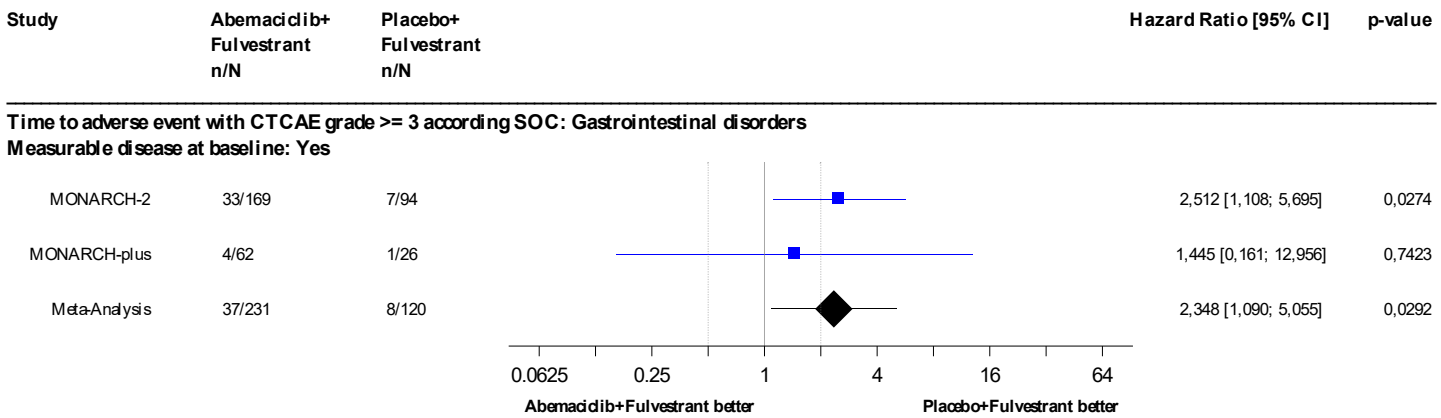
Figure 1317.1.6.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,2144, p-value=0,6434, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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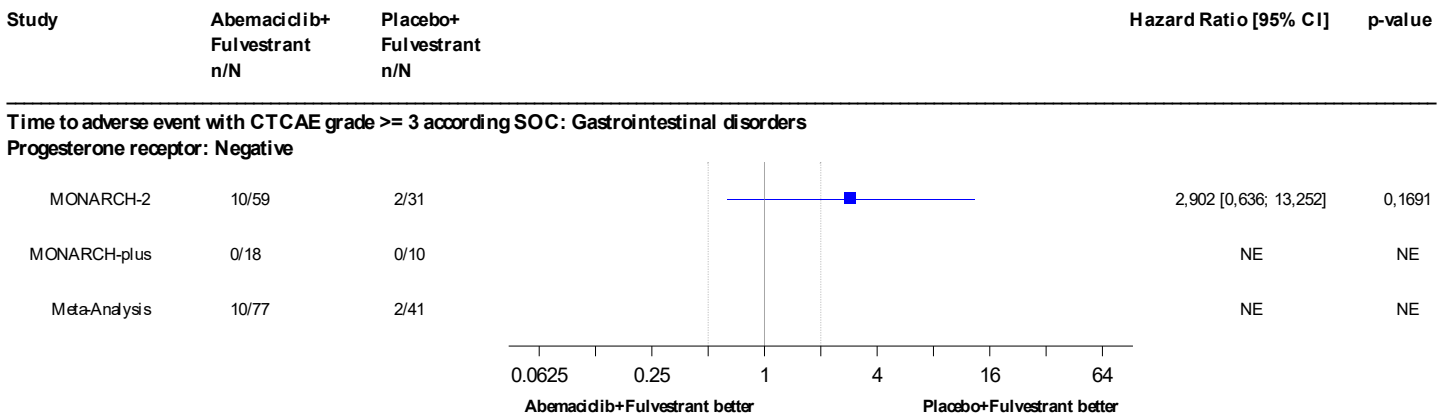
Figure 1317.1.7.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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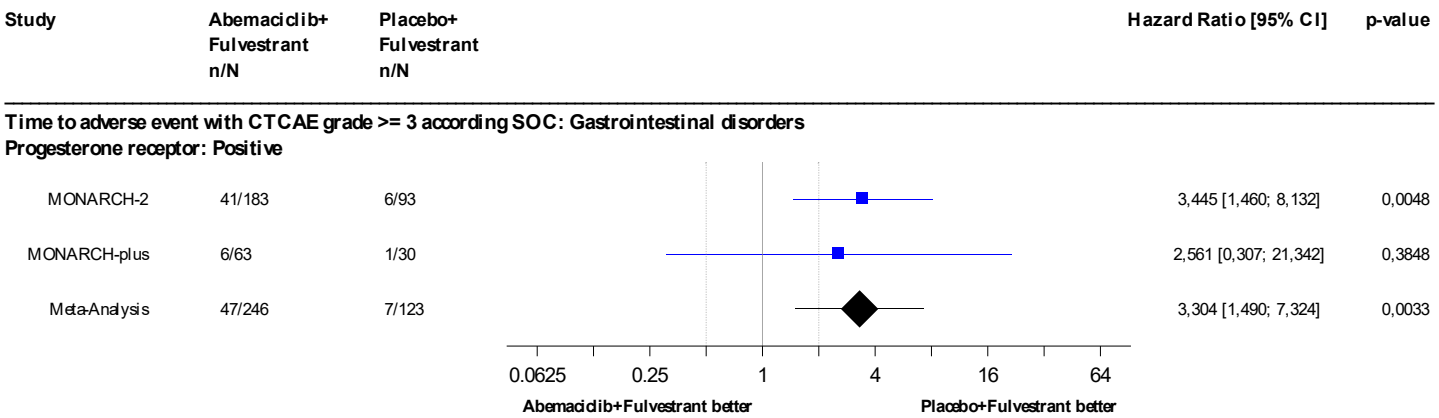
Figure 1317.1.7.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0646, p-value=0,7993, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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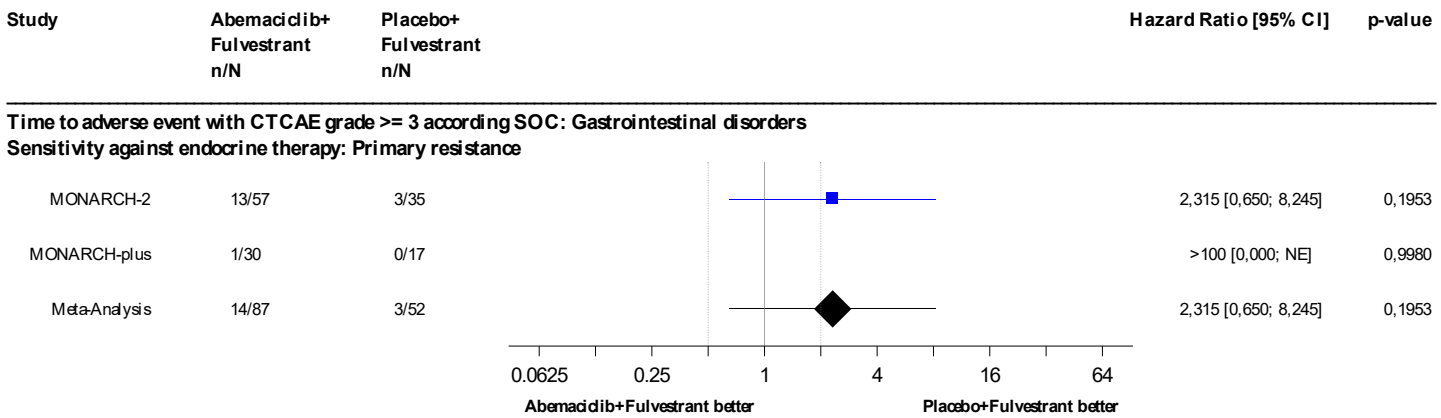
Figure 1317.1.8.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9981, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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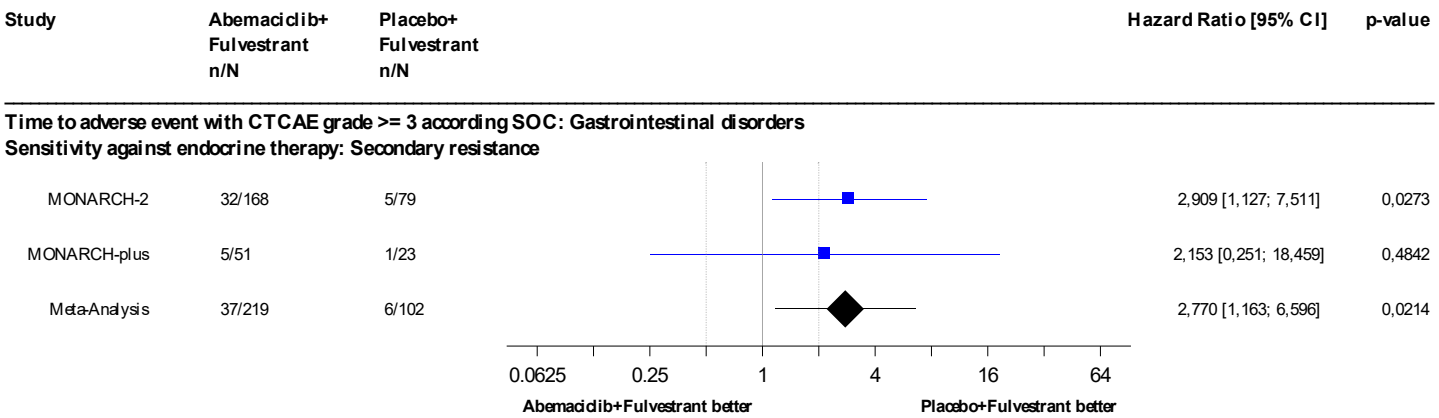
Figure 1317.1.8.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0631, p-value=0,8016, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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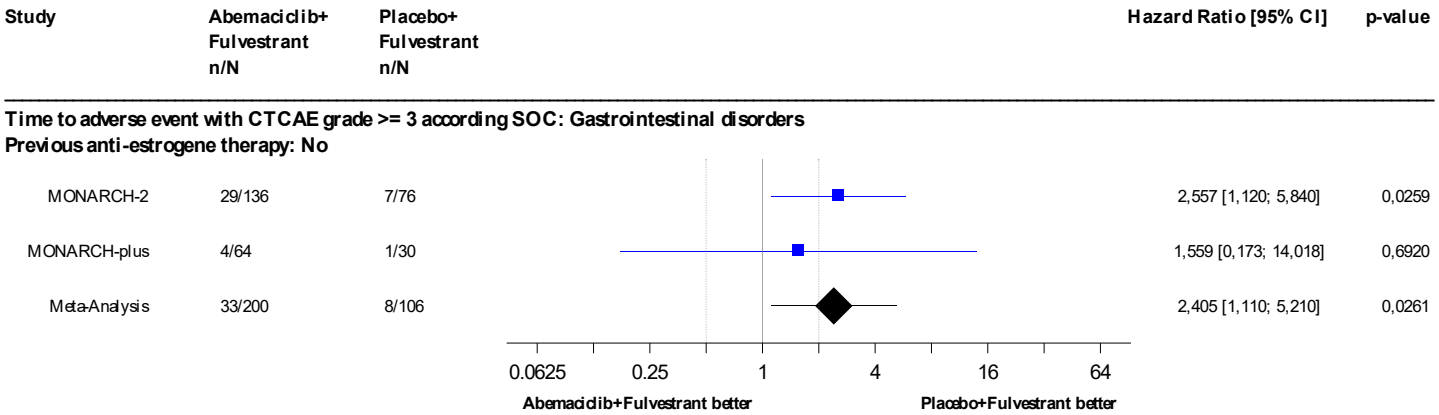
Figure 1317.1.9.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1709, p-value=0,6793, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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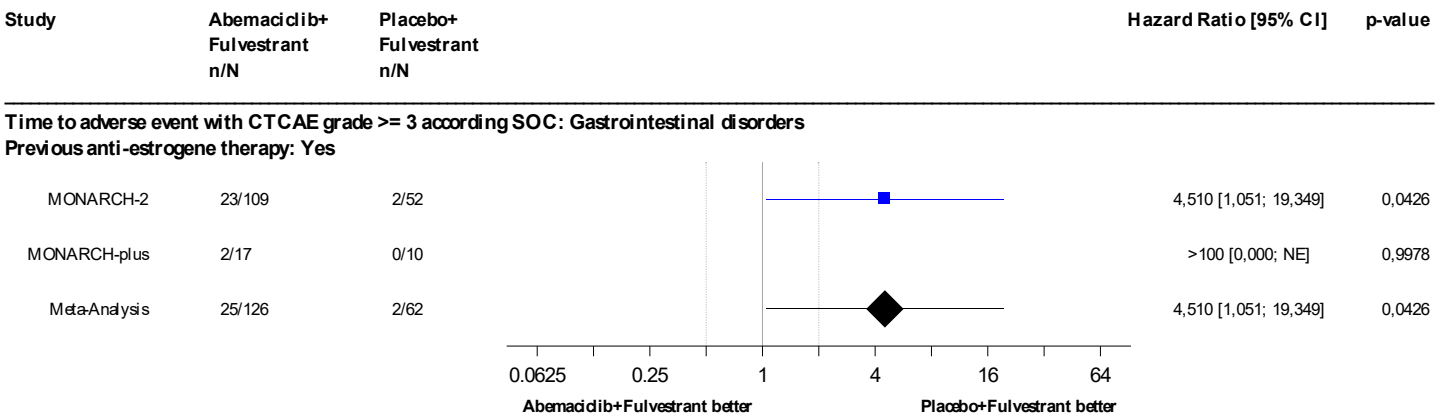
Figure 1317.1.9.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9980, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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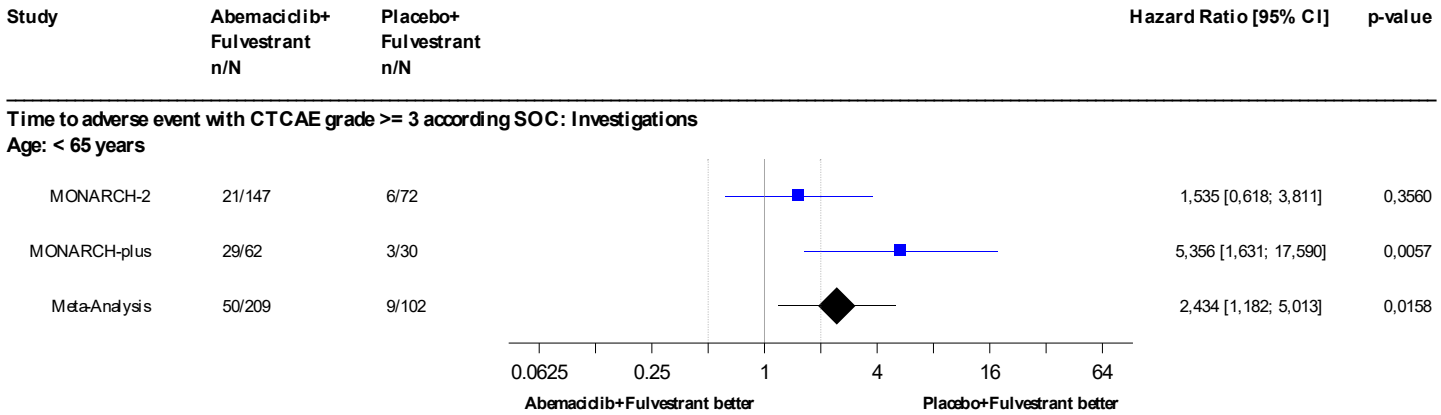
Figure 1321.1.1.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,6774, p-value=0,1018, I2 index=62,7%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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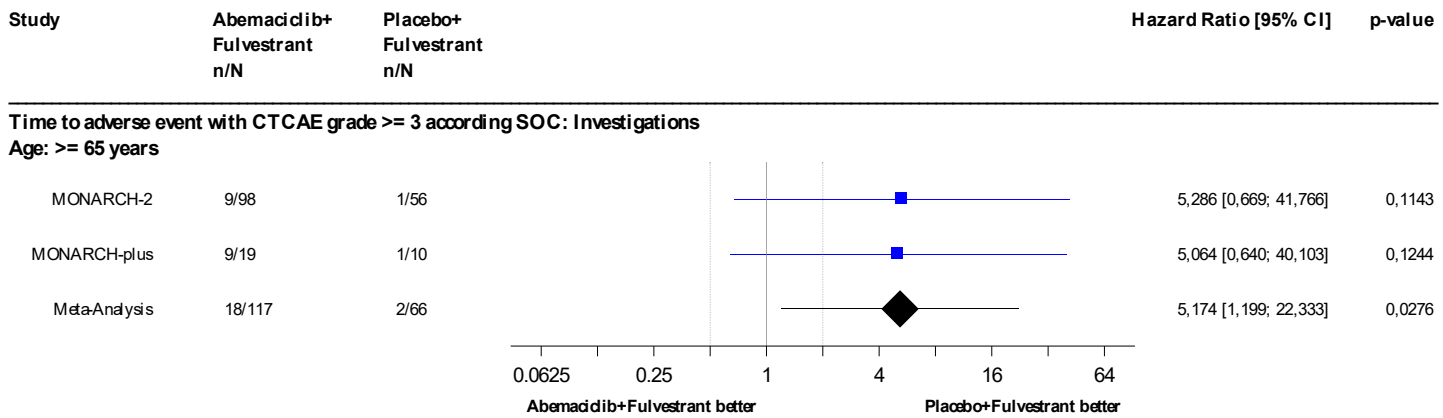
Figure 1321.1.1.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0008, p-value=0,9771, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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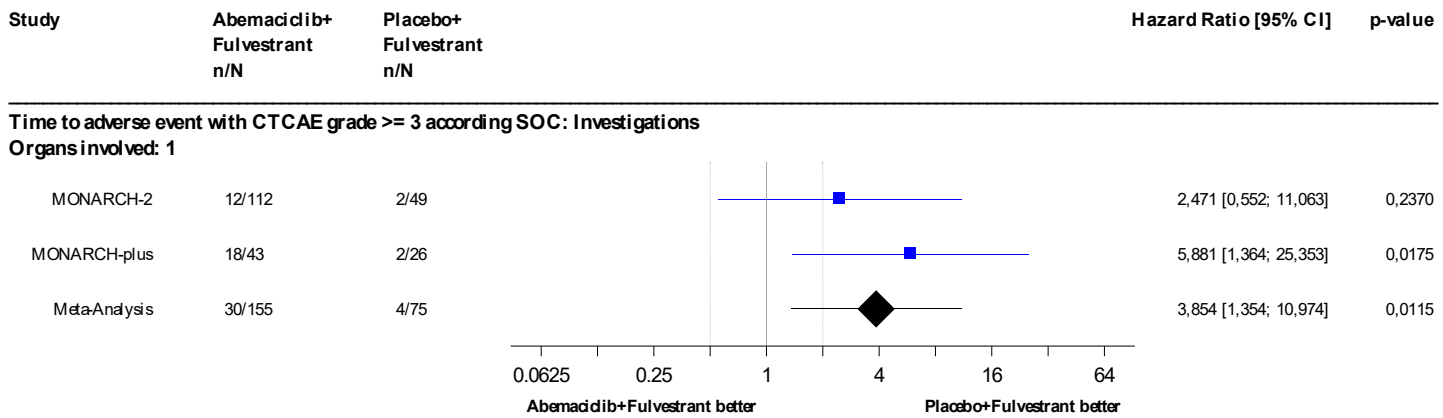
Figure 1321.1.2.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6593, p-value=0,4168, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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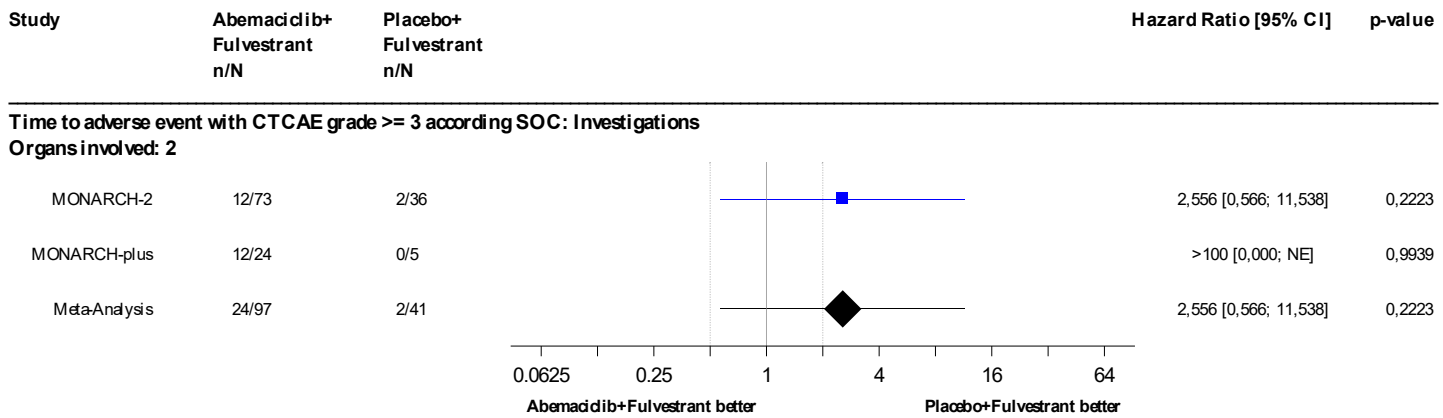
Figure 1321.1.2.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9942, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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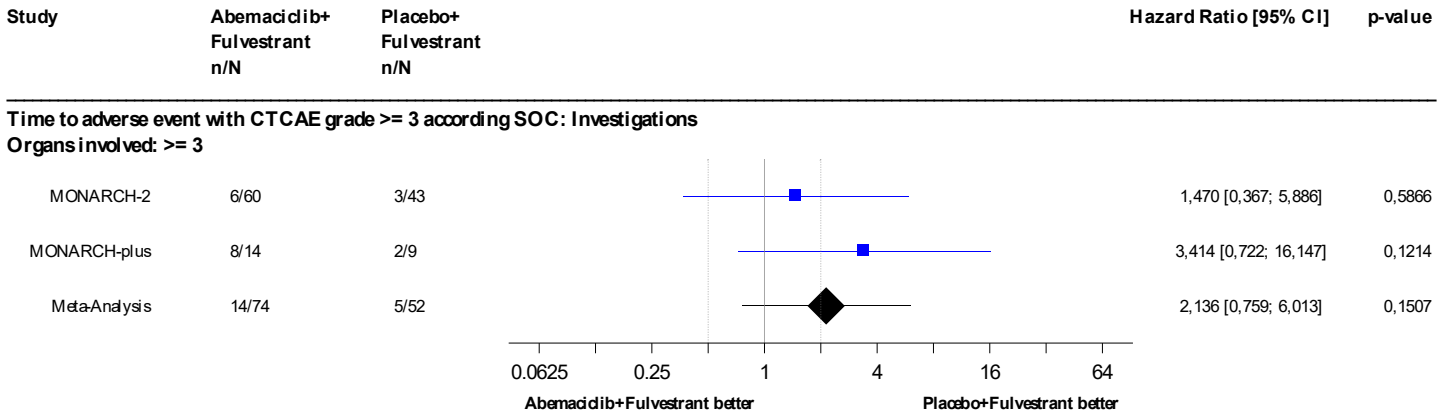
Figure 1321.1.2.3: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,6288, p-value=0,4278, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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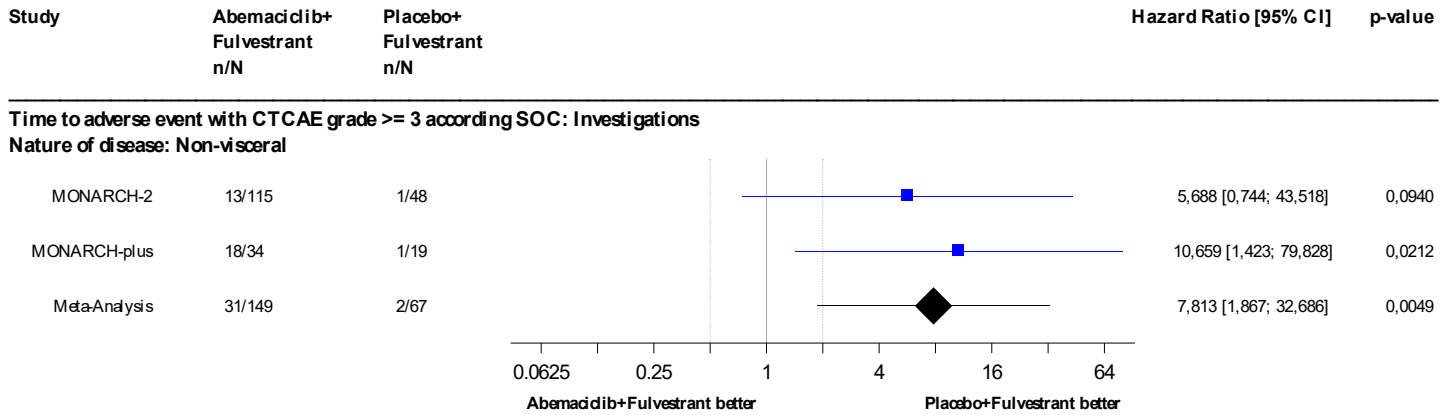
Figure 1321.1.3.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,1849, p-value=0,6672, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

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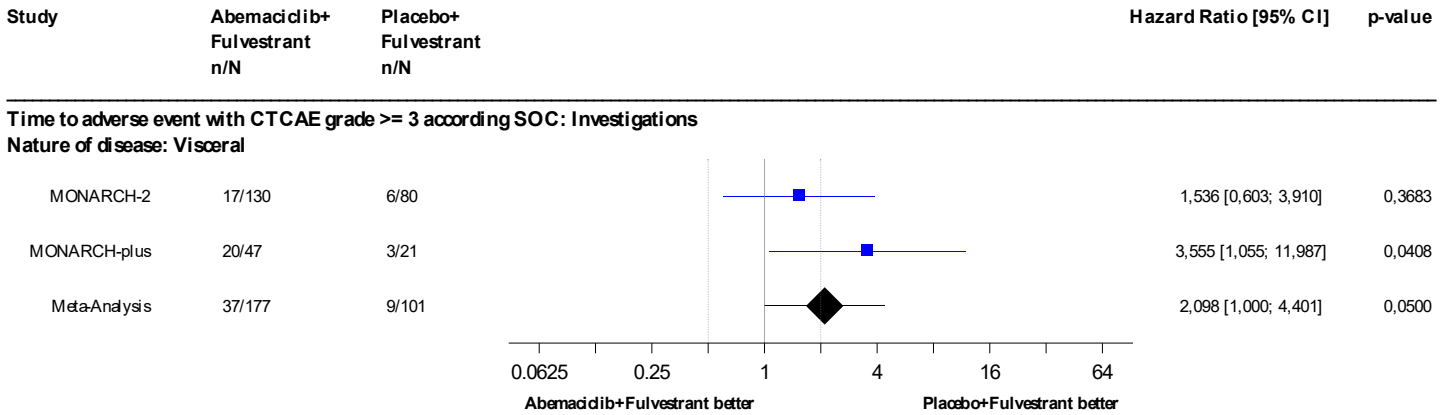
Figure 1321.1.3.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,1519, p-value=0,2832, I2 index=13,2%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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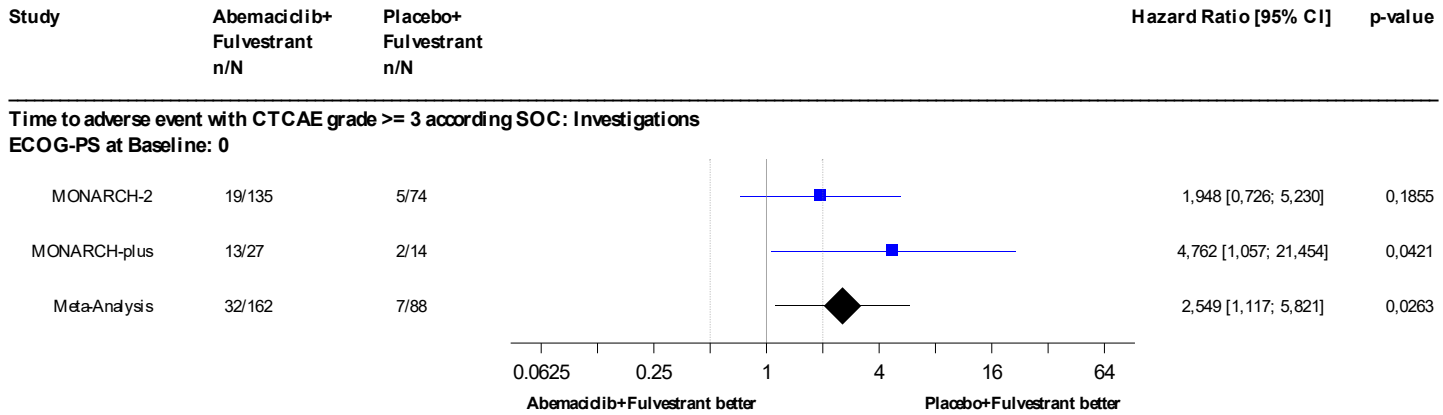
Figure 1321.1.4.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,9469, p-value=0,3305, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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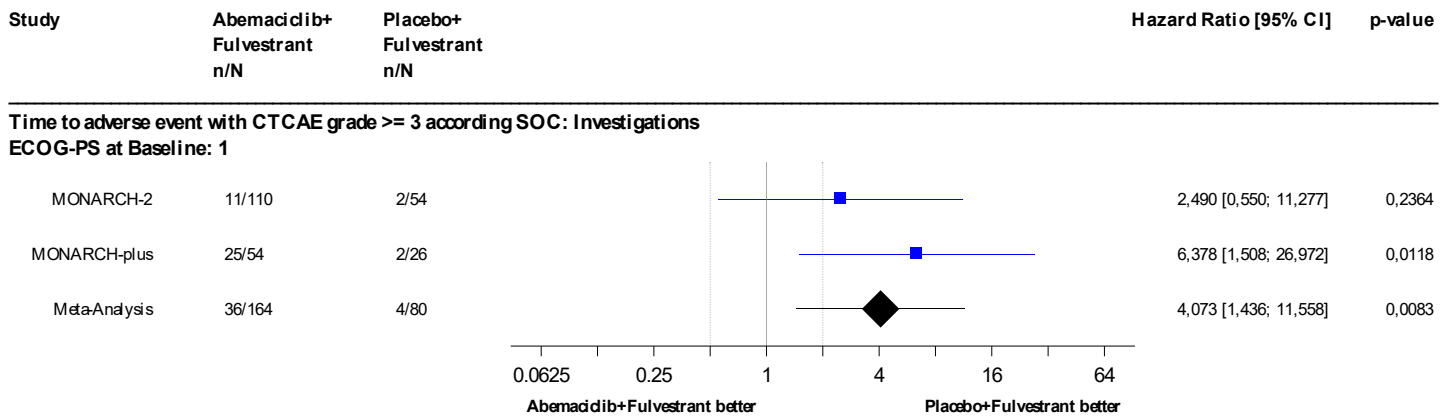
Figure 1321.1.4.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,7792, p-value=0,3774, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttirgr3s006_popa1_ecogbl_2.rtf
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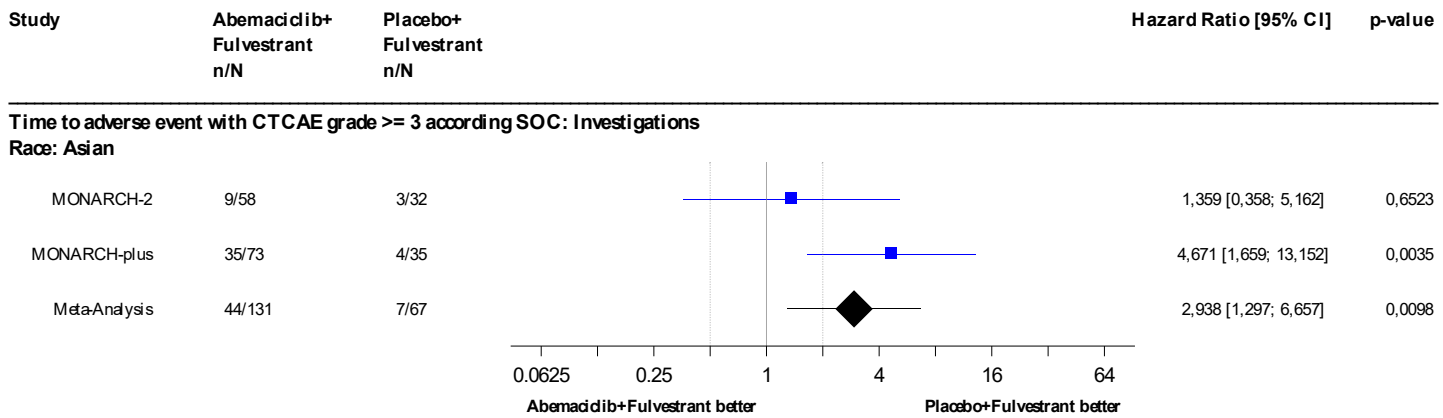
Figure 1321.1.5.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Subgroup analysis for Race: Asian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=2,0530, p-value=0,1519, I2 index=51,3%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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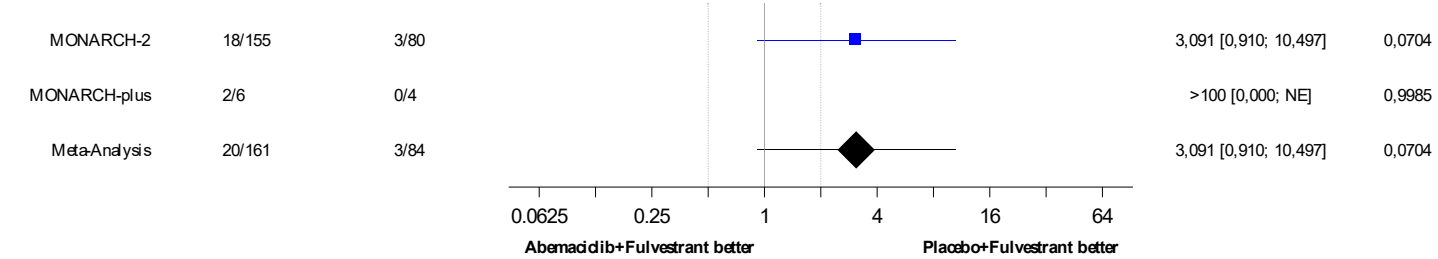
Figure 1321.1.5.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Subgroup analysis for Race: Caucasian
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttirgr3s006_popa1_racegr1_2.rtf
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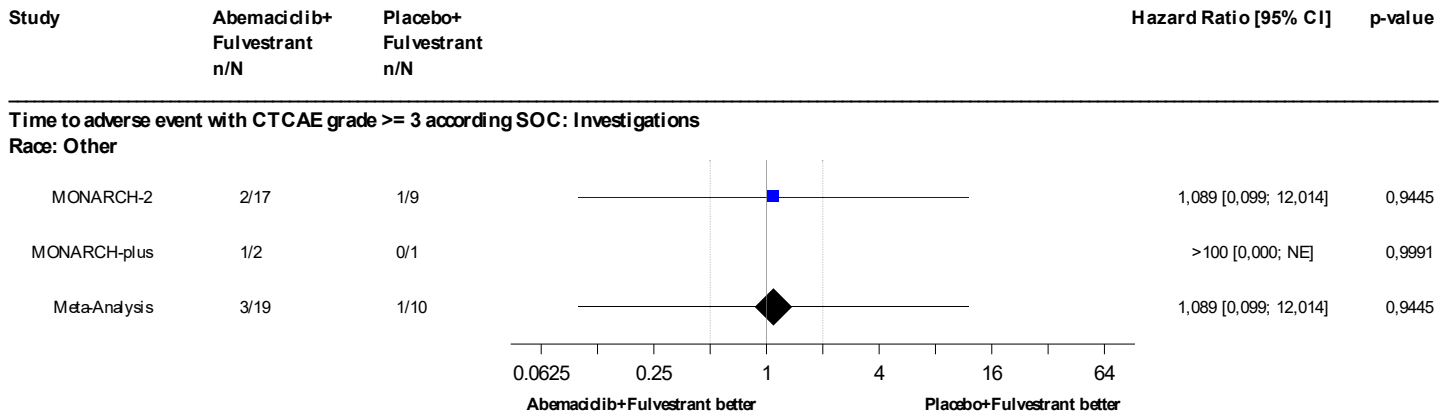
Figure 1321.1.5.3: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Subgroup analysis for Race: Other
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9991, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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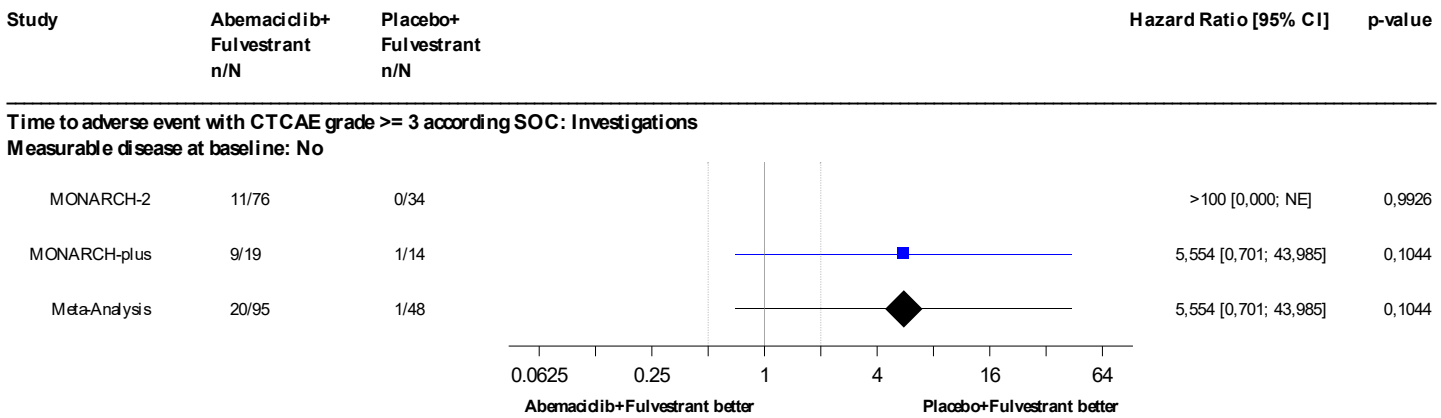
Figure 1321.1.6.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0001, p-value=0,9933, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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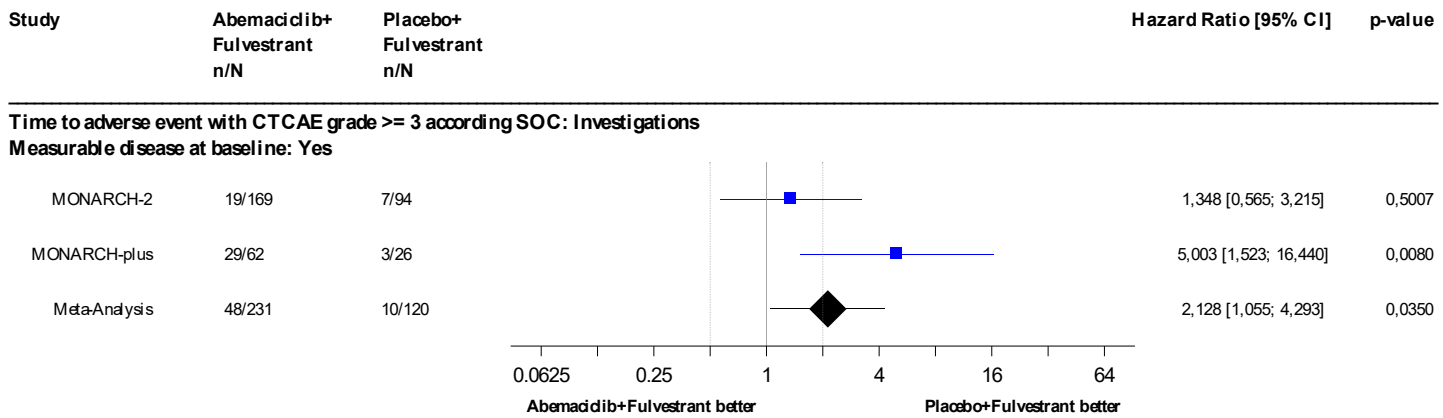
Figure 1321.1.6.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=3,0431, p-value=0,0811, I2 index=67,1%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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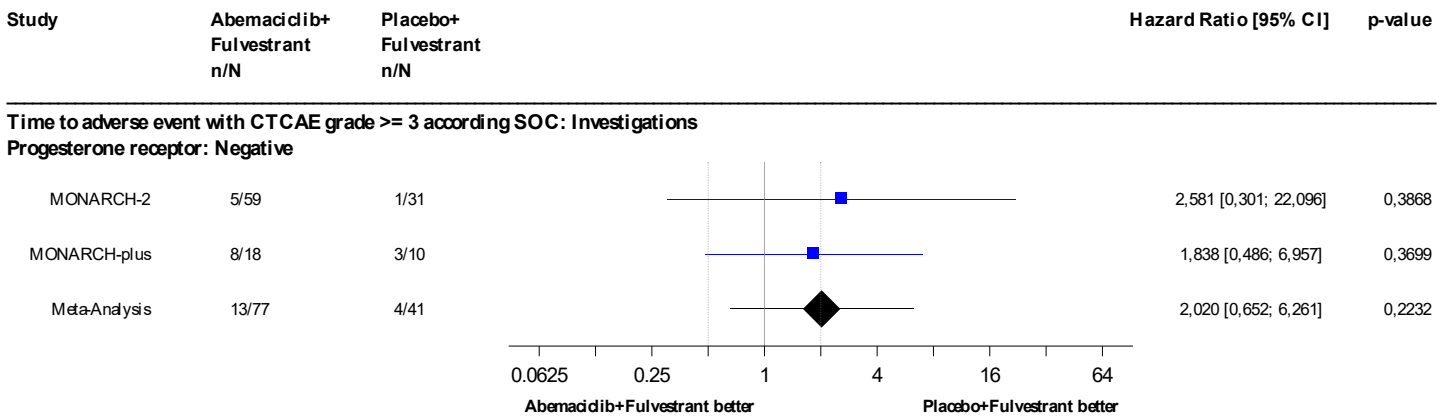
Figure 1321.1.7.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0693, p-value=0,7924, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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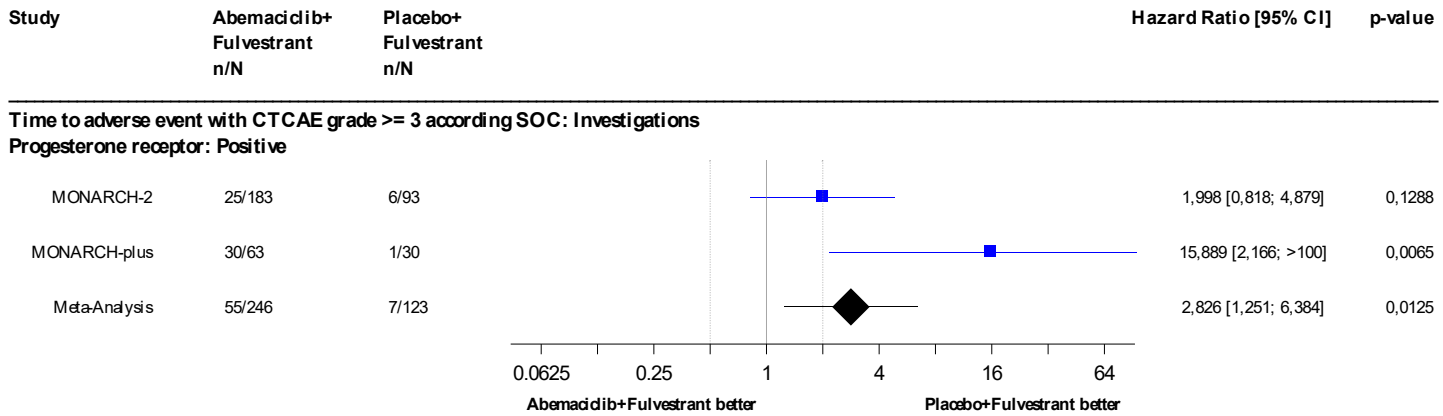
Figure 1321.1.7.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=3,4647, p-value=0,0627, I2 index=71,1%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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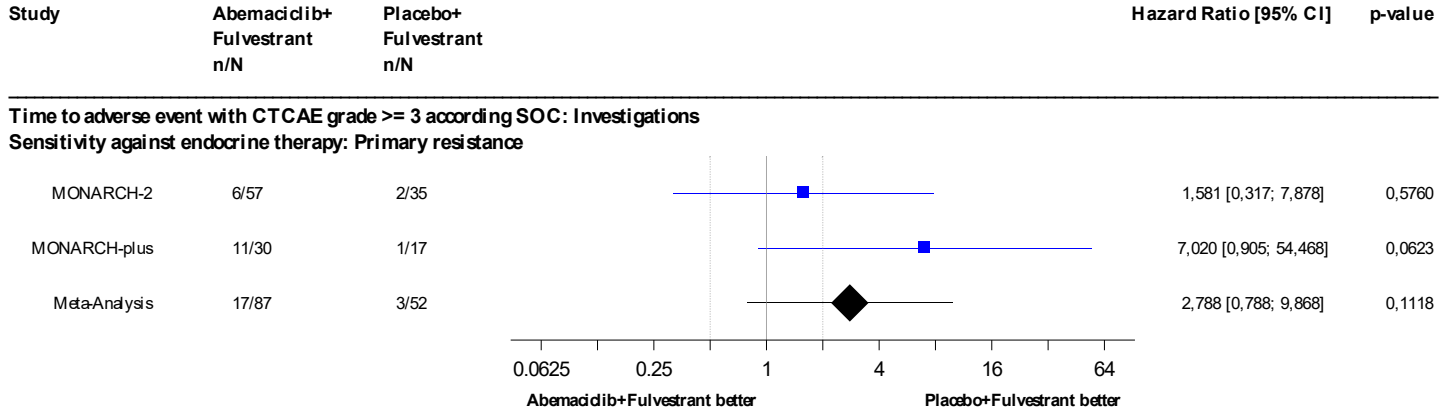
Figure 1321.1.8.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,2594, p-value=0,2618, I2 index=20,6%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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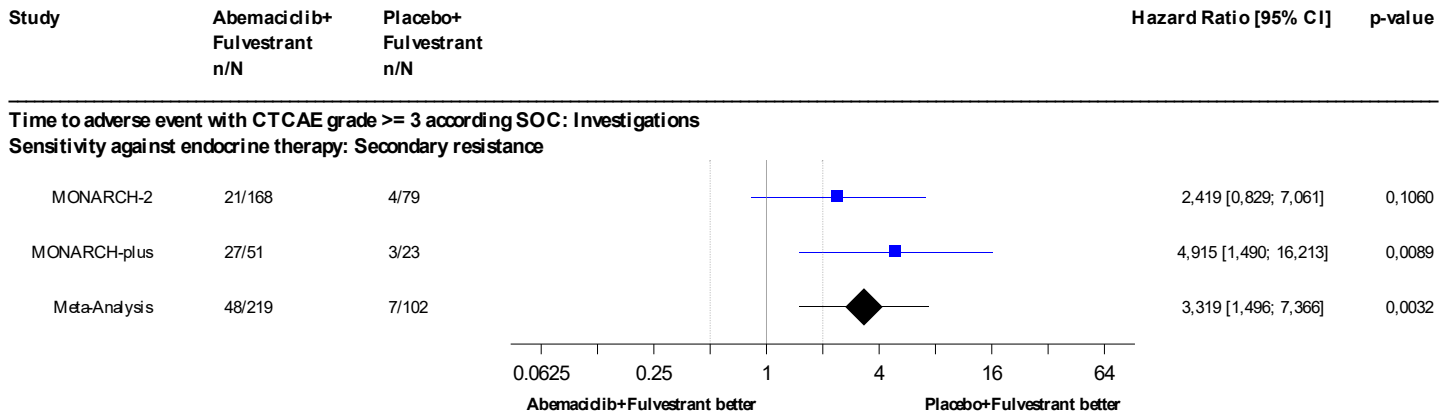
Figure 1321.1.8.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,7507, p-value=0,3862, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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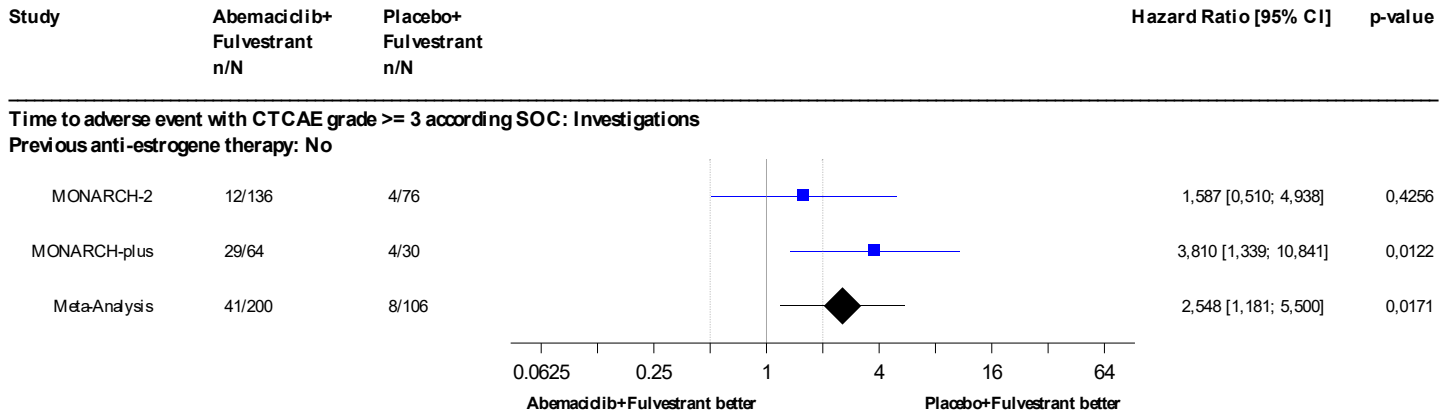
Figure 1321.1.9.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=1,2370, p-value=0,2661, I2 index=19,2%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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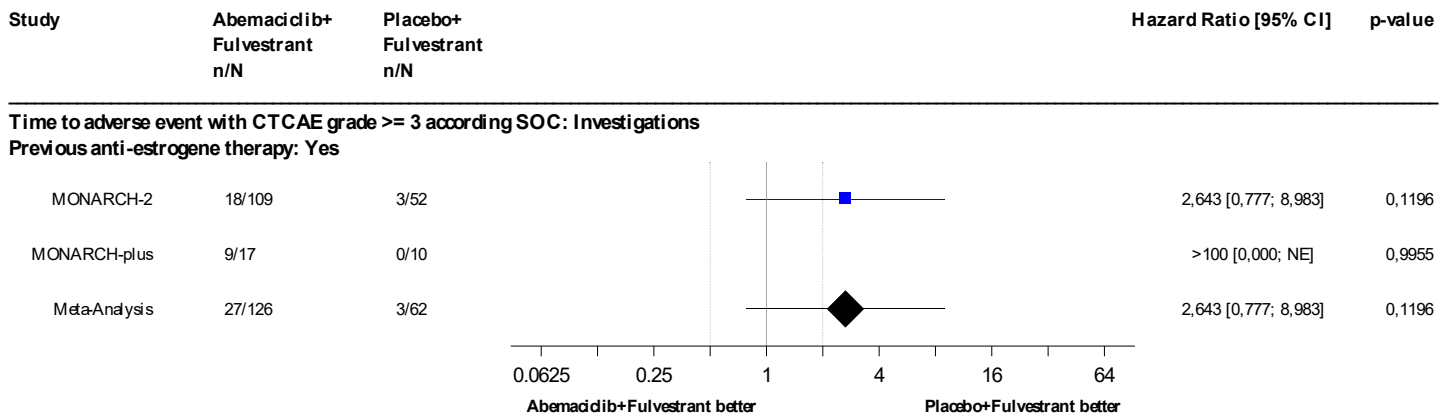
Figure 1321.1.9.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Investigations
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (1st line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9957, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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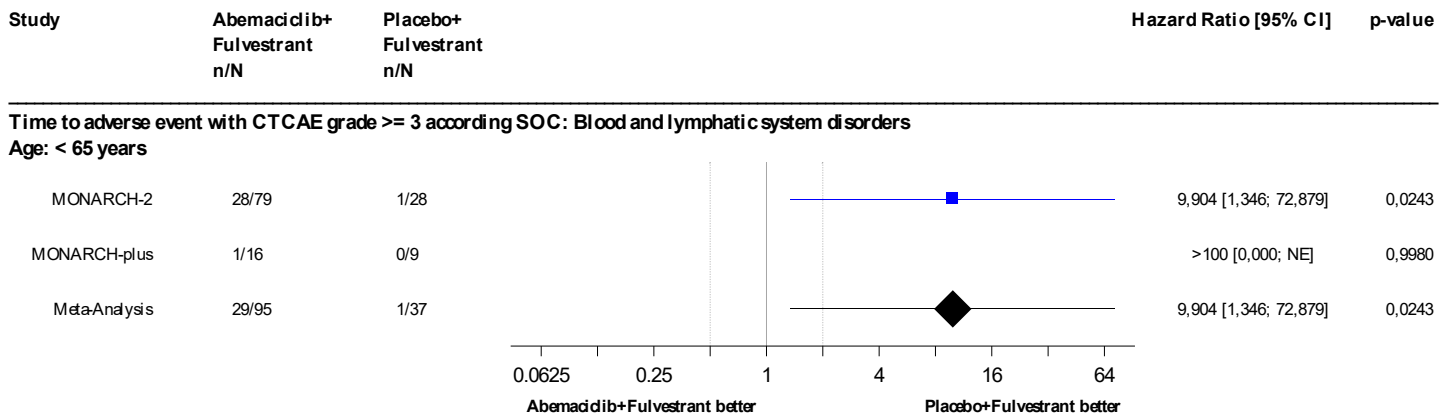
Figure 1326.2.1.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9983, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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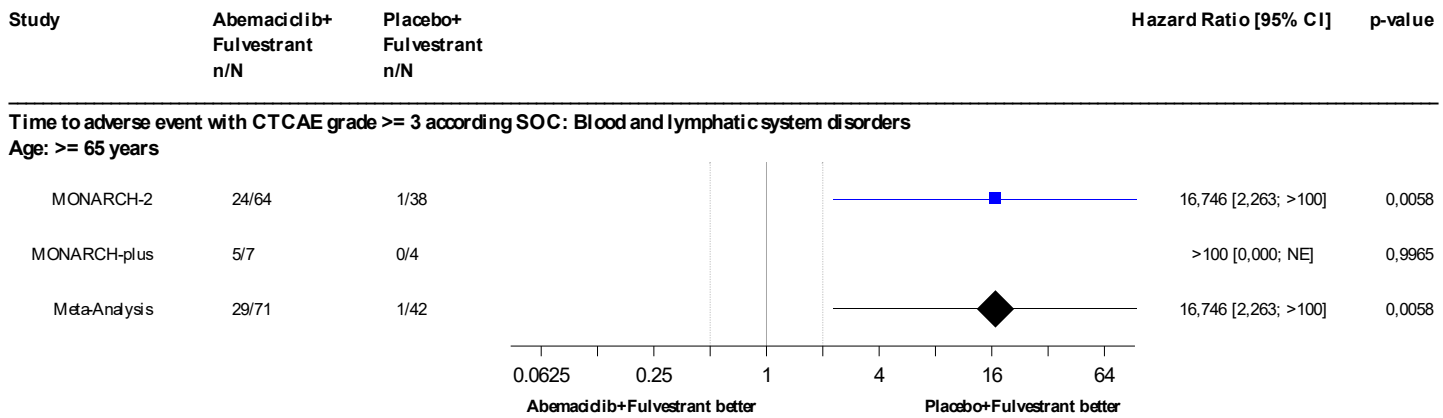
Figure 1326.2.1.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9971, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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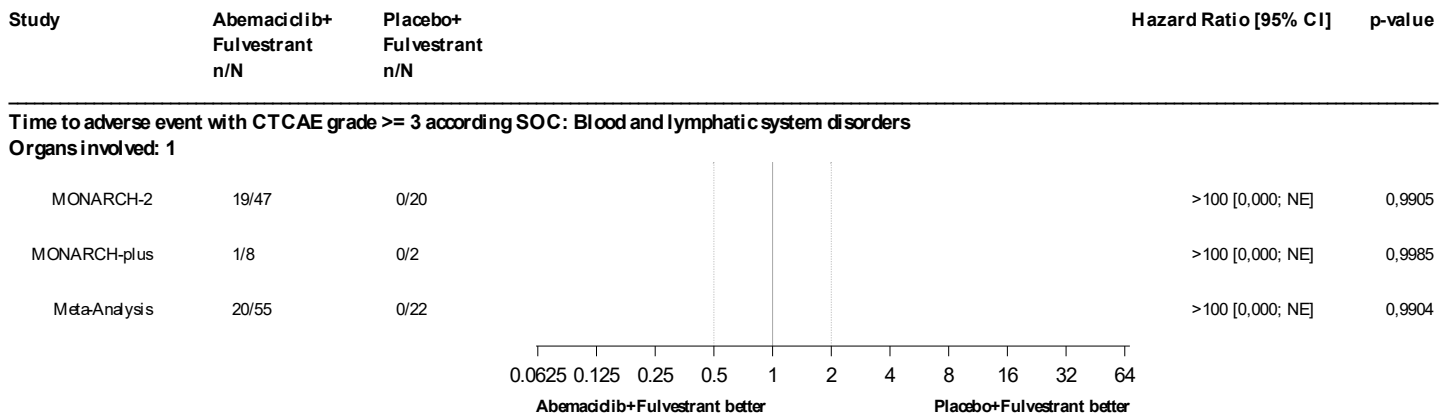
Figure 1326.2.2.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=1,0000, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

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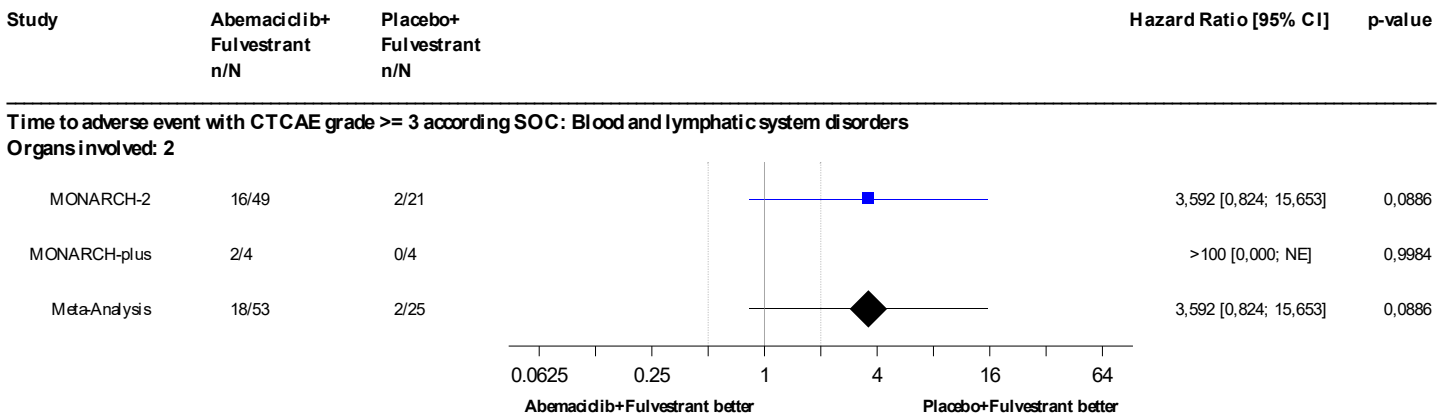
Figure 1326.2.2.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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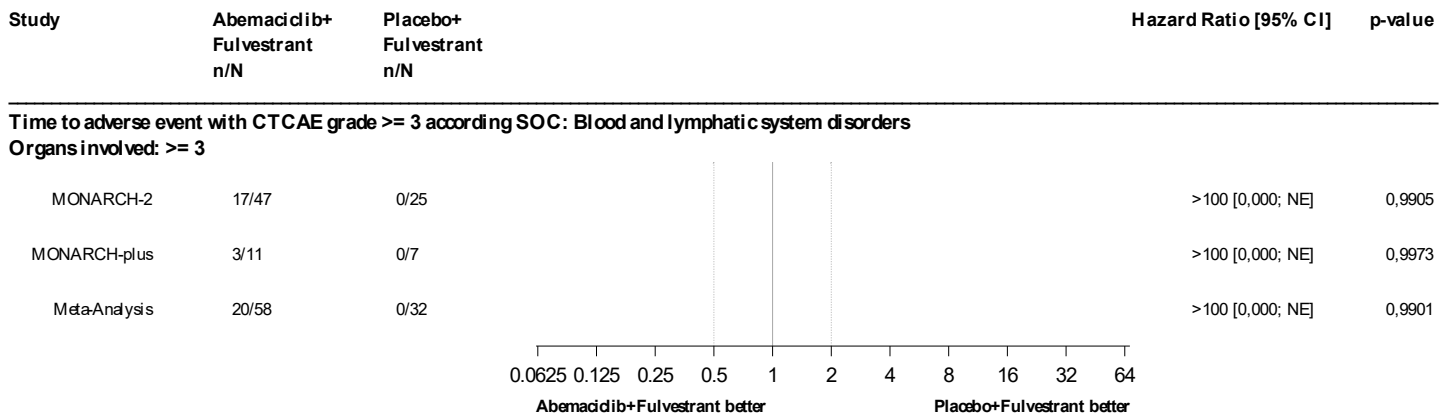
Figure 1326.2.2.3: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9998, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttirgr3s001_popa2_norggr_3.rtf

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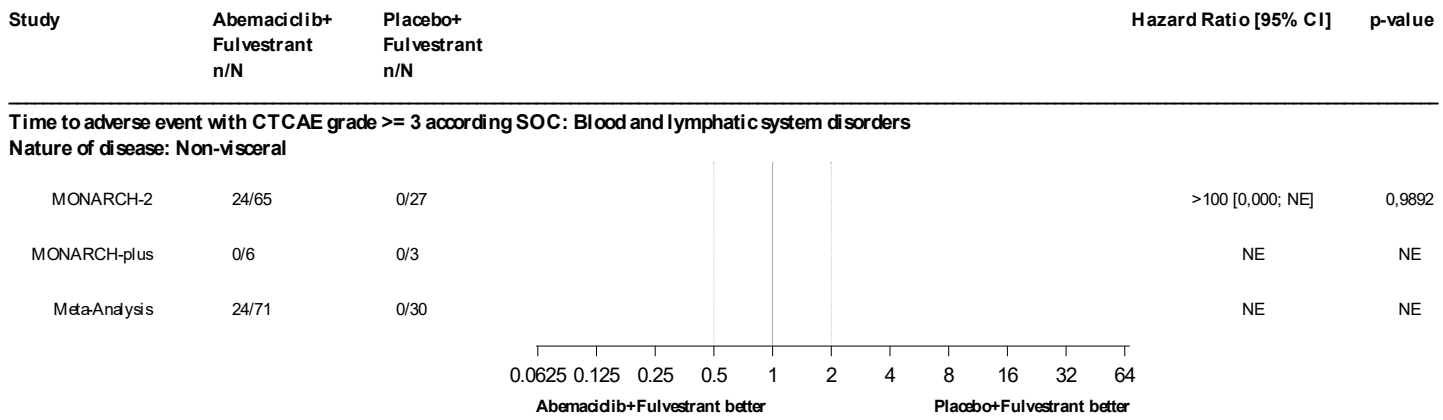
Figure 1326.2.3.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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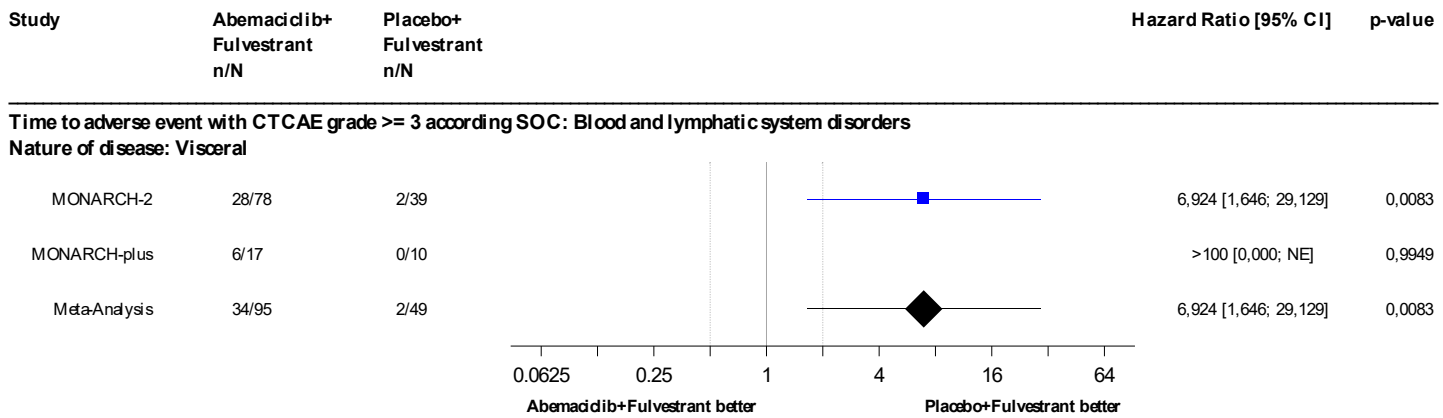
Figure 1326.2.3.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9955, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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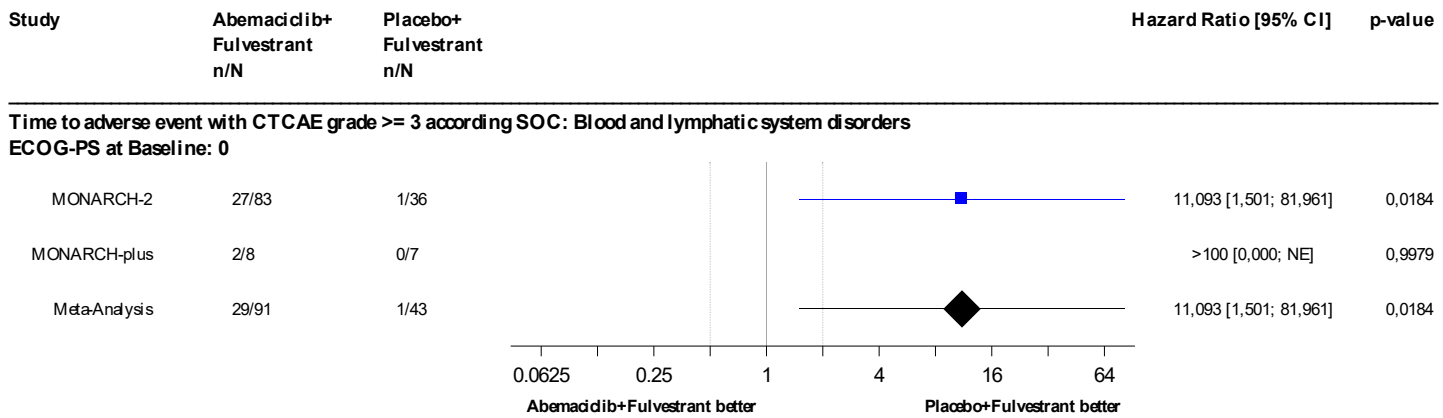
Figure 1326.2.4.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9982, I2 index=0%

Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttirgr3s001_popa2_ecogbl_1.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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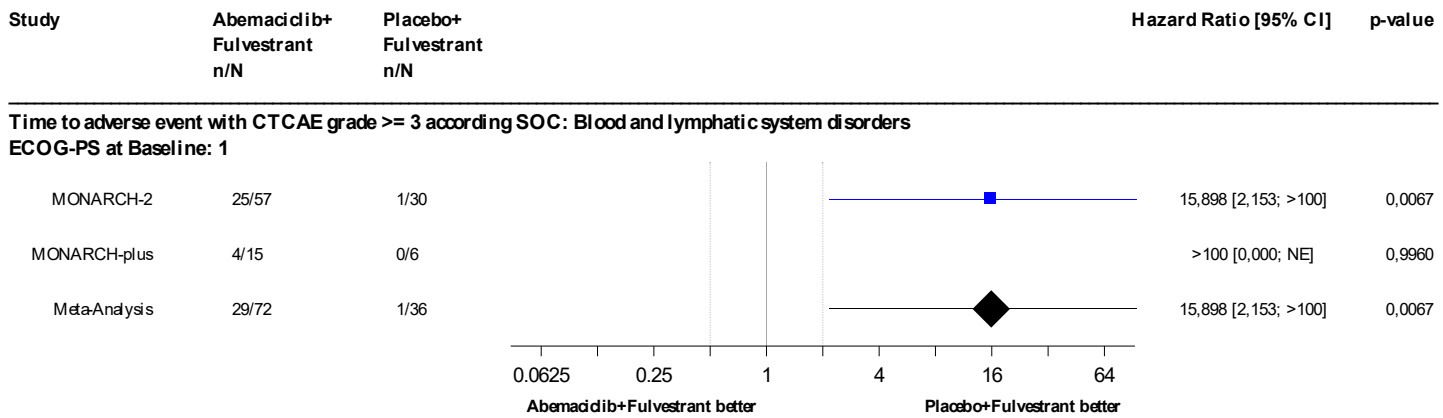
Figure 1326.2.4.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9967, I2 index=0%

Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas

Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttirgr3s001_popa2_ecogbl_2.rtf

Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared

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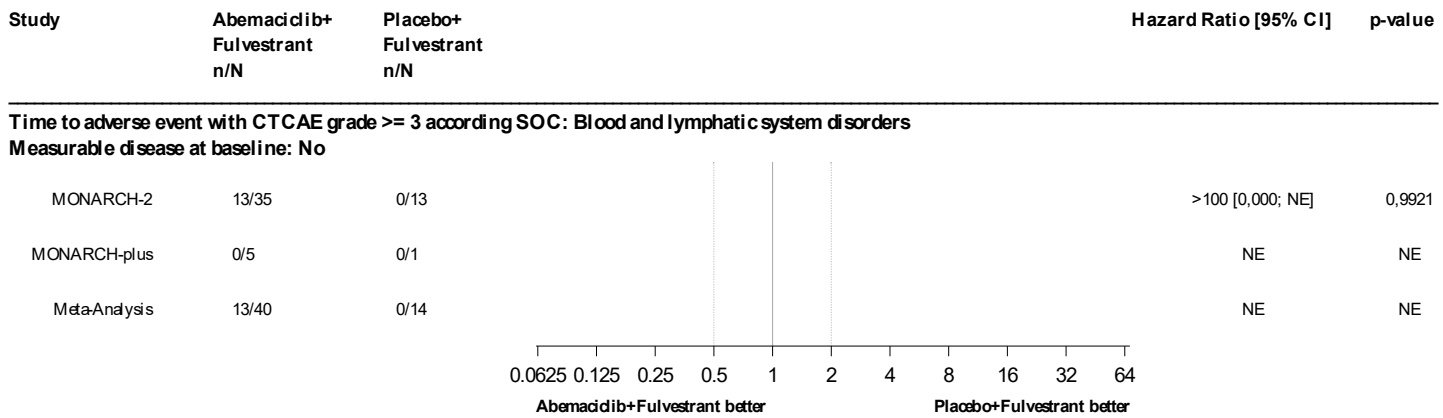
Figure 1326.2.6.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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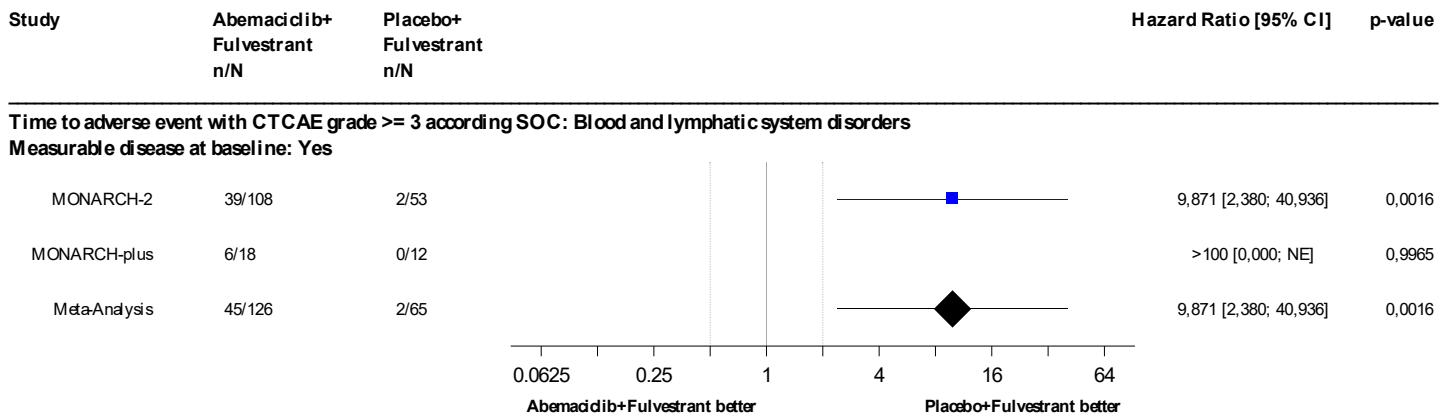
Figure 1326.2.6.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9969, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.

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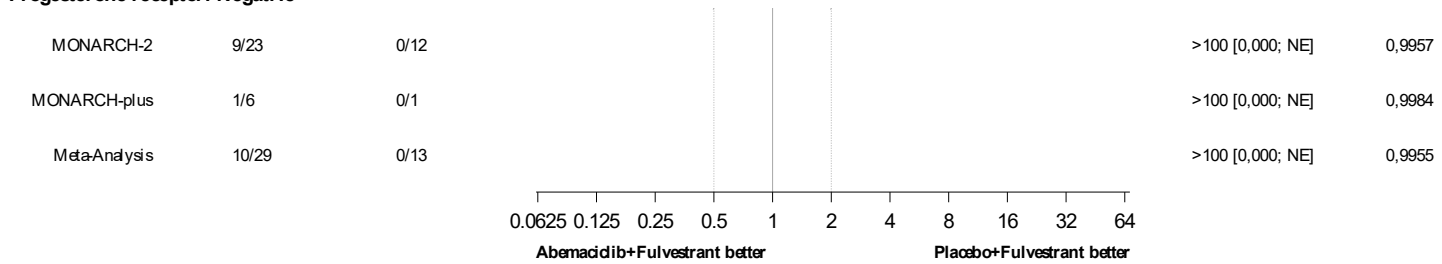
Figure 1326.2.7.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9999, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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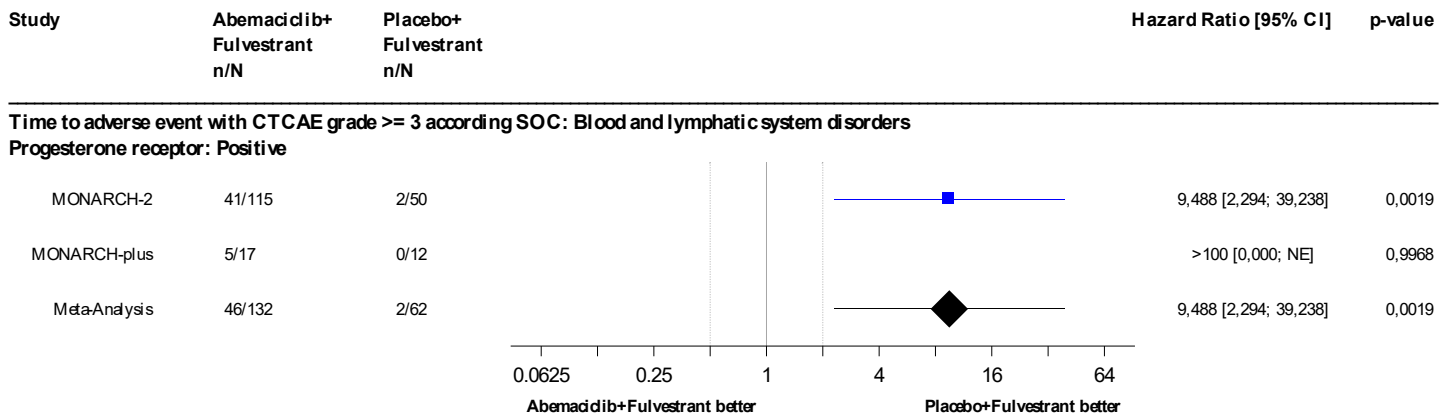
Figure 1326.2.7.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9972, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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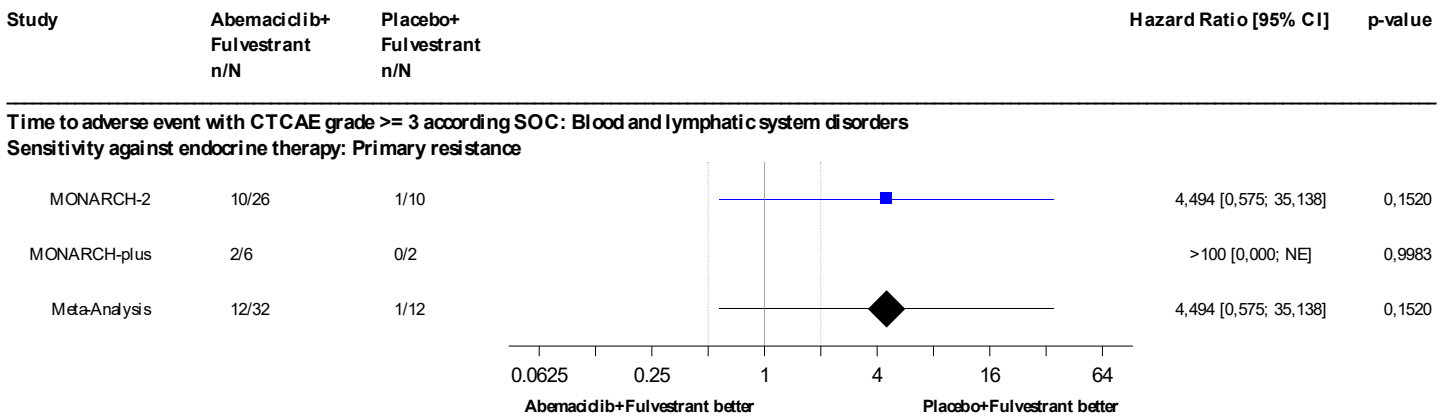
Figure 1326.2.8.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Blood and lymphatic system disorders
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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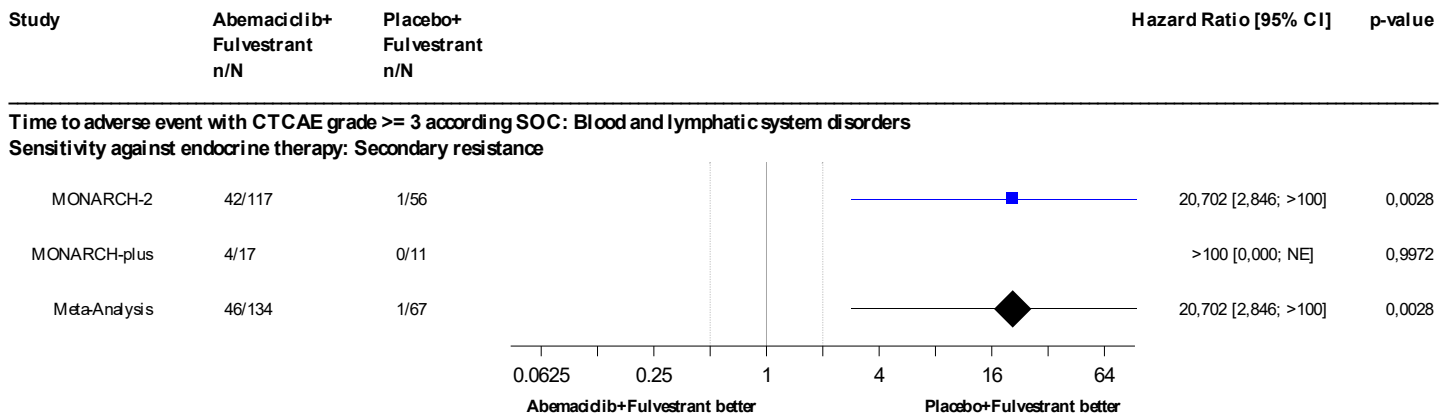
Figure 1326.2.8.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Blood and lymphatic system disorders
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9977, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_m_ttirgr3s001_popa2_snthr_2.rtf
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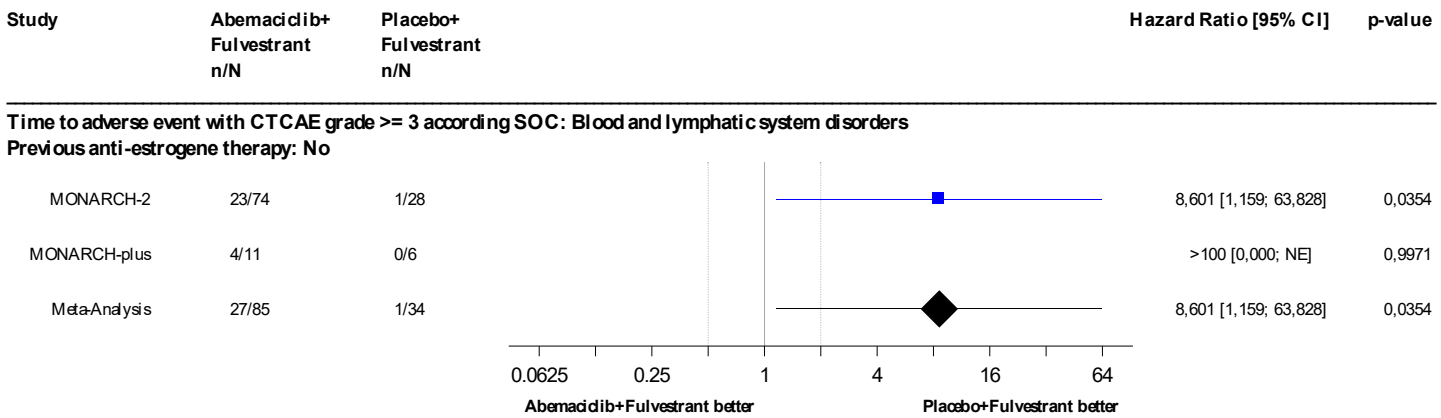
Figure 1326.2.9.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9975, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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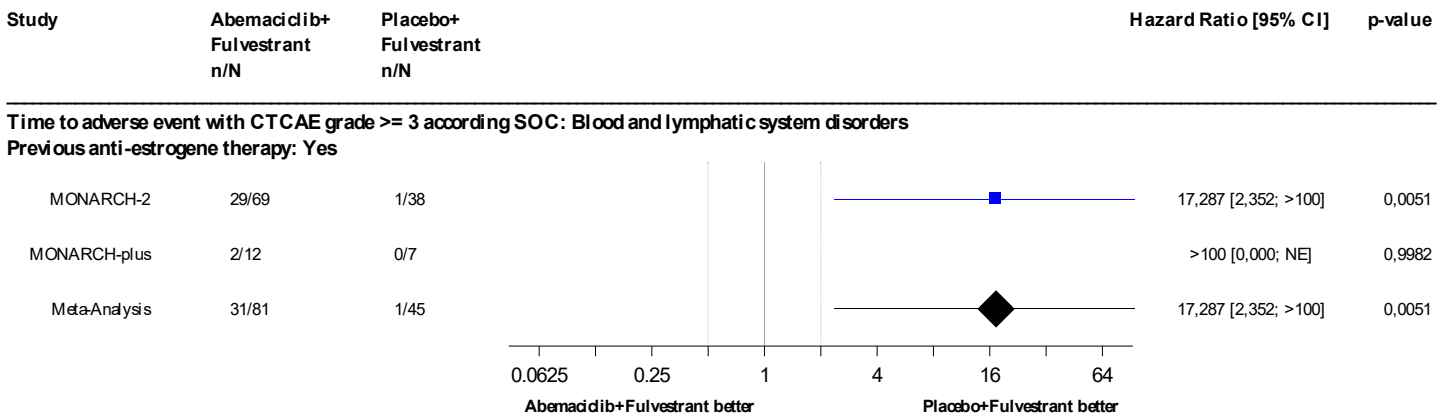
Figure 1326.2.9.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] -
Blood and lymphatic system disorders
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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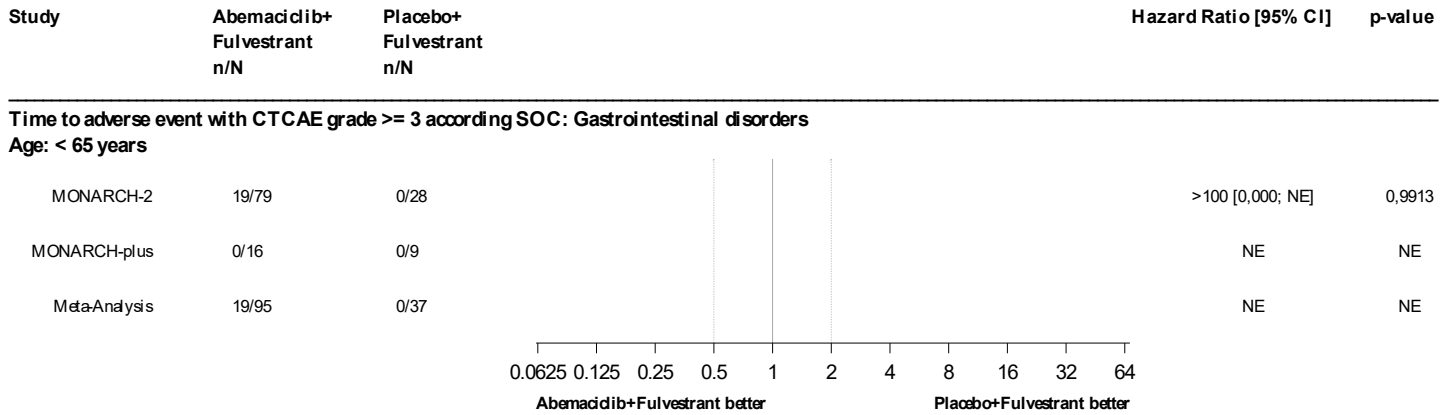
Figure 1327.2.1.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Age: < 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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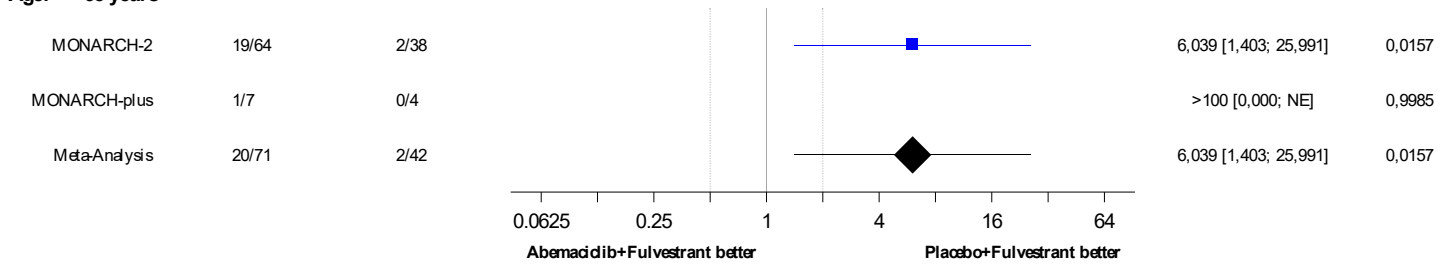
Figure 1327.2.1.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Age: >= 65 years
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9987, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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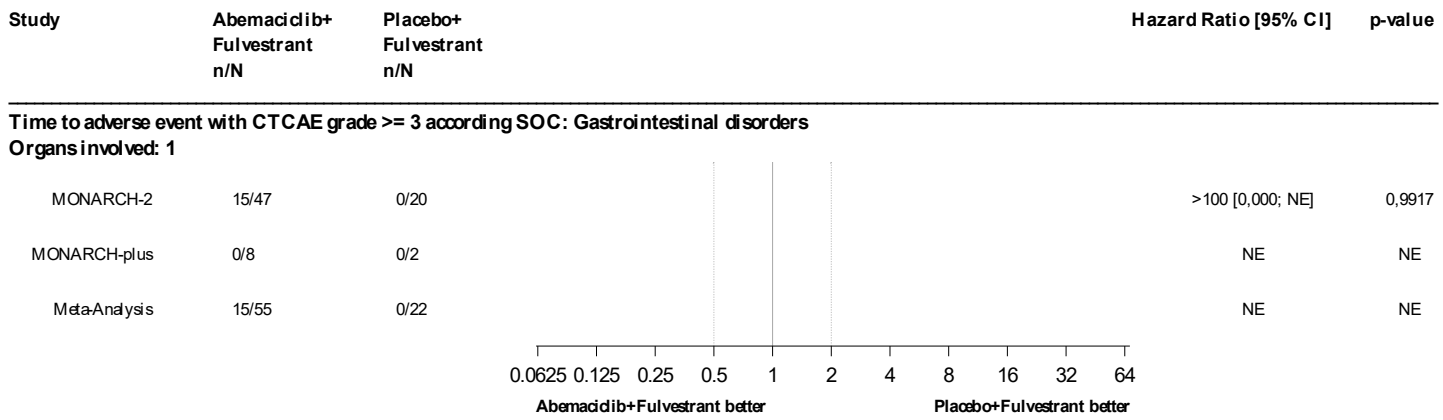
Figure 1327.2.2.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Organs involved: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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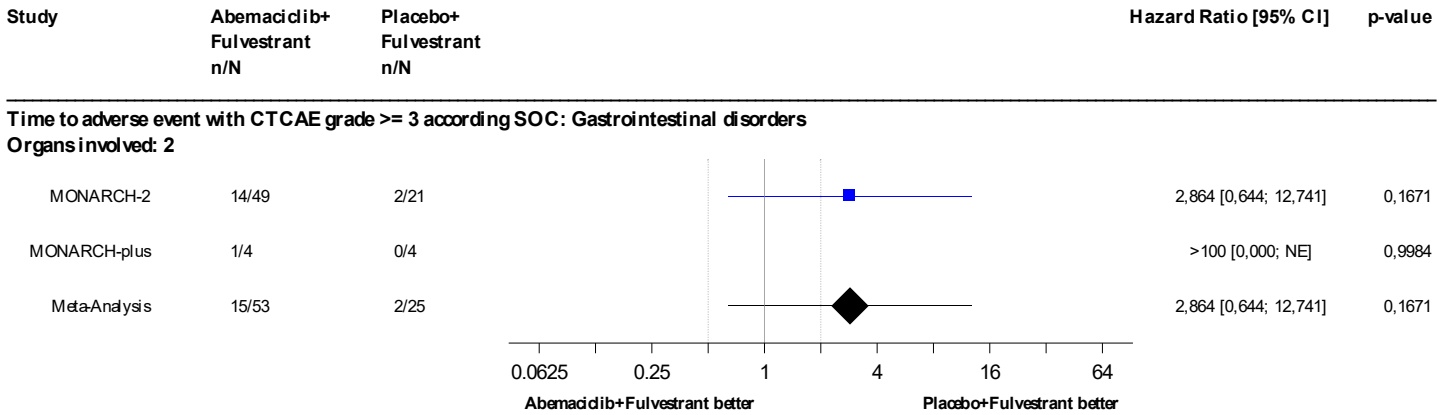
Figure 1327.2.2.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Organs involved: 2
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9985, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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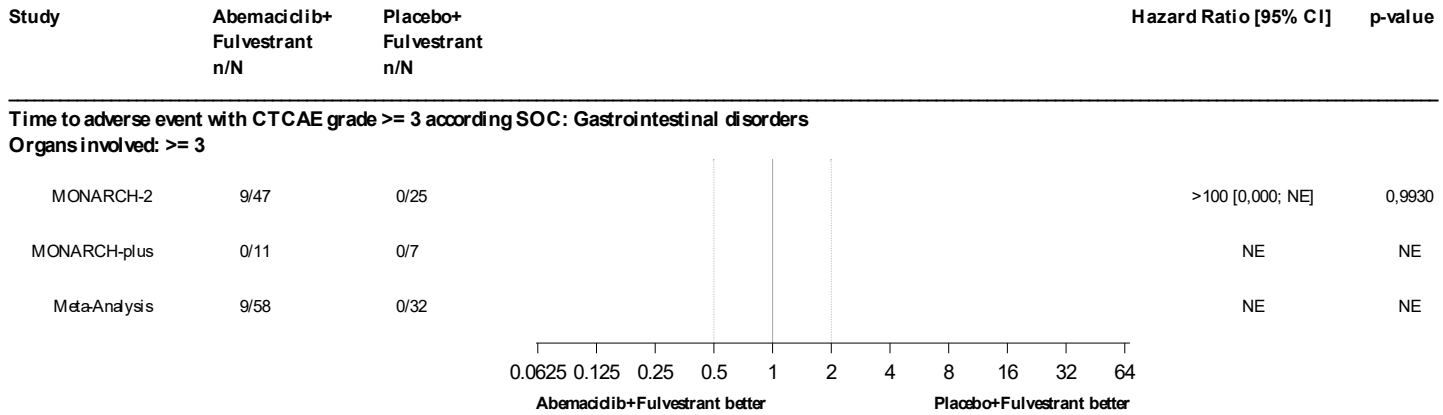
Figure 1327.2.2.3: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Organs involved: >= 3
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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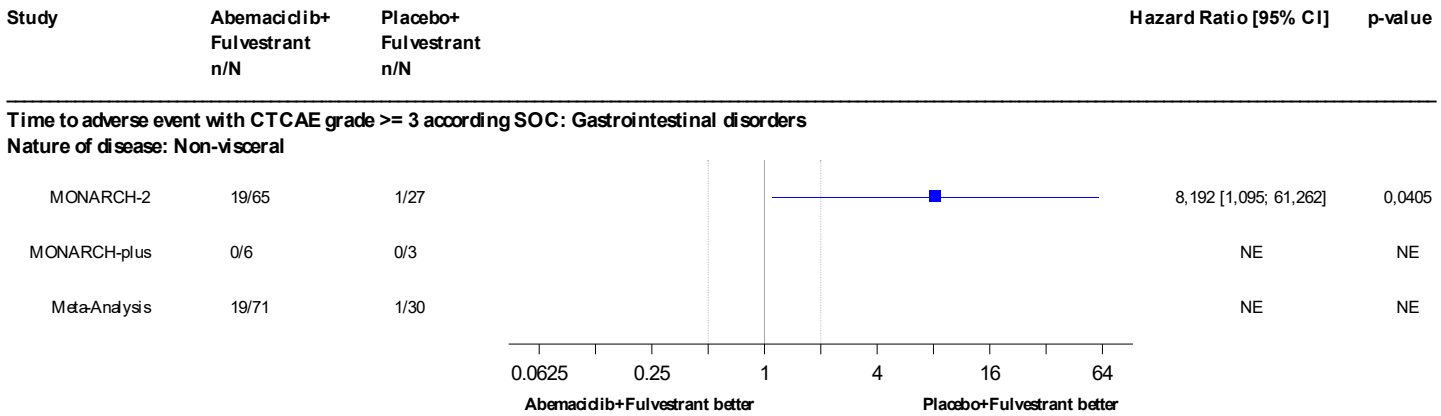
Figure 1327.2.3.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Nature of disease: Non-visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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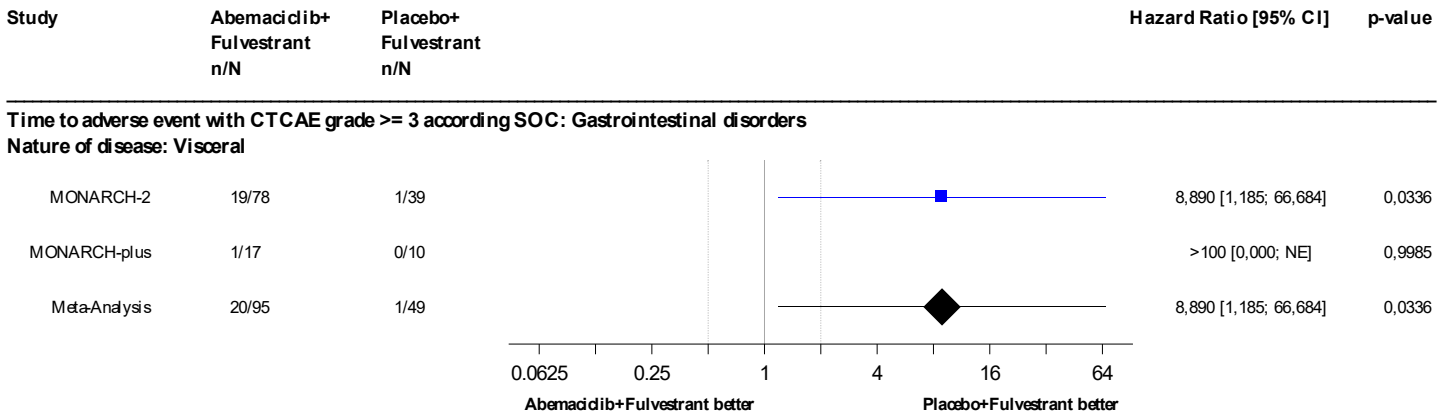
Figure 1327.2.3.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Nature of disease: Visceral
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9987, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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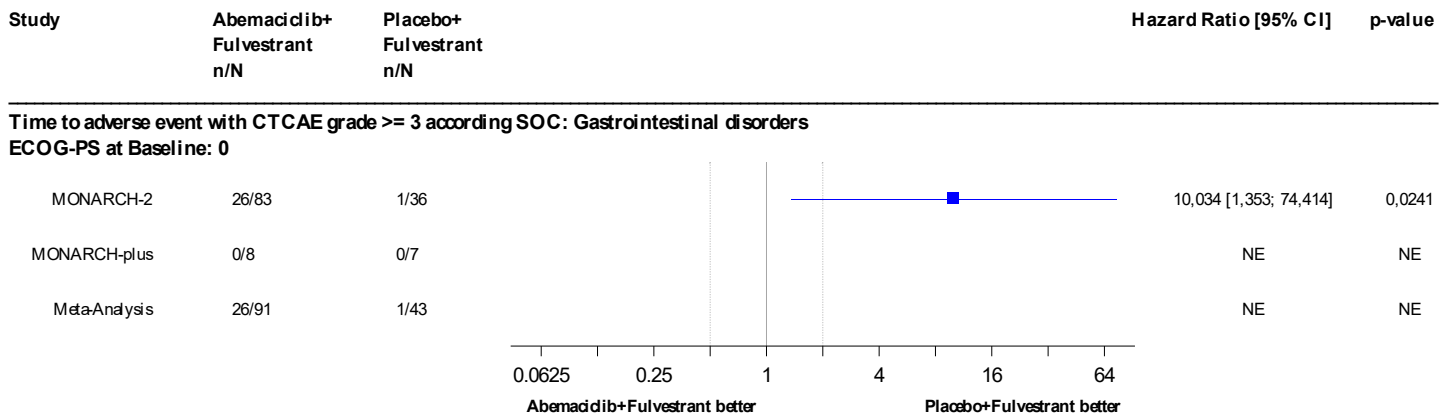
Figure 1327.2.4.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for ECOG-PS at Baseline: 0
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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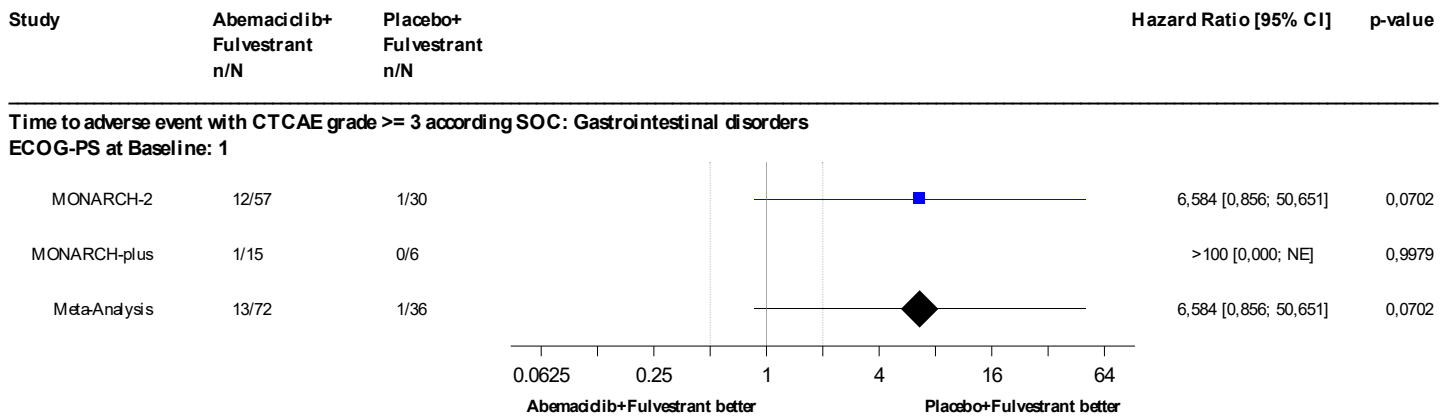
Figure 1327.2.4.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for ECOG-PS at Baseline: 1
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9981, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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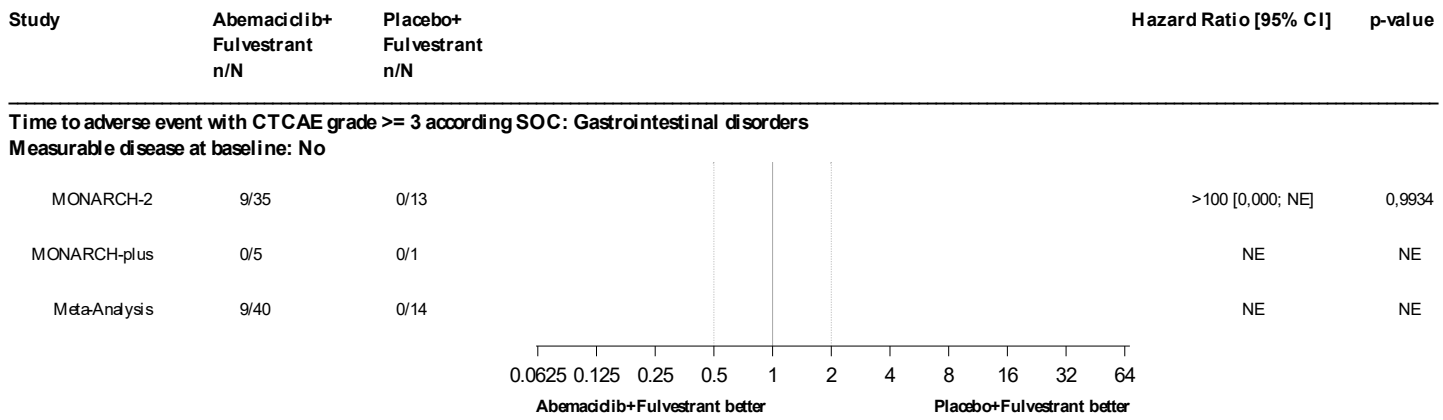
Figure 1327.2.6.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Measurable disease at baseline: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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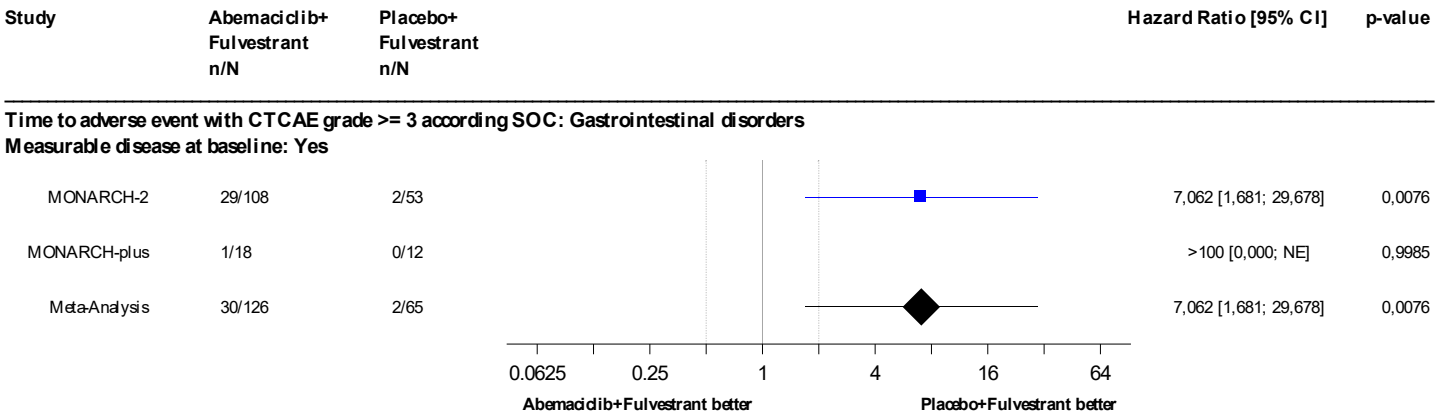
Figure 1327.2.6.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Measurable disease at baseline: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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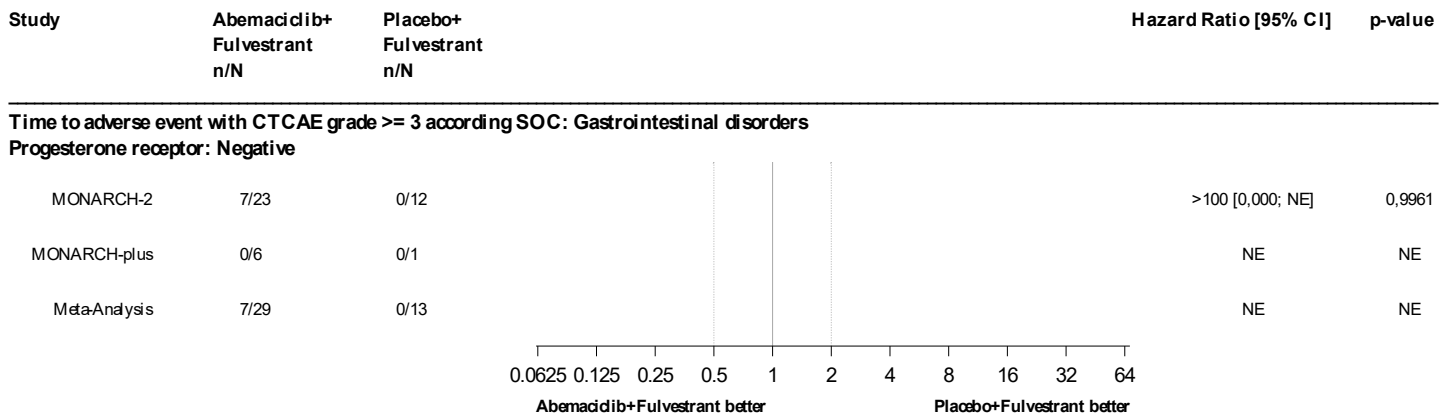
Figure 1327.2.7.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Progesterone receptor: Negative
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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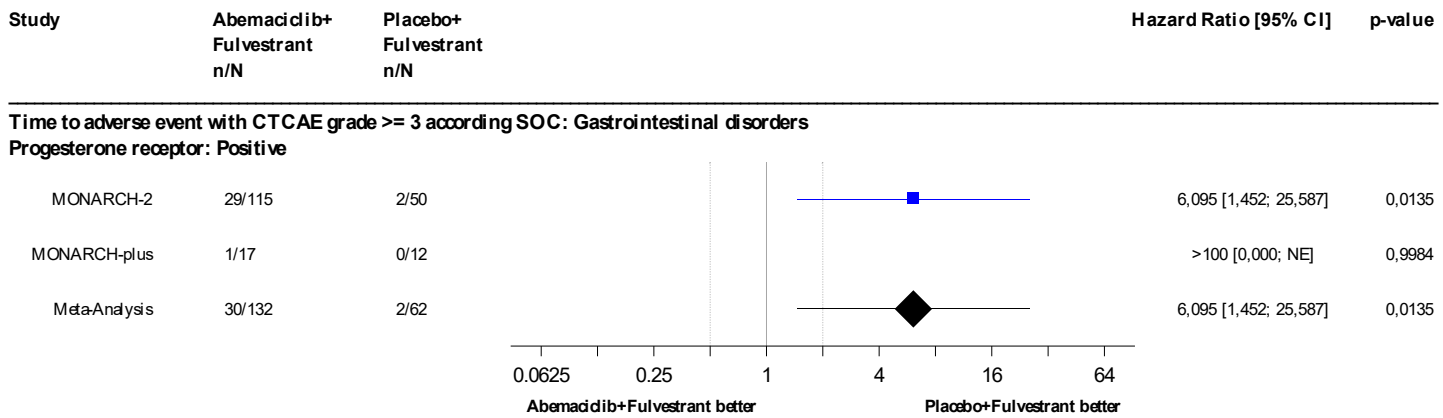
Figure 1327.2.7.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Progesterone receptor: Positive
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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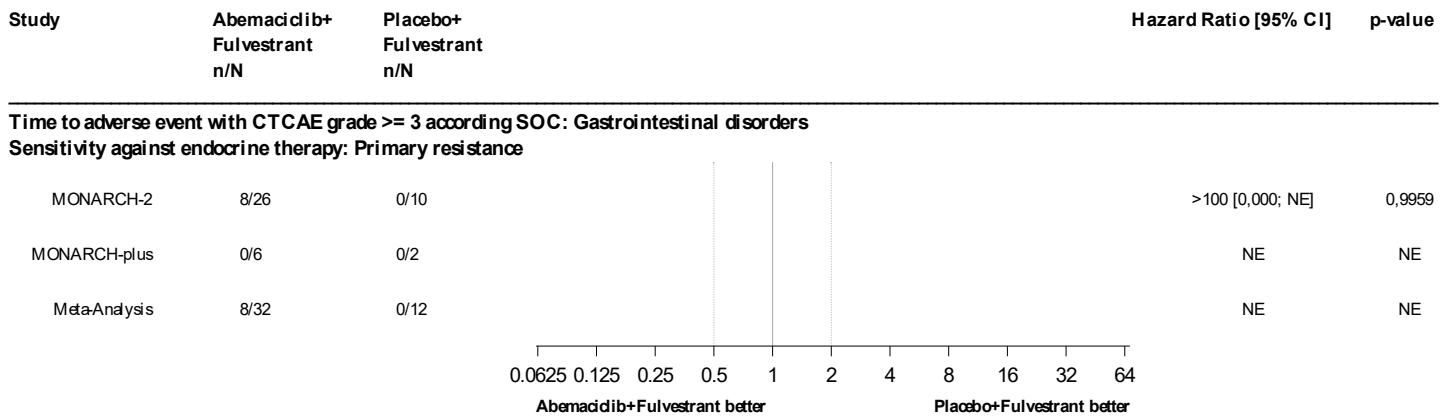
Figure 1327.2.8.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Sensitivity against endocrine therapy: Primary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
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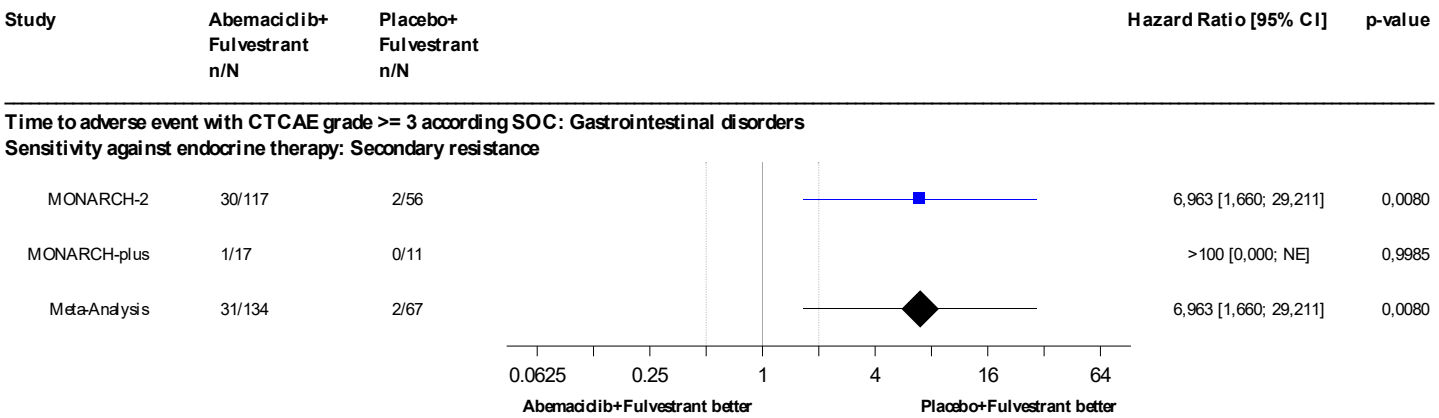
Figure 1327.2.8.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Sensitivity against endocrine therapy: Secondary resistance
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9986, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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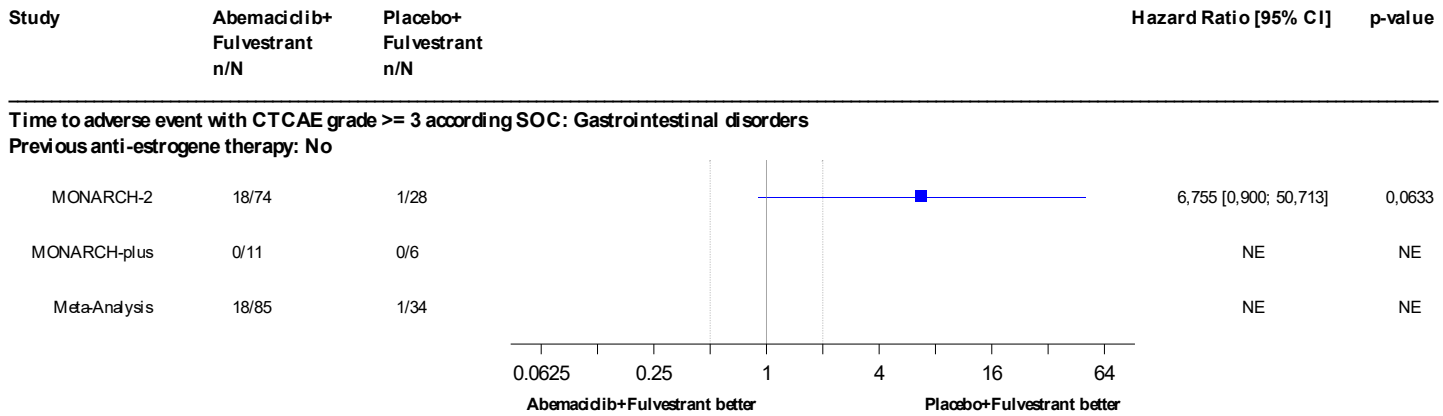
Figure 1327.2.9.1: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Previous anti-estrogene therapy: No
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=NE, p-value=NE, I2 index=NE
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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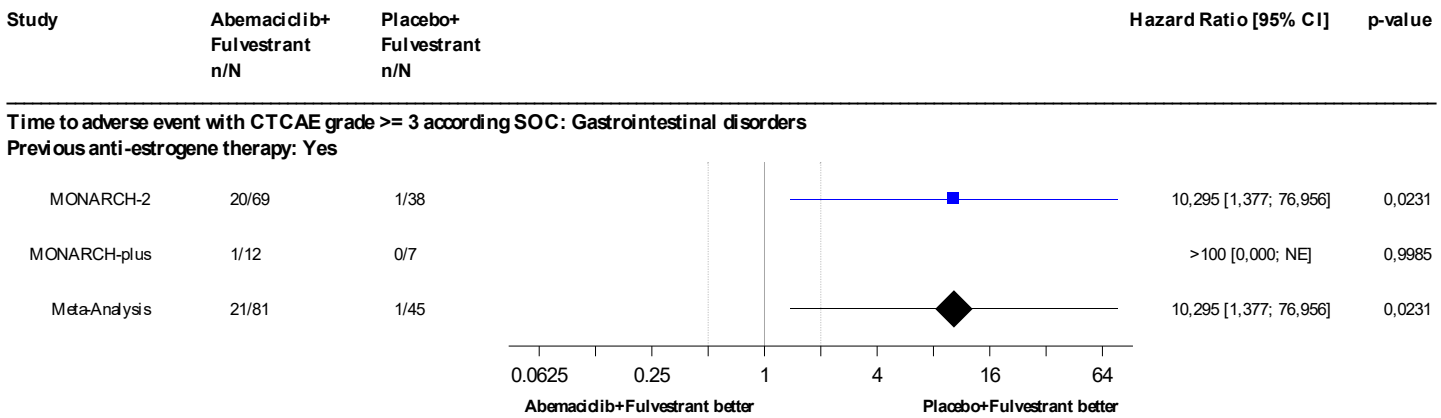
Figure 1327.2.9.2: Metaanalysis results for adverse events with CTCAE Grade ≥ 3 according SOC[1] - Gastrointestinal disorders
Subgroup analysis for Previous anti-estrogene therapy: Yes
Safety Population - Postmenopausal (2nd line) (MONARCH-2 and MONARCH-plus)



Heterogeneity: Cochran Q-test=0,0000, p-value=0,9987, I2 index=0%
Abbreviations: CI: Confidence Interval; CTCAE: Common Terminology Criteria for Adverse Events; n: number of patients with event; N: number of patients; NE: not evaluable; SOC: System Organ Class

1: Adverse events with CTCAE Grade ≥ 3 occurring in ≥5% of patients in one treatment arm, and events occurring in ≥10 patients and ≥1% of patients in one treatment arm, based on the pooled numbers of both combined trials. Only endpoints with p-value of Z-test <0.05 in main analysis are taken into account.
Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_aesocpt_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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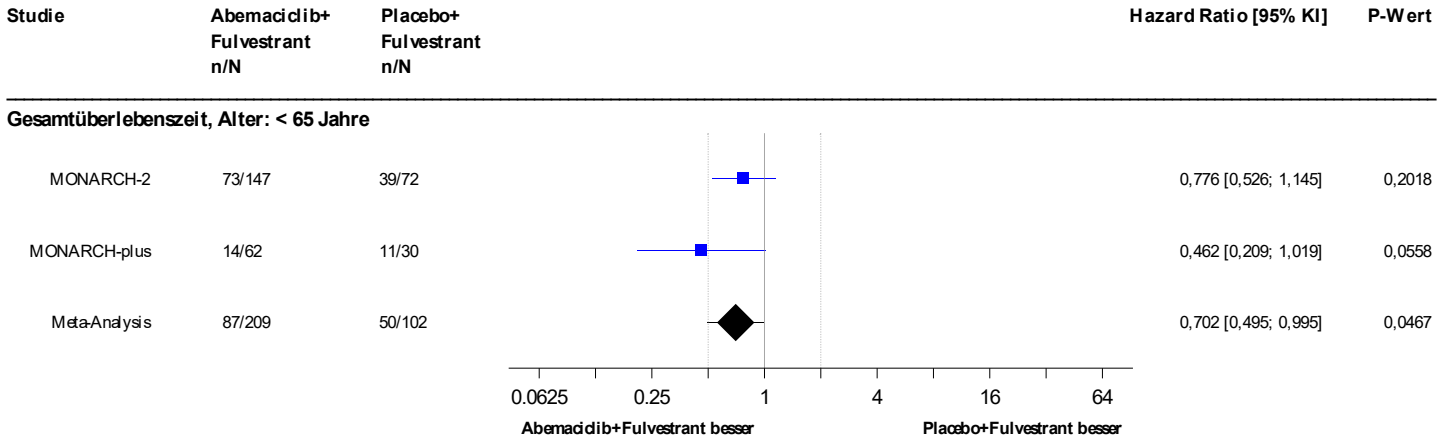
Abbildung 160 (Anhang): Ergebnisse der Subgruppenanalyse nicht interagierender Subgruppen (Metaanalyse der Studien MONARCH-2 und MONARCH-plus, A1)

Abbildung 1401.1.1.1: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,3322, P-Wert=0,2484, I2 Index=24,9%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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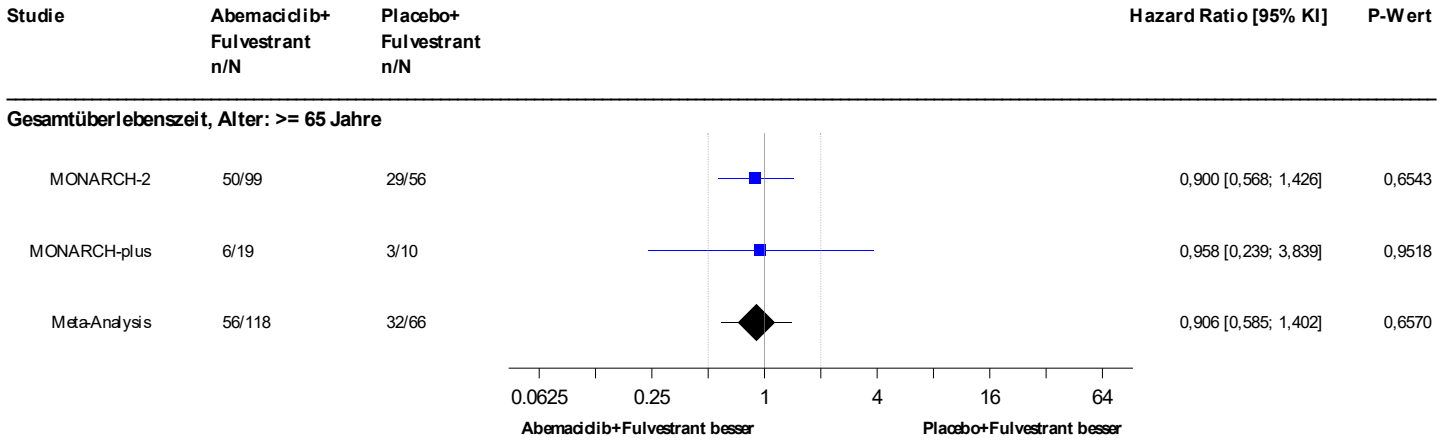
Abbildung 1401.1.1.2: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0070, P-Wert=0,9334, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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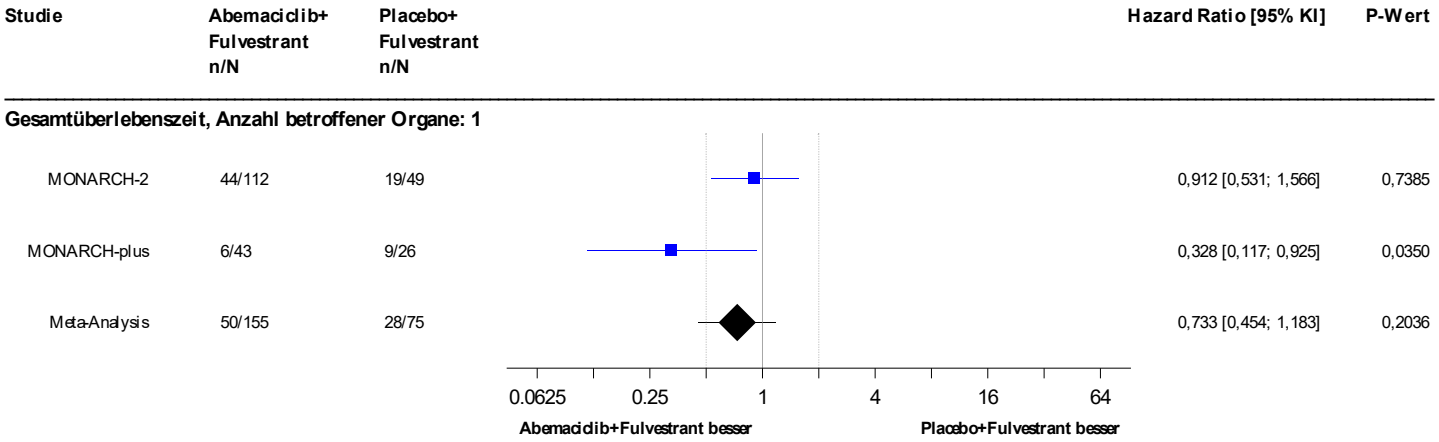
Abbildung 1401.1.2.1: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Anzahl betroffener Organe: 1 Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,9399, P-Wert=0,0864, I2 Index=66,0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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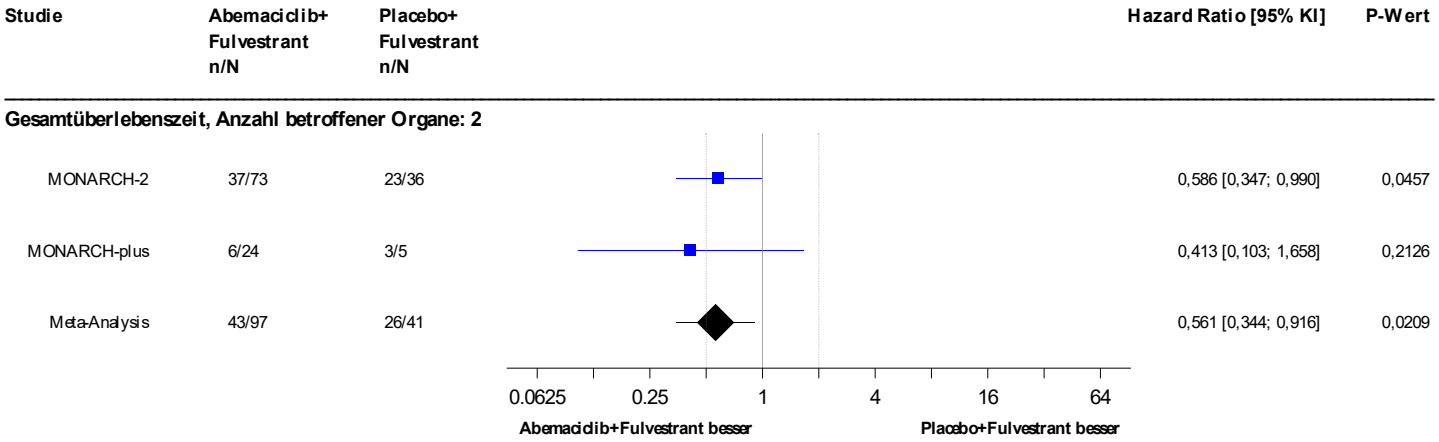
Abbildung 1401.1.2.2: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2134, P-Wert=0,6441, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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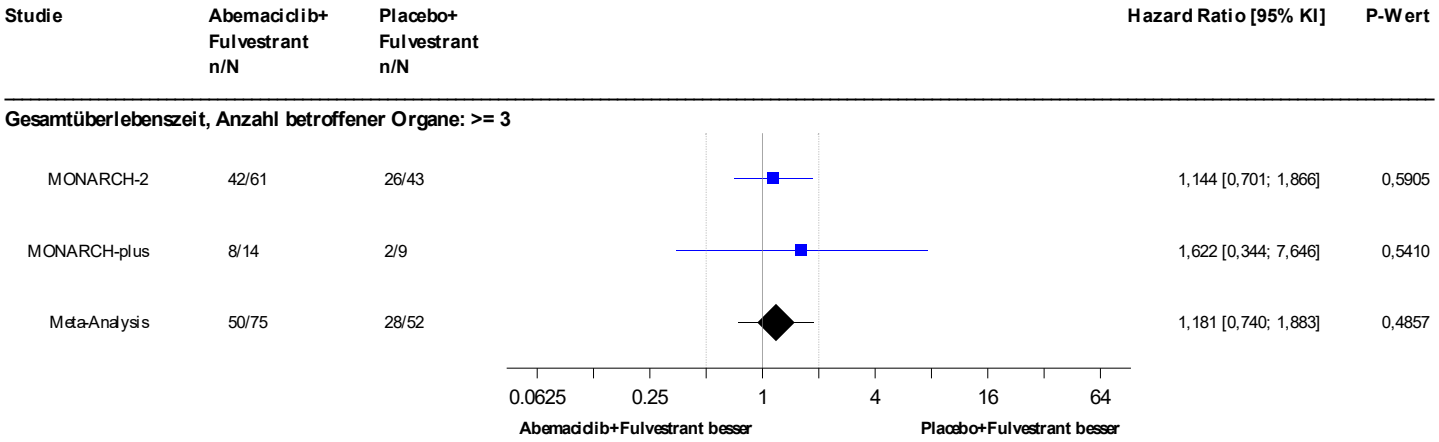
Abbildung 1401.1.2.3: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Anzahl betroffener Organe: >= 3 Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1772, P-Wert=0,6737, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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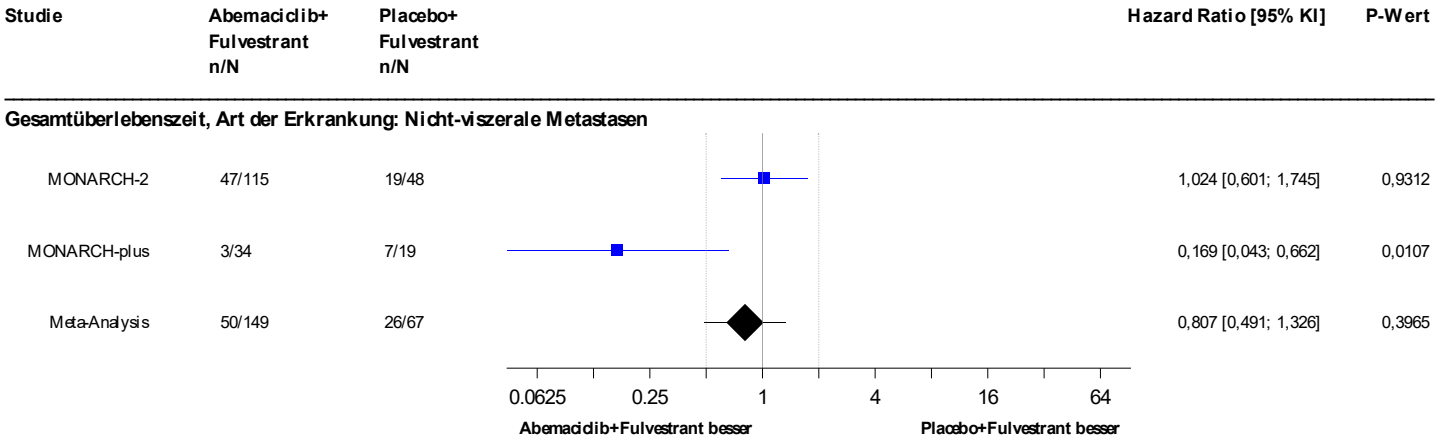
Abbildung 1401.1.3.1: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=5,7983, P-Wert=0,0160, I2 Index=82,8%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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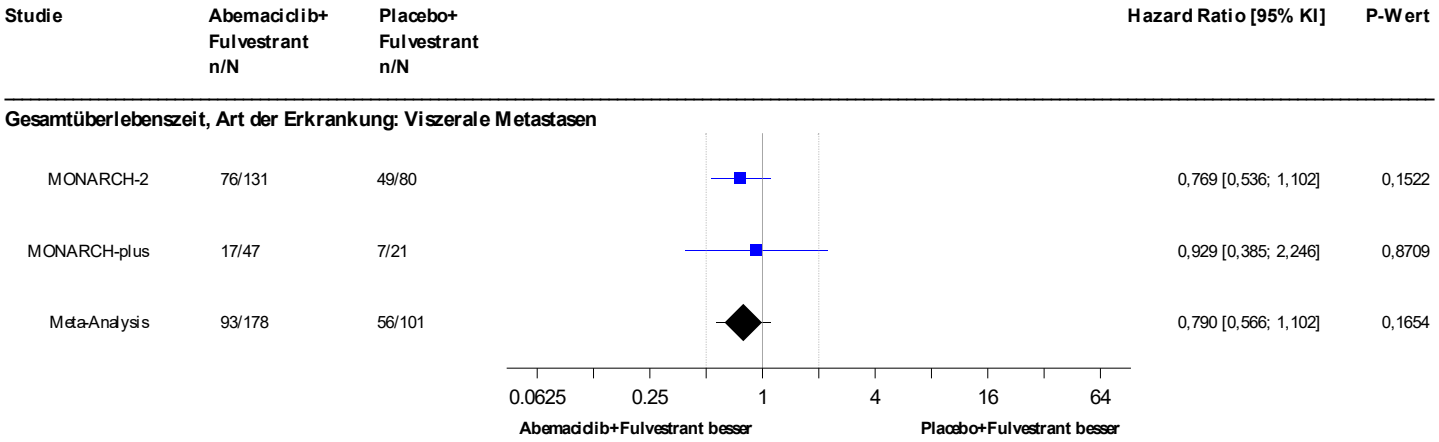
Abbildung 1401.1.3.2: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1528, P-Wert=0,6959, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_os_popa1_natdis2_2.rtf
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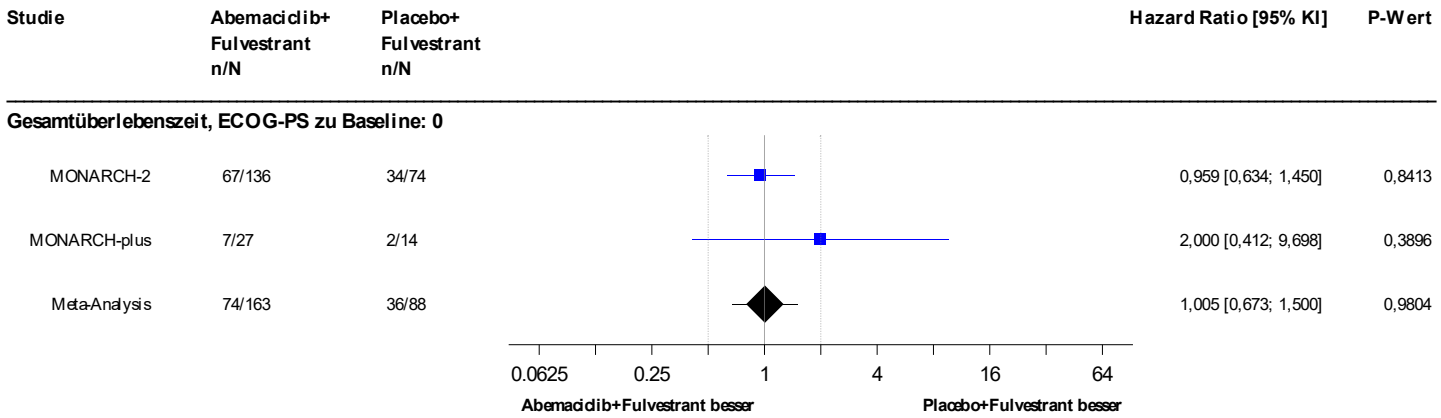
Abbildung 1401.1.4.1: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7797, P-Wert=0,3772, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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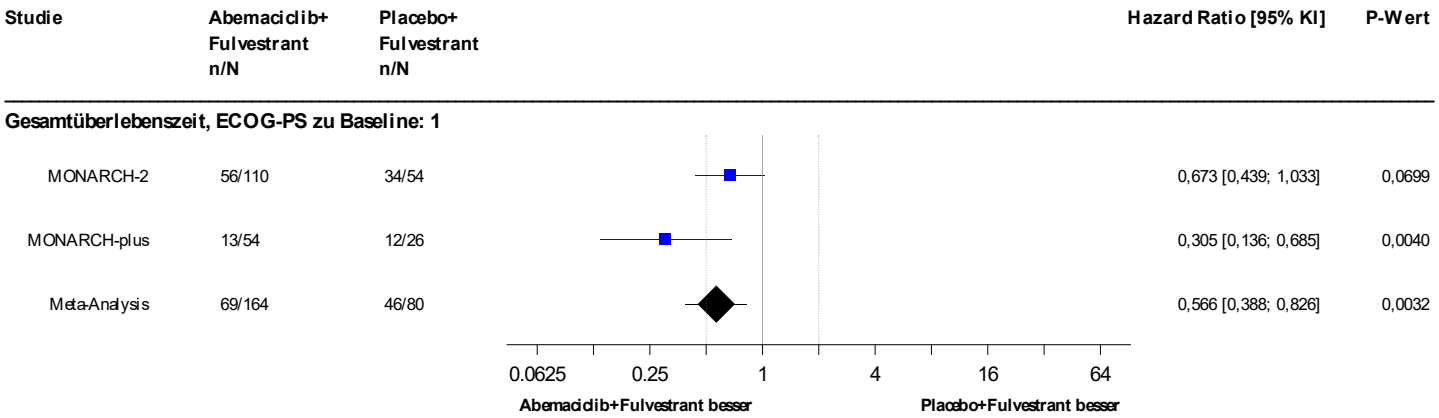
Abbildung 1401.1.4.2: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,8782, P-Wert=0,0898, I2 Index=65,3%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_os_popa1_ecogbl_2.rtf
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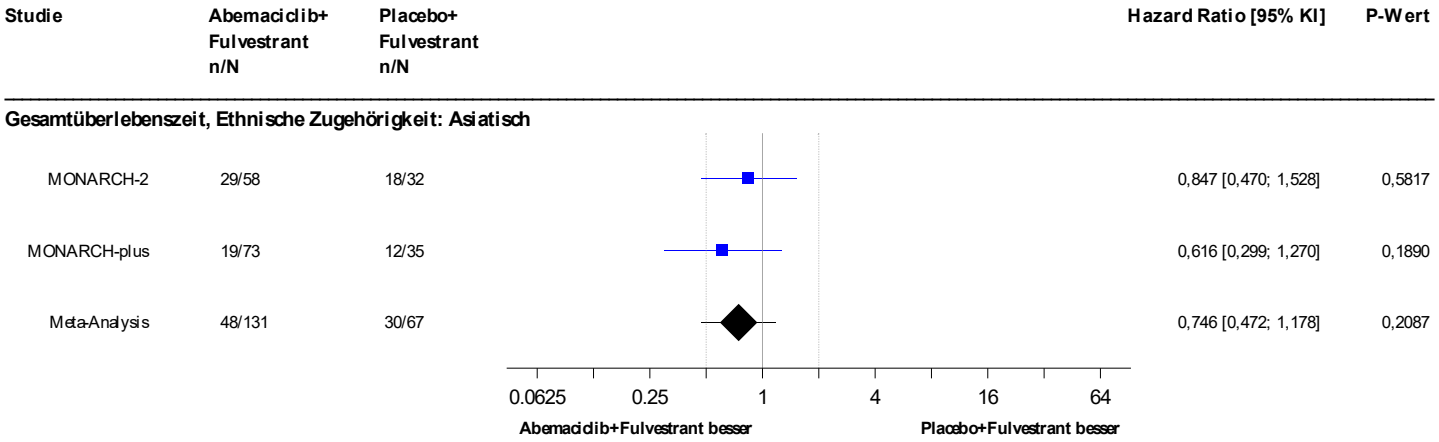
17SEP2021 / 07:48

Abbildung 1401.1.5.1: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4483, P-Wert=0,5031, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_os_popa1_racegr1_1.rtf
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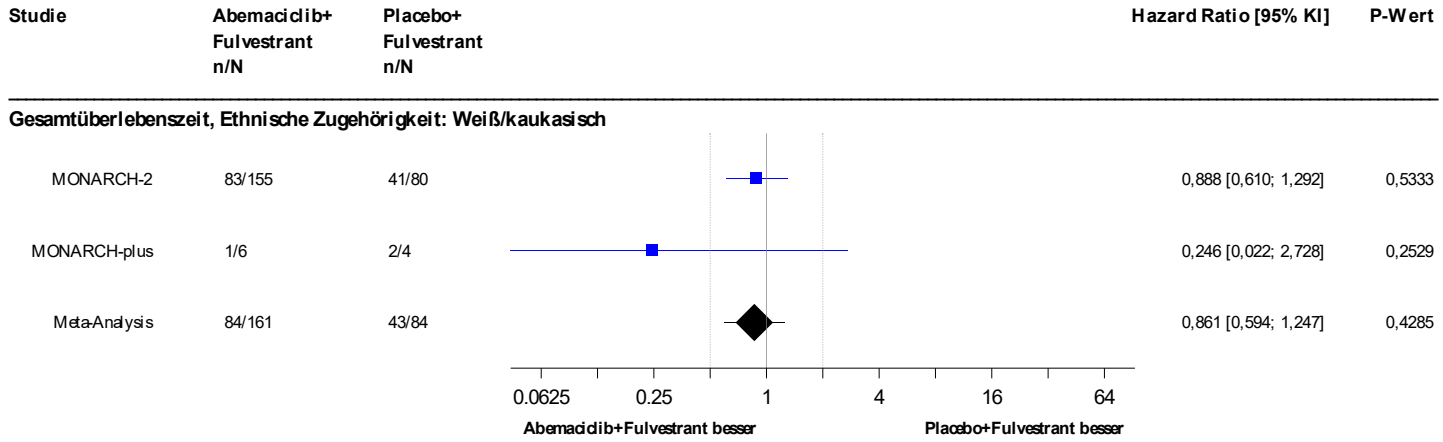
17SEP2021 / 07:48

Abbildung 1401.1.5.2: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,0684, P-Wert=0,3013, I2 Index=6,4%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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Abbildung 1401.1.5.3: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Ethnische Zugehörigkeit: Andere Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)

Studie	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% KI]	P-Wert
Gesamtüberlebenszeit, Ethnische Zugehörigkeit: Andere				
MONARCH-2	4/18	4/9	0,274 [0,066; 1,130]	0,0733
MONARCH-plus	0/2	0/1	NE	NE
Meta-Analysis	4/20	4/10	NE	NE

Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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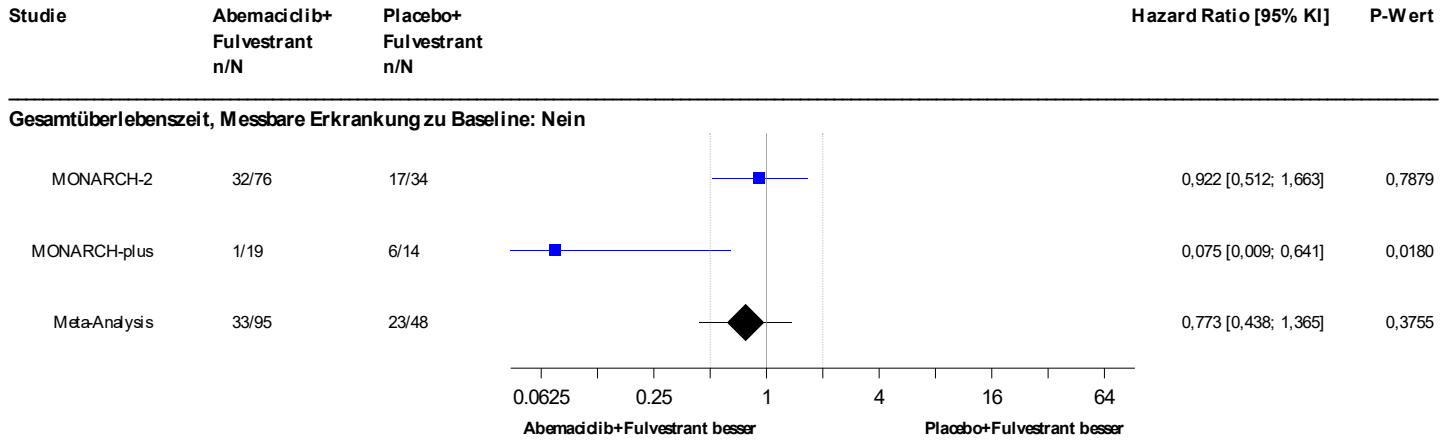
Abbildung 1401.1.6.1: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=4,8859, P-Wert=0,0271, I2 Index=79,5%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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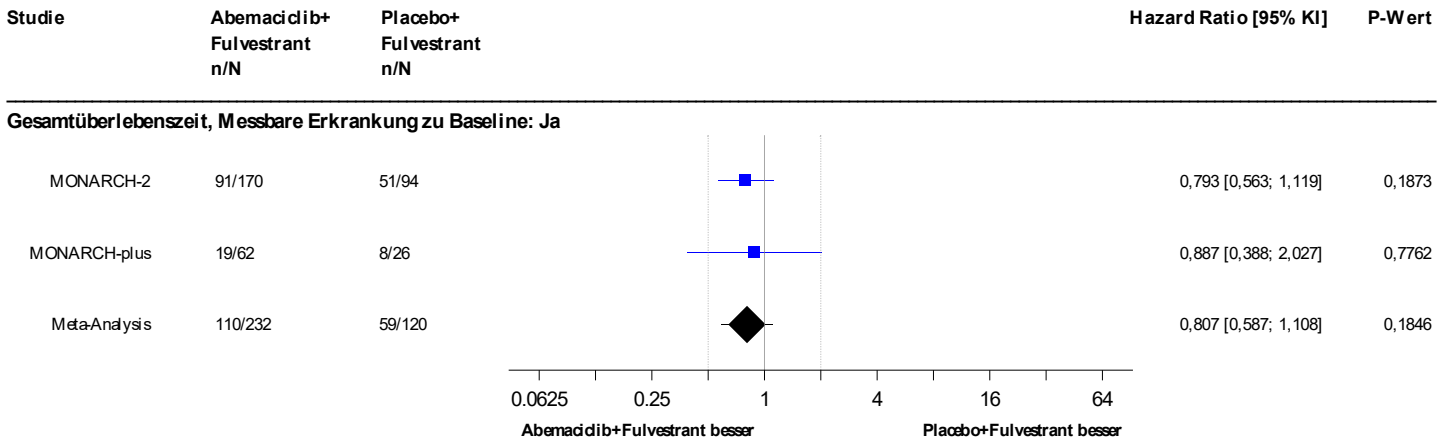
Abbildung 1401.1.6.2: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0595, P-Wert=0,8073, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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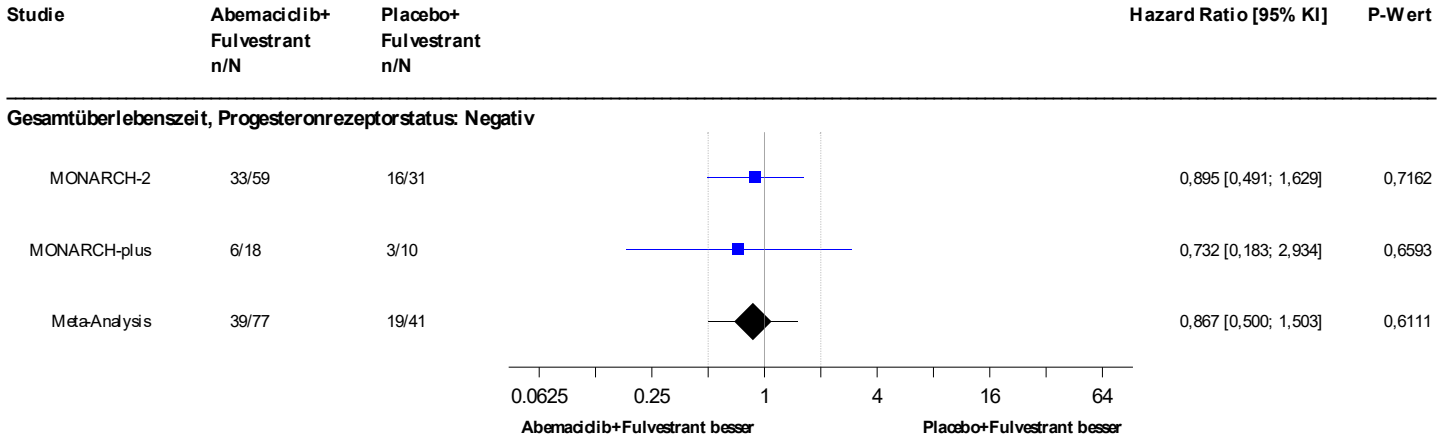
Abbildung 1401.1.7.1: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Progesteronrezeptorstatus: Negativ Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0680, P-Wert=0,7943, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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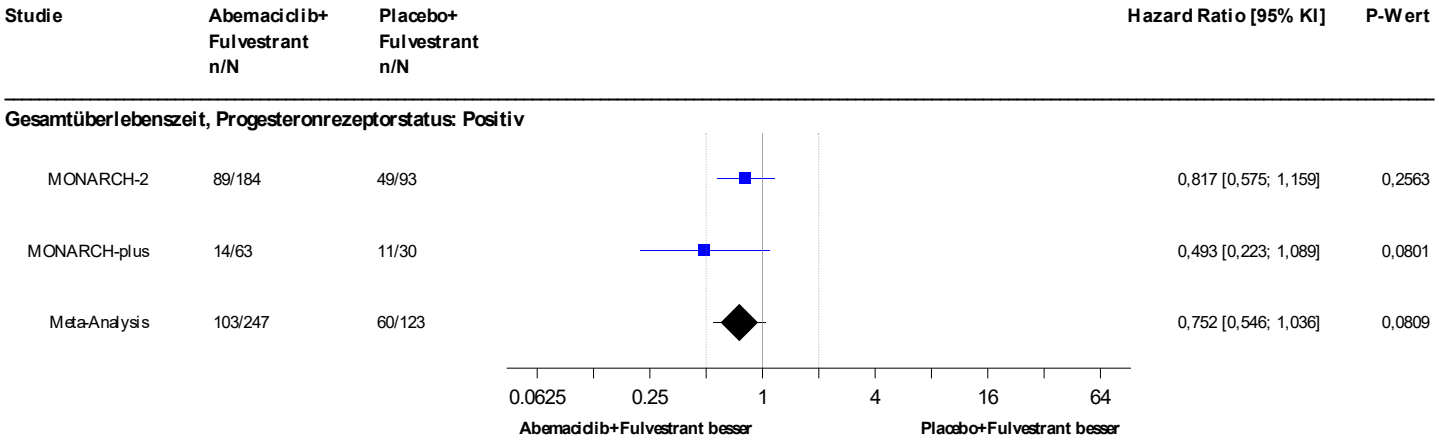
Abbildung 1401.1.7.2: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Progesteronrezeptorstatus: Positiv Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,3057, P-Wert=0,2532, I2 Index=23,4%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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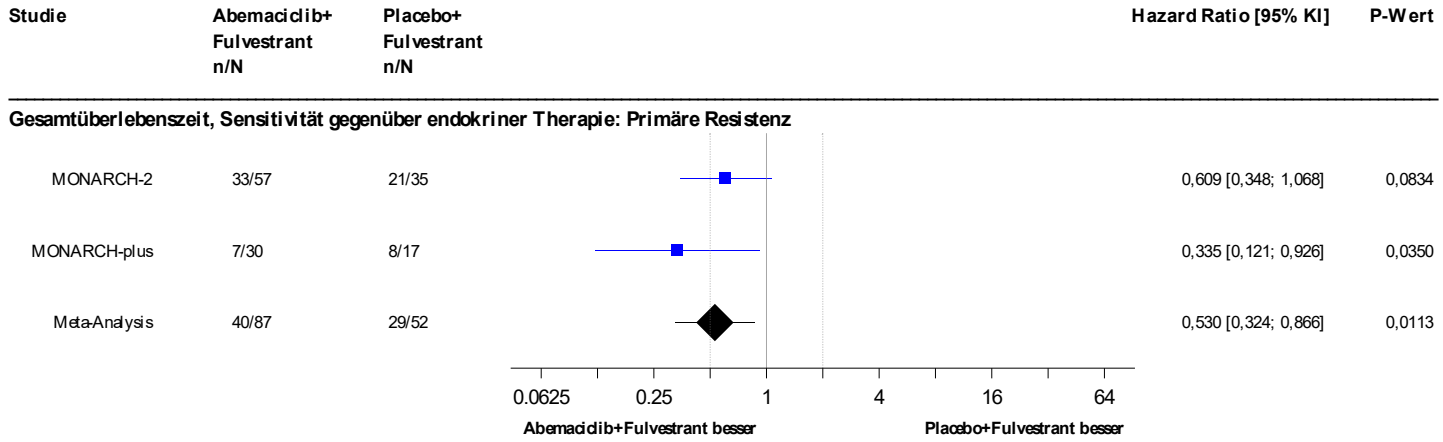
Abbildung 1401.1.8.1: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,0202, P-Wert=0,3125, I2 Index=2,0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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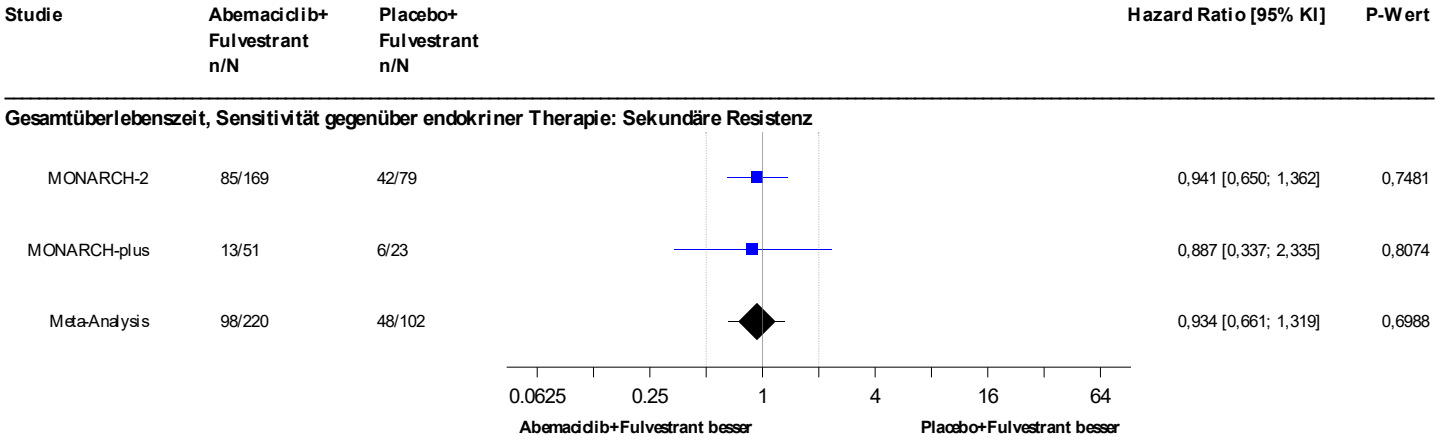
Abbildung 1401.1.8.2: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0128, P-Wert=0,9099, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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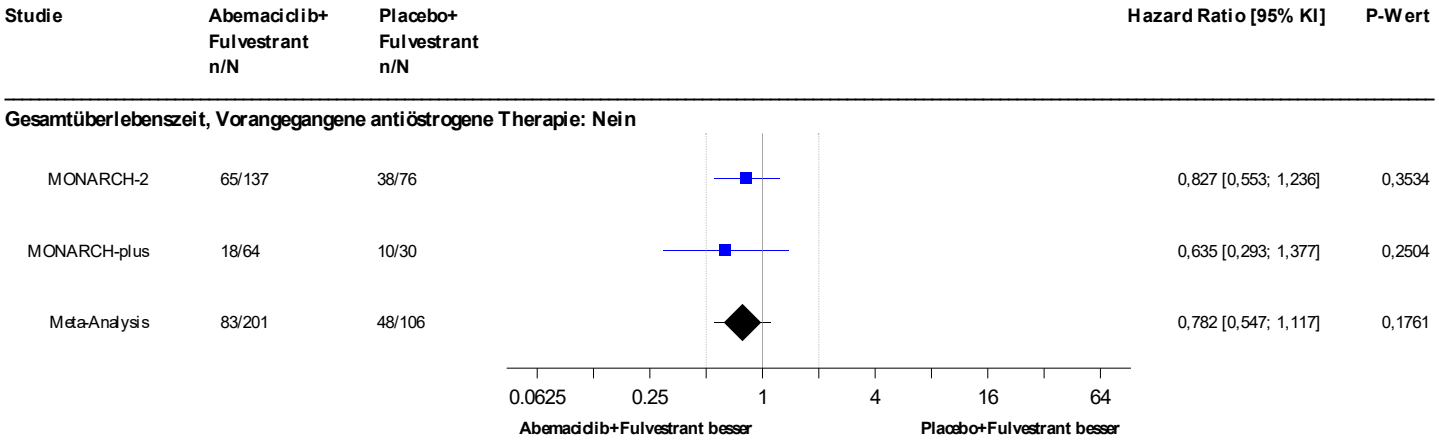
Abbildung 1401.1.9.1: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3514, P-Wert=0,5533, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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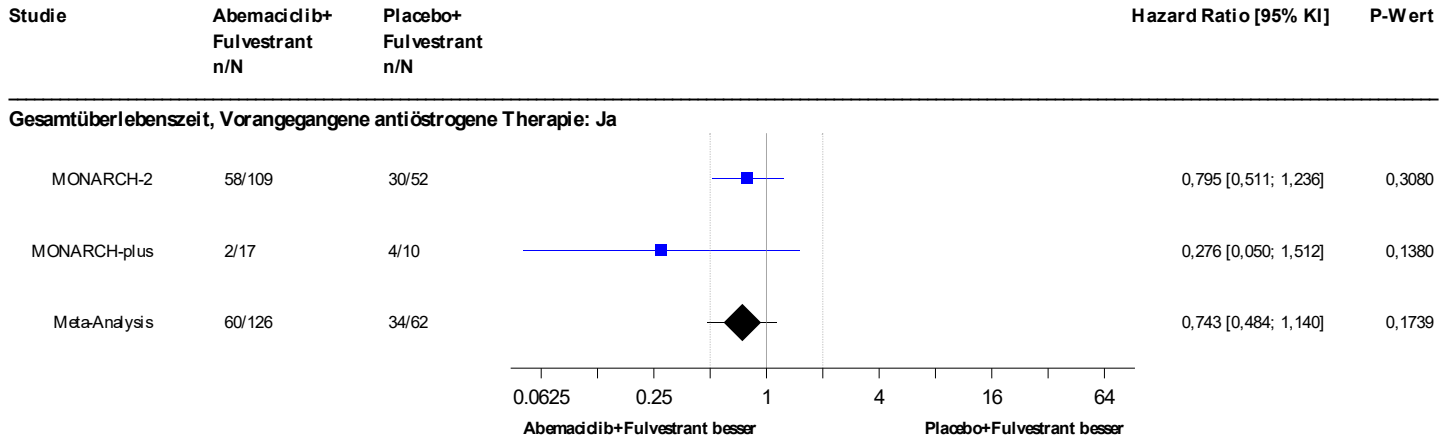
Abbildung 1401.1.9.2: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,3905, P-Wert=0,2383, I2 Index=28,1%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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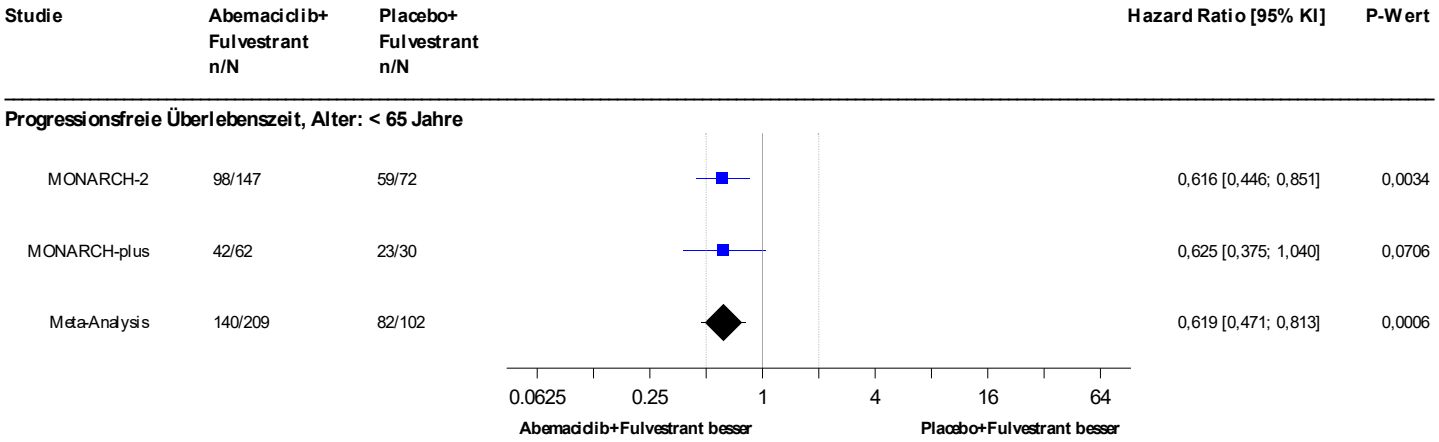
Abbildung 1402.1.1.1: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Alter: < 65 Jahre Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0022, P-Wert=0,9624, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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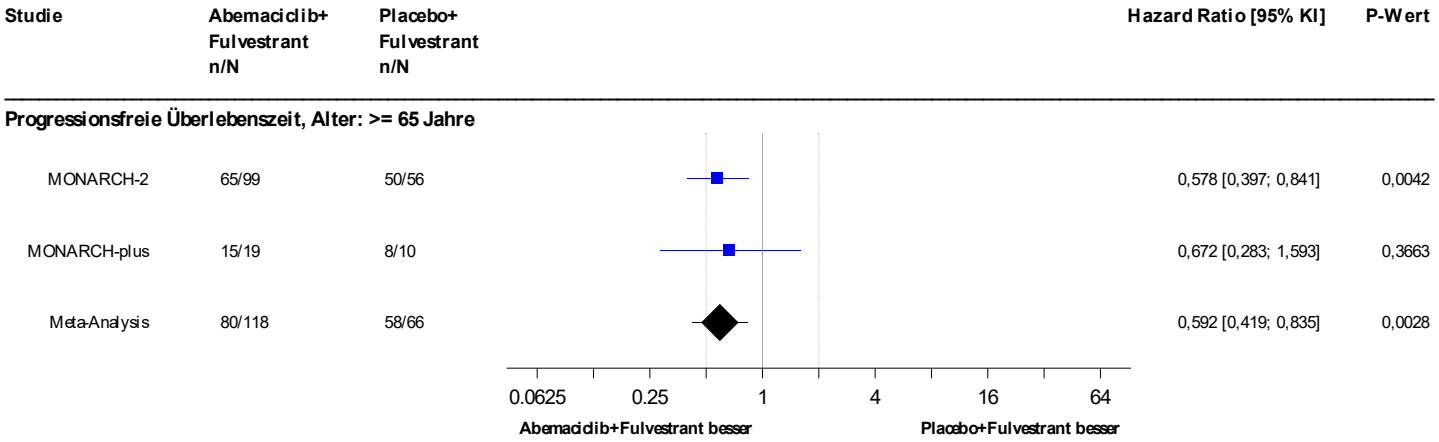
Abbildung 1402.1.1.2: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Alter: >= 65 Jahre Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0987, P-Wert=0,7534, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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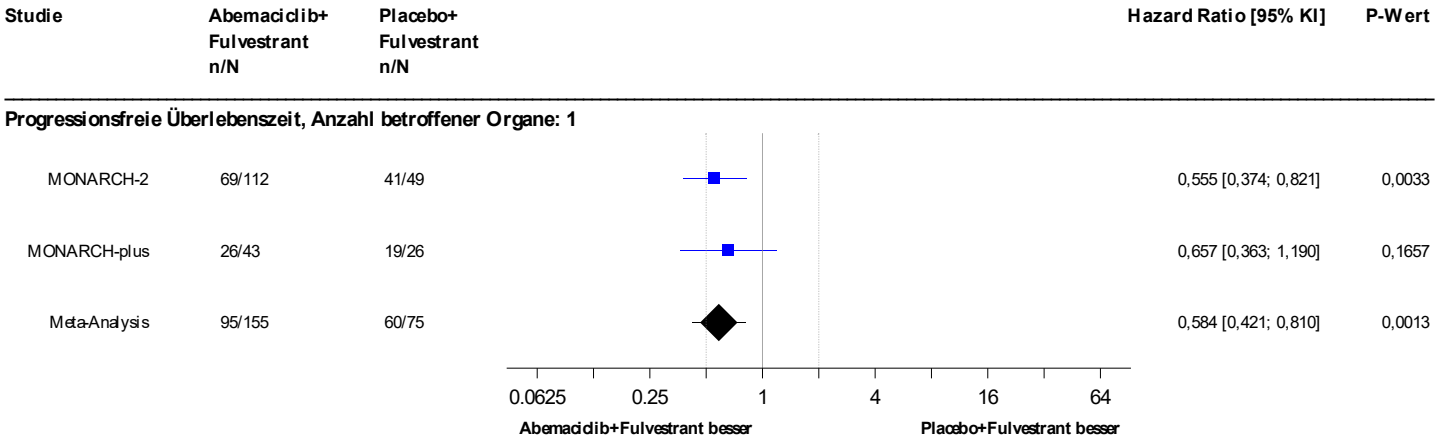
Abbildung 1402.1.2.1: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Anzahl betroffener Organe: 1 Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2201, P-Wert=0,6389, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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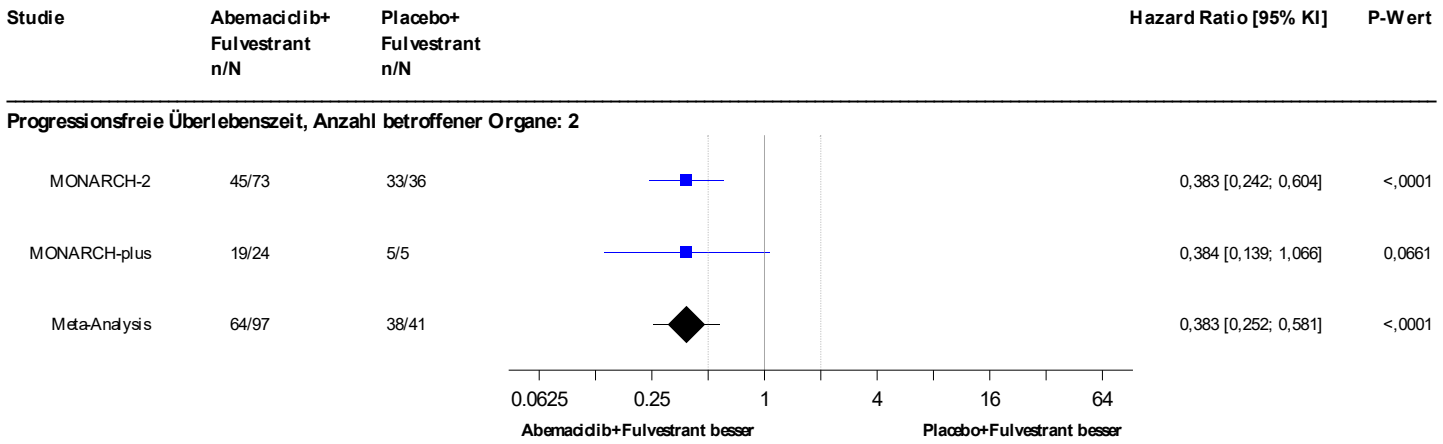
Abbildung 1402.1.2.2: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9936, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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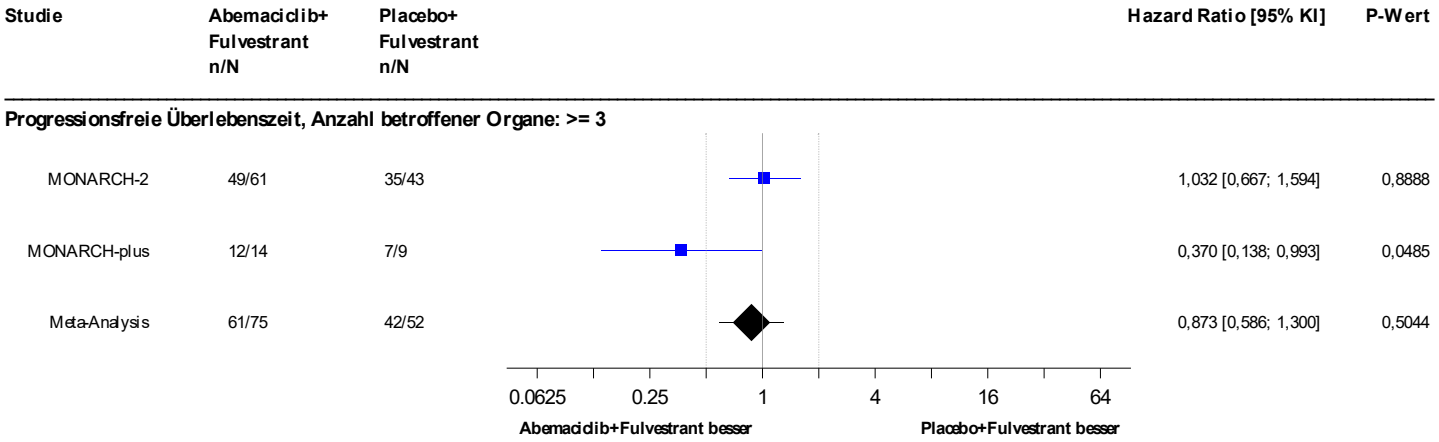
Abbildung 1402.1.2.3: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Anzahl betroffener Organe: >= 3 Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=3,4680, P-Wert=0,0626, I2 Index=71,2%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_pfs_popa1_norggr_3.rtf
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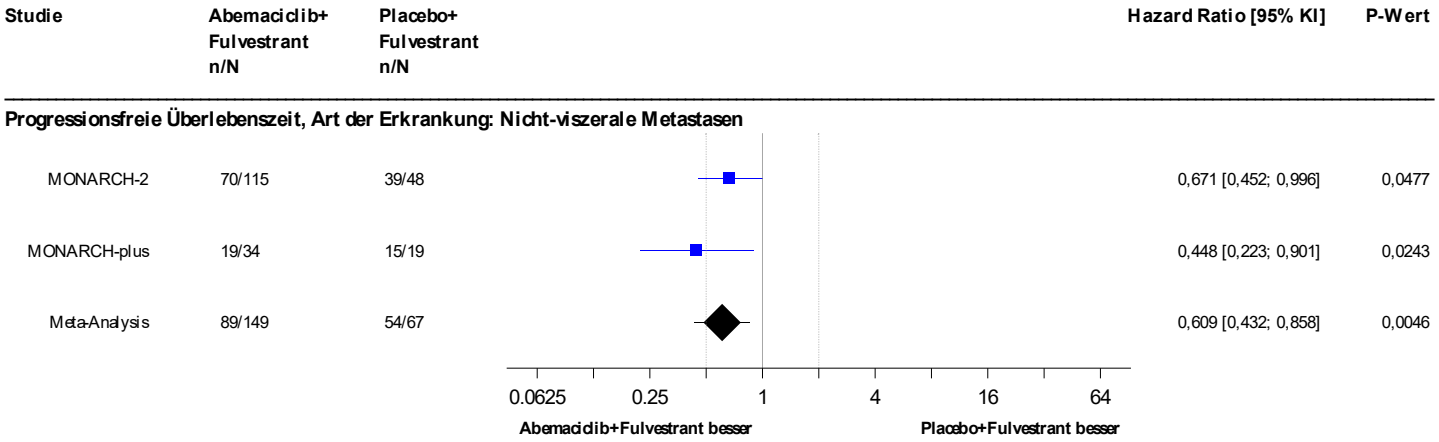
Abbildung 1402.1.3.1: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,9766, P-Wert=0,3230, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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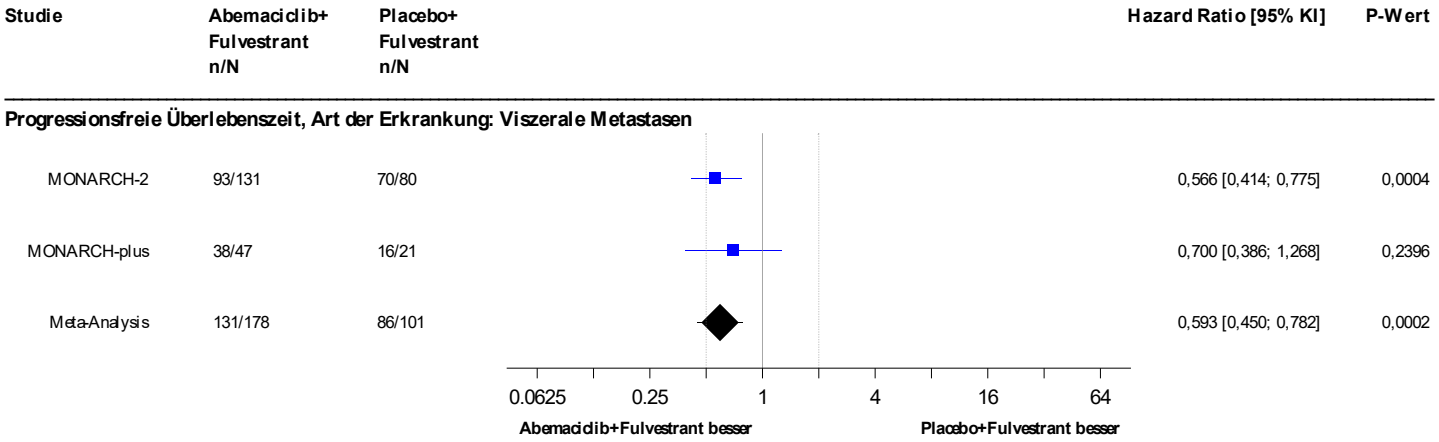
Abbildung 1402.1.3.2: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3821, P-Wert=0,5365, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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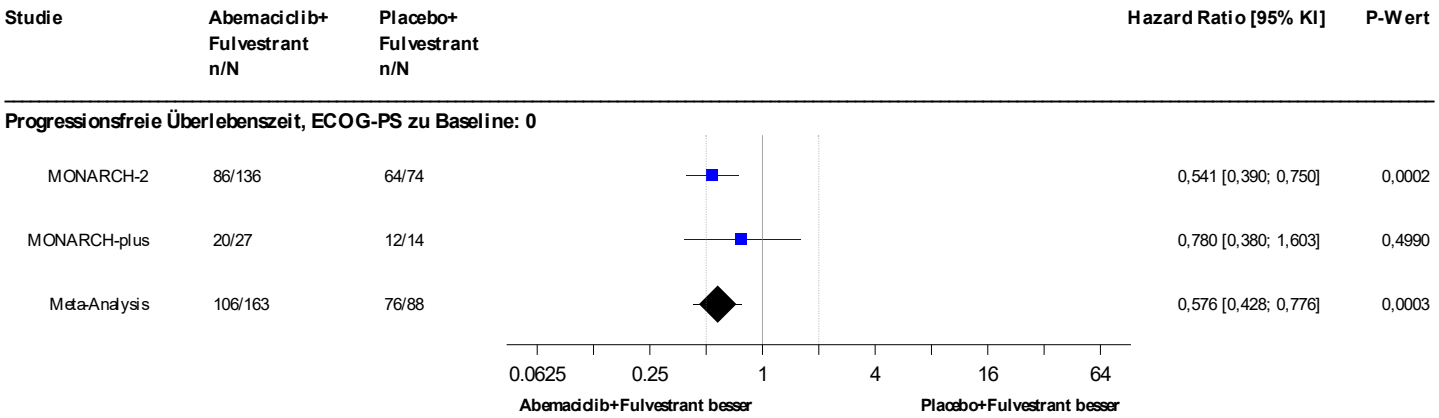
Abbildung 1402.1.4.1: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,8216, P-Wert=0,3647, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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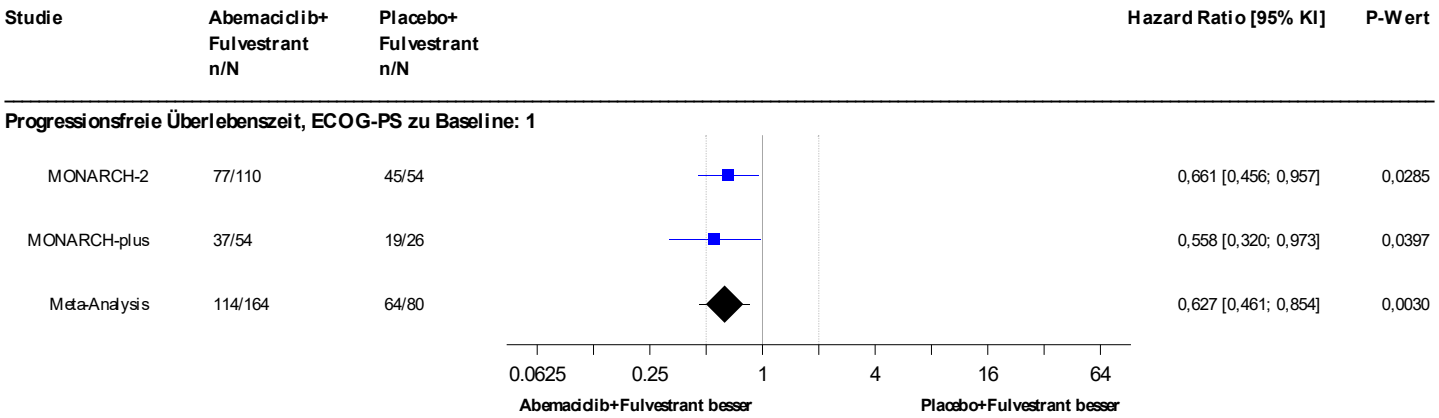
Abbildung 1402.1.4.2: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2474, P-Wert=0,6189, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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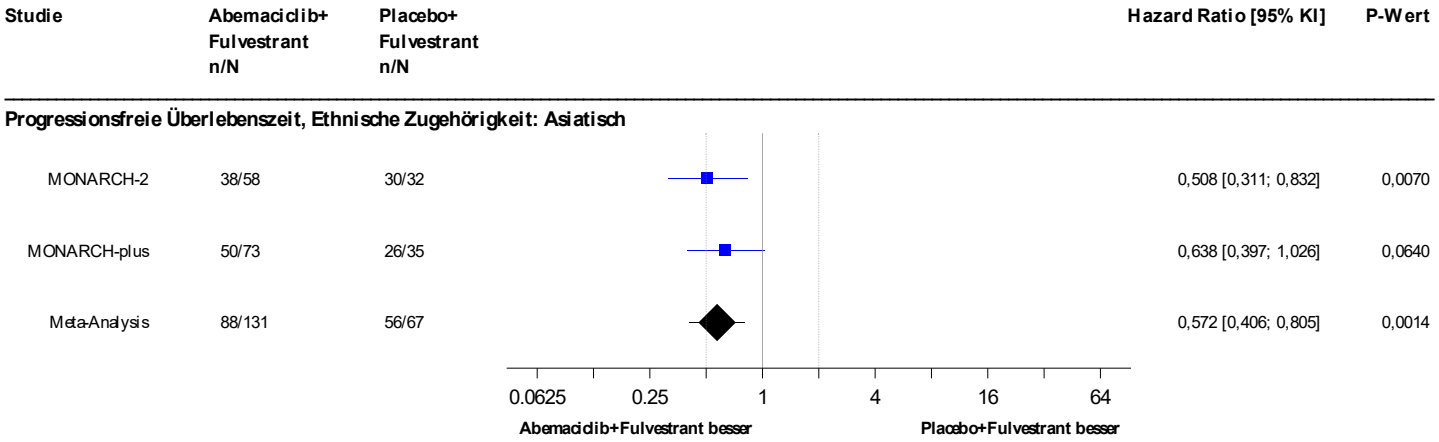
Abbildung 1402.1.5.1: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4256, P-Wert=0,5142, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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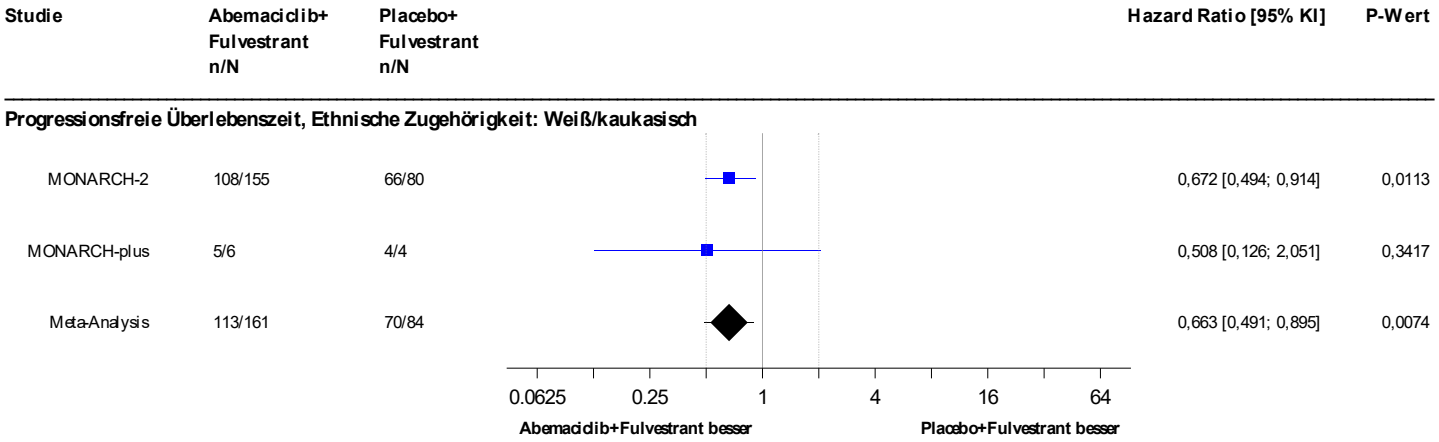
Abbildung 1402.1.5.2: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1459, P-Wert=0,7025, I2 Index=0%
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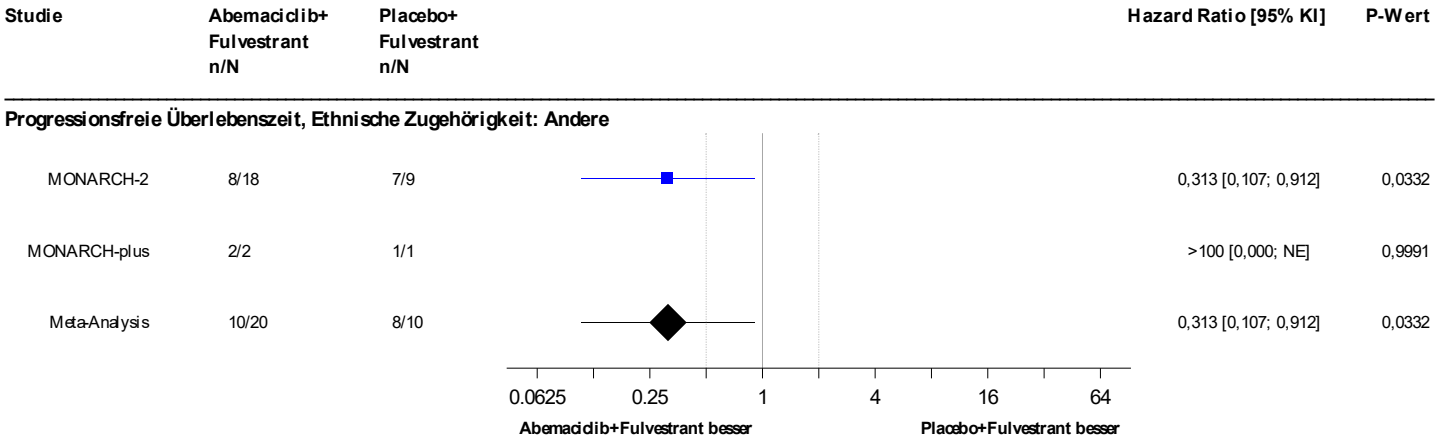
Abbildung 1402.1.5.3: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Ethnische Zugehörigkeit: Andere Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9991, I2 Index=0%
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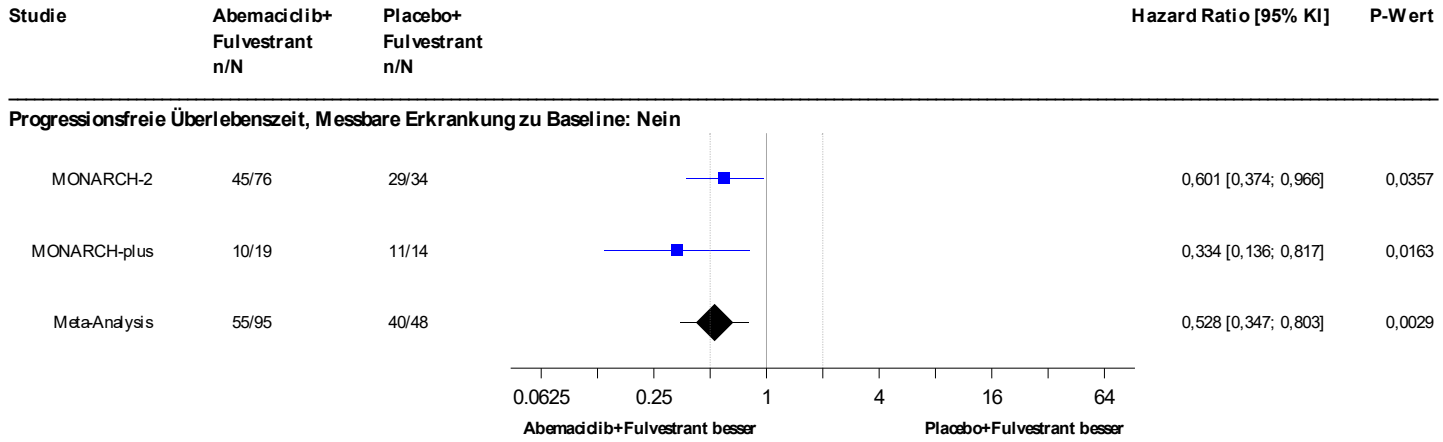
Abbildung 1402.1.6.1: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,2919, P-Wert=0,2557, I2 Index=22,6%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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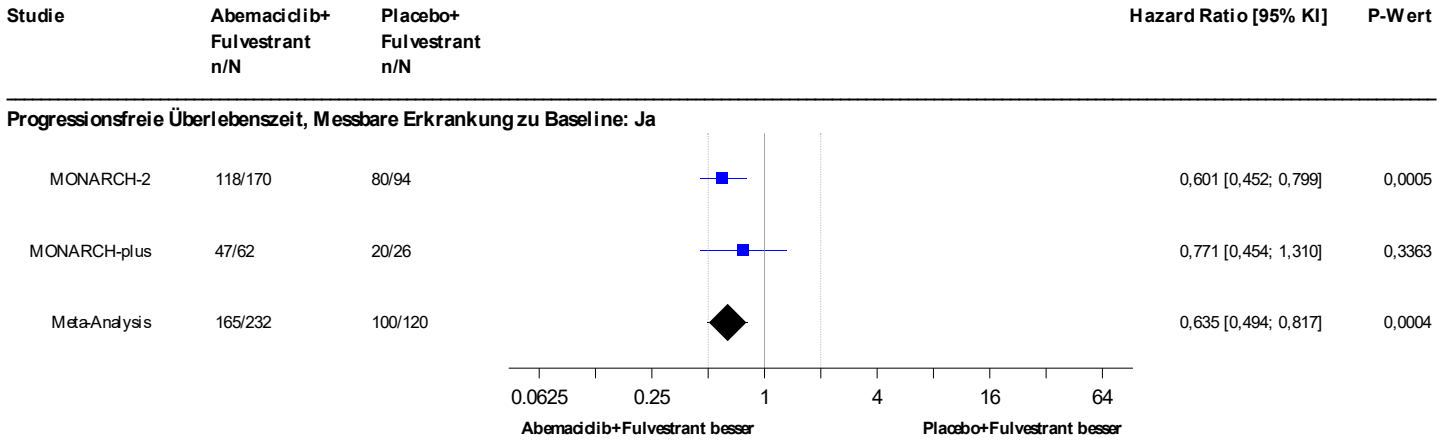
Abbildung 1402.1.6.2: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6595, P-Wert=0,4167, I2 Index=0%
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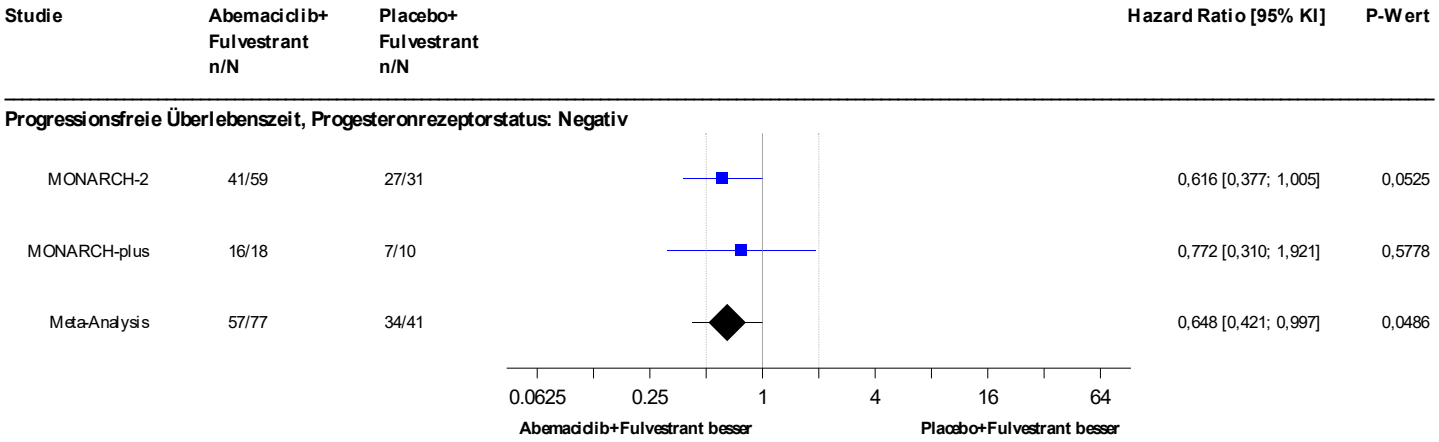
Abbildung 1402.1.7.1: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Progesteronrezeptorstatus: Negativ Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1829, P-Wert=0,6689, I2 Index=0%
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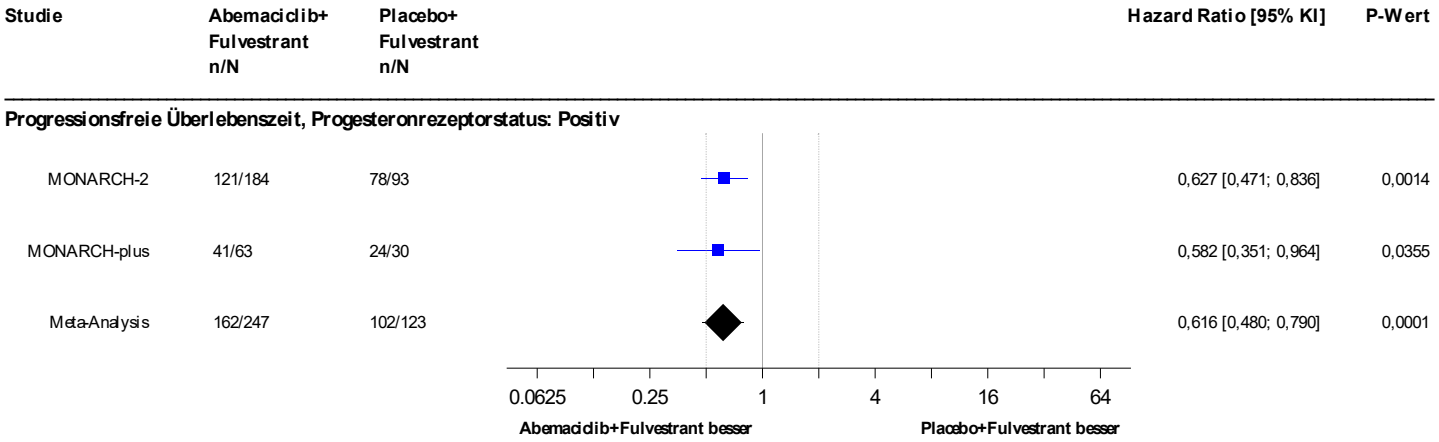
Abbildung 1402.1.7.2: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Progesteronrezeptorstatus: Positiv Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0652, P-Wert=0,7984, I2 Index=0%
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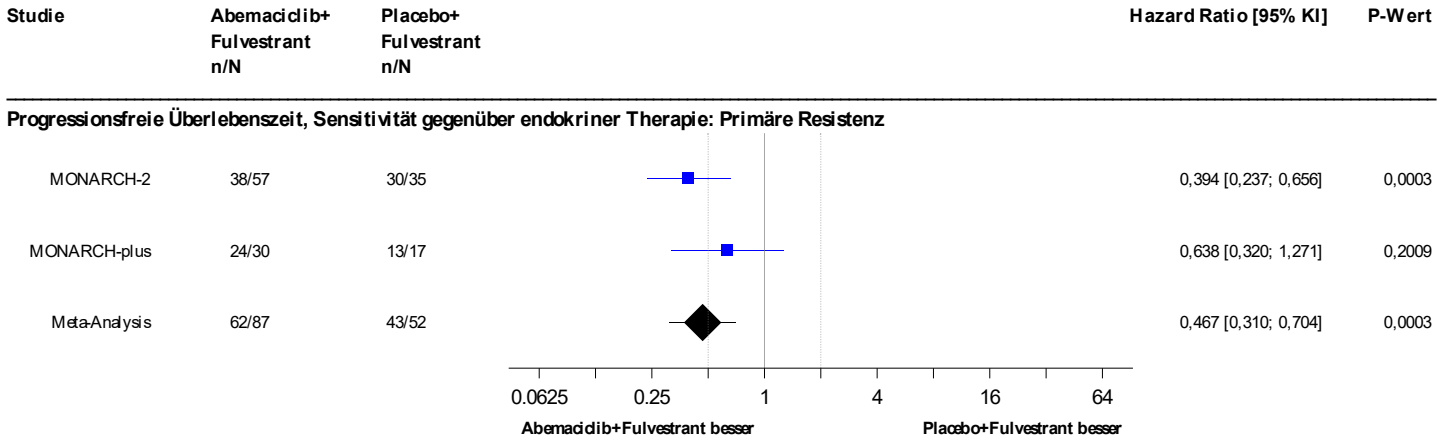
Abbildung 1402.1.8.1: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,2093, P-Wert=0,2715, I2 Index=17,3%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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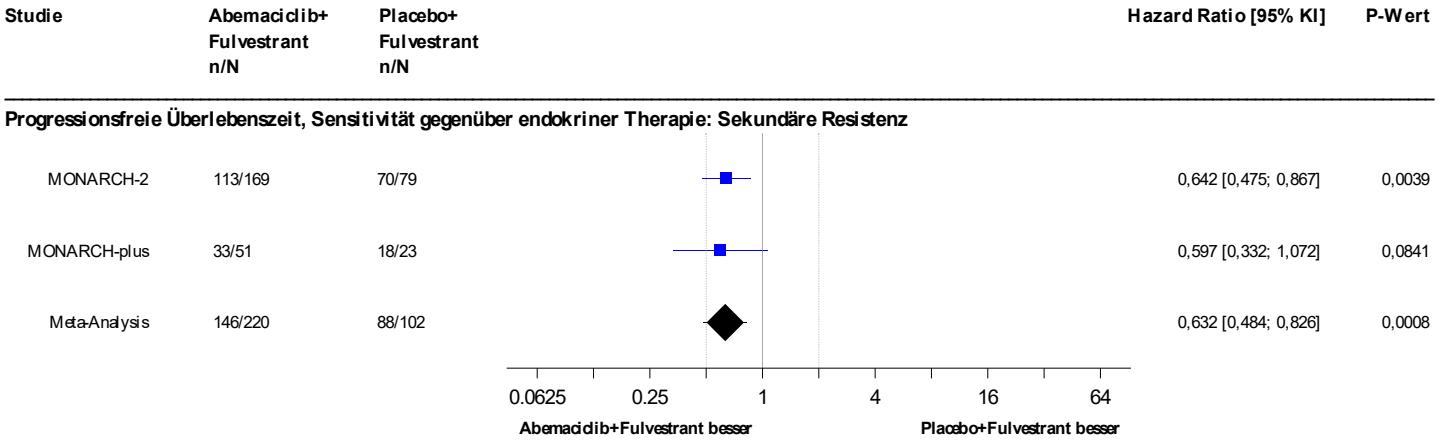
Abbildung 1402.1.8.2: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0477, P-Wert=0,8271, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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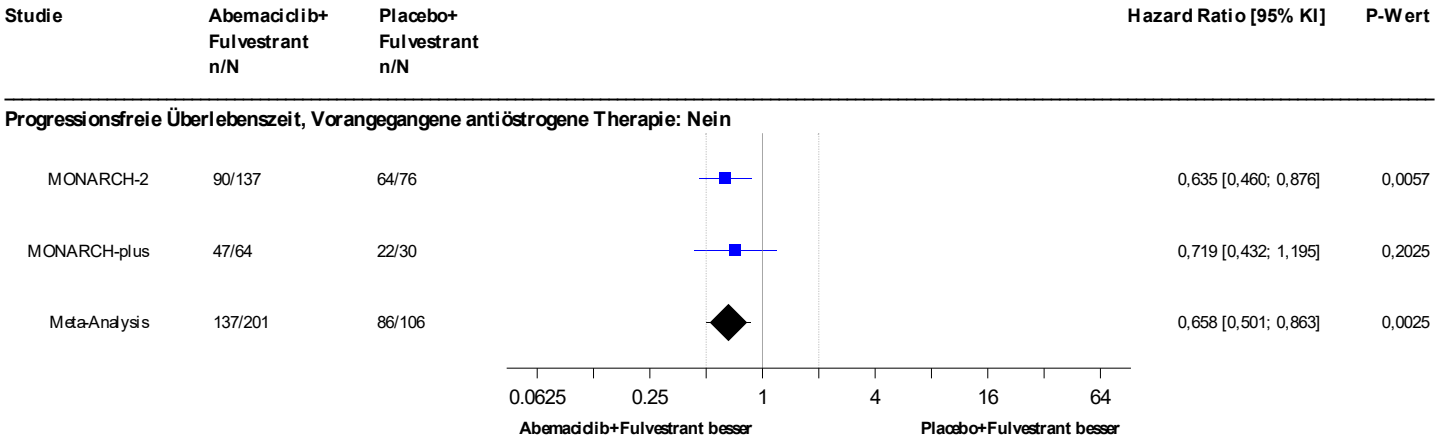
Abbildung 1402.1.9.1: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1621, P-Wert=0,6872, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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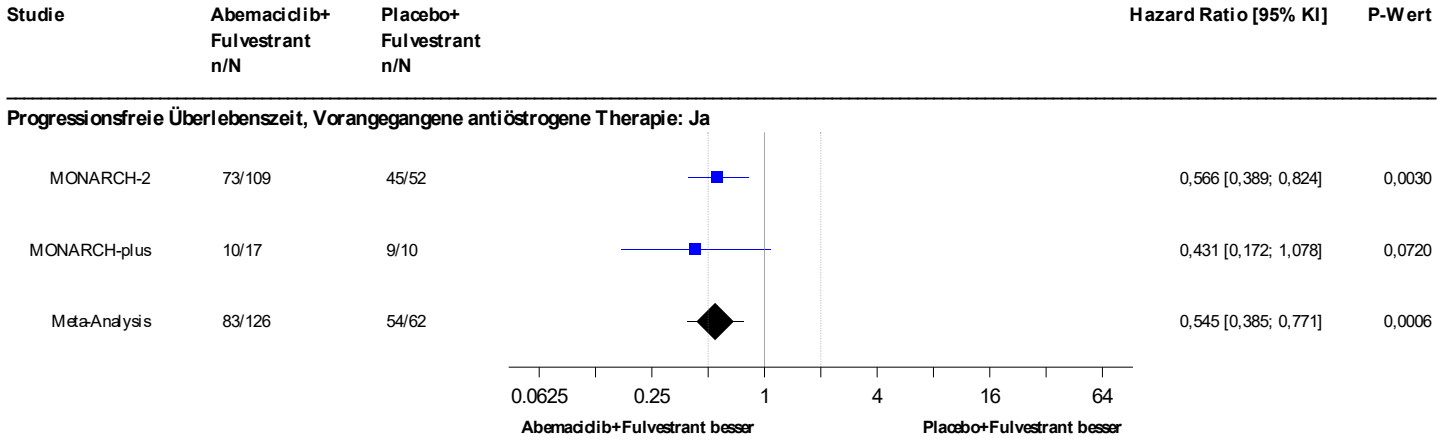
17SEP2021 / 07:48

Abbildung 1402.1.9.2: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2937, P-Wert=0,5879, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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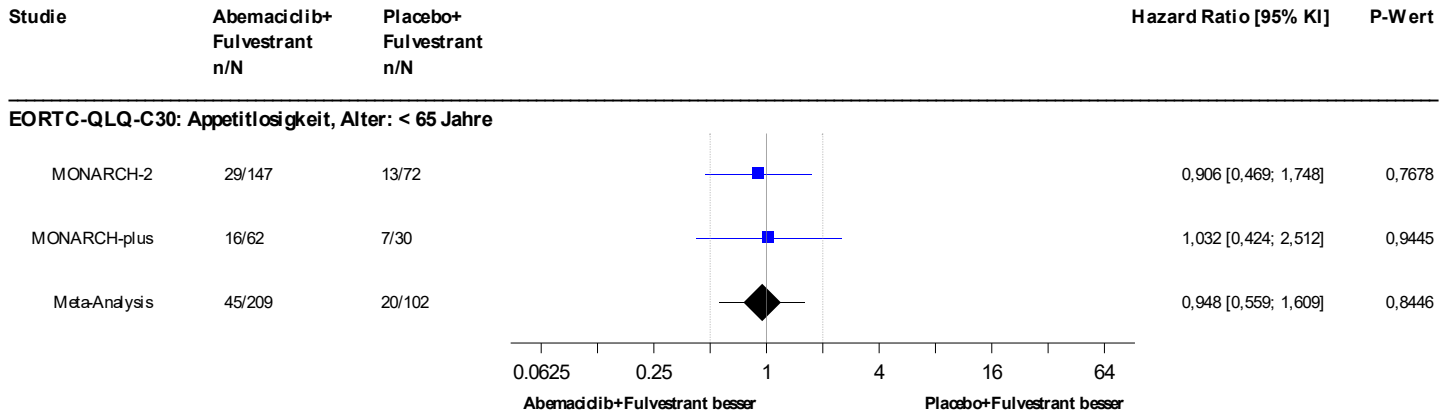
Abbildung 1403.1.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0535, P-Wert=0,8170, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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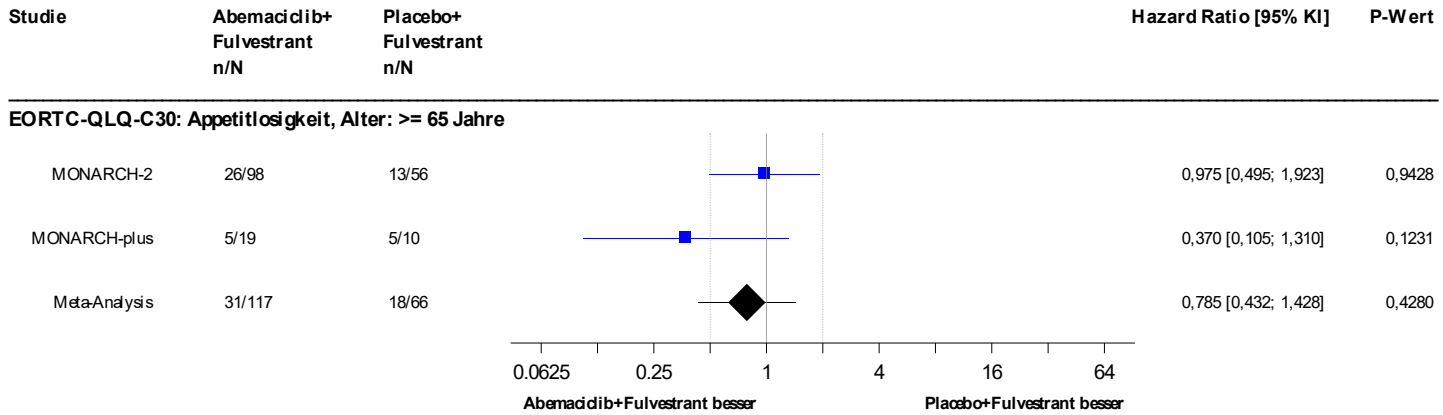
Abbildung 1403.1.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,7538, P-Wert=0,1854, I2 Index=43,0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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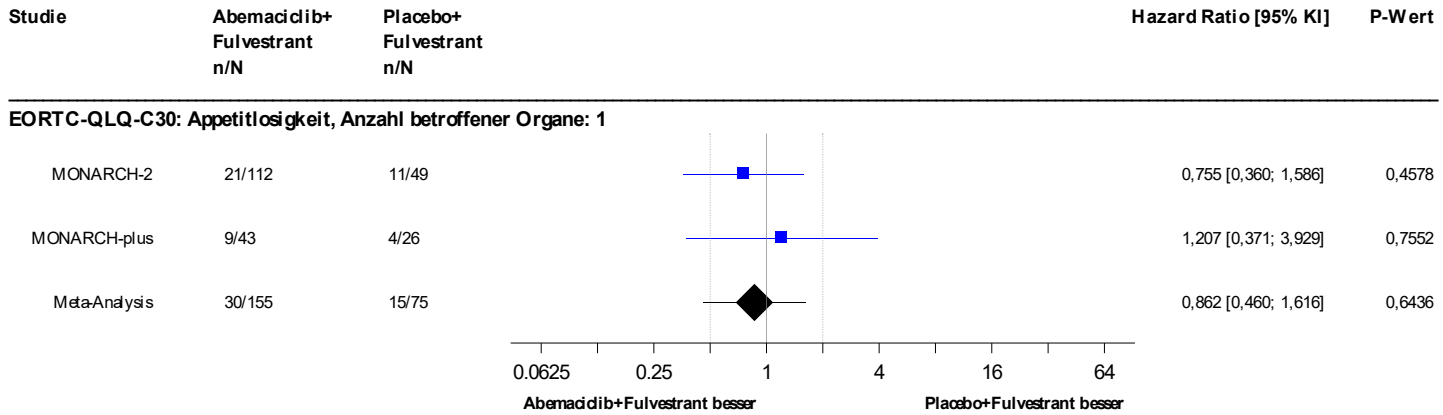
Abbildung 1403.1.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4343, P-Wert=0,5099, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwaplo6_popa1_norggr_1.rtf
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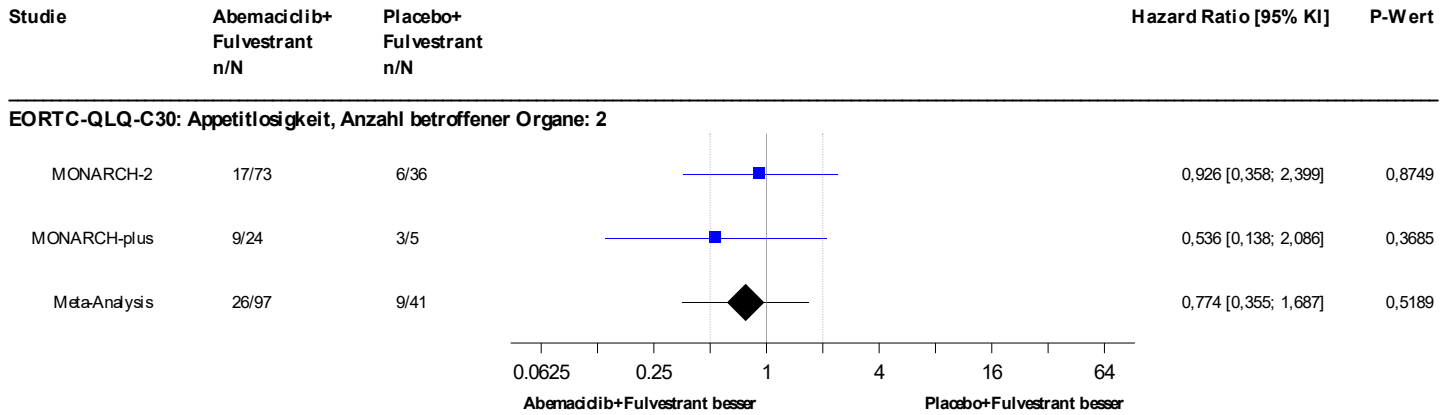
Abbildung 1403.1.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4176, P-Wert=0,5181, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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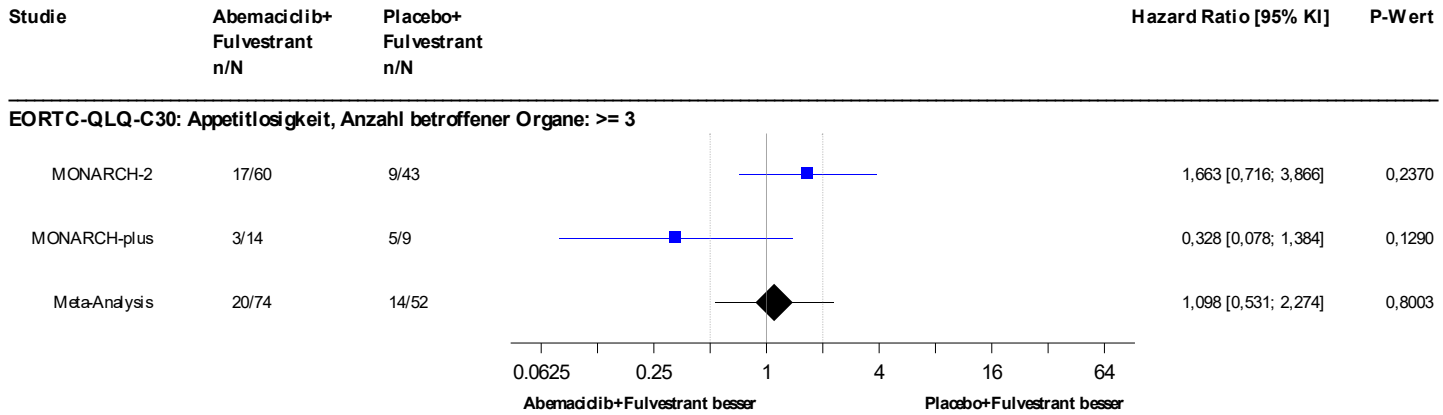
Abbildung 1403.1.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=3,6385, P-Wert=0,0565, I2 Index=72,5%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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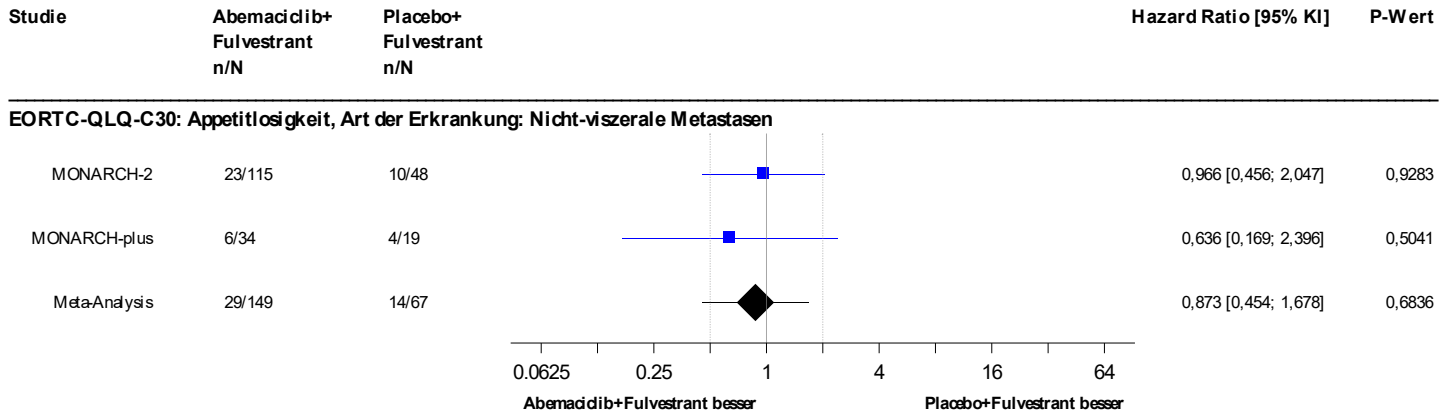
Abbildung 1403.1.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2882, P-Wert=0,5914, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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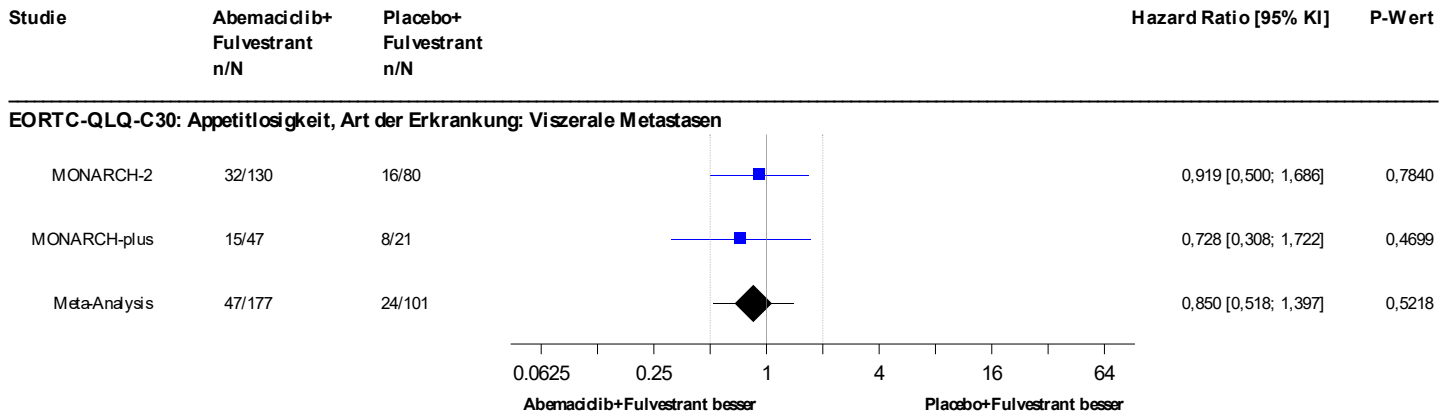
Abbildung 1403.1.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1871, P-Wert=0,6653, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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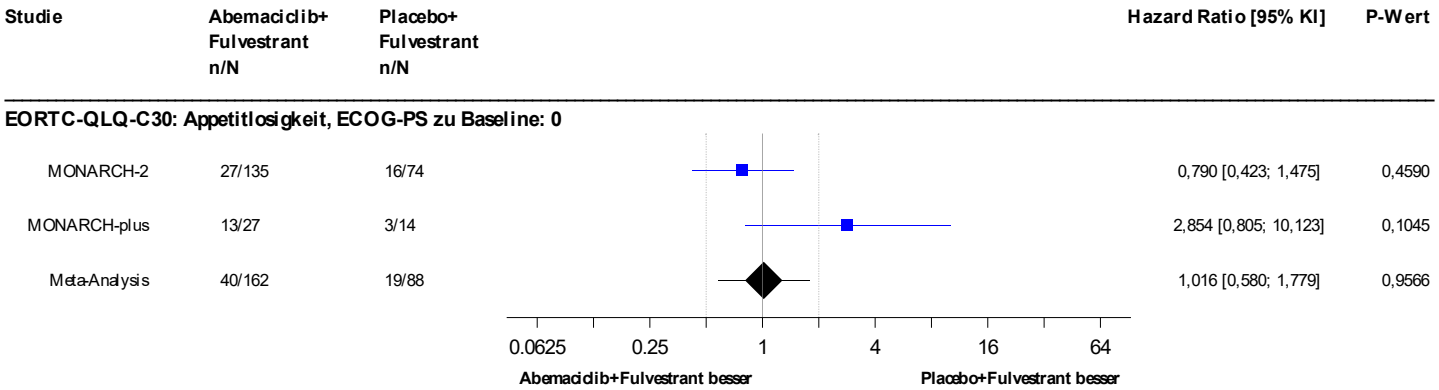
Abbildung 1403.1.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=3,1813, P-Wert=0,0745, I2 Index=68,6%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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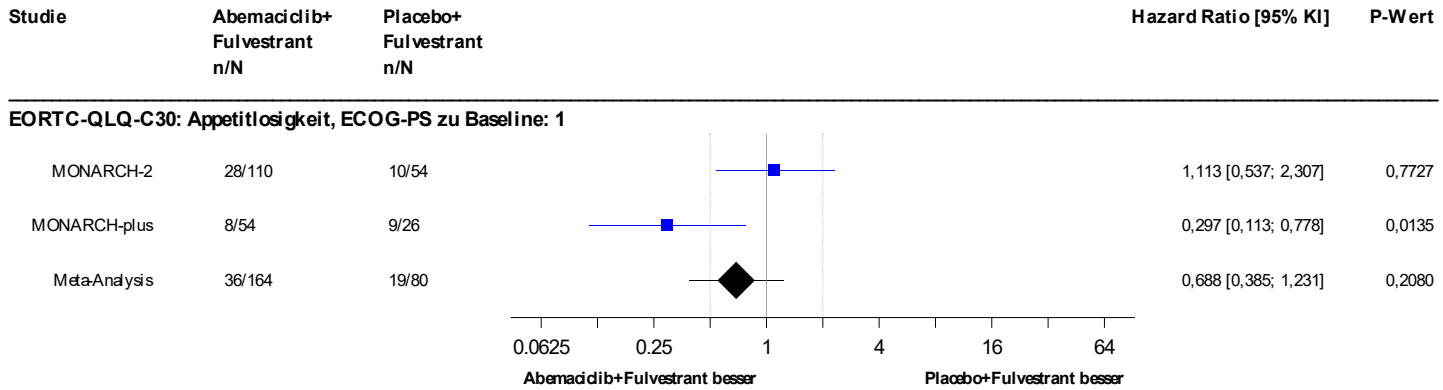
Abbildung 1403.1.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=4,5983, P-Wert=0,0320, I2 Index=78,3%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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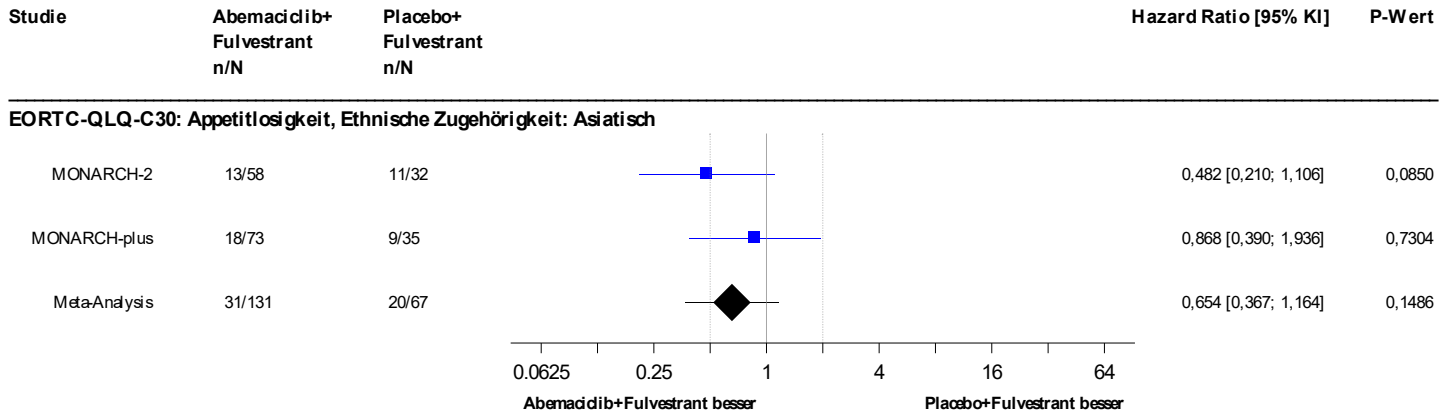
Abbildung 1403.1.5.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,9992, P-Wert=0,3175, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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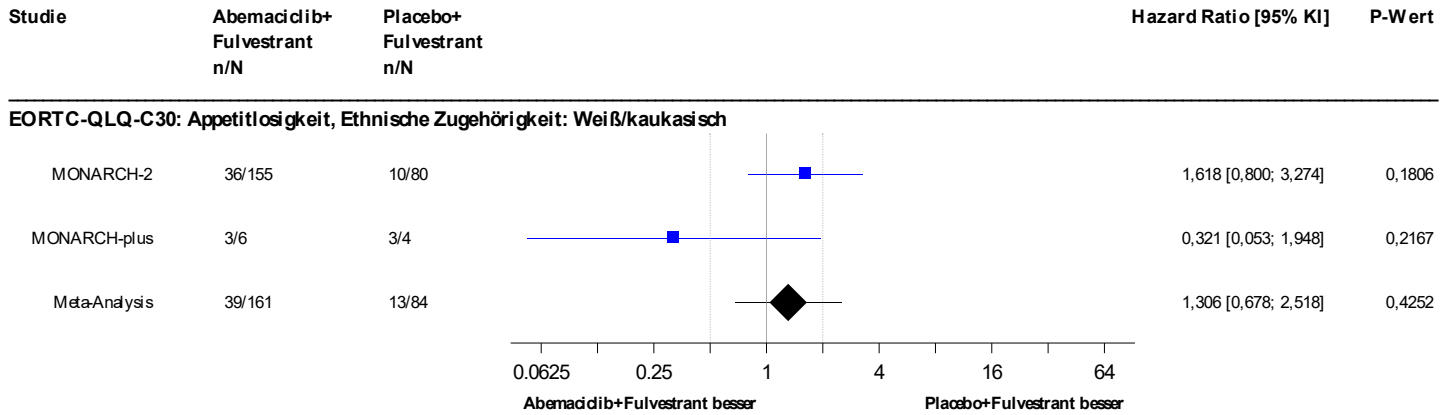
Abbildung 1403.1.5.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,6828, P-Wert=0,1014, I2 Index=62,7%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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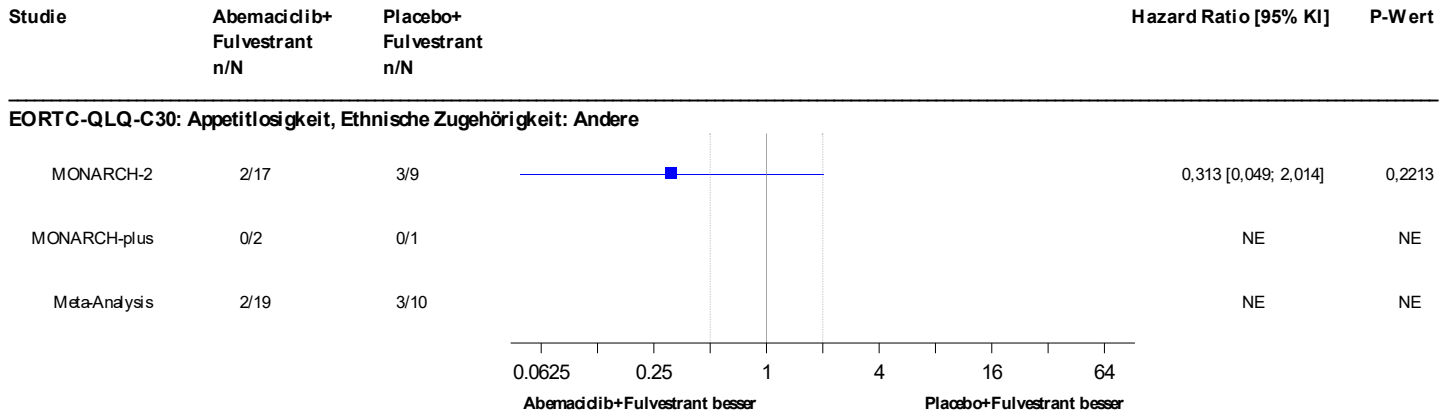
Abbildung 1403.1.5.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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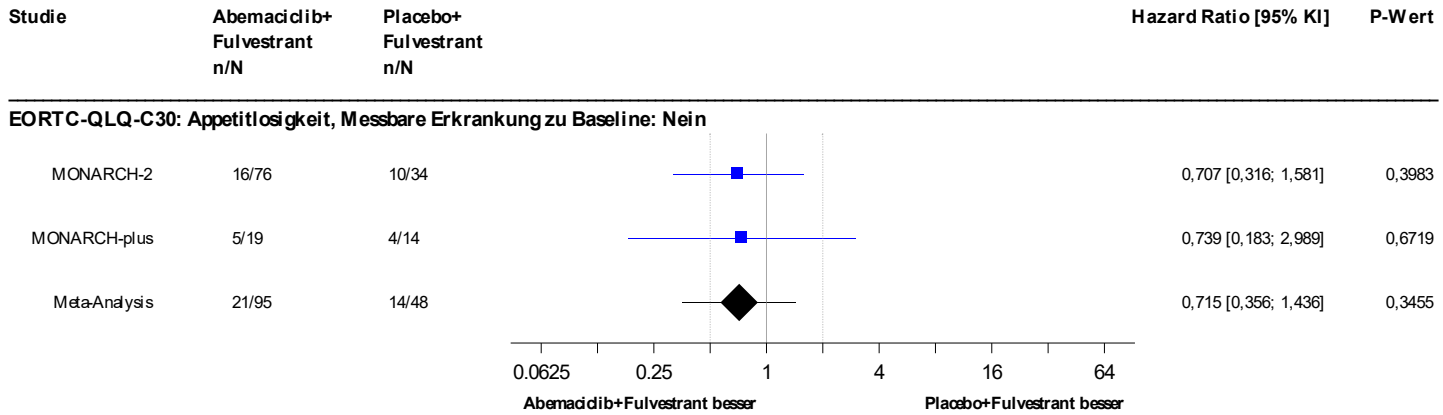
Abbildung 1403.1.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0030, P-Wert=0,9562, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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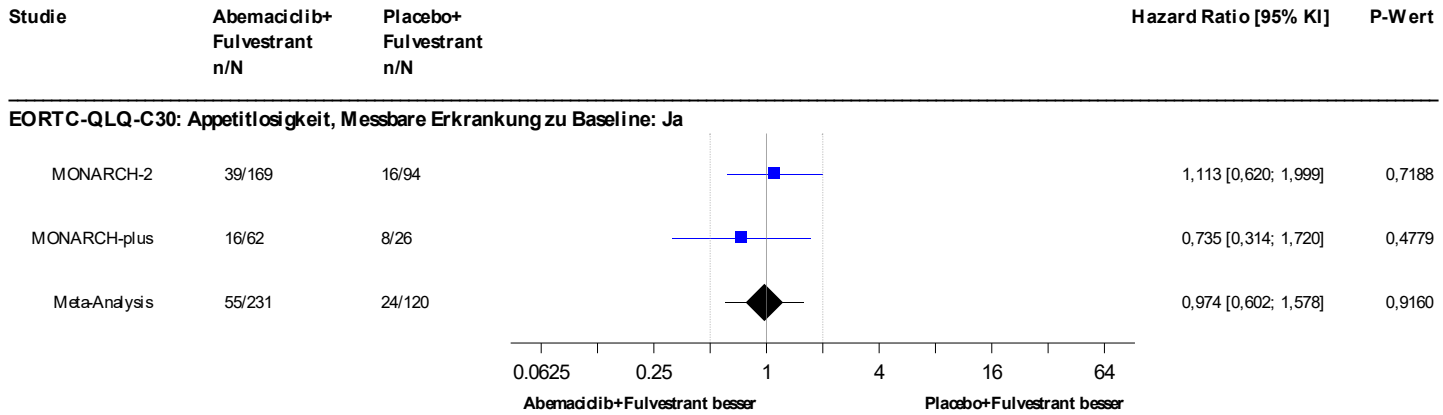
Abbildung 1403.1.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6222, P-Wert=0,4302, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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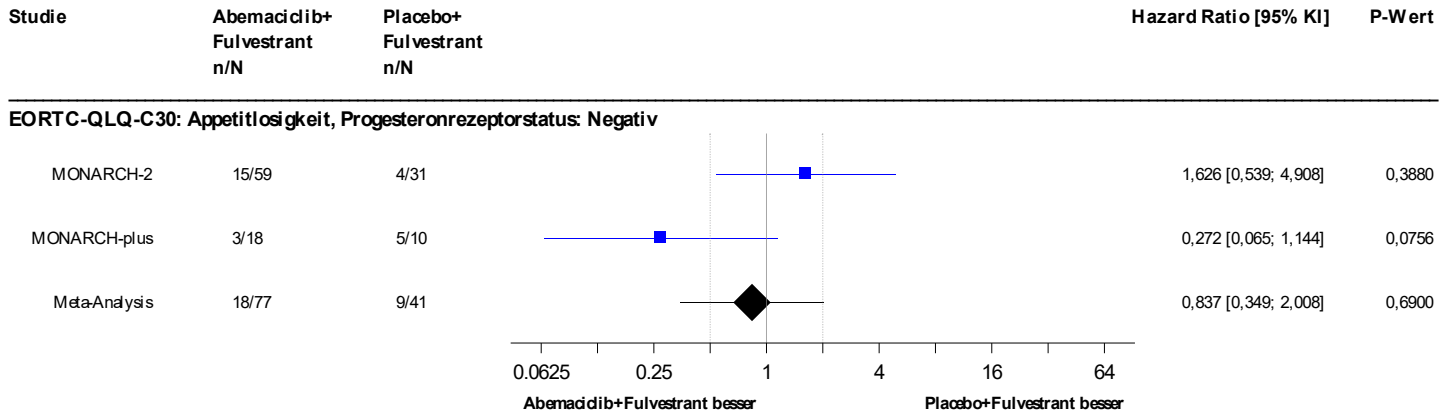
Abbildung 1403.1.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=3,7424, P-Wert=0,0530, I2 Index=73,3%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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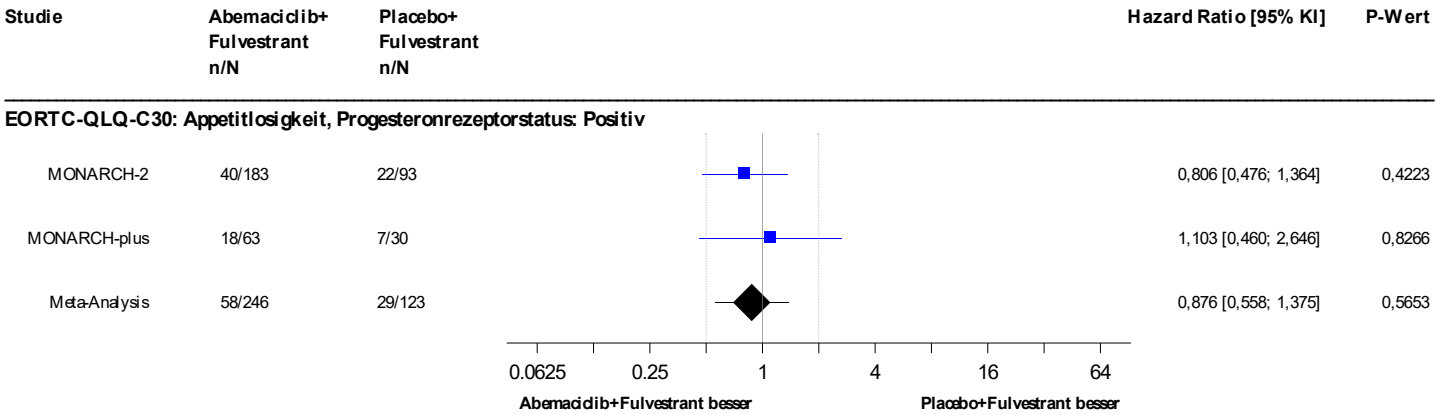
Abbildung 1403.1.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3613, P-Wert=0,5478, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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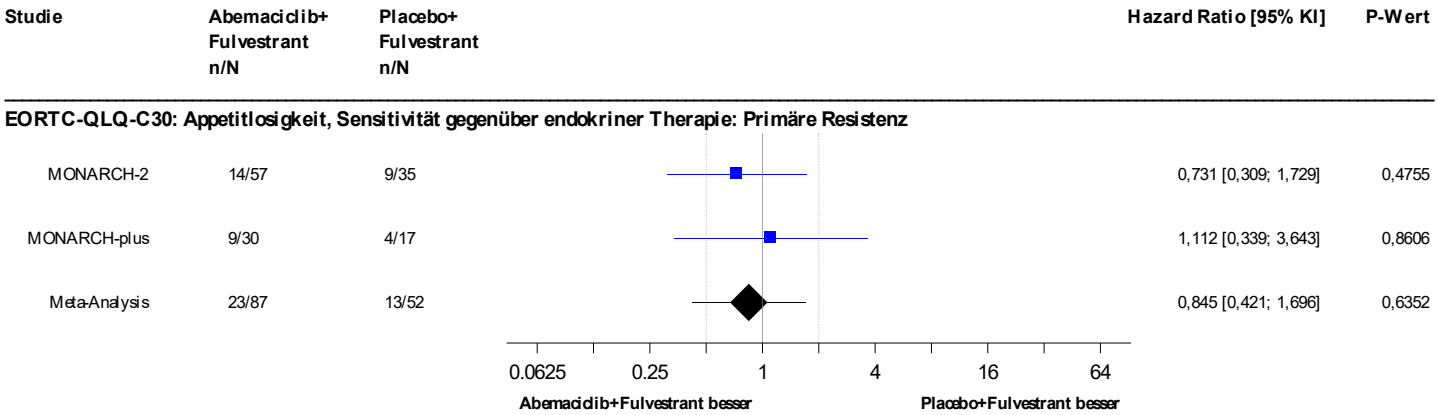
Abbildung 1403.1.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3150, P-Wert=0,5746, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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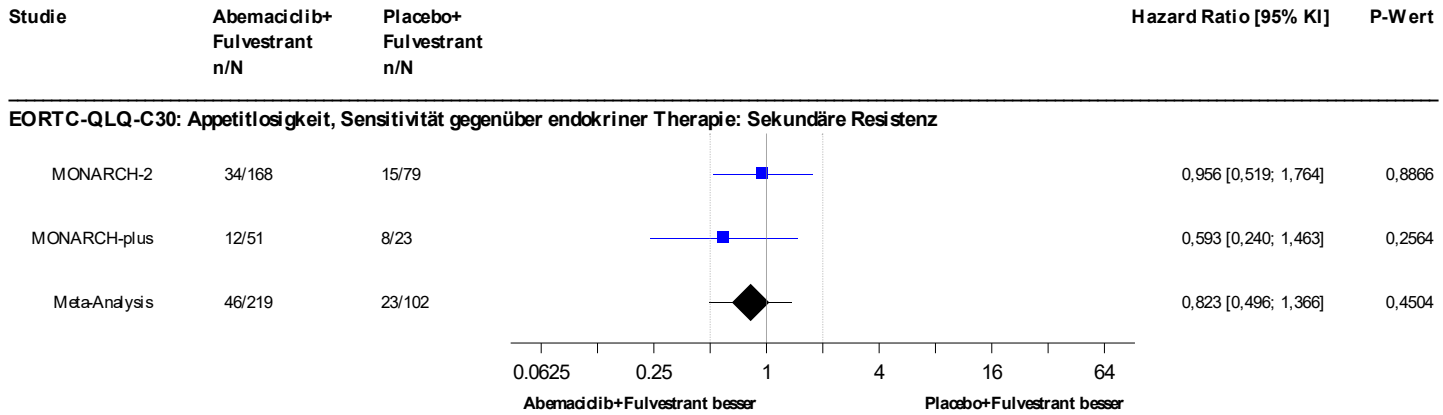
Abbildung 1403.1.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7391, P-Wert=0,3899, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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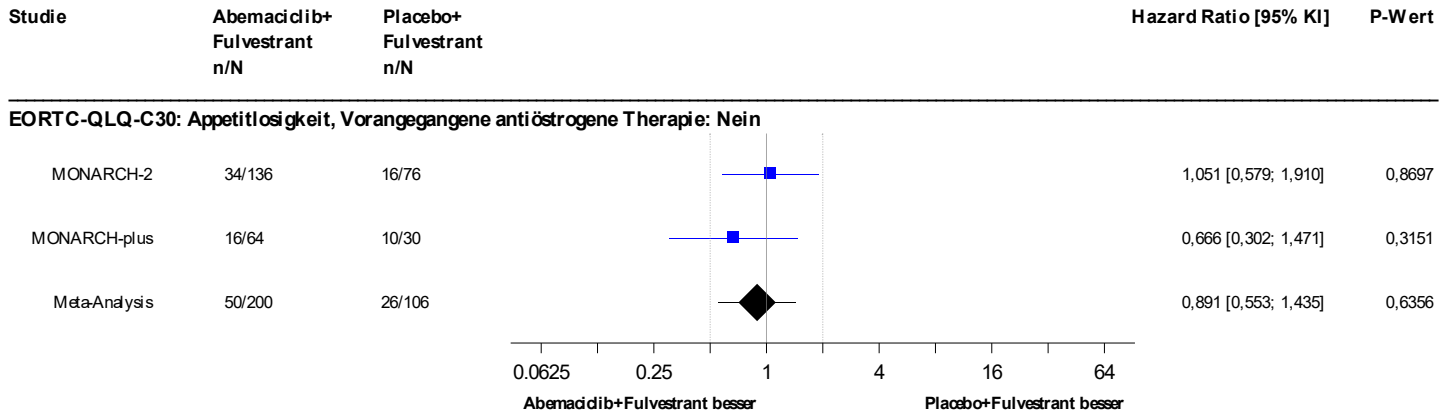
Abbildung 1403.1.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,8115, P-Wert=0,3677, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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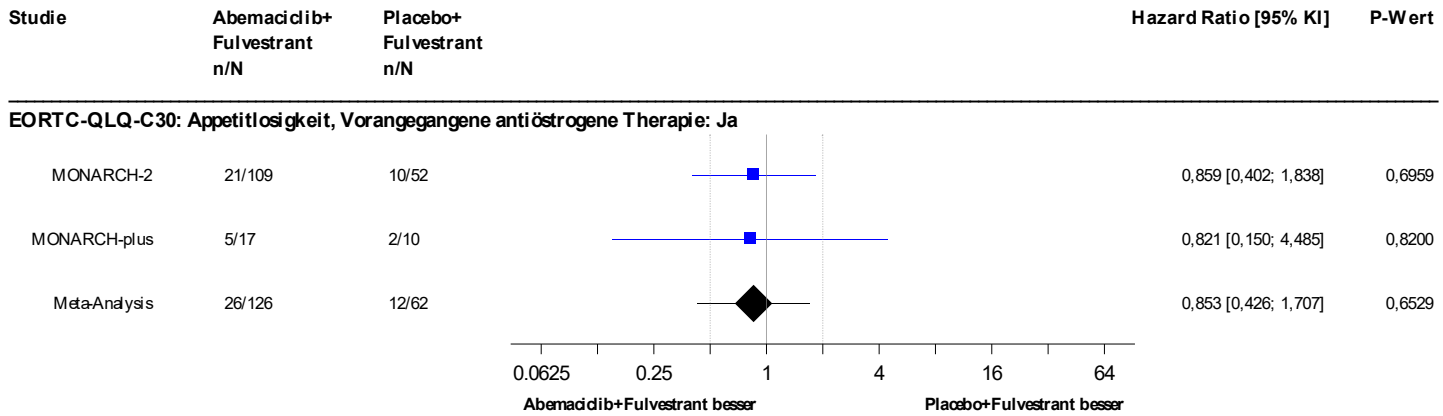
Abbildung 1403.1.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0023, P-Wert=0,9617, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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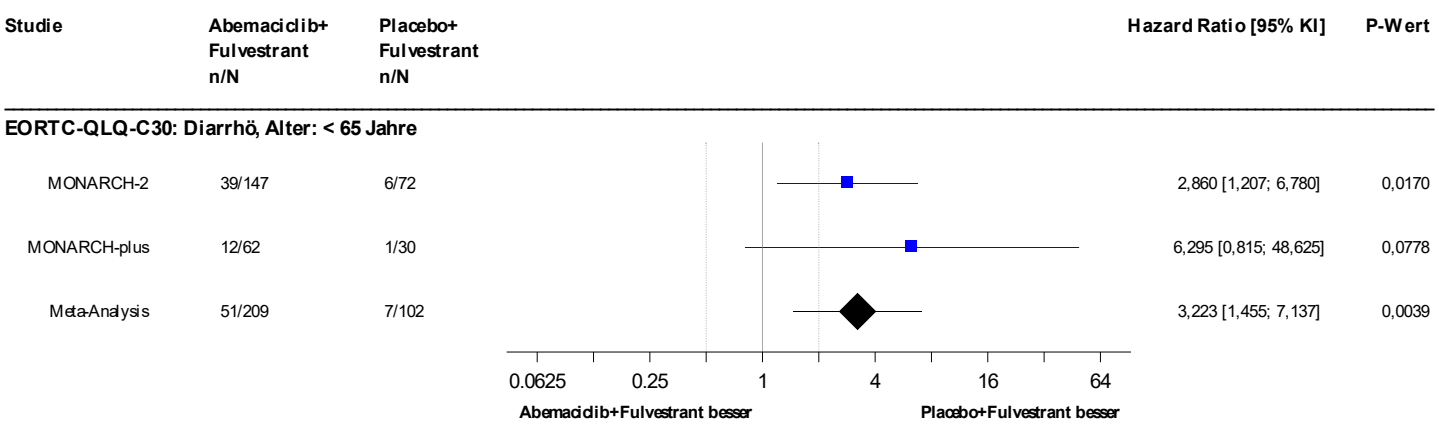
Abbildung 1404.1.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4854, P-Wert=0,4860, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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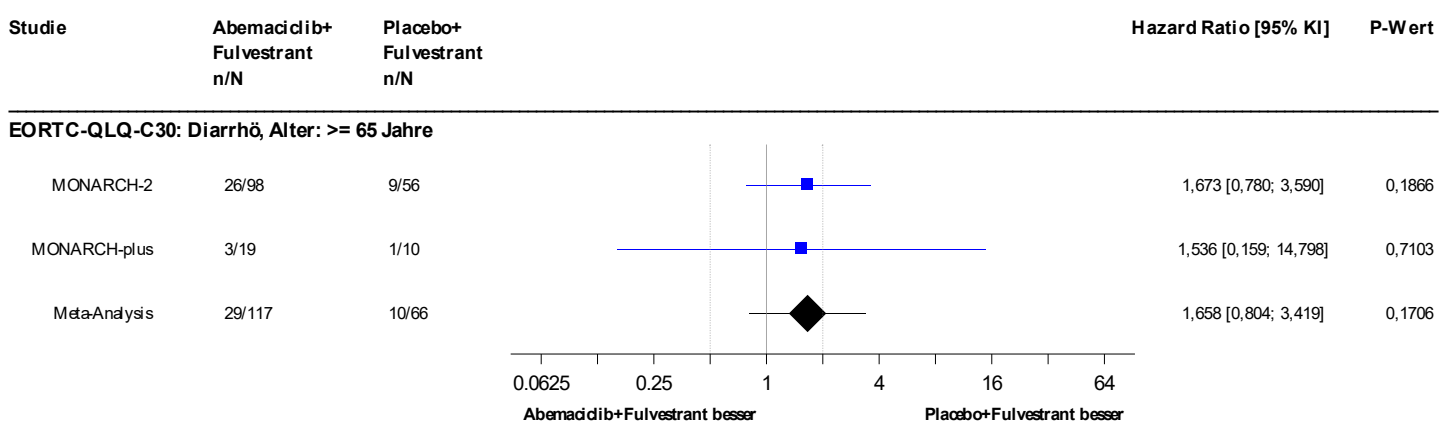
Abbildung 1404.1.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0049, P-Wert=0,9442, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwdiar6_popa1_agegr1_2.rtf
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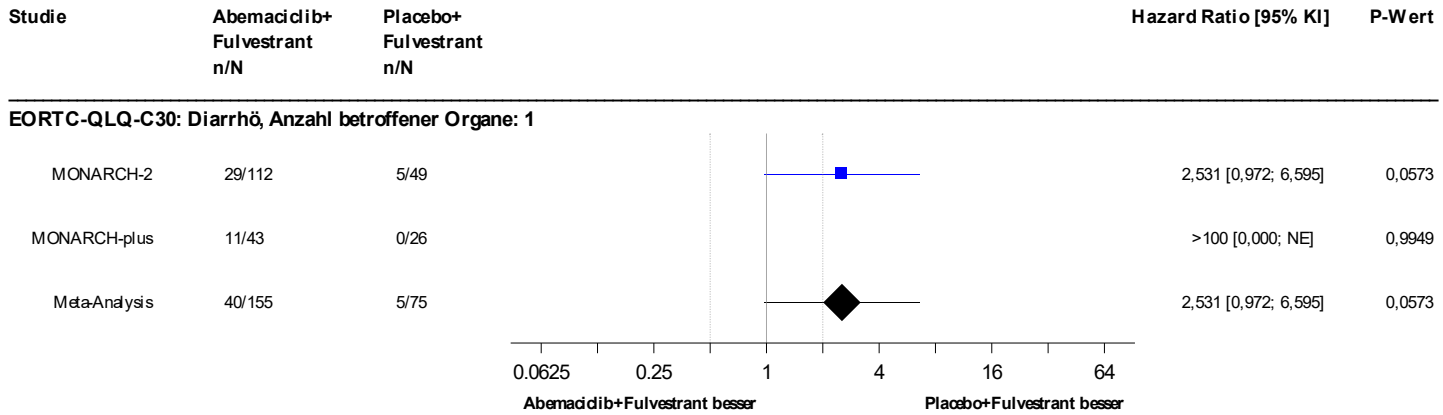
Abbildung 1404.1.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9951, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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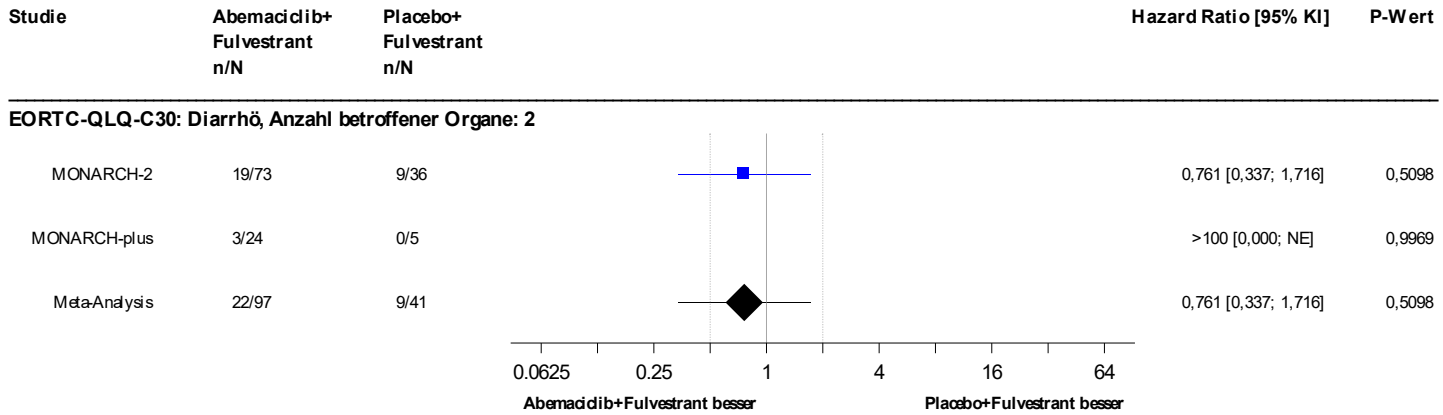
Abbildung 1404.1.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9969, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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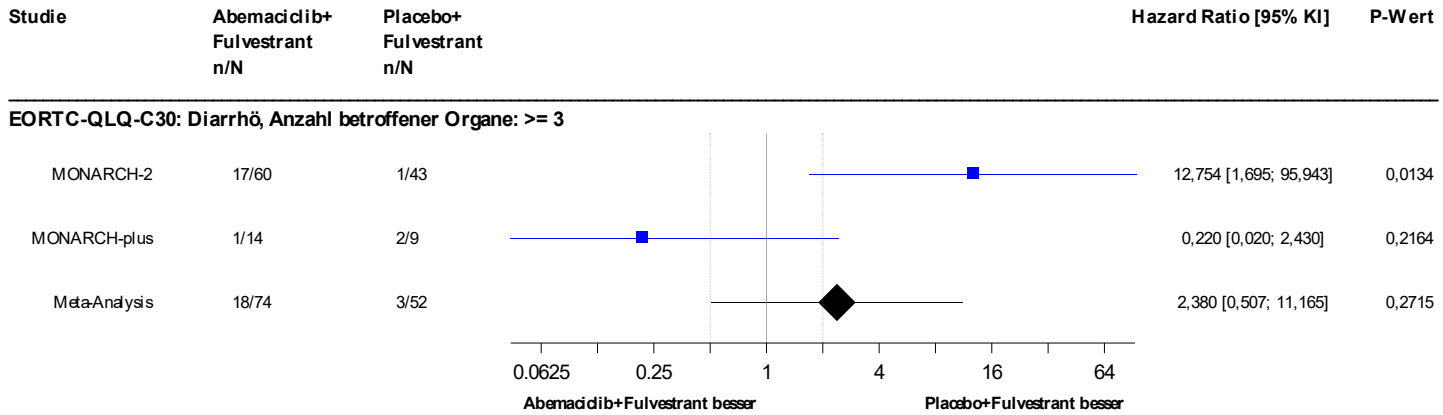
Abbildung 1404.1.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=6,4337, P-Wert=0,0112, I2 Index=84,5%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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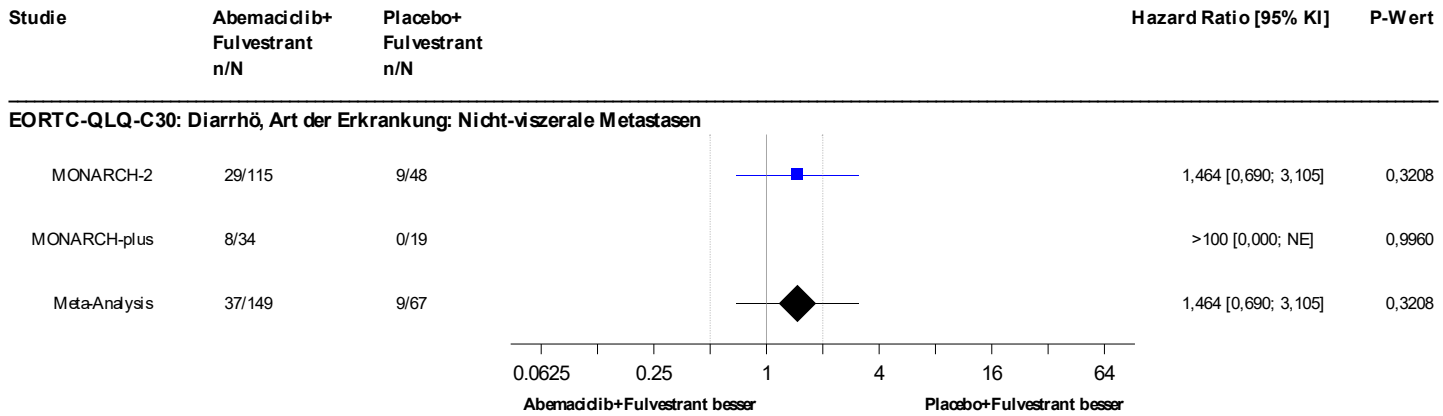
Abbildung 1404.1.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9960, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwdiar6_popa1_natdis2_1.rtf
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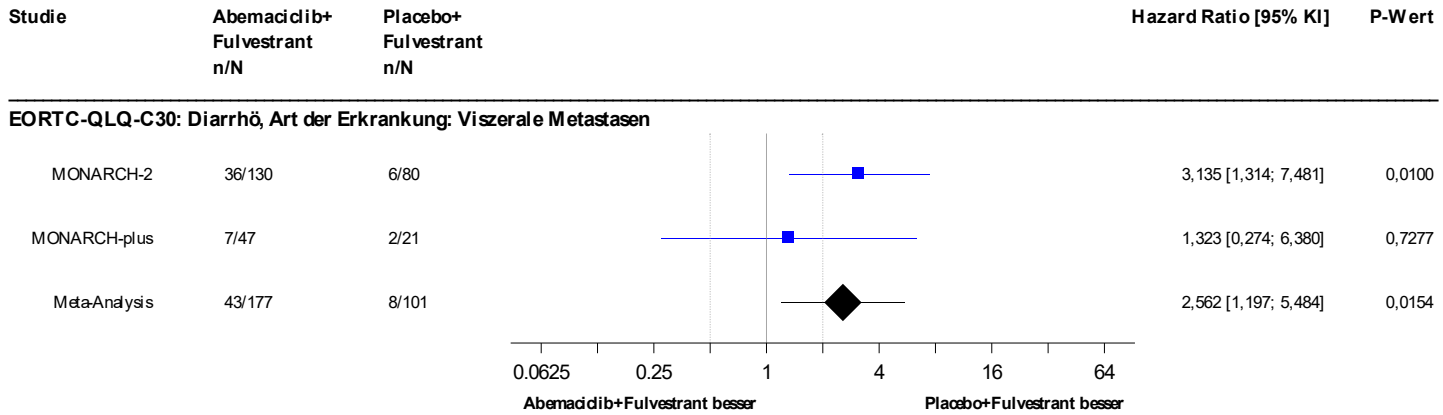
Abbildung 1404.1.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,8852, P-Wert=0,3468, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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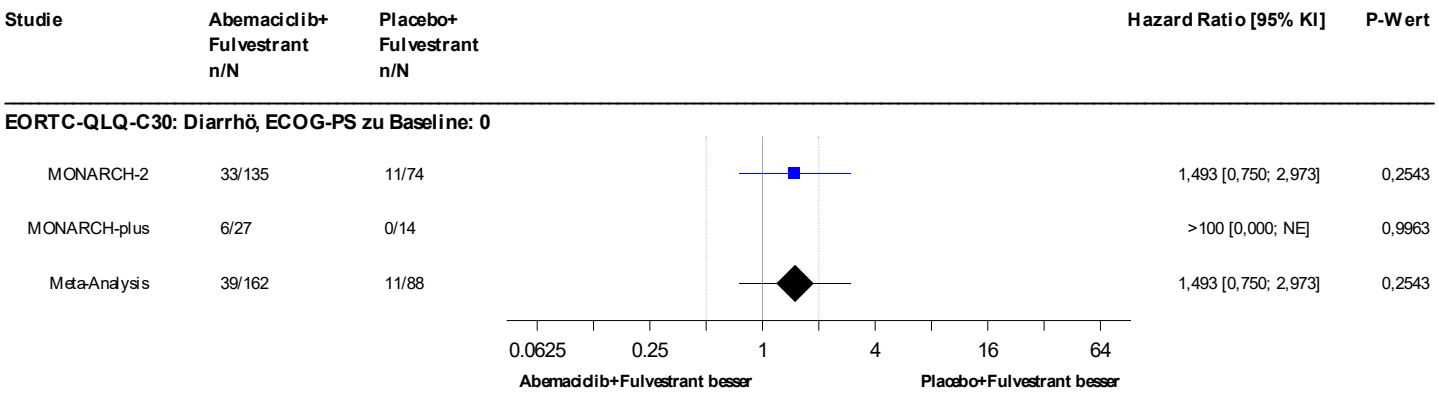
Abbildung 1404.1.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9964, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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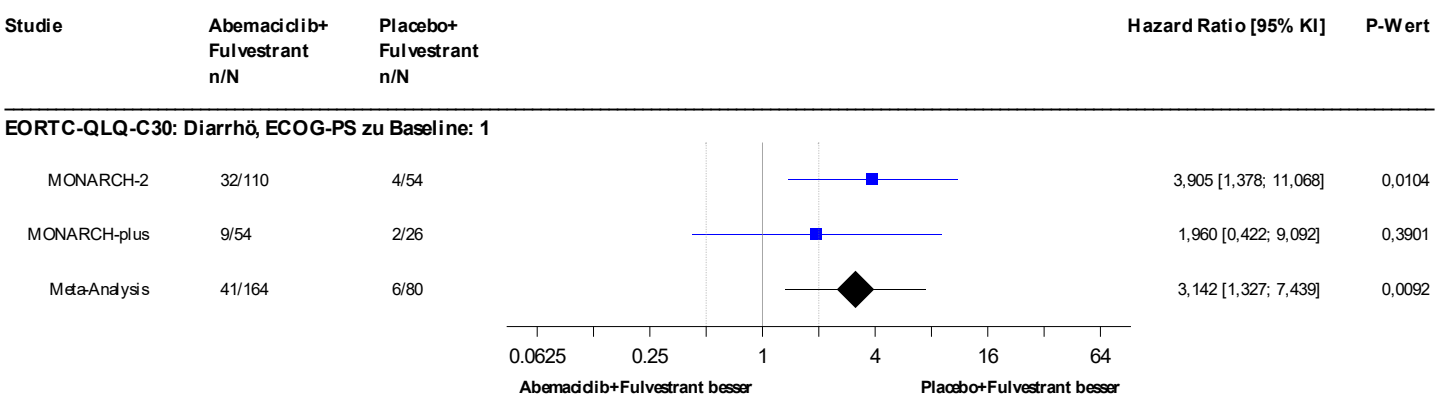
Abbildung 1404.1.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,5309, P-Wert=0,4662, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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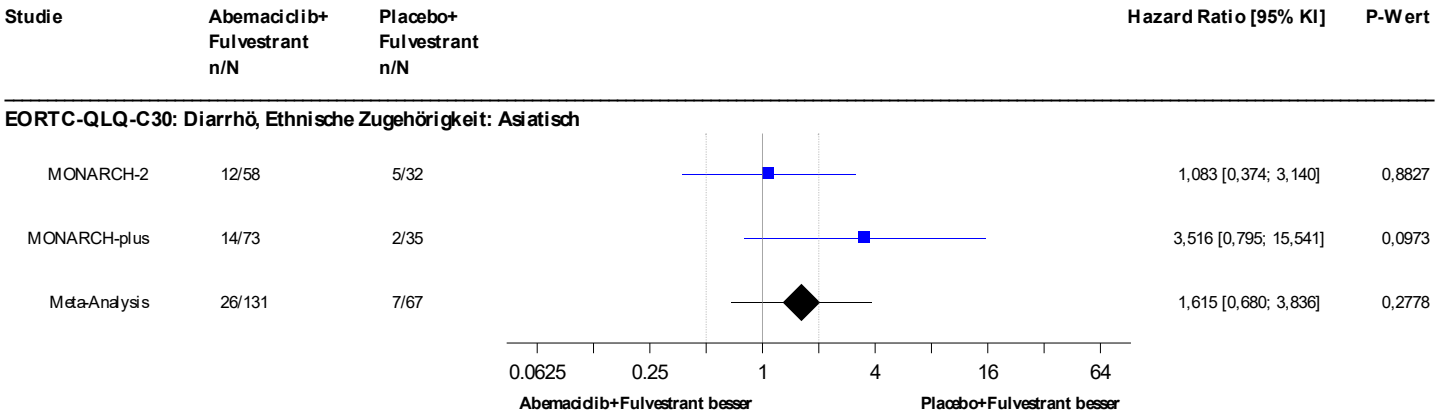
Abbildung 1404.1.5.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,5930, P-Wert=0,2069, I2 Index=37,2%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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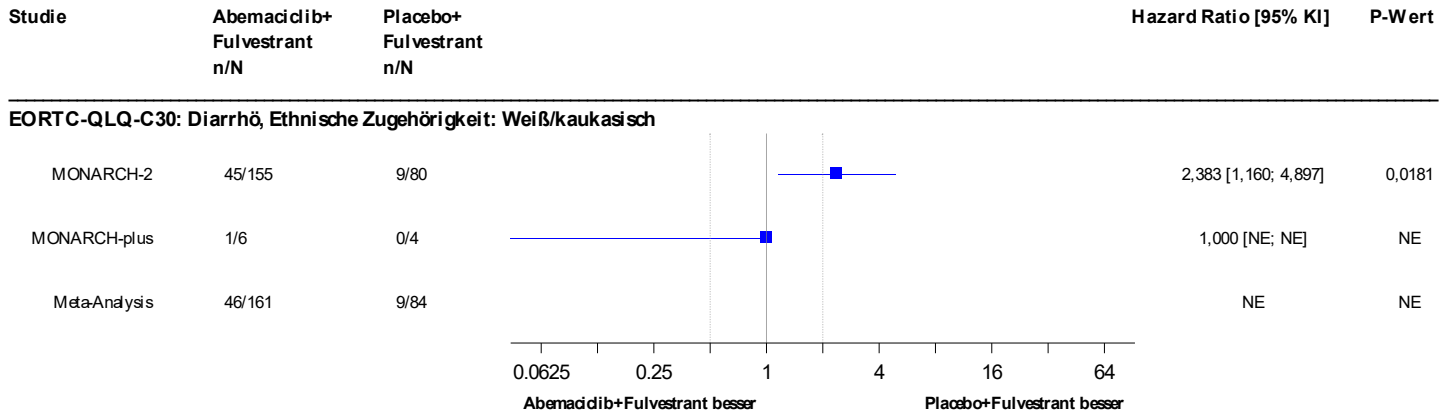
Abbildung 1404.1.5.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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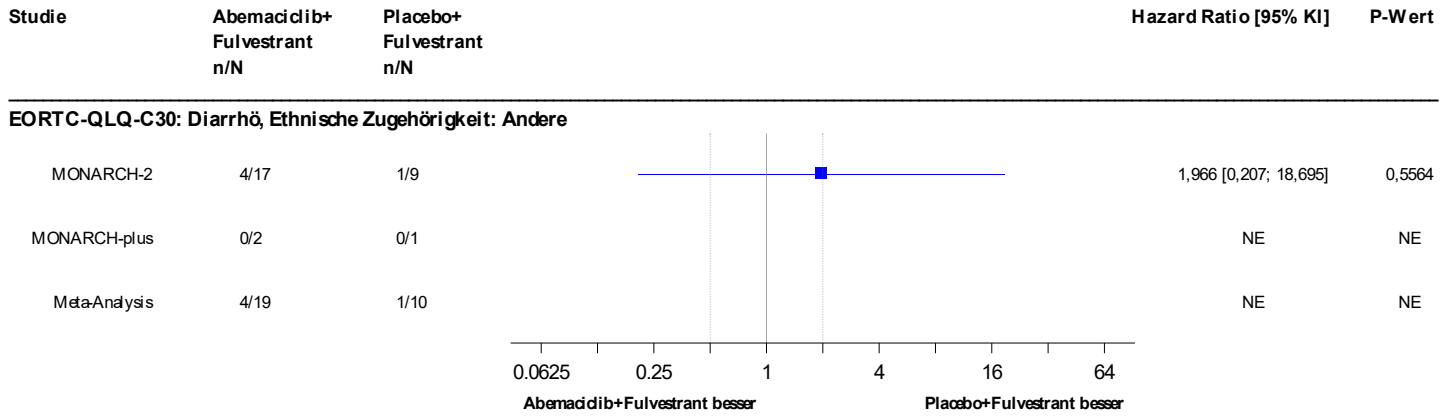
Abbildung 1404.1.5.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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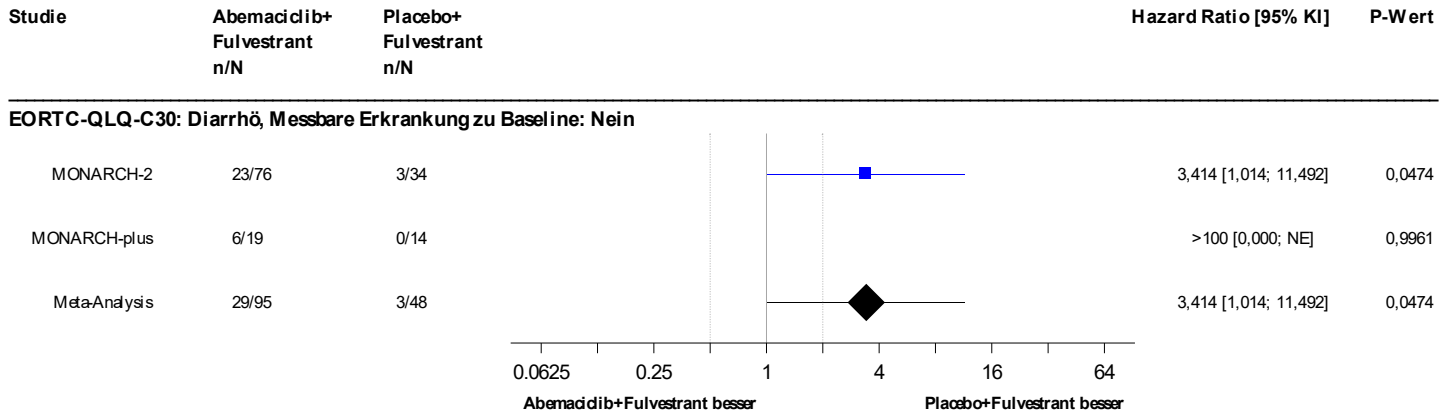
Abbildung 1404.1.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9963, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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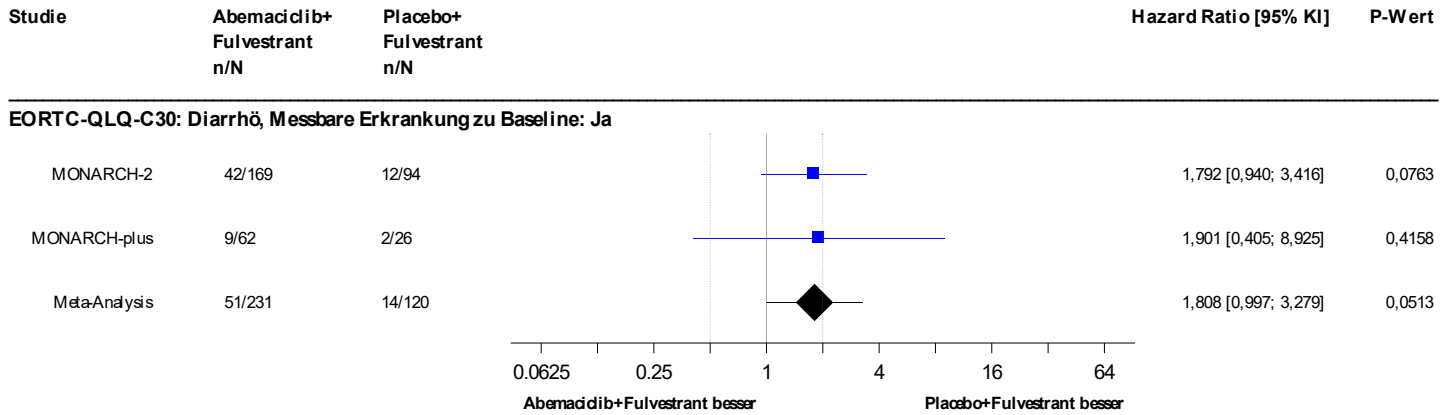
Abbildung 1404.1.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0047, P-Wert=0,9452, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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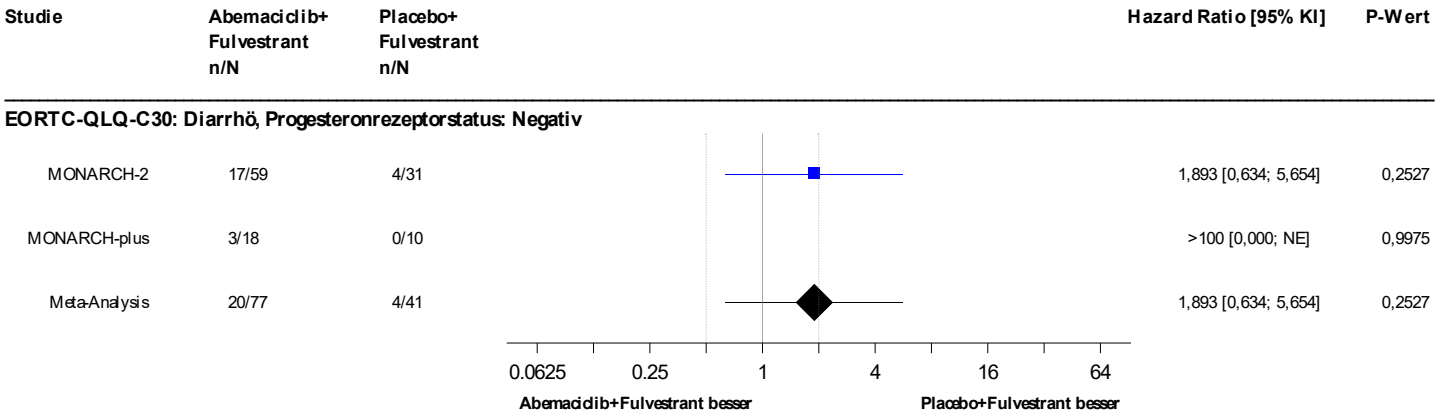
Abbildung 1404.1.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9976, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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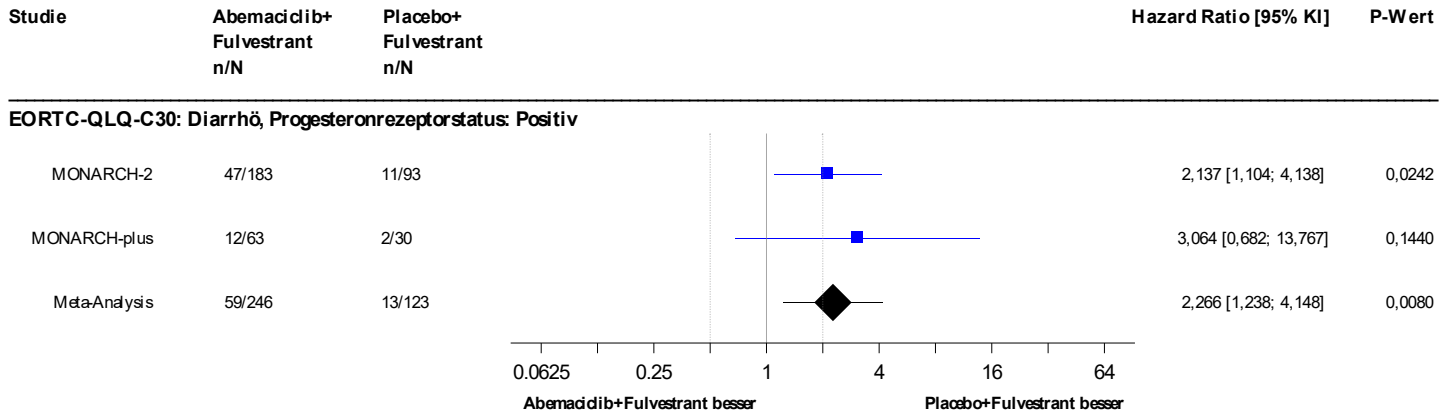
Abbildung 1404.1.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1851, P-Wert=0,6670, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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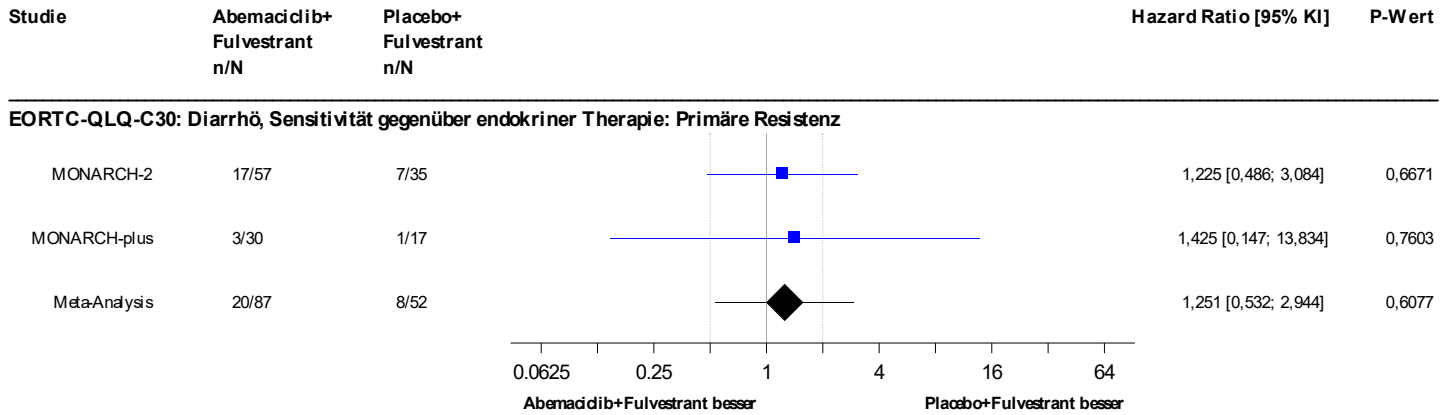
Abbildung 1404.1.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0146, P-Wert=0,9039, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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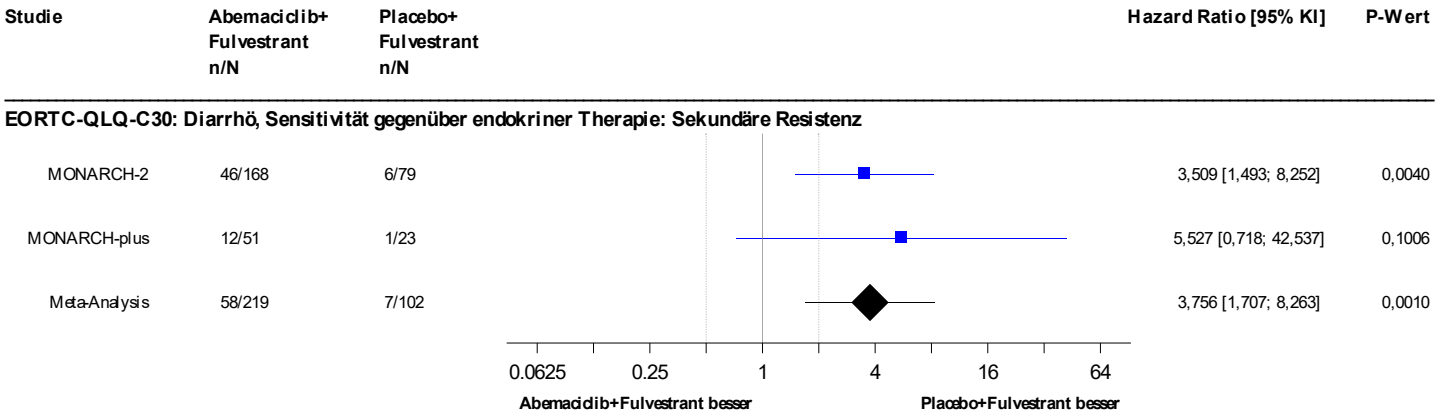
Abbildung 1404.1.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1619, P-Wert=0,6874, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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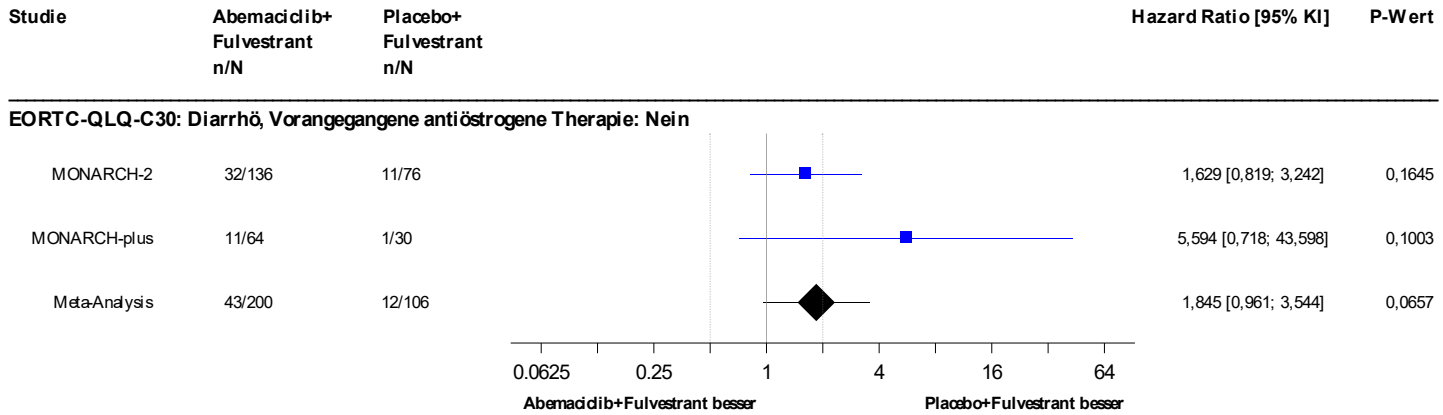
Abbildung 1404.1.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,2469, P-Wert=0,2641, I2 Index=19,8%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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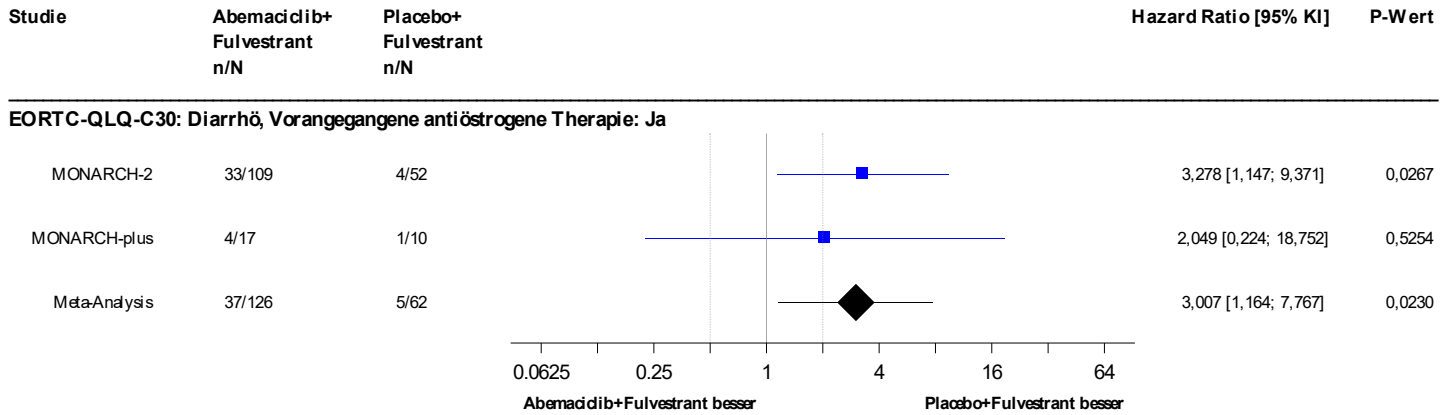
Abbildung 1404.1.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1413, P-Wert=0,7070, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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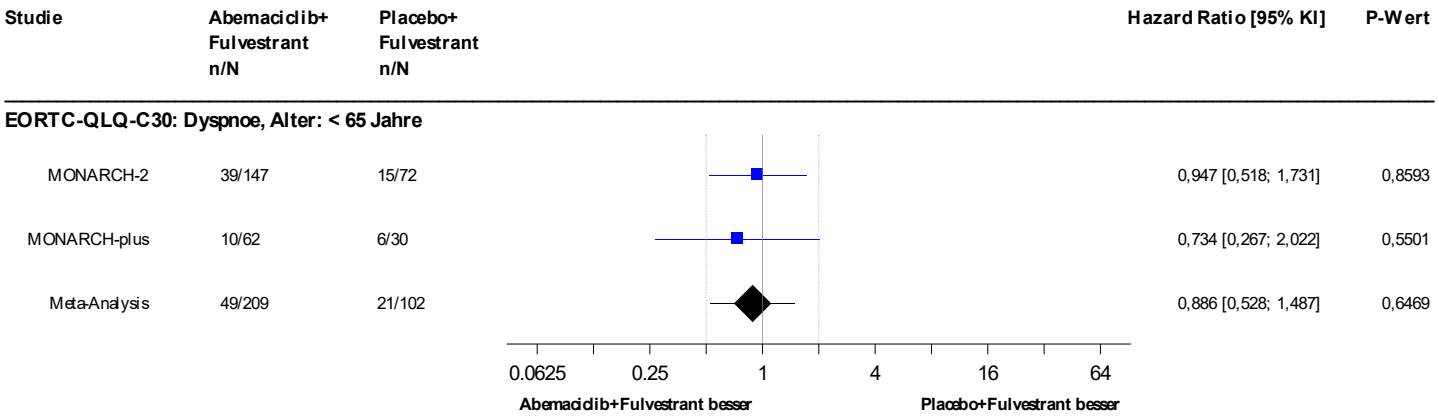
Abbildung 1405.1.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1788, P-Wert=0,6724, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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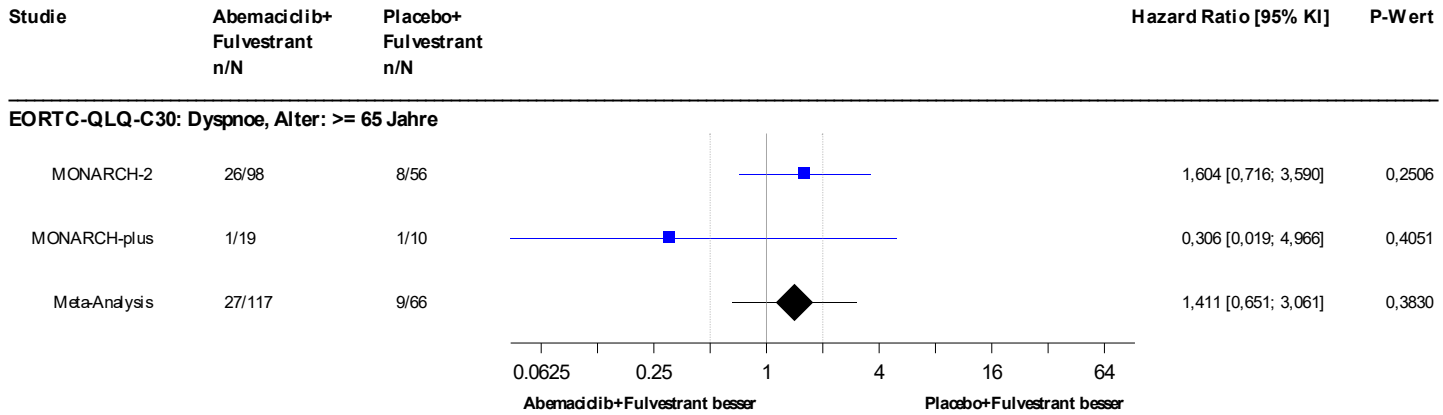
Abbildung 1405.1.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,2523, P-Wert=0,2631, I2 Index=20,1%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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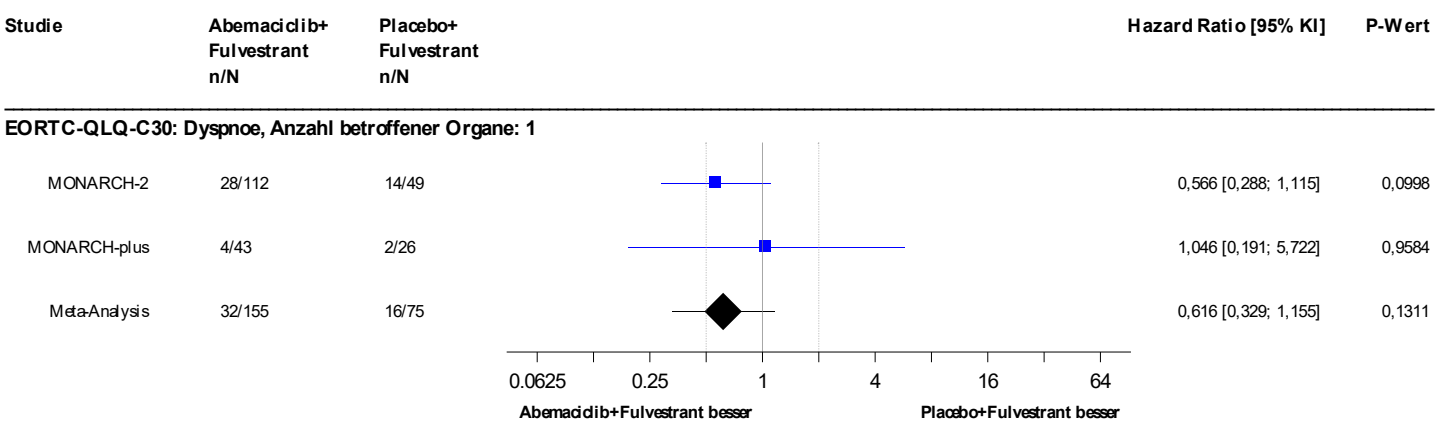
Abbildung 1405.1.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4324, P-Wert=0,5108, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwdysp6_popa1_norggr_1.rtf
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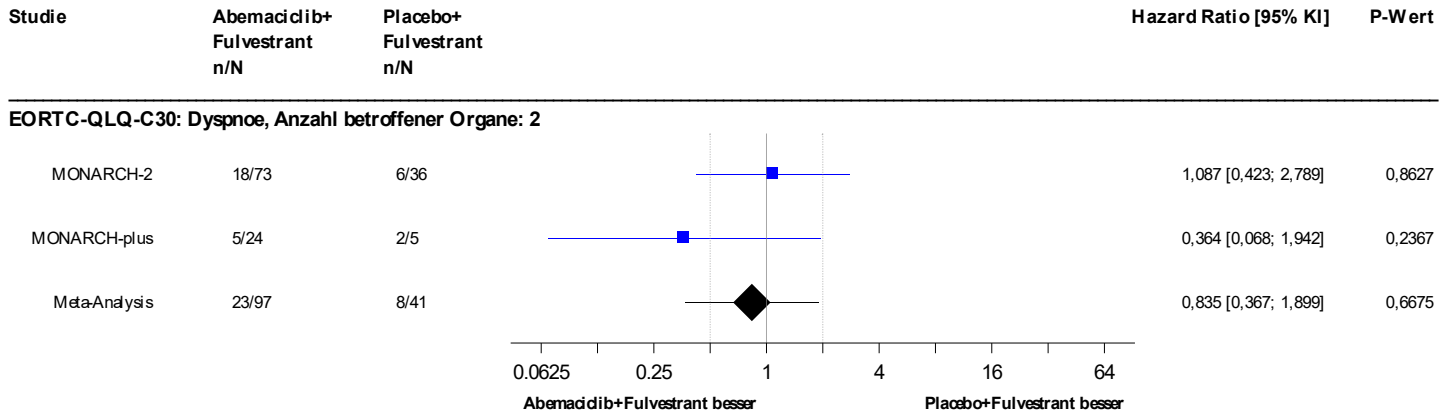
Abbildung 1405.1.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,2453, P-Wert=0,2645, I2 Index=19,7%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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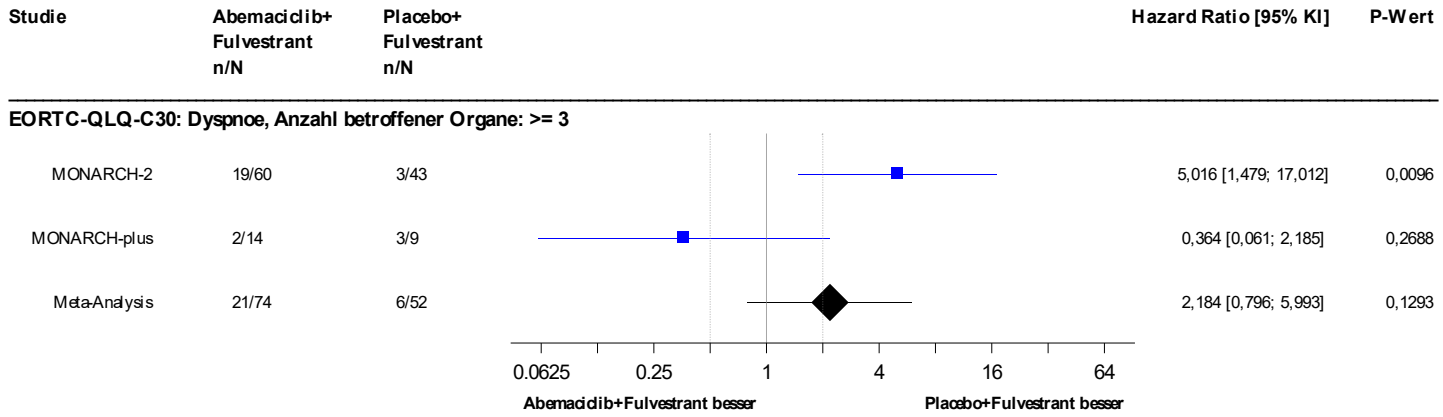
Abbildung 1405.1.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=5,6211, P-Wert=0,0177, I2 Index=82,2%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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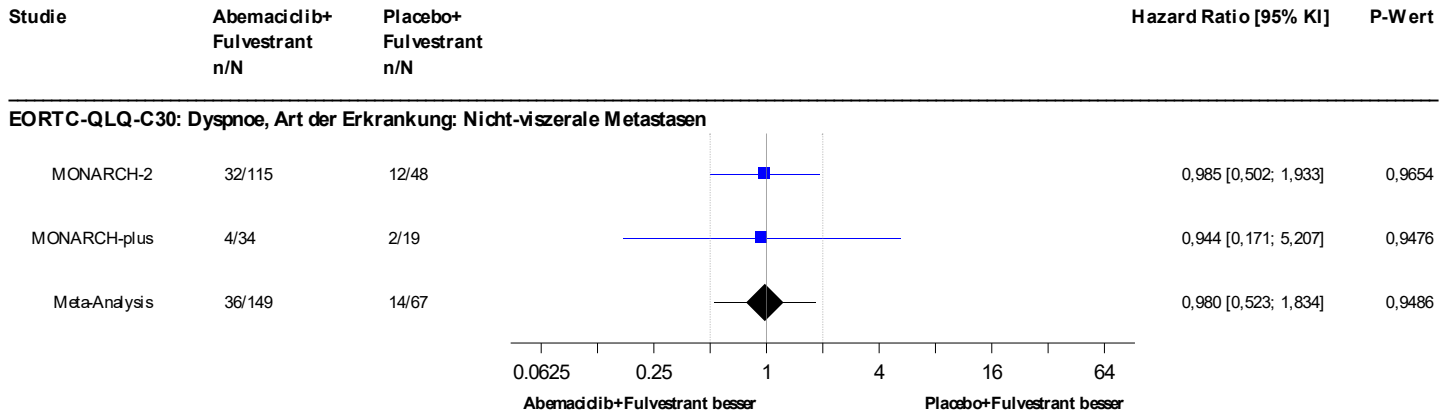
Abbildung 1405.1.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0020, P-Wert=0,9639, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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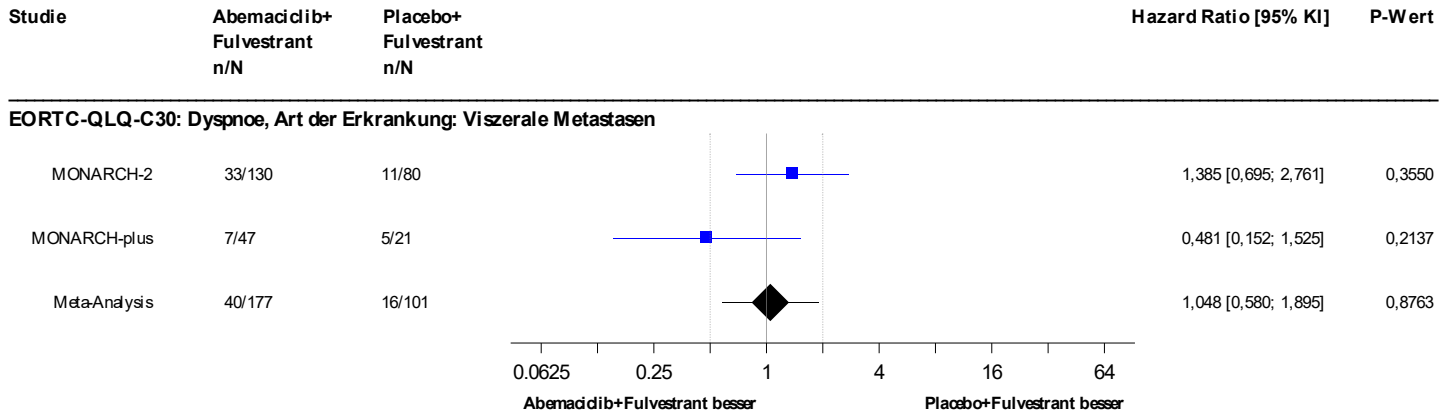
Abbildung 1405.1.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,3774, P-Wert=0,1231, I2 Index=57,9%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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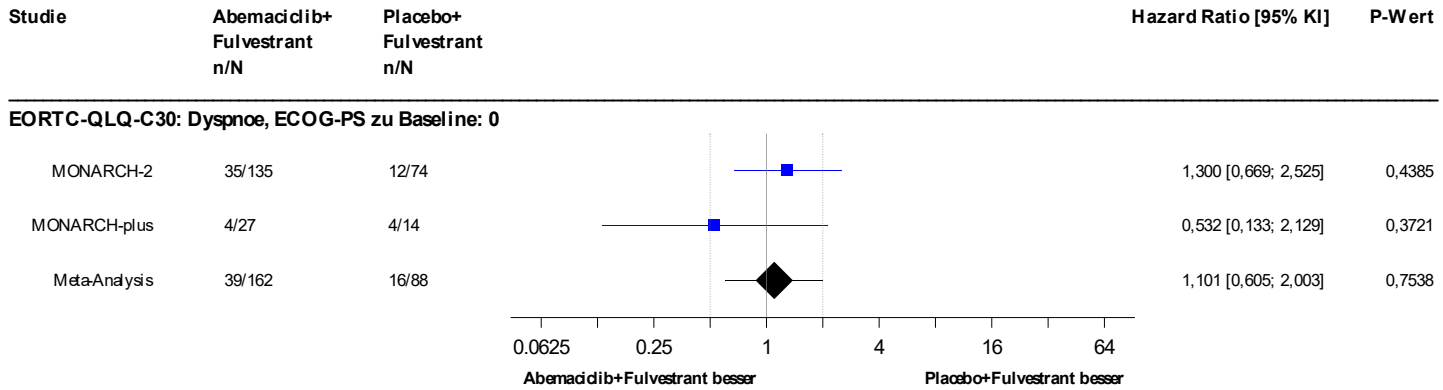
Abbildung 1405.1.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,2985, P-Wert=0,2545, I2 Index=23,0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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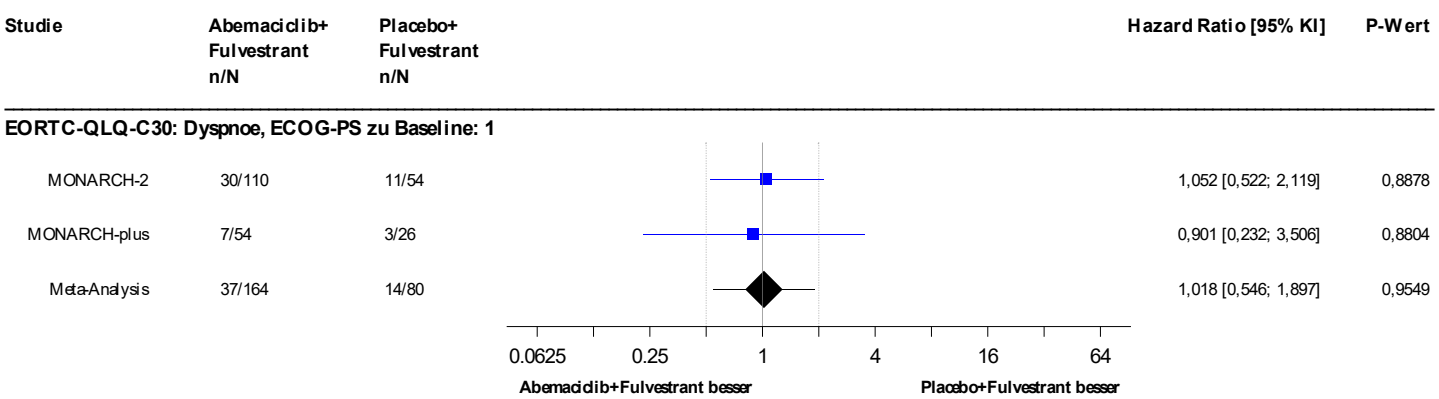
Abbildung 1405.1.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0393, P-Wert=0,8428, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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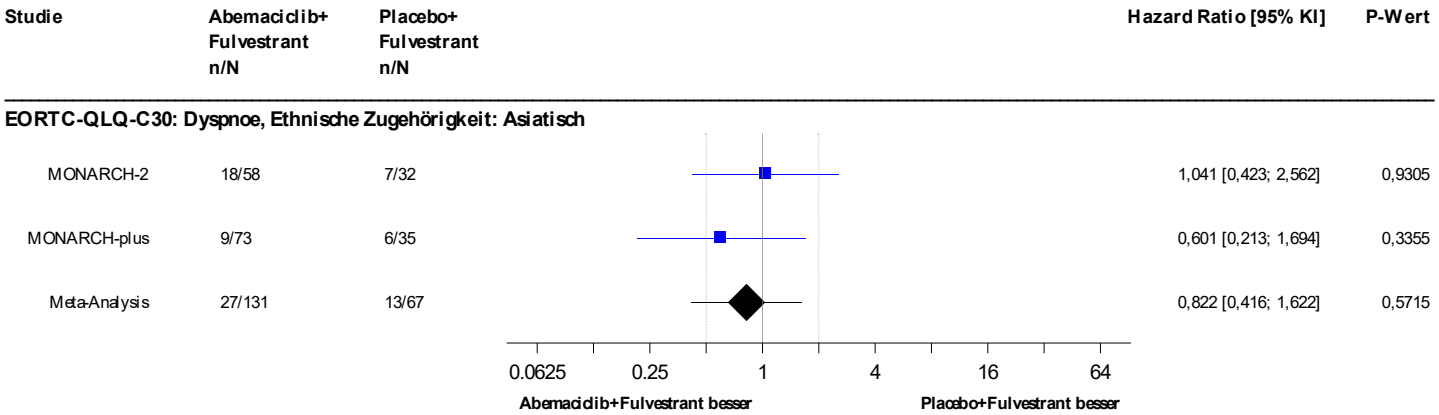
Abbildung 1405.1.5.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6148, P-Wert=0,4330, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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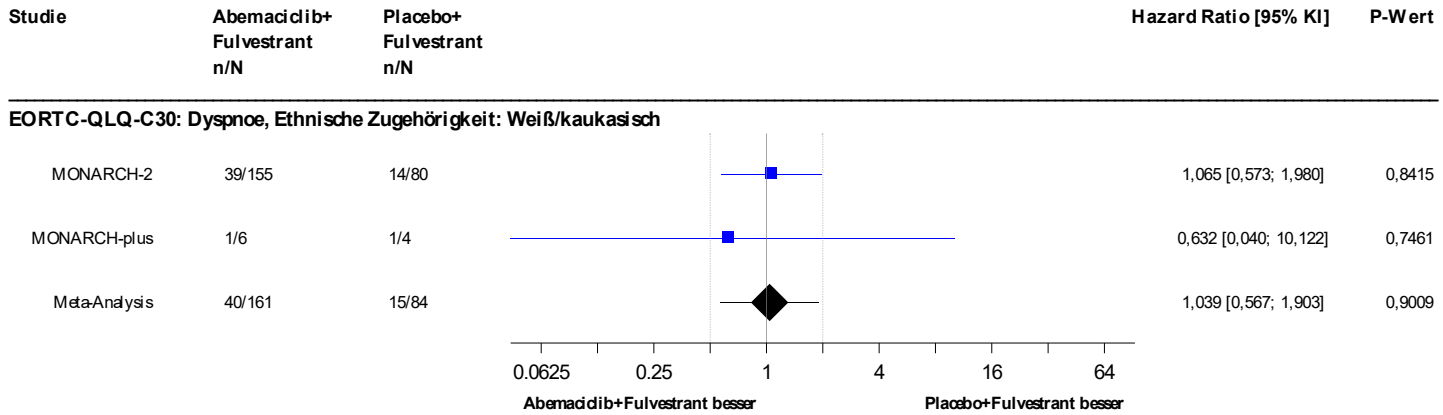
Abbildung 1405.1.5.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1294, P-Wert=0,7191, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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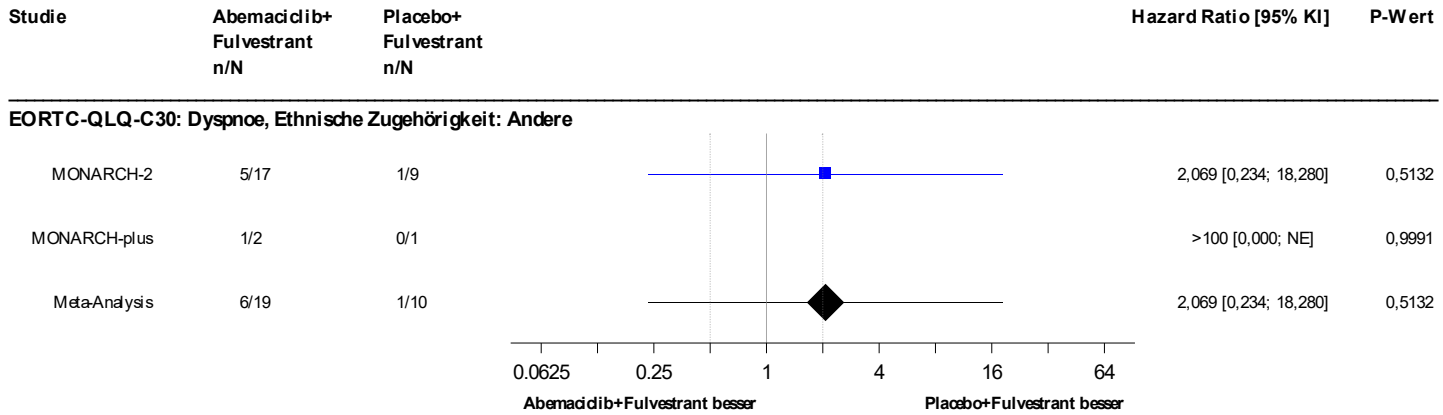
Abbildung 1405.1.5.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9991, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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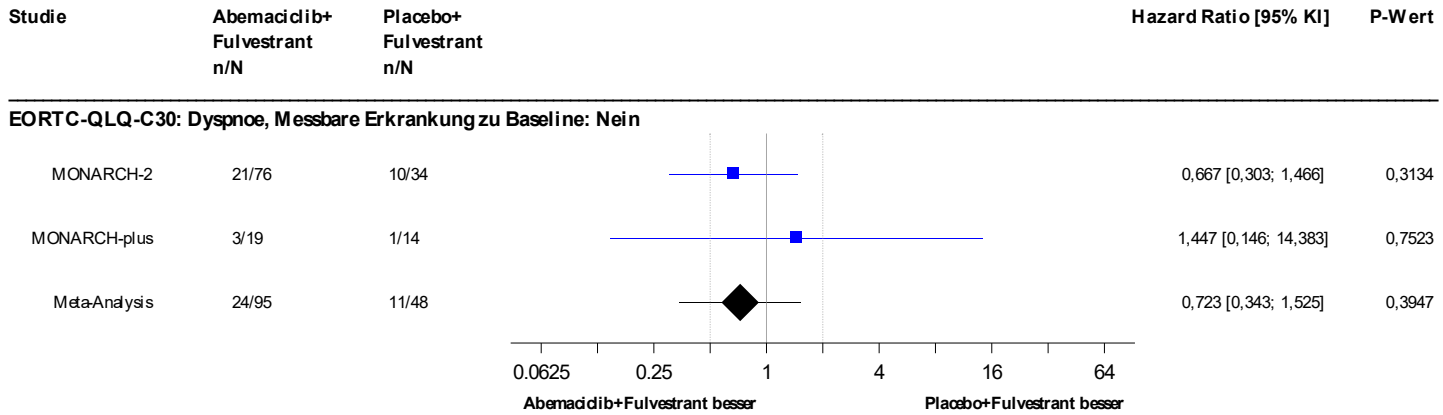
Abbildung 1405.1.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3917, P-Wert=0,5314, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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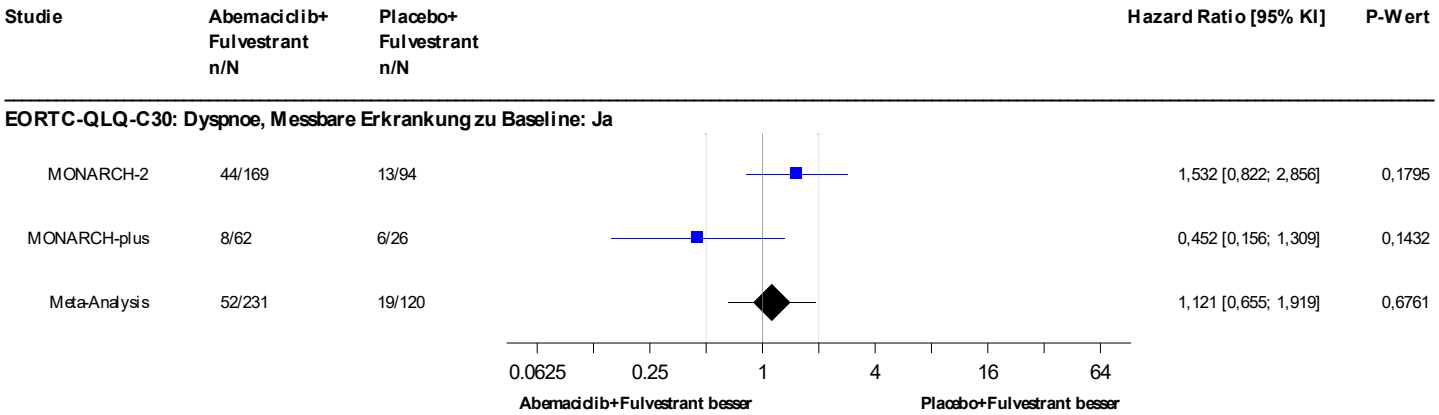
Abbildung 1405.1.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=3,7703, P-Wert=0,0522, I2 Index=73,5%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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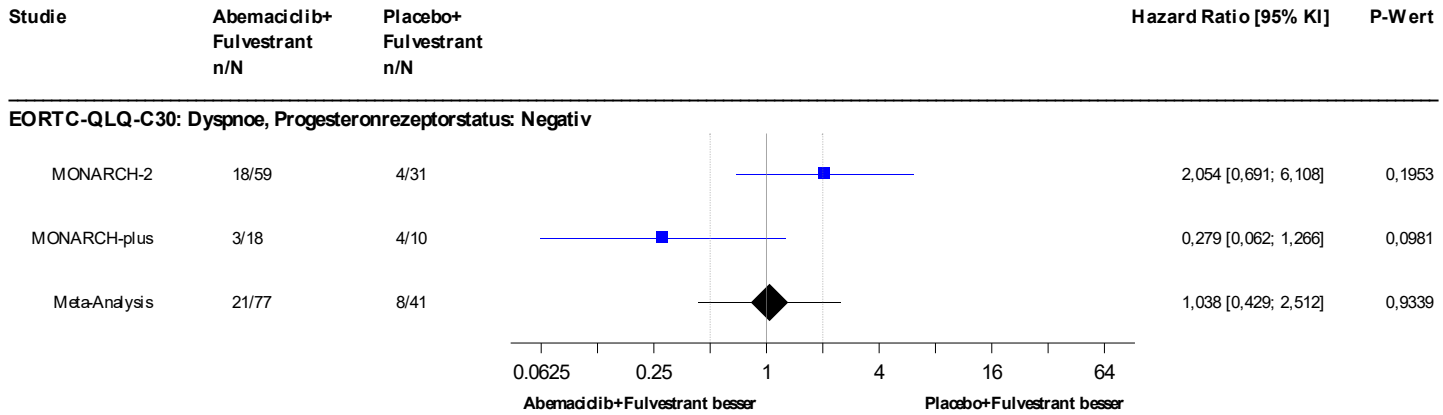
Abbildung 1405.1.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=4,4070, P-Wert=0,0358, I2 Index=77,3%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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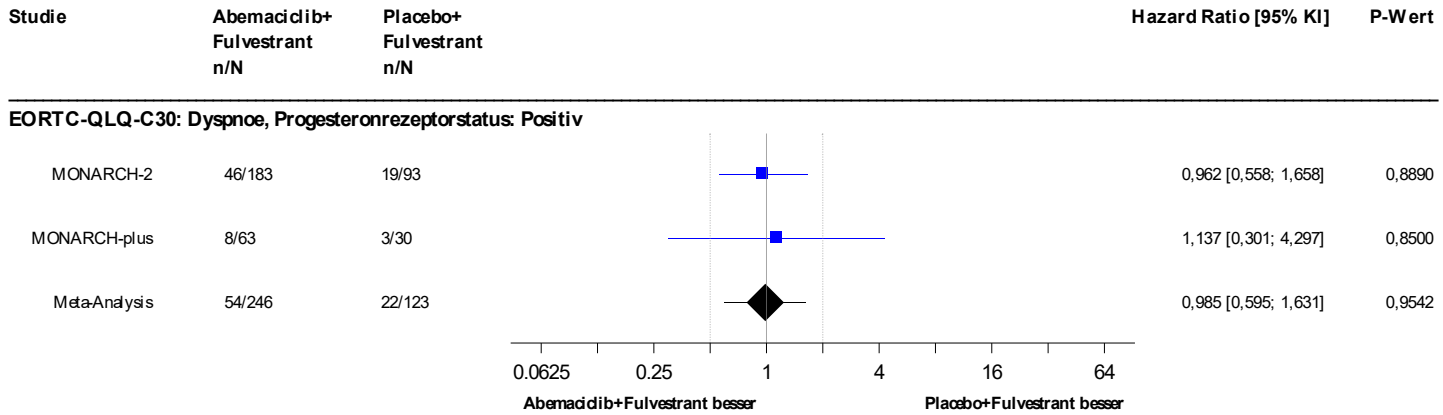
Abbildung 1405.1.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0519, P-Wert=0,8197, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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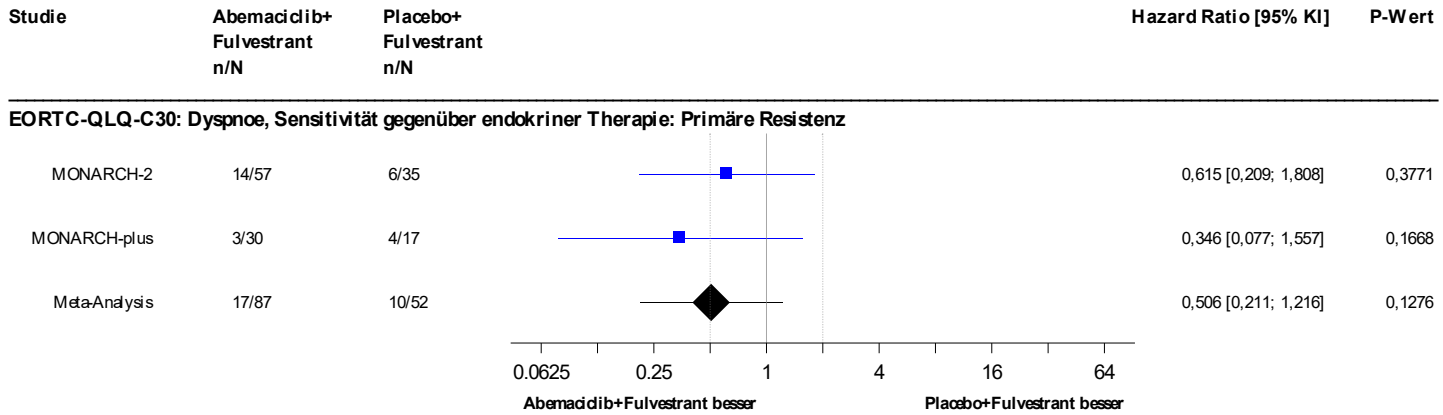
Abbildung 1405.1.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3711, P-Wert=0,5424, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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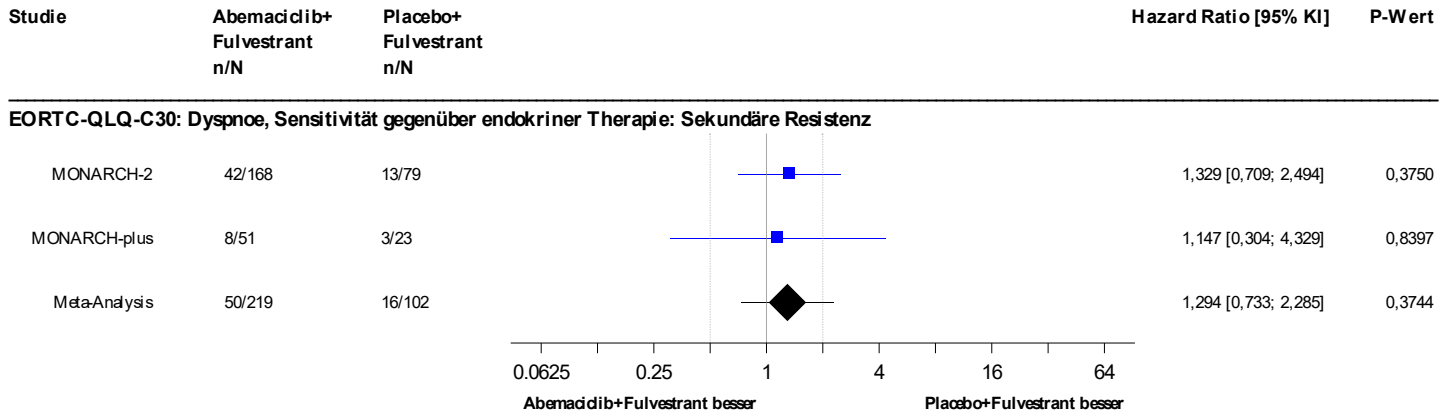
Abbildung 1405.1.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0388, P-Wert=0,8439, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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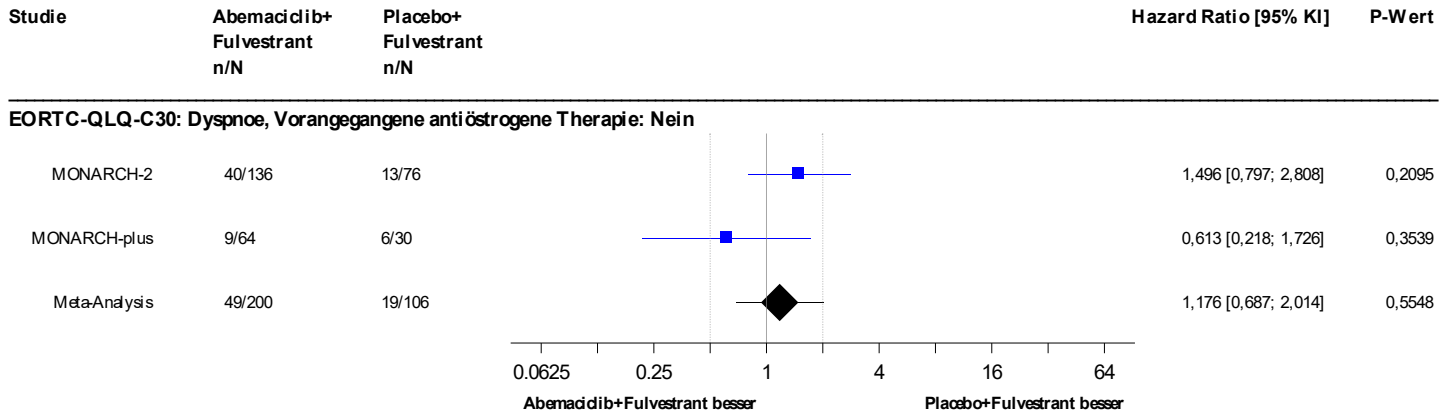
Abbildung 1405.1.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,0854, P-Wert=0,1487, I2 Index=52,0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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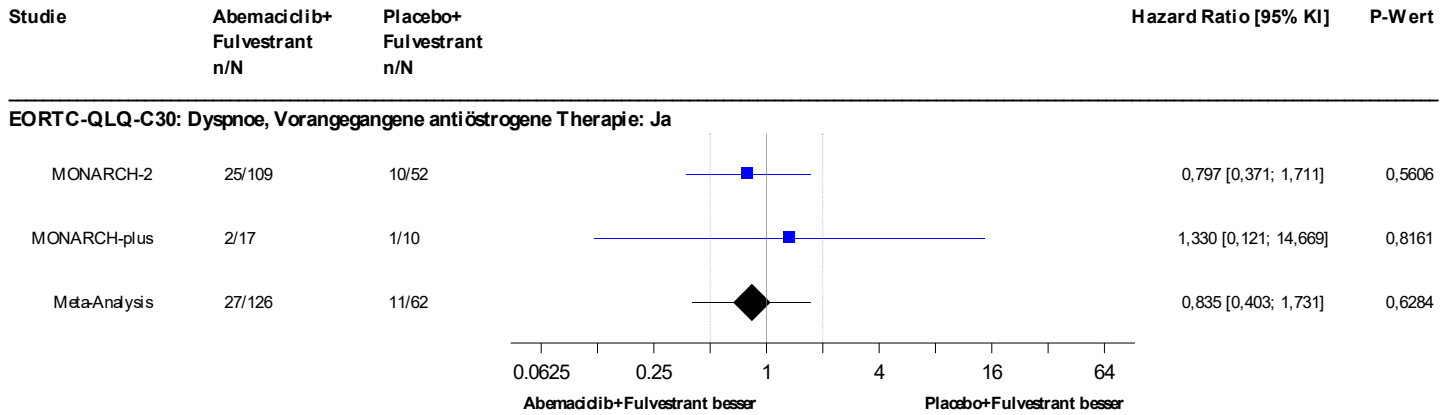
Abbildung 1405.1.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1586, P-Wert=0,6905, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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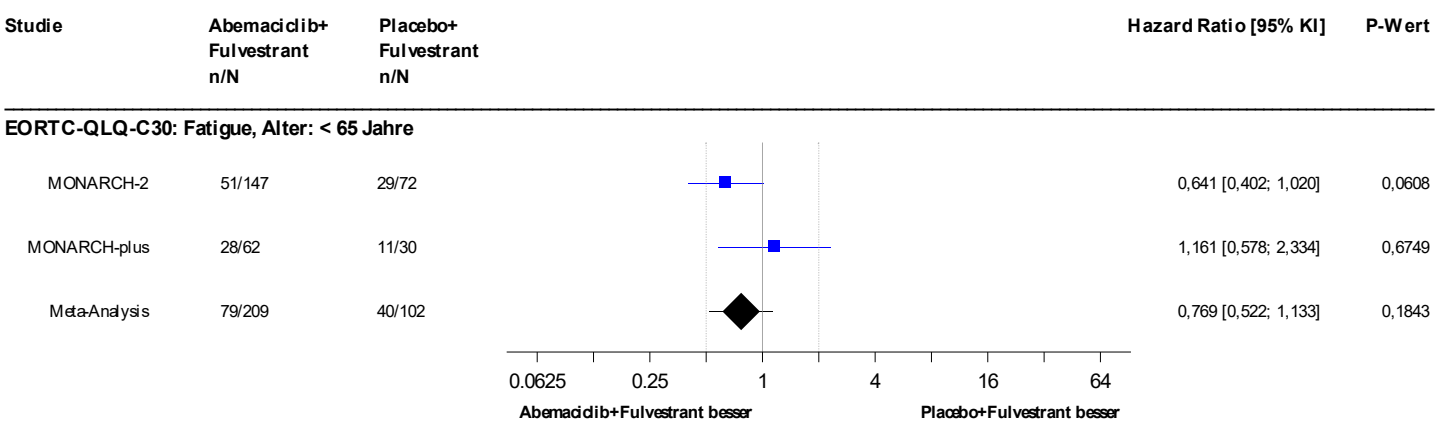
Abbildung 1406.1.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,9300, P-Wert=0,1648, I2 Index=48,2%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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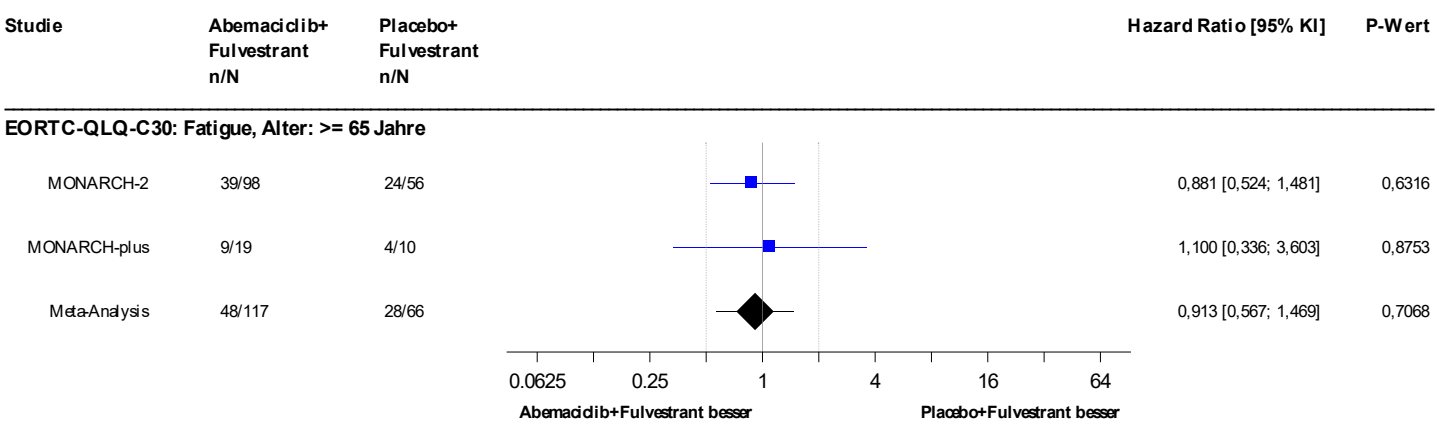
Abbildung 1406.1.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1130, P-Wert=0,7368, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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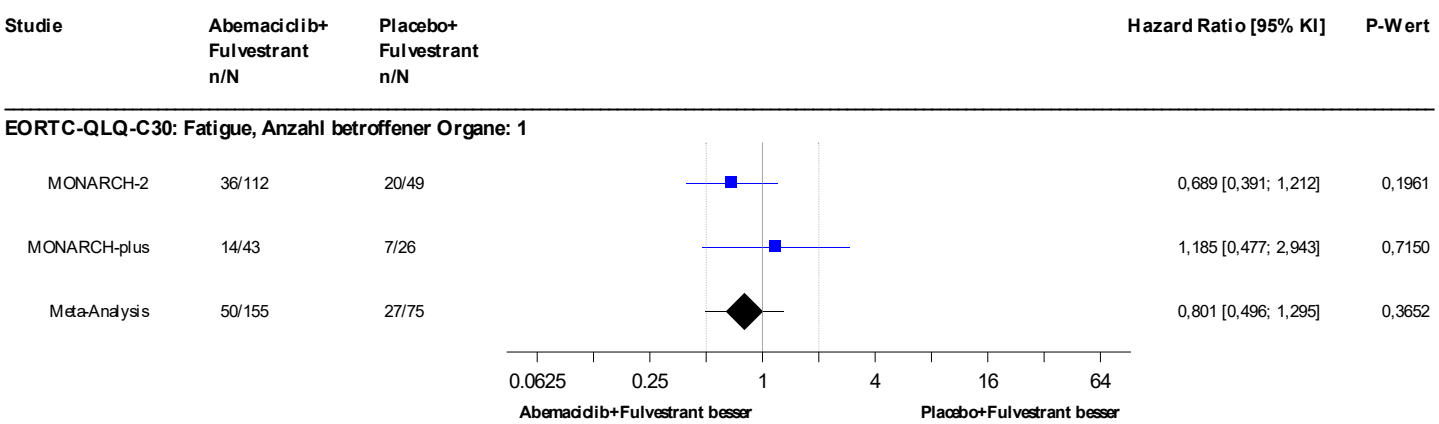
Abbildung 1406.1.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,9846, P-Wert=0,3211, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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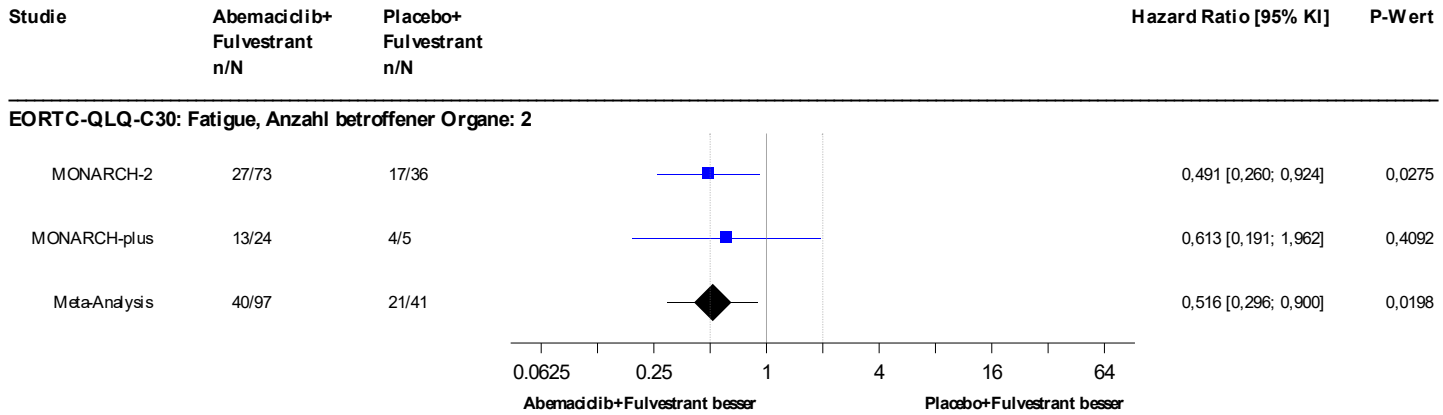
Abbildung 1406.1.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1078, P-Wert=0,7426, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwfati6_popa1_norggr_2.rtf
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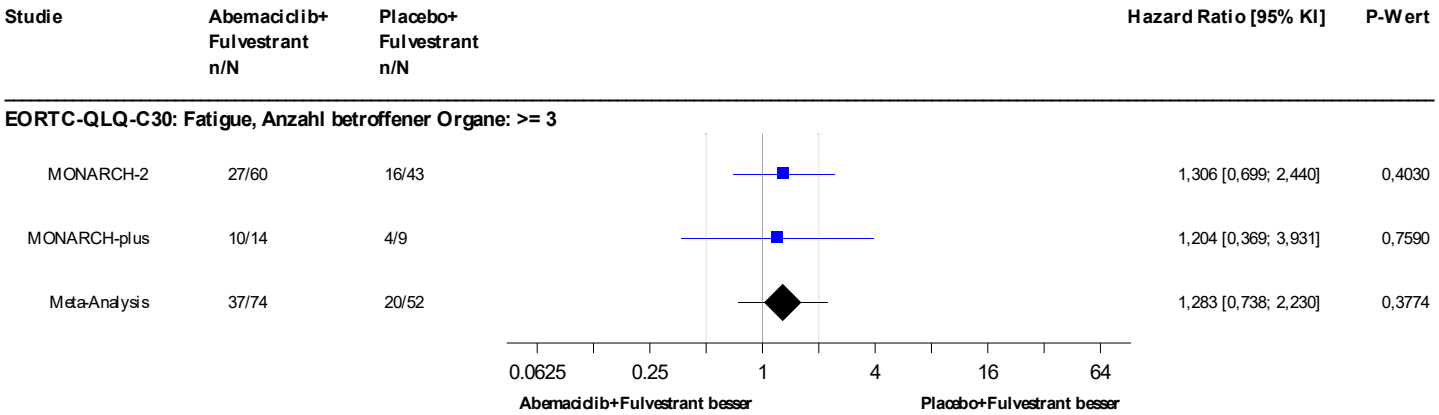
Abbildung 1406.1.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0142, P-Wert=0,9050, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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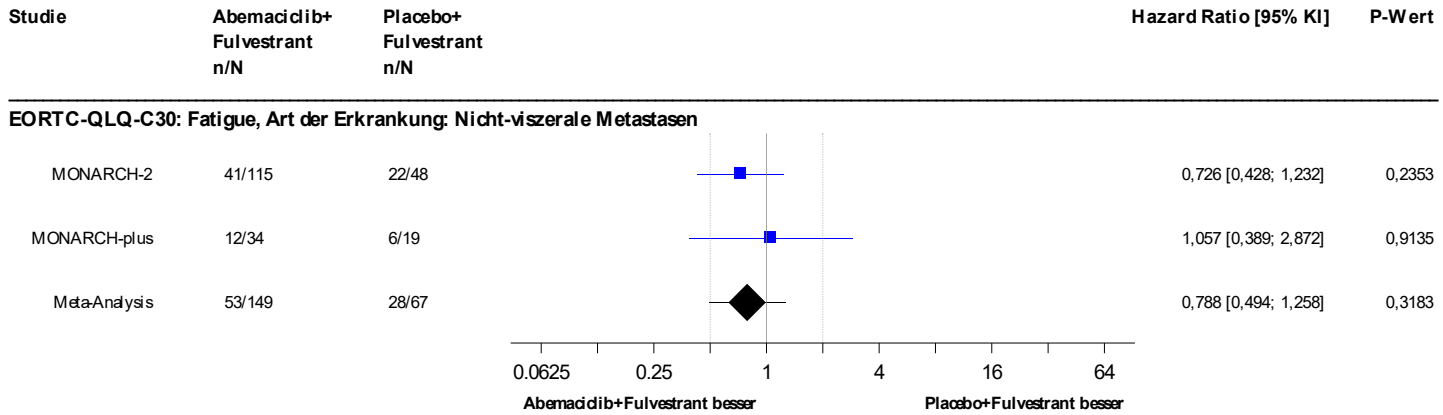
Abbildung 1406.1.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4243, P-Wert=0,5148, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwfati6_popa1_natdis2_1.rtf
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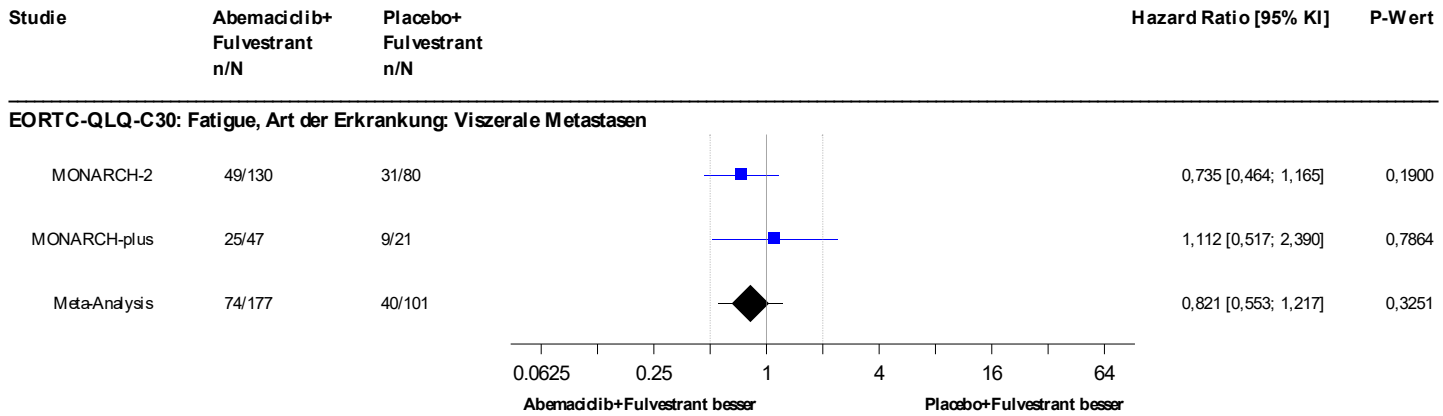
Abbildung 1406.1.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,8227, P-Wert=0,3644, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwfati6_popa1_natdis2_2.rtf
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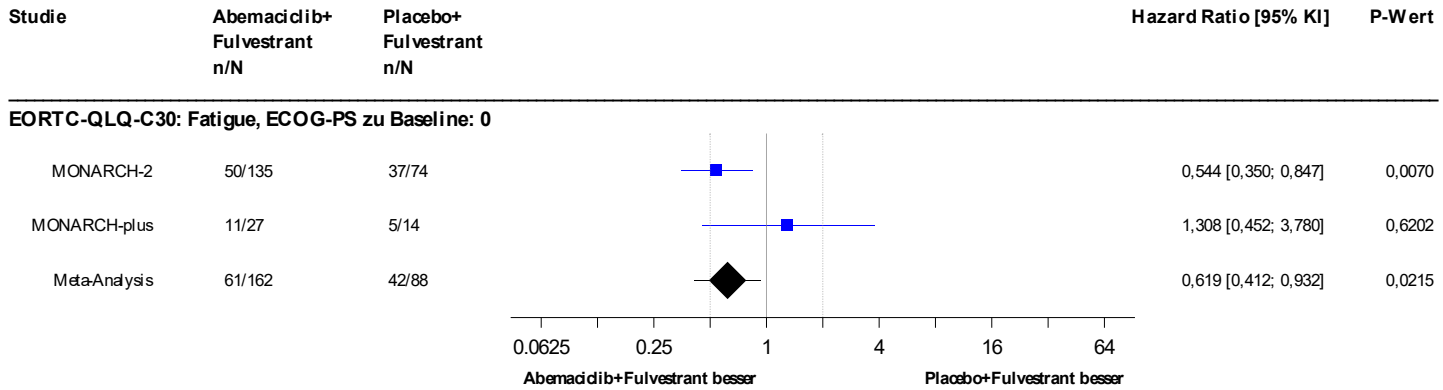
Abbildung 1406.1.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,2344, P-Wert=0,1350, I2 Index=55,2%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwfati6_popa1_ecogbl_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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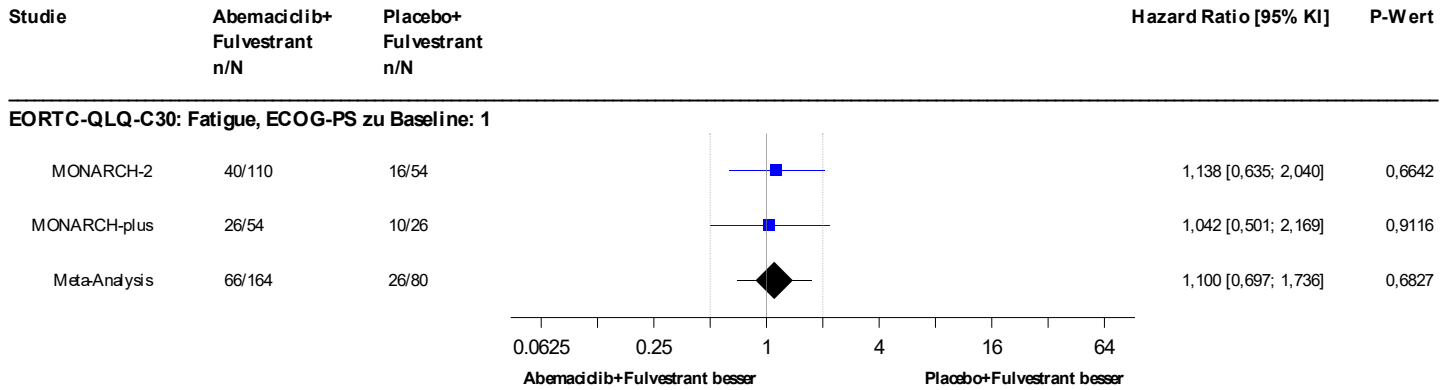
Abbildung 1406.1.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0337, P-Wert=0,8543, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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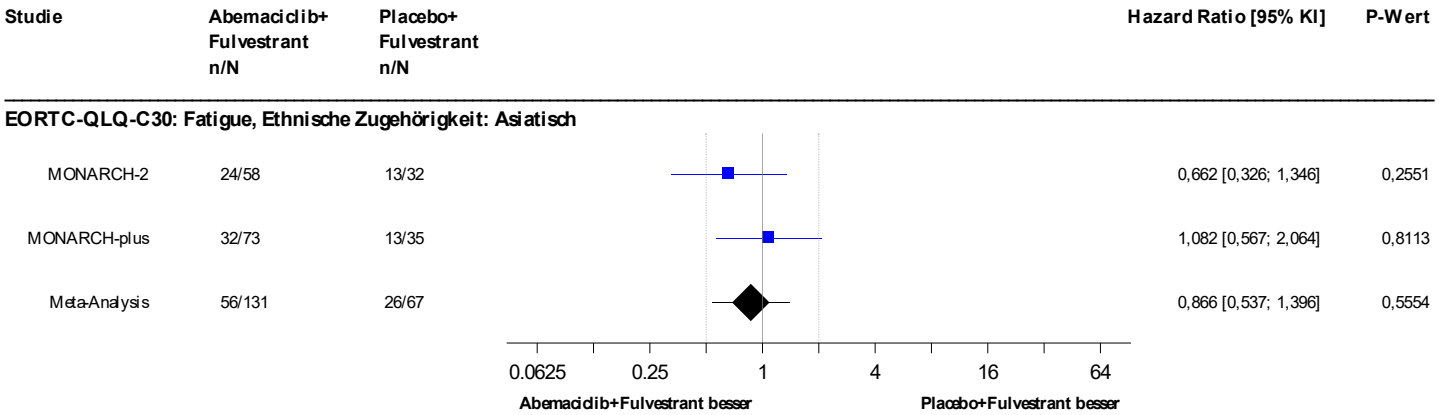
Abbildung 1406.1.5.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,0044, P-Wert=0,3162, I2 Index=0,4%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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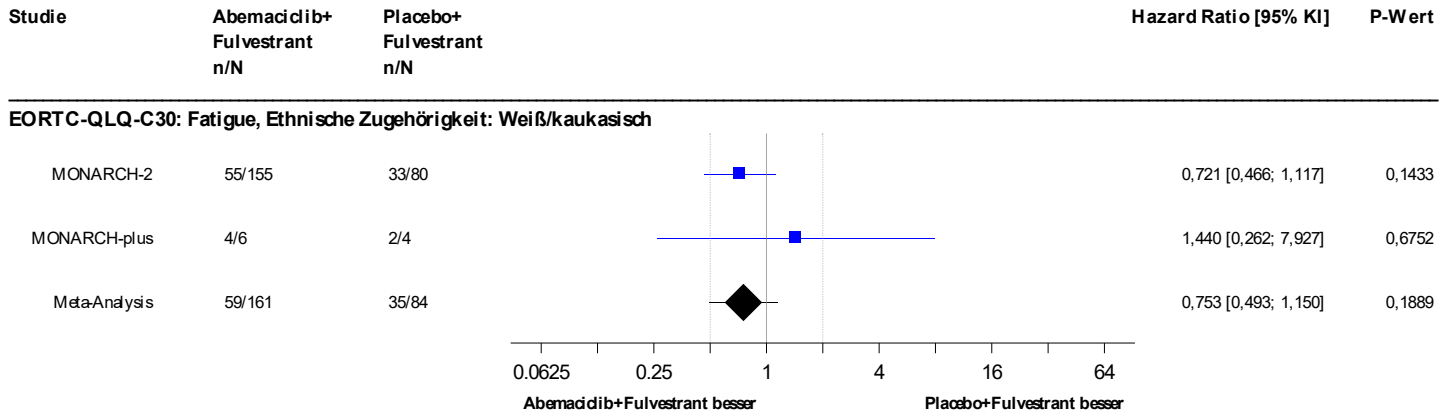
Abbildung 1406.1.5.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,5923, P-Wert=0,4415, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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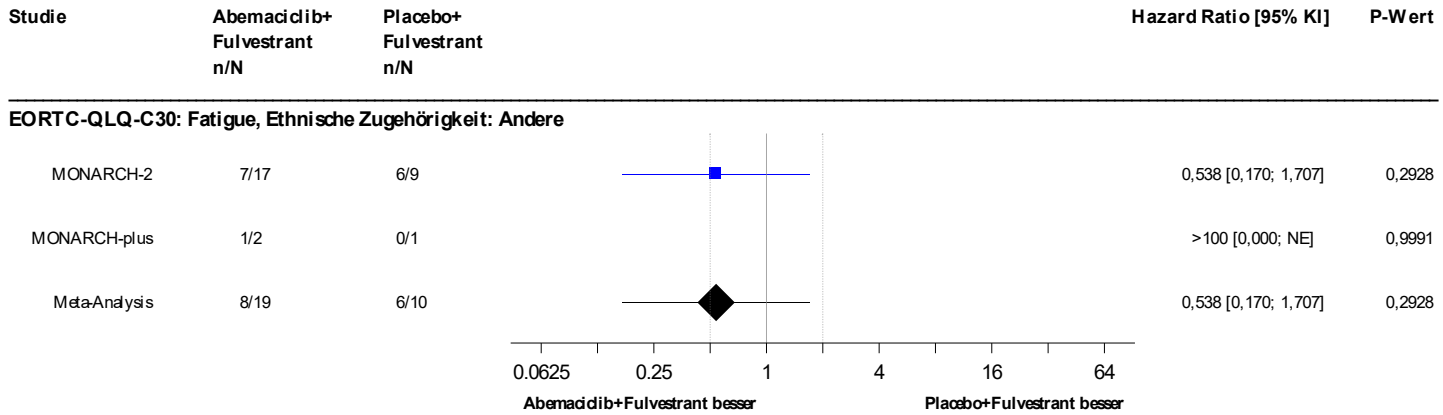
Abbildung 1406.1.5.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9990, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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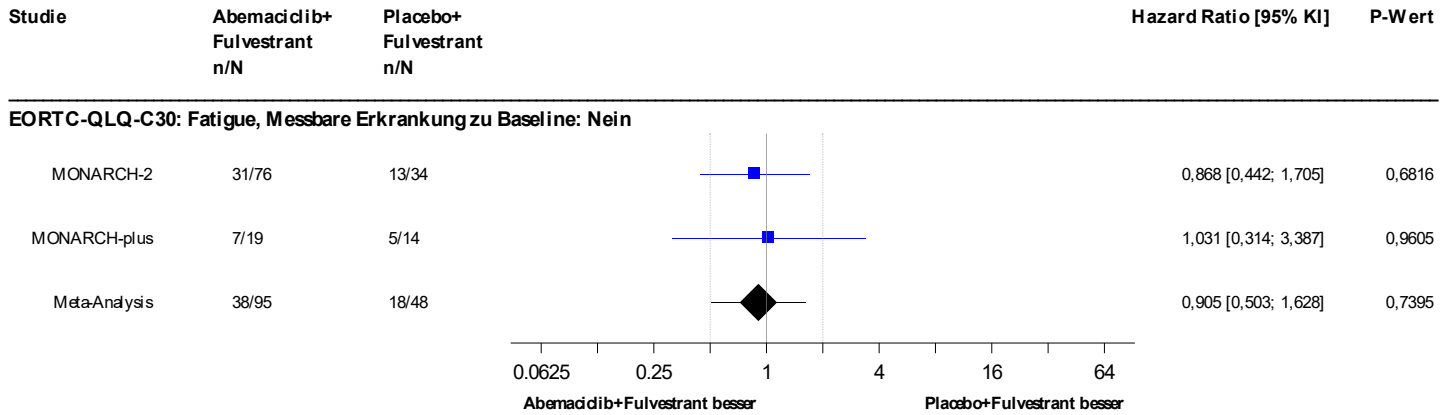
Abbildung 1406.1.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0602, P-Wert=0,8061, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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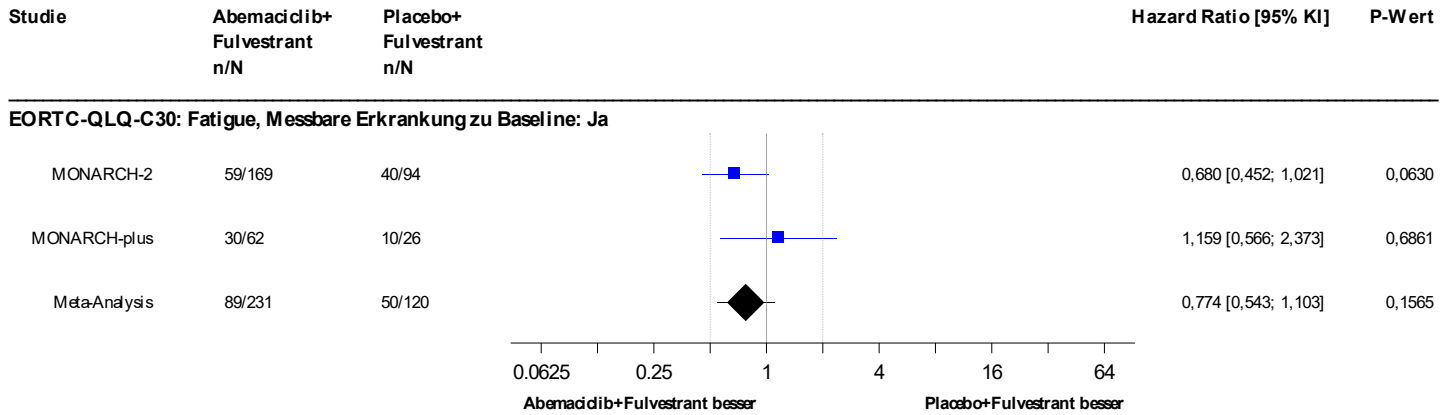
Abbildung 1406.1.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,6131, P-Wert=0,2041, I2 Index=38,0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwfati6_popa1_measdis_2.rtf
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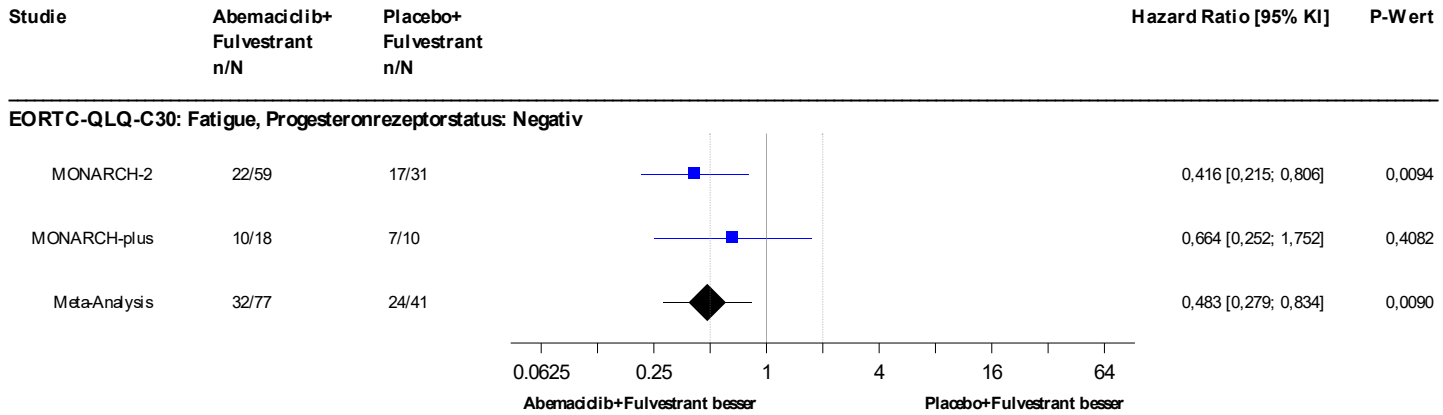
Abbildung 1406.1.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6103, P-Wert=0,4347, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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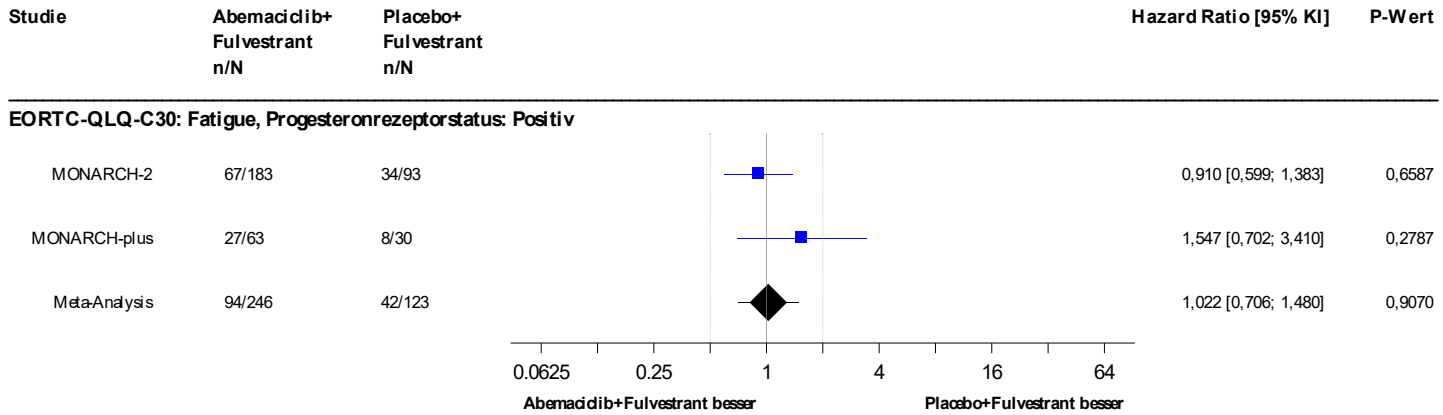
Abbildung 1406.1.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,3547, P-Wert=0,2445, I2 Index=26,2%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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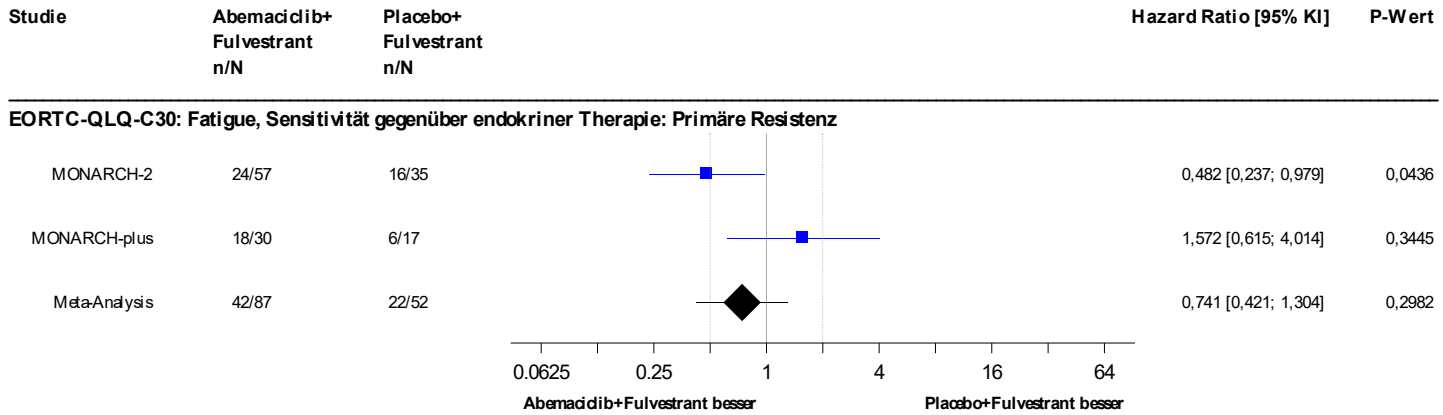
Abbildung 1406.1.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=3,8837, P-Wert=0,0488, I2 Index=74,3%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwfati6_popa1_snthr_1.rtf
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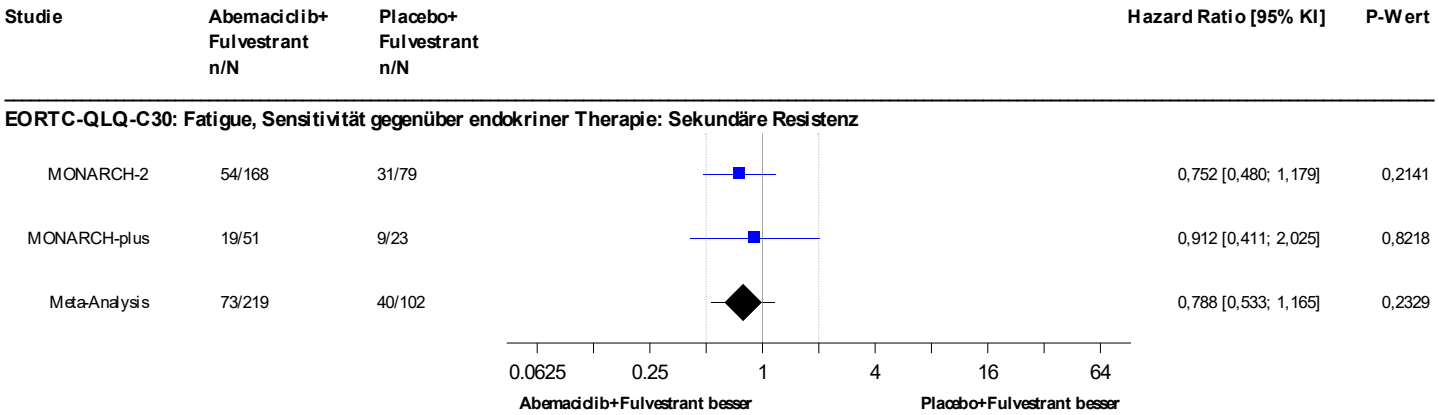
Abbildung 1406.1.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1708, P-Wert=0,6794, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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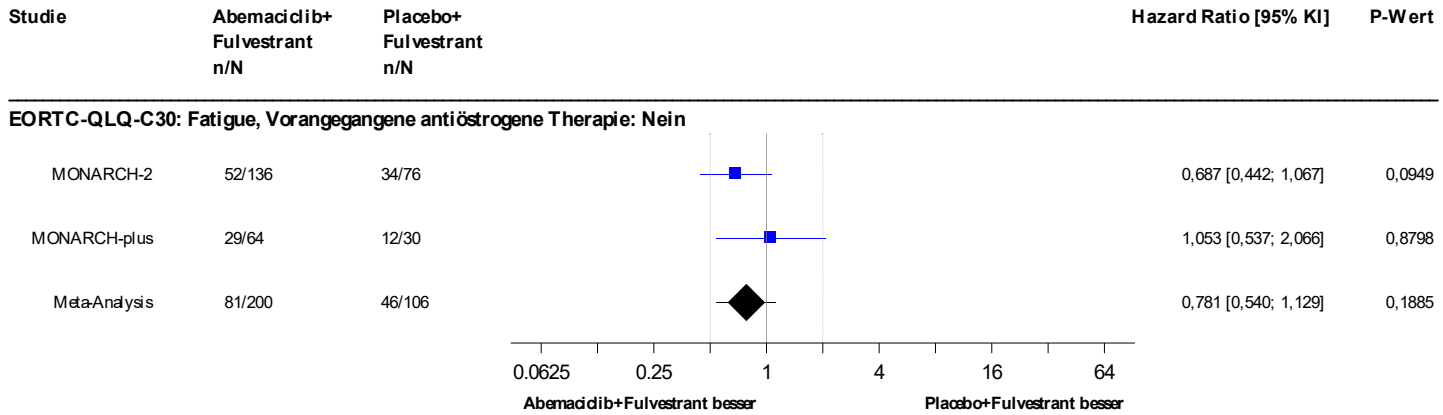
Abbildung 1406.1.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,0826, P-Wert=0,2981, I2 Index=7,6%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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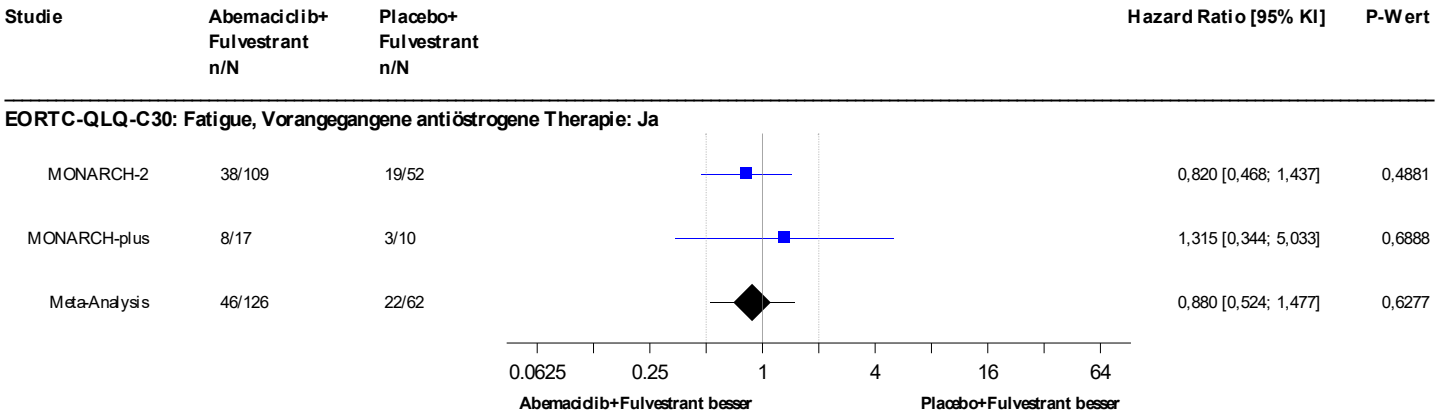
Abbildung 1406.1.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4058, P-Wert=0,5241, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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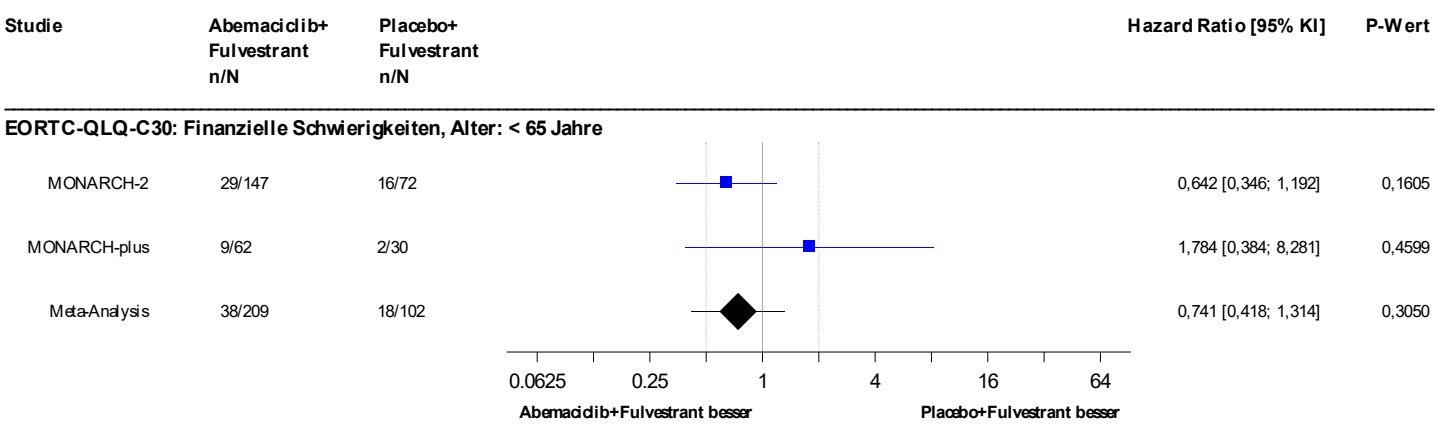
Abbildung 1407.1.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,4631, P-Wert=0,2264, I2 Index=31,7%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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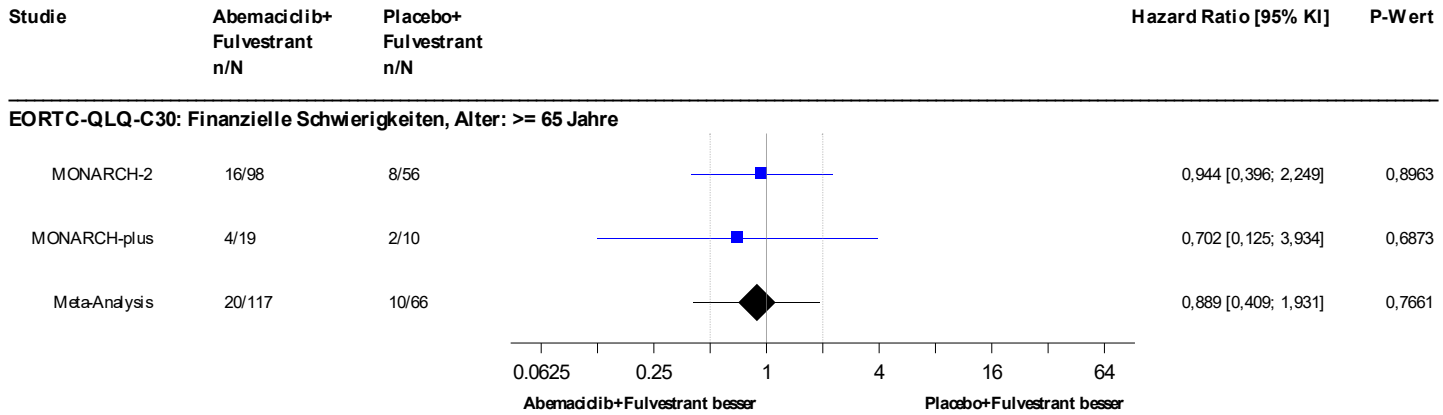
Abbildung 1407.1.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0905, P-Wert=0,7636, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwfind6_popa1_agegr1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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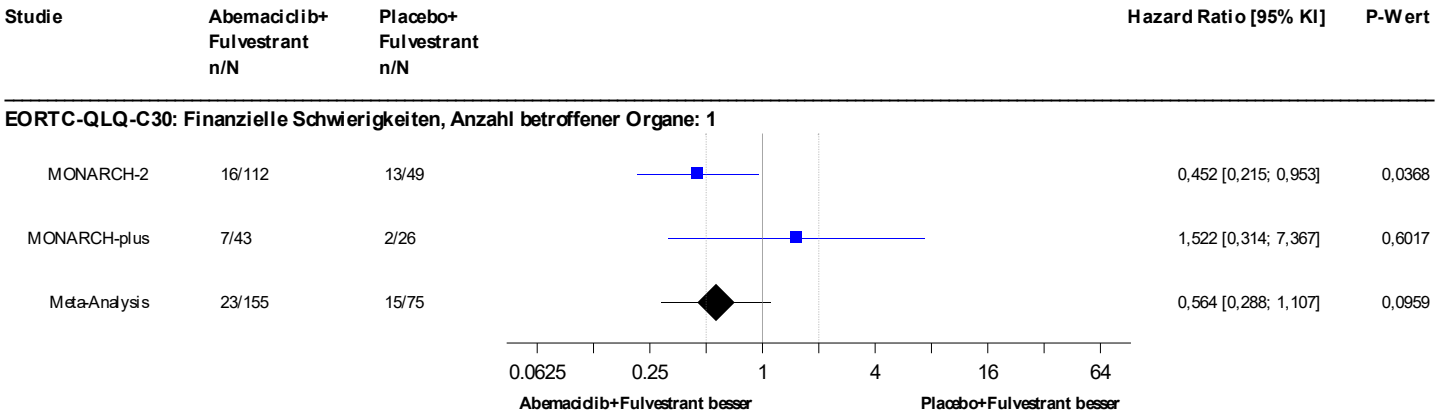
Abbildung 1407.1.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,8586, P-Wert=0,1728, I2 Index=46,2%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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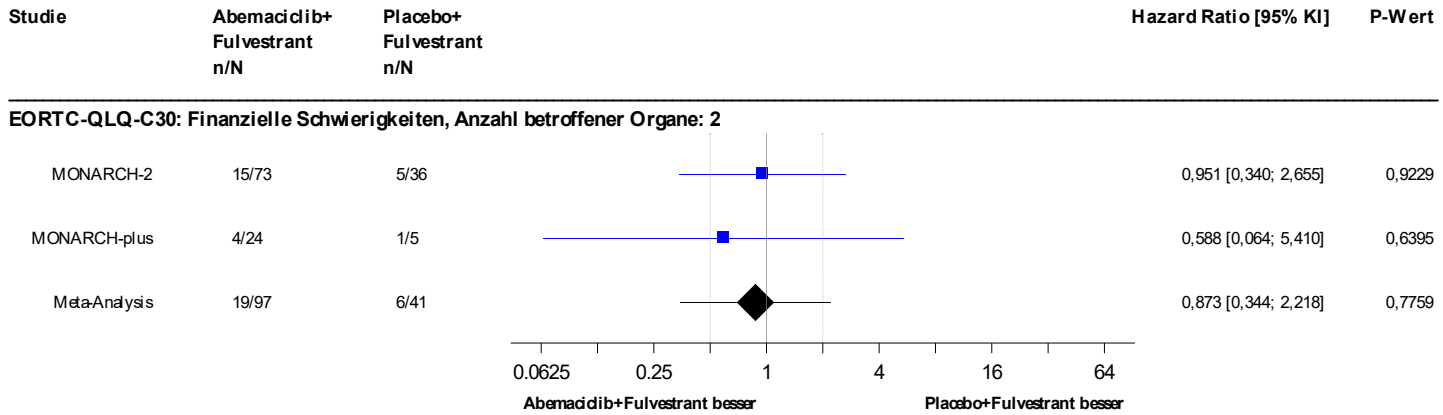
Abbildung 1407.1.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1478, P-Wert=0,7007, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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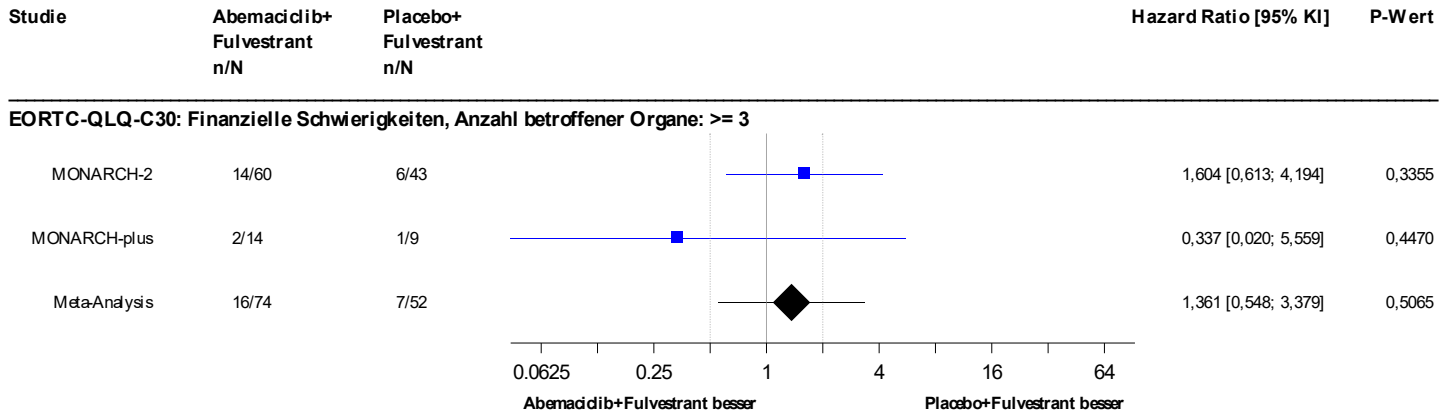
Abbildung 1407.1.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,0645, P-Wert=0,3022, I2 Index=6,1%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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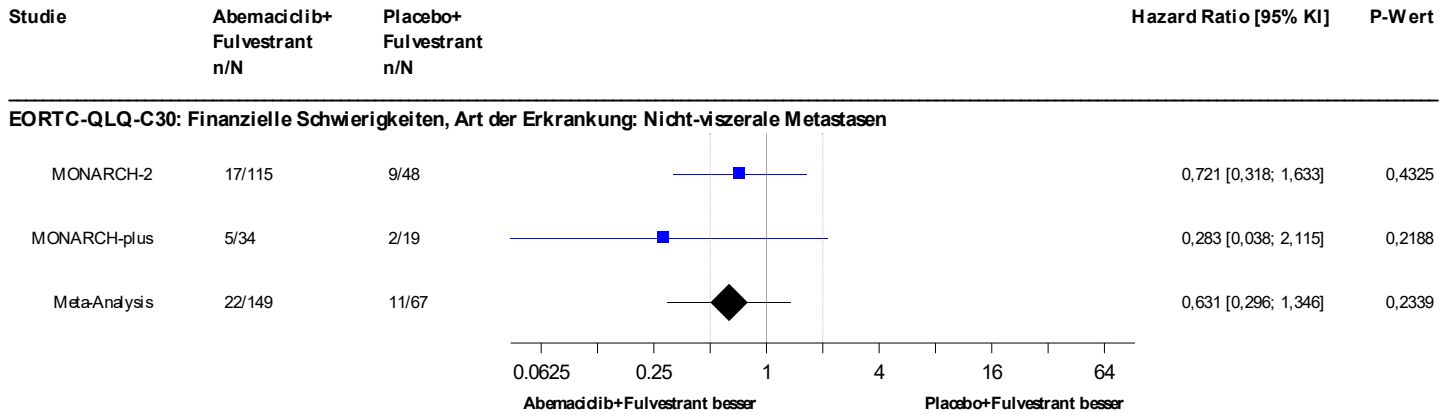
Abbildung 1407.1.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7114, P-Wert=0,3990, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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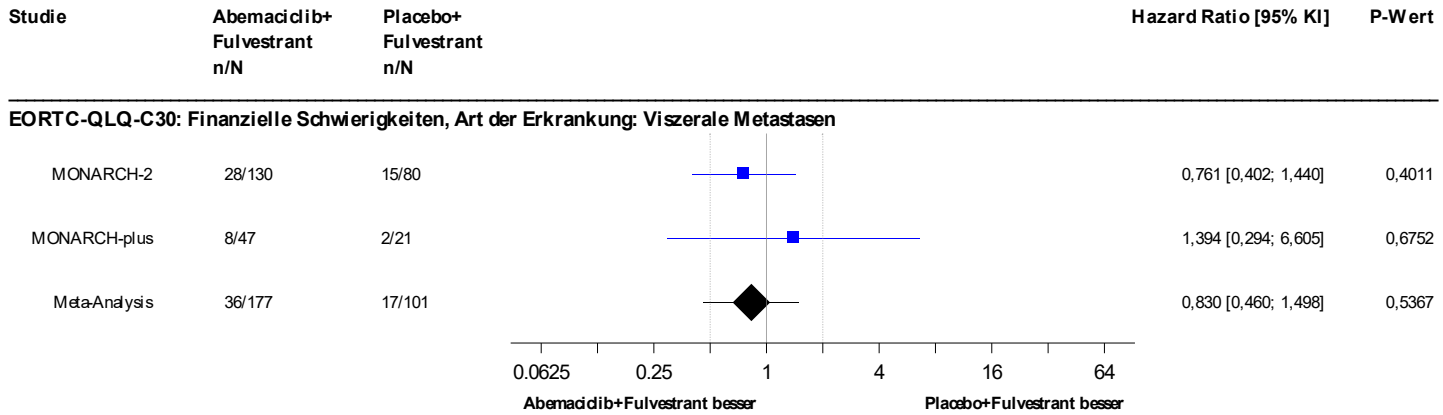
Abbildung 1407.1.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4990, P-Wert=0,4799, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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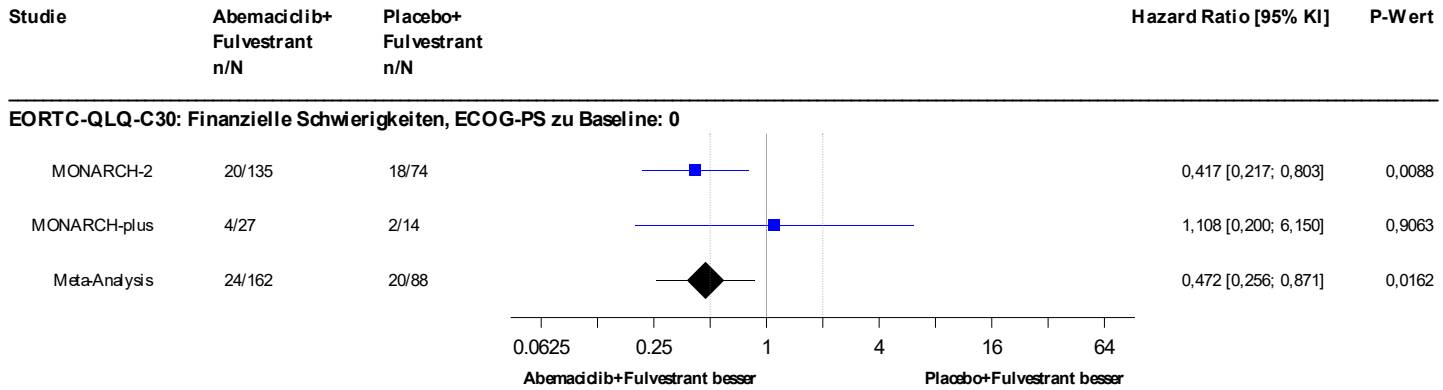
Abbildung 1407.1.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,0911, P-Wert=0,2962, I2 Index=8,4%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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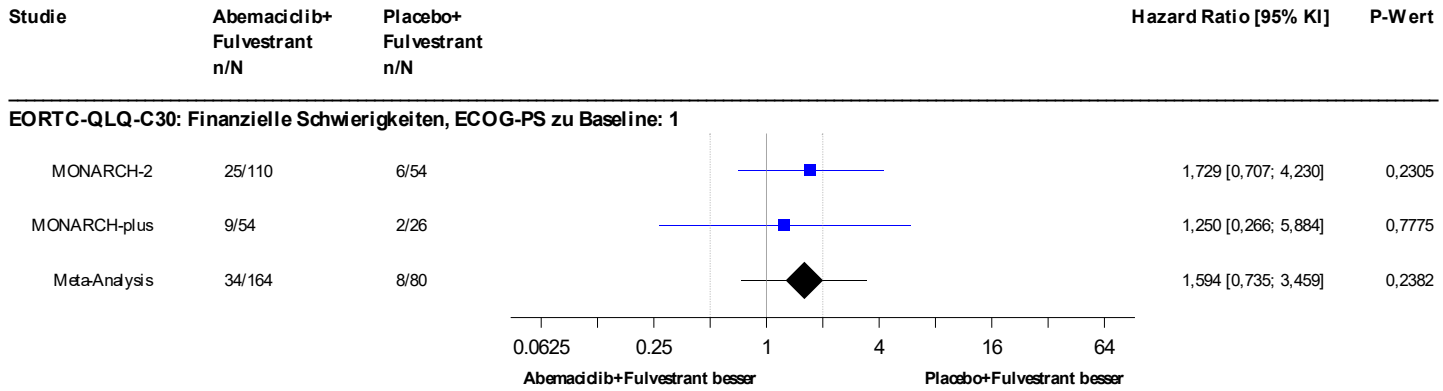
Abbildung 1407.1.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1261, P-Wert=0,7225, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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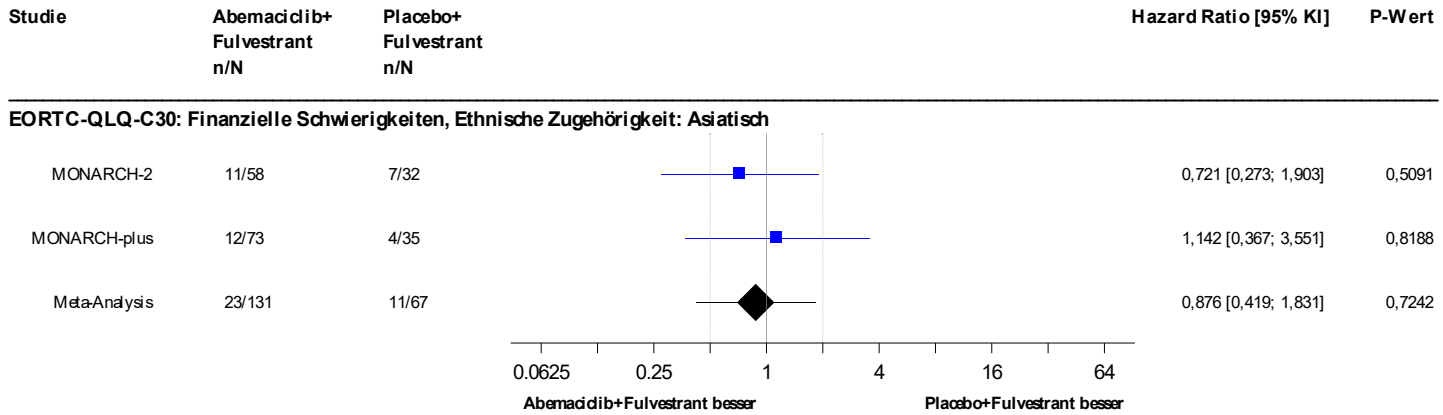
Abbildung 1407.1.5.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3639, P-Wert=0,5463, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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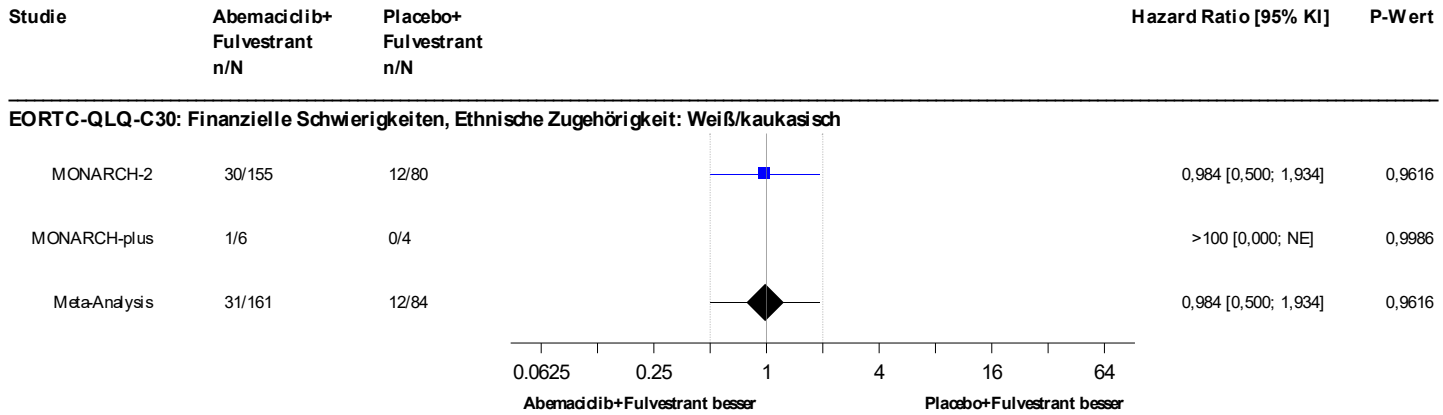
Abbildung 1407.1.5.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9986, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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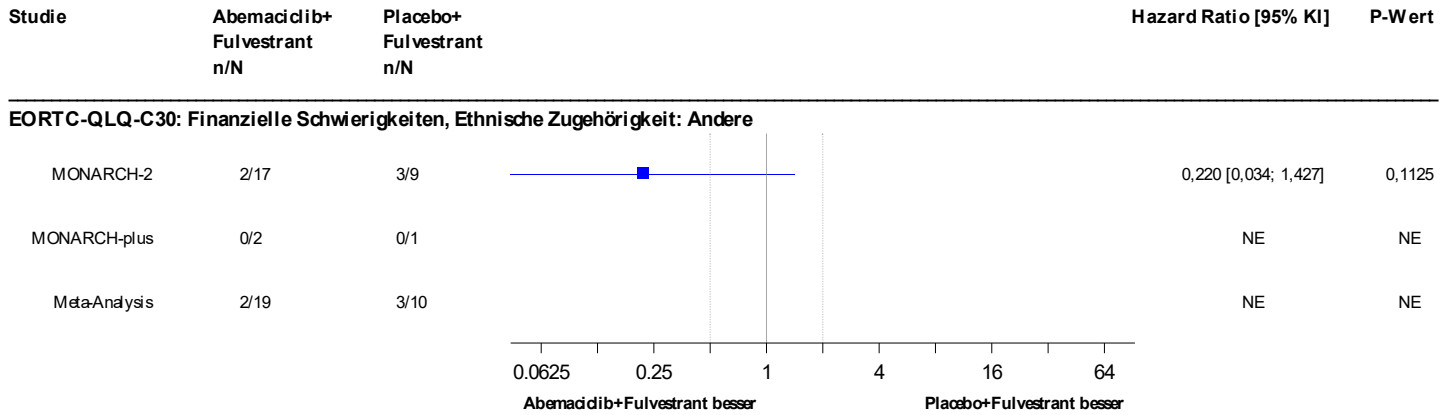
Abbildung 1407.1.5.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwfind6_popa1_racegr1_3.rtf
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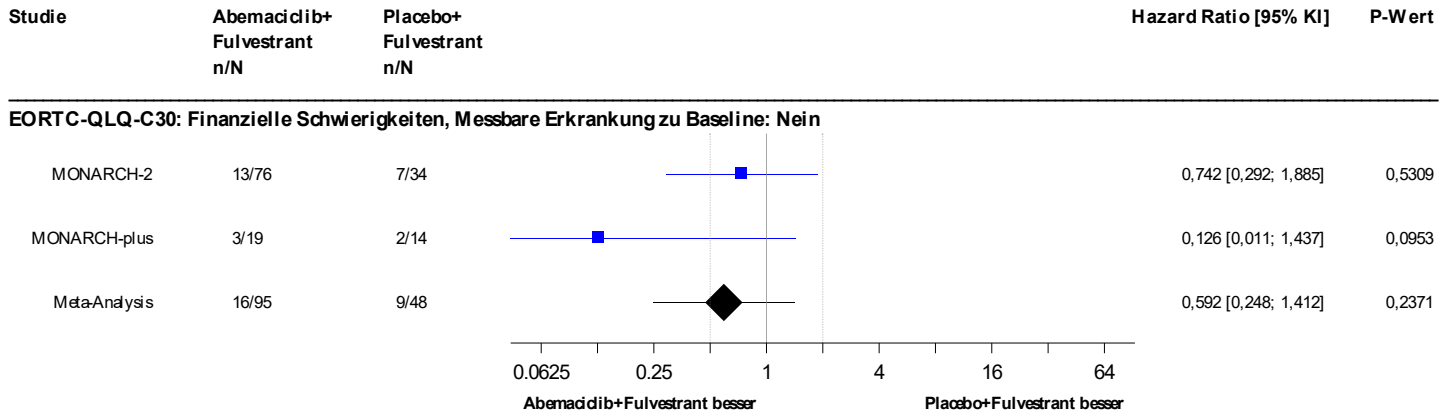
Abbildung 1407.1.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,7768, P-Wert=0,1825, I2 Index=43,7%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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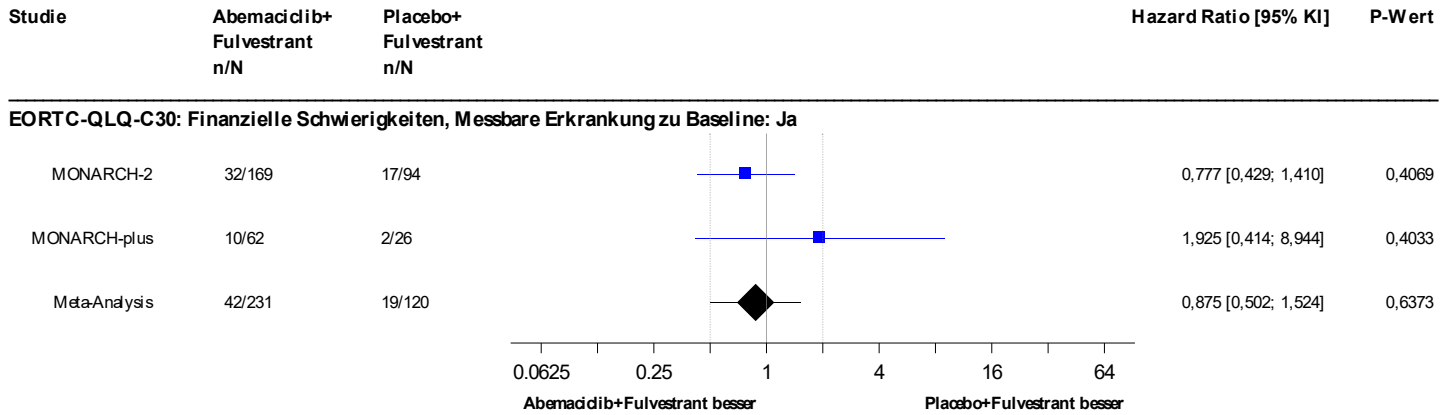
Abbildung 1407.1.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,1642, P-Wert=0,2806, I2 Index=14,1%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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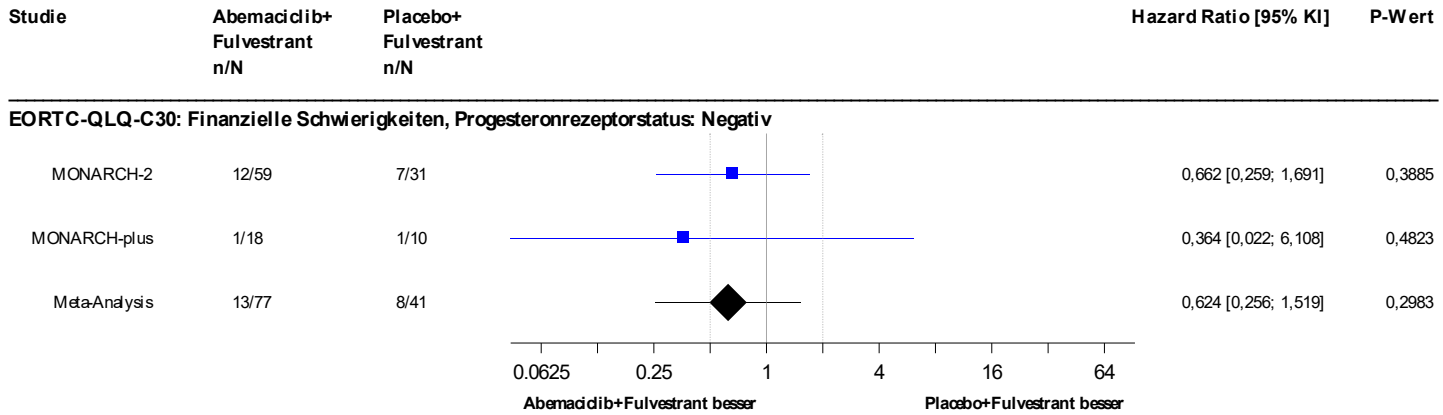
Abbildung 1407.1.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1557, P-Wert=0,6931, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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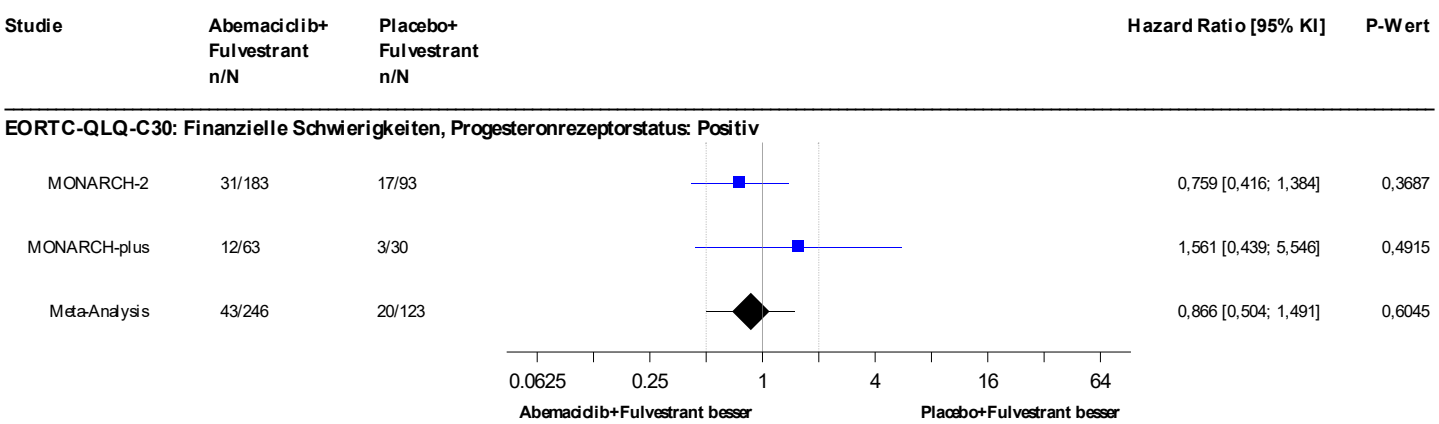
Abbildung 1407.1.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,0132, P-Wert=0,3141, I2 Index=1,3%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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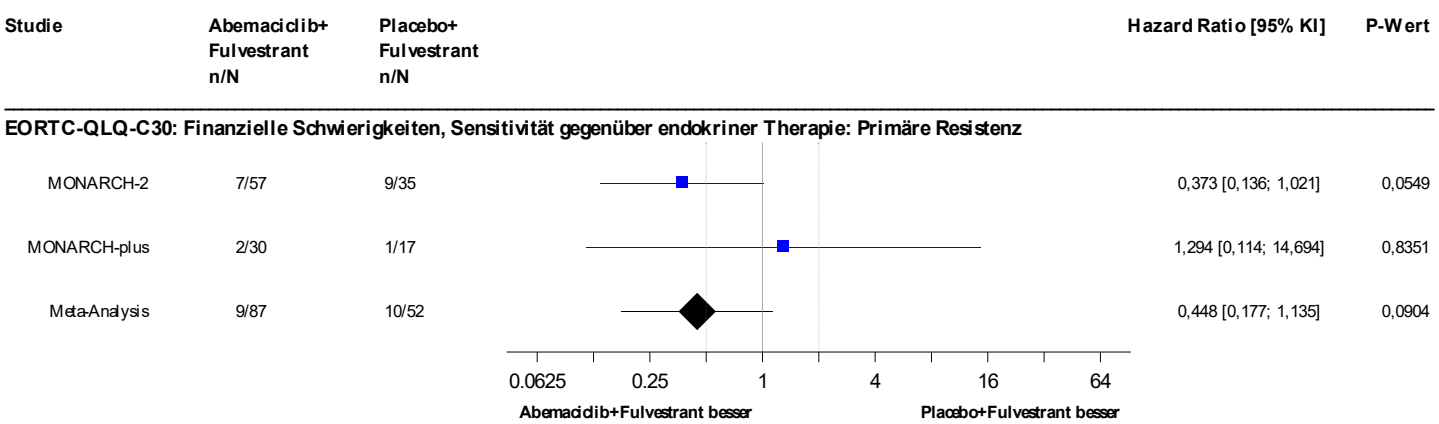
Abbildung 1407.1.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,8595, P-Wert=0,3539, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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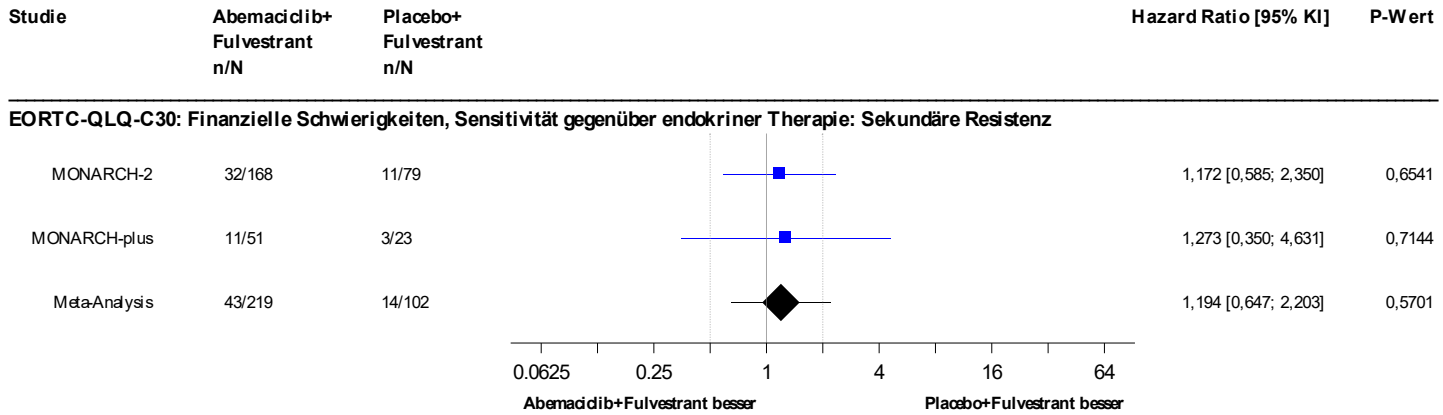
Abbildung 1407.1.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0121, P-Wert=0,9126, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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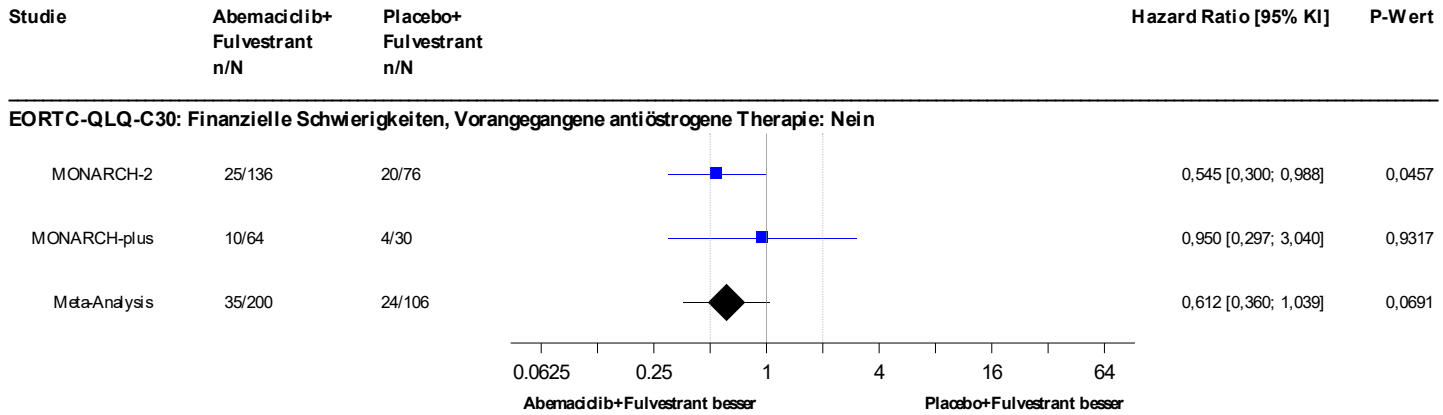
Abbildung 1407.1.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6966, P-Wert=0,4039, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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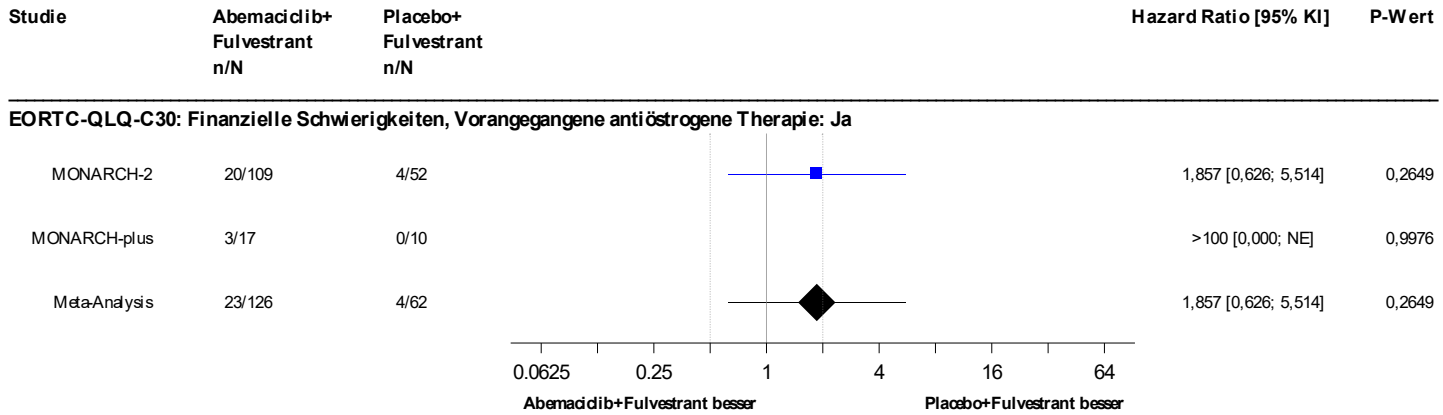
Abbildung 1407.1.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9977, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwfind6_popa1_paet_2.rtf
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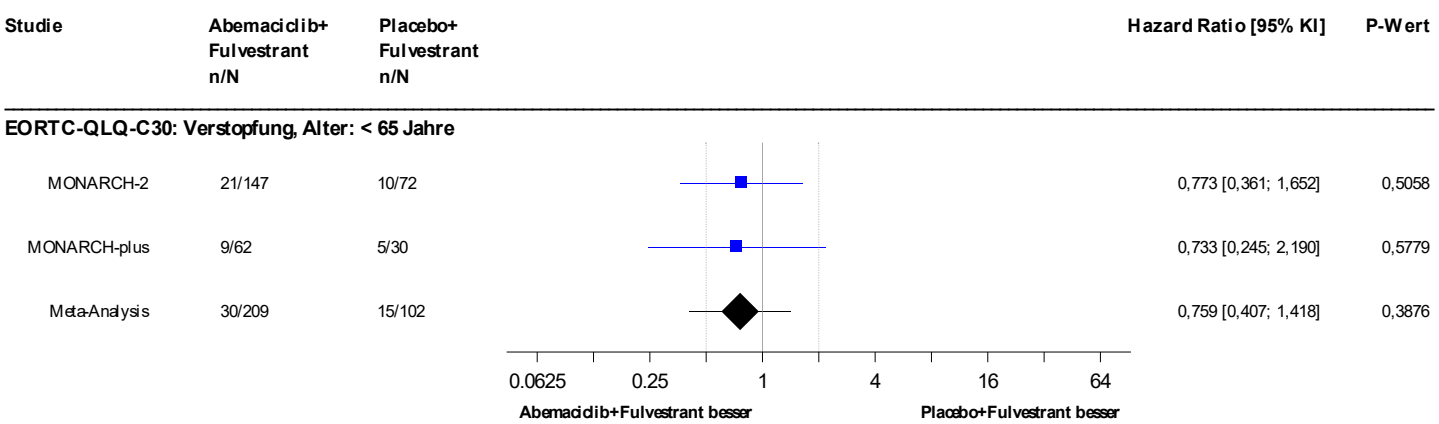
Abbildung 1408.1.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0060, P-Wert=0,9380, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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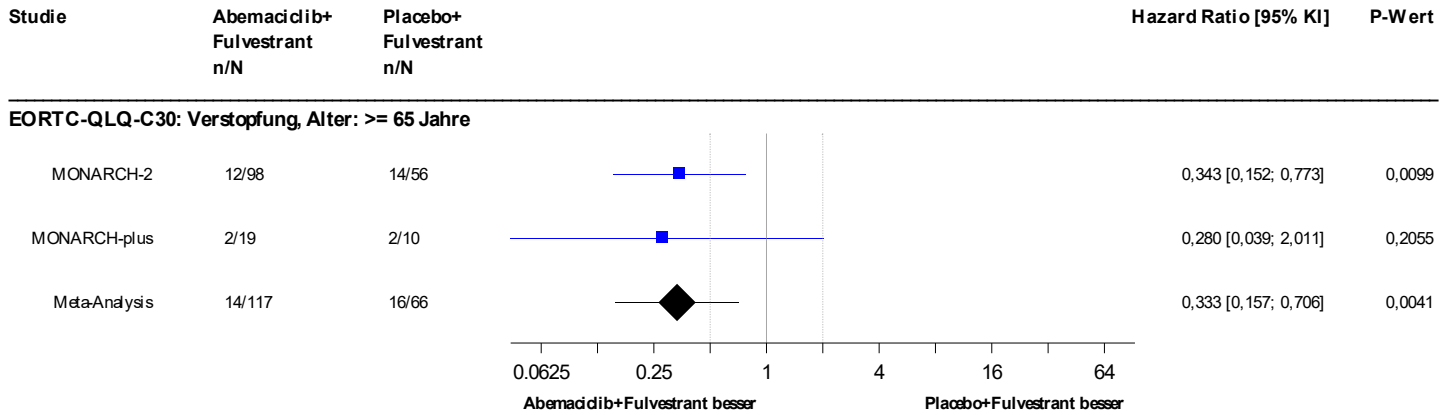
Abbildung 1408.1.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0349, P-Wert=0,8518, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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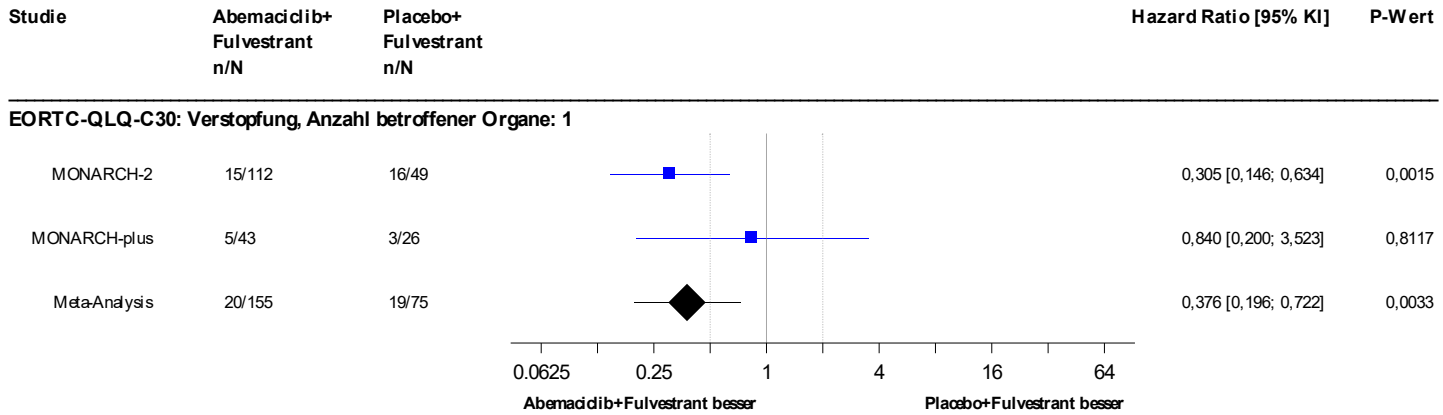
Abbildung 1408.1.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,5230, P-Wert=0,2172, I2 Index=34,3%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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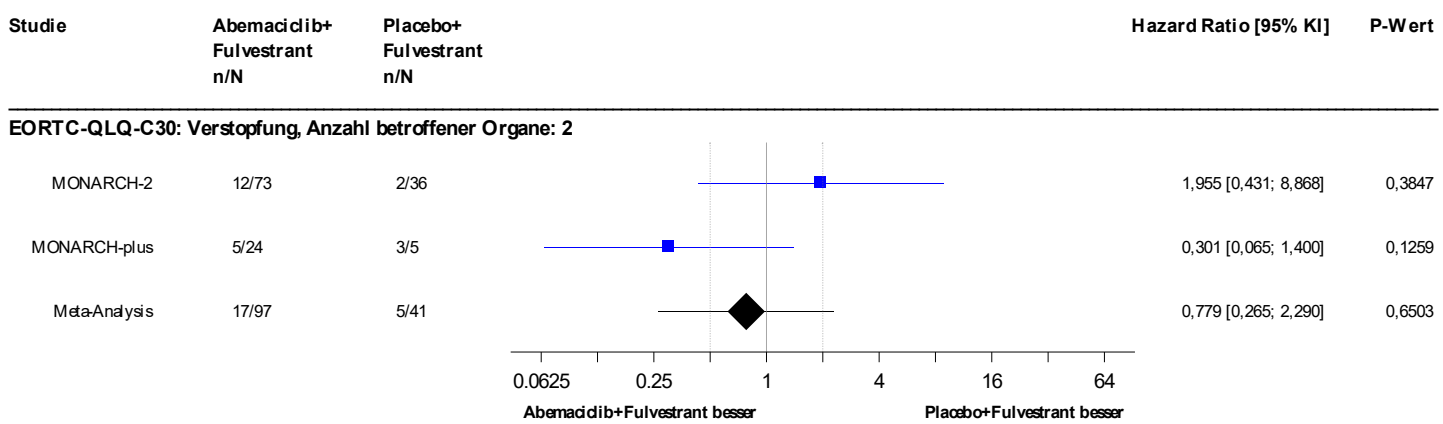
Abbildung 1408.1.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,8929, P-Wert=0,0890, I2 Index=65,4%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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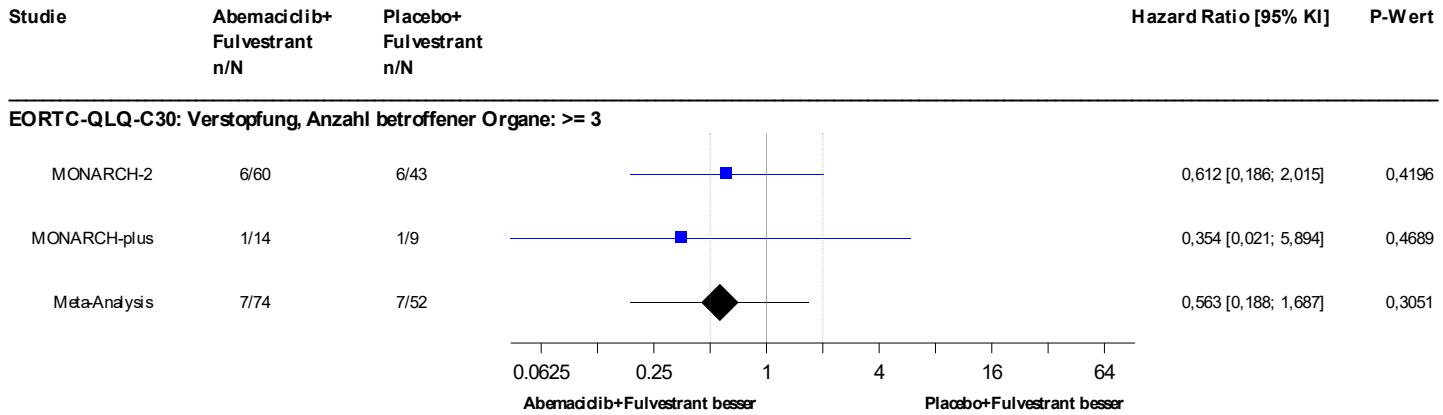
Abbildung 1408.1.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1242, P-Wert=0,7245, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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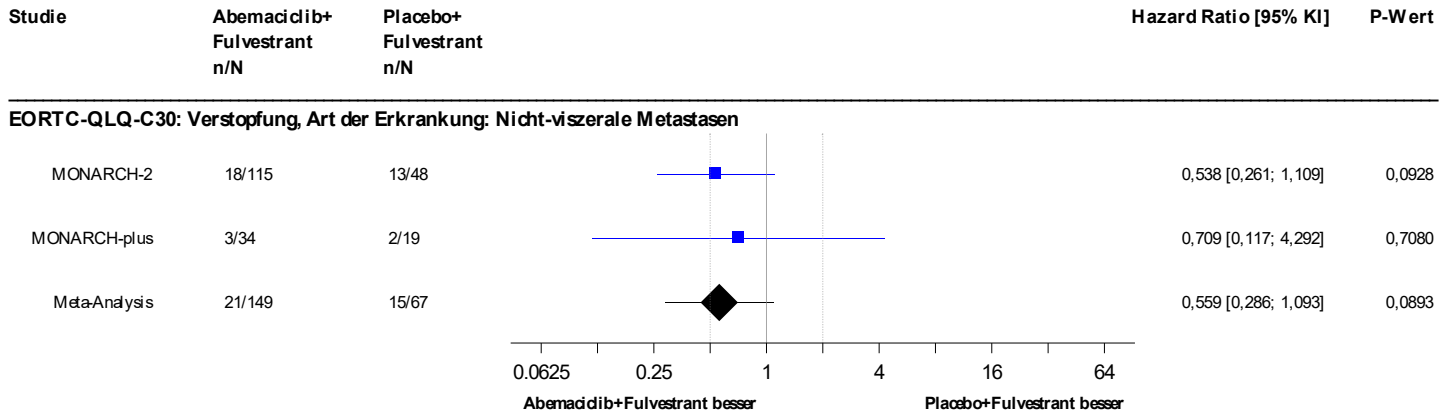
Abbildung 1408.1.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0774, P-Wert=0,7809, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwcons6_popa1_natdis2_1.rtf
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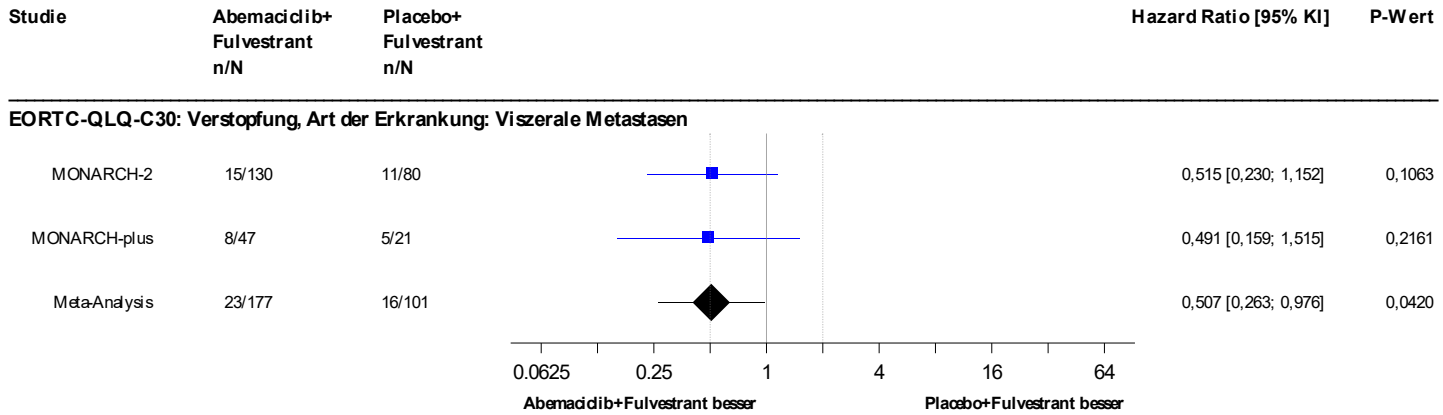
Abbildung 1408.1.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0043, P-Wert=0,9477, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwcons6_popa1_natdis2_2.rtf
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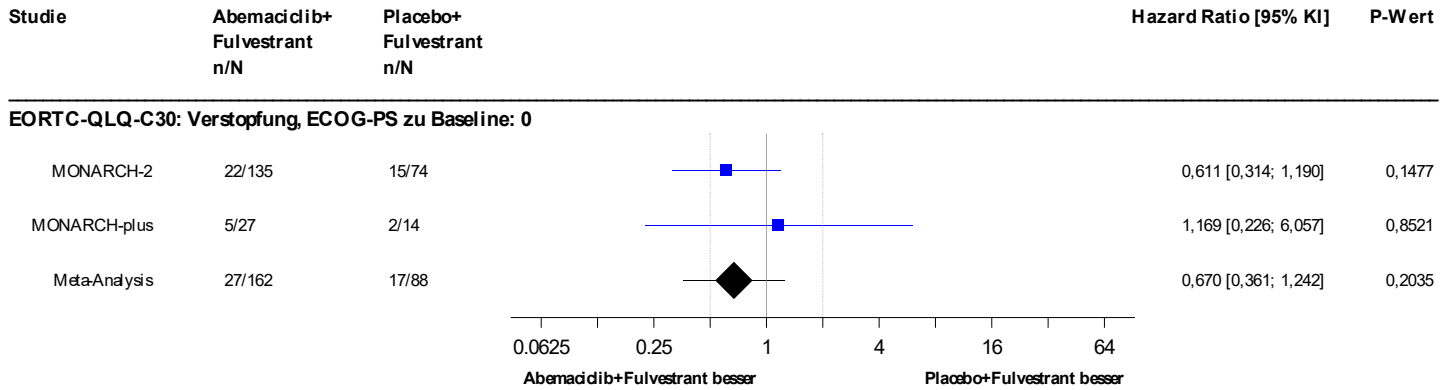
Abbildung 1408.1.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,5137, P-Wert=0,4736, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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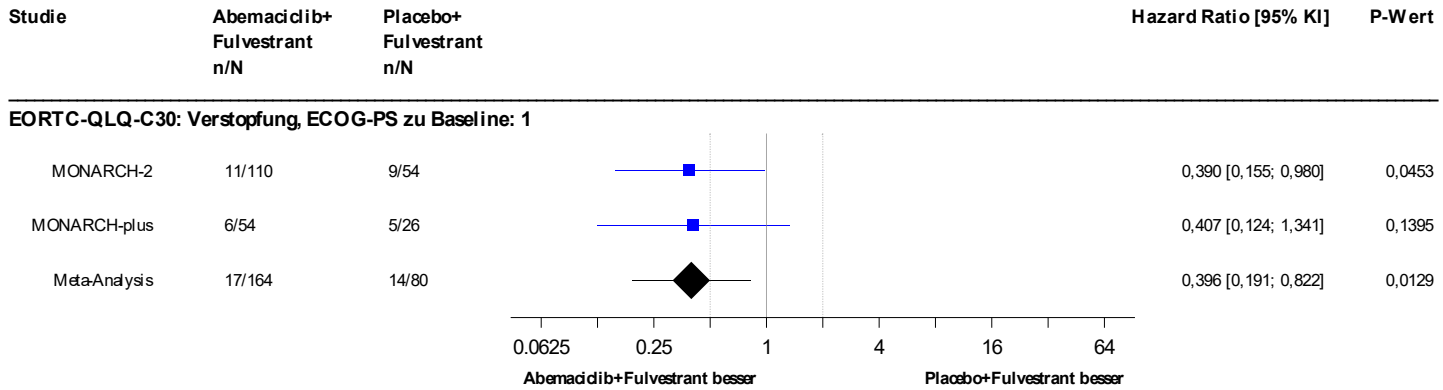
Abbildung 1408.1.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0032, P-Wert=0,9548, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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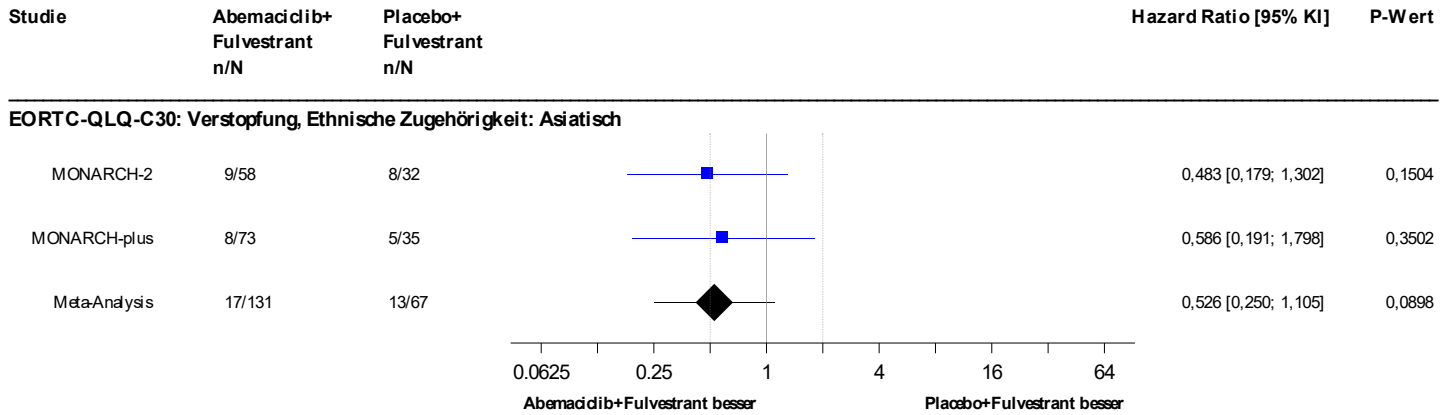
Abbildung 1408.1.5.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0638, P-Wert=0,8007, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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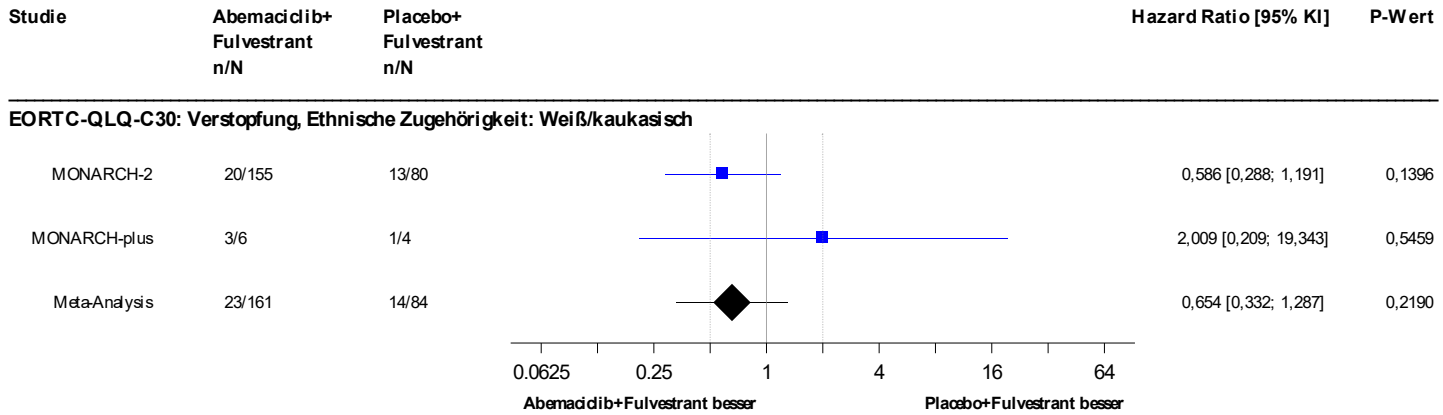
Abbildung 1408.1.5.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,0364, P-Wert=0,3087, I2 Index=3,5%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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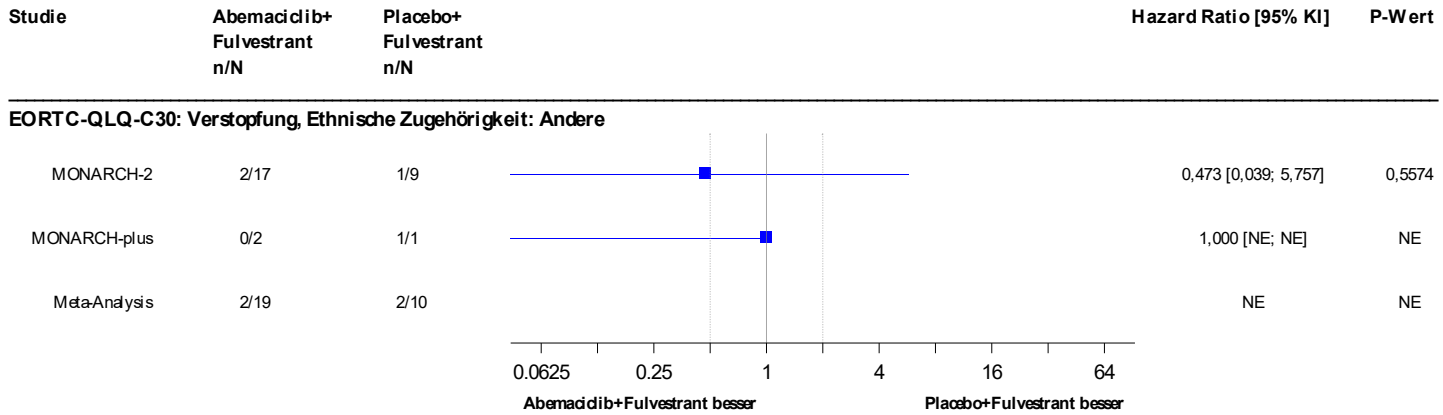
Abbildung 1408.1.5.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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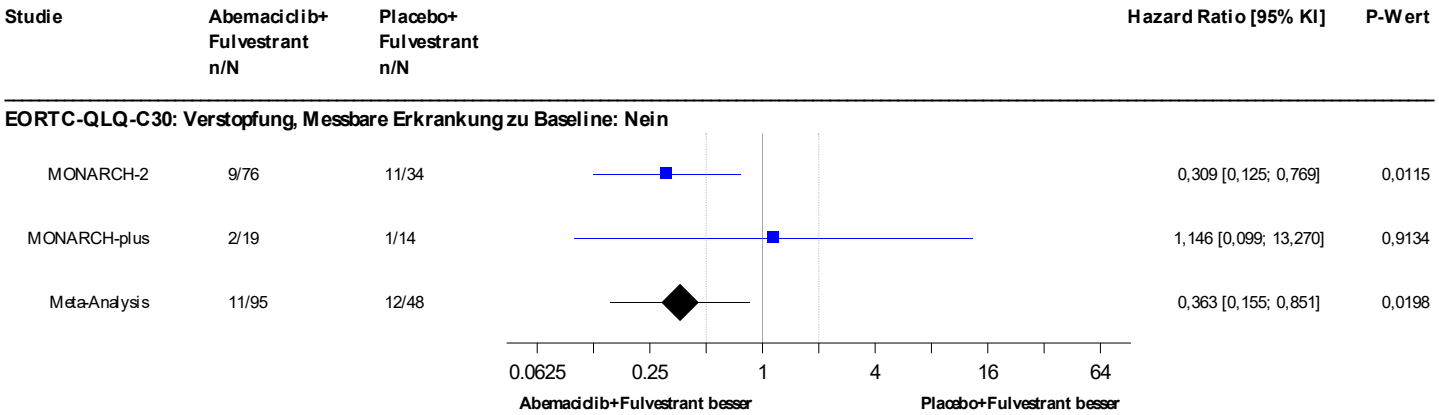
Abbildung 1408.1.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,9638, P-Wert=0,3262, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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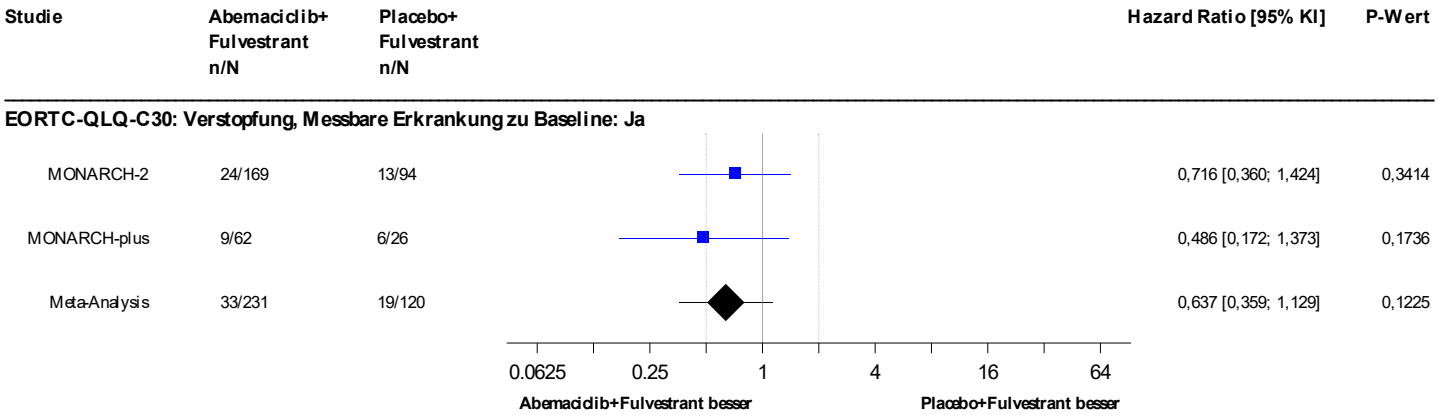
Abbildung 1408.1.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3712, P-Wert=0,5423, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwcons6_popa1_measdis_2.rtf
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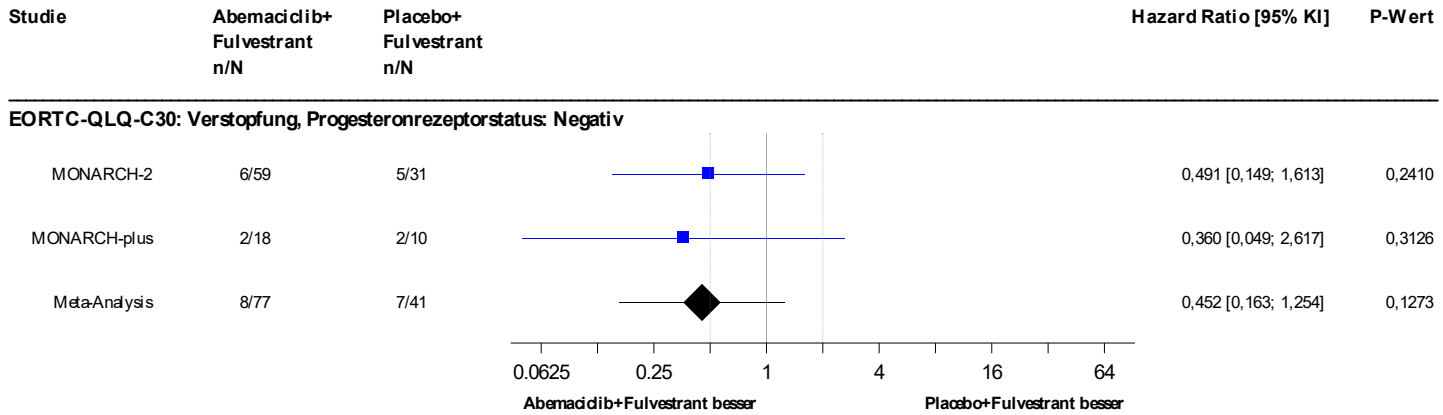
Abbildung 1408.1.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0695, P-Wert=0,7921, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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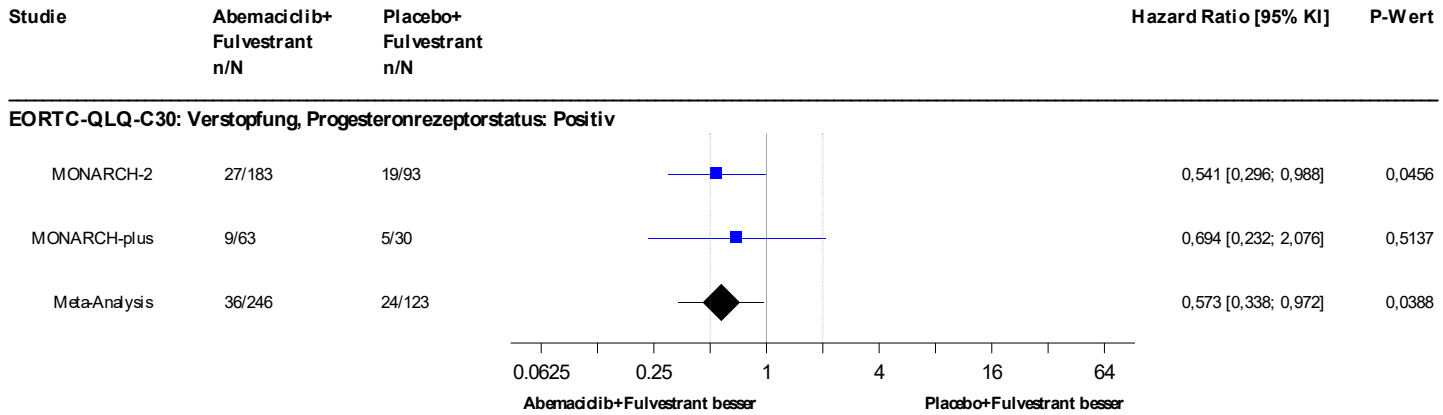
Abbildung 1408.1.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1529, P-Wert=0,6958, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwcons6_popa1_pgrstat_2.rtf
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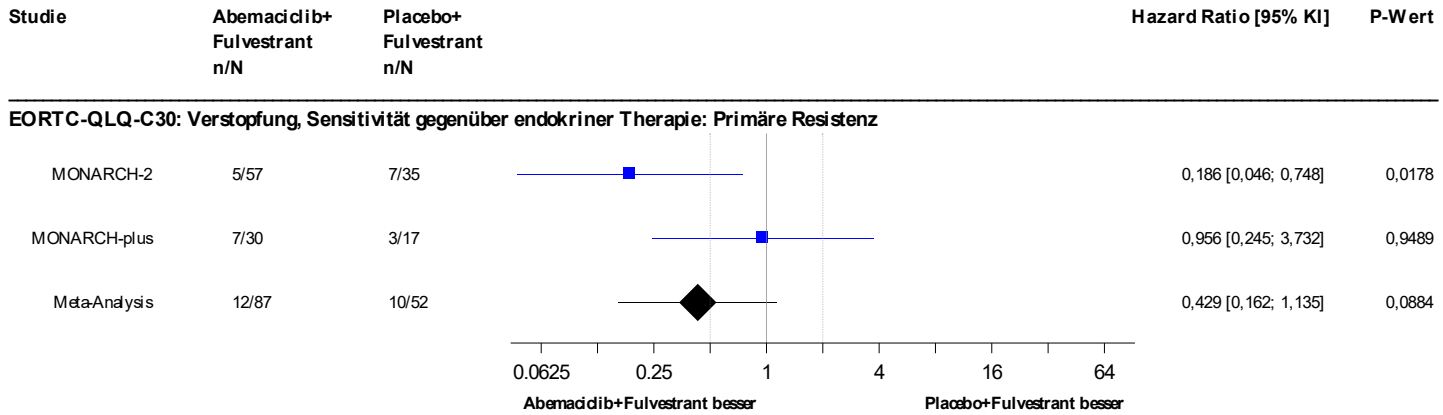
Abbildung 1408.1.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,7147, P-Wert=0,0994, I2 Index=63,2%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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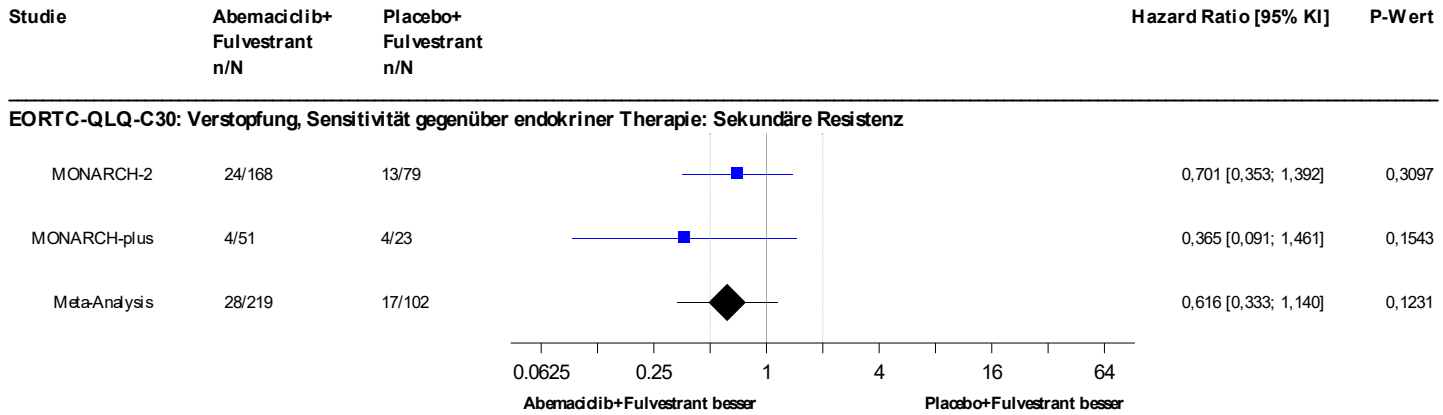
Abbildung 1408.1.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6832, P-Wert=0,4085, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwcons6_popa1_snthr_2.rtf
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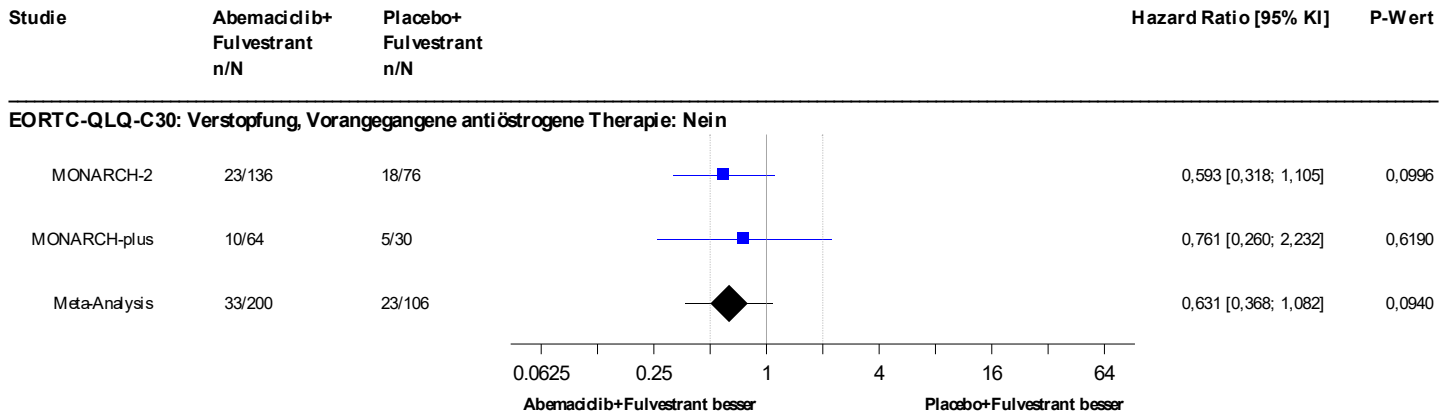
Abbildung 1408.1.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1552, P-Wert=0,6936, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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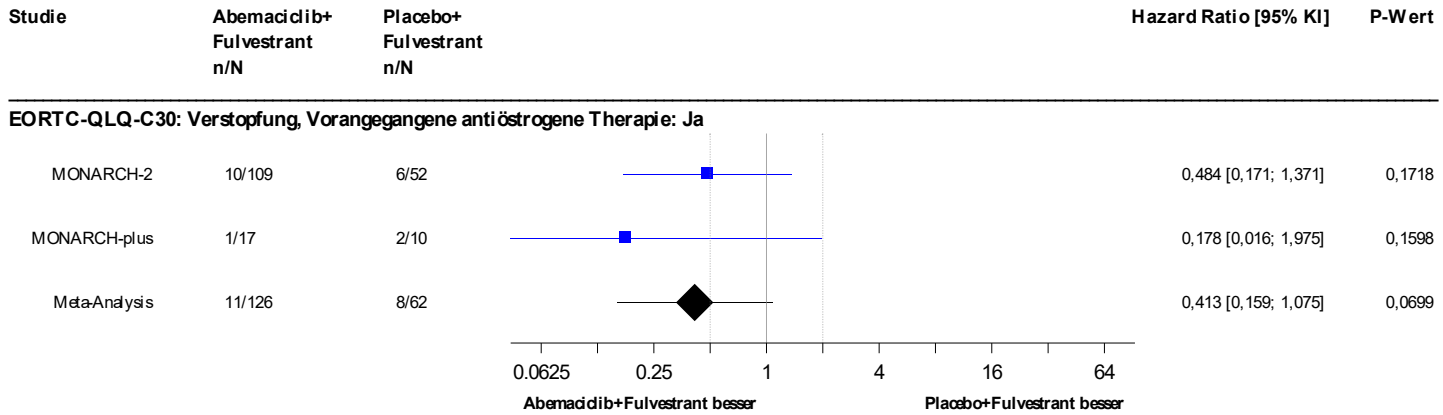
Abbildung 1408.1.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,5581, P-Wert=0,4550, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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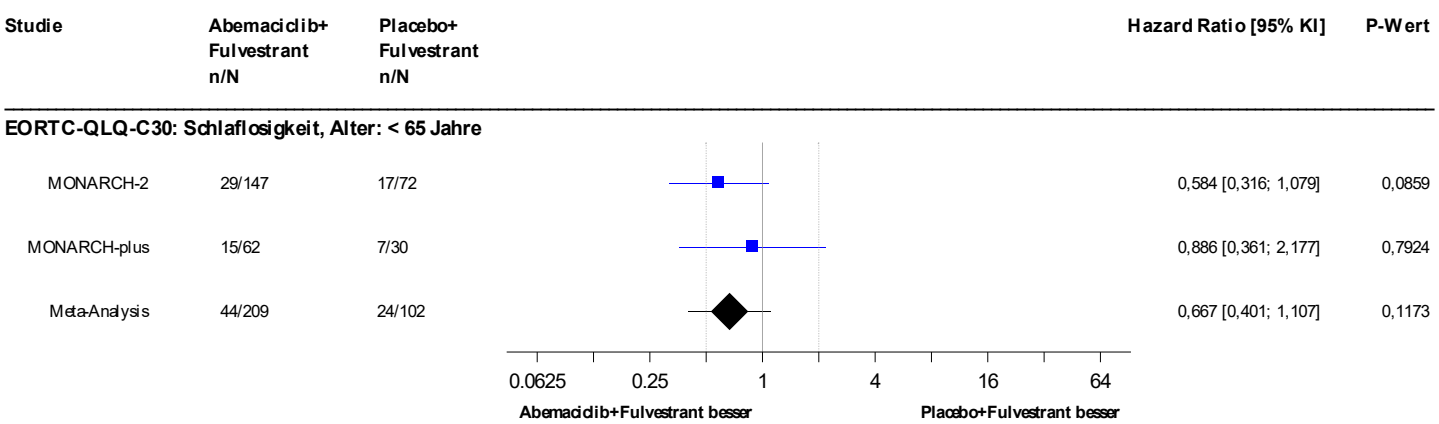
Abbildung 1409.1.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,5657, P-Wert=0,4520, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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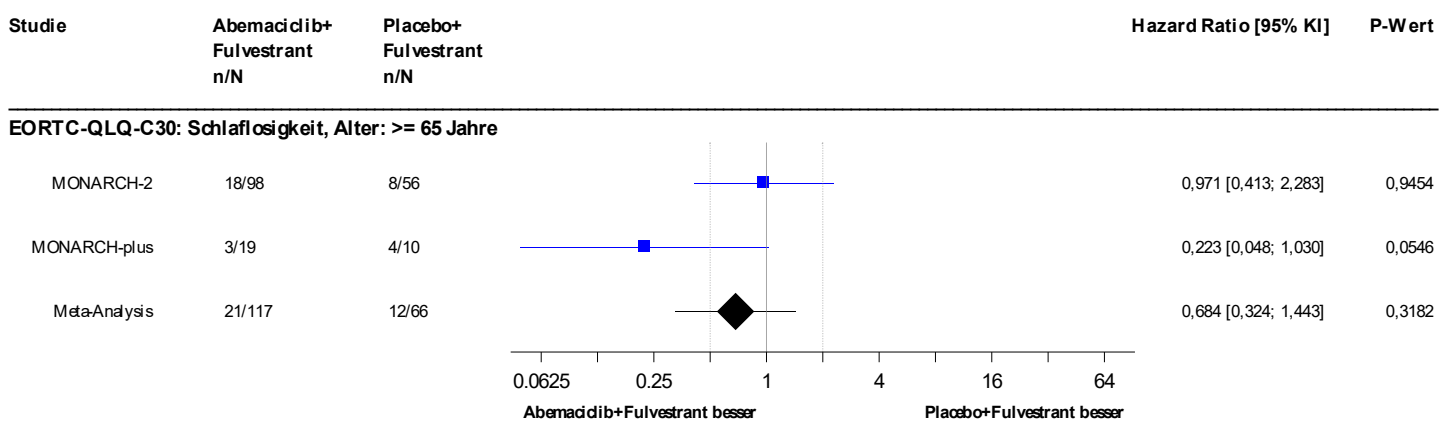
Abbildung 1409.1.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,7043, P-Wert=0,1001, I2 Index=63,0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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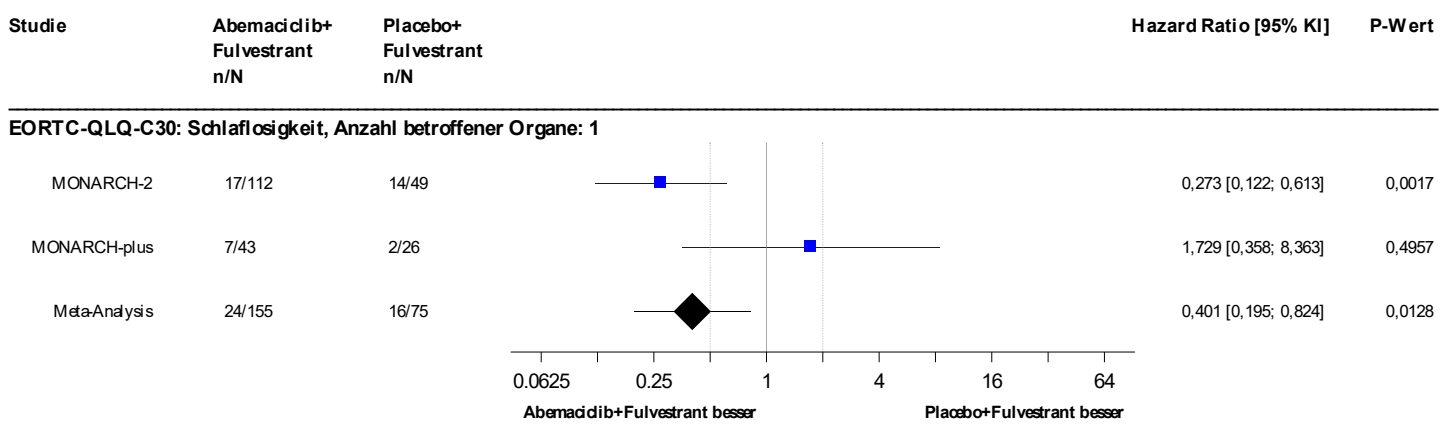
Abbildung 1409.1.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=4,1711, P-Wert=0,0411, I2 Index=76,0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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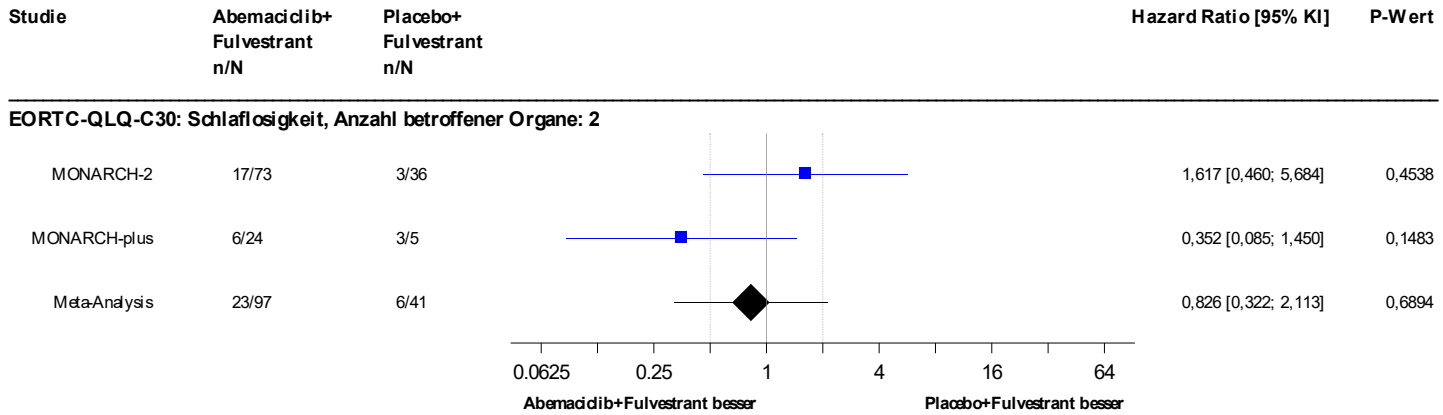
Abbildung 1409.1.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,4906, P-Wert=0,1145, I2 Index=59,8%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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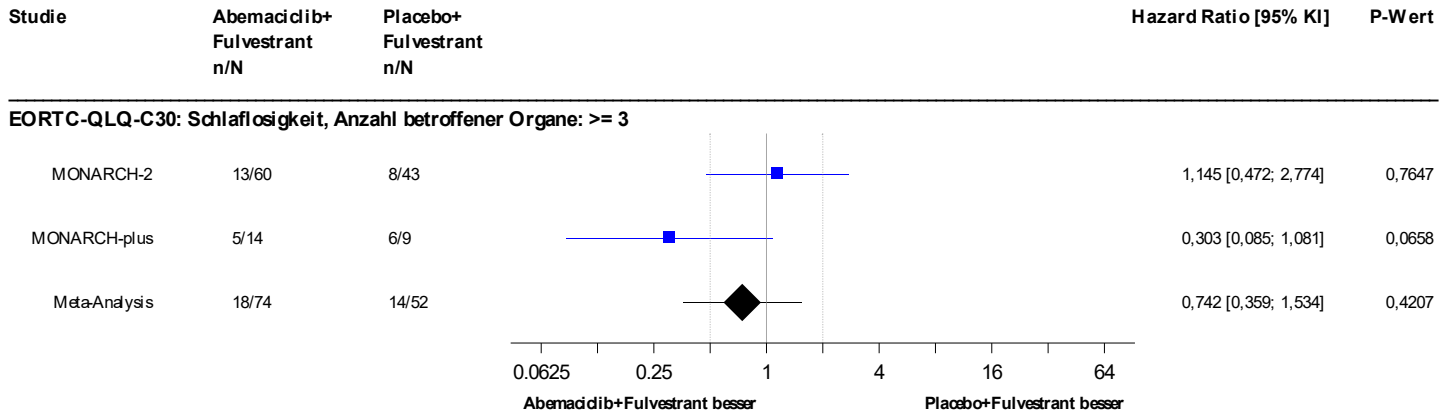
Abbildung 1409.1.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,8251, P-Wert=0,0928, I2 Index=64,6%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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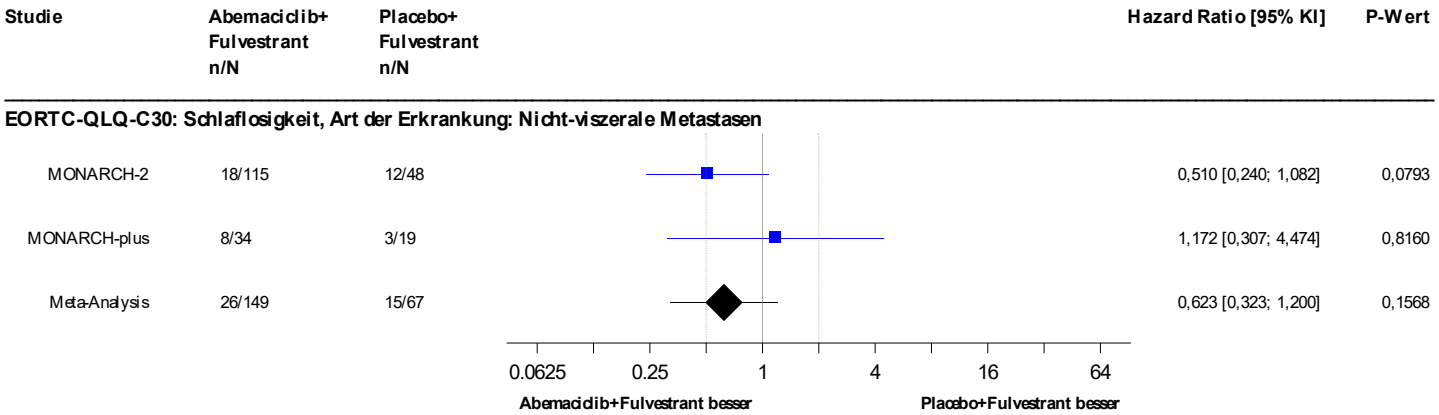
Abbildung 1409.1.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,1287, P-Wert=0,2881, I2 Index=11,4%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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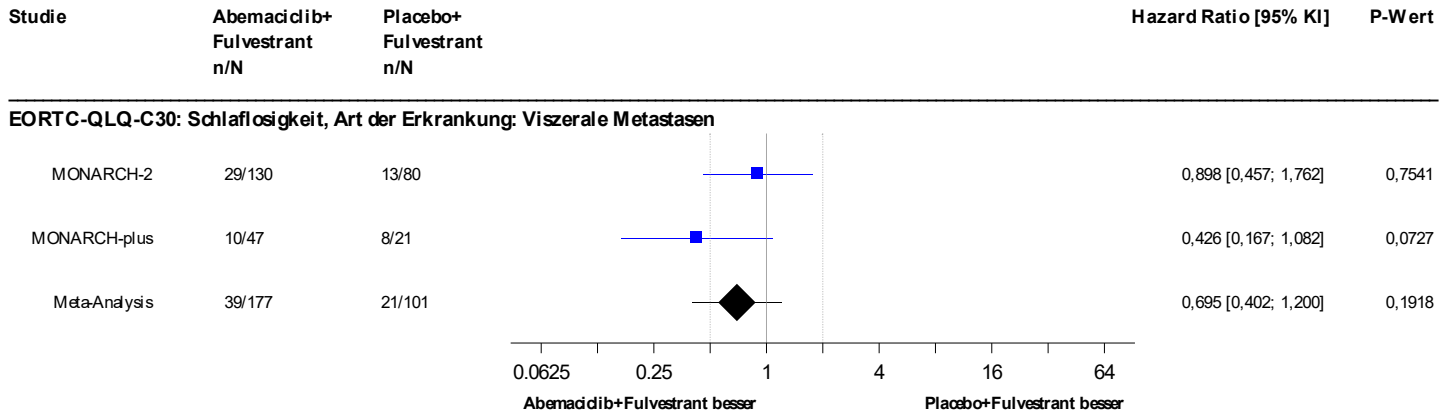
Abbildung 1409.1.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,6155, P-Wert=0,2037, I2 Index=38,1%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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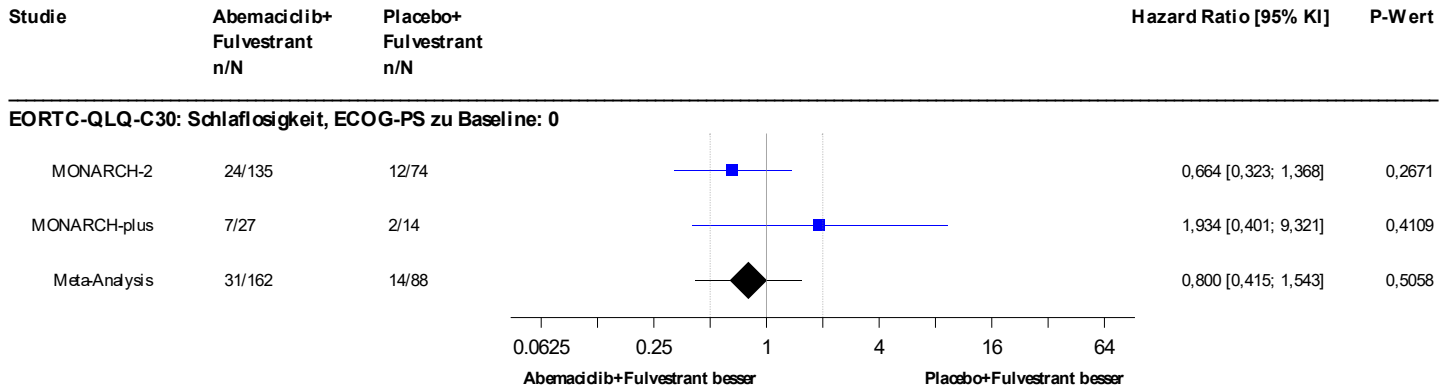
Abbildung 1409.1.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,4649, P-Wert=0,2262, I2 Index=31,7%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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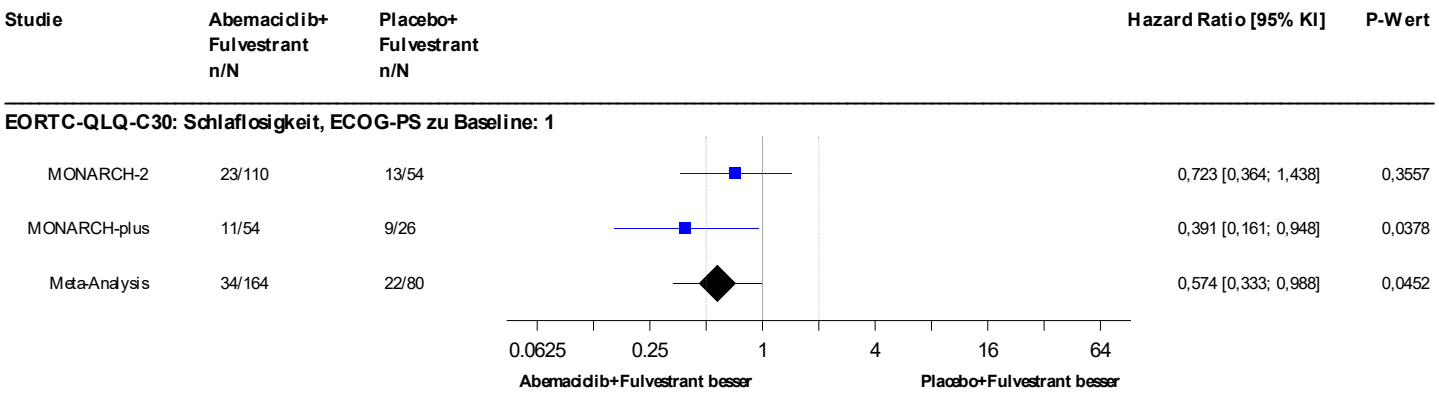
Abbildung 1409.1.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,1576, P-Wert=0,2820, I2 Index=13,6%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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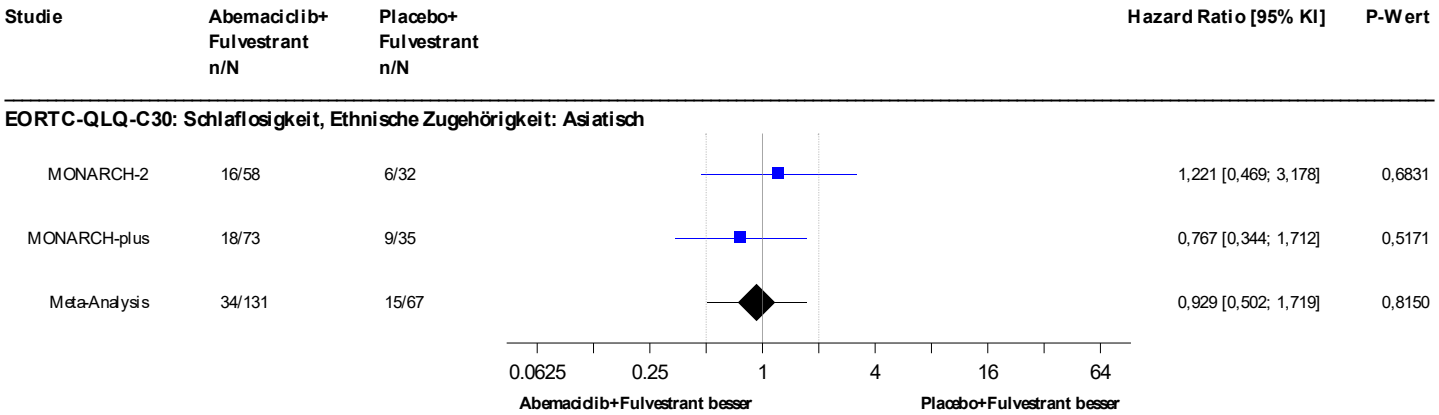
Abbildung 1409.1.5.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,5317, P-Wert=0,4659, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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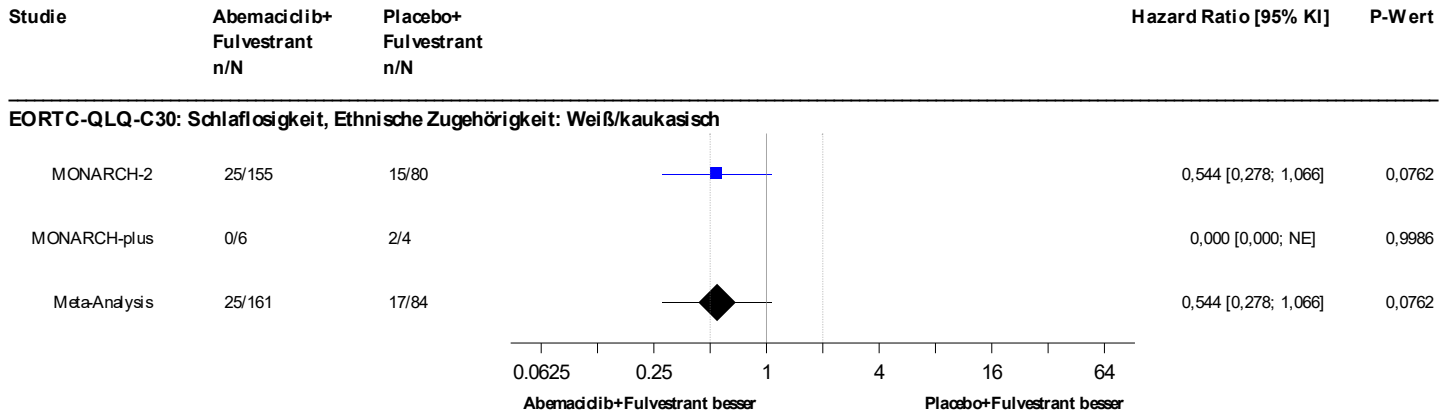
Abbildung 1409.1.5.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9987, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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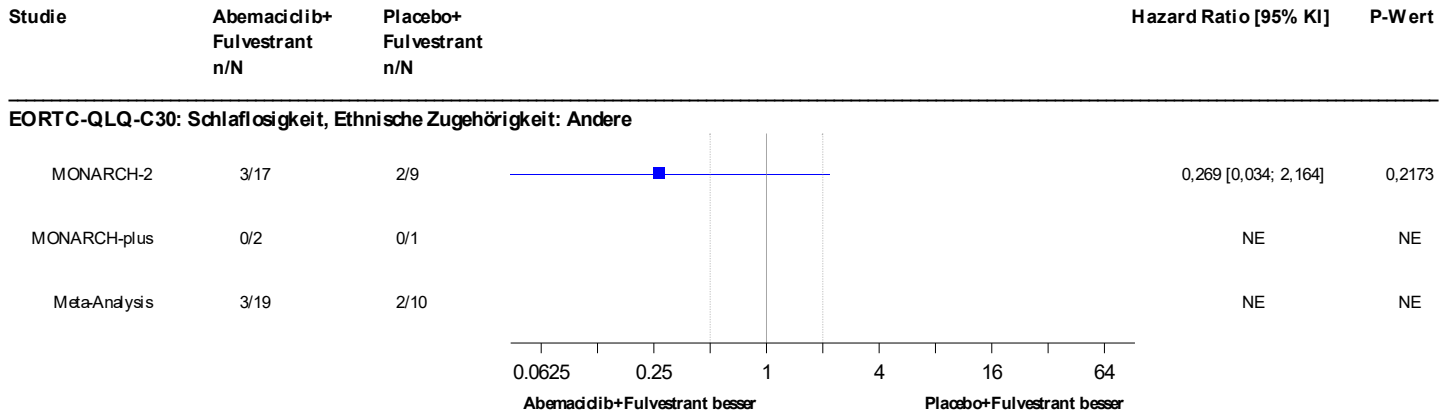
Abbildung 1409.1.5.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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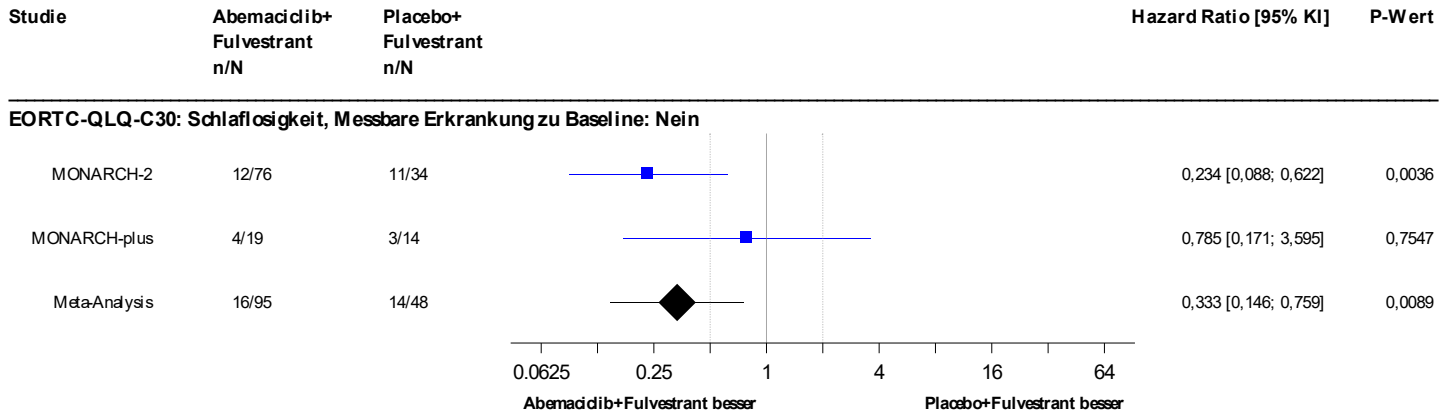
Abbildung 1409.1.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,7217, P-Wert=0,1895, I2 Index=41,9%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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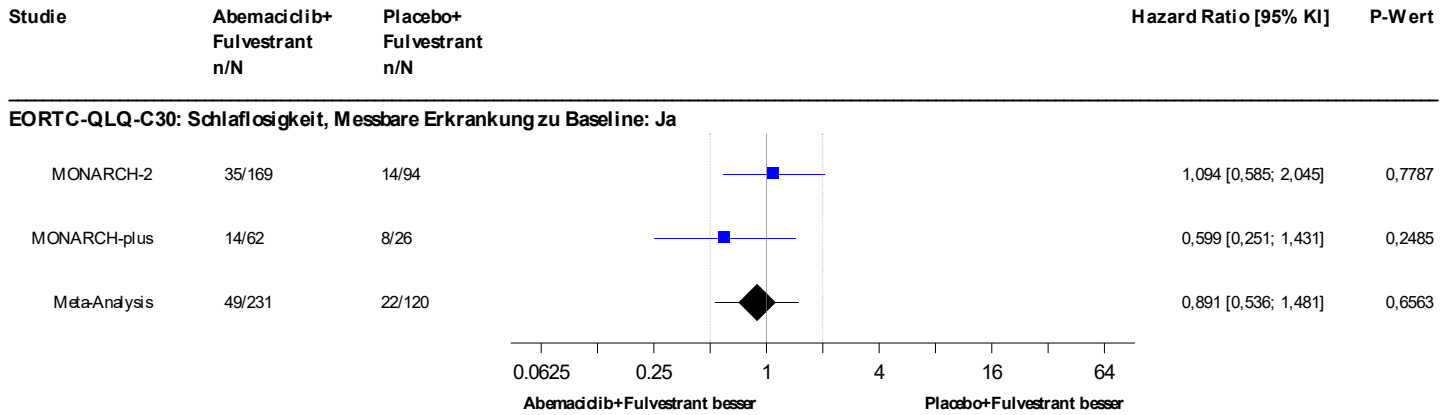
Abbildung 1409.1.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,2125, P-Wert=0,2708, I2 Index=17,5%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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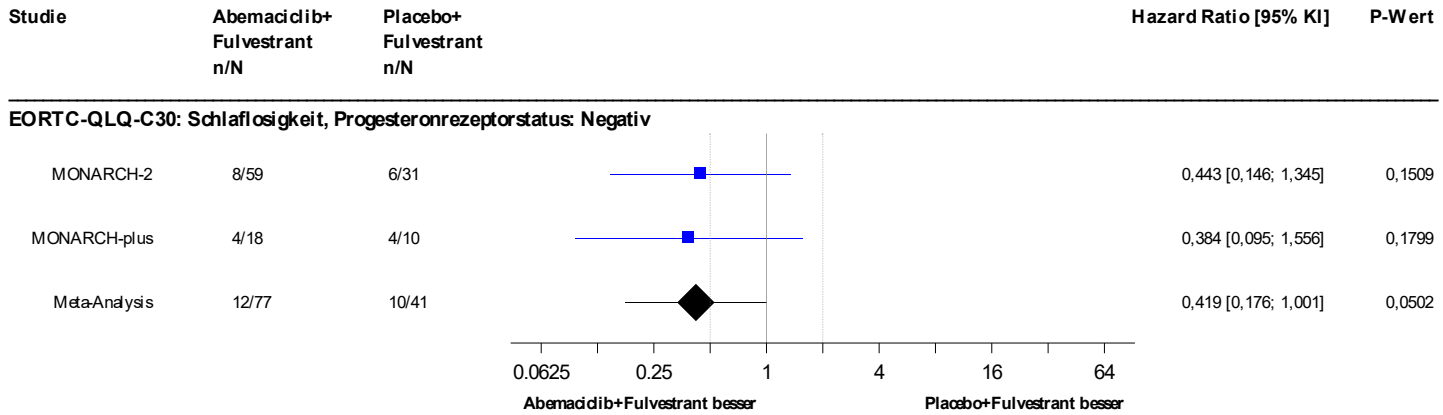
Abbildung 1409.1.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0249, P-Wert=0,8746, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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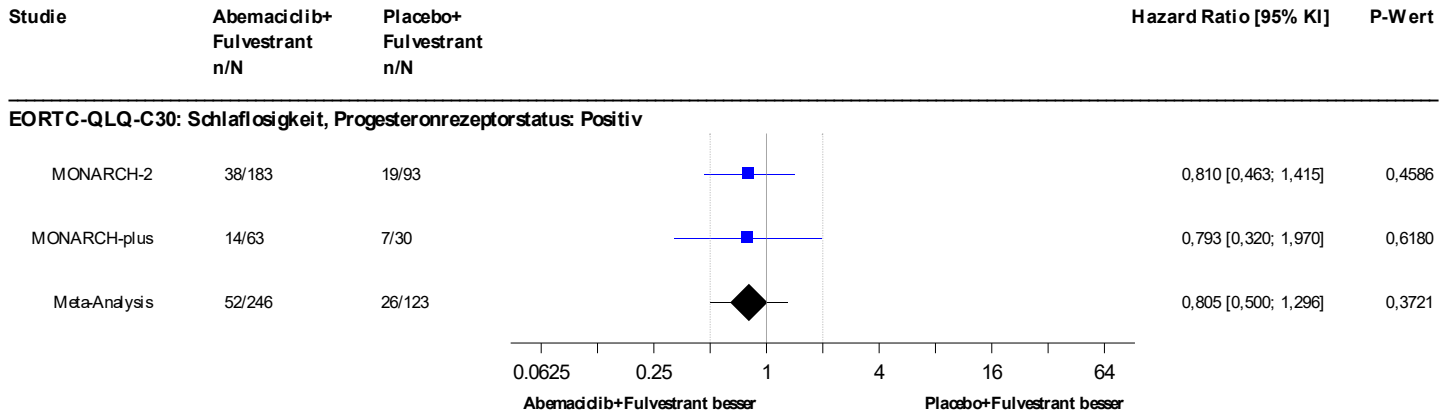
Abbildung 1409.1.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0014, P-Wert=0,9704, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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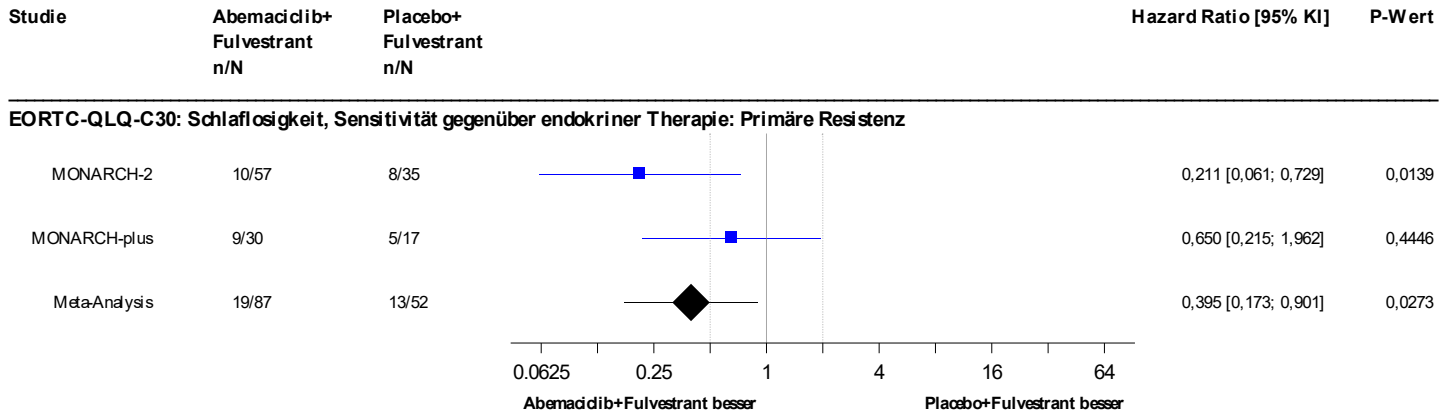
Abbildung 1409.1.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,7595, P-Wert=0,1847, I2 Index=43,2%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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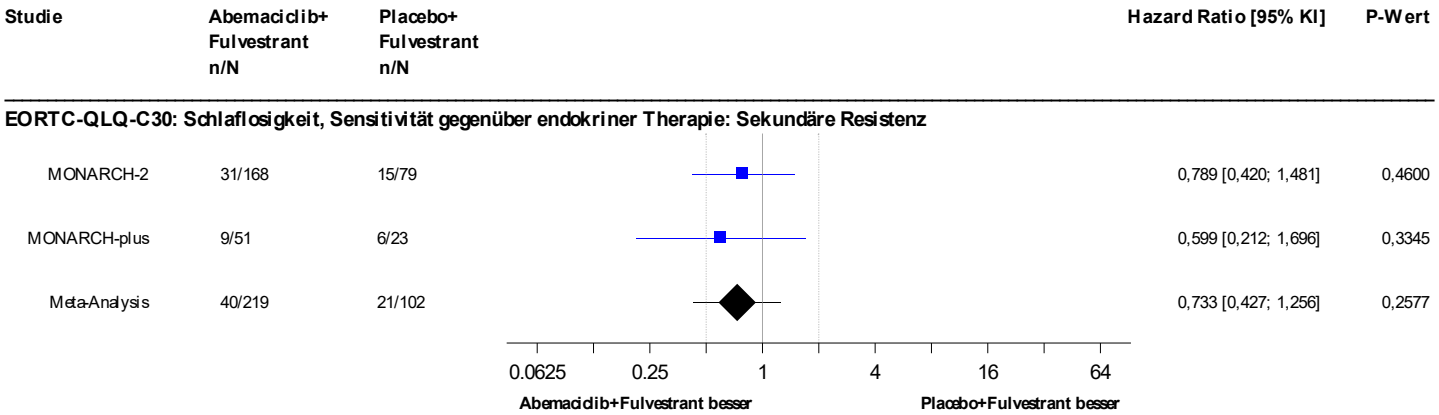
Abbildung 1409.1.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1964, P-Wert=0,6577, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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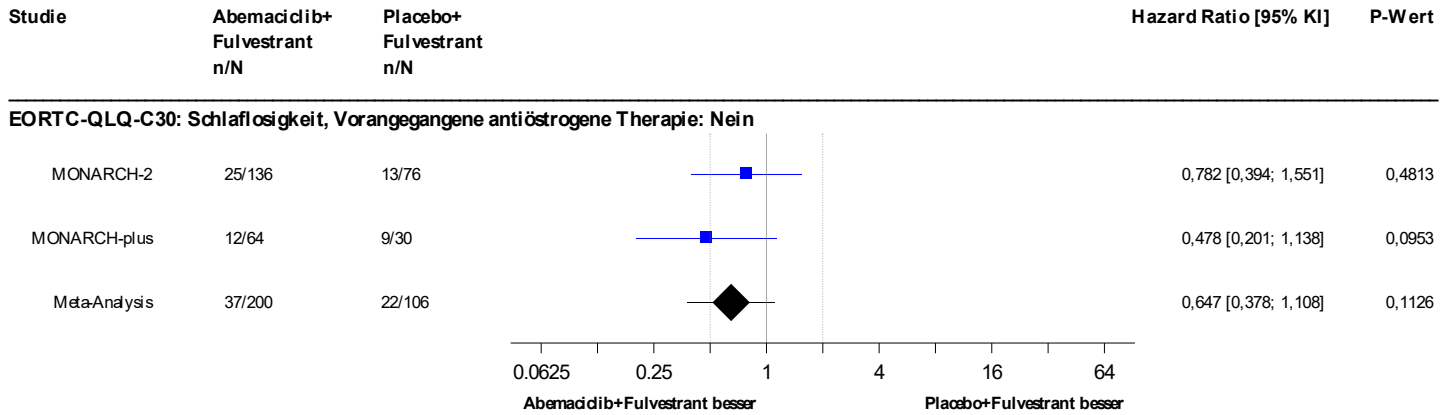
Abbildung 1409.1.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7608, P-Wert=0,3831, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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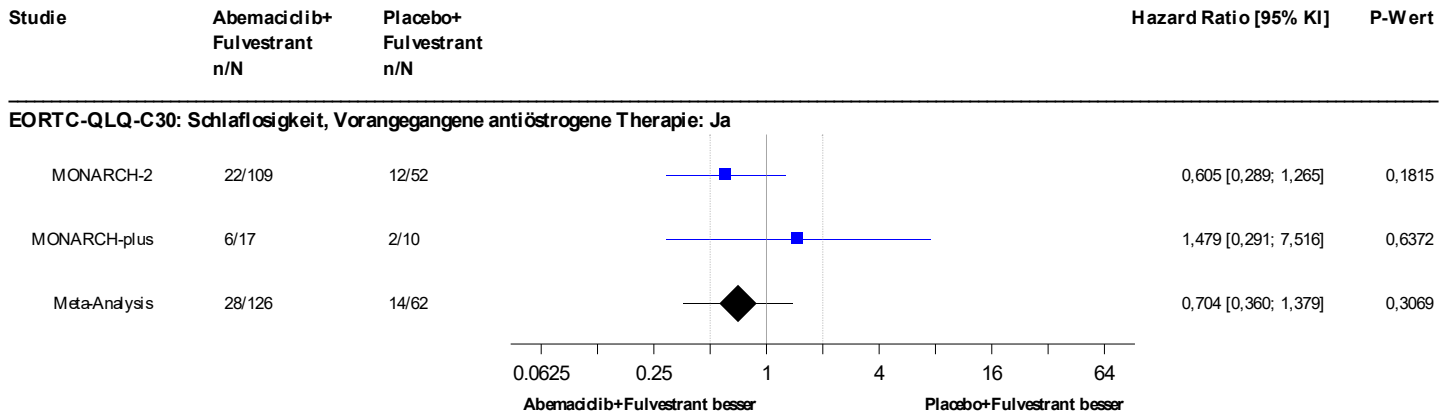
Abbildung 1409.1.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,9640, P-Wert=0,3262, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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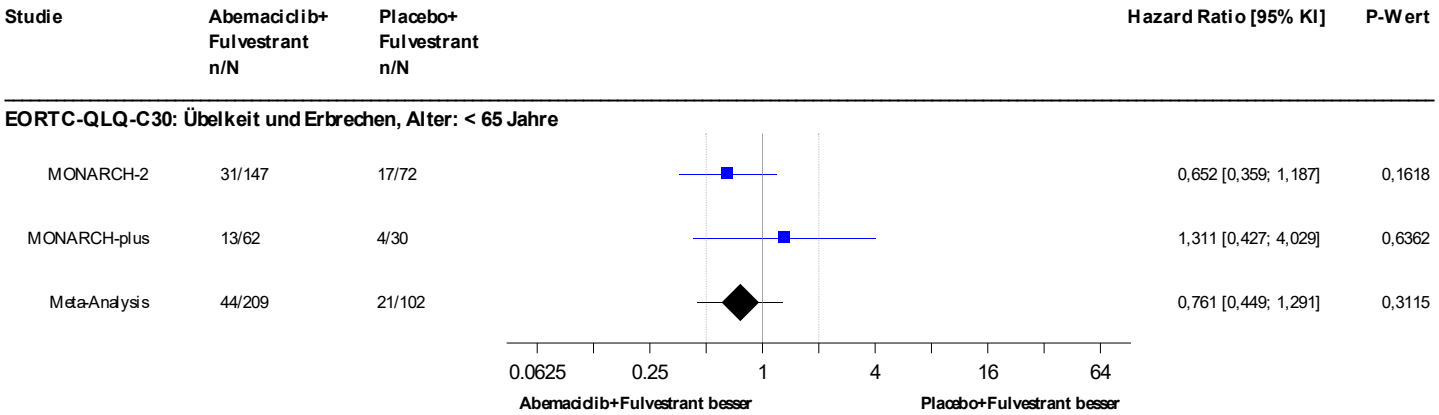
Abbildung 1410.1.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,1567, P-Wert=0,2821, I2 Index=13,5%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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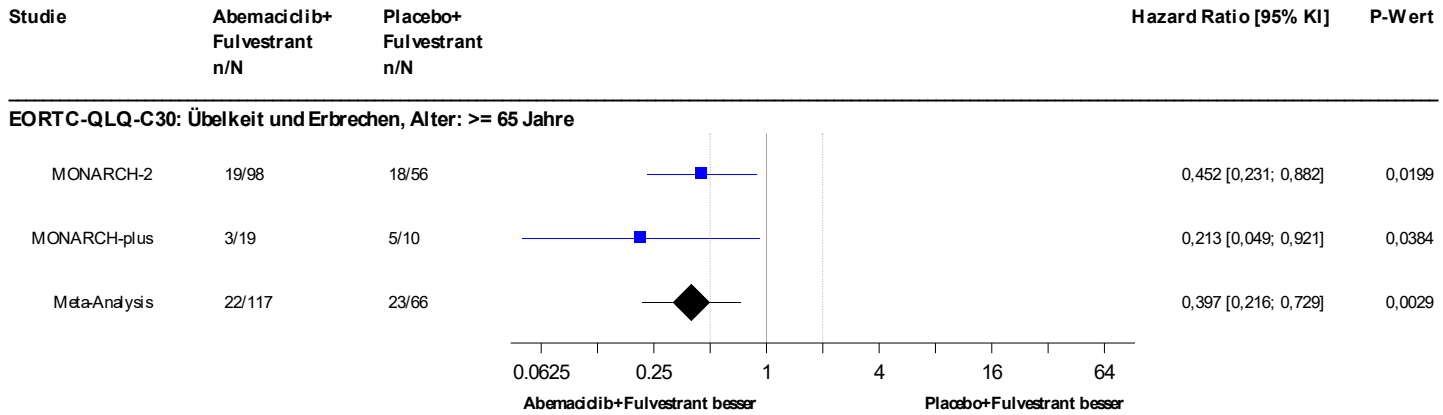
Abbildung 1410.1.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,8364, P-Wert=0,3604, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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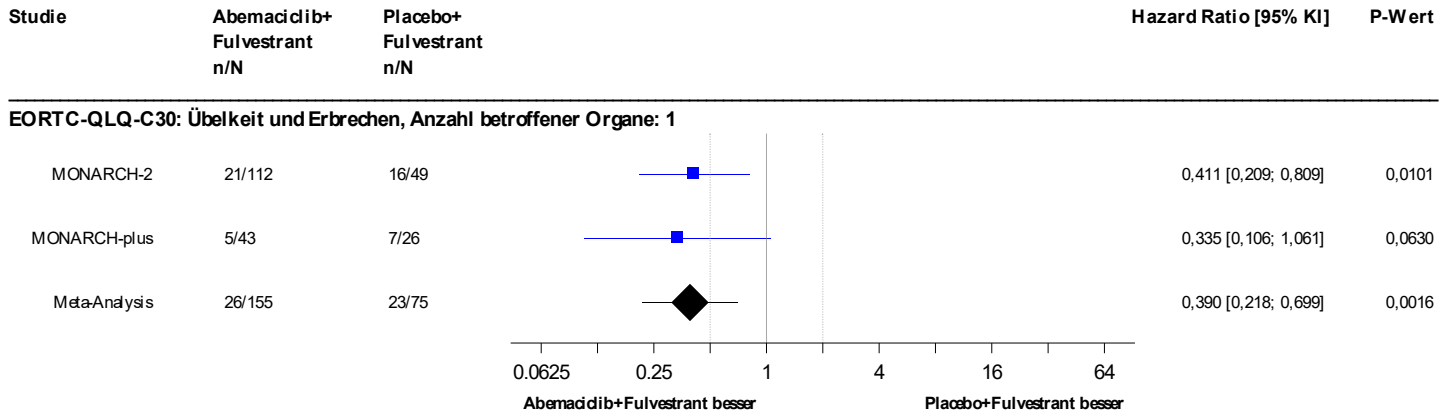
Abbildung 1410.1.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0901, P-Wert=0,7641, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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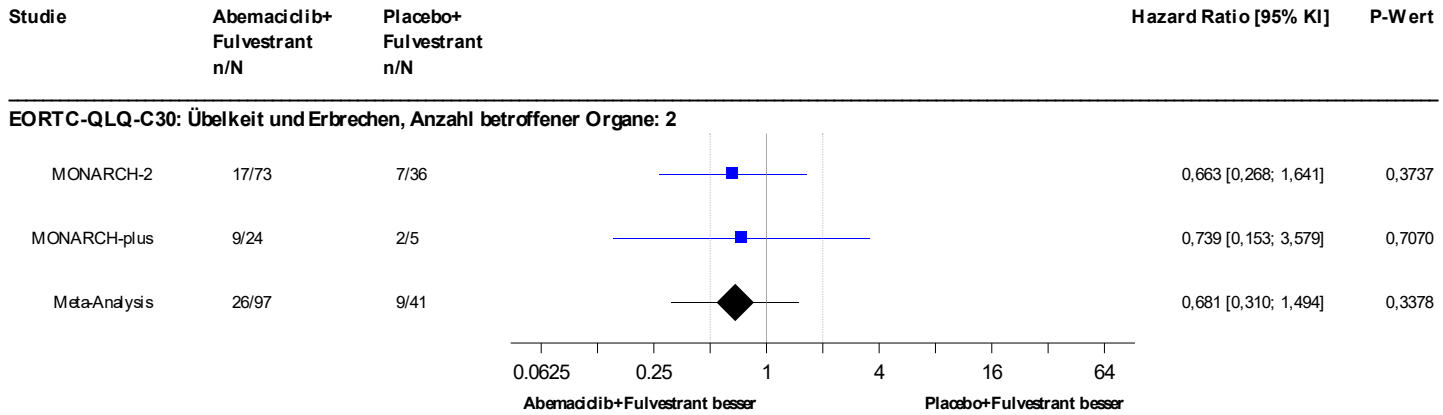
Abbildung 1410.1.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0138, P-Wert=0,9066, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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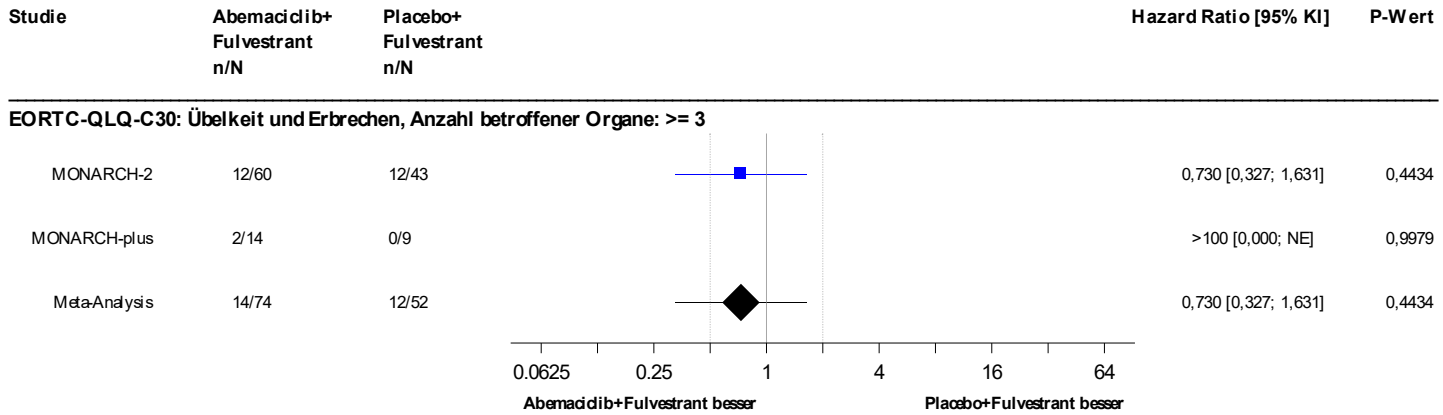
Abbildung 1410.1.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9979, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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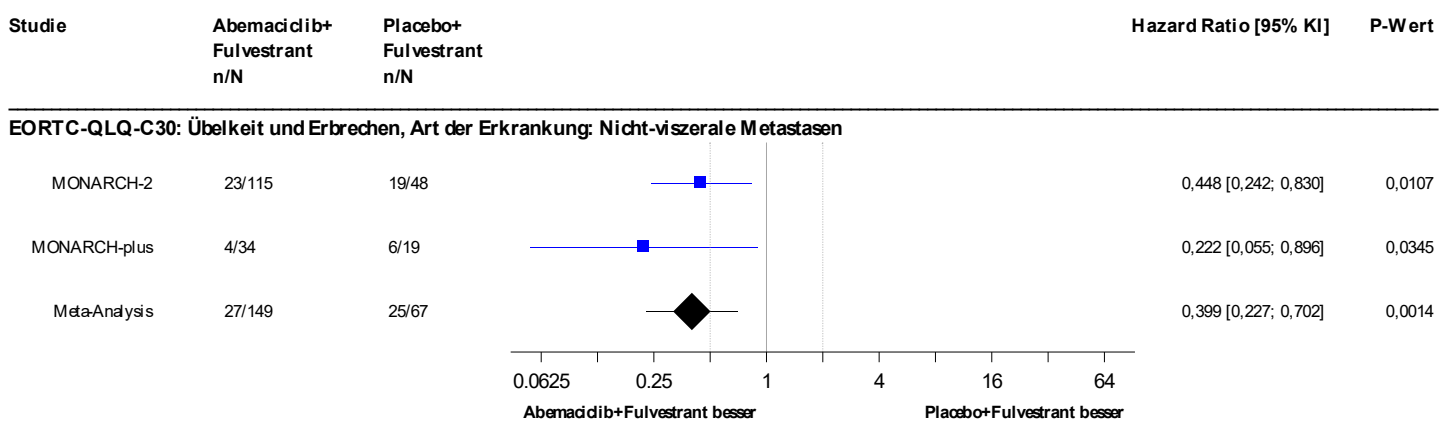
Abbildung 1410.1.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,8158, P-Wert=0,3664, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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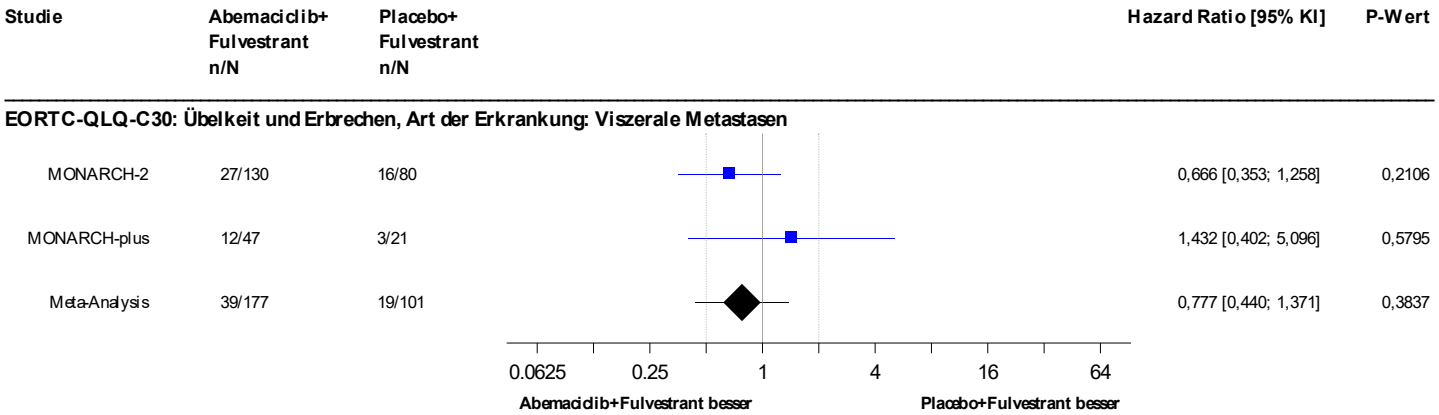
Abbildung 1410.1.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,1155, P-Wert=0,2909, I2 Index=10,4%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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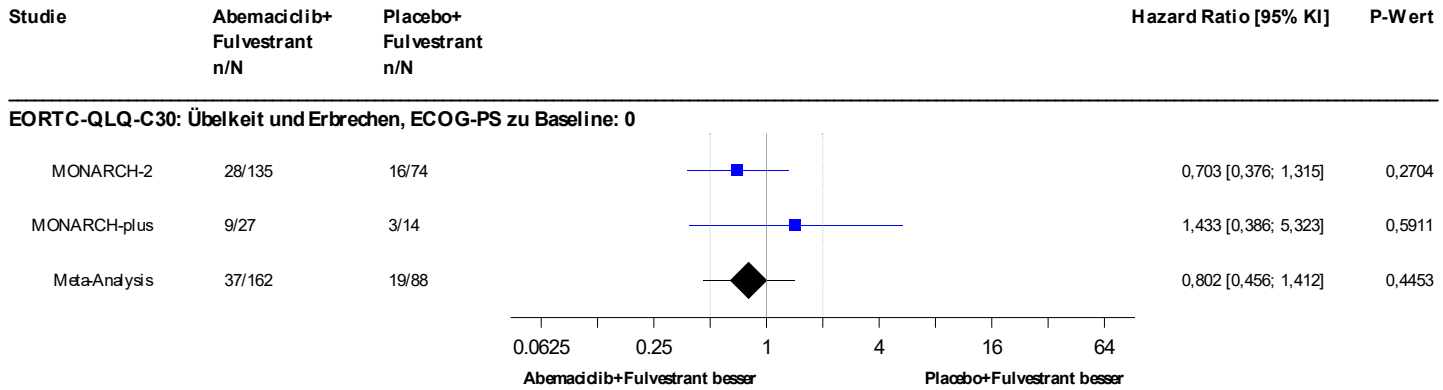
Abbildung 1410.1.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,9210, P-Wert=0,3372, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwnavo6_popa1_ecogbl_1.rtf
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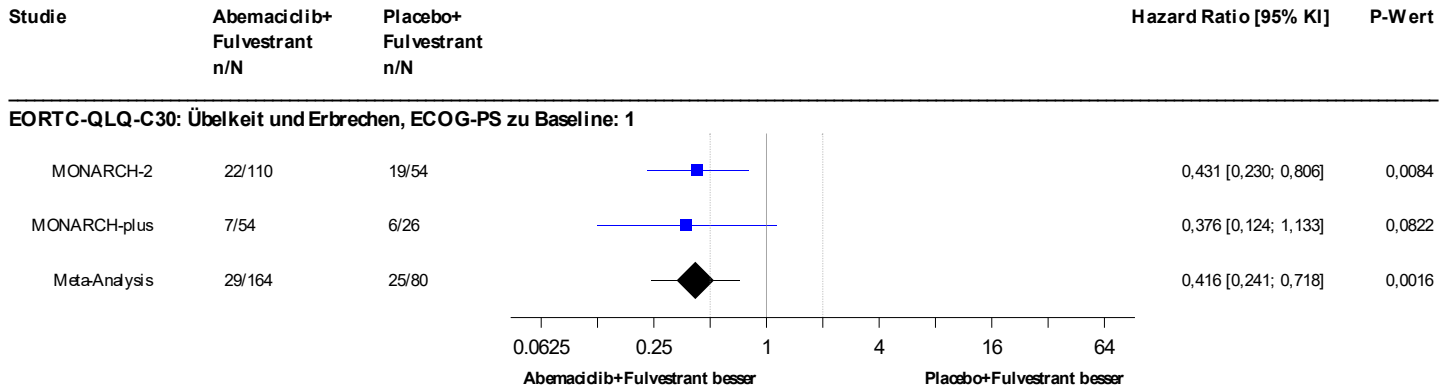
Abbildung 1410.1.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0447, P-Wert=0,8326, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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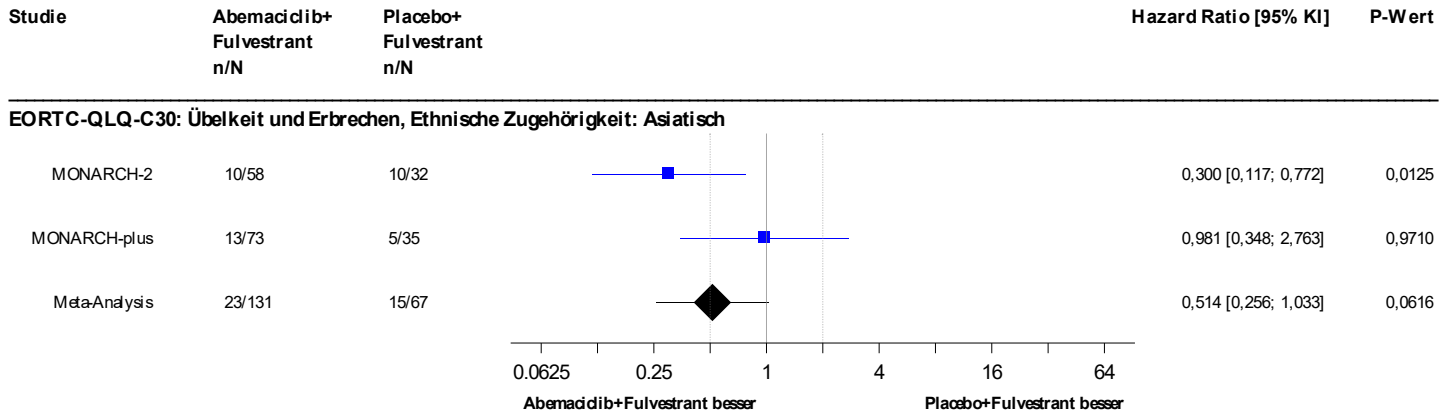
Abbildung 1410.1.5.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,7445, P-Wert=0,0976, I2 Index=63,6%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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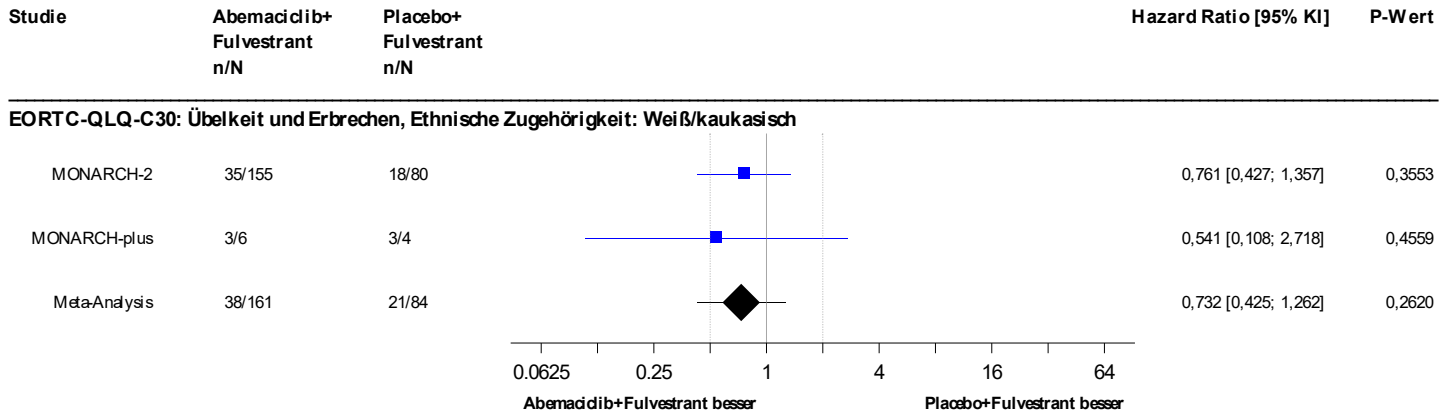
Abbildung 1410.1.5.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1523, P-Wert=0,6963, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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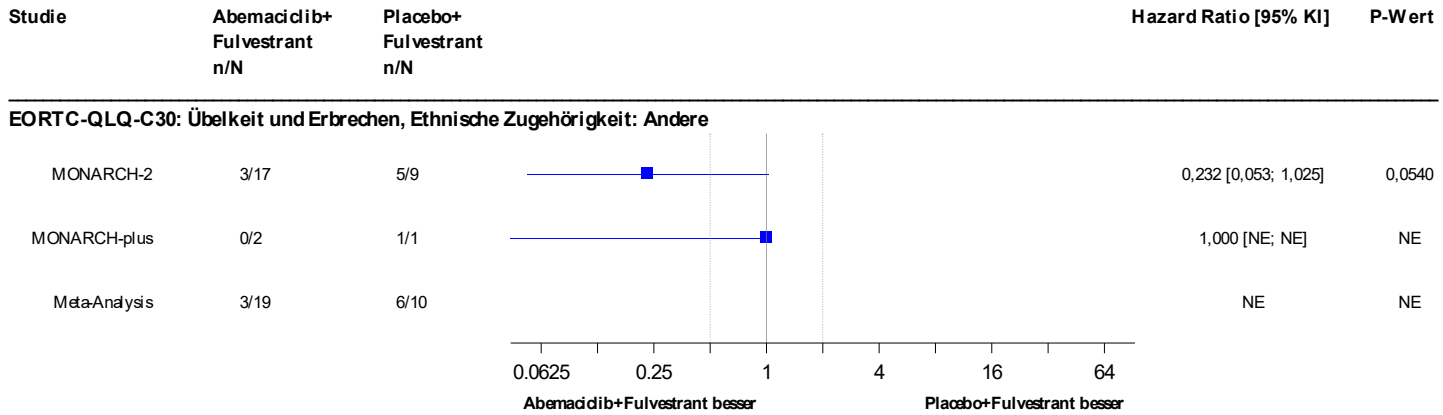
Abbildung 1410.1.5.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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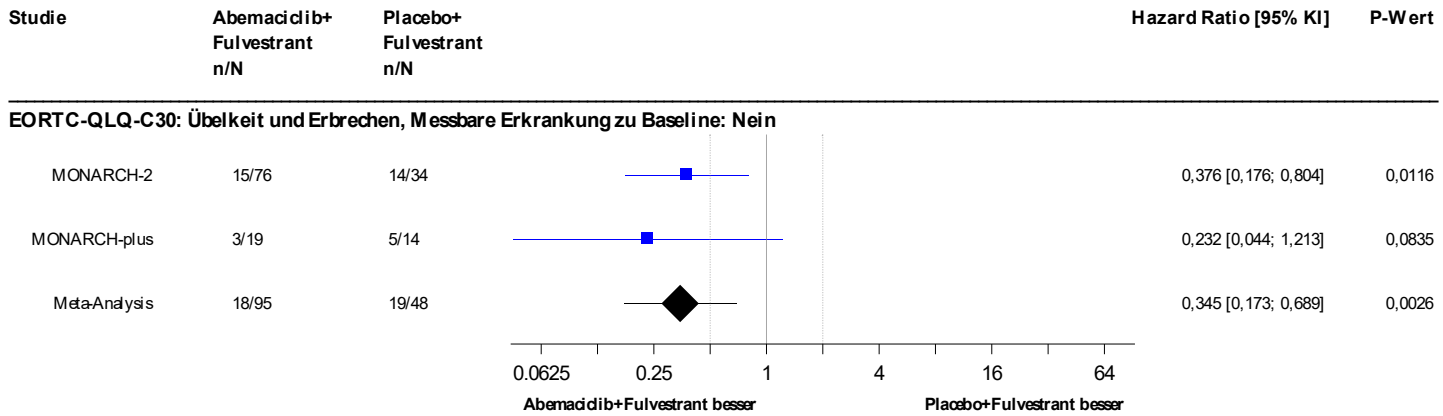
Abbildung 1410.1.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2685, P-Wert=0,6043, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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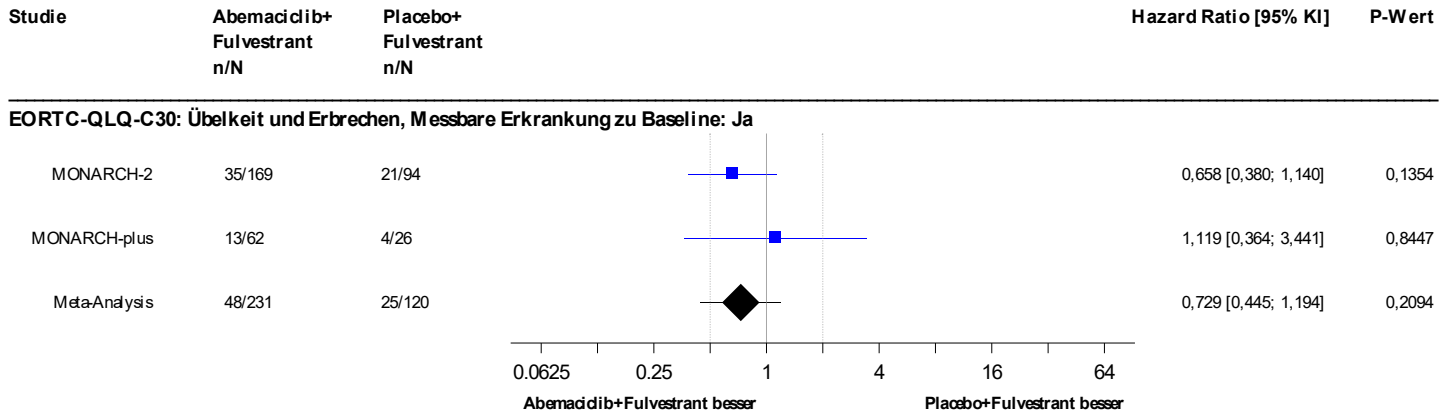
Abbildung 1410.1.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6928, P-Wert=0,4052, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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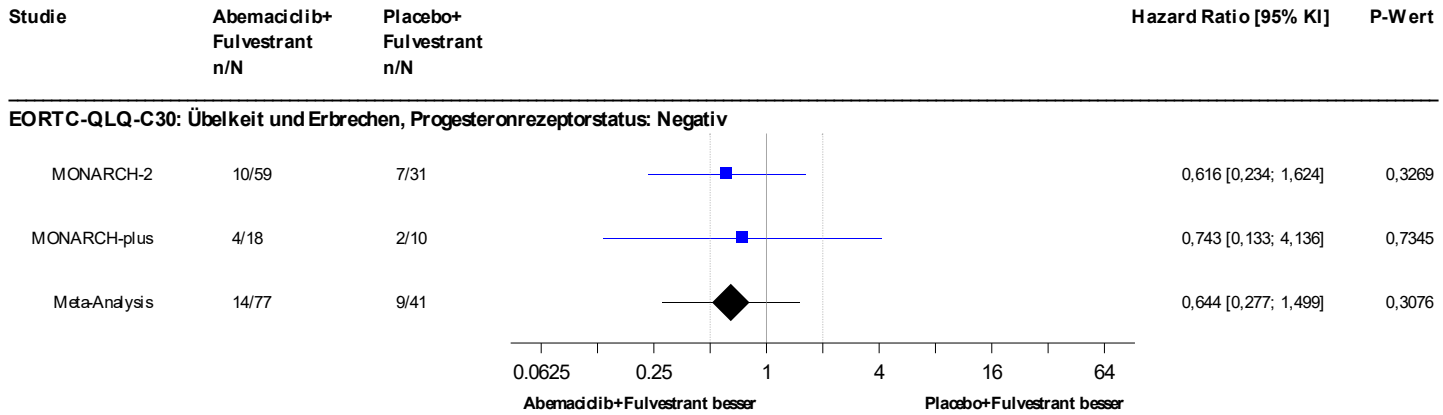
Abbildung 1410.1.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0348, P-Wert=0,8519, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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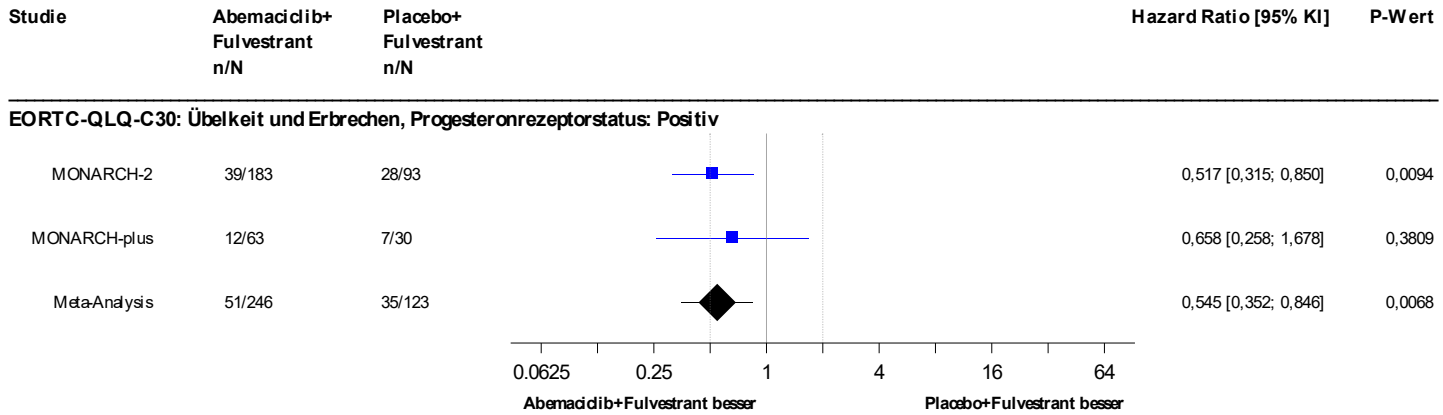
Abbildung 1410.1.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1977, P-Wert=0,6566, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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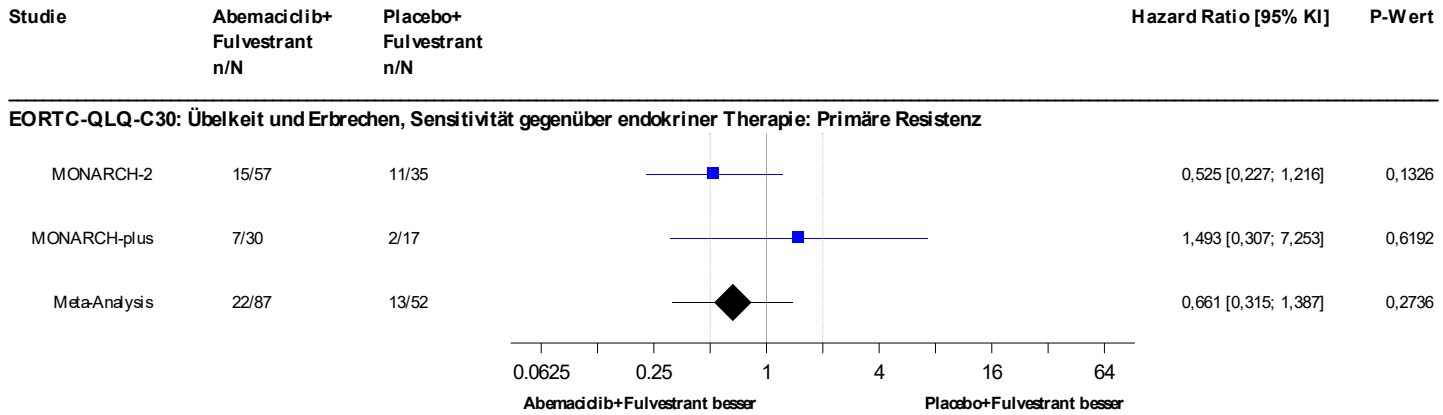
Abbildung 1410.1.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,3100, P-Wert=0,2524, I2 Index=23,7%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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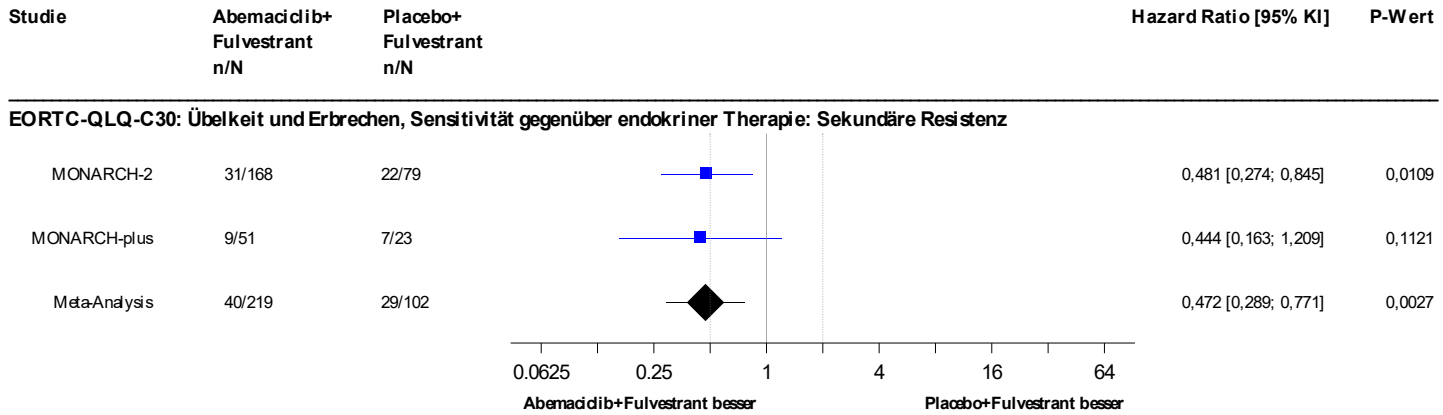
Abbildung 1410.1.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0194, P-Wert=0,8891, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwnavo6_popa1_snthr_2.rtf
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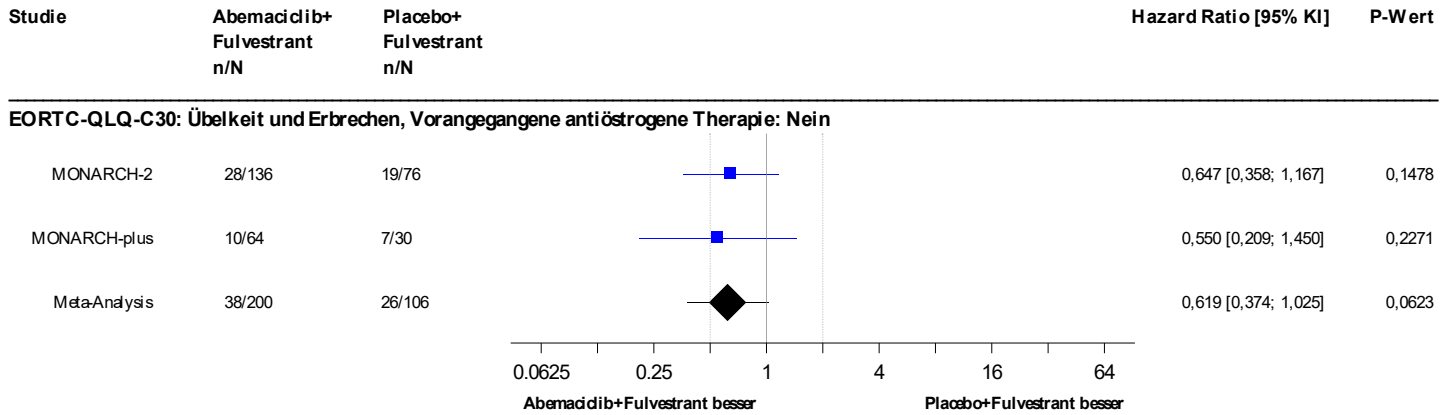
Abbildung 1410.1.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0776, P-Wert=0,7806, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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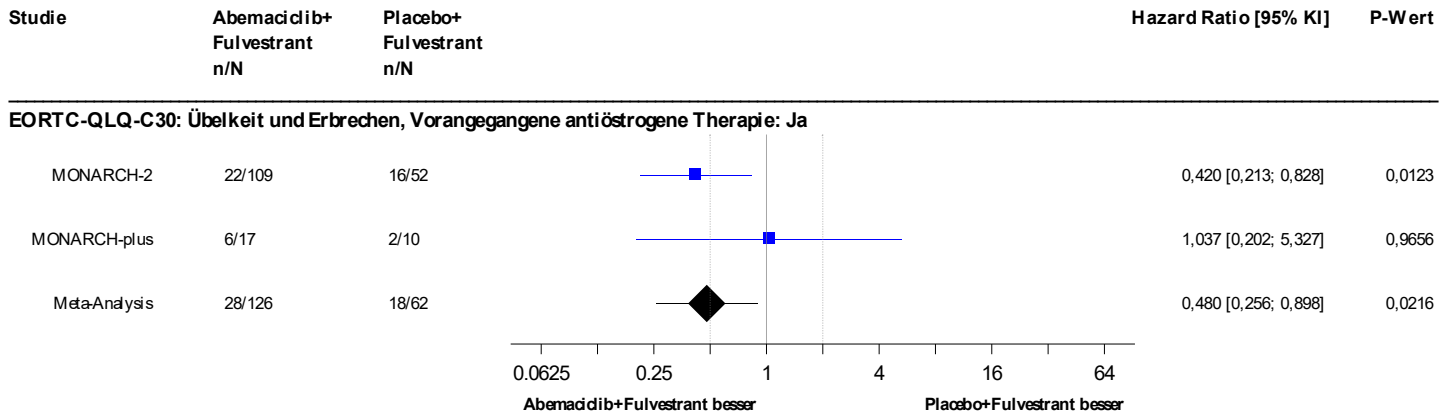
Abbildung 1410.1.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,9990, P-Wert=0,3176, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwnavo6_popa1_paet_2.rtf
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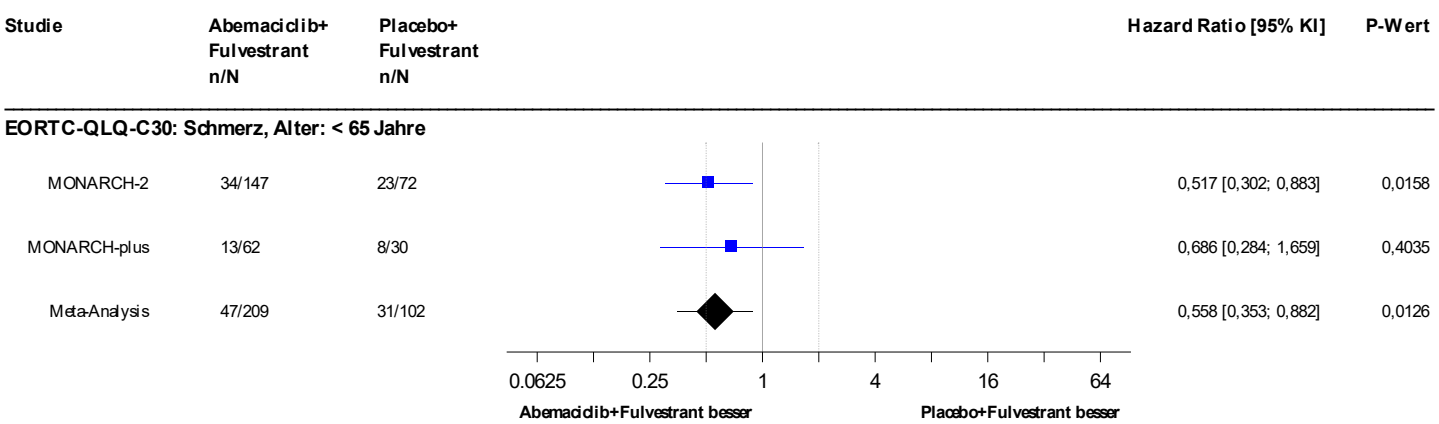
Abbildung 1411.1.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2914, P-Wert=0,5893, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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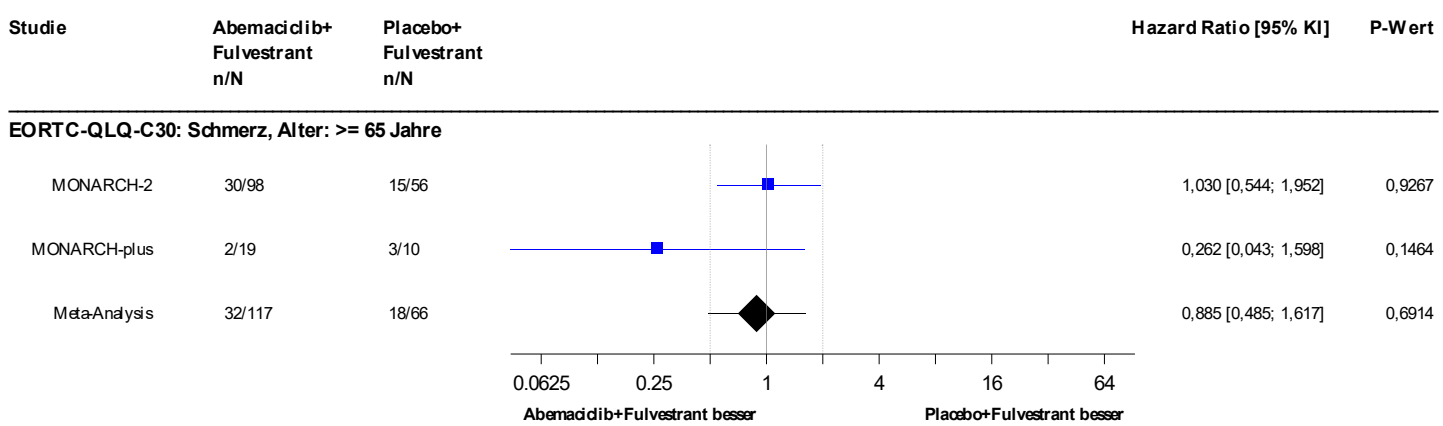
Abbildung 1411.1.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,9608, P-Wert=0,1614, I2 Index=49,0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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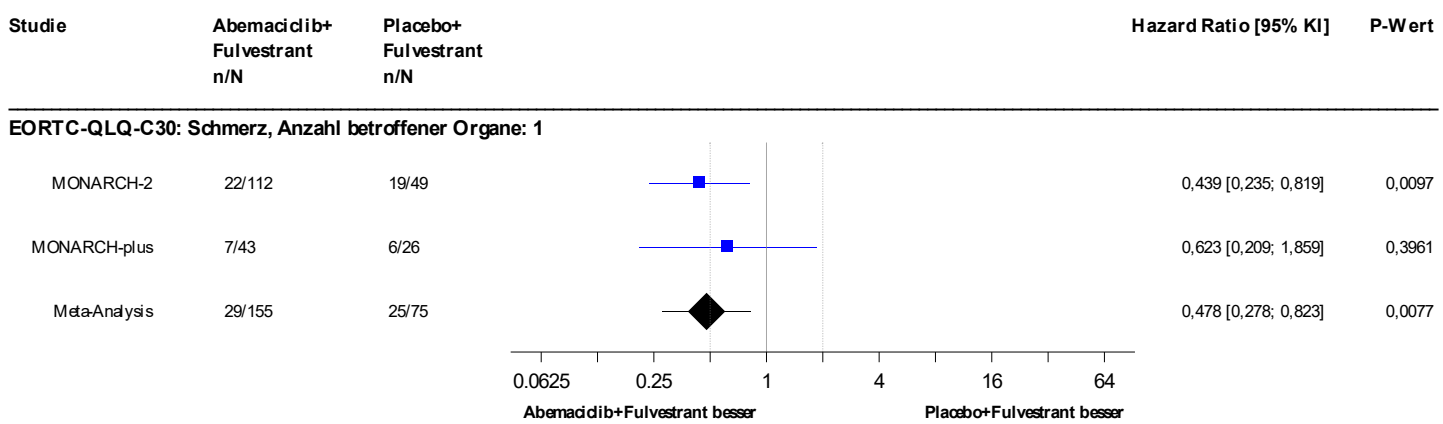
Abbildung 1411.1.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2974, P-Wert=0,5855, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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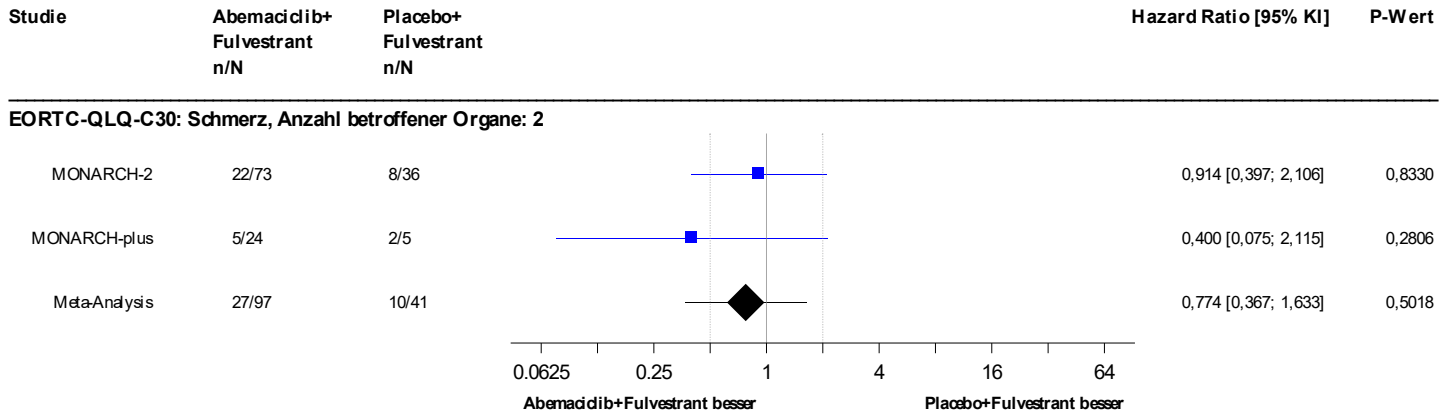
Abbildung 1411.1.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7575, P-Wert=0,3841, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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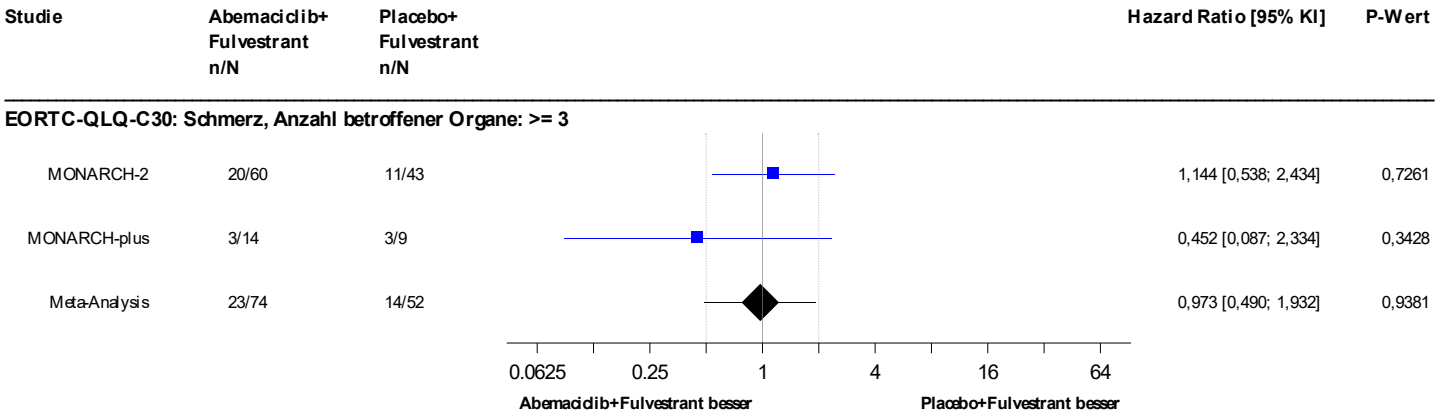
Abbildung 1411.1.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,0167, P-Wert=0,3133, I2 Index=1,6%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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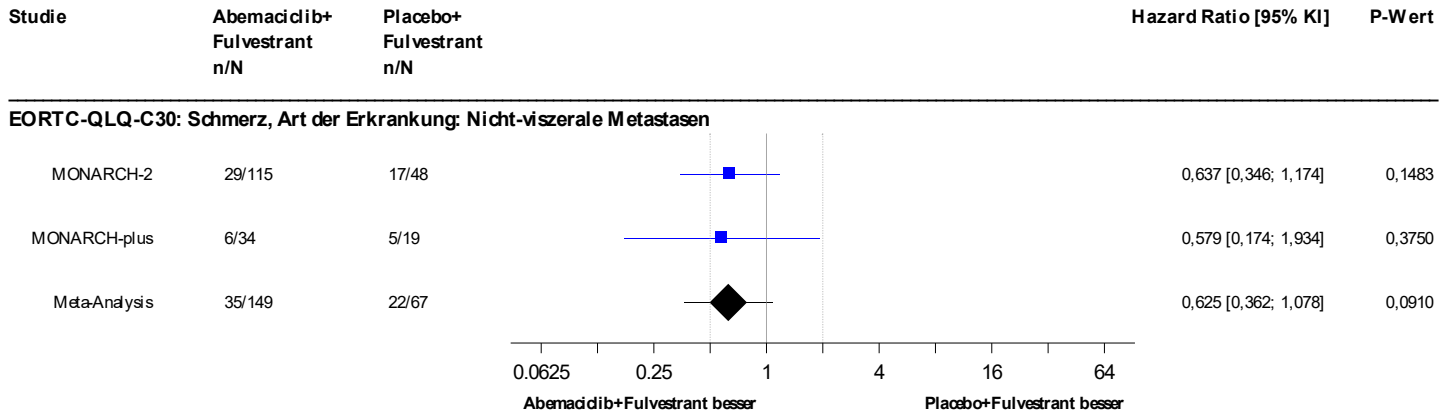
Abbildung 1411.1.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0188, P-Wert=0,8908, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwpain6_popa1_natdis2_1.rtf
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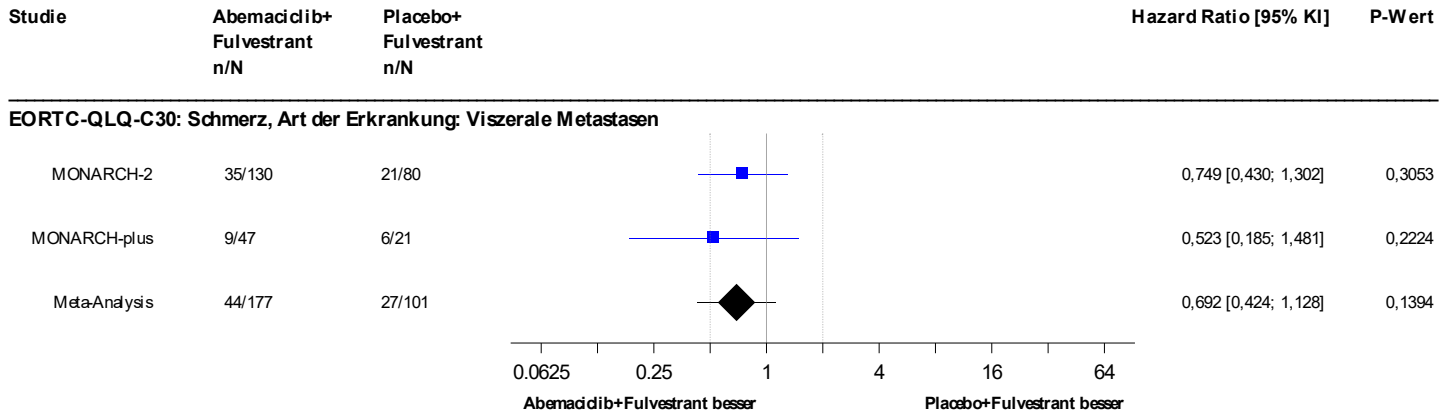
Abbildung 1411.1.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3551, P-Wert=0,5512, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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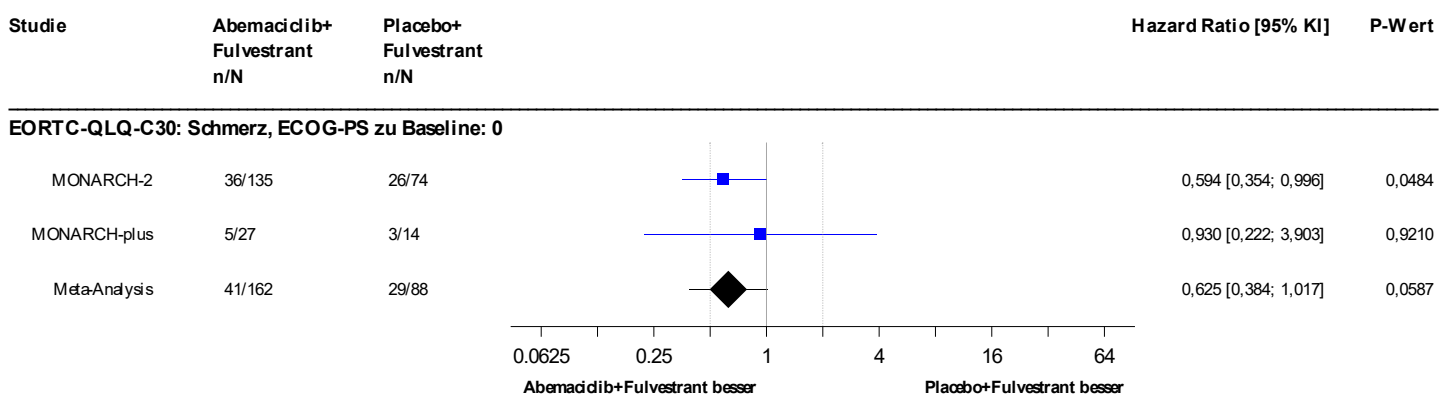
Abbildung 1411.1.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3323, P-Wert=0,5643, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwpain6_popa1_ecogbl_1.rtf
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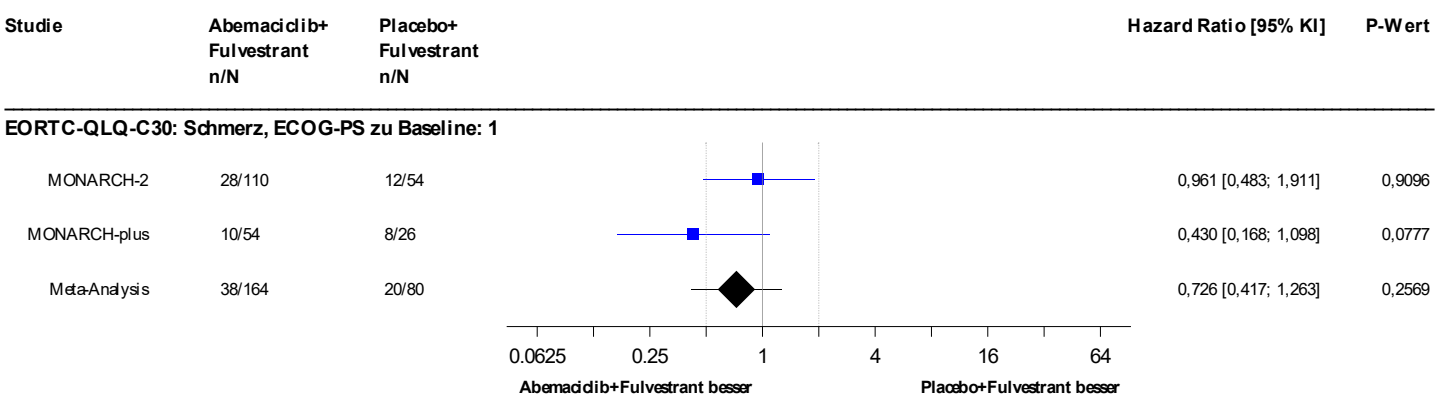
Abbildung 1411.1.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,8400, P-Wert=0,1749, I2 Index=45,7%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwpain6_popa1_ecogbl_2.rtf
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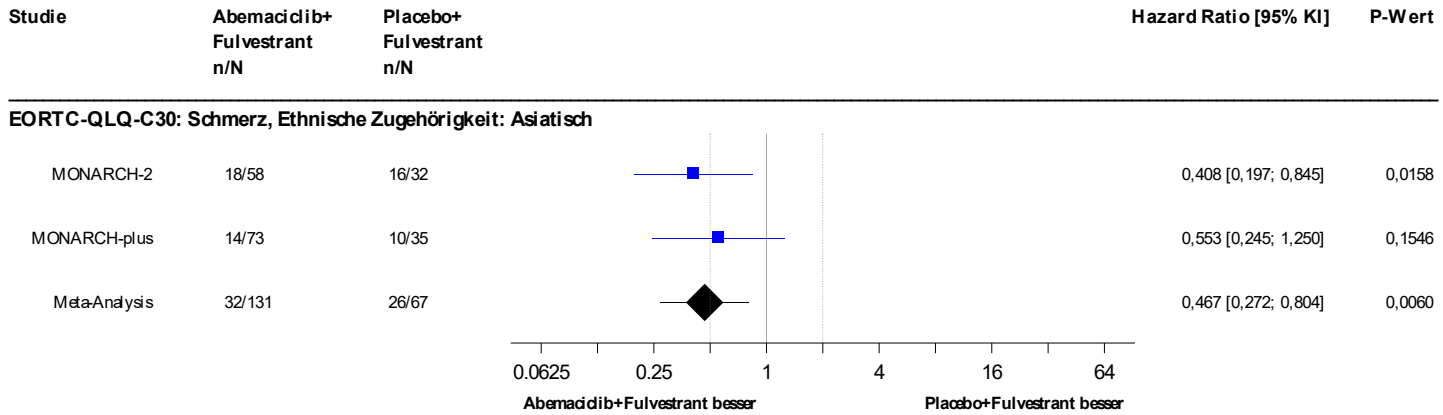
Abbildung 1411.1.5.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2972, P-Wert=0,5857, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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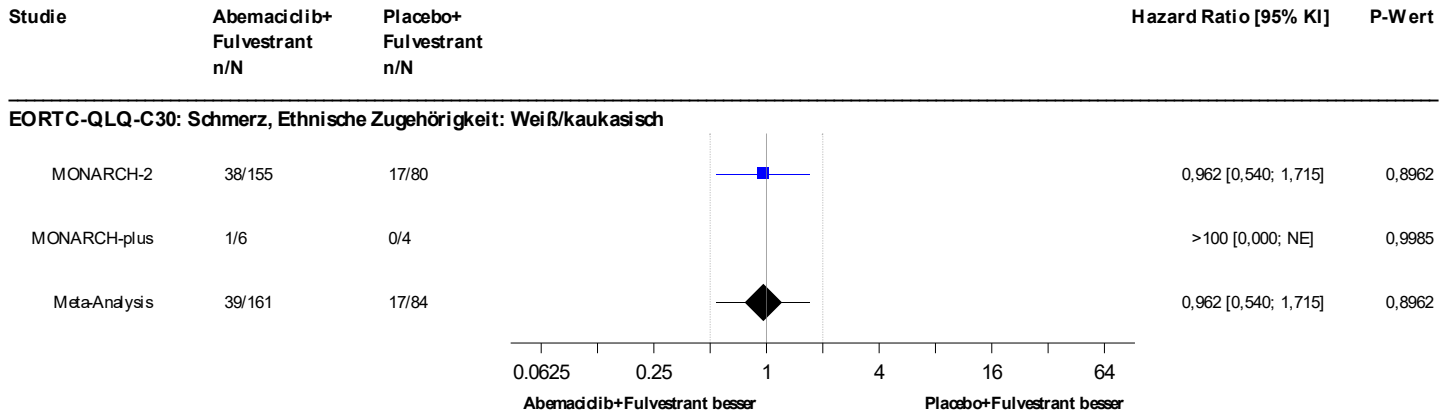
Abbildung 1411.1.5.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9985, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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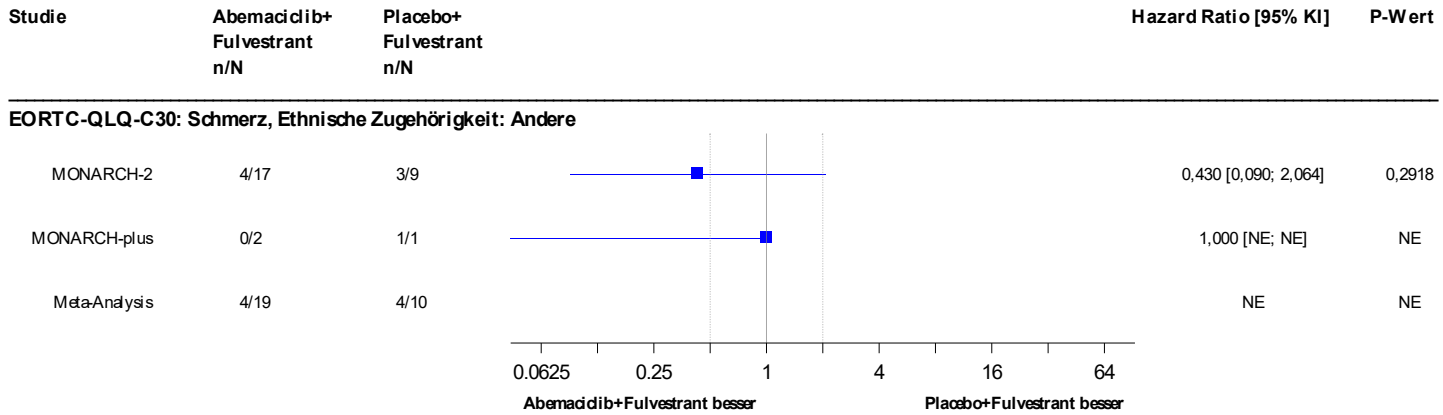
Abbildung 1411.1.5.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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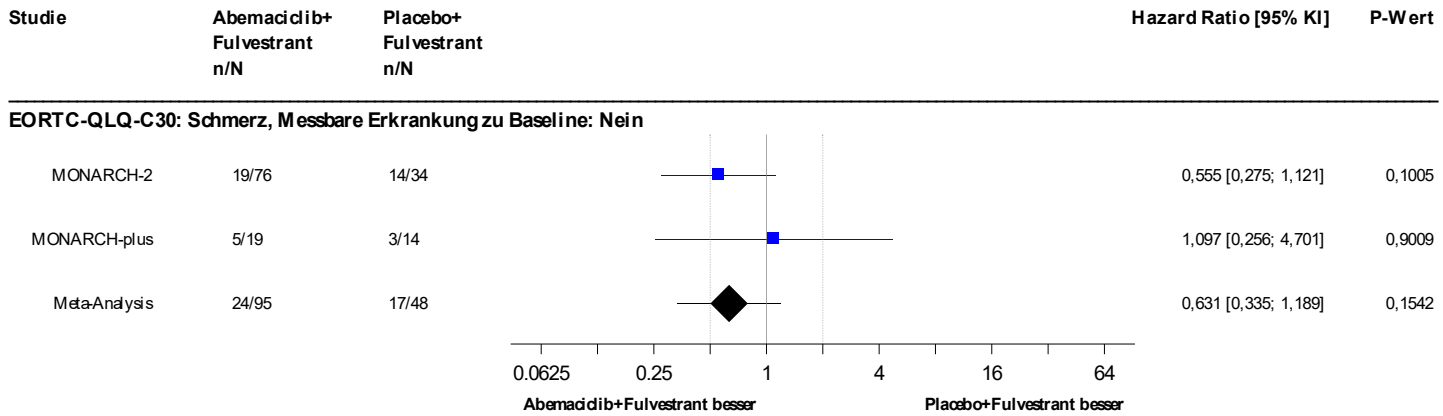
Abbildung 1411.1.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6825, P-Wert=0,4087, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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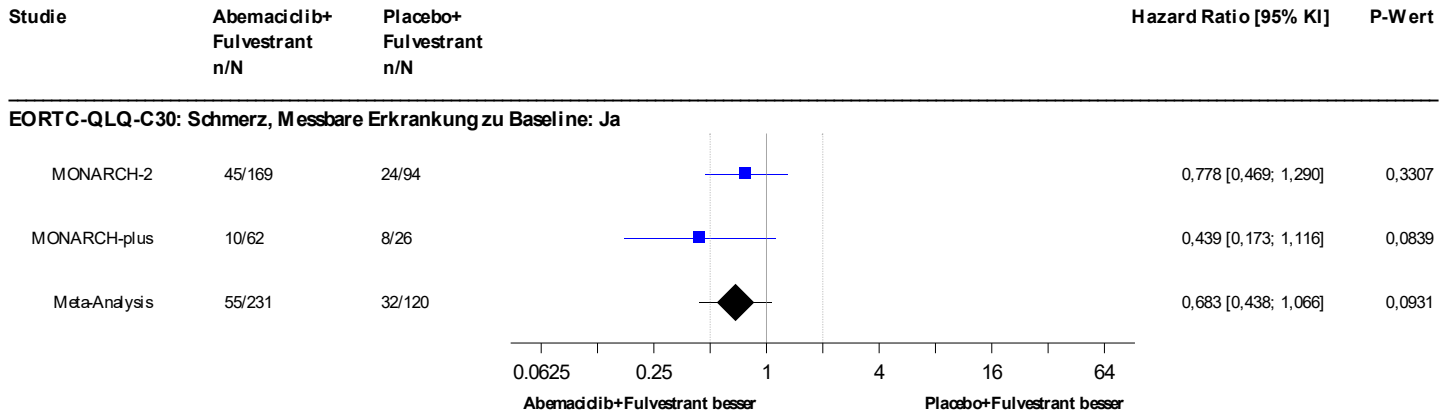
Abbildung 1411.1.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,1144, P-Wert=0,2911, I2 Index=10,3%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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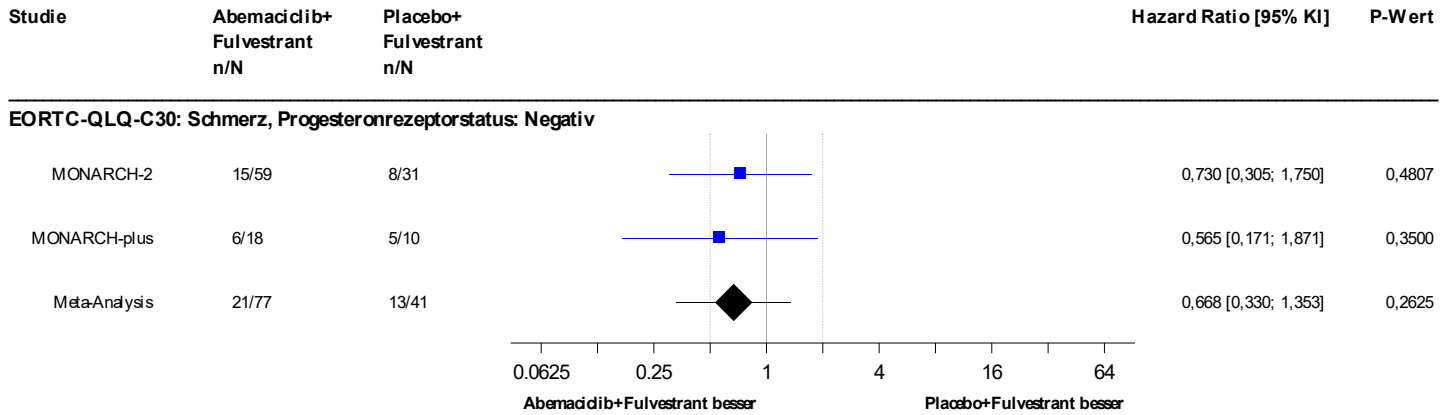
Abbildung 1411.1.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1150, P-Wert=0,7345, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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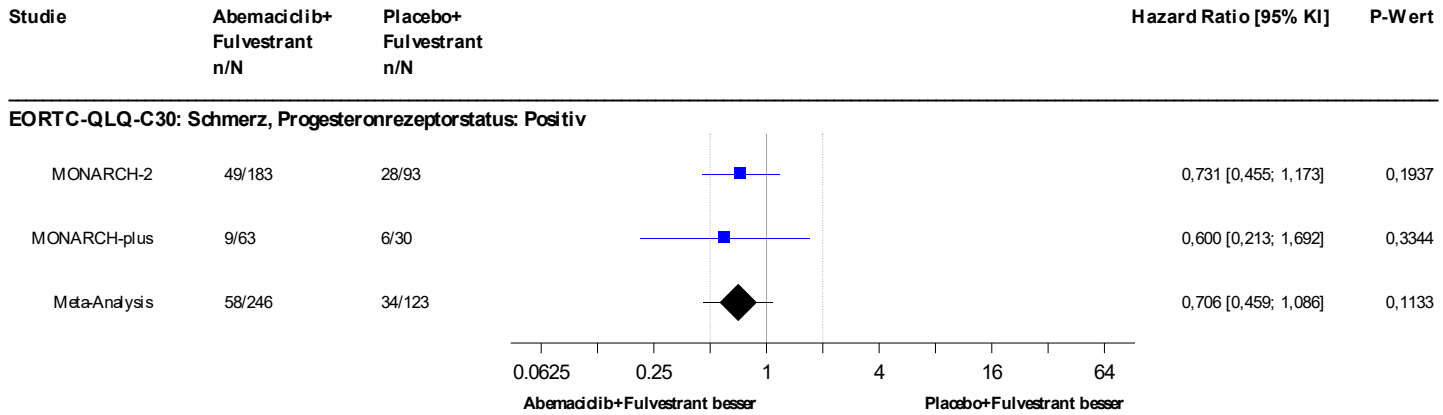
Abbildung 1411.1.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1141, P-Wert=0,7356, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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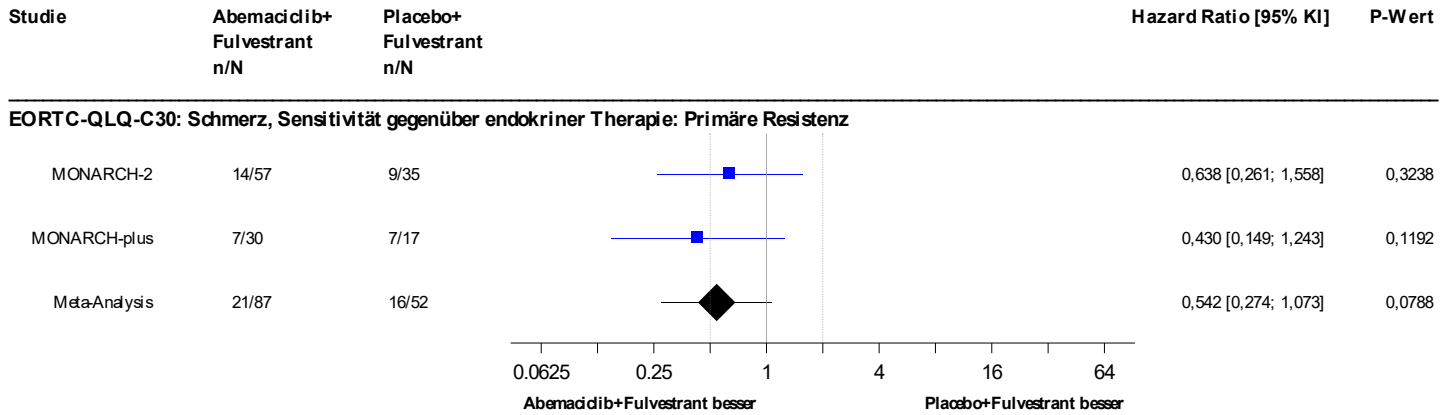
Abbildung 1411.1.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3106, P-Wert=0,5773, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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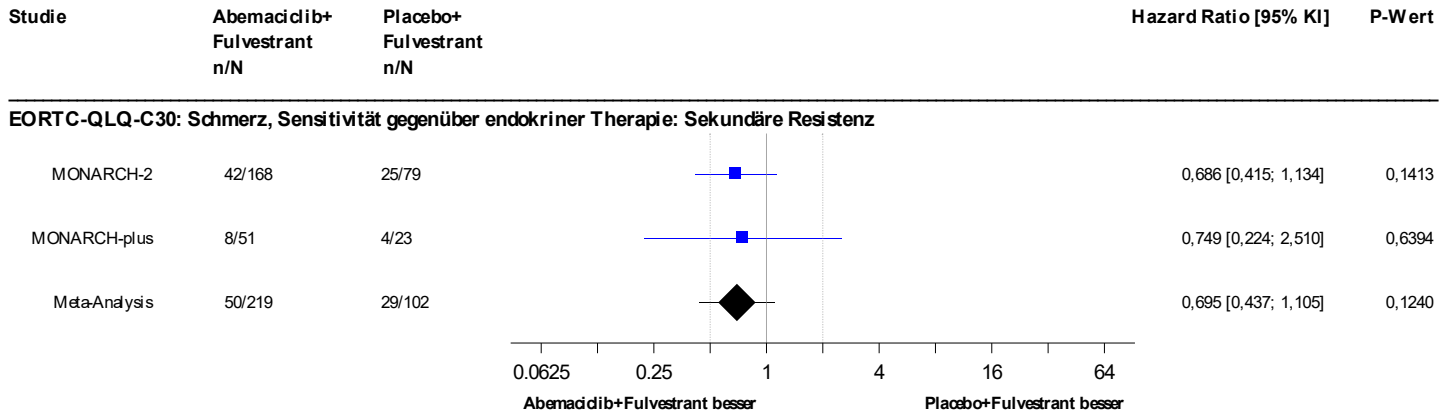
Abbildung 1411.1.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0173, P-Wert=0,8953, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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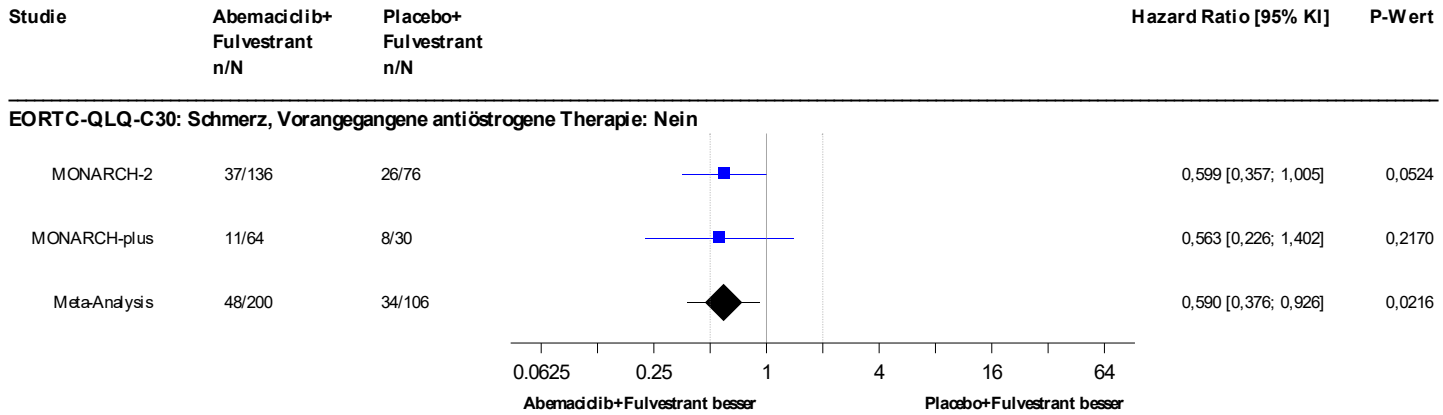
Abbildung 1411.1.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0134, P-Wert=0,9079, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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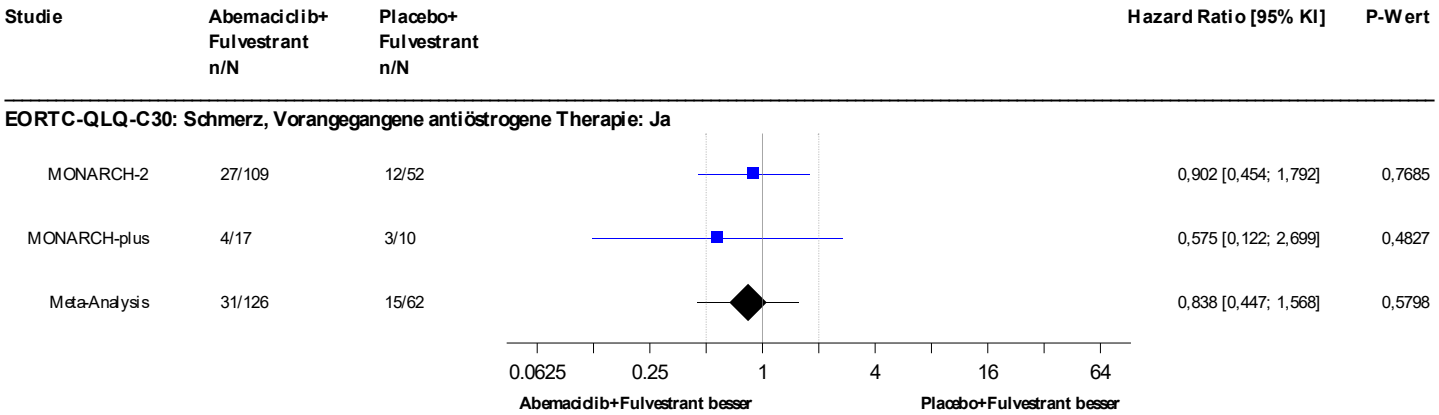
Abbildung 1411.1.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2727, P-Wert=0,6015, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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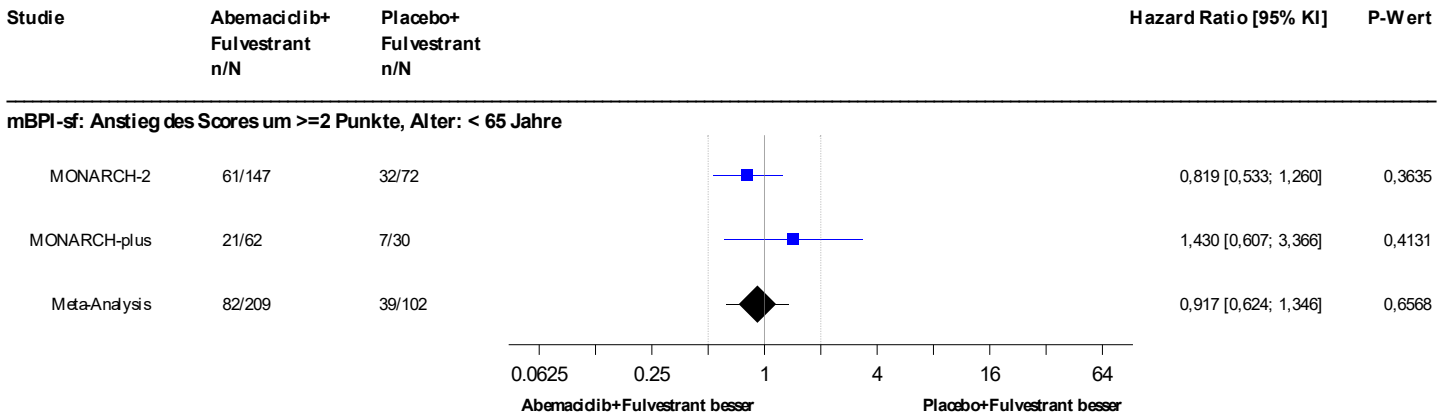
Abbildung 1412.1.1.1: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Alter: < 65 Jahre Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,2981, P-Wert=0,2546, I2 Index=23,0%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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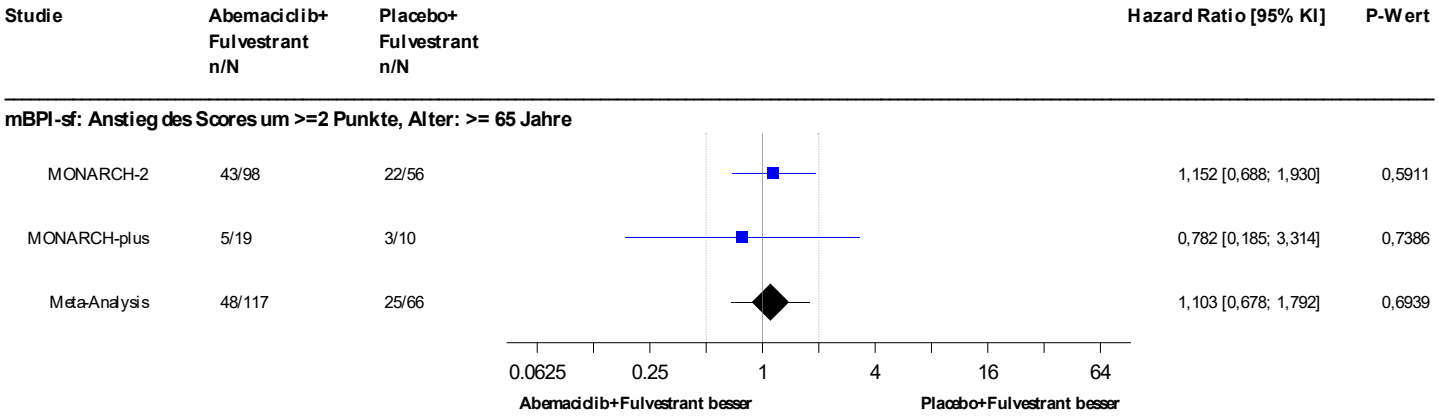
Abbildung 1412.1.1.2: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Alter: >= 65 Jahre Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2450, P-Wert=0,6206, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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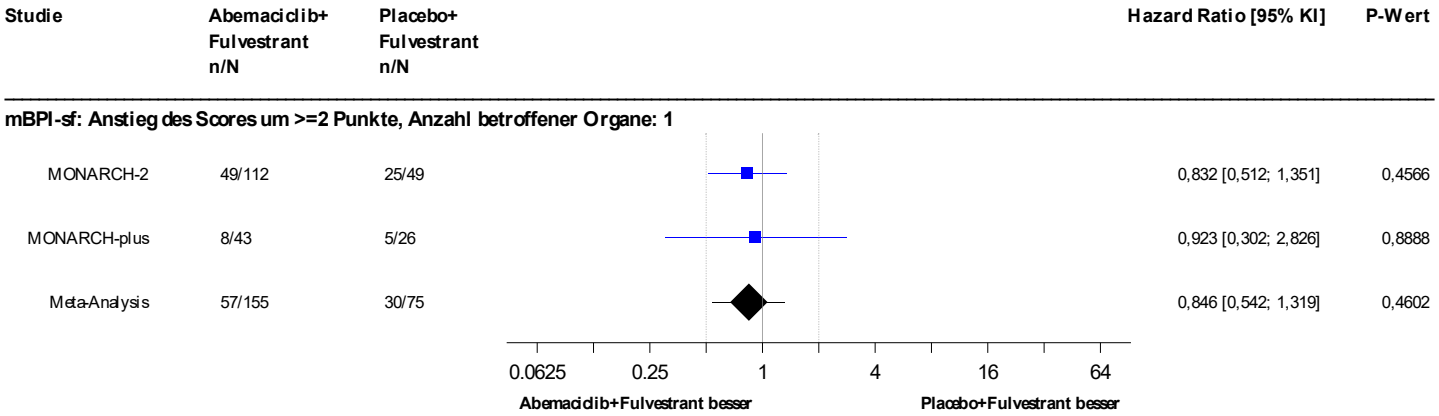
Abbildung 1412.1.2.1: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Anzahl betroffener Organe: 1 Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0281, P-Wert=0,8668, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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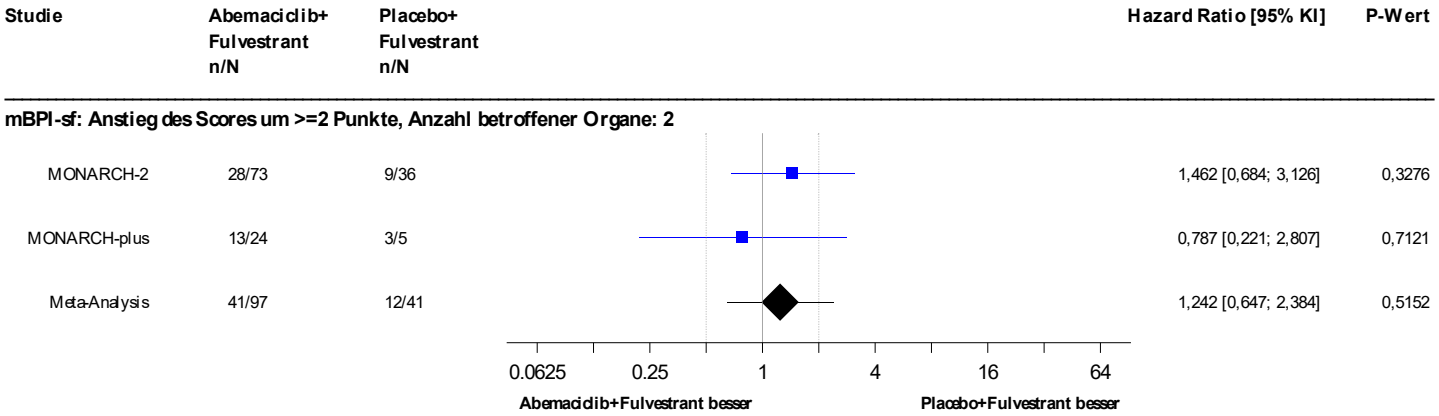
Abbildung 1412.1.2.2: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Anzahl betroffener Organe: 2 Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6709, P-Wert=0,4128, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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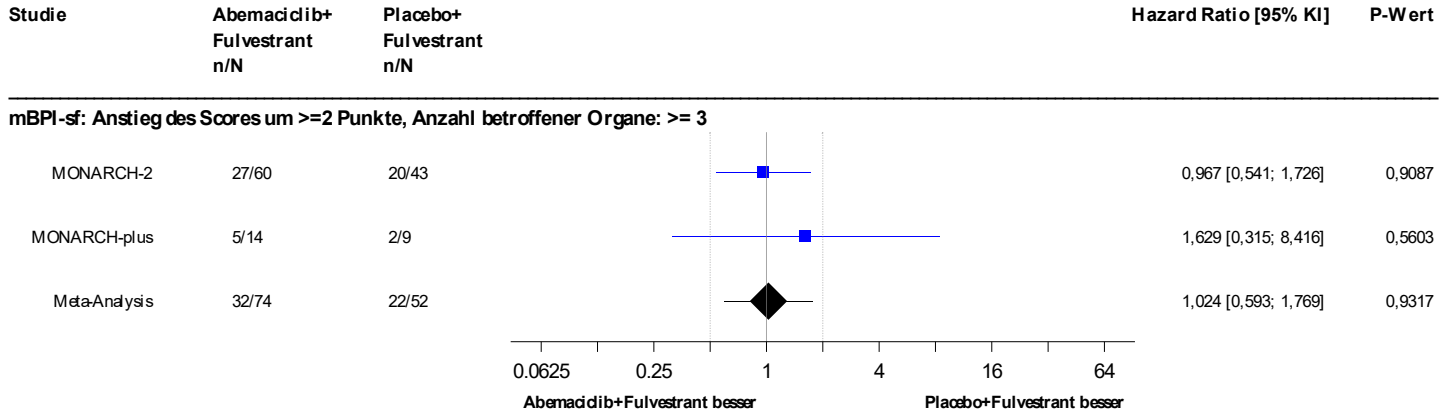
Abbildung 1412.1.2.3: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Anzahl betroffener Organe: >= 3 Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3450, P-Wert=0,5570, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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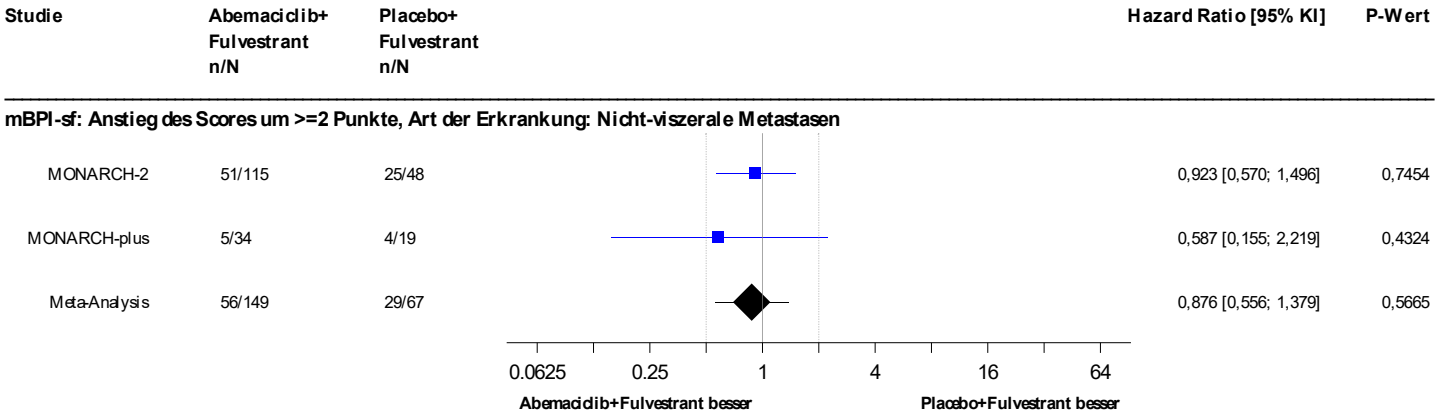
Abbildung 1412.1.3.1: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3932, P-Wert=0,5306, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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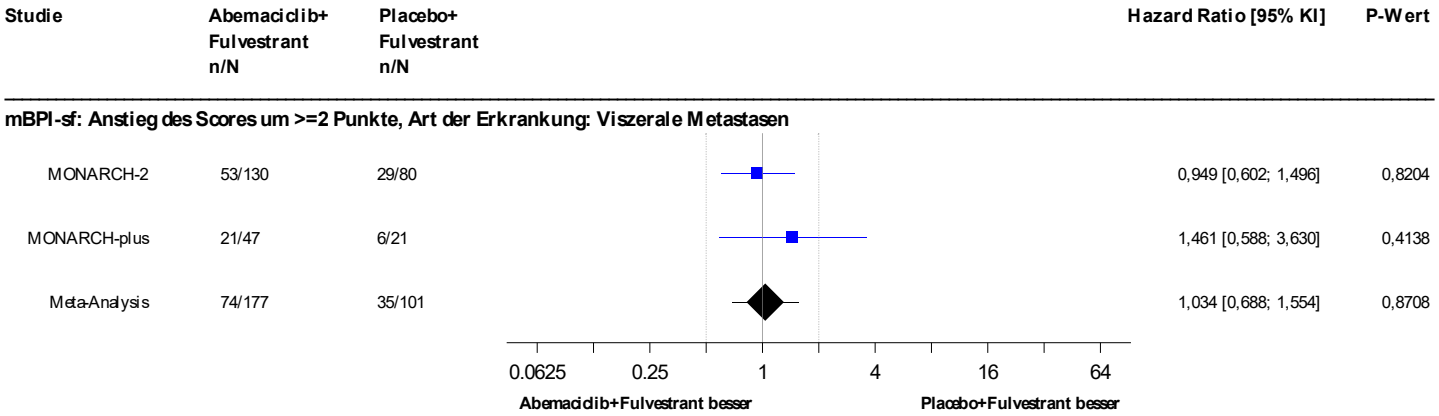
Abbildung 1412.1.3.2: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6928, P-Wert=0,4052, I2 Index=0%

Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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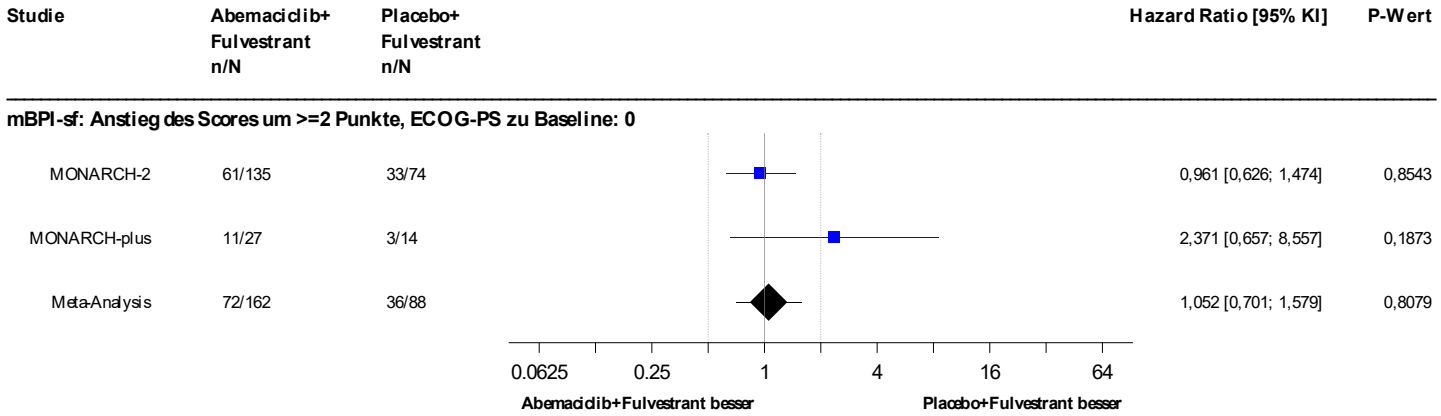
Abbildung 1412.1.4.1: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,7133, P-Wert=0,1906, I2 Index=41,6%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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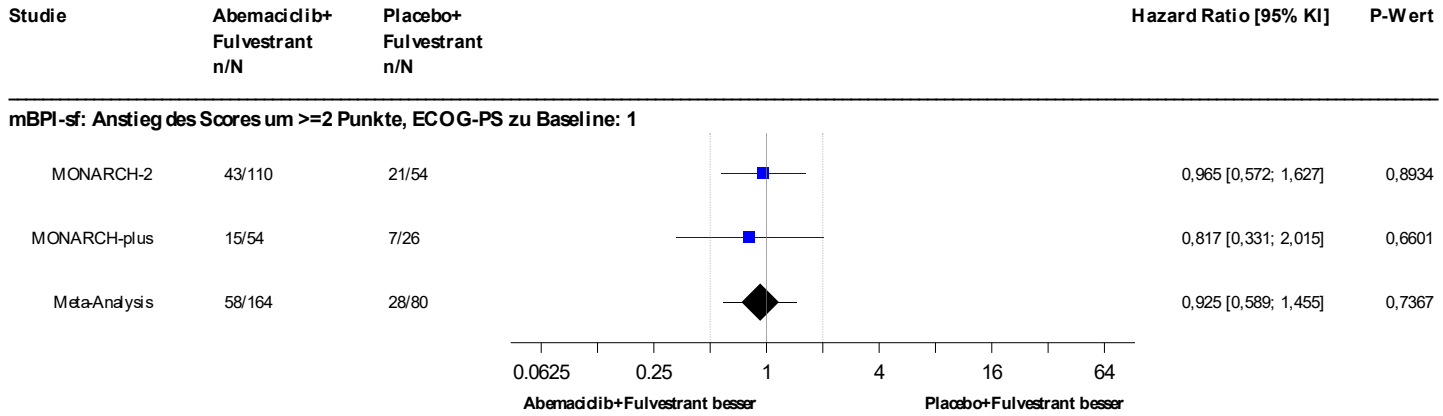
Abbildung 1412.1.4.2: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0983, P-Wert=0,7539, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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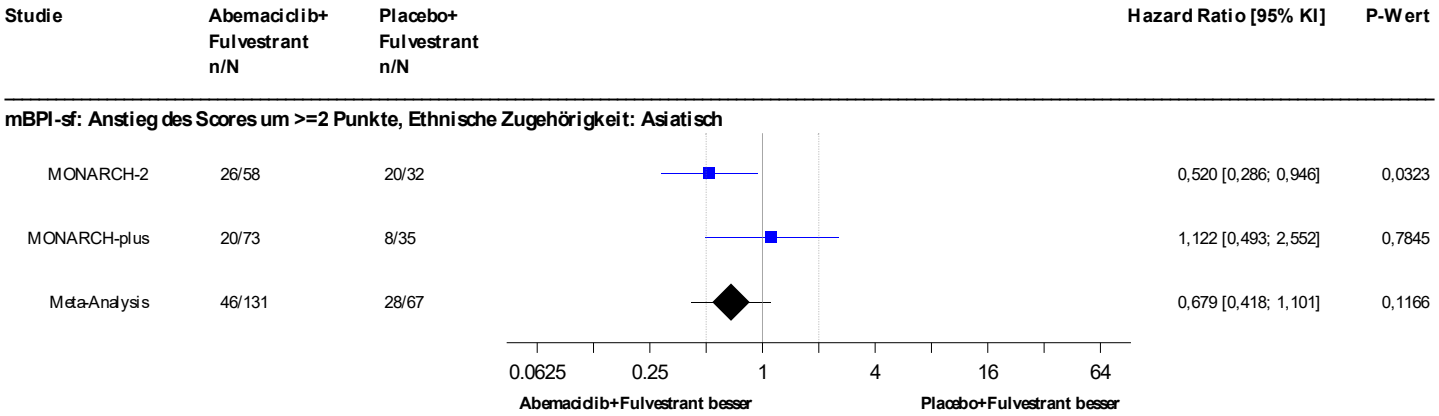
Abbildung 1412.1.5.1: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,1923, P-Wert=0,1387, I2 Index=54,4%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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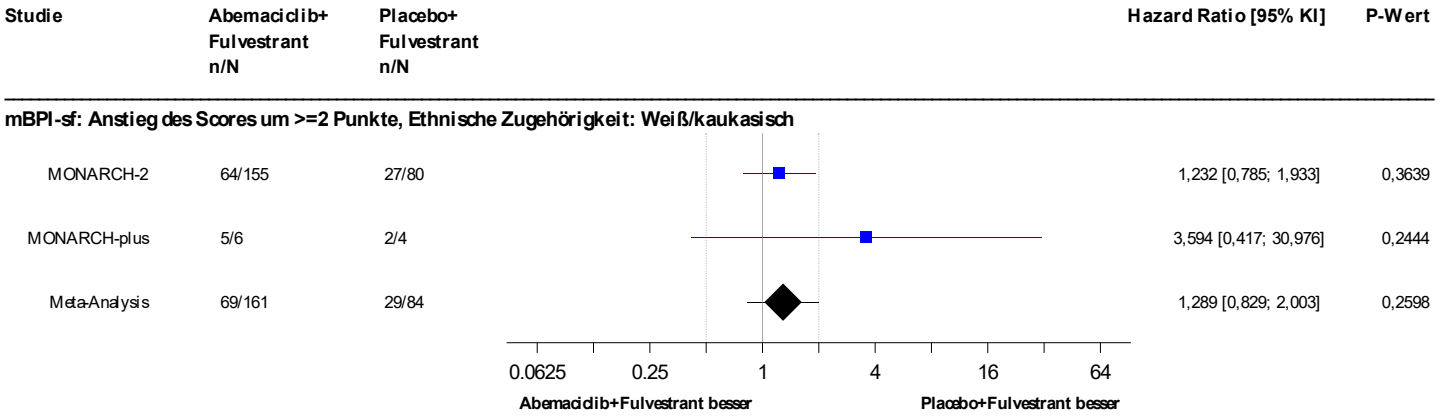
Abbildung 1412.1.5.2: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,9094, P-Wert=0,3403, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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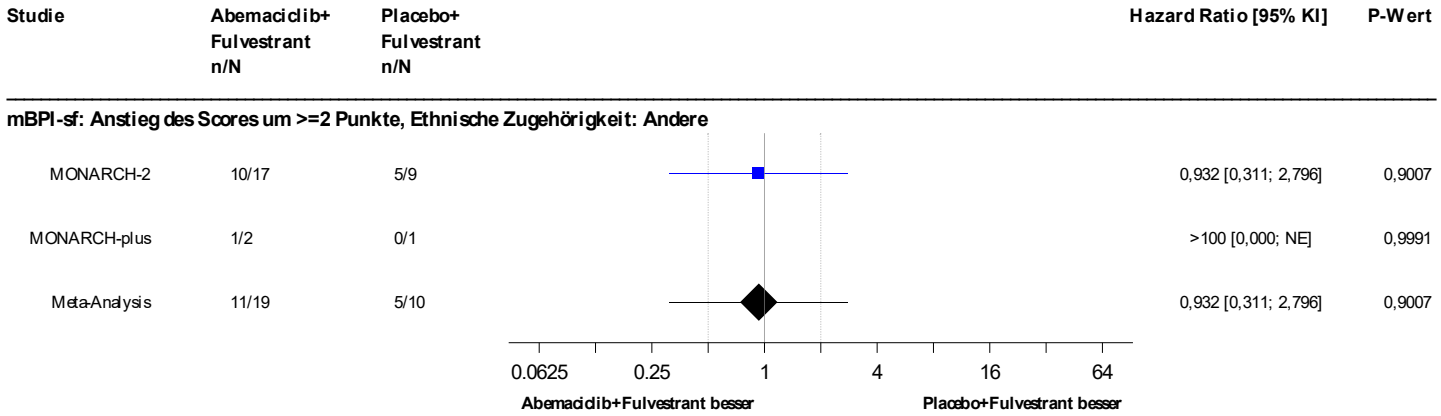
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
17SEP2021 / 07:48

Abbildung 1412.1.5.3: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Ethnische Zugehörigkeit: Andere Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9991, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwpa2dc_popa1_racegr1_3.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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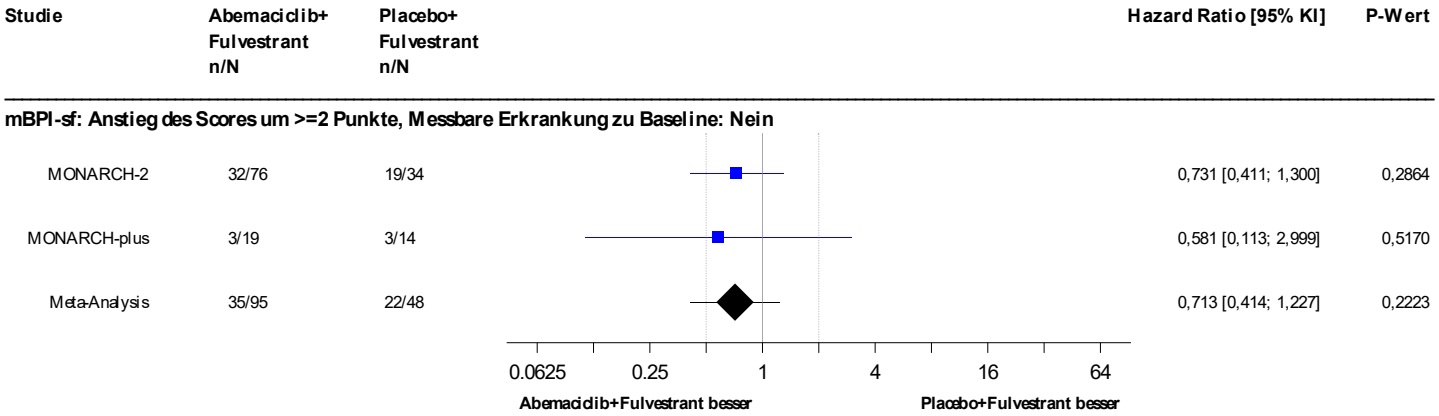
Abbildung 1412.1.6.1: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0669, P-Wert=0,7959, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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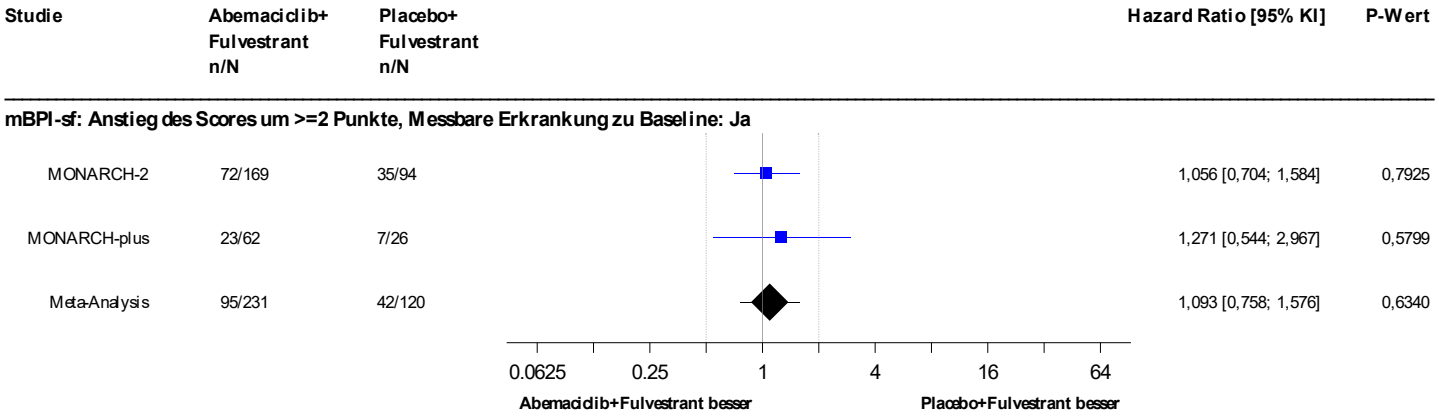
Abbildung 1412.1.6.2: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1489, P-Wert=0,6996, I2 Index=0%

Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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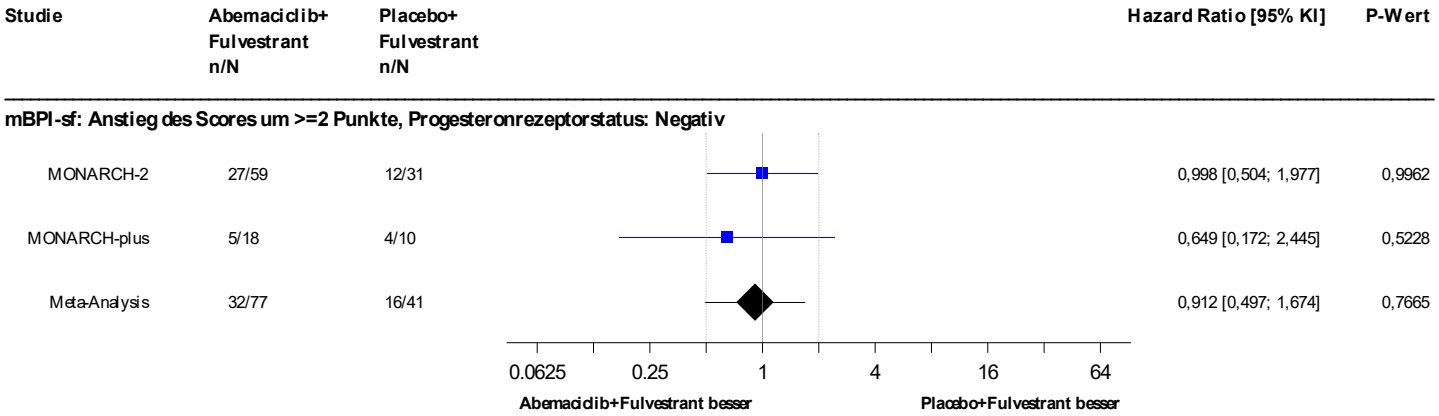
Abbildung 1412.1.7.1: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Progesteronrezeptorstatus: Negativ Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3203, P-Wert=0,5714, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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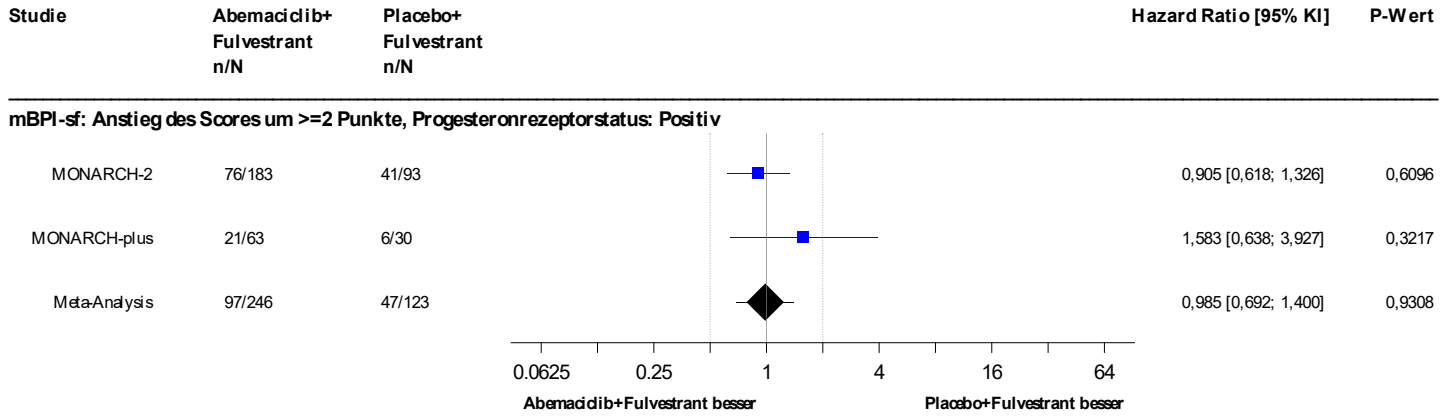
17SEP2021 / 07:48

Abbildung 1412.1.7.2: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Progesteronrezeptorstatus: Positiv Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,2353, P-Wert=0,2664, I2 Index=19,1%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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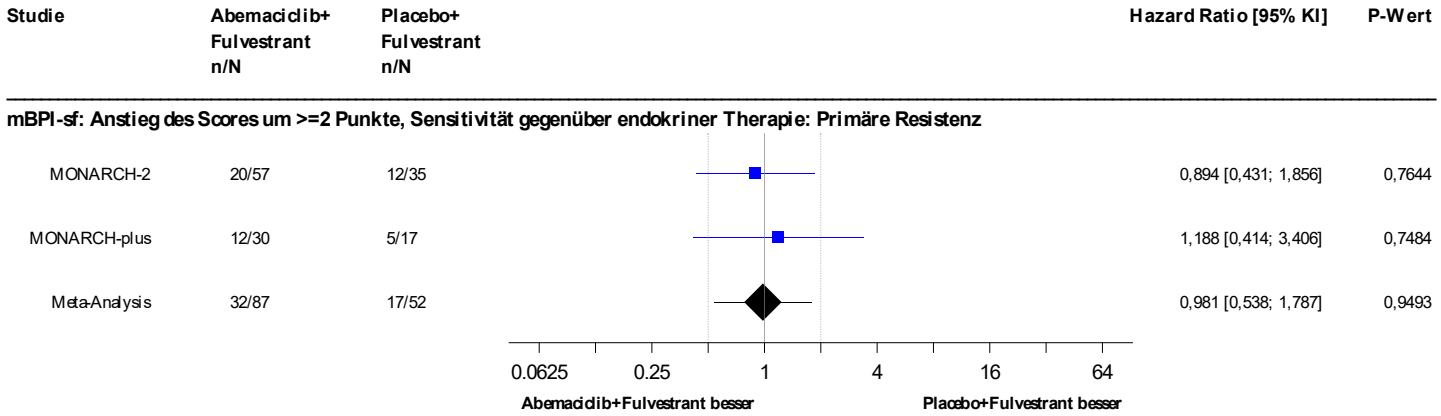
17SEP2021 / 07:48

Abbildung 1412.1.8.1: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1886, P-Wert=0,6641, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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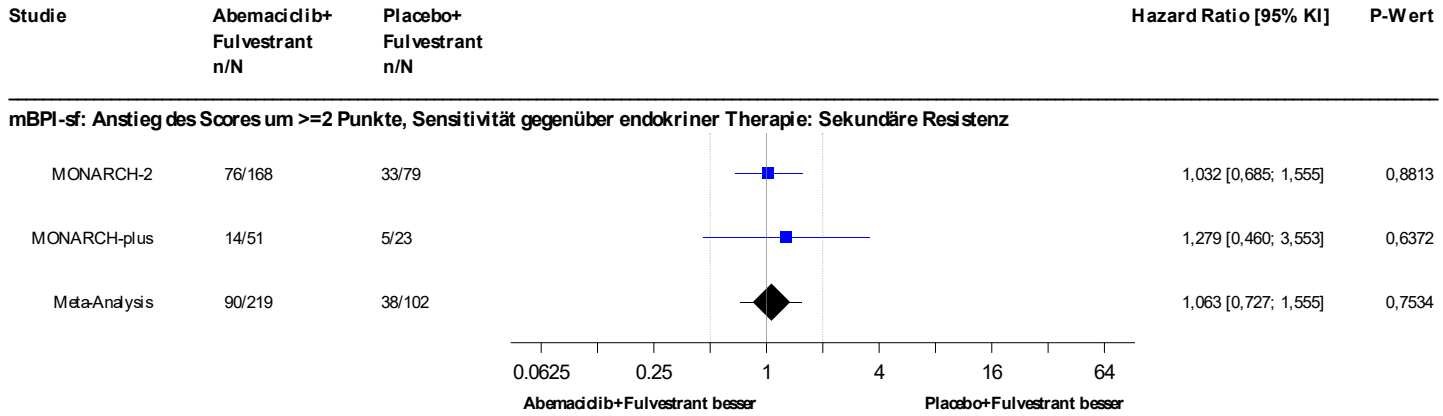
Abbildung 1412.1.8.2: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1460, P-Wert=0,7024, I2 Index=0%

Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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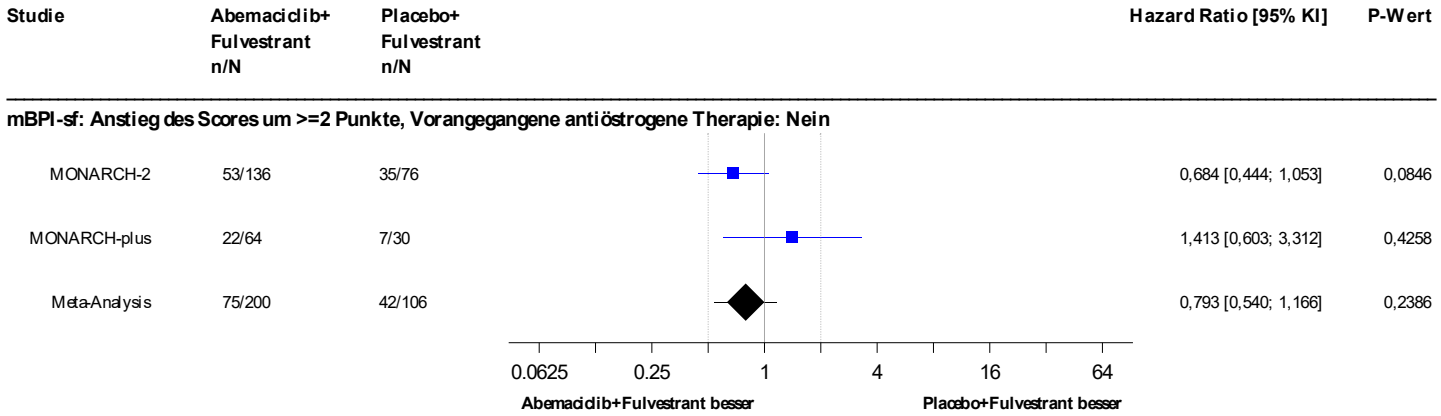
Abbildung 1412.1.9.1: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,2193, P-Wert=0,1363, I2 Index=54,9%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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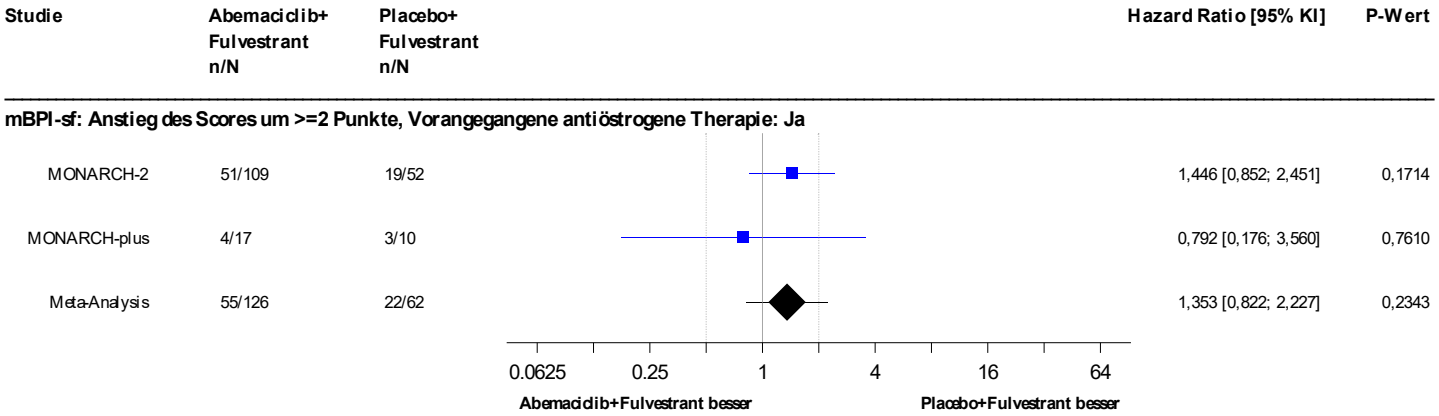
Abbildung 1412.1.9.2: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,5481, P-Wert=0,4591, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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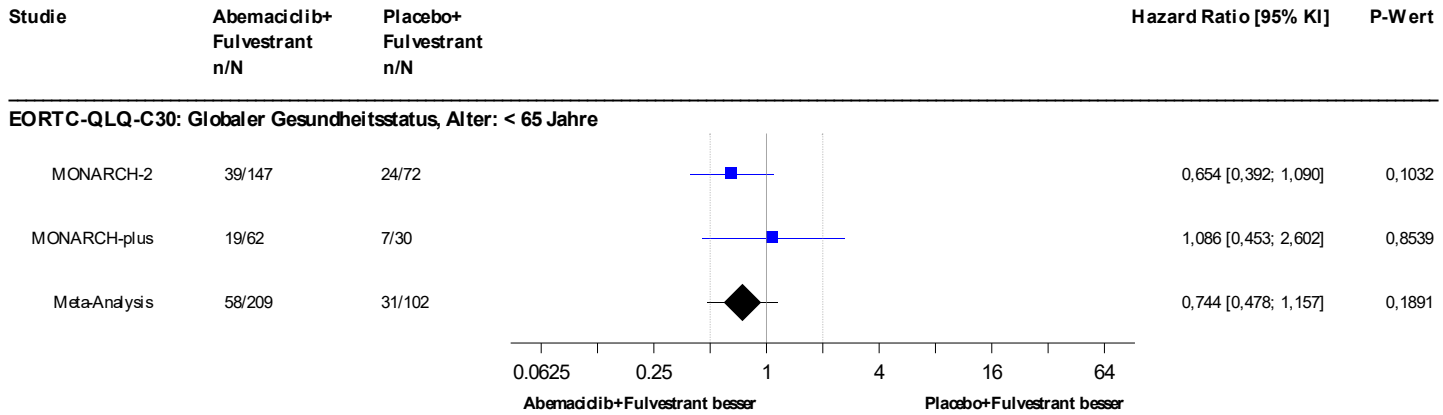
Abbildung 1413.1.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,9643, P-Wert=0,3261, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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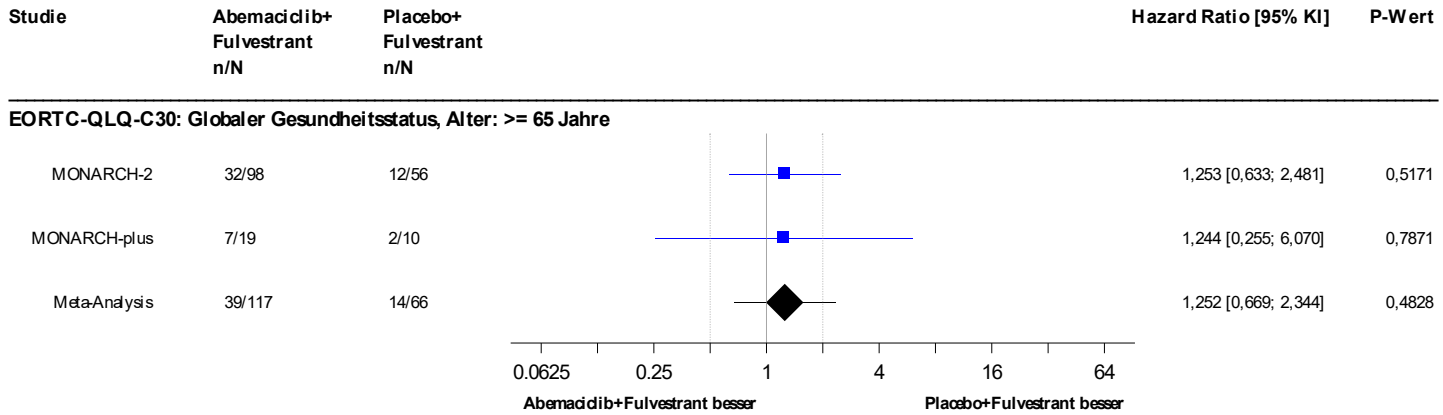
Abbildung 1413.1.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9933, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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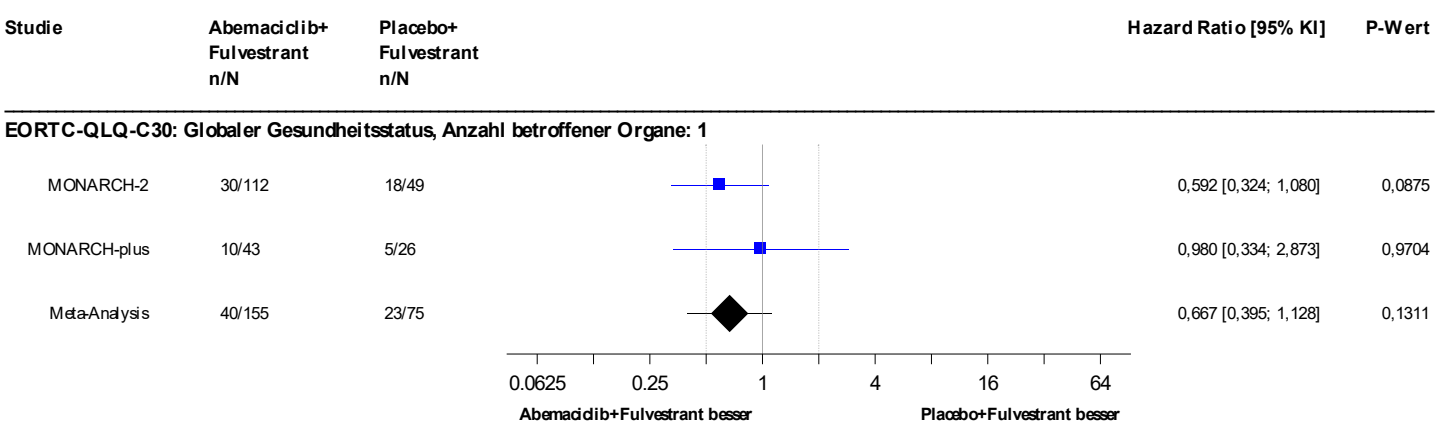
Abbildung 1413.1.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6431, P-Wert=0,4226, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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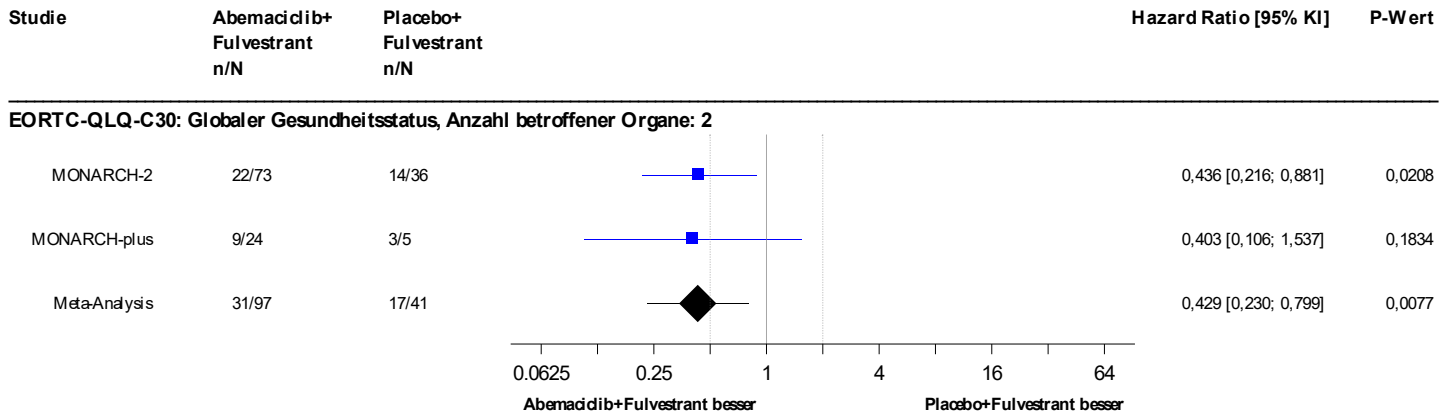
Abbildung 1413.1.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0104, P-Wert=0,9189, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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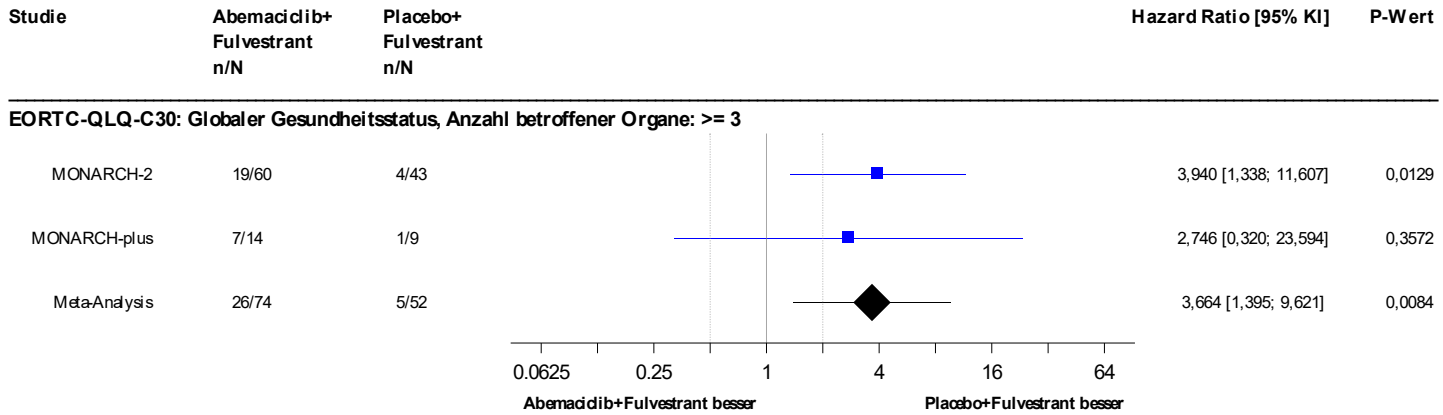
Abbildung 1413.1.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0864, P-Wert=0,7688, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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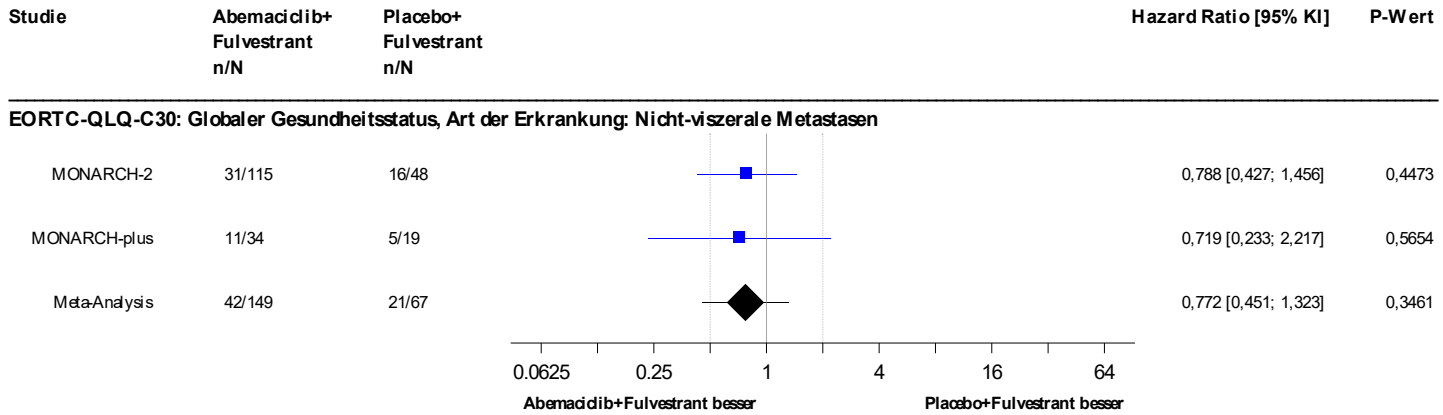
Abbildung 1413.1.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0201, P-Wert=0,8873, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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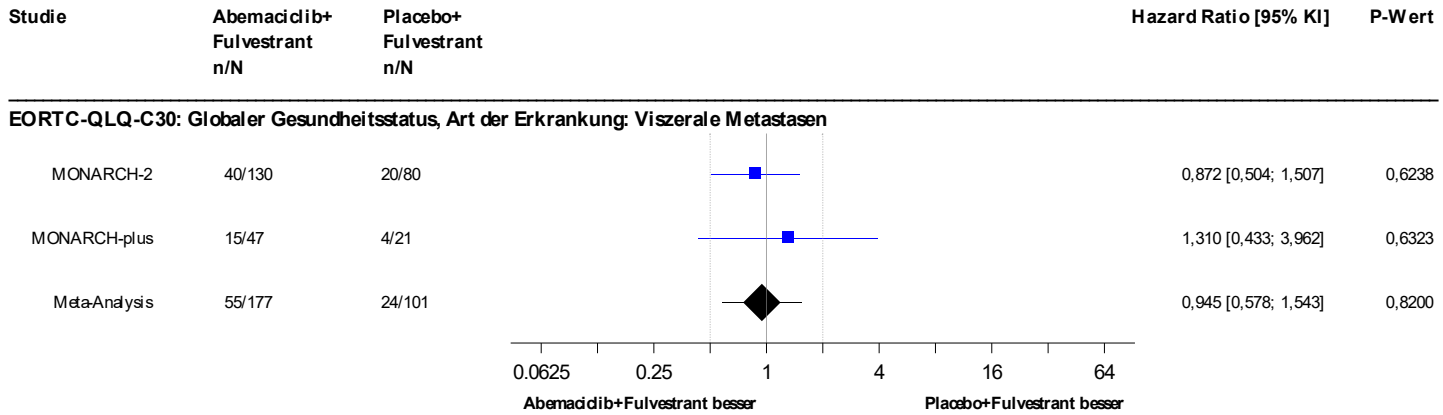
Abbildung 1413.1.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4178, P-Wert=0,5180, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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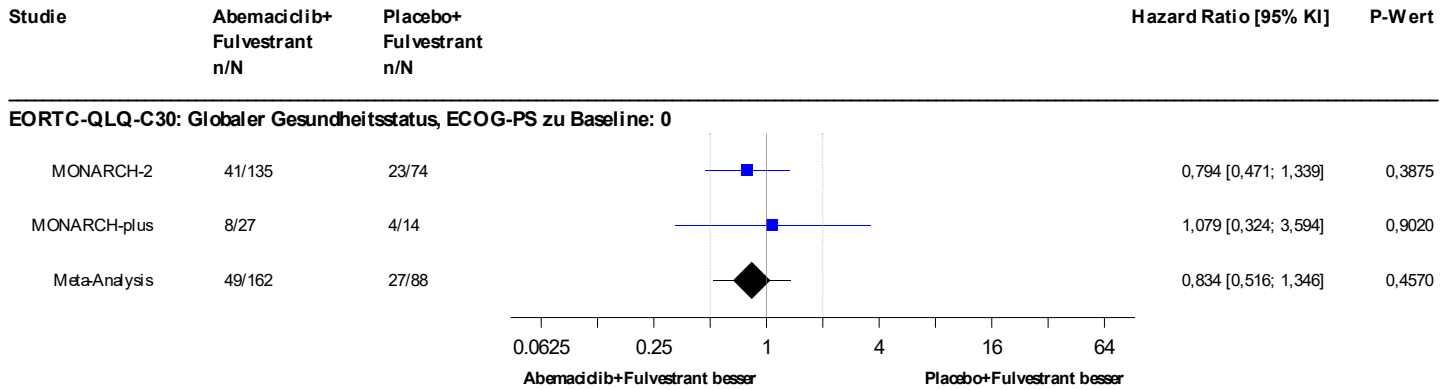
Abbildung 1413.1.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2087, P-Wert=0,6478, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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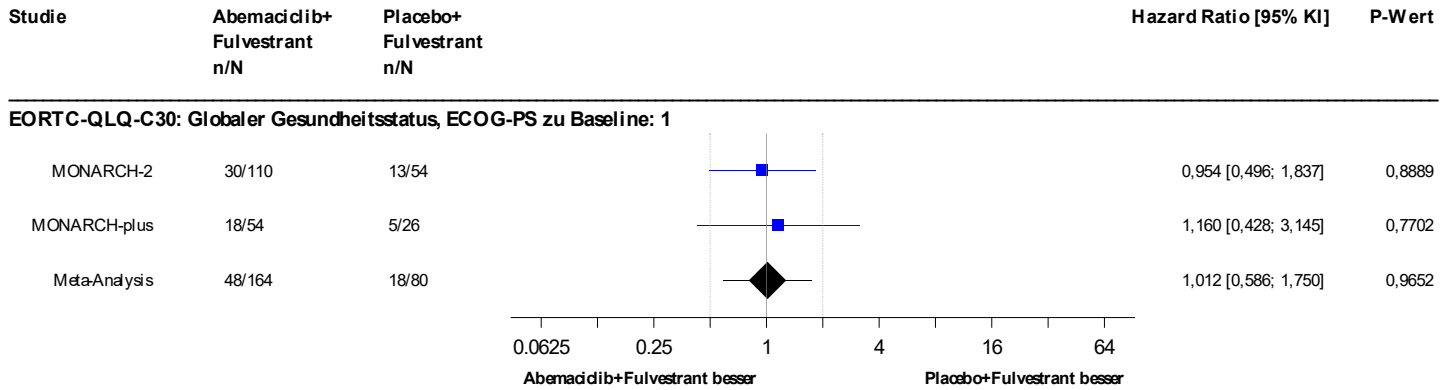
Abbildung 1413.1.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1029, P-Wert=0,7483, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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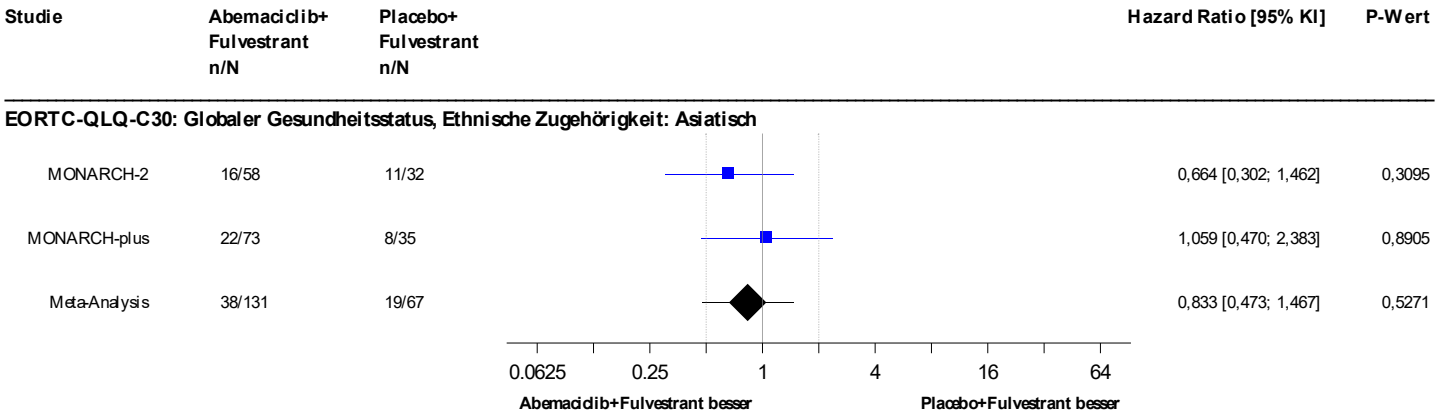
Abbildung 1413.1.5.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6515, P-Wert=0,4196, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwghs6_popa1_racegr1_1.rtf
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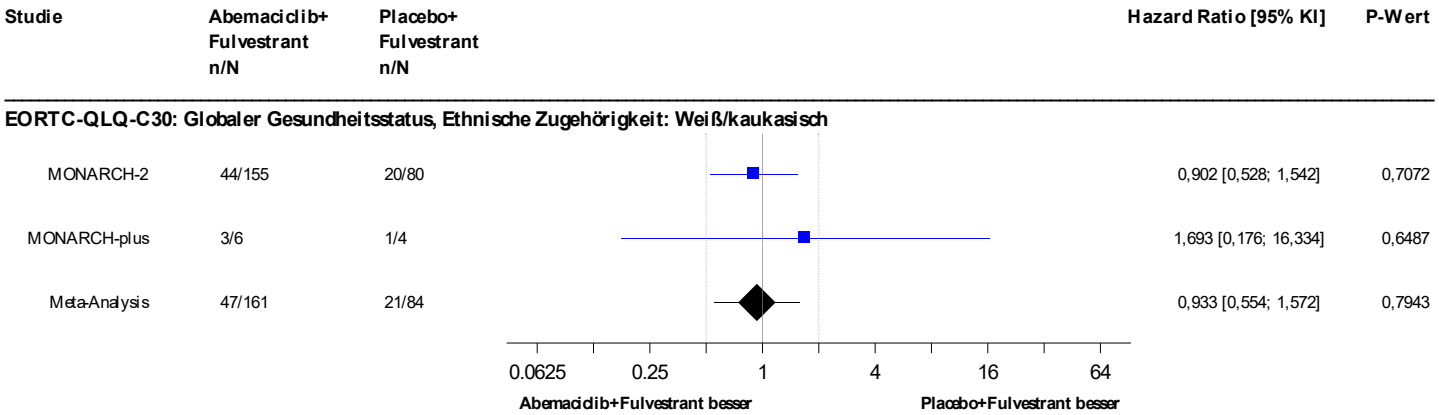
Abbildung 1413.1.5.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2806, P-Wert=0,5963, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwghs6_popa1_racegr1_2.rtf
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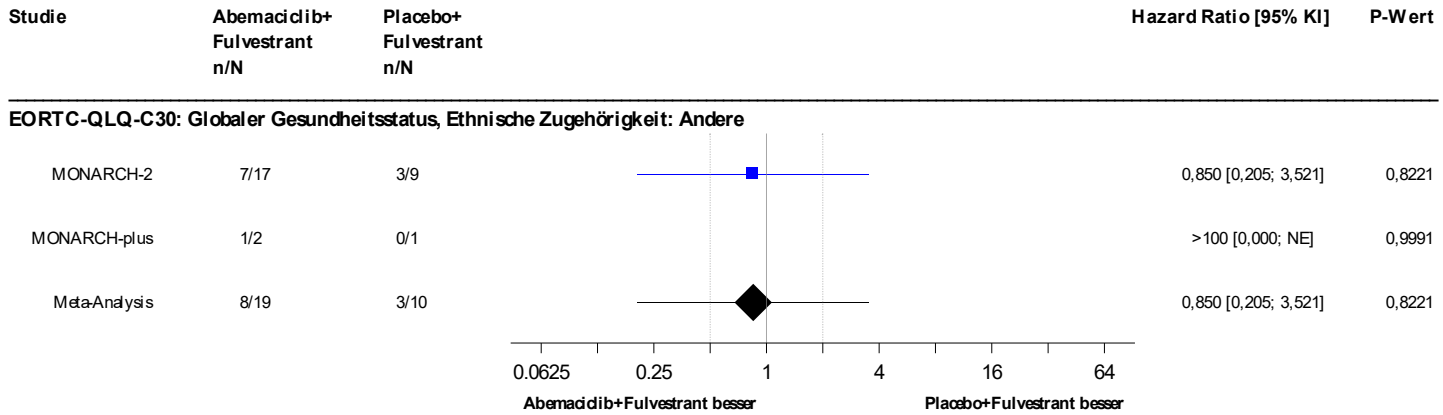
Abbildung 1413.1.5.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9991, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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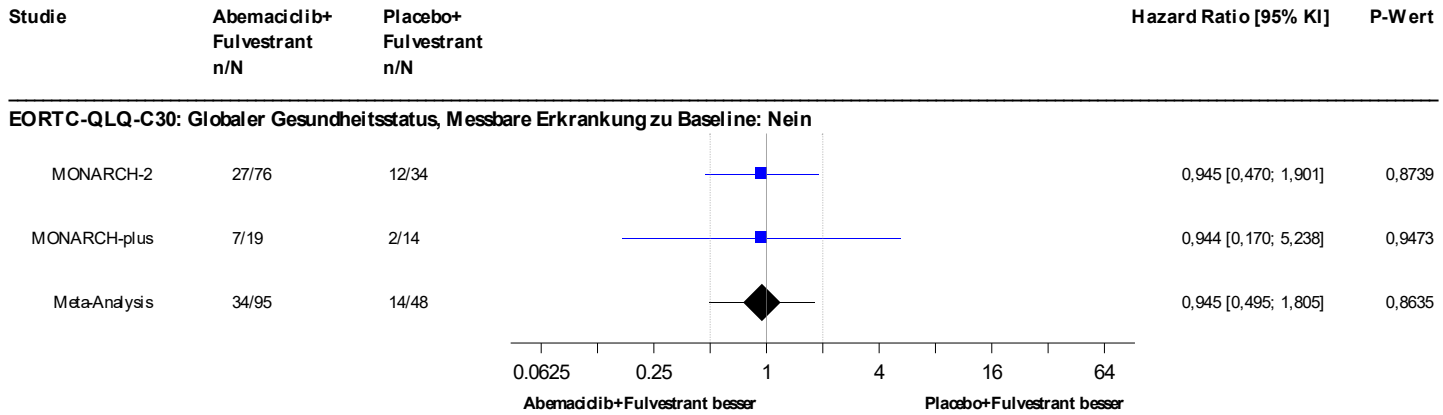
Abbildung 1413.1.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9990, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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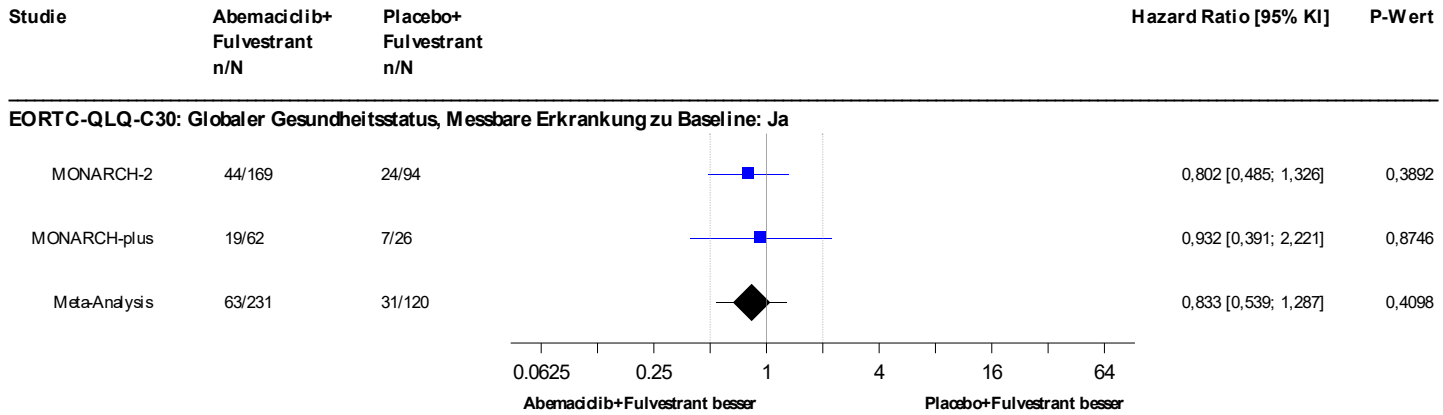
Abbildung 1413.1.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0870, P-Wert=0,7680, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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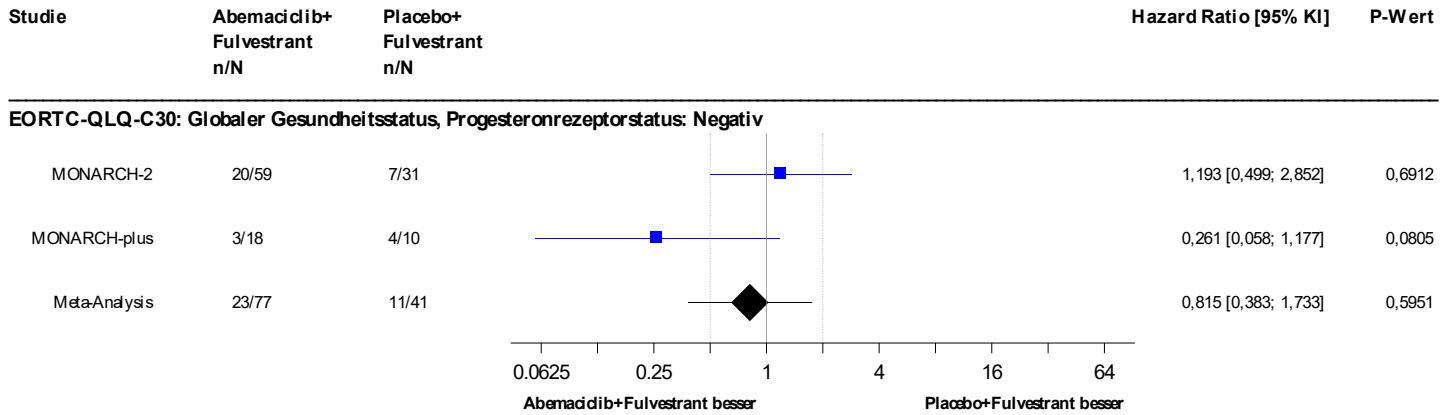
Abbildung 1413.1.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,9306, P-Wert=0,0869, I2 Index=65,9%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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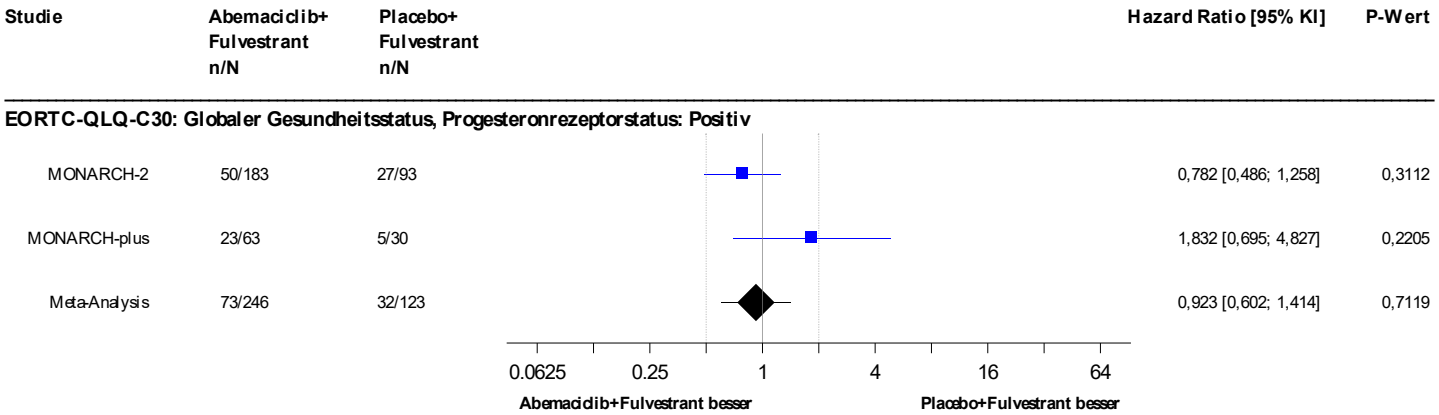
Abbildung 1413.1.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,3898, P-Wert=0,1221, I2 Index=58,2%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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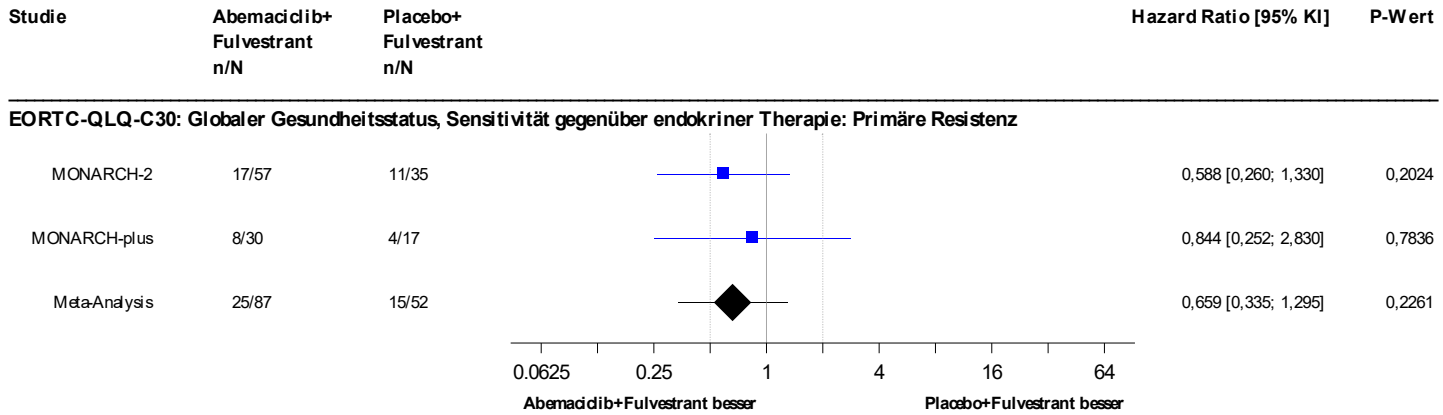
Abbildung 1413.1.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2353, P-Wert=0,6276, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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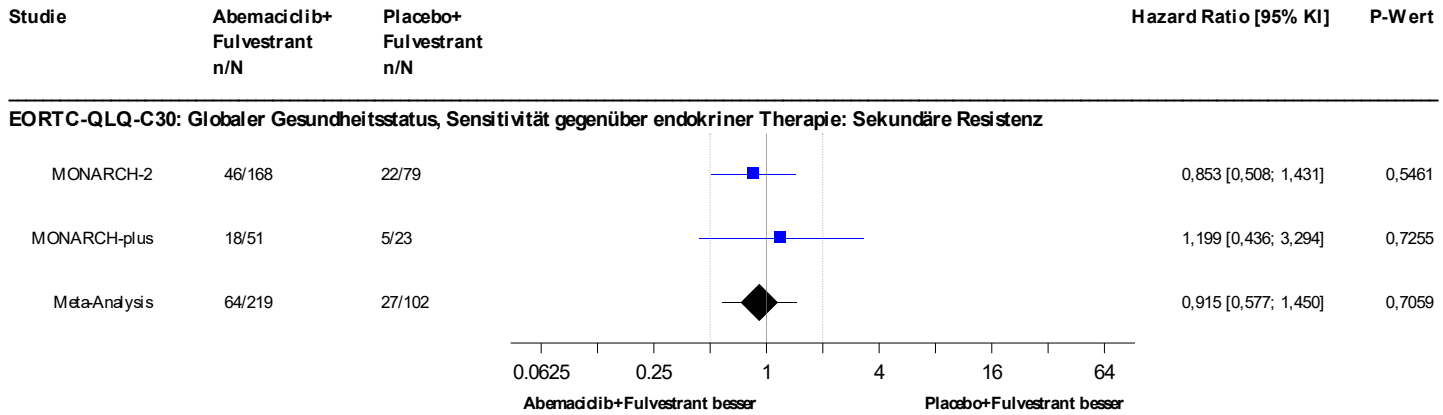
Abbildung 1413.1.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3453, P-Wert=0,5568, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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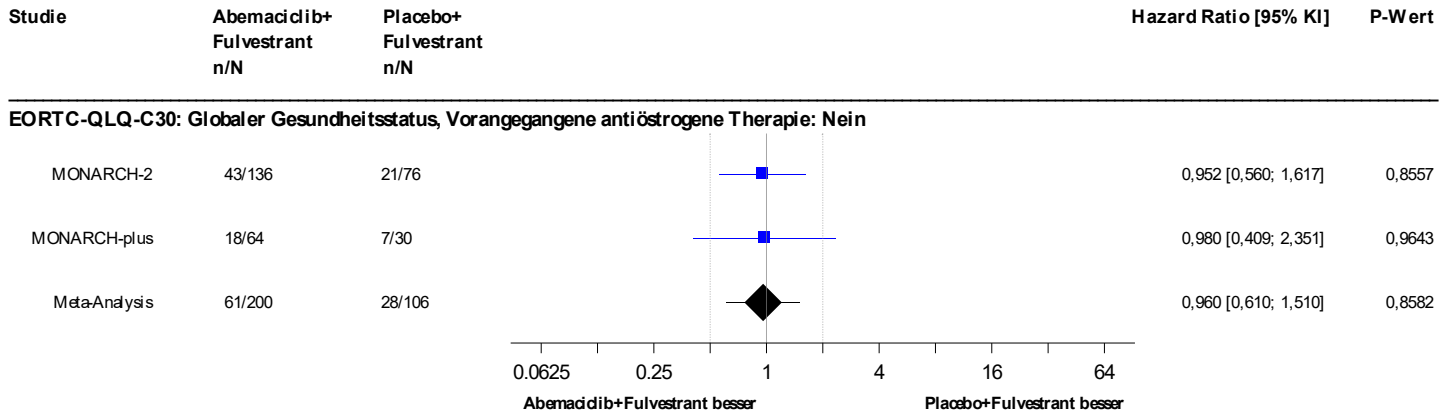
Abbildung 1413.1.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0031, P-Wert=0,9554, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwghs6_popa1_paet_1.rtf
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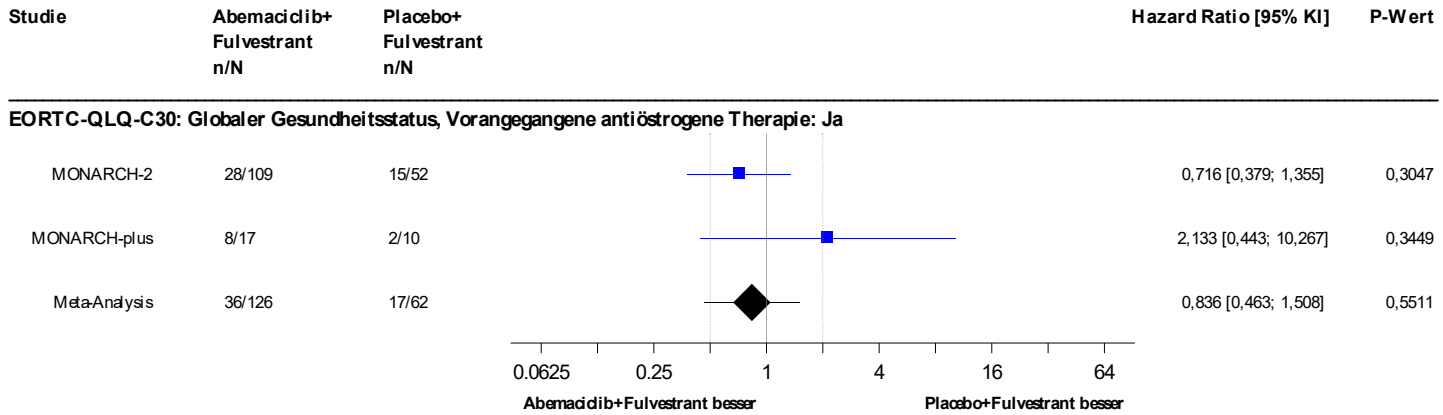
Abbildung 1413.1.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,5905, P-Wert=0,2073, I2 Index=37,1%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwghs6_popa1_paet_2.rtf
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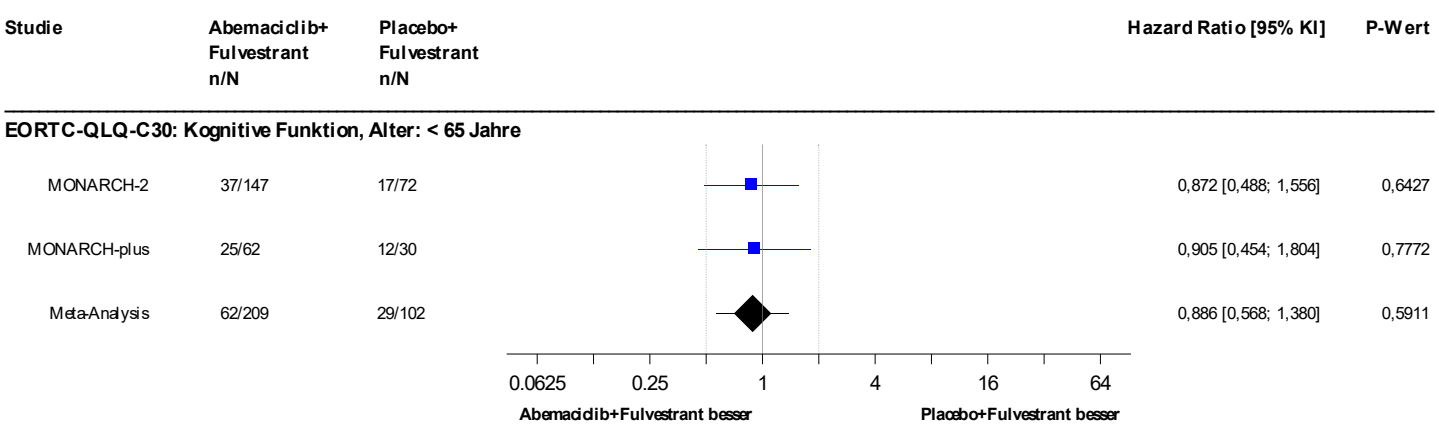
Abbildung 1414.1.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0067, P-Wert=0,9349, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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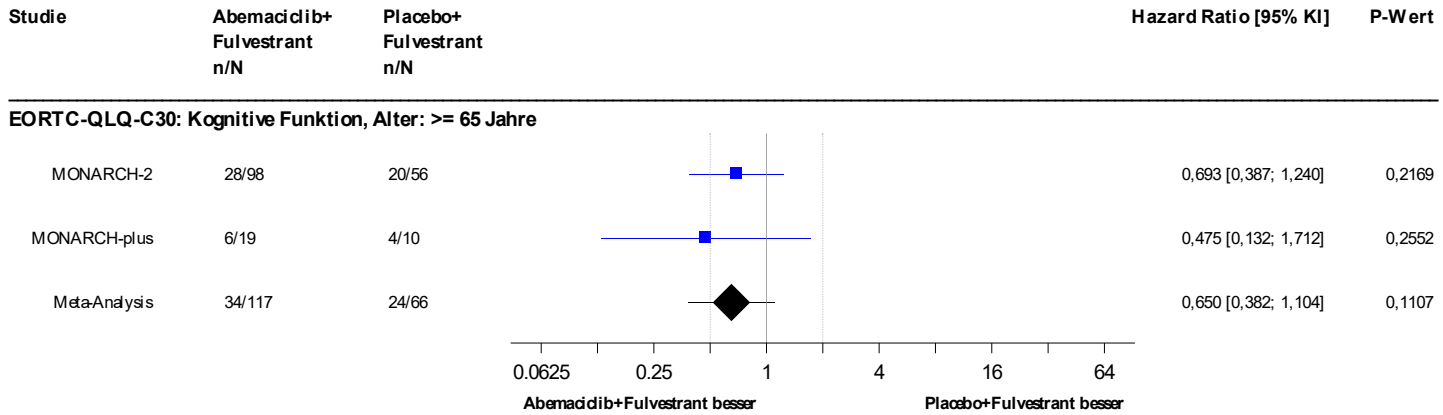
Abbildung 1414.1.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2755, P-Wert=0,5997, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwcogn6_popa1_agegr1_2.rtf
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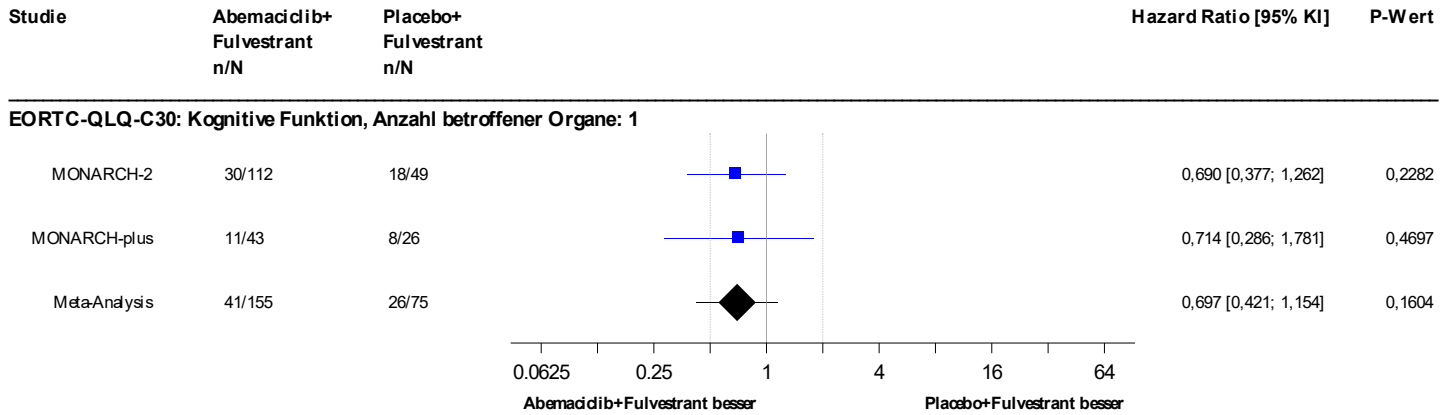
Abbildung 1414.1.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0037, P-Wert=0,9513, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwcogn6_popa1_norggr_1.rtf
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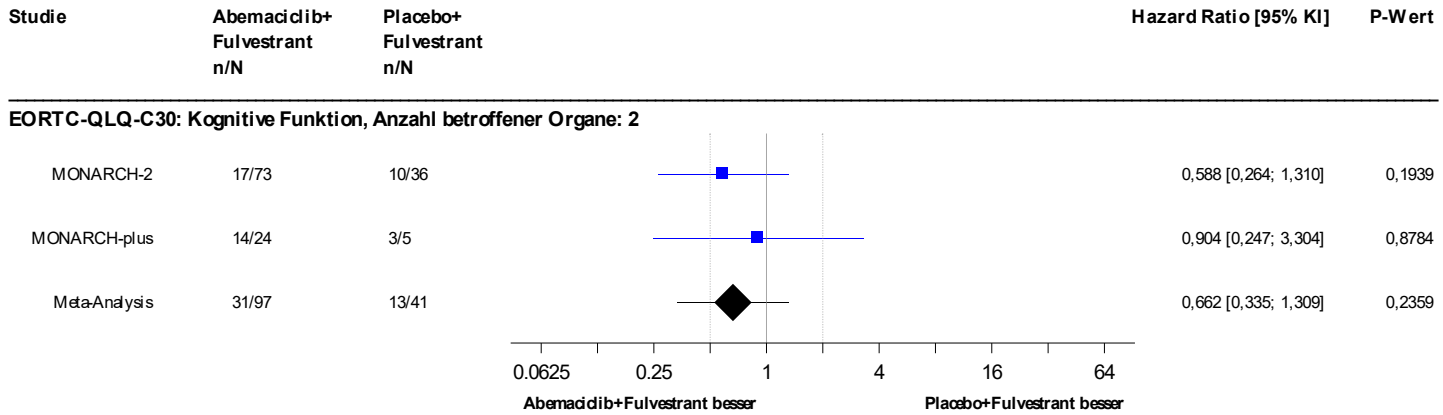
Abbildung 1414.1.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3061, P-Wert=0,5801, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwcogn6_popa1_norggr_2.rtf
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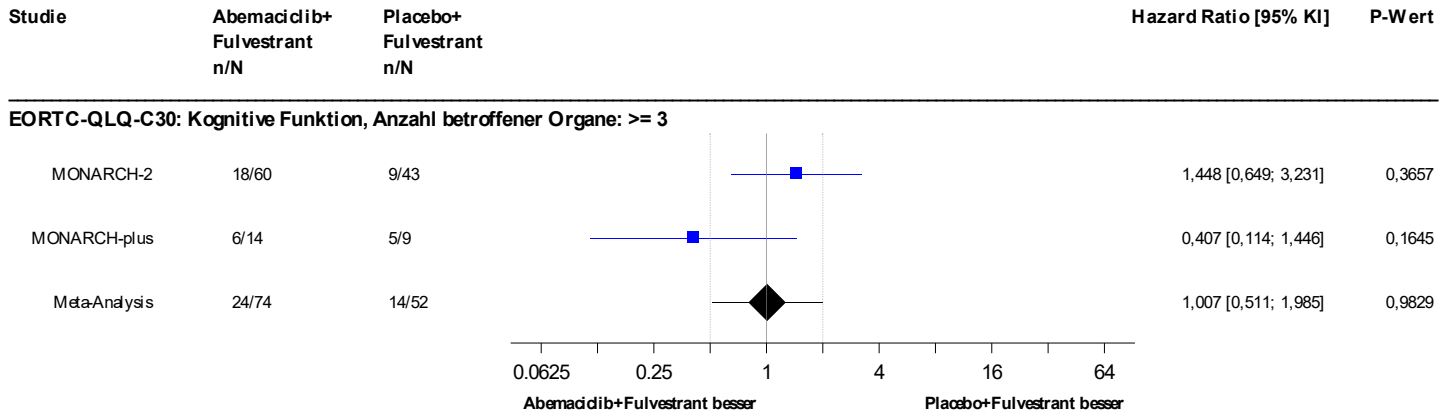
Abbildung 1414.1.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,7503, P-Wert=0,0972, I2 Index=63,6%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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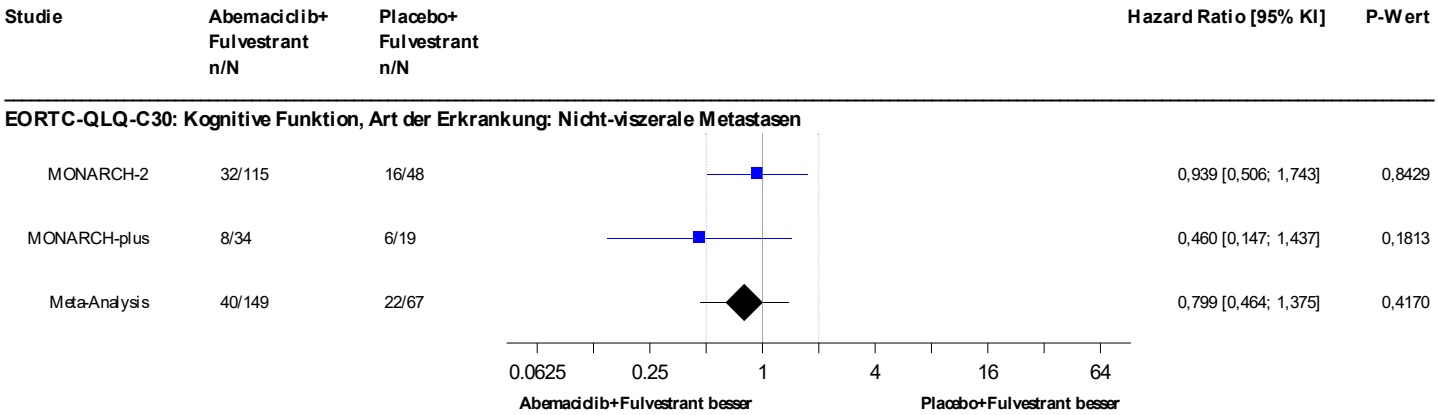
Abbildung 1414.1.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,1675, P-Wert=0,2799, I2 Index=14,4%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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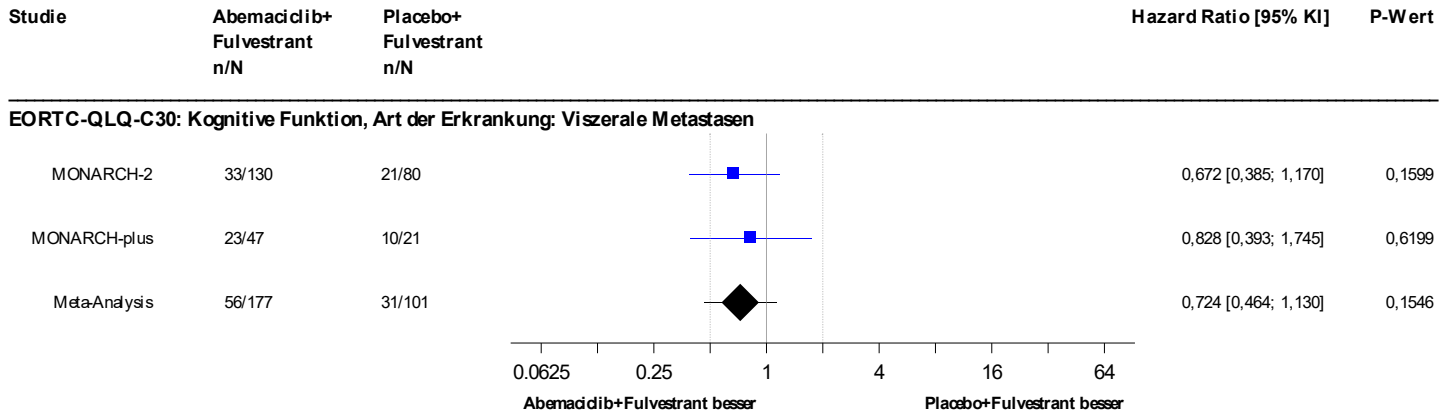
Abbildung 1414.1.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1951, P-Wert=0,6587, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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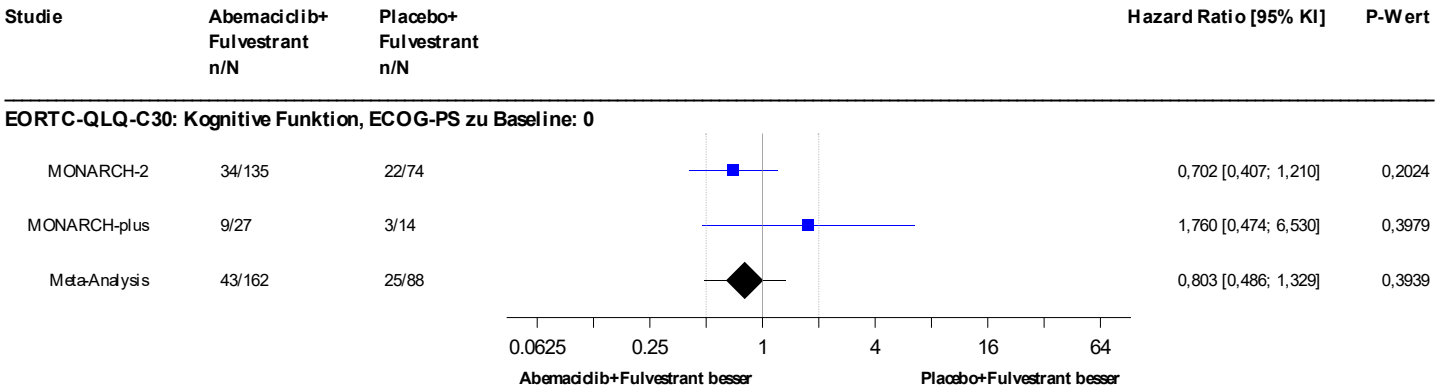
Abbildung 1414.1.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,6126, P-Wert=0,2041, I2 Index=38,0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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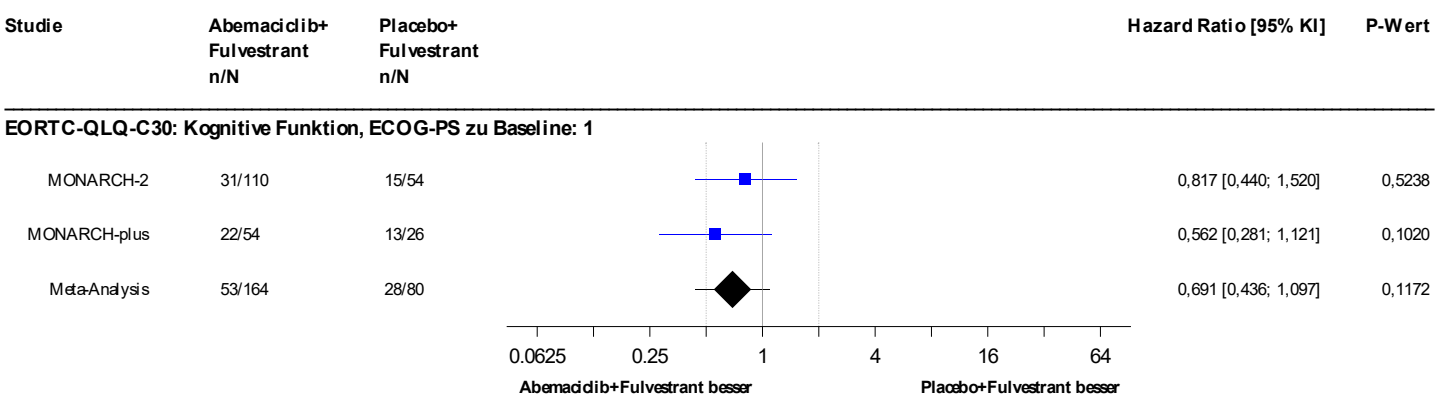
Abbildung 1414.1.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6262, P-Wert=0,4287, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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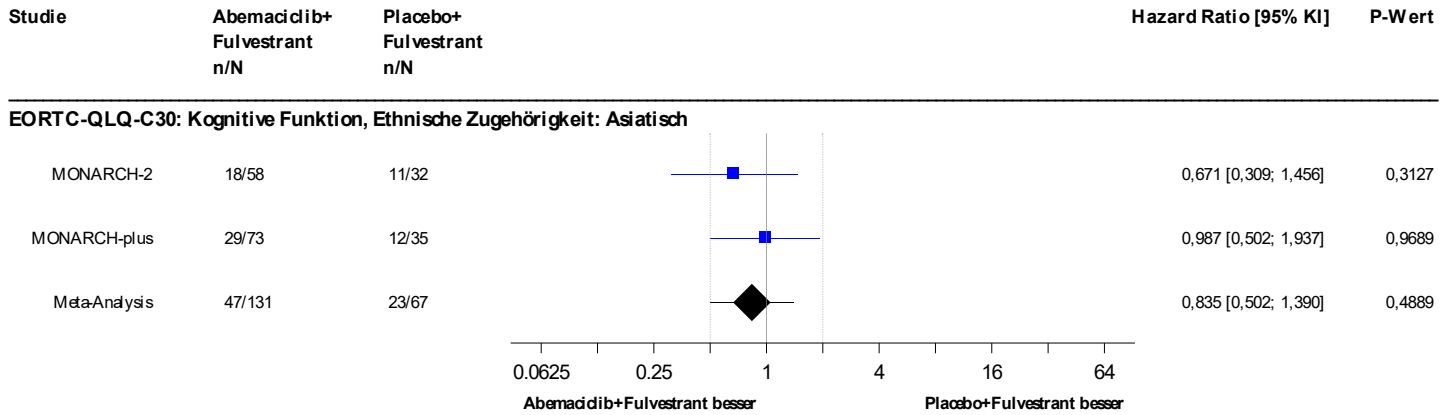
Abbildung 1414.1.5.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,5417, P-Wert=0,4617, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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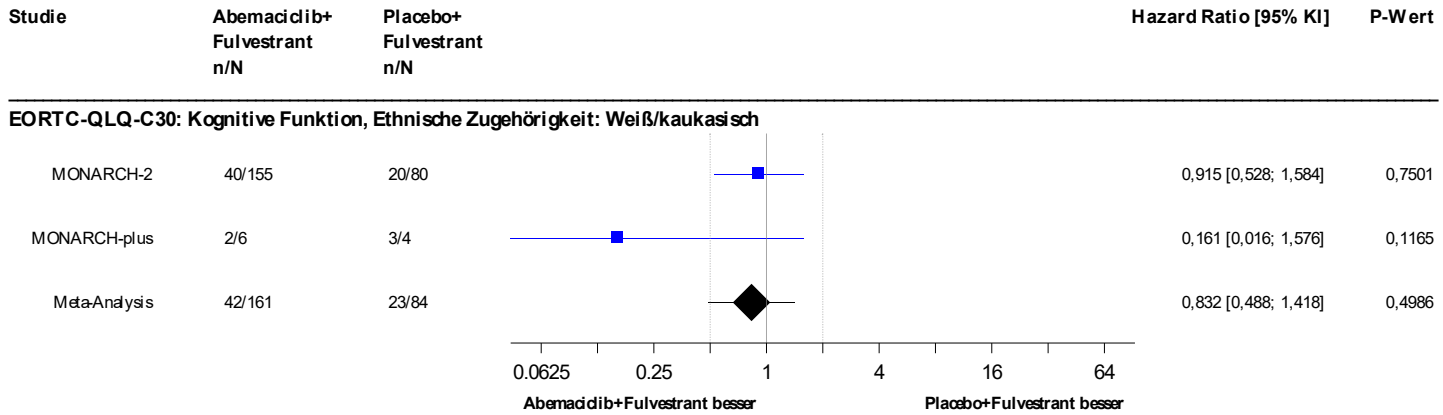
Abbildung 1414.1.5.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,1074, P-Wert=0,1466, I2 Index=52,5%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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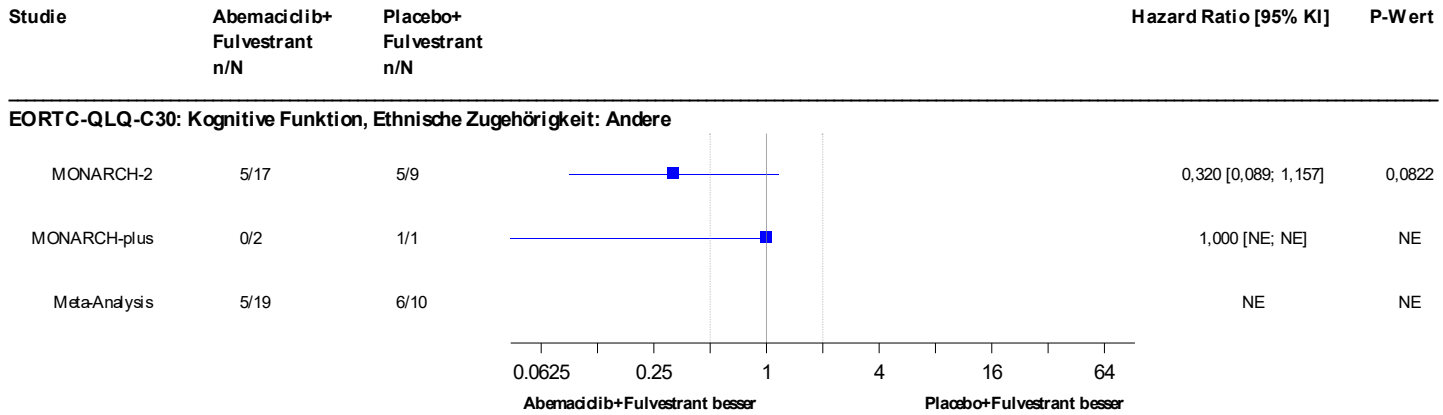
Abbildung 1414.1.5.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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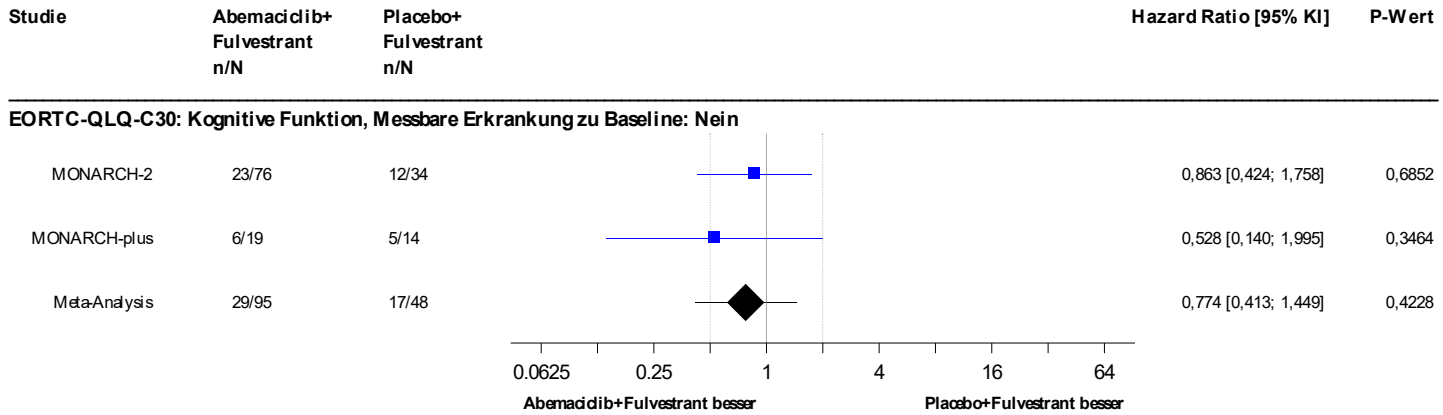
Abbildung 1414.1.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4085, P-Wert=0,5227, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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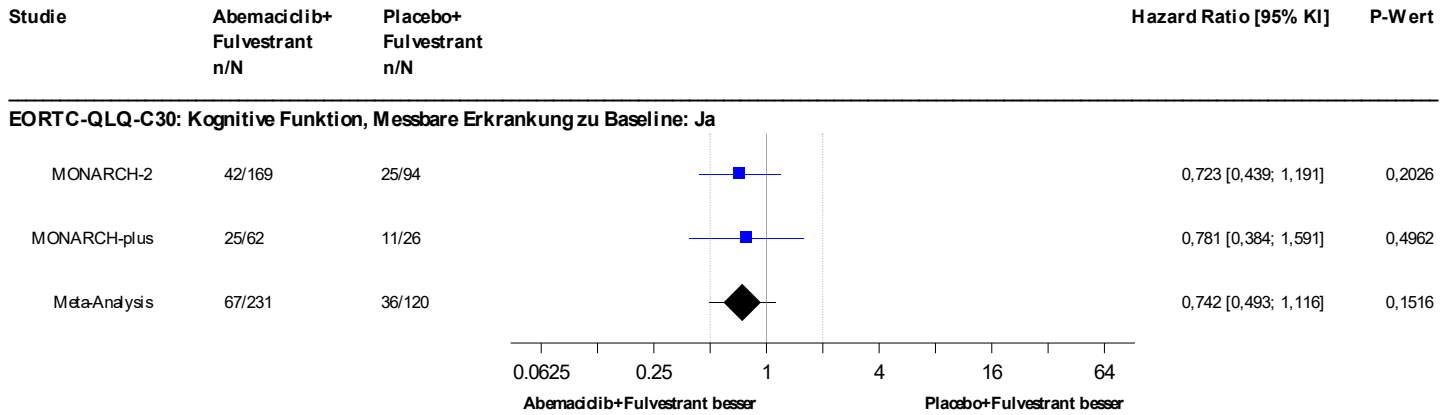
Abbildung 1414.1.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0306, P-Wert=0,8611, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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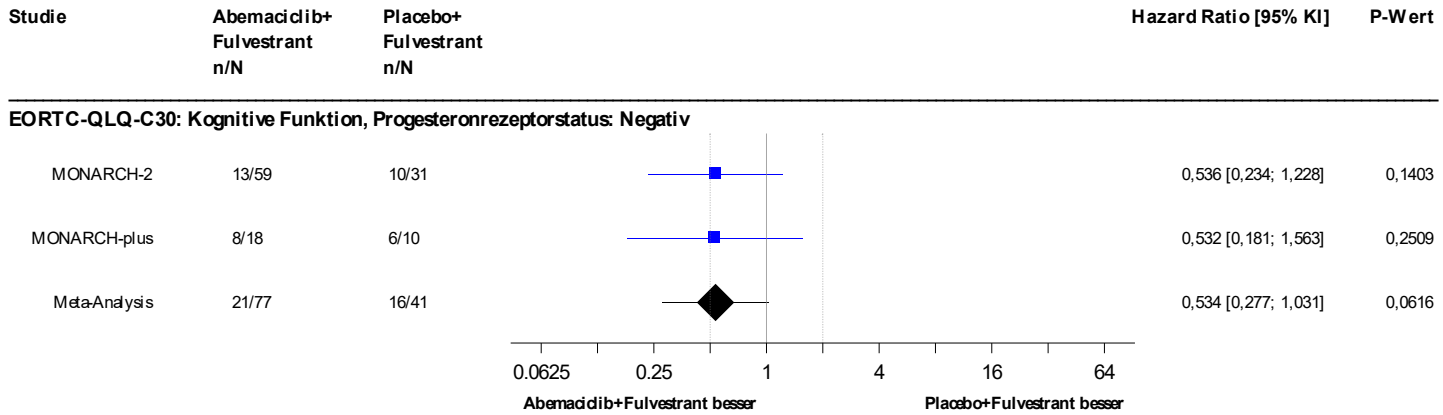
Abbildung 1414.1.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9915, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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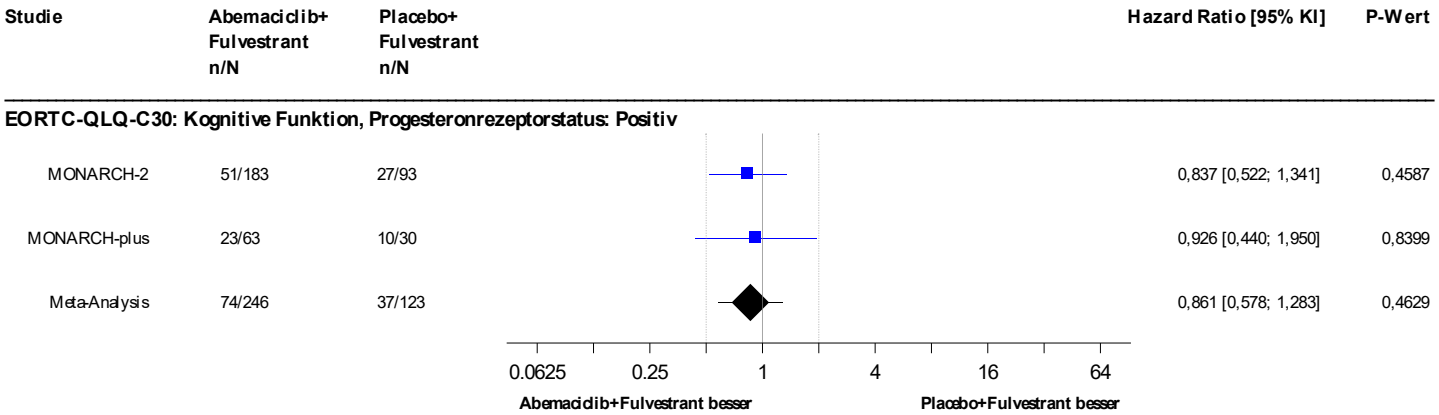
Abbildung 1414.1.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0509, P-Wert=0,8215, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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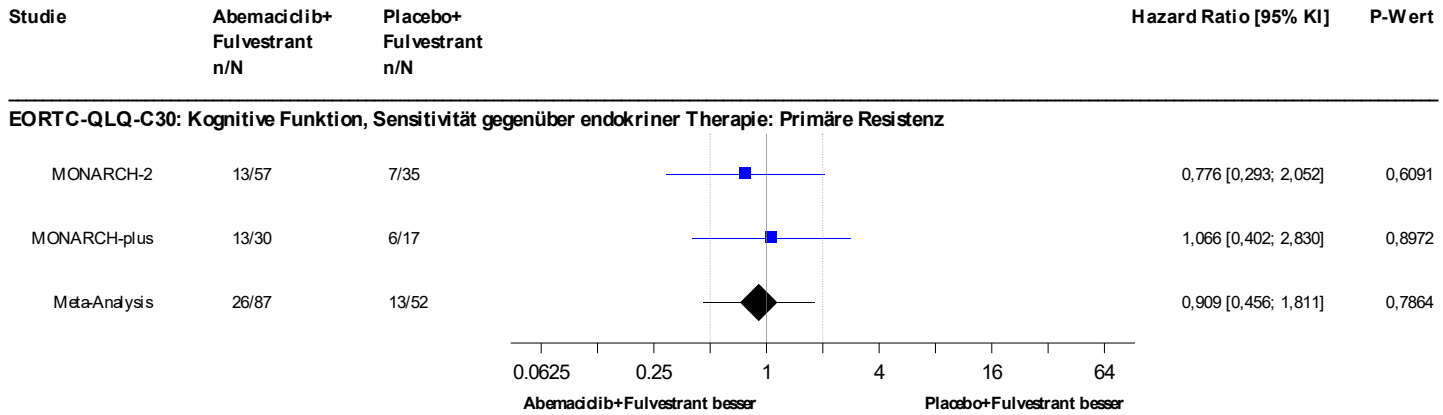
Abbildung 1414.1.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2047, P-Wert=0,6510, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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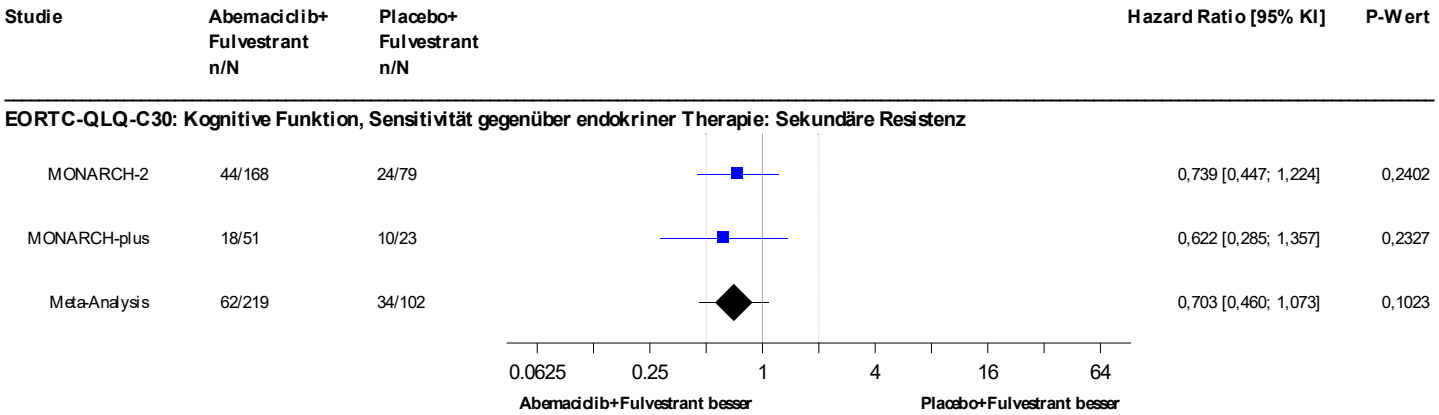
Abbildung 1414.1.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1339, P-Wert=0,7145, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwcogn6_popa1_snthr_2.rtf
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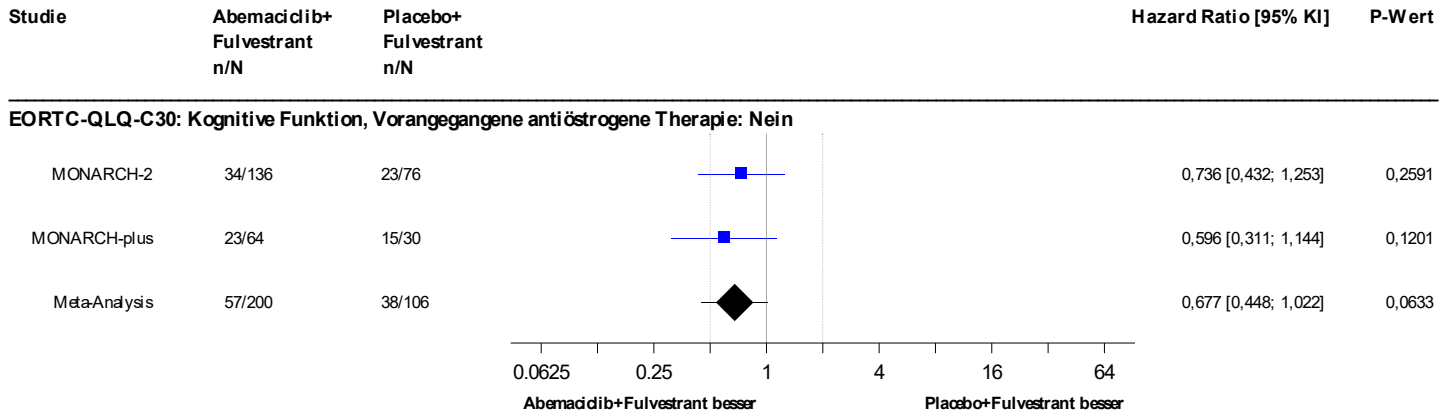
Abbildung 1414.1.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2402, P-Wert=0,6241, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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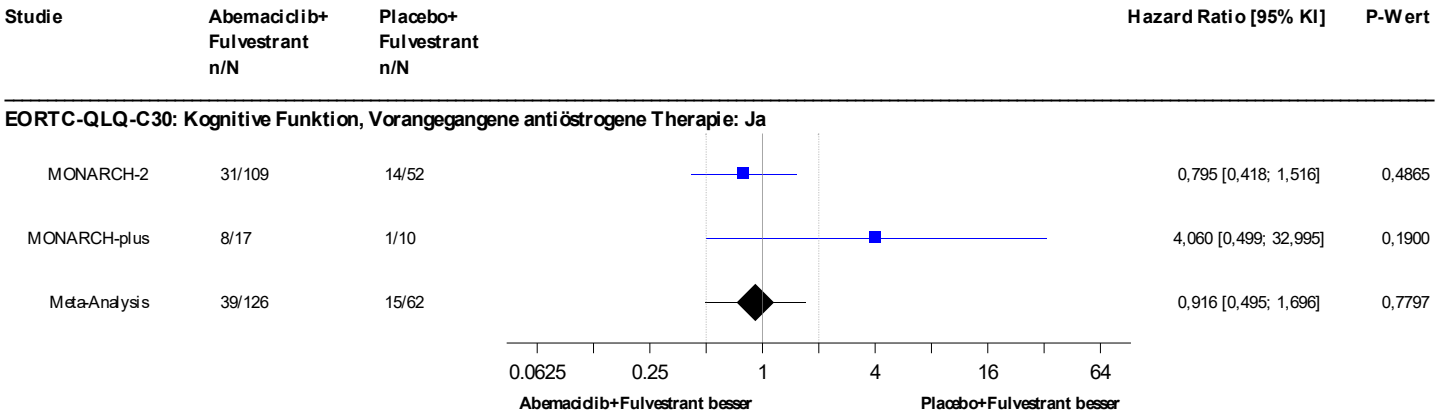
Abbildung 1414.1.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,1238, P-Wert=0,1450, I2 Index=52,9%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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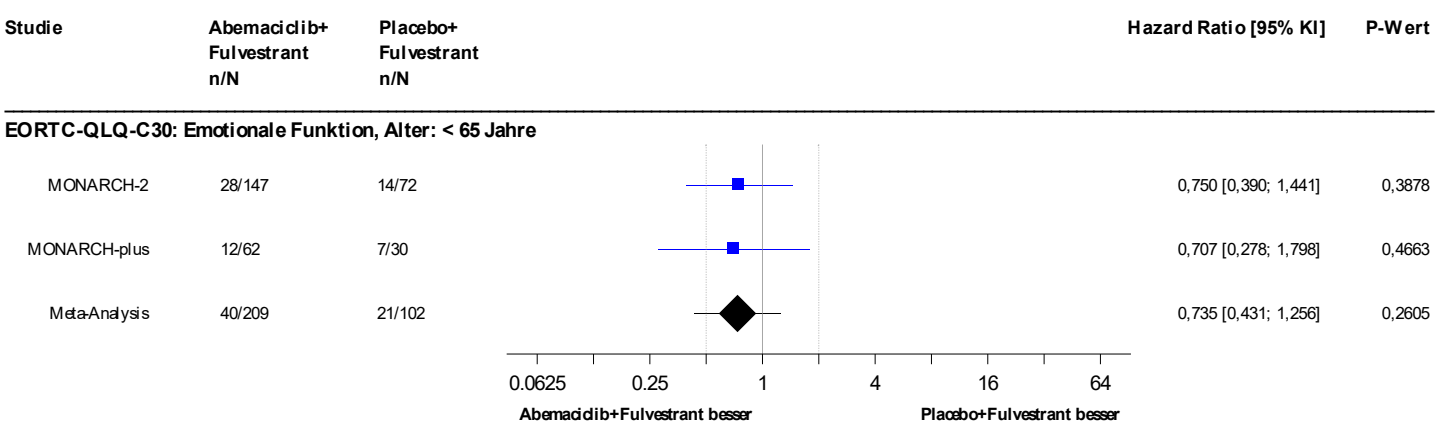
Abbildung 1415.1.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0104, P-Wert=0,9189, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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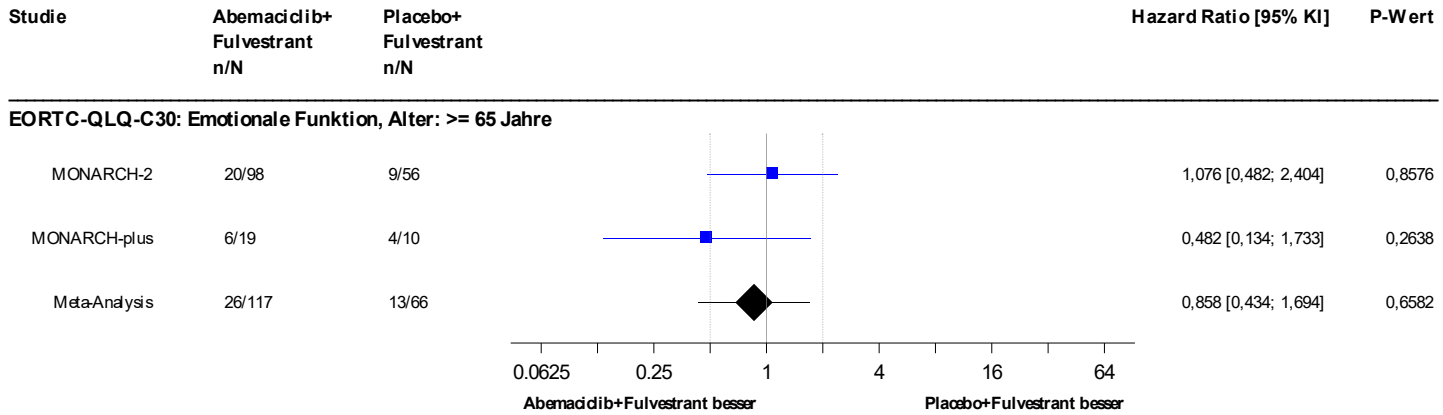
Abbildung 1415.1.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,0854, P-Wert=0,2975, I2 Index=7,9%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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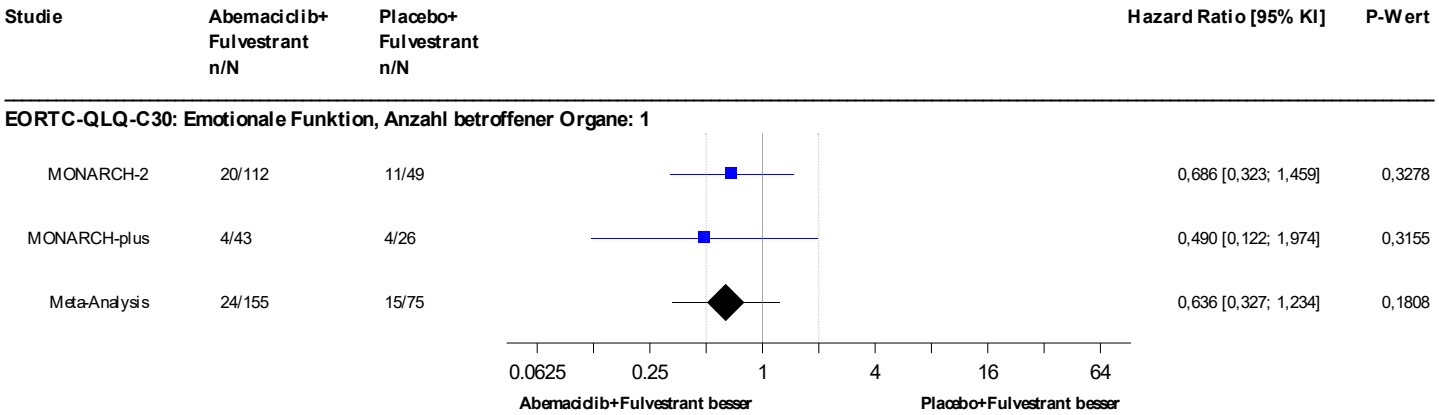
Abbildung 1415.1.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1737, P-Wert=0,6768, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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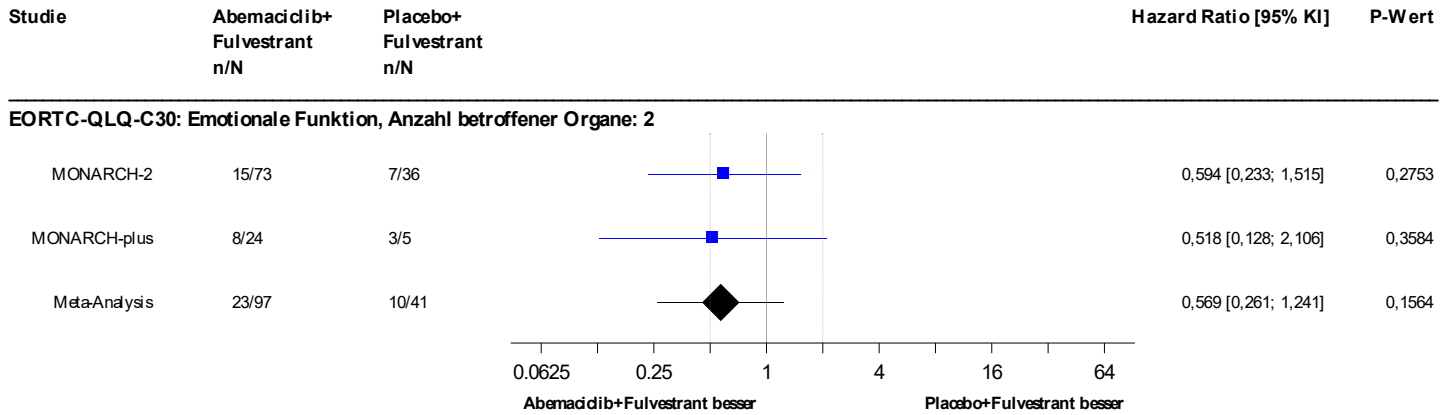
Abbildung 1415.1.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0249, P-Wert=0,8747, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwemo6_popa1_norggr_2.rtf
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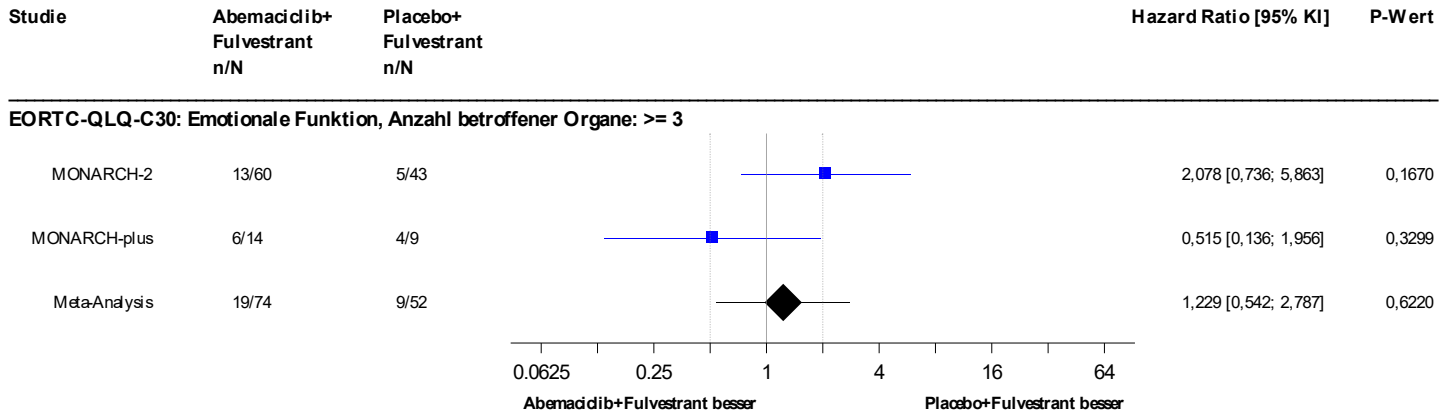
Abbildung 1415.1.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,6157, P-Wert=0,1058, I2 Index=61,8%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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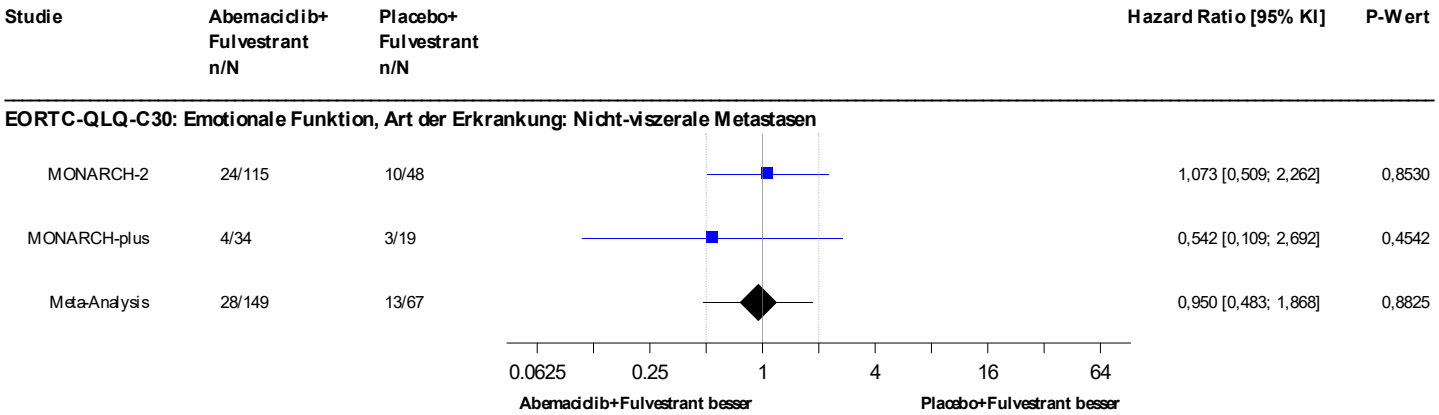
Abbildung 1415.1.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,5726, P-Wert=0,4492, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwemo6_popa1_natdis2_1.rtf
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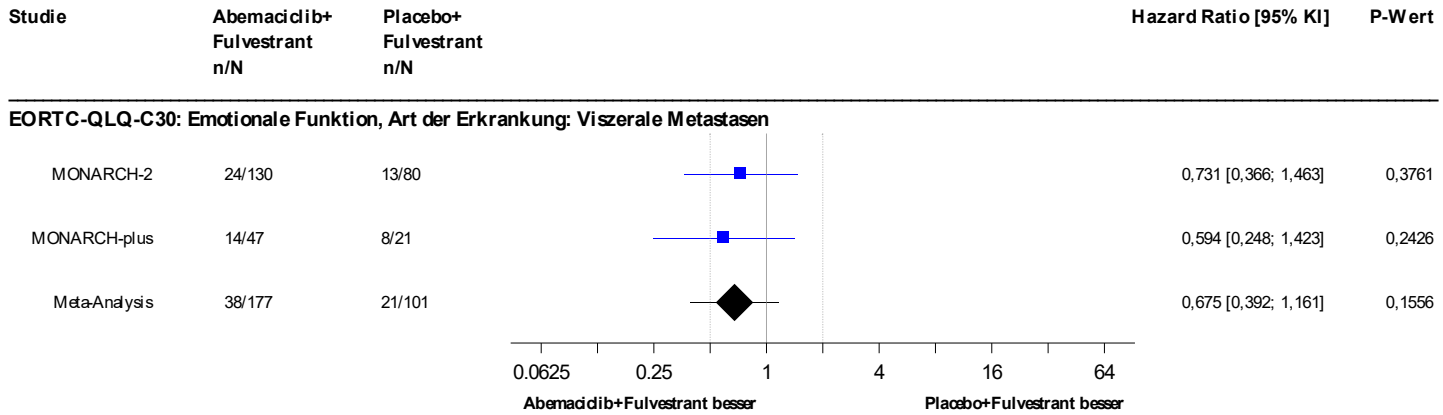
Abbildung 1415.1.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1331, P-Wert=0,7153, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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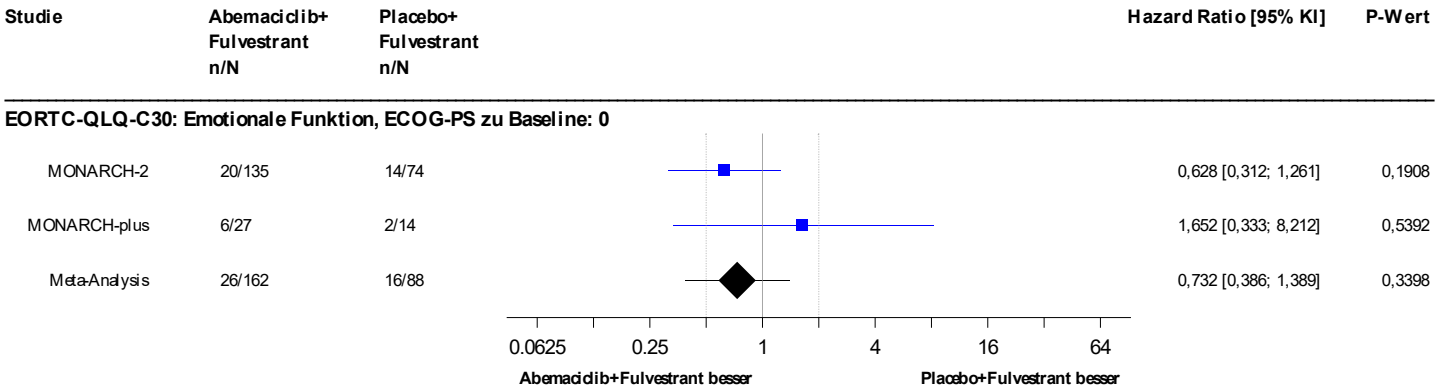
Abbildung 1415.1.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,1776, P-Wert=0,2779, I2 Index=15,1%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwemo6_popa1_ecogbl_1.rtf
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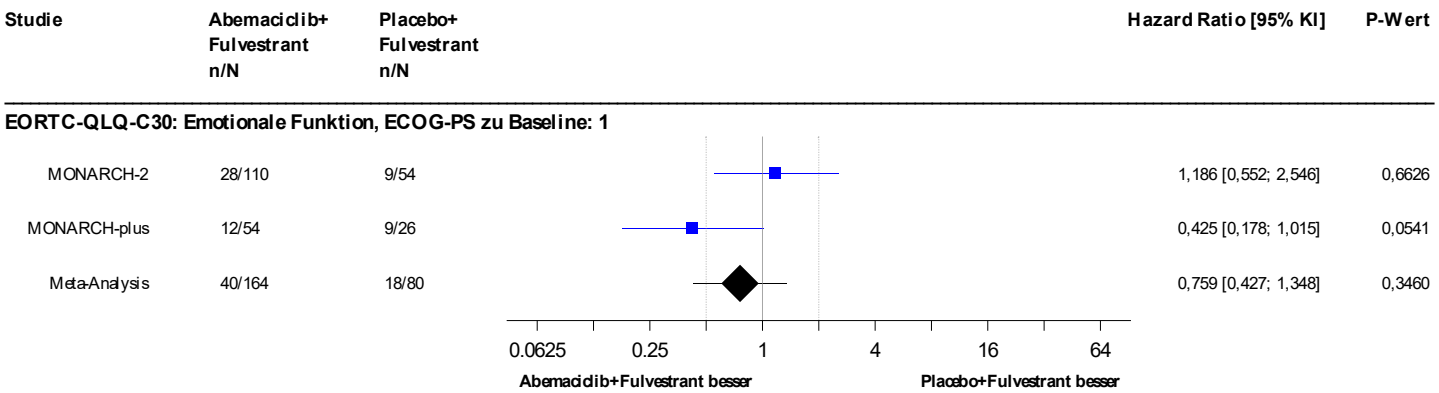
Abbildung 1415.1.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=3,0108, P-Wert=0,0827, I2 Index=66,8%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwemo6_popa1_ecogbl_2.rtf
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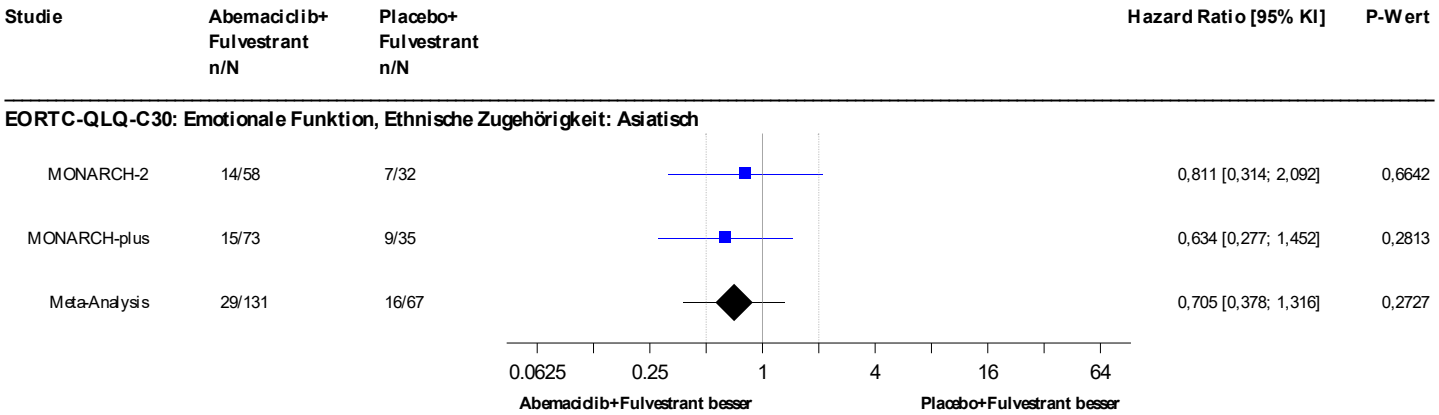
Abbildung 1415.1.5.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1461, P-Wert=0,7023, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwemo6_popa1_racegr1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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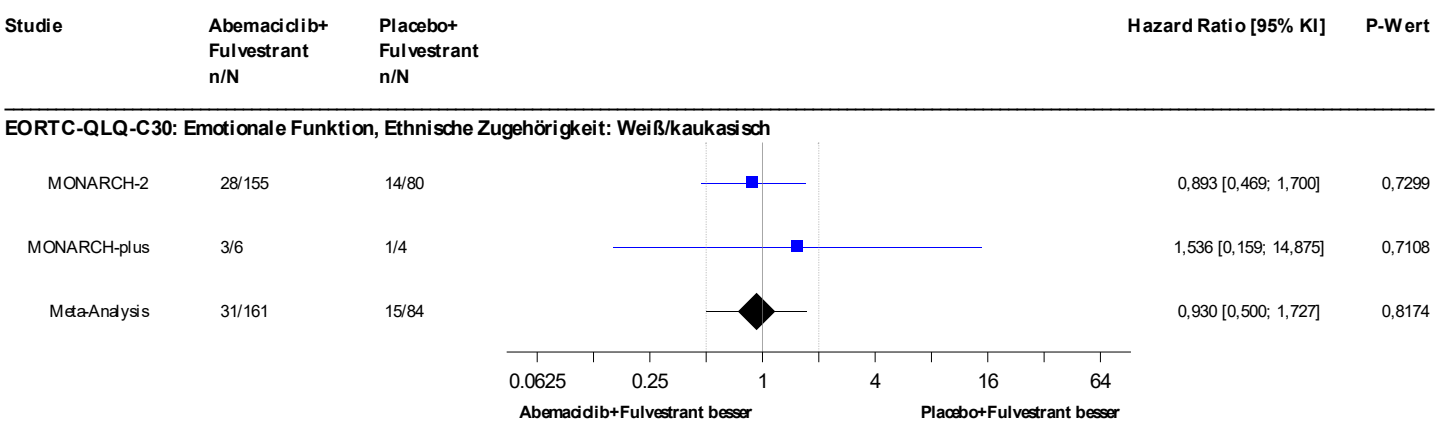
Abbildung 1415.1.5.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2034, P-Wert=0,6520, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwemo6_popa1_racegr1_2.rtf
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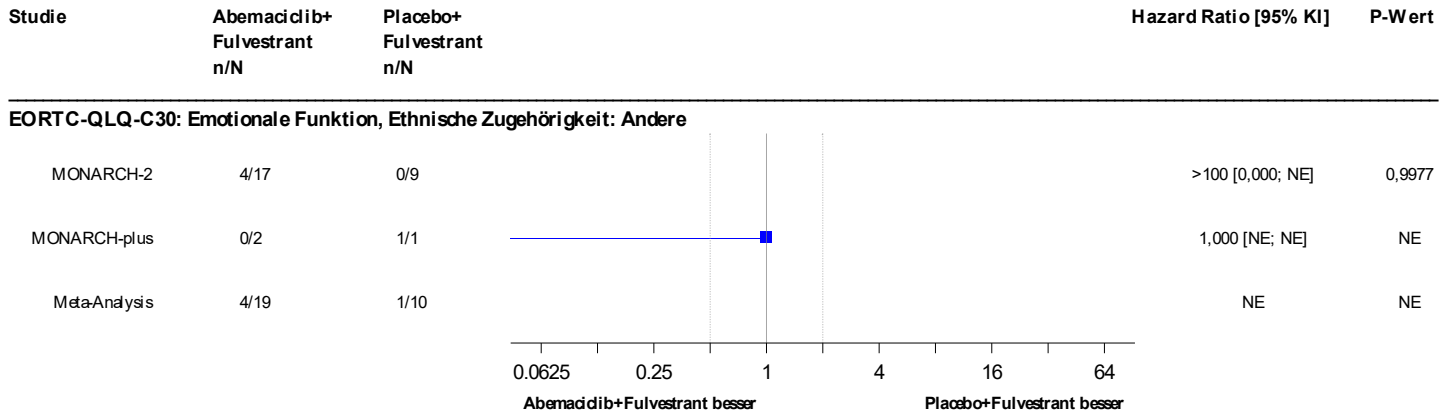
Abbildung 1415.1.5.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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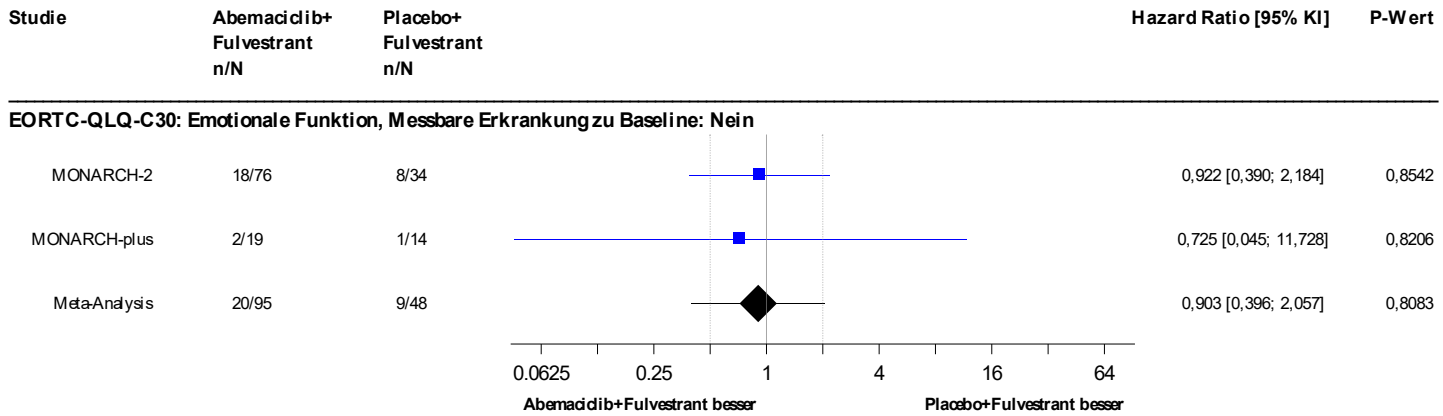
Abbildung 1415.1.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0263, P-Wert=0,8711, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwemo6_popa1_measdis_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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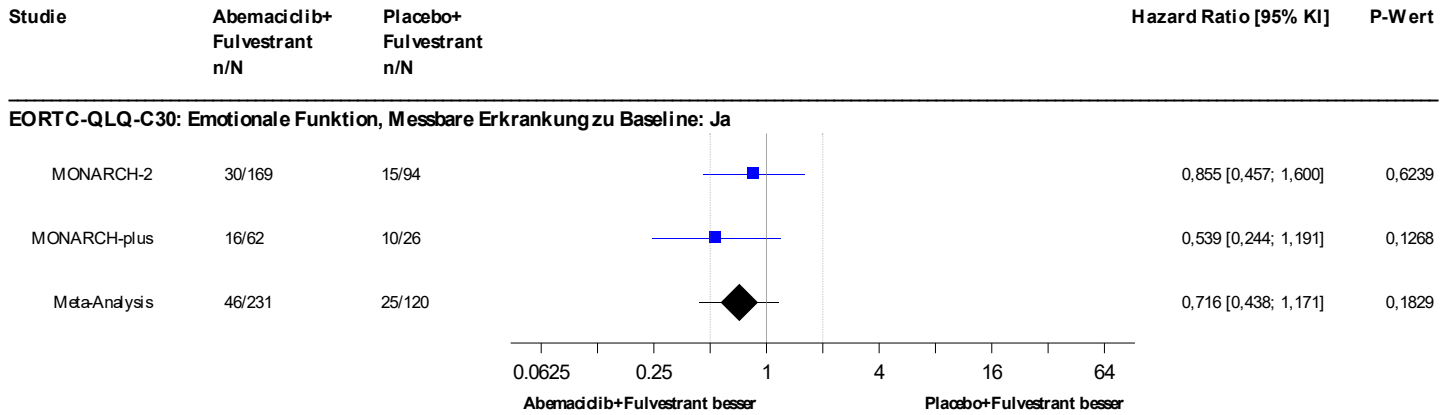
Abbildung 1415.1.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7972, P-Wert=0,3719, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwemo6_popa1_measdis_2.rtf
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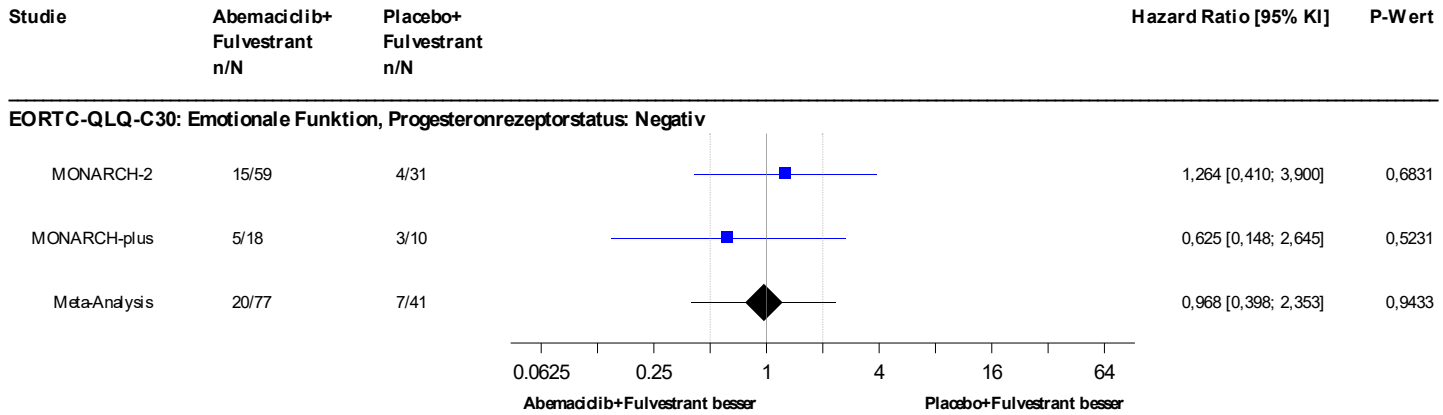
Abbildung 1415.1.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,5693, P-Wert=0,4505, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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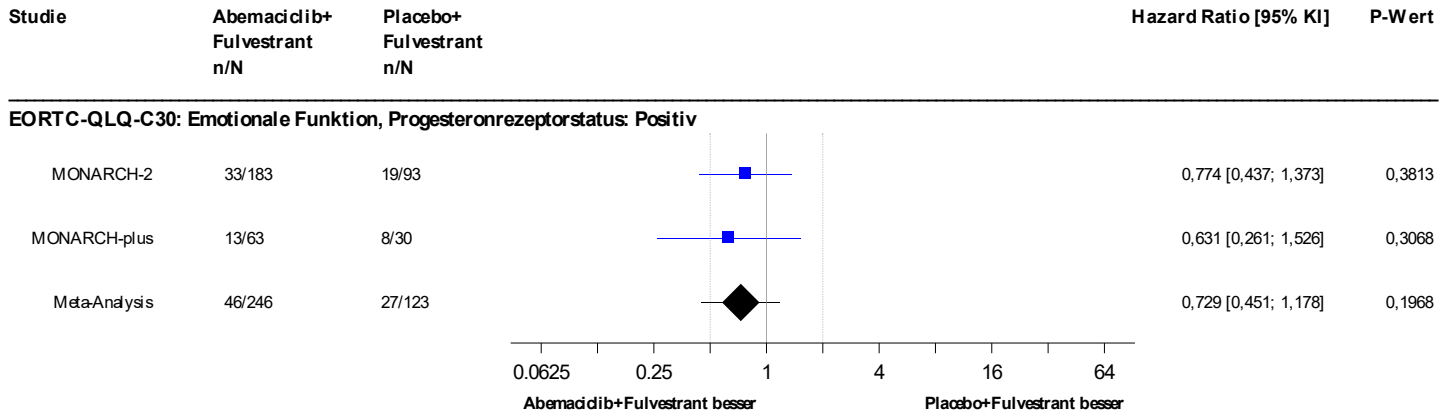
Abbildung 1415.1.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1452, P-Wert=0,7032, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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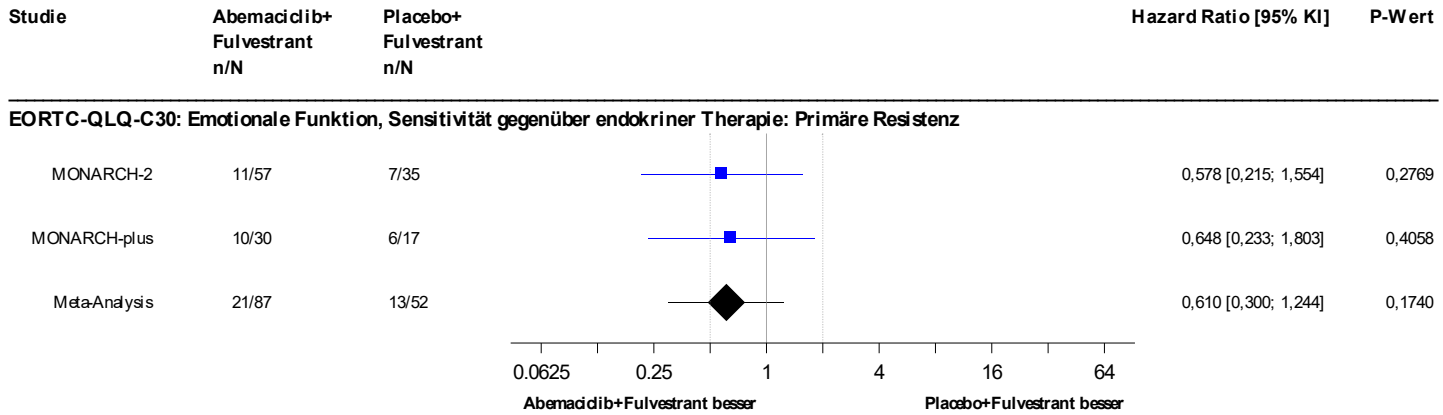
Abbildung 1415.1.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0249, P-Wert=0,8747, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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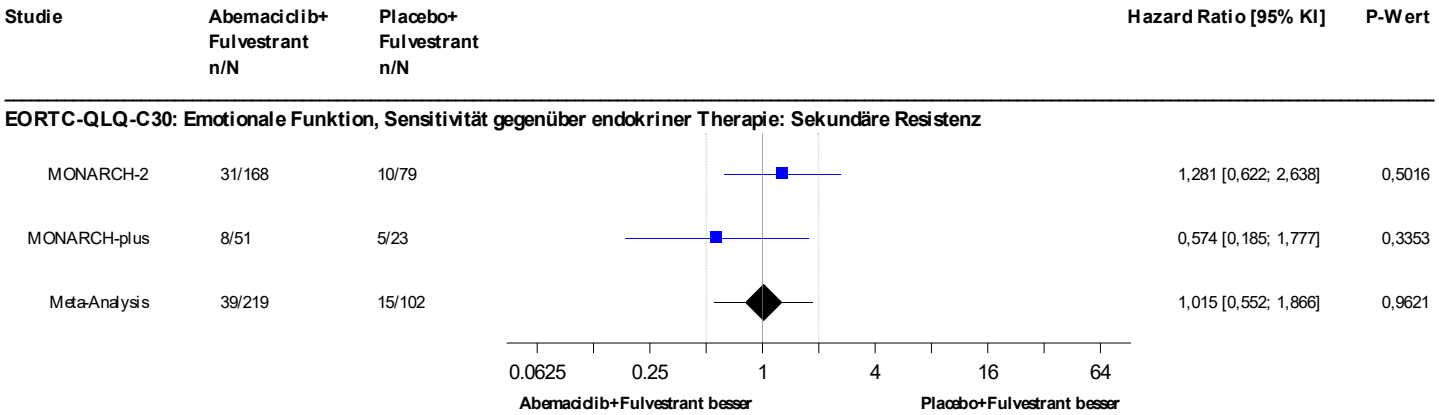
Abbildung 1415.1.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,3777, P-Wert=0,2405, I2 Index=27,4%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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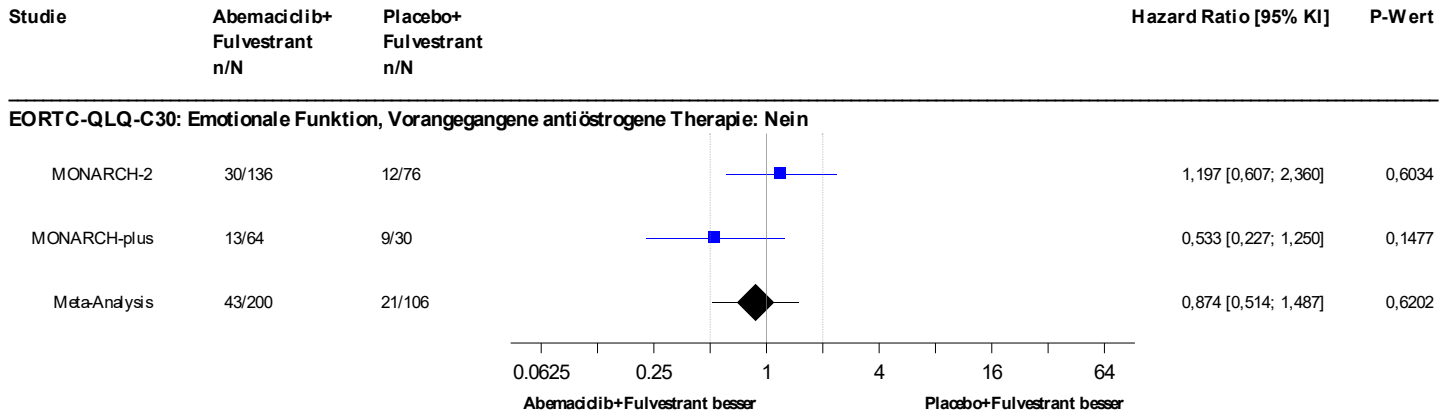
Abbildung 1415.1.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,1200, P-Wert=0,1454, I2 Index=52,8%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwemo6_popa1_paet_1.rtf
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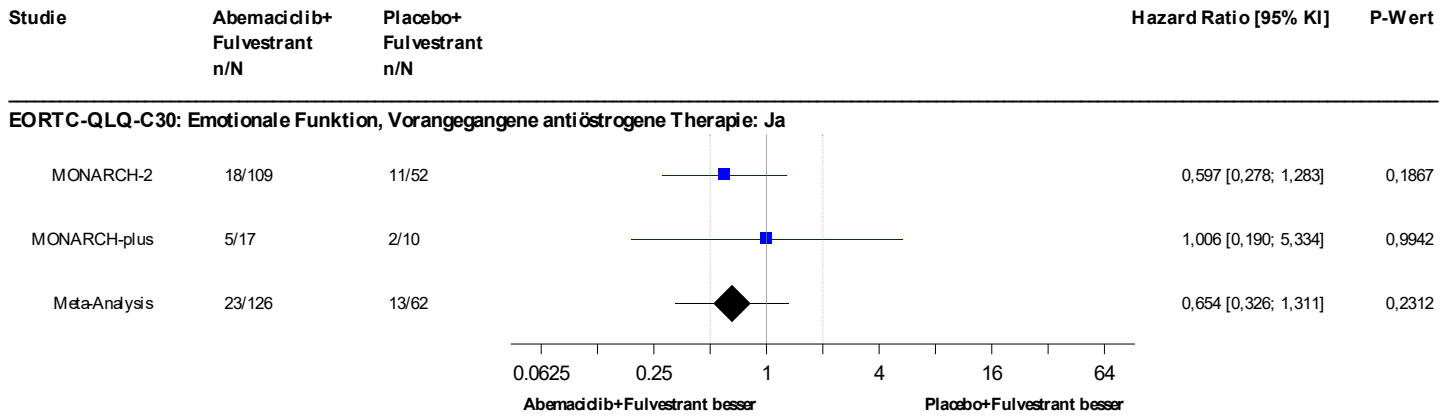
Abbildung 1415.1.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3103, P-Wert=0,5775, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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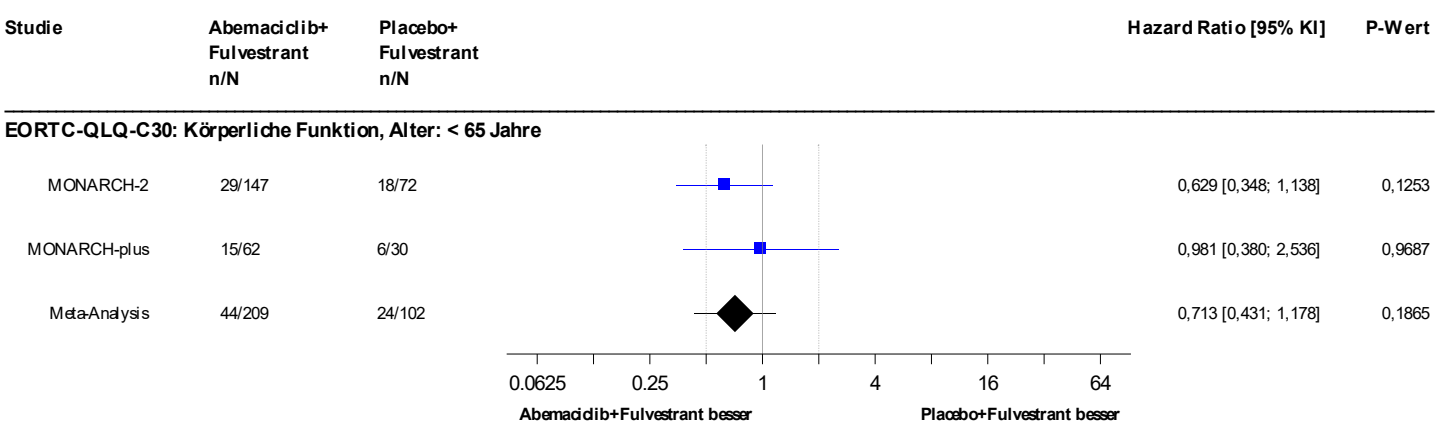
Abbildung 1416.1.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6061, P-Wert=0,4363, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwphys6_popa1_agegr1_1.rtf
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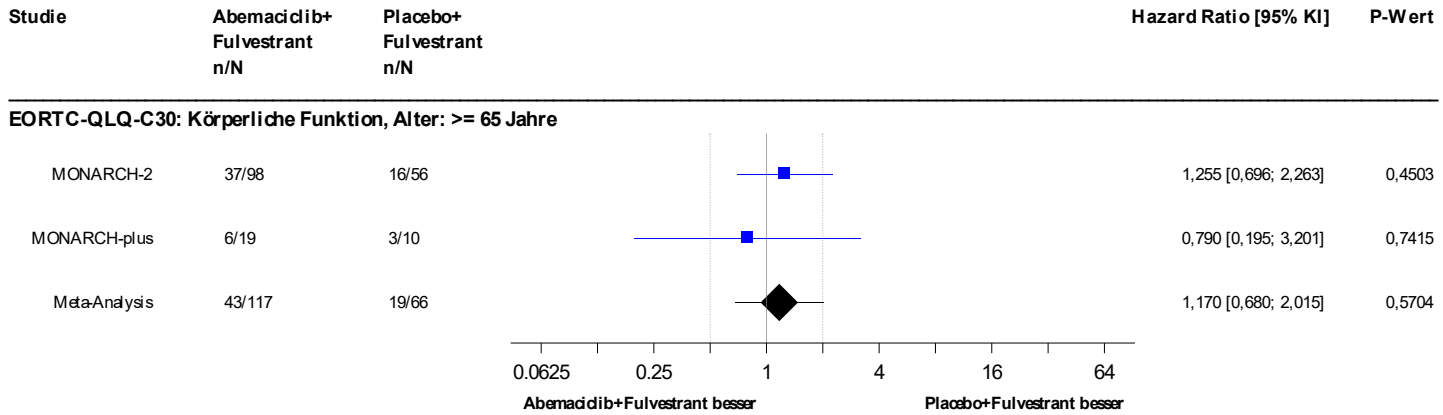
Abbildung 1416.1.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3566, P-Wert=0,5504, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwphys6_popa1_agegr1_2.rtf
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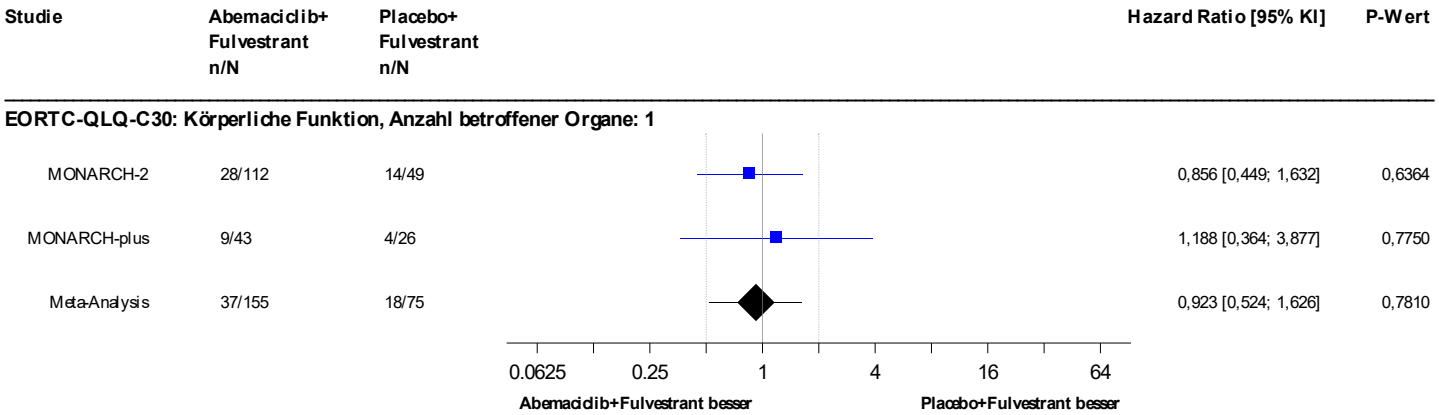
Abbildung 1416.1.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2279, P-Wert=0,6331, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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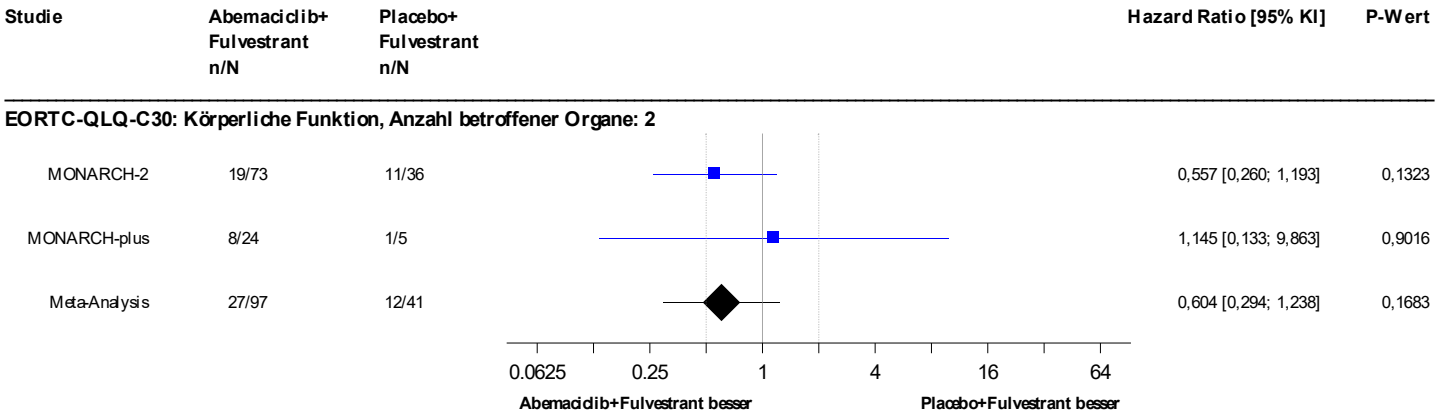
Abbildung 1416.1.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3825, P-Wert=0,5363, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwphys6_popa1_norggr_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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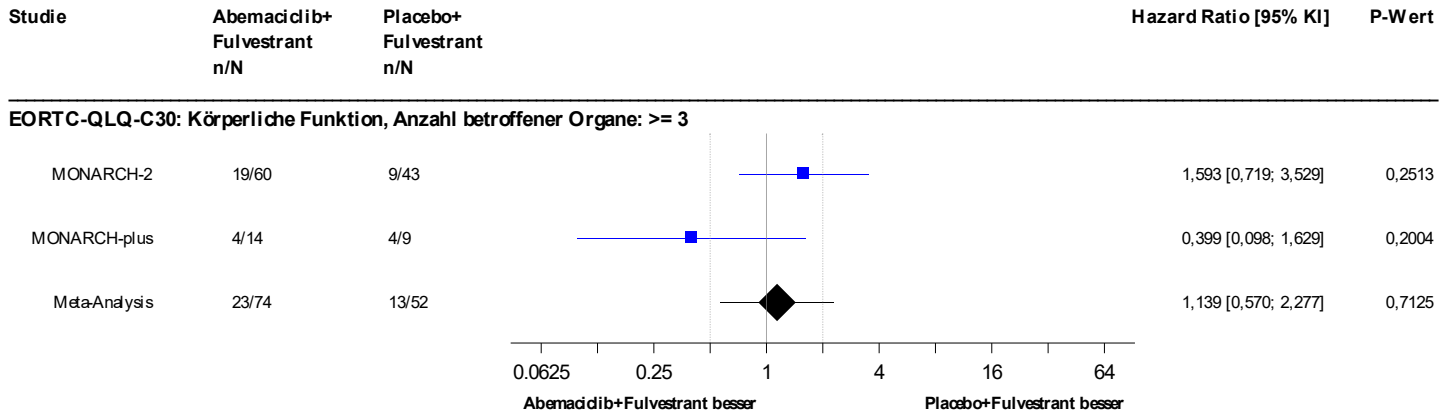
Abbildung 1416.1.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,8193, P-Wert=0,0931, I2 Index=64,5%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwphys6_popa1_norggr_3.rtf
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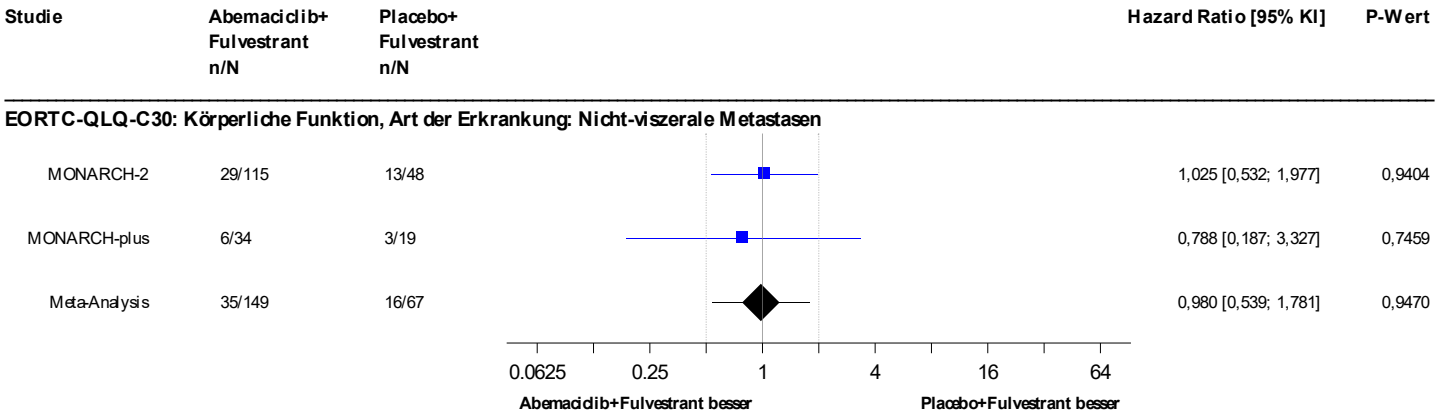
Abbildung 1416.1.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1062, P-Wert=0,7445, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwphys6_popa1_natdis2_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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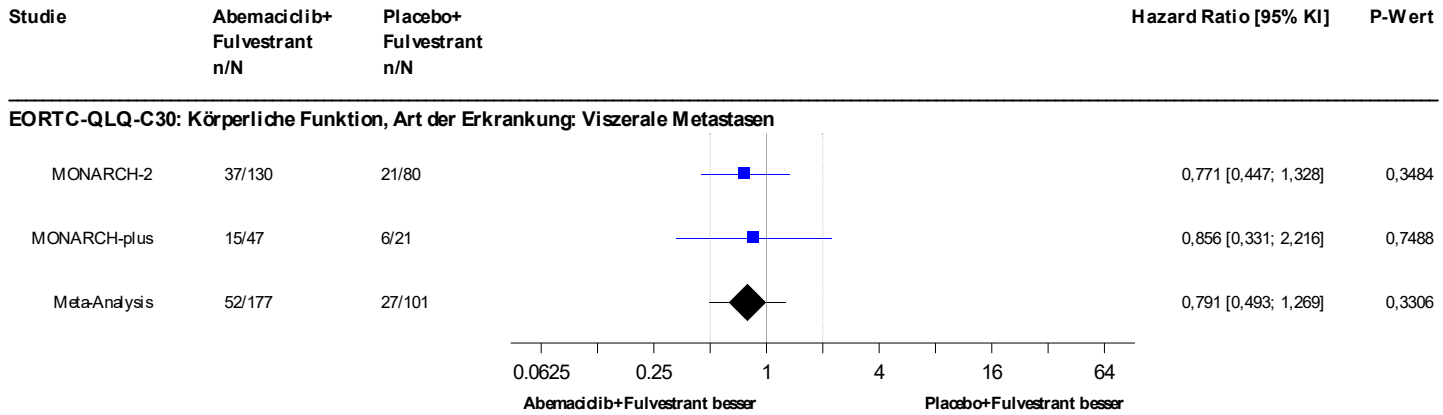
Abbildung 1416.1.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0352, P-Wert=0,8512, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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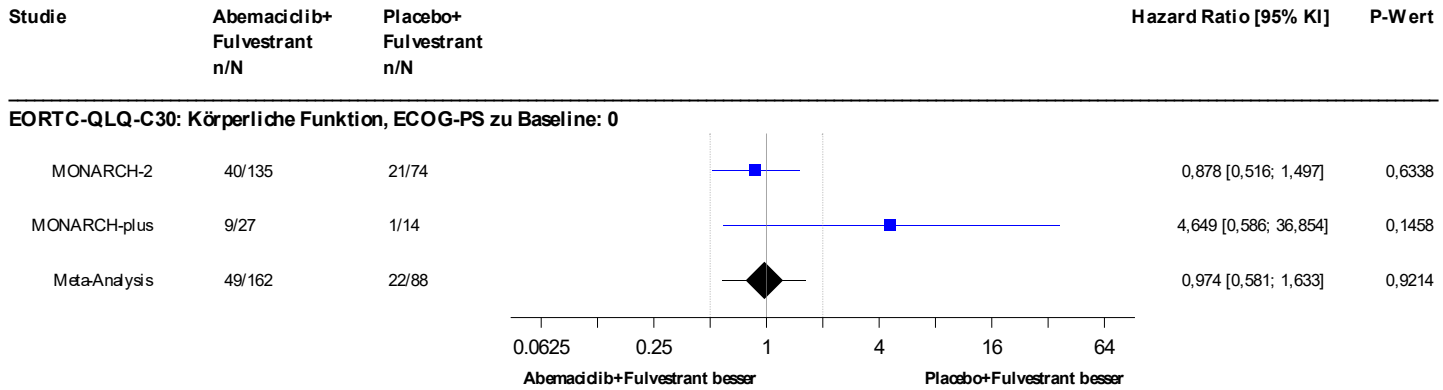
Abbildung 1416.1.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,3333, P-Wert=0,1266, I2 Index=57,1%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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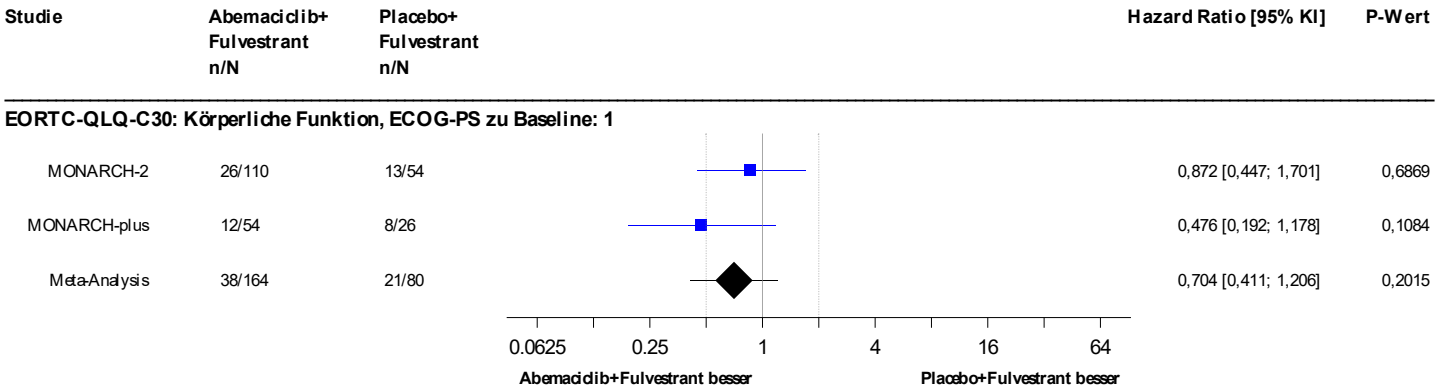
Abbildung 1416.1.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,1080, P-Wert=0,2925, I2 Index=9,7%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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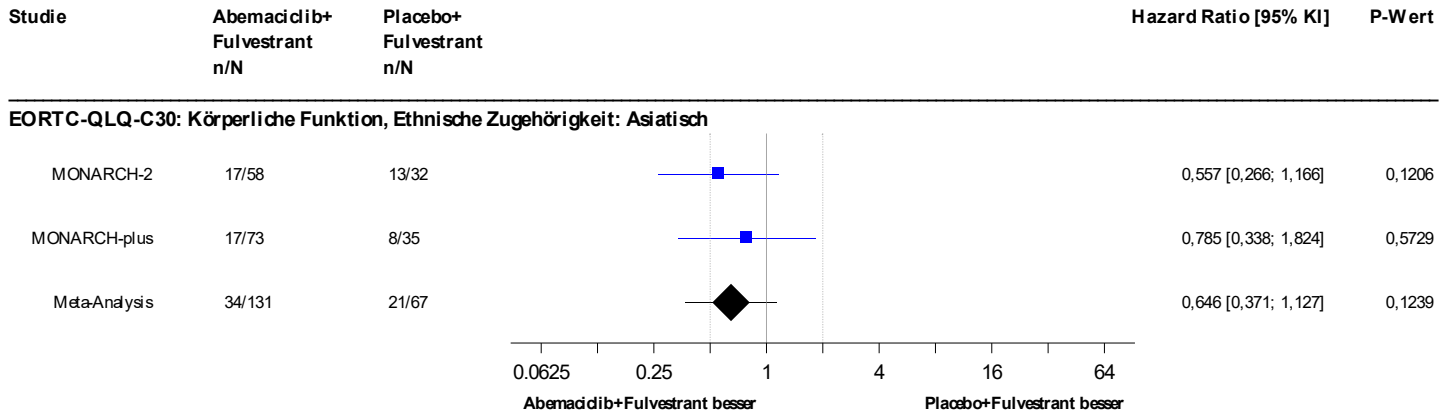
Abbildung 1416.1.5.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3599, P-Wert=0,5486, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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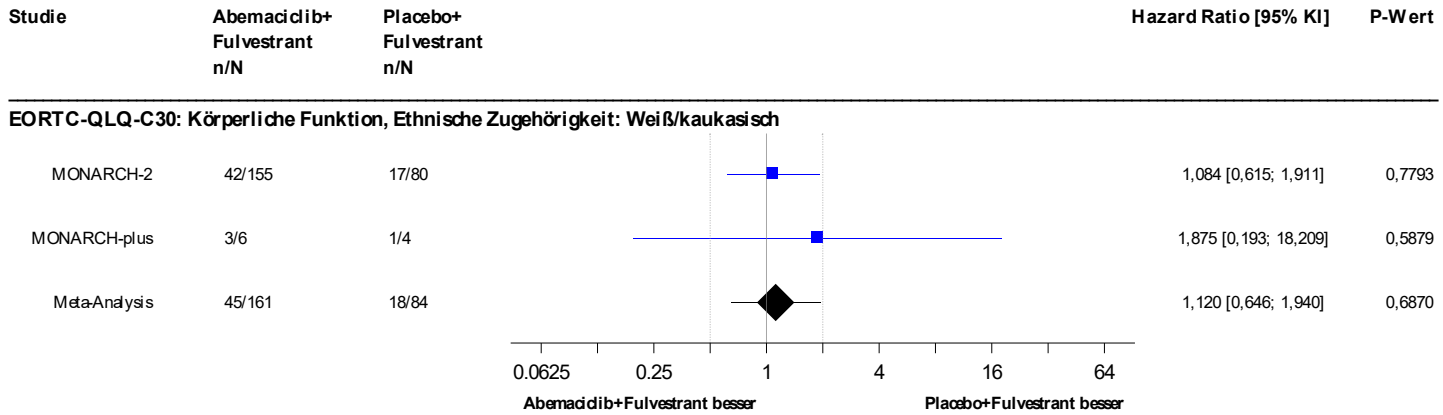
Abbildung 1416.1.5.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2099, P-Wert=0,6469, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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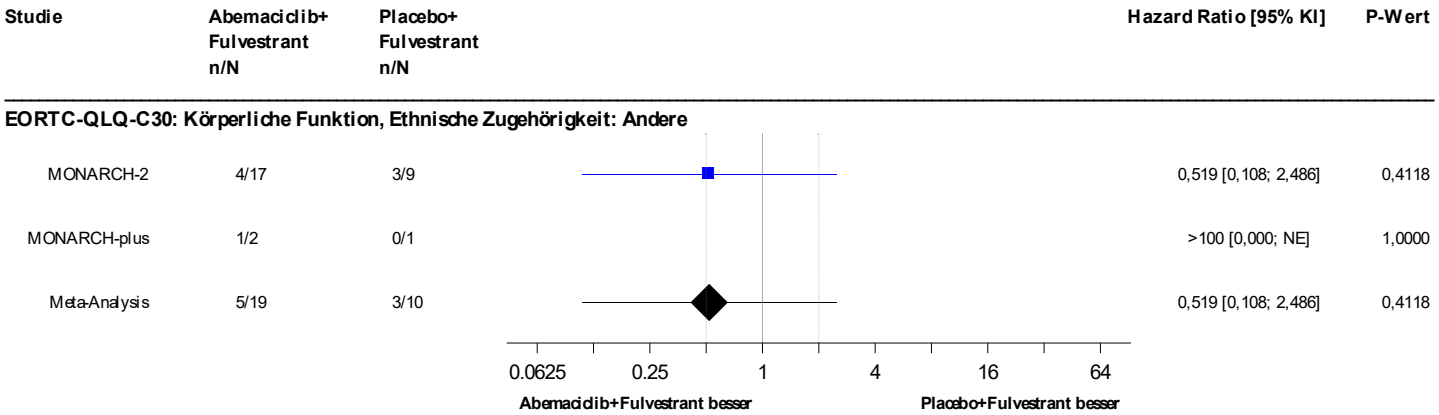
Abbildung 1416.1.5.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwphys6_popa1_racegr1_3.rtf
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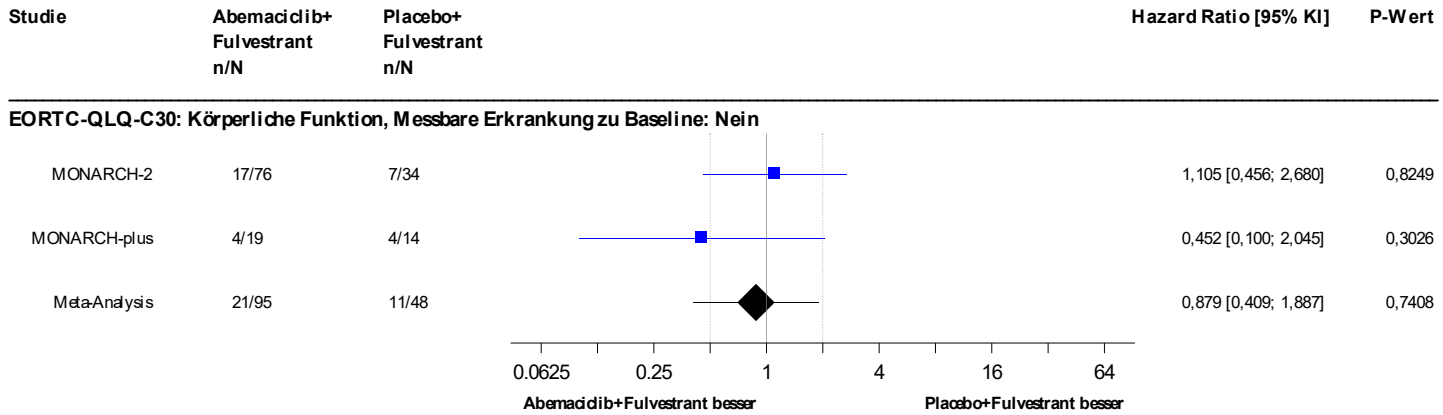
Abbildung 1416.1.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,0024, P-Wert=0,3167, I2 Index=0,2%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwphys6_popa1_measdis_1.rtf
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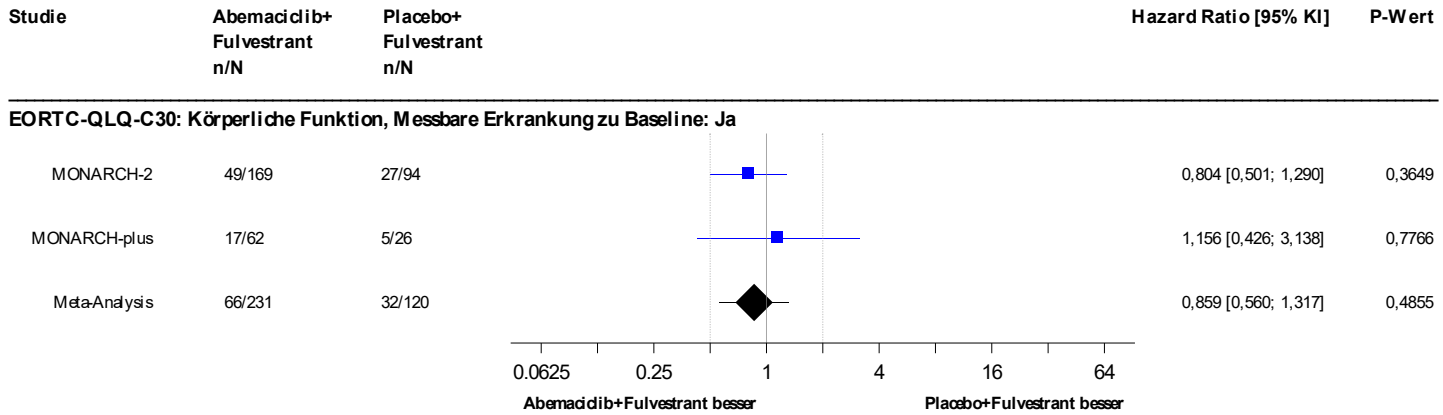
Abbildung 1416.1.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4151, P-Wert=0,5194, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwphys6_popa1_measdis_2.rtf
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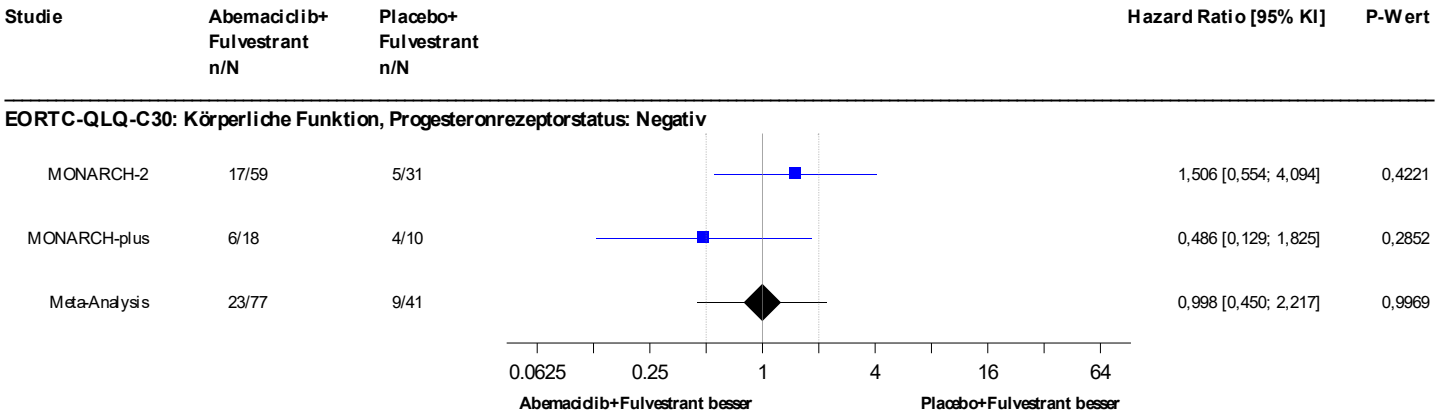
Abbildung 1416.1.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,7867, P-Wert=0,1813, I2 Index=44,0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwphys6_popa1_pgrstat_1.rtf
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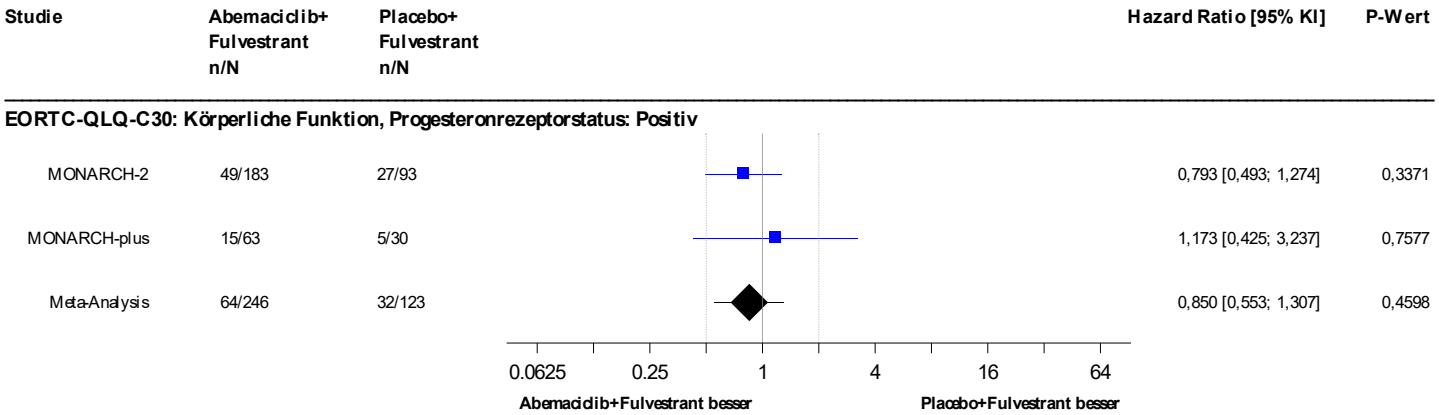
Abbildung 1416.1.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4704, P-Wert=0,4928, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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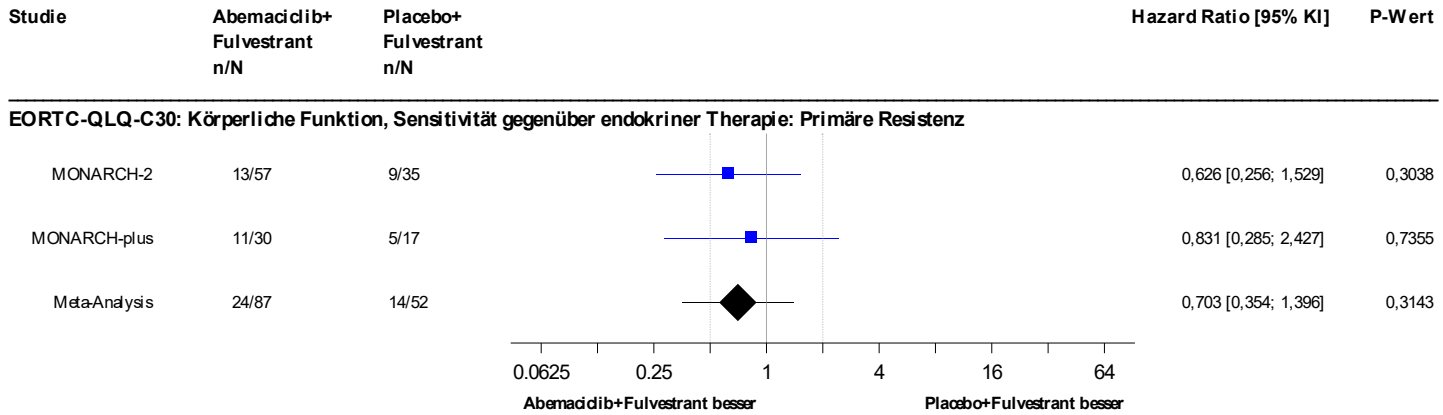
Abbildung 1416.1.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1592, P-Wert=0,6899, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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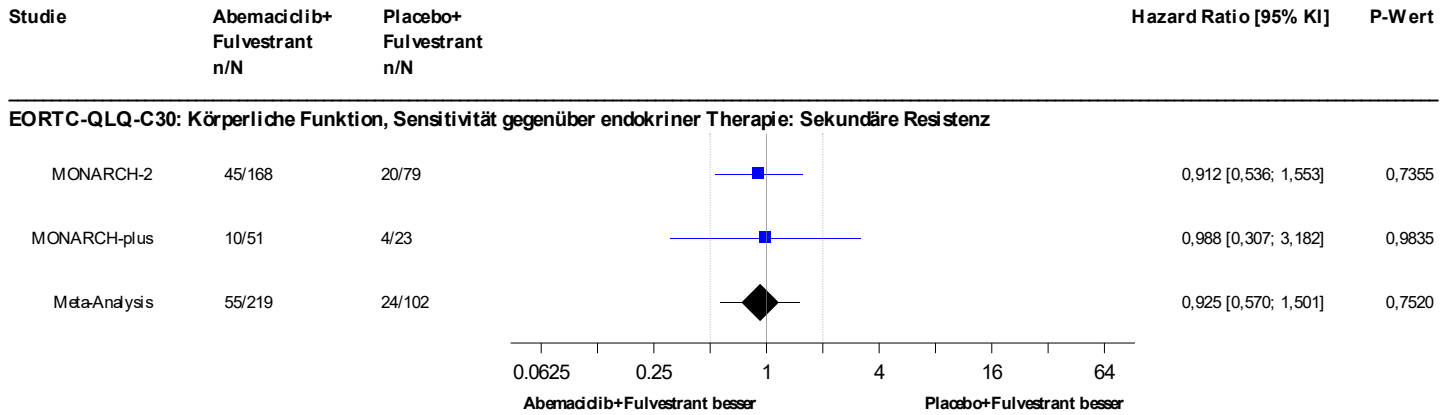
Abbildung 1416.1.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0147, P-Wert=0,9037, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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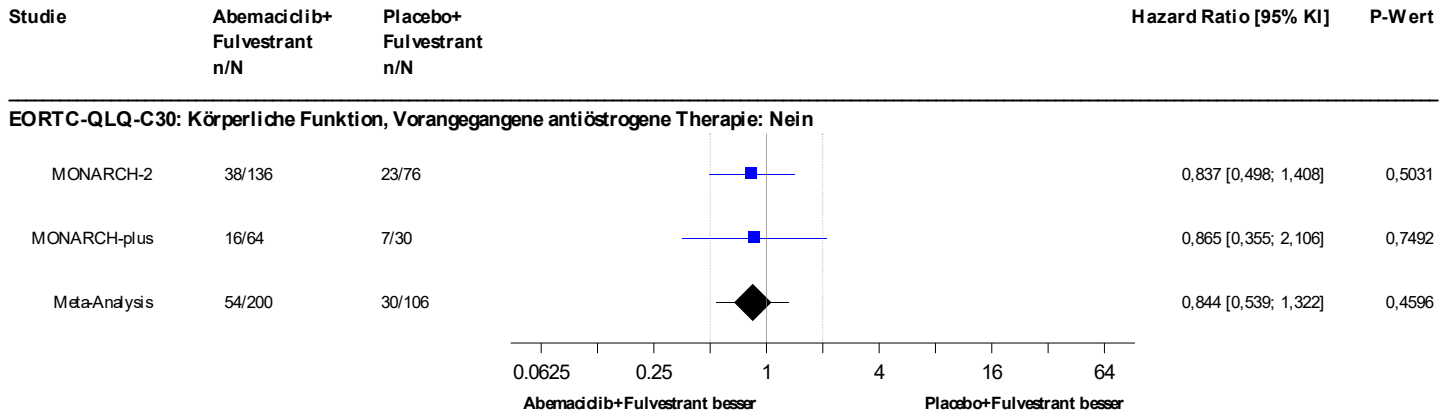
Abbildung 1416.1.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0038, P-Wert=0,9511, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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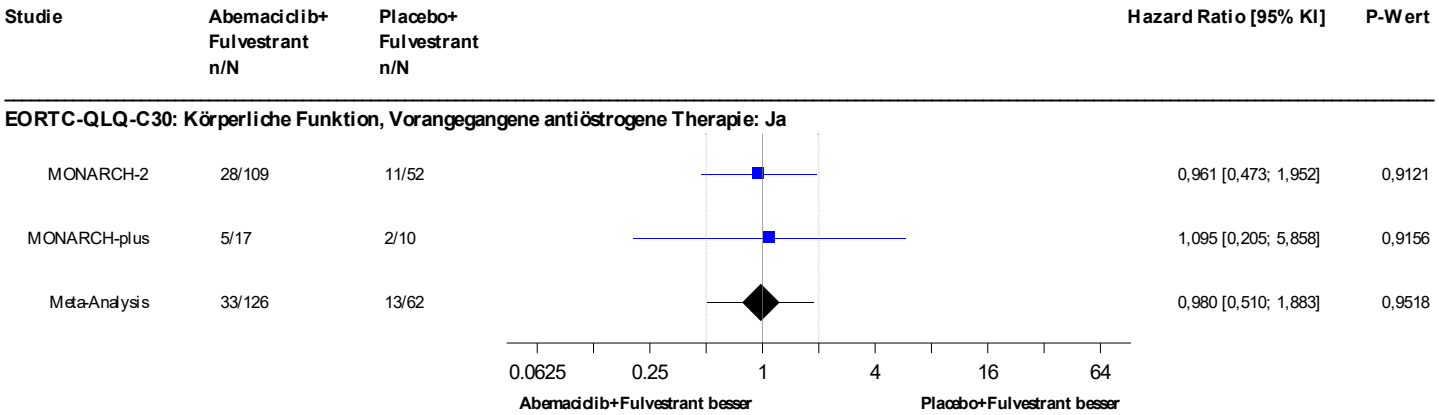
Abbildung 1416.1.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0198, P-Wert=0,8882, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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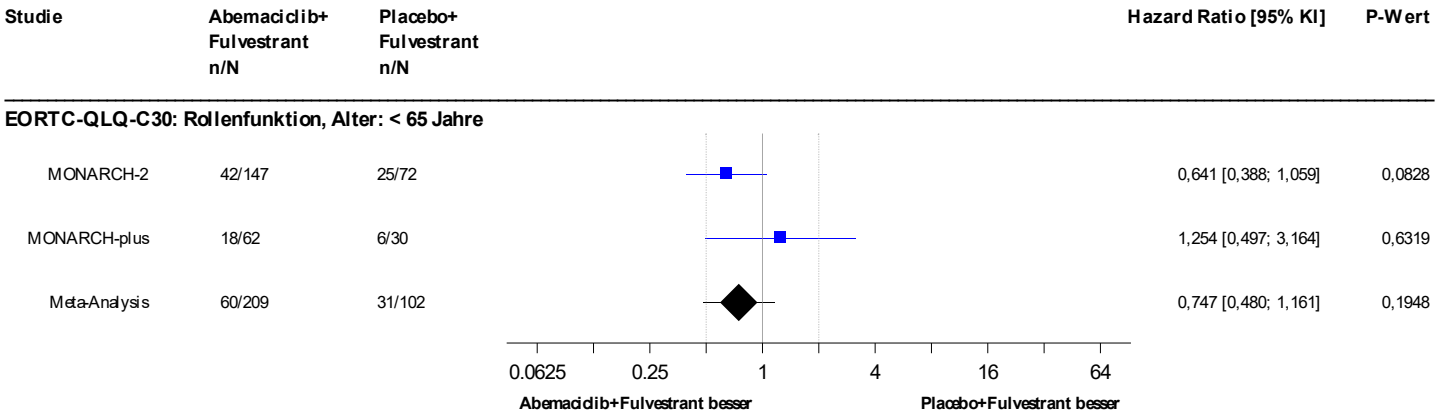
Abbildung 1417.1.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,5573, P-Wert=0,2121, I2 Index=35,8%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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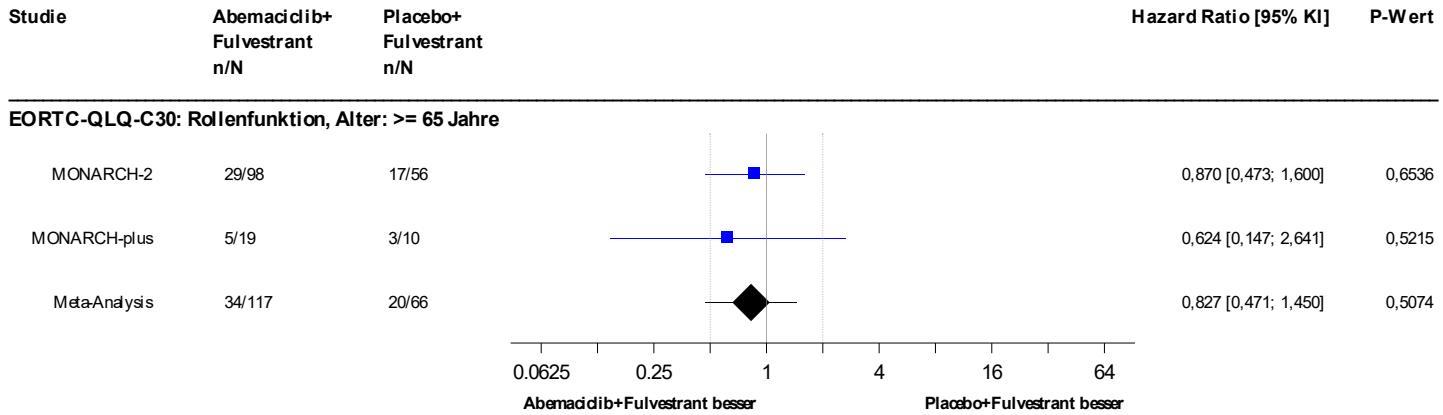
Abbildung 1417.1.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1729, P-Wert=0,6775, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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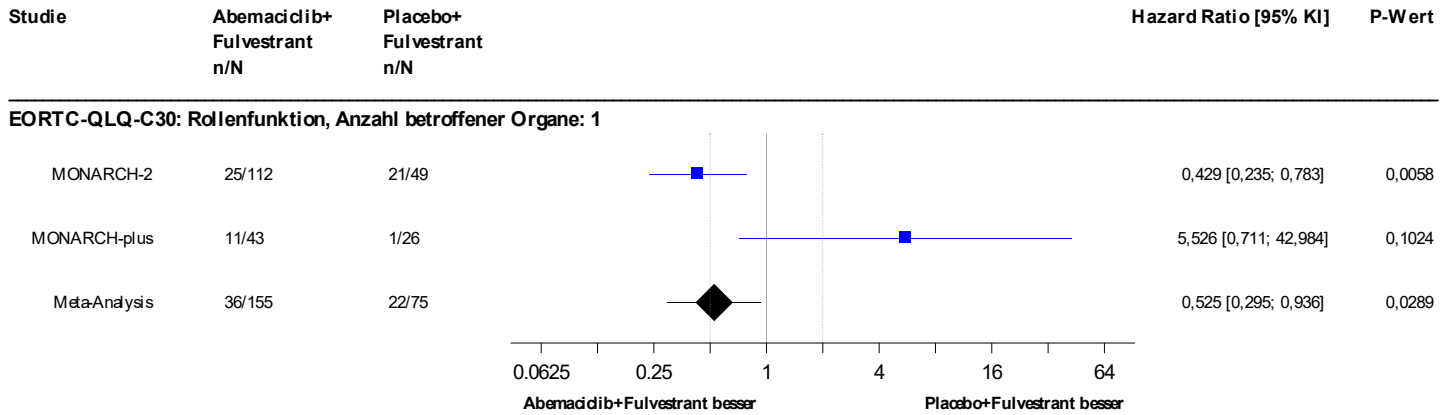
Abbildung 1417.1.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=5,4895, P-Wert=0,0191, I2 Index=81,8%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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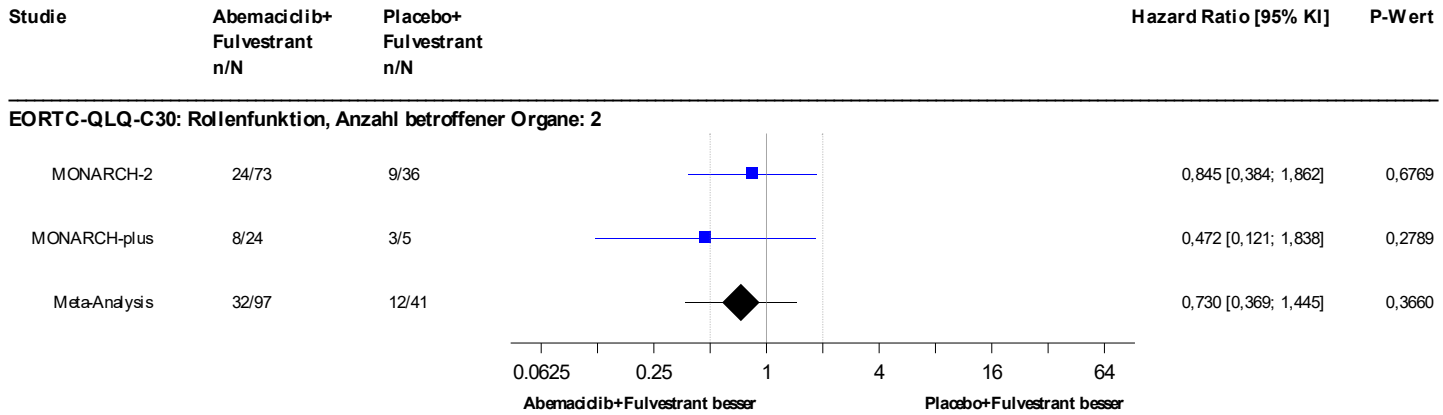
Abbildung 1417.1.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,5288, P-Wert=0,4671, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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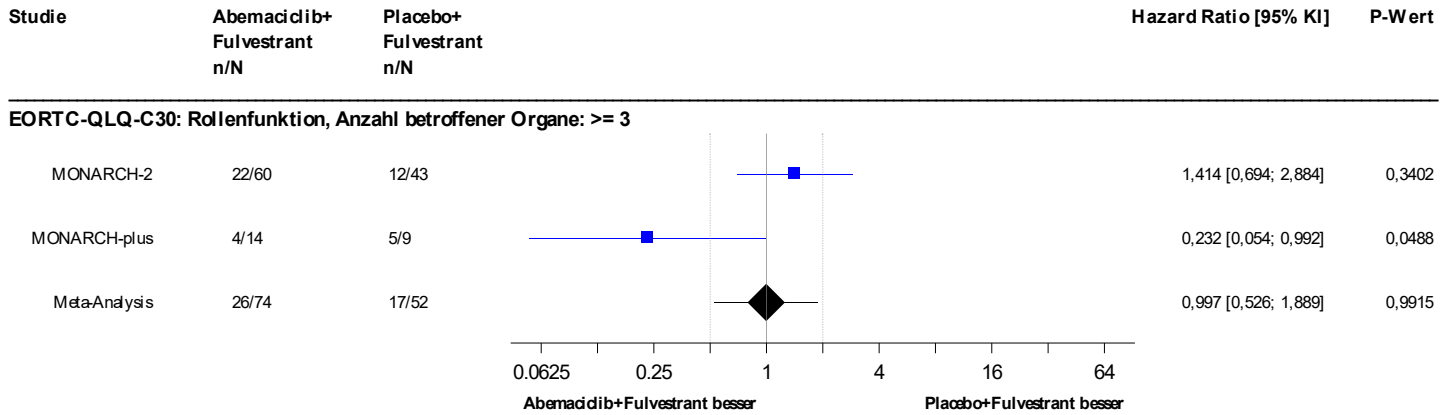
Abbildung 1417.1.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=4,7913, P-Wert=0,0286, I2 Index=79,1%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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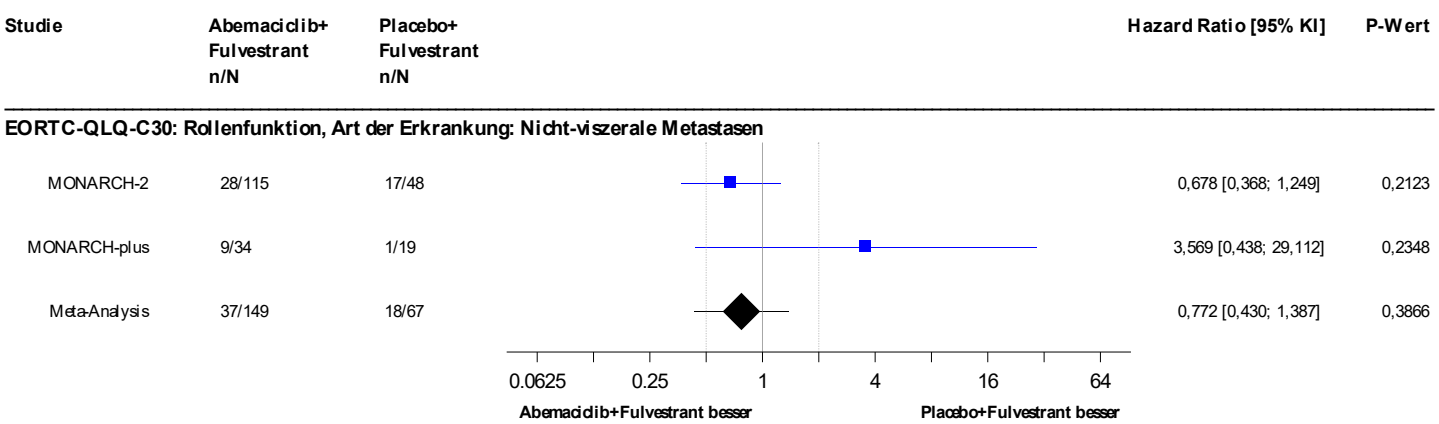
Abbildung 1417.1.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,2174, P-Wert=0,1365, I2 Index=54,9%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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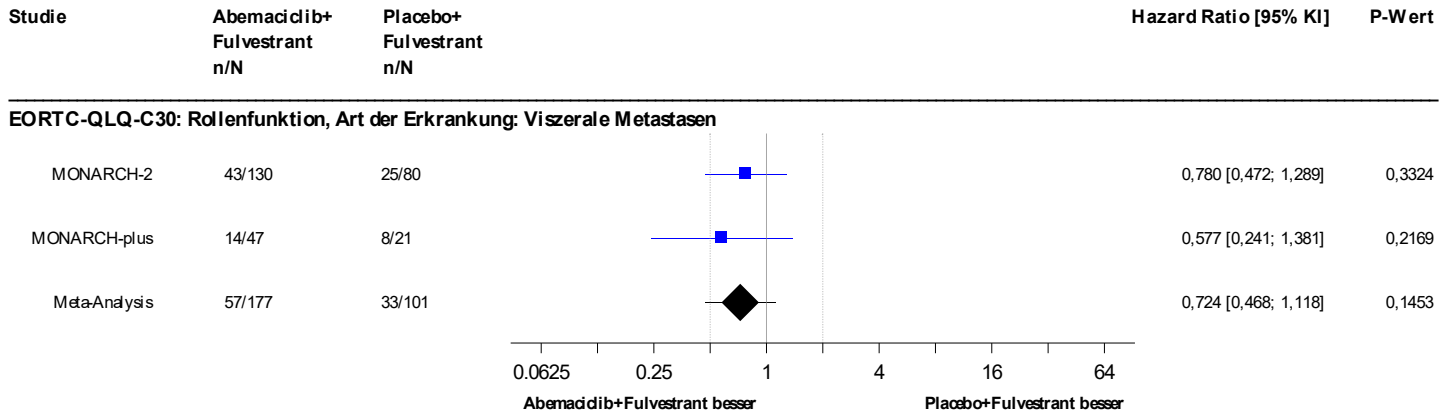
Abbildung 1417.1.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3436, P-Wert=0,5578, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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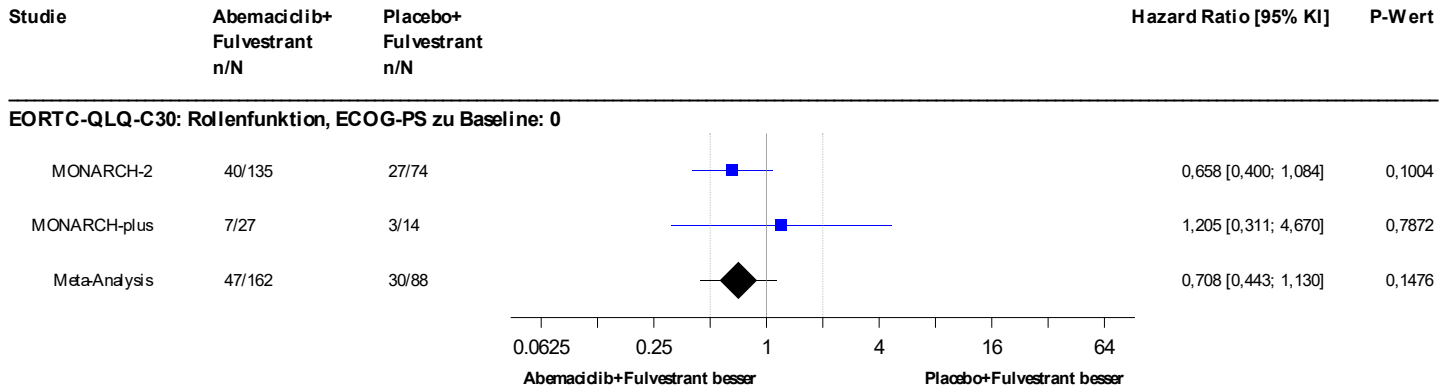
Abbildung 1417.1.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6742, P-Wert=0,4116, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwrole6_popa1_ecogbl_1.rtf
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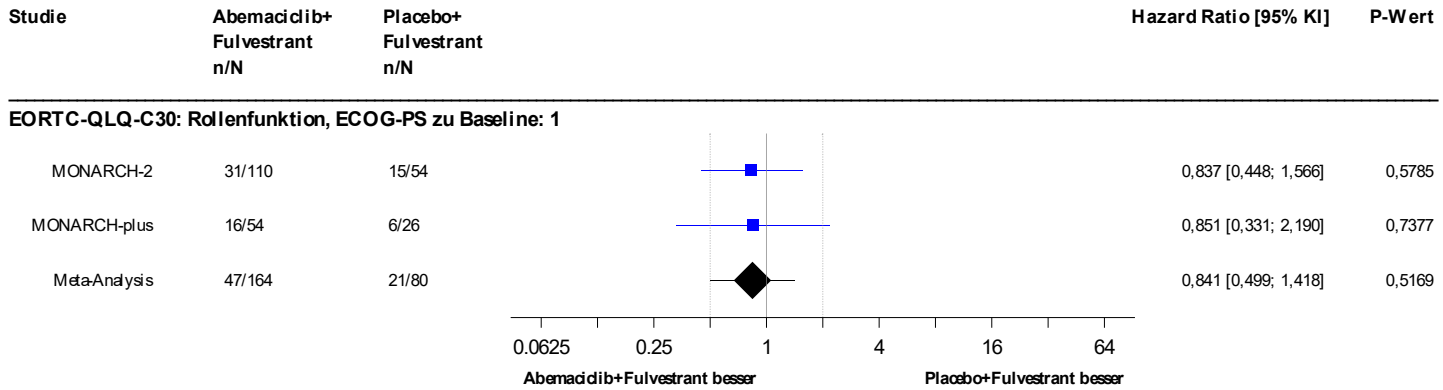
Abbildung 1417.1.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0008, P-Wert=0,9780, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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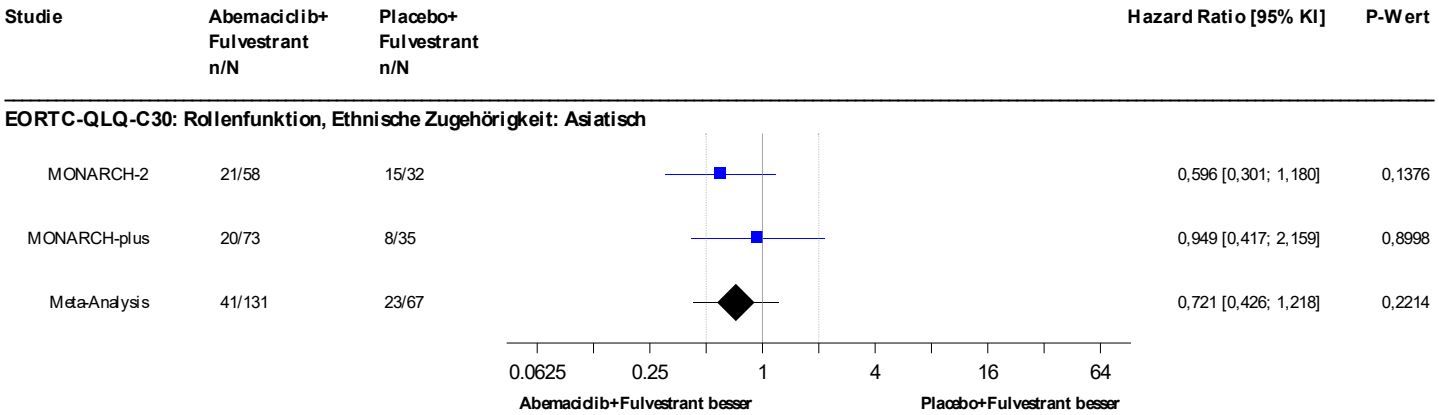
Abbildung 1417.1.5.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7246, P-Wert=0,3946, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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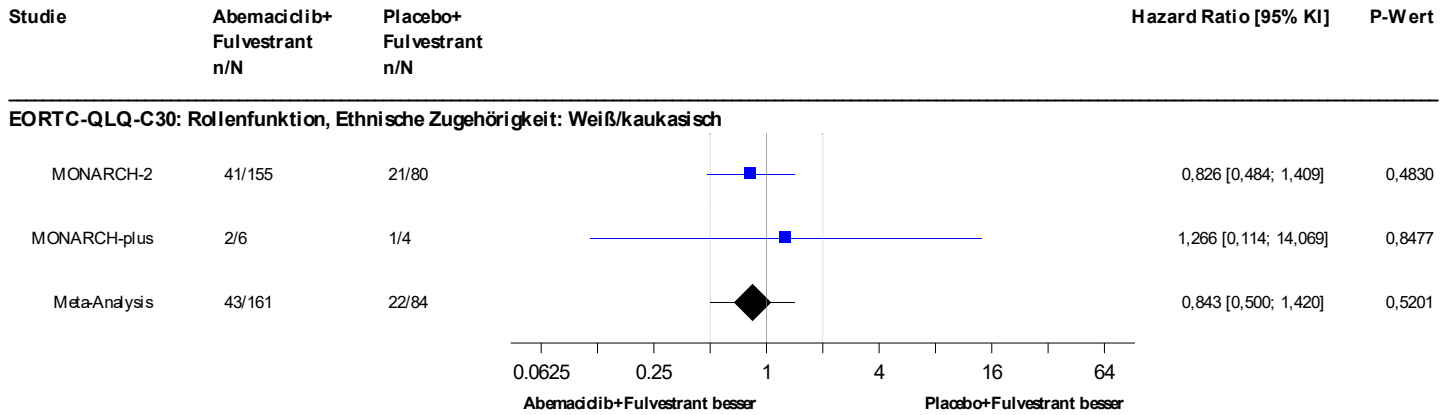
Abbildung 1417.1.5.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1152, P-Wert=0,7343, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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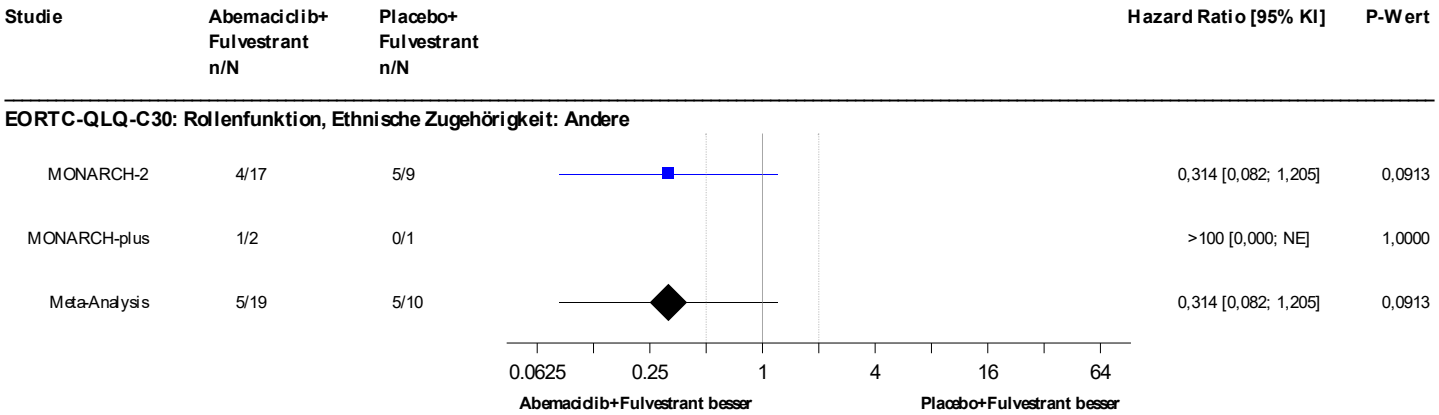
Abbildung 1417.1.5.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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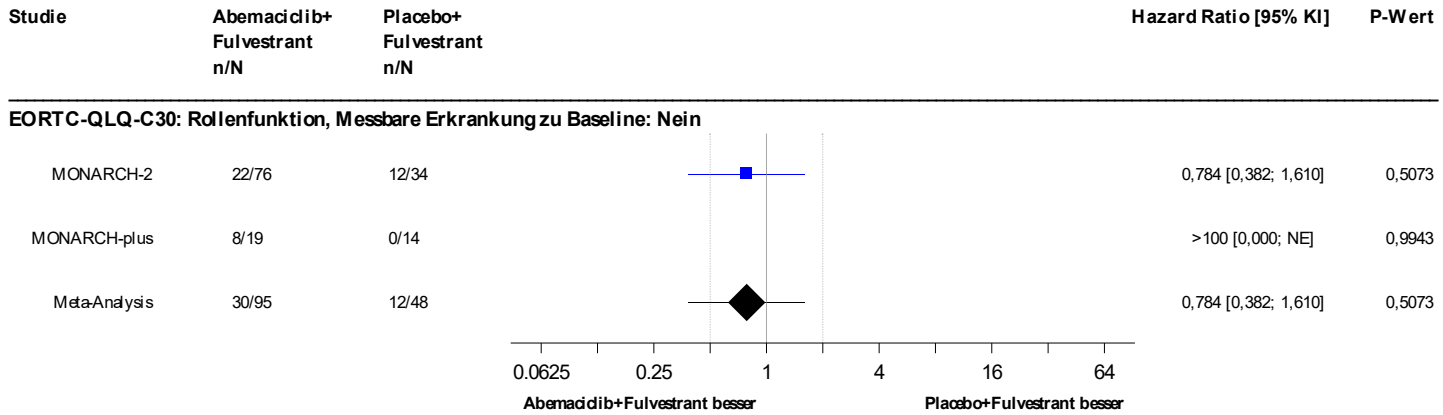
Abbildung 1417.1.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9942, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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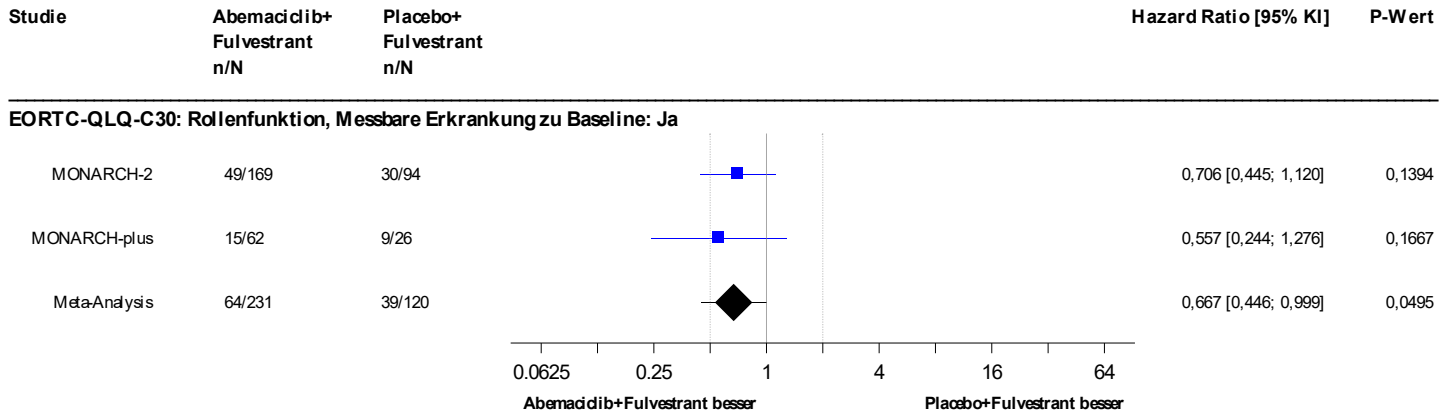
Abbildung 1417.1.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2382, P-Wert=0,6255, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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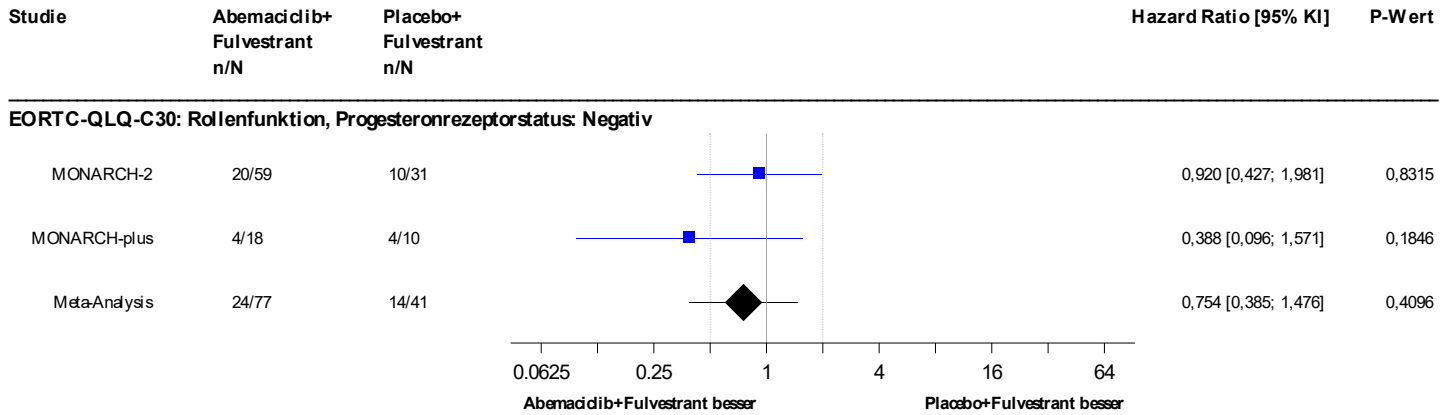
Abbildung 1417.1.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,1254, P-Wert=0,2888, I2 Index=11,1%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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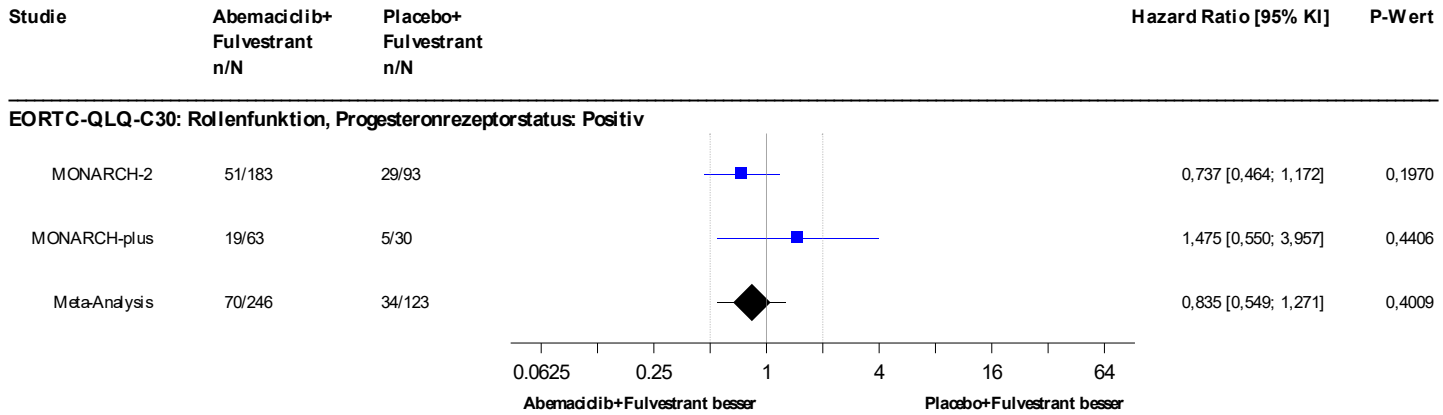
Abbildung 1417.1.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,5535, P-Wert=0,2126, I2 Index=35,6%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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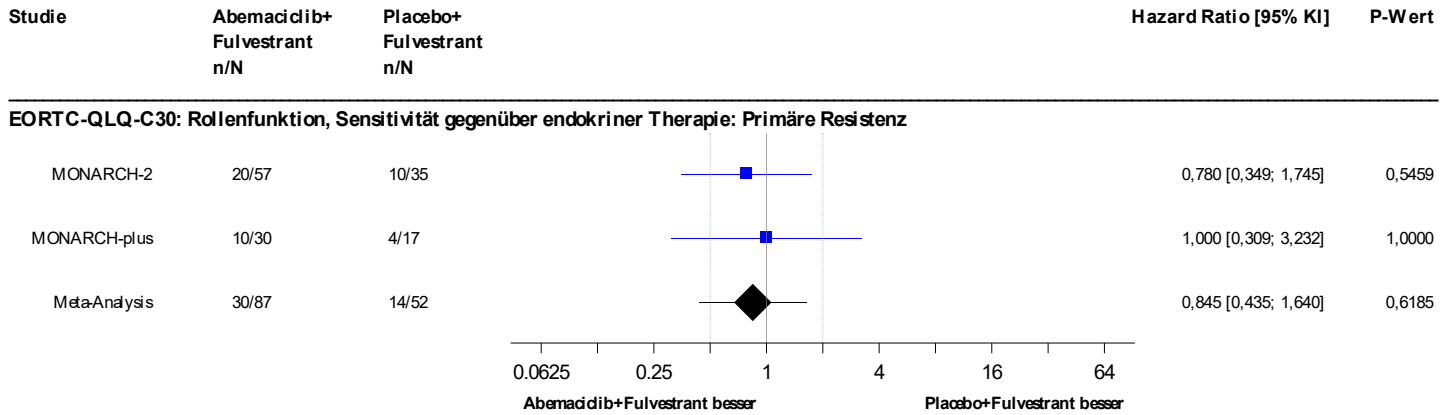
Abbildung 1417.1.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1167, P-Wert=0,7327, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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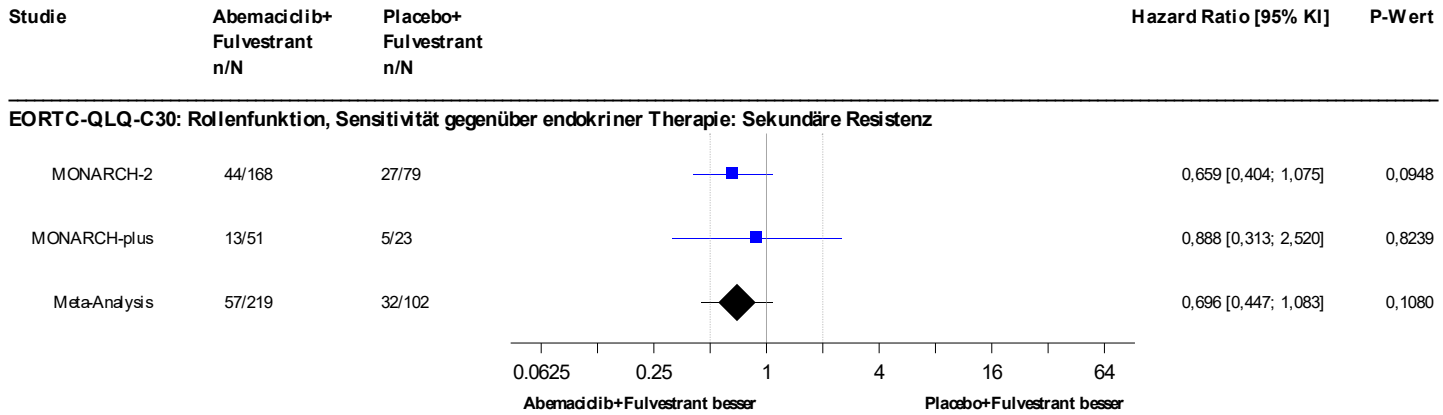
Abbildung 1417.1.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2578, P-Wert=0,6117, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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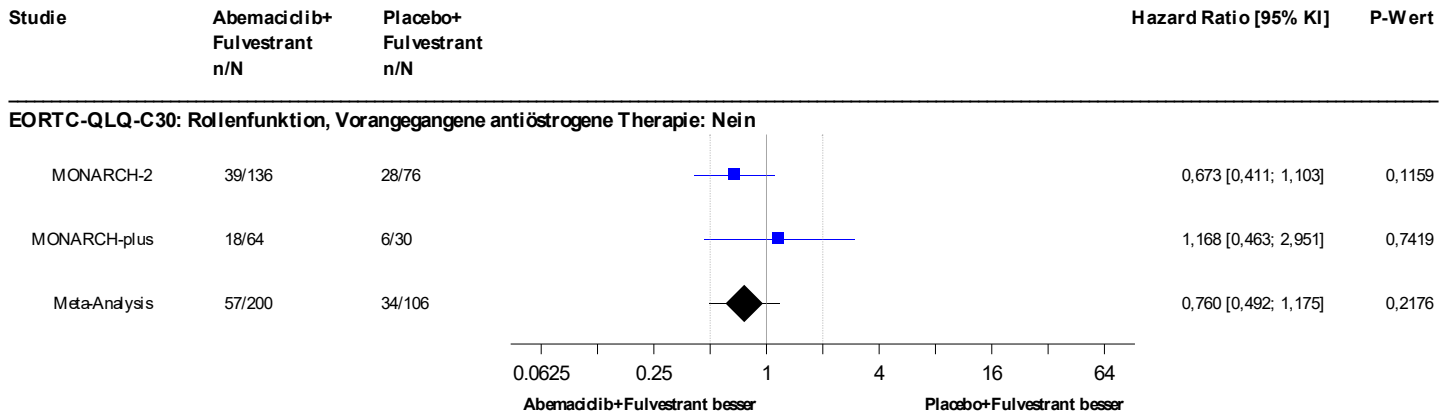
Abbildung 1417.1.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,0599, P-Wert=0,3032, I2 Index=5,7%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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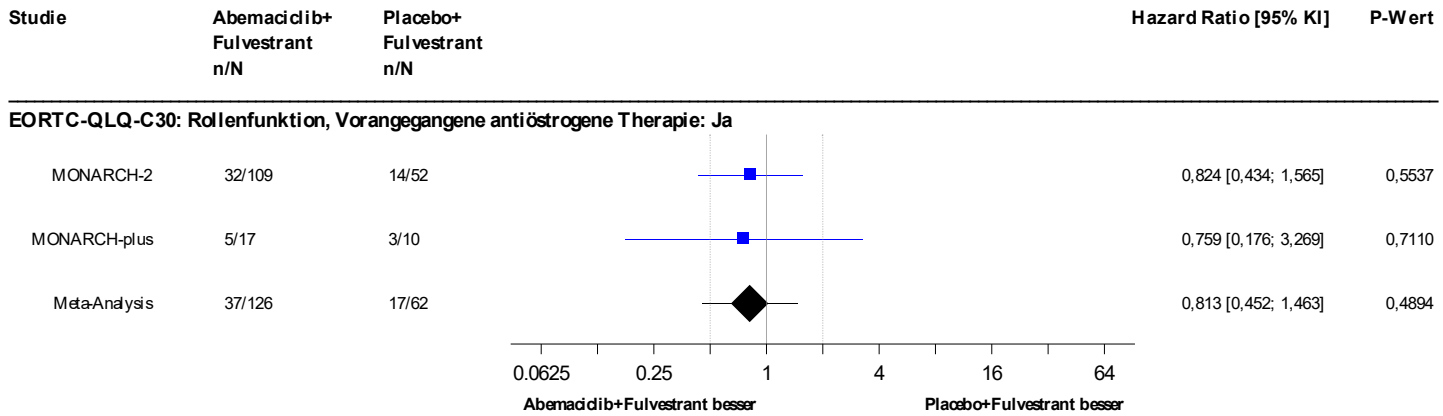
Abbildung 1417.1.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0102, P-Wert=0,9196, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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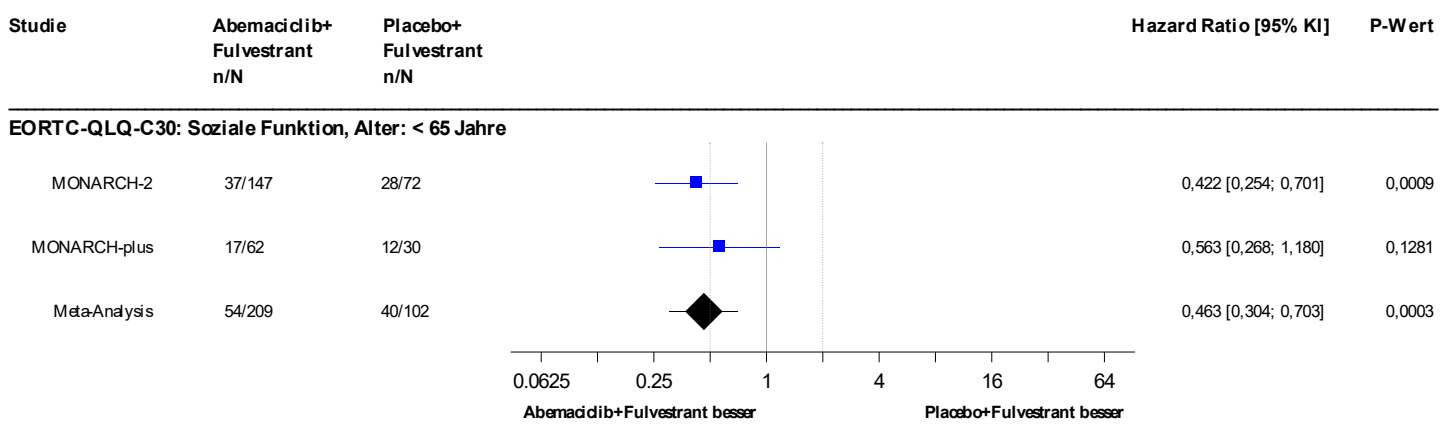
Abbildung 1418.1.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3944, P-Wert=0,5300, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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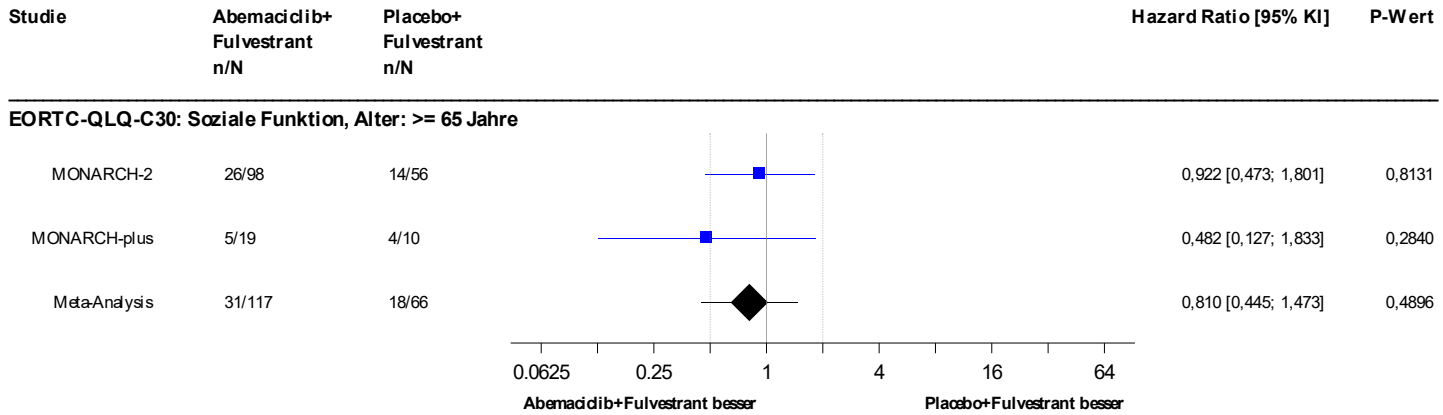
17SEP2021 / 07:48

Abbildung 1418.1.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7265, P-Wert=0,3940, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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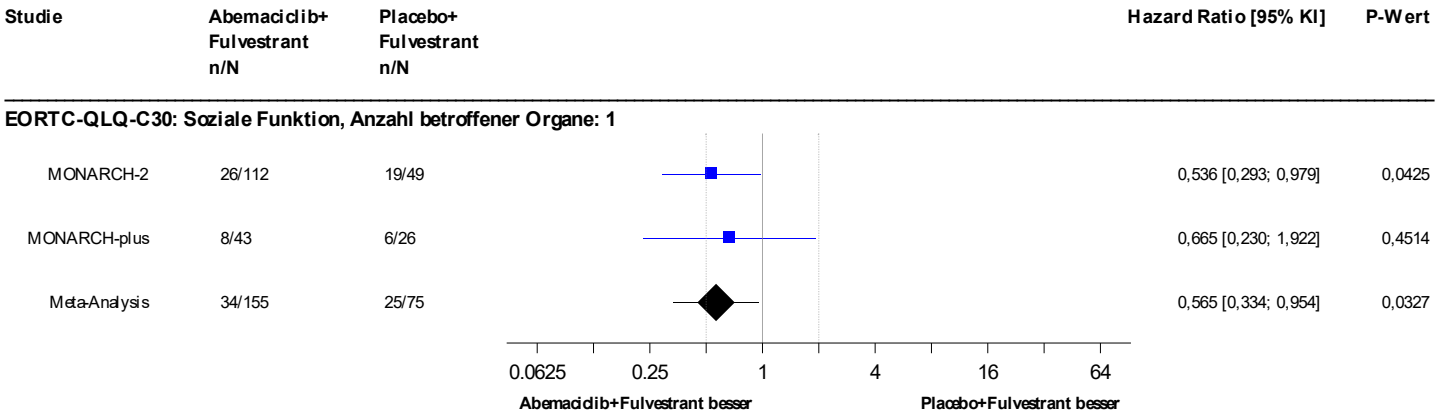
17SEP2021 / 07:48

Abbildung 1418.1.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1208, P-Wert=0,7282, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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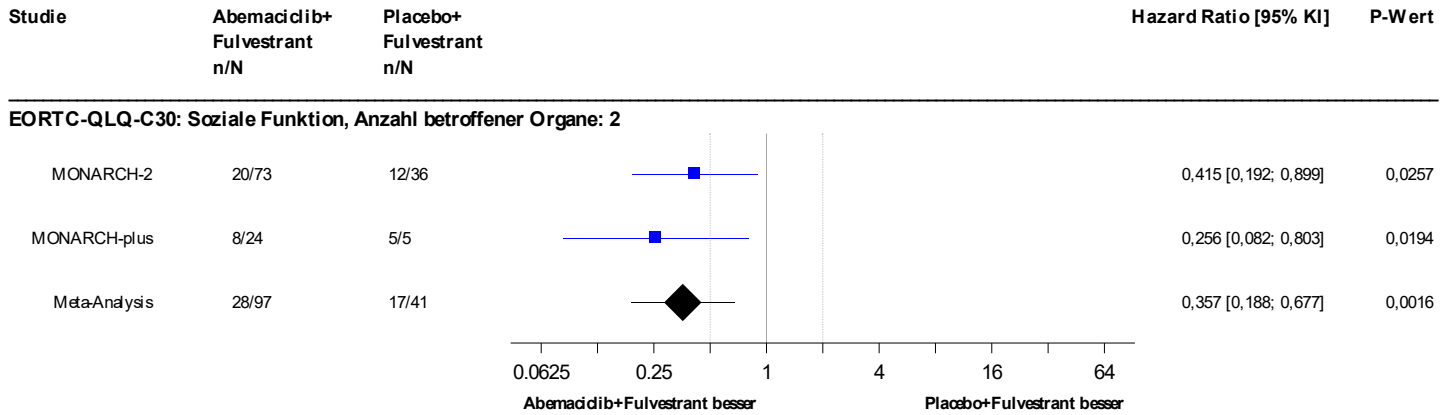
Abbildung 1418.1.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4708, P-Wert=0,4926, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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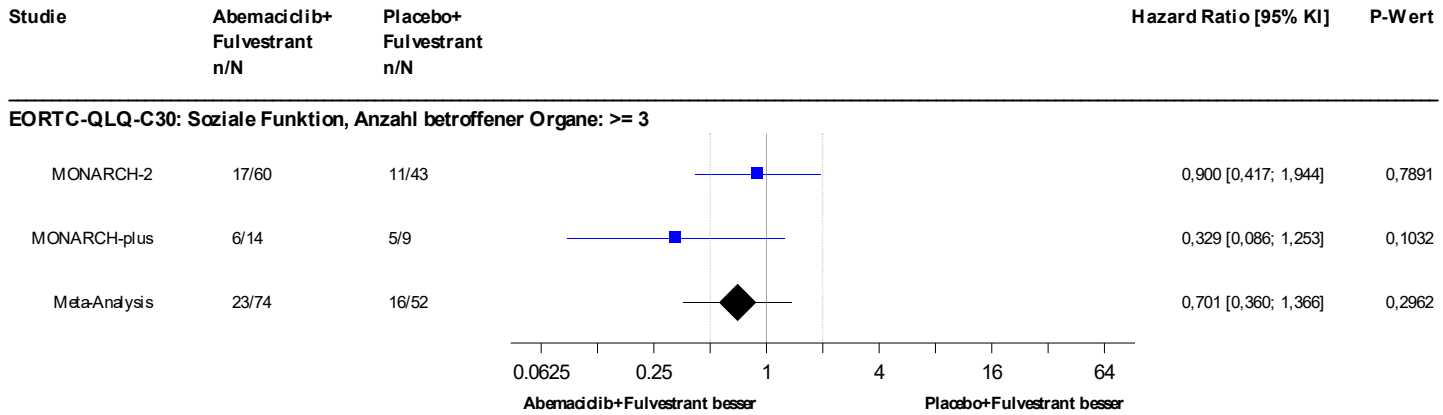
Abbildung 1418.1.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,6363, P-Wert=0,2008, I2 Index=38,9%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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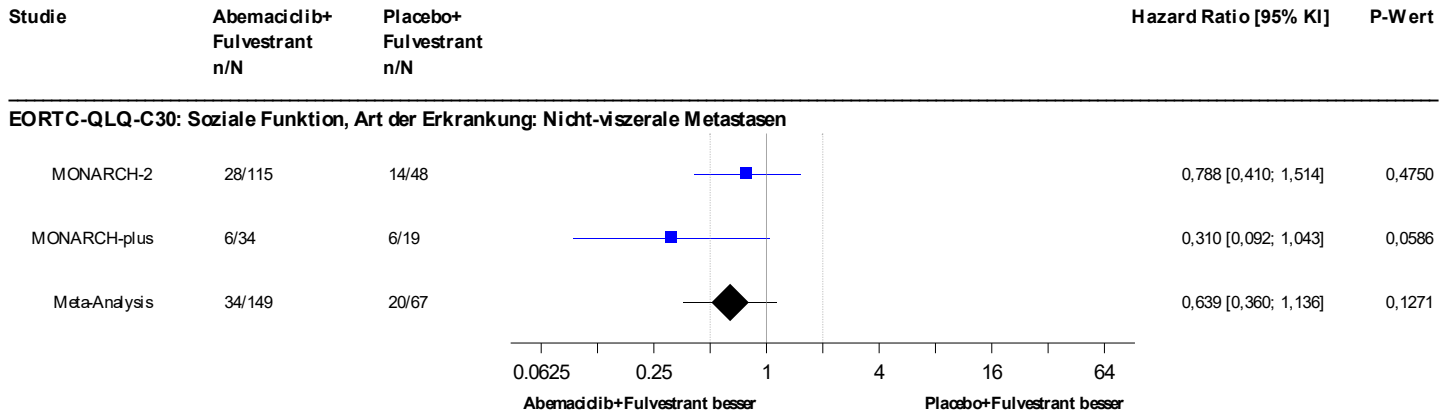
Abbildung 1418.1.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,7601, P-Wert=0,1846, I2 Index=43,2%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwsoci6_popa1_natdis2_1.rtf
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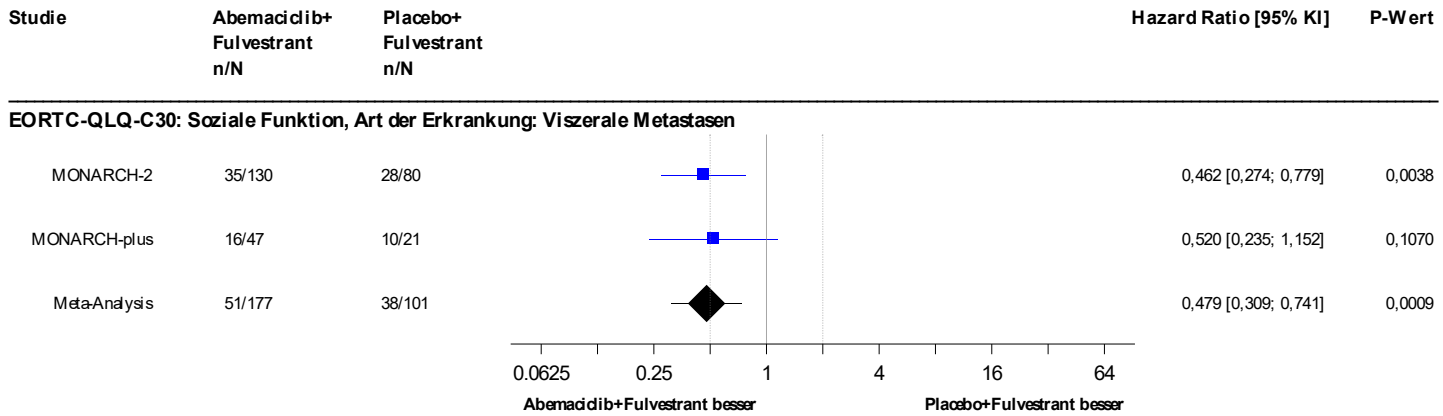
Abbildung 1418.1.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0597, P-Wert=0,8070, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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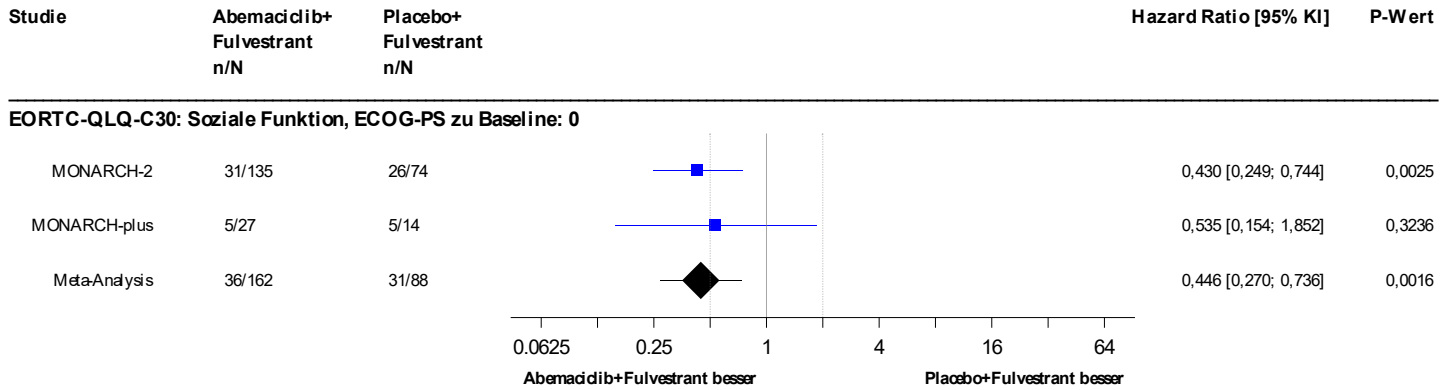
Abbildung 1418.1.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0994, P-Wert=0,7526, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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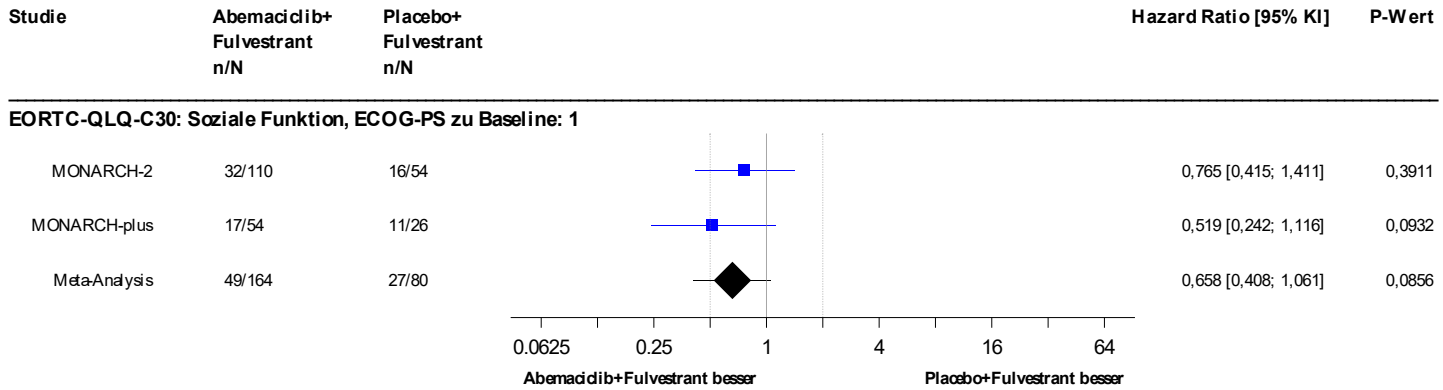
Abbildung 1418.1.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,5994, P-Wert=0,4388, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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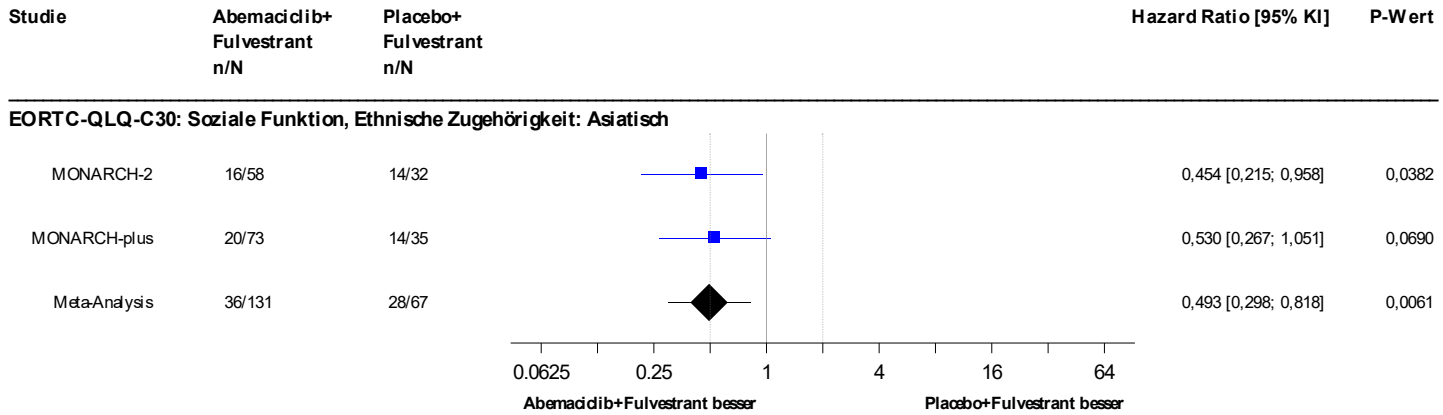
Abbildung 1418.1.5.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0894, P-Wert=0,7650, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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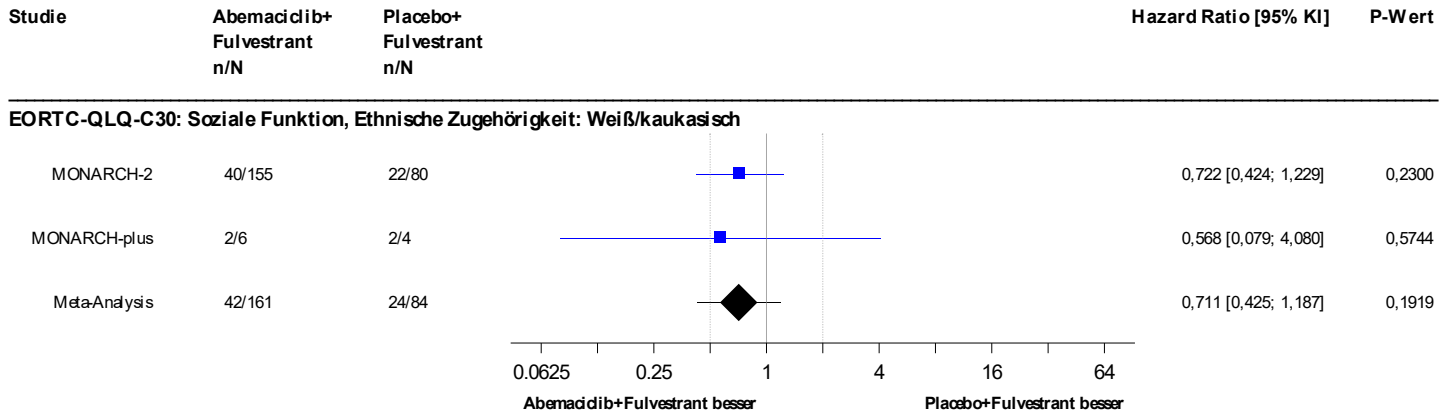
Abbildung 1418.1.5.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0527, P-Wert=0,8183, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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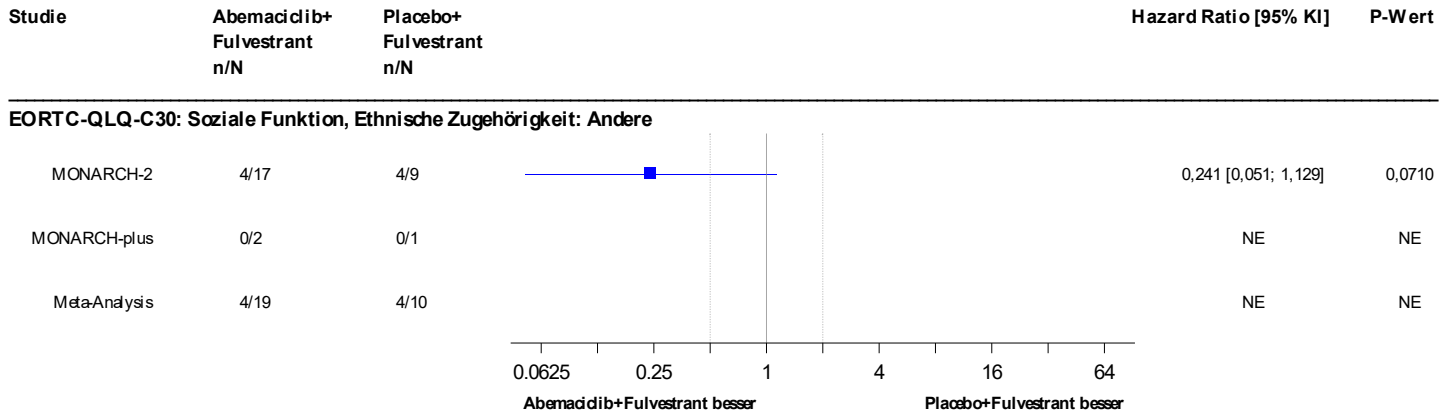
Abbildung 1418.1.5.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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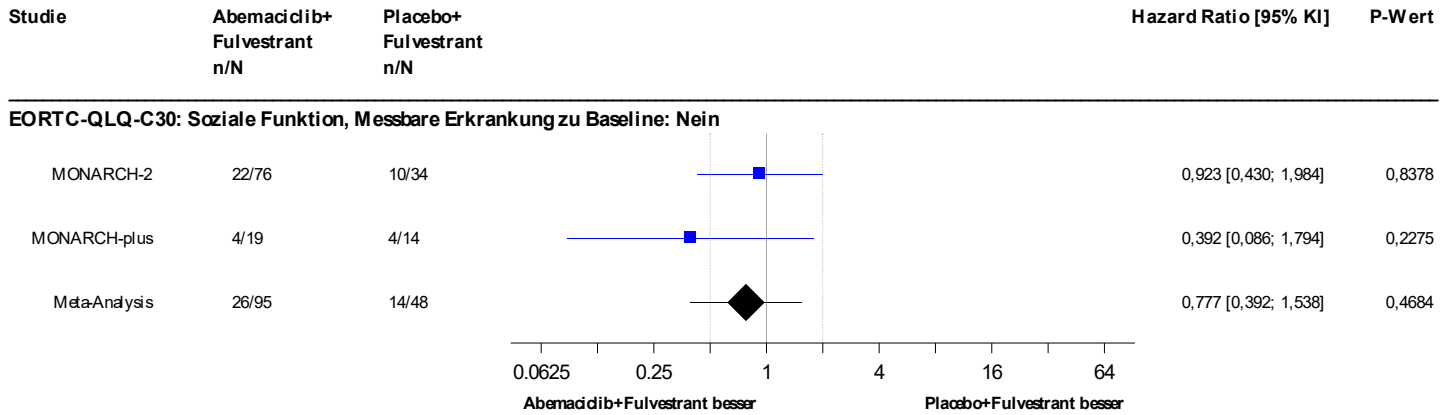
Abbildung 1418.1.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,9724, P-Wert=0,3241, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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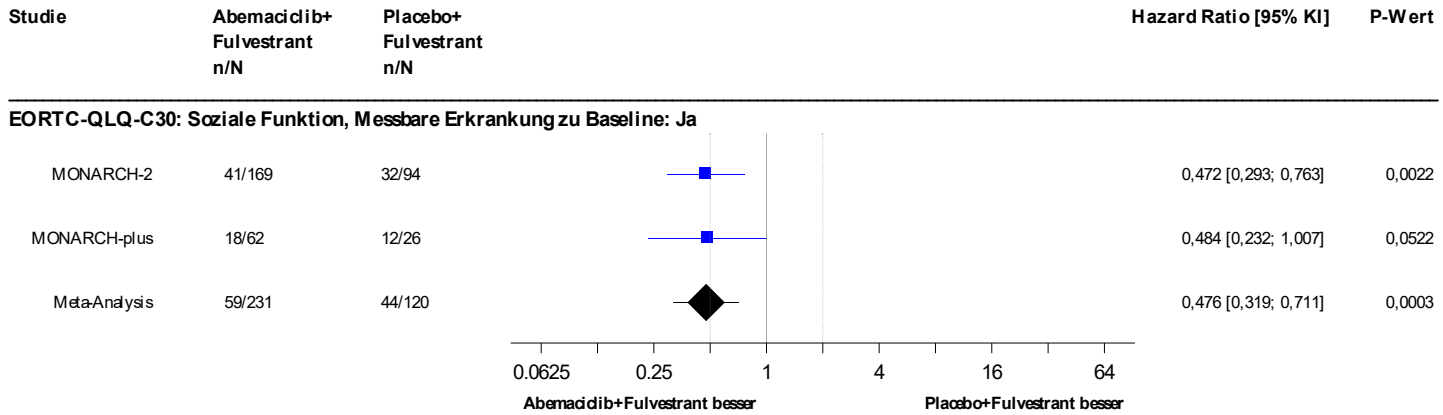
Abbildung 1418.1.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0028, P-Wert=0,9579, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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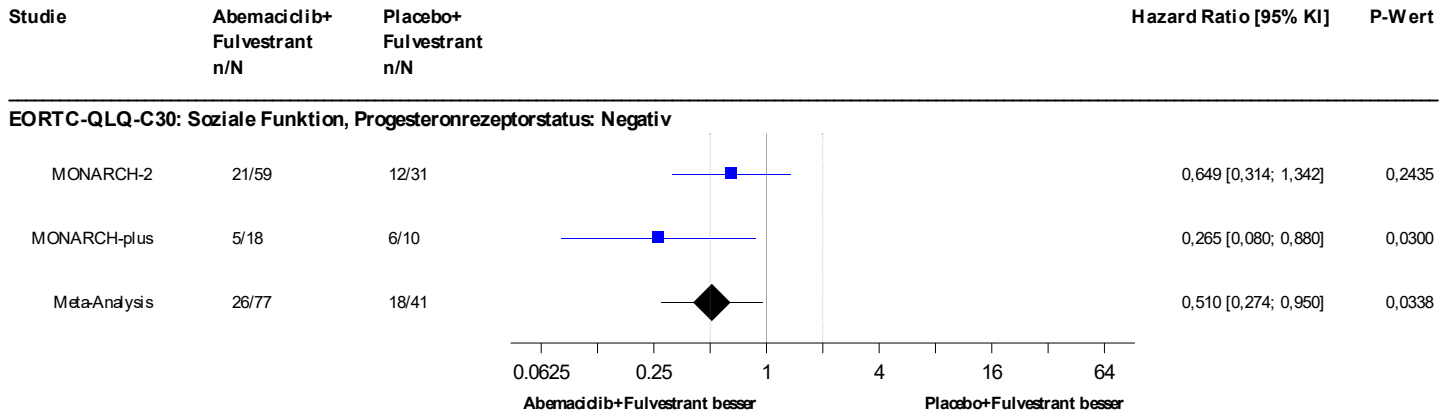
Abbildung 1418.1.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,5646, P-Wert=0,2110, I2 Index=36,1%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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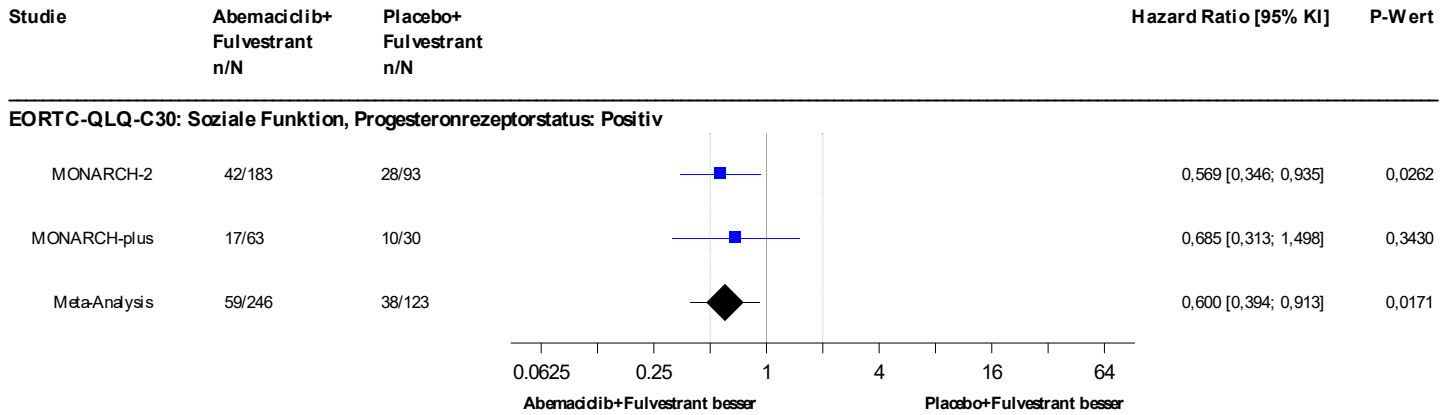
Abbildung 1418.1.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1534, P-Wert=0,6953, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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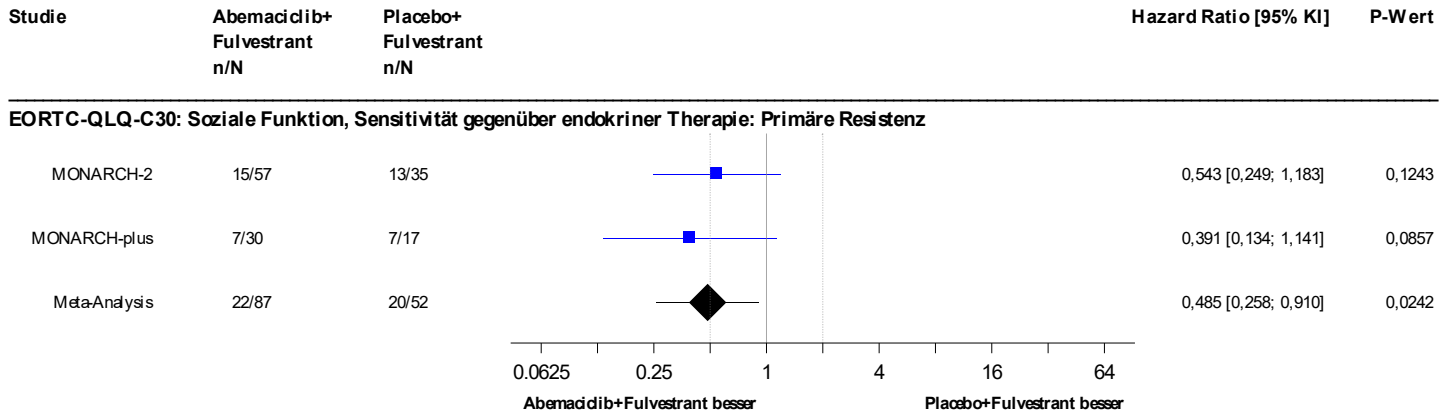
Abbildung 1418.1.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2343, P-Wert=0,6283, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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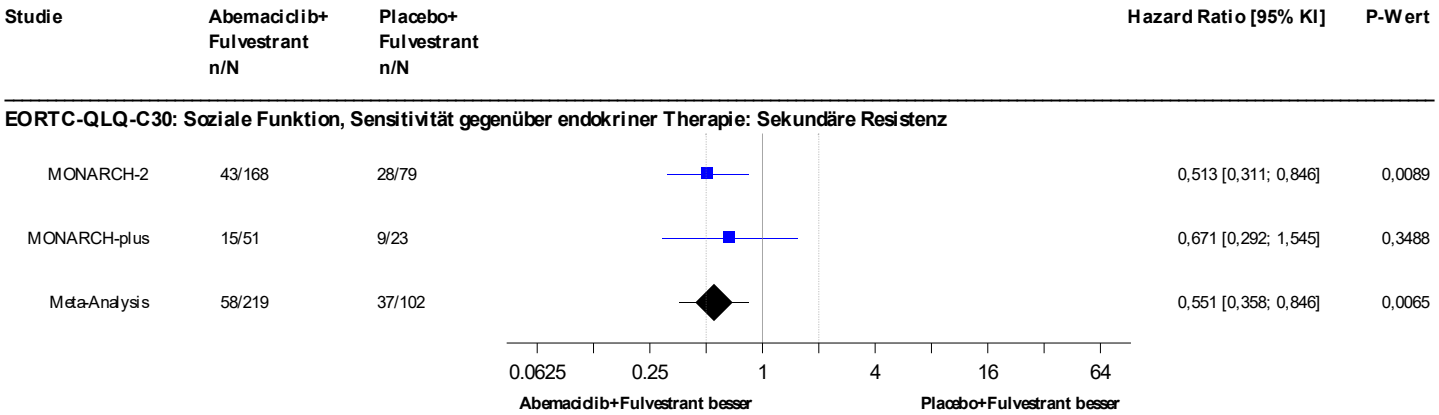
Abbildung 1418.1.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2953, P-Wert=0,5868, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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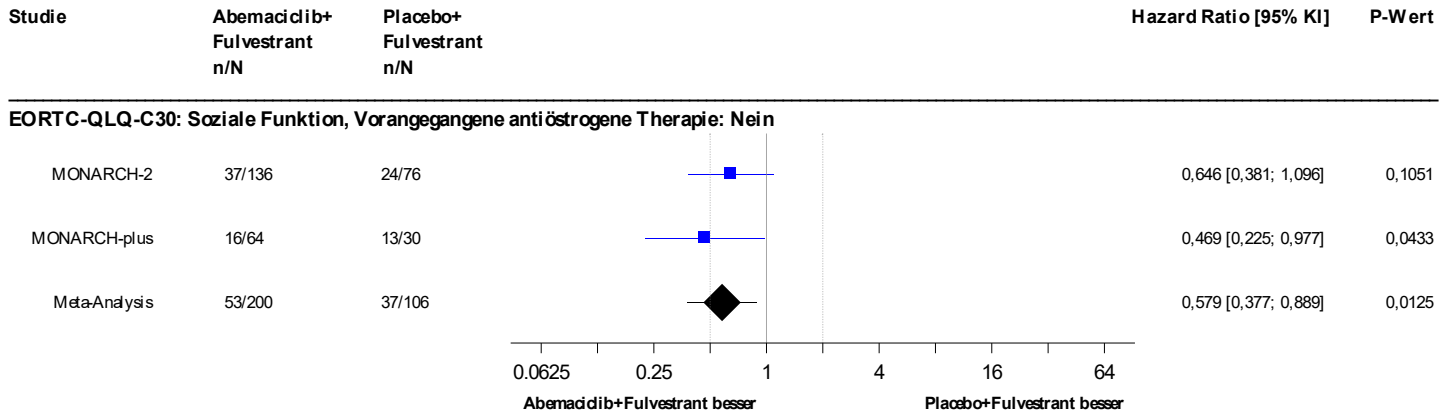
Abbildung 1418.1.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4797, P-Wert=0,4886, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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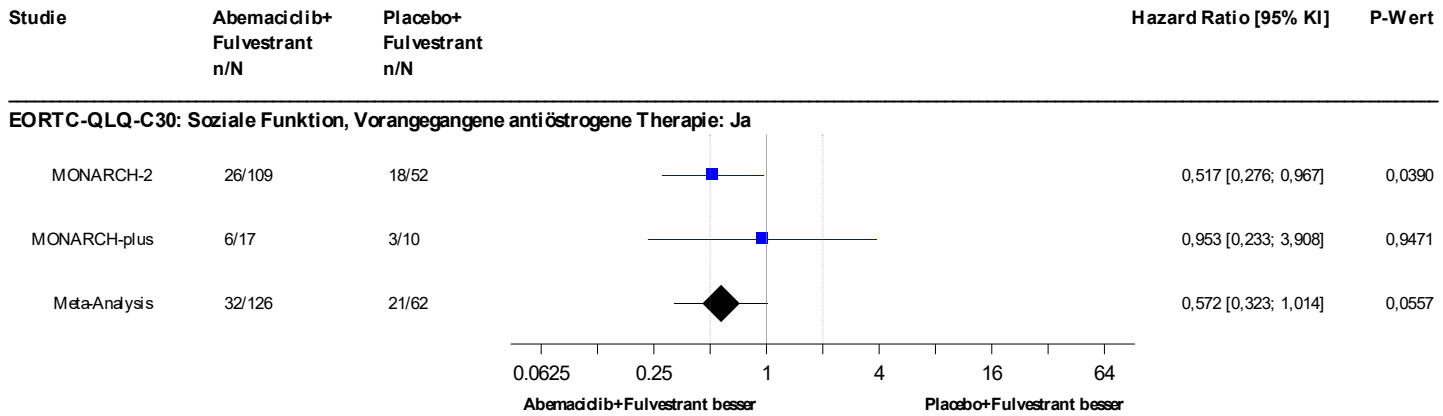
Abbildung 1418.1.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6038, P-Wert=0,4371, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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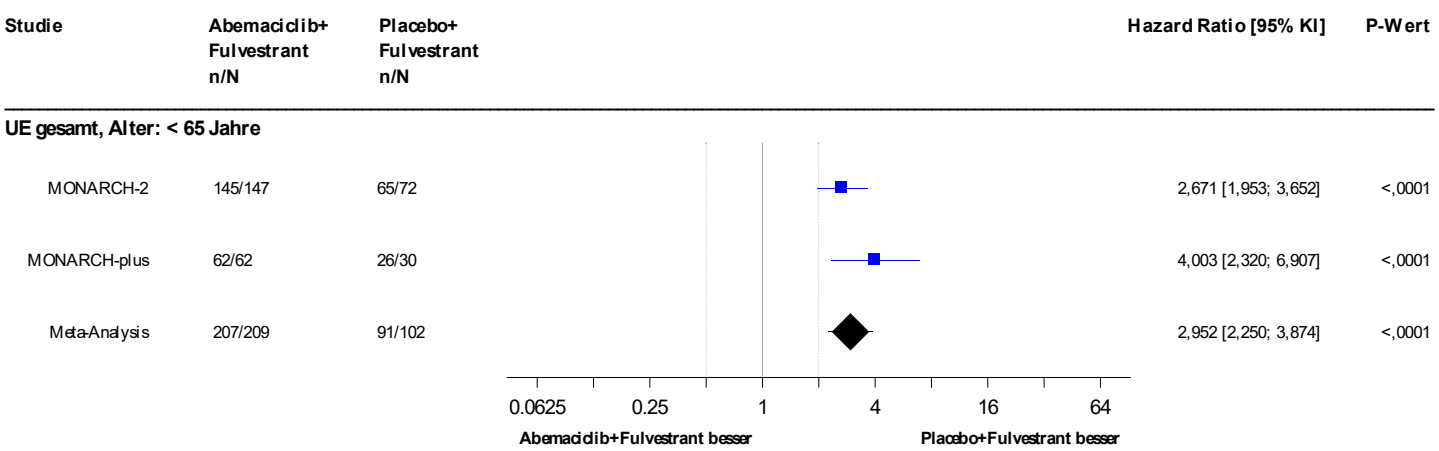
Abbildung 1419.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,5922, P-Wert=0,2070, I2 Index=37,2%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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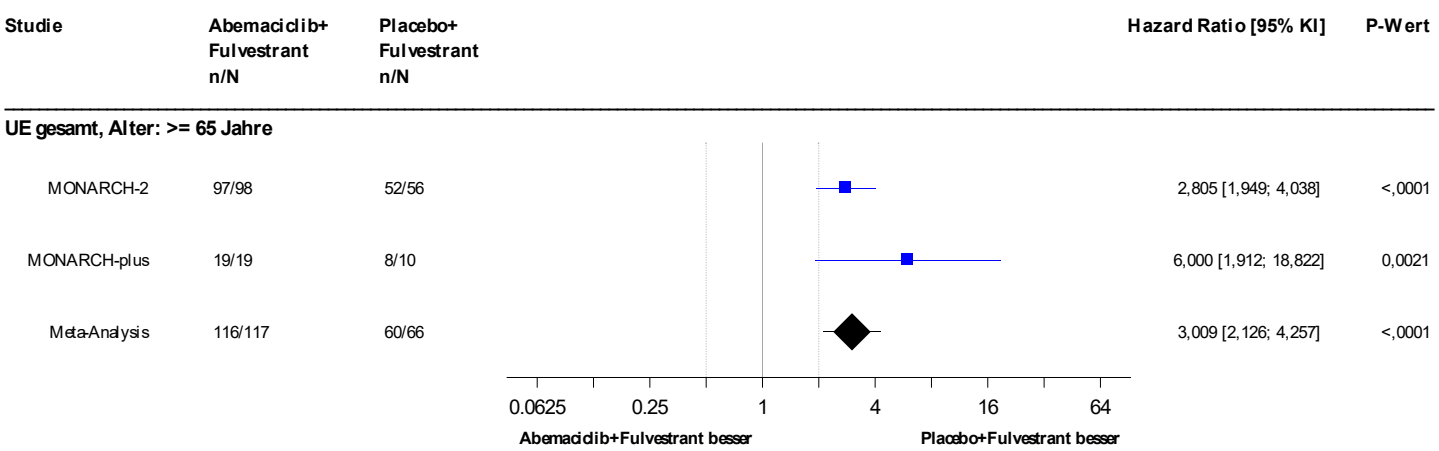
Abbildung 1419.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,5418, P-Wert=0,2143, I2 Index=35,1%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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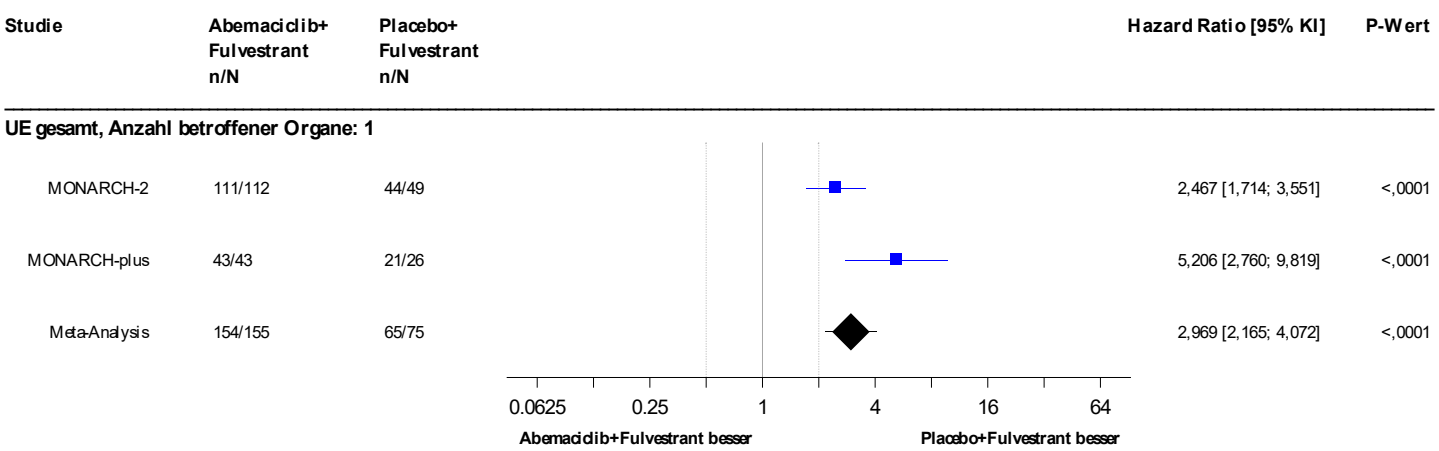
Abbildung 1419.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=4,0000, P-Wert=0,0455, I2 Index=75,0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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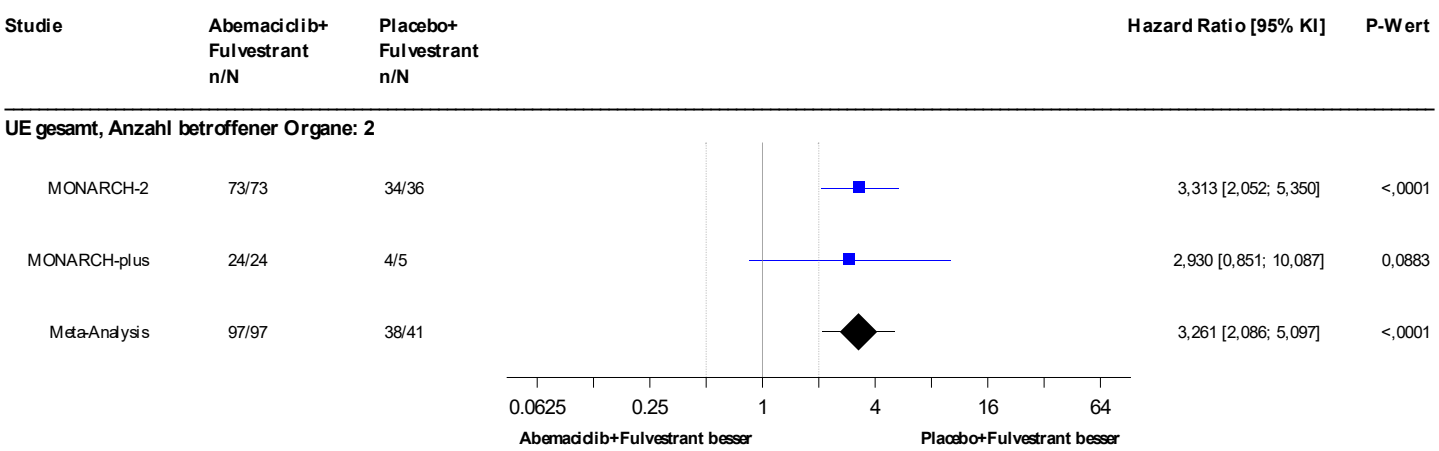
Abbildung 1419.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0330, P-Wert=0,8558, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttteae_popa1_norggr_2.rtf
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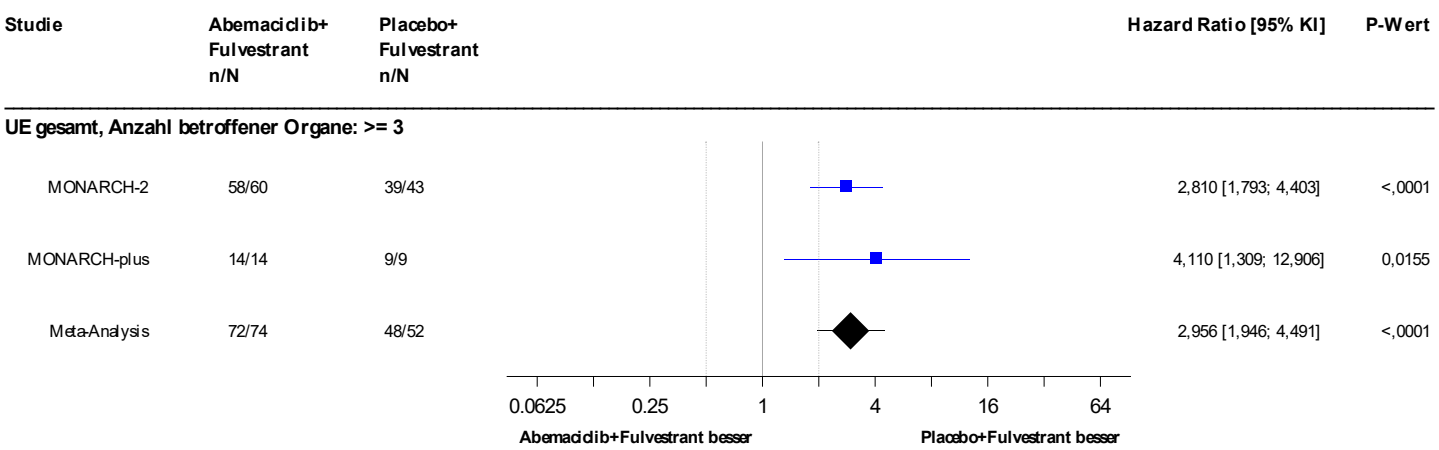
Abbildung 1419.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3679, P-Wert=0,5441, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttteae_popa1_norggr_3.rtf
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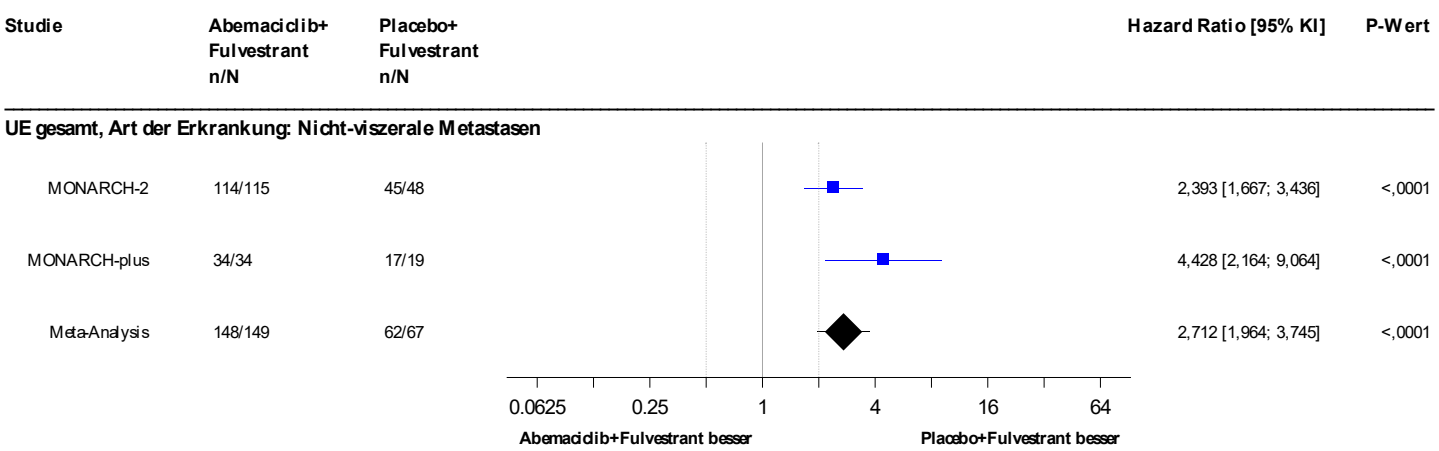
Abbildung 1419.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,2599, P-Wert=0,1328, I2 Index=55,7%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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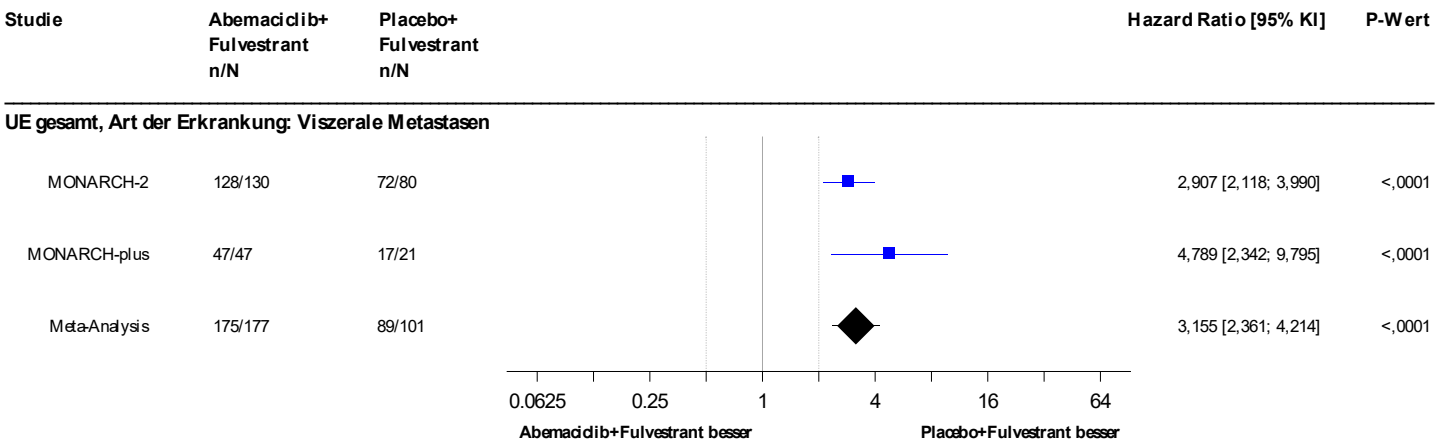
Abbildung 1419.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,5646, P-Wert=0,2110, I2 Index=36,1%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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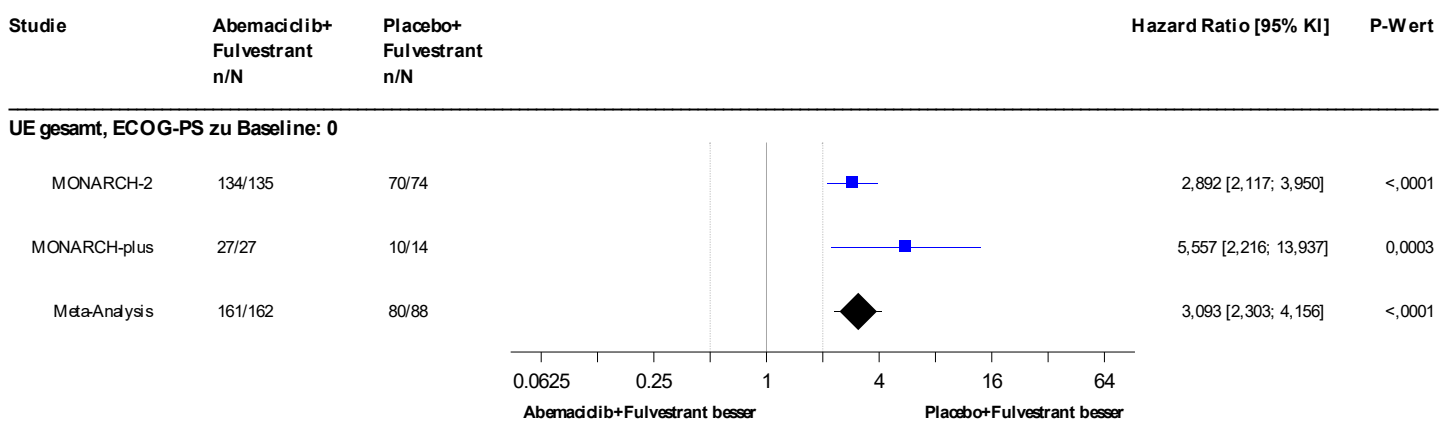
Abbildung 1419.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,7389, P-Wert=0,1873, I2 Index=42,5%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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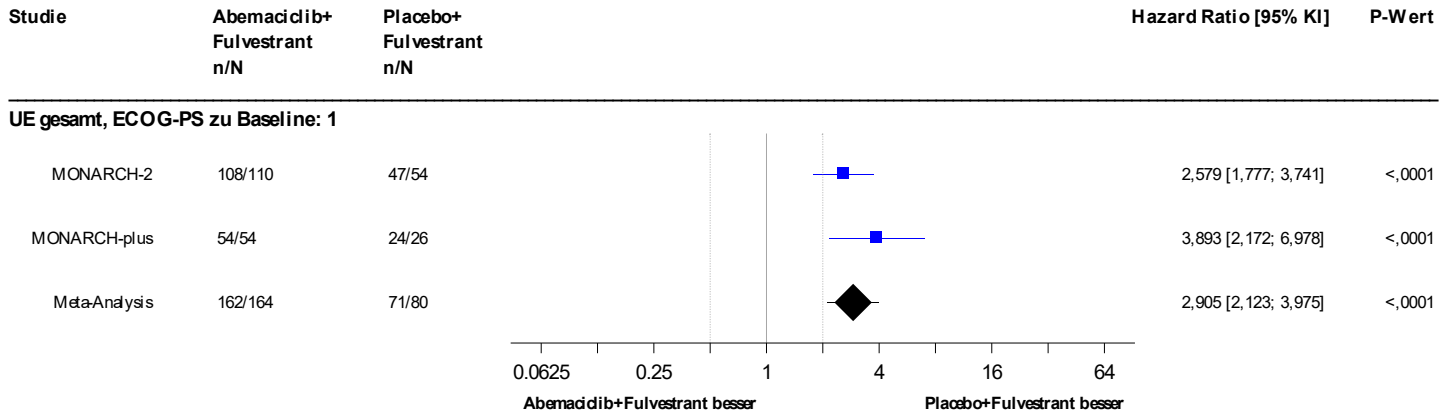
Abbildung 1419.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,3614, P-Wert=0,2433, I2 Index=26,5%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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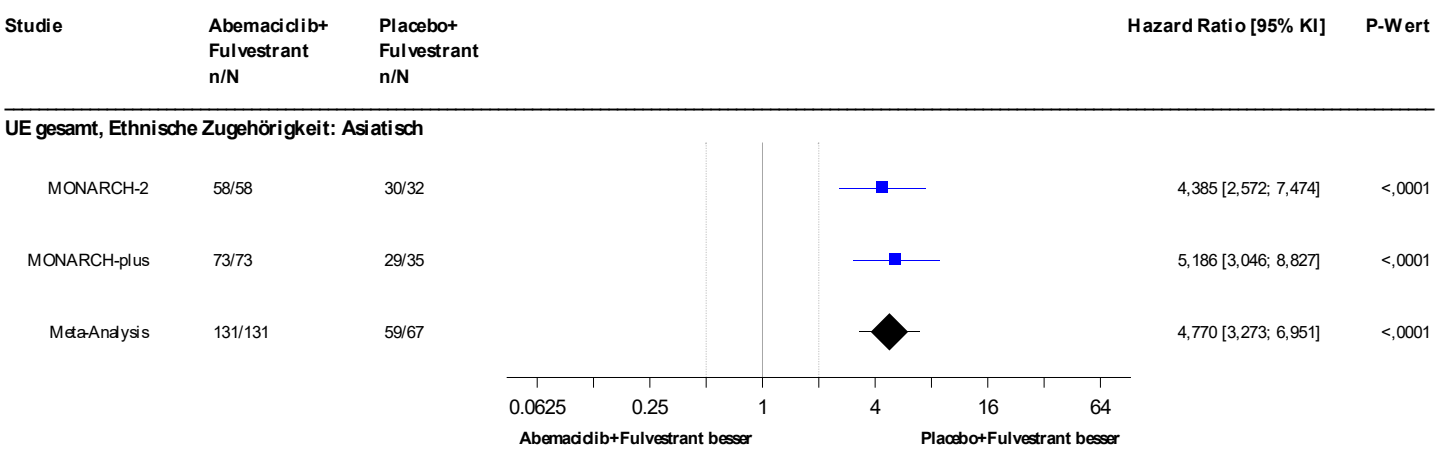
Abbildung 1419.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1905, P-Wert=0,6625, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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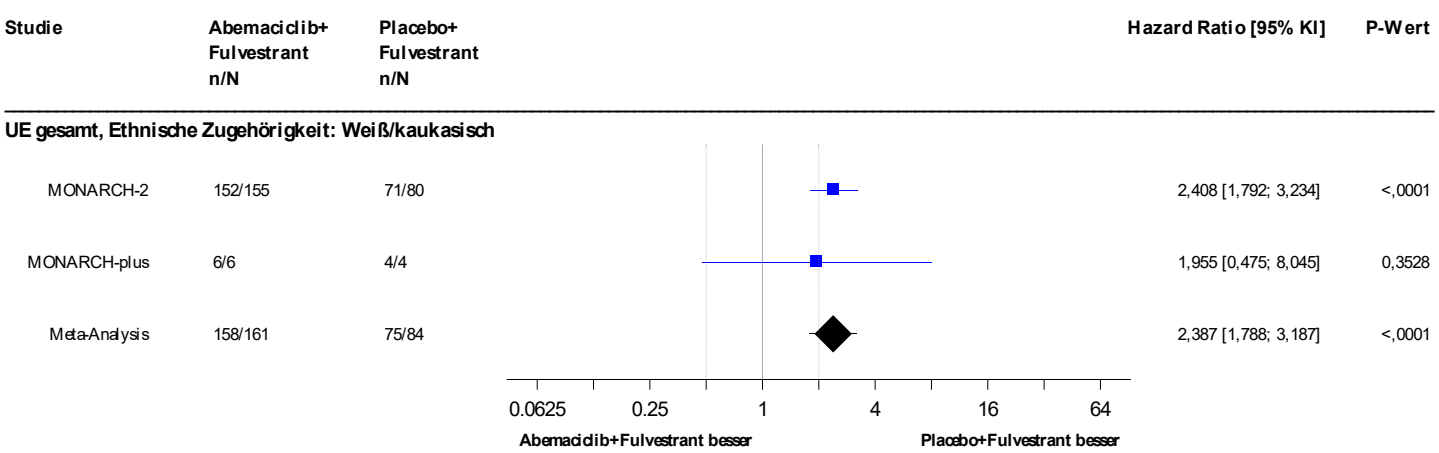
Abbildung 1419.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0797, P-Wert=0,7777, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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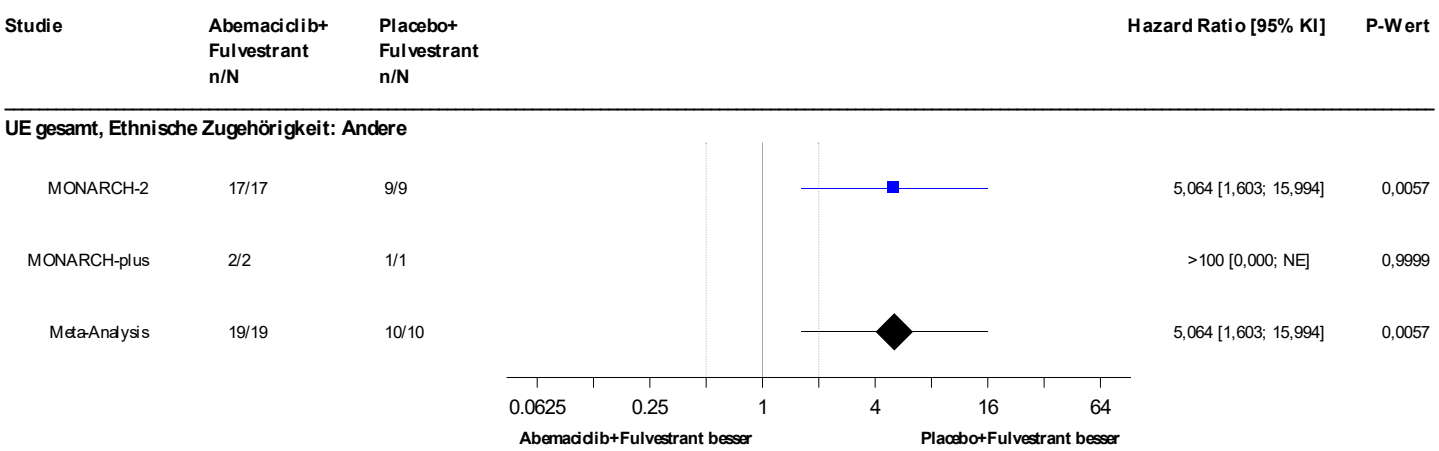
Abbildung 1419.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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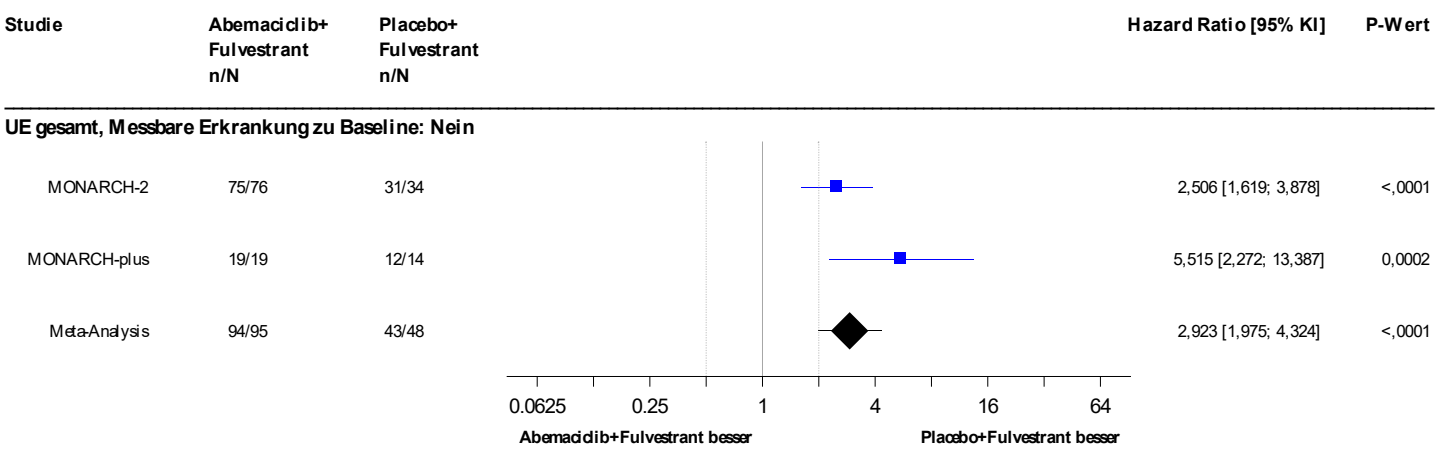
Abbildung 1419.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,4472, P-Wert=0,1177, I2 Index=59,1%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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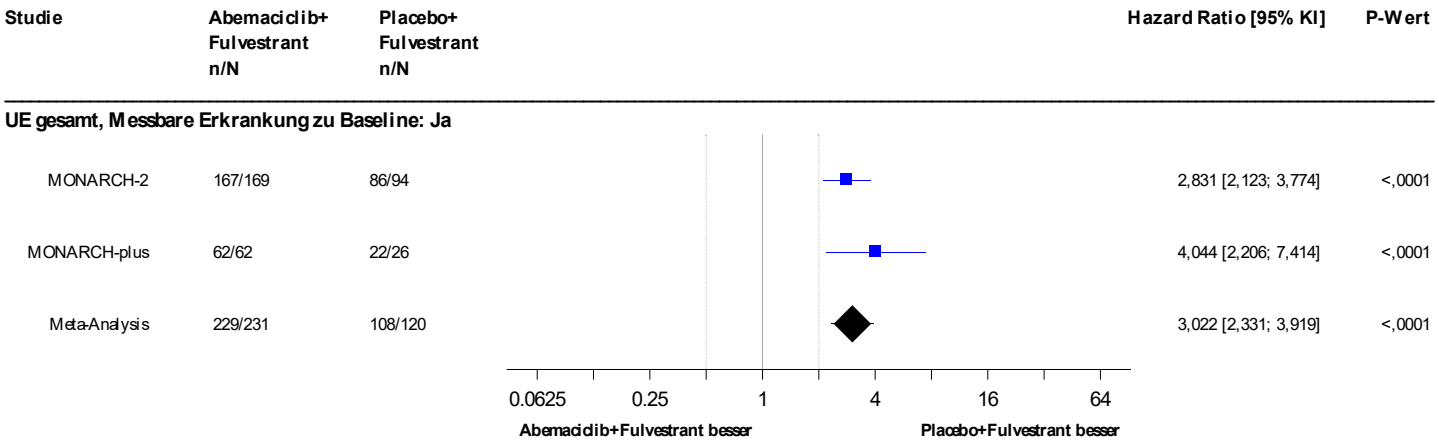
Abbildung 1419.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,0856, P-Wert=0,2975, I2 Index=7,9%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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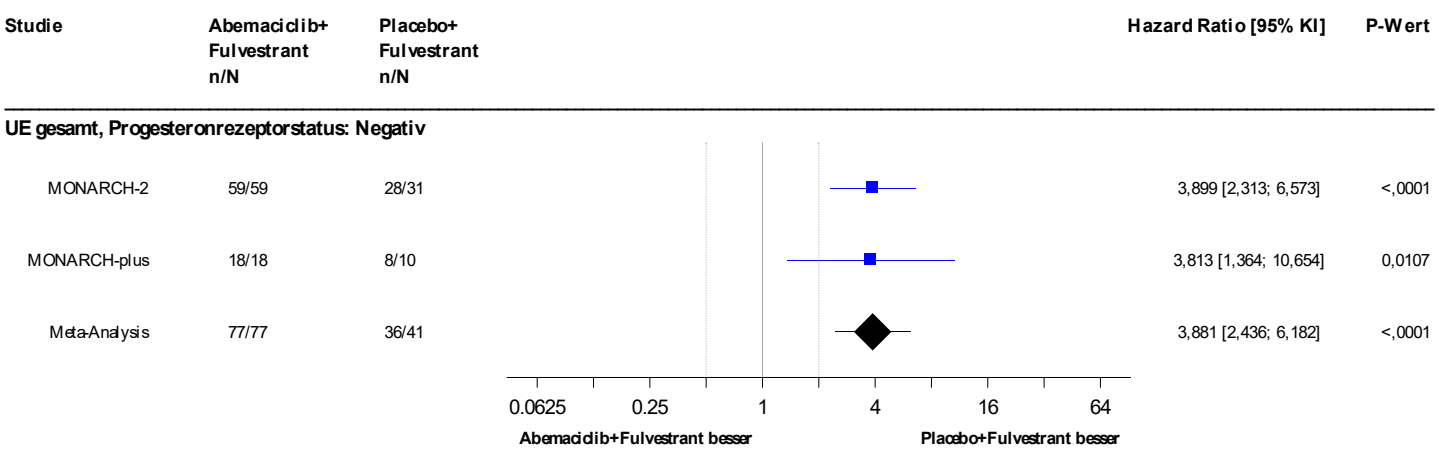
Abbildung 1419.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0014, P-Wert=0,9696, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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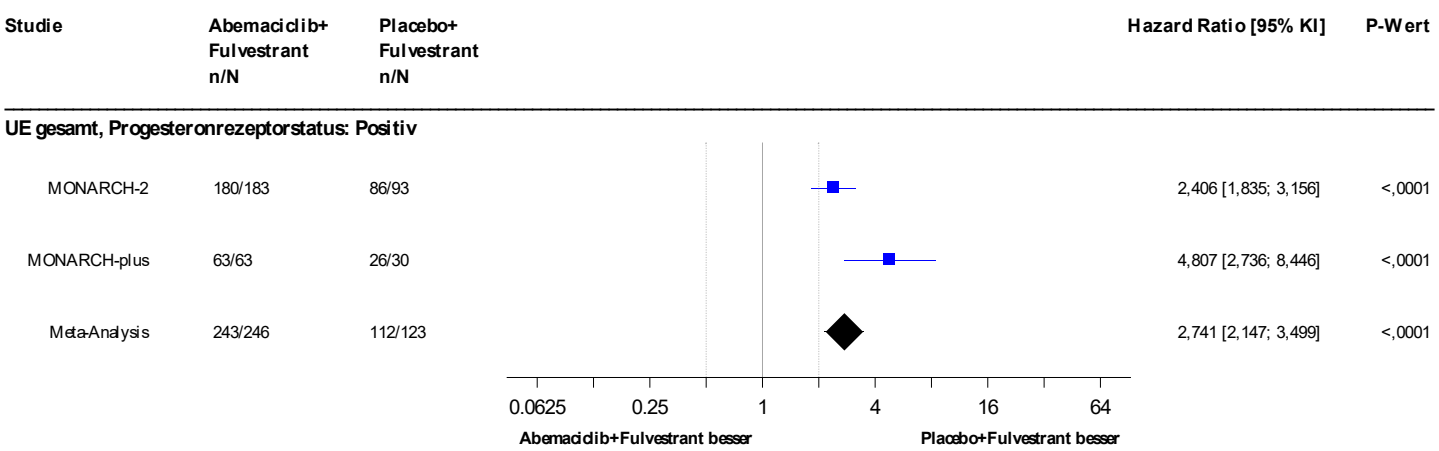
Abbildung 1419.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=4,7049, P-Wert=0,0301, I2 Index=78,7%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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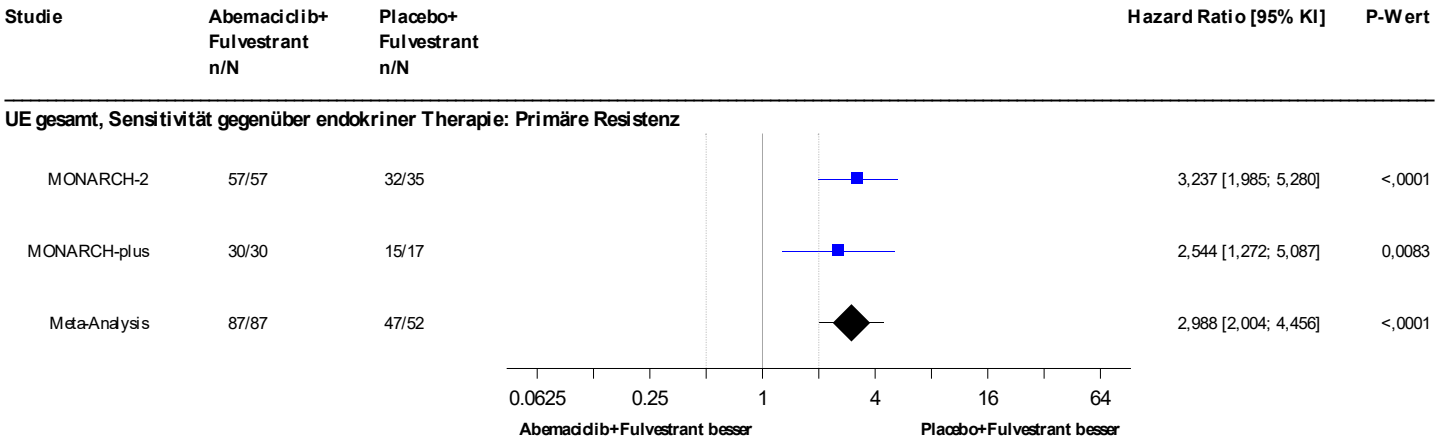
Abbildung 1419.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3101, P-Wert=0,5776, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttteae_popa1_snthr_1.rtf
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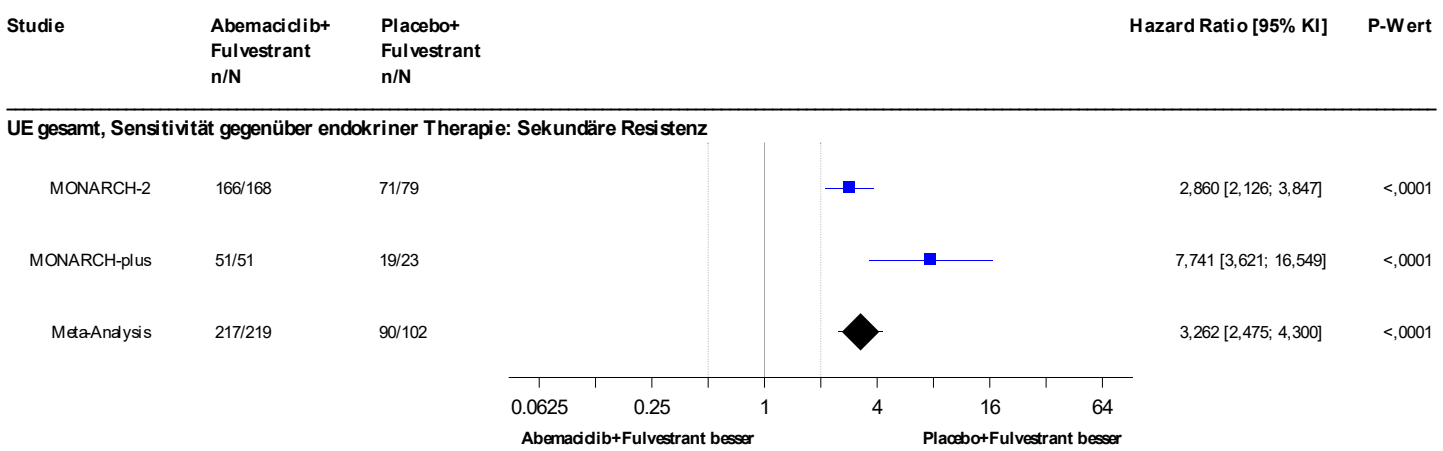
Abbildung 1419.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=5,7271, P-Wert=0,0167, I2 Index=82,5%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttteae_popa1_snthr_2.rtf
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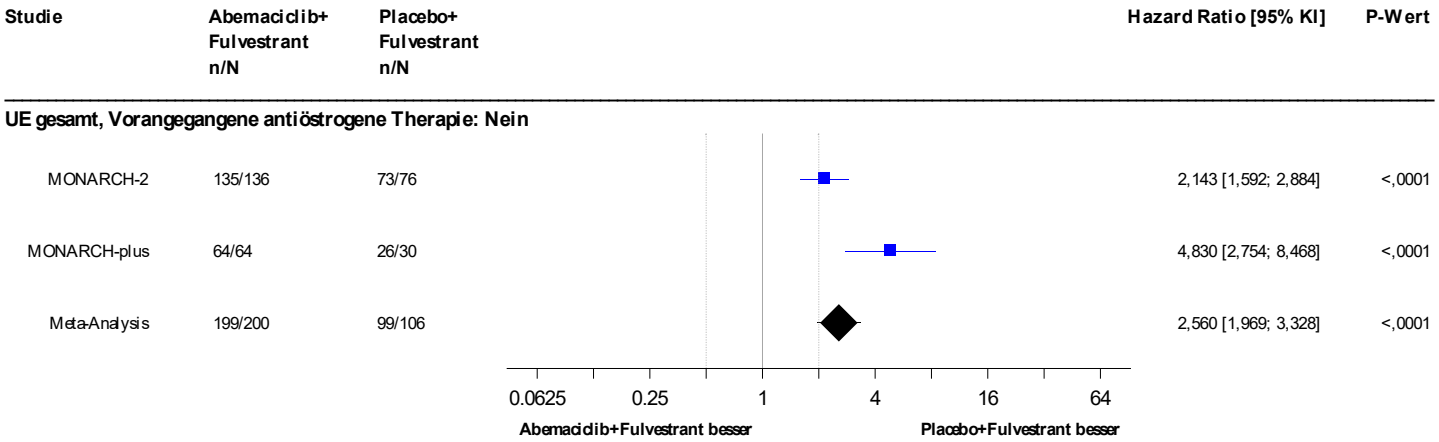
Abbildung 1419.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=6,2846, P-Wert=0,0122, I2 Index=84,1%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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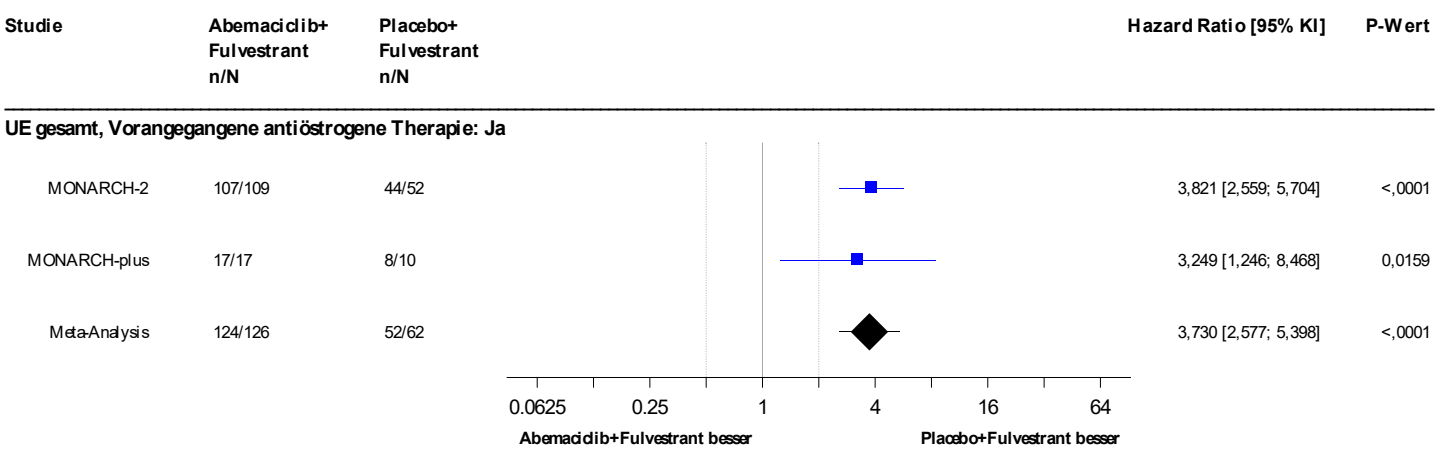
Abbildung 1419.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0937, P-Wert=0,7595, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttteae_popa1_paet_2.rtf
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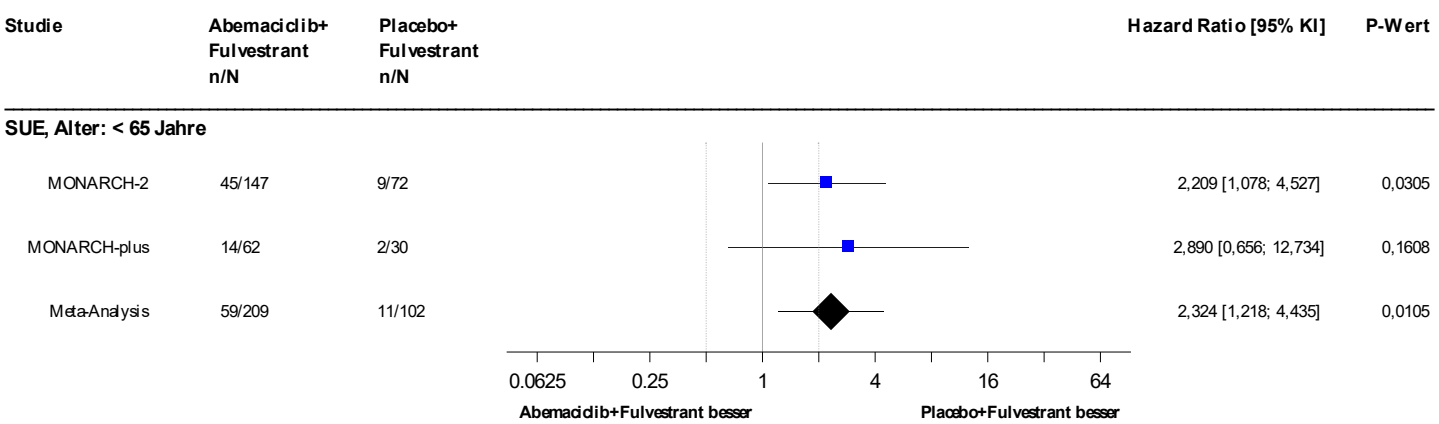
Abbildung 1420.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1023, P-Wert=0,7491, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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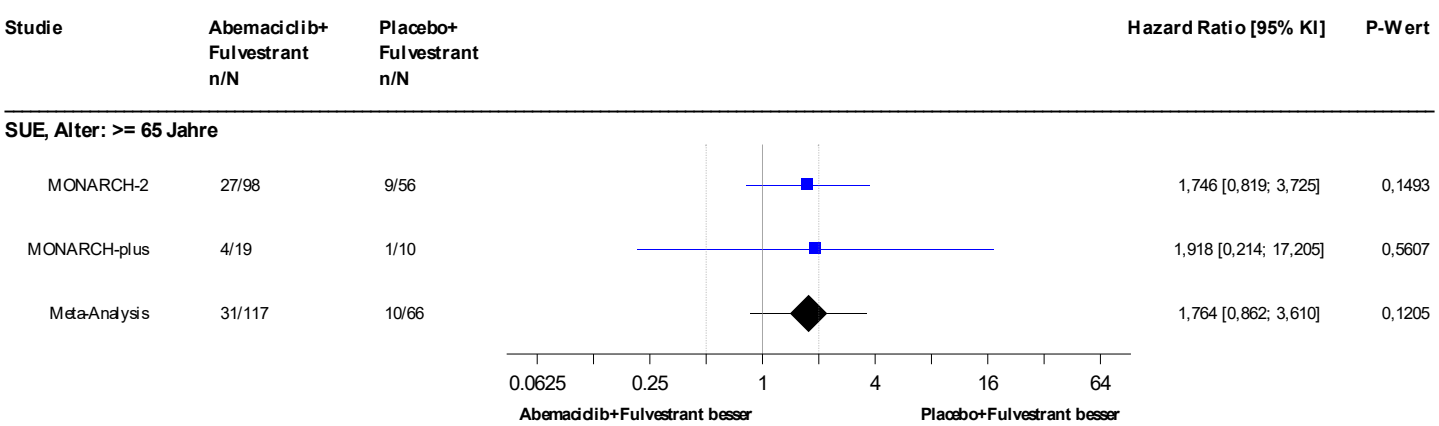
Abbildung 1420.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0063, P-Wert=0,9368, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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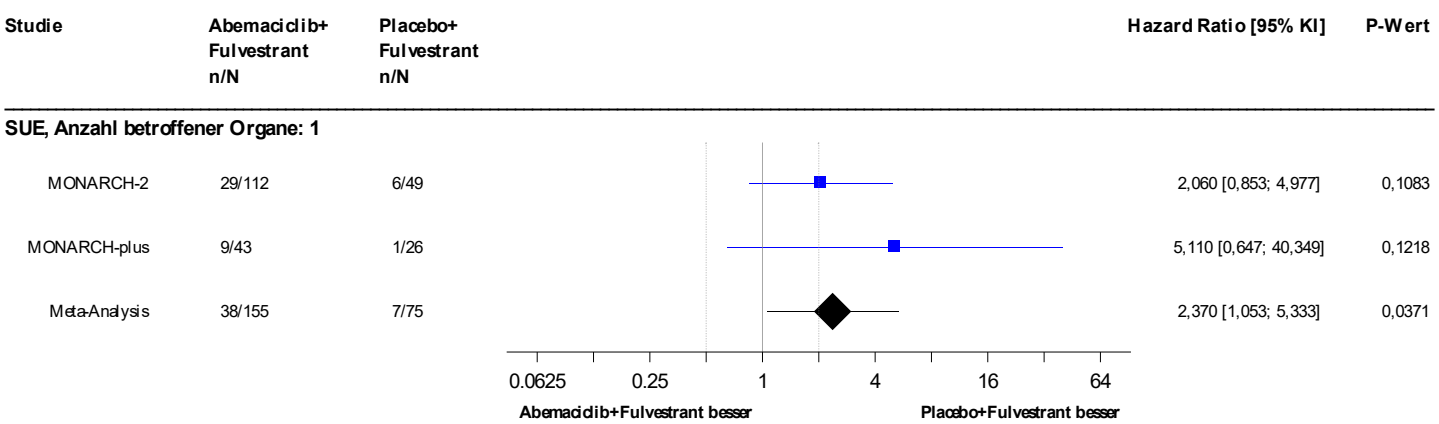
Abbildung 1420.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6281, P-Wert=0,4281, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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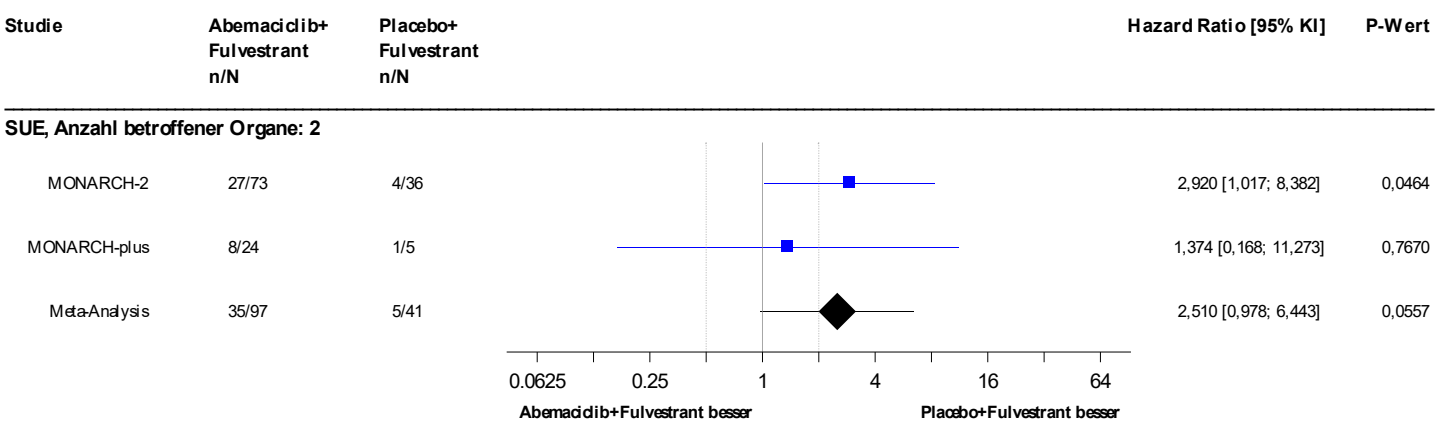
Abbildung 1420.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3936, P-Wert=0,5304, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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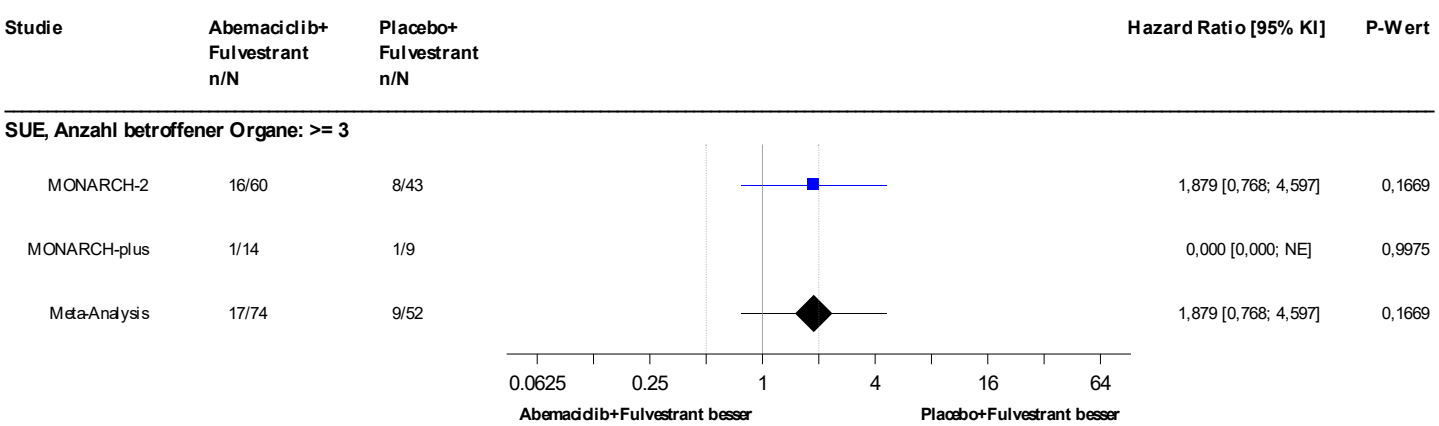
Abbildung 1420.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9974, I2 Index=0%
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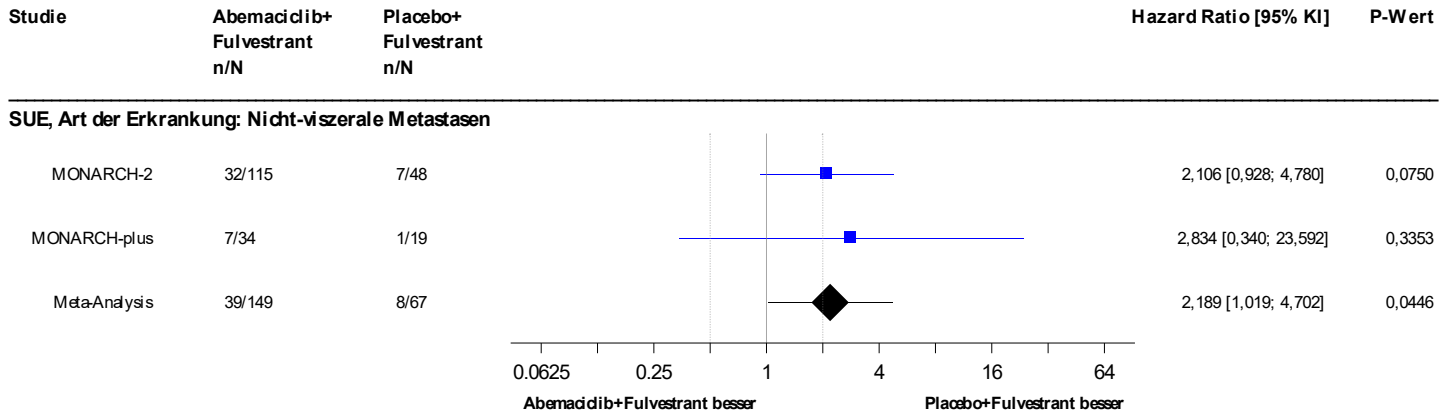
Abbildung 1420.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0657, P-Wert=0,7978, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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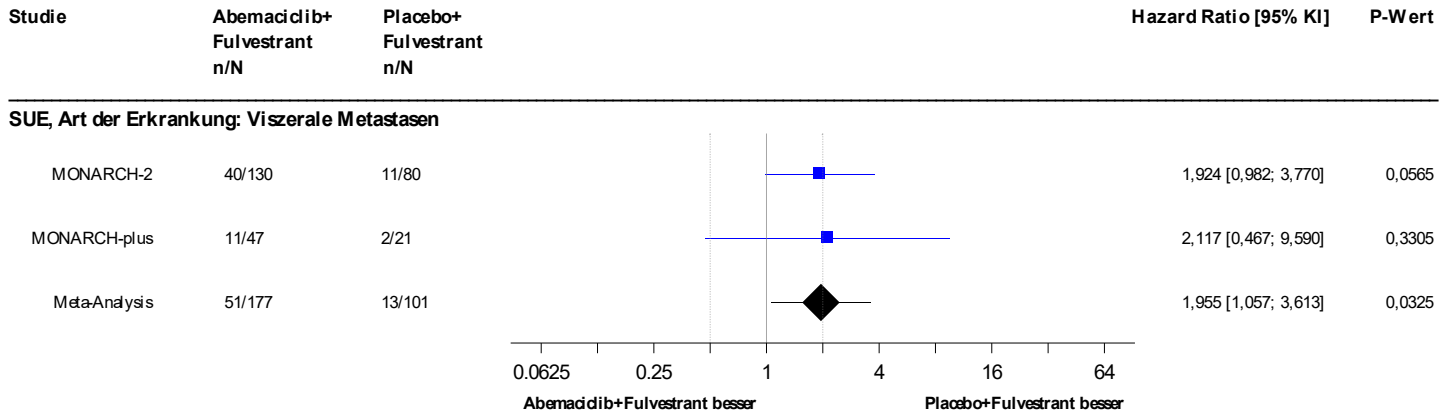
Abbildung 1420.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0128, P-Wert=0,9098, I2 Index=0%
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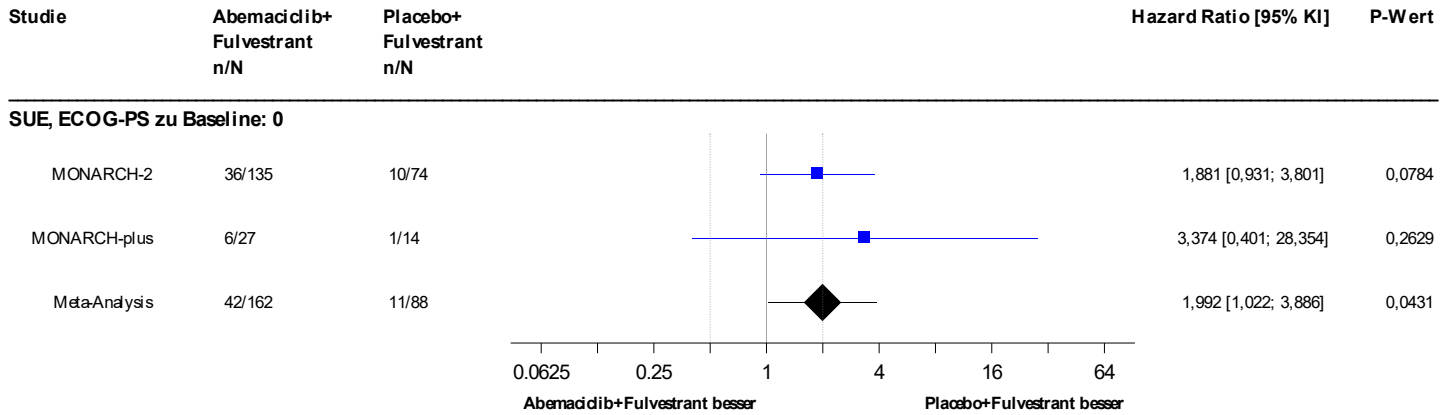
Abbildung 1420.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2609, P-Wert=0,6095, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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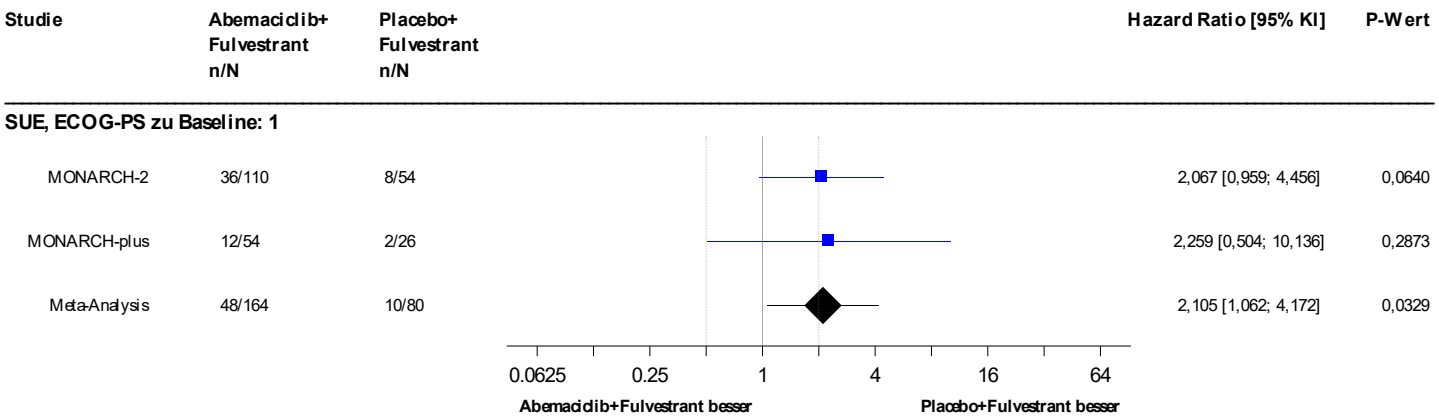
Abbildung 1420.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0107, P-Wert=0,9176, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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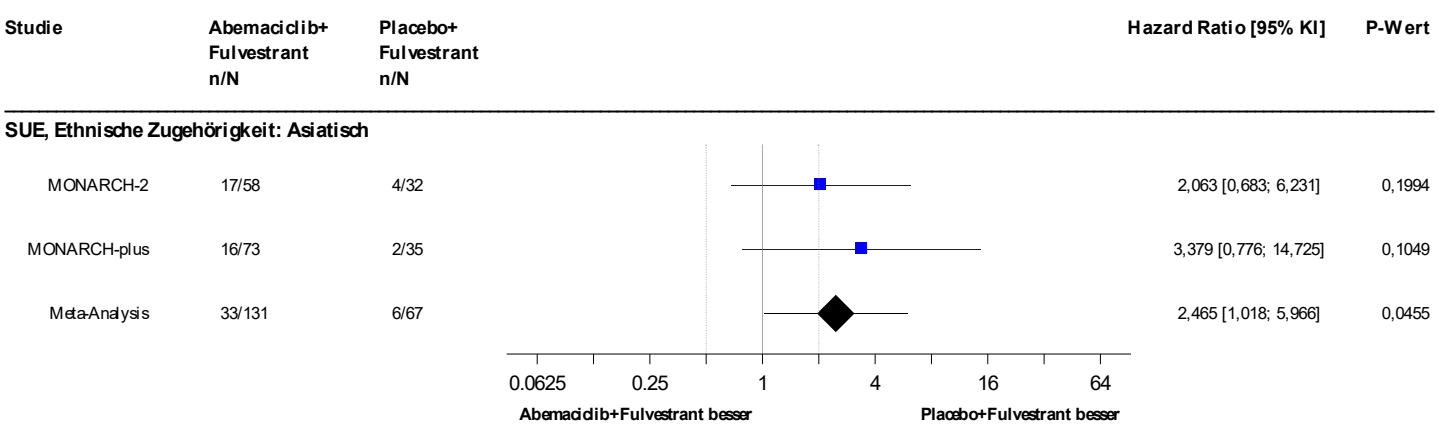
Abbildung 1420.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2764, P-Wert=0,5991, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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Abbildung 1420.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

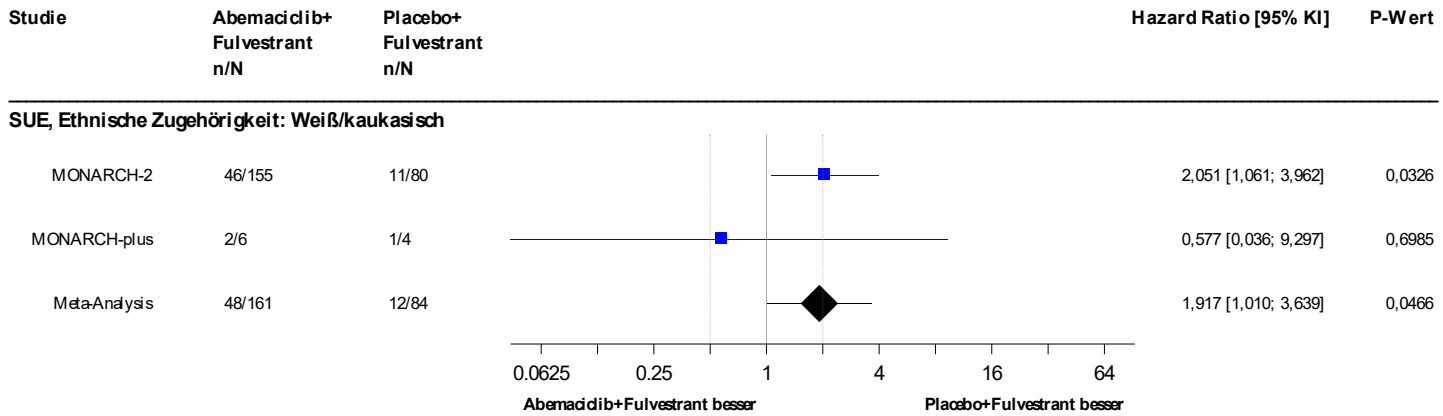

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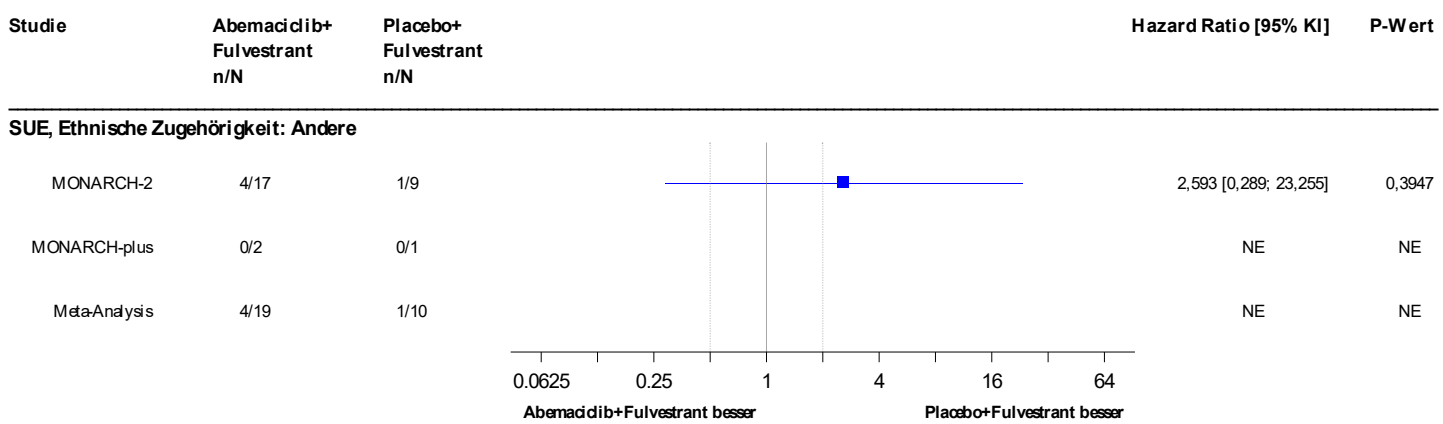
Abbildung 1420.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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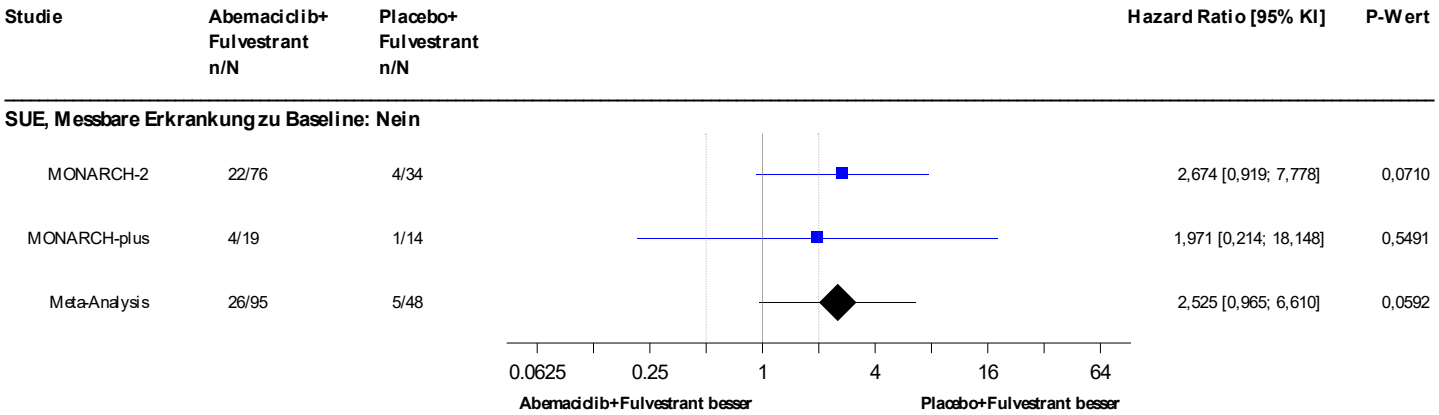
Abbildung 1420.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0589, P-Wert=0,8082, I2 Index=0%
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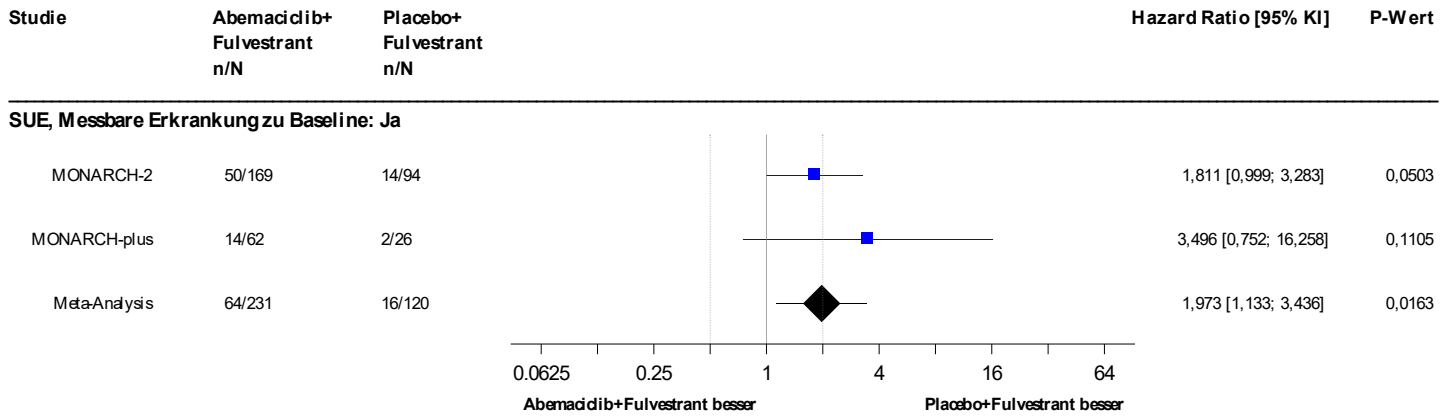
17SEP2021 / 07:48

Abbildung 1420.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6112, P-Wert=0,4344, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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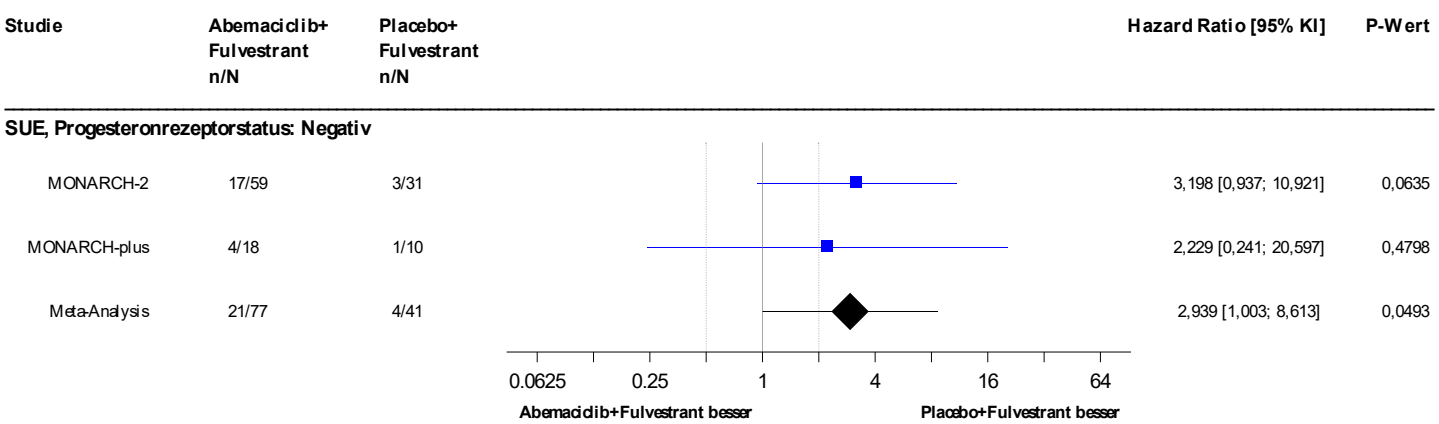
17SEP2021 / 07:48

Abbildung 1420.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0776, P-Wert=0,7806, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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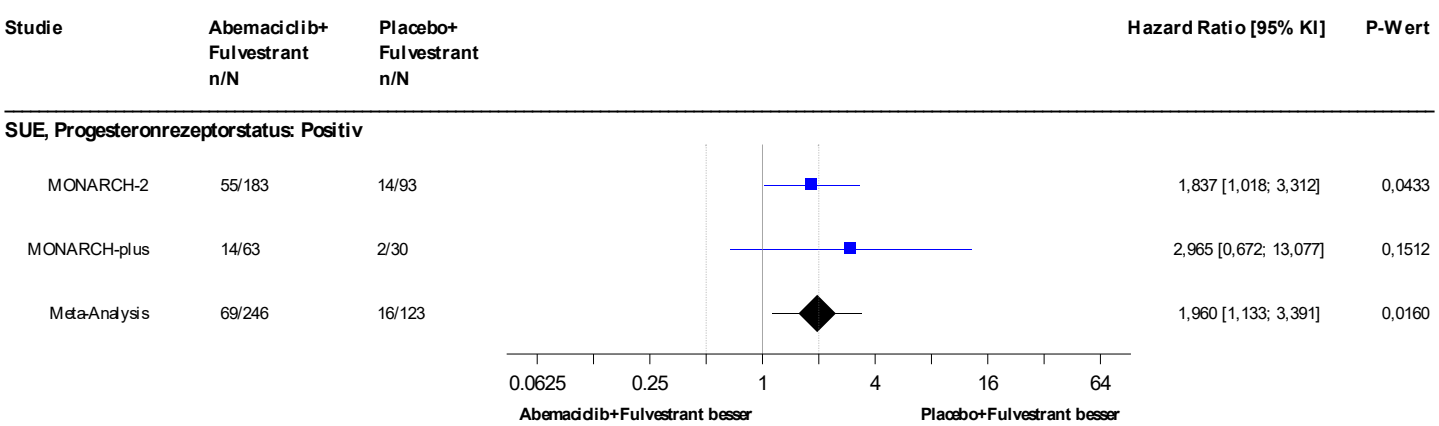
17SEP2021 / 07:48

Abbildung 1420.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3455, P-Wert=0,5567, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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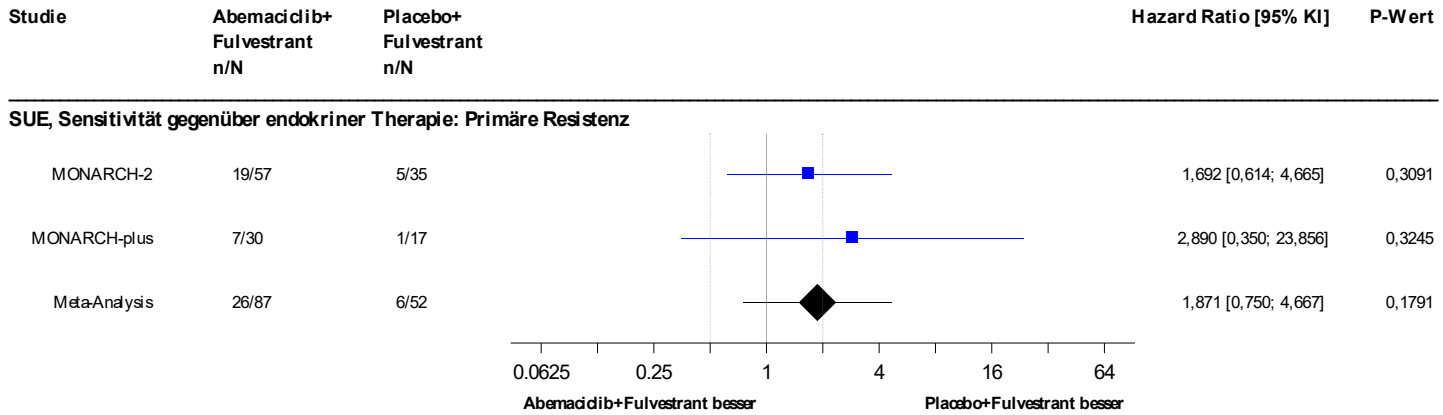
Abbildung 1420.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2004, P-Wert=0,6544, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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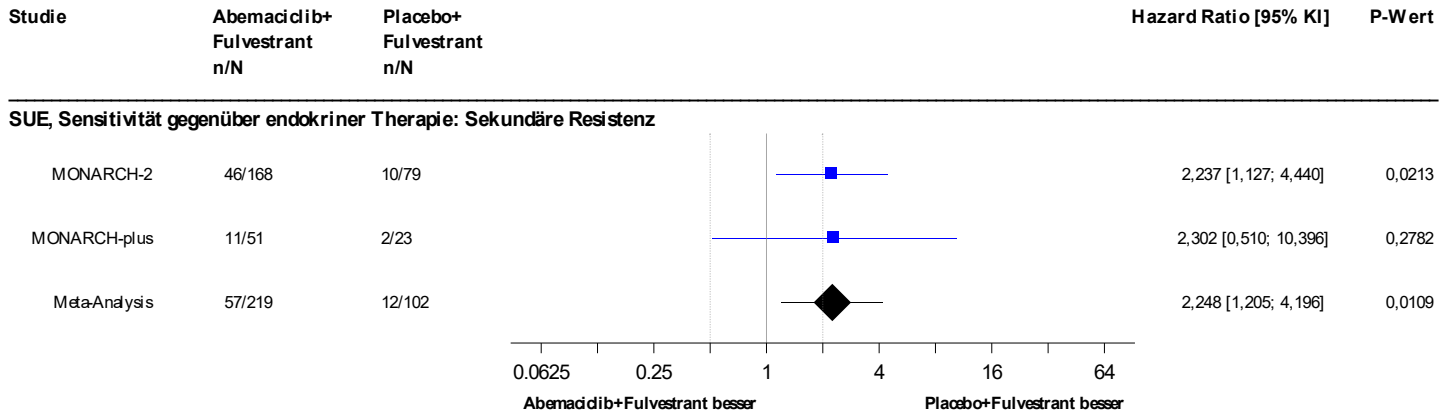
Abbildung 1420.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0012, P-Wert=0,9729, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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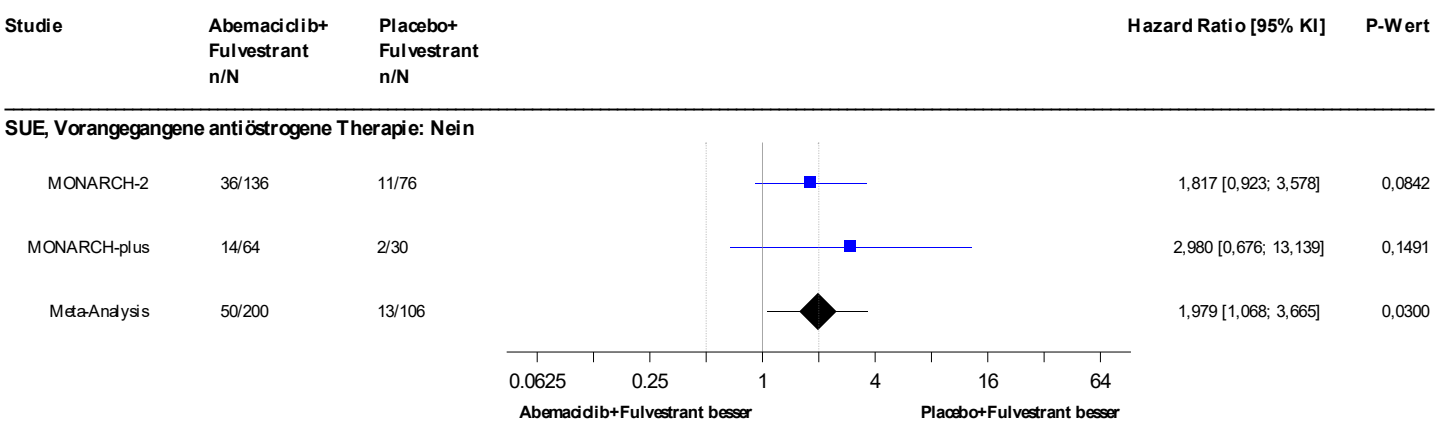
Abbildung 1420.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3538, P-Wert=0,5520, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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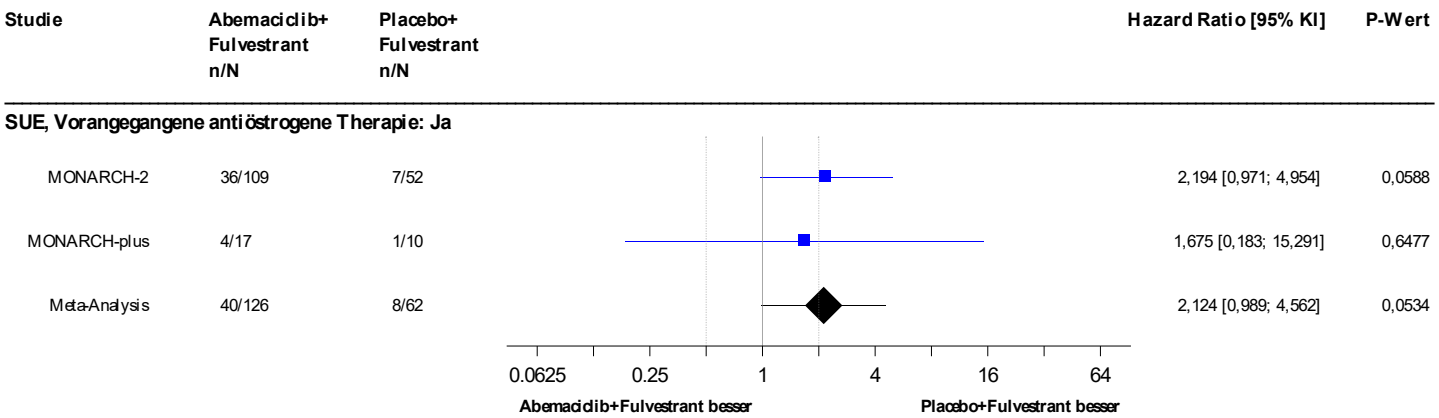
Abbildung 1420.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0504, P-Wert=0,8224, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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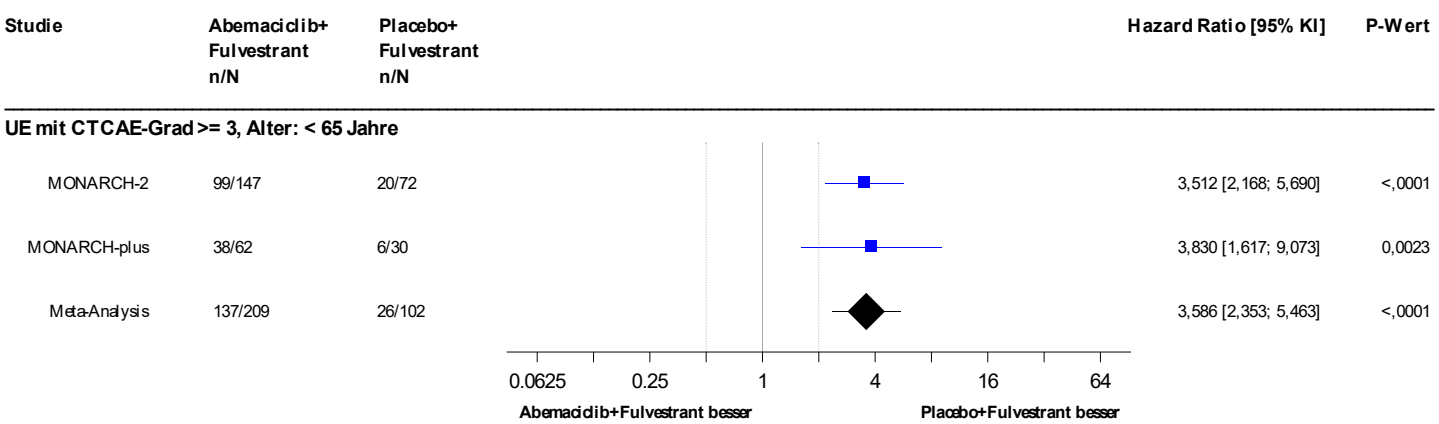
Abbildung 1421.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0296, P-Wert=0,8635, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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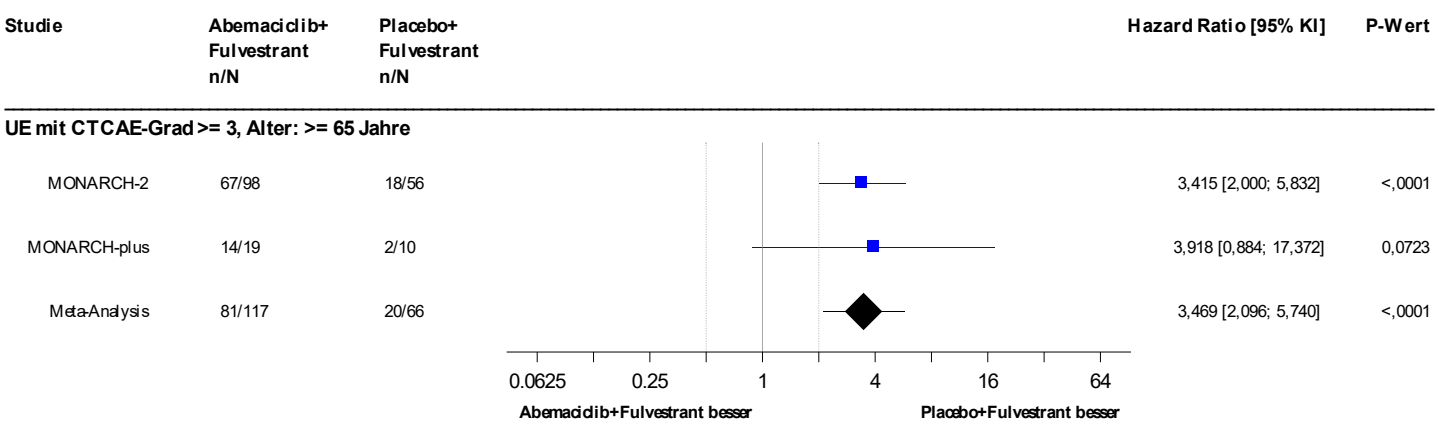
Abbildung 1421.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0290, P-Wert=0,8647, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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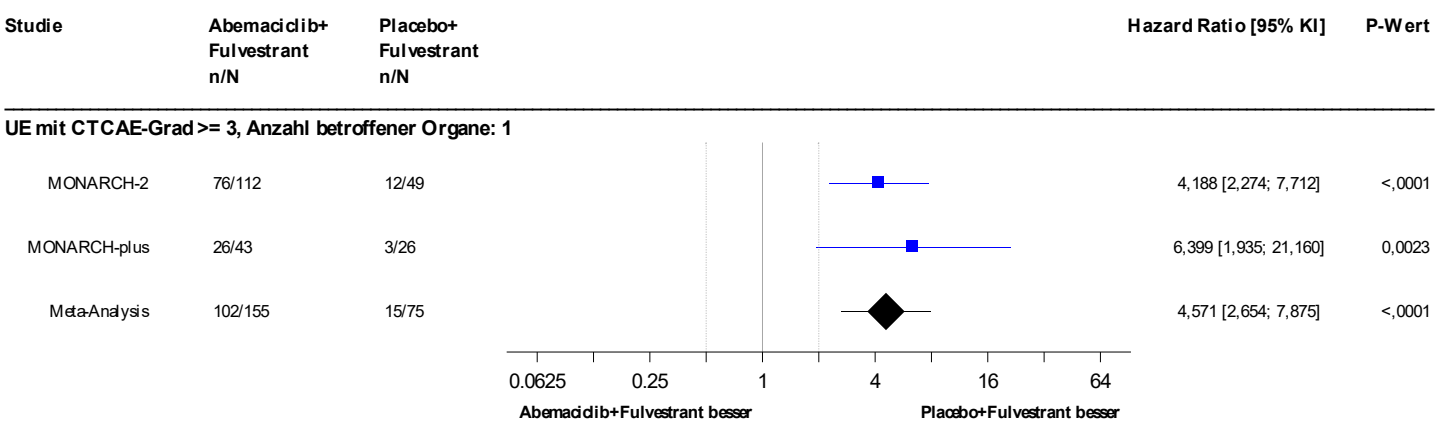
Abbildung 1421.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3831, P-Wert=0,5360, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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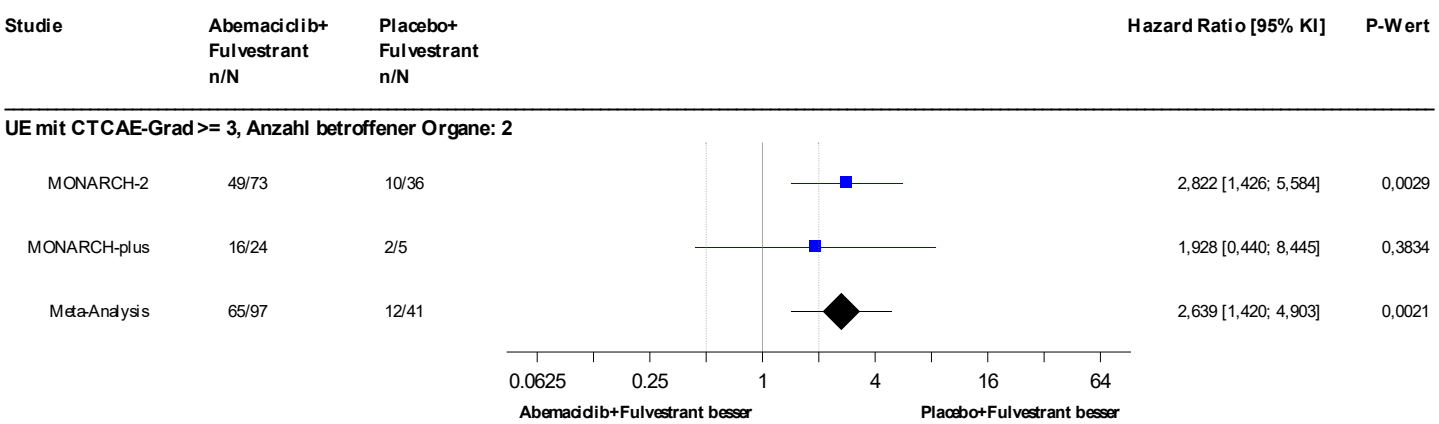
17SEP2021 / 07:48

Abbildung 1421.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2103, P-Wert=0,6465, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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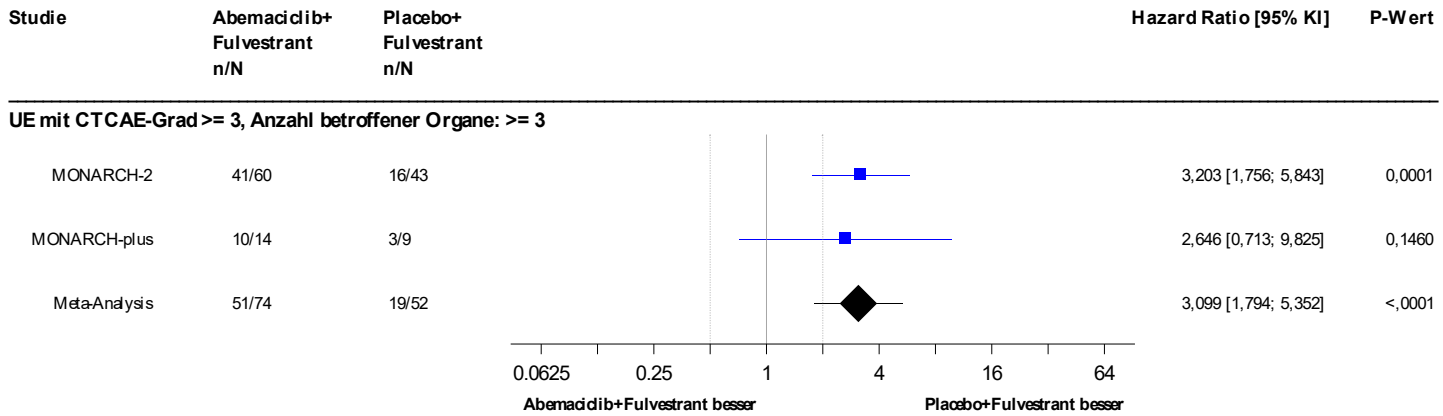
Abbildung 1421.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0674, P-Wert=0,7951, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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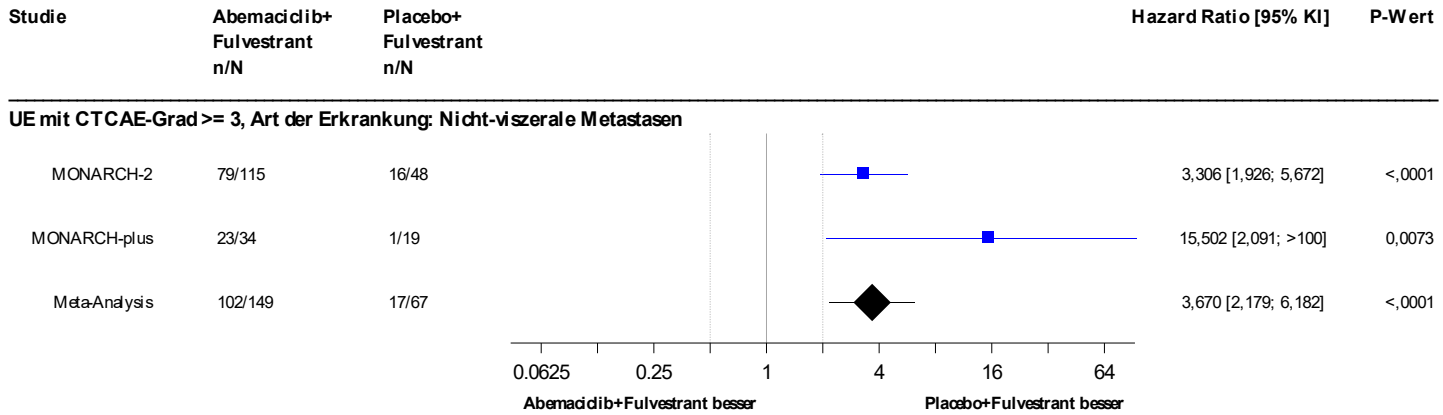
Abbildung 1421.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,1309, P-Wert=0,1444, I2 Index=53,1%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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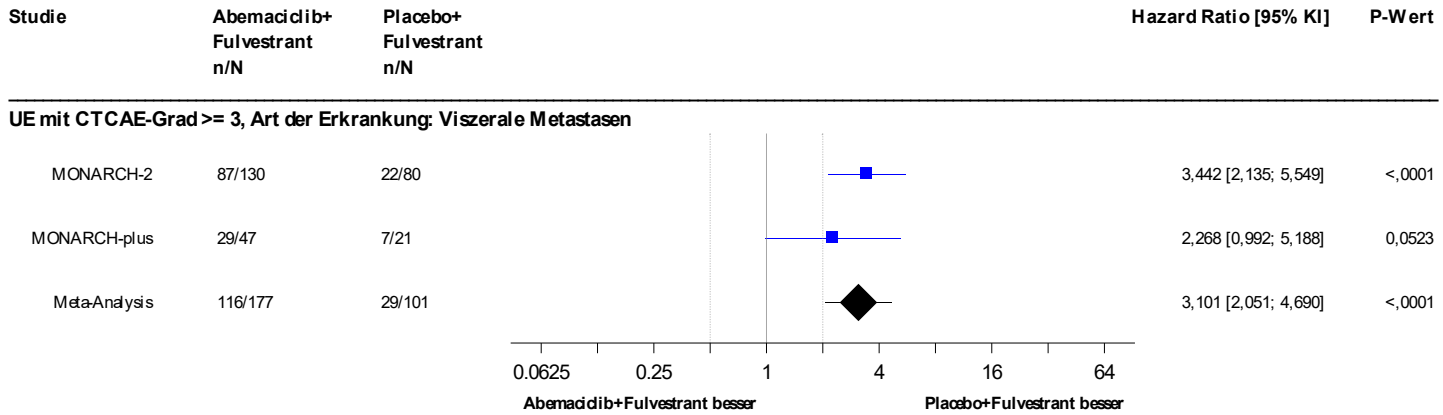
Abbildung 1421.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7319, P-Wert=0,3923, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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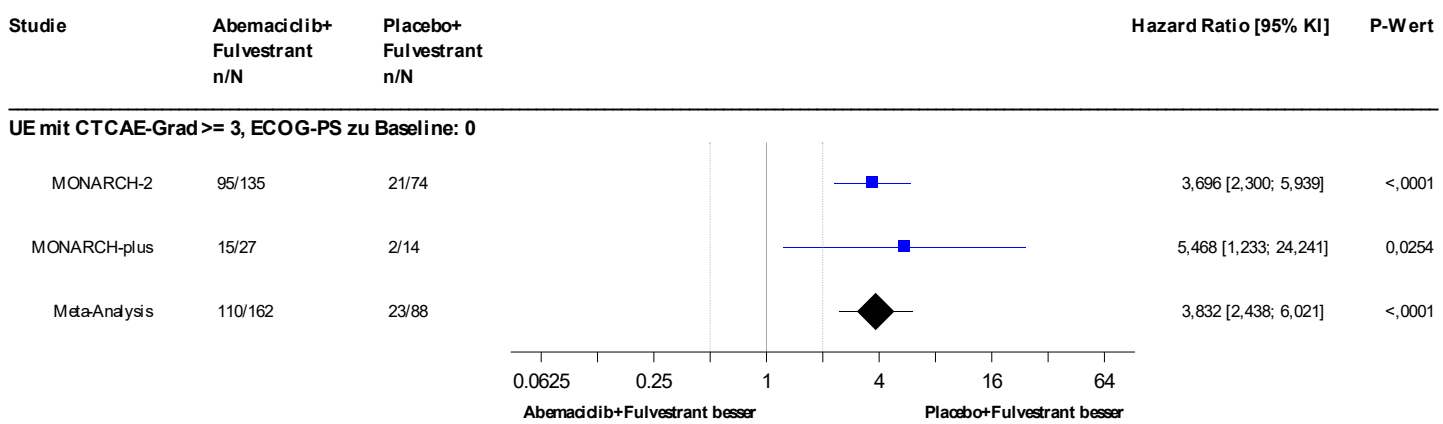
17SEP2021 / 07:48

Abbildung 1421.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2412, P-Wert=0,6234, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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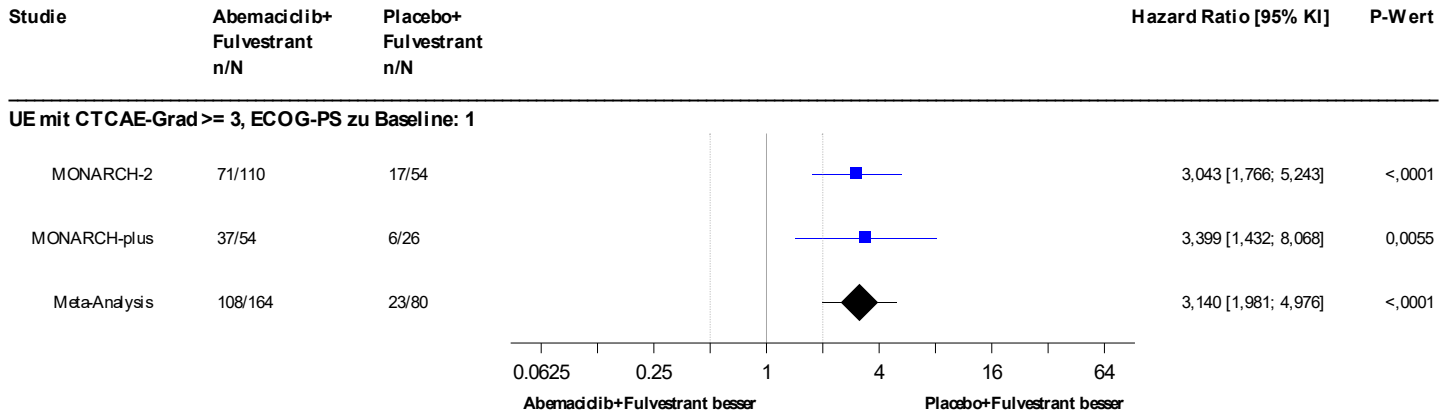
17SEP2021 / 07:48

Abbildung 1421.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0451, P-Wert=0,8318, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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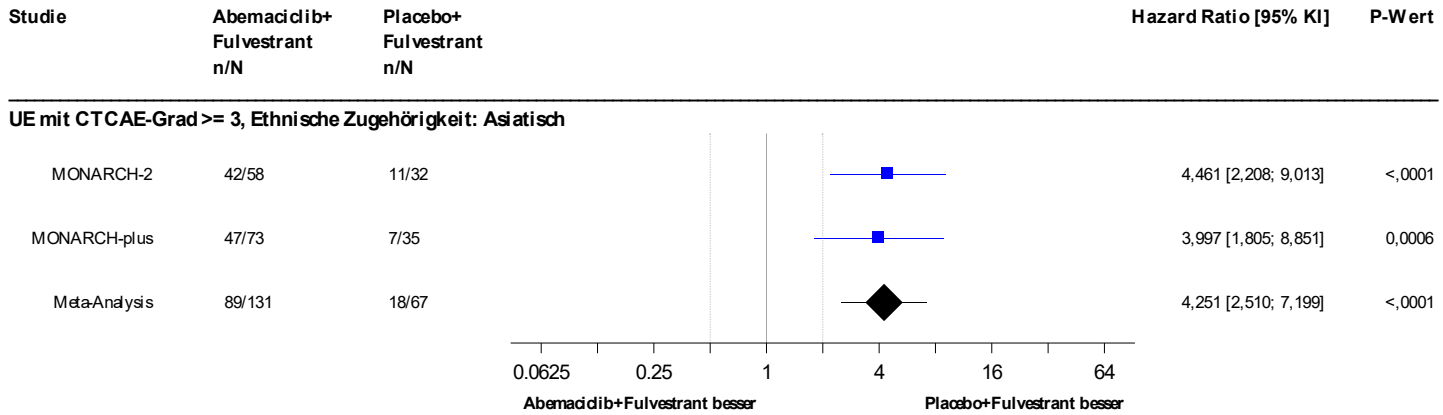
Abbildung 1421.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0411, P-Wert=0,8394, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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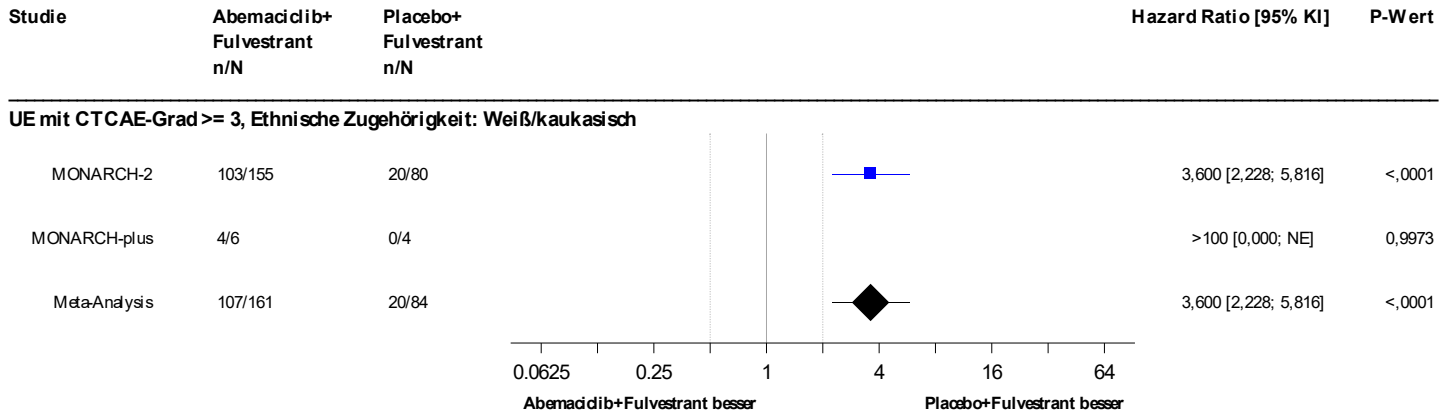
17SEP2021 / 07:48

Abbildung 1421.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9974, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttgr3_popa1_racegr1_2.rtf
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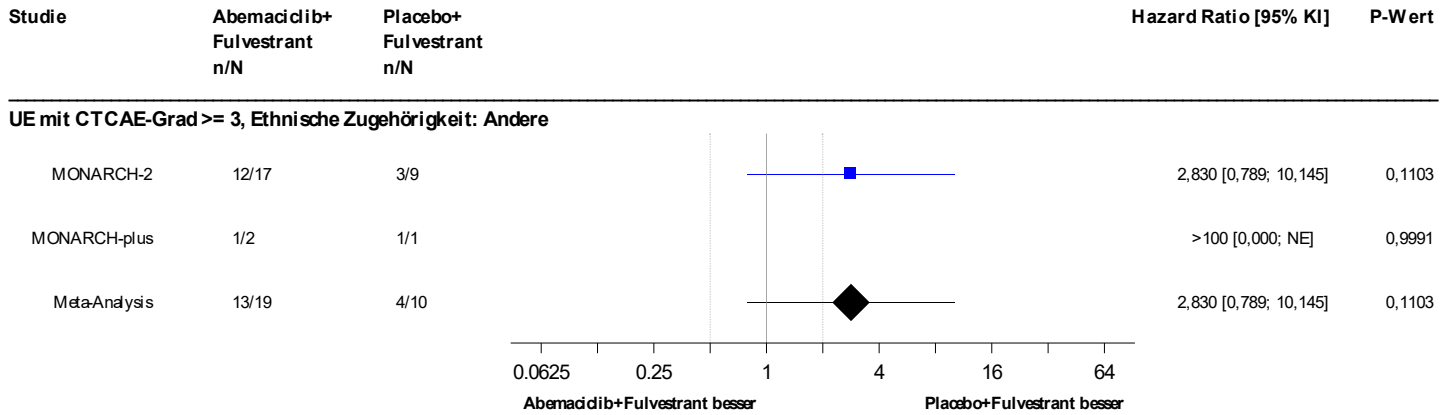
17SEP2021 / 07:48

Abbildung 1421.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9991, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttgr3_popa1_racegr1_3.rtf
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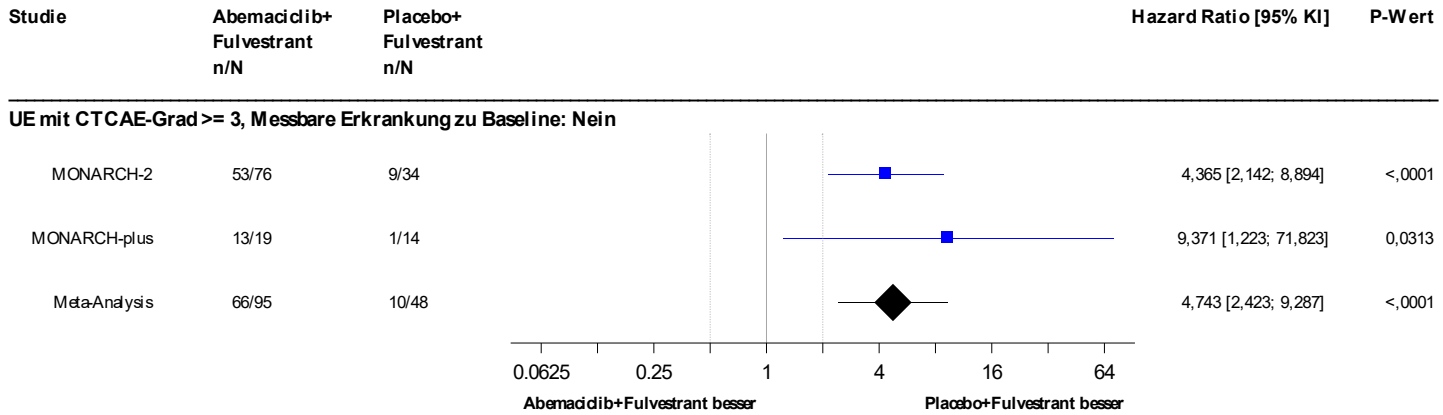
Abbildung 1421.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4818, P-Wert=0,4876, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttgr3_popa1_measdis_1.rtf
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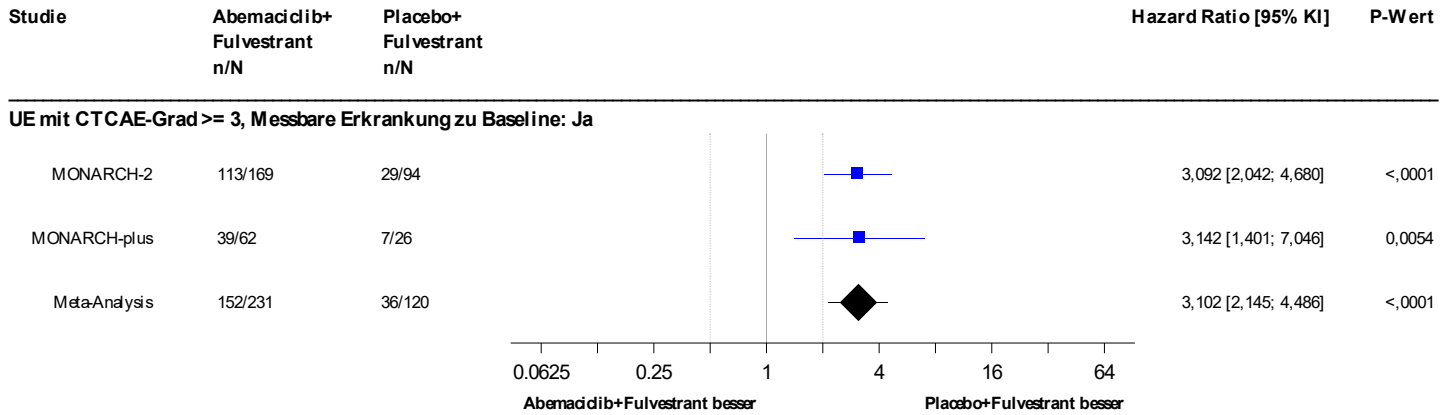
17SEP2021 / 07:48

Abbildung 1421.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0012, P-Wert=0,9719, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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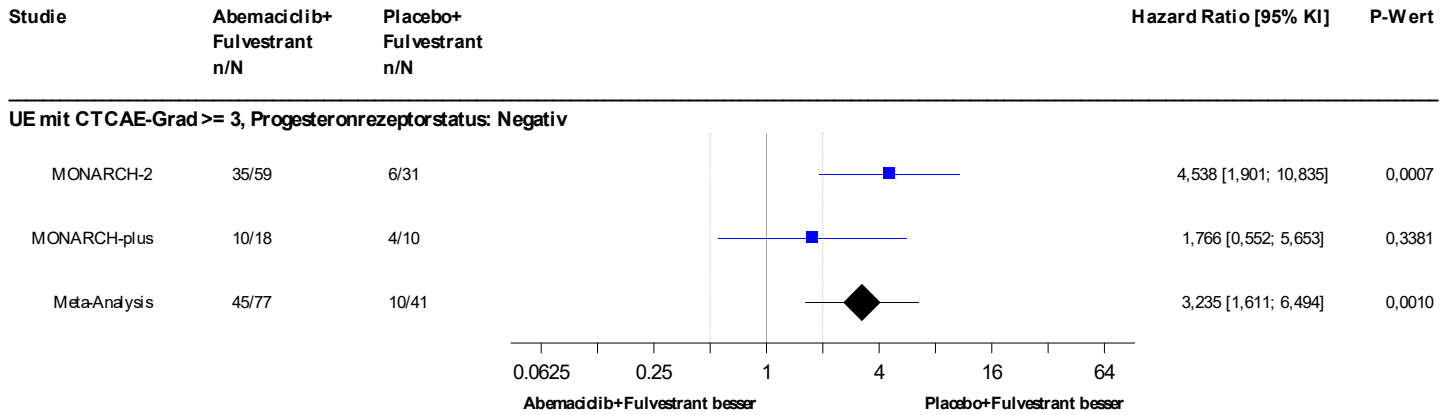
Abbildung 1421.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,6214, P-Wert=0,2029, I2 Index=38,3%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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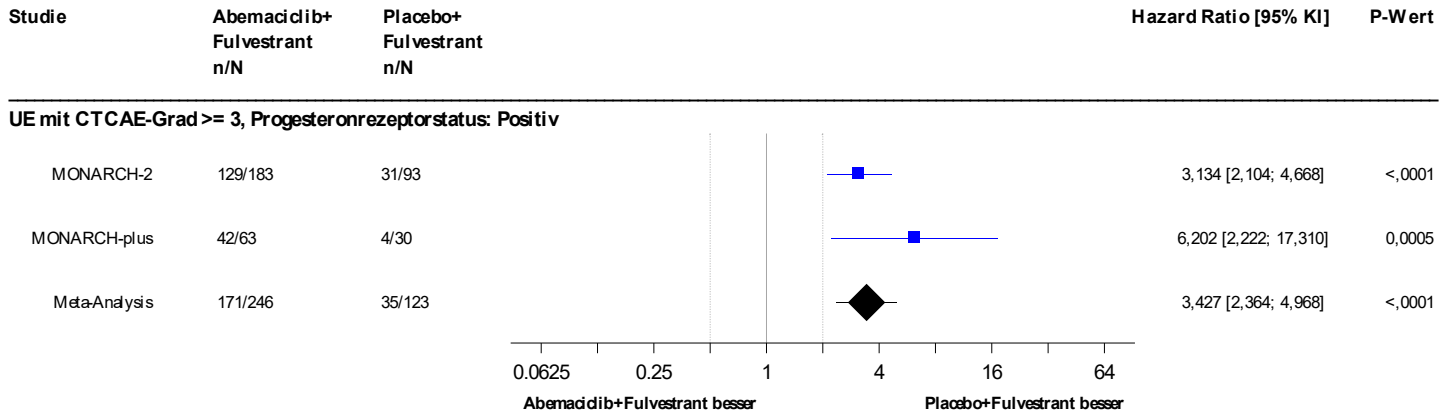
Abbildung 1421.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,4768, P-Wert=0,2243, I2 Index=32,3%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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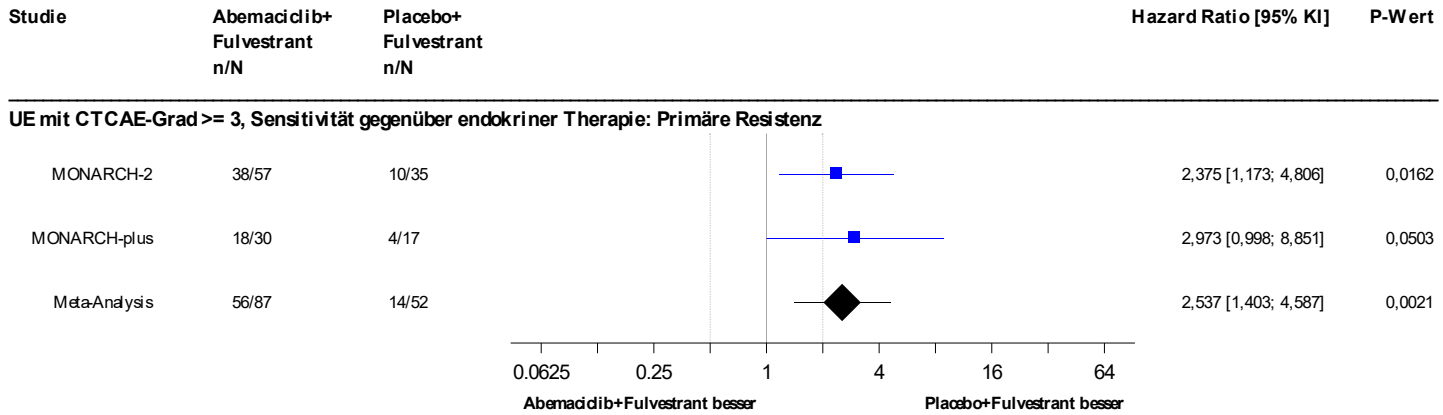
Abbildung 1421.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1149, P-Wert=0,7346, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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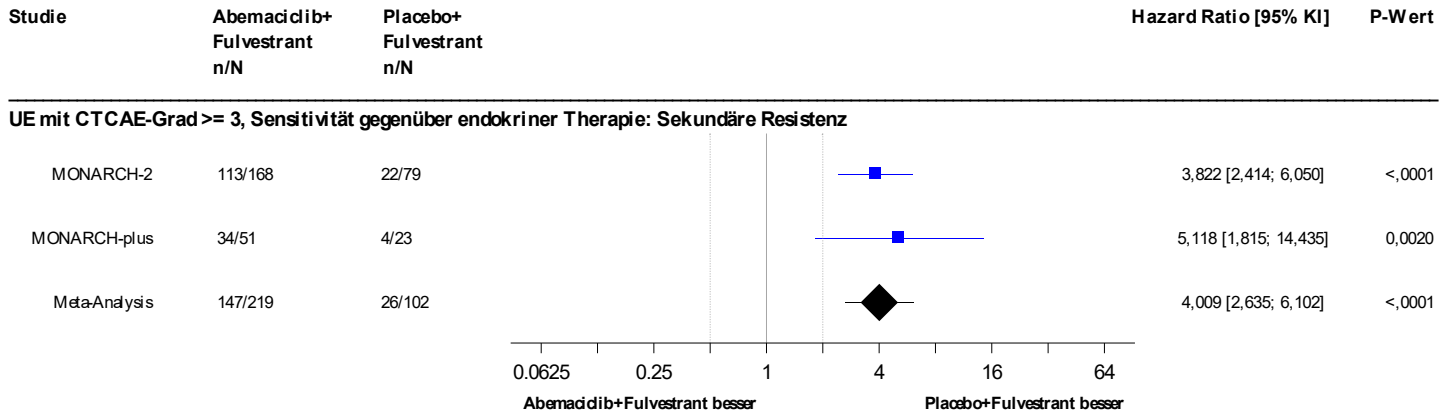
Abbildung 1421.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2547, P-Wert=0,6138, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttgr3_popa1_snthr_2.rtf
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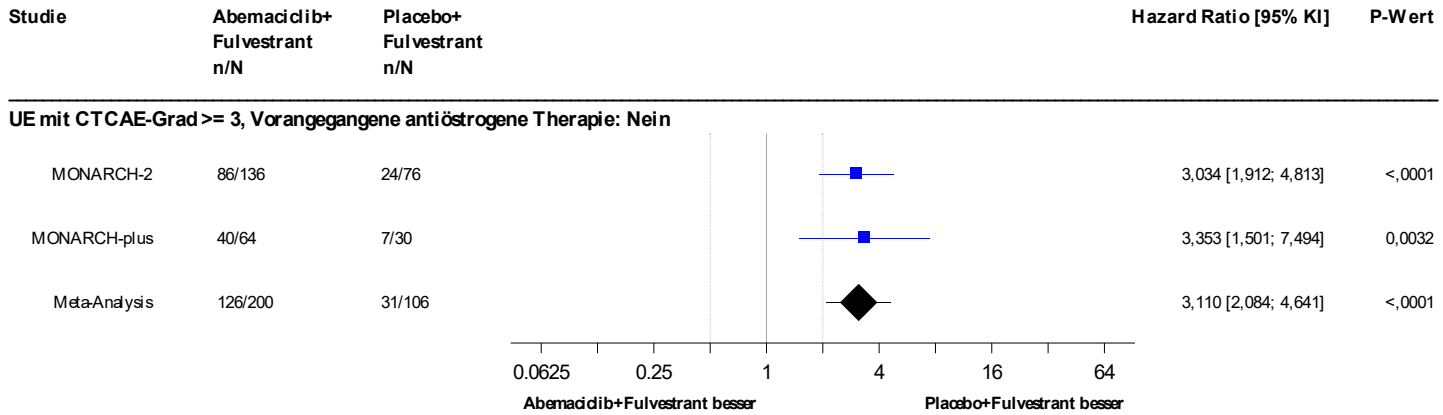
Abbildung 1421.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0449, P-Wert=0,8321, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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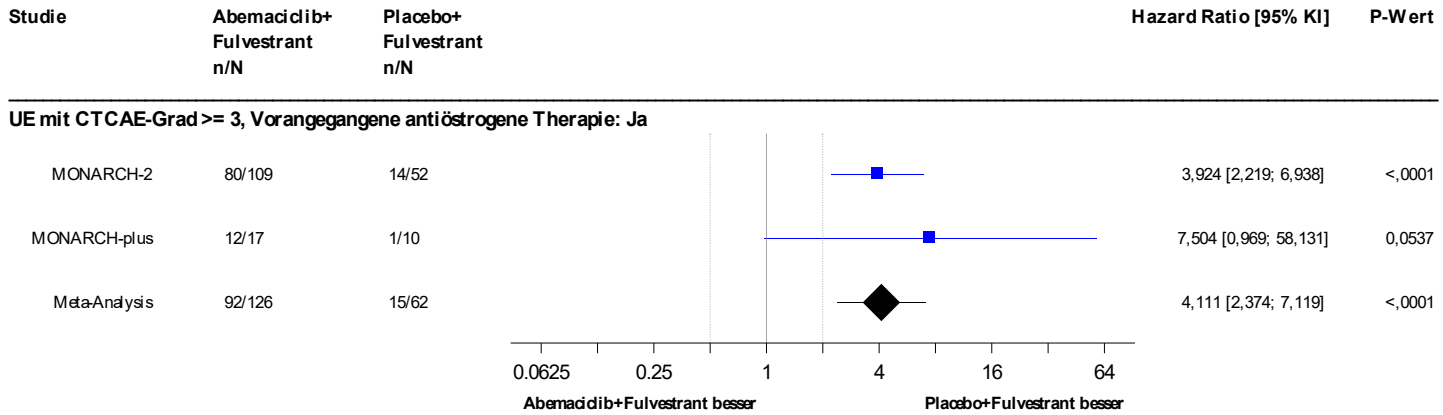
Abbildung 1421.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3576, P-Wert=0,5498, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttgr3_popa1_paet_2.rtf
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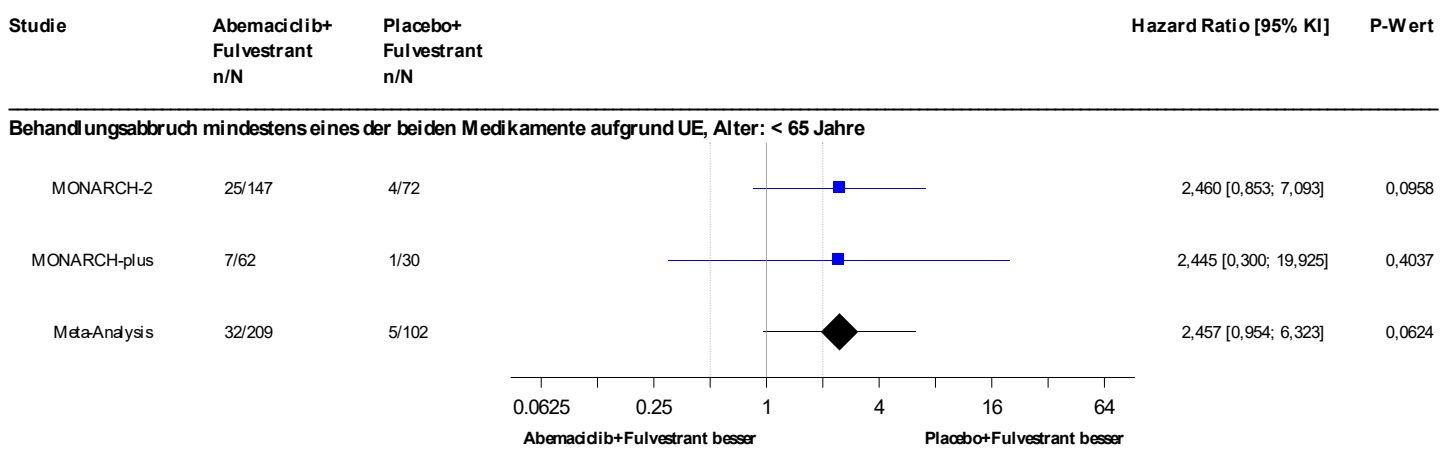
Abbildung 1422.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9959, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttdiscf_popa1_agegr1_1.rtf
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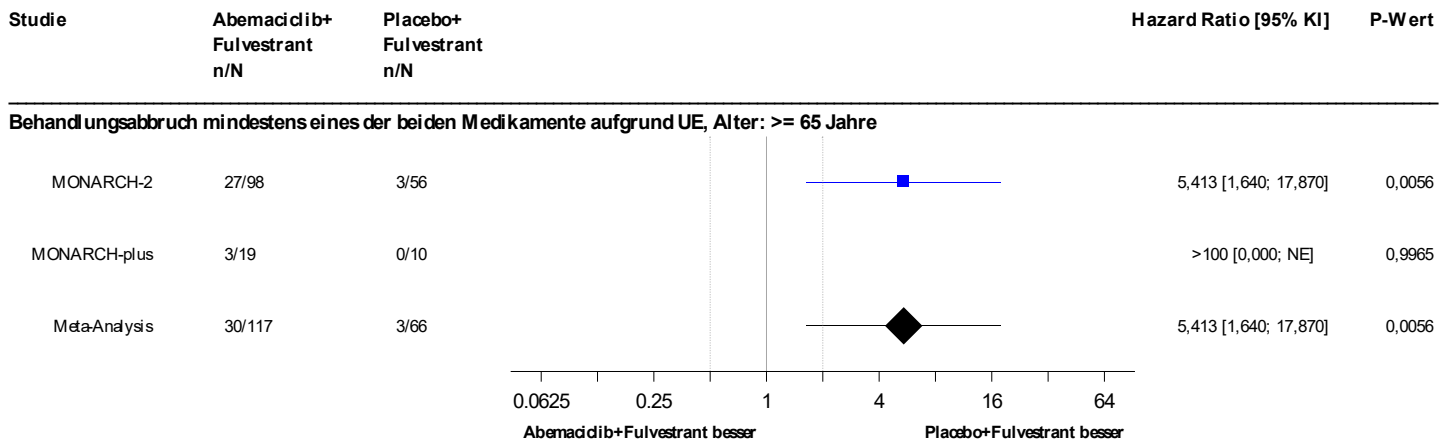
Abbildung 1422.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9968, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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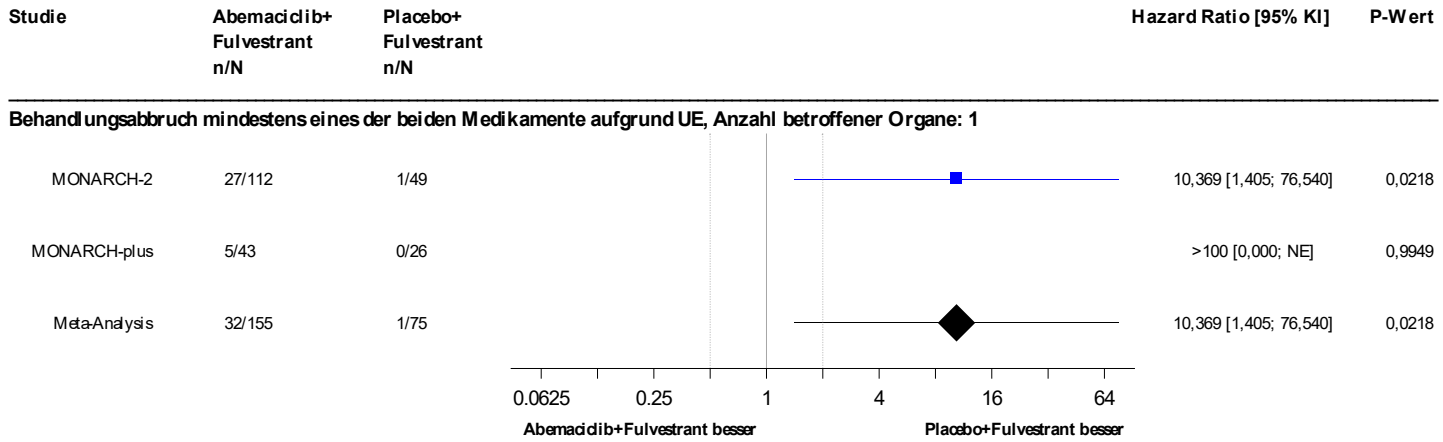
Abbildung 1422.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9956, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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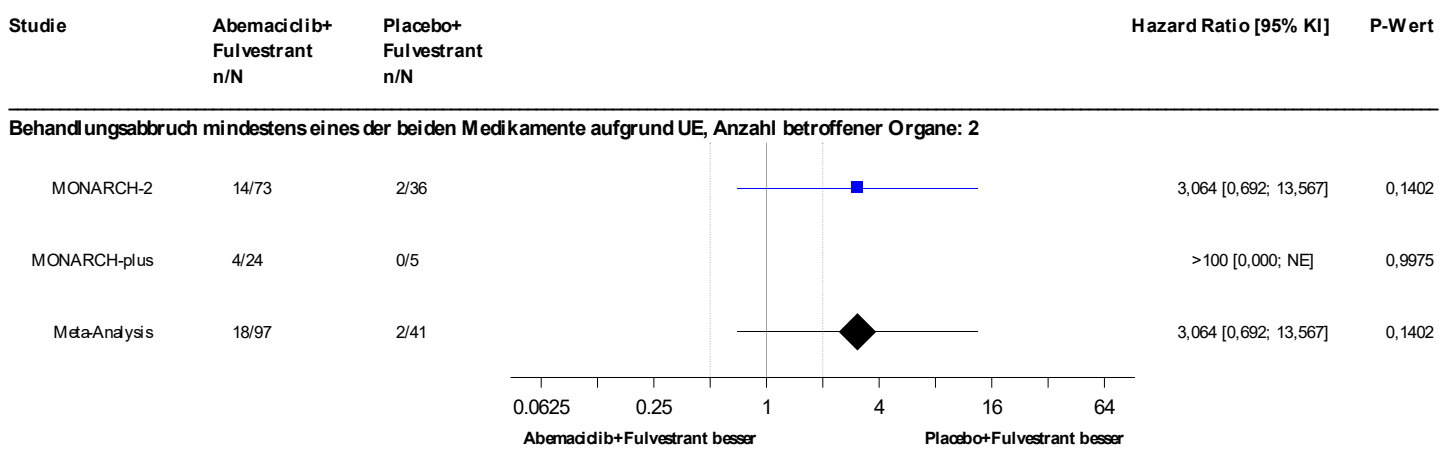
Abbildung 1422.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



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Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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Abbildung 1422.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

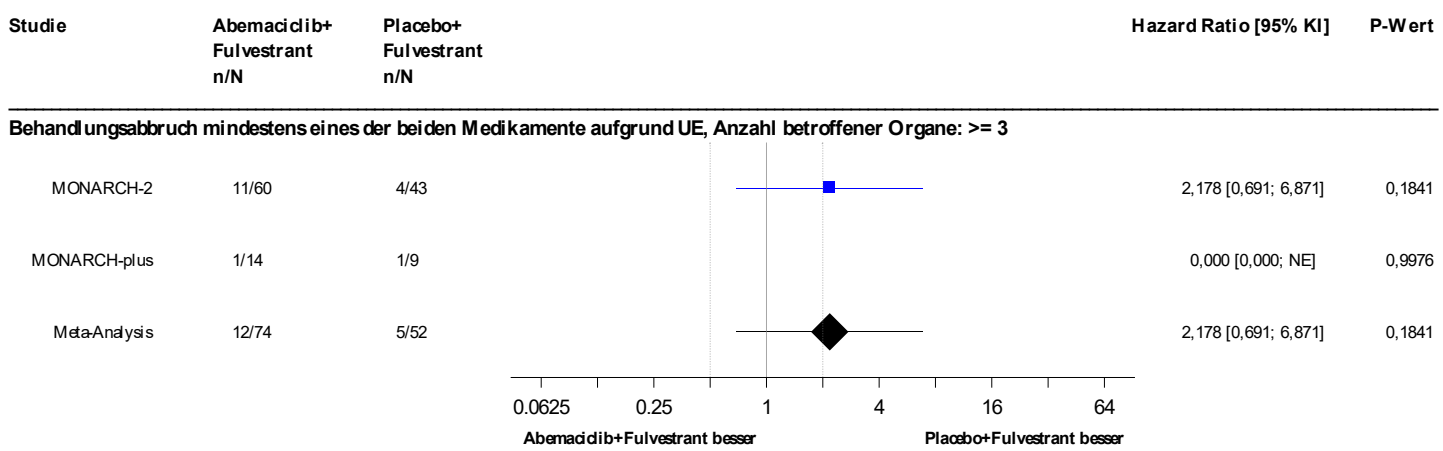

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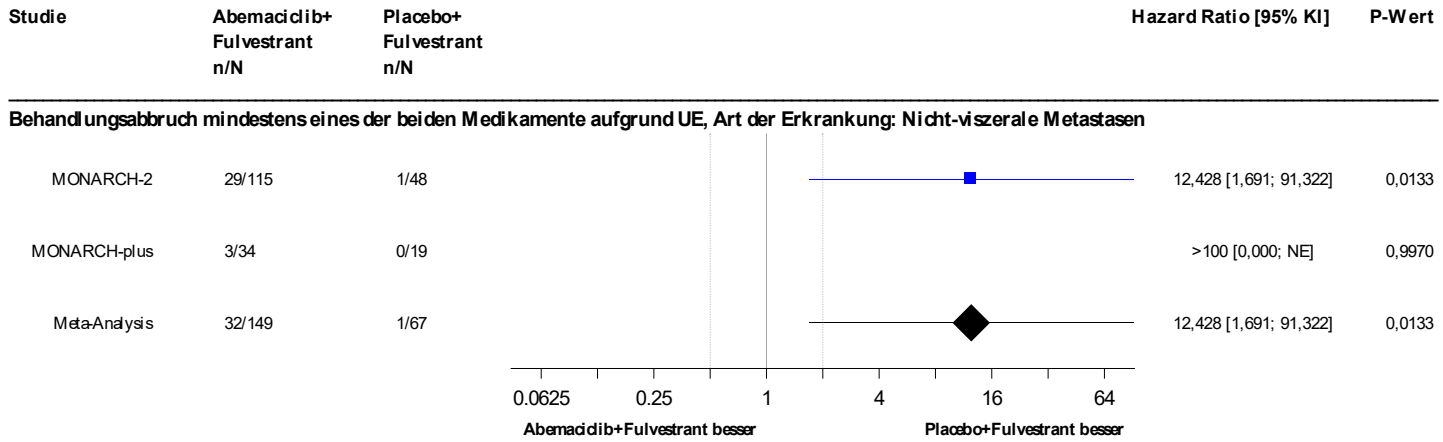
Abbildung 1422.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9974, I2 Index=0%
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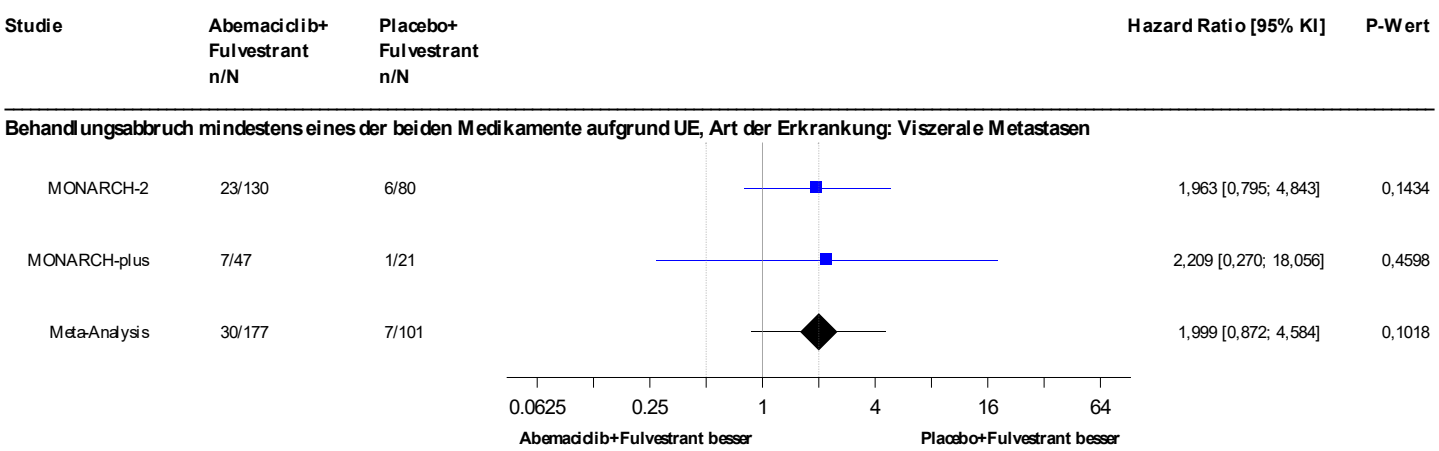
Abbildung 1422.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0102, P-Wert=0,9194, I2 Index=0%
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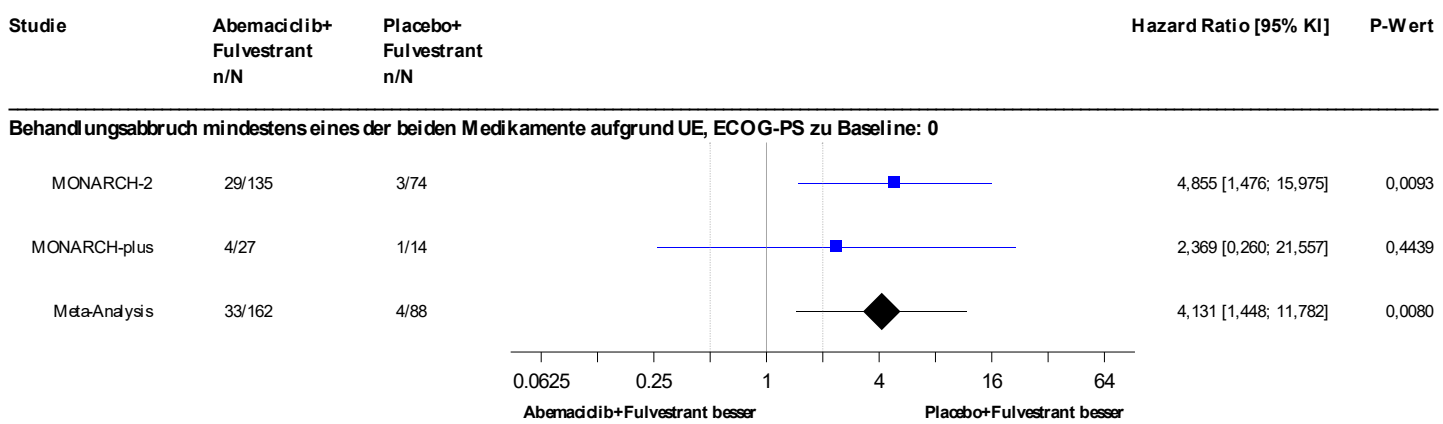
Abbildung 1422.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3142, P-Wert=0,5751, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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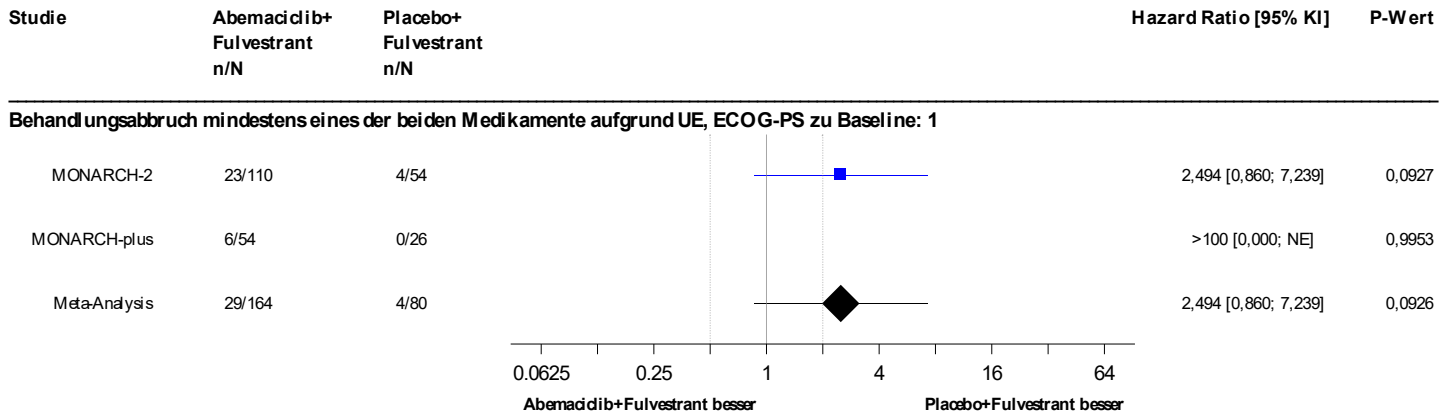
Abbildung 1422.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9956, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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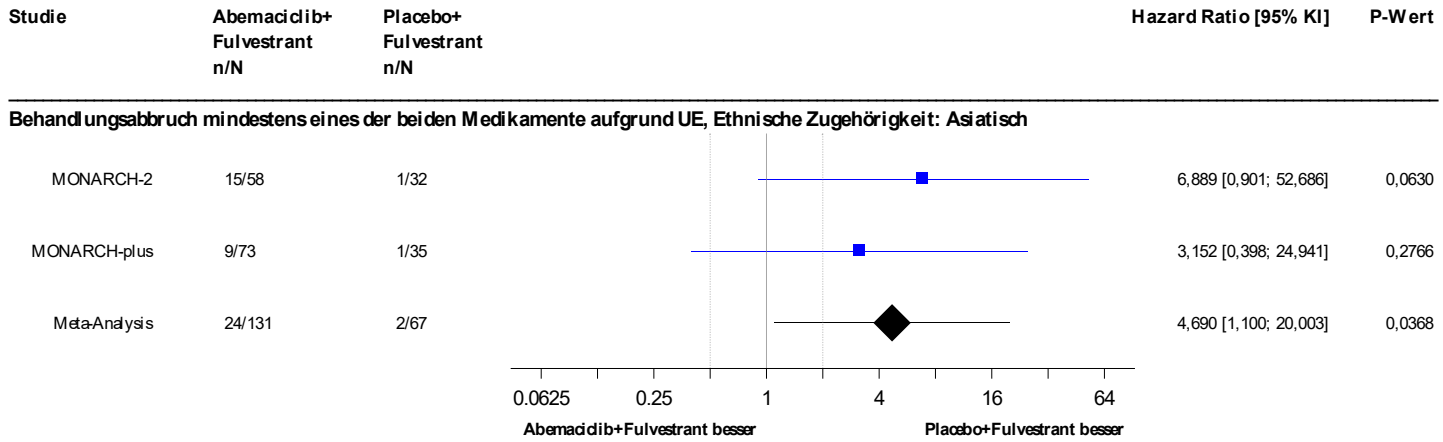
Abbildung 1422.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2789, P-Wert=0,5974, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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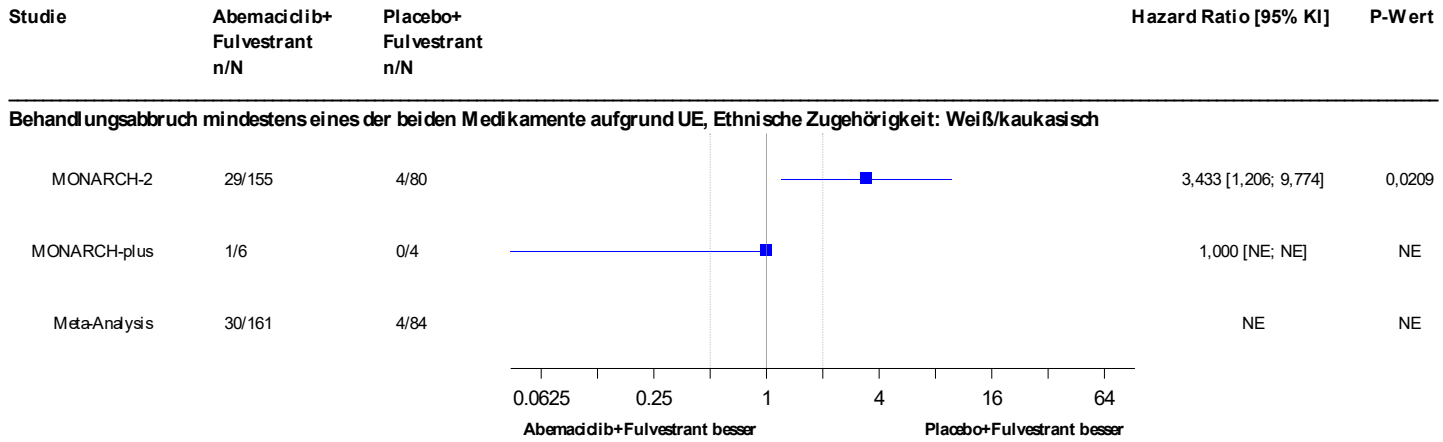
Abbildung 1422.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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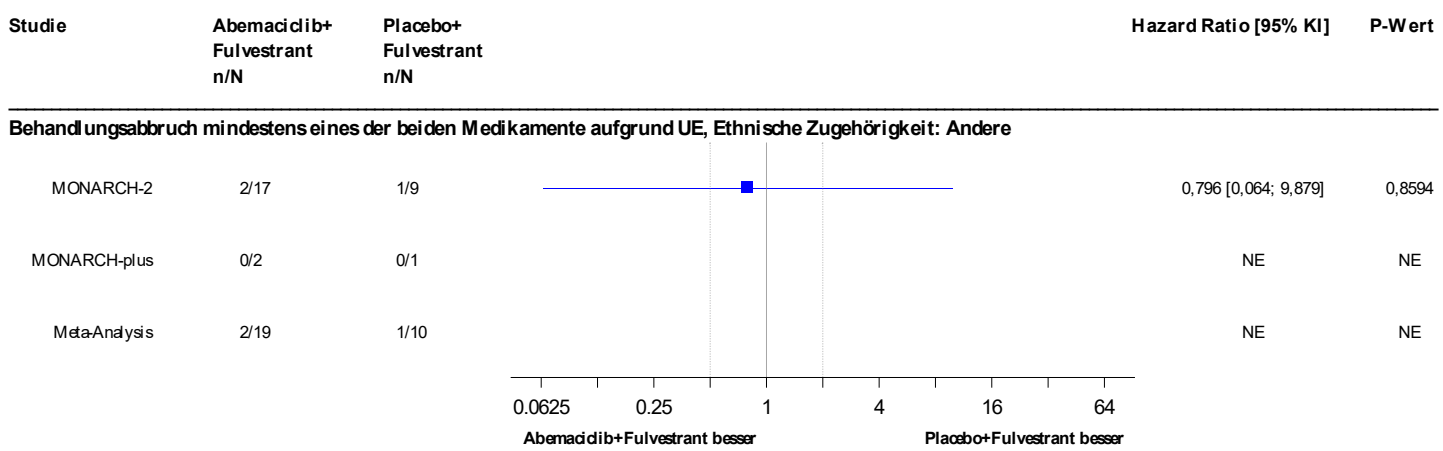
Abbildung 1422.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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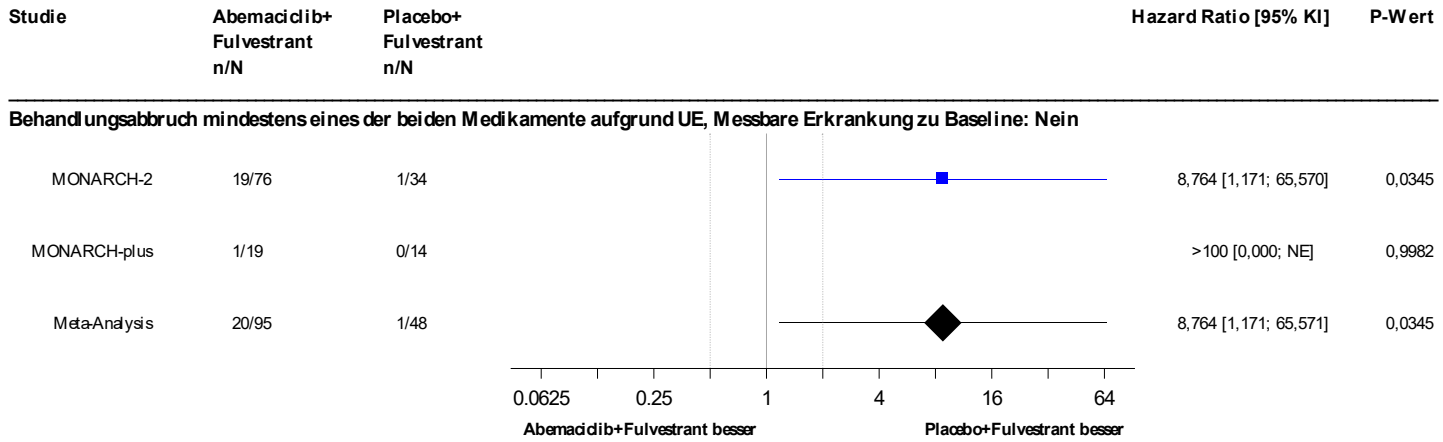
17SEP2021 / 07:48

Abbildung 1422.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9985, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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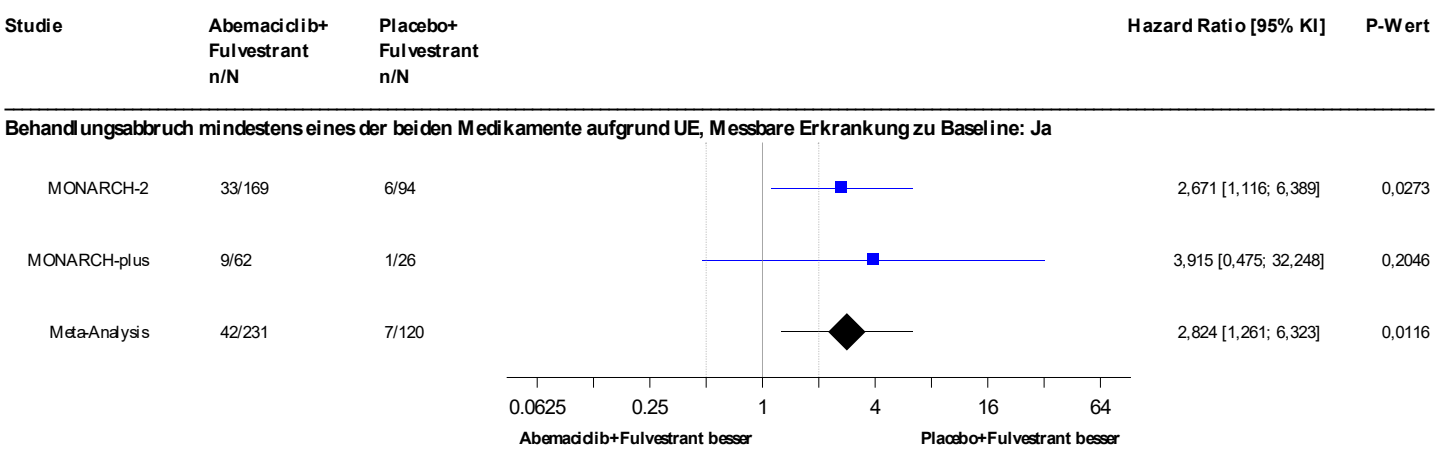
17SEP2021 / 07:48

Abbildung 1422.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1079, P-Wert=0,7425, I2 Index=0%
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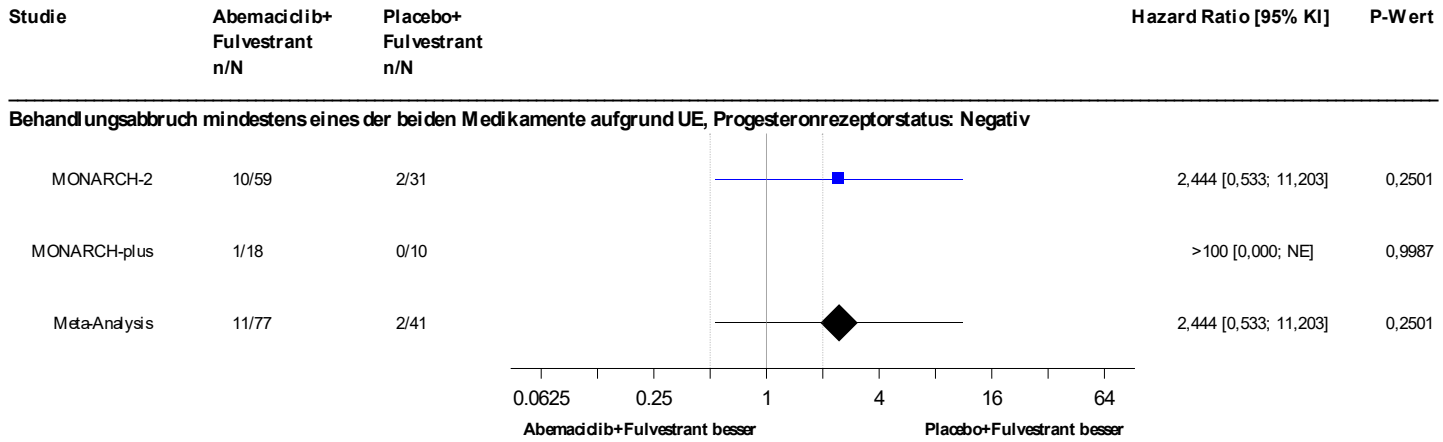
Abbildung 1422.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9988, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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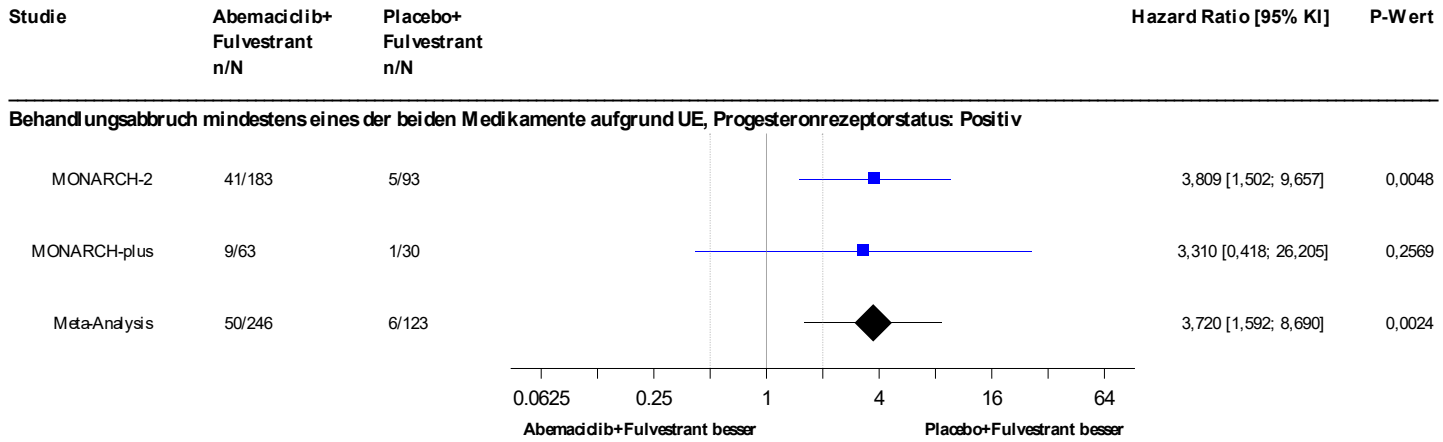
17SEP2021 / 07:48

Abbildung 1422.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0147, P-Wert=0,9035, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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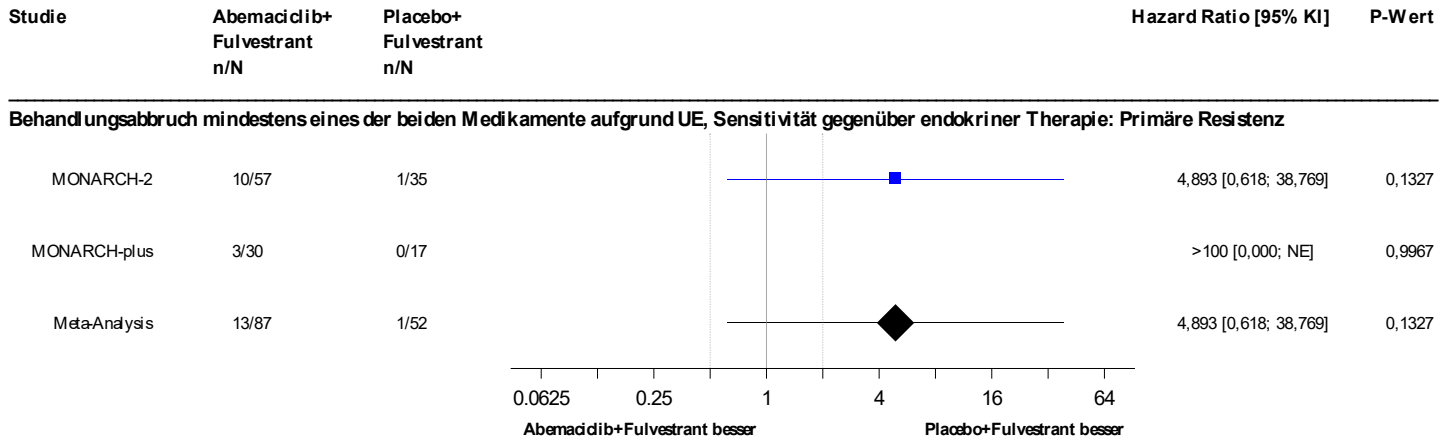
Abbildung 1422.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9970, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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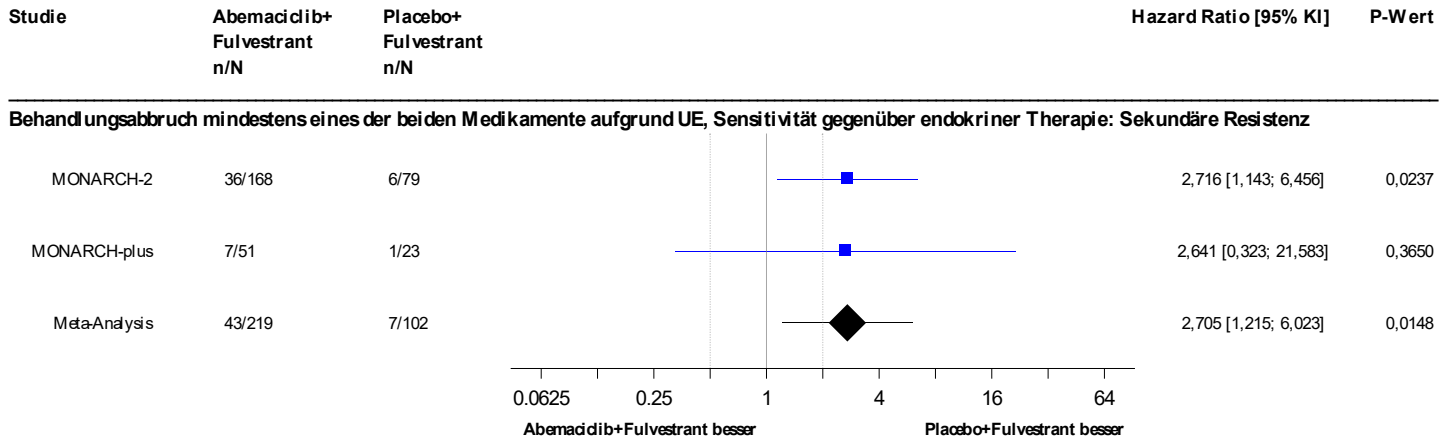
Abbildung 1422.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0006, P-Wert=0,9805, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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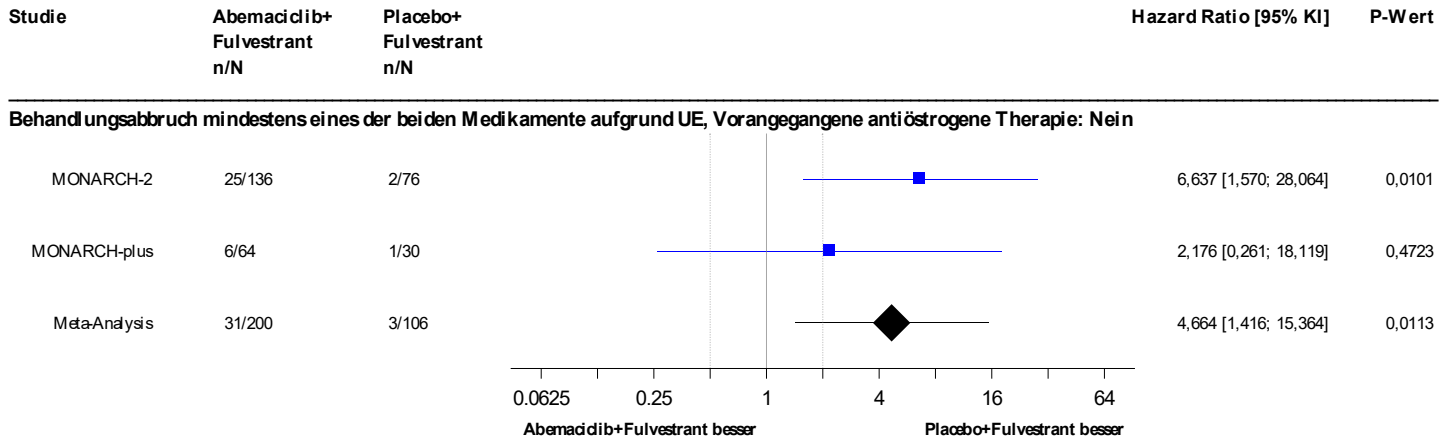
Abbildung 1422.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7273, P-Wert=0,3938, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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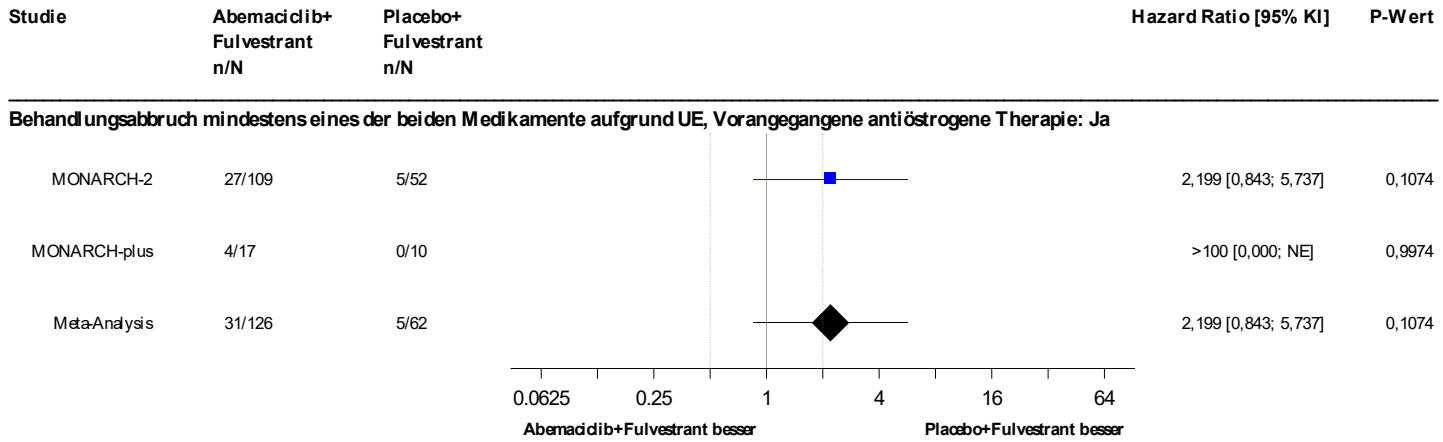
Abbildung 1422.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9975, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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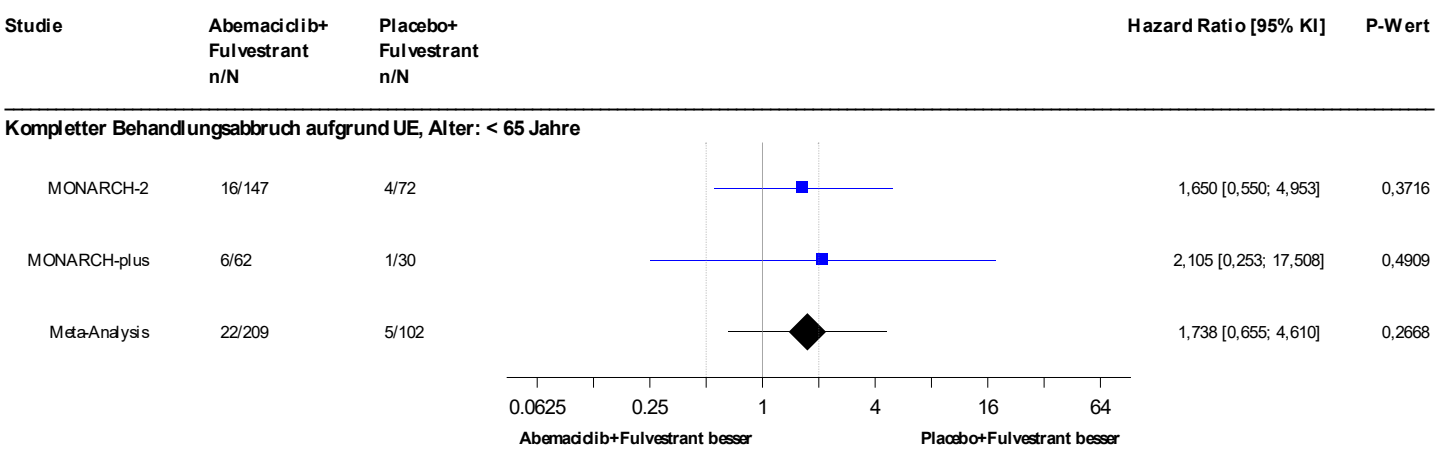
Abbildung 1423.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0400, P-Wert=0,8415, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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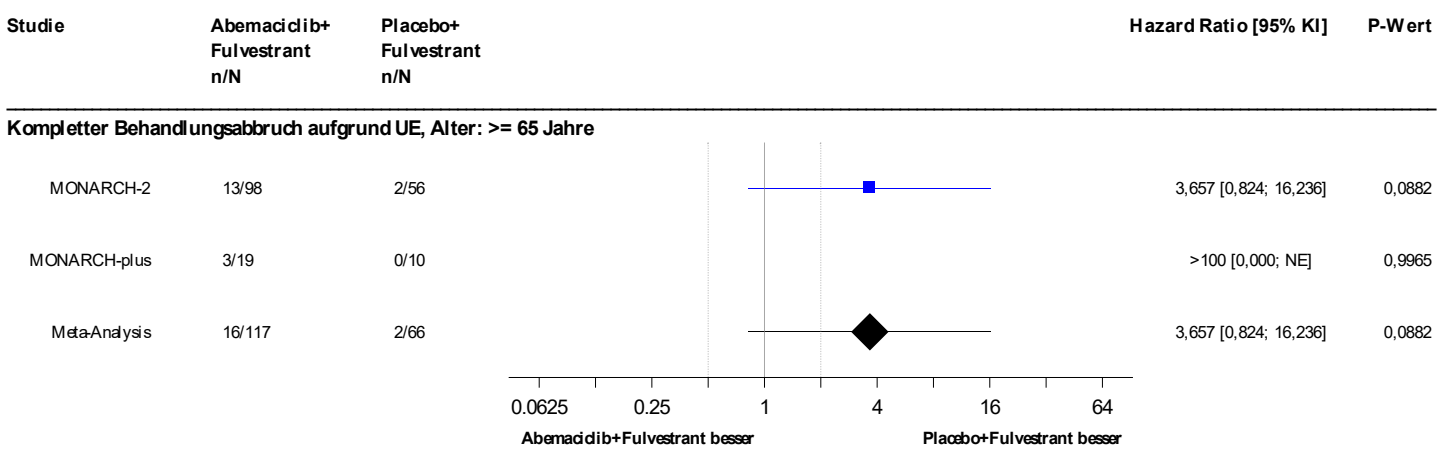
Abbildung 1423.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9967, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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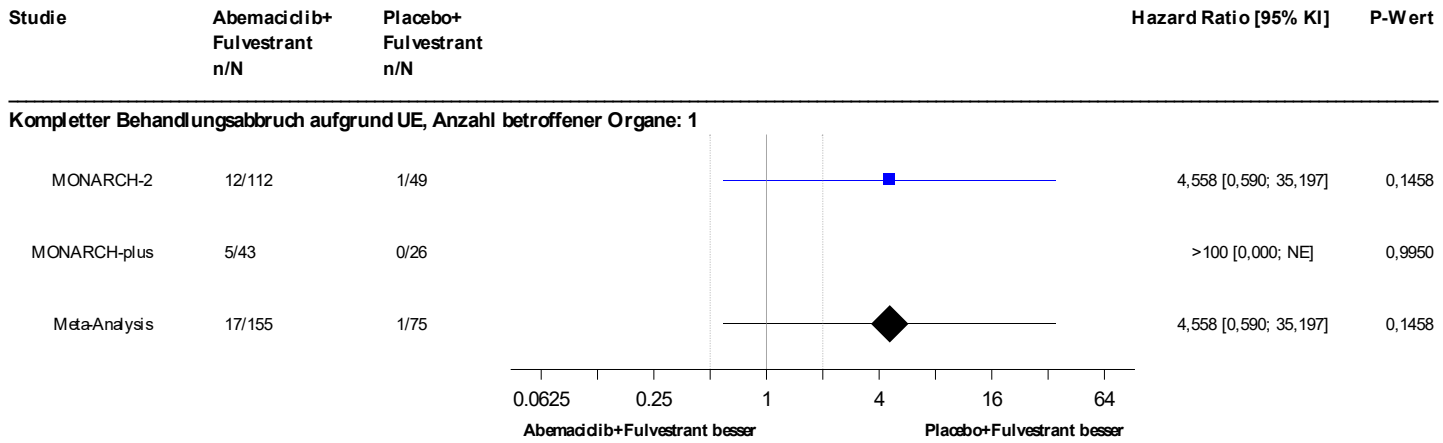
Abbildung 1423.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9954, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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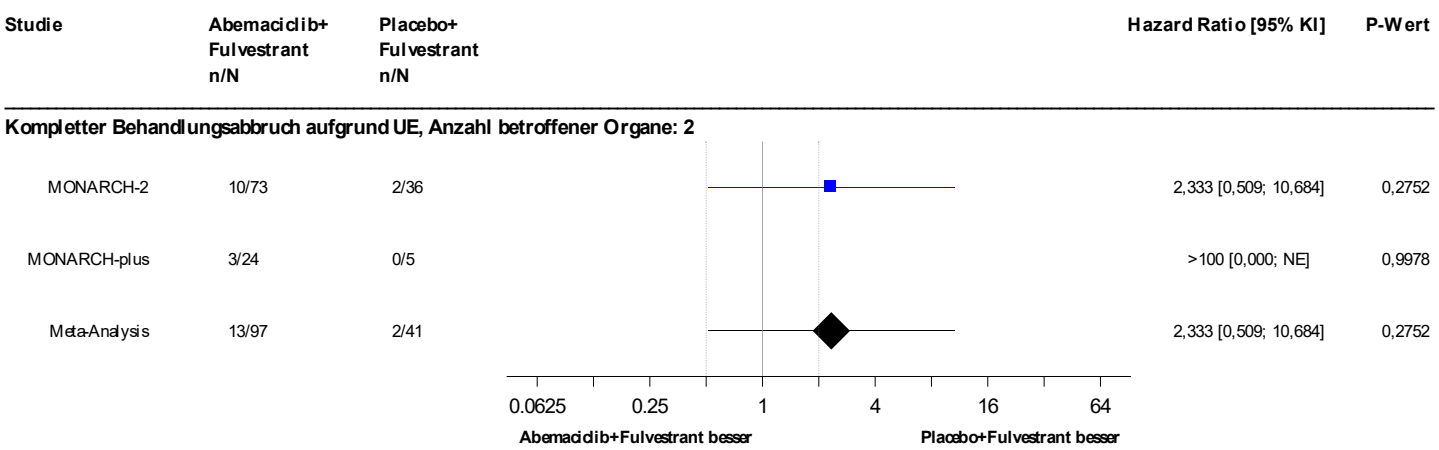
Abbildung 1423.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9979, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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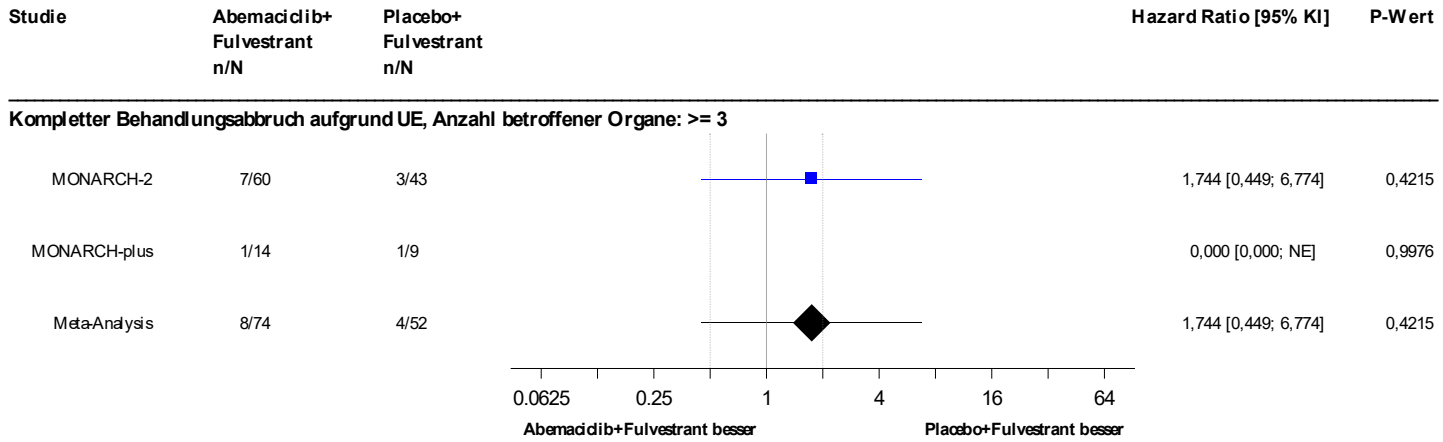
Abbildung 1423.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9975, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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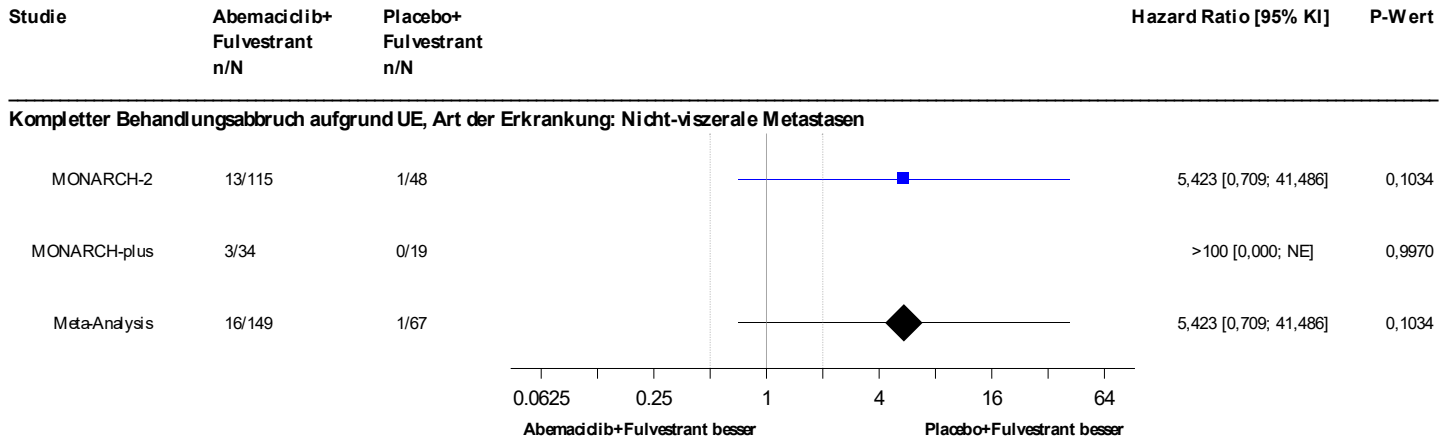
Abbildung 1423.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9973, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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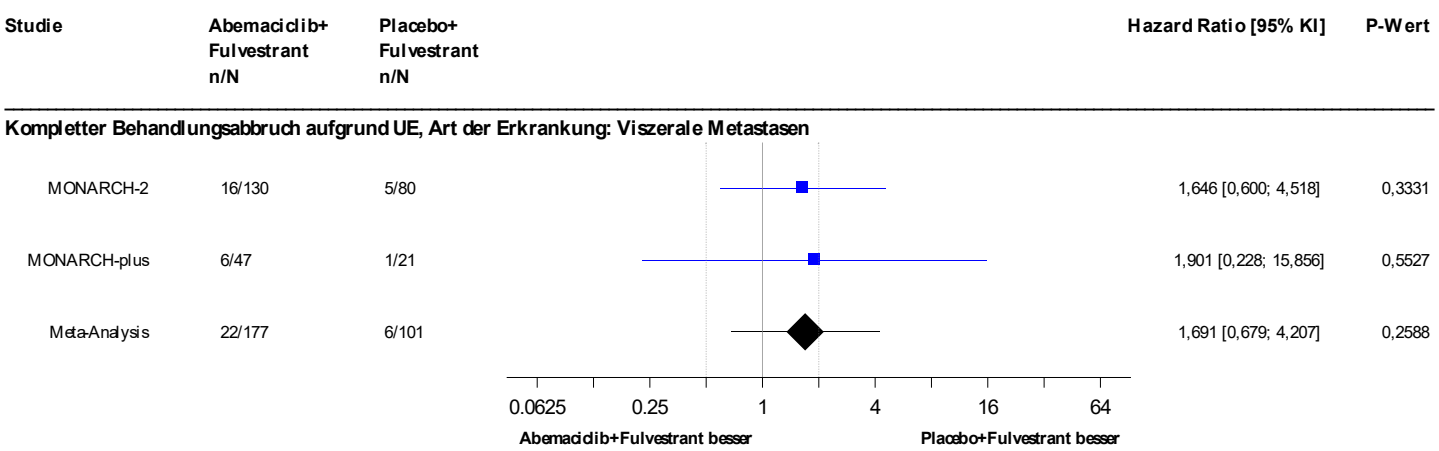
Abbildung 1423.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0144, P-Wert=0,9044, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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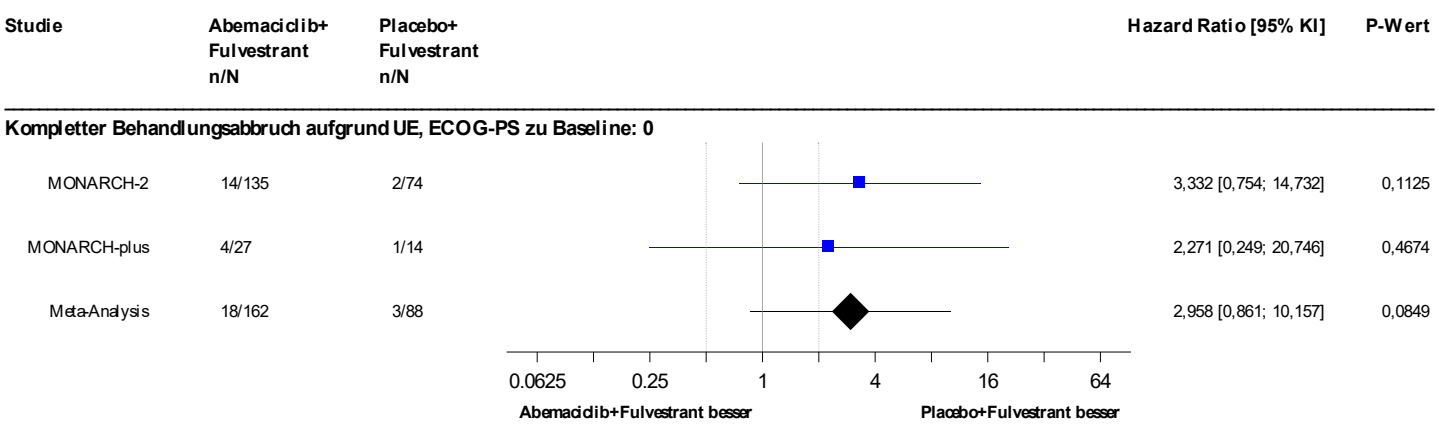
Abbildung 1423.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0795, P-Wert=0,7780, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttdisca_popa1_ecogbl_1.rtf
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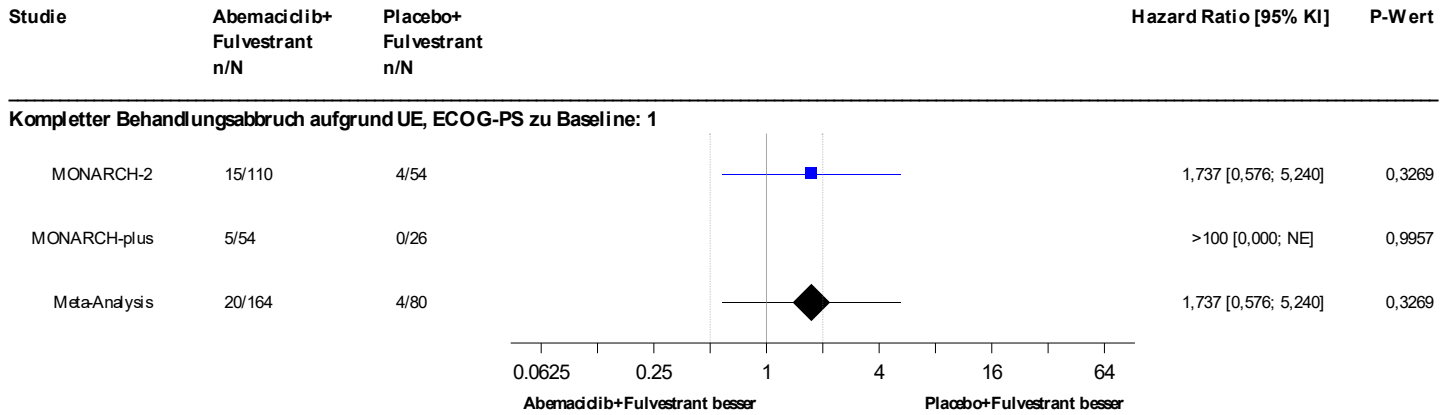
Abbildung 1423.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9958, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttdisca_popa1_ecogbl_2.rtf
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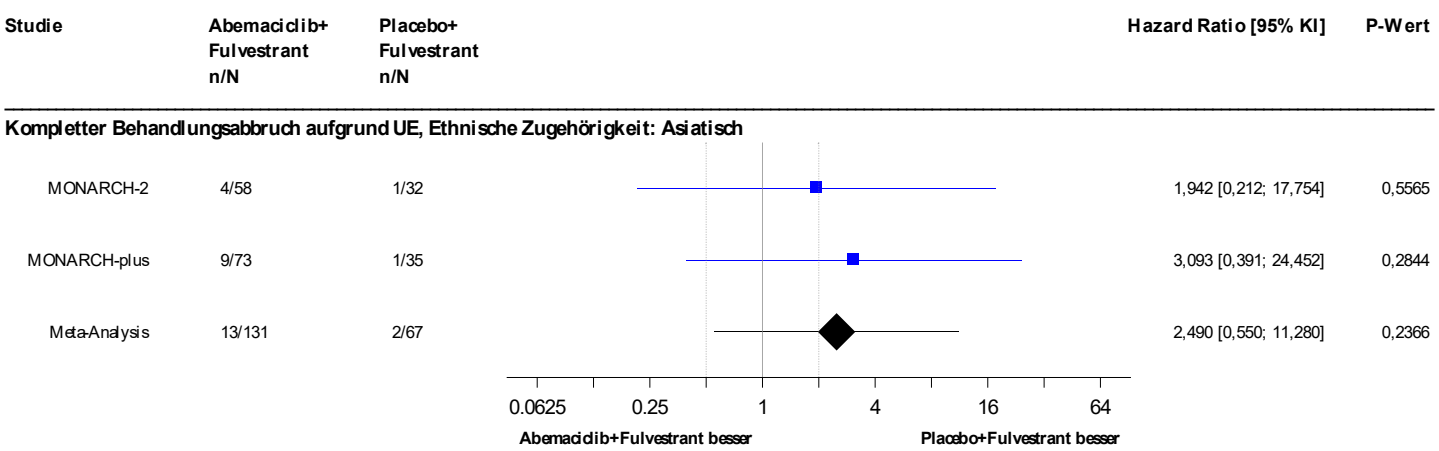
Abbildung 1423.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0907, P-Wert=0,7633, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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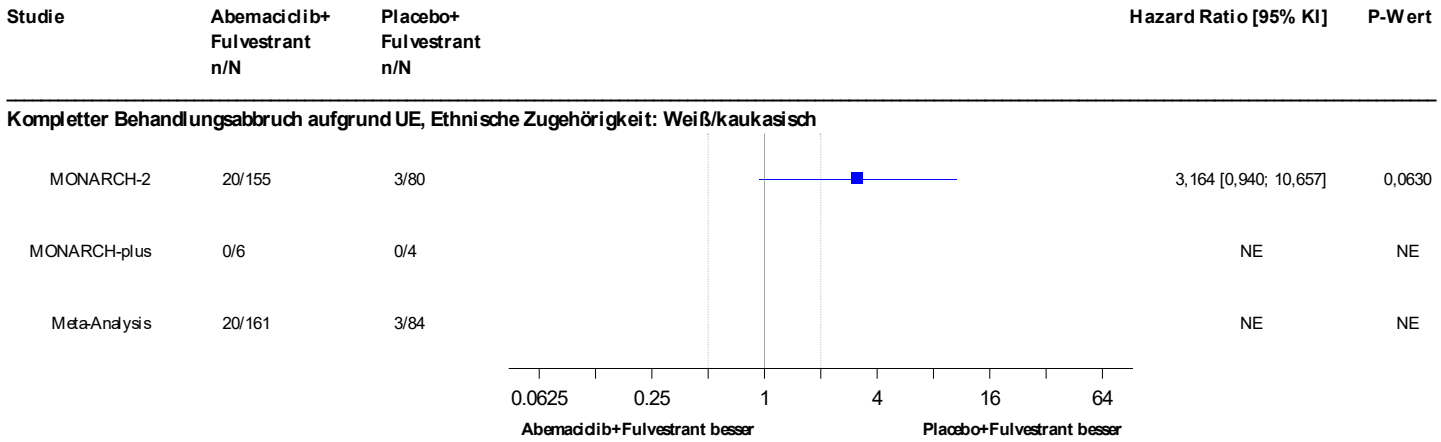
Abbildung 1423.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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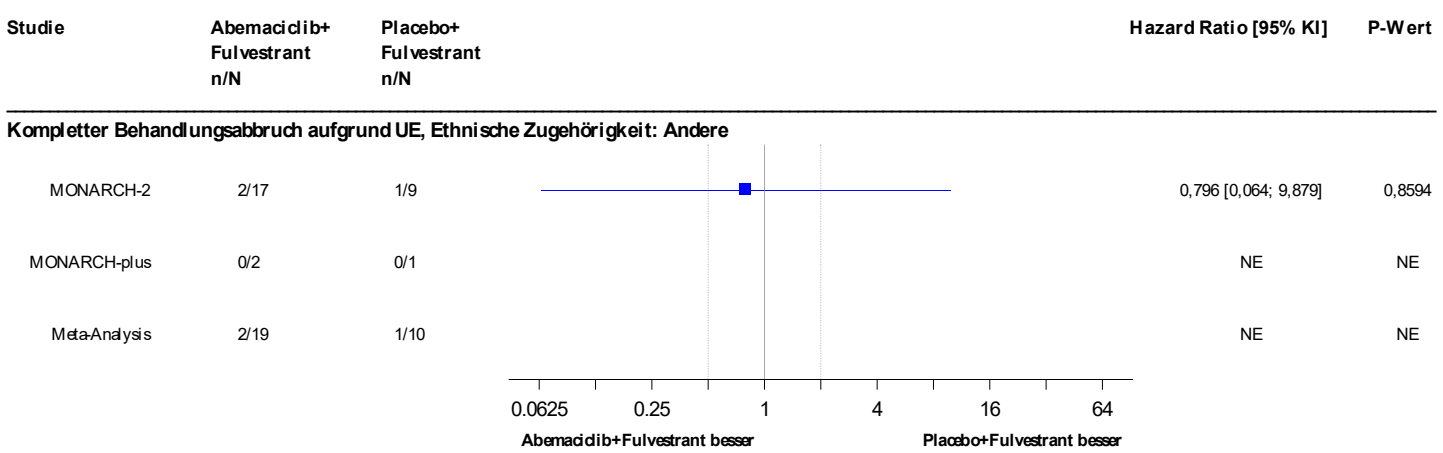
Abbildung 1423.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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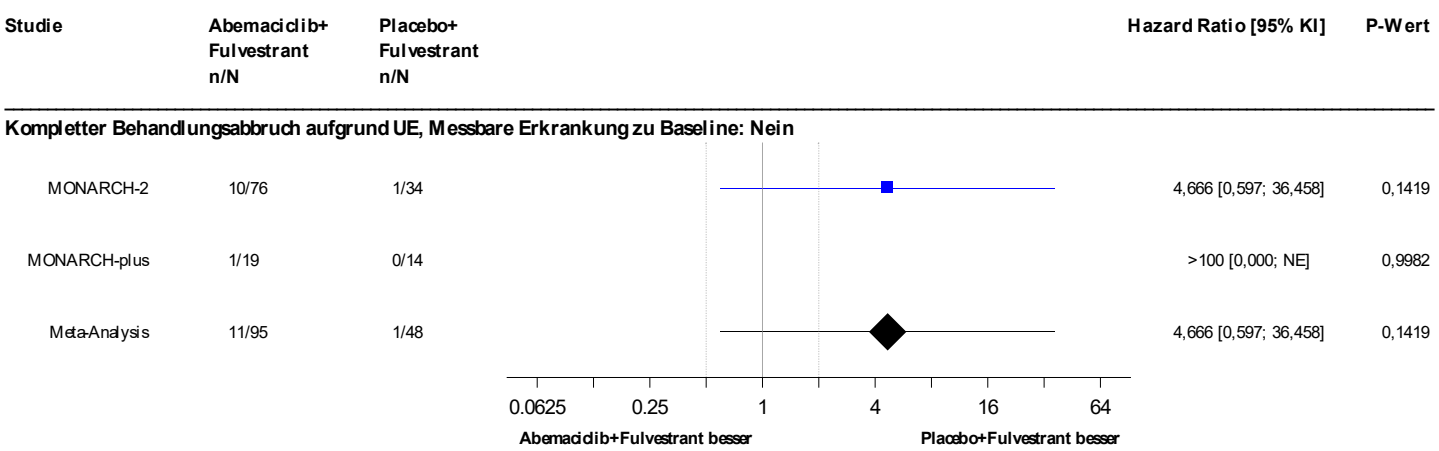
Abbildung 1423.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9984, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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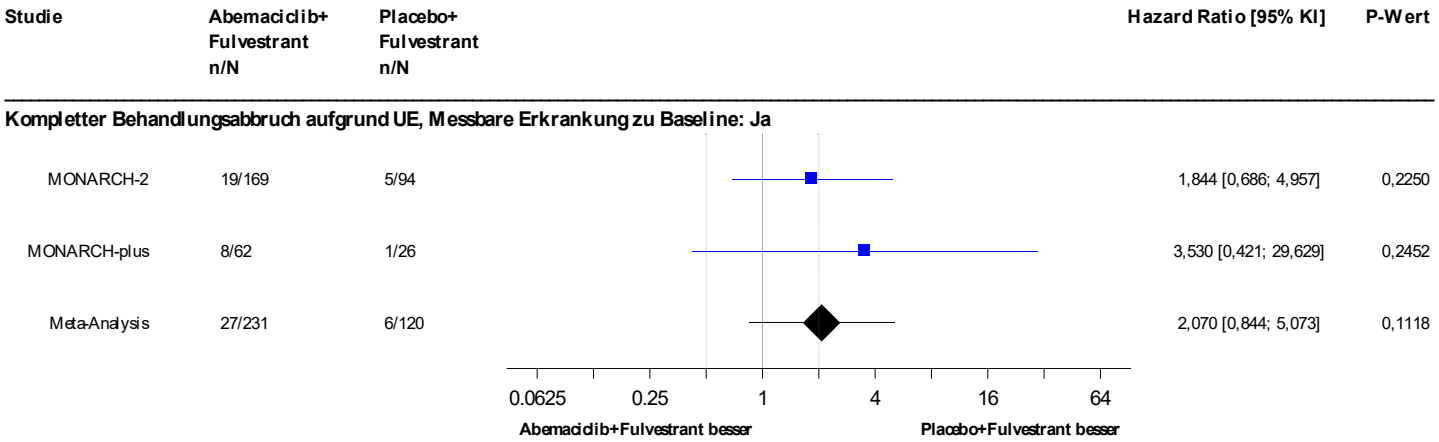
Abbildung 1423.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2942, P-Wert=0,5875, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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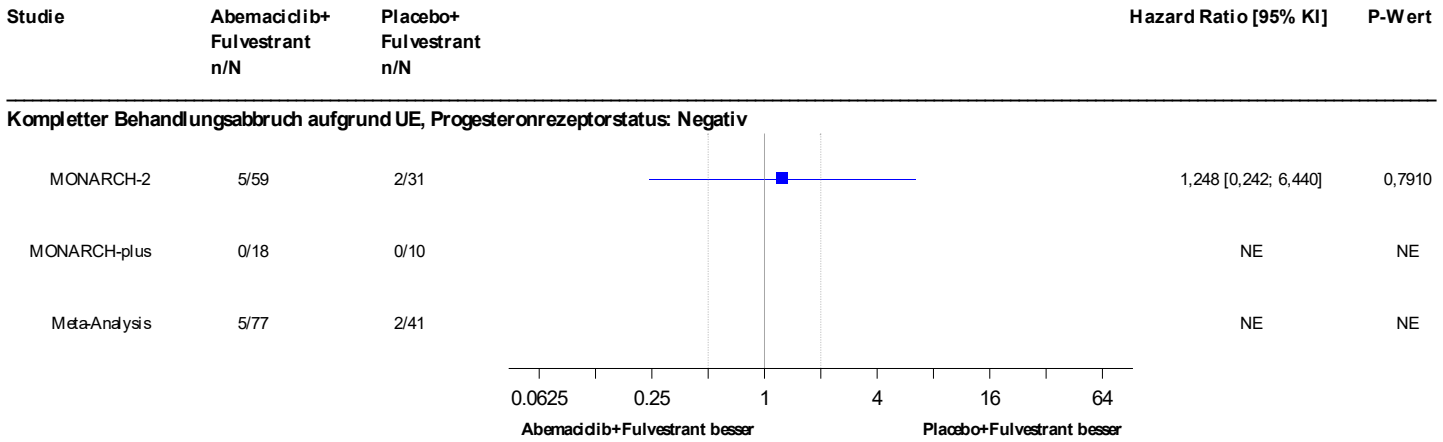
Abbildung 1423.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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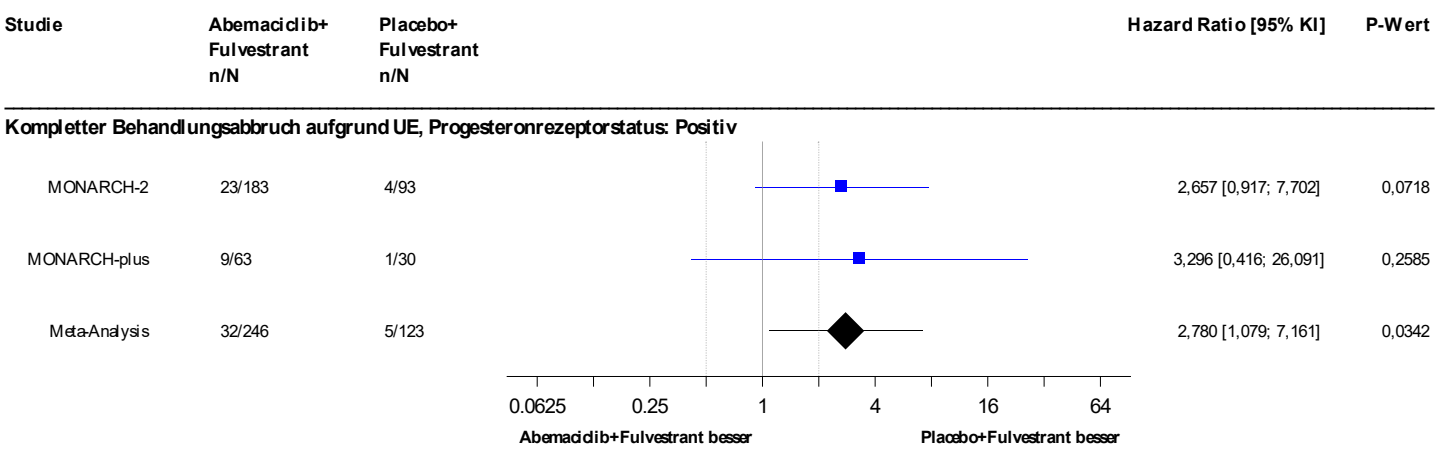
Abbildung 1423.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0329, P-Wert=0,8561, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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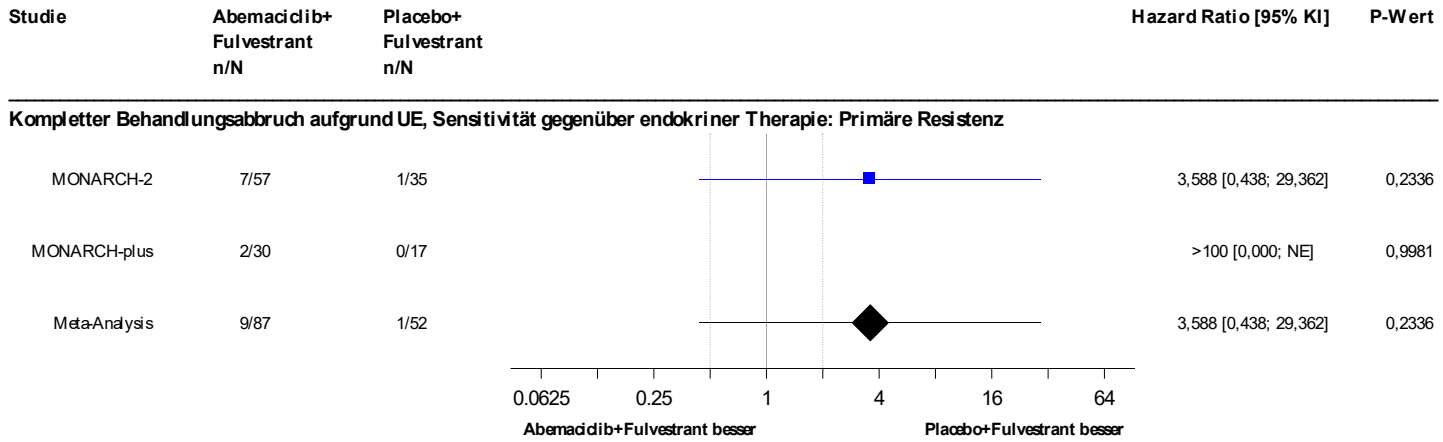
Abbildung 1423.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9983, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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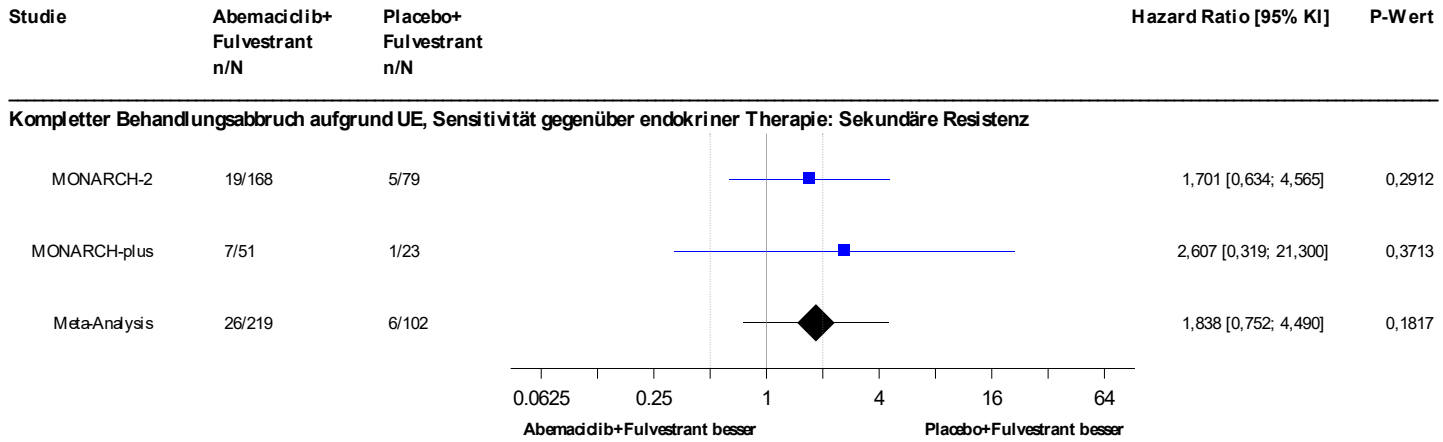
Abbildung 1423.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1299, P-Wert=0,7185, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttdisca_popa1_snthr_2.rtf
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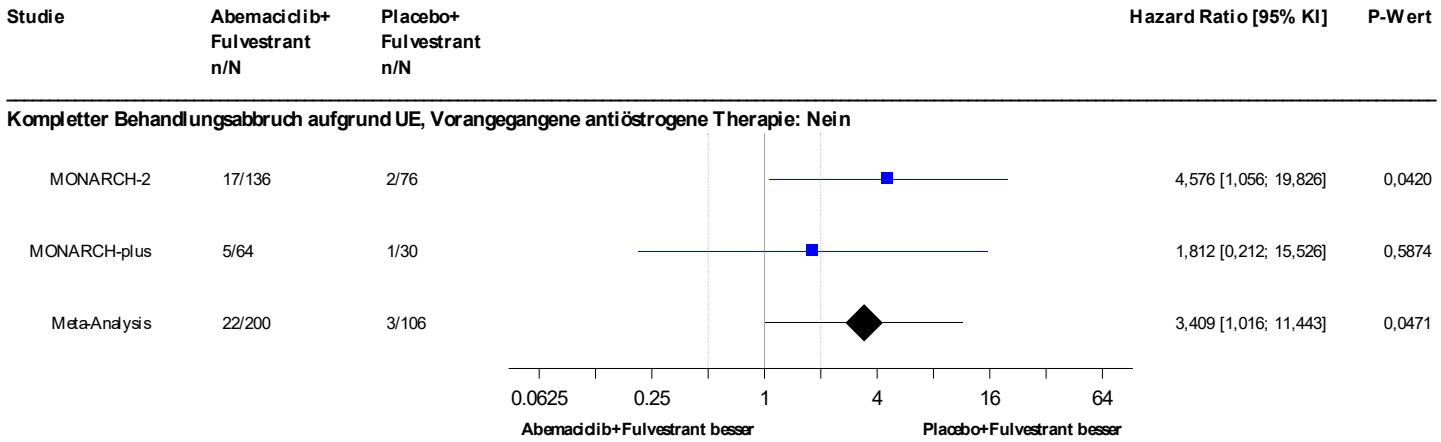
Abbildung 1423.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4873, P-Wert=0,4851, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttdisca_popa1_paet_1.rtf
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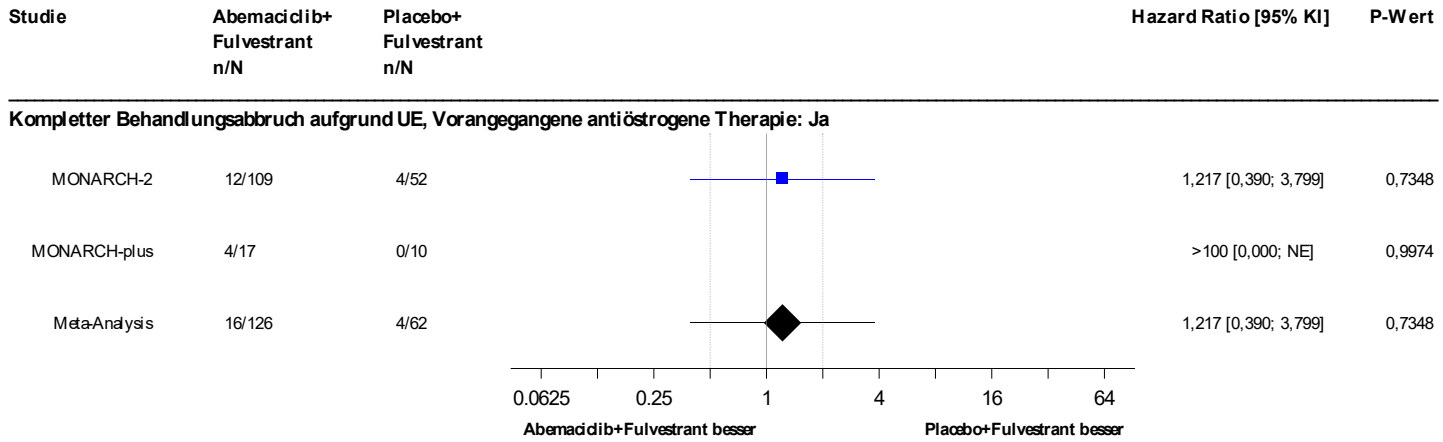
Abbildung 1423.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9974, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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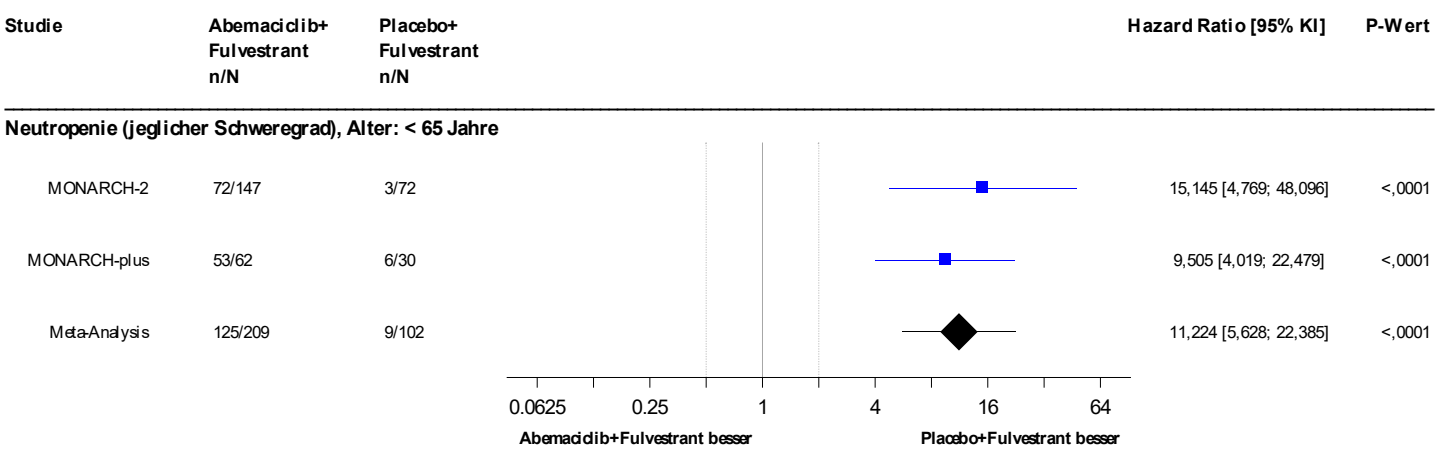
Abbildung 1424.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4016, P-Wert=0,5263, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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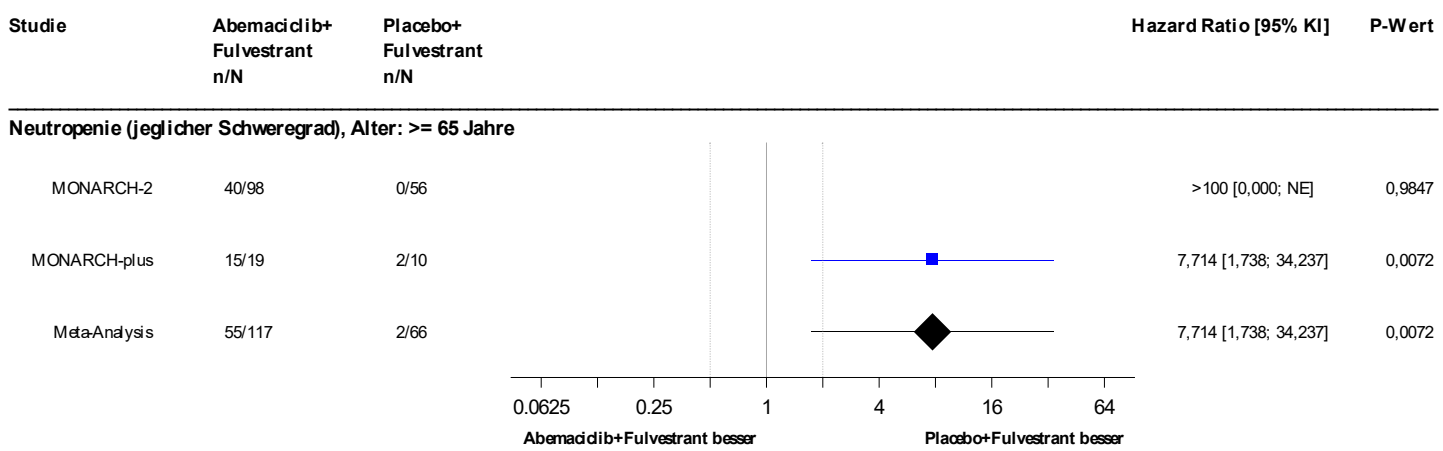
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
17SEP2021 / 07:48

Abbildung 1424.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0003, P-Wert=0,9865, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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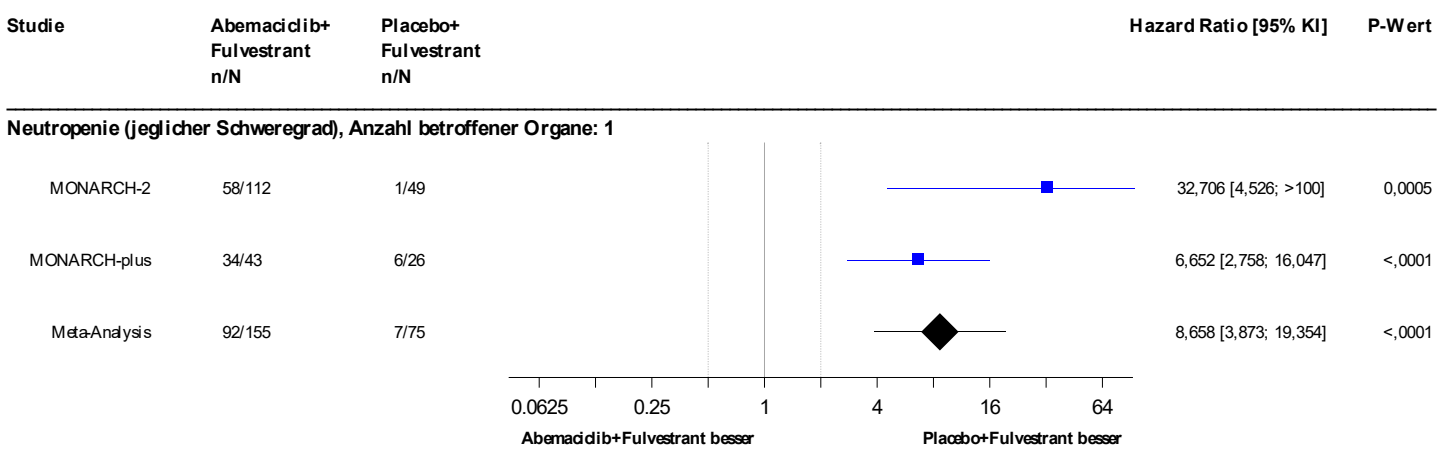
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
17SEP2021 / 07:48

Abbildung 1424.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,0790, P-Wert=0,1493, I2 Index=51,9%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttnpaesi_popa1_norggr_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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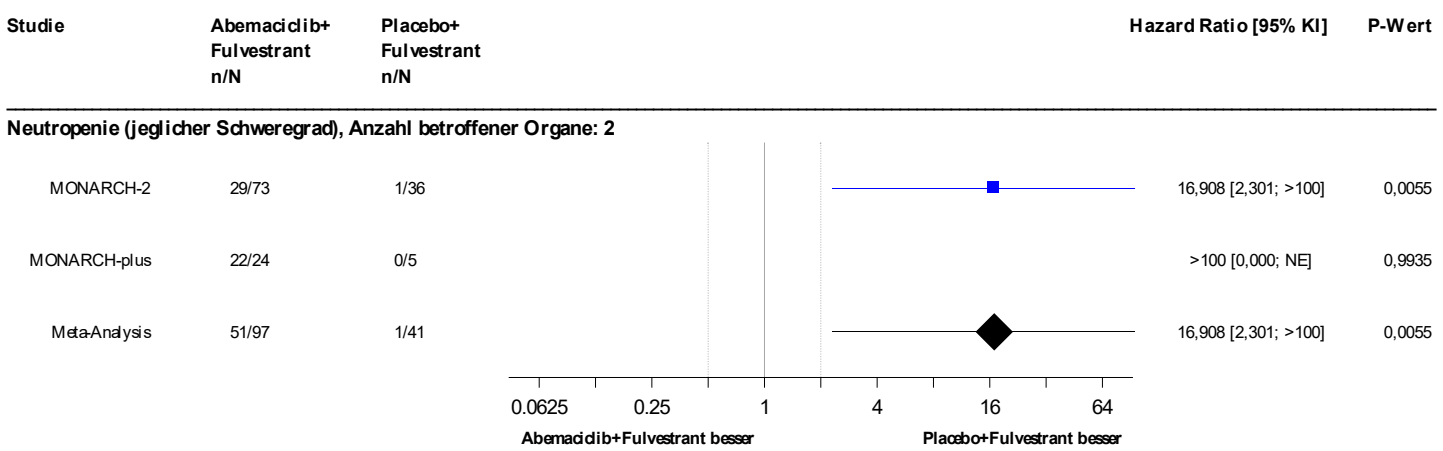
Abbildung 1424.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9945, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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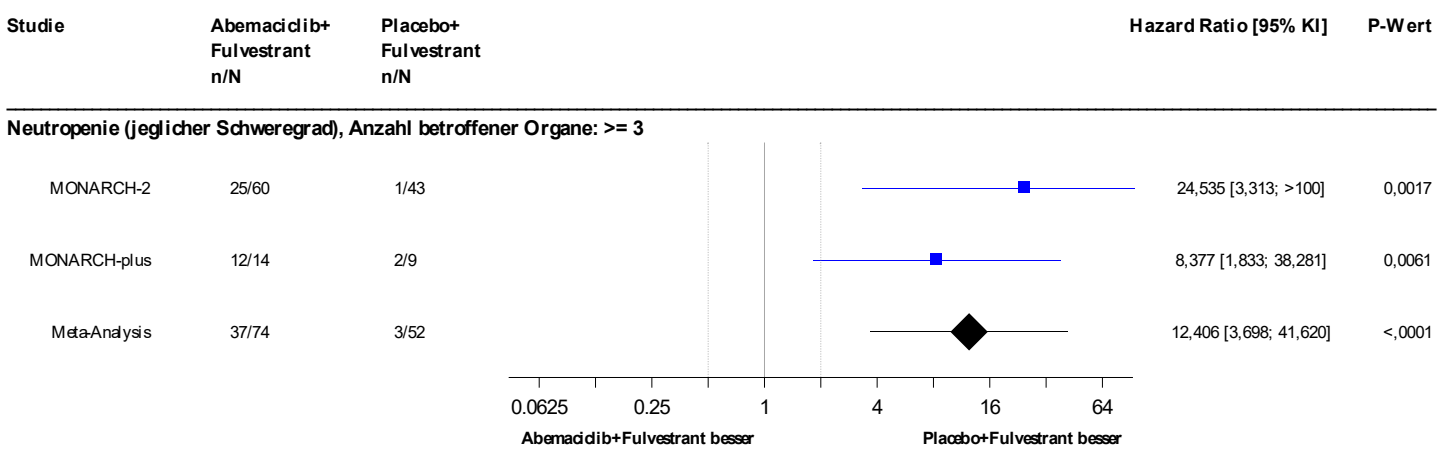
Abbildung 1424.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7021, P-Wert=0,4021, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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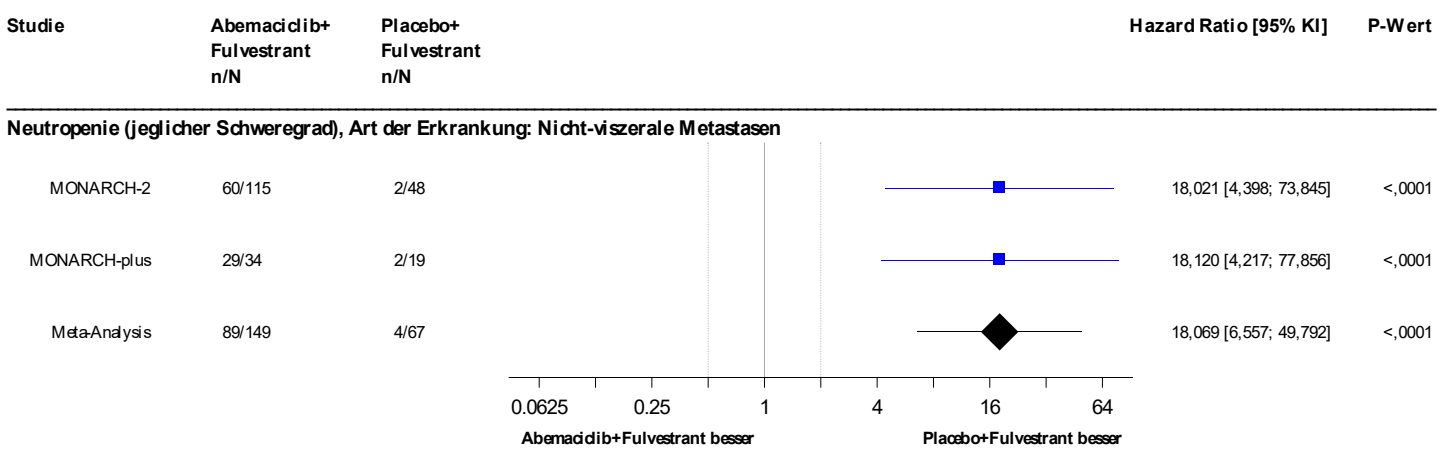
Abbildung 1424.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9958, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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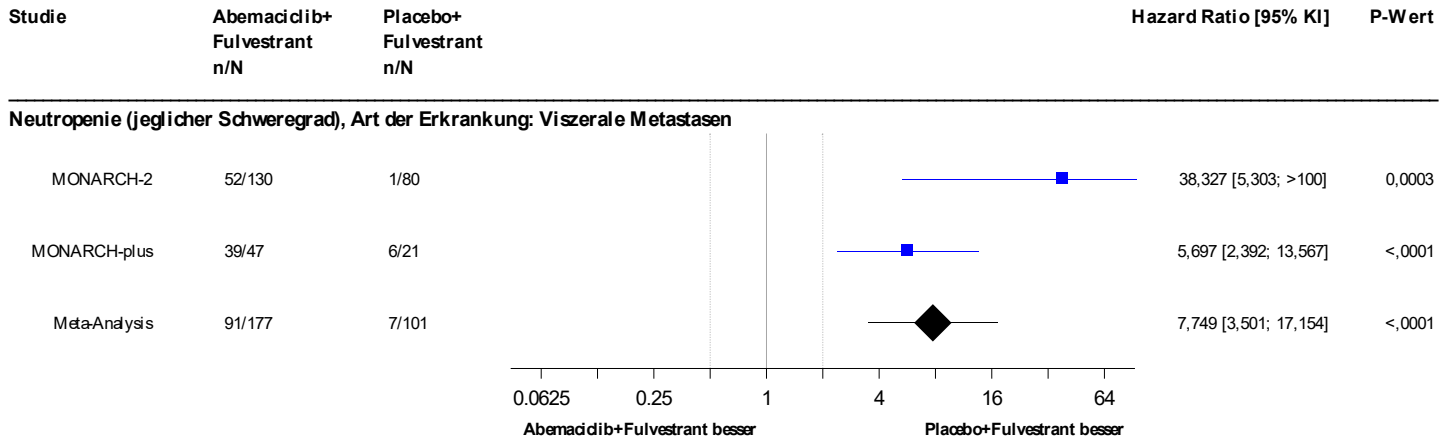
Abbildung 1424.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,9921, P-Wert=0,0837, I2 Index=66,6%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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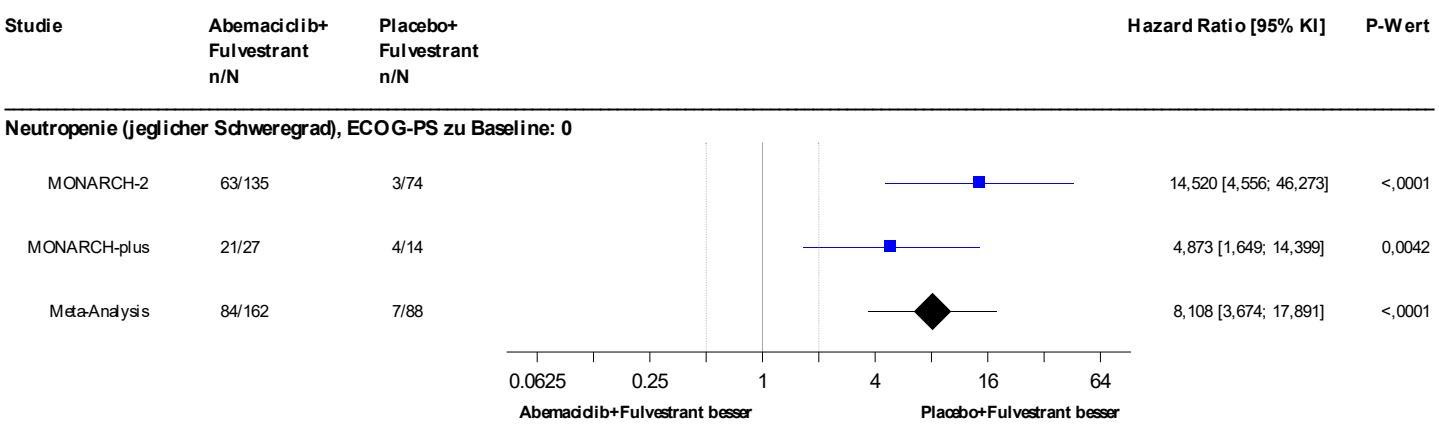
Abbildung 1424.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,8191, P-Wert=0,1774, I2 Index=45,0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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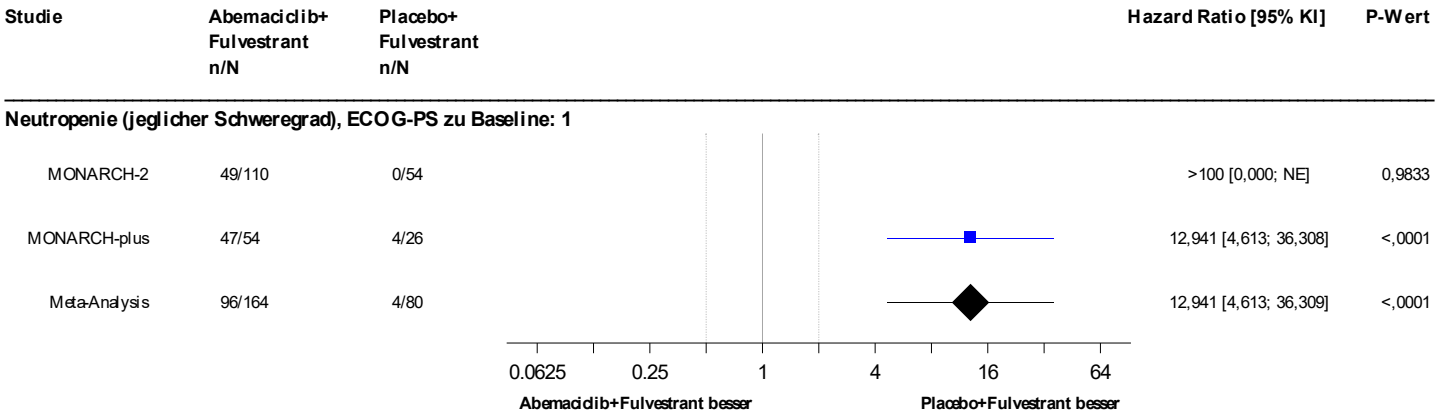
Abbildung 1424.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0003, P-Wert=0,9859, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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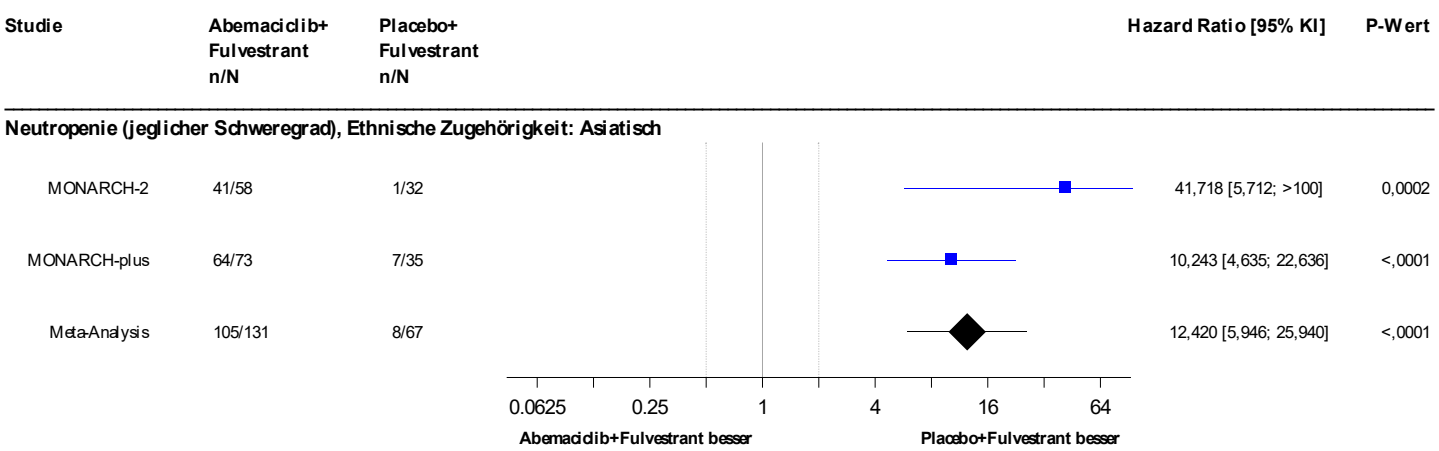
Abbildung 1424.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,6533, P-Wert=0,1985, I2 Index=39,5%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttnpaesi_popa1_racegr1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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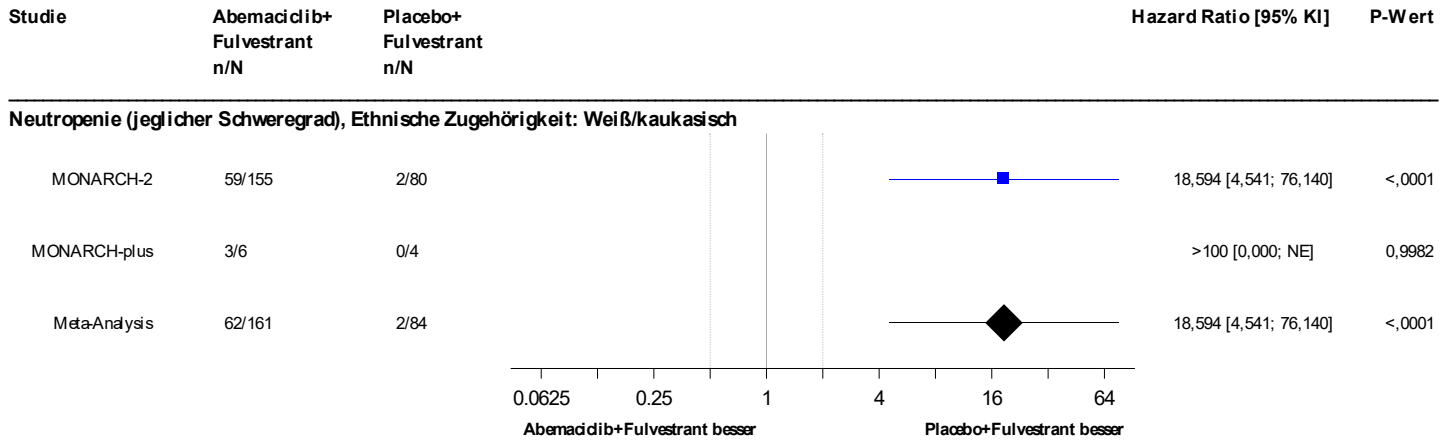
Abbildung 1424.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9985, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttnpaesi_popa1_racegr1_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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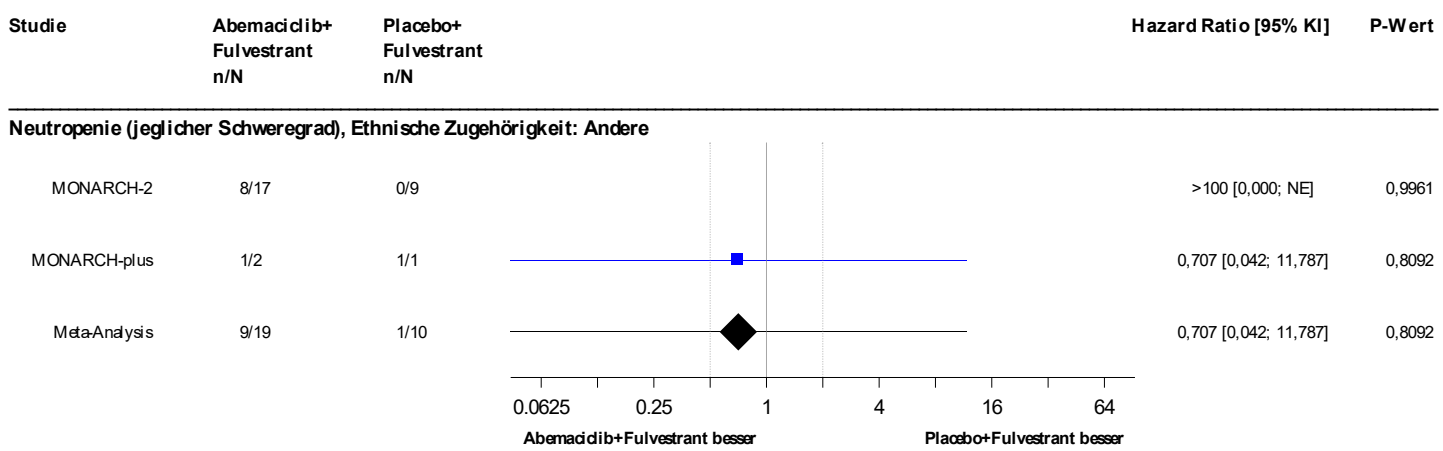
Abbildung 1424.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9961, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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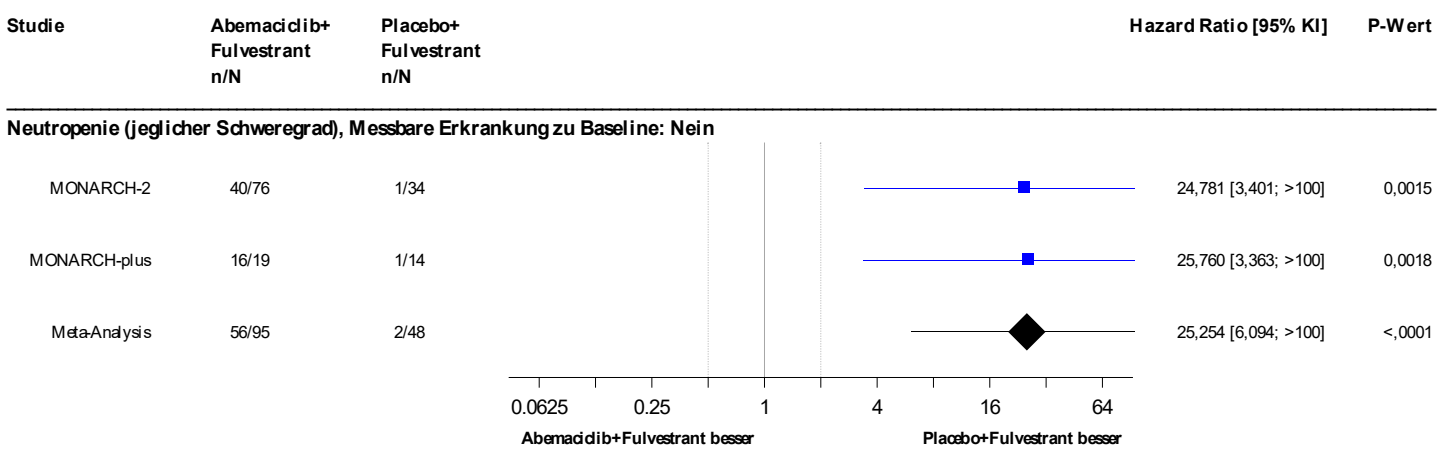
Abbildung 1424.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0007, P-Wert=0,9787, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttnpaesi_popa1_measdis_1.rtf
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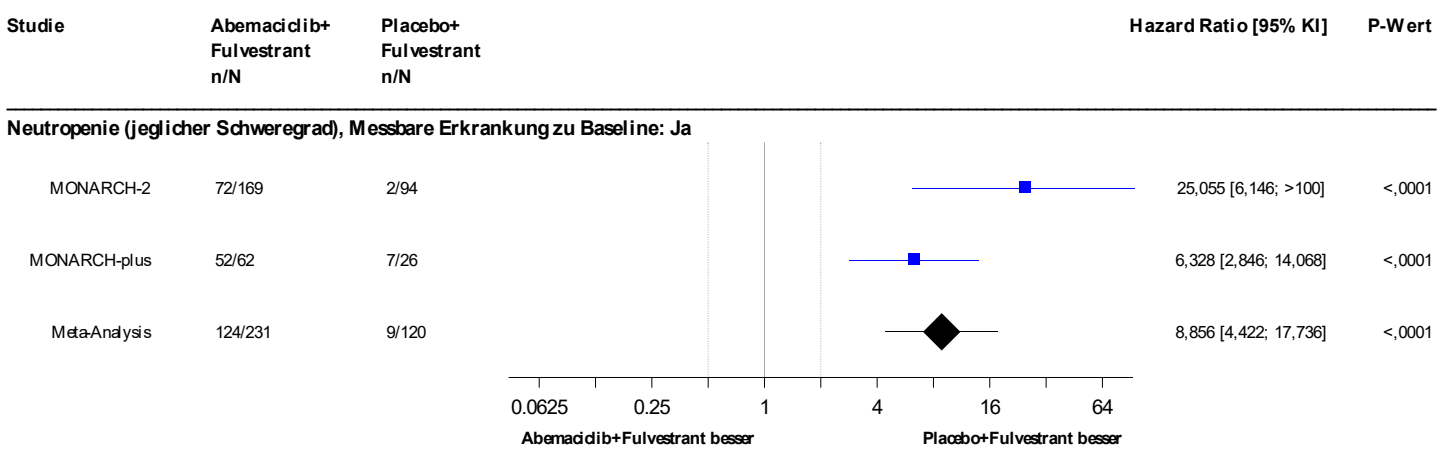
Abbildung 1424.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,7840, P-Wert=0,0952, I2 Index=64,1%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttnpaesi_popa1_measdis_2.rtf
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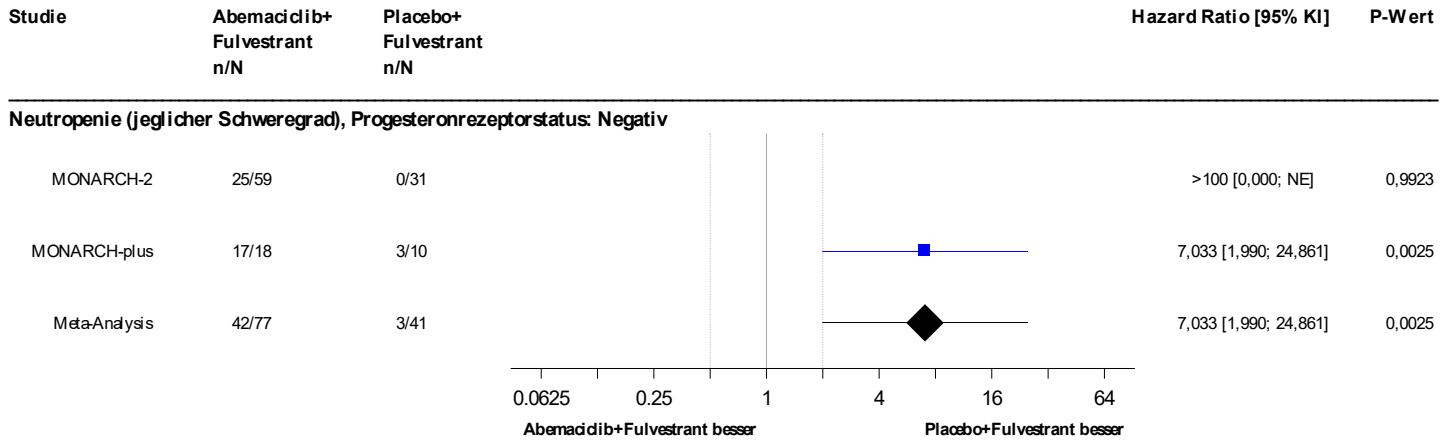
Abbildung 1424.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9932, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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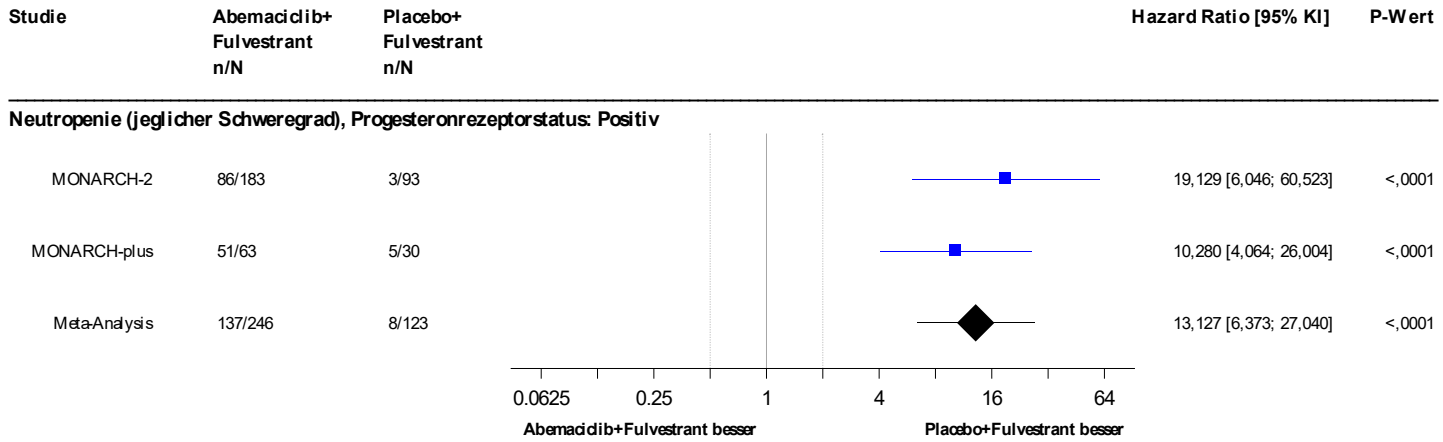
Abbildung 1424.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6770, P-Wert=0,4106, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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Abbildung 1424.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

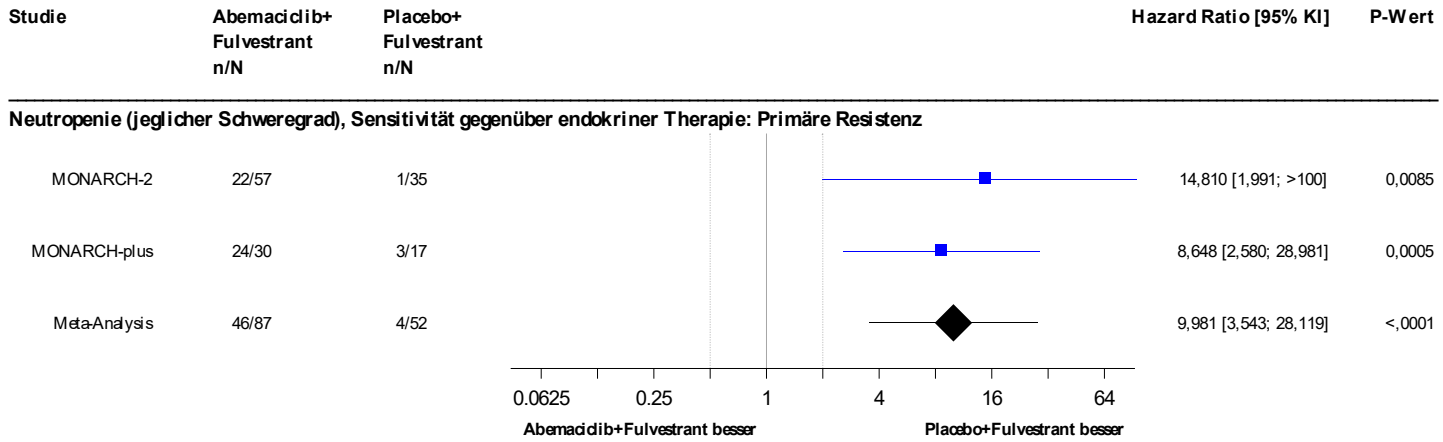

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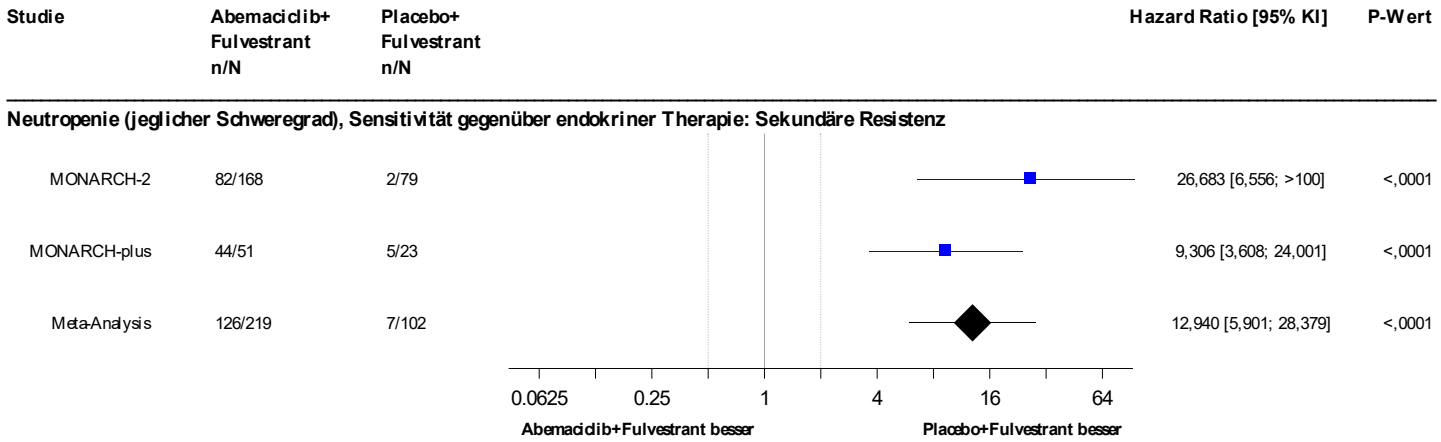
Abbildung 1424.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,4863, P-Wert=0,2228, I2 Index=32,7%
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Abbildung 1424.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

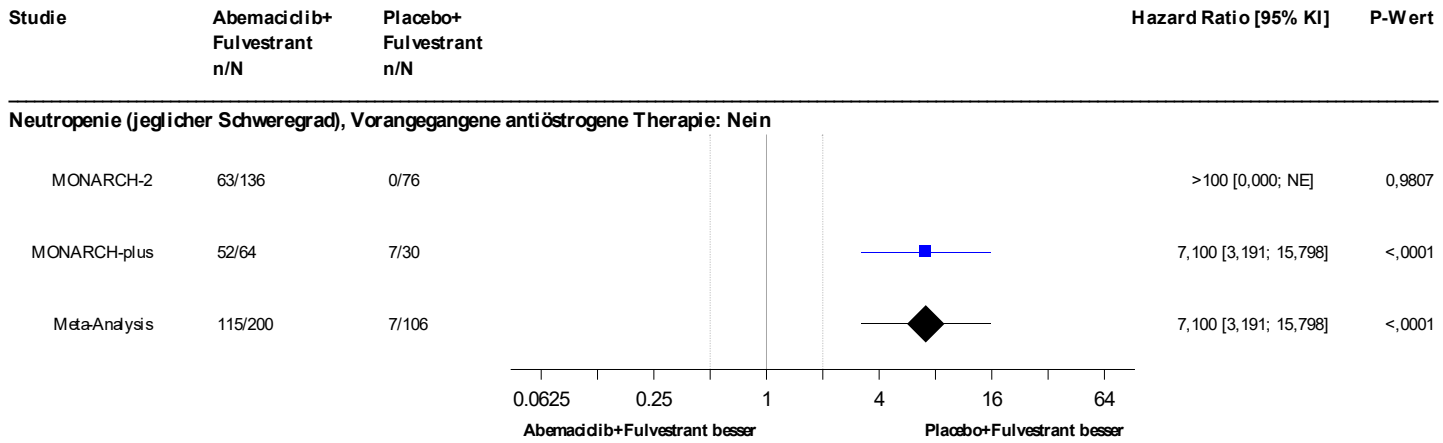

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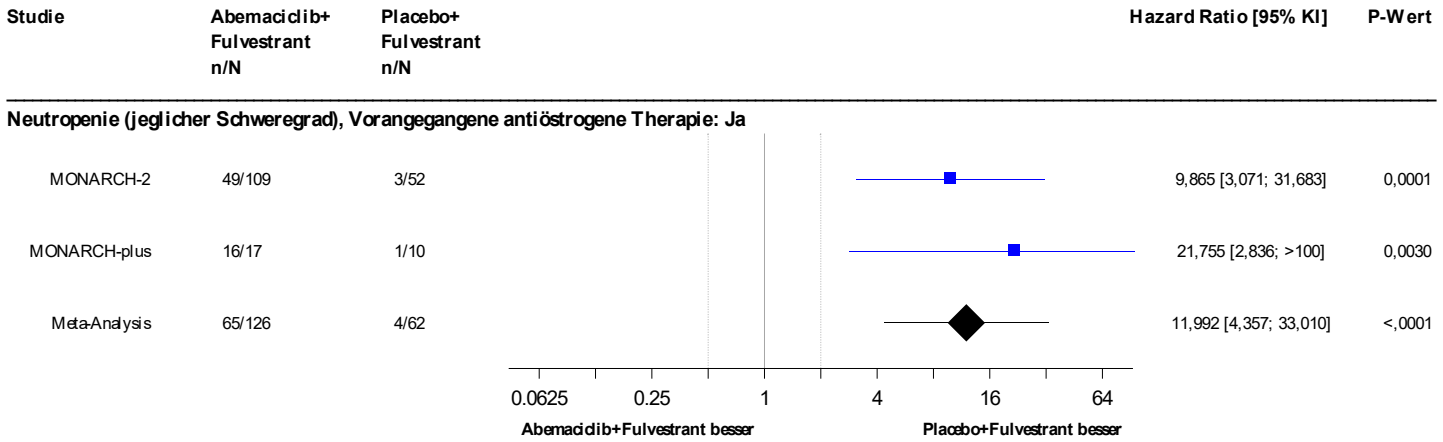
Abbildung 1424.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4359, P-Wert=0,5091, I2 Index=0%
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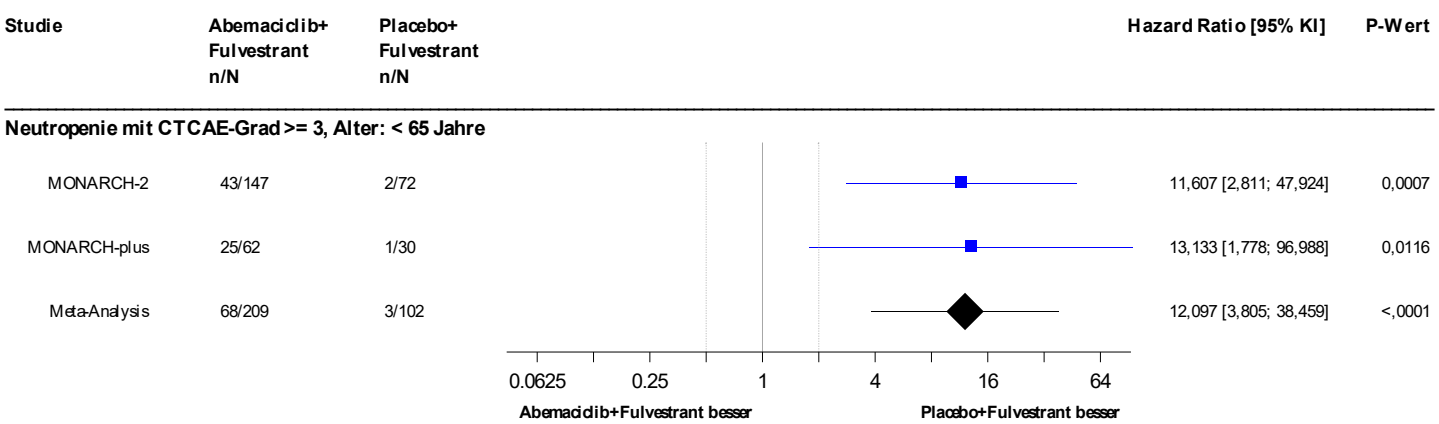
Abbildung 1425.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0098, P-Wert=0,9213, I2 Index=0%
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Abbildung 1425.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

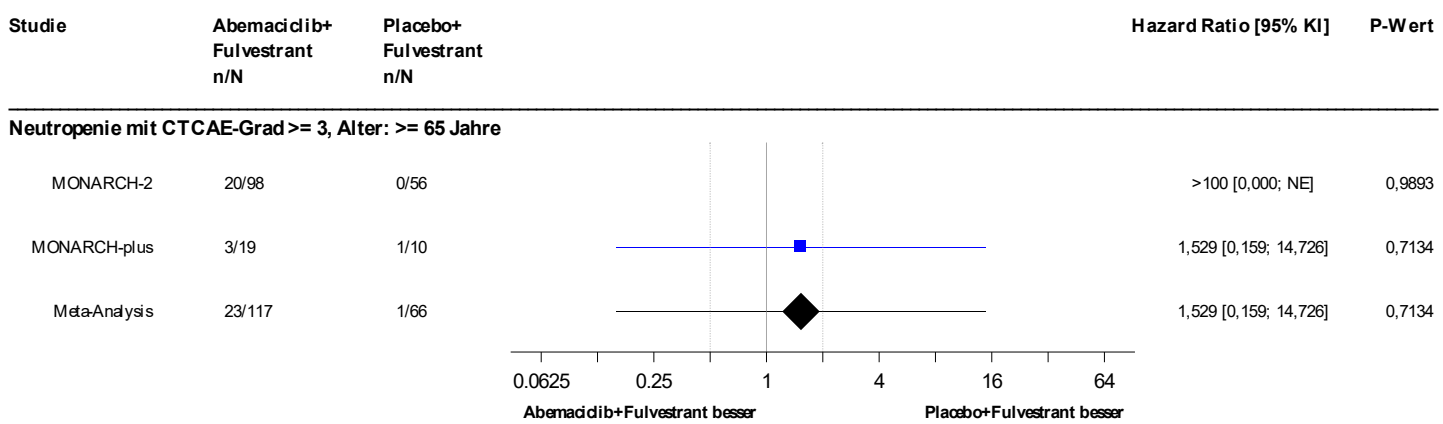

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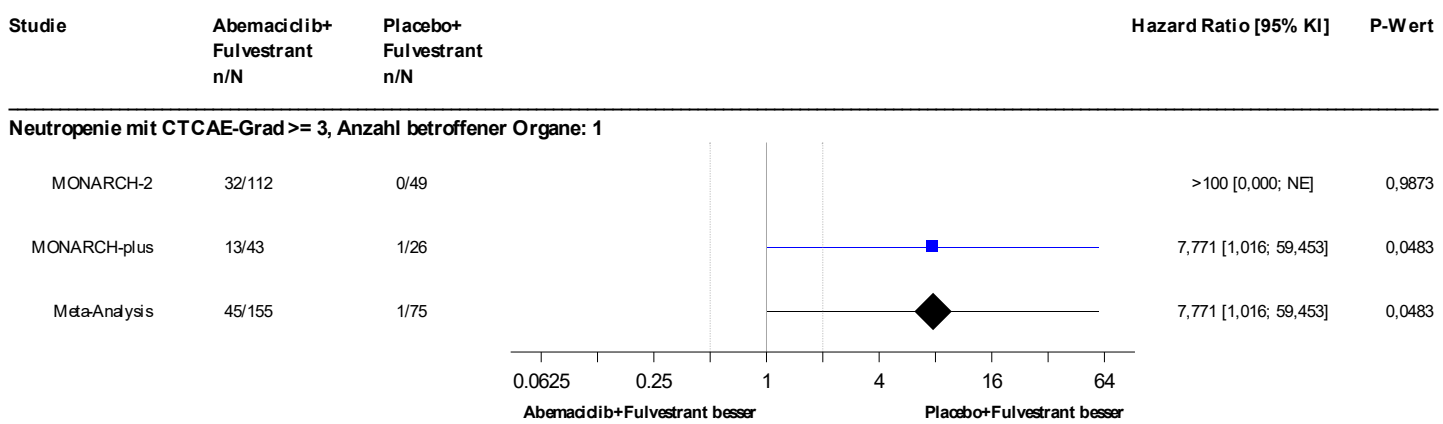
Abbildung 1425.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0002, P-Wert=0,9889, I2 Index=0%
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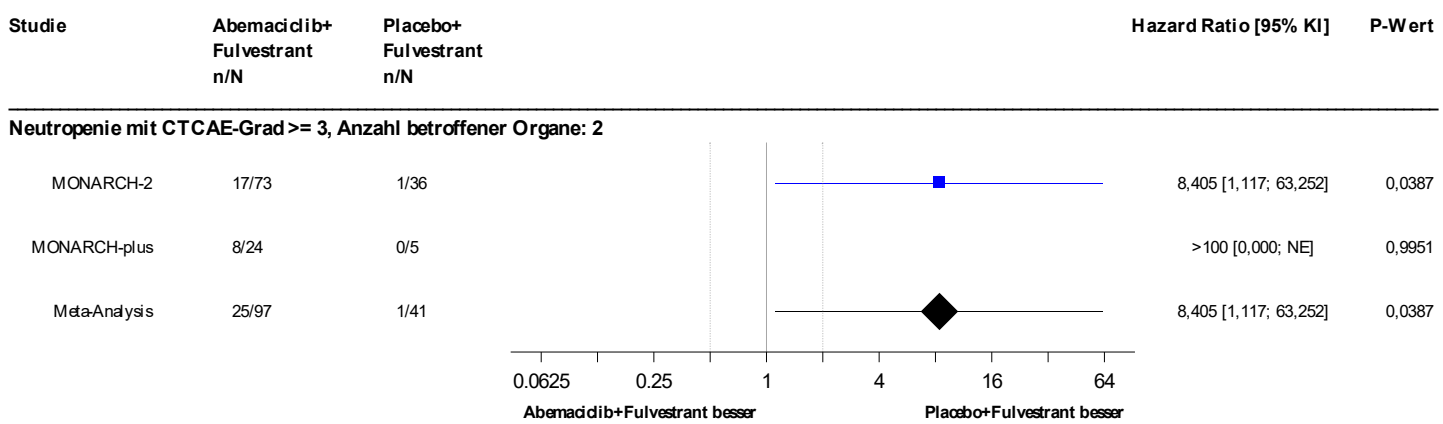
Abbildung 1425.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9958, I2 Index=0%
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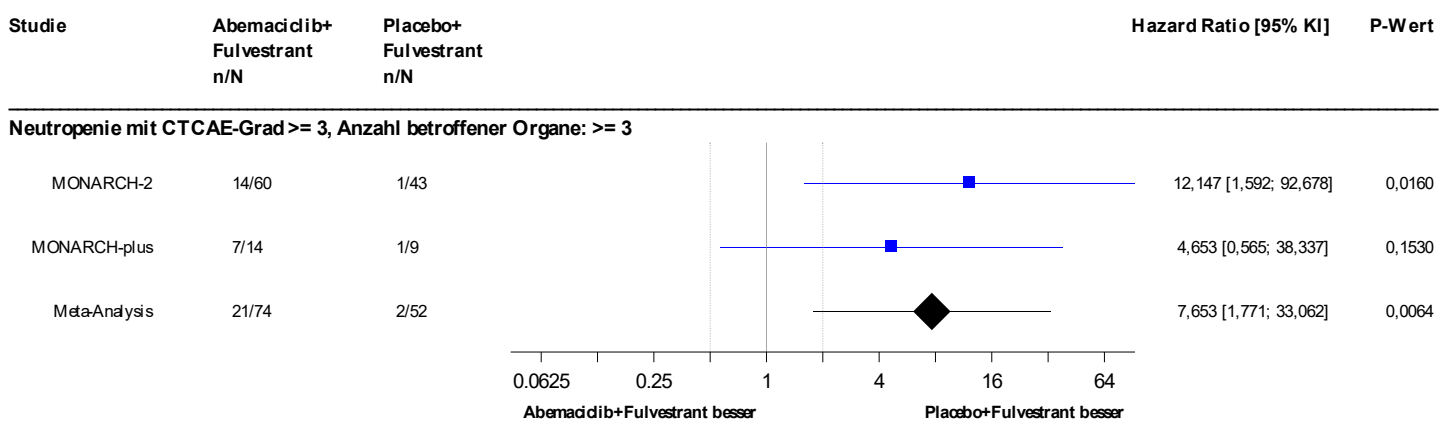
Abbildung 1425.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4124, P-Wert=0,5207, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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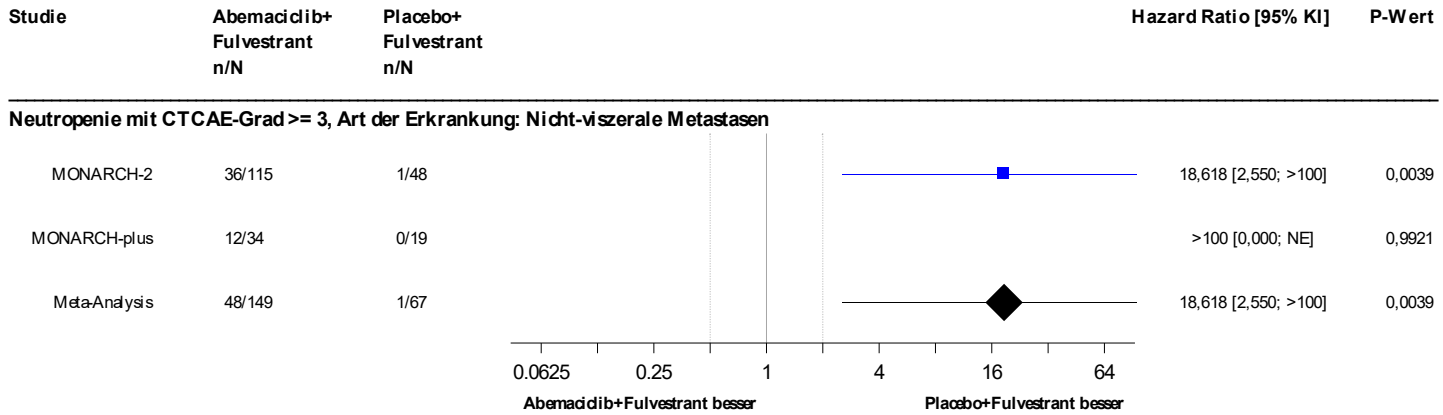
Abbildung 1425.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9935, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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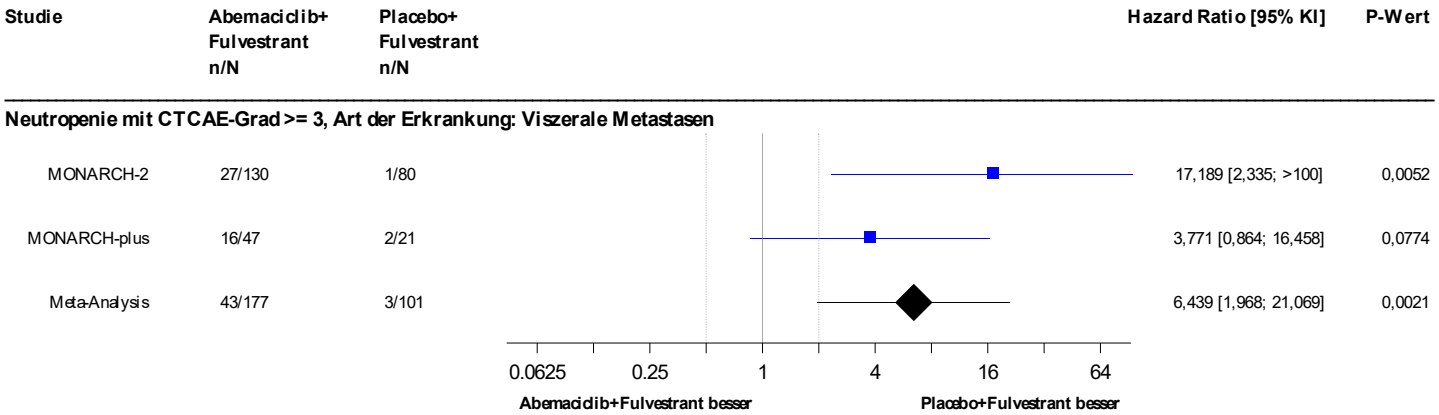
Abbildung 1425.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,4356, P-Wert=0,2308, I2 Index=30,3%
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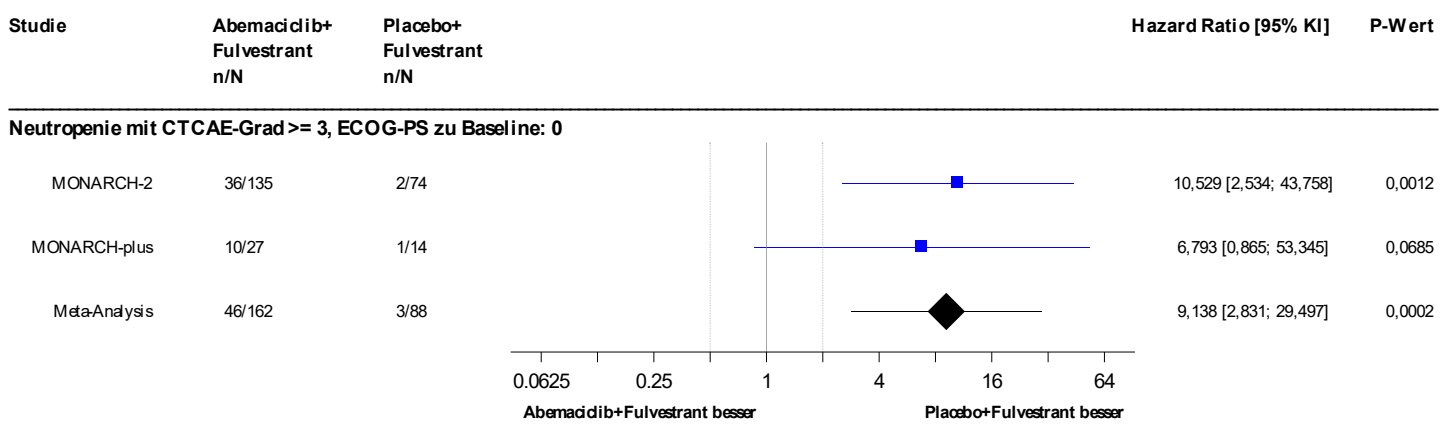
17SEP2021 / 07:48

Abbildung 1425.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1176, P-Wert=0,7317, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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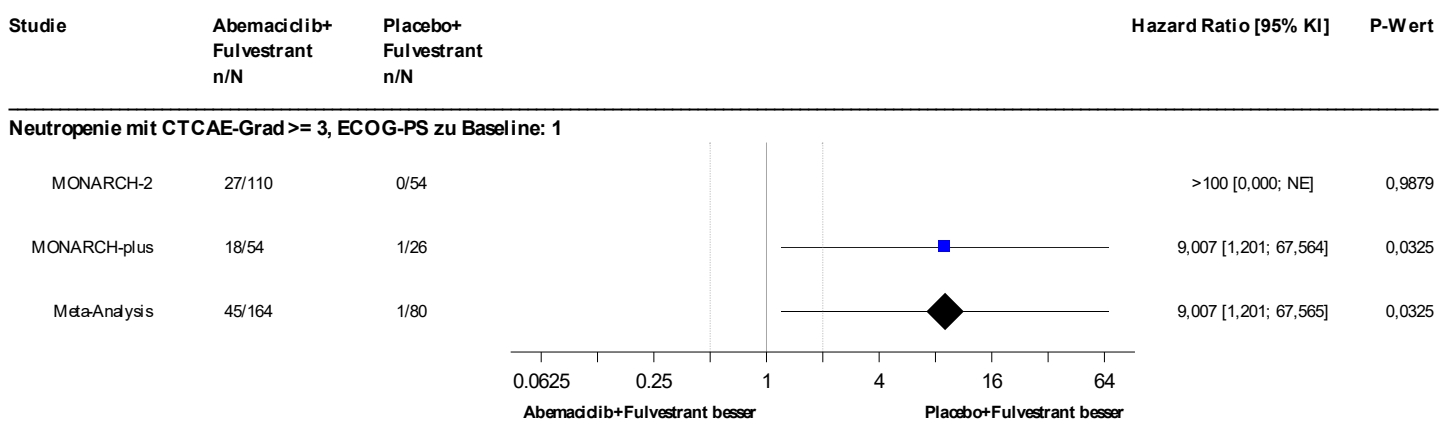
Abbildung 1425.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0002, P-Wert=0,9895, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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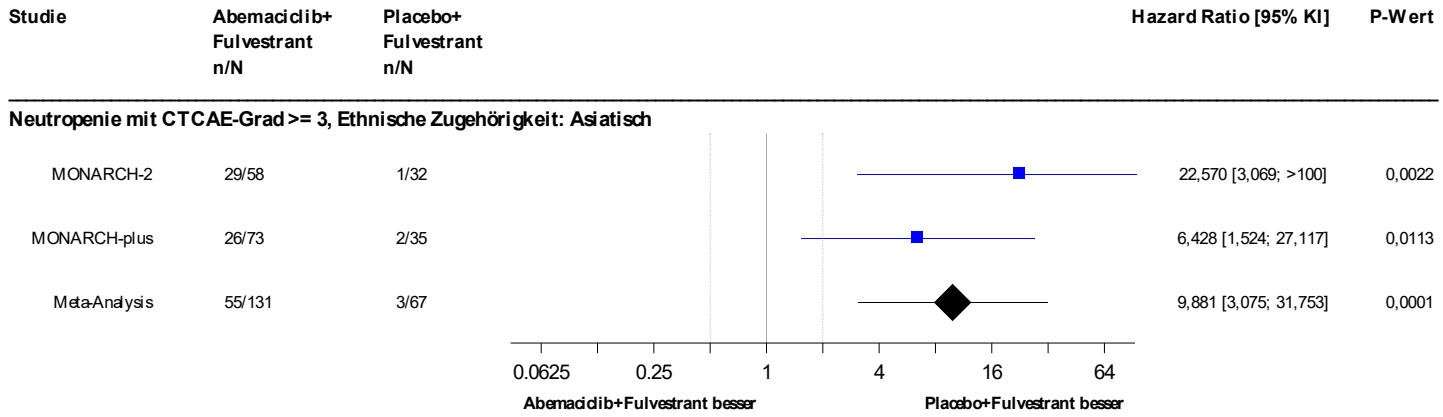
Abbildung 1425.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,0010, P-Wert=0,3171, I2 Index=0,1%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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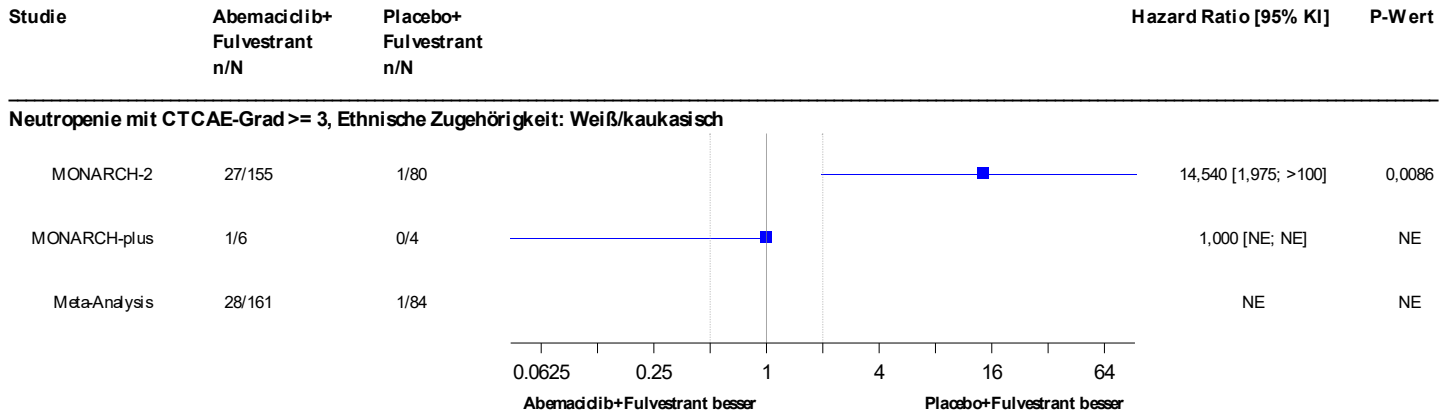
Abbildung 1425.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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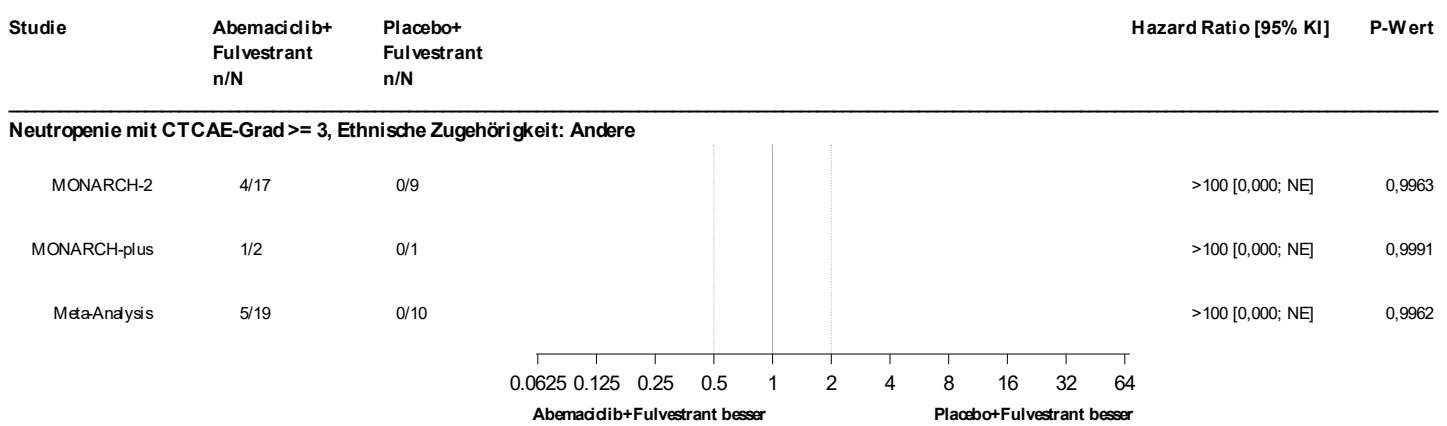
17SEP2021 / 07:48

Abbildung 1425.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Abbildung 1425.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

Studie	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% KI]	P-Wert
Neutropenie mit CTCAE-Grad >= 3, Messbare Erkrankung zu Baseline: Nein				
MONARCH-2	23/76	0/34	>100 [0,000; NE]	0,9891
MONARCH-plus	7/19	0/14	>100 [0,000; NE]	0,9963
Meta-Analysis	30/95	0/48	>100 [0,000; NE]	0,9884

Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9998, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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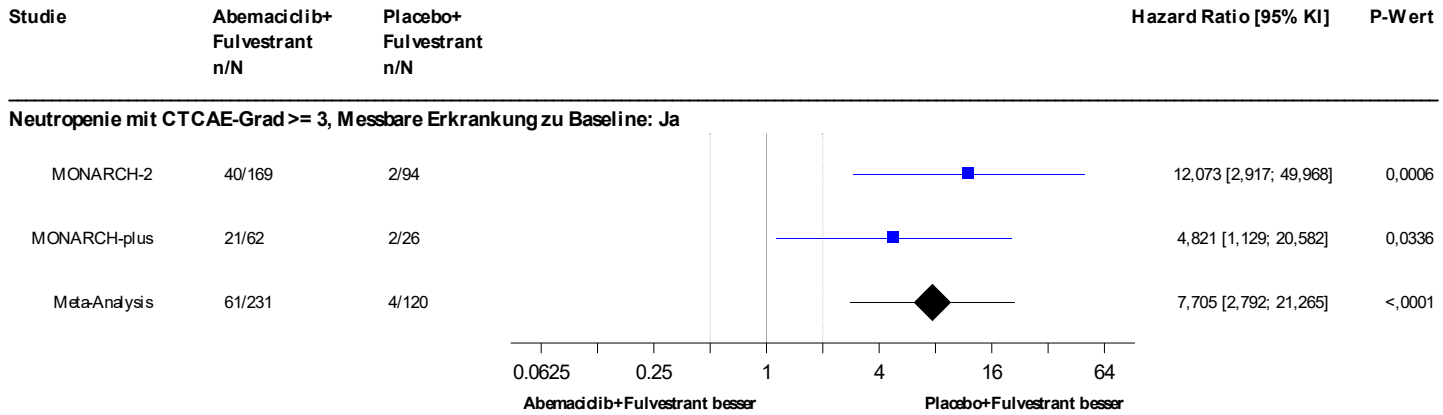
Abbildung 1425.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7849, P-Wert=0,3756, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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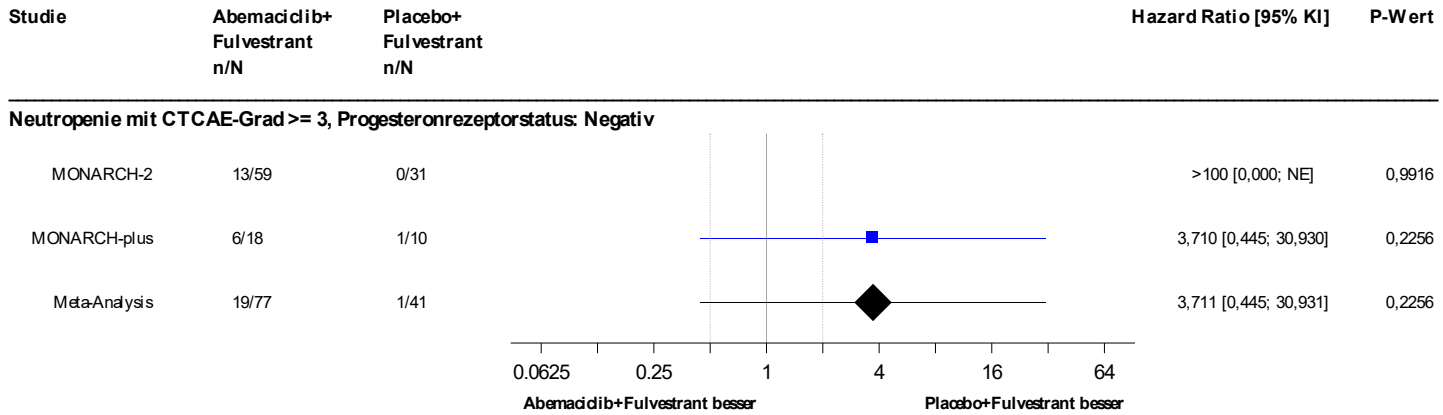
Abbildung 1425.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9923, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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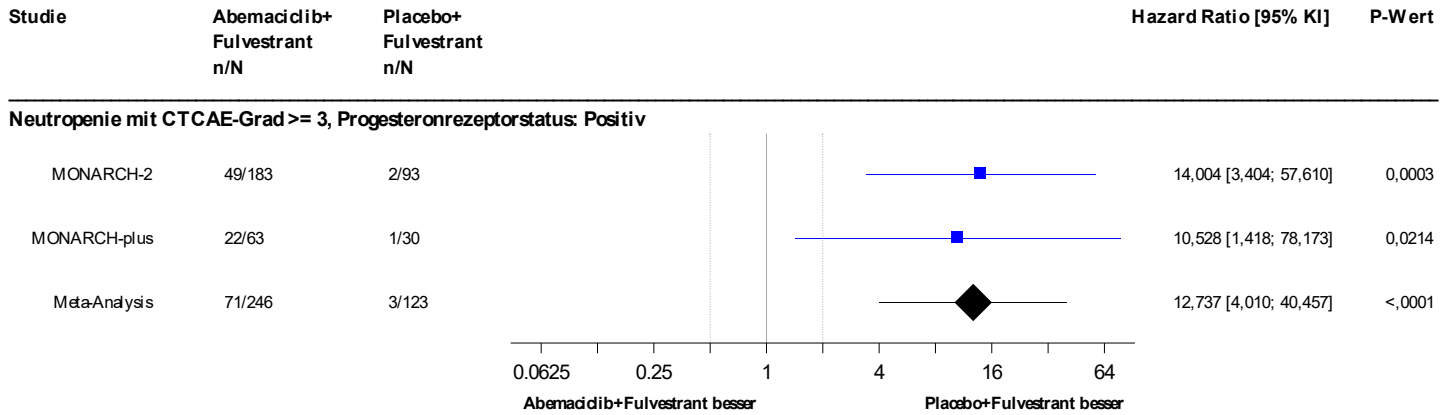
Abbildung 1425.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0519, P-Wert=0,8197, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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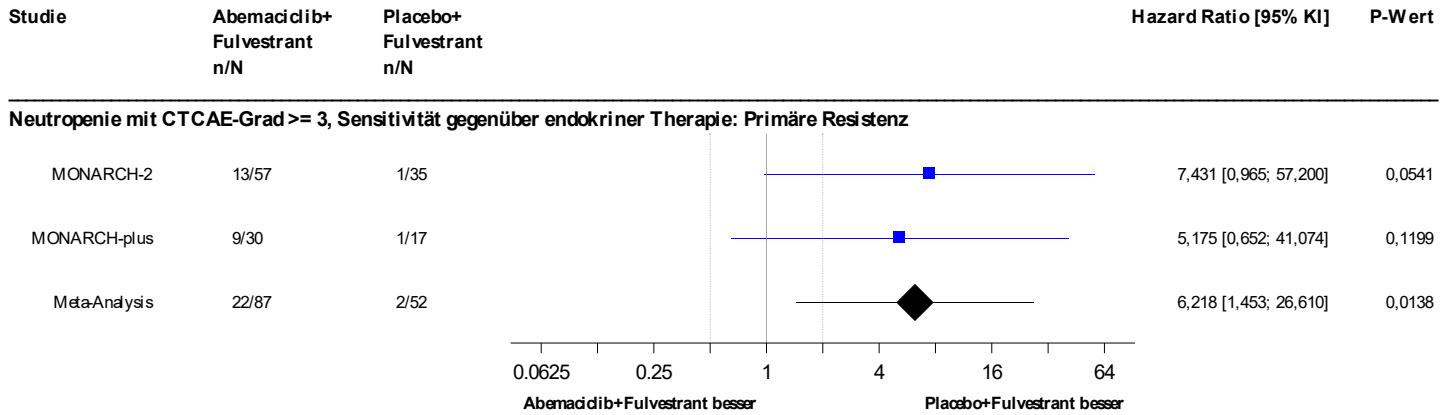
Abbildung 1425.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0595, P-Wert=0,8074, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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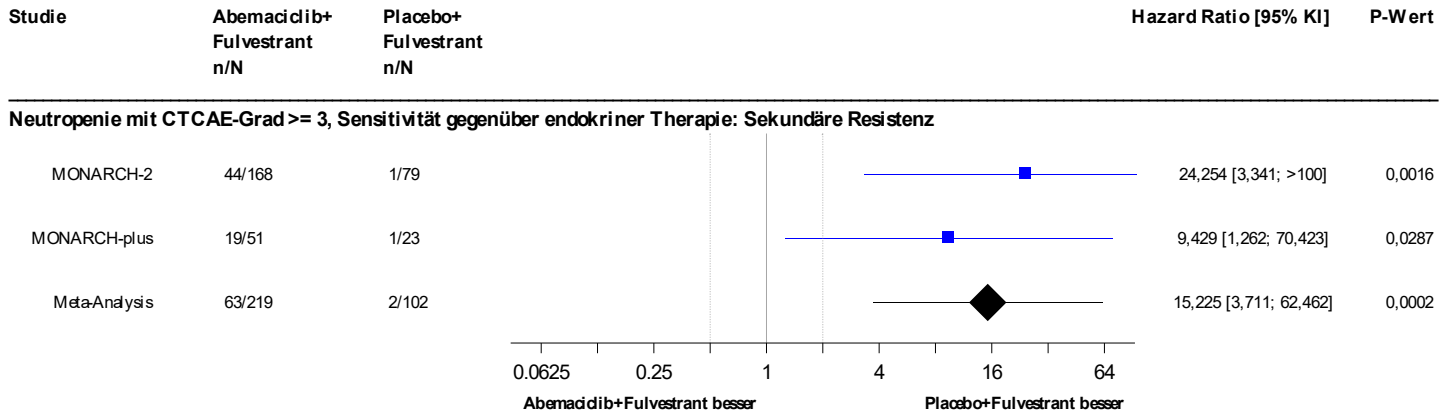
Abbildung 1425.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4301, P-Wert=0,5119, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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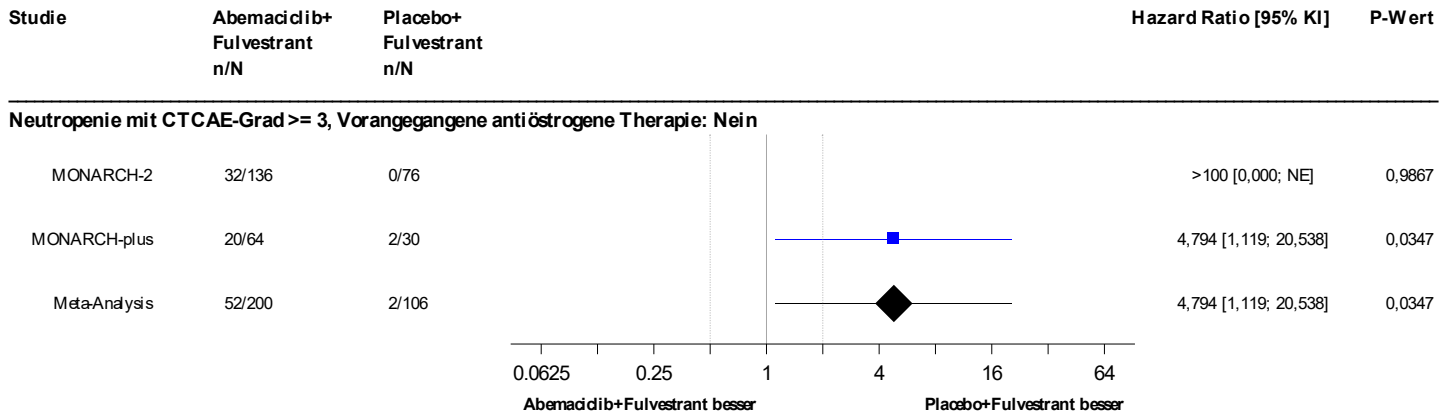
Abbildung 1425.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0002, P-Wert=0,9879, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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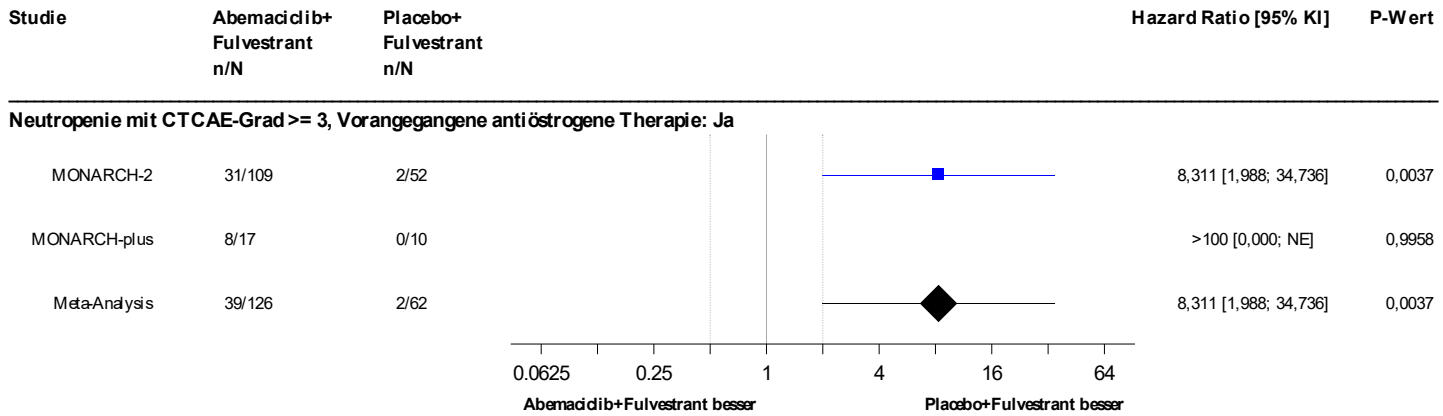
Abbildung 1425.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9963, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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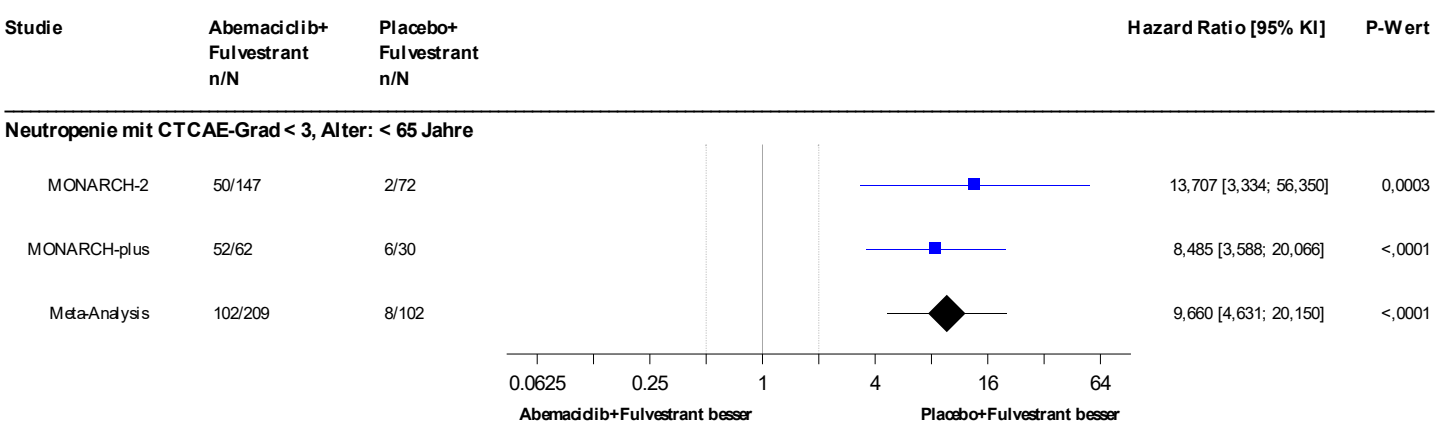
Abbildung 1426.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3226, P-Wert=0,5700, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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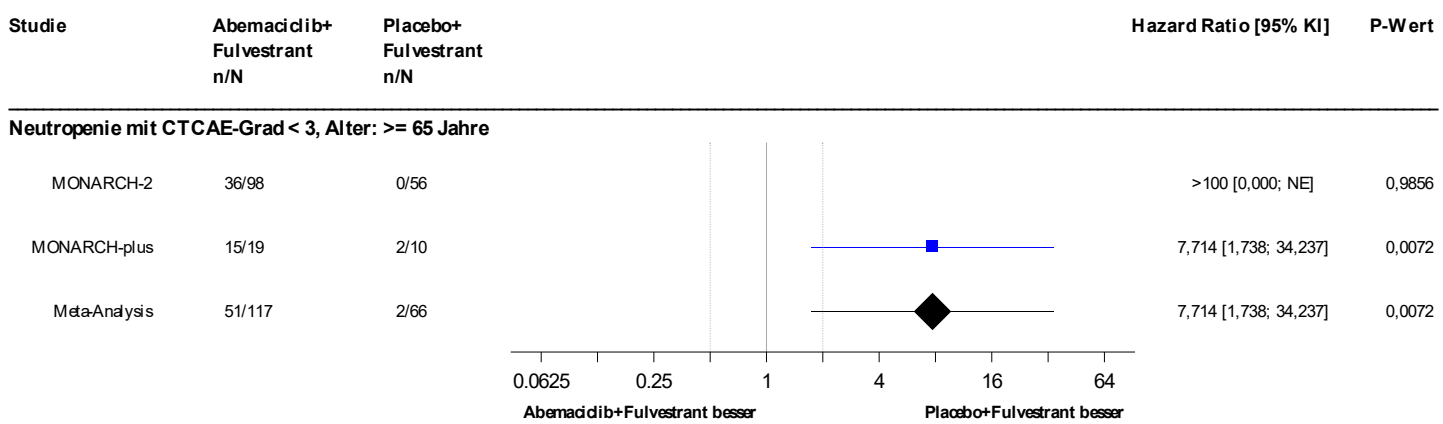
17SEP2021 / 07:48

Abbildung 1426.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0003, P-Wert=0,9874, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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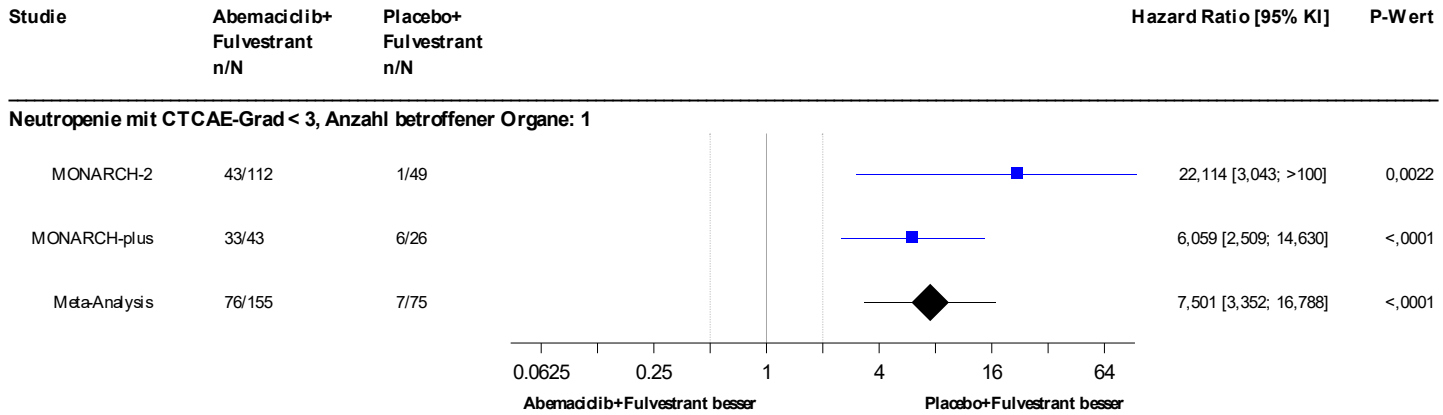
17SEP2021 / 07:48

Abbildung 1426.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,3669, P-Wert=0,2423, I2 Index=26,8%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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17SEP2021 / 07:48

Abbildung 1426.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

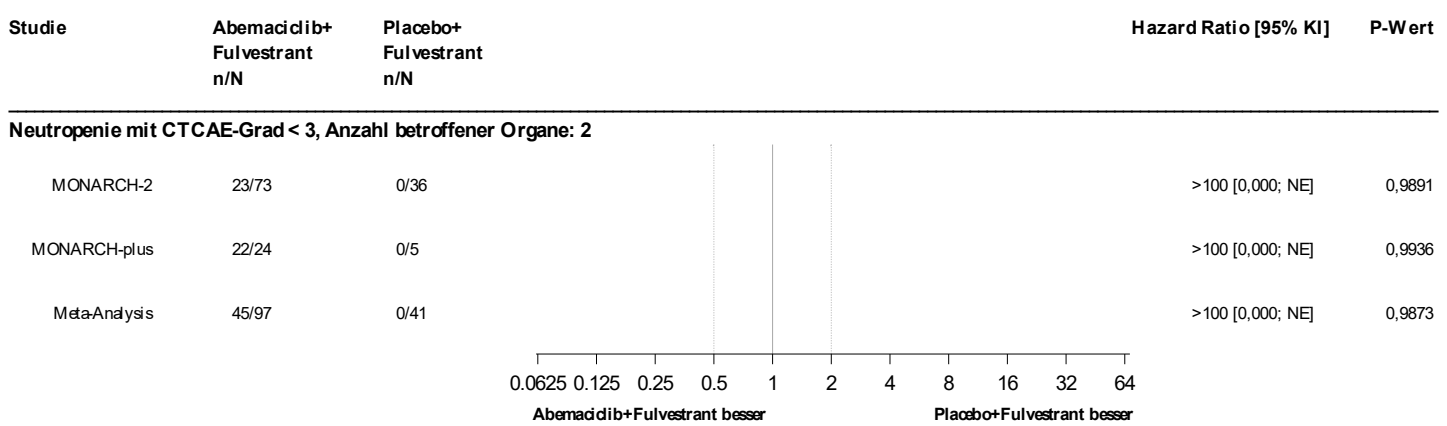

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Abbildung 1426.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

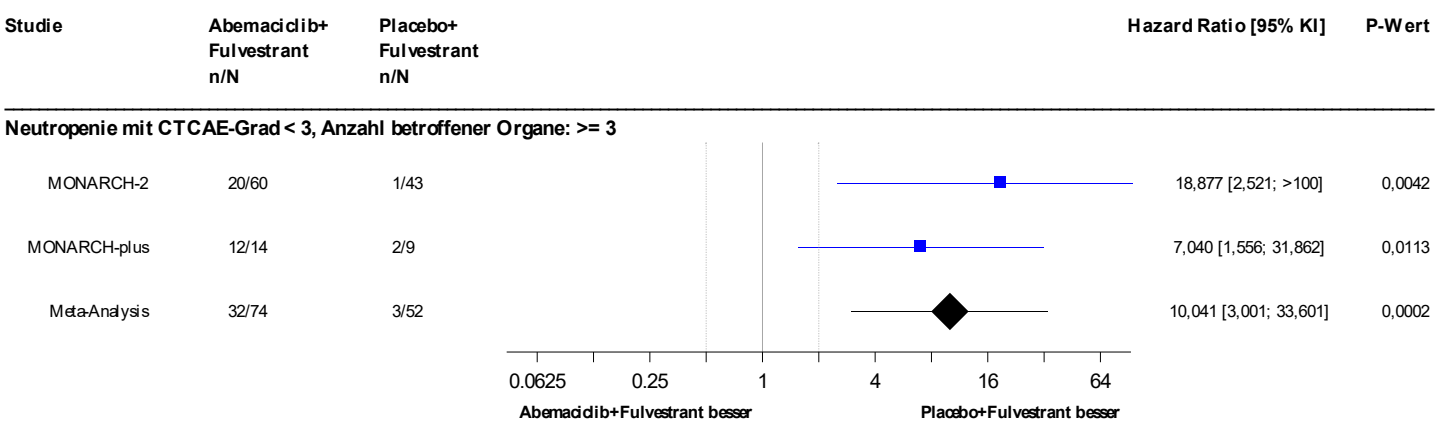

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Abbildung 1426.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

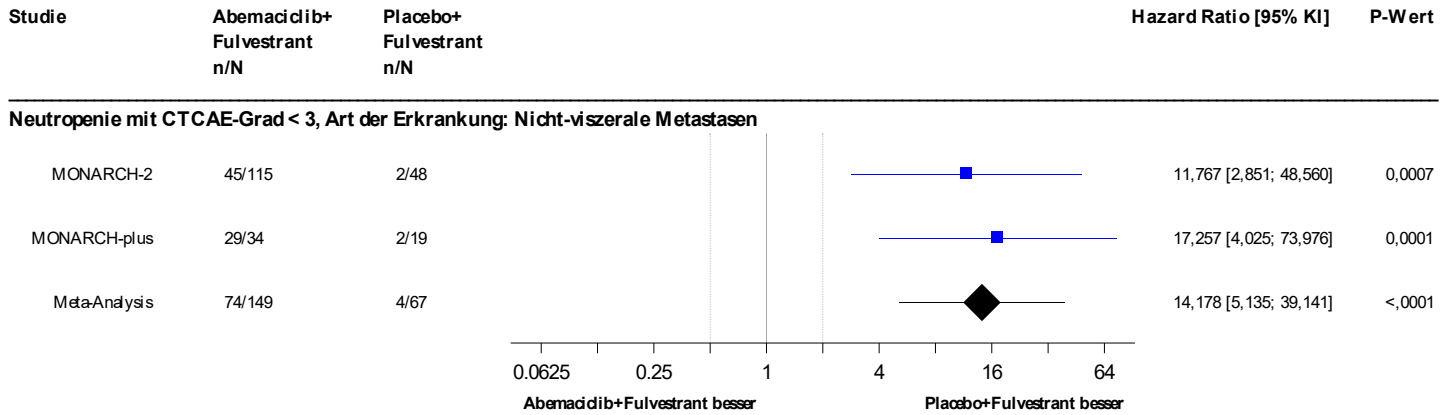

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Abbildung 1426.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

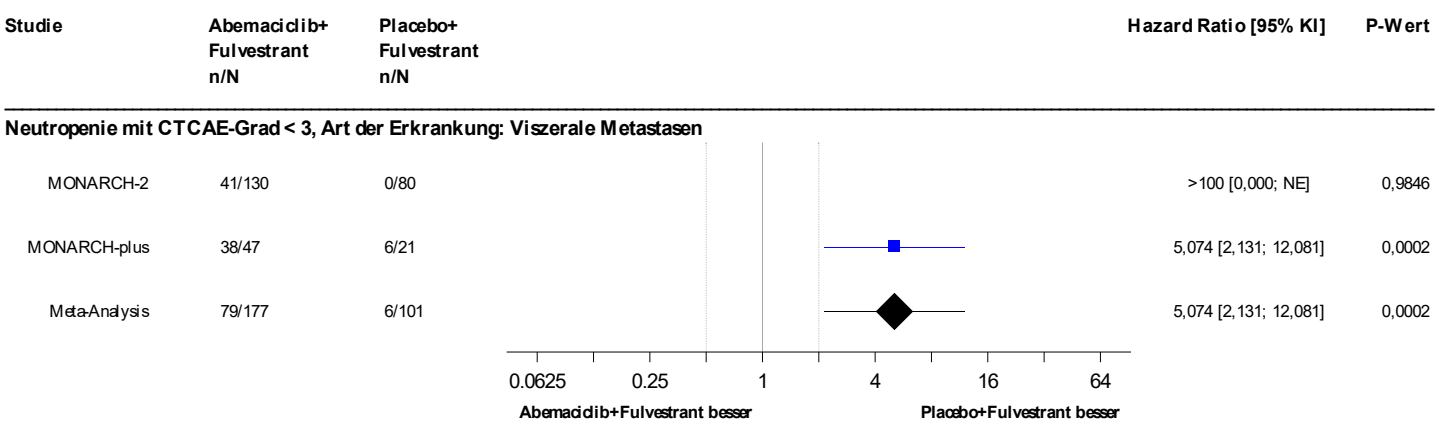

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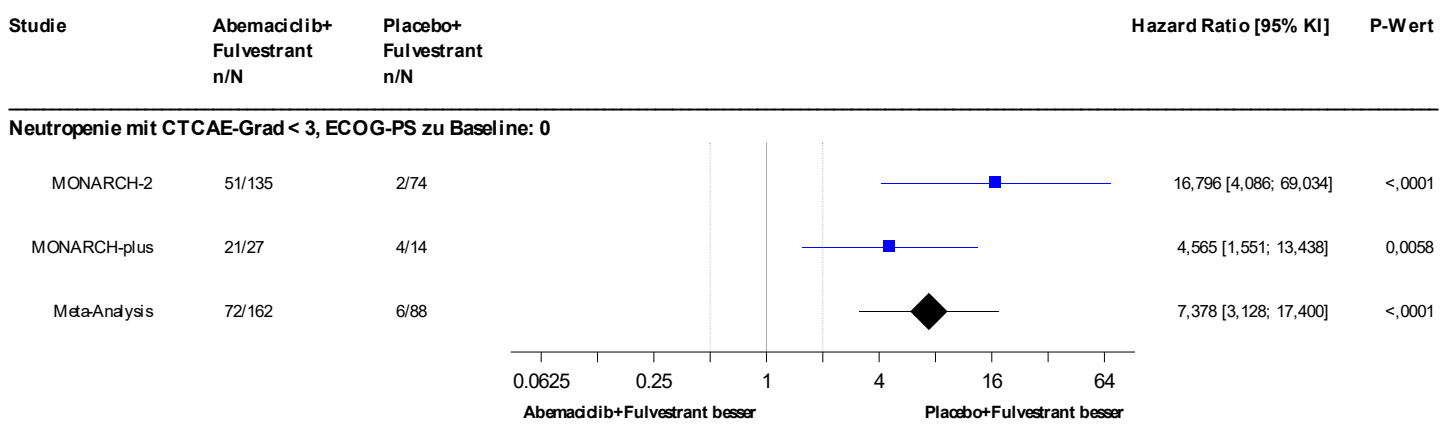
Abbildung 1426.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,0608, P-Wert=0,1511, I2 Index=51,5%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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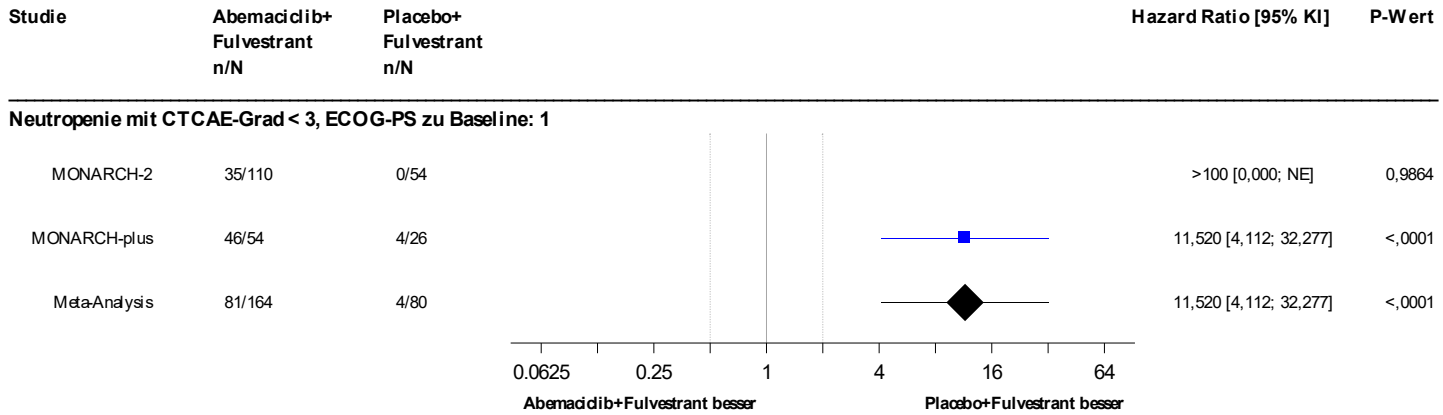
Abbildung 1426.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0002, P-Wert=0,9884, I2 Index=0%
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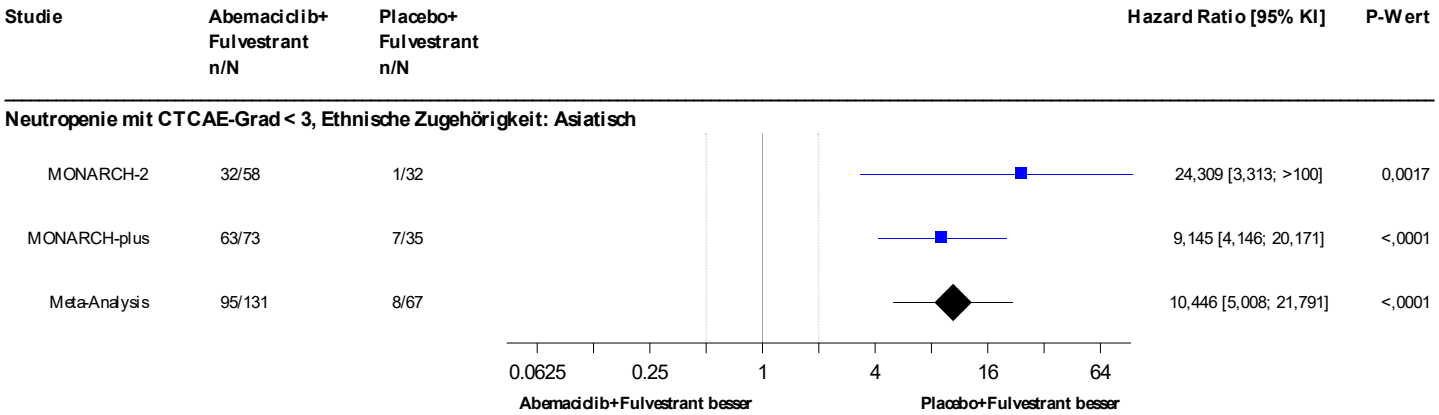
Abbildung 1426.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7986, P-Wert=0,3715, I2 Index=0%
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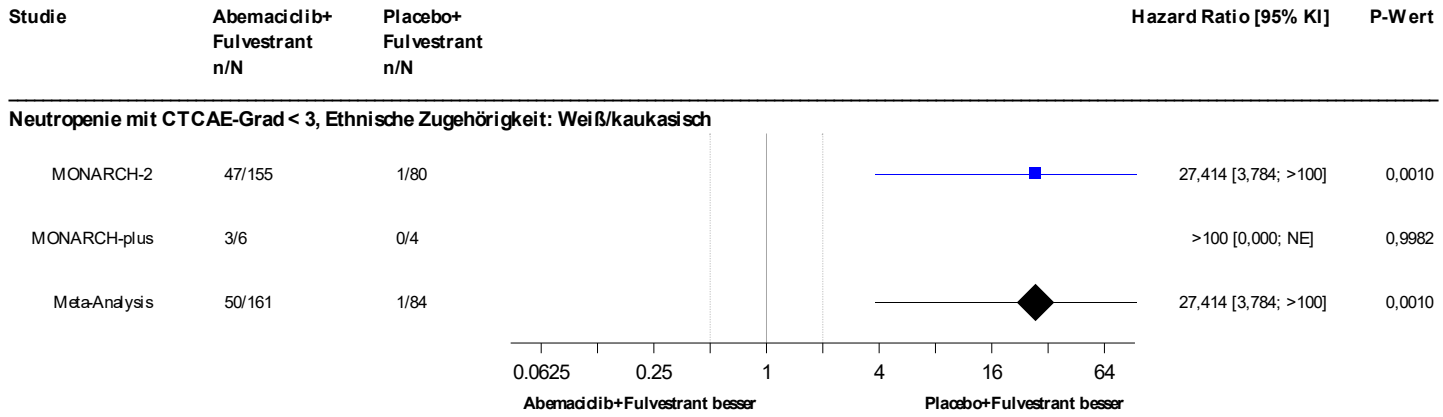
Abbildung 1426.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9985, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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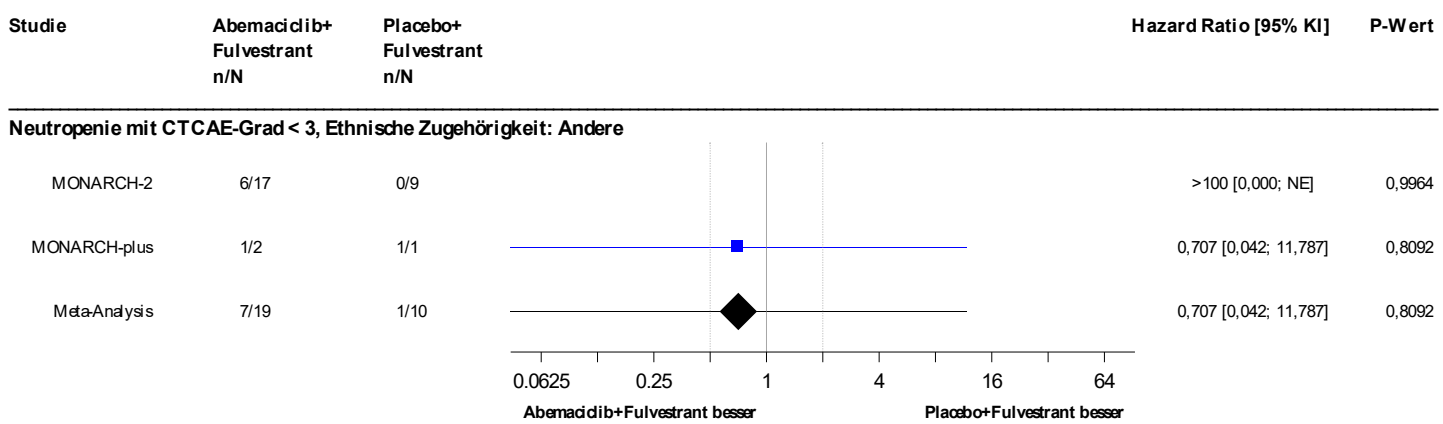
Abbildung 1426.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



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17SEP2021 / 07:48

Abbildung 1426.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

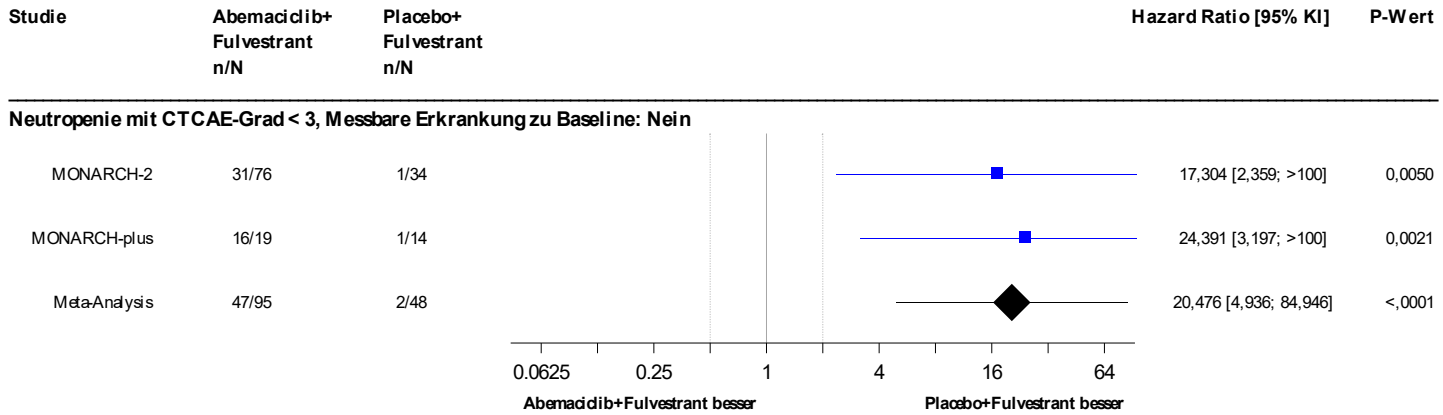

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Abbildung 1426.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

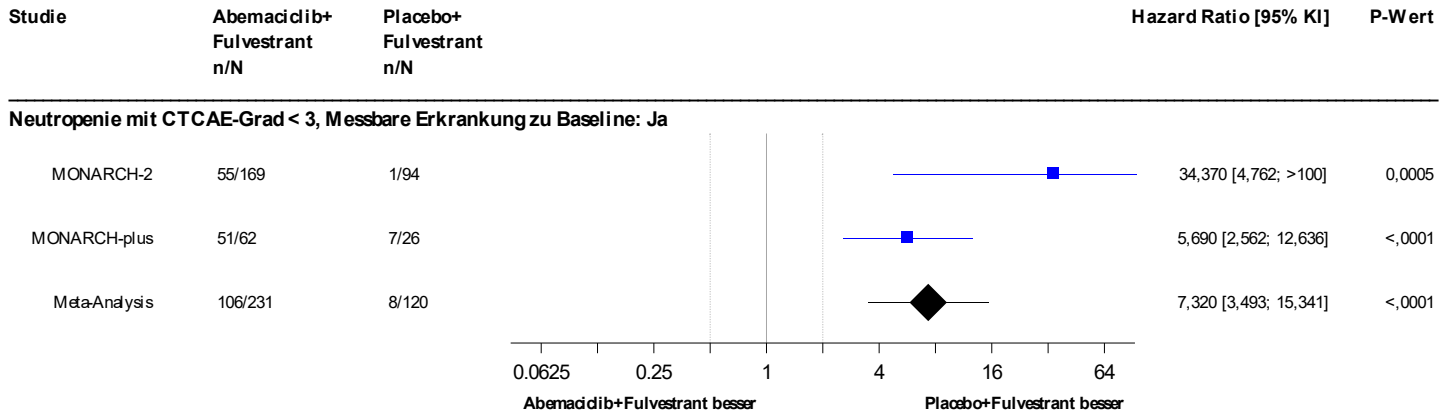

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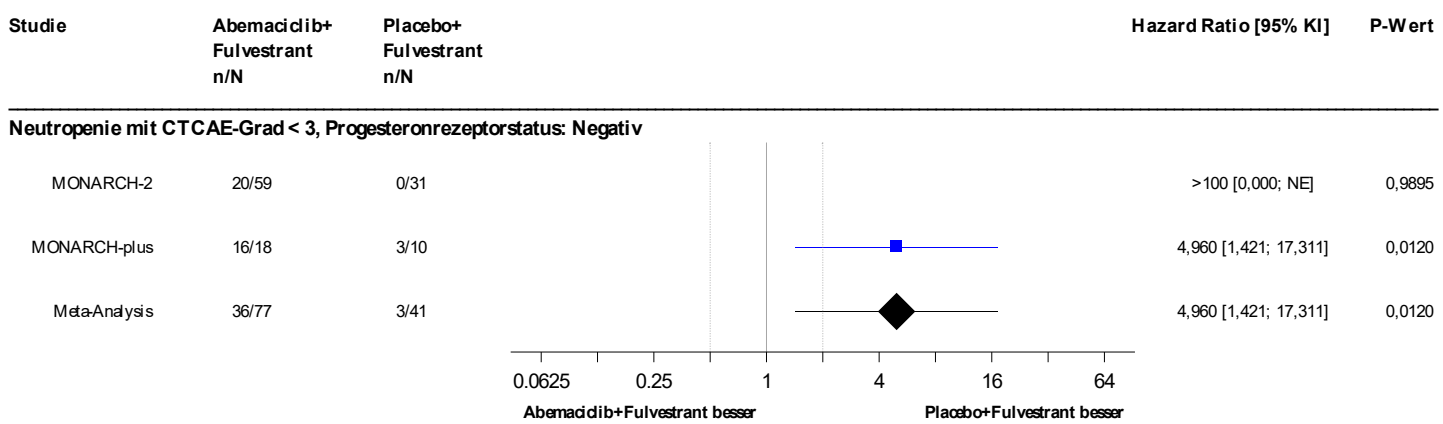
Abbildung 1426.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



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17SEP2021 / 07:48

Abbildung 1426.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

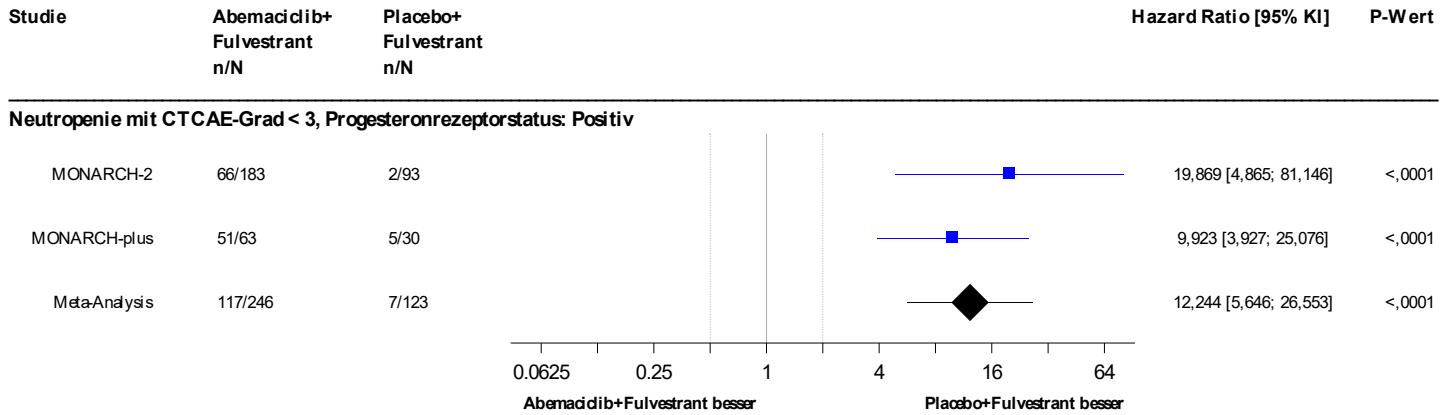

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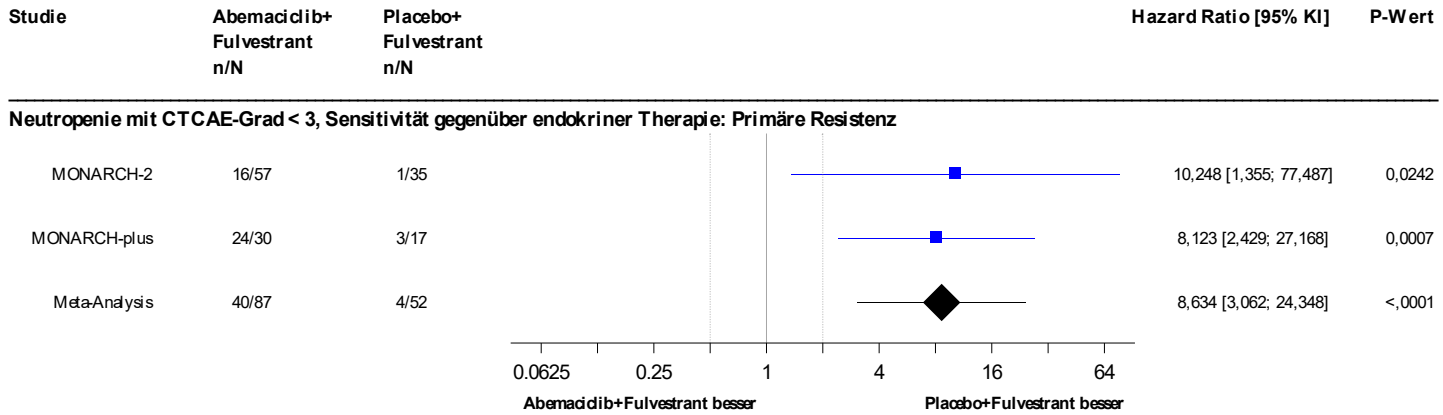
Abbildung 1426.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0374, P-Wert=0,8467, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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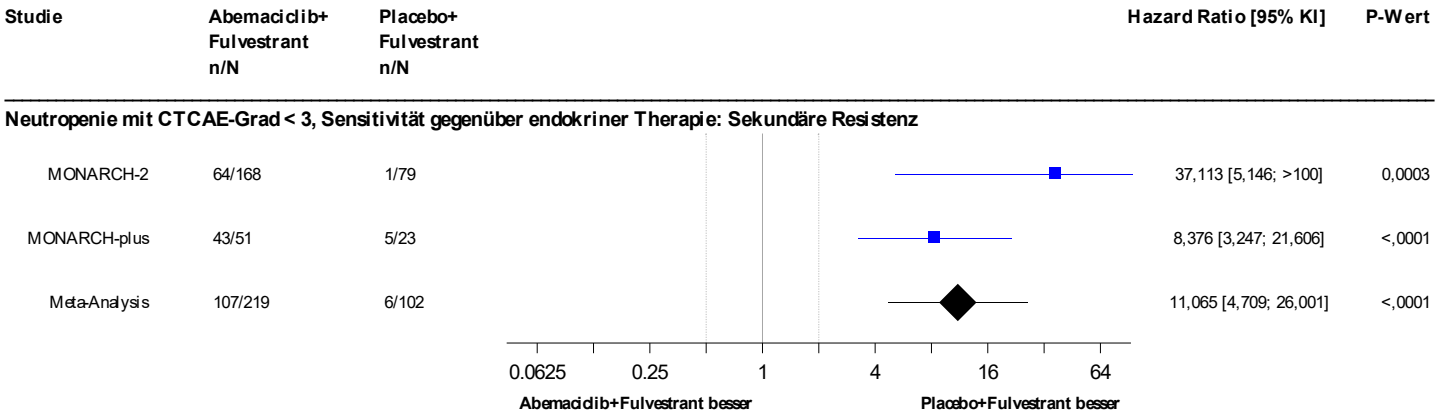
Abbildung 1426.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,7728, P-Wert=0,1830, I2 Index=43,6%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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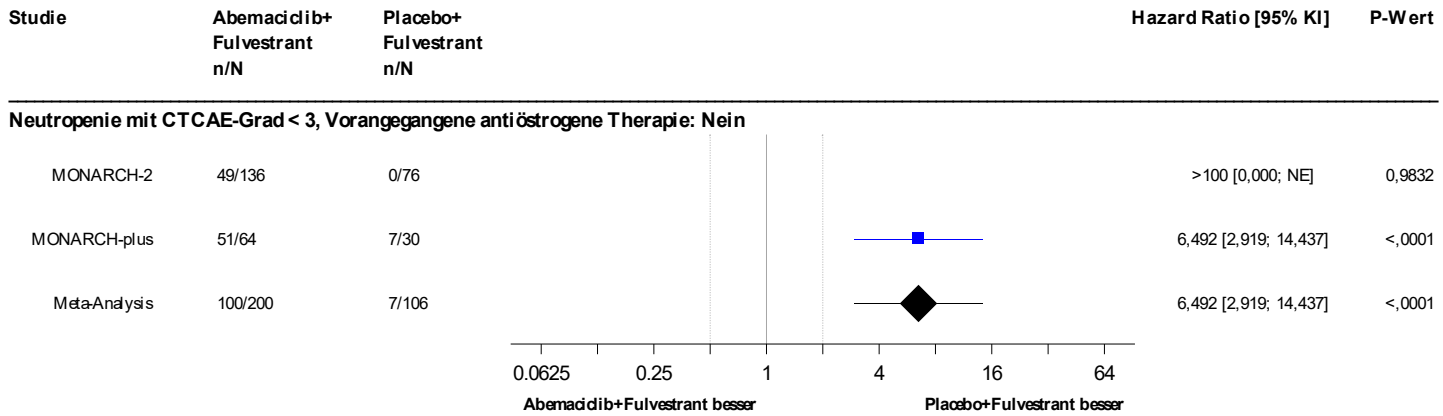
Abbildung 1426.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0003, P-Wert=0,9851, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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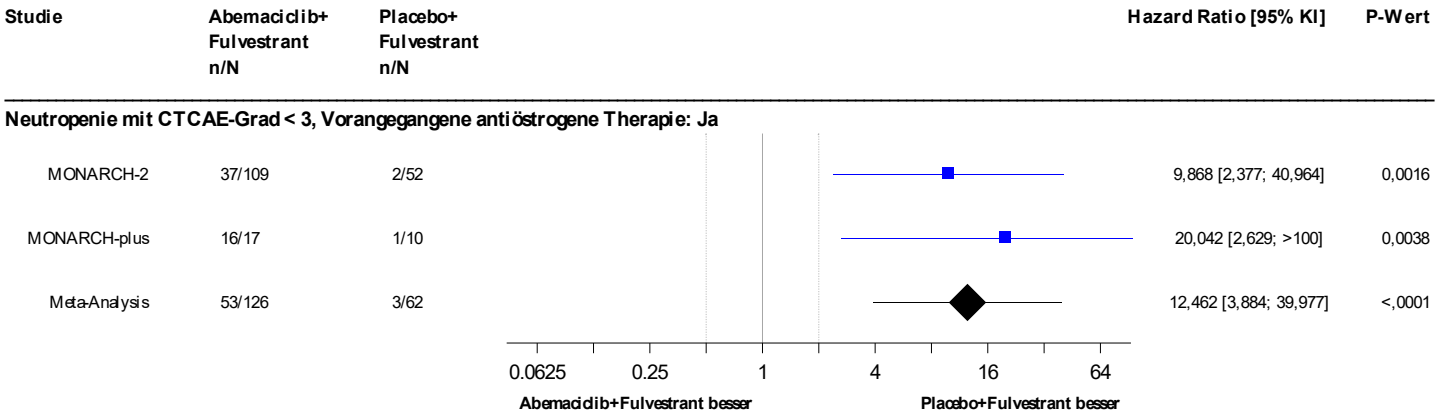
Abbildung 1426.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3134, P-Wert=0,5756, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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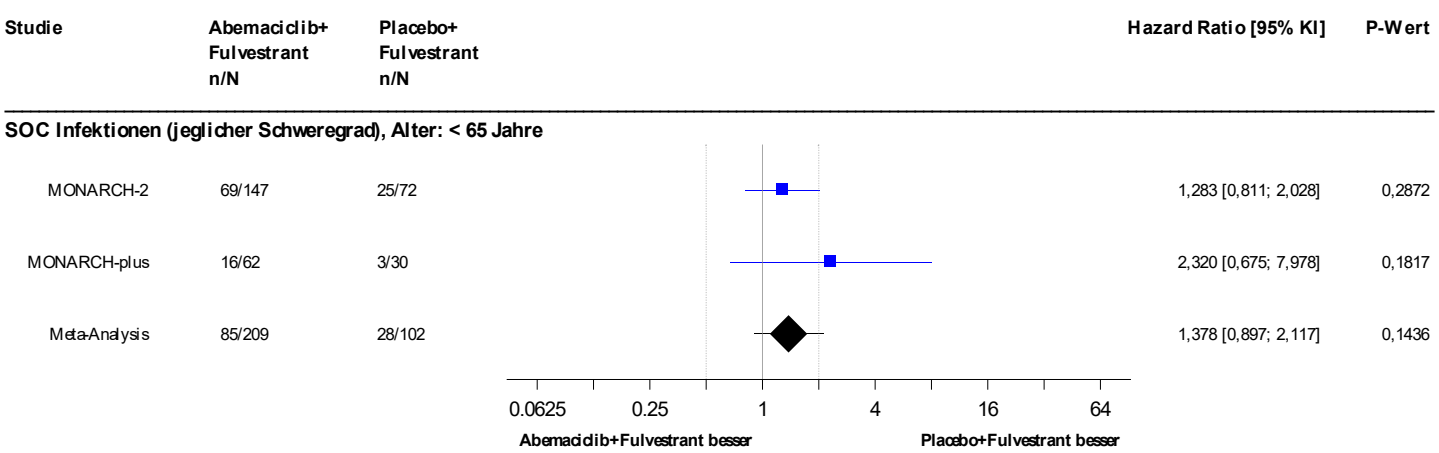
Abbildung 1428.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7778, P-Wert=0,3778, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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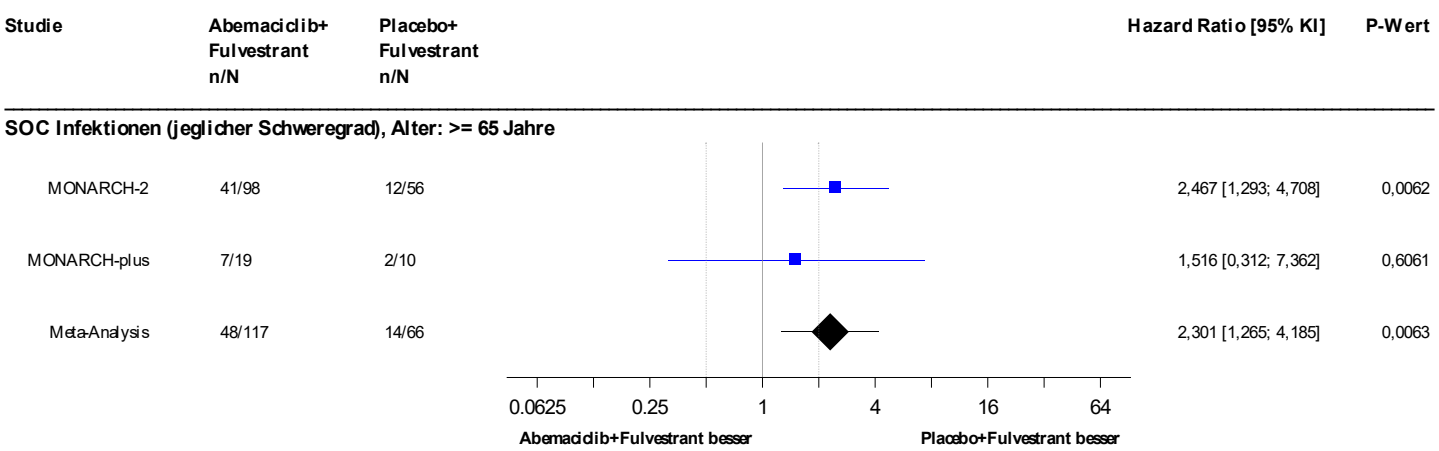
Abbildung 1428.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3127, P-Wert=0,5760, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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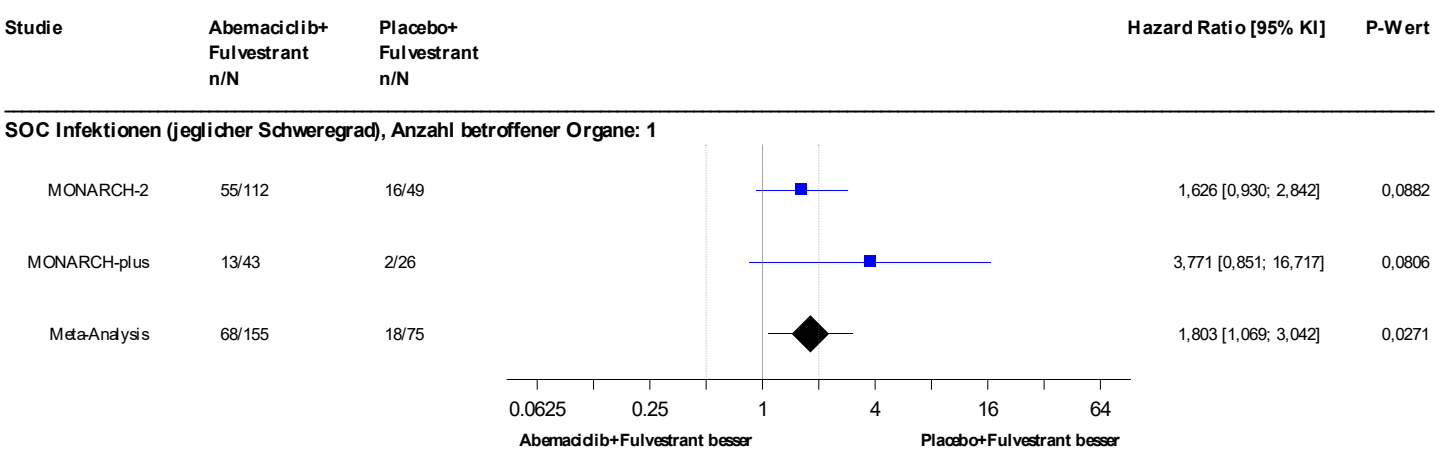
Abbildung 1428.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,0758, P-Wert=0,2996, I2 Index=7,0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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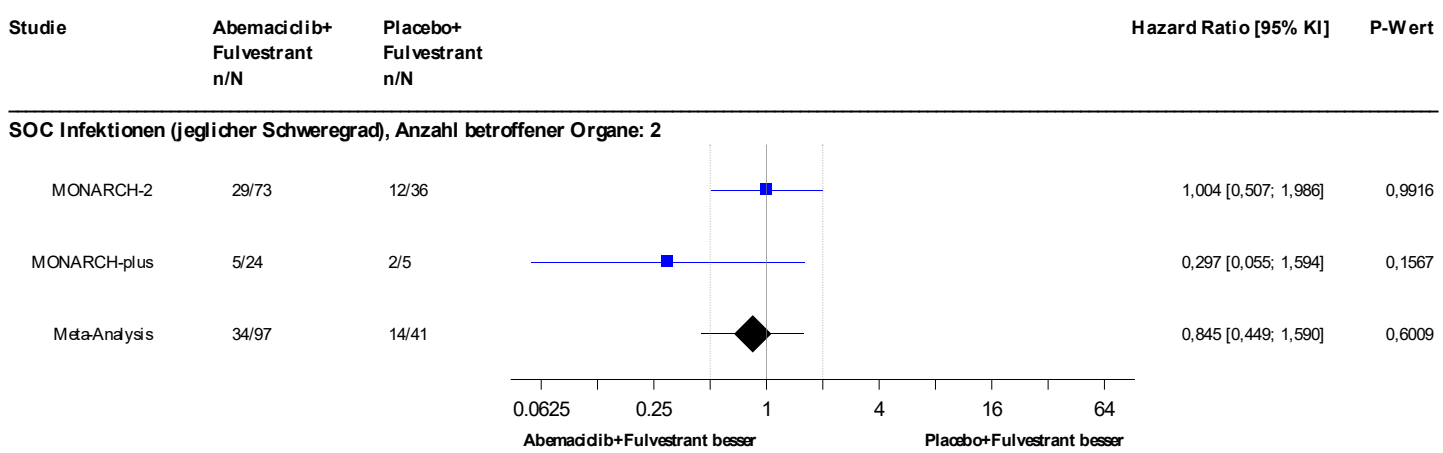
Abbildung 1428.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,7325, P-Wert=0,1881, I2 Index=42,3%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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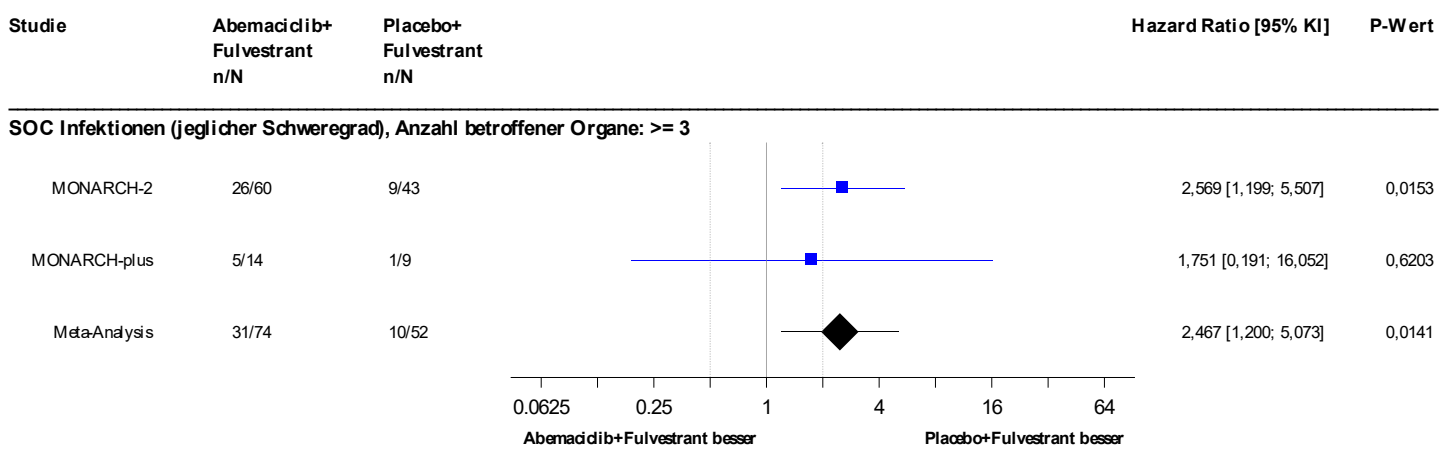
Abbildung 1428.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1029, P-Wert=0,7484, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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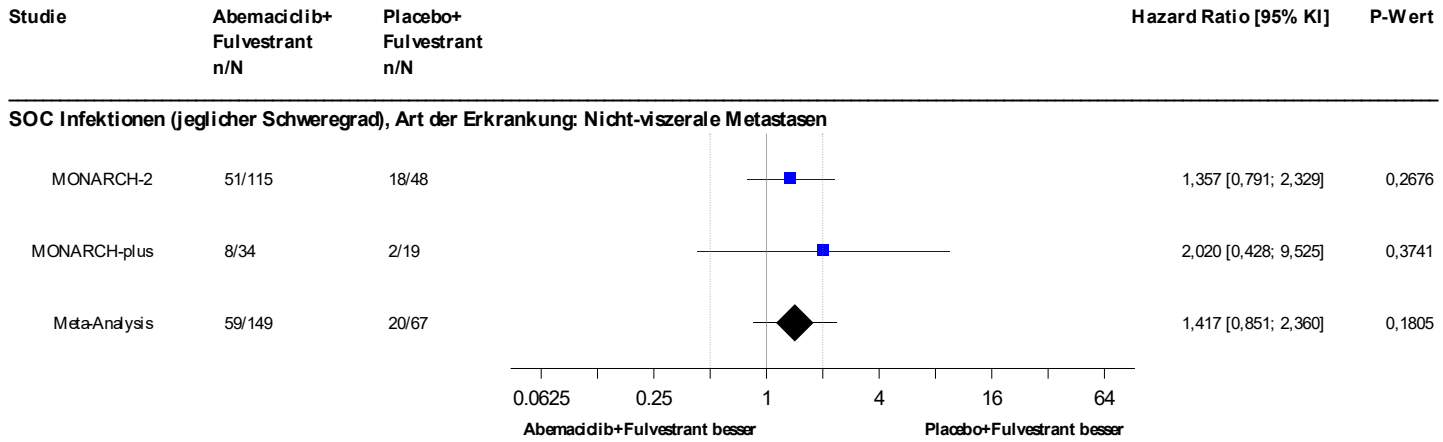
Abbildung 1428.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2253, P-Wert=0,6350, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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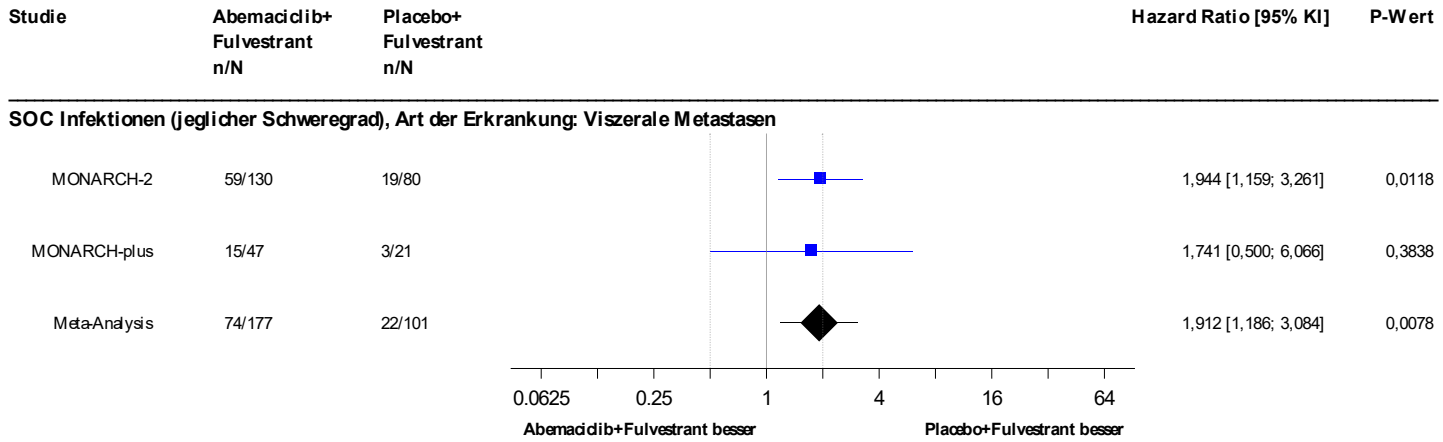
Abbildung 1428.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0255, P-Wert=0,8732, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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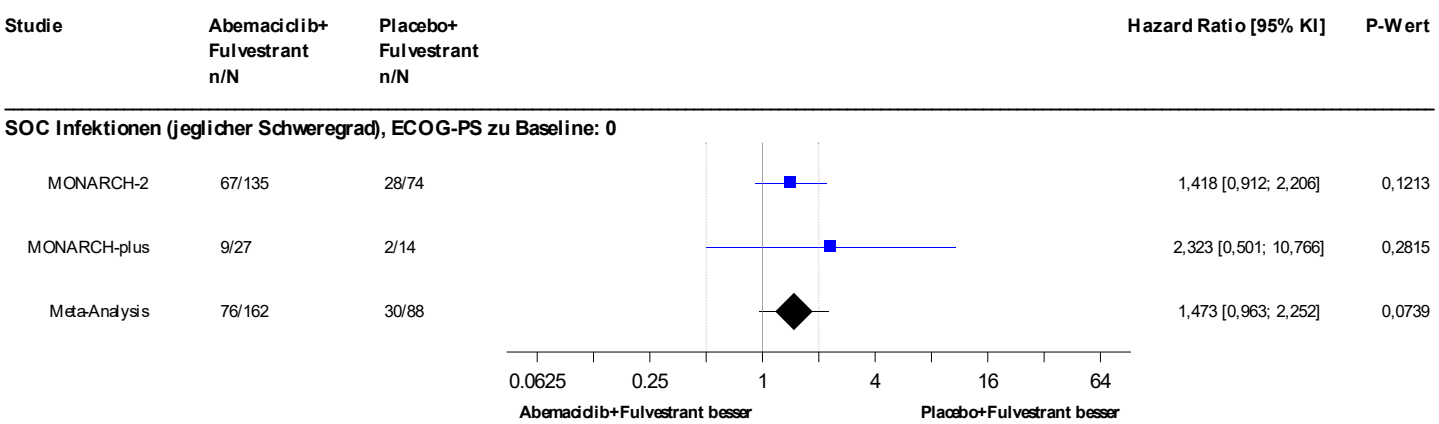
Abbildung 1428.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3672, P-Wert=0,5445, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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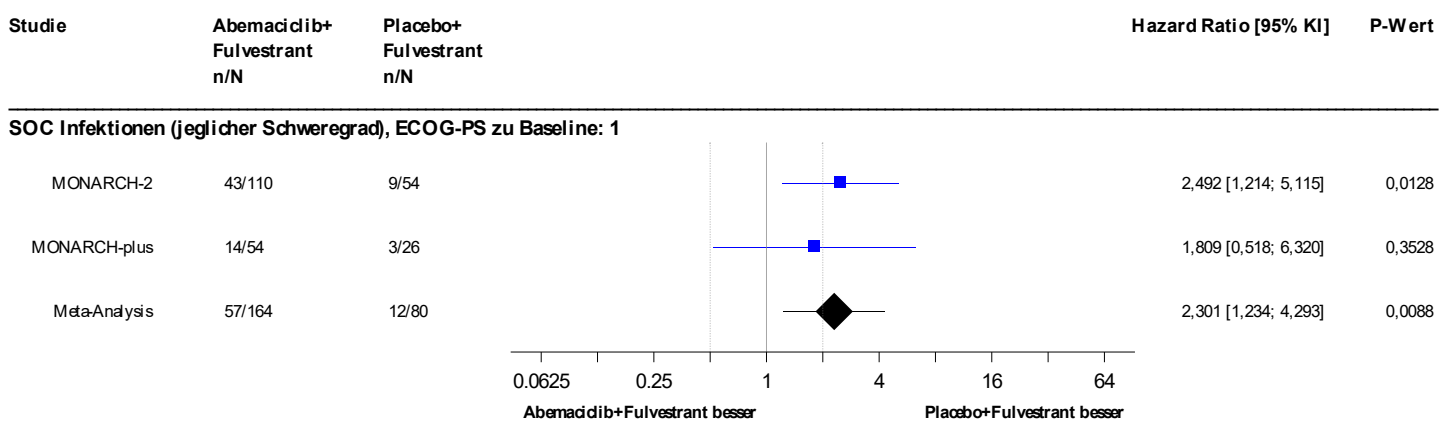
Abbildung 1428.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1890, P-Wert=0,6637, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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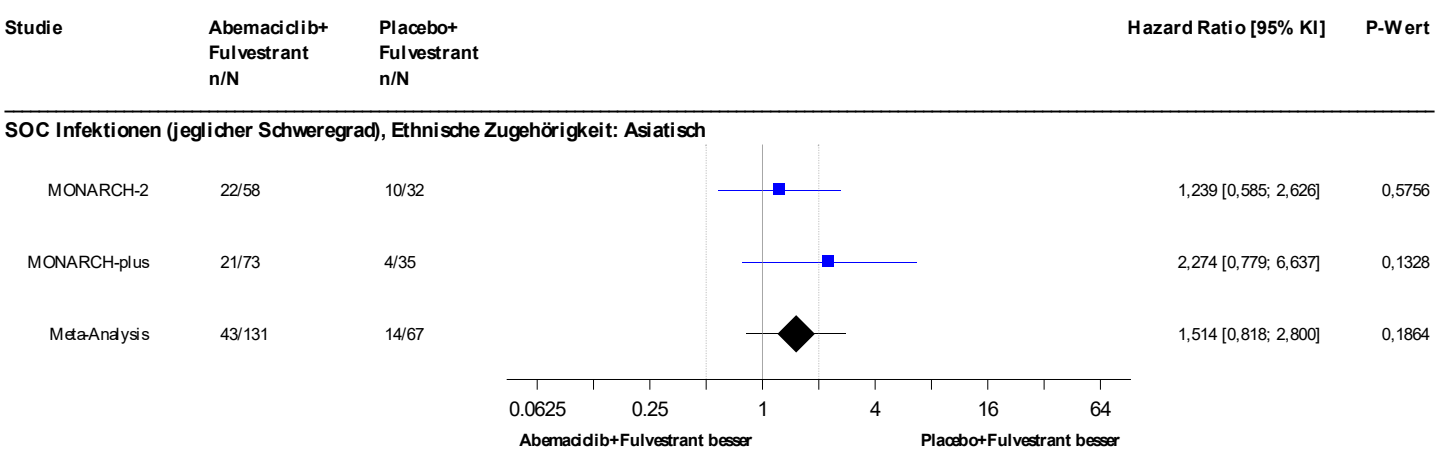
Abbildung 1428.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,8271, P-Wert=0,3631, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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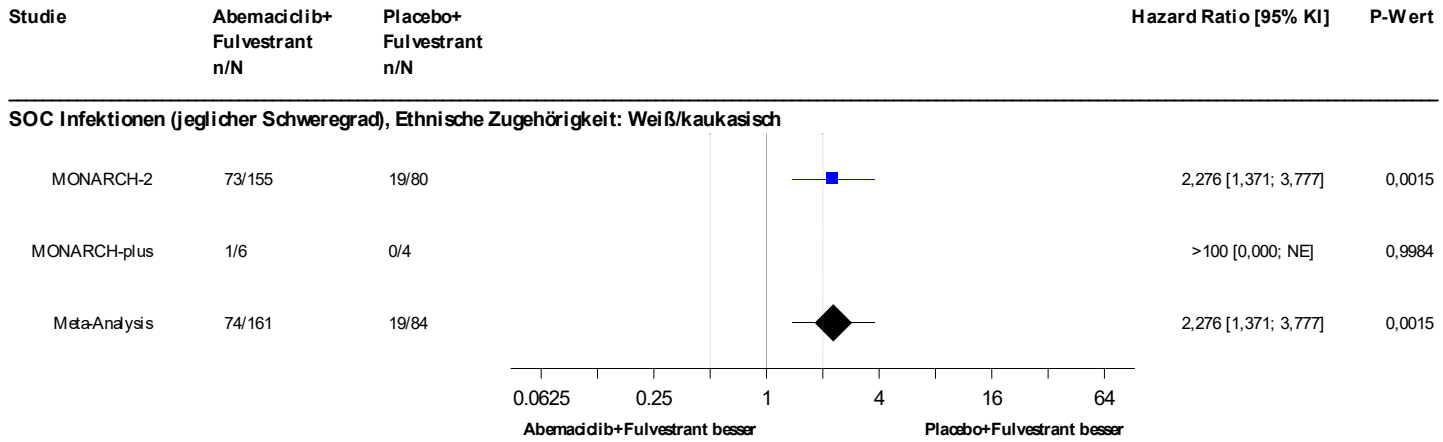
Abbildung 1428.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9985, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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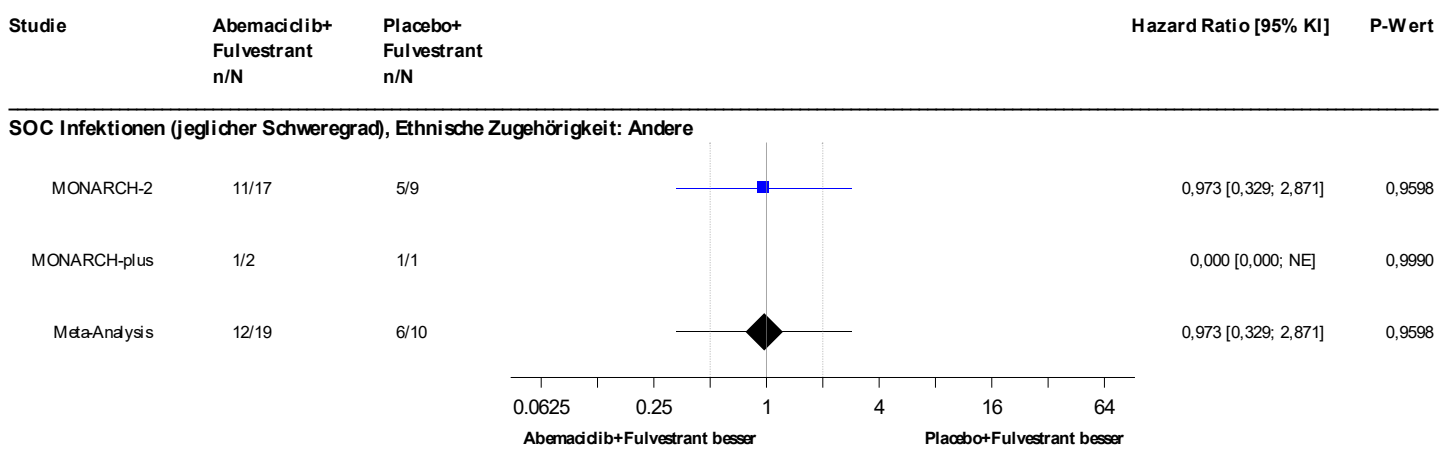
Abbildung 1428.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9990, I2 Index=0%
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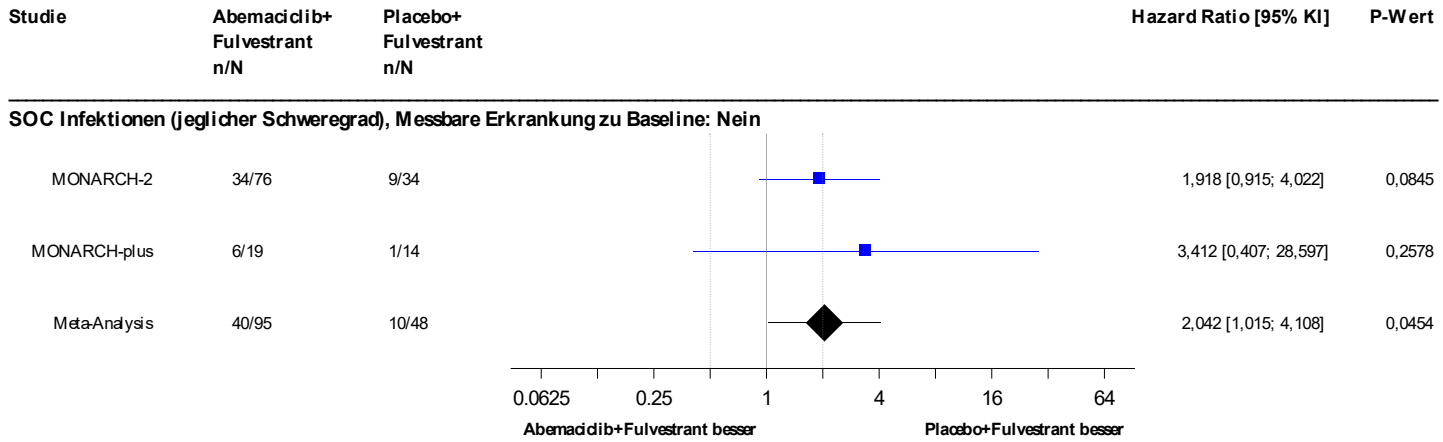
Abbildung 1428.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2514, P-Wert=0,6161, I2 Index=0%
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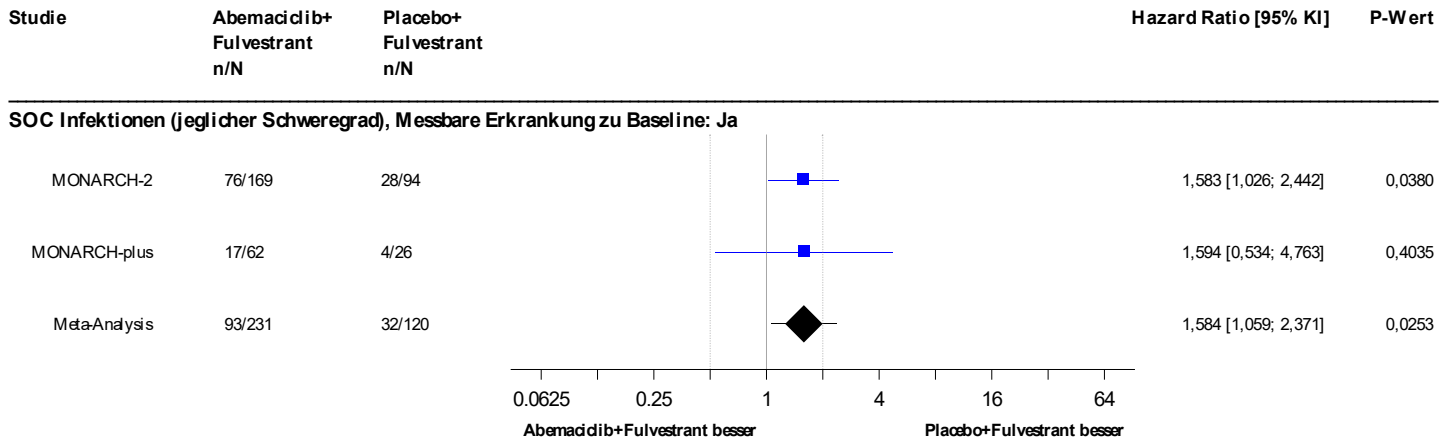
Abbildung 1428.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0002, P-Wert=0,9900, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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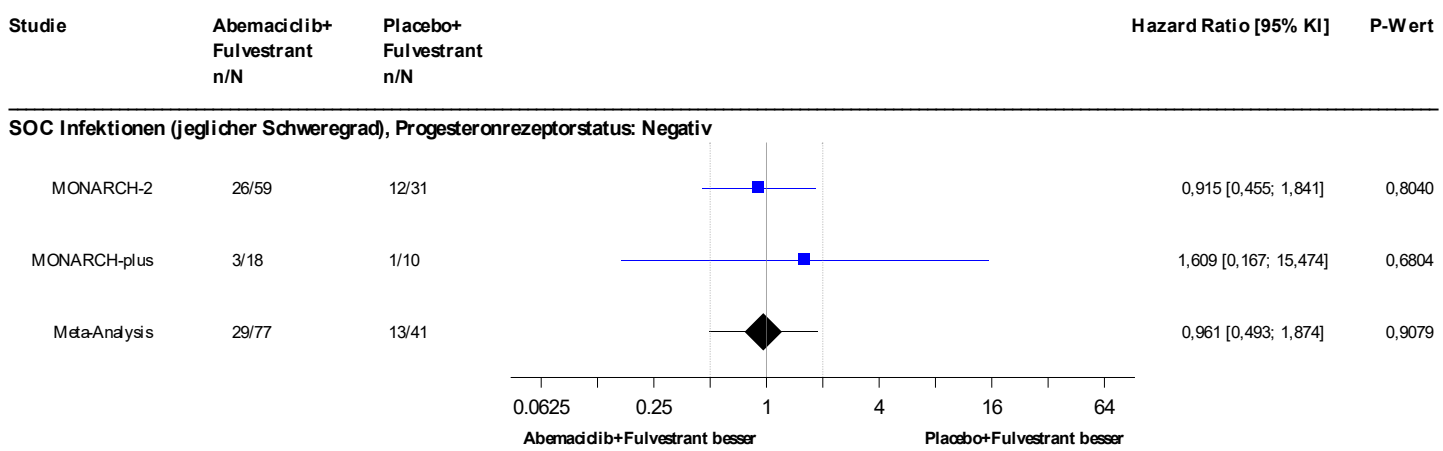
Abbildung 1428.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2179, P-Wert=0,6406, I2 Index=0%
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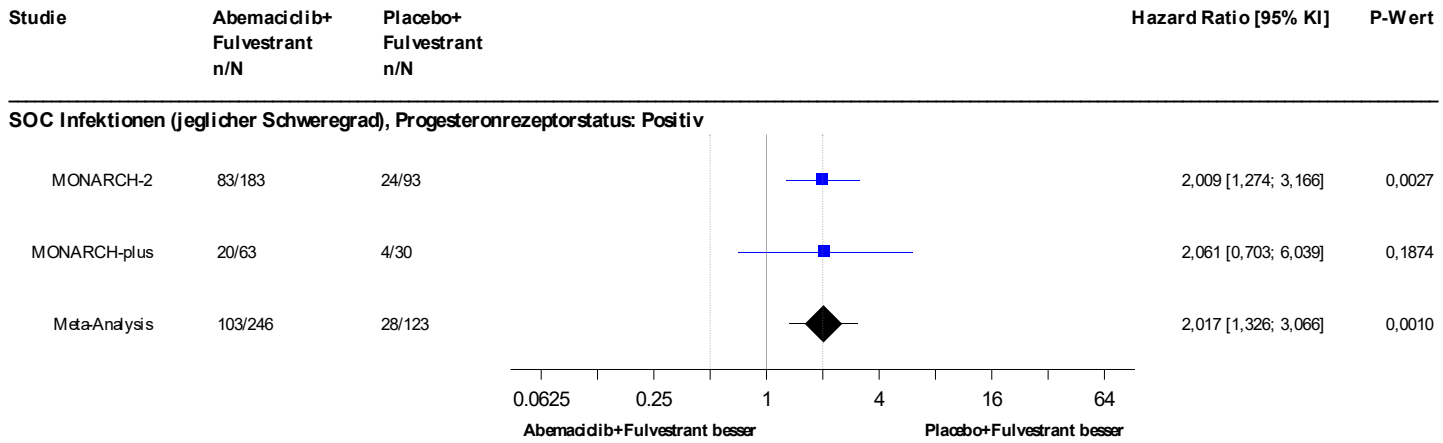
Abbildung 1428.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0018, P-Wert=0,9657, I2 Index=0%
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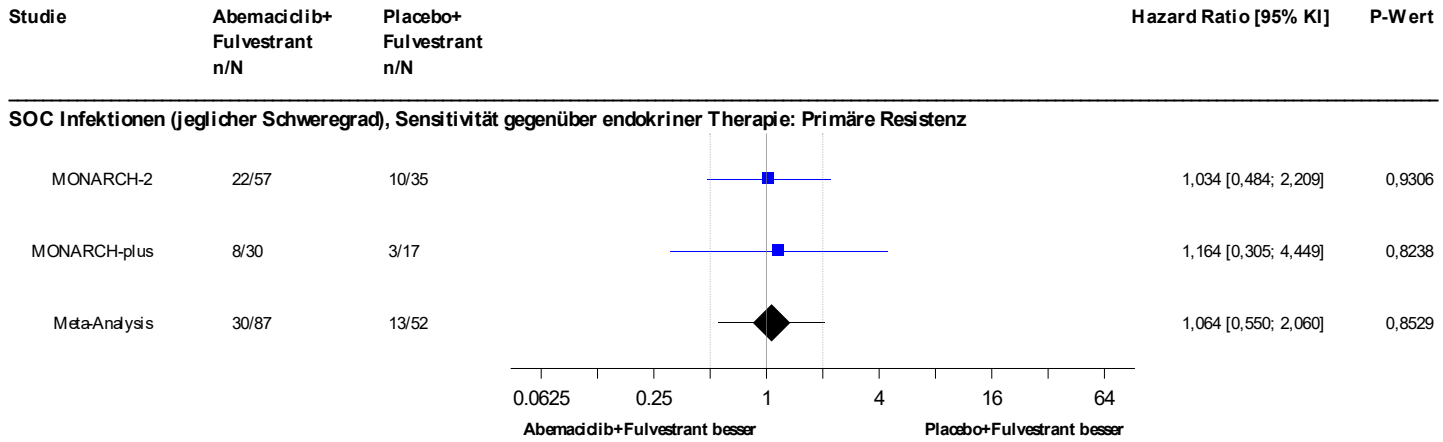
Abbildung 1428.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0228, P-Wert=0,8801, I2 Index=0%
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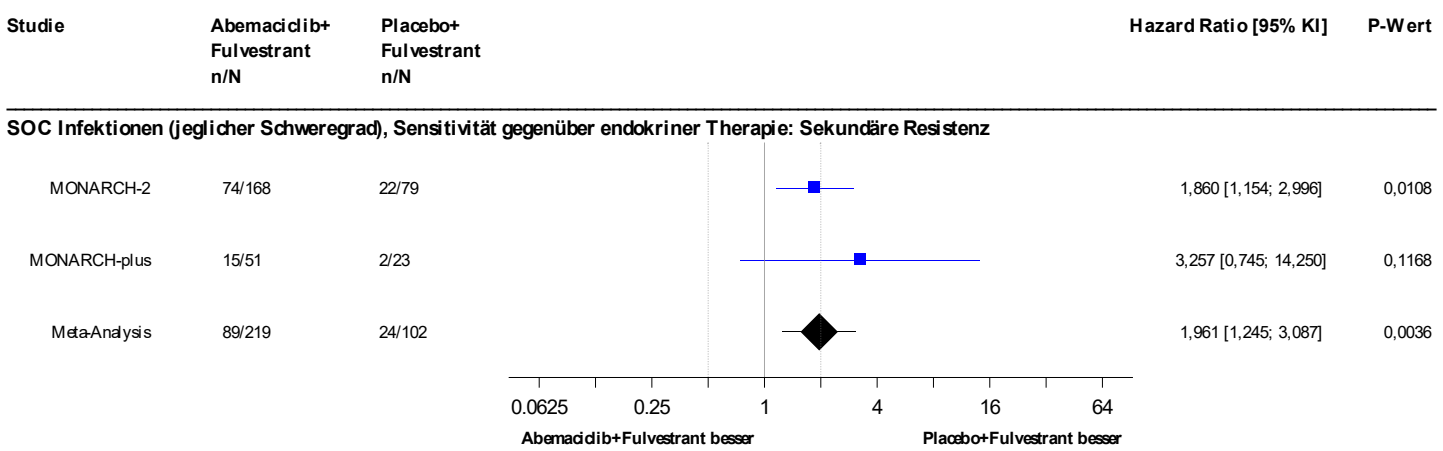
Abbildung 1428.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,5017, P-Wert=0,4788, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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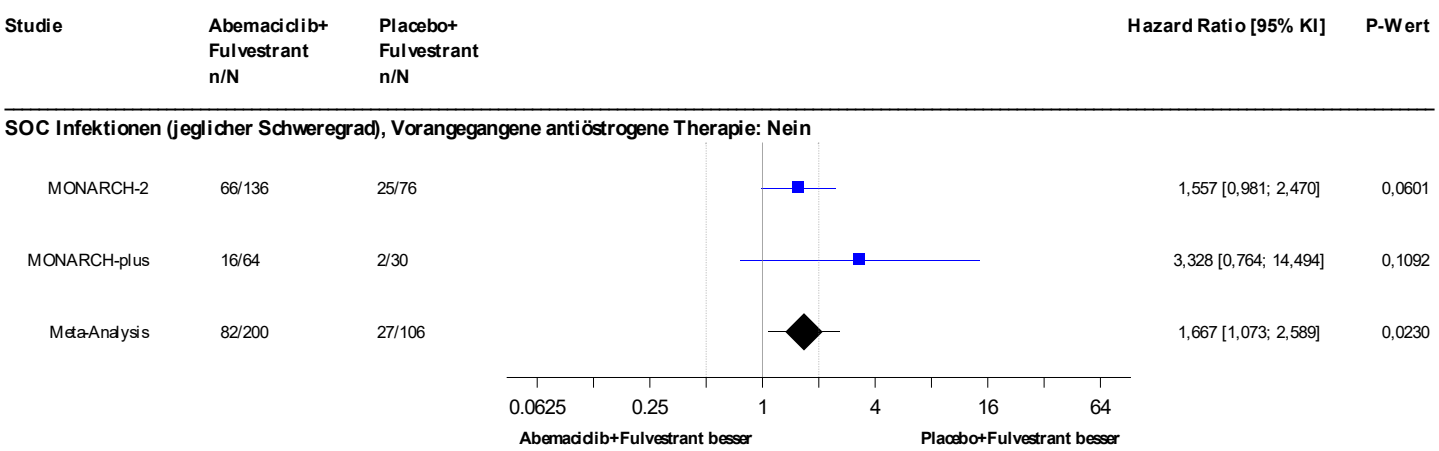
Abbildung 1428.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,9322, P-Wert=0,3343, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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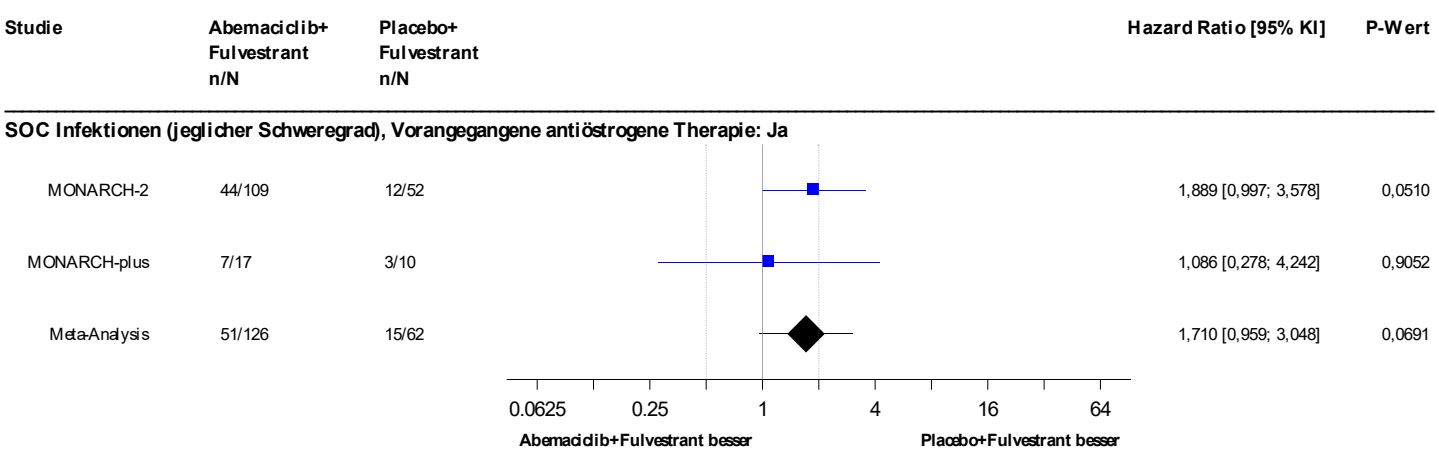
Abbildung 1428.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,5193, P-Wert=0,4712, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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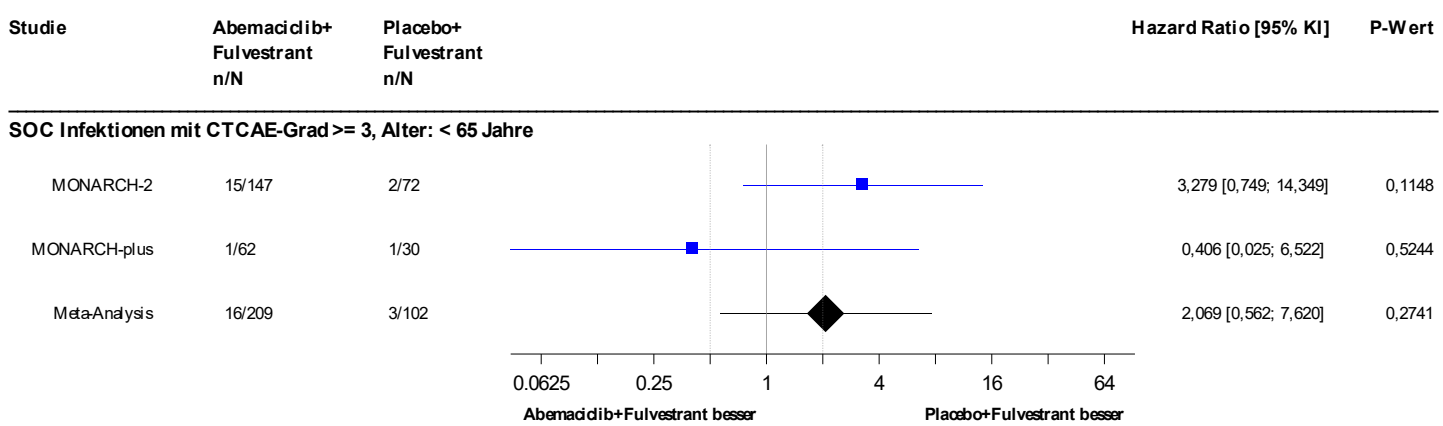
Abbildung 1429.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,6956, P-Wert=0,1929, I2 Index=41,0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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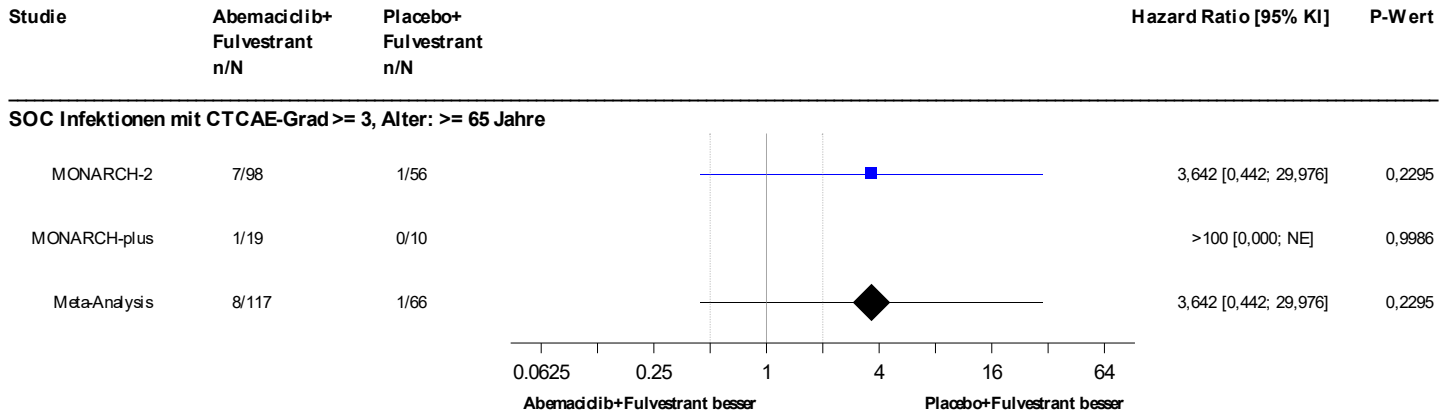
Abbildung 1429.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9987, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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Abbildung 1429.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

Studie	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% KI]	P-Wert
SOC Infektionen mit CTCAE-Grad >= 3, Anzahl betroffener Organe: 1				
MONARCH-2	12/112	0/49	>100 [0,000; NE]	0,9927
MONARCH-plus	1/43	0/26	>100 [0,000; NE]	0,9976
Meta-Analysis	13/155	0/75	>100 [0,000; NE]	0,9924

Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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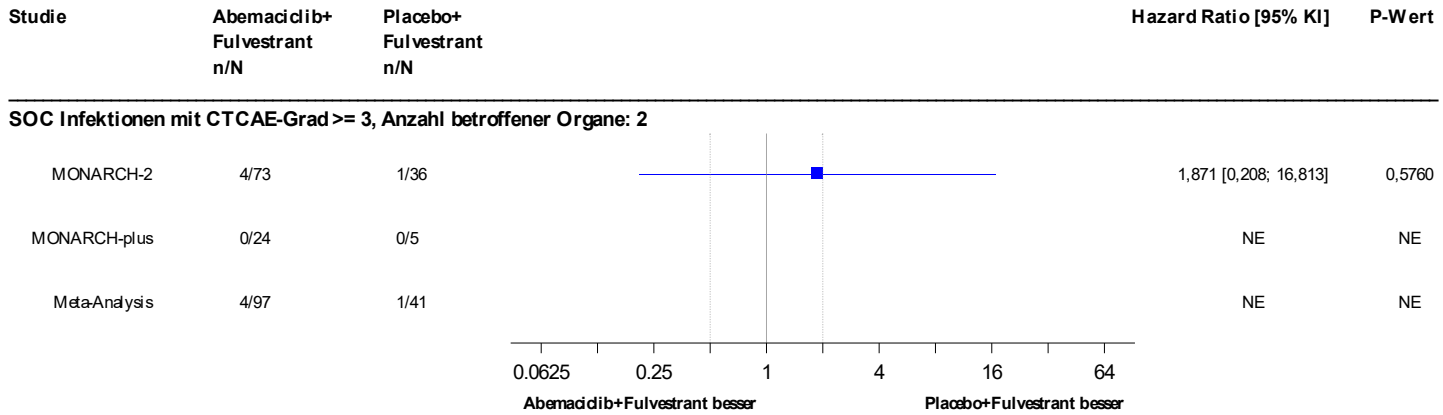
Abbildung 1429.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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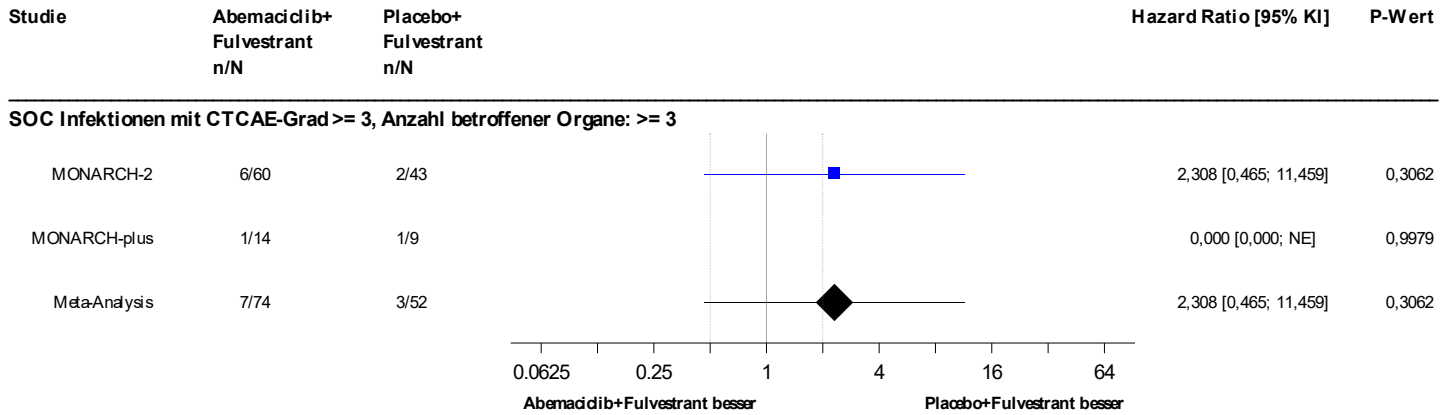
Abbildung 1429.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9978, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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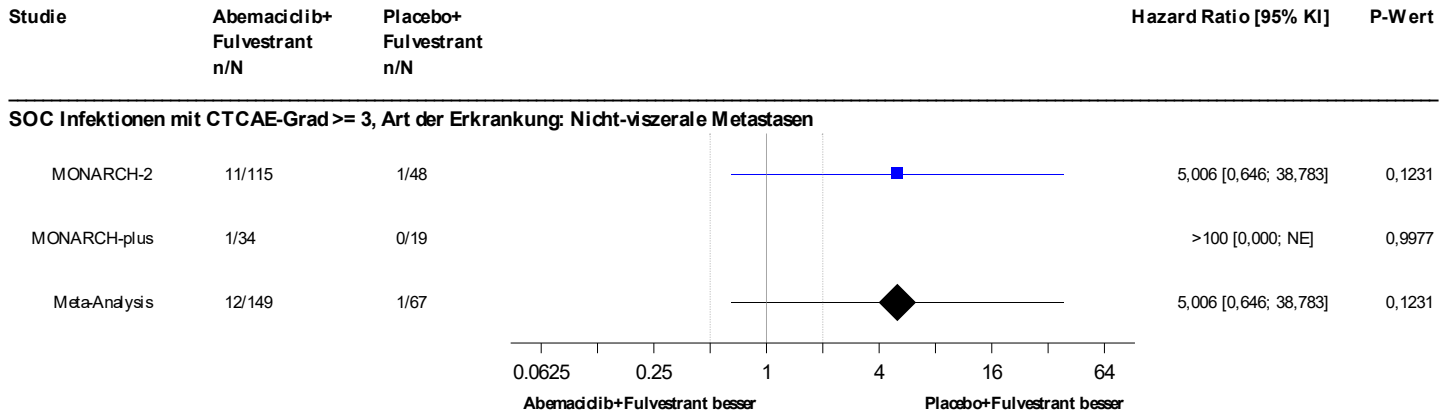
Abbildung 1429.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9979, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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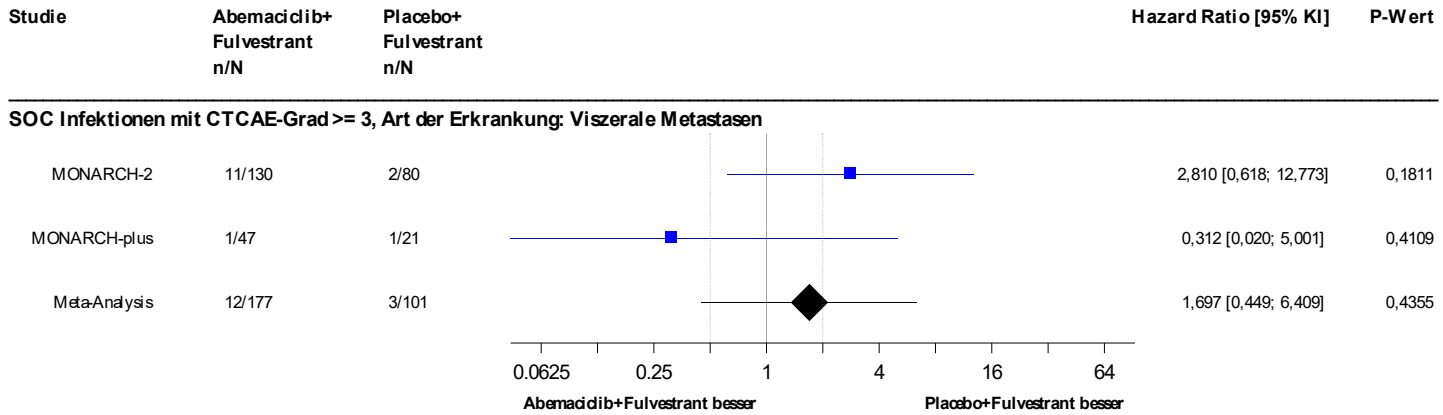
Abbildung 1429.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,8570, P-Wert=0,1730, I2 Index=46,2%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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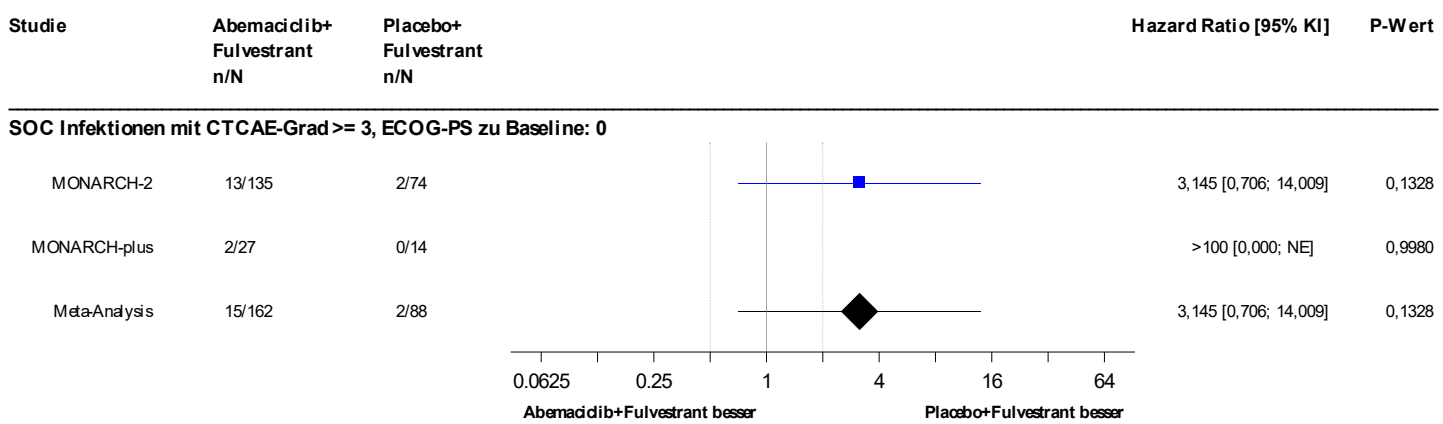
Abbildung 1429.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9981, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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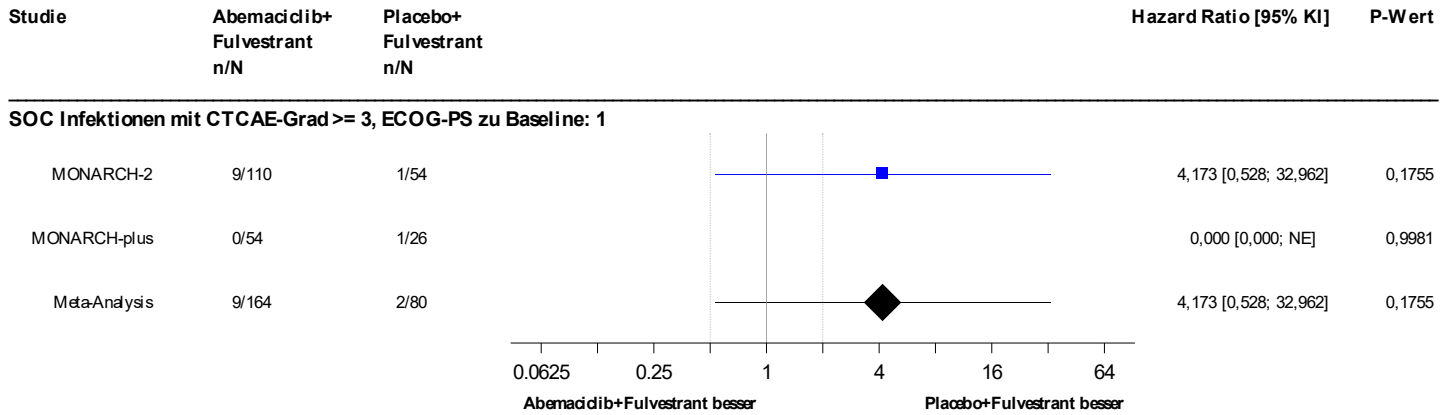
Abbildung 1429.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9980, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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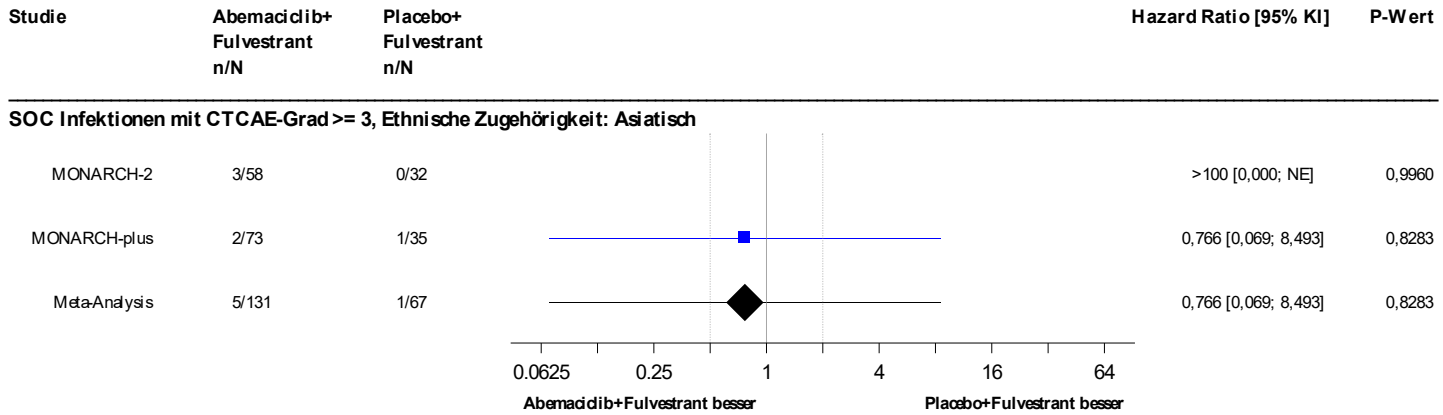
Abbildung 1429.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9959, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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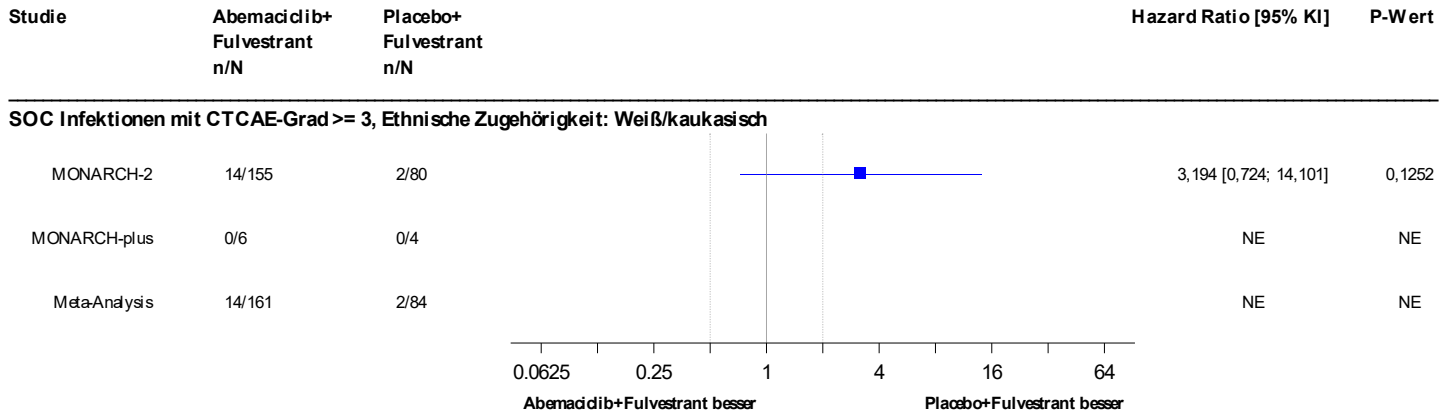
Abbildung 1429.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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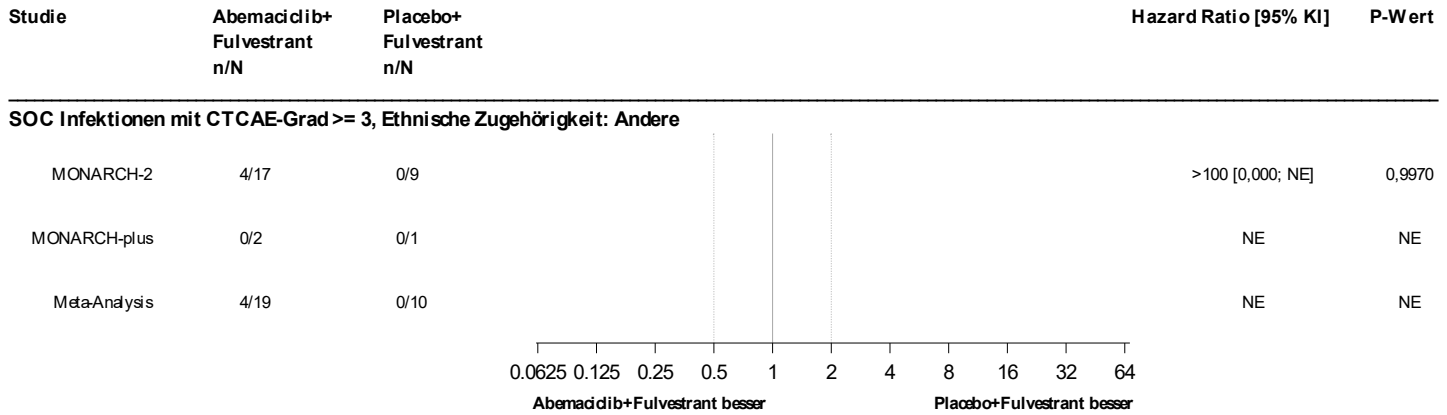
Abbildung 1429.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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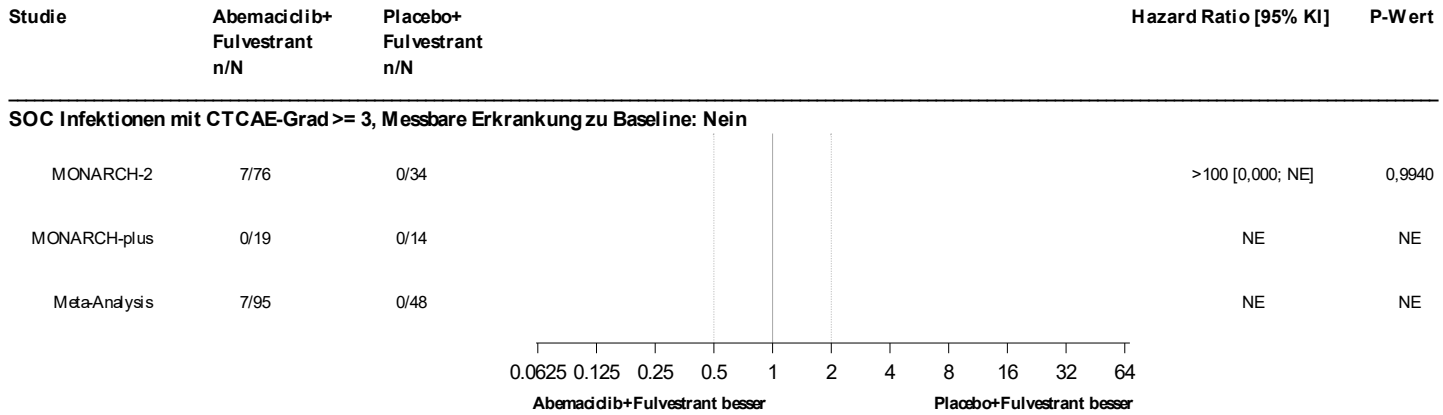
Abbildung 1429.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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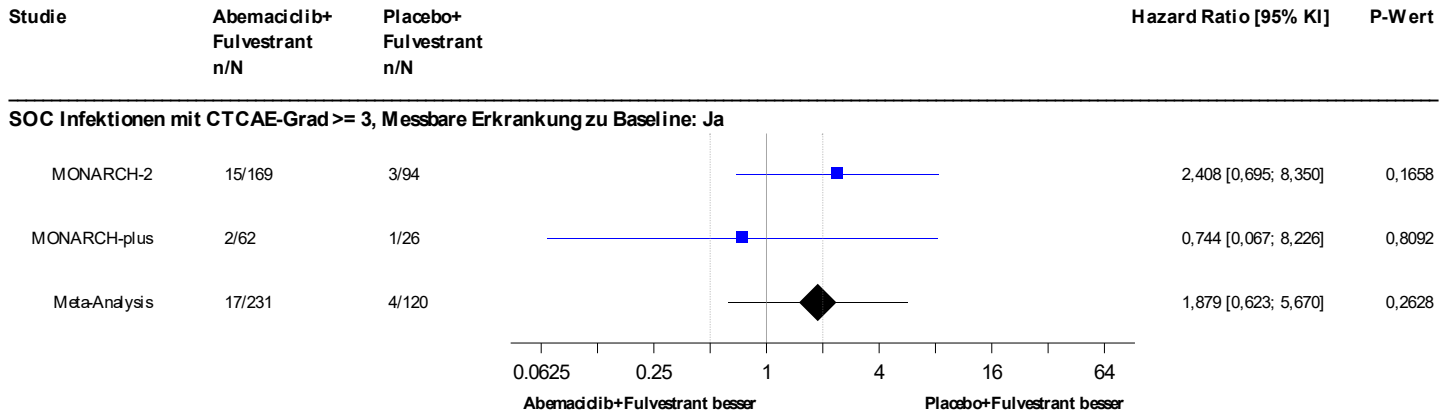
Abbildung 1429.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7245, P-Wert=0,3947, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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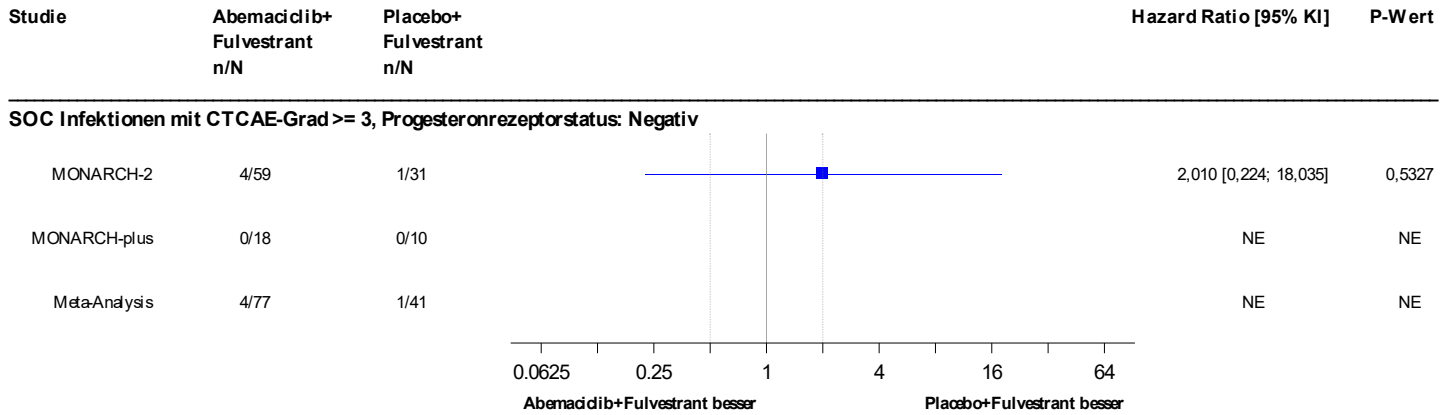
Abbildung 1429.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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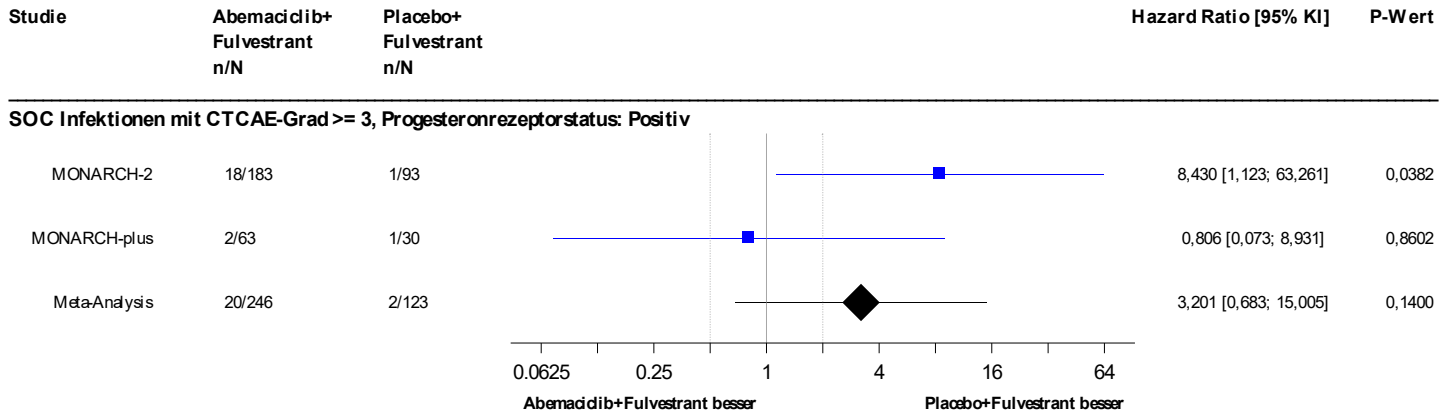
Abbildung 1429.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,1500, P-Wert=0,1426, I2 Index=53,5%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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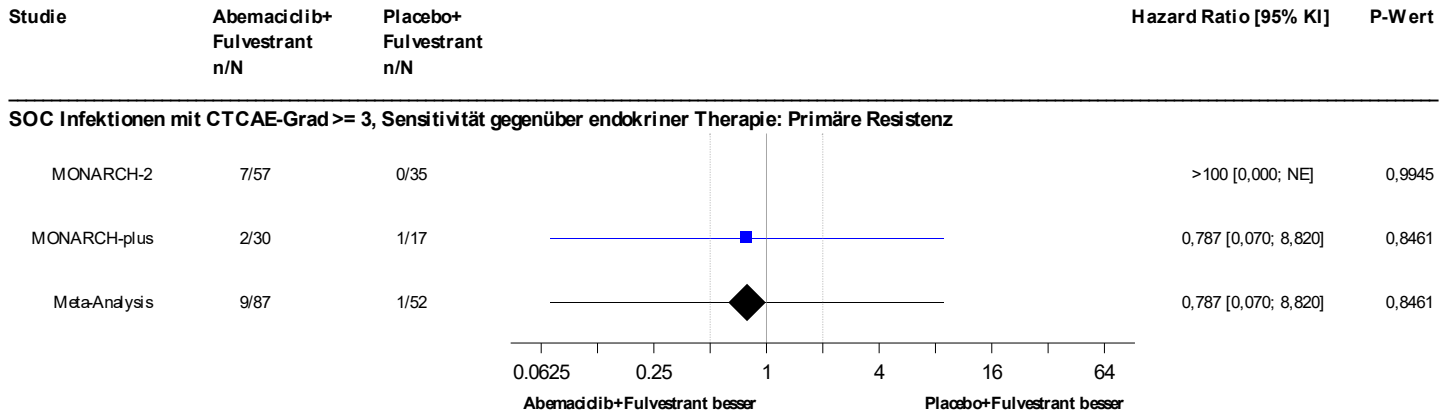
Abbildung 1429.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9945, I2 Index=0%
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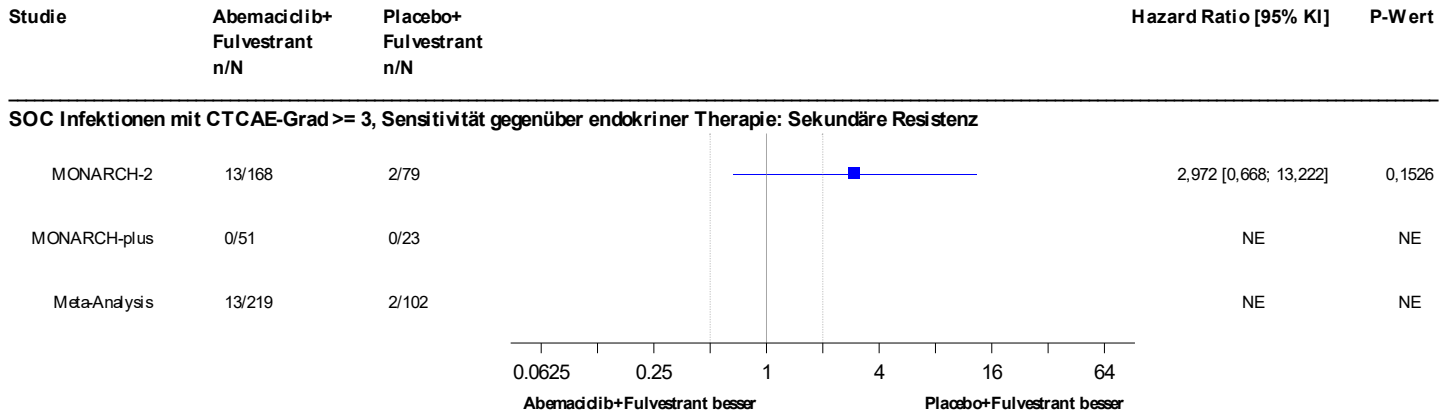
Abbildung 1429.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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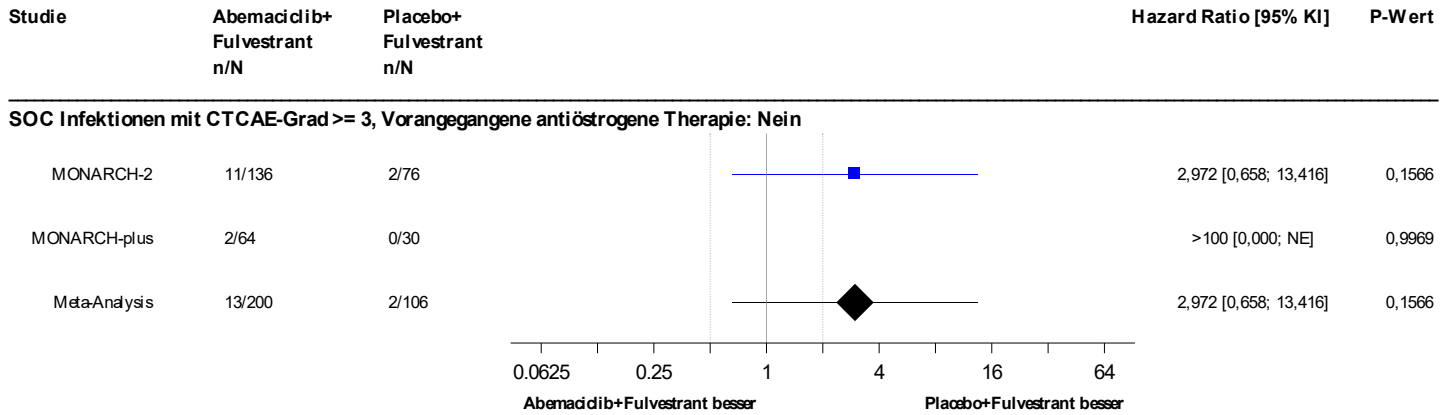
Abbildung 1429.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9971, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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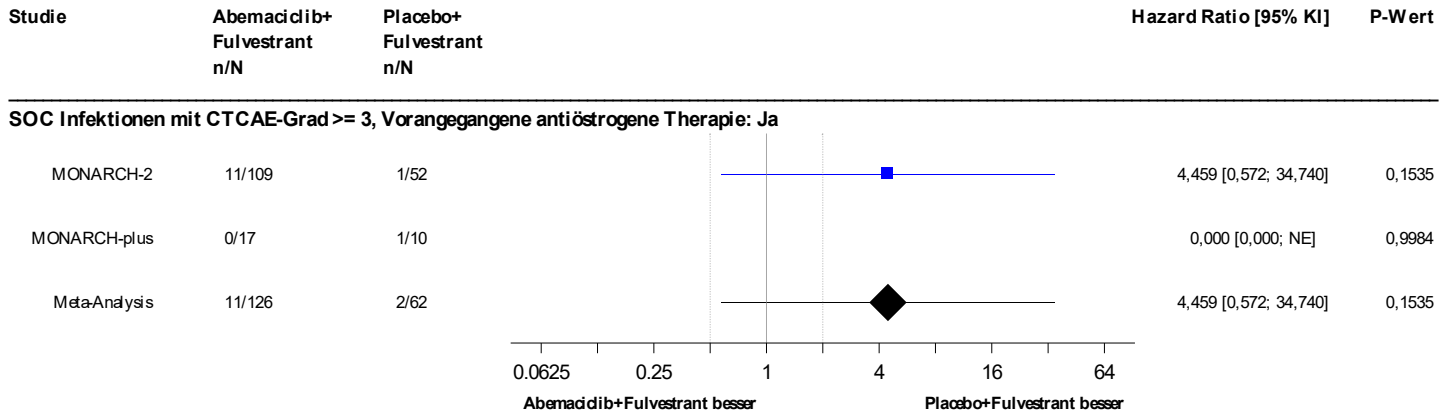
Abbildung 1429.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9983, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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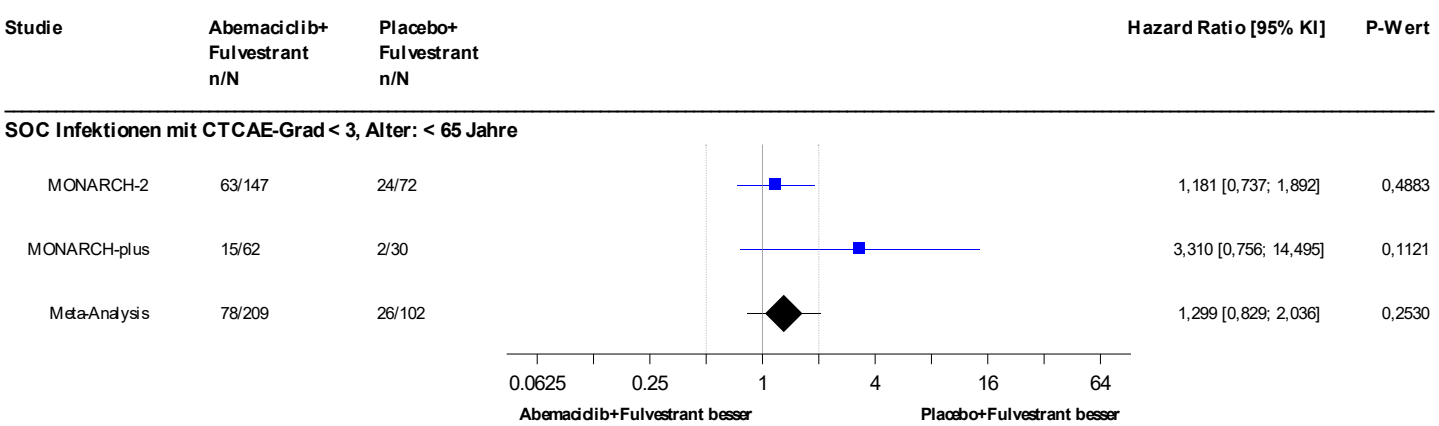
Abbildung 1430.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,6973, P-Wert=0,1926, I2 Index=41,1%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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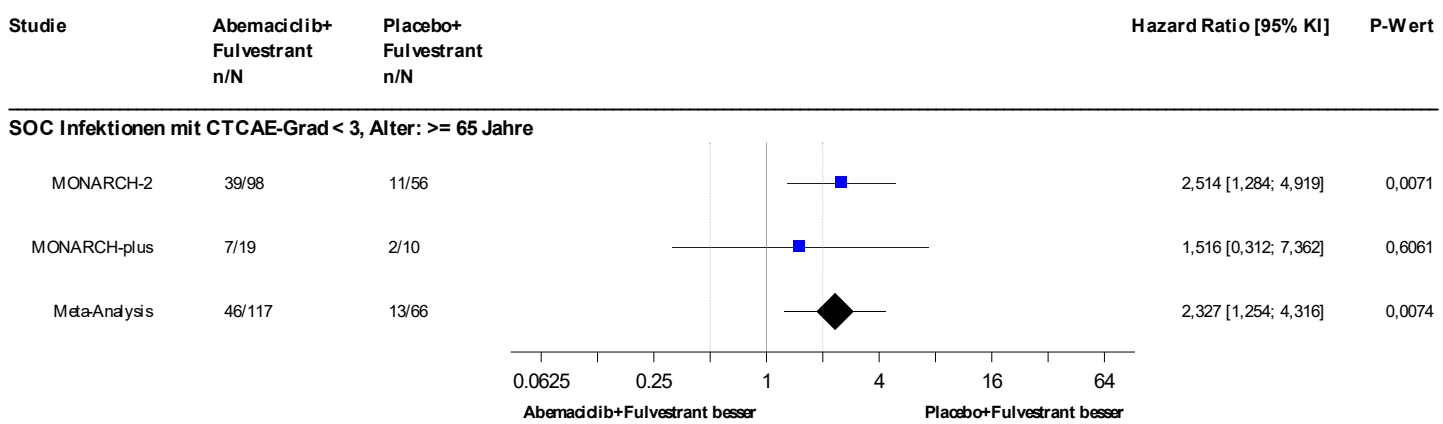
Abbildung 1430.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3335, P-Wert=0,5636, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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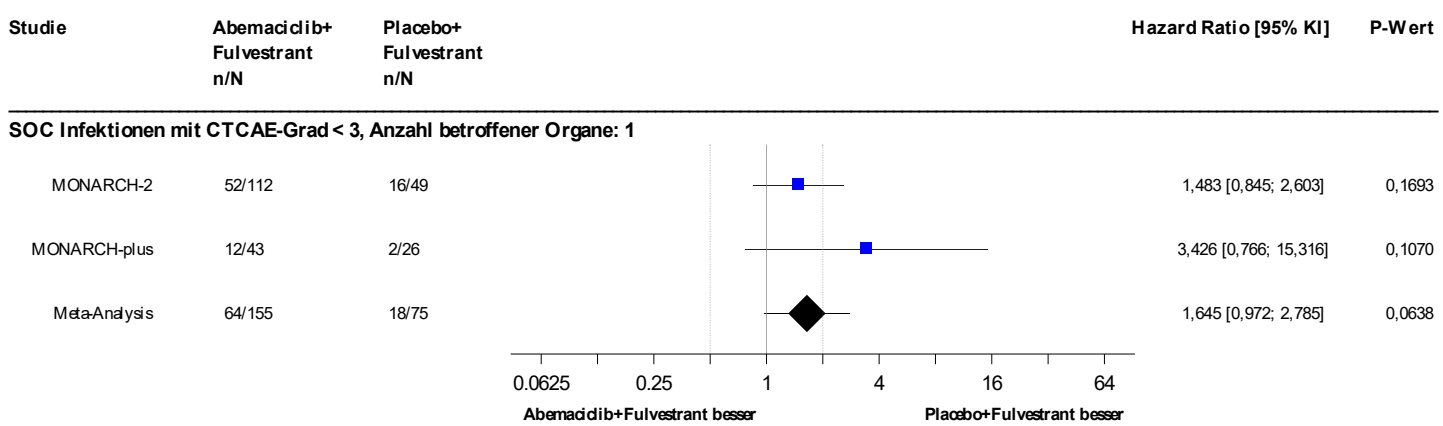
Abbildung 1430.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,0521, P-Wert=0,3050, I2 Index=4,9%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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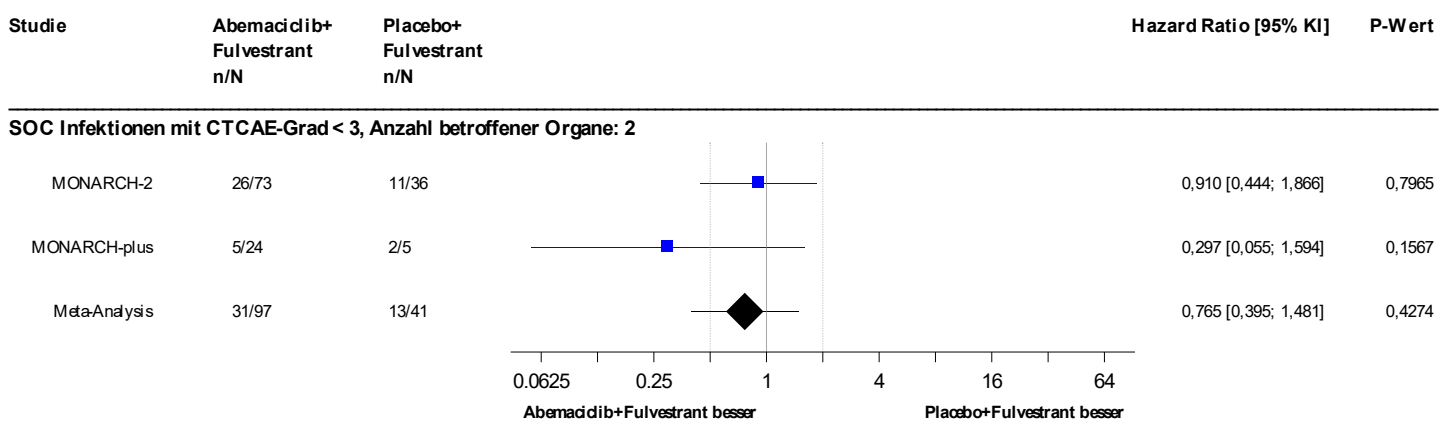
Abbildung 1430.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,4428, P-Wert=0,2297, I2 Index=30,7%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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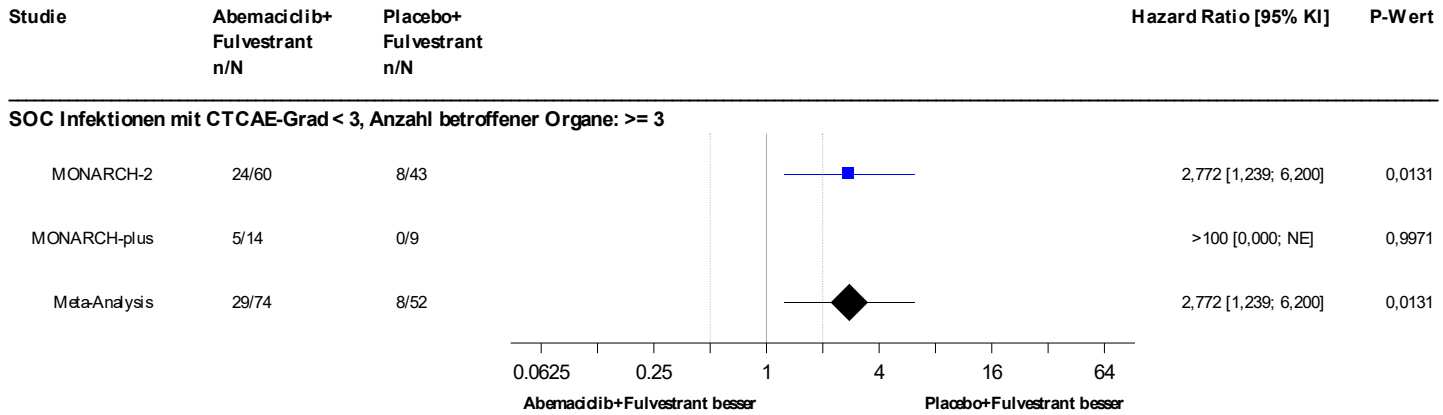
Abbildung 1430.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9973, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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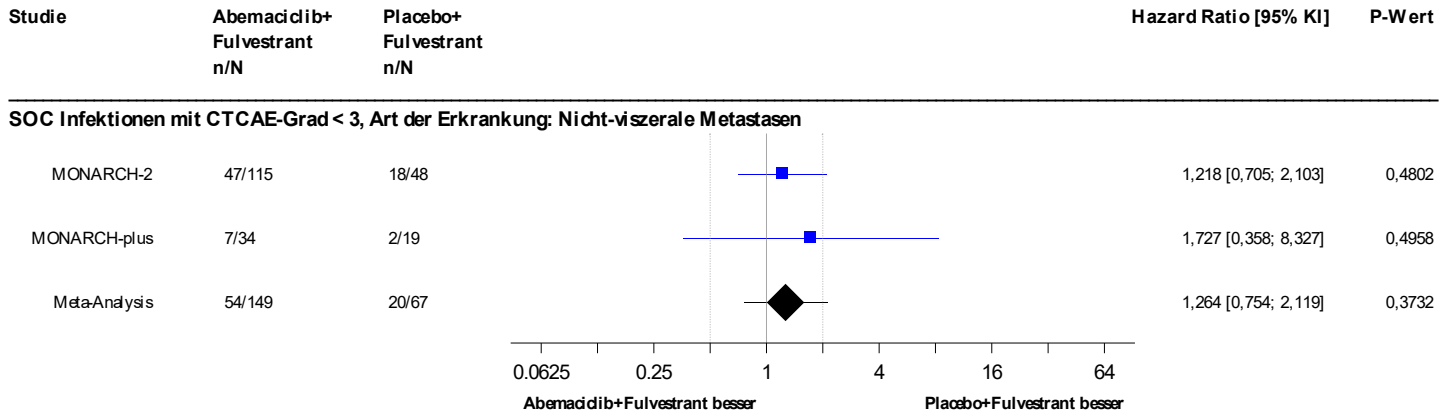
Abbildung 1430.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1695, P-Wert=0,6805, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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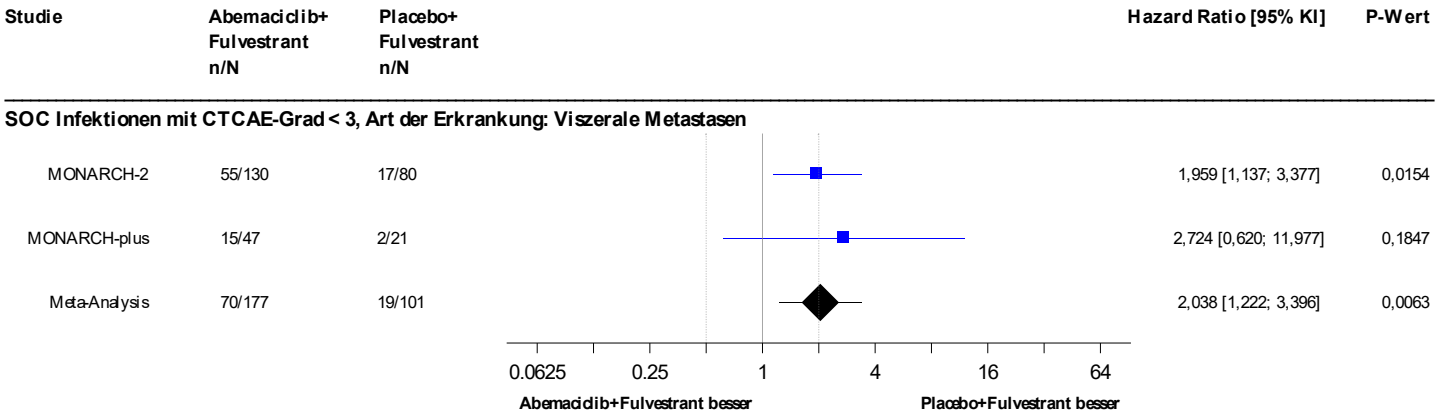
Abbildung 1430.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1677, P-Wert=0,6822, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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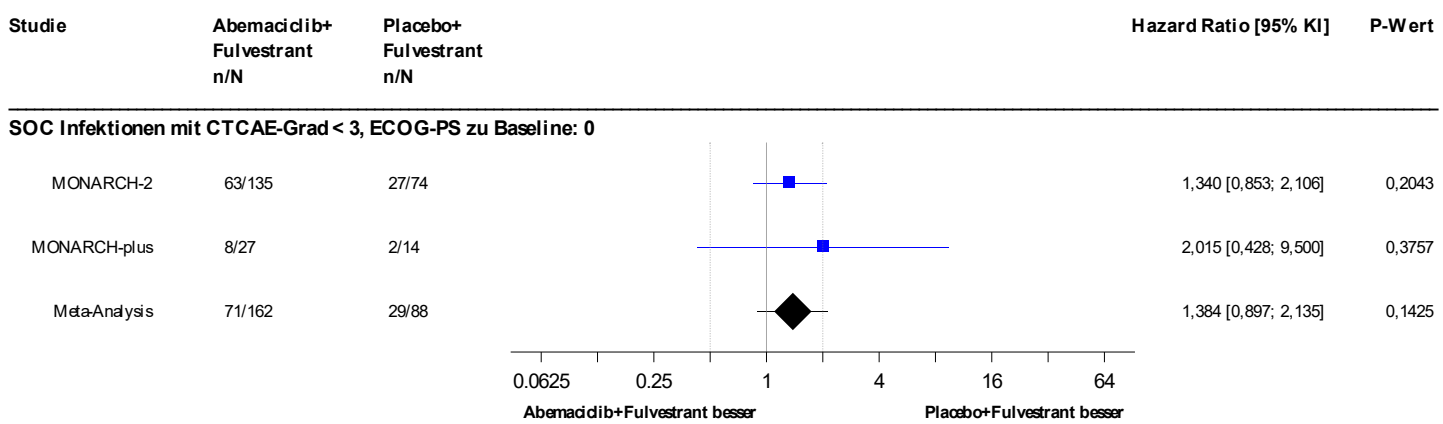
Abbildung 1430.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2453, P-Wert=0,6204, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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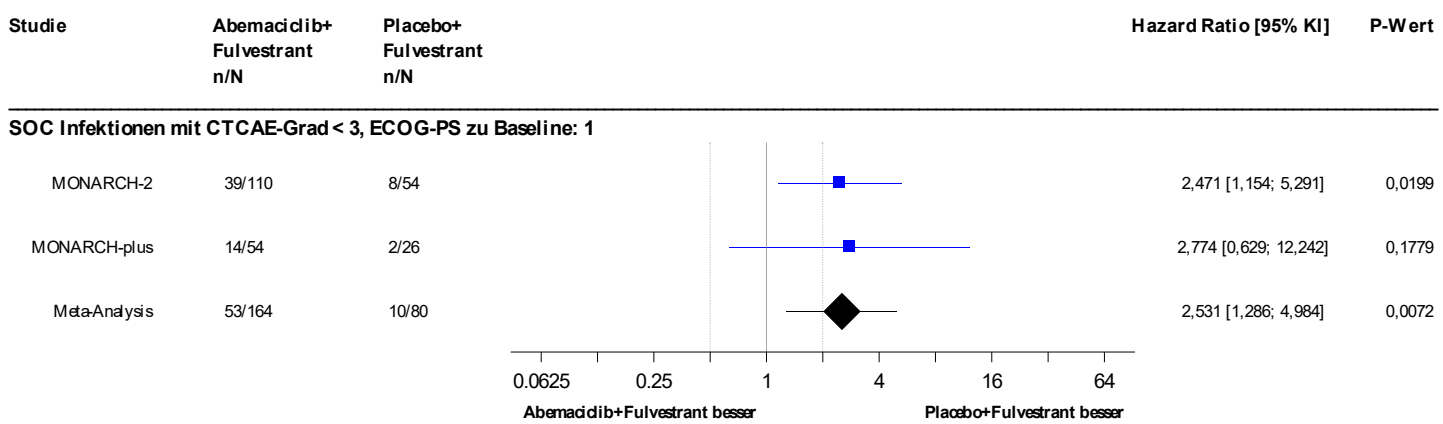
Abbildung 1430.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0185, P-Wert=0,8917, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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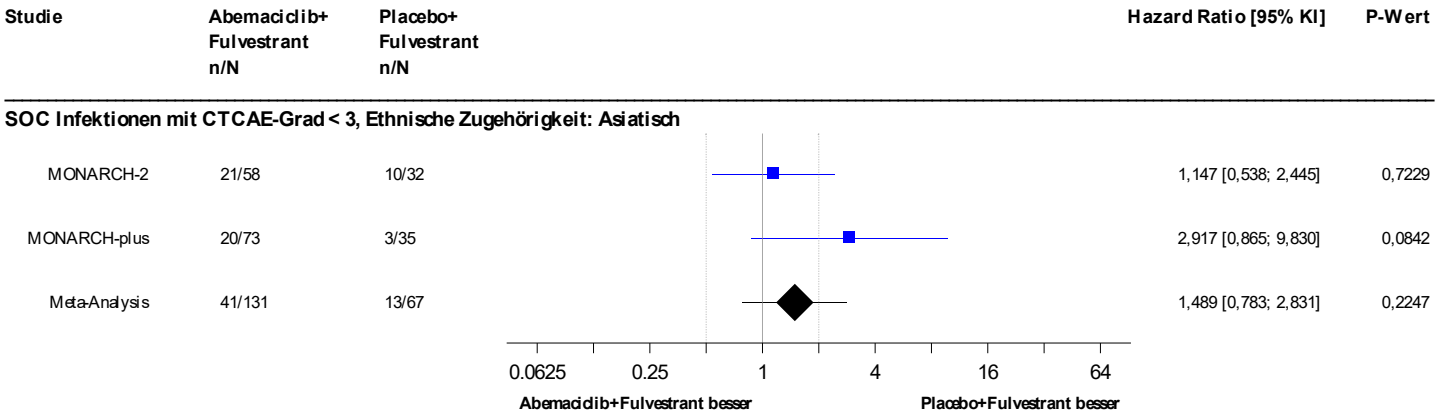
Abbildung 1430.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,6331, P-Wert=0,2013, I2 Index=38,8%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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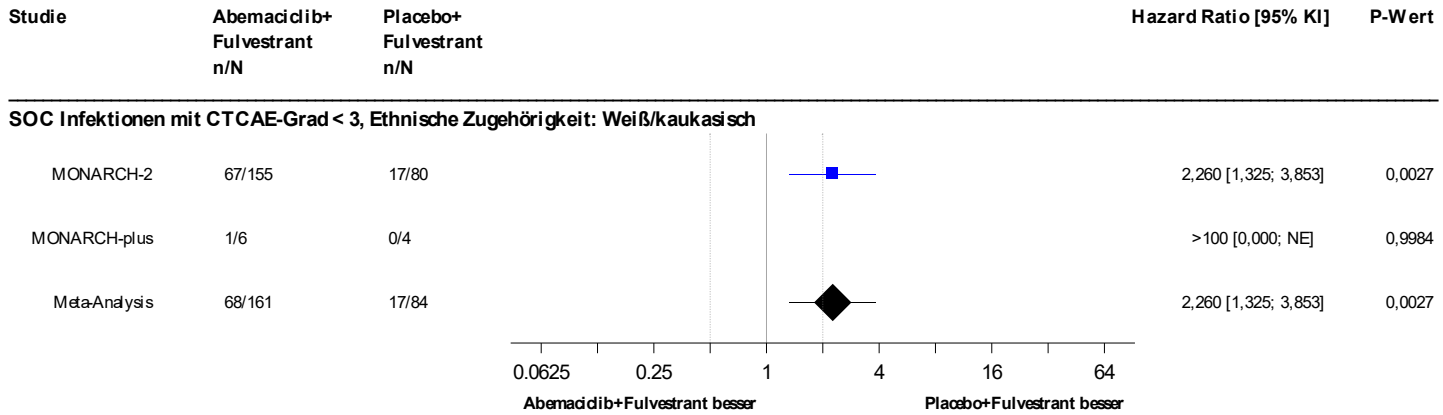
Abbildung 1430.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



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Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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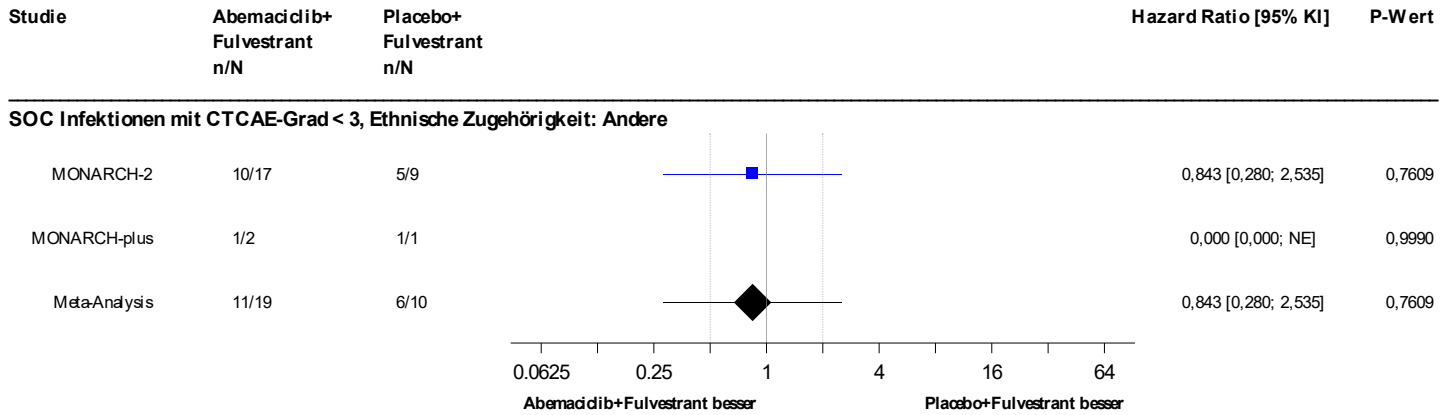
Abbildung 1430.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9991, I2 Index=0%
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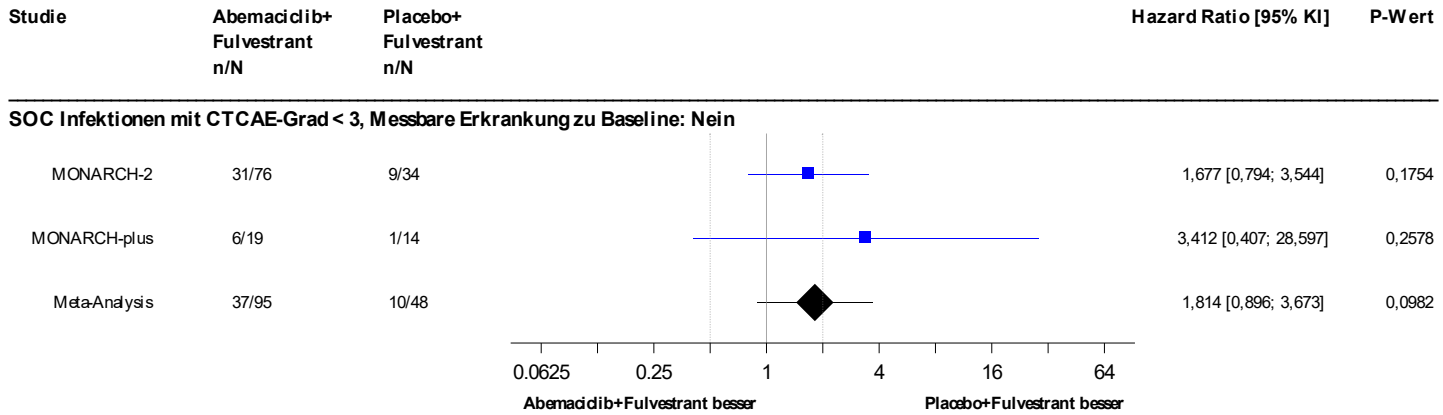
Abbildung 1430.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3816, P-Wert=0,5368, I2 Index=0%
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Abbildung 1430.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

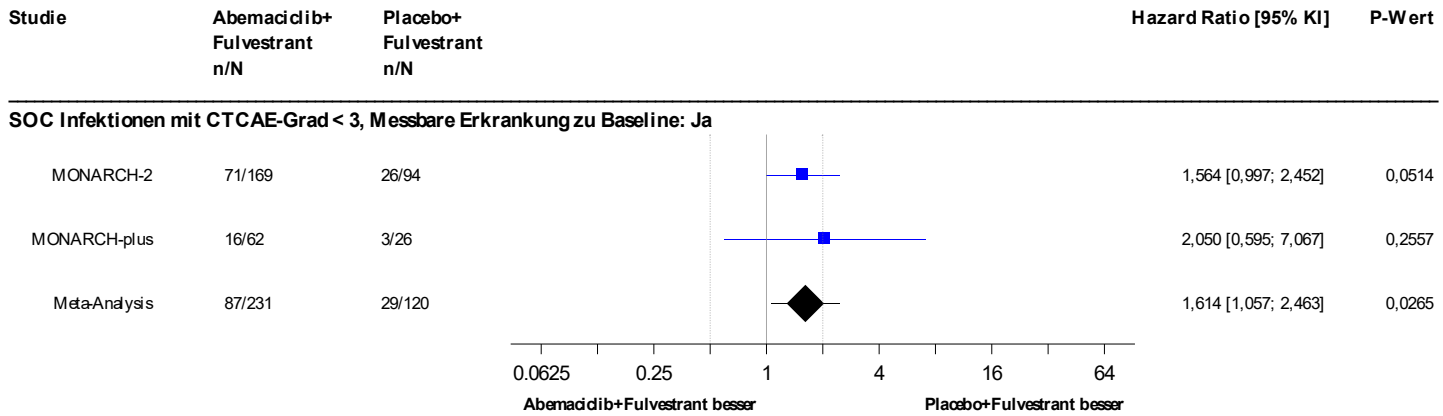

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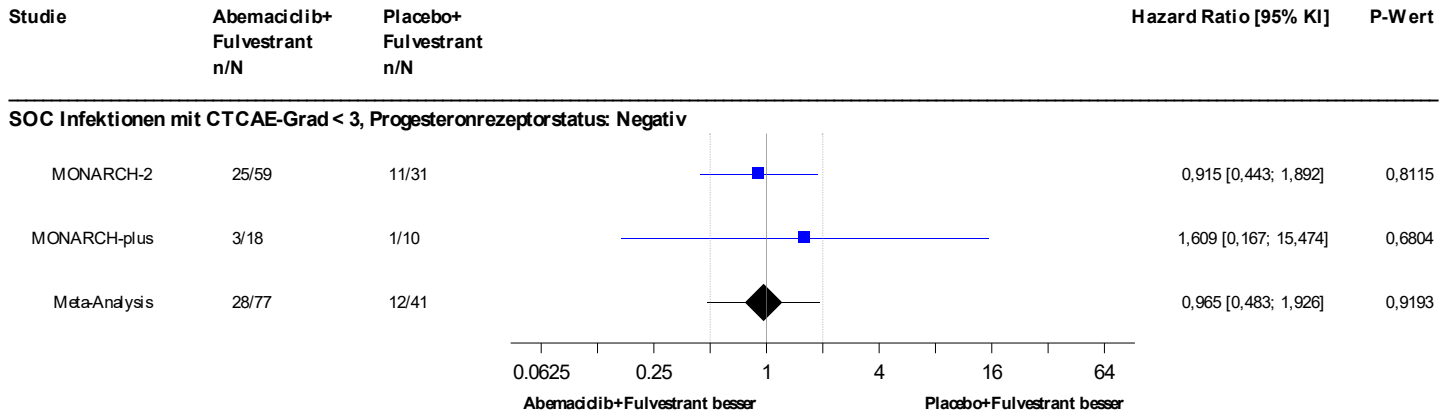
Abbildung 1430.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2163, P-Wert=0,6419, I2 Index=0%
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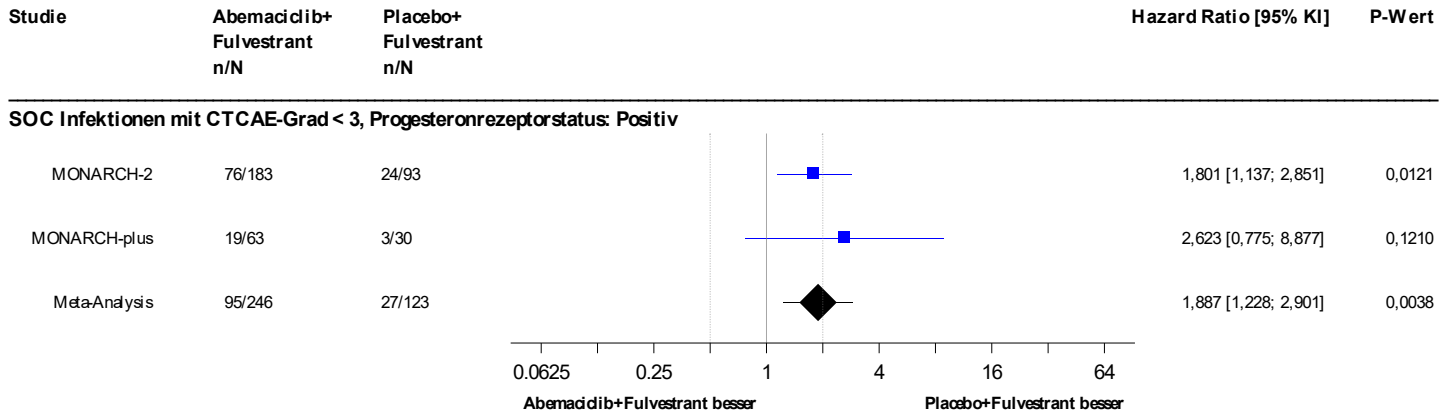
Abbildung 1430.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3204, P-Wert=0,5713, I2 Index=0%
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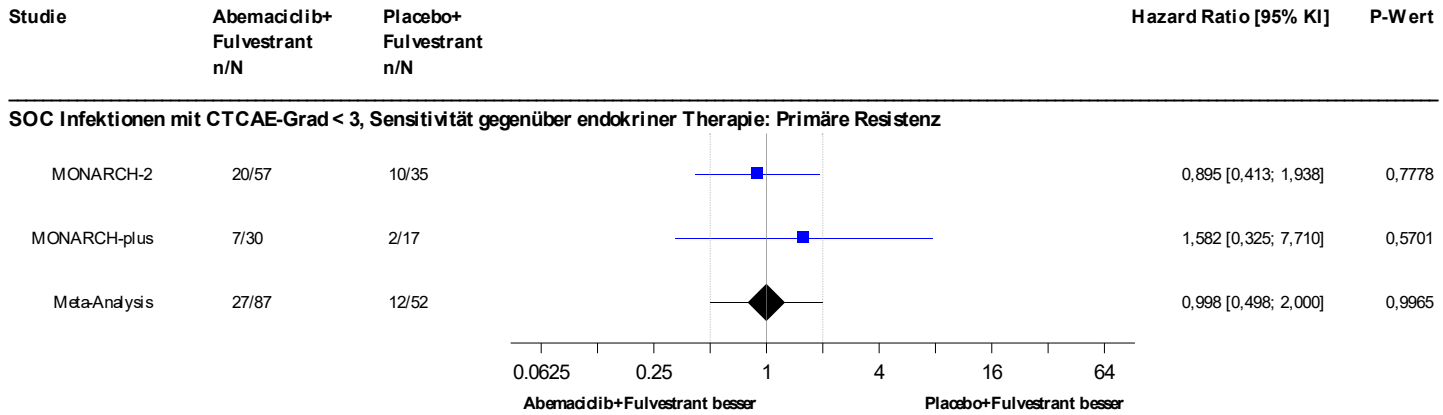
Abbildung 1430.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4021, P-Wert=0,5260, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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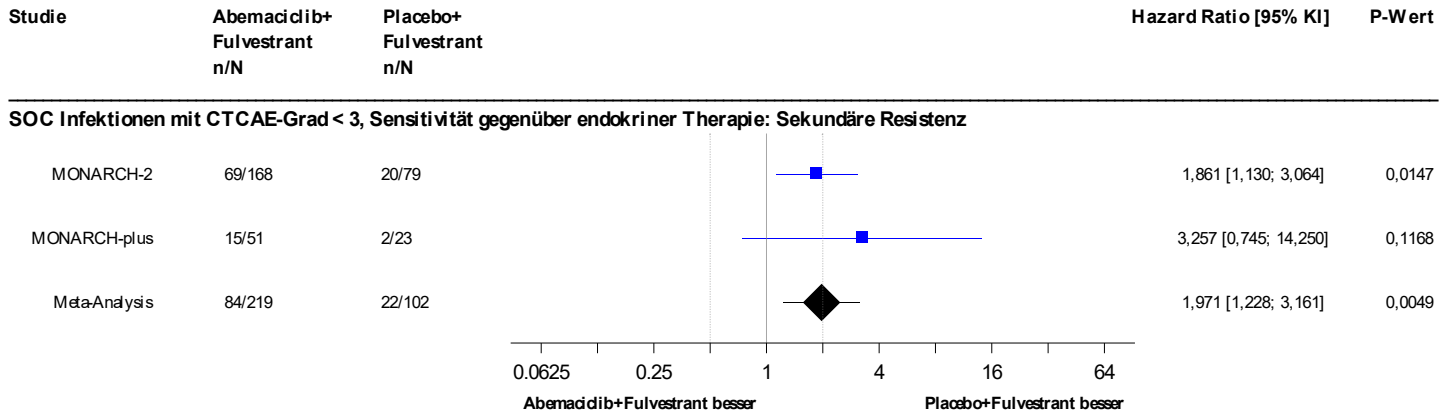
Abbildung 1430.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4964, P-Wert=0,4811, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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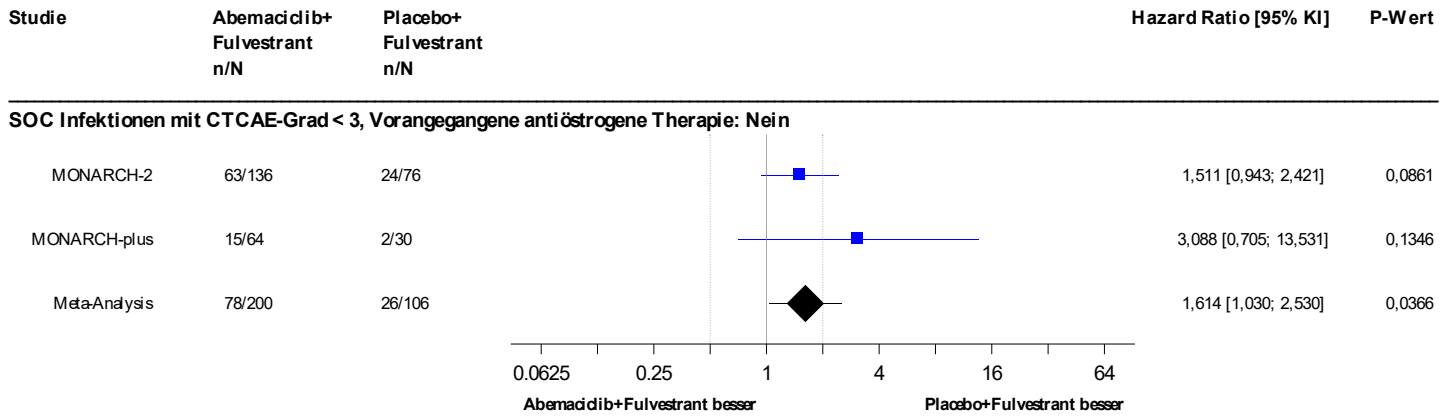
Abbildung 1430.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,8162, P-Wert=0,3663, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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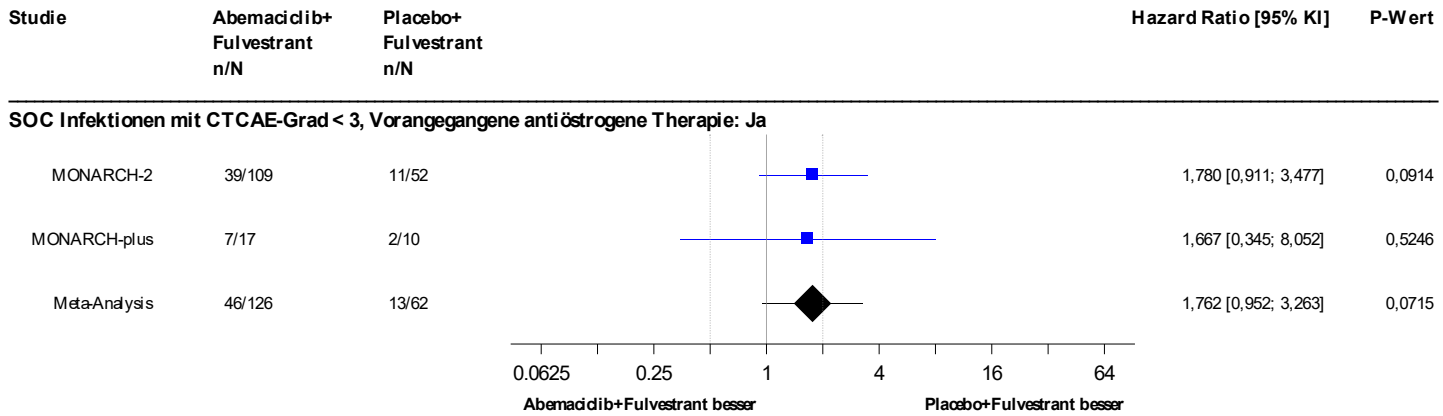
Abbildung 1430.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0056, P-Wert=0,9403, I2 Index=0%
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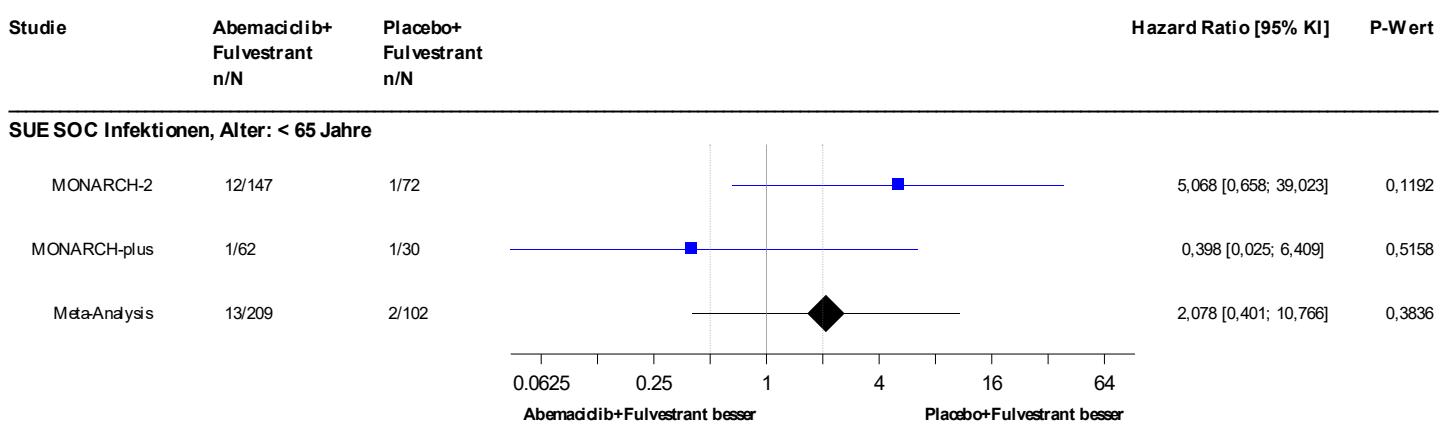
Abbildung 1431.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,0916, P-Wert=0,1481, I2 Index=52,2%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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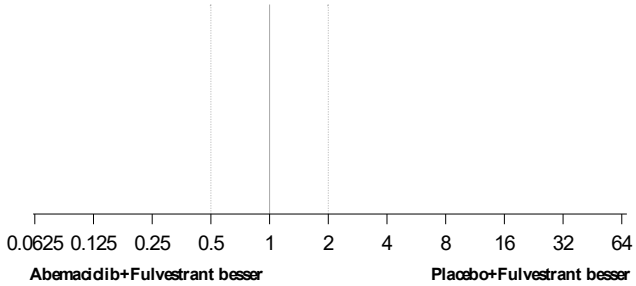
Abbildung 1431.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

Studie	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% KI]	P-Wert
SUE SOC Infektionen, Alter: >= 65 Jahre				
MONARCH-2	4/98	0/56	>100 [0,000; NE]	0,9953
MONARCH-plus	0/19	0/10	NE	NE
Meta-Analysis	4/117	0/66	NE	NE



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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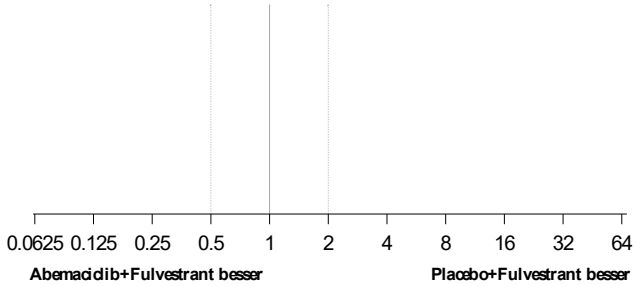
Abbildung 1431.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

Studie	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% KI]	P-Wert
SUE SOC Infektionen, Art der Erkrankung: Nicht-viszerale Metastasen				
MONARCH-2	7/115	0/48	>100 [0,000; NE]	0,9942
MONARCH-plus	0/34	0/19	NE	NE
Meta-Analysis	7/149	0/67	NE	NE



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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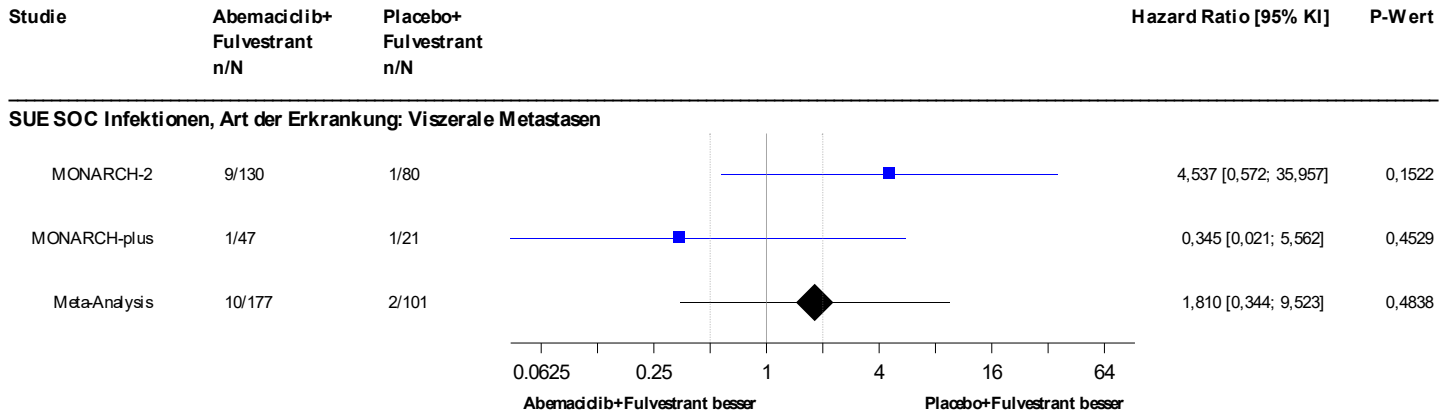
Abbildung 1431.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,1227, P-Wert=0,1451, I2 Index=52,9%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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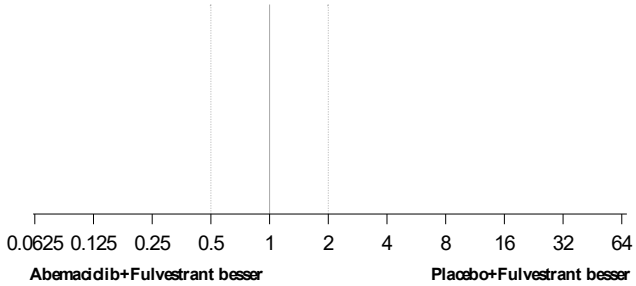
Abbildung 1431.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

Studie	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% KI]	P-Wert
SUE SOC Infektionen, ECOG-PS zu Baseline: 0				
MONARCH-2	7/135	0/74	>100 [0,000; NE]	0,9940
MONARCH-plus	0/27	0/14	NE	NE
Meta-Analysis	7/162	0/88	NE	NE



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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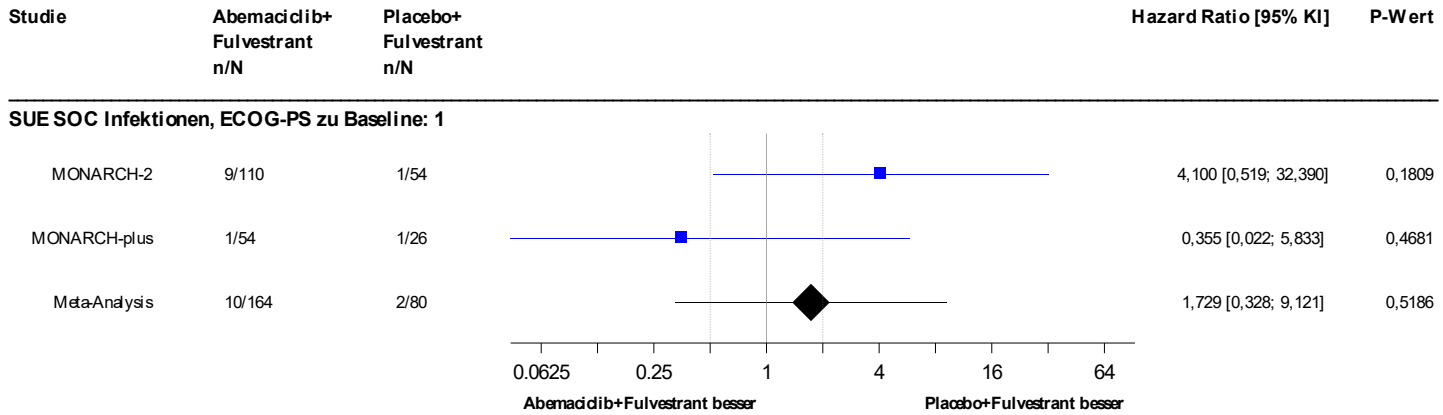
Abbildung 1431.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,8999, P-Wert=0,1681, I2 Index=47,4%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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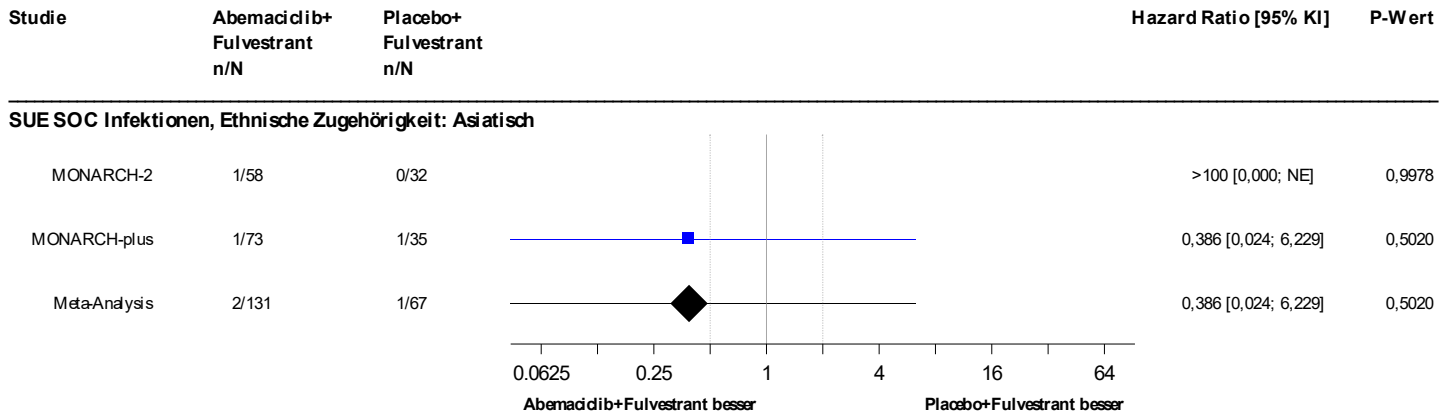
Abbildung 1431.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9977, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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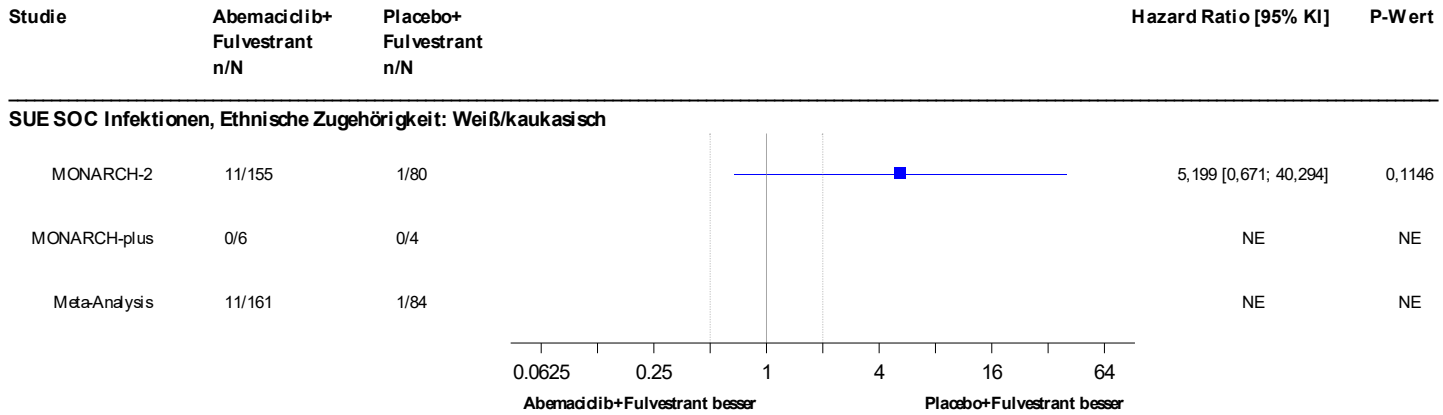
Abbildung 1431.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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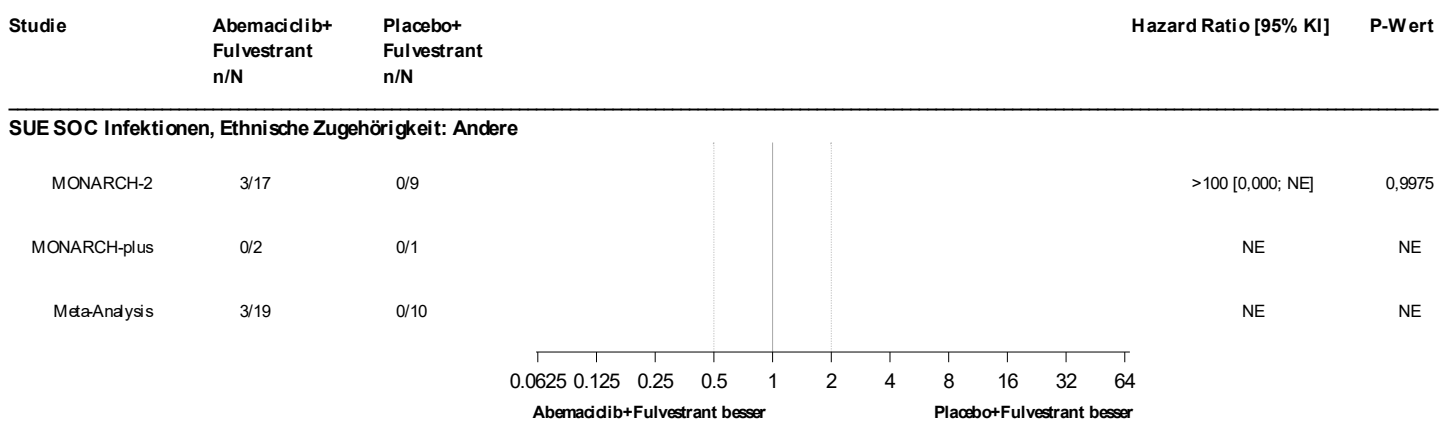
Abbildung 1431.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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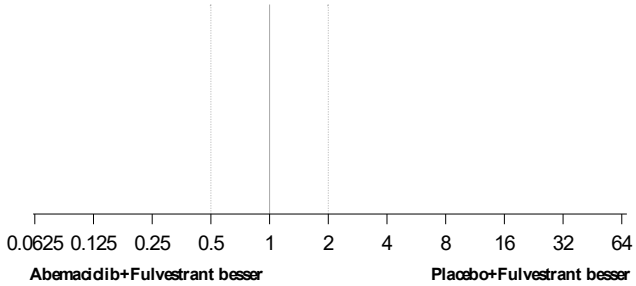
Abbildung 1431.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

Studie	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% KI]	P-Wert
SUE SOC Infektionen, Messbare Erkrankung zu Baseline: Nein				
MONARCH-2	5/76	0/34	>100 [0,000; NE]	0,9950
MONARCH-plus	0/19	0/14	NE	NE
Meta-Analysis	5/95	0/48	NE	NE



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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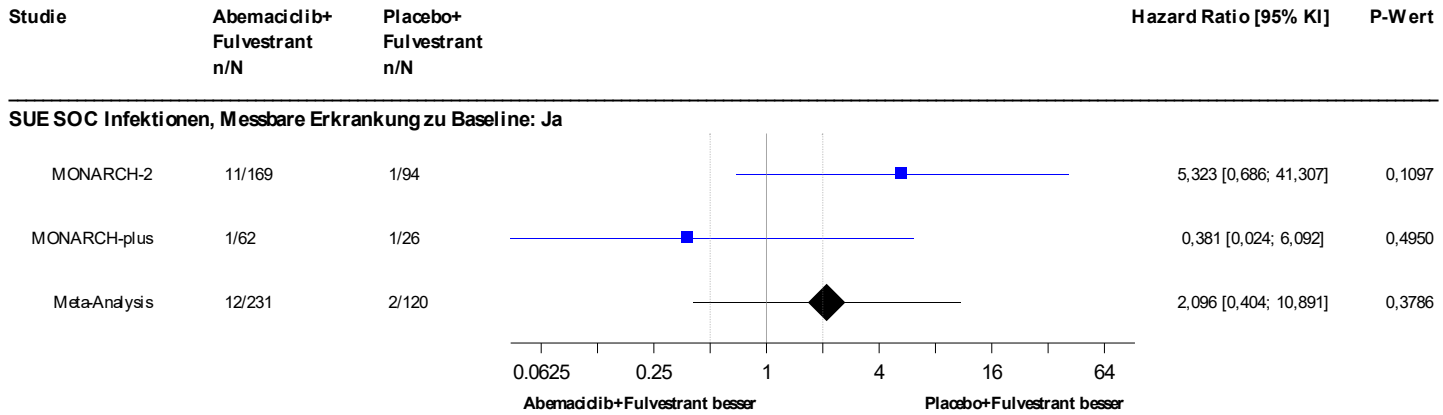
Abbildung 1431.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,2481, P-Wert=0,1338, I2 Index=55,5%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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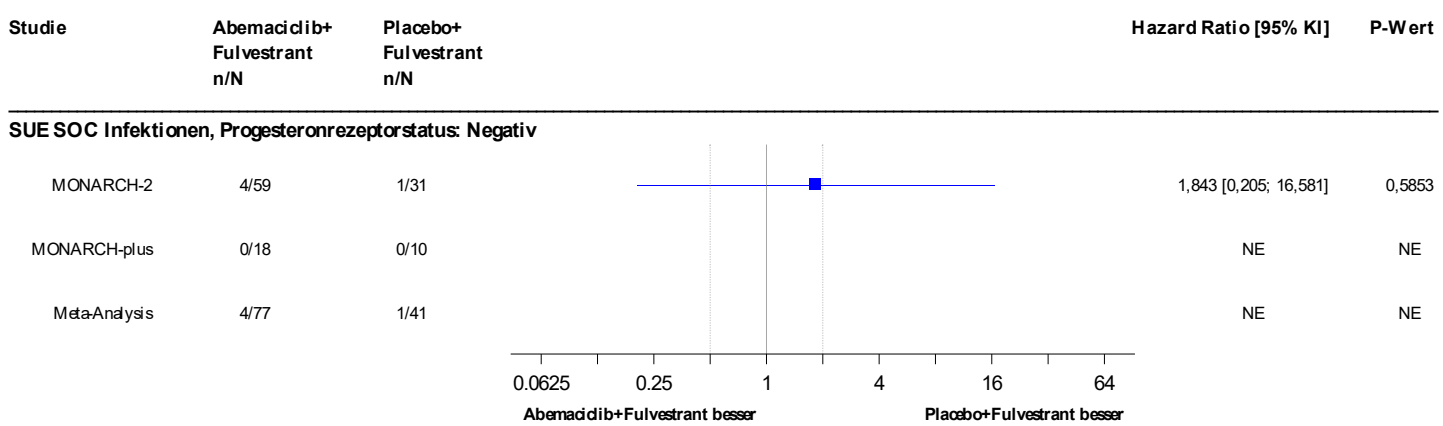
Abbildung 1431.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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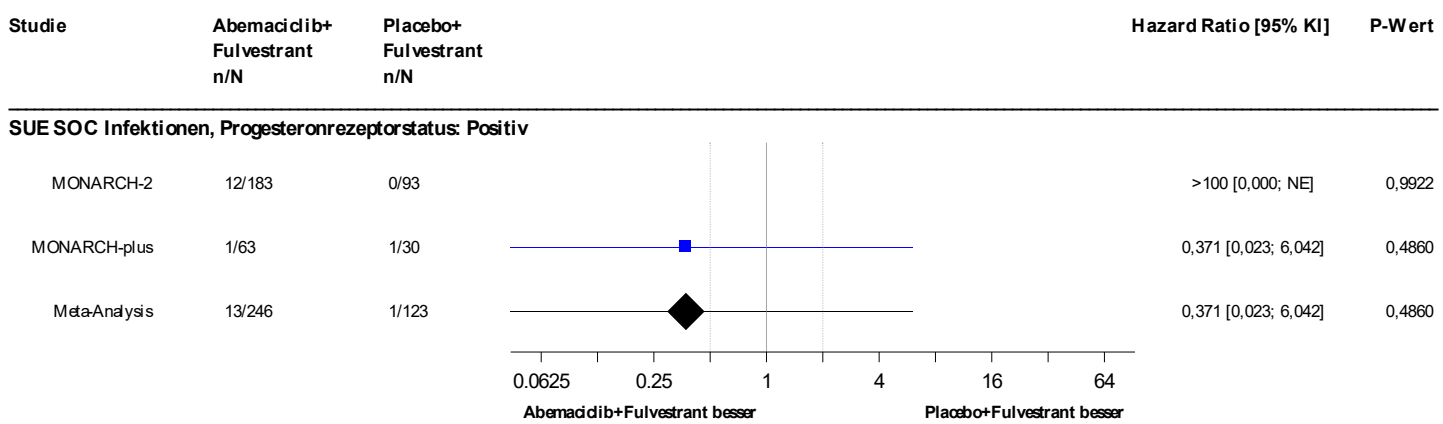
Abbildung 1431.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9918, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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Abbildung 1431.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9958, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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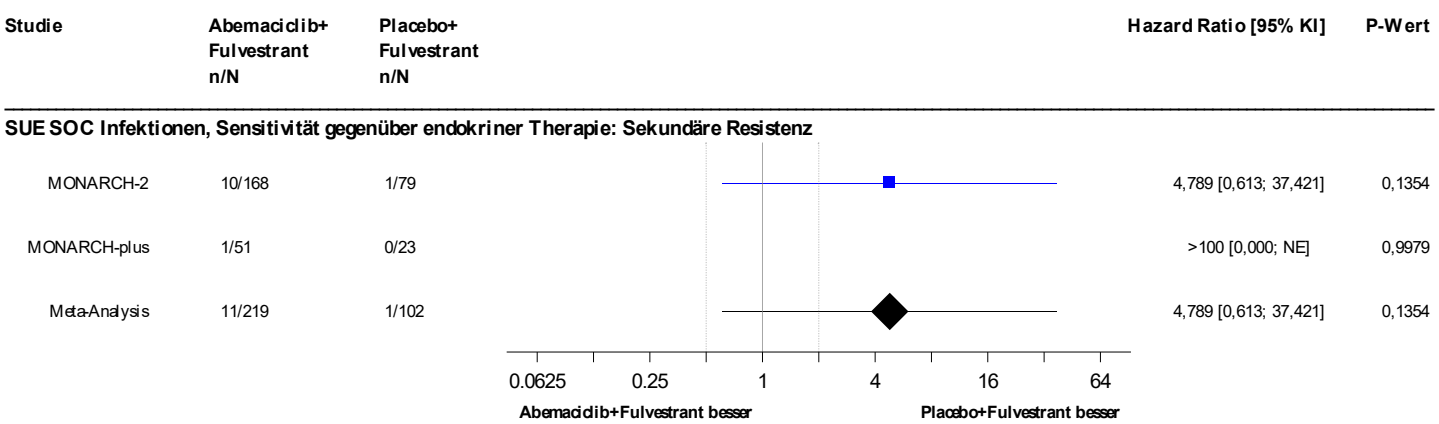
Abbildung 1431.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9981, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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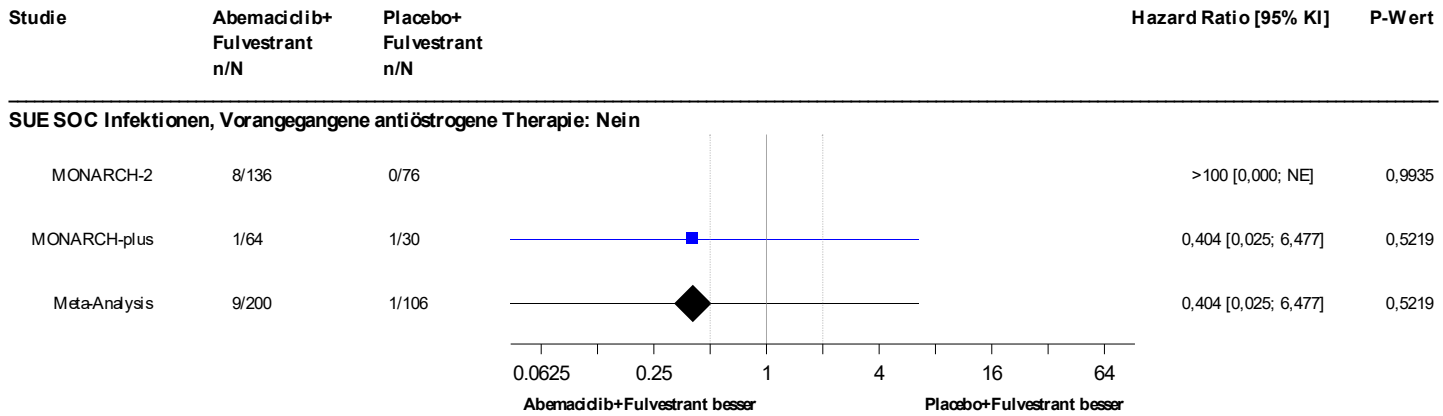
Abbildung 1431.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9931, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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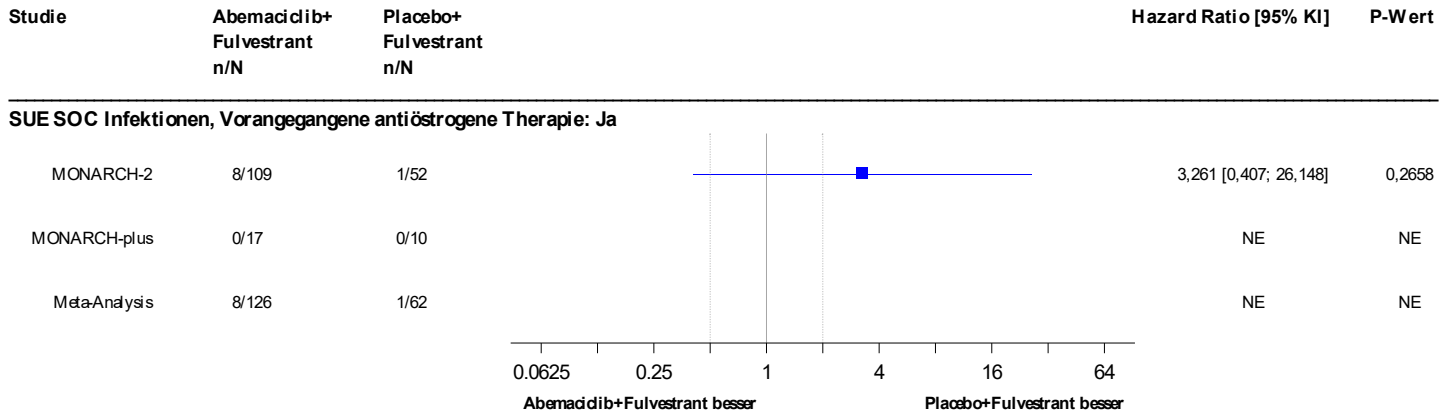
Abbildung 1431.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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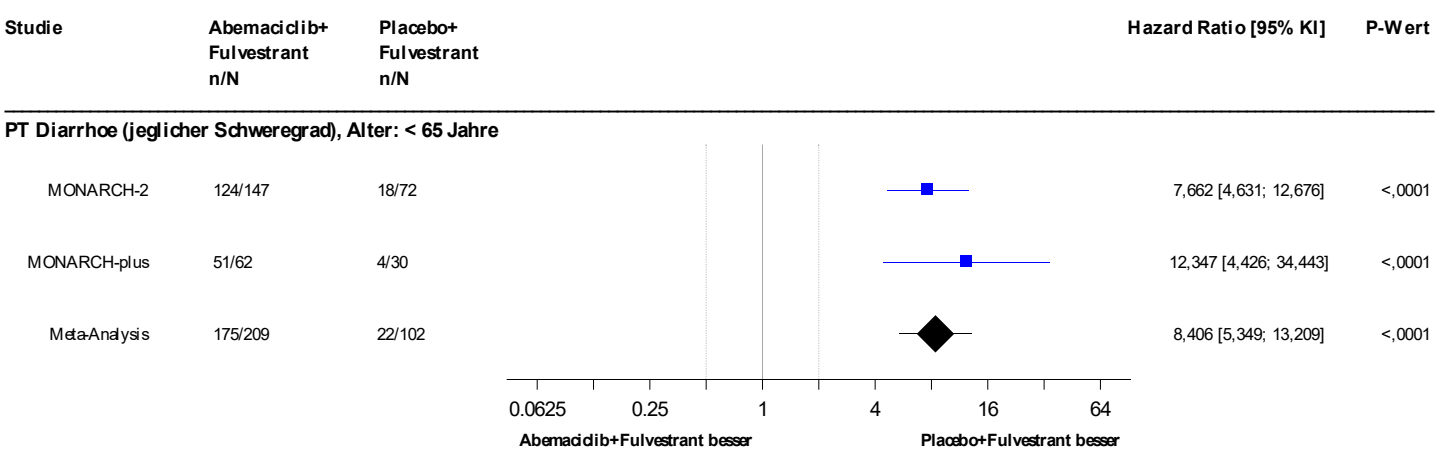
Abbildung 1432.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6697, P-Wert=0,4132, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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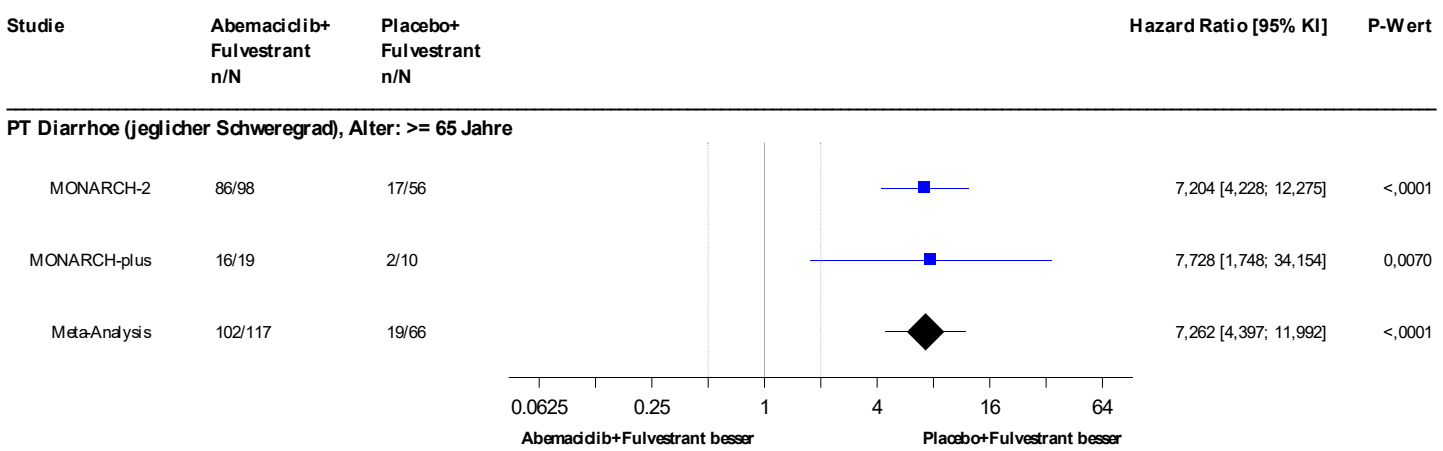
Abbildung 1432.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0076, P-Wert=0,9306, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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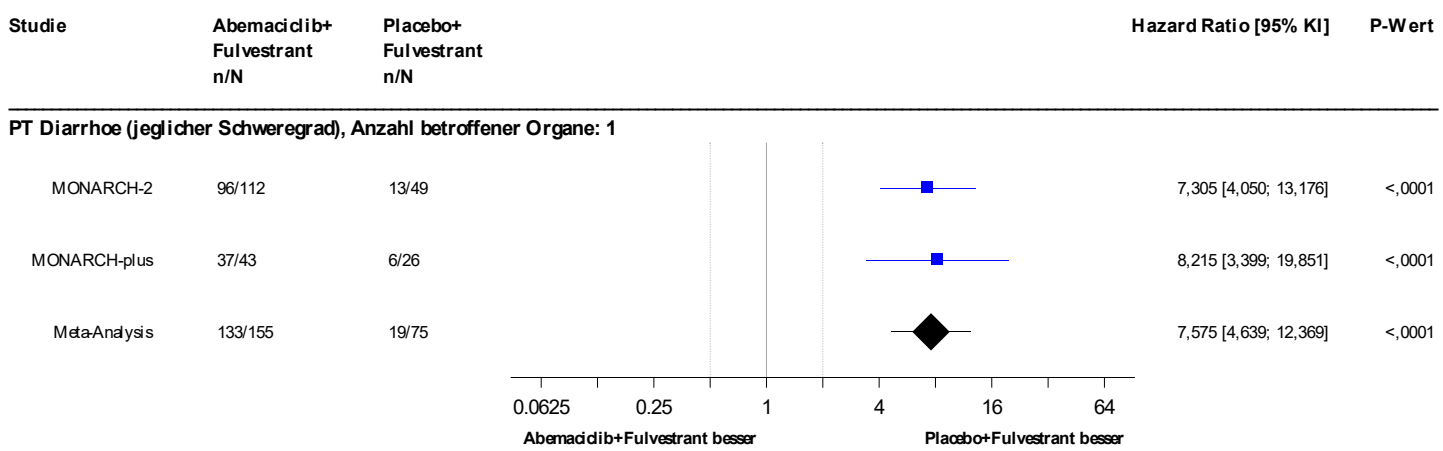
Abbildung 1432.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0469, P-Wert=0,8285, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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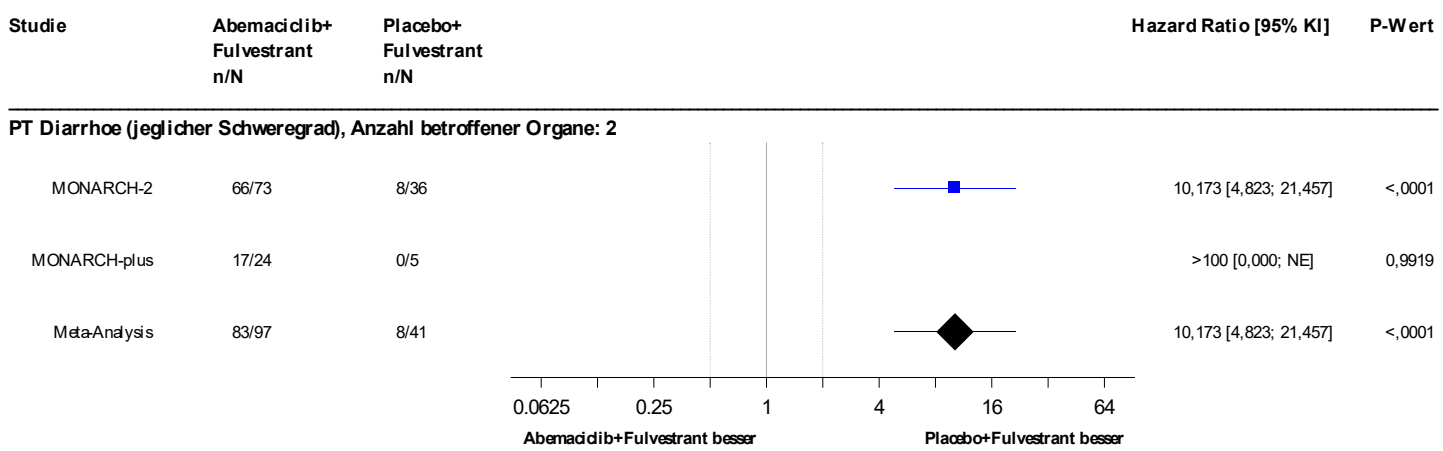
Abbildung 1432.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9930, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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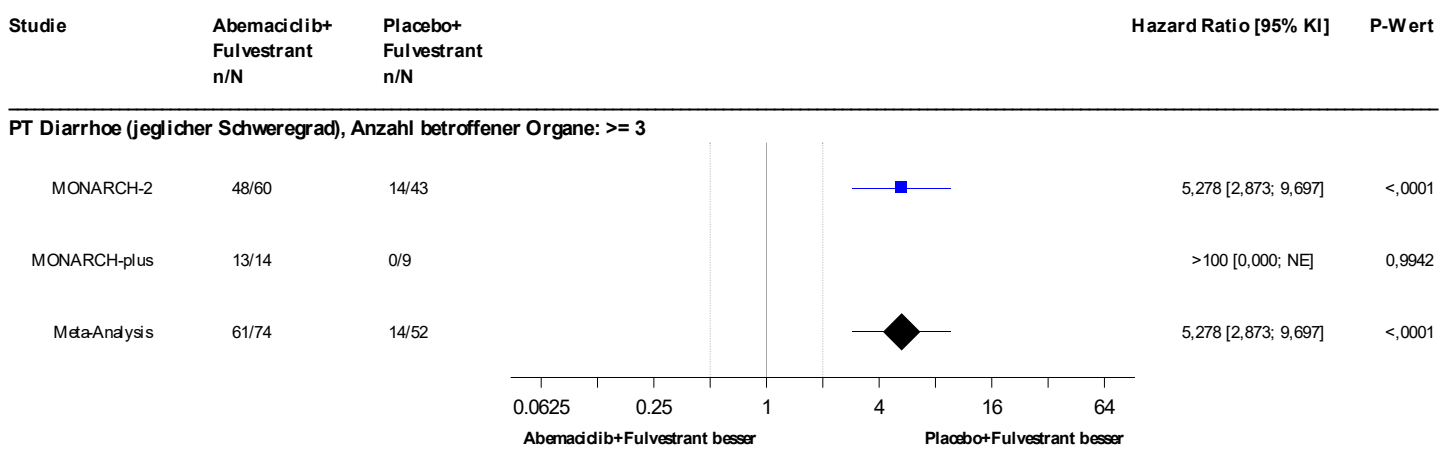
Abbildung 1432.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9947, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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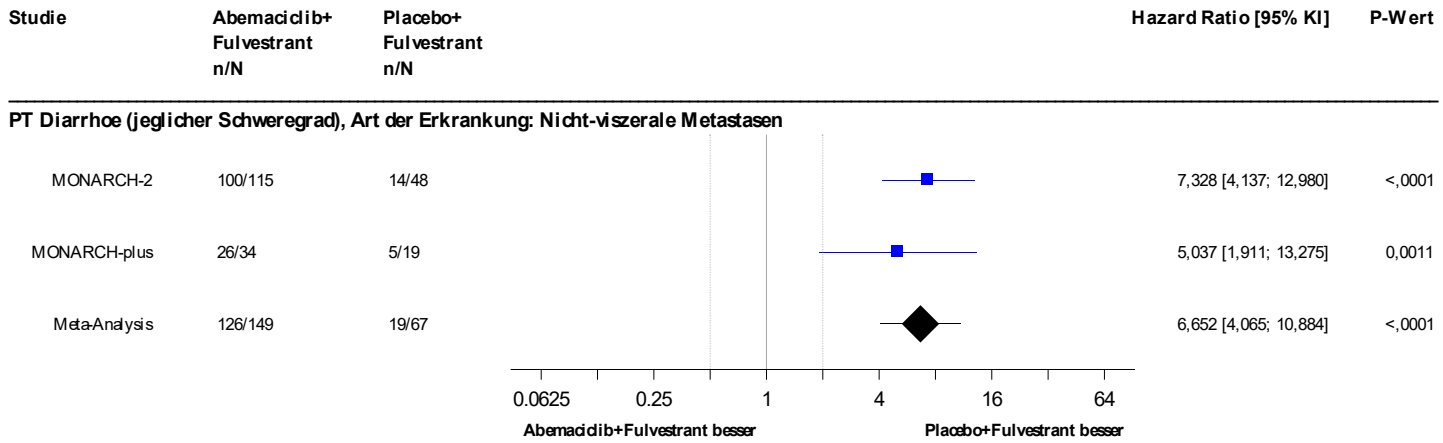
Abbildung 1432.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4264, P-Wert=0,5137, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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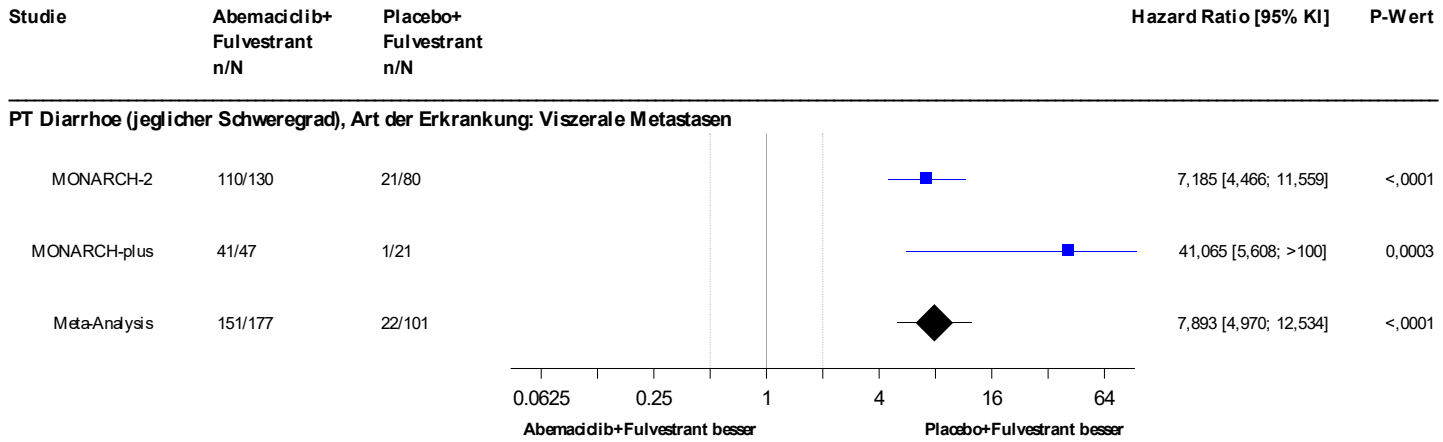
Abbildung 1432.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,7862, P-Wert=0,0951, I2 Index=64,1%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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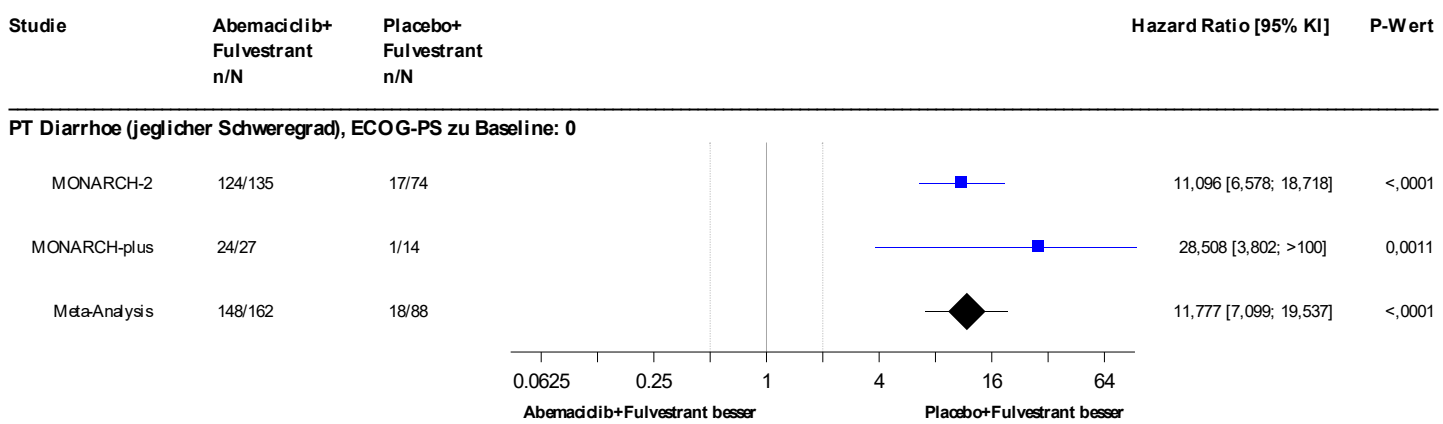
Abbildung 1432.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7895, P-Wert=0,3742, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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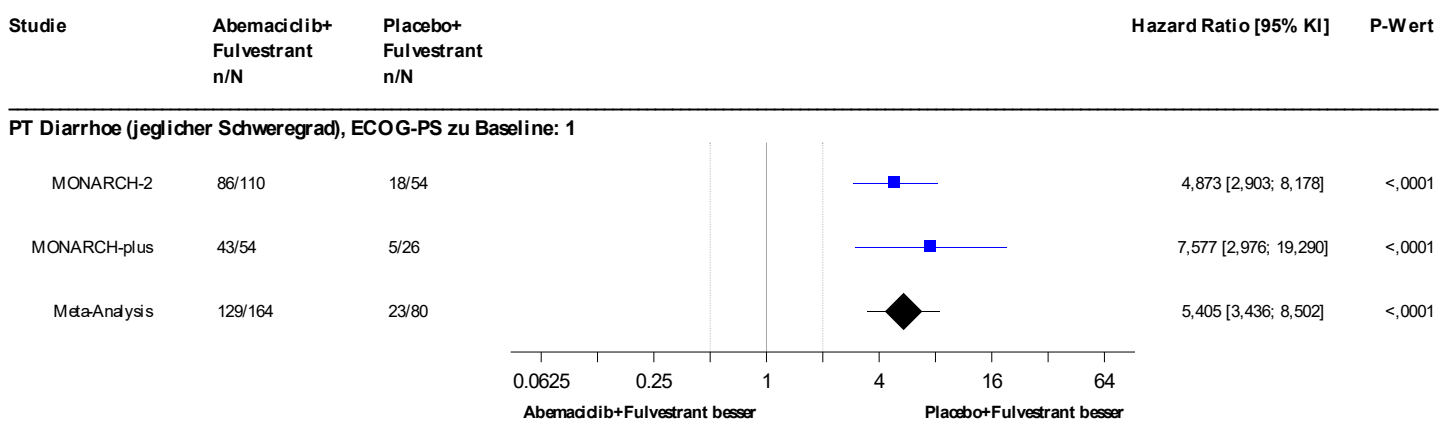
Abbildung 1432.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6561, P-Wert=0,4179, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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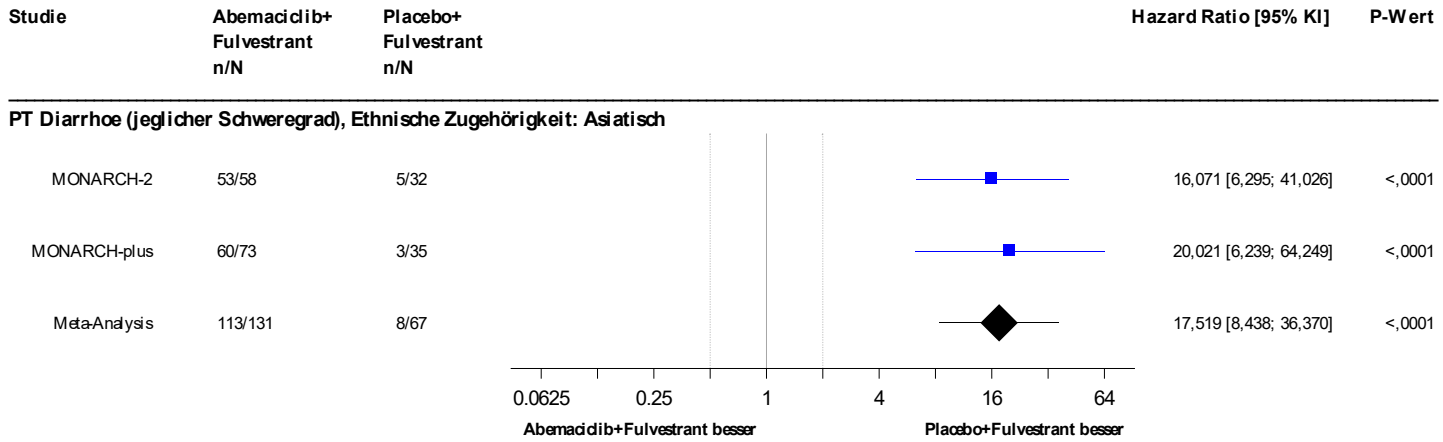
Abbildung 1432.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0829, P-Wert=0,7734, I2 Index=0%
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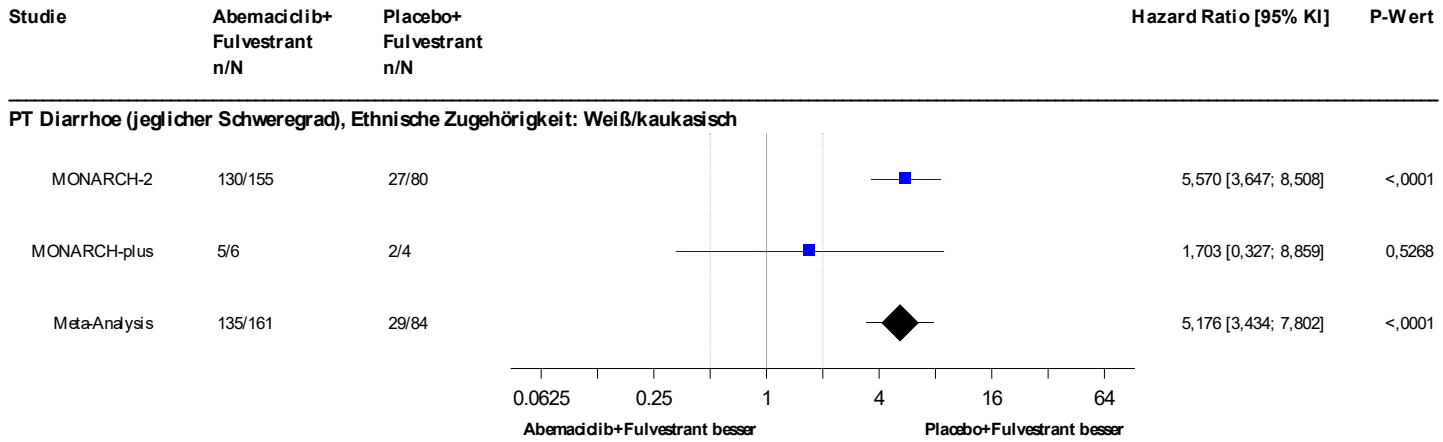
Abbildung 1432.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,8610, P-Wert=0,1725, I2 Index=46,3%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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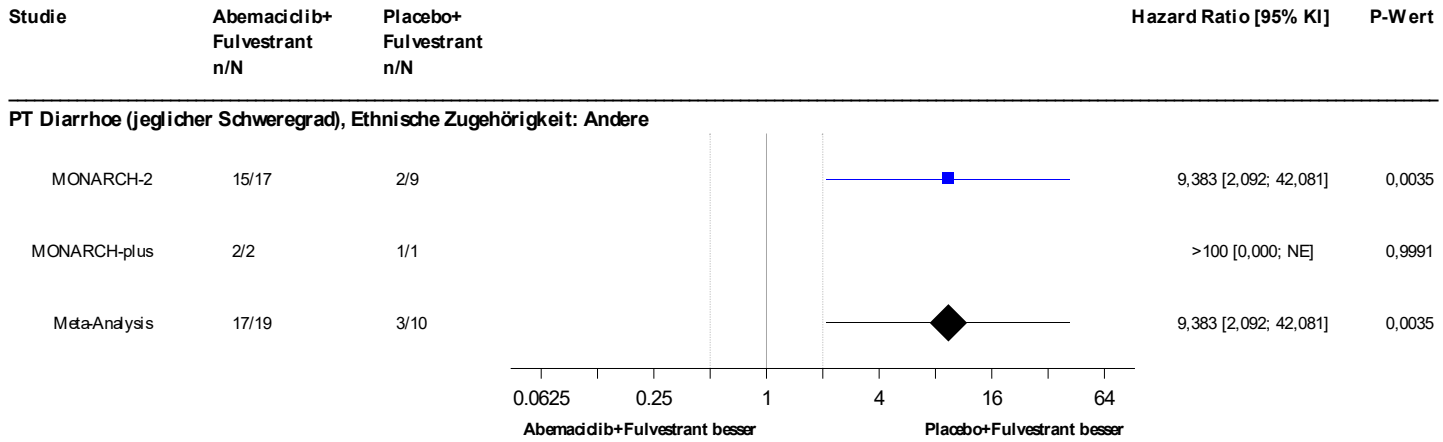
Abbildung 1432.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9992, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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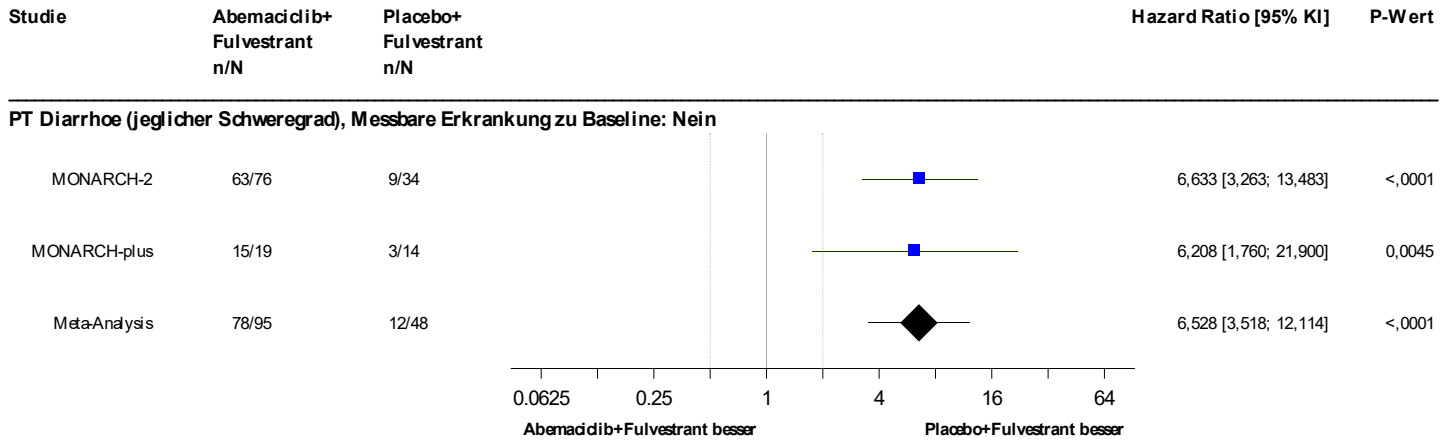
17SEP2021 / 07:48

Abbildung 1432.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0081, P-Wert=0,9285, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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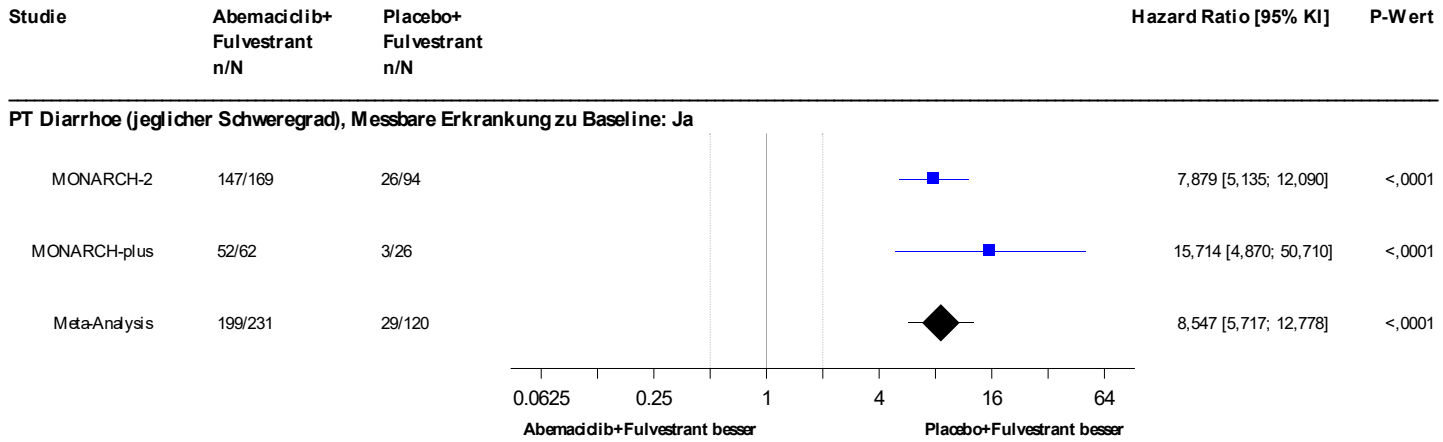
Abbildung 1432.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,1769, P-Wert=0,2780, I2 Index=15,0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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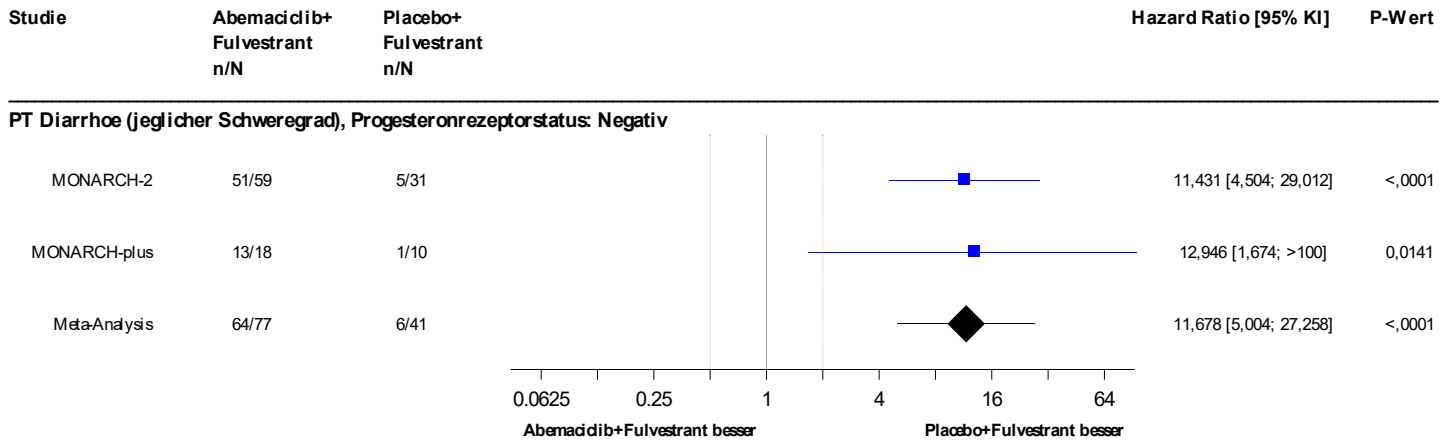
Abbildung 1432.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0118, P-Wert=0,9136, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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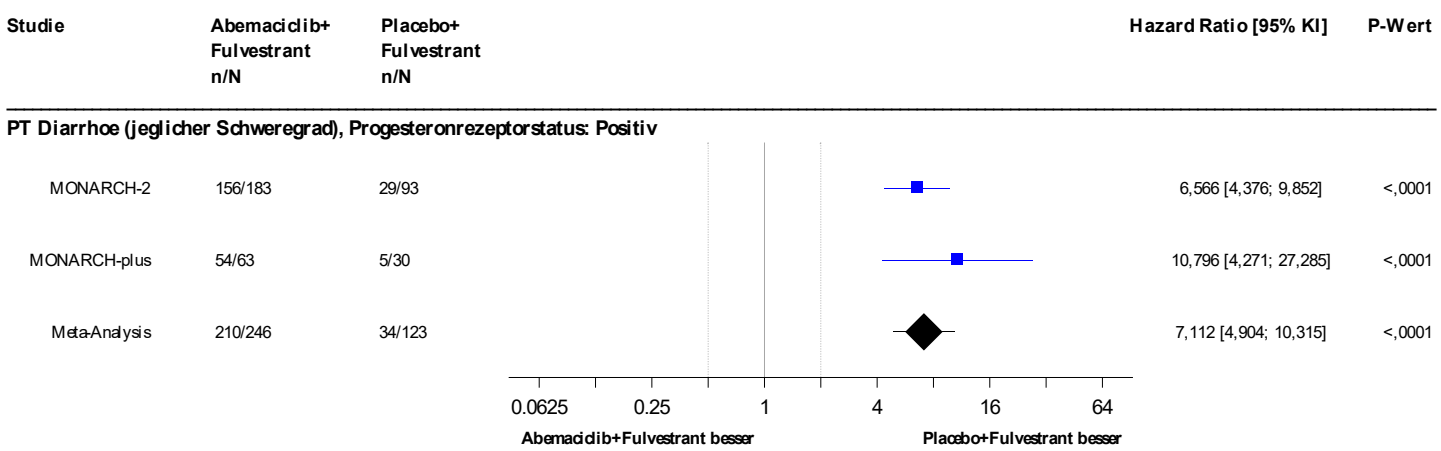
Abbildung 1432.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,9273, P-Wert=0,3356, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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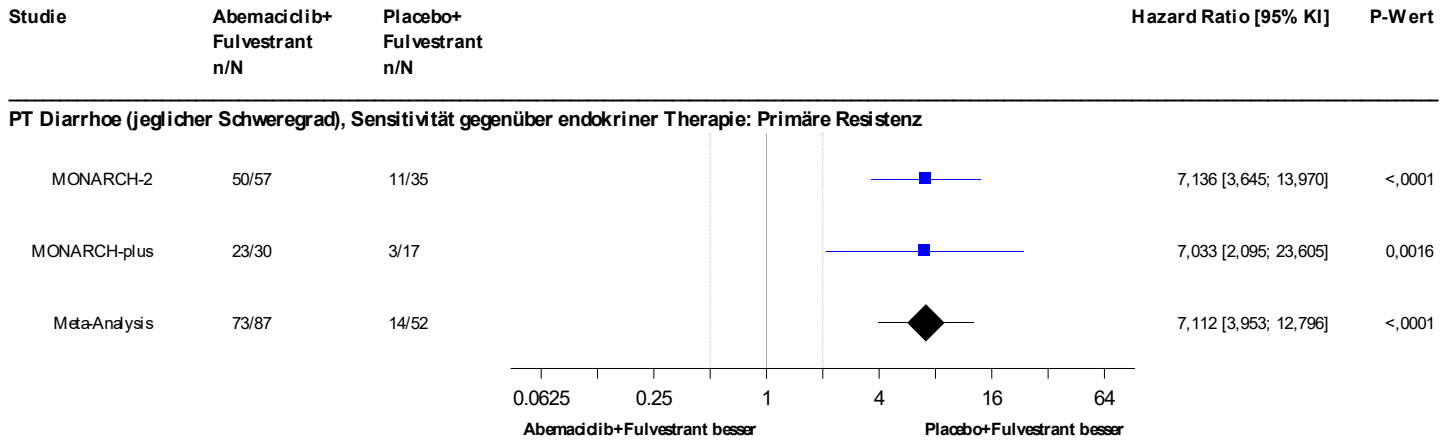
Abbildung 1432.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0004, P-Wert=0,9835, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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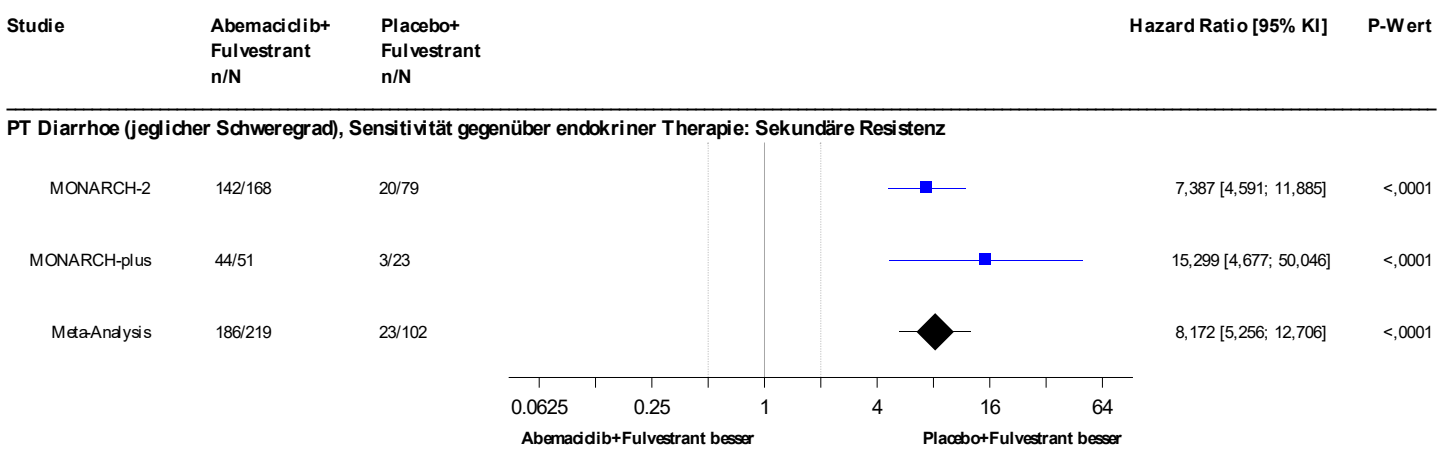
Abbildung 1432.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,2488, P-Wert=0,2638, I2 Index=19,9%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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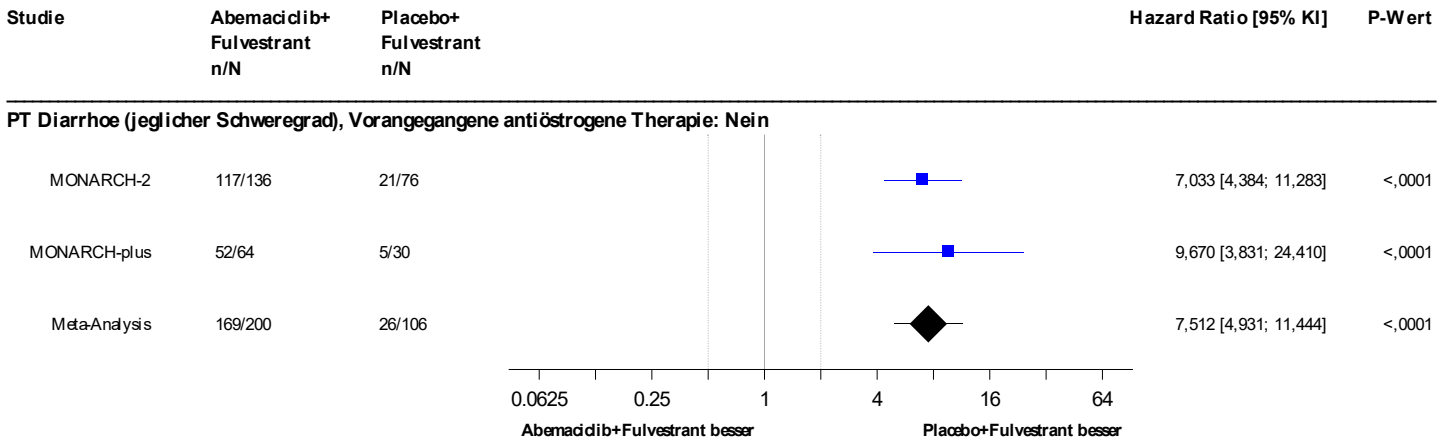
Abbildung 1432.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3604, P-Wert=0,5483, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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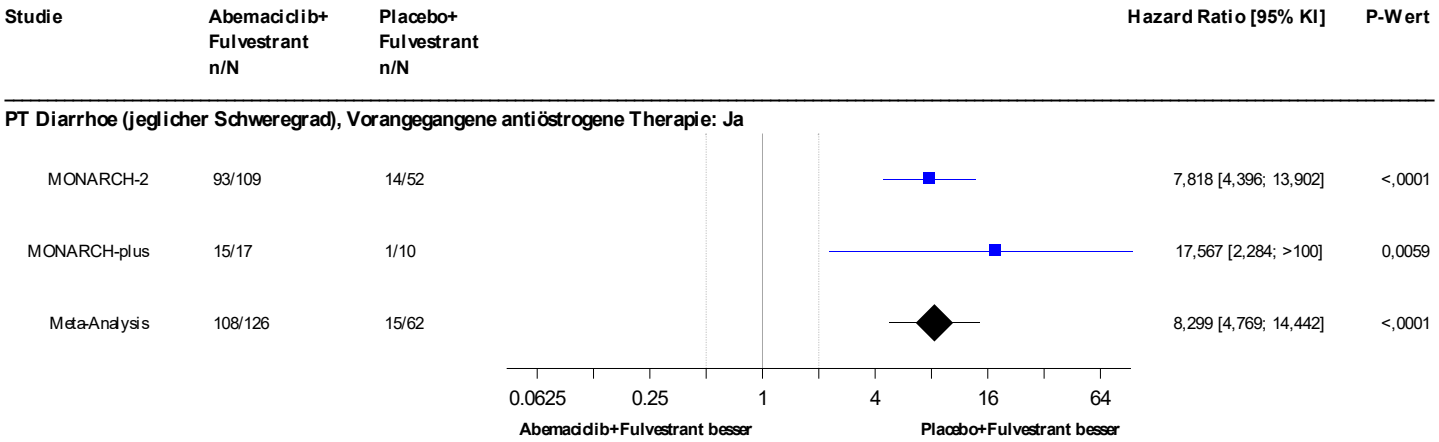
Abbildung 1432.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,5604, P-Wert=0,4541, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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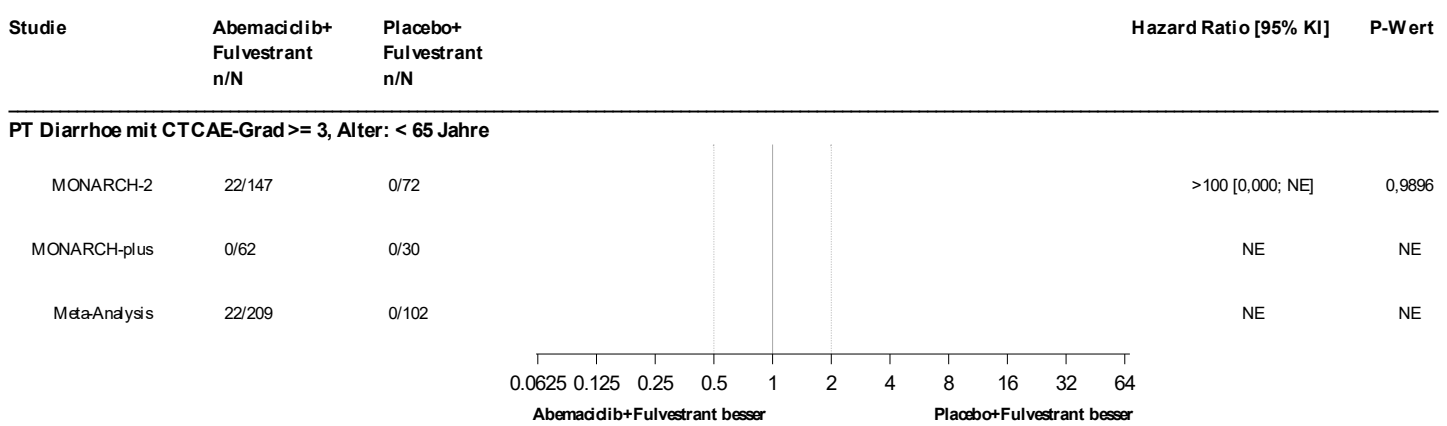
Abbildung 1433.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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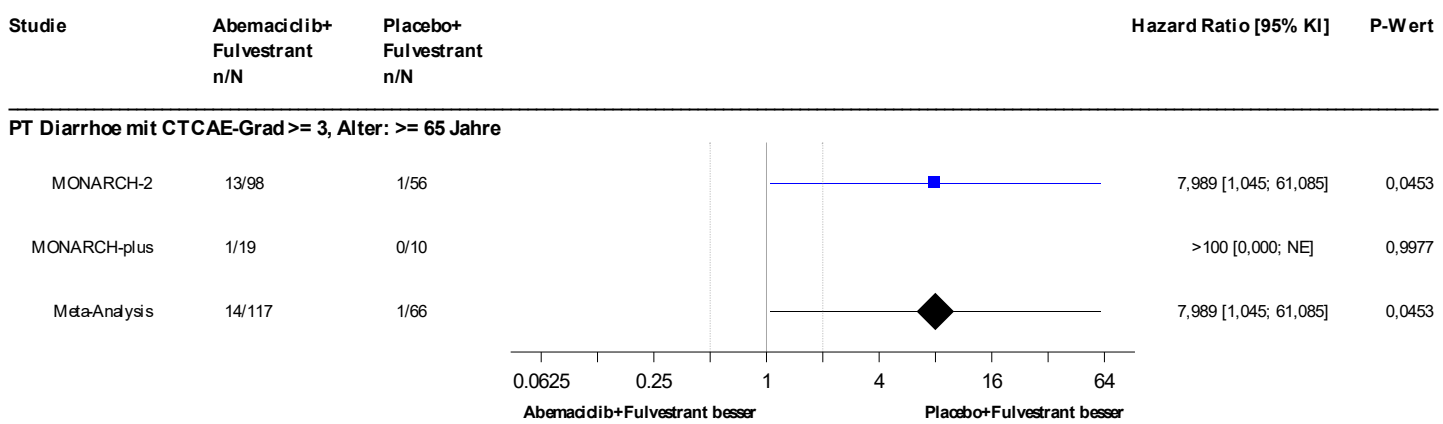
Abbildung 1433.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9980, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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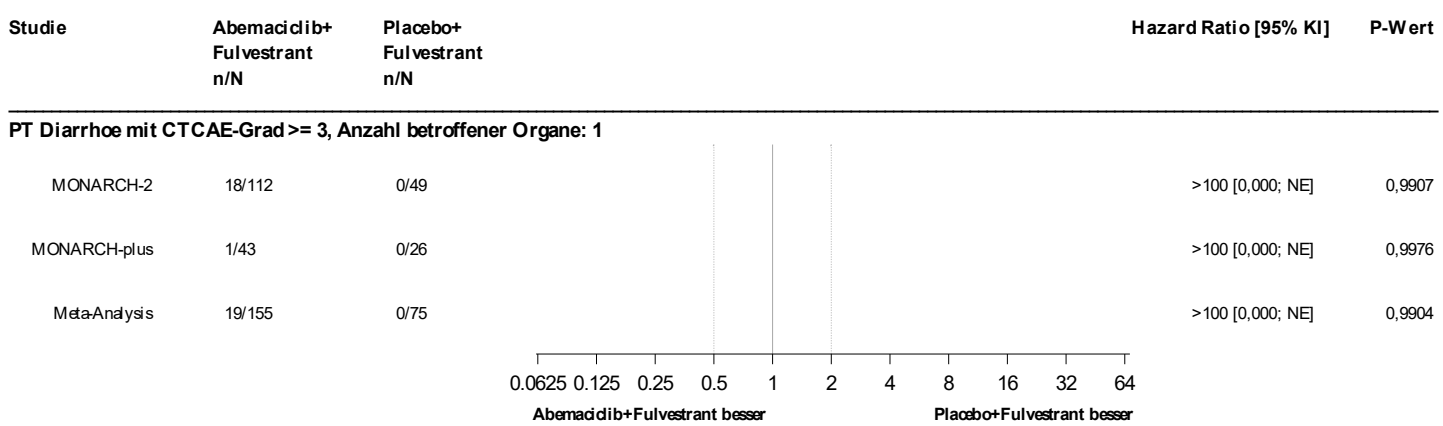
Abbildung 1433.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
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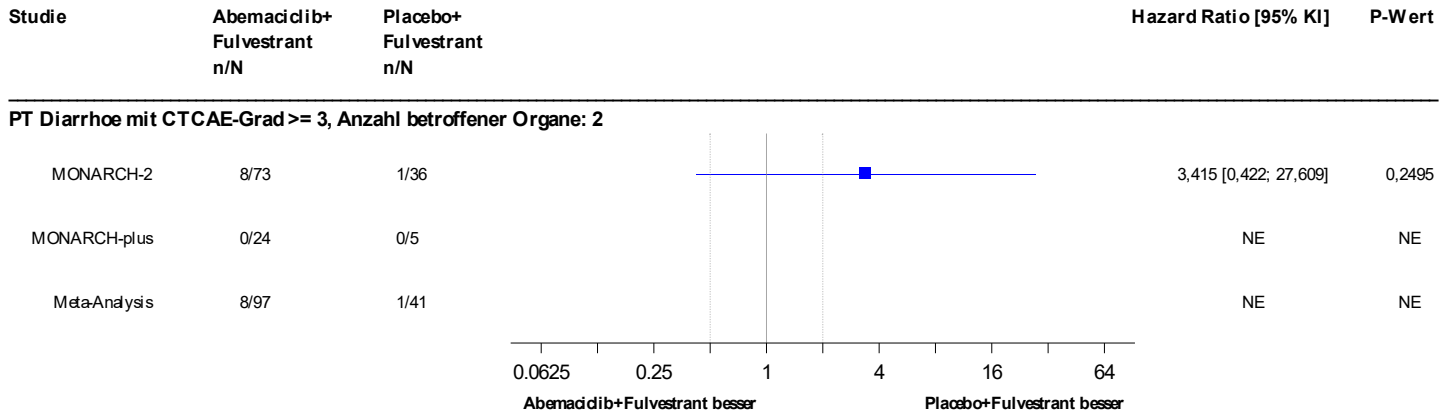
Abbildung 1433.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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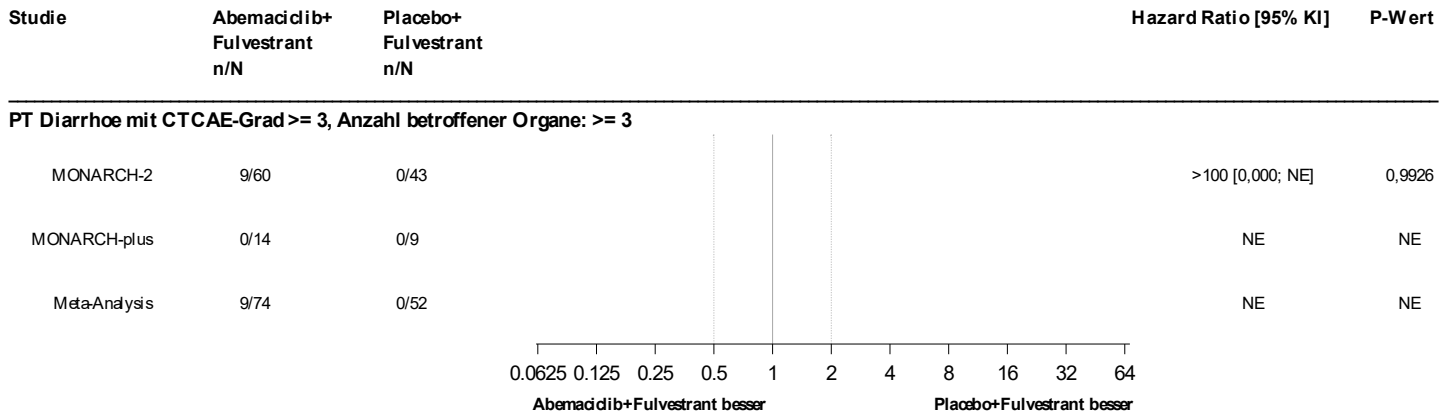
Abbildung 1433.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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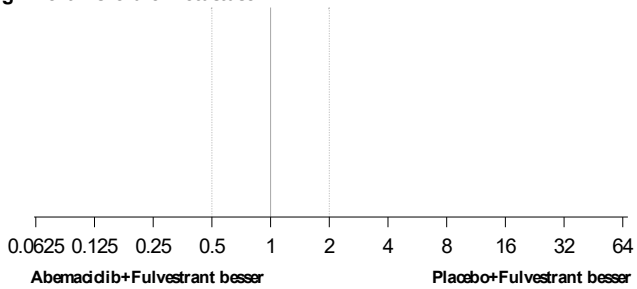
Abbildung 1433.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

Studie	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% KI]	P-Wert
PT Diarrhoe mit CTCAE-Grad >= 3, Art der Erkrankung: Nicht-viszerale Metastasen				
MONARCH-2	19/115	0/48	>100 [0,000; NE]	0,9903
MONARCH-plus	1/34	0/19	>100 [0,000; NE]	0,9977
Meta-Analysis	20/149	0/67	>100 [0,000; NE]	0,9900



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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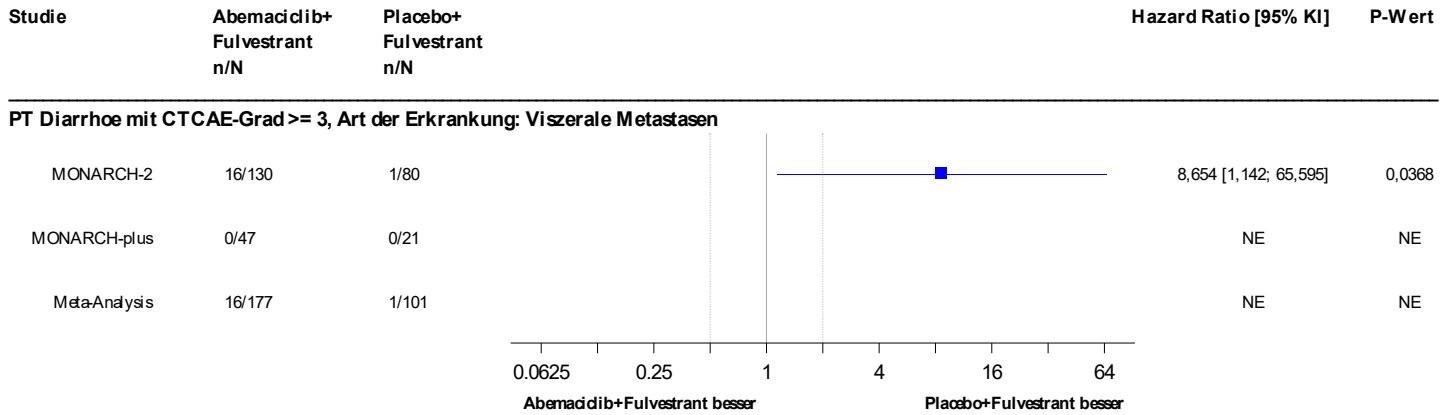
Abbildung 1433.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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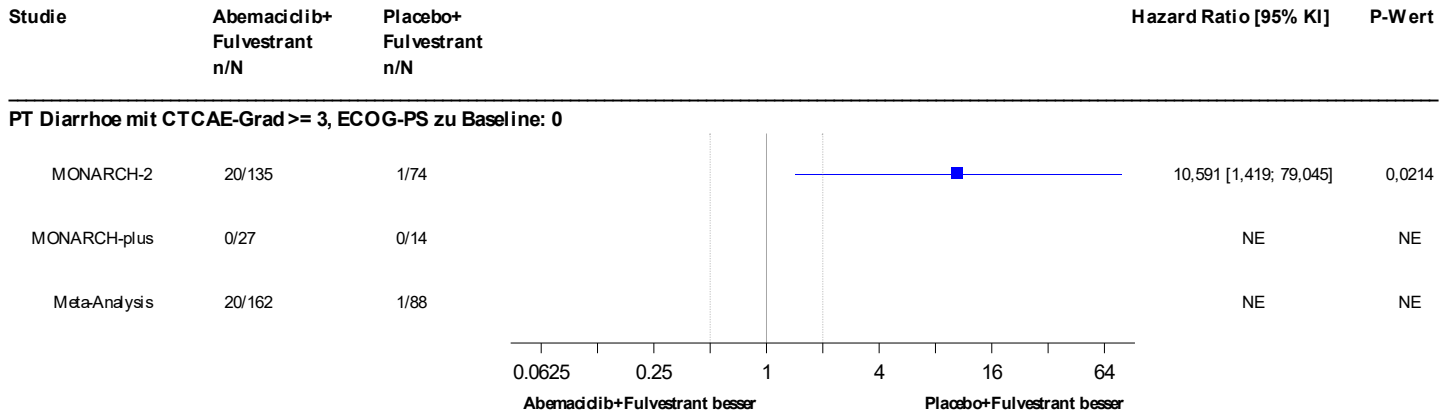
Abbildung 1433.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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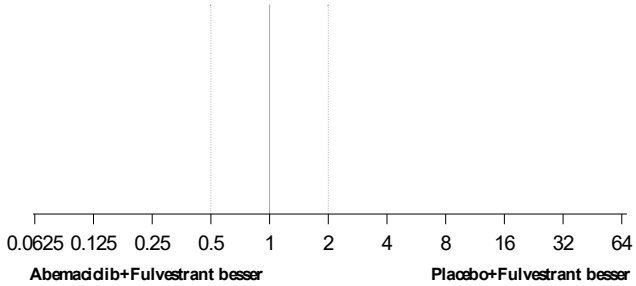
Abbildung 1433.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

Studie	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% KI]	P-Wert
PT Diarrhoe mit CTCAE-Grad >= 3, ECOG-PS zu Baseline: 1				
MONARCH-2	15/110	0/54	>100 [0,000; NE]	0,9912
MONARCH-plus	1/54	0/26	>100 [0,000; NE]	0,9978
Meta-Analysis	16/164	0/80	>100 [0,000; NE]	0,9909



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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Abbildung 1433.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

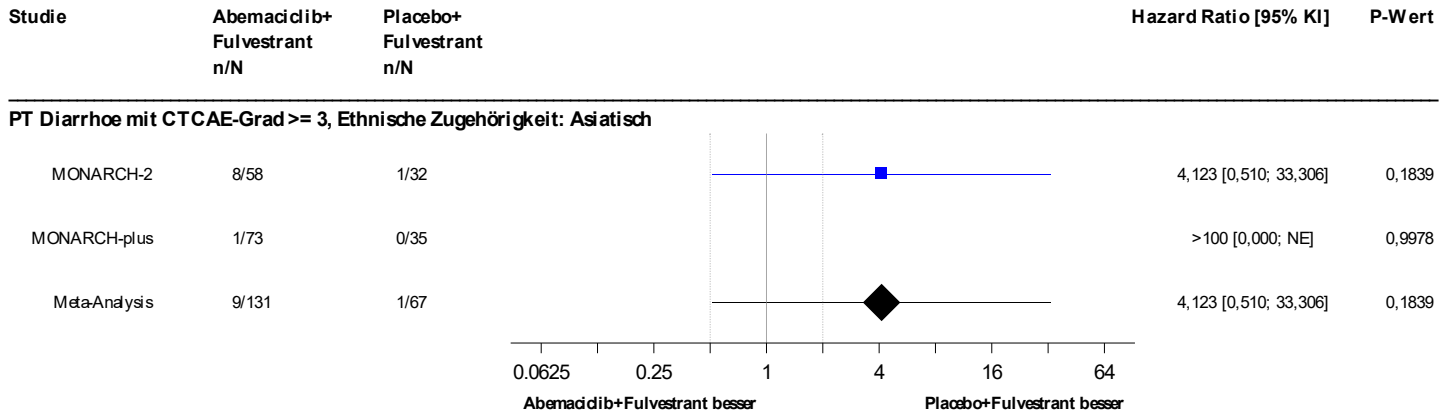

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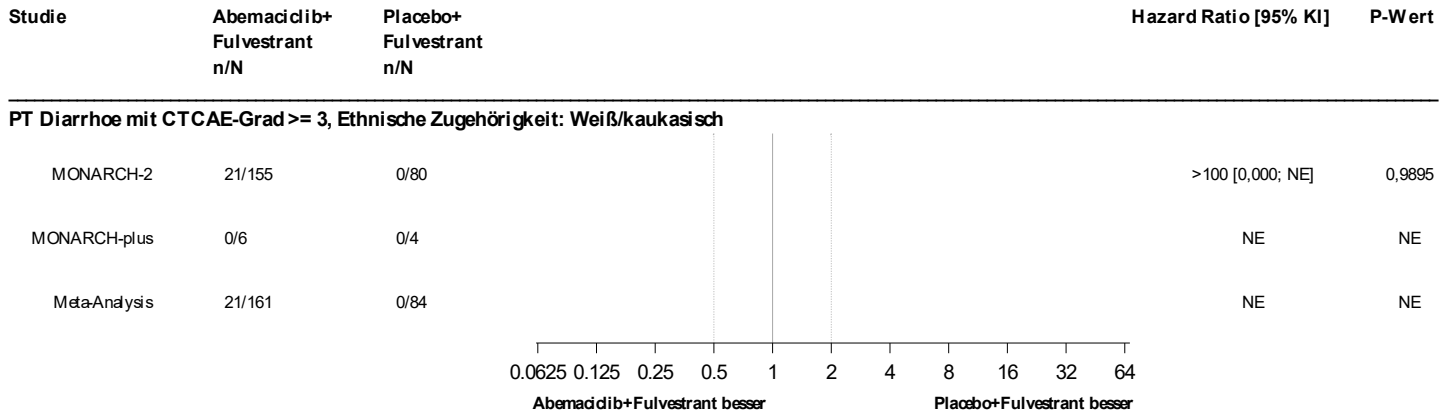
Abbildung 1433.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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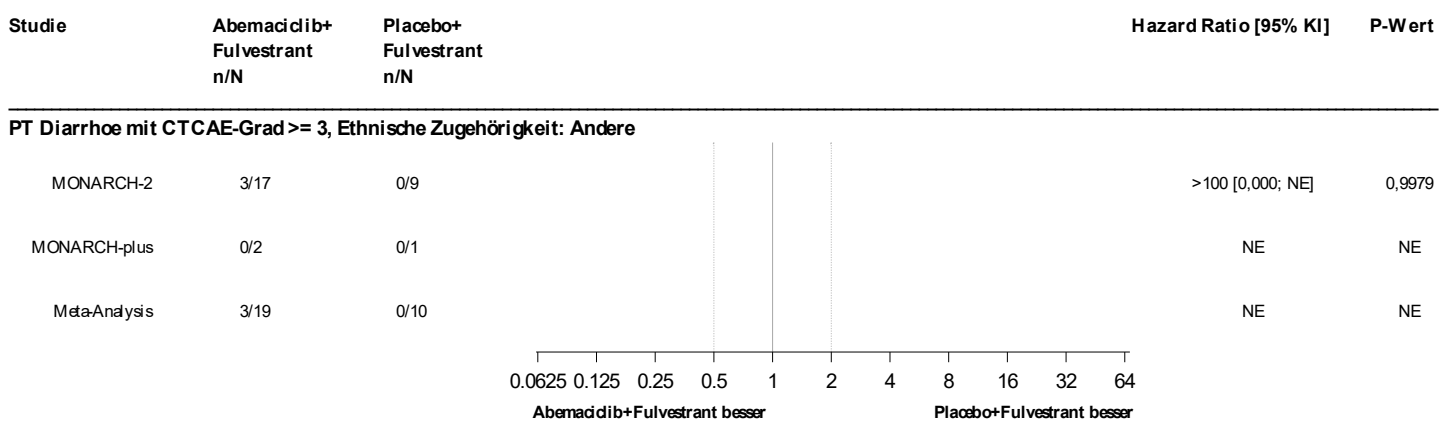
Abbildung 1433.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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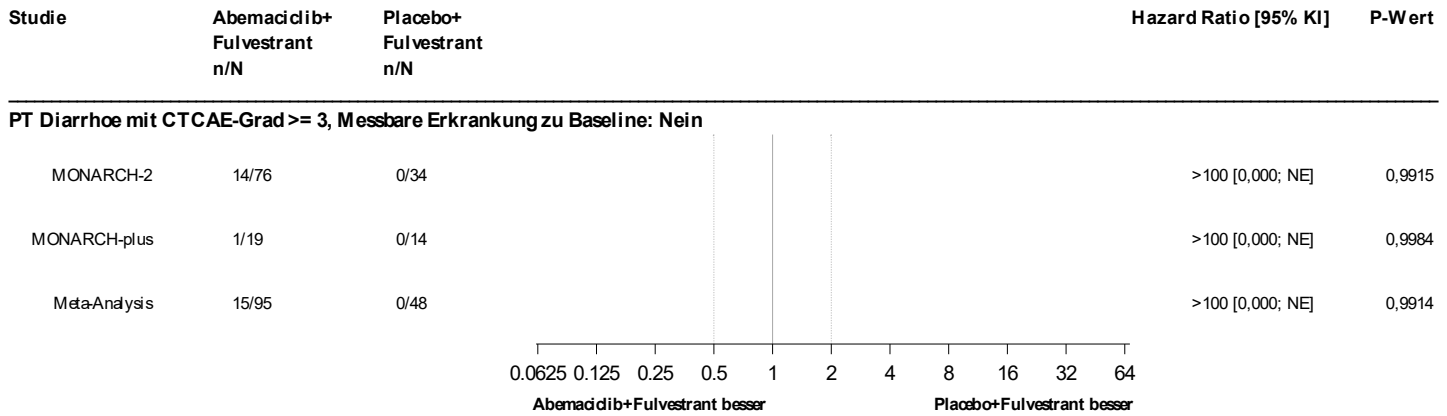
Abbildung 1433.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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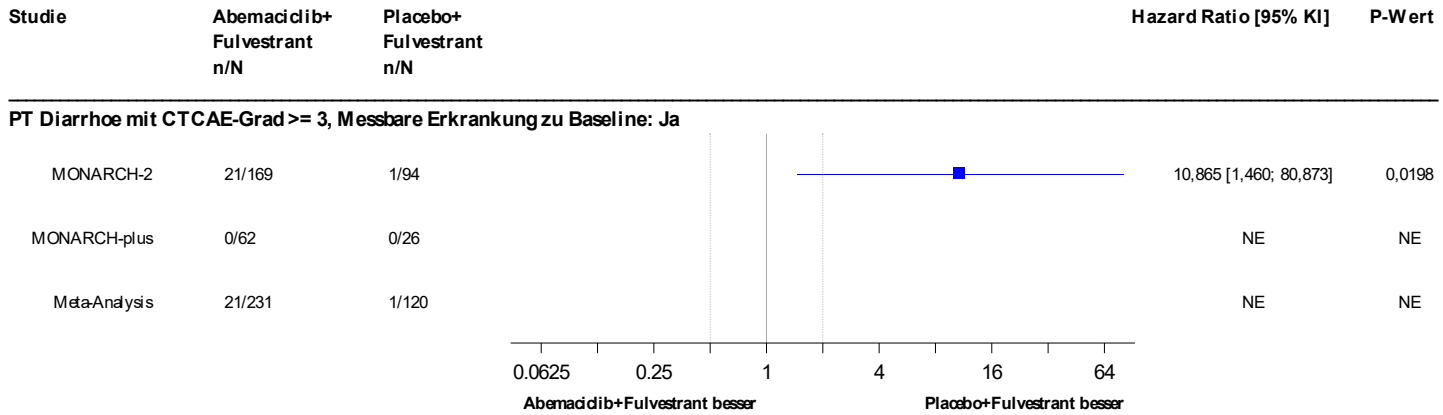
Abbildung 1433.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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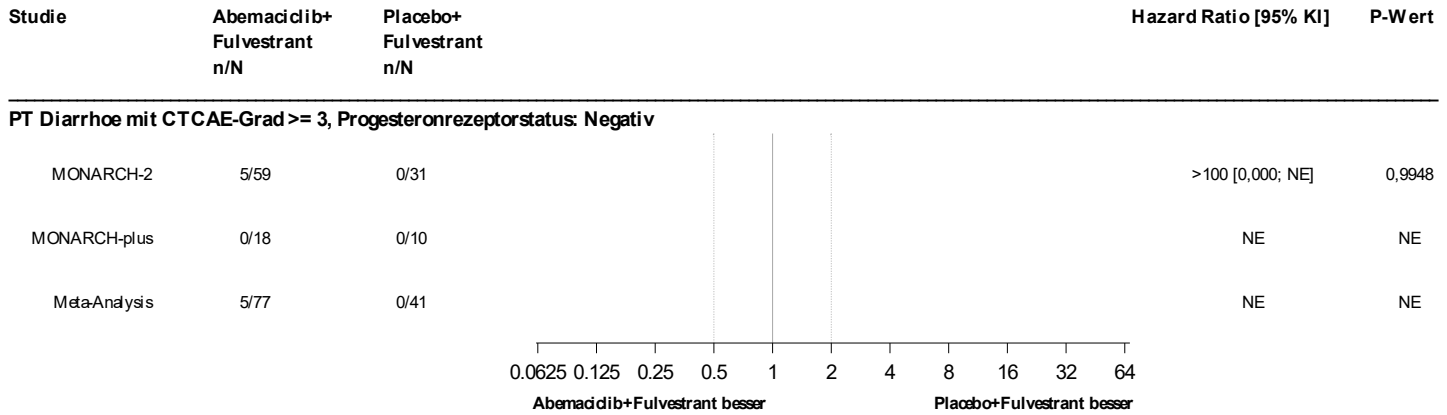
Abbildung 1433.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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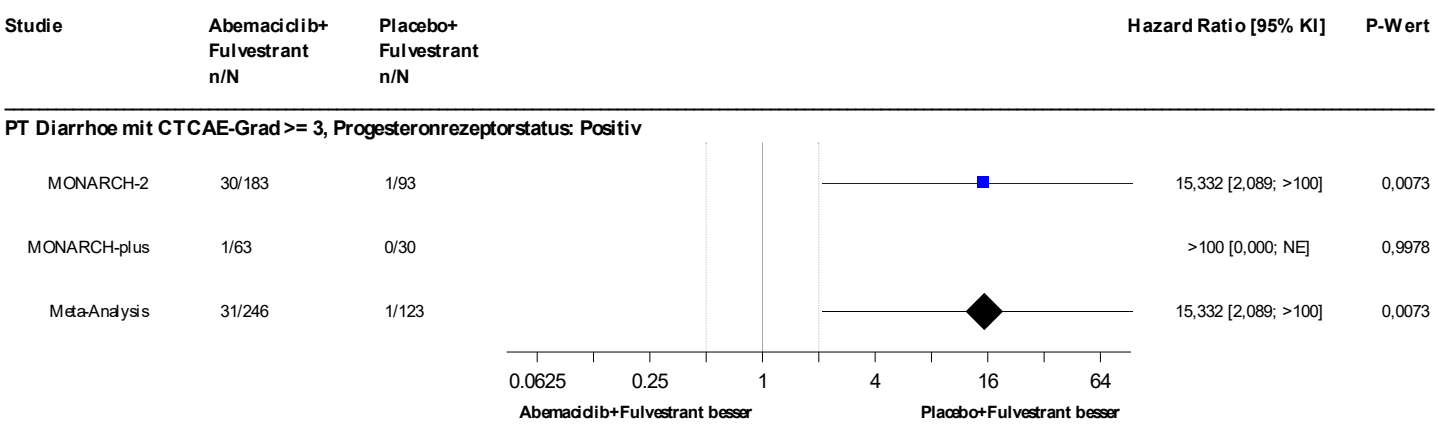
Abbildung 1433.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9981, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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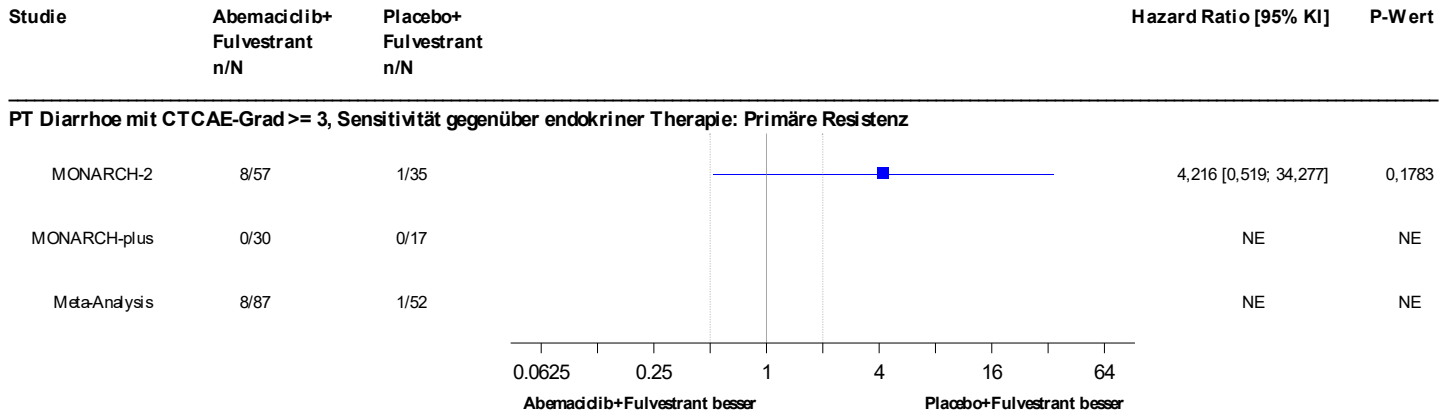
Abbildung 1433.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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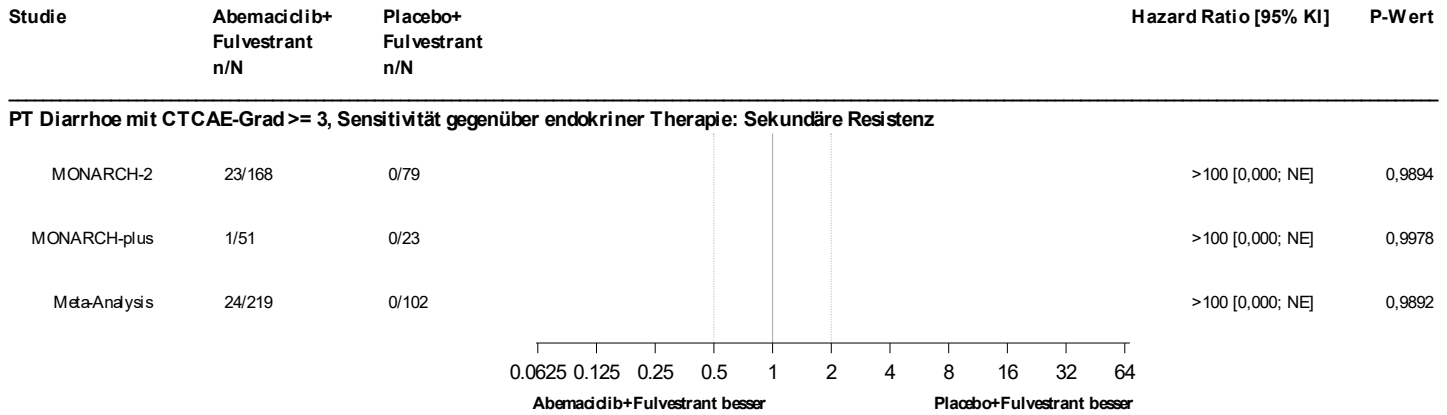
Abbildung 1433.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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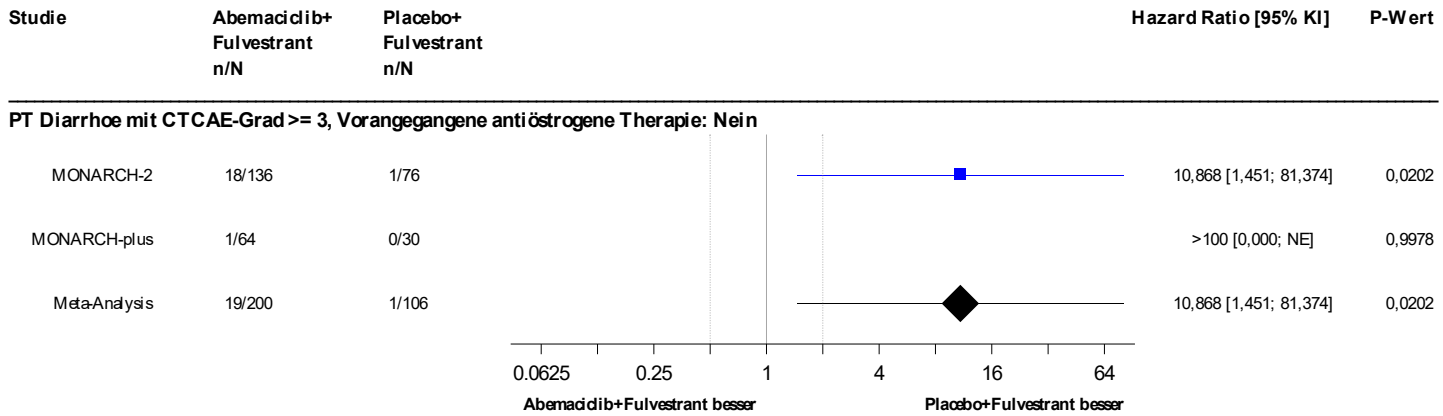
Abbildung 1433.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9981, I2 Index=0%
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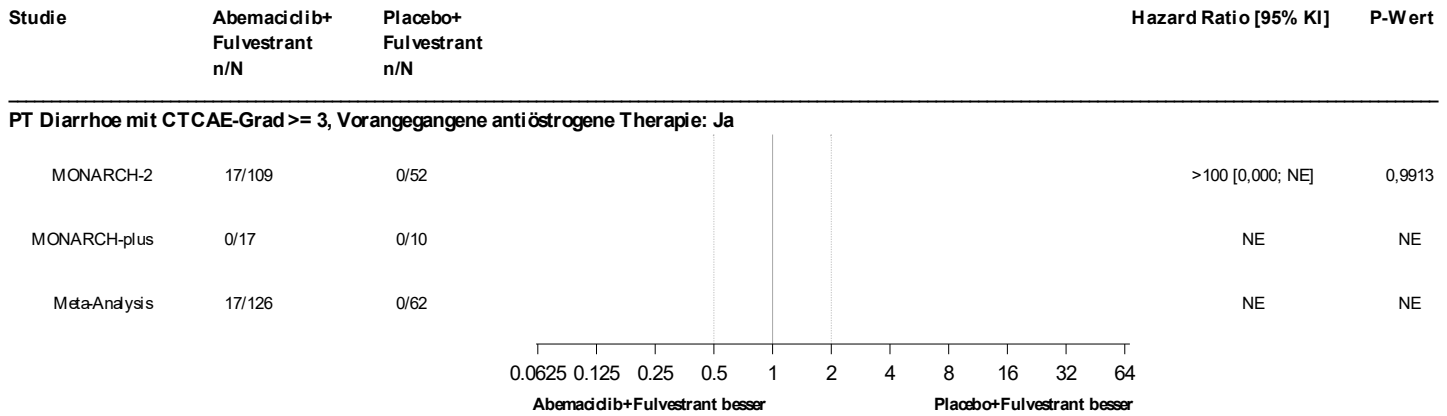
Abbildung 1433.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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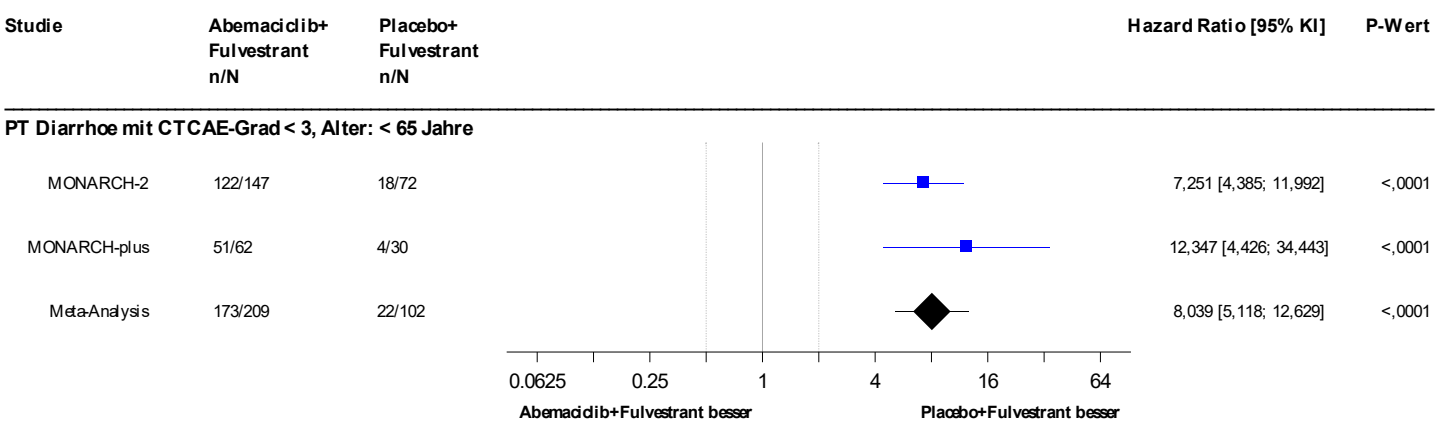
Abbildung 1434.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,8336, P-Wert=0,3612, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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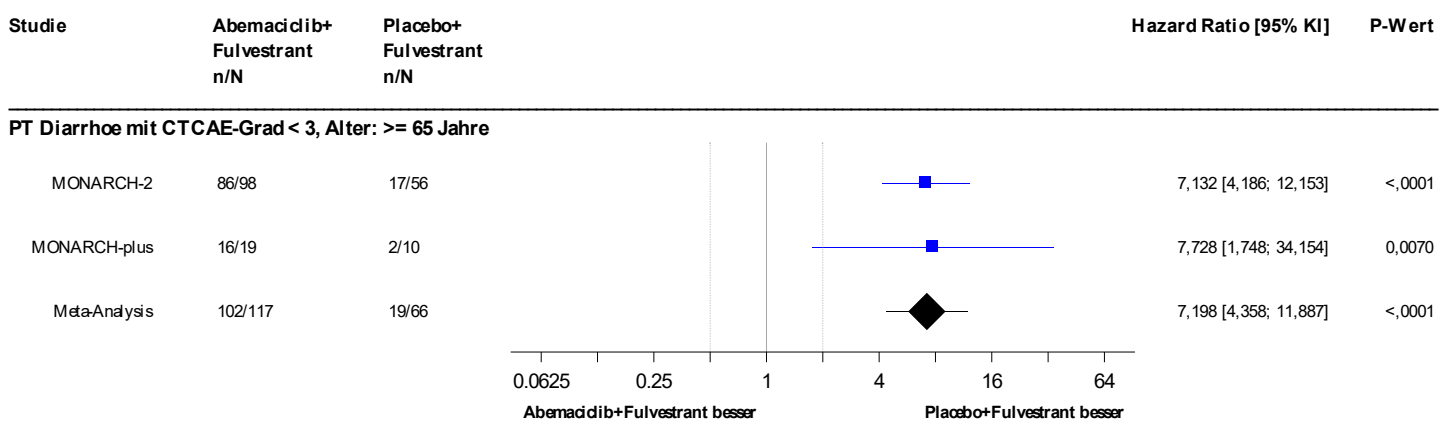
Abbildung 1434.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0099, P-Wert=0,9207, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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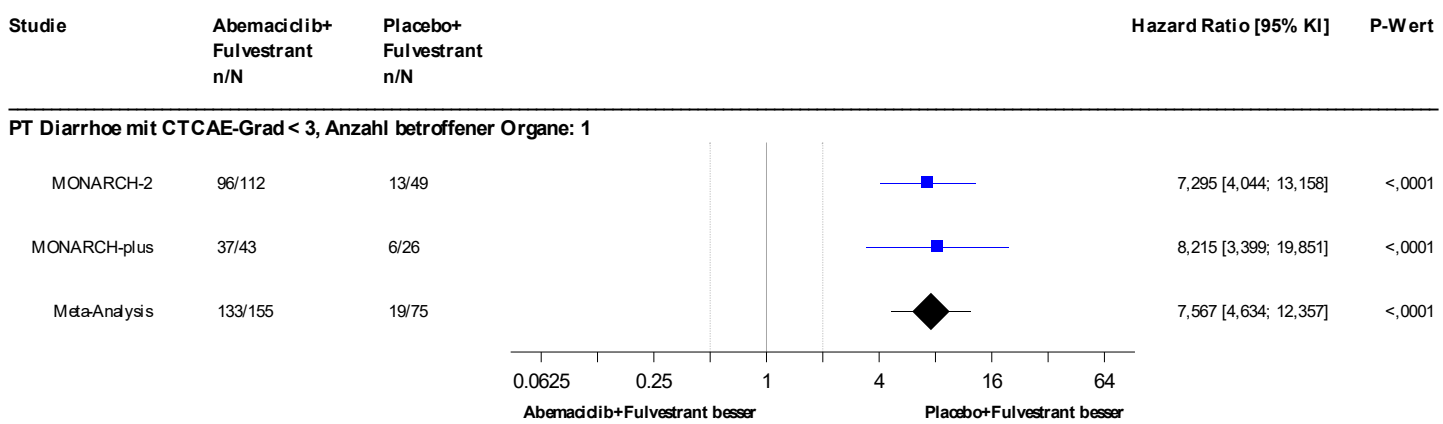
Abbildung 1434.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0481, P-Wert=0,8264, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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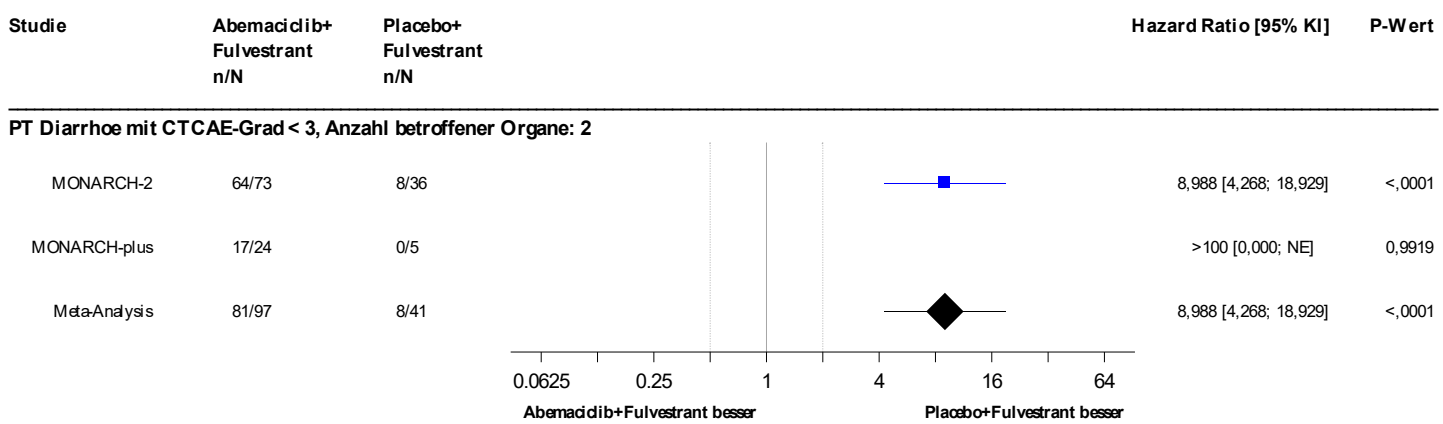
Abbildung 1434.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9930, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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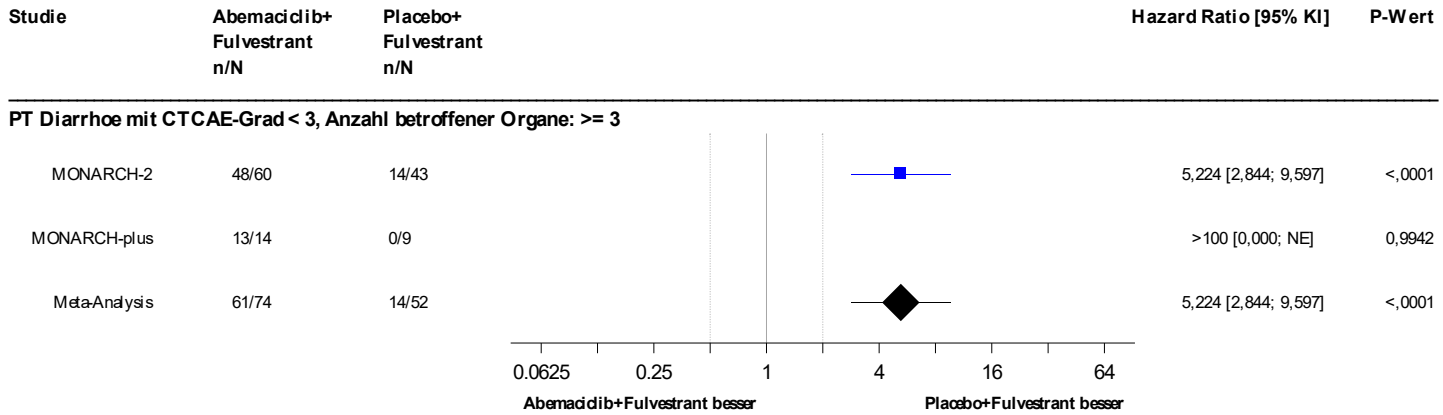
Abbildung 1434.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9947, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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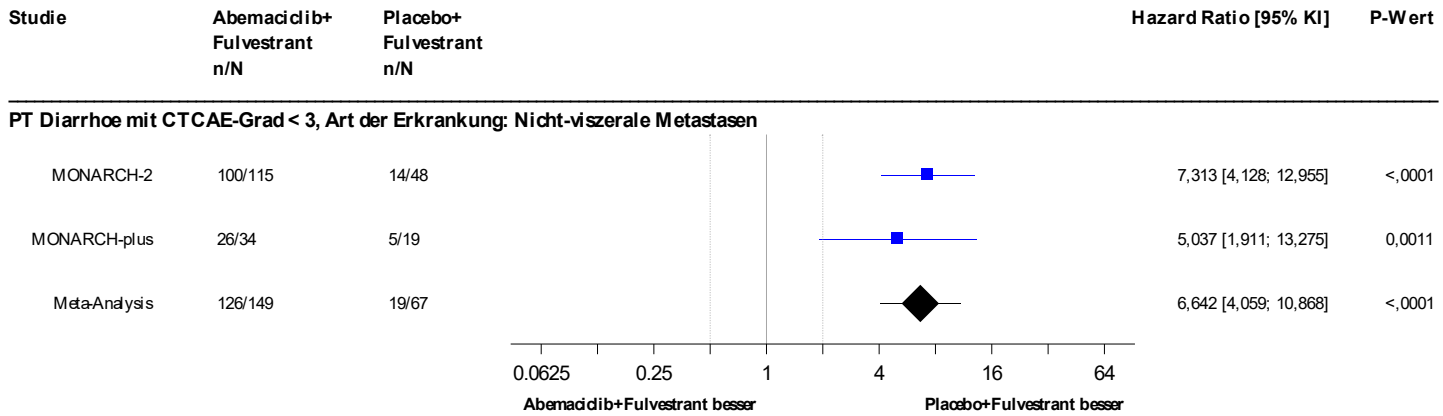
Abbildung 1434.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4220, P-Wert=0,5159, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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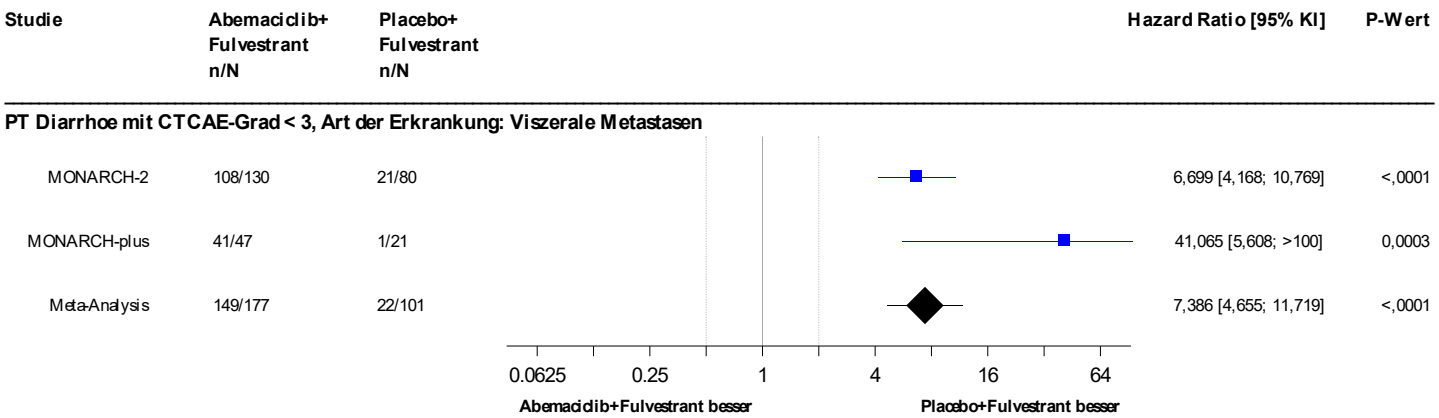
Abbildung 1434.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=3,0147, P-Wert=0,0825, I2 Index=66,8%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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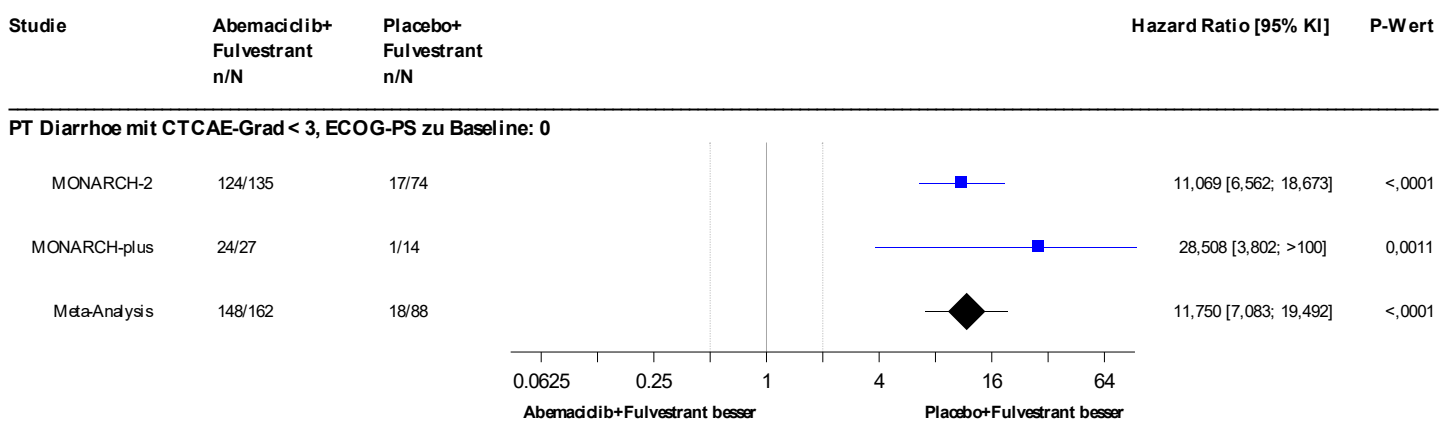
Abbildung 1434.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7936, P-Wert=0,3730, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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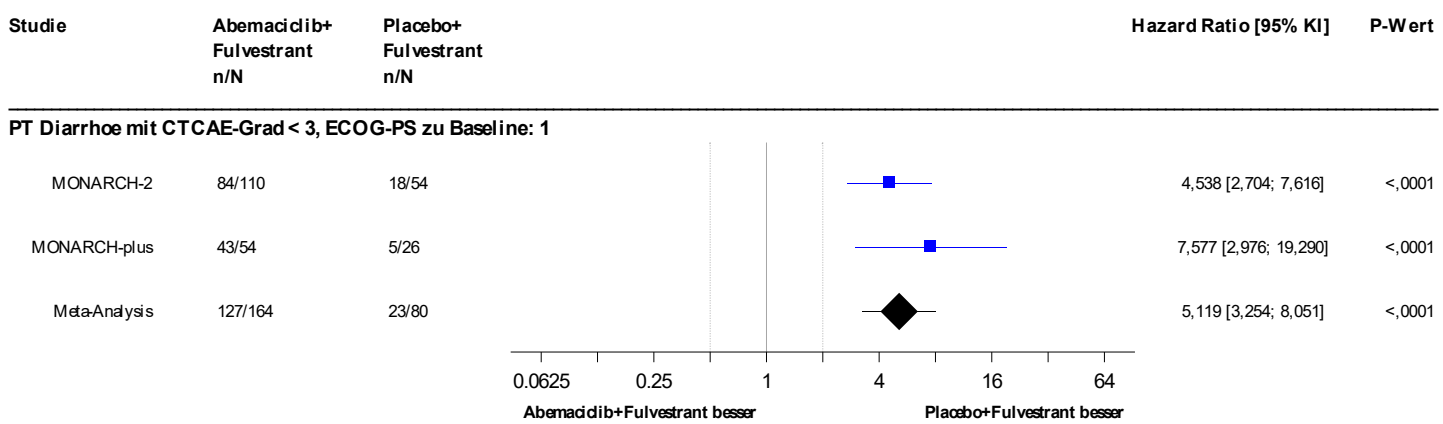
Abbildung 1434.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,8848, P-Wert=0,3469, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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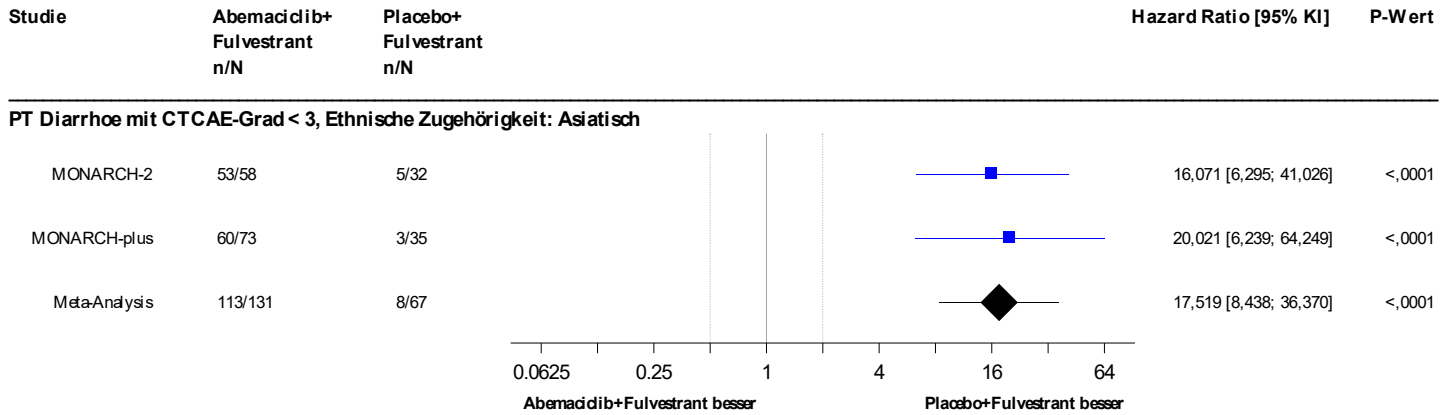
Abbildung 1434.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0829, P-Wert=0,7734, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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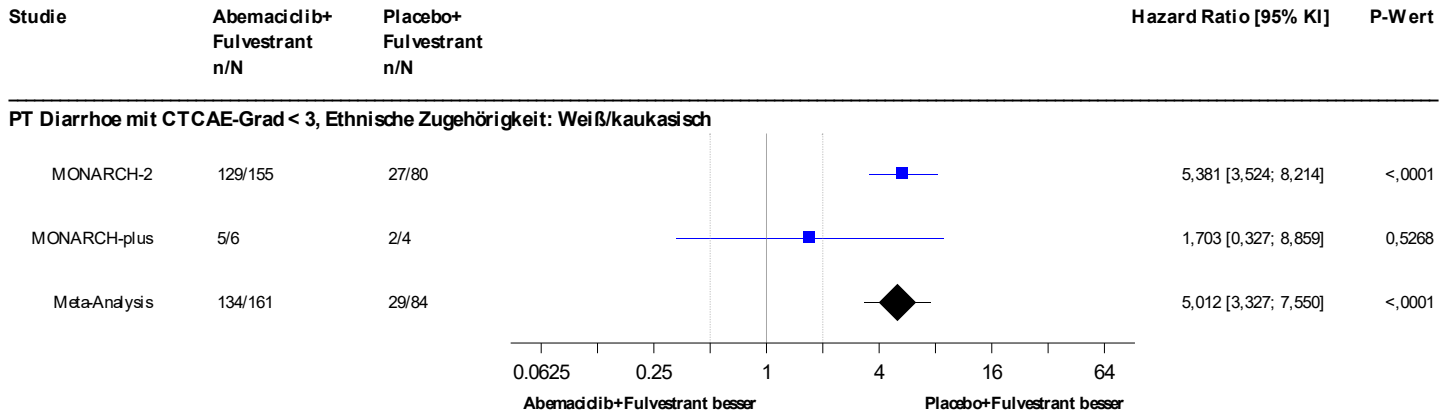
Abbildung 1434.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,7541, P-Wert=0,1854, I2 Index=43,0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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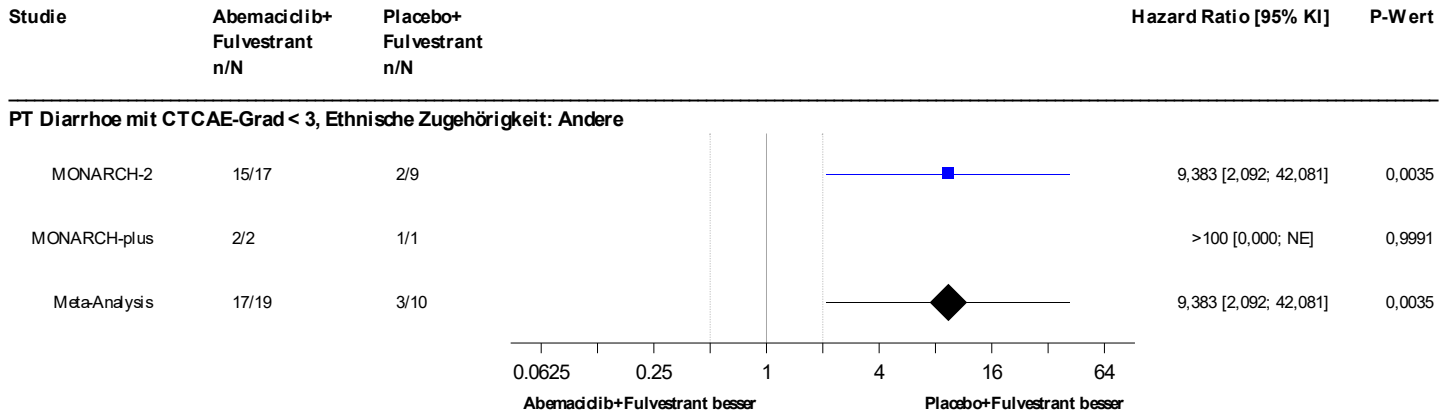
Abbildung 1434.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9992, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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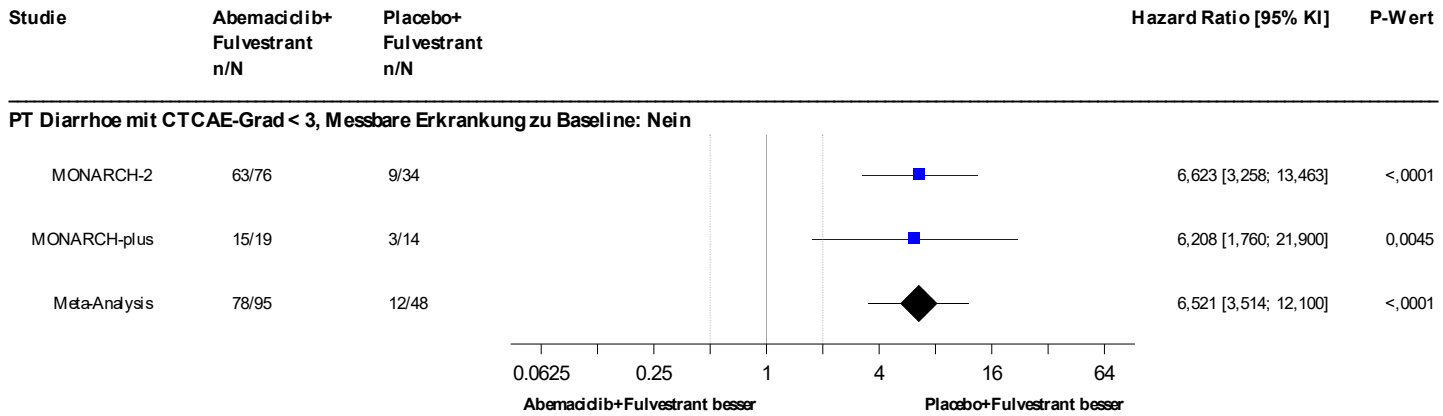
Abbildung 1434.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0077, P-Wert=0,9301, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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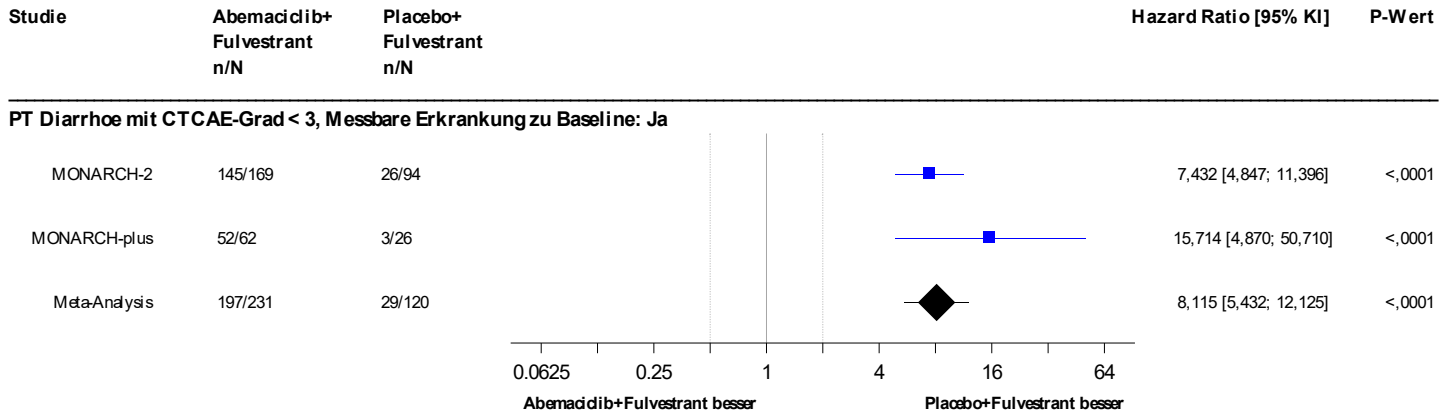
Abbildung 1434.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,3849, P-Wert=0,2393, I2 Index=27,8%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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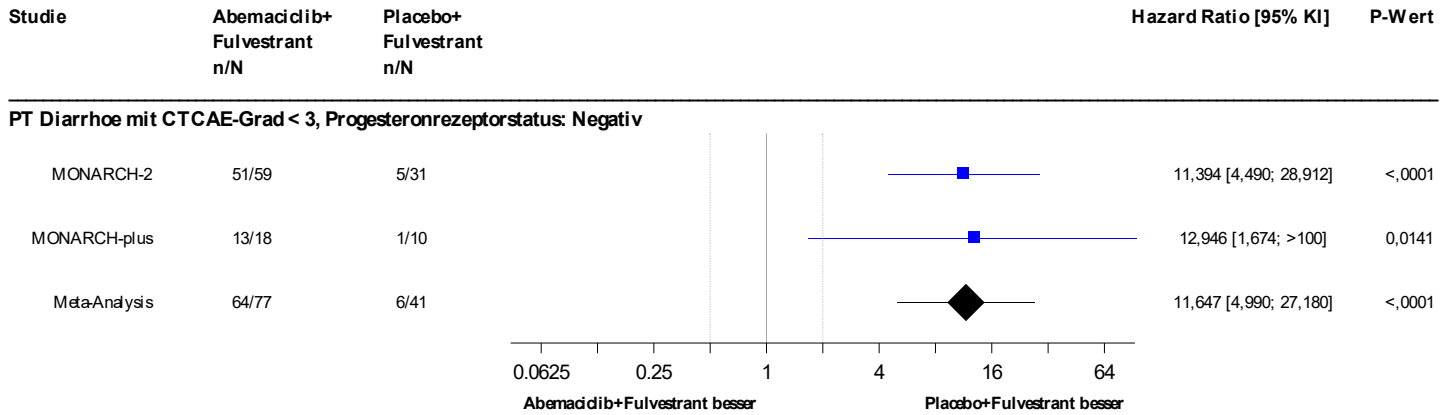
Abbildung 1434.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0124, P-Wert=0,9113, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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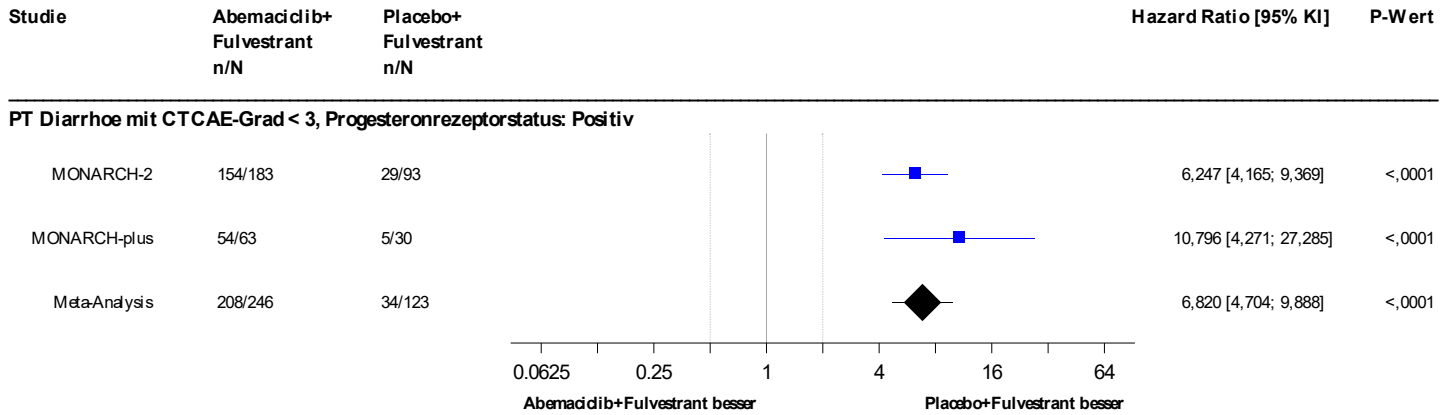
Abbildung 1434.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,1225, P-Wert=0,2894, I2 Index=10,9%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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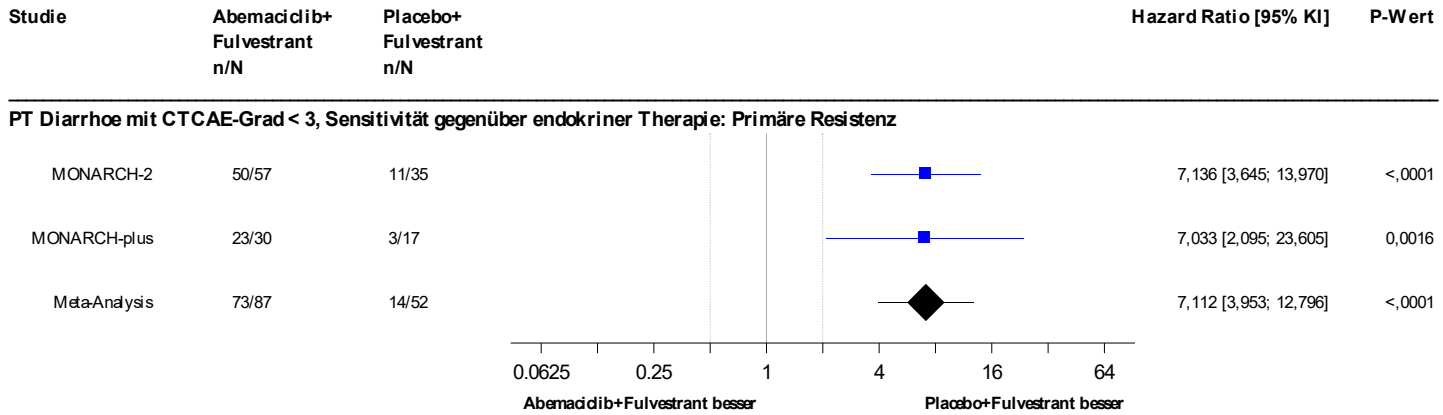
Abbildung 1434.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0004, P-Wert=0,9835, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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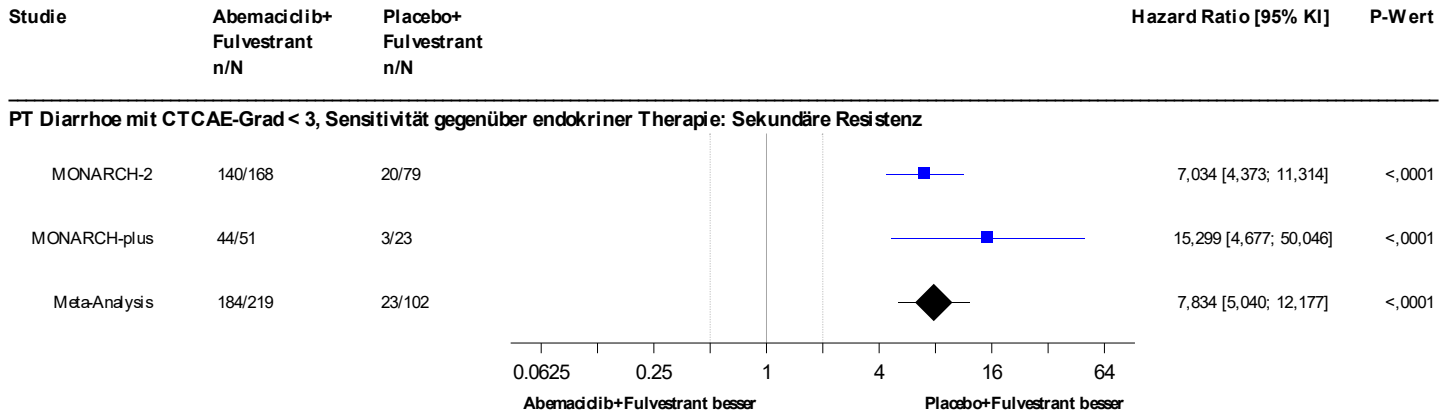
Abbildung 1434.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,4225, P-Wert=0,2330, I2 Index=29,7%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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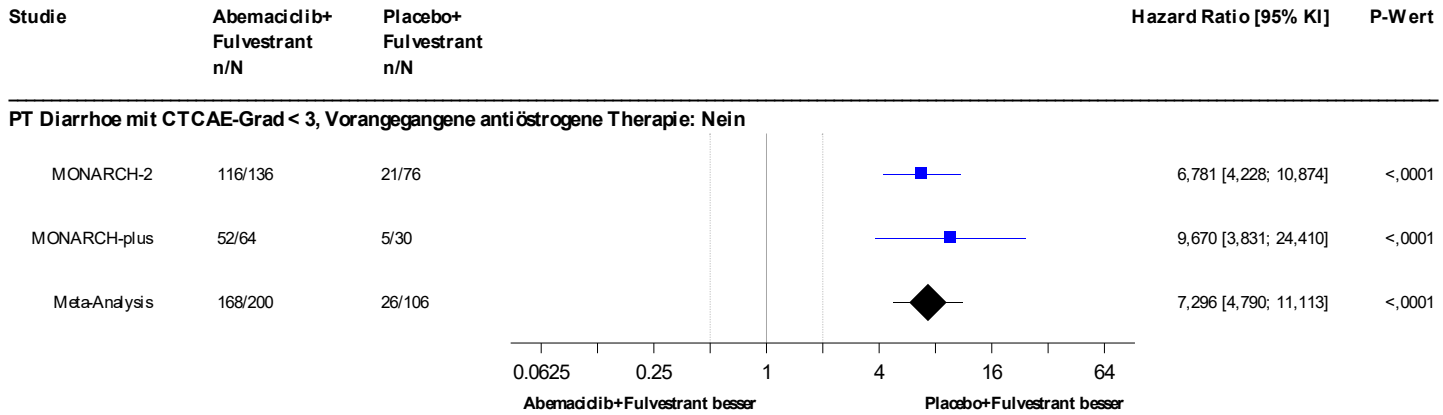
Abbildung 1434.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4480, P-Wert=0,5033, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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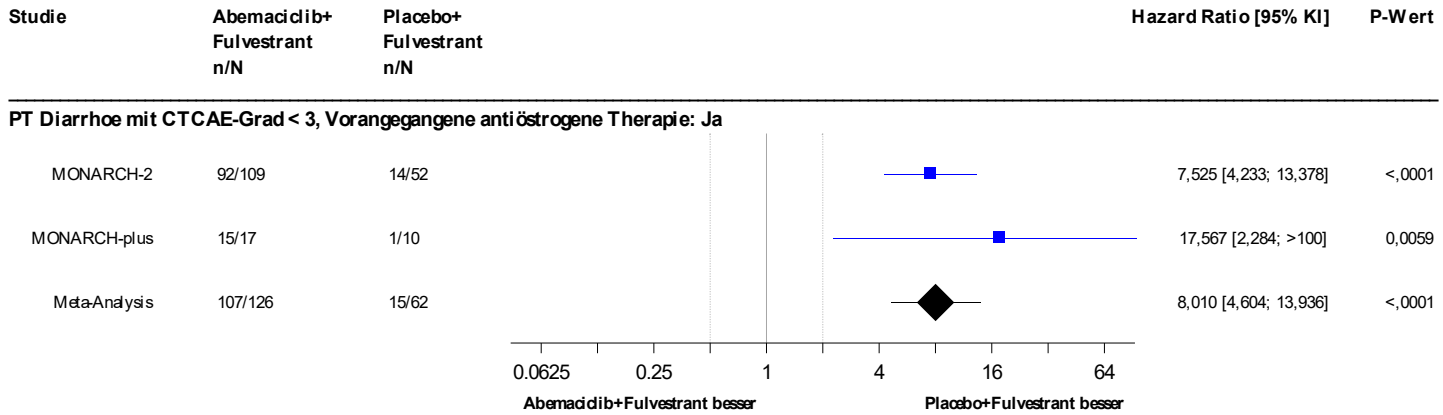
Abbildung 1434.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6144, P-Wert=0,4331, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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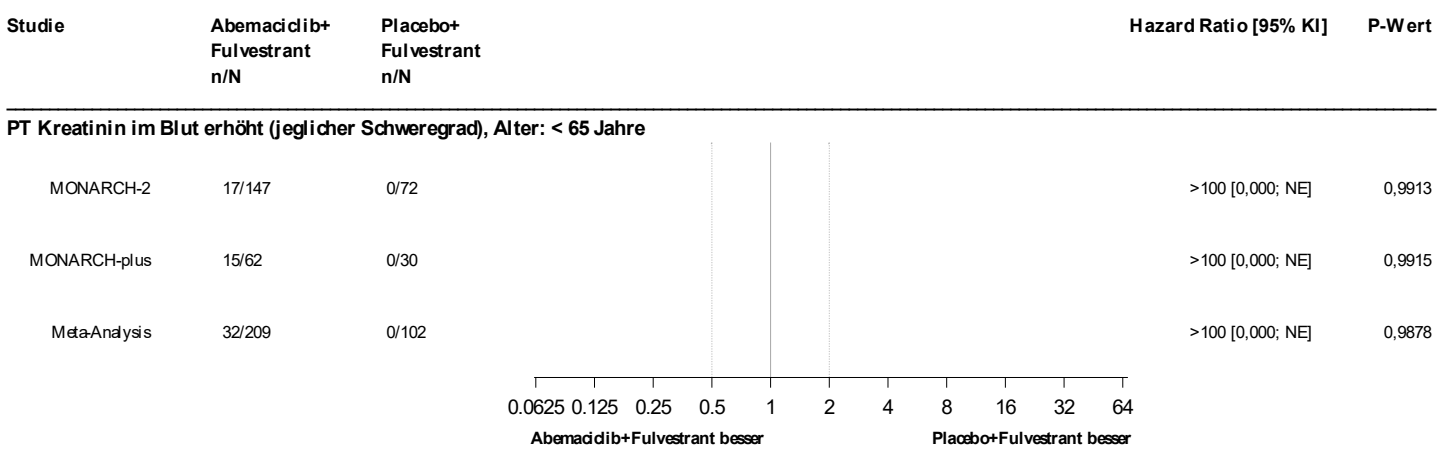
Abbildung 1436.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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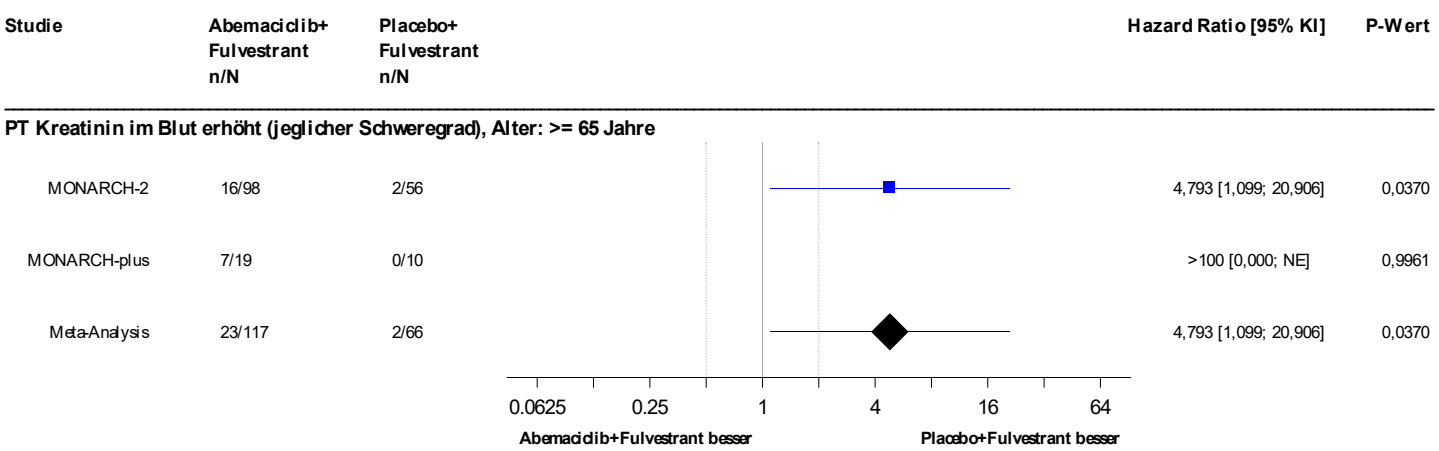
17SEP2021 / 07:48

Abbildung 1436.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9964, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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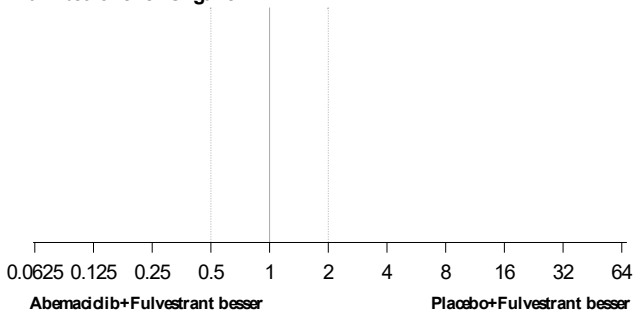
Abbildung 1436.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

Studie	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% KI]	P-Wert
PT Kreatinin im Blut erhöht (jeglicher Schweregrad), Anzahl betroffener Organe: 1				
MONARCH-2	14/112	0/49	>100 [0,000; NE]	0,9926
MONARCH-plus	14/43	0/26	>100 [0,000; NE]	0,9943
Meta-Analysis	28/155	0/75	>100 [0,000; NE]	0,9906



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9997, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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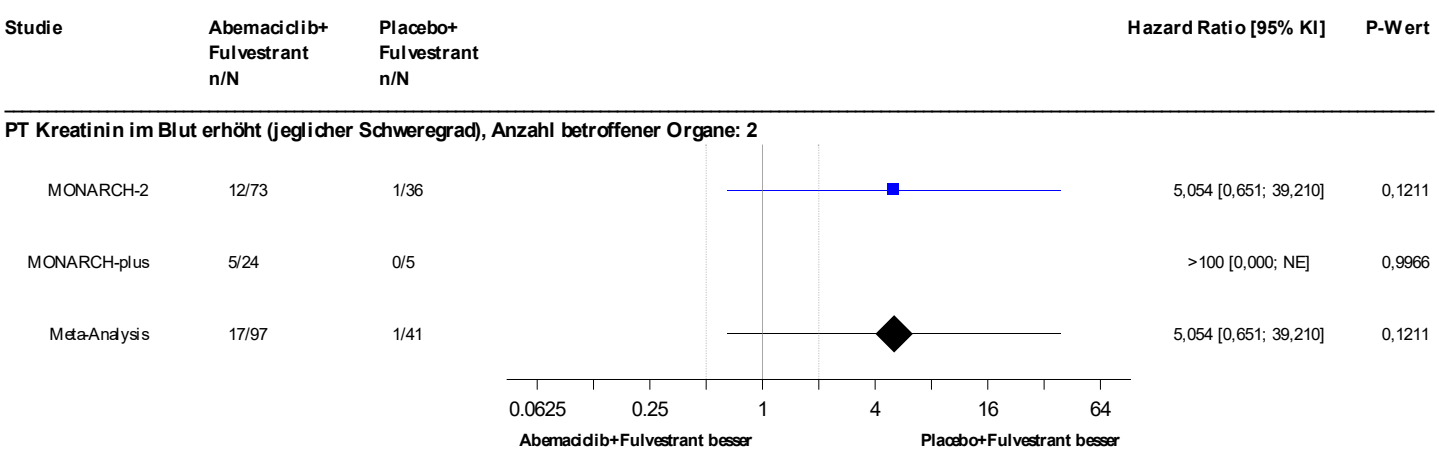
Abbildung 1436.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9969, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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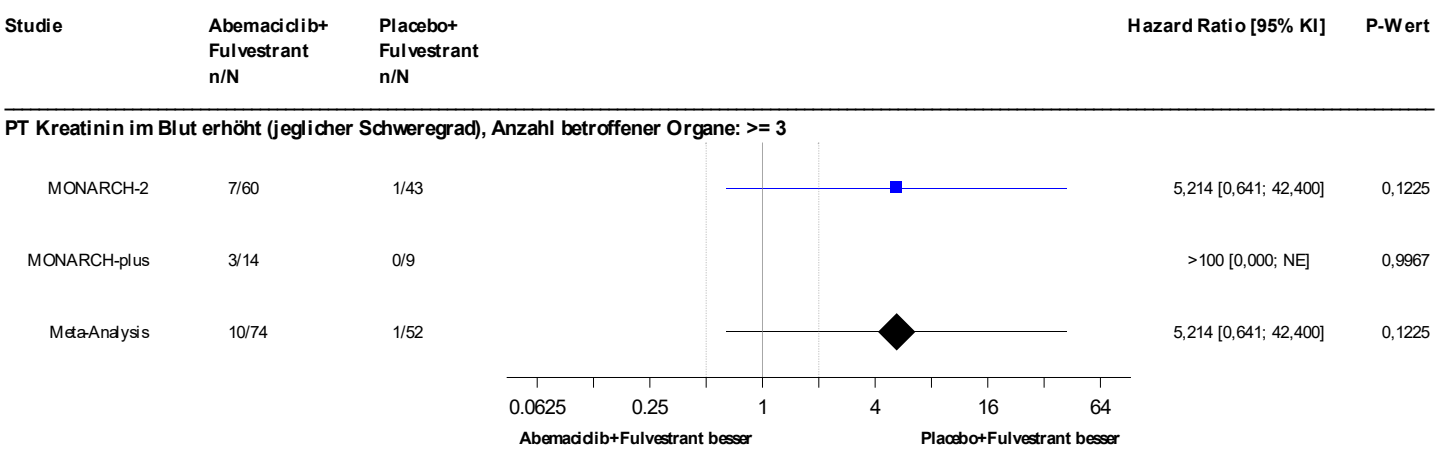
Abbildung 1436.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9971, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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Abbildung 1436.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

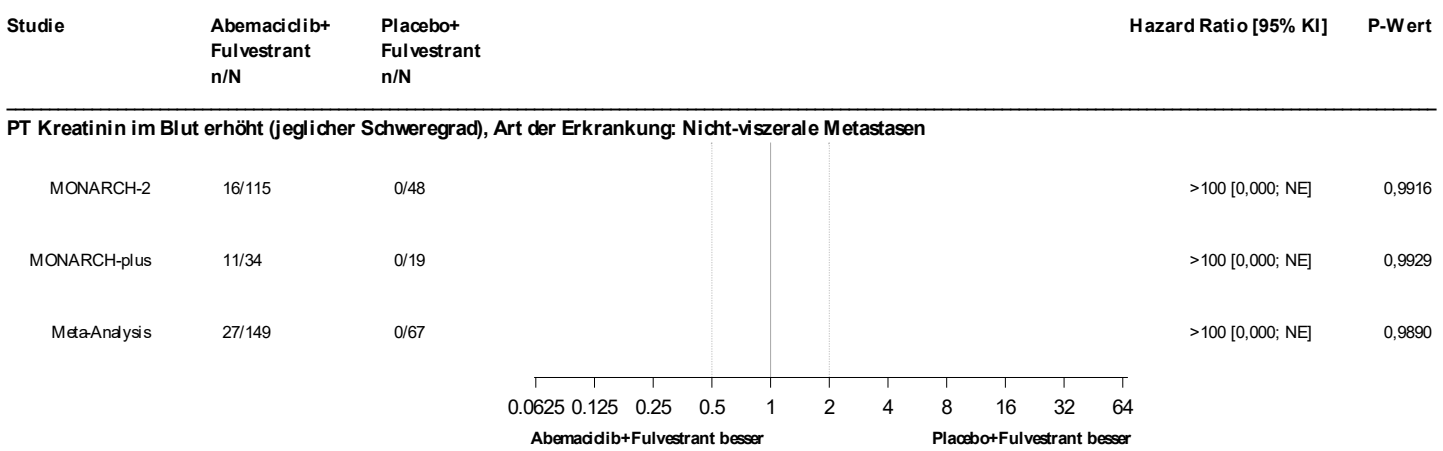

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Abbildung 1436.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

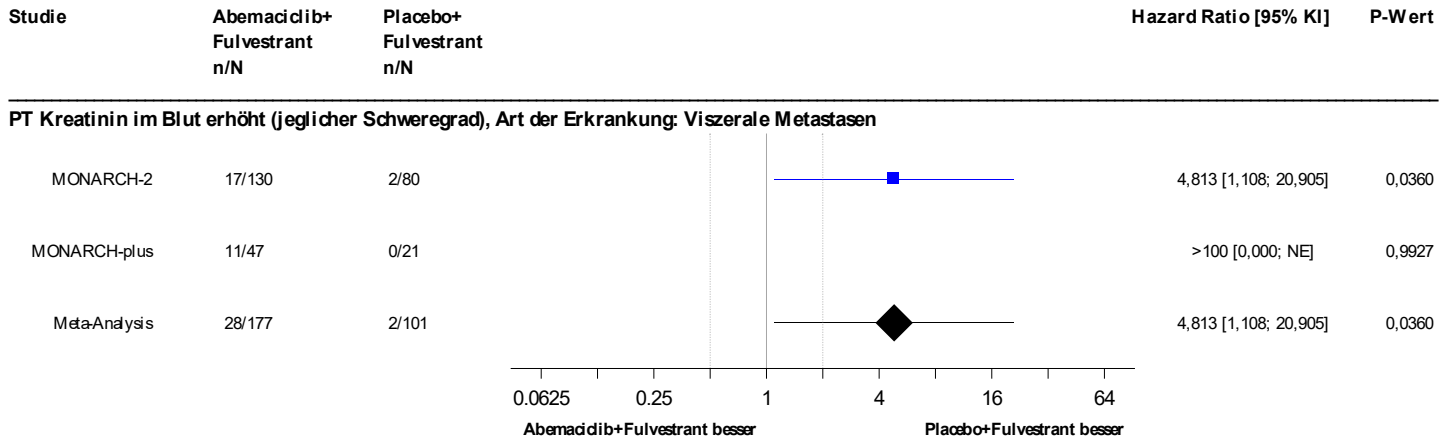

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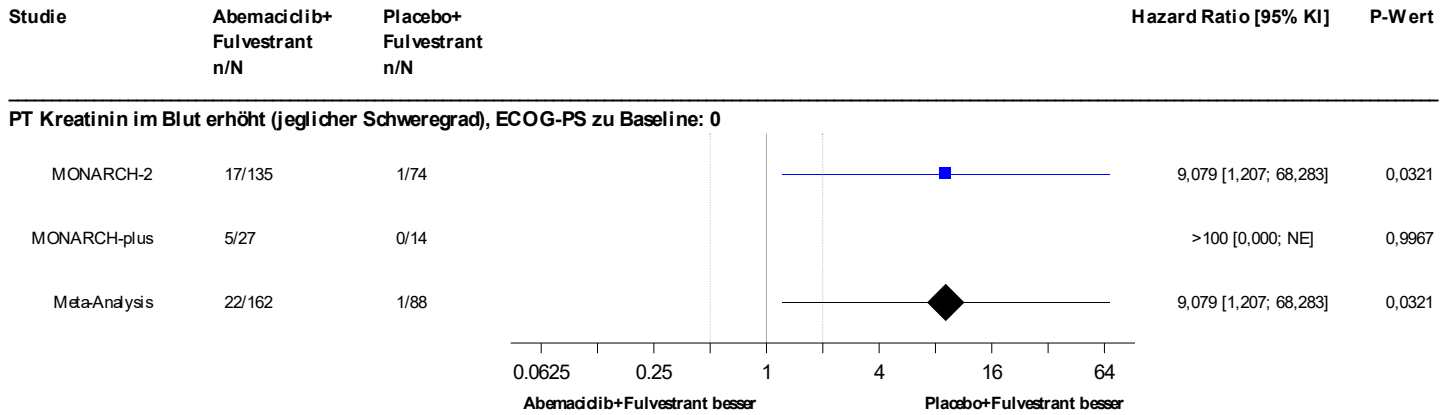
Abbildung 1436.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9971, I2 Index=0%
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Abbildung 1436.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

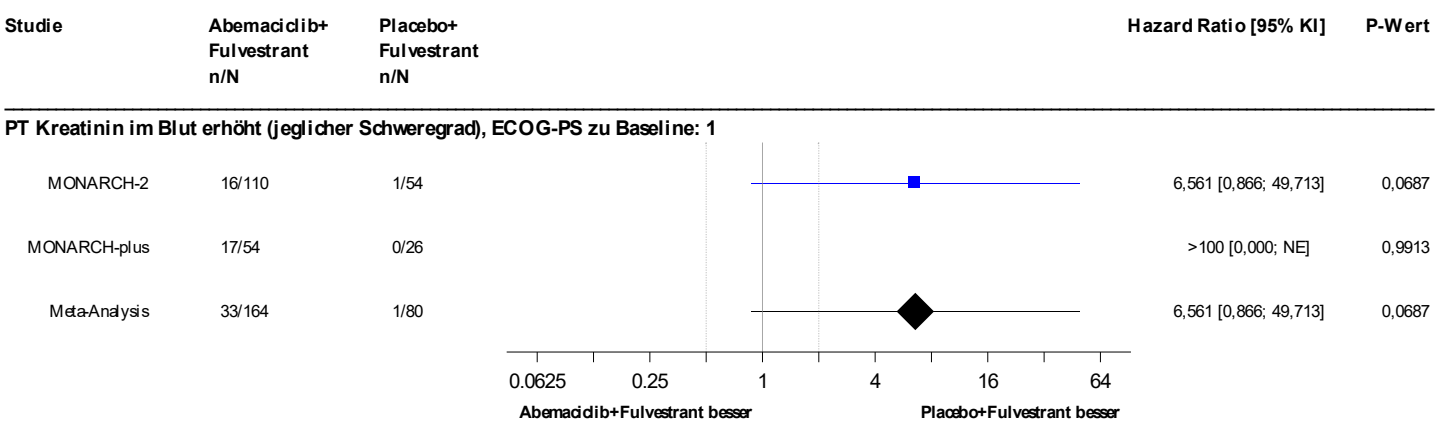

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Abbildung 1436.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

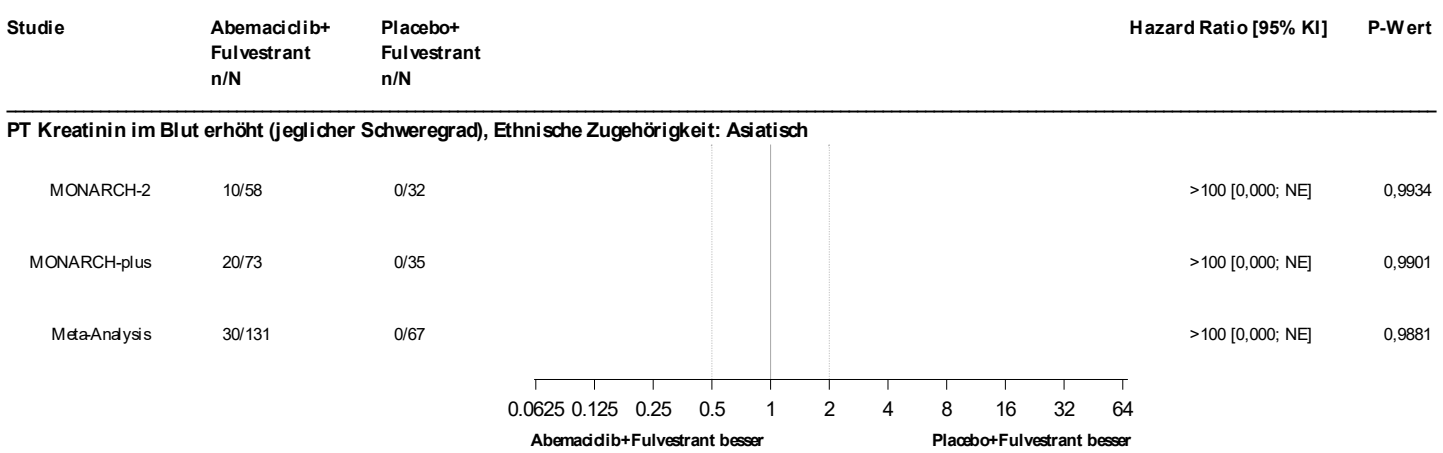

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Abbildung 1436.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

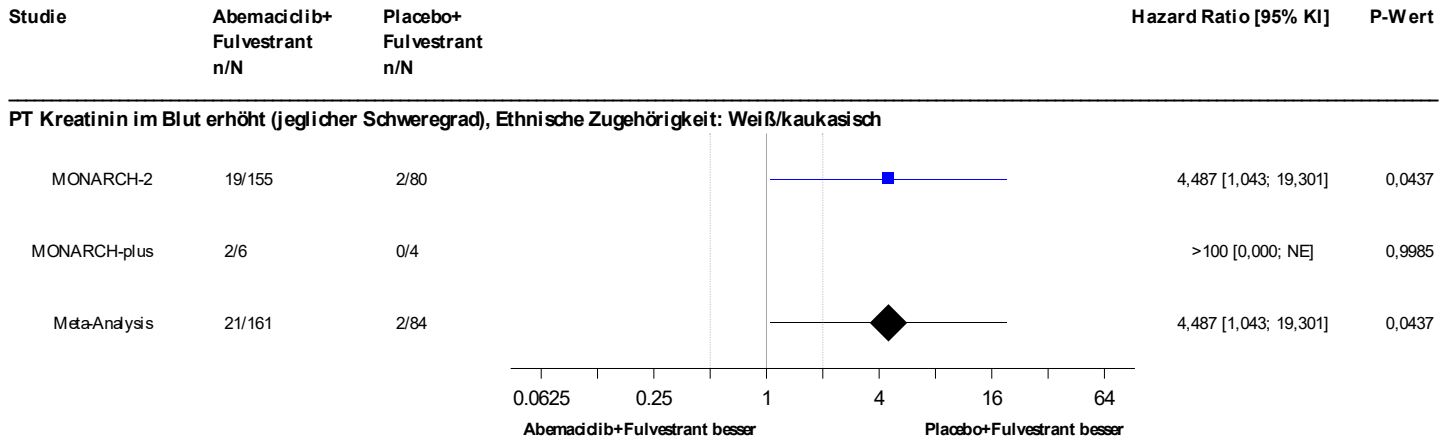

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Abbildung 1436.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

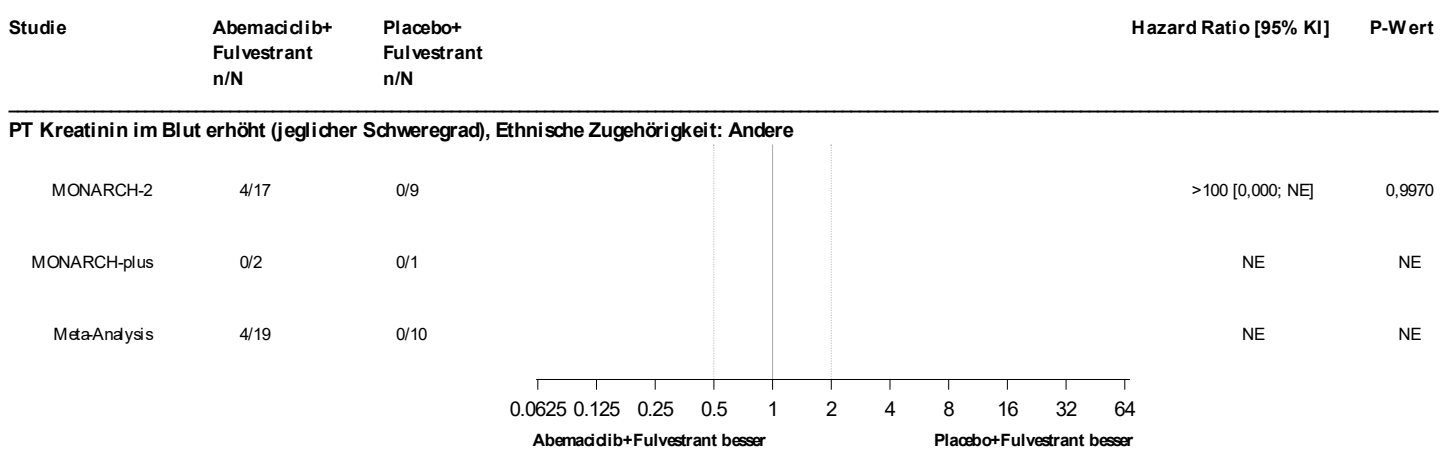

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Abbildung 1436.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

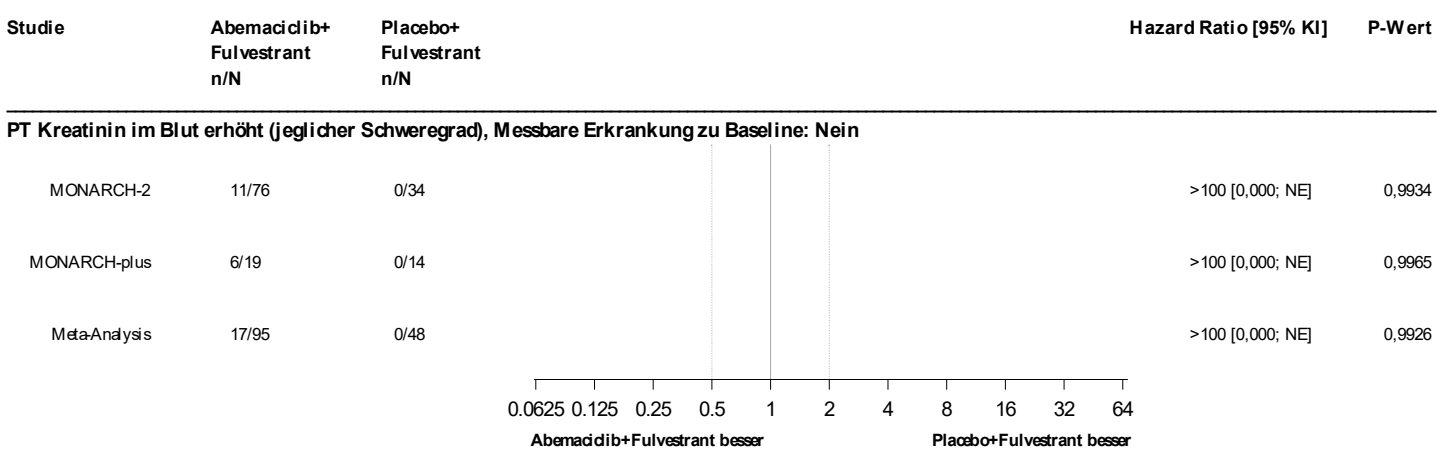

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Abbildung 1436.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

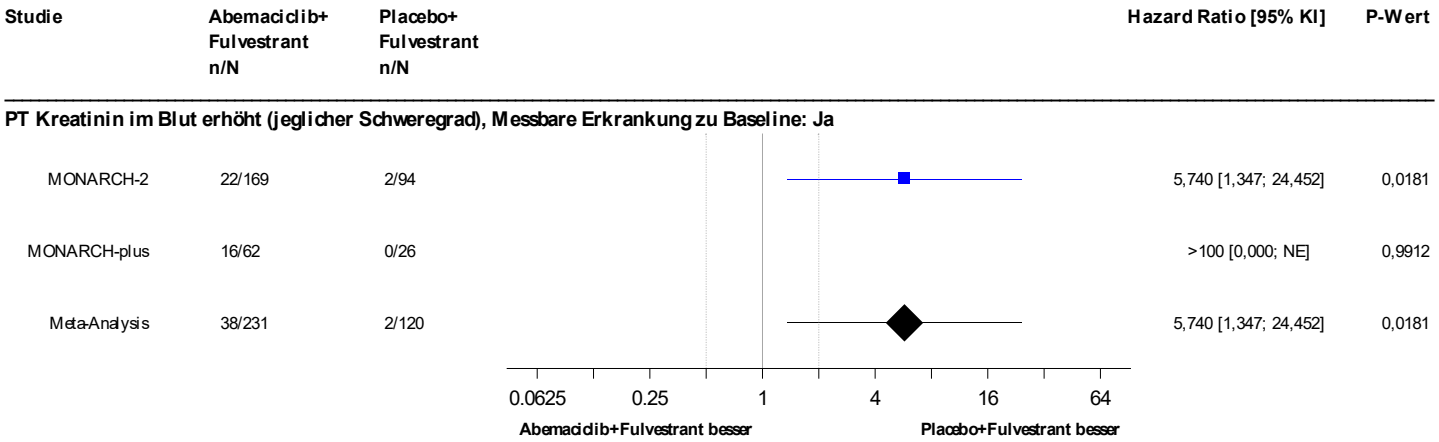

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Abbildung 1436.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

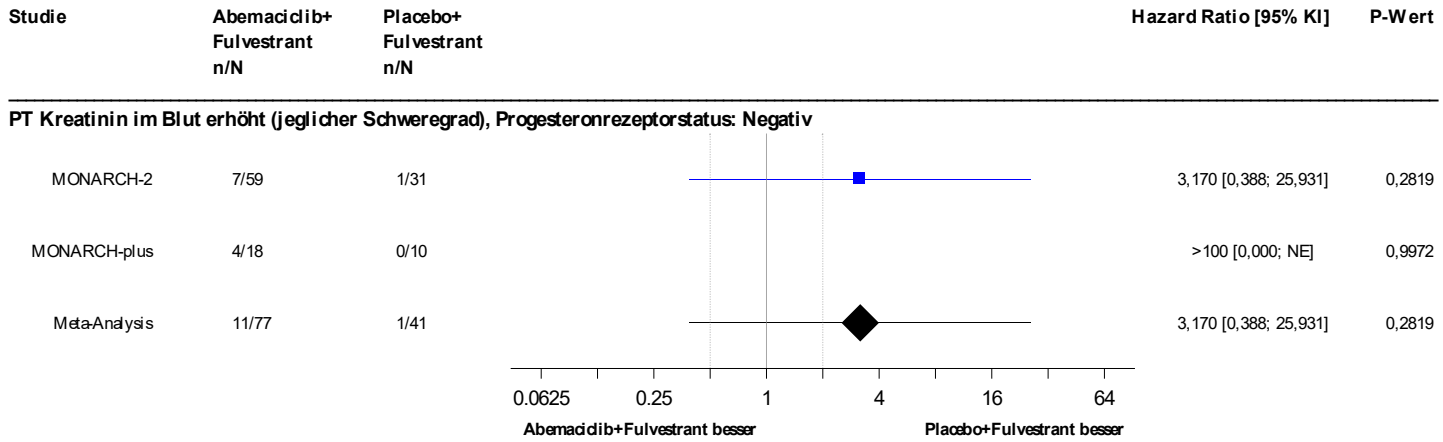

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Abbildung 1436.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

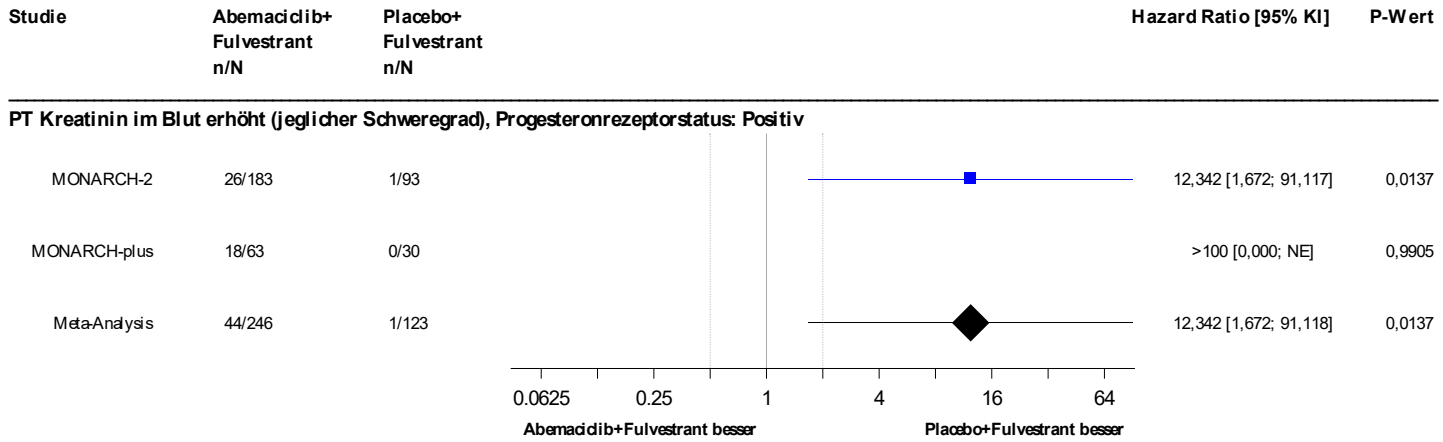

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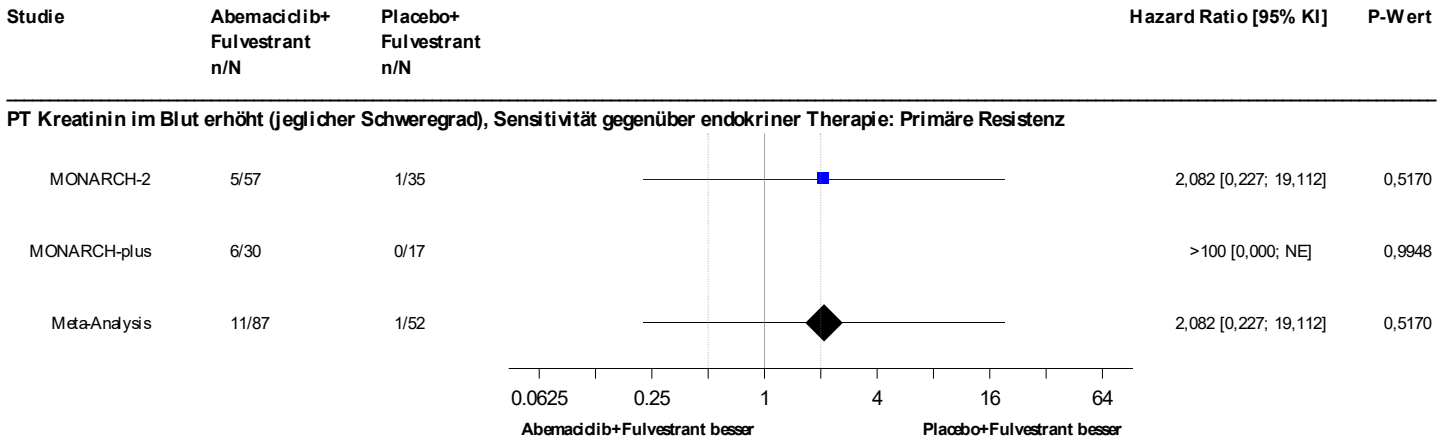
Abbildung 1436.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



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Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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Abbildung 1436.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

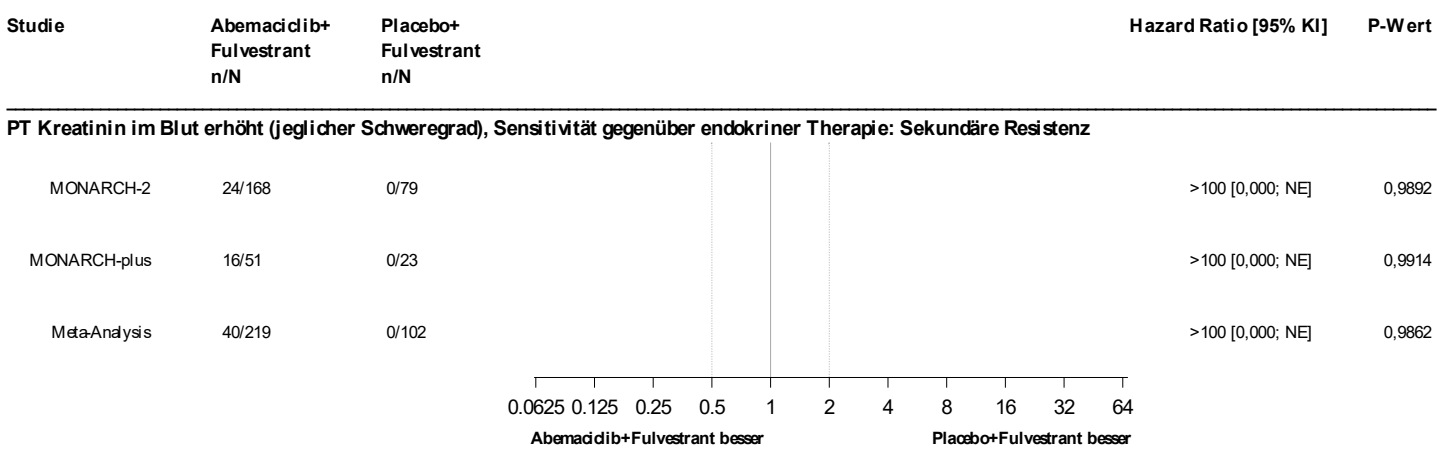

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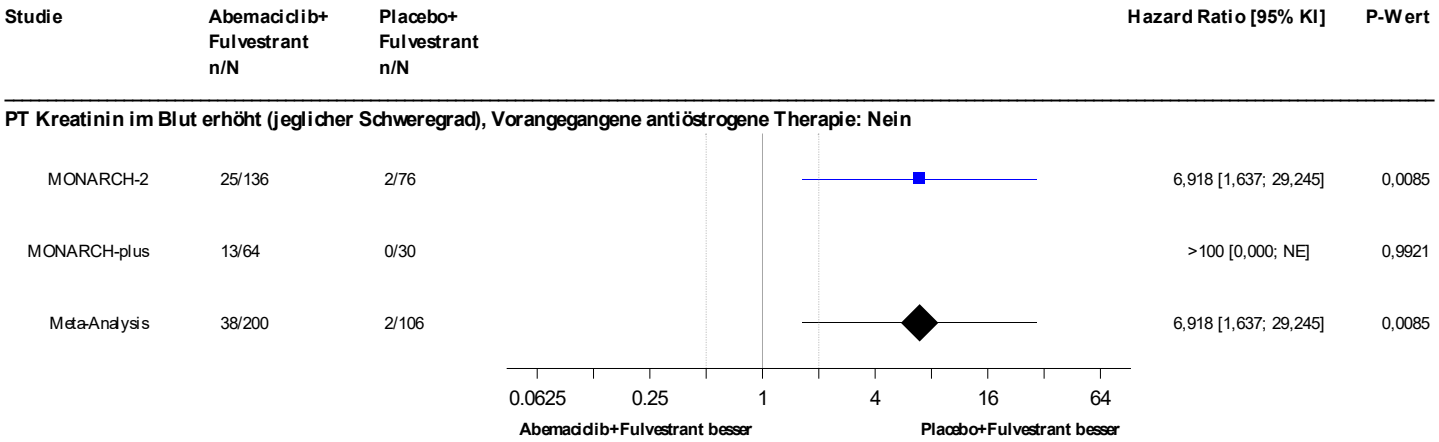
Abbildung 1436.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



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Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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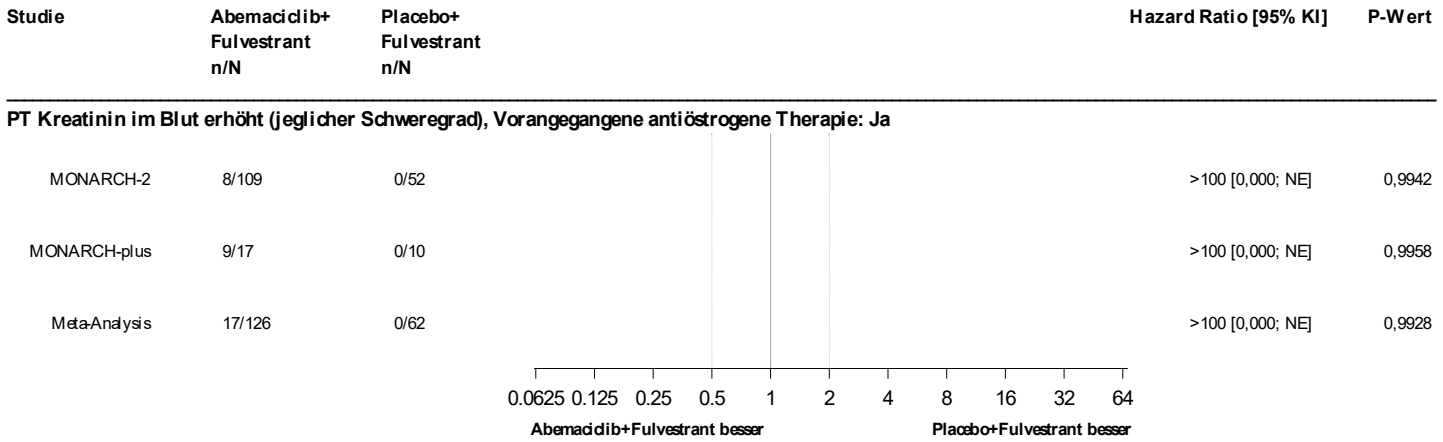
Abbildung 1436.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9998, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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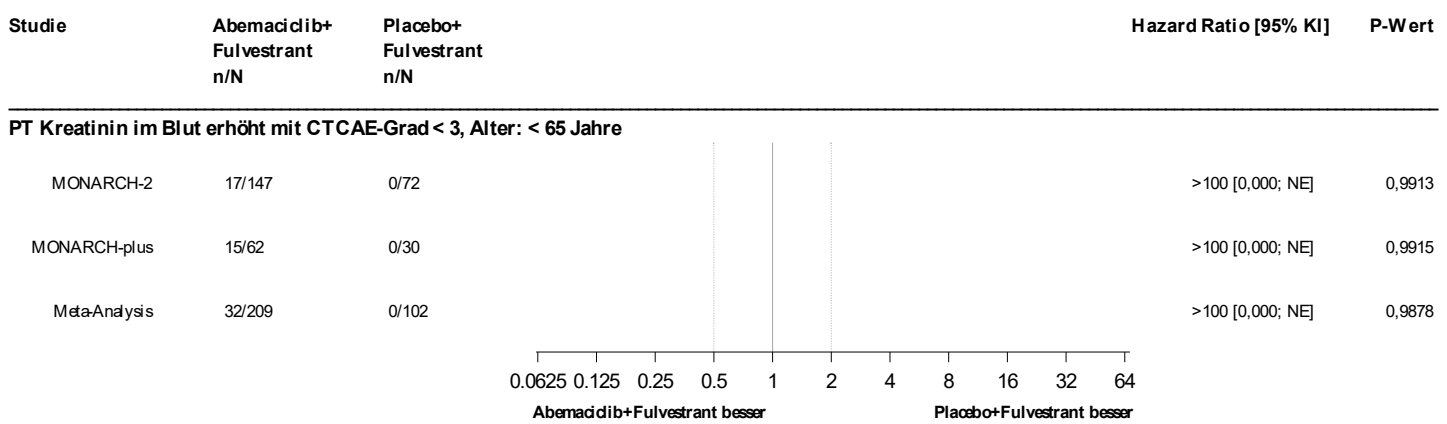
Abbildung 1438.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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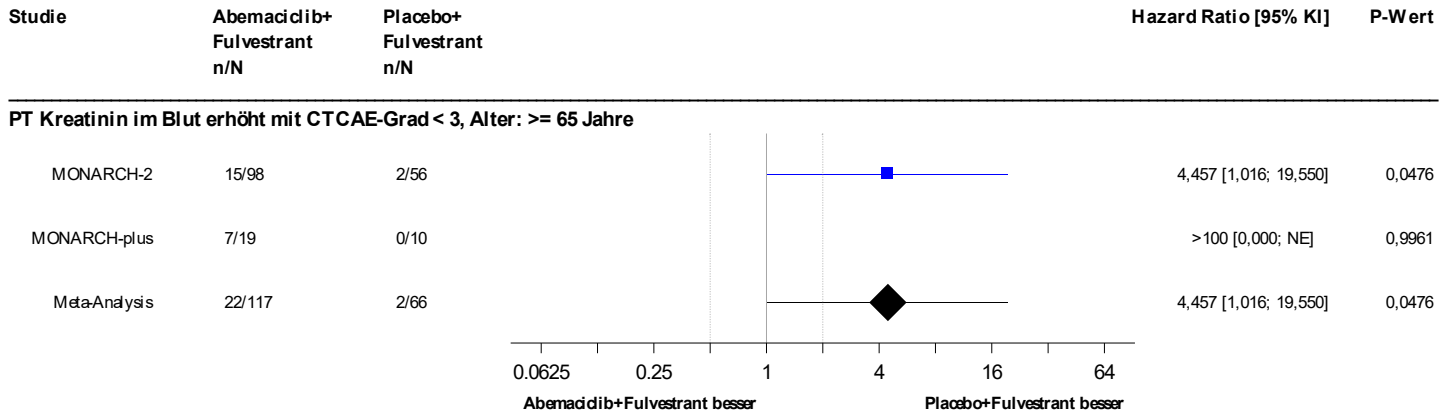
Abbildung 1438.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9964, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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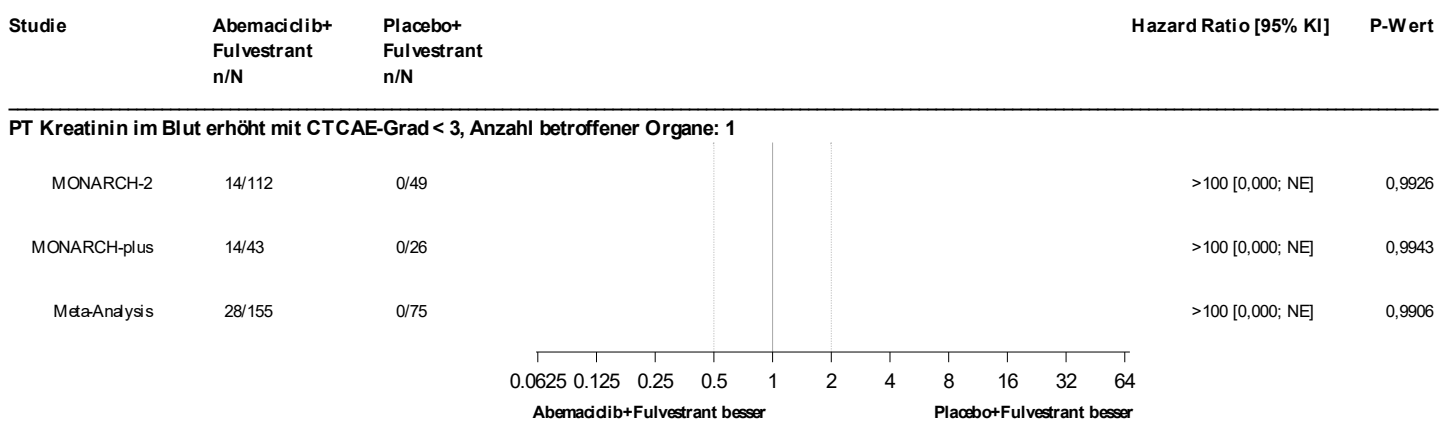
Abbildung 1438.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9997, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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Abbildung 1438.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

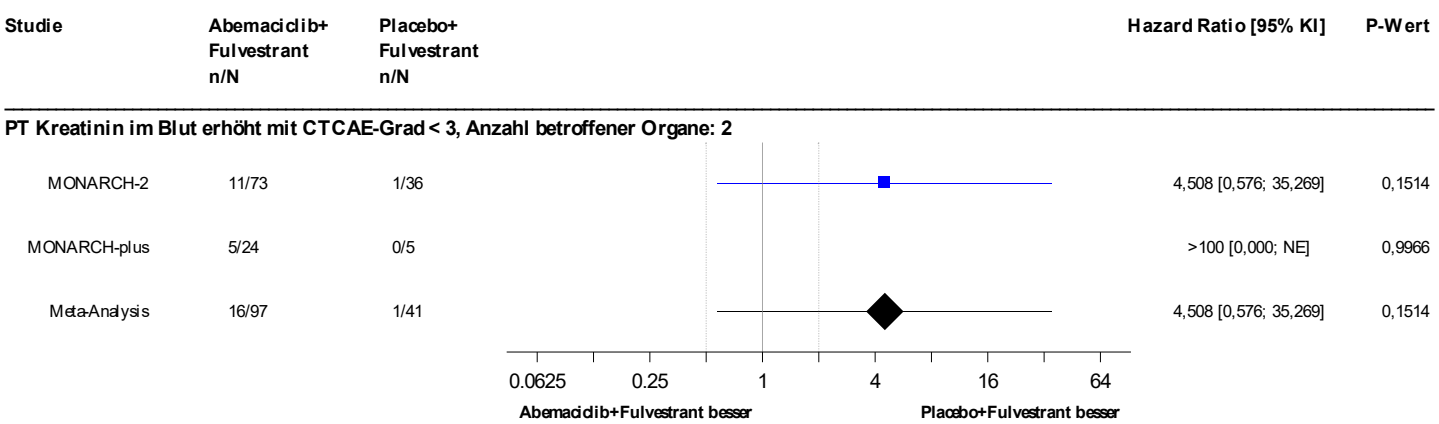

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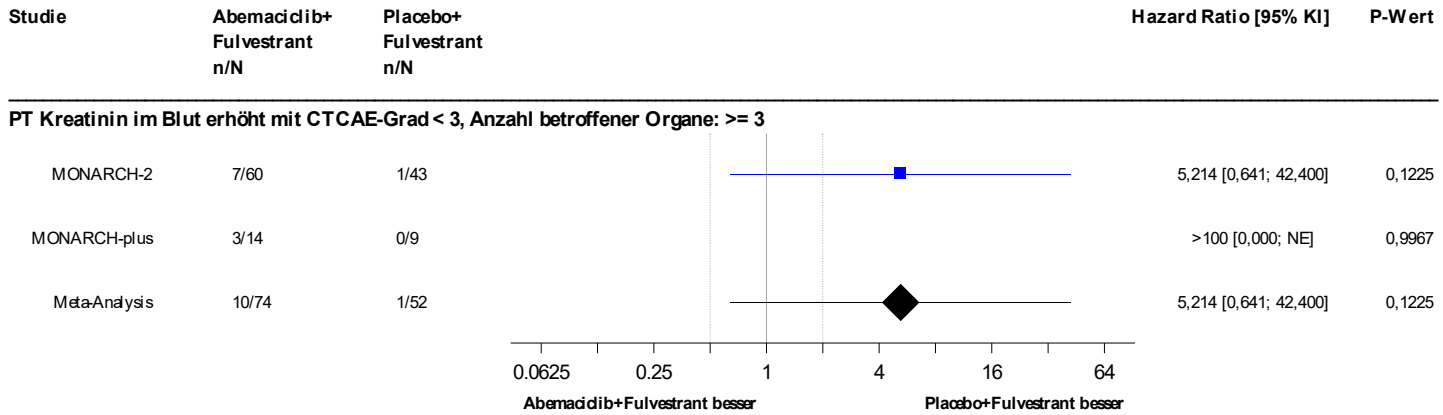
Abbildung 1438.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9971, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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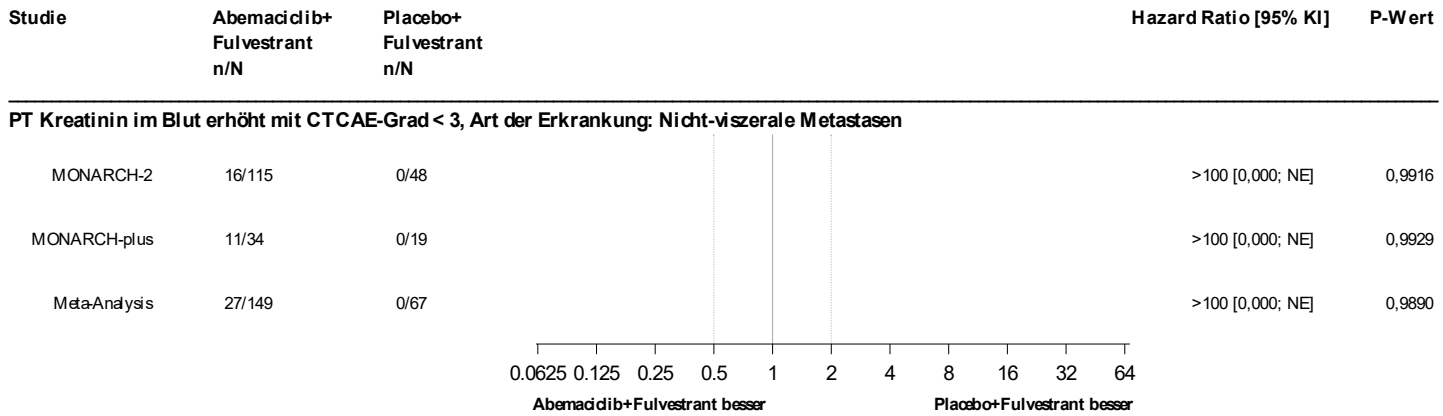
Abbildung 1438.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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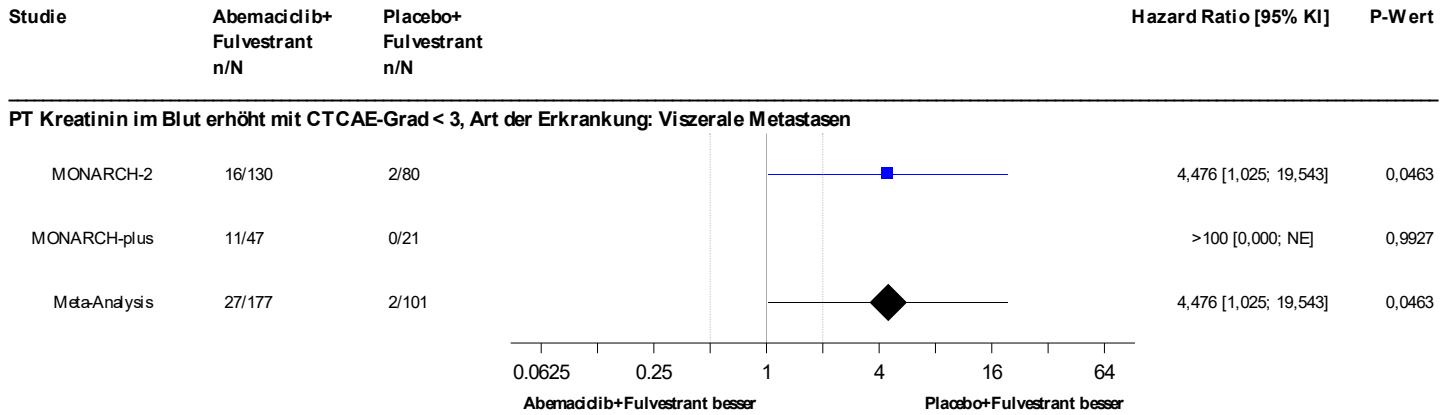
Abbildung 1438.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9934, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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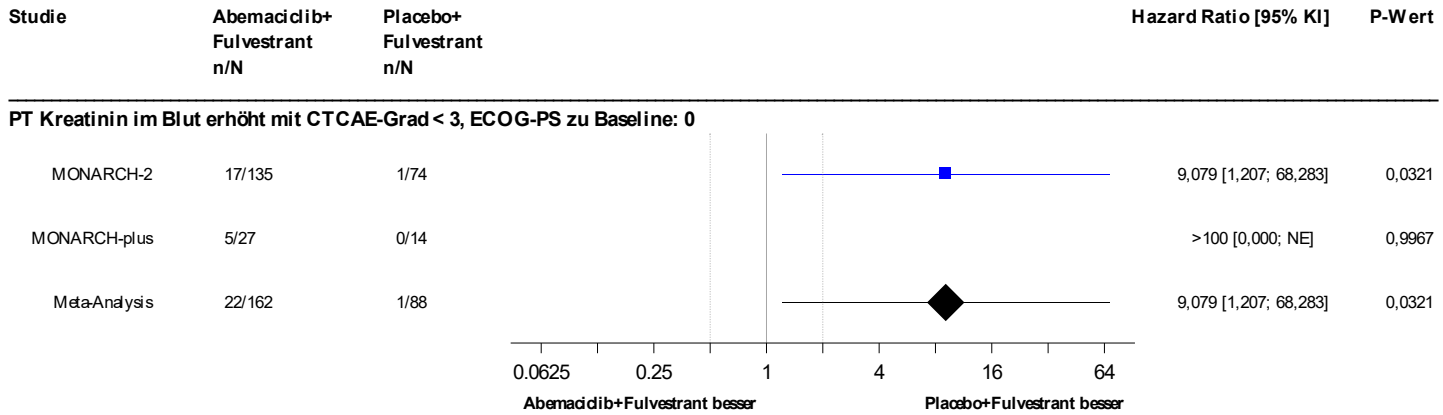
Abbildung 1438.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9971, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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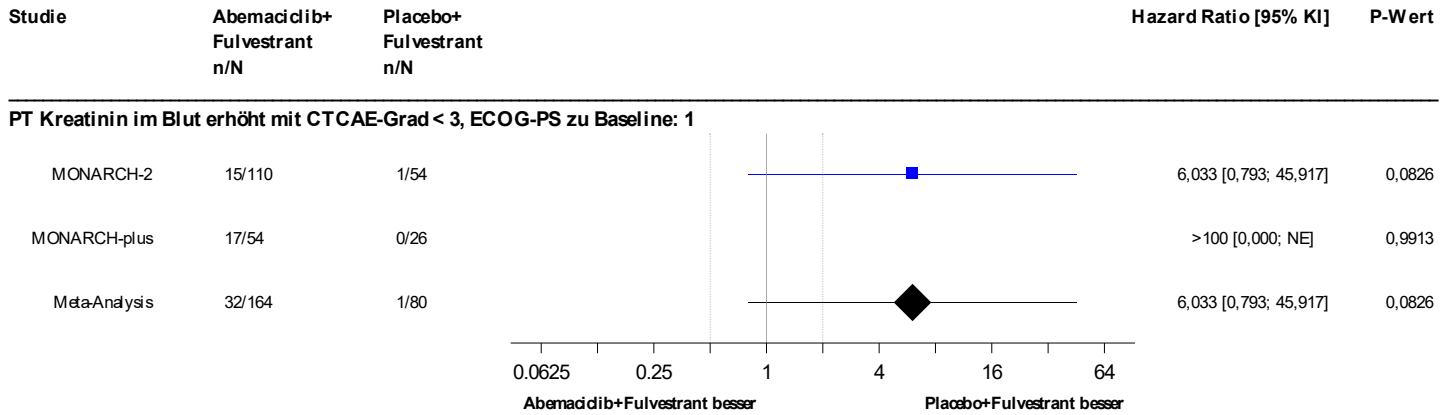
Abbildung 1438.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9922, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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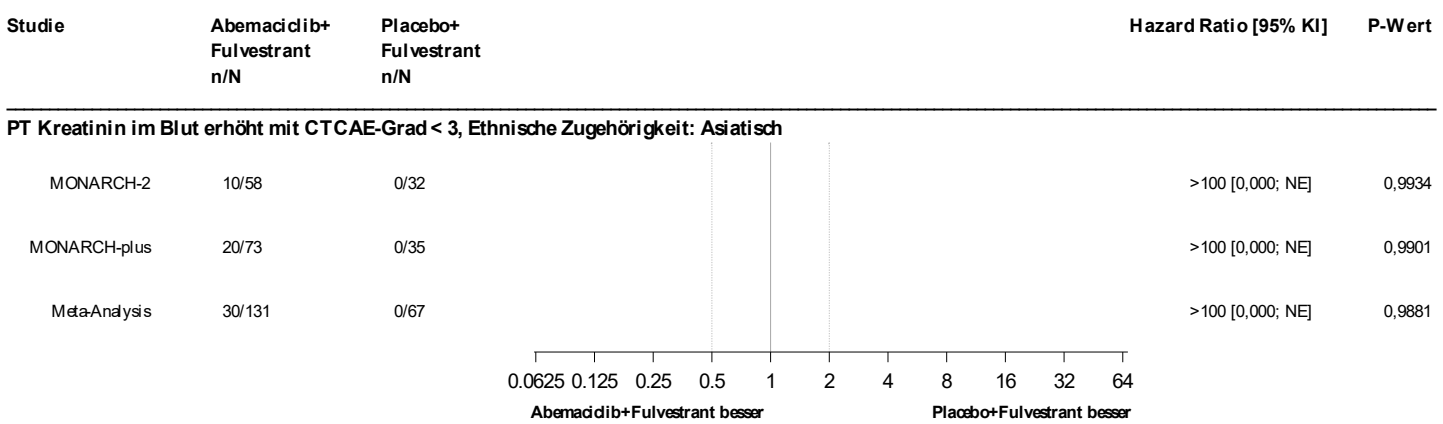
Abbildung 1438.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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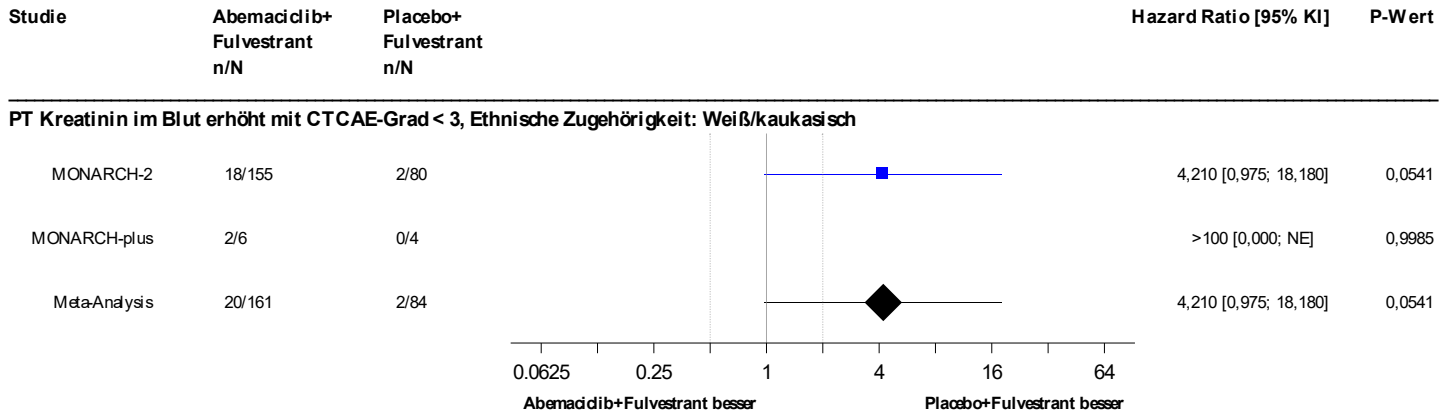
Abbildung 1438.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9986, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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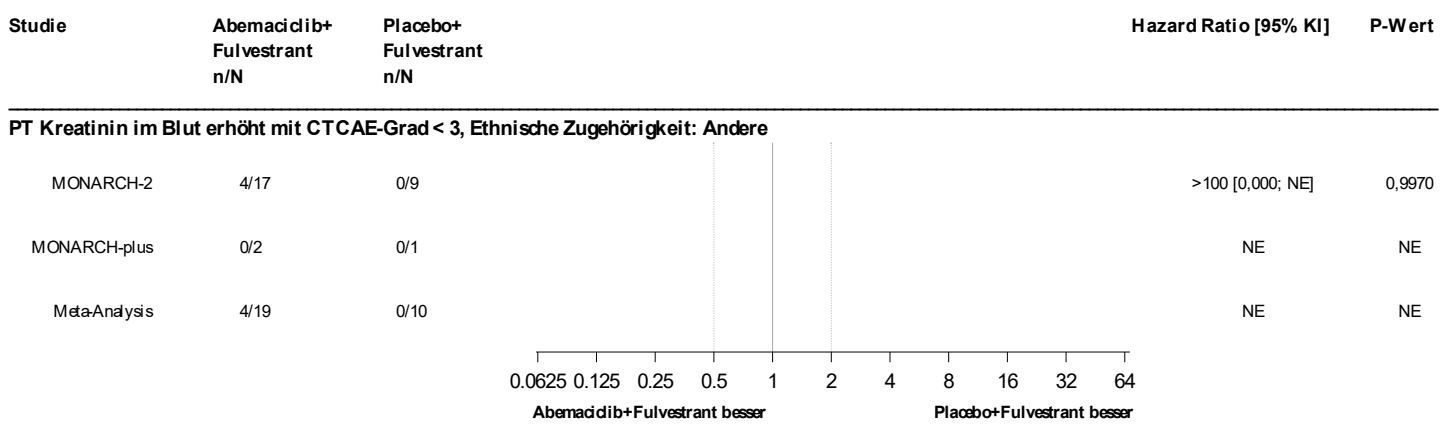
Abbildung 1438.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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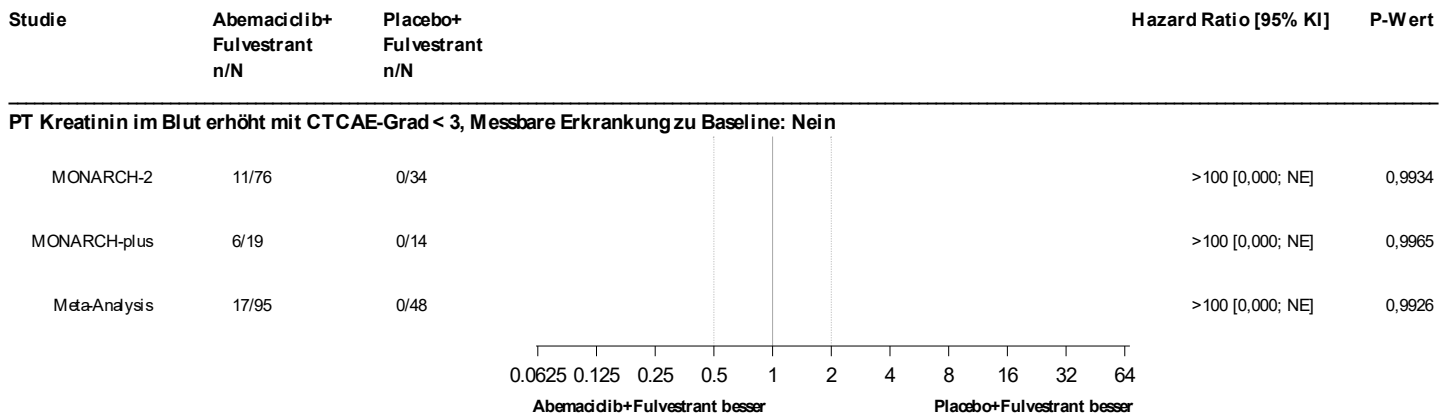
Abbildung 1438.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9998, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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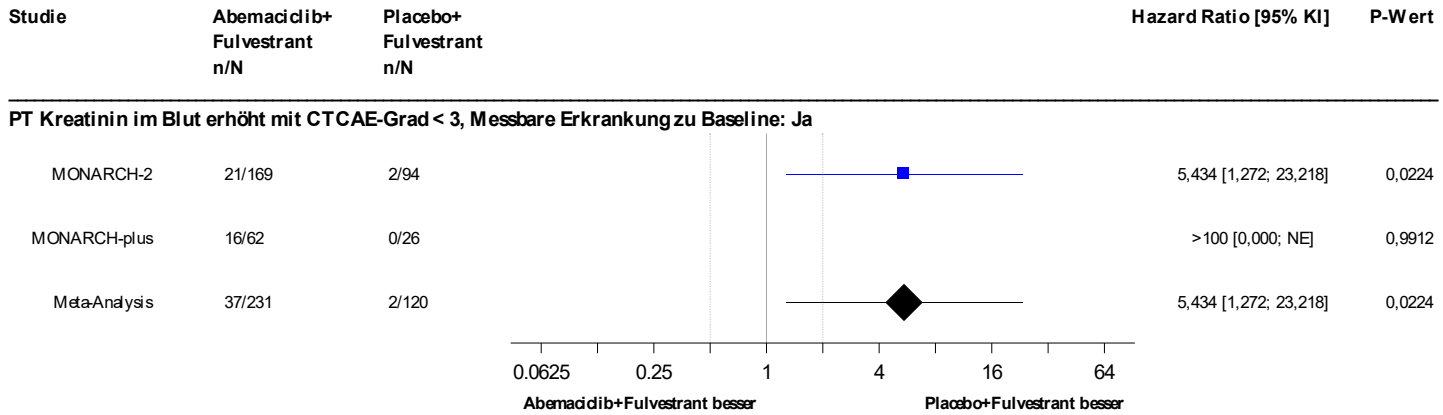
Abbildung 1438.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9921, I2 Index=0%
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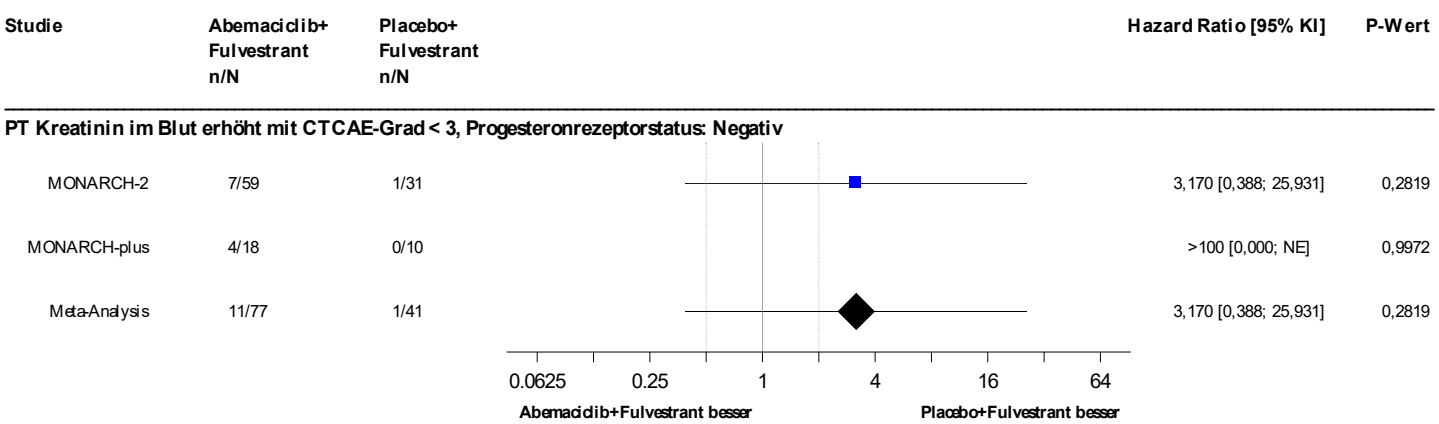
Abbildung 1438.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9974, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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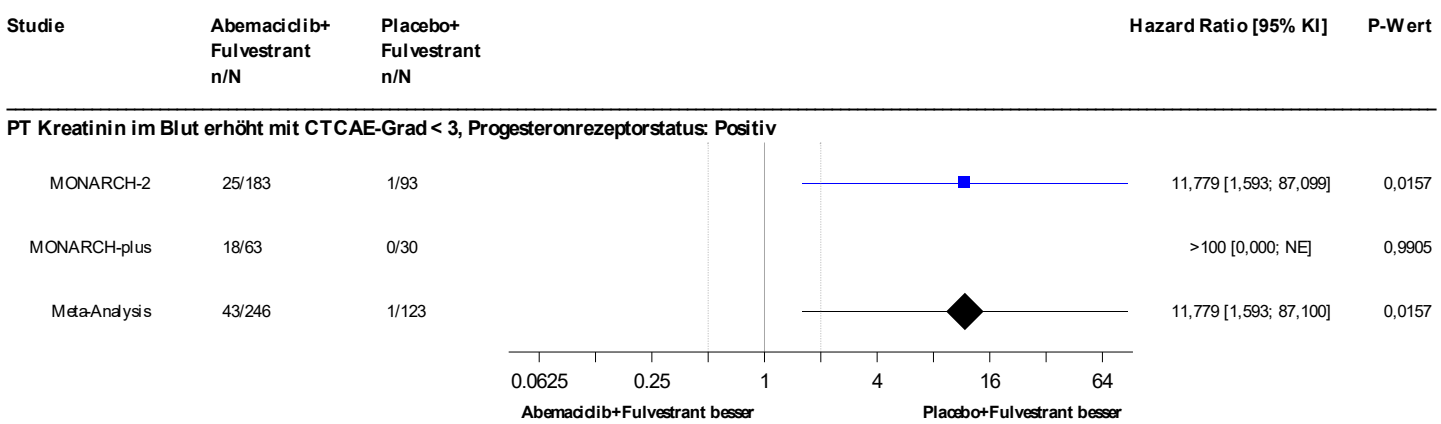
Abbildung 1438.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9919, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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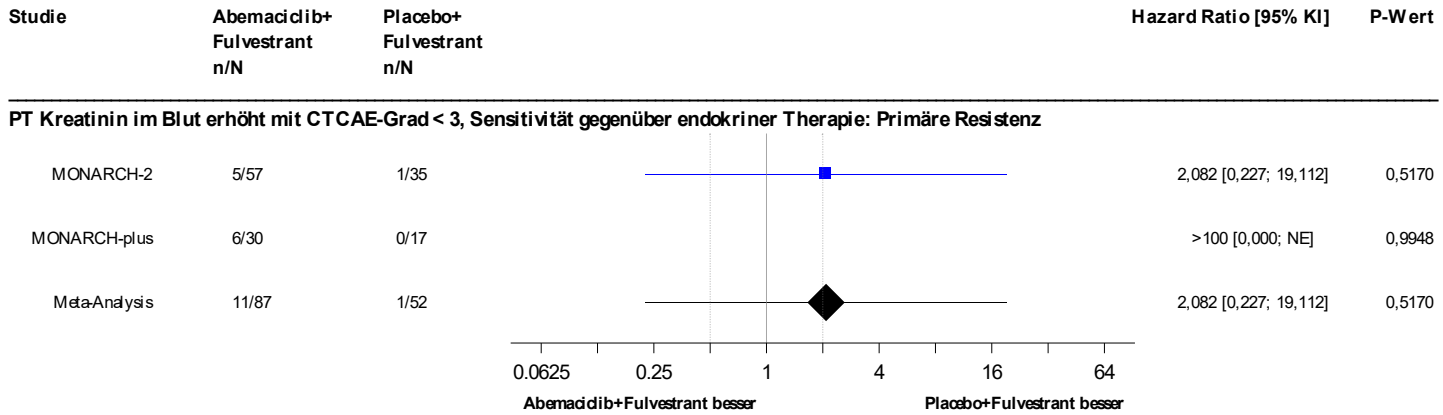
Abbildung 1438.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9951, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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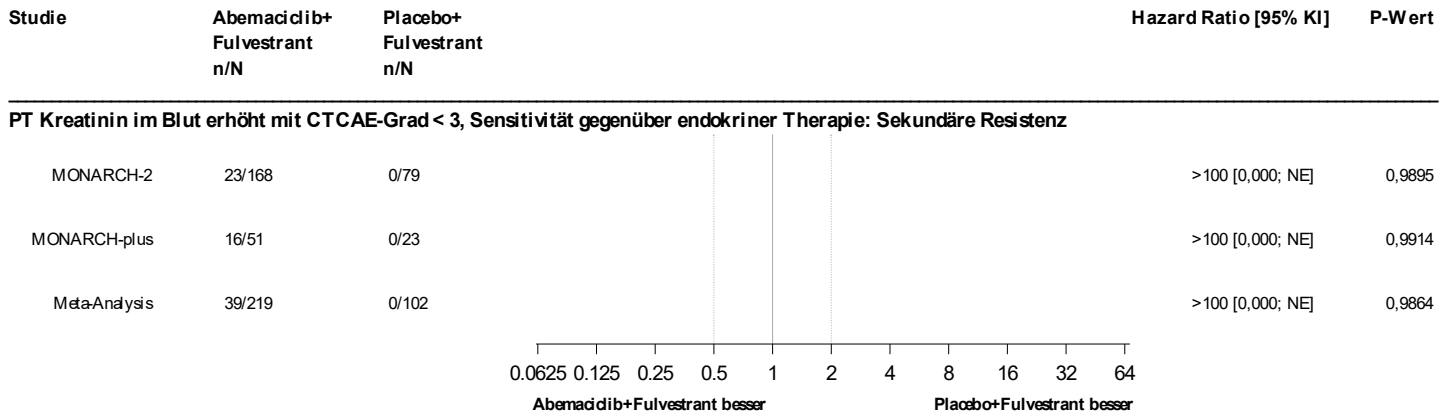
Abbildung 1438.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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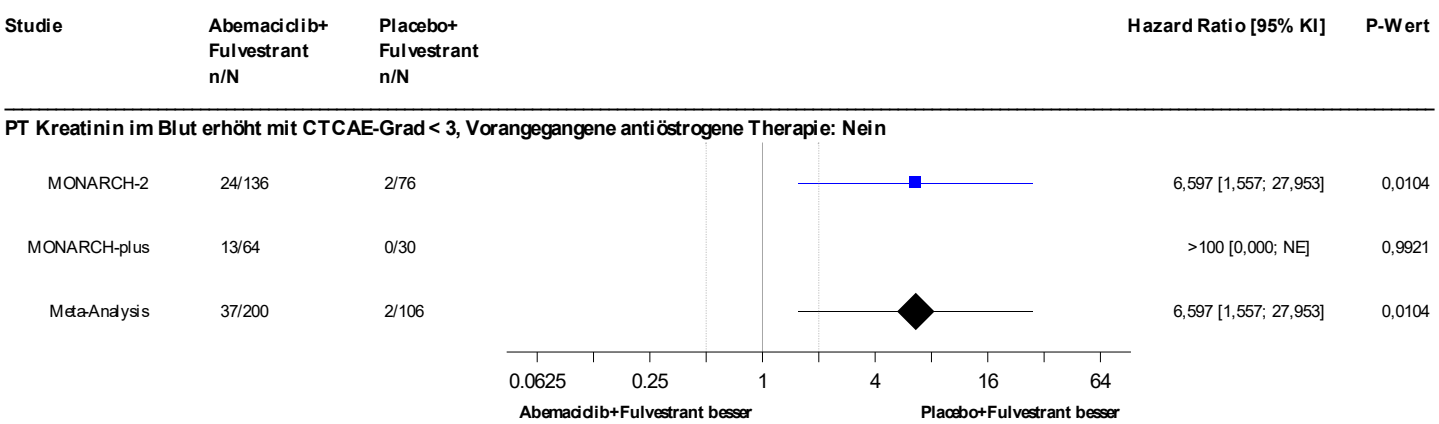
Abbildung 1438.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9930, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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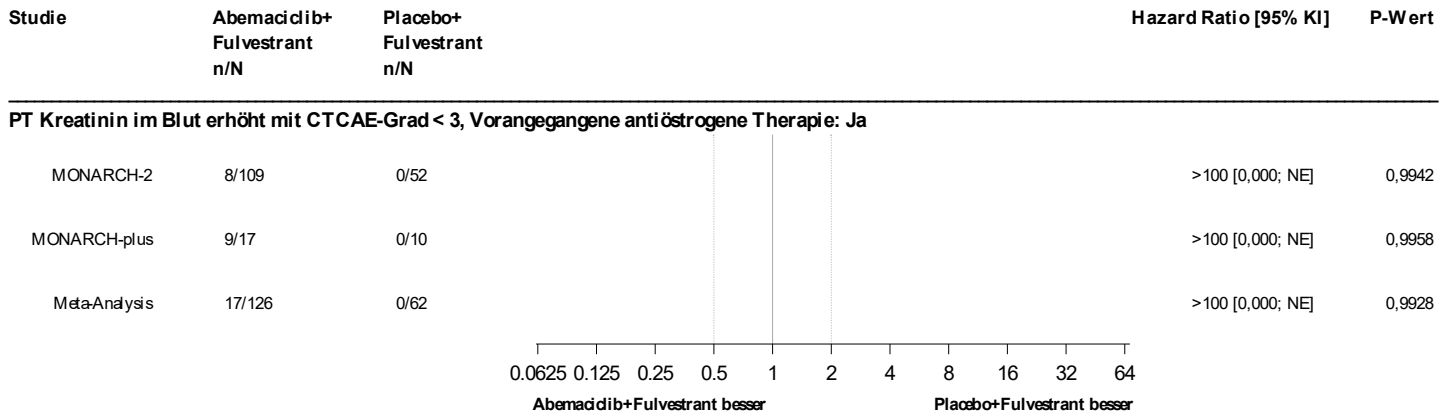
Abbildung 1438.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9998, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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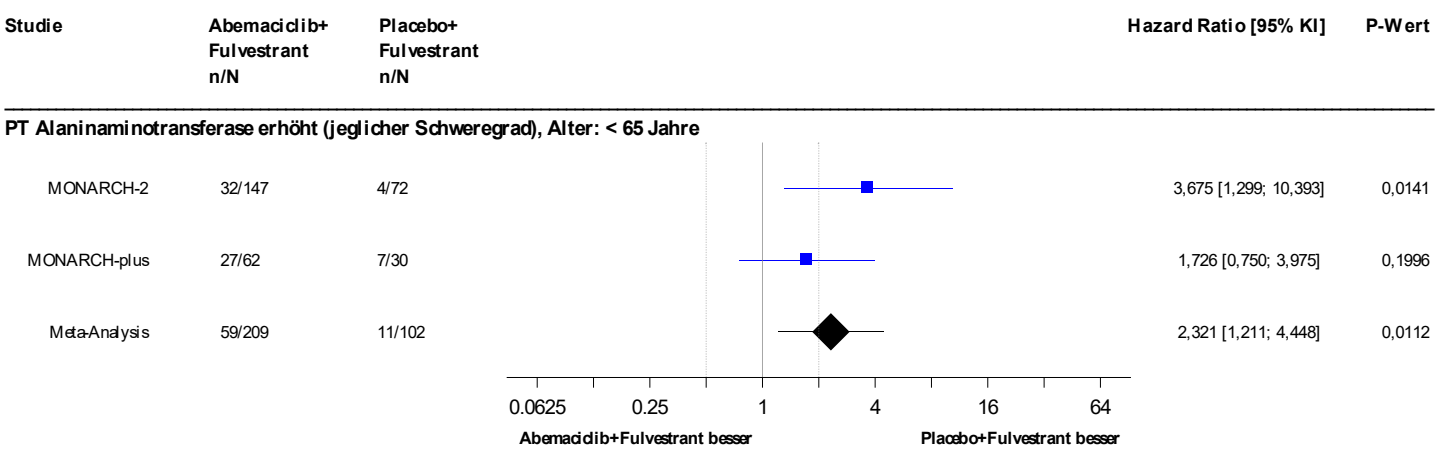
Abbildung 1440.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,2343, P-Wert=0,2666, I2 Index=19,0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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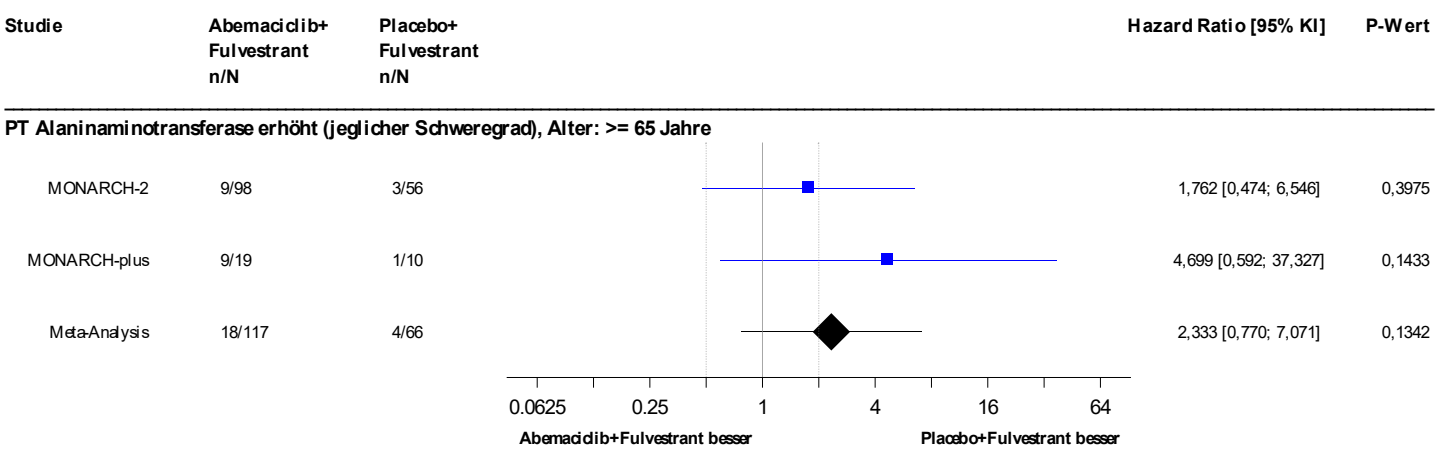
Abbildung 1440.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6142, P-Wert=0,4332, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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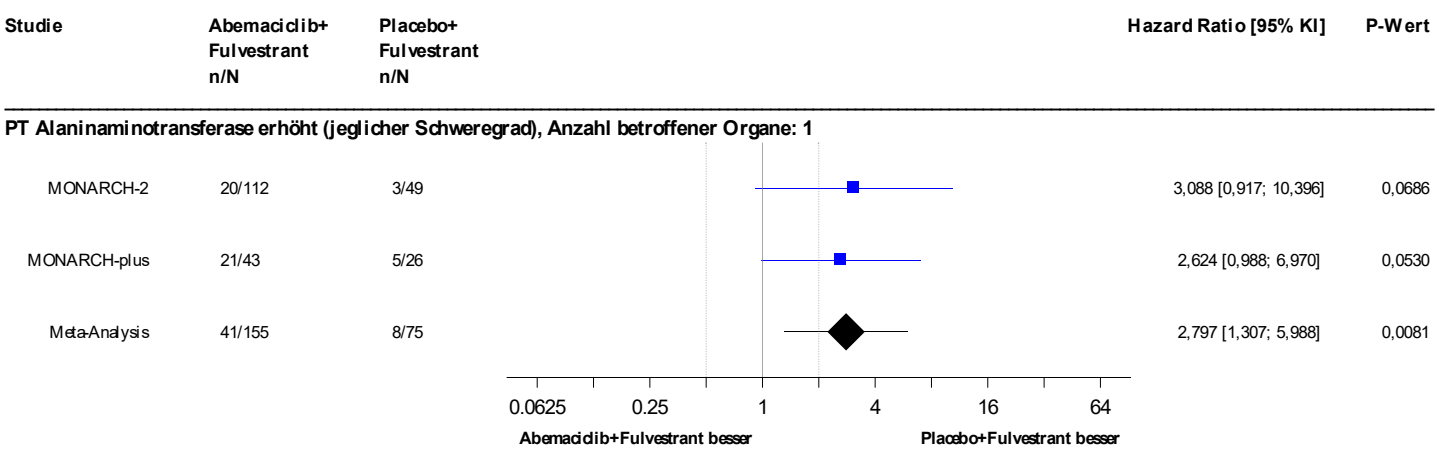
Abbildung 1440.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0420, P-Wert=0,8376, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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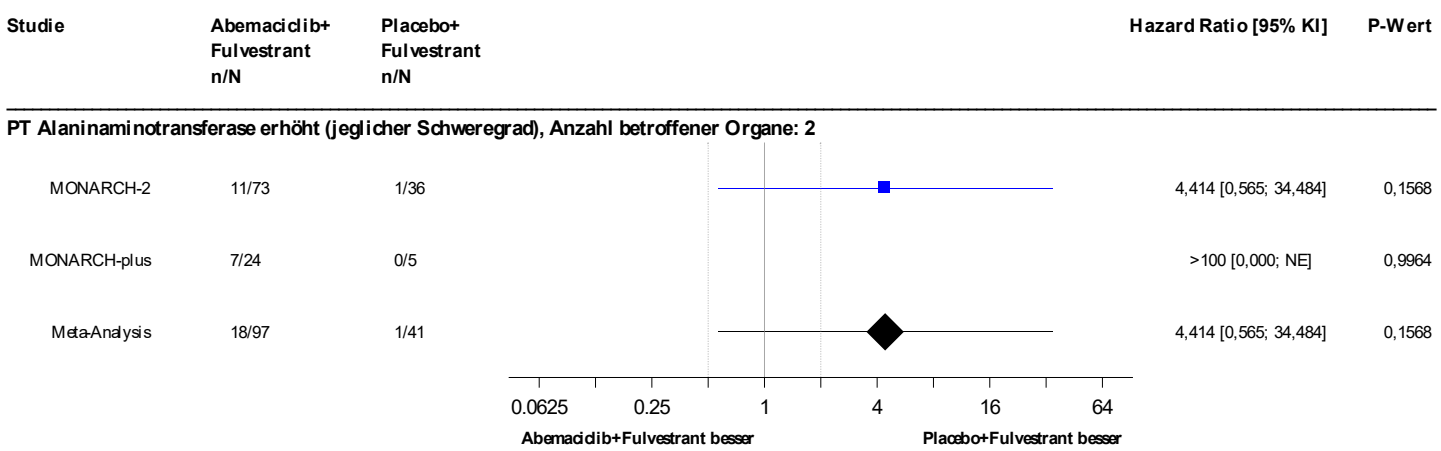
Abbildung 1440.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9967, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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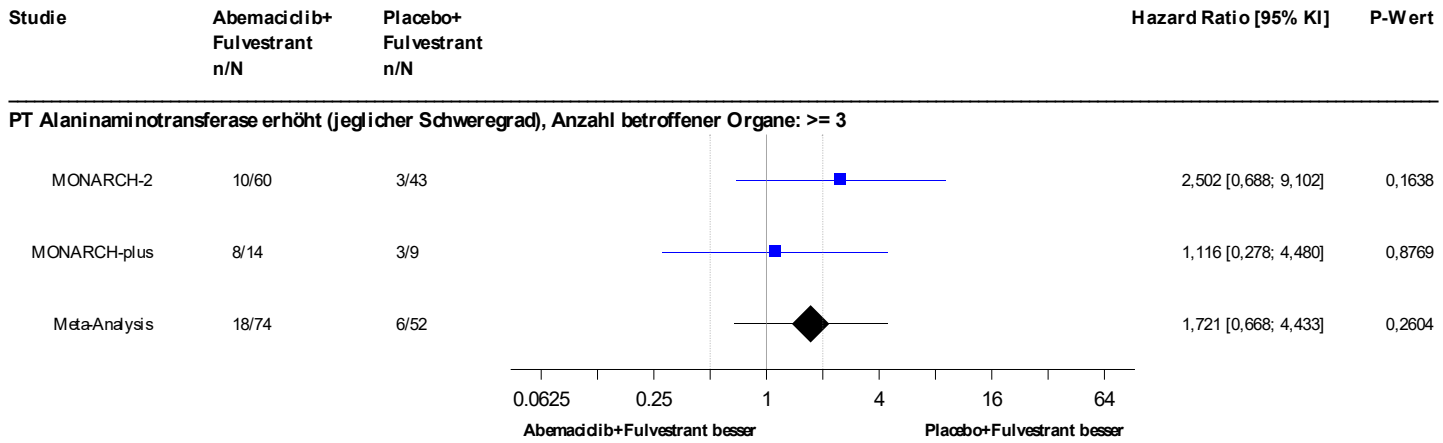
Abbildung 1440.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6958, P-Wert=0,4042, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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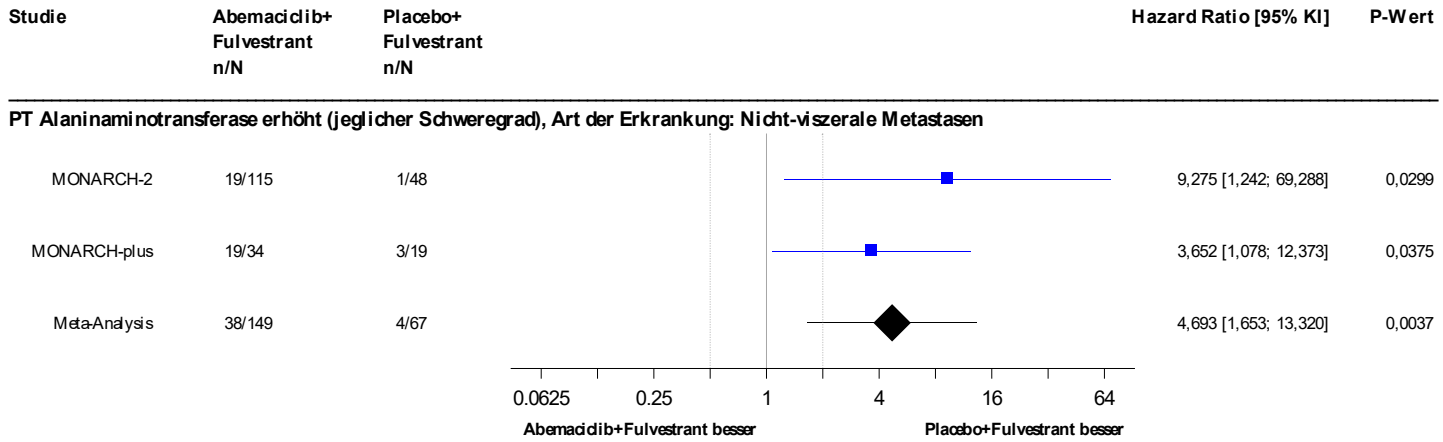
Abbildung 1440.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6031, P-Wert=0,4374, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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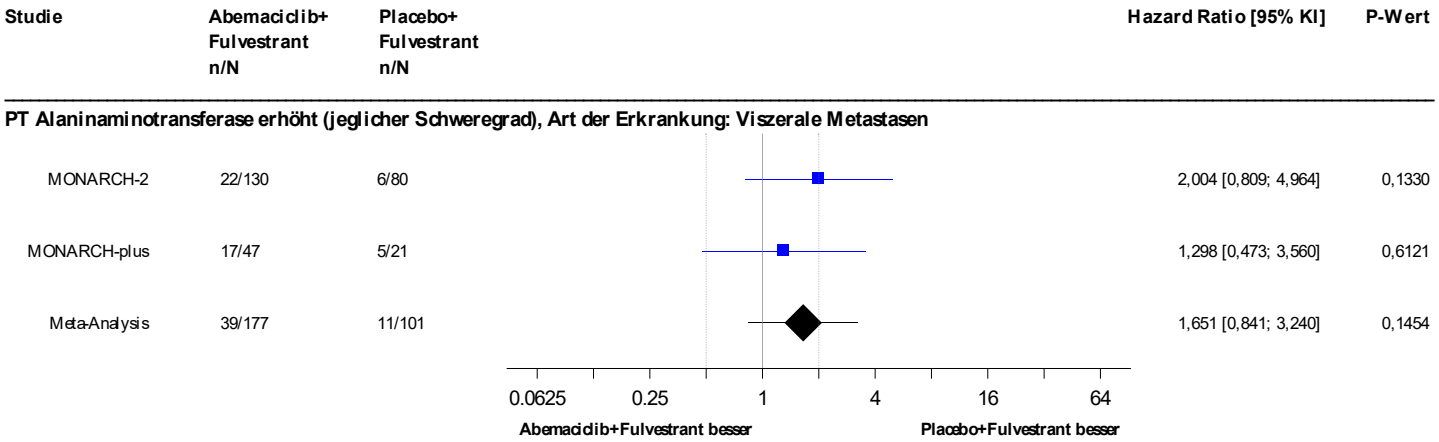
Abbildung 1440.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3934, P-Wert=0,5305, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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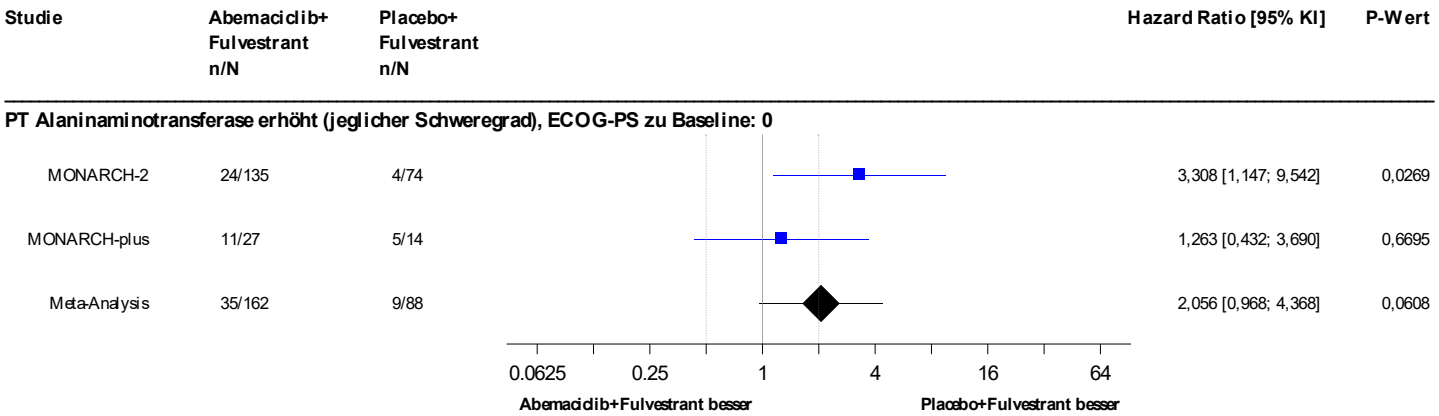
Abbildung 1440.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,5676, P-Wert=0,2105, I2 Index=36,2%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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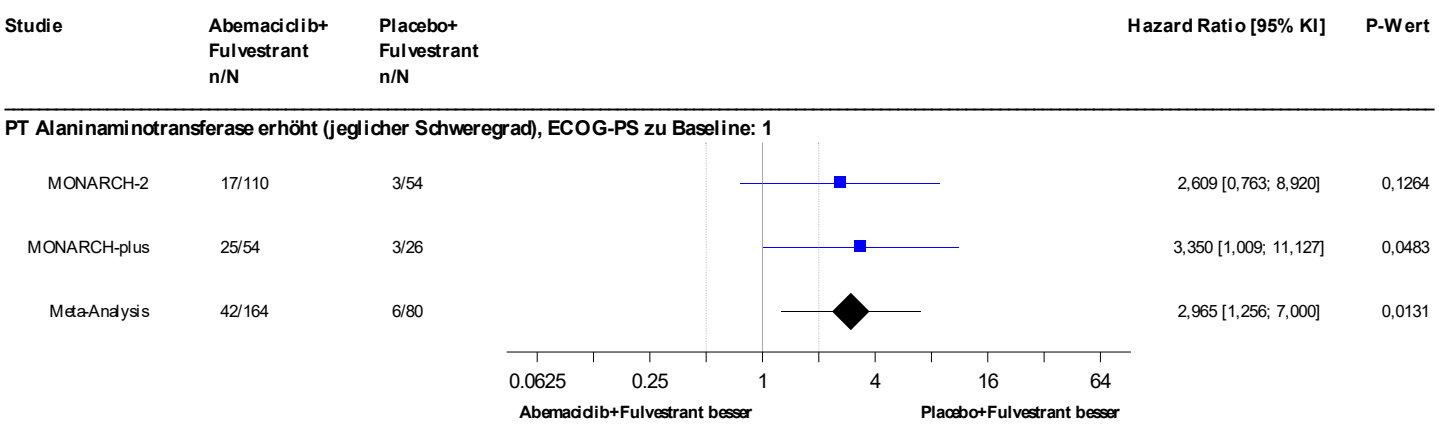
Abbildung 1440.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0815, P-Wert=0,7753, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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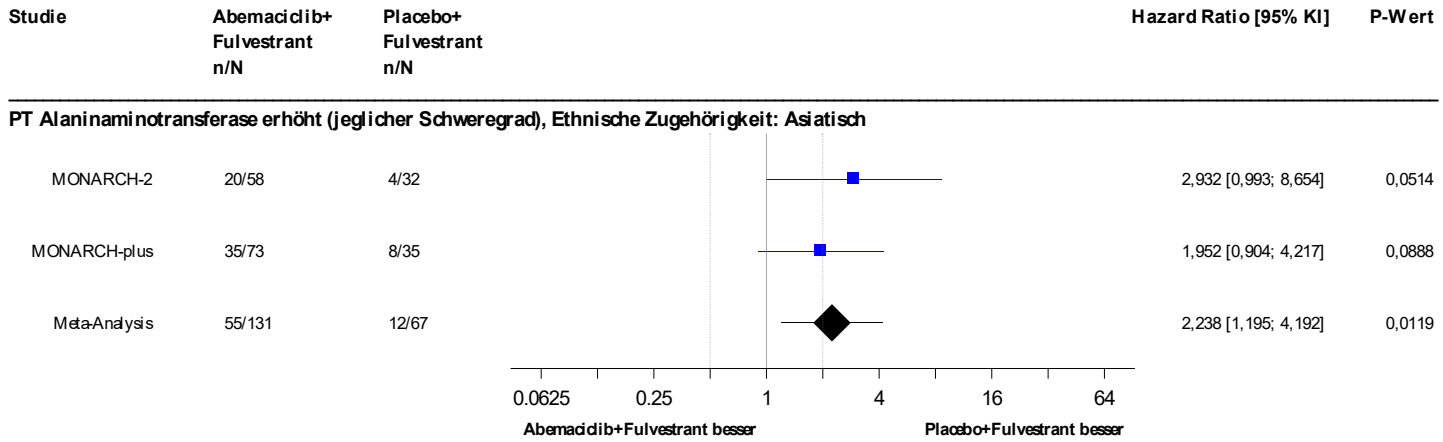
Abbildung 1440.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3604, P-Wert=0,5483, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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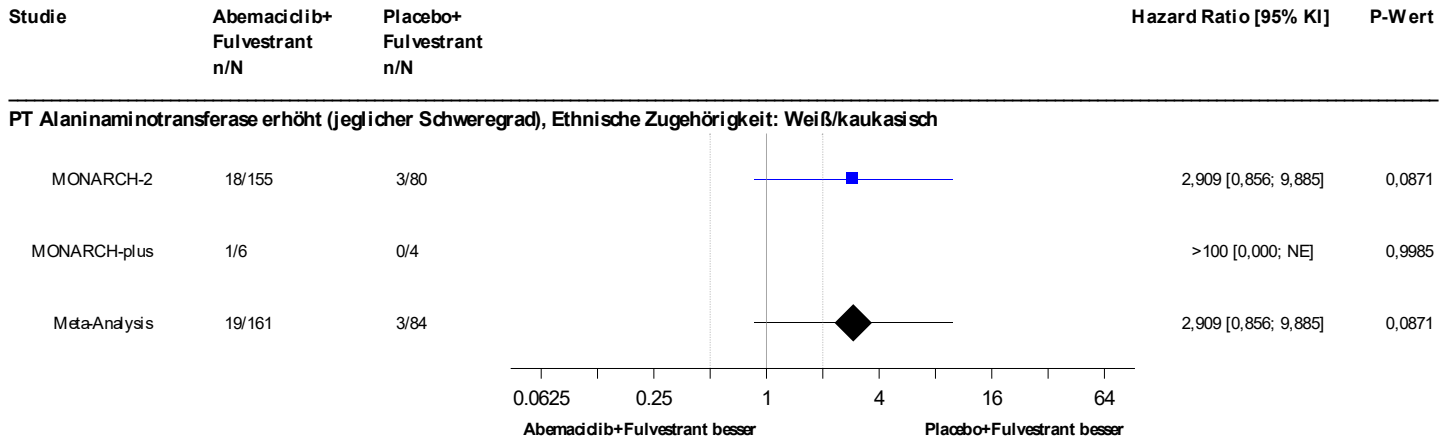
Abbildung 1440.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9986, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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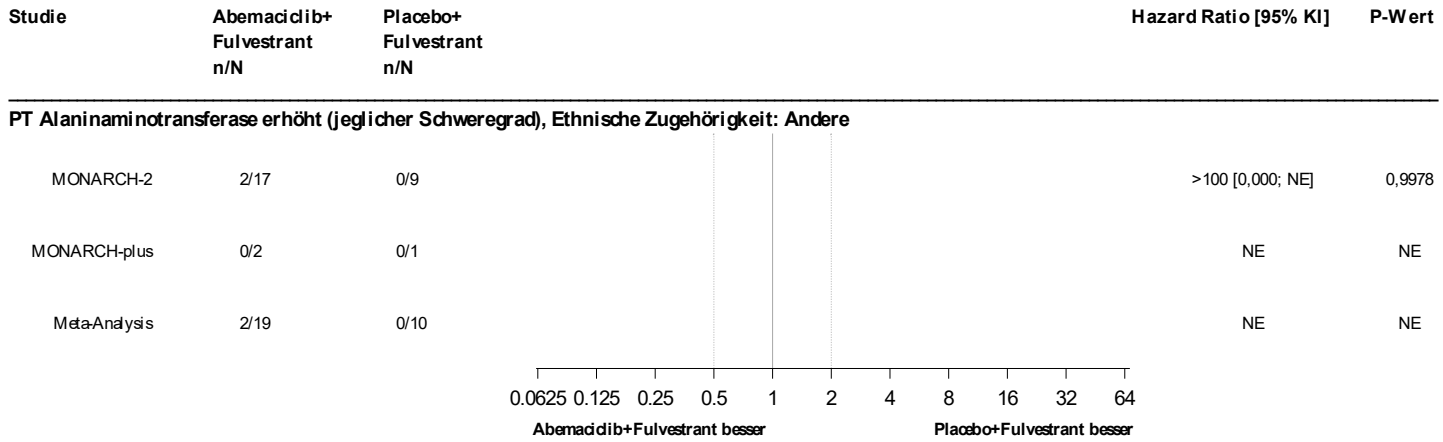
Abbildung 1440.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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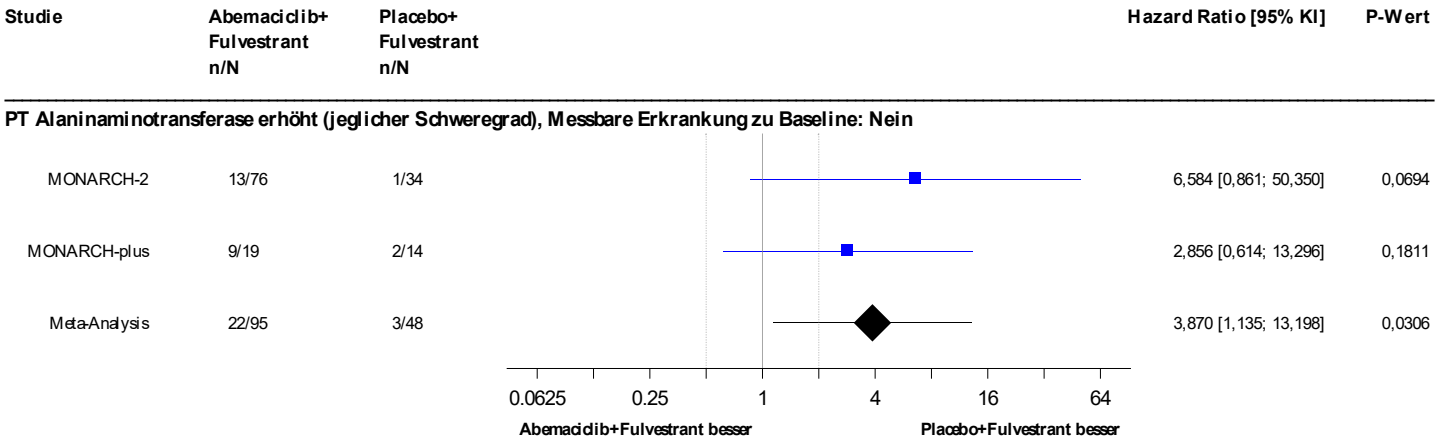
Abbildung 1440.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4119, P-Wert=0,5210, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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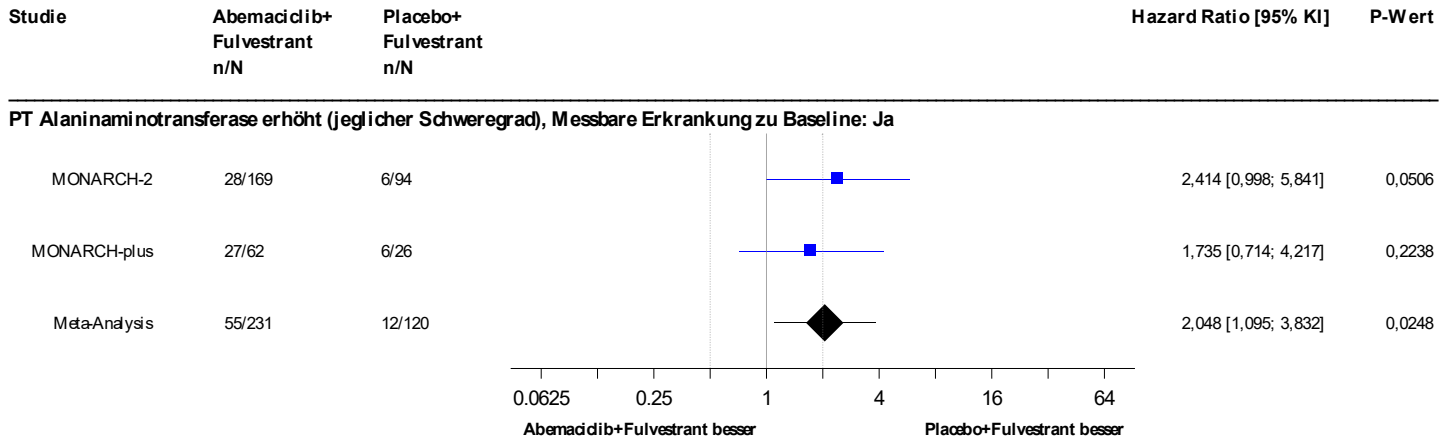
Abbildung 1440.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2670, P-Wert=0,6054, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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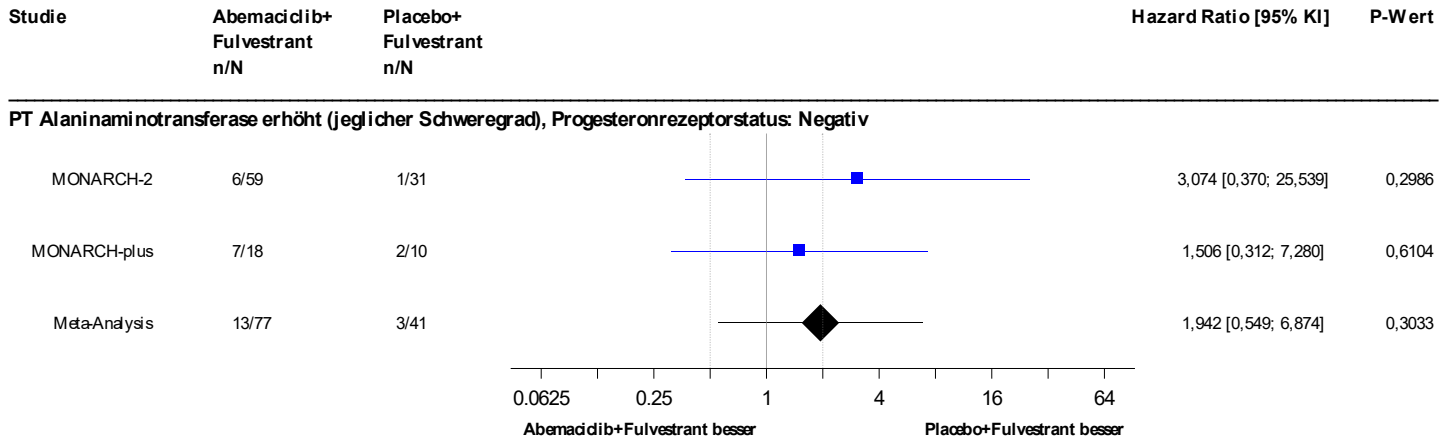
Abbildung 1440.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2806, P-Wert=0,5963, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttalaesi_popa1_pgrstat_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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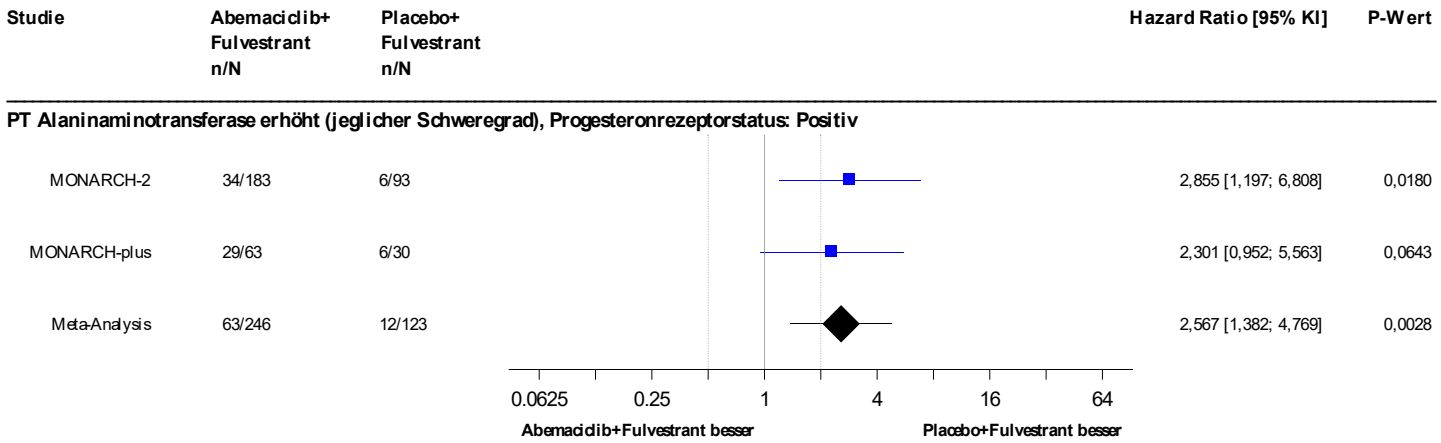
Abbildung 1440.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1165, P-Wert=0,7329, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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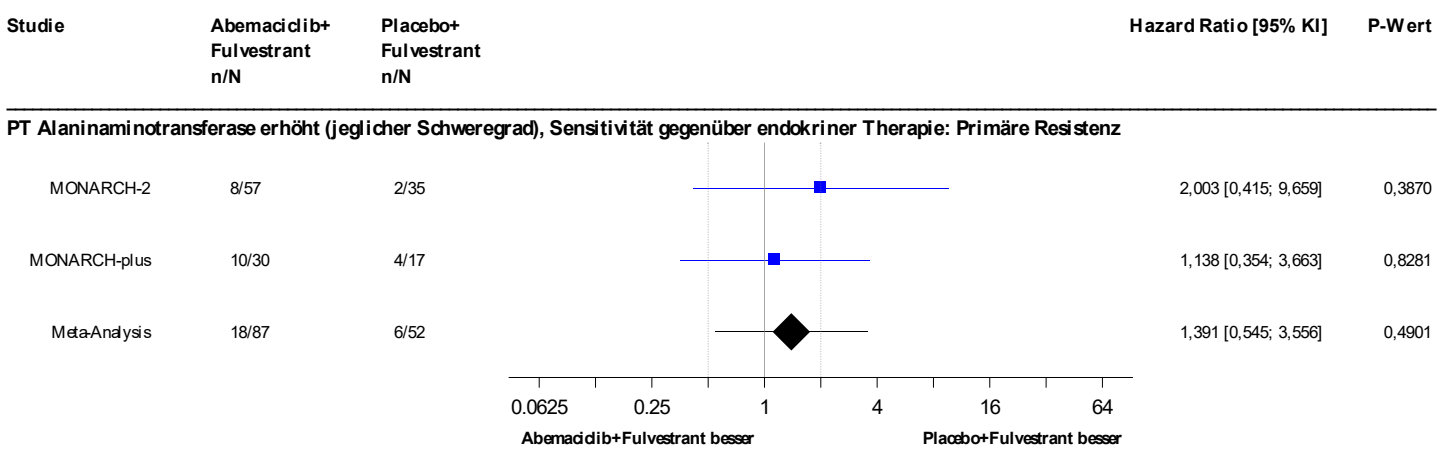
Abbildung 1440.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3193, P-Wert=0,5720, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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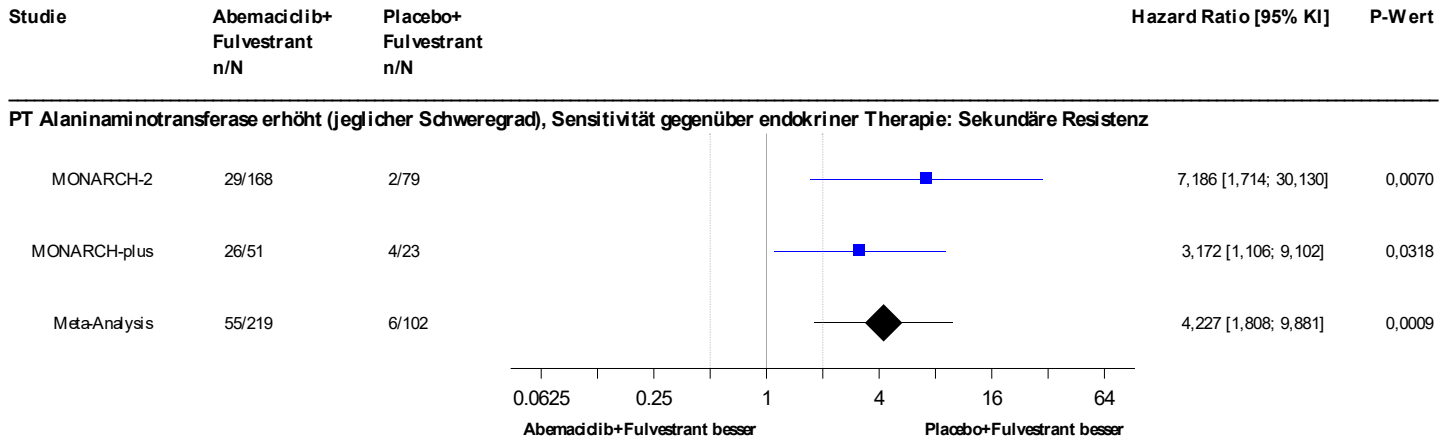
Abbildung 1440.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,8114, P-Wert=0,3677, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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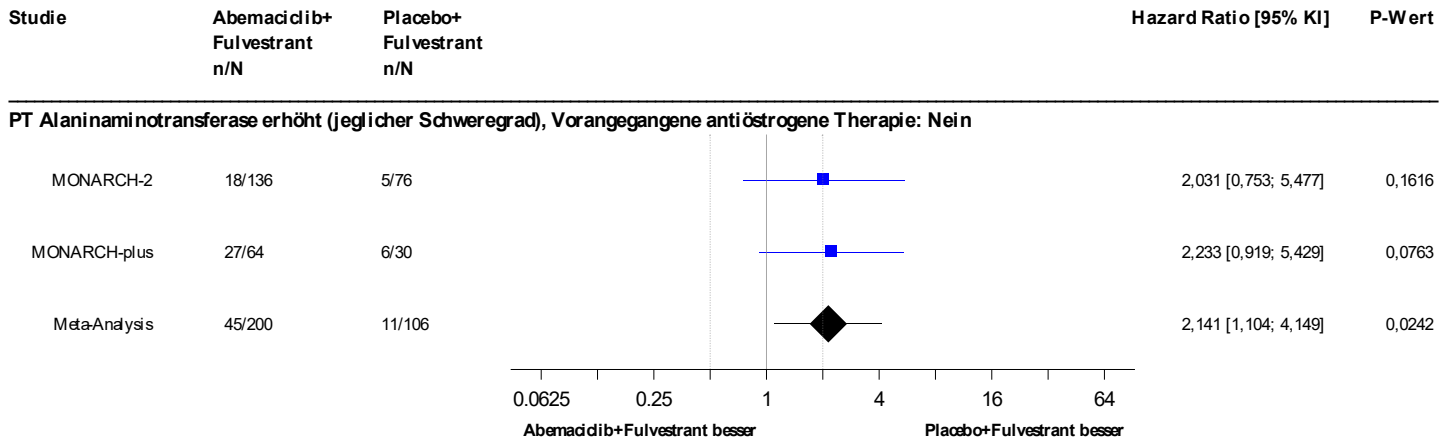
Abbildung 1440.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0195, P-Wert=0,8890, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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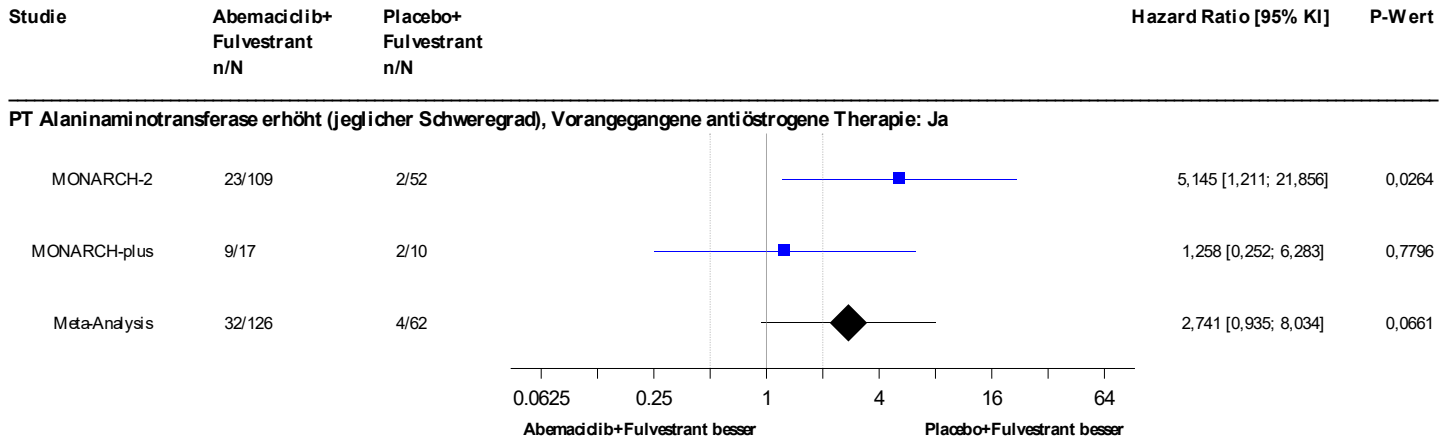
Abbildung 1440.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,6289, P-Wert=0,2019, I2 Index=38,6%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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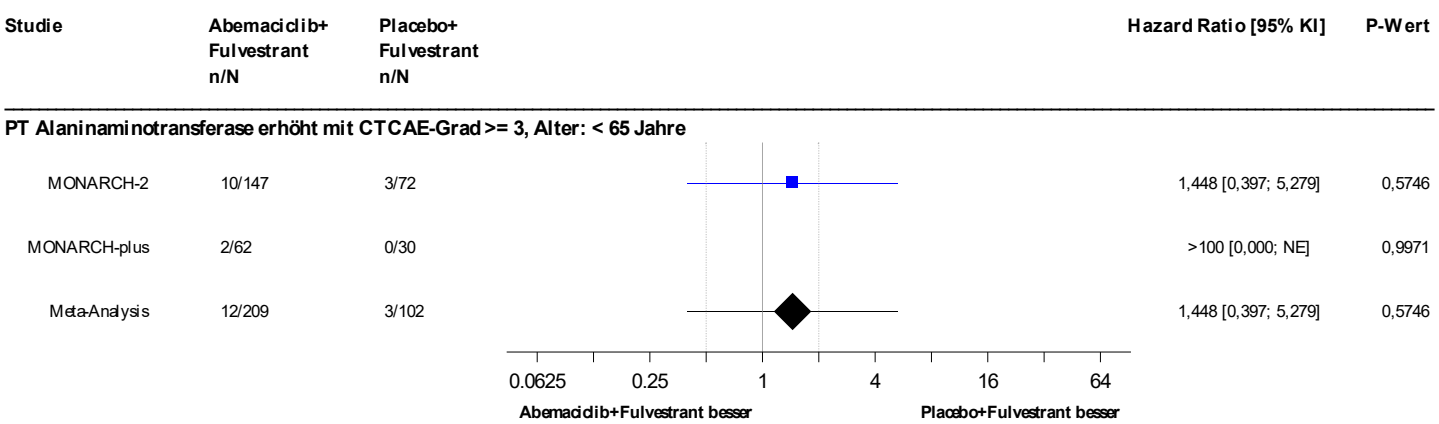
Abbildung 1441.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9972, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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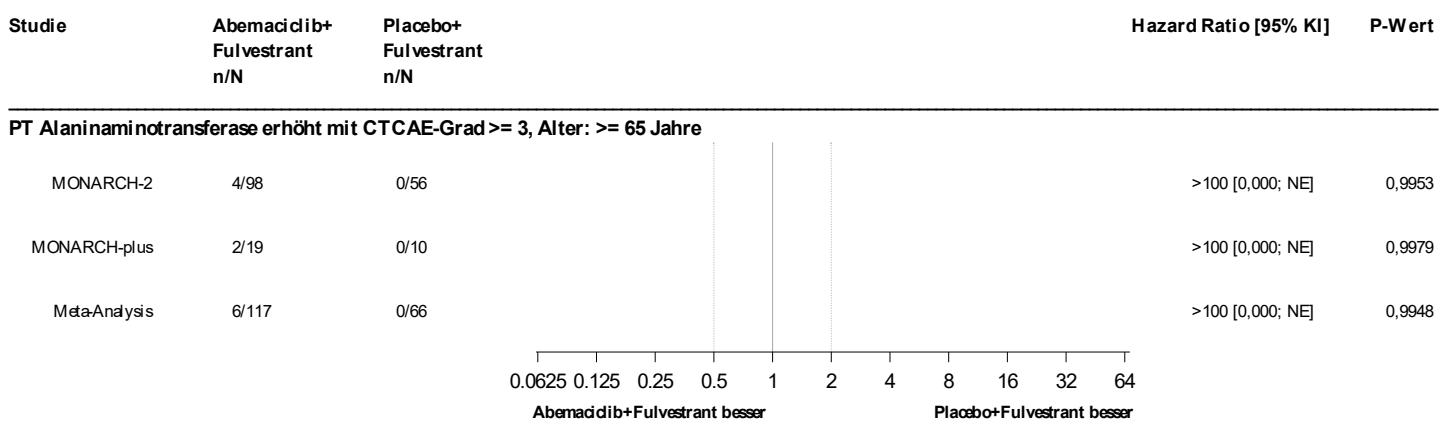
Abbildung 1441.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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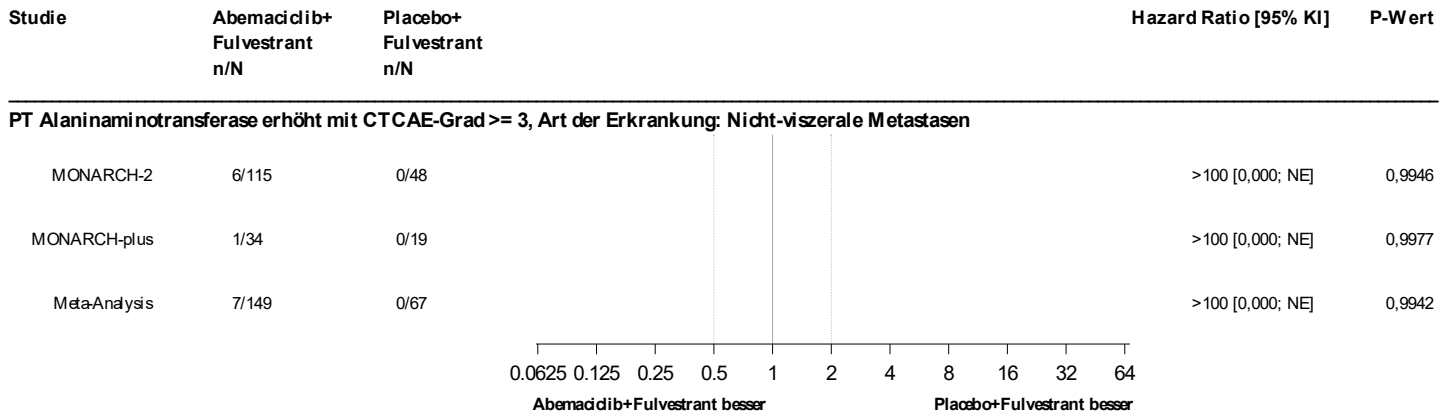
Abbildung 1441.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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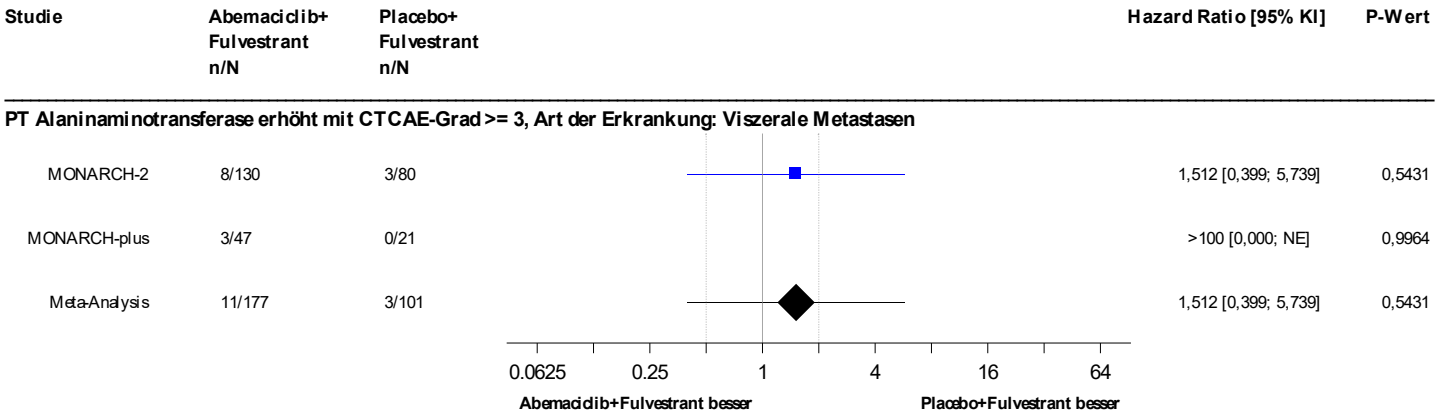
Abbildung 1441.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9965, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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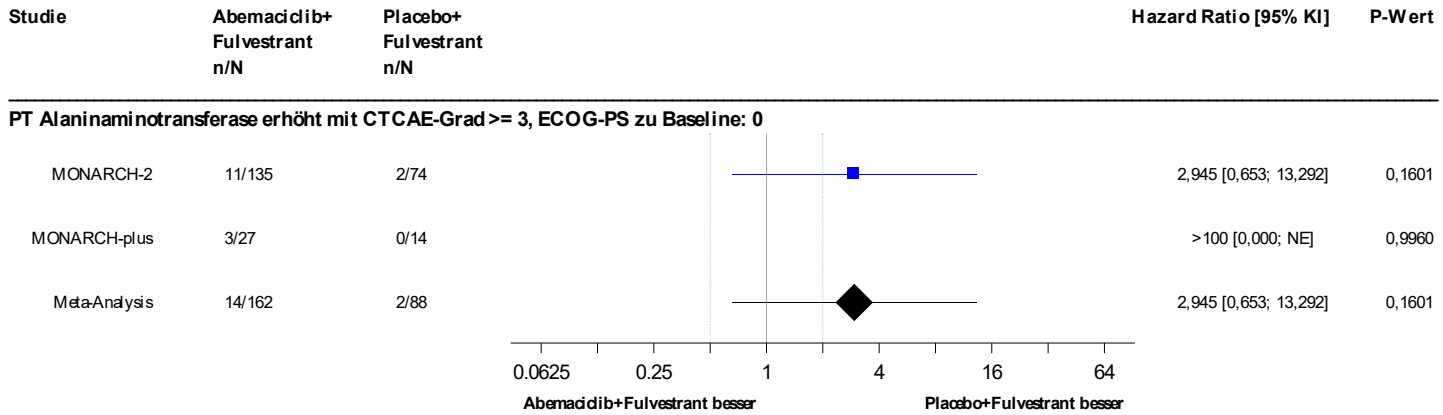
Abbildung 1441.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9963, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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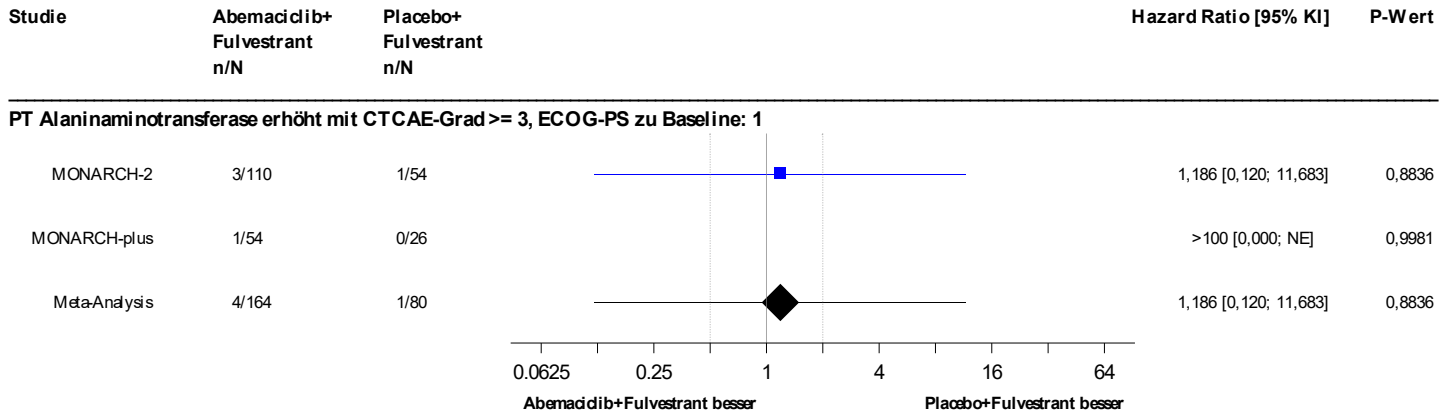
Abbildung 1441.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9981, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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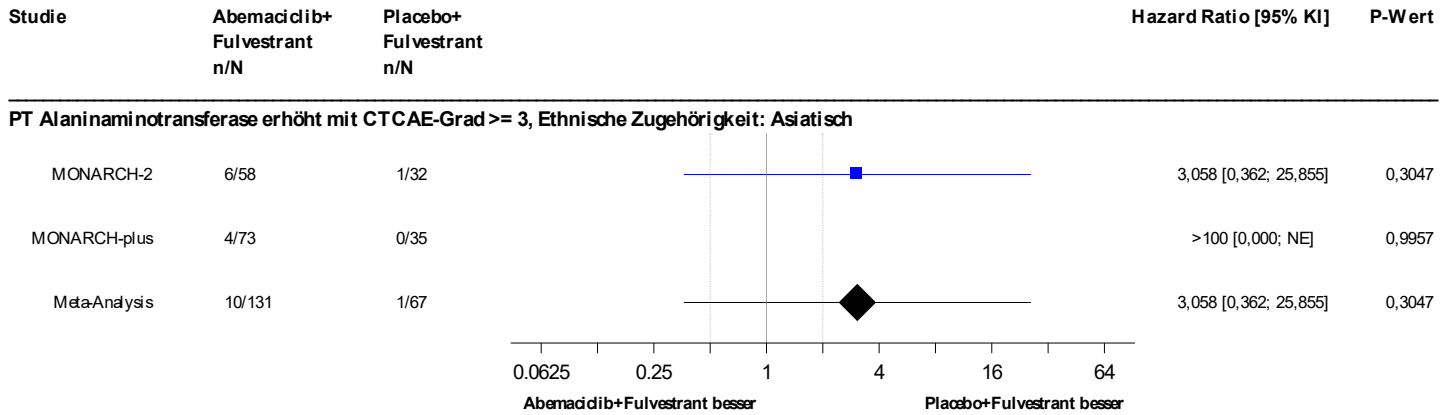
Abbildung 1441.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9960, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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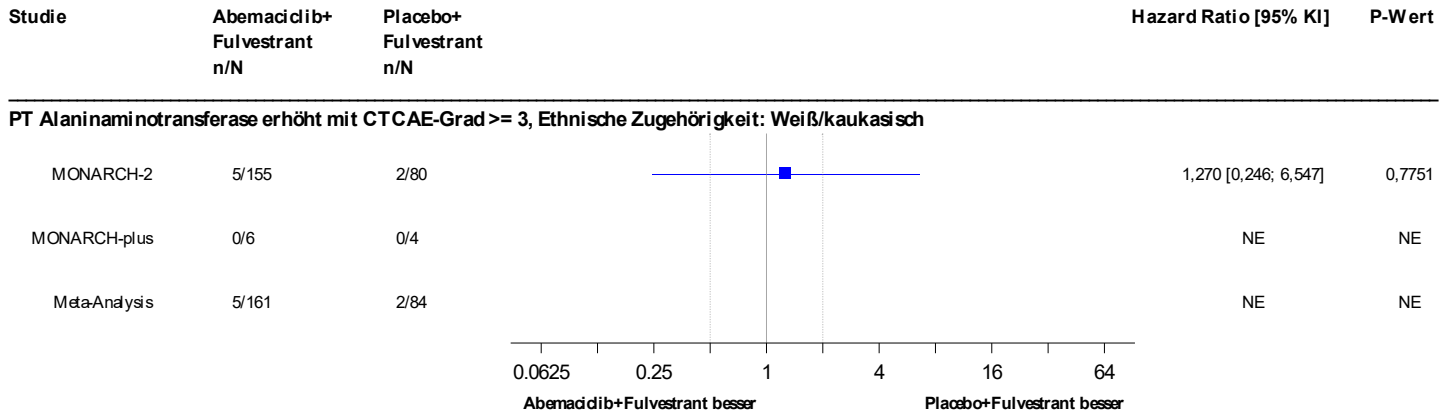
Abbildung 1441.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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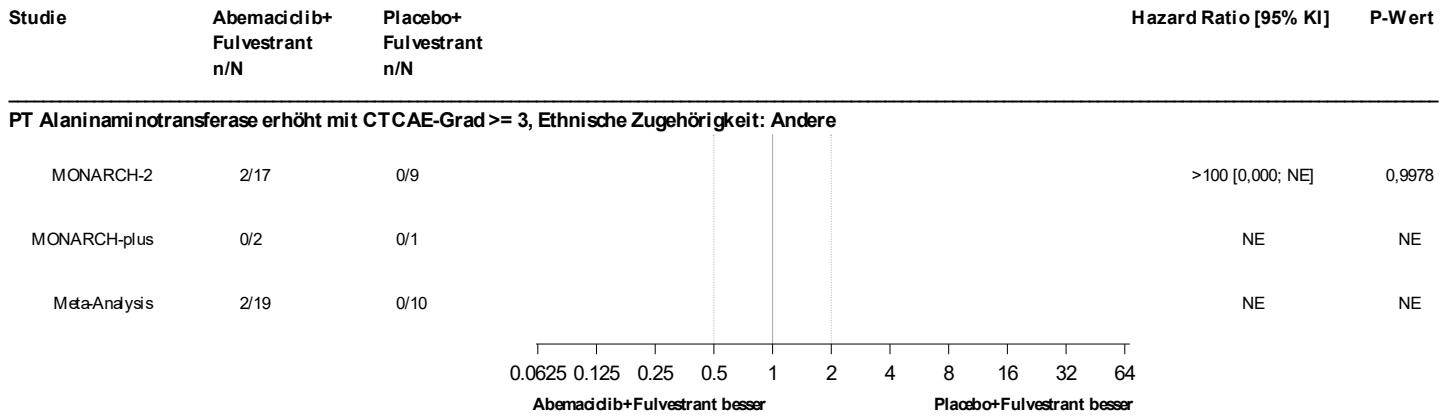
Abbildung 1441.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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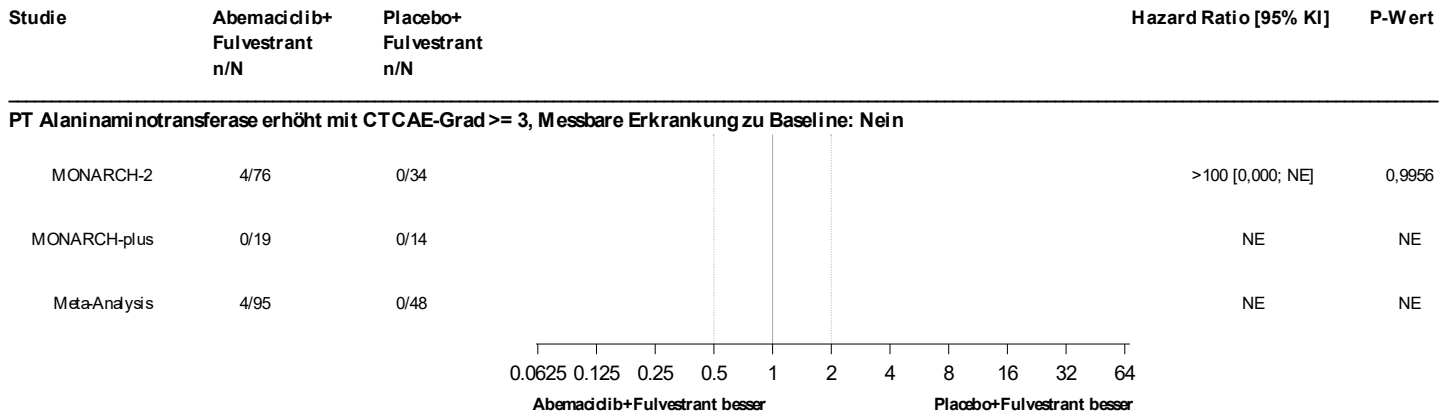
Abbildung 1441.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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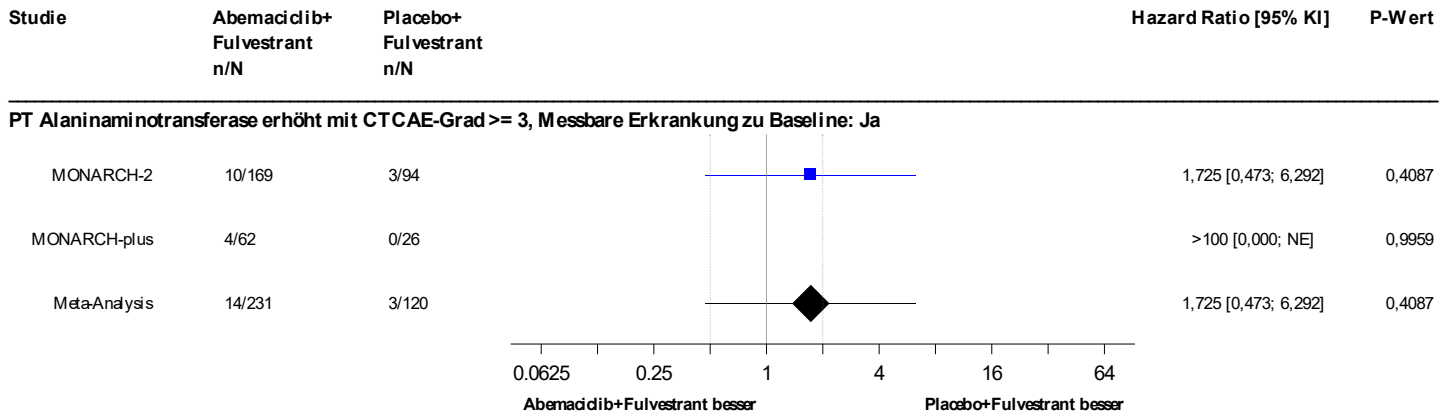
Abbildung 1441.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9960, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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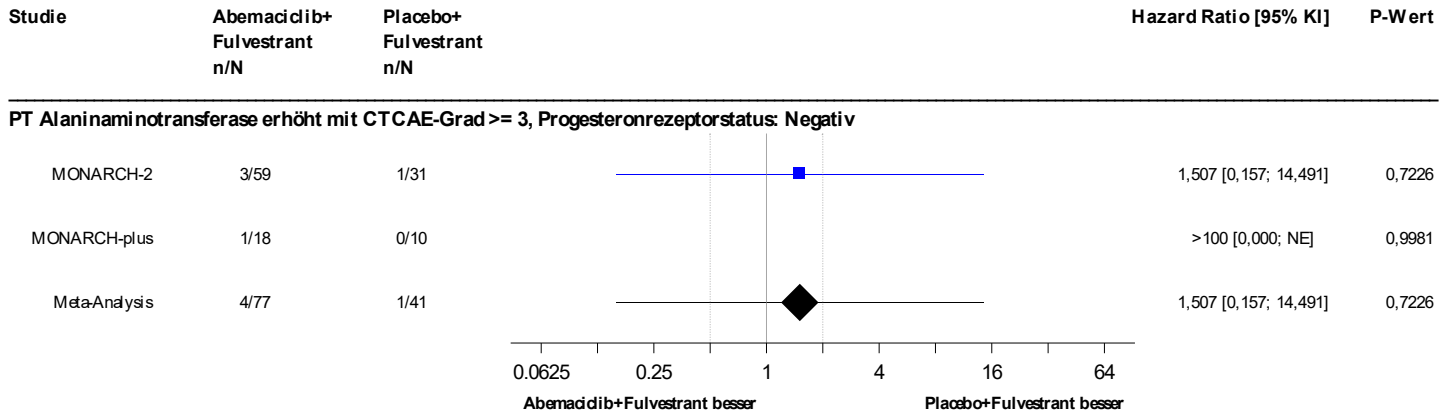
Abbildung 1441.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9981, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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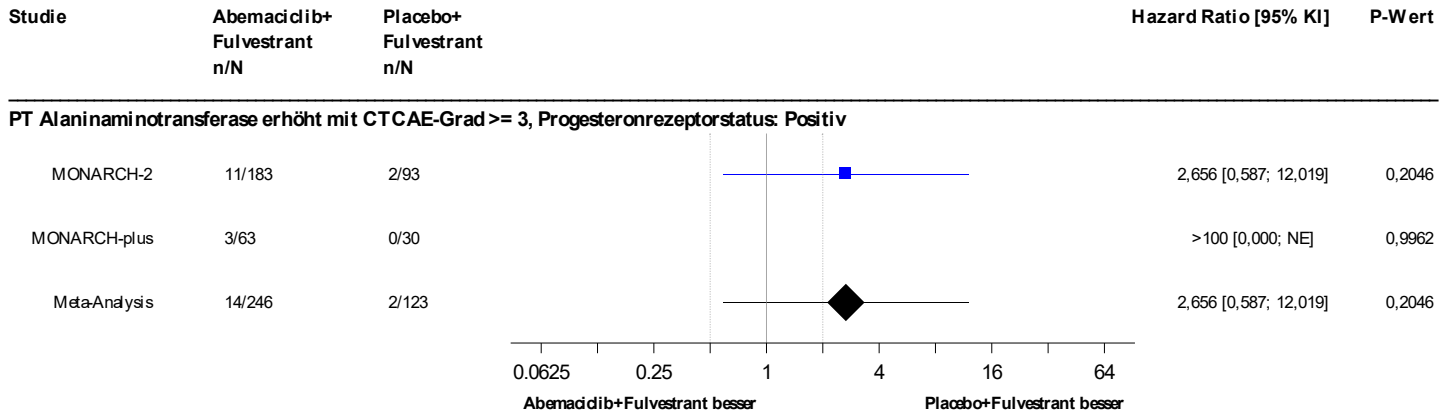
Abbildung 1441.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9964, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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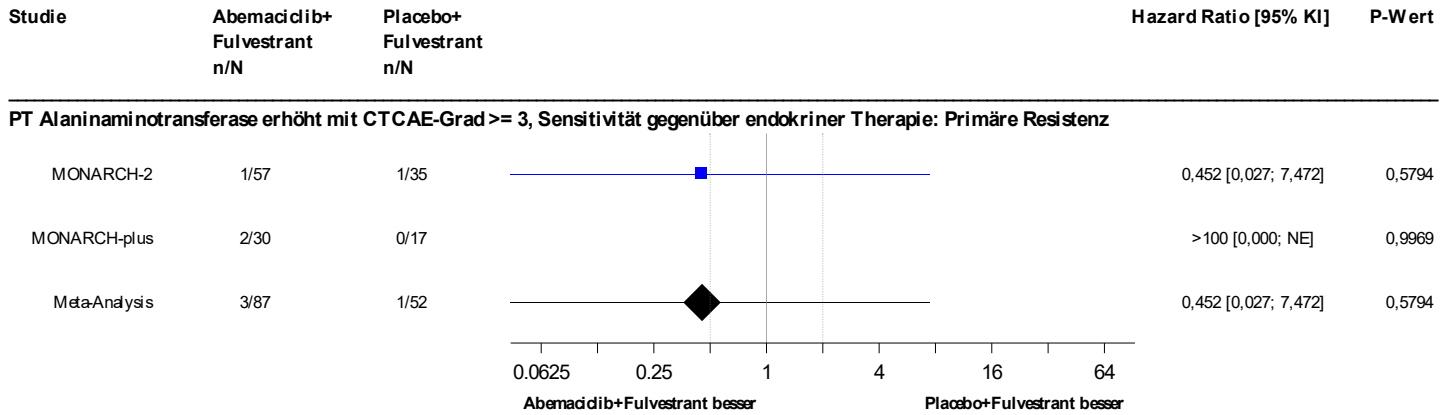
Abbildung 1441.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9967, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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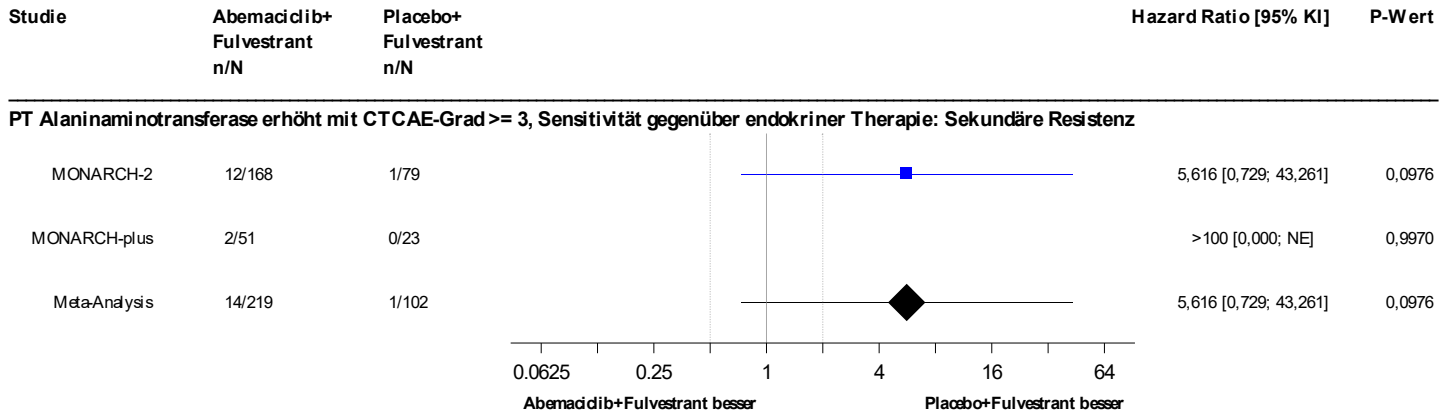
Abbildung 1441.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9973, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttal3aesi_popa1_snthr_2.rtf
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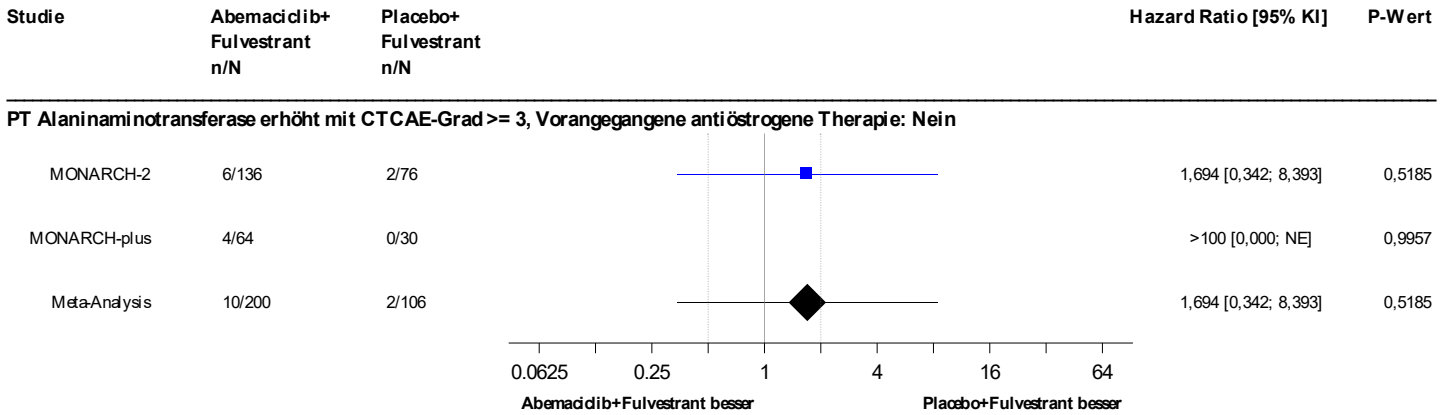
Abbildung 1441.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9959, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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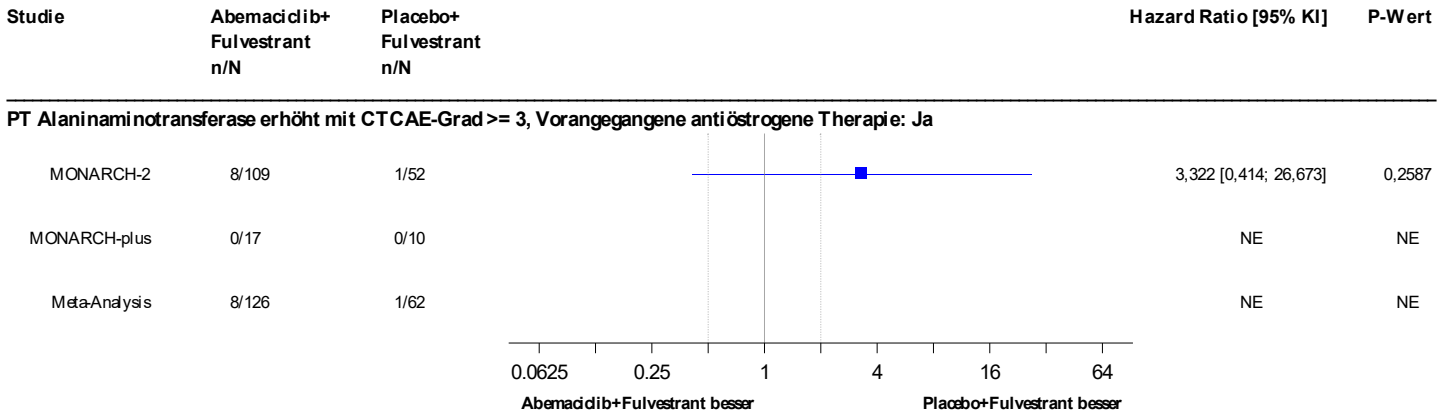
Abbildung 1441.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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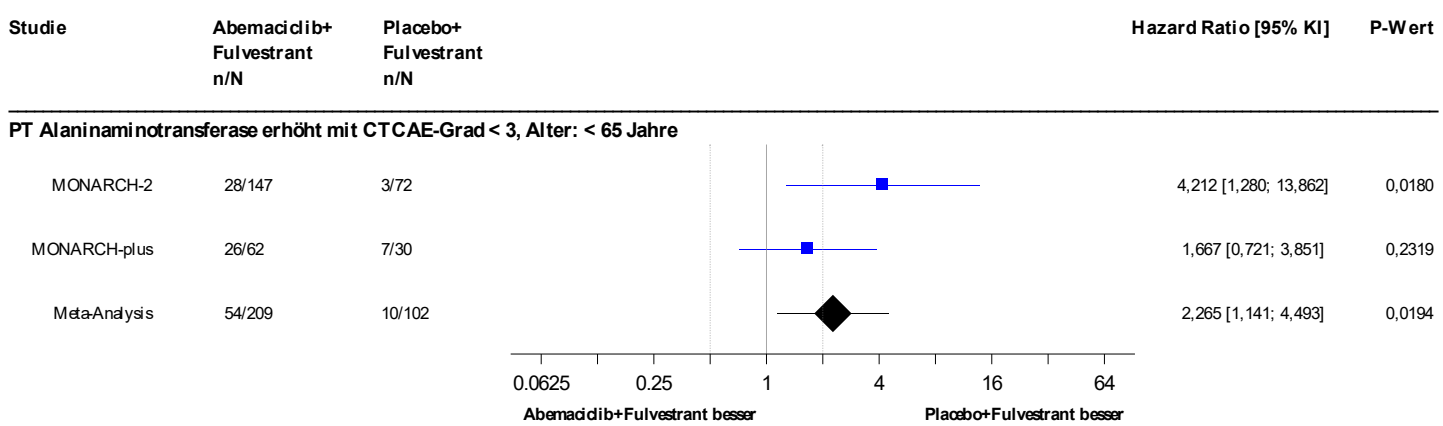
Abbildung 1442.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,5565, P-Wert=0,2122, I2 Index=35,8%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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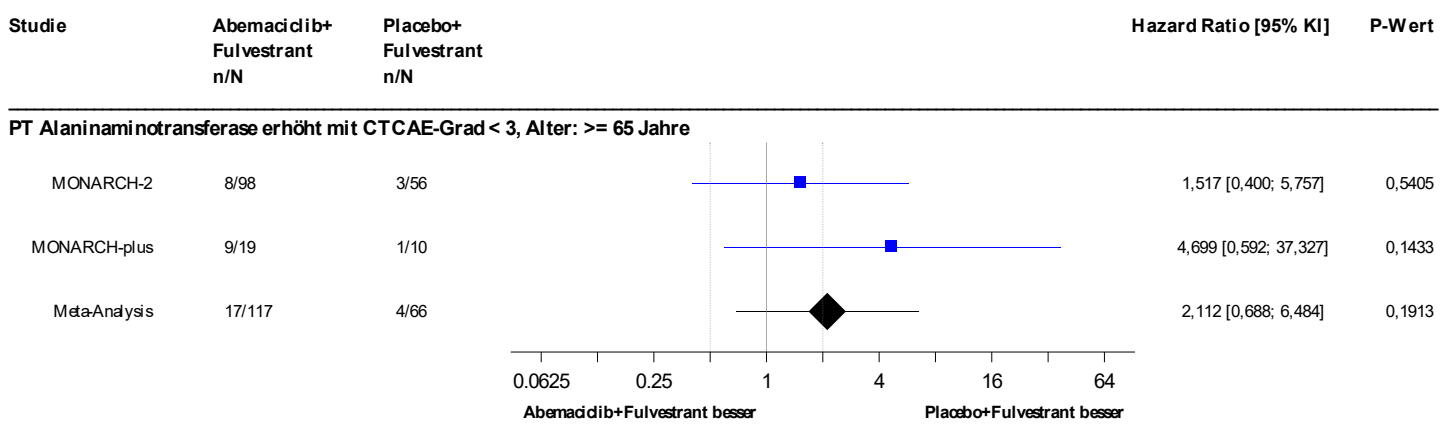
Abbildung 1442.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,8088, P-Wert=0,3685, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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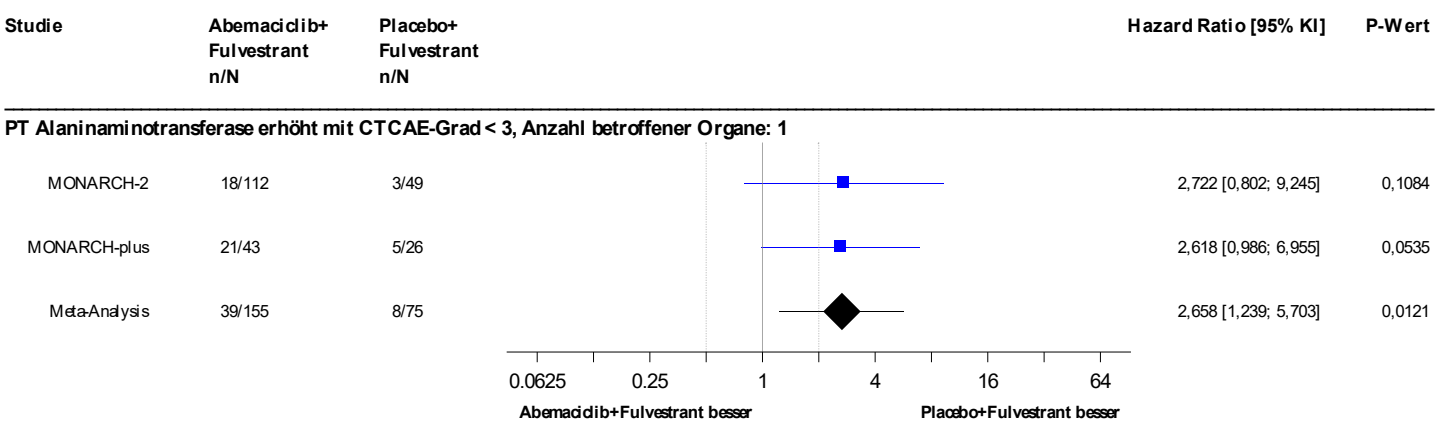
Abbildung 1442.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0024, P-Wert=0,9610, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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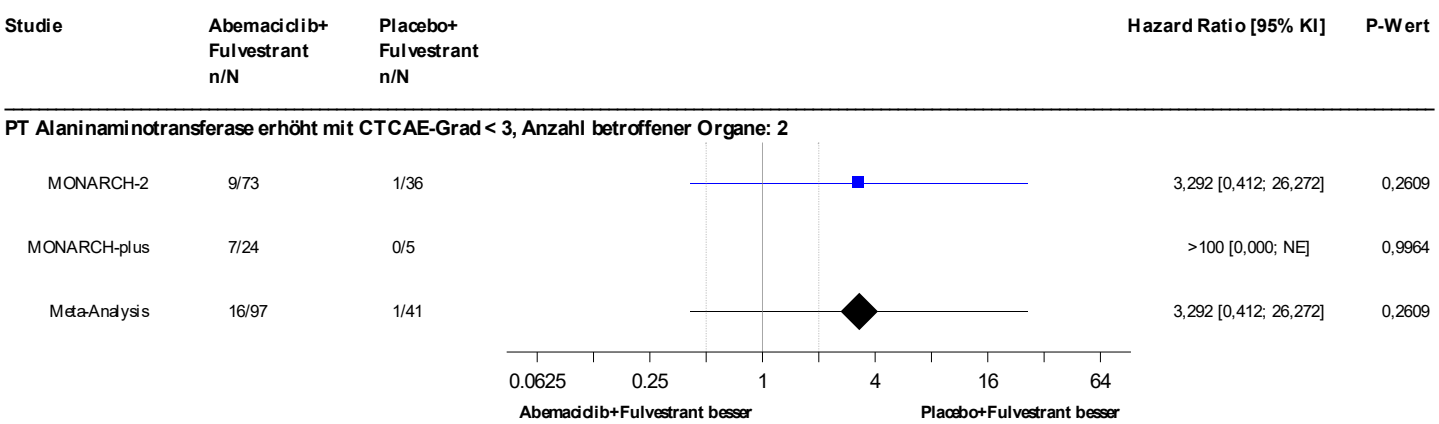
Abbildung 1442.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9967, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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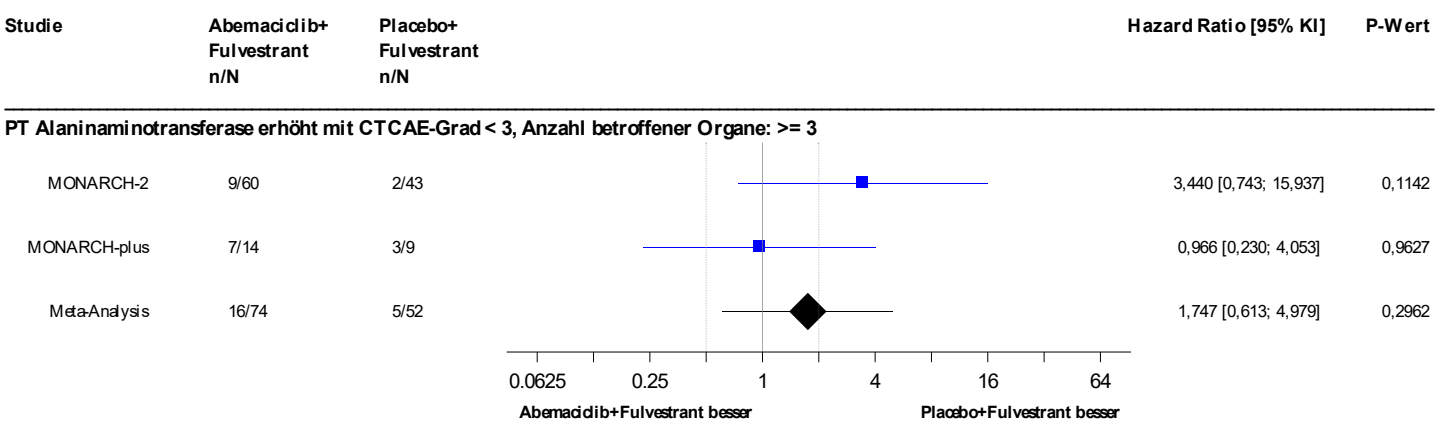
Abbildung 1442.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,4057, P-Wert=0,2358, I2 Index=28,9%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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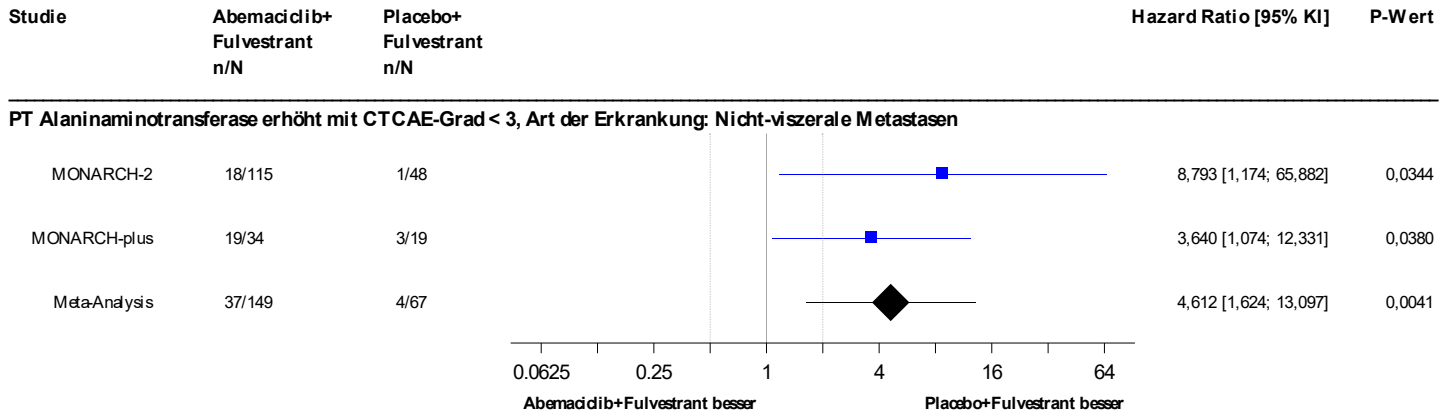
17SEP2021 / 07:48

Abbildung 1442.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,5391, P-Wert=0,4628, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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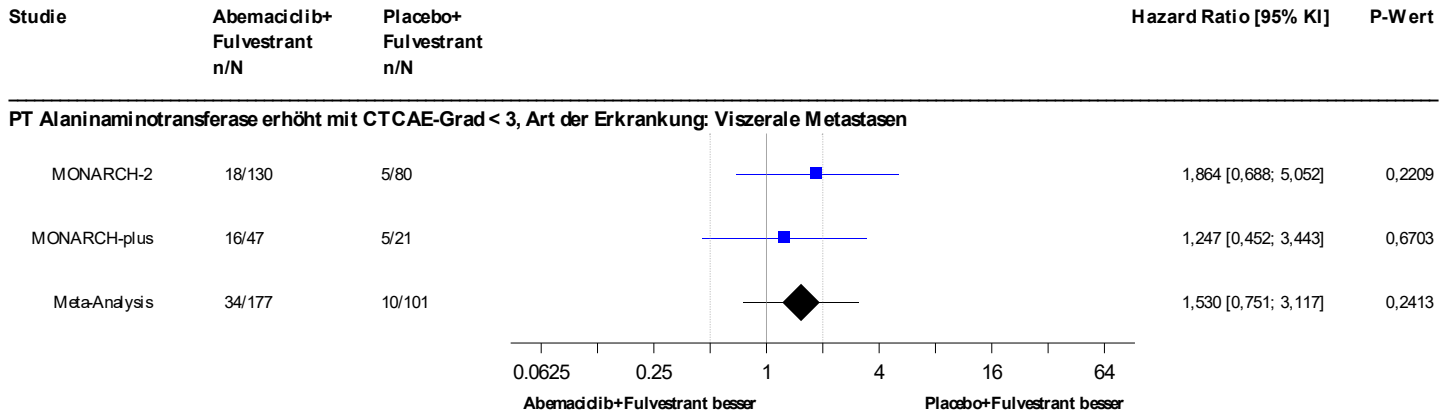
Abbildung 1442.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3066, P-Wert=0,5798, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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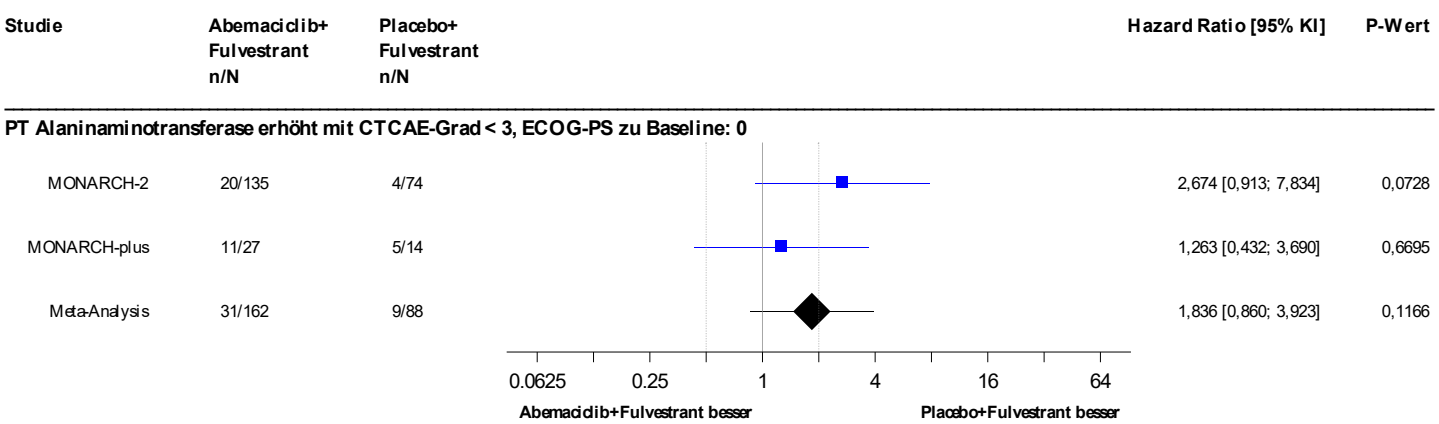
Abbildung 1442.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,9379, P-Wert=0,3328, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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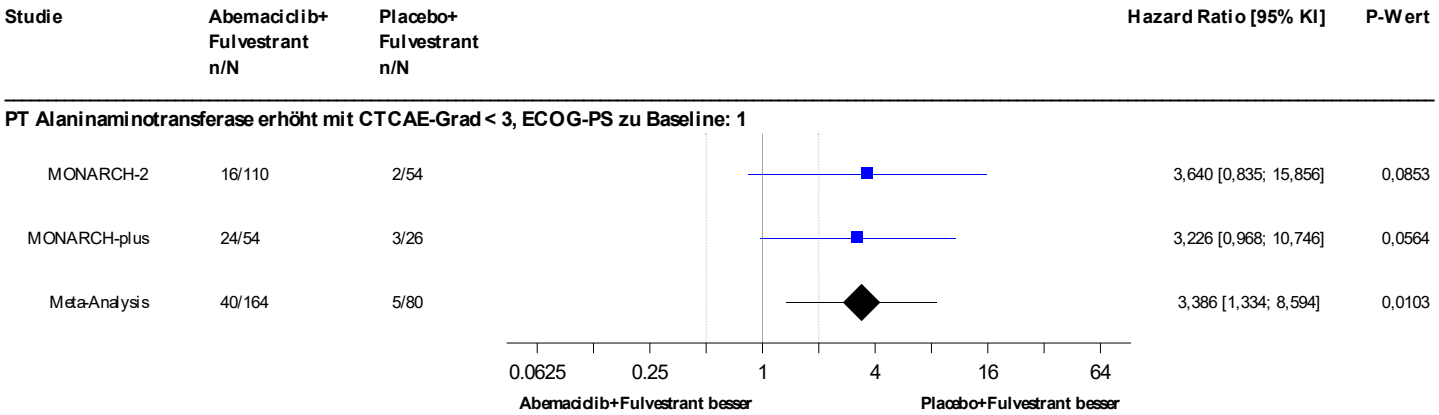
Abbildung 1442.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0155, P-Wert=0,9010, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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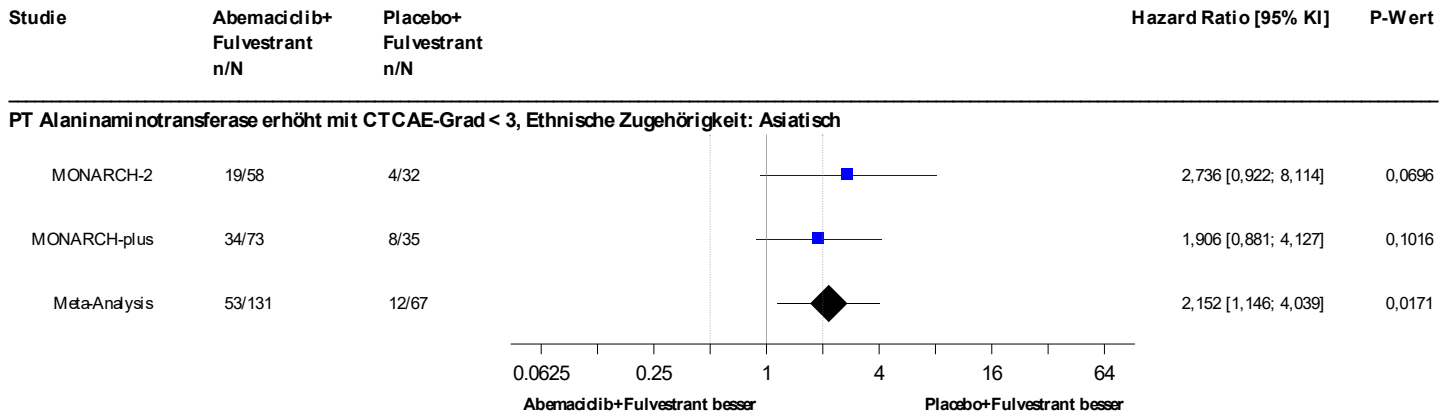
Abbildung 1442.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2818, P-Wert=0,5955, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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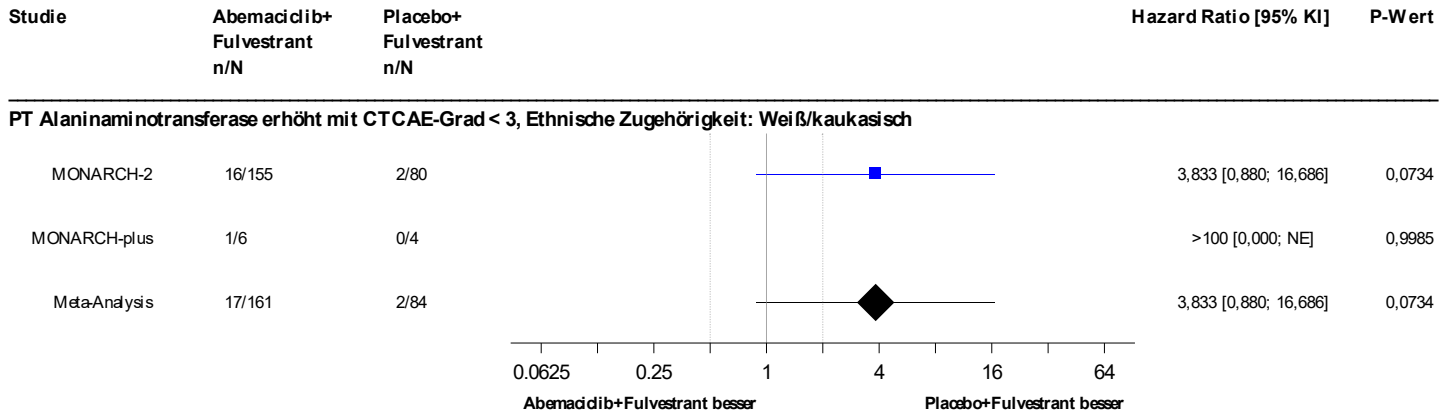
Abbildung 1442.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9987, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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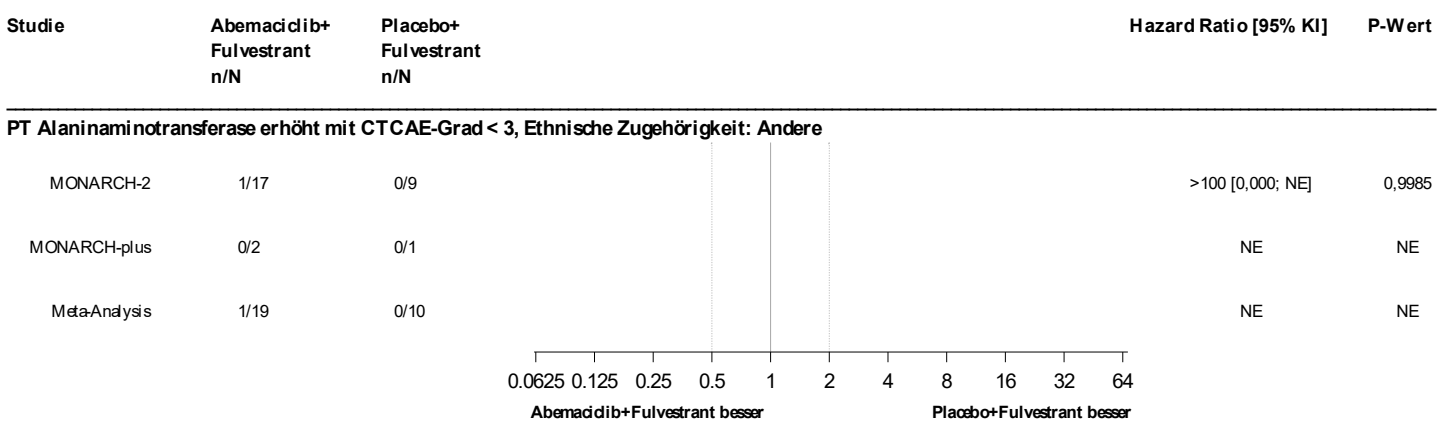
Abbildung 1442.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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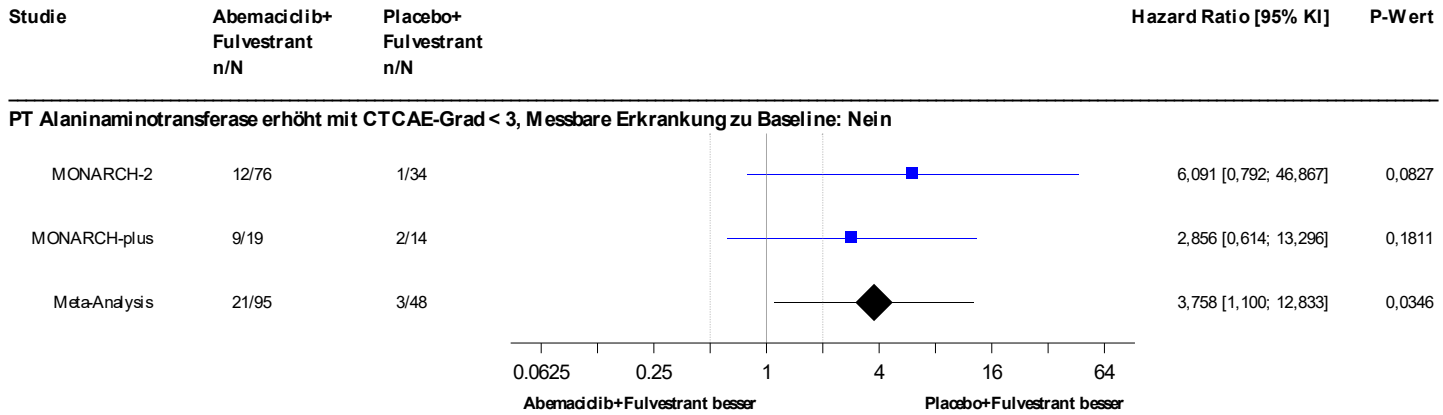
Abbildung 1442.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3374, P-Wert=0,5613, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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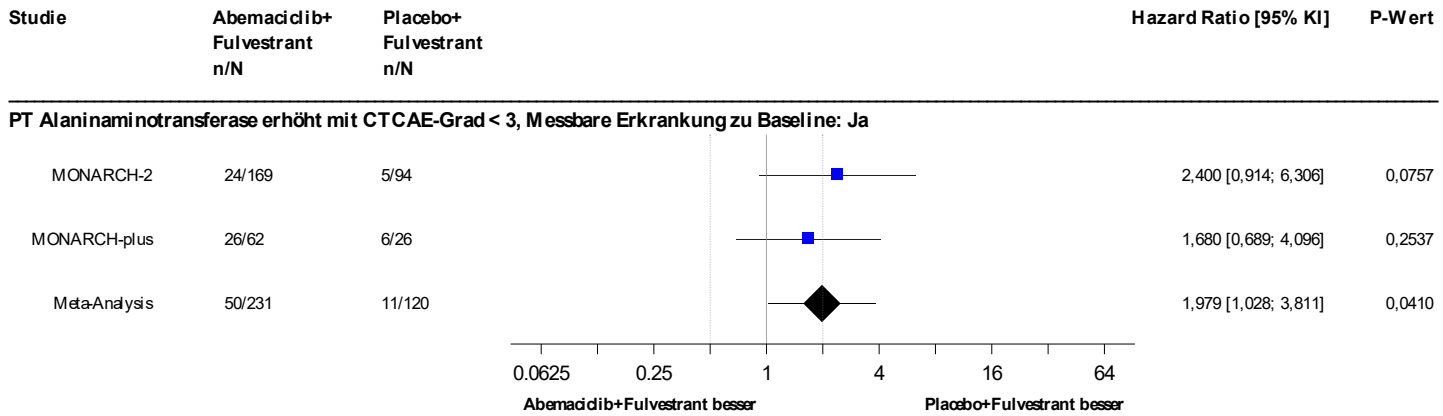
Abbildung 1442.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2828, P-Wert=0,5948, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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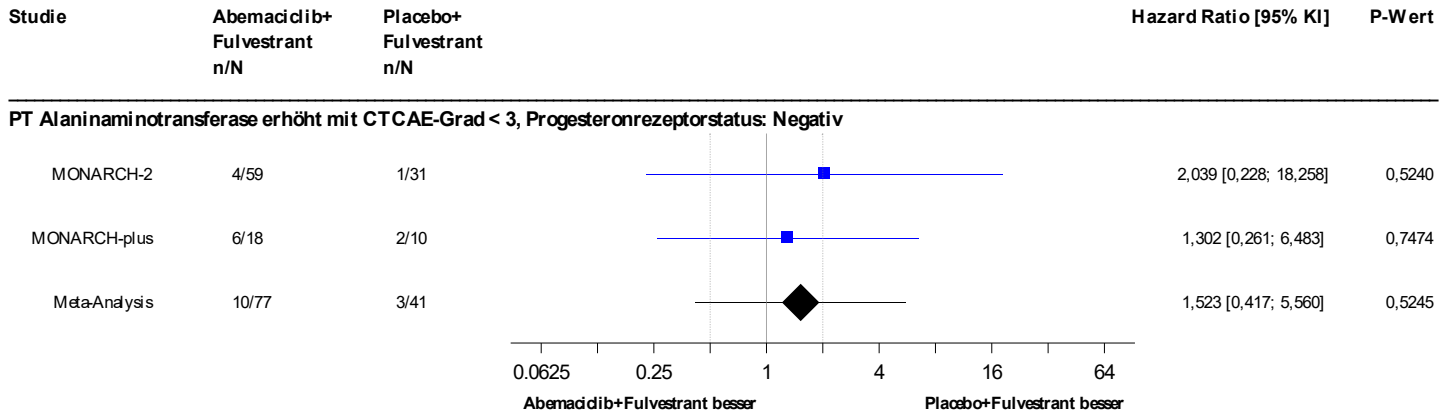
Abbildung 1442.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1048, P-Wert=0,7461, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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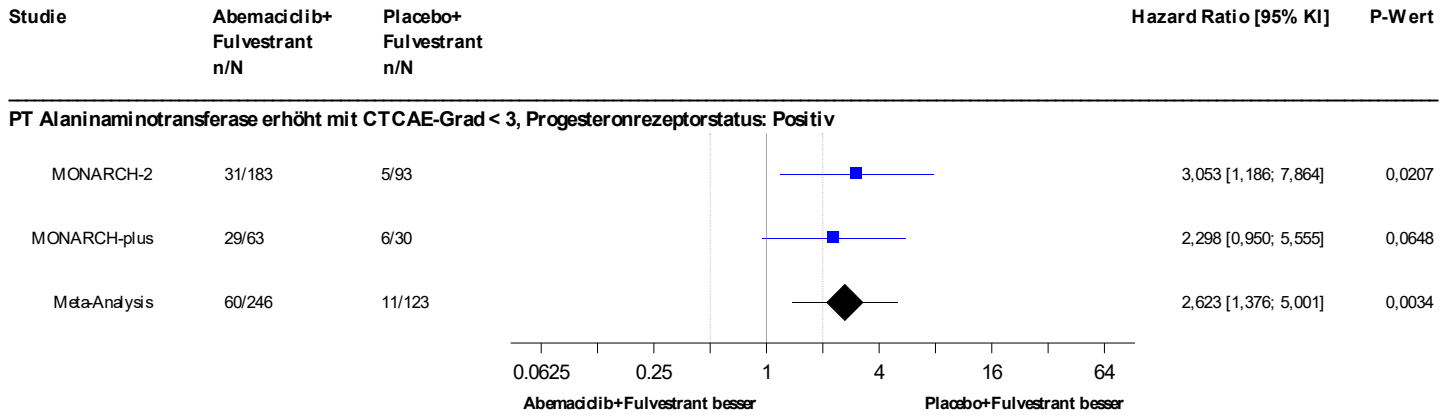
Abbildung 1442.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1855, P-Wert=0,6667, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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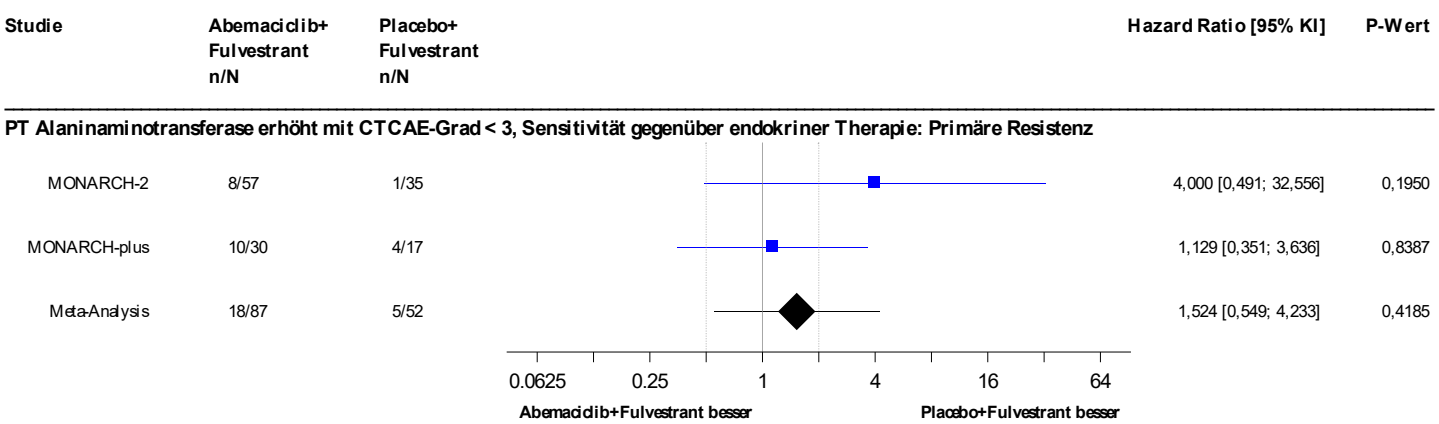
Abbildung 1442.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,0662, P-Wert=0,3018, I2 Index=6,2%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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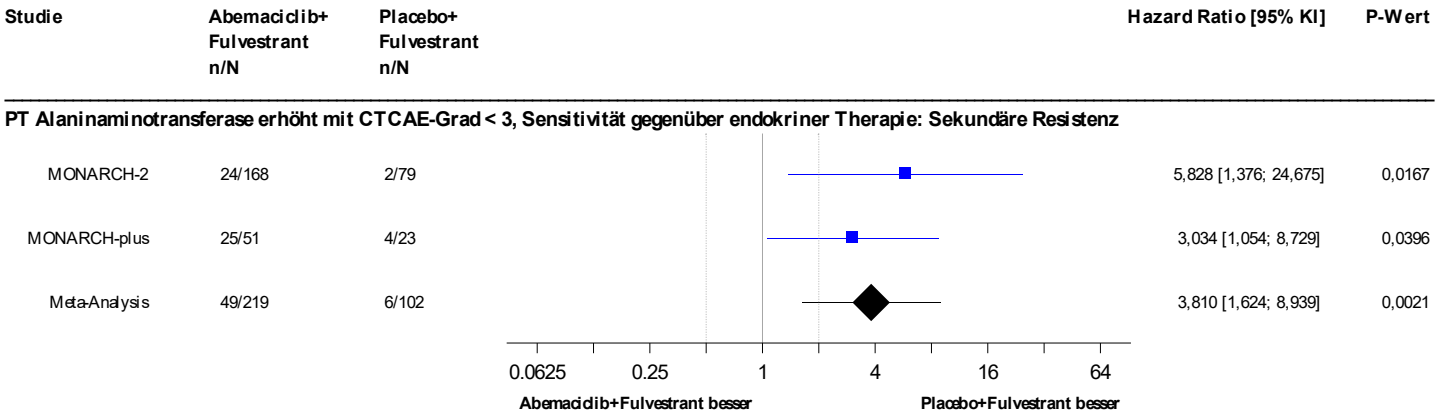
Abbildung 1442.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,5117, P-Wert=0,4744, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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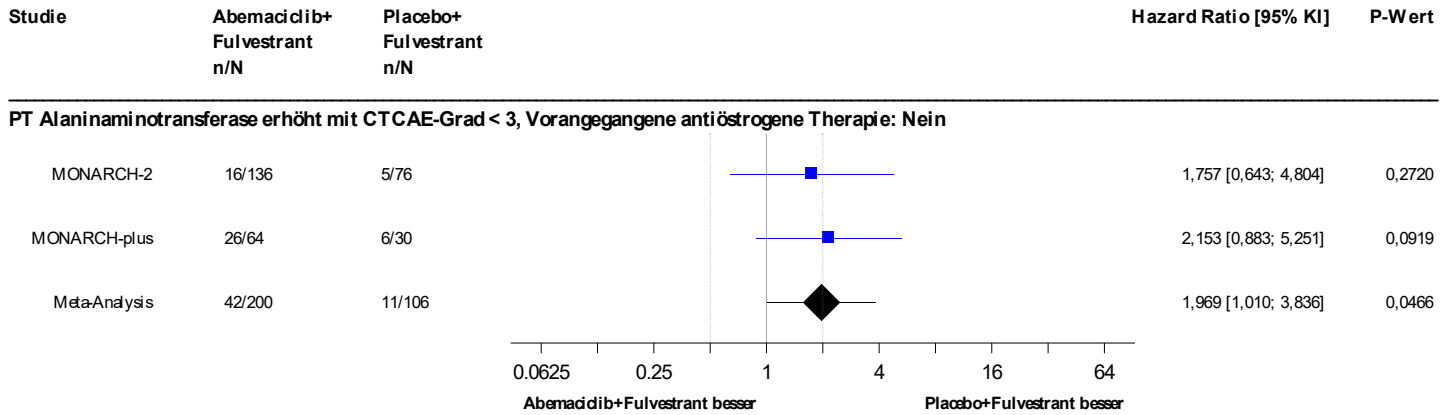
Abbildung 1442.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0877, P-Wert=0,7672, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttal2aesi_popa1_paet_1.rtf
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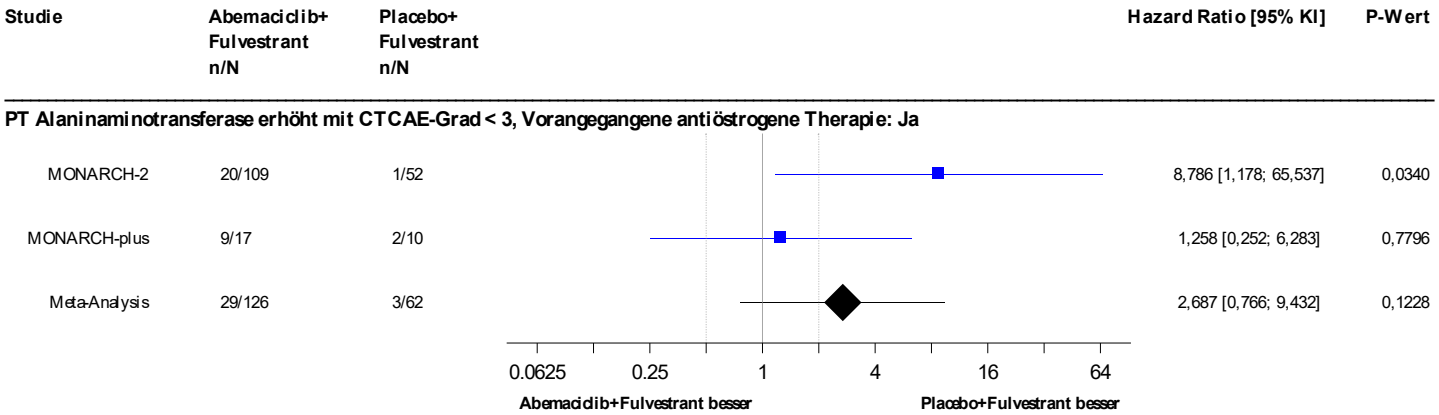
Abbildung 1442.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,1904, P-Wert=0,1389, I2 Index=54,3%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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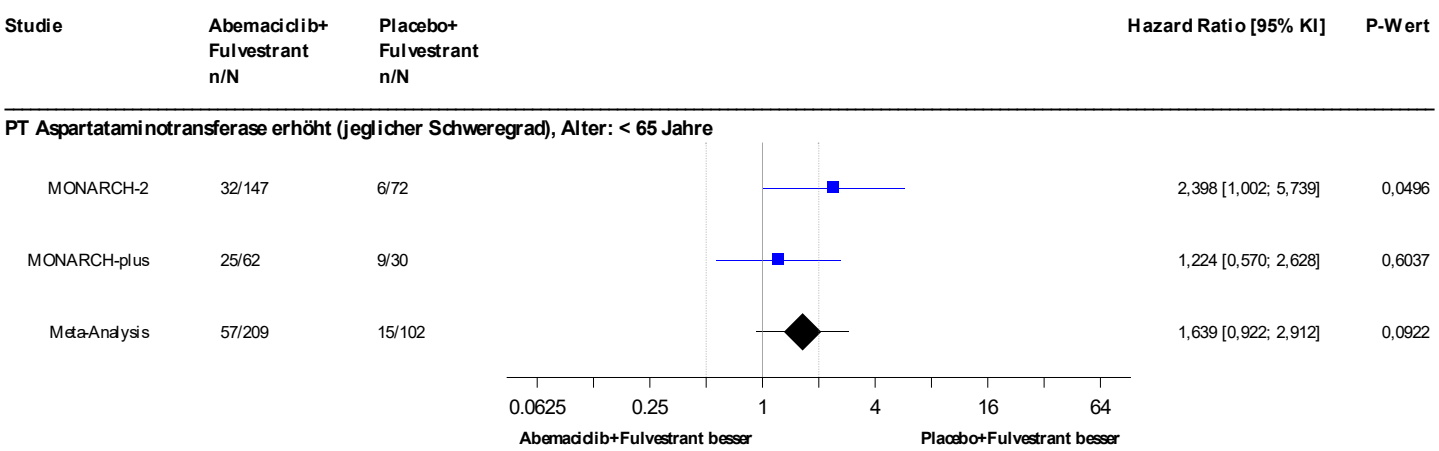
Abbildung 1444.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,2901, P-Wert=0,2560, I2 Index=22,5%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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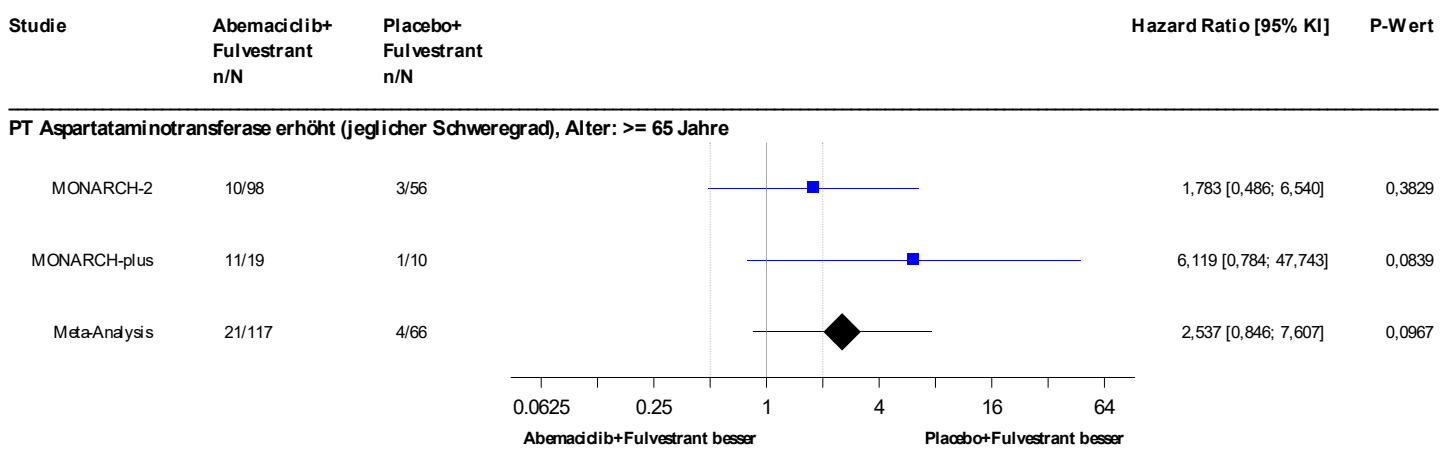
Abbildung 1444.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,9884, P-Wert=0,3201, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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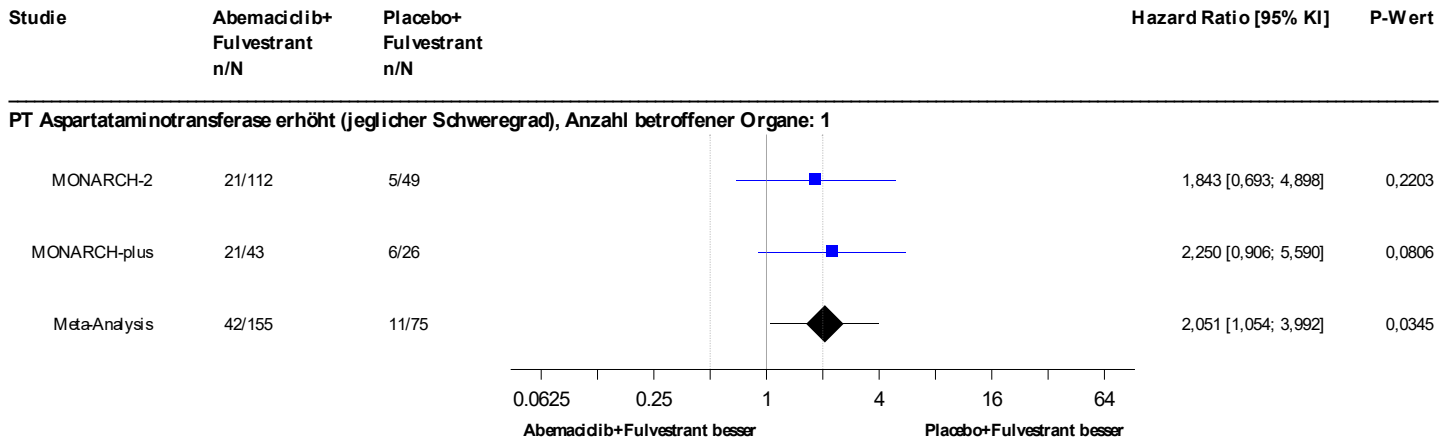
Abbildung 1444.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0860, P-Wert=0,7694, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttasaesi_popa1_norggr_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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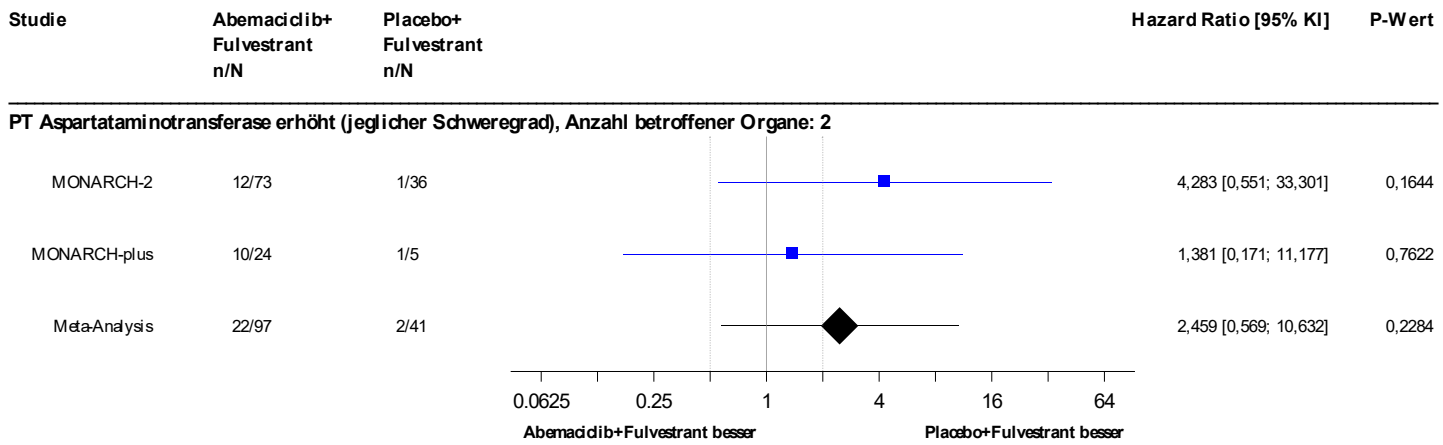
Abbildung 1444.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,5737, P-Wert=0,4488, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttasaesi_popa1_norggr_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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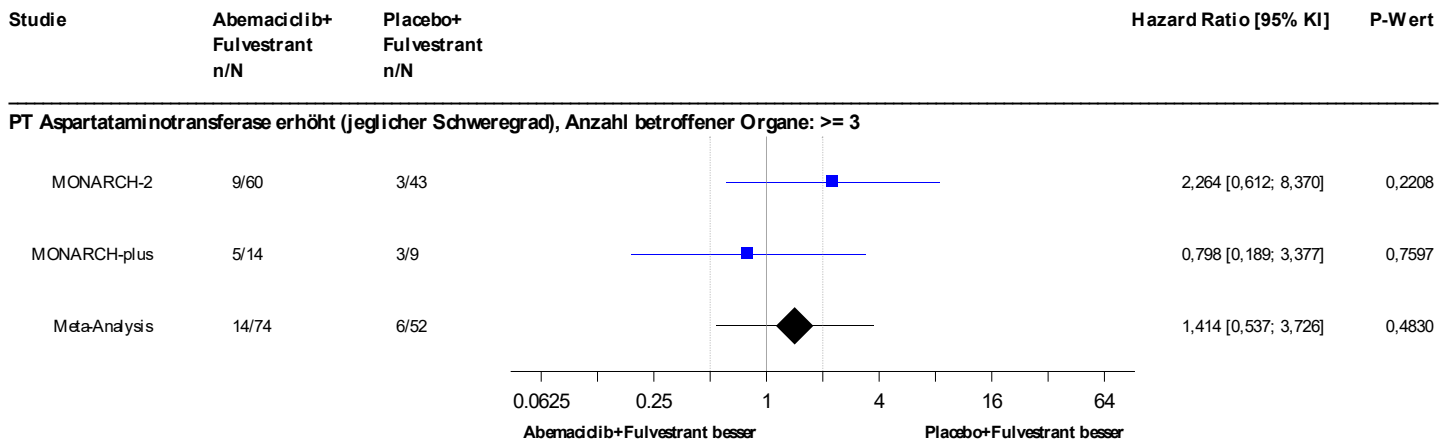
Abbildung 1444.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,1008, P-Wert=0,2941, I2 Index=9,2%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttasaesi_popa1_norggr_3.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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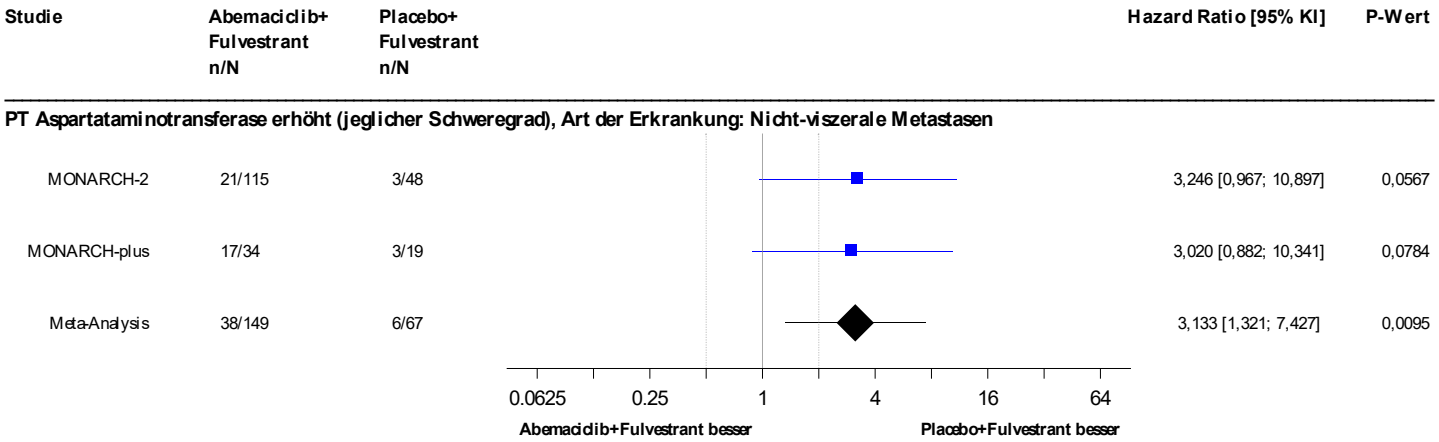
Abbildung 1444.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0067, P-Wert=0,9348, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttasaesi_popa1_natdis2_1.rtf
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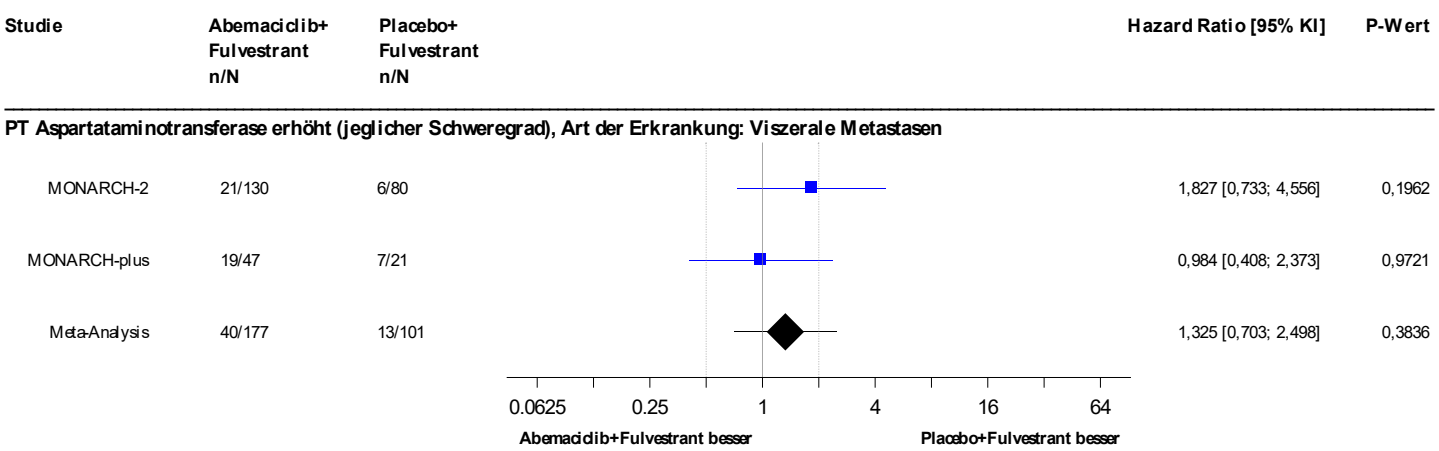
Abbildung 1444.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,9126, P-Wert=0,3394, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttasaesi_popa1_natdis2_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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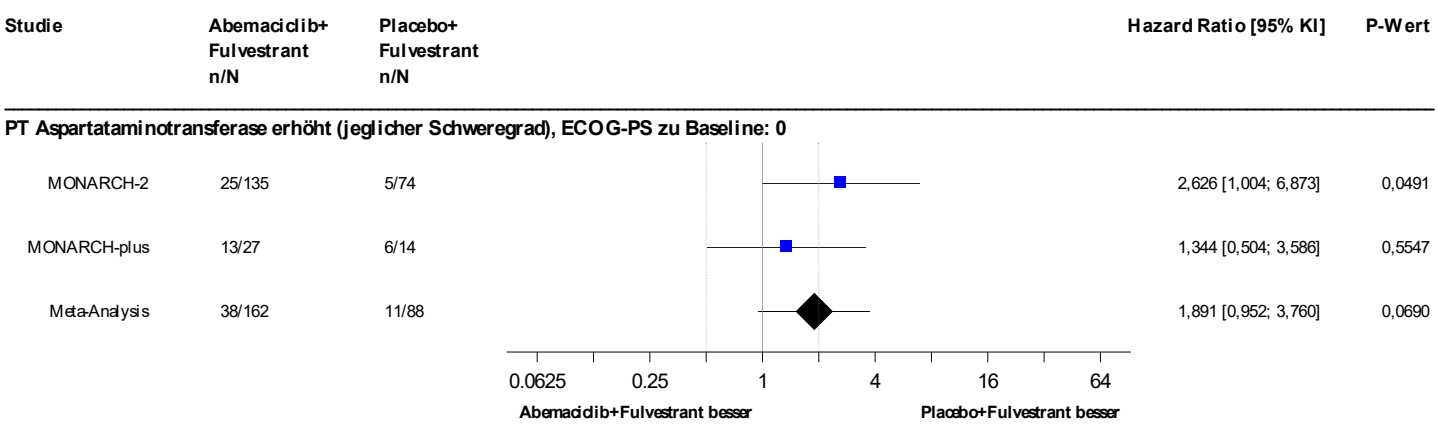
Abbildung 1444.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,9127, P-Wert=0,3394, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttasaesi_popa1_ecogbl_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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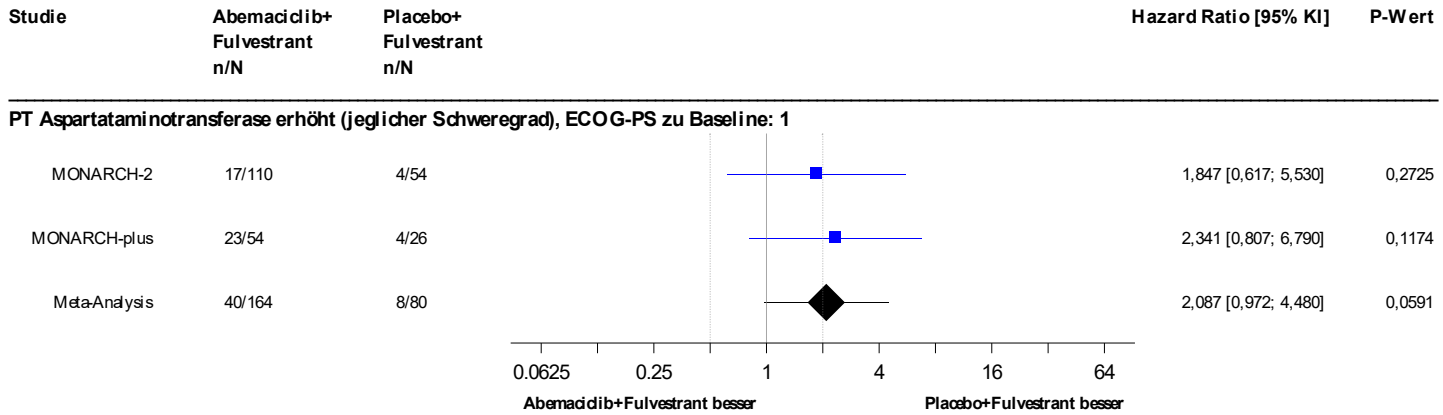
Abbildung 1444.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0923, P-Wert=0,7613, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttasaesi_popa1_ecogbl_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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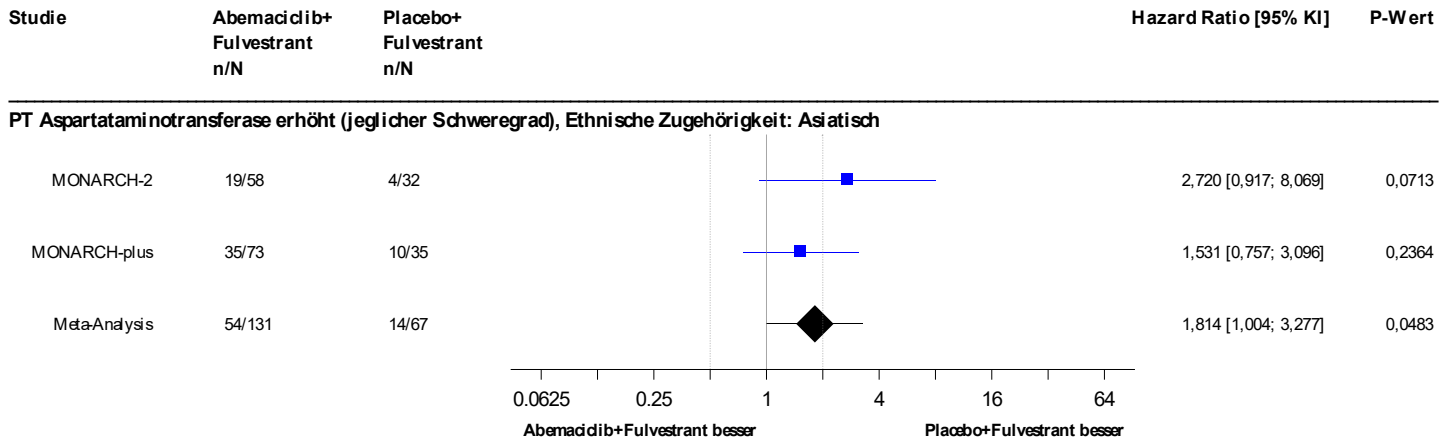
Abbildung 1444.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7566, P-Wert=0,3844, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttasaesi_popa1_racegr1_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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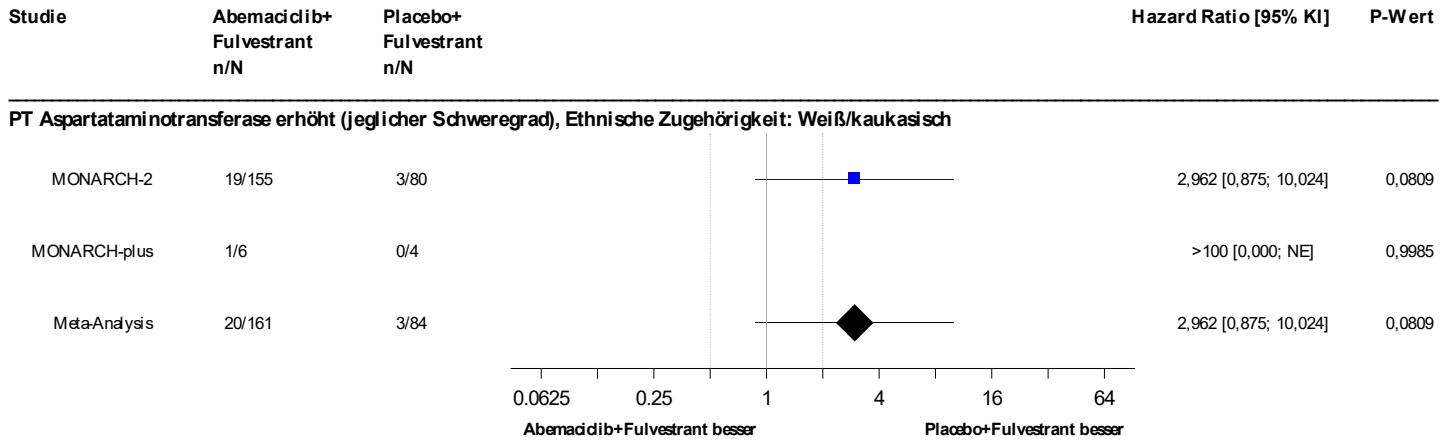
Abbildung 1444.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9986, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttasaesi_popa1_racegr1_2.rtf
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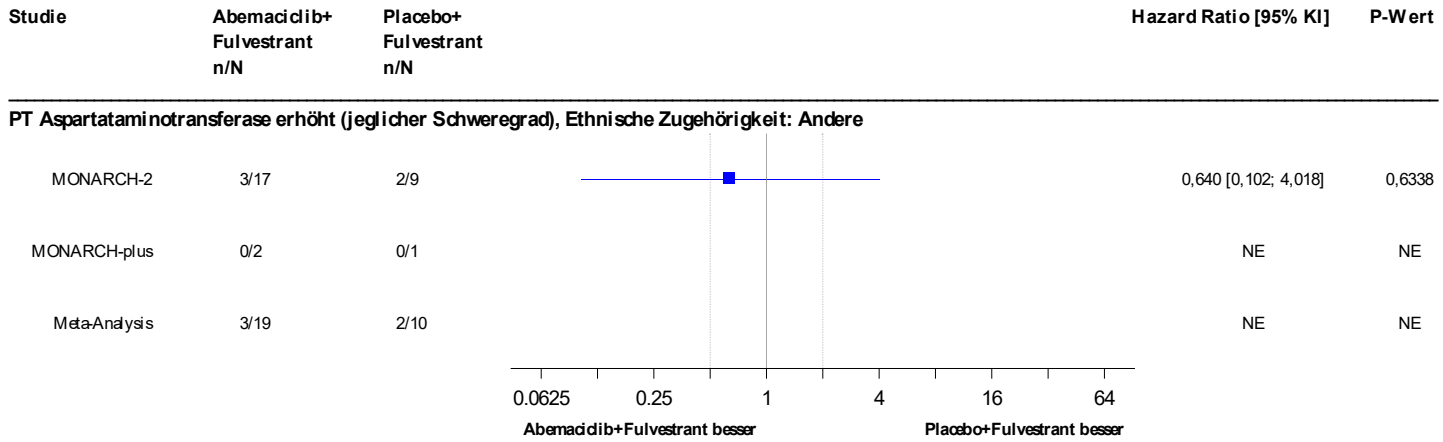
Abbildung 1444.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttasaesi_popa1_racegr1_3.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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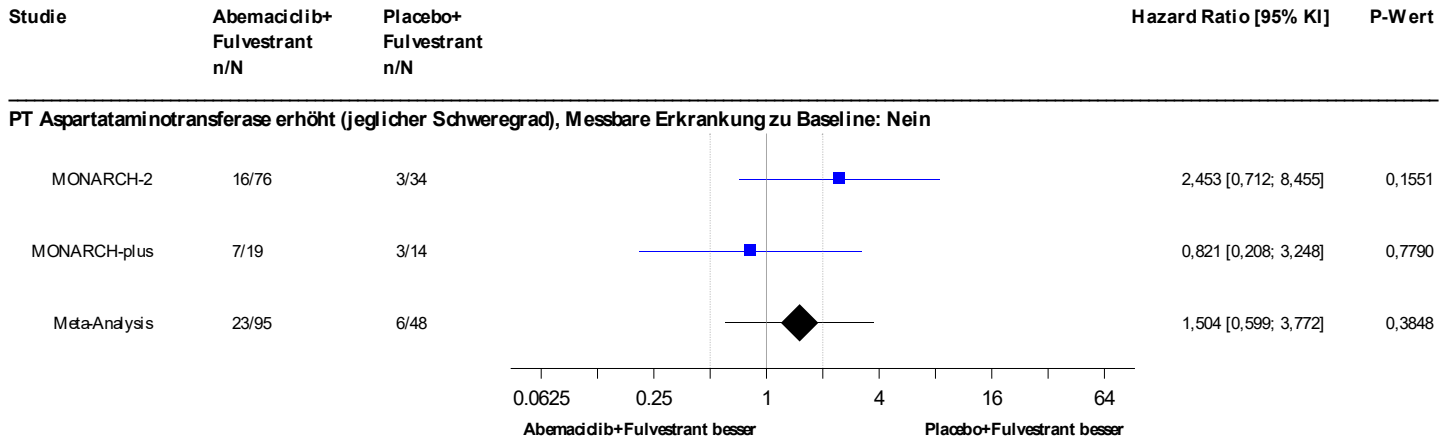
Abbildung 1444.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,3446, P-Wert=0,2462, I2 Index=25,6%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttasaesi_popa1_measdis_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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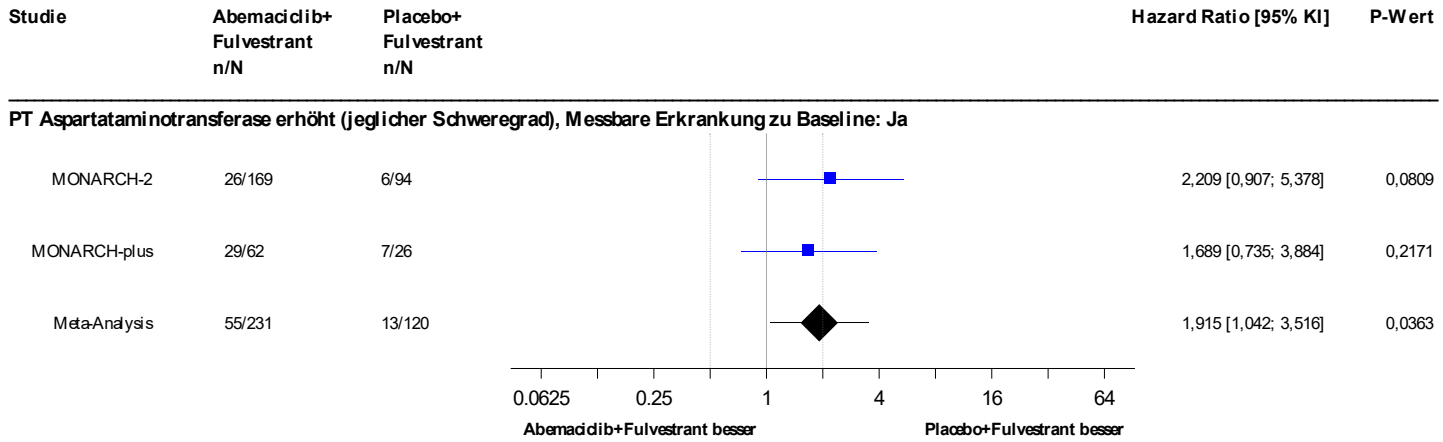
Abbildung 1444.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1861, P-Wert=0,6662, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttasaesi_popa1_measdis_2.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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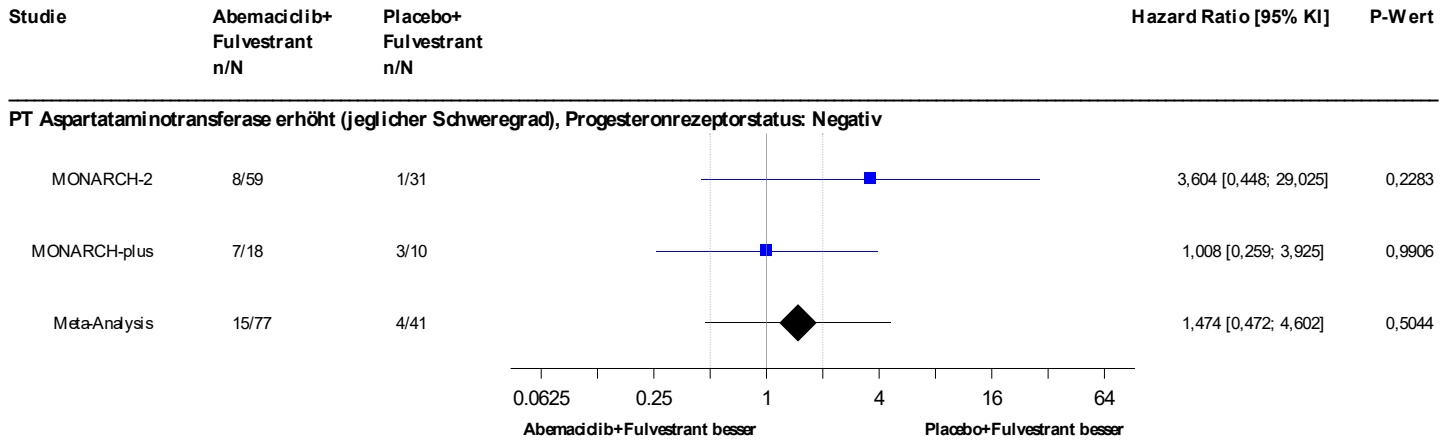
Abbildung 1444.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,0059, P-Wert=0,3159, I2 Index=0,6%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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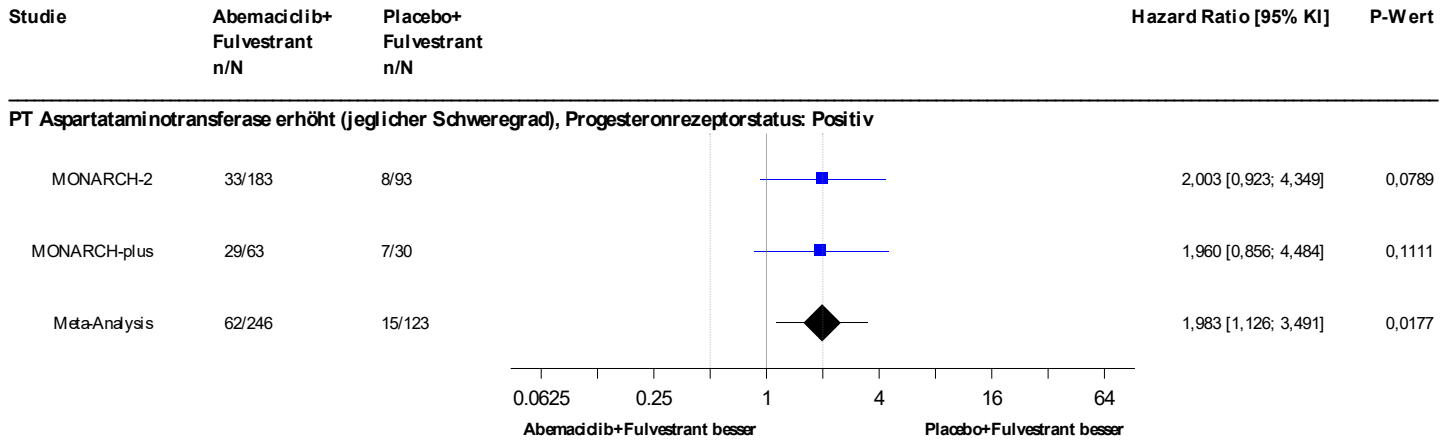
Abbildung 1444.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0015, P-Wert=0,9695, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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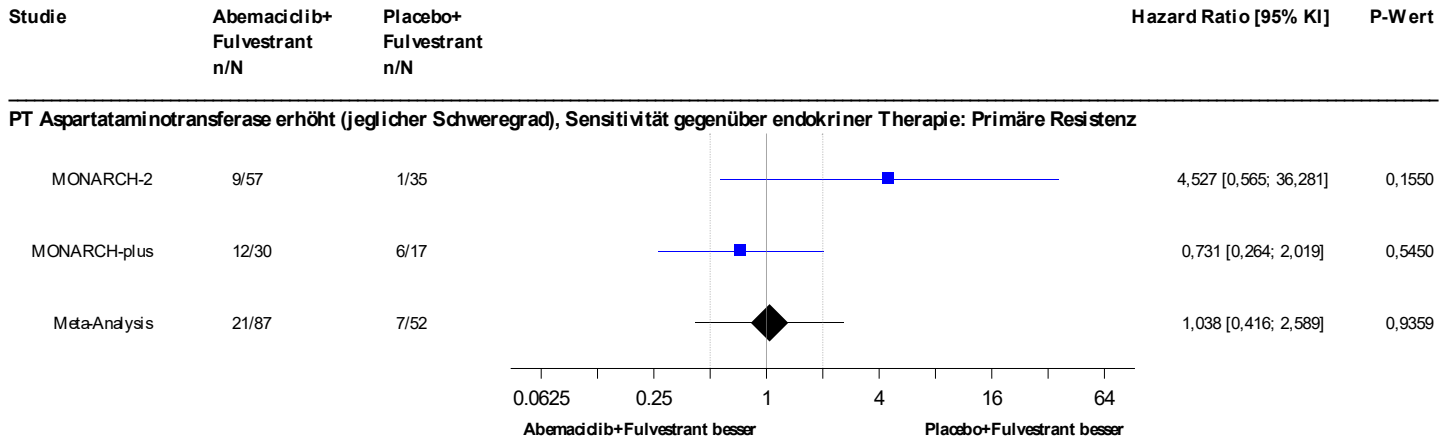
Abbildung 1444.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,3826, P-Wert=0,1227, I2 Index=58,0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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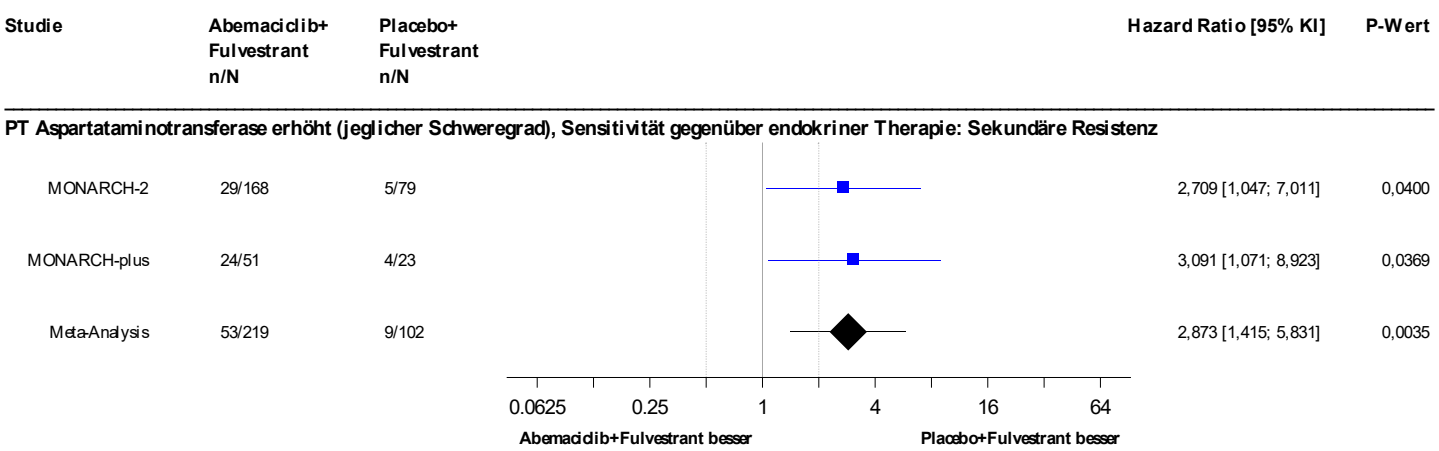
Abbildung 1444.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0330, P-Wert=0,8559, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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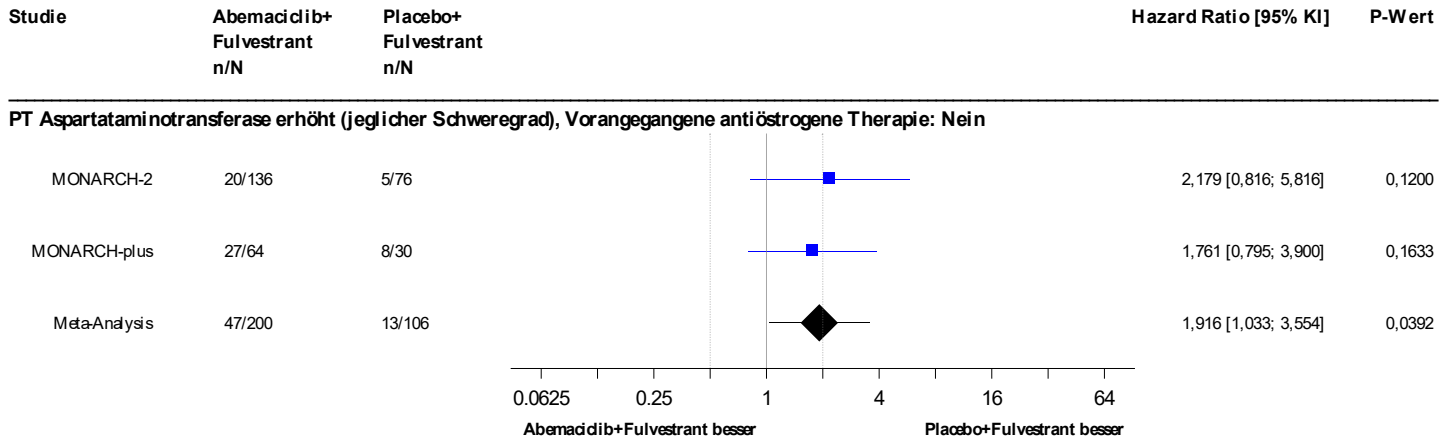
Abbildung 1444.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1094, P-Wert=0,7408, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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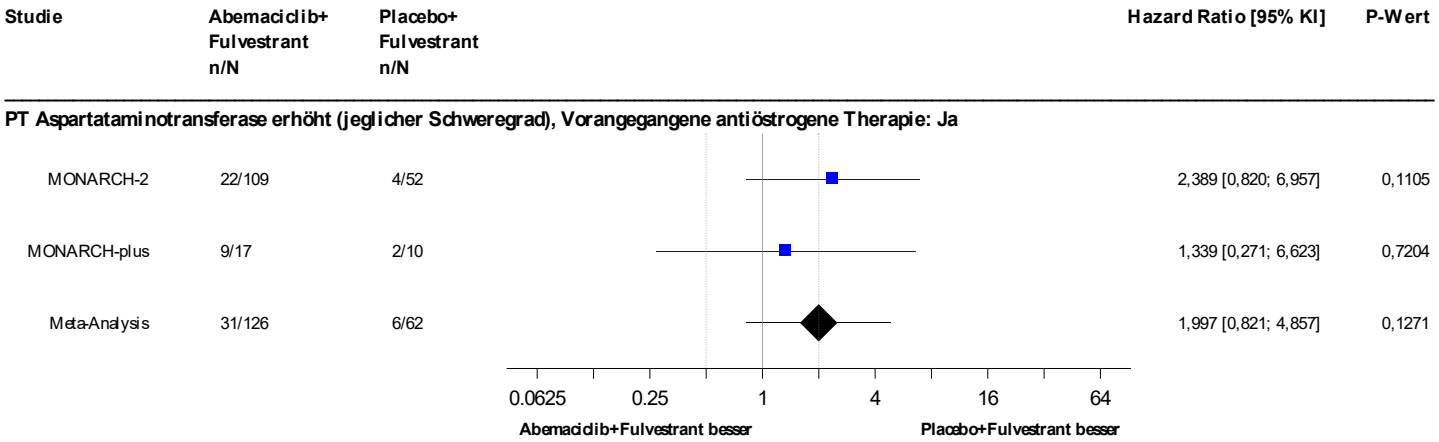
Abbildung 1444.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3479, P-Wert=0,5553, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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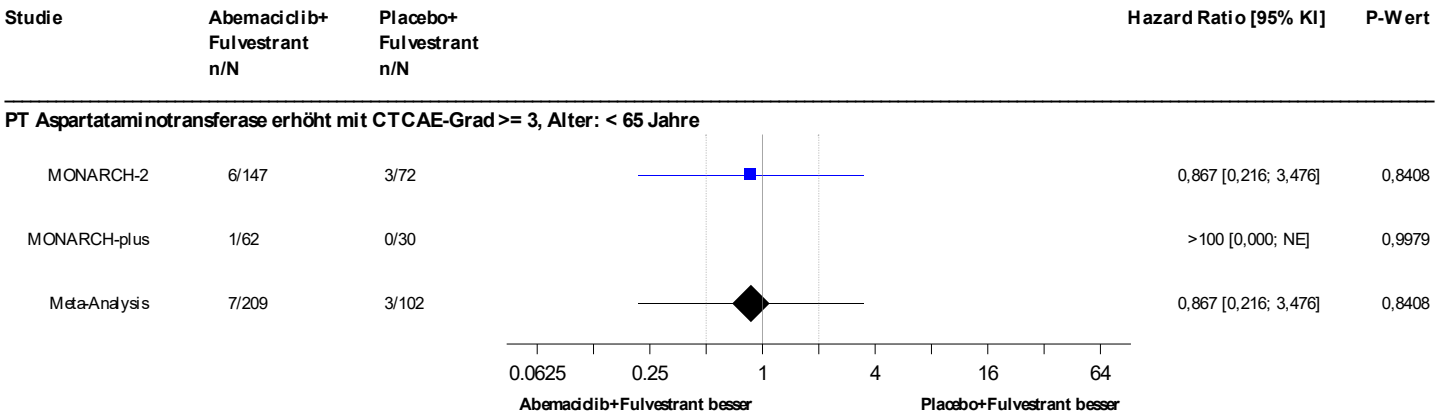
Abbildung 1445.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9979, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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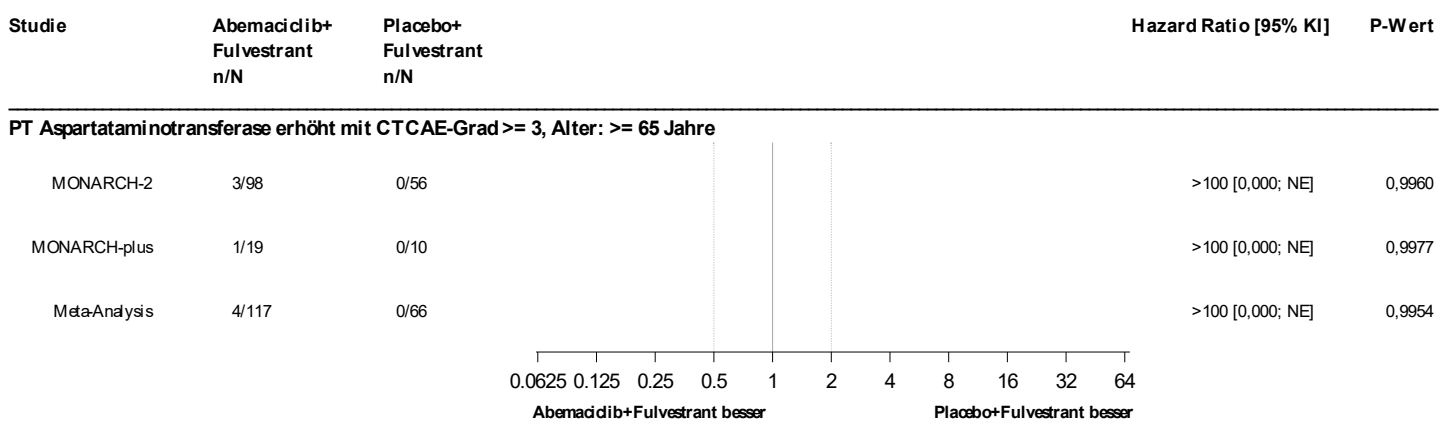
Abbildung 1445.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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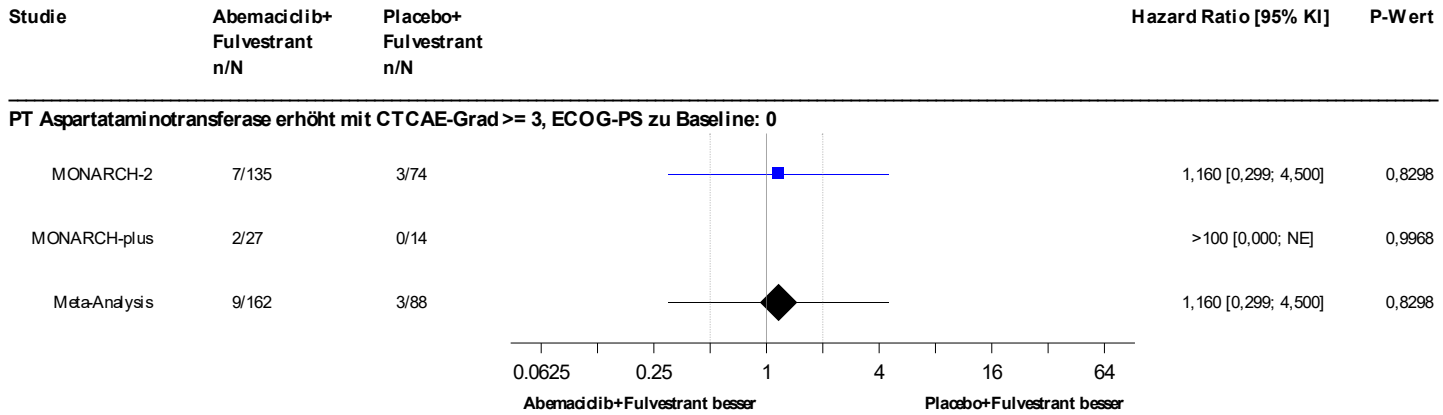
Abbildung 1445.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9968, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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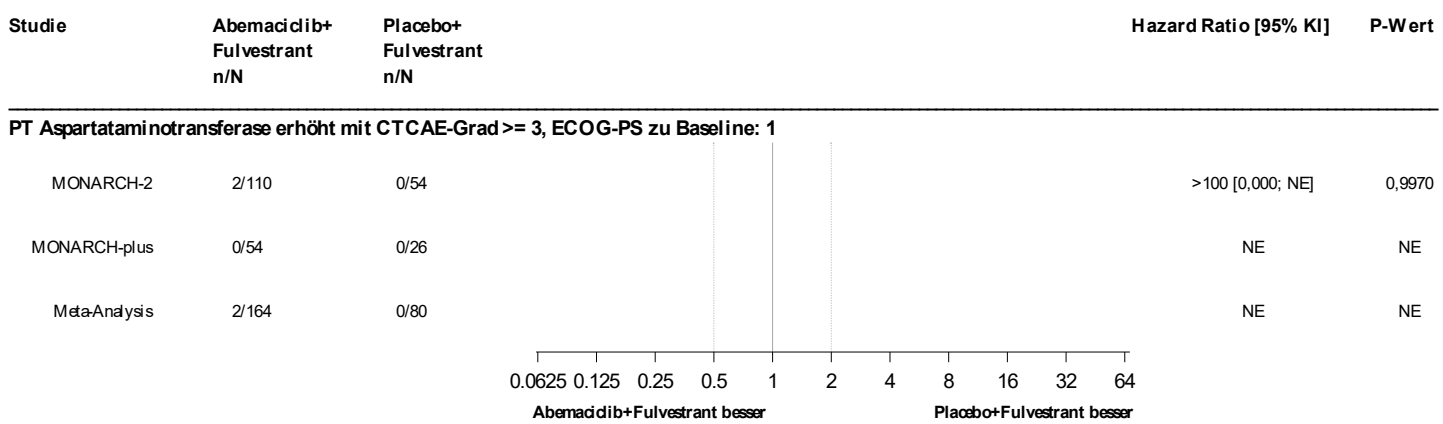
Abbildung 1445.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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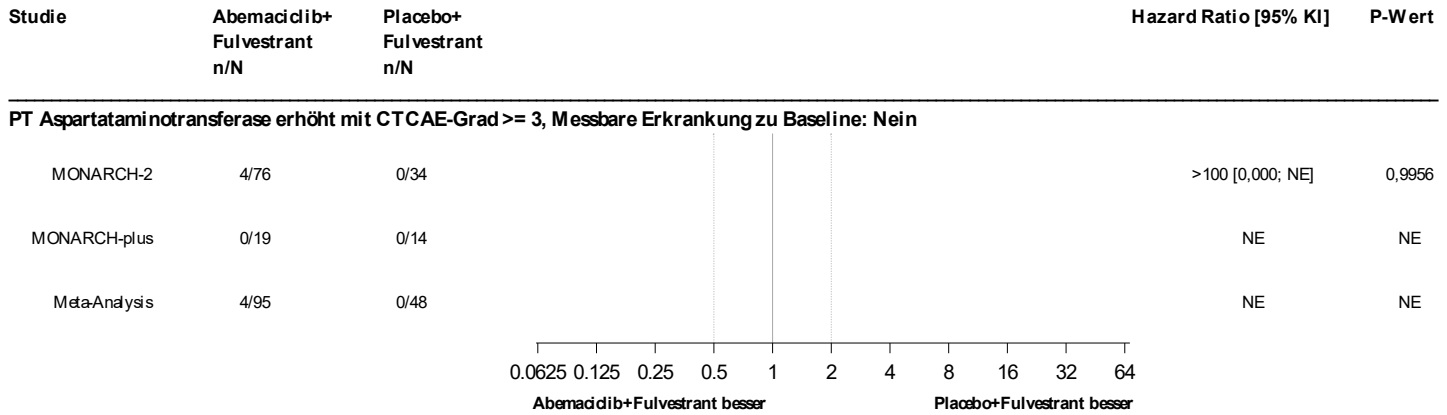
Abbildung 1445.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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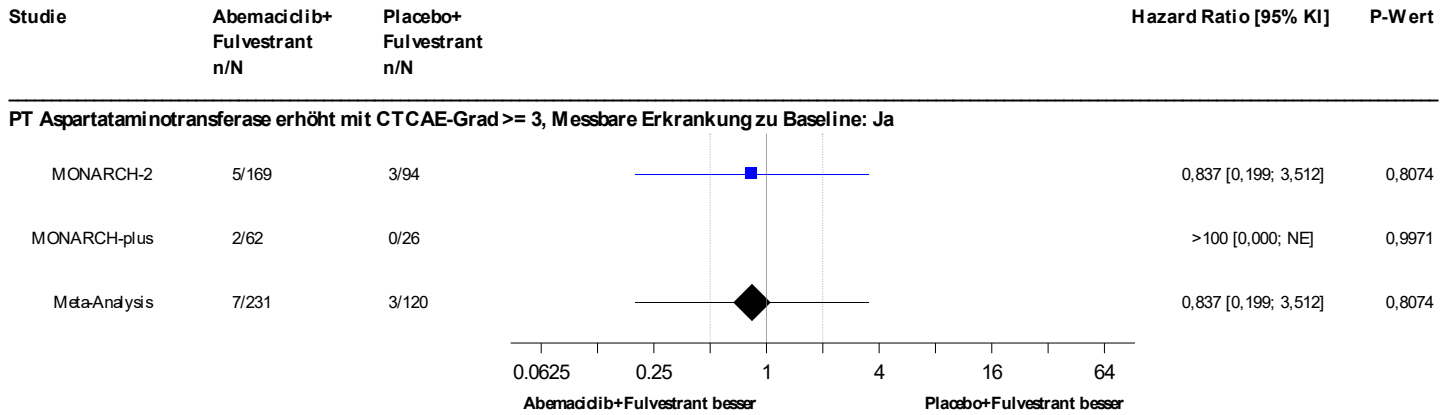
Abbildung 1445.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9970, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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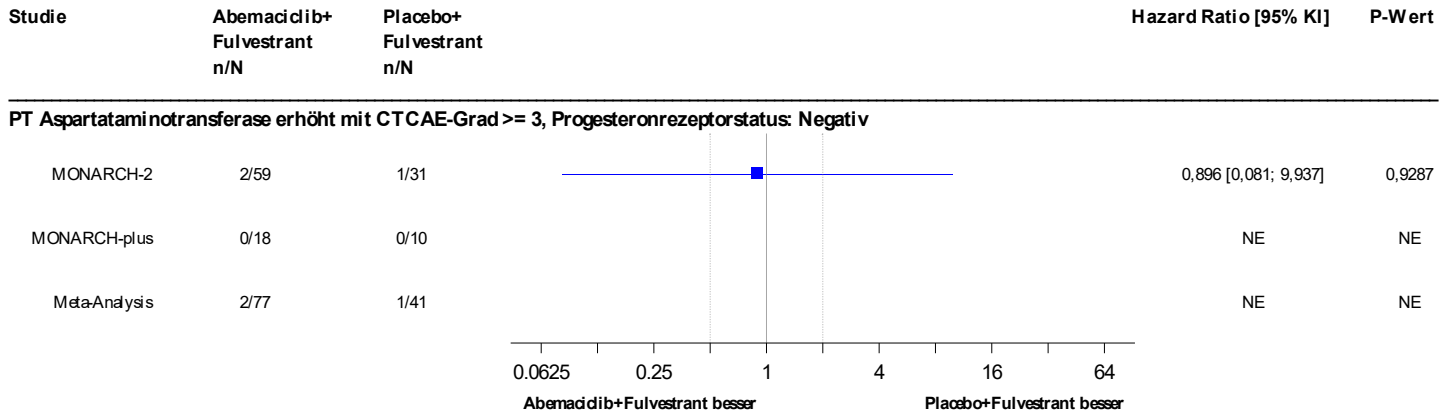
Abbildung 1445.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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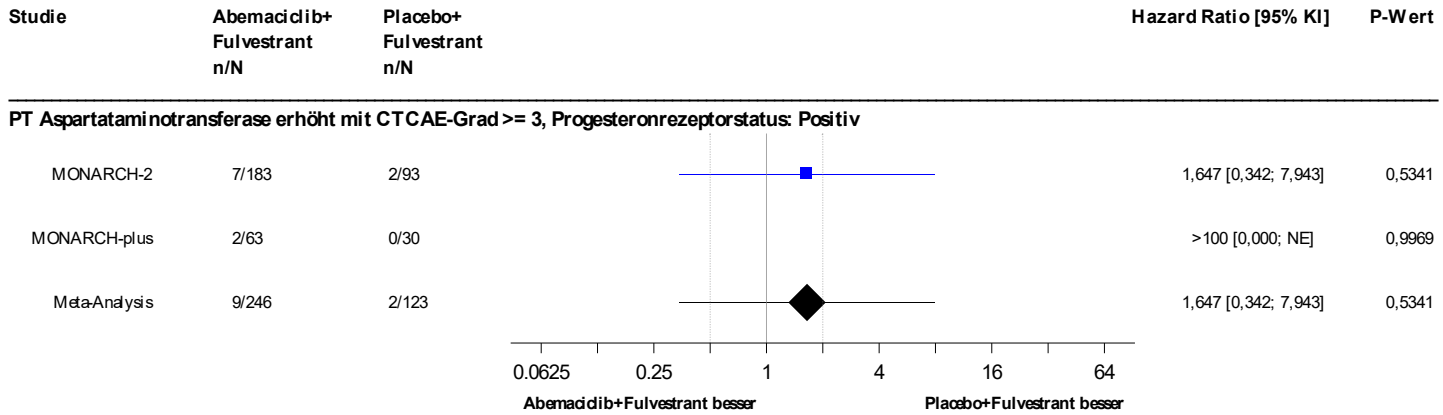
17SEP2021 / 07:48

Abbildung 1445.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9970, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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Abbildung 1445.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

Studie	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% KI]	P-Wert
PT Aspartataminotransferase erhöht mit CTCAE-Grad >= 3, Sensitivität gegenüber endokriner Therapie: Primäre Resistenz				
MONARCH-2	0/57	0/35	NE	NE
MONARCH-plus	2/30	0/17	>100 [0,000; NE]	0,9969
Meta-Analysis	2/87	0/52	NE	NE

Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttas3aesi_popa1_snthr_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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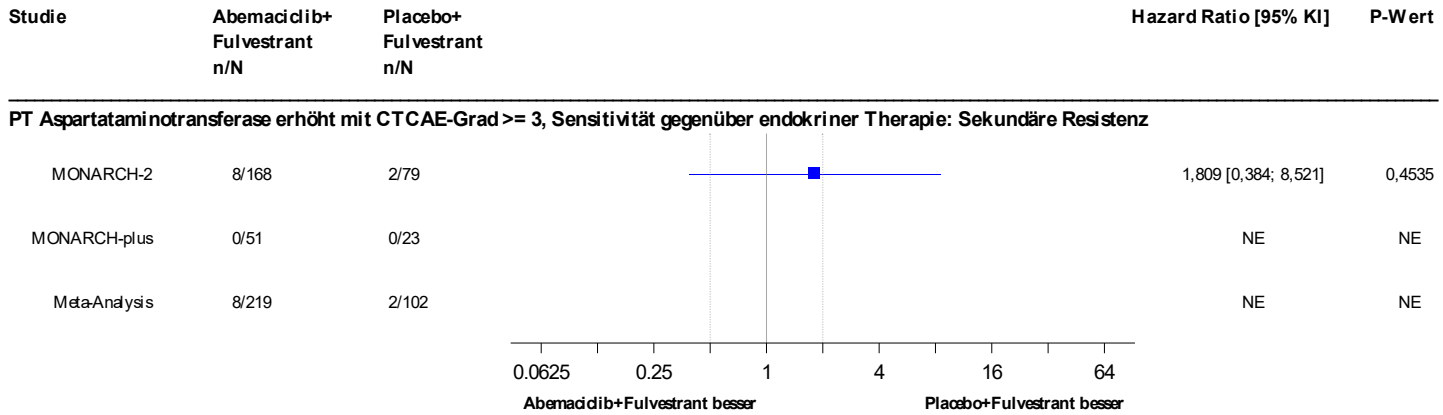
Abbildung 1445.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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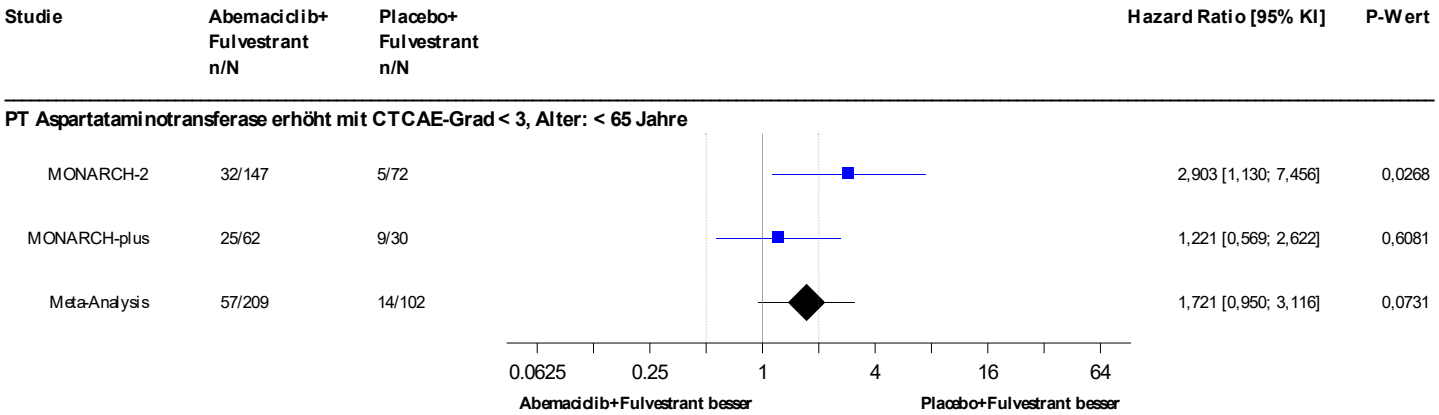
Abbildung 1446.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,9546, P-Wert=0,1621, I2 Index=48,8%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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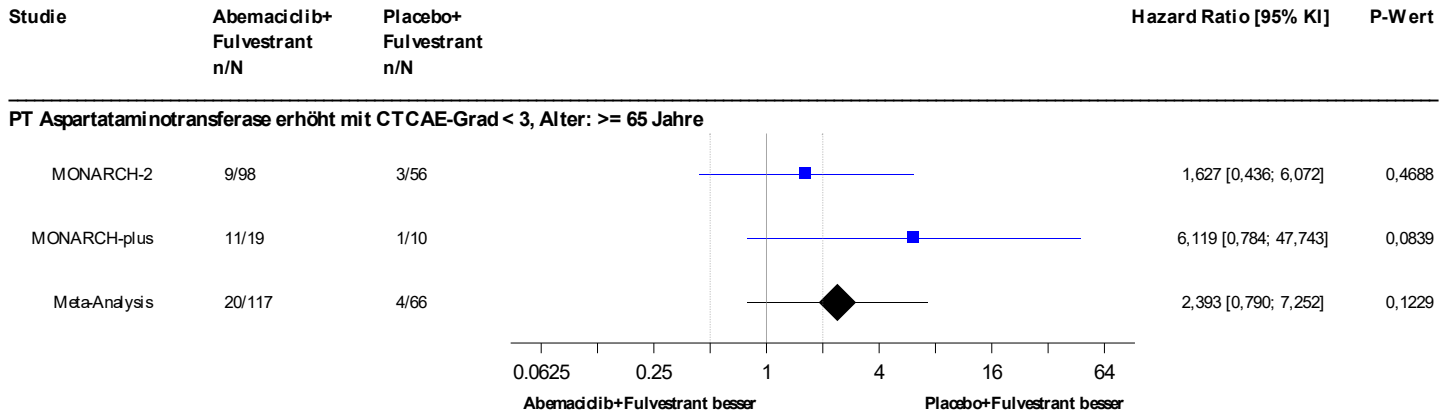
Abbildung 1446.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,1323, P-Wert=0,2873, I2 Index=11,7%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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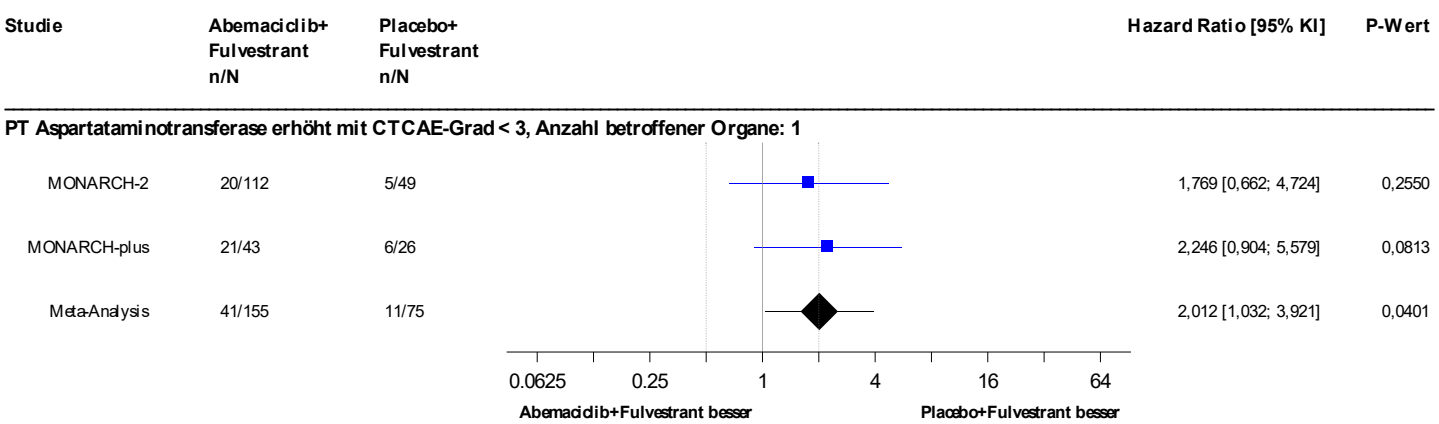
17SEP2021 / 07:48

Abbildung 1446.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1221, P-Wert=0,7268, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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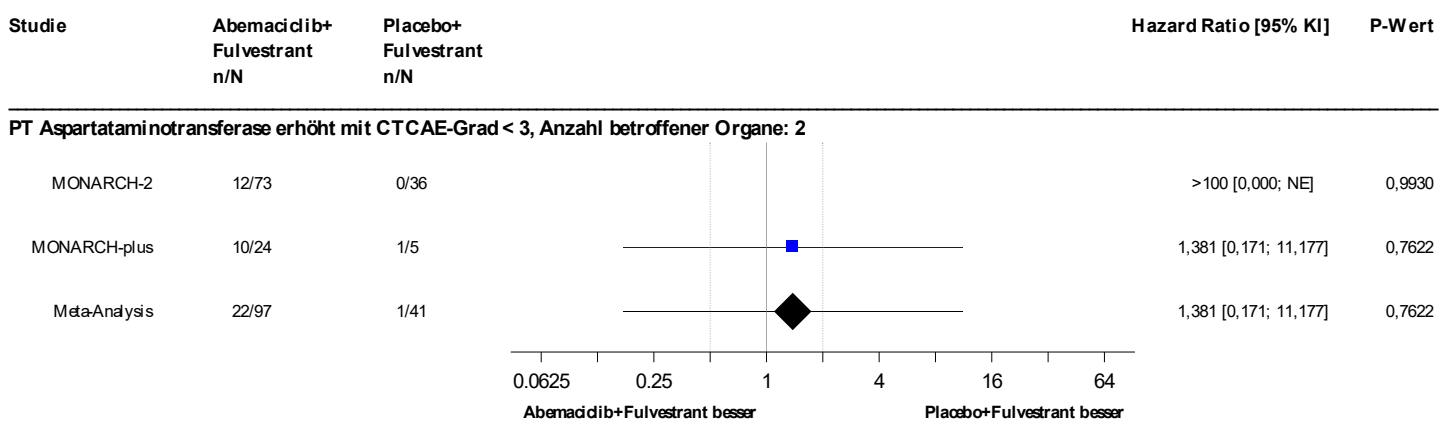
Abbildung 1446.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9931, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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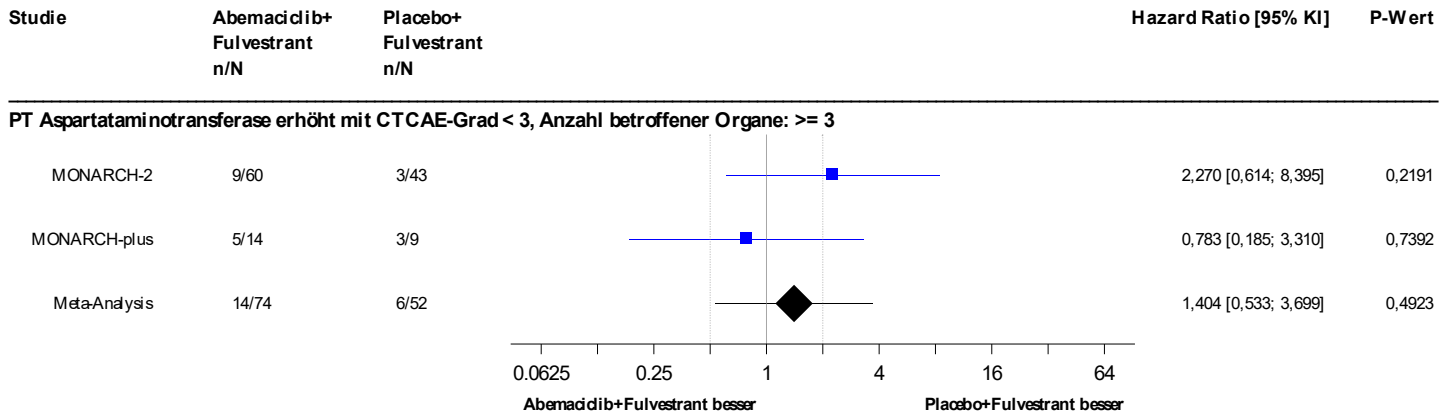
Abbildung 1446.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,1495, P-Wert=0,2837, I2 Index=13,0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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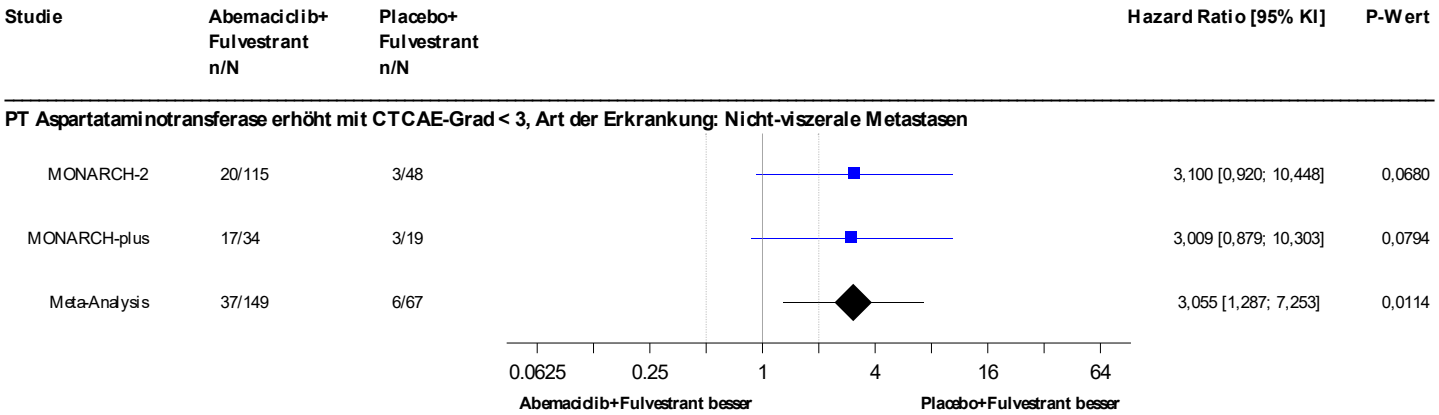
Abbildung 1446.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0011, P-Wert=0,9731, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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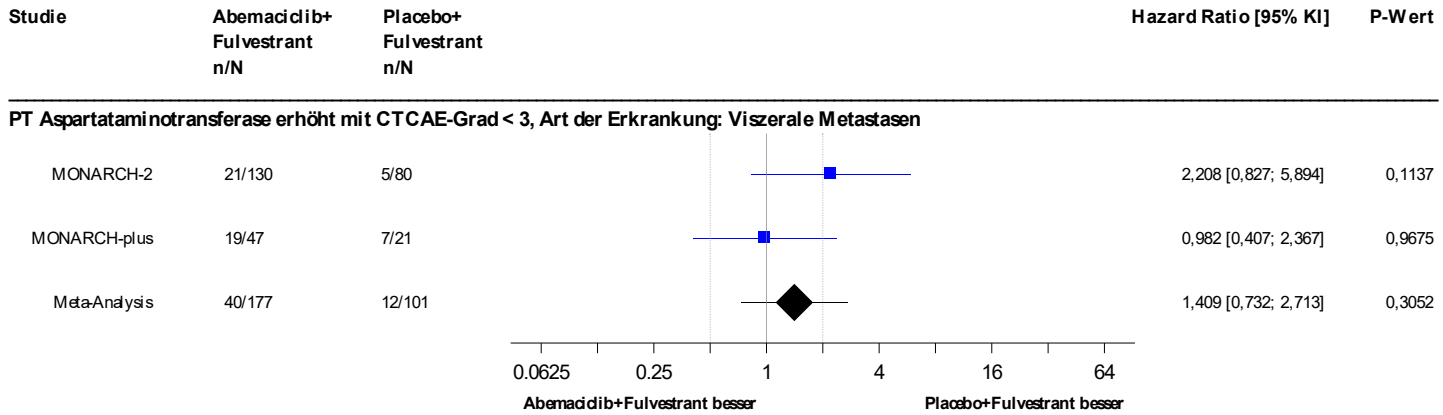
Abbildung 1446.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,4523, P-Wert=0,2282, I2 Index=31,1%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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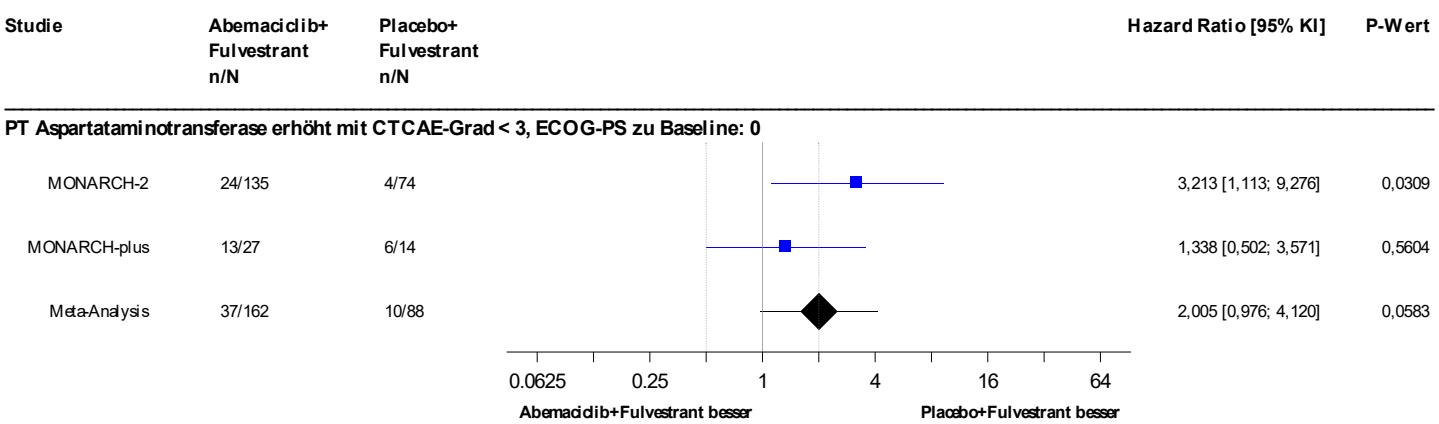
Abbildung 1446.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,4119, P-Wert=0,2347, I2 Index=29,2%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttas2aesi_popa1_ecogbl_1.rtf
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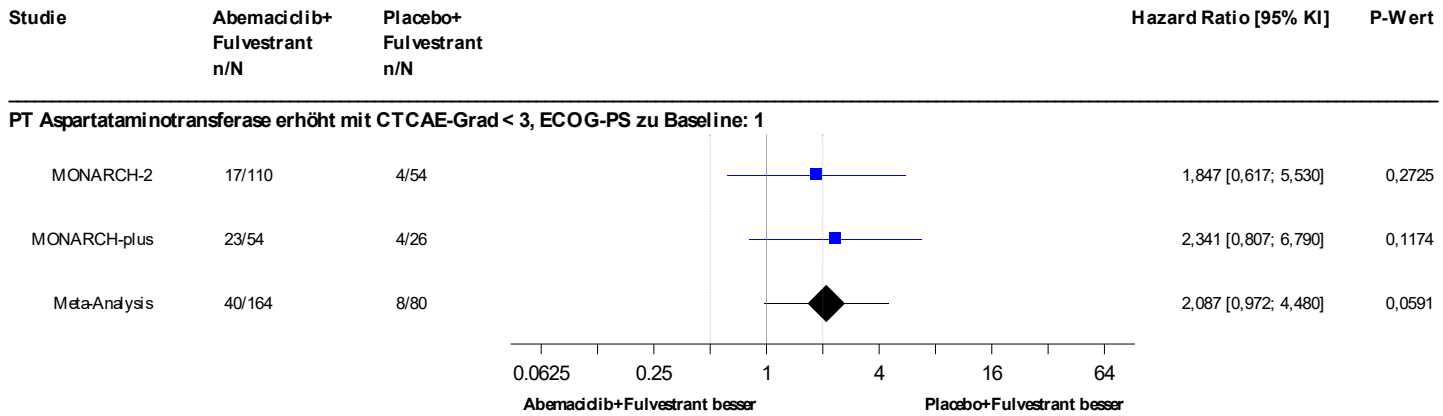
Abbildung 1446.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0923, P-Wert=0,7613, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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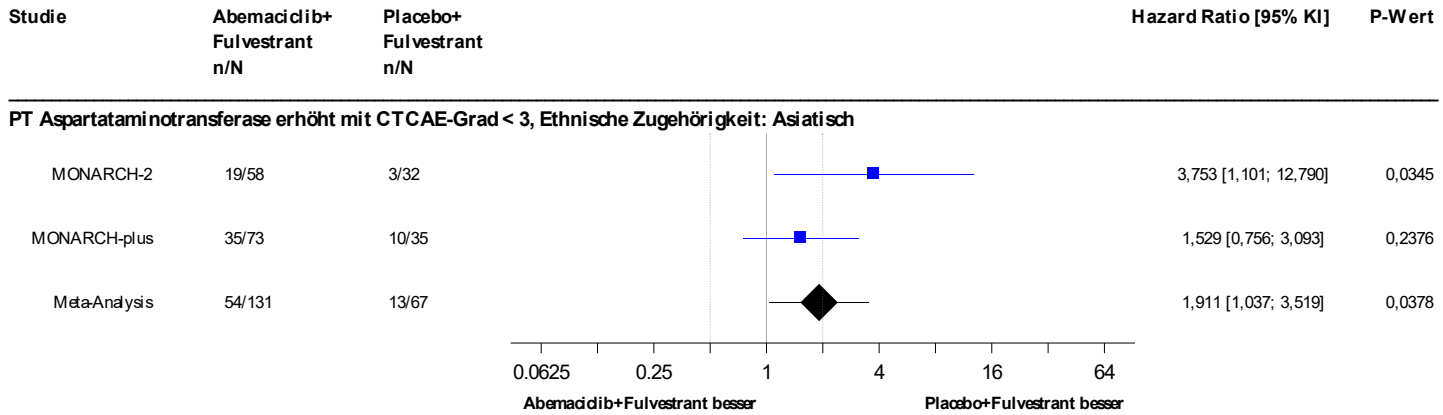
Abbildung 1446.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,5491, P-Wert=0,2133, I2 Index=35,4%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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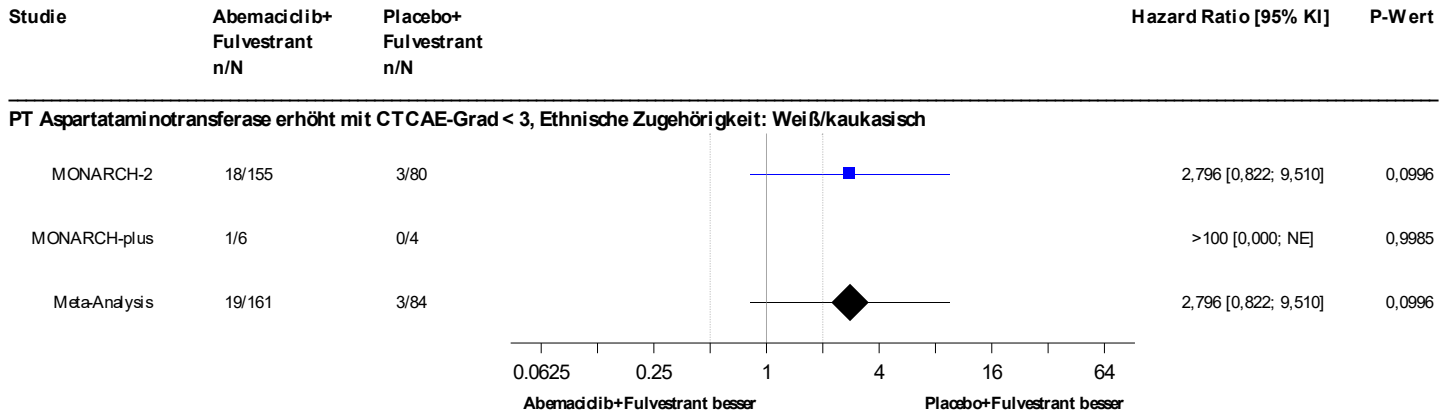
Abbildung 1446.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9986, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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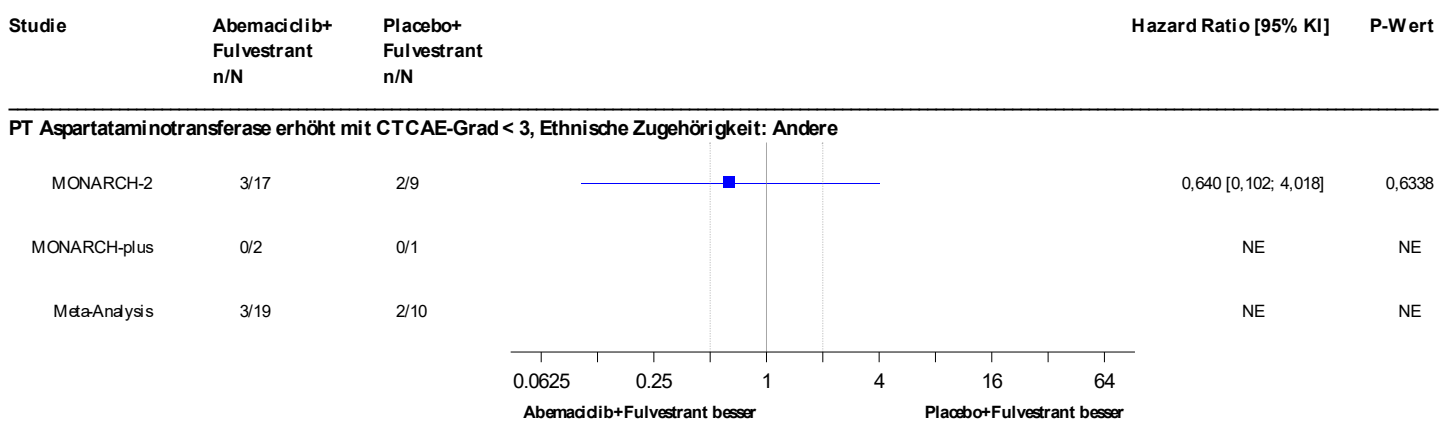
Abbildung 1446.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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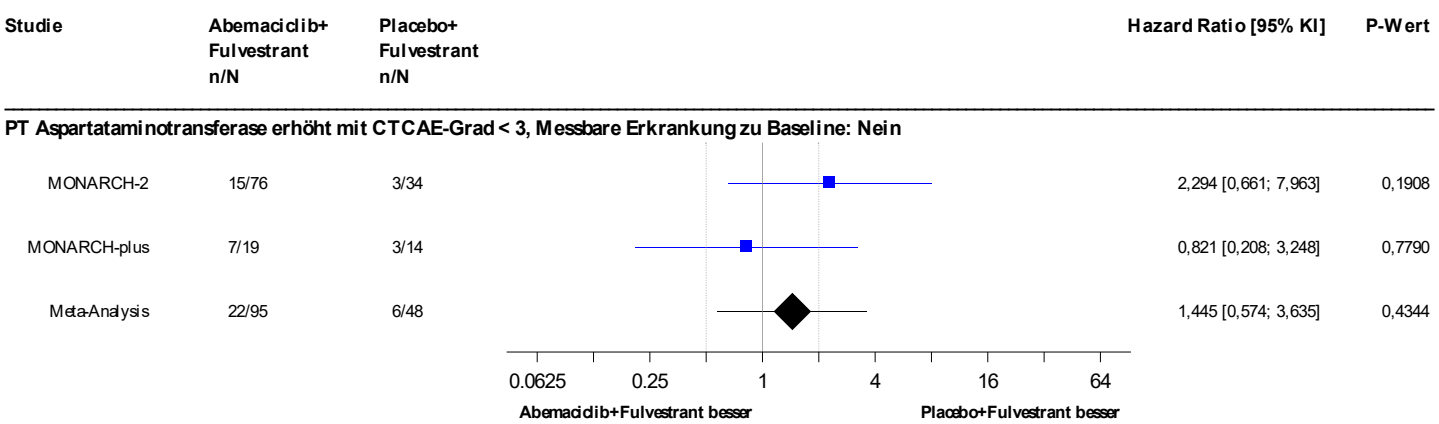
Abbildung 1446.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,1791, P-Wert=0,2775, I2 Index=15,2%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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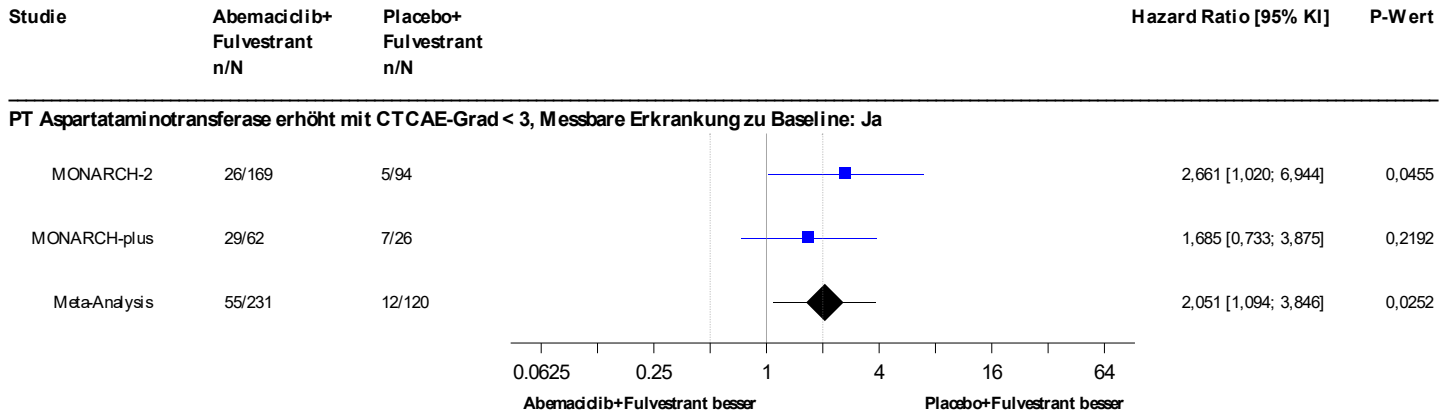
Abbildung 1446.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4971, P-Wert=0,4808, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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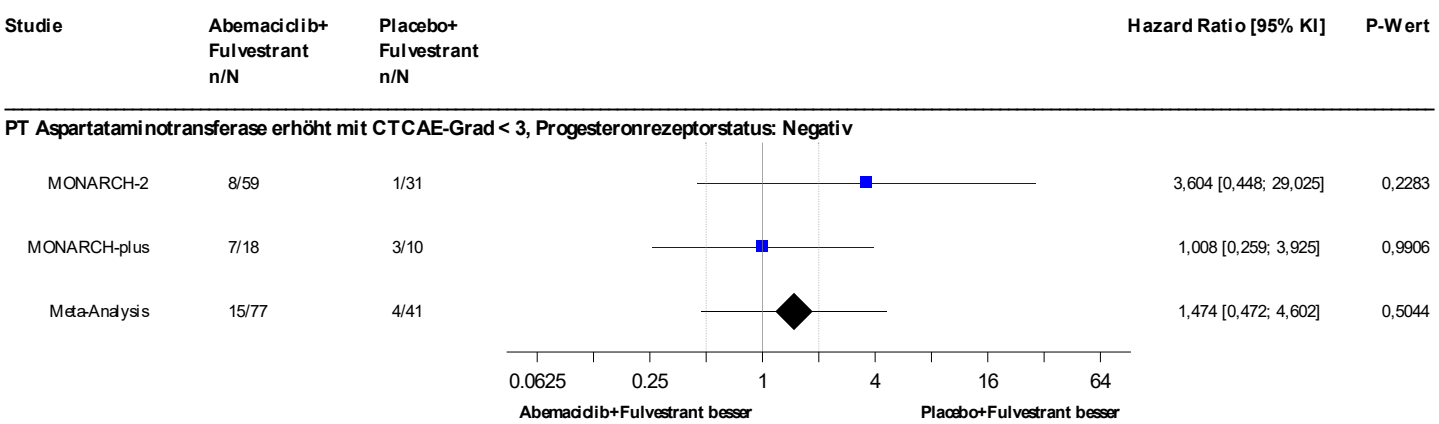
Abbildung 1446.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,0059, P-Wert=0,3159, I2 Index=0,6%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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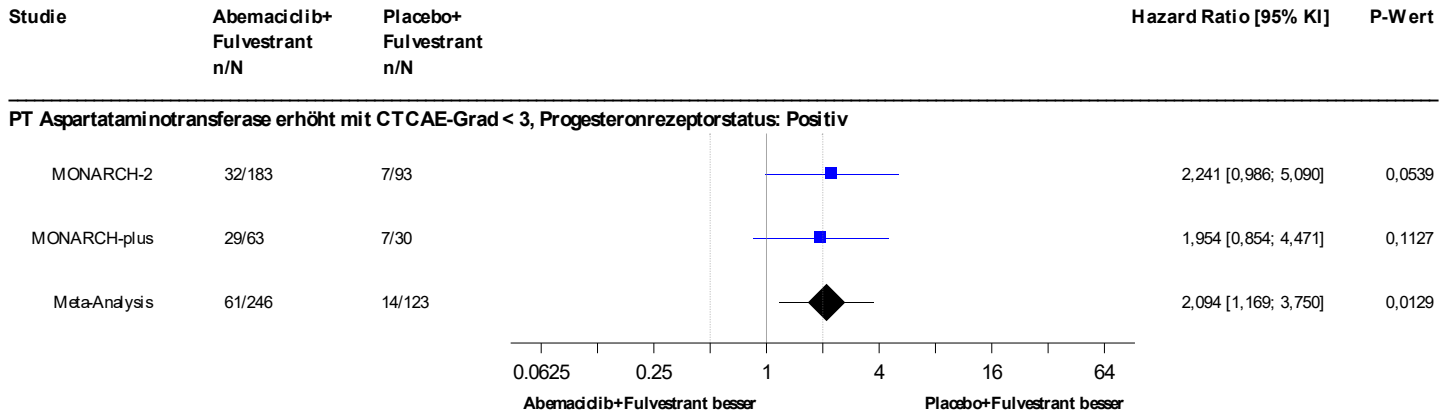
17SEP2021 / 07:48

Abbildung 1446.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0530, P-Wert=0,8178, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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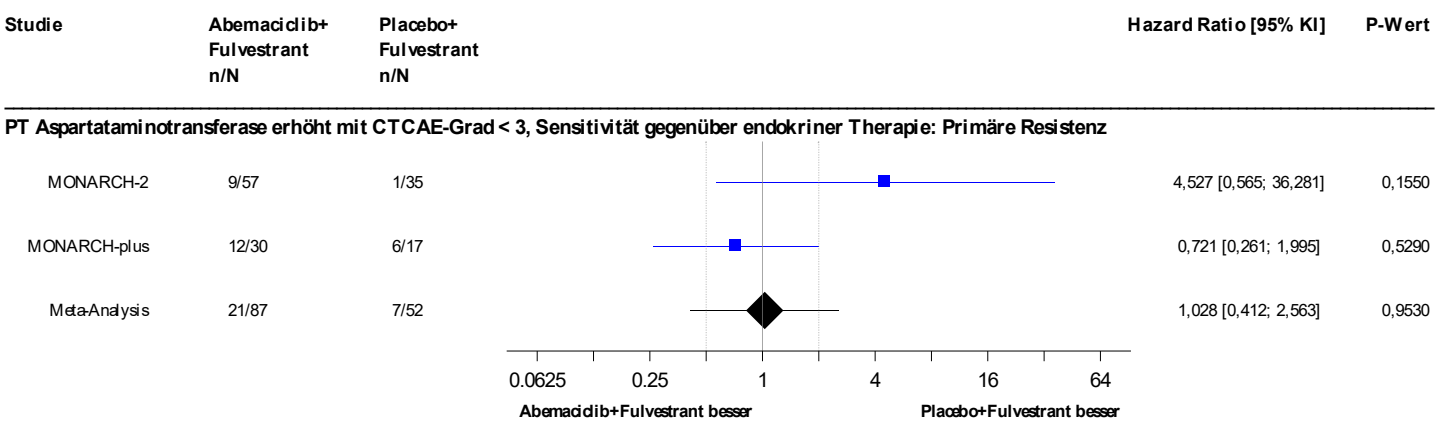
Abbildung 1446.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,4155, P-Wert=0,1201, I2 Index=58,6%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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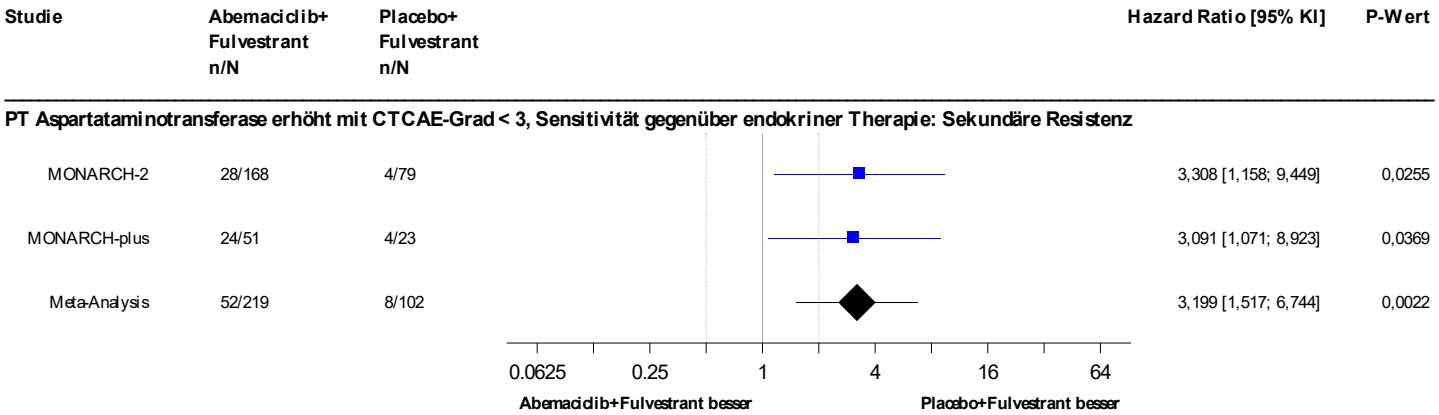
Abbildung 1446.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0080, P-Wert=0,9289, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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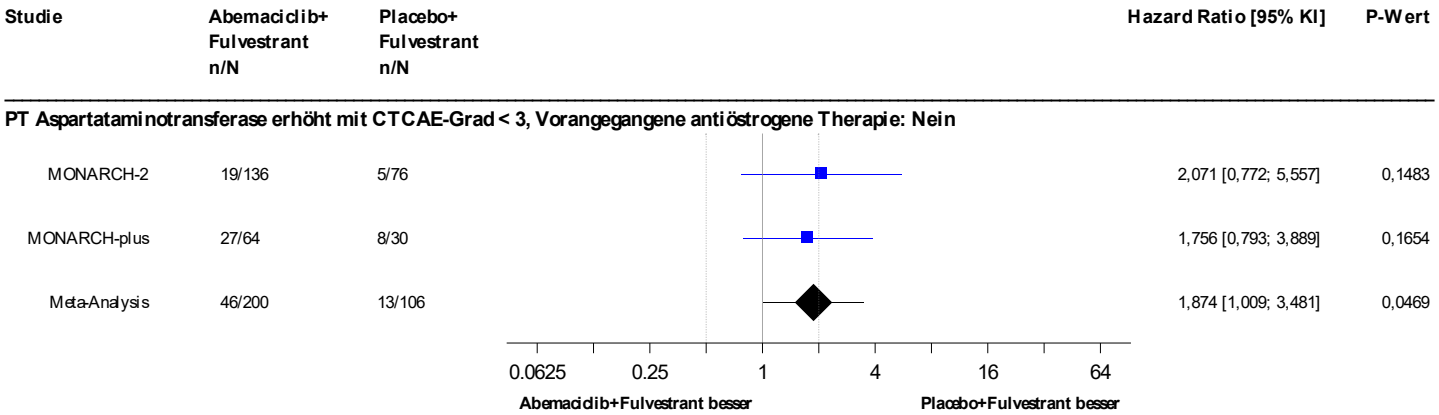
Abbildung 1446.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0652, P-Wert=0,7985, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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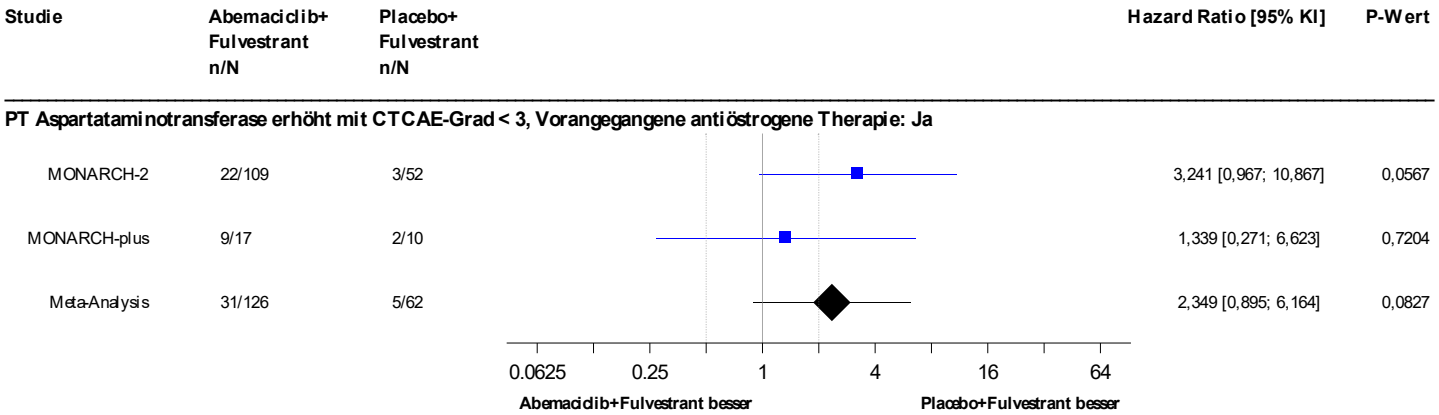
Abbildung 1446.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7471, P-Wert=0,3874, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttas2aesi_popa1_paet_2.rtf
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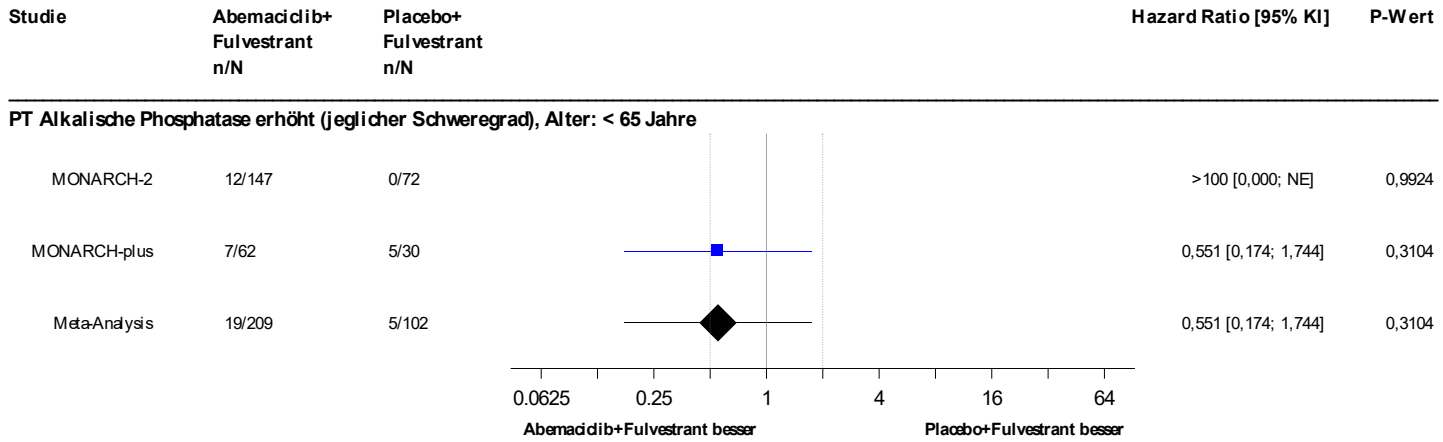
Abbildung 1448.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9922, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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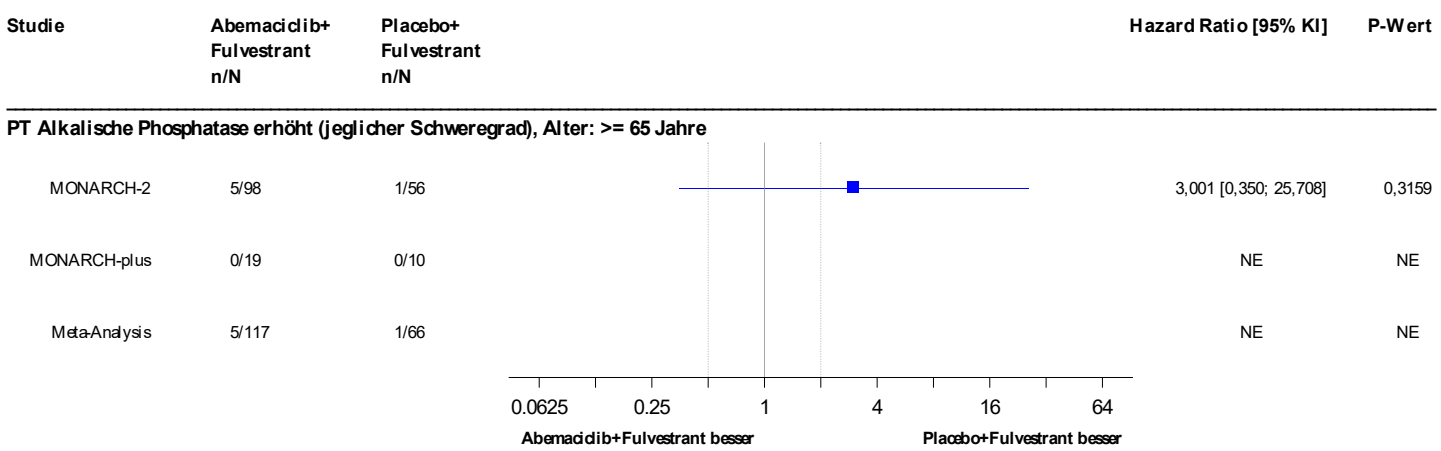
17SEP2021 / 07:48

Abbildung 1448.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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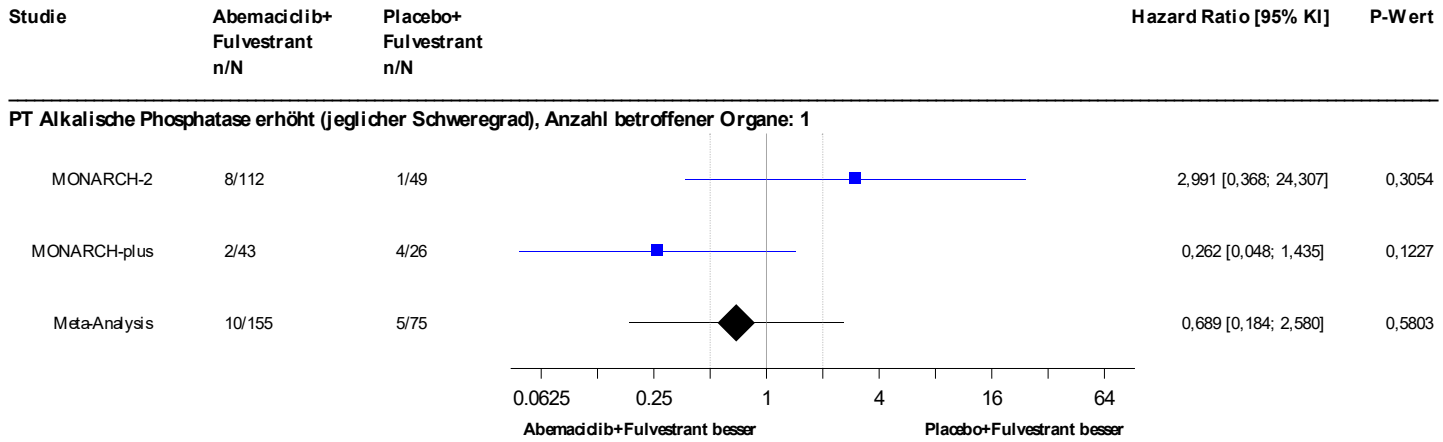
17SEP2021 / 07:48

Abbildung 1448.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=3,1270, P-Wert=0,0770, I2 Index=68,0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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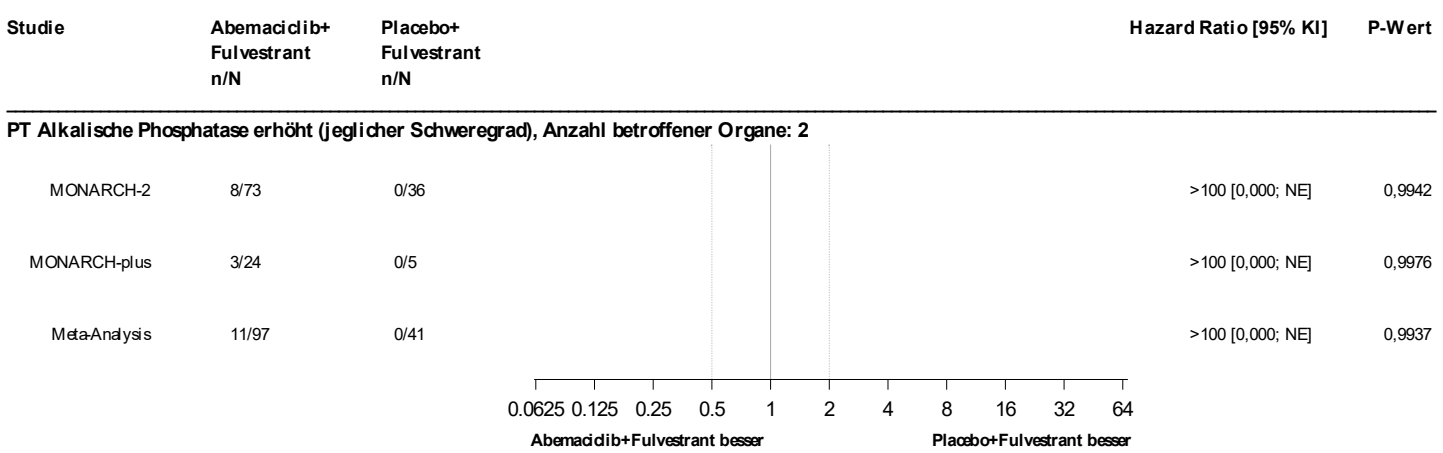
Abbildung 1448.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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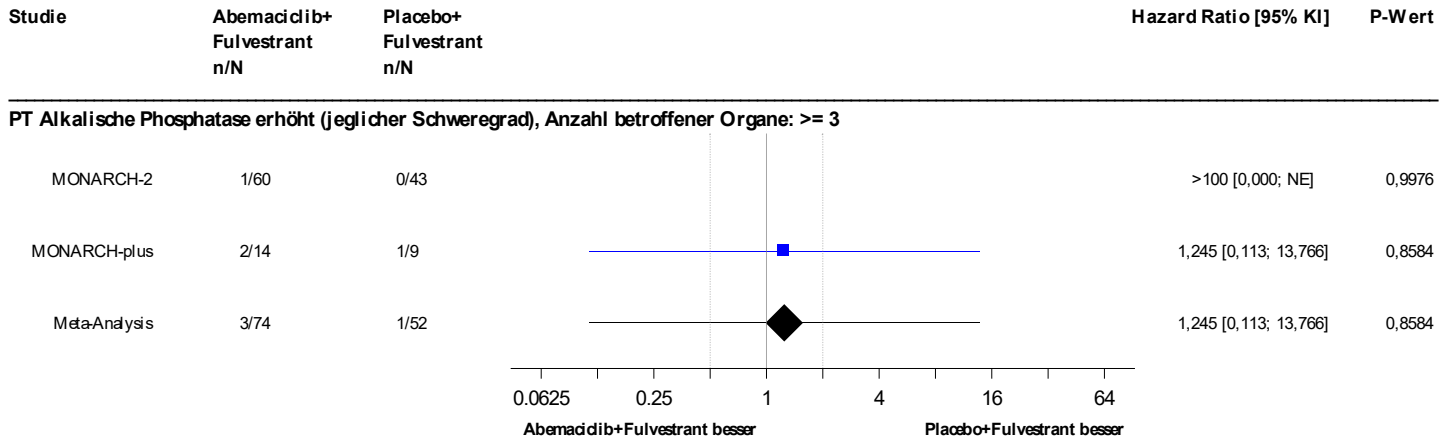
Abbildung 1448.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9976, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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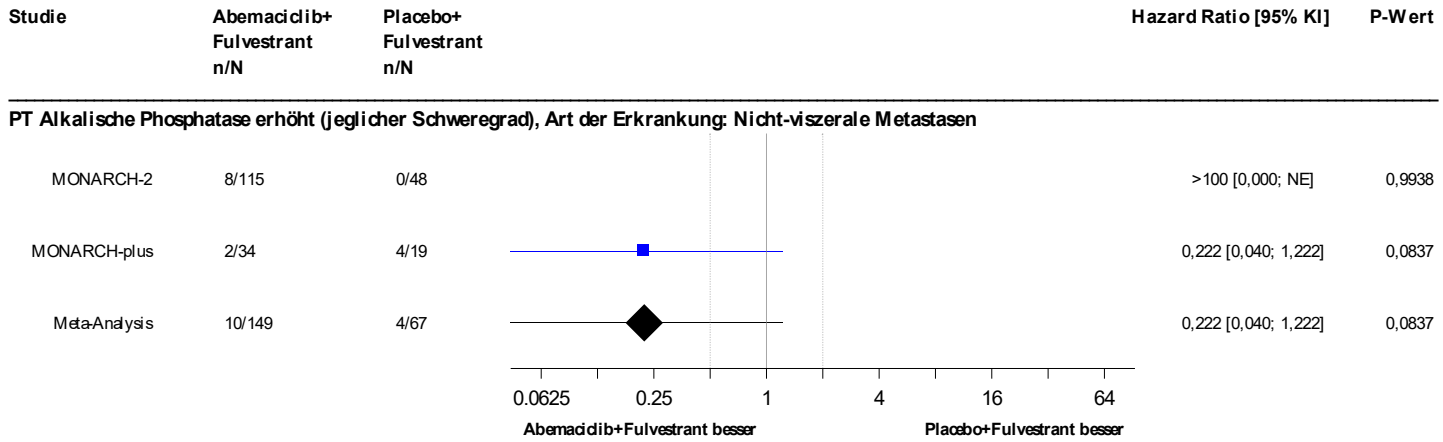
Abbildung 1448.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9933, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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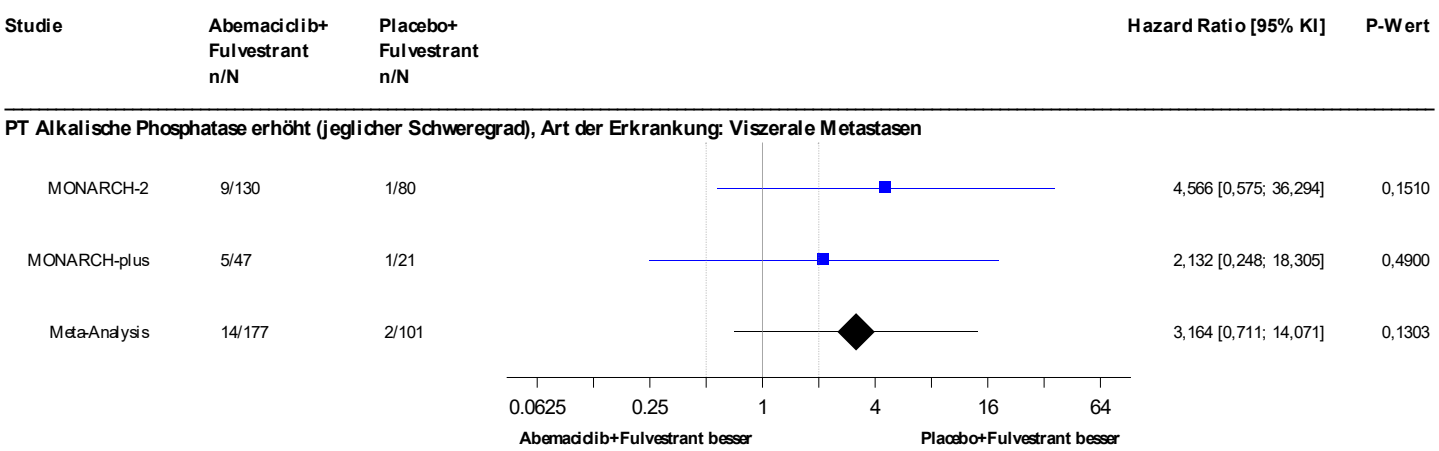
Abbildung 1448.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2498, P-Wert=0,6172, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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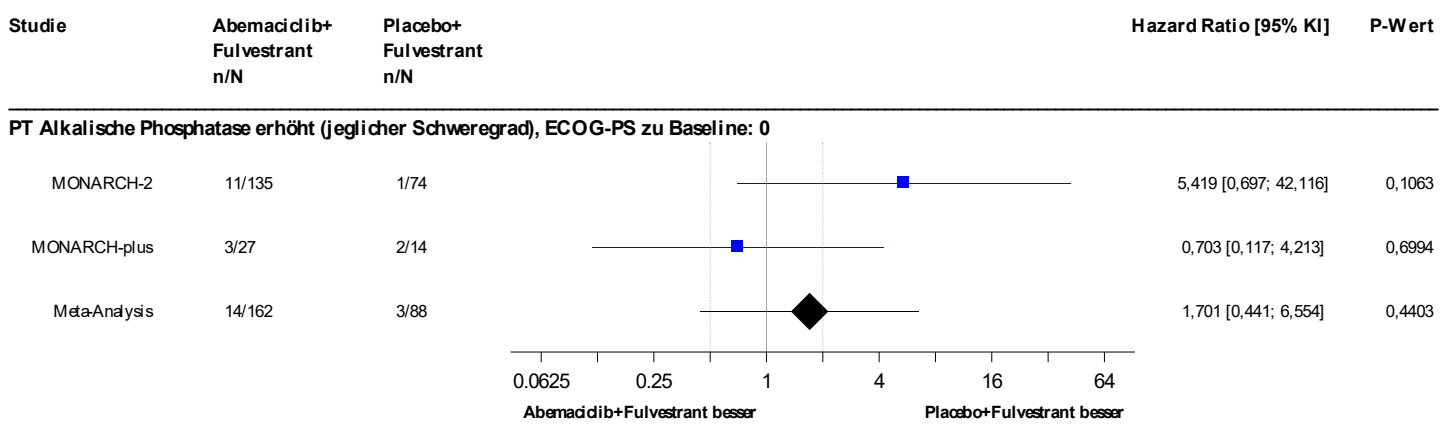
Abbildung 1448.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,1624, P-Wert=0,1414, I2 Index=53,8%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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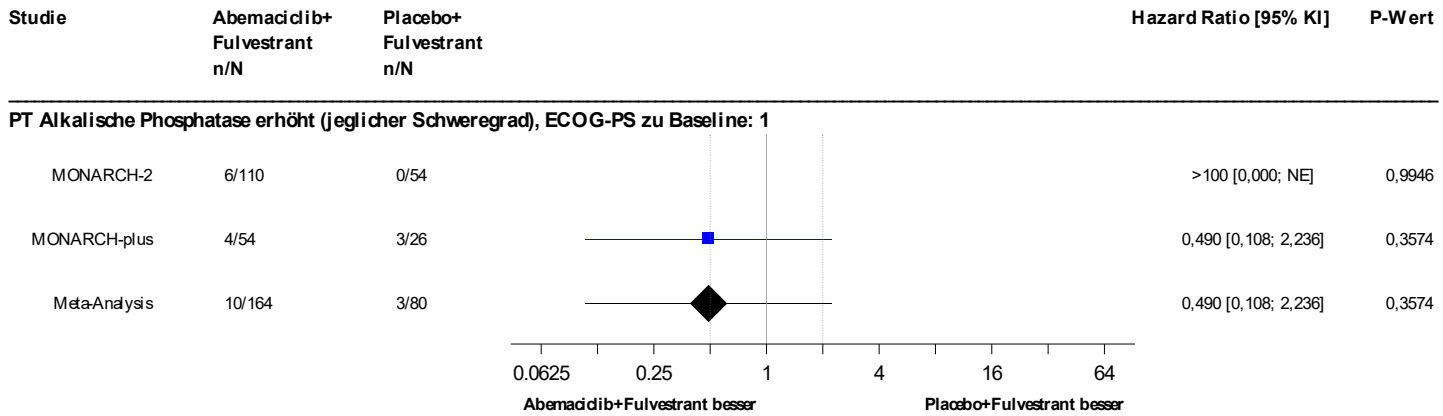
Abbildung 1448.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9943, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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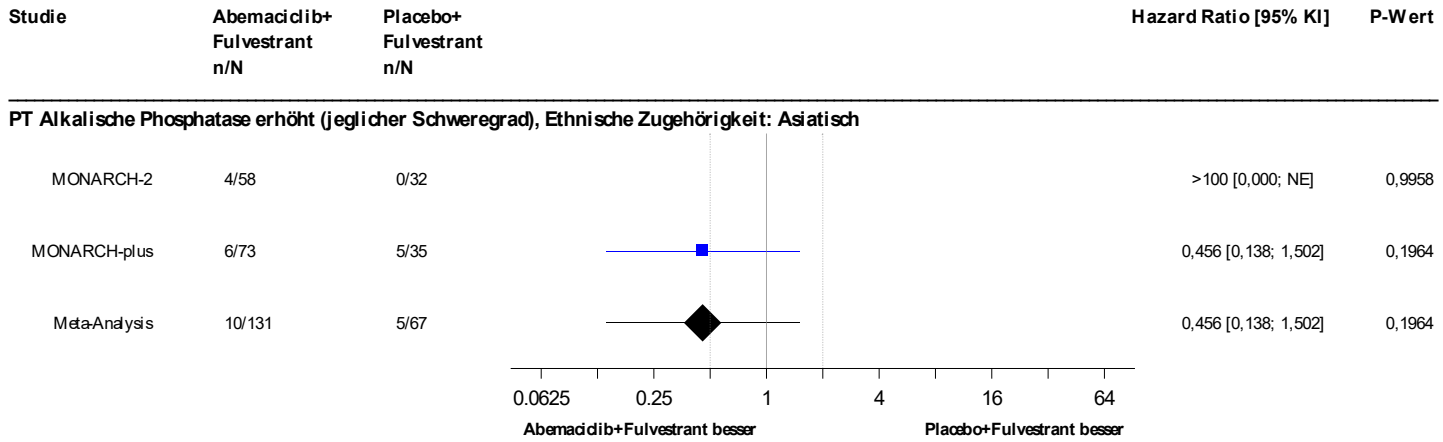
Abbildung 1448.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9956, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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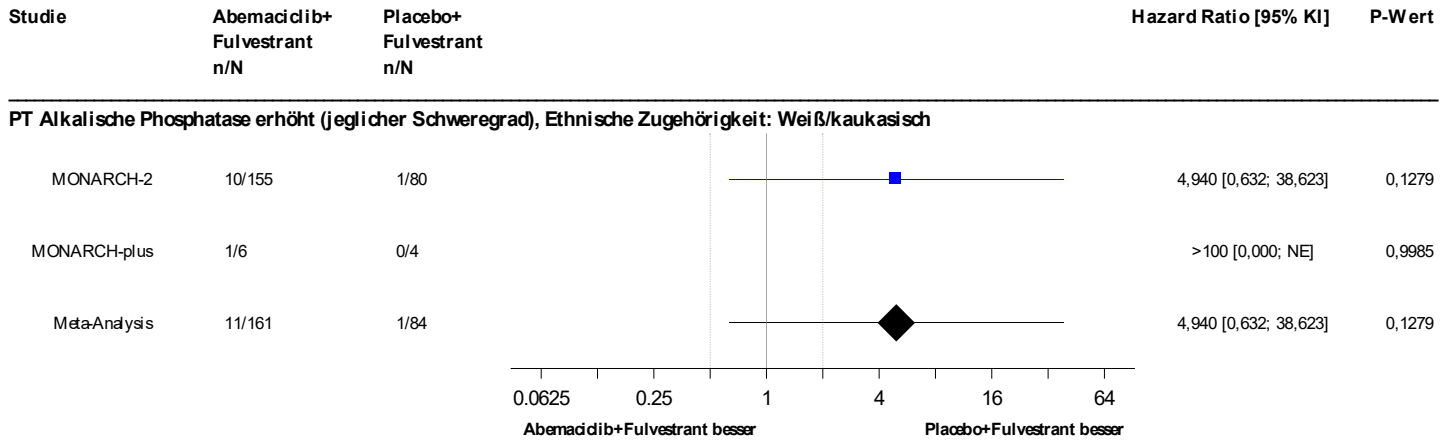
Abbildung 1448.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9986, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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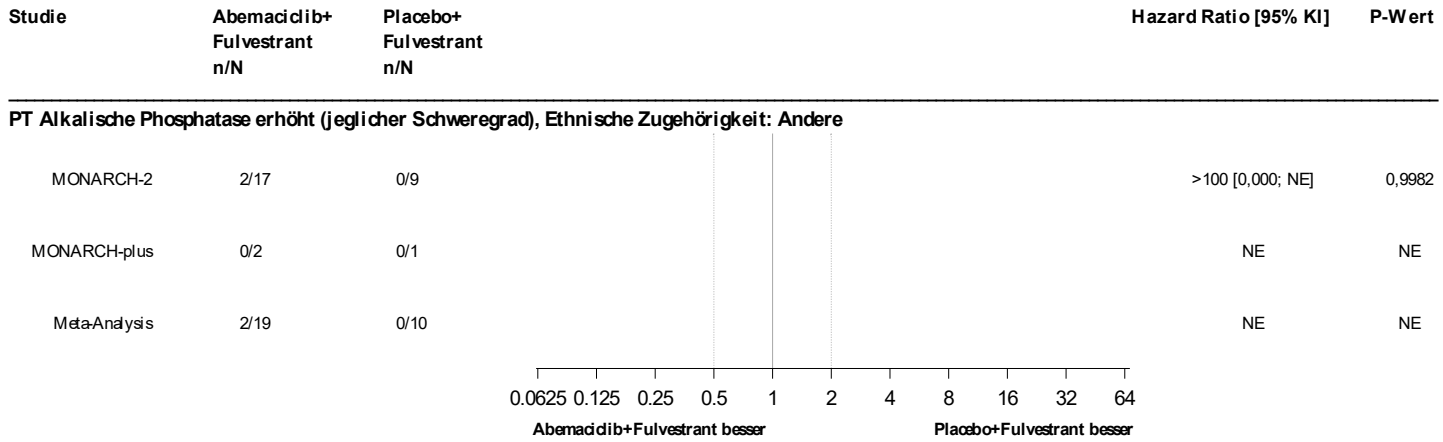
Abbildung 1448.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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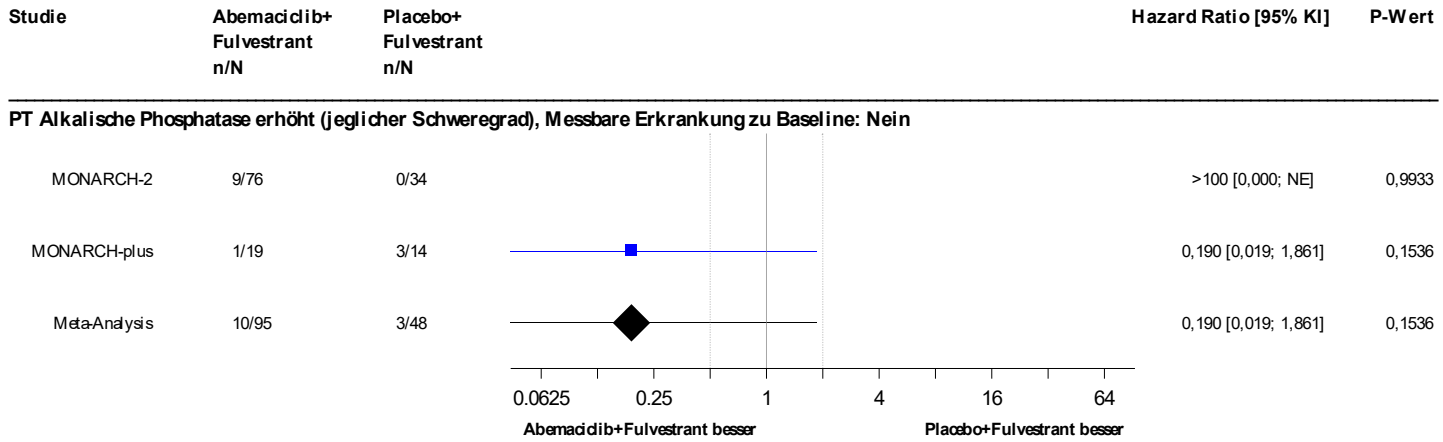
Abbildung 1448.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9927, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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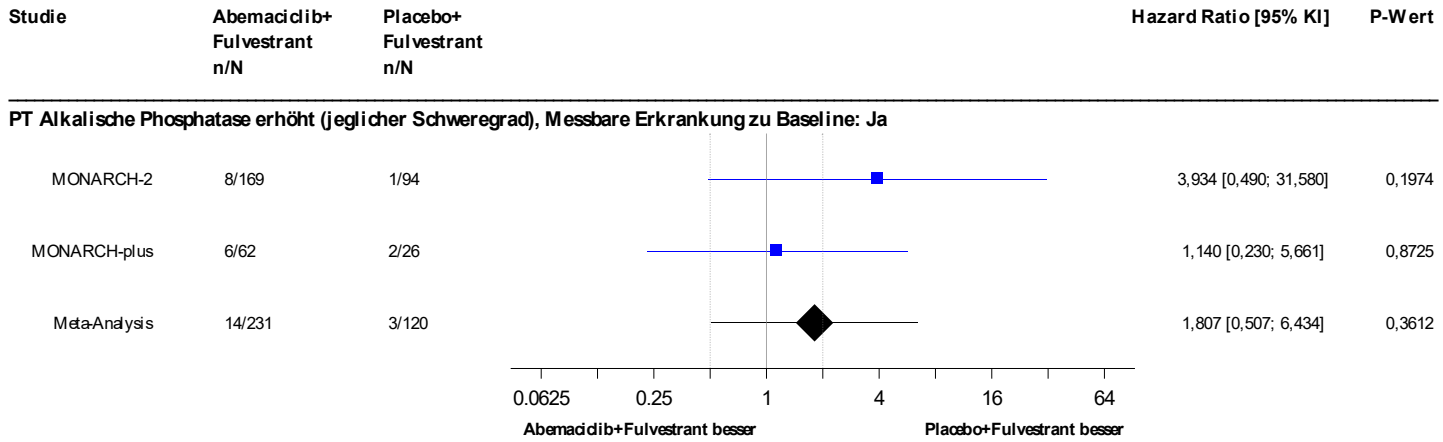
Abbildung 1448.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,8532, P-Wert=0,3556, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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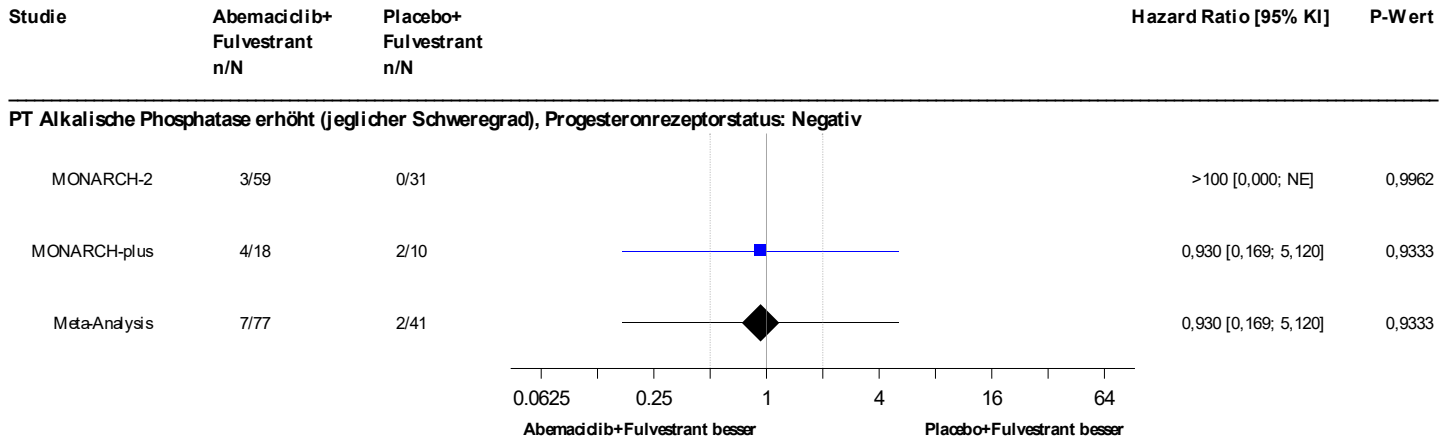
Abbildung 1448.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9962, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttapaesi_popa1_pgrstat_1.rtf
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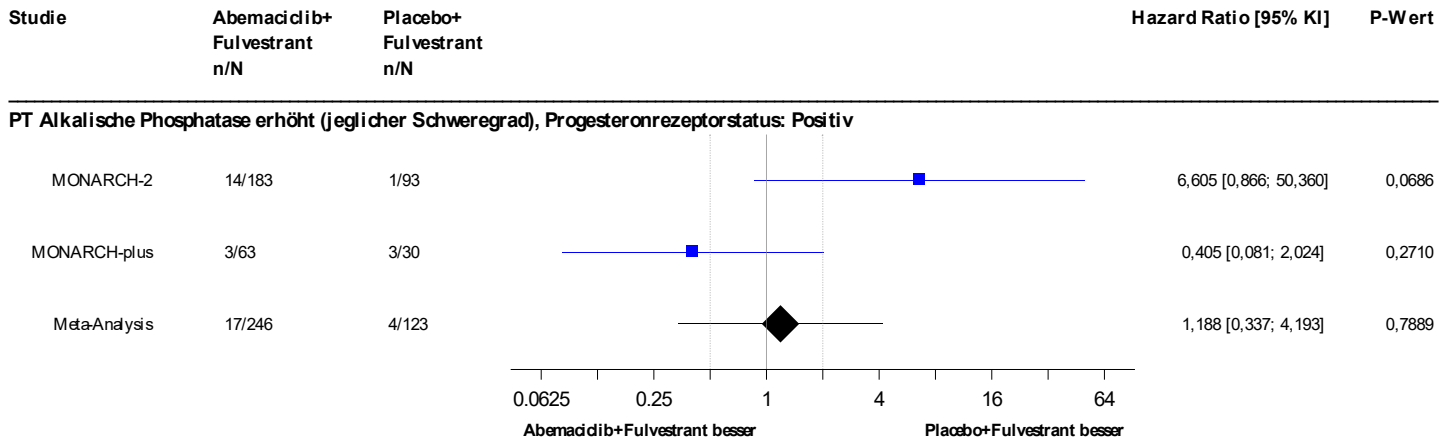
Abbildung 1448.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=4,4572, P-Wert=0,0348, I2 Index=77,6%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttapaesi_popa1_pgrstat_2.rtf
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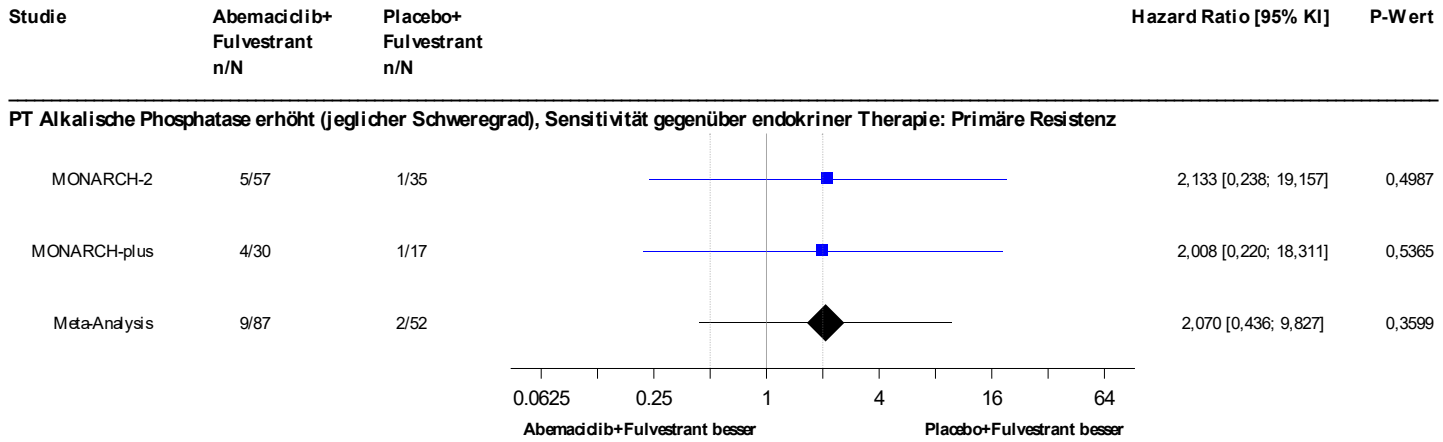
Abbildung 1448.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0015, P-Wert=0,9696, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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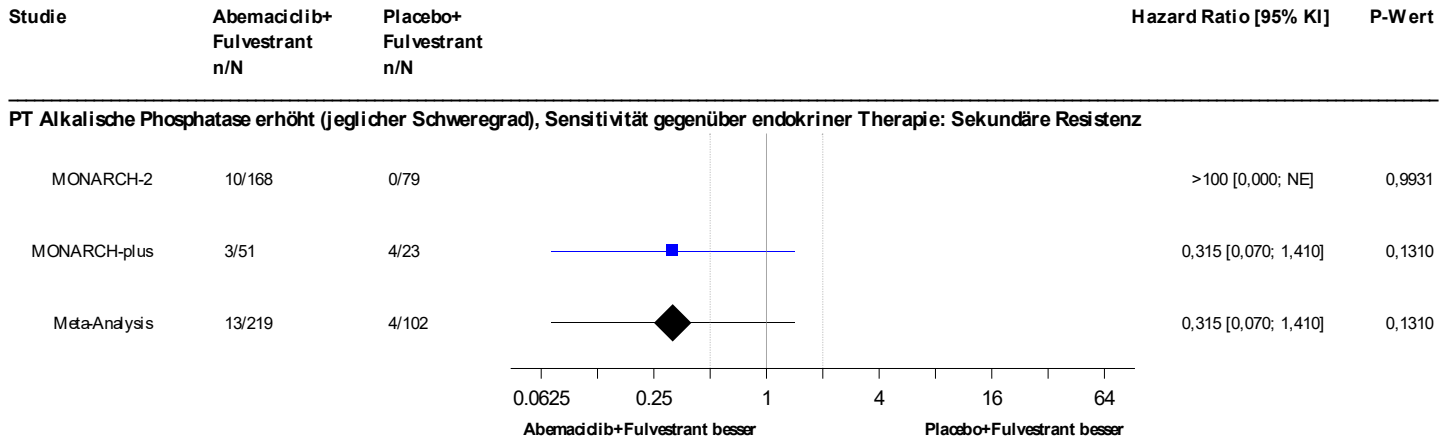
Abbildung 1448.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9926, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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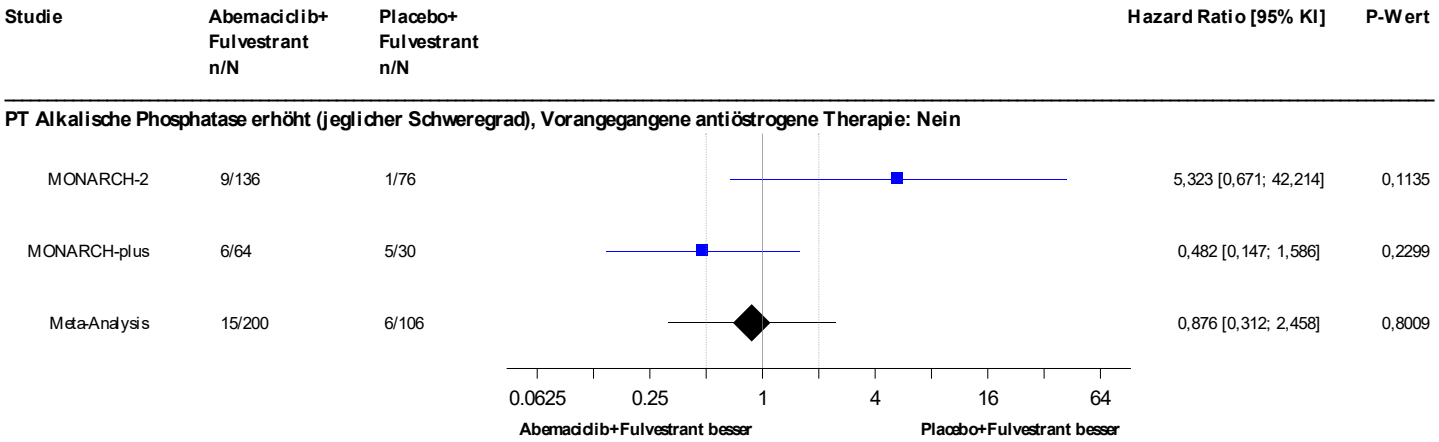
Abbildung 1448.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=3,8825, P-Wert=0,0488, I2 Index=74,2%
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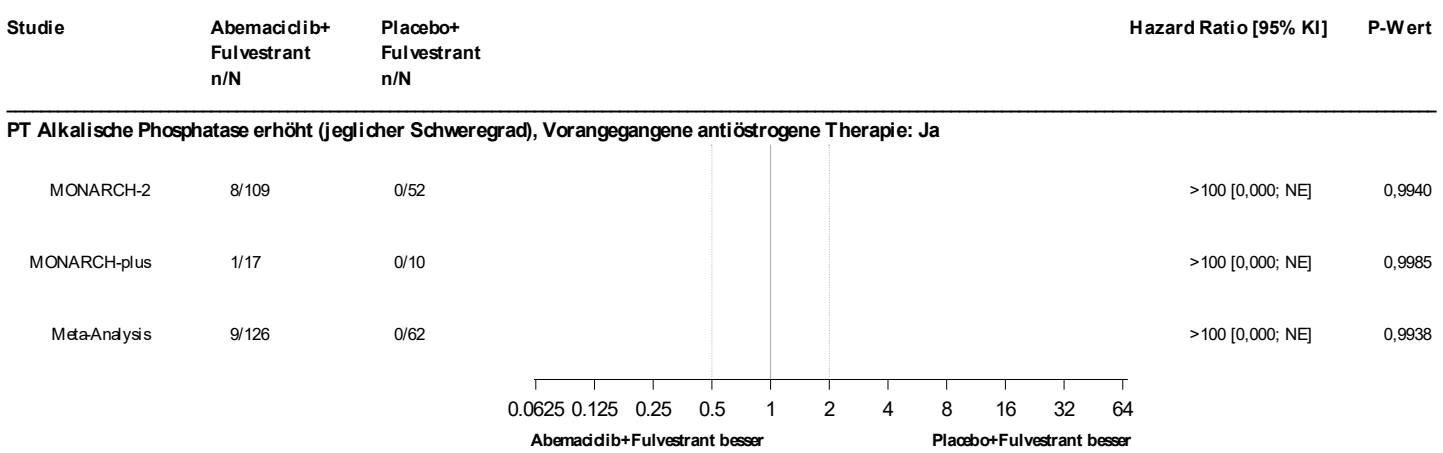
Abbildung 1448.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alkalische Phosphatase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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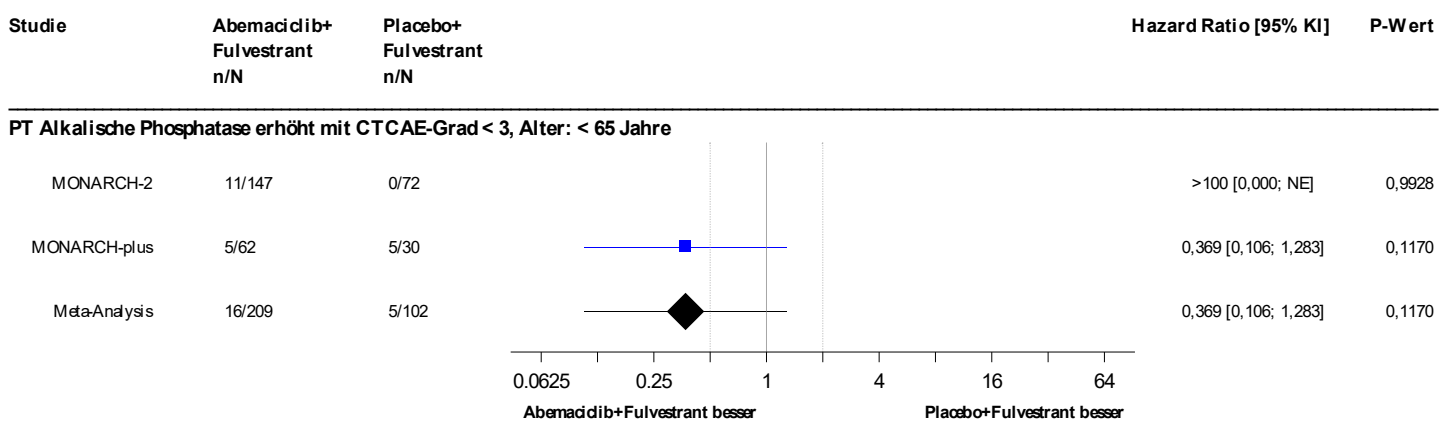
Abbildung 1450.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9923, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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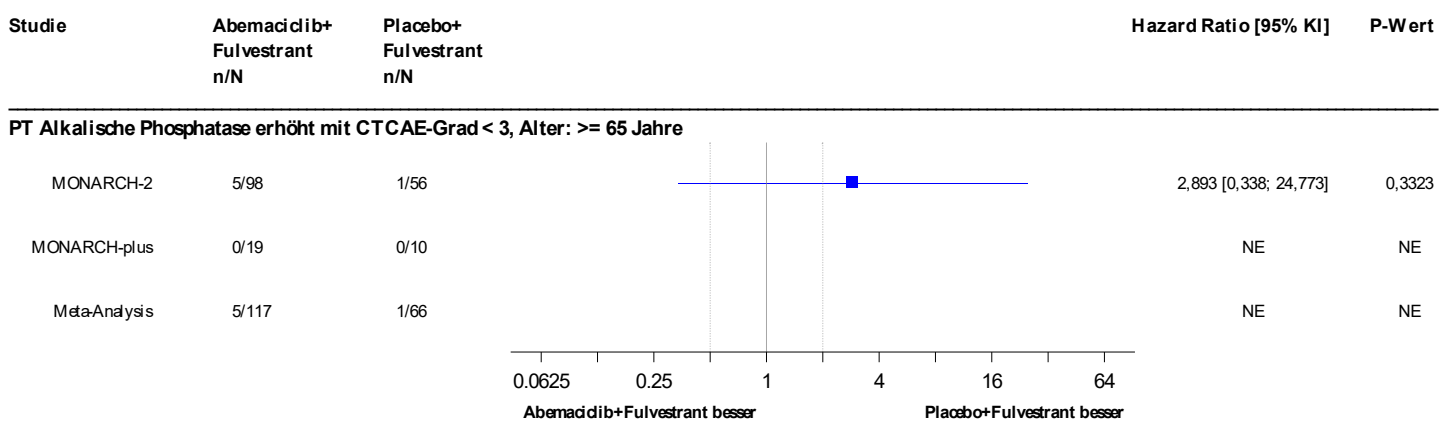
Abbildung 1450.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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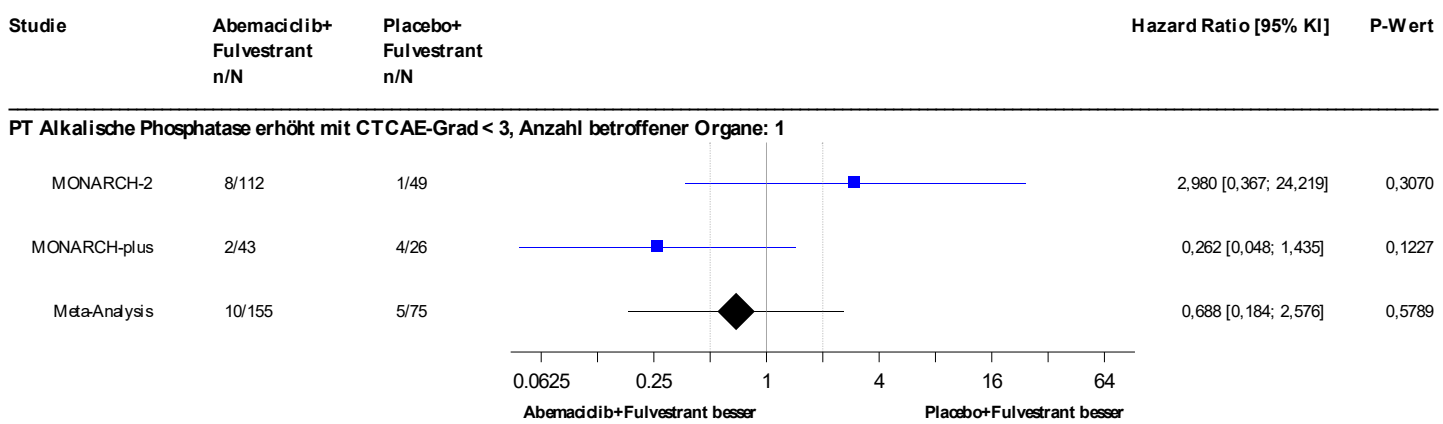
Abbildung 1450.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=3,1180, P-Wert=0,0774, I2 Index=67,9%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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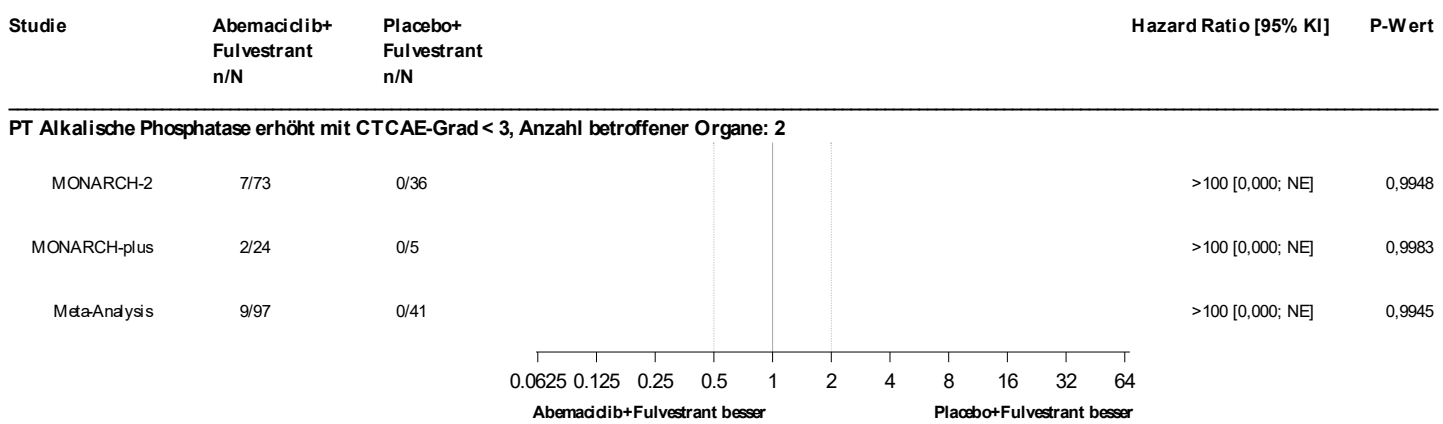
Abbildung 1450.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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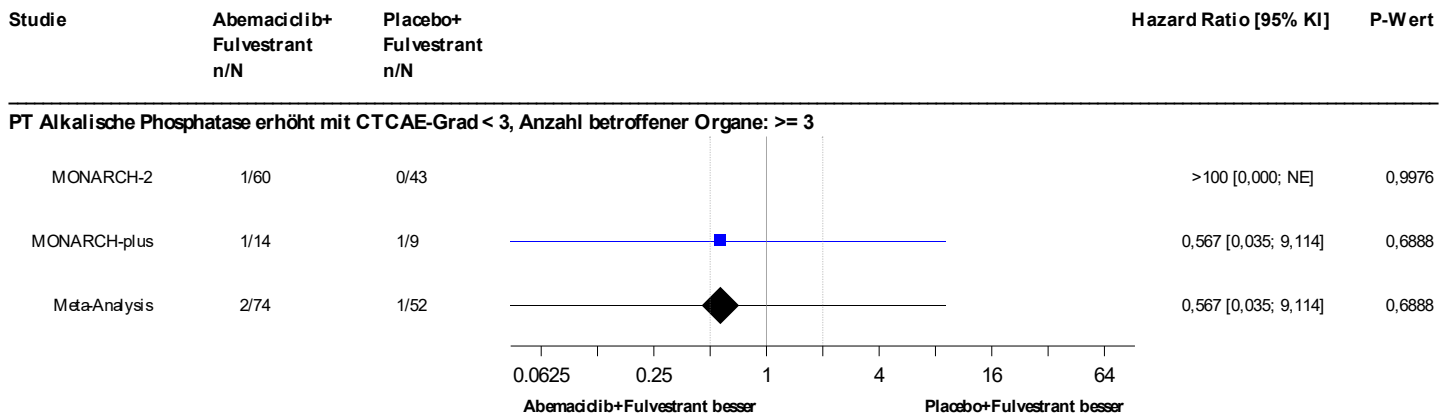
Abbildung 1450.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9975, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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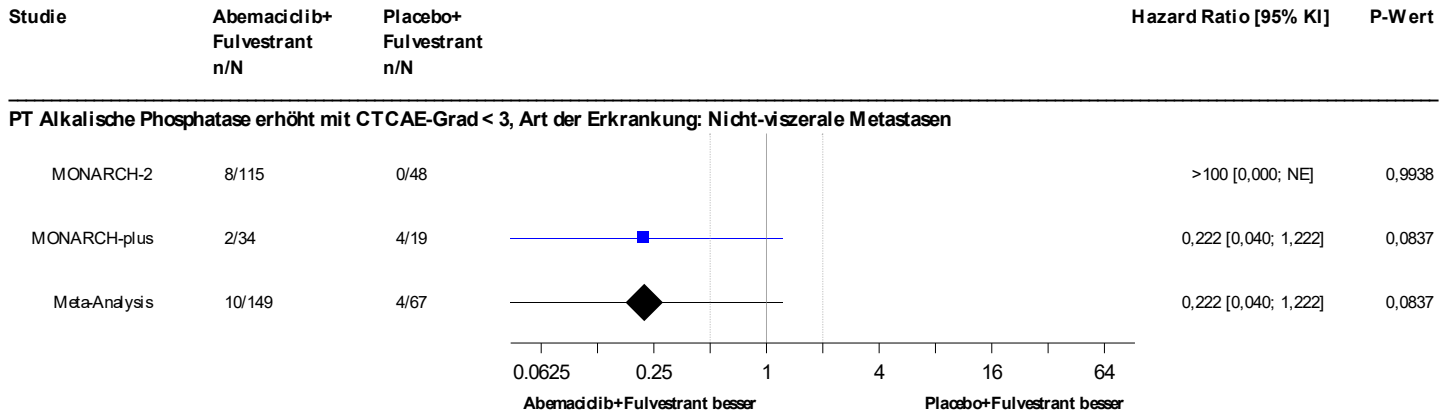
Abbildung 1450.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9933, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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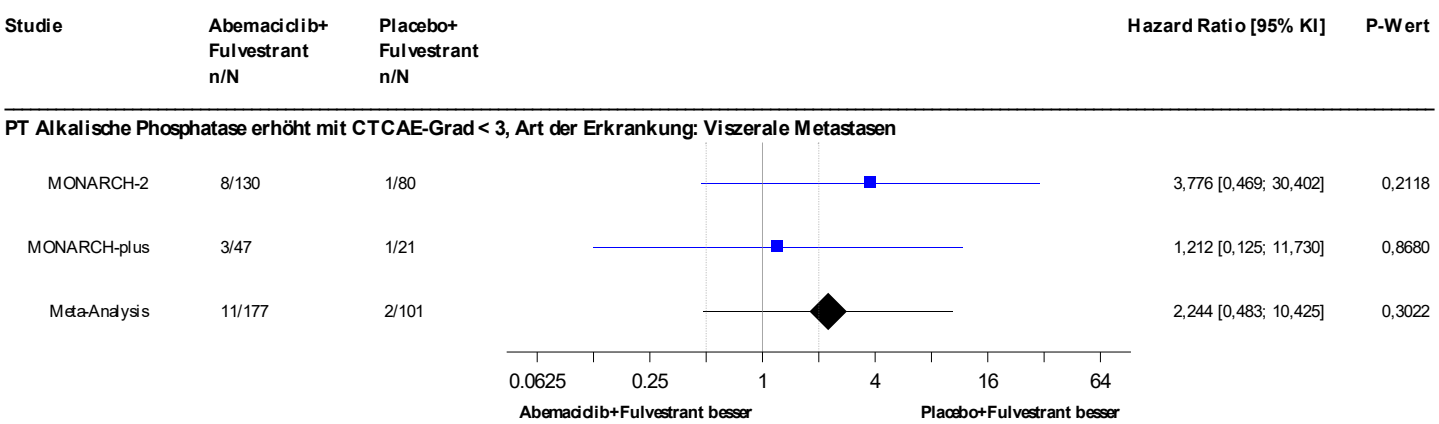
Abbildung 1450.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,5220, P-Wert=0,4700, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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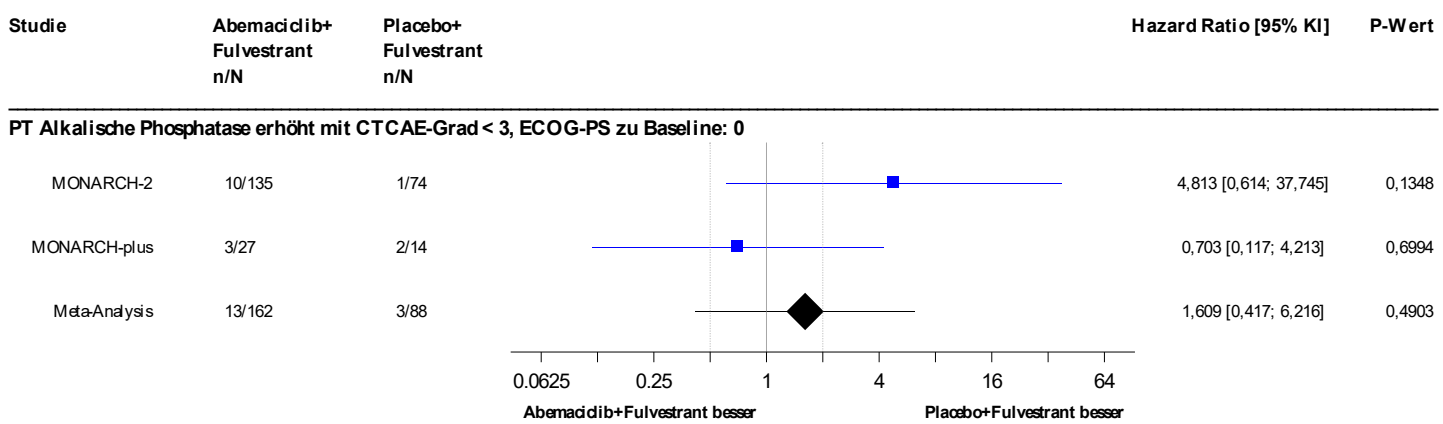
Abbildung 1450.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,9093, P-Wert=0,1670, I2 Index=47,6%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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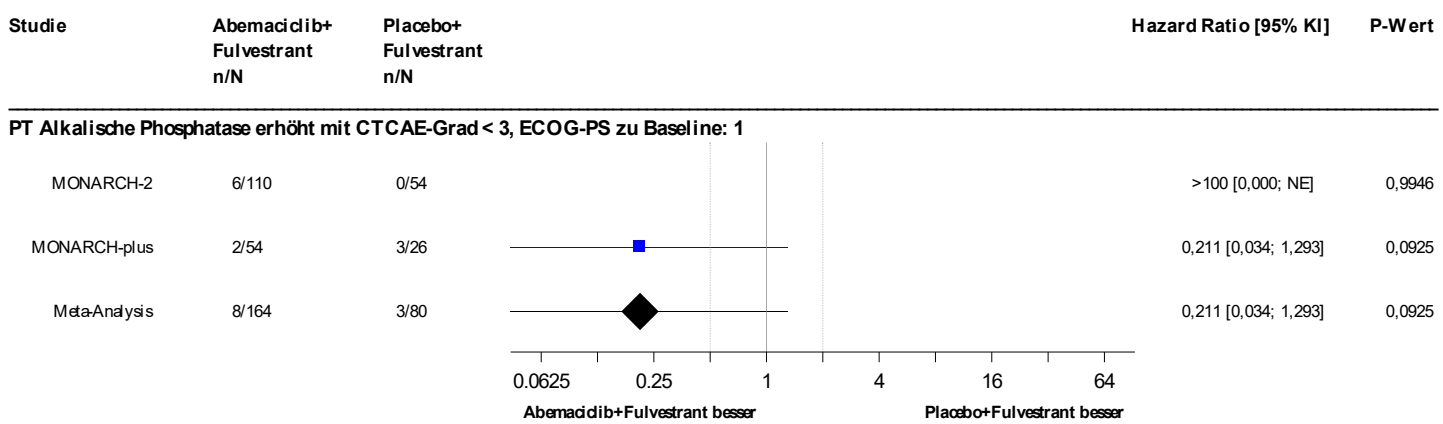
Abbildung 1450.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9941, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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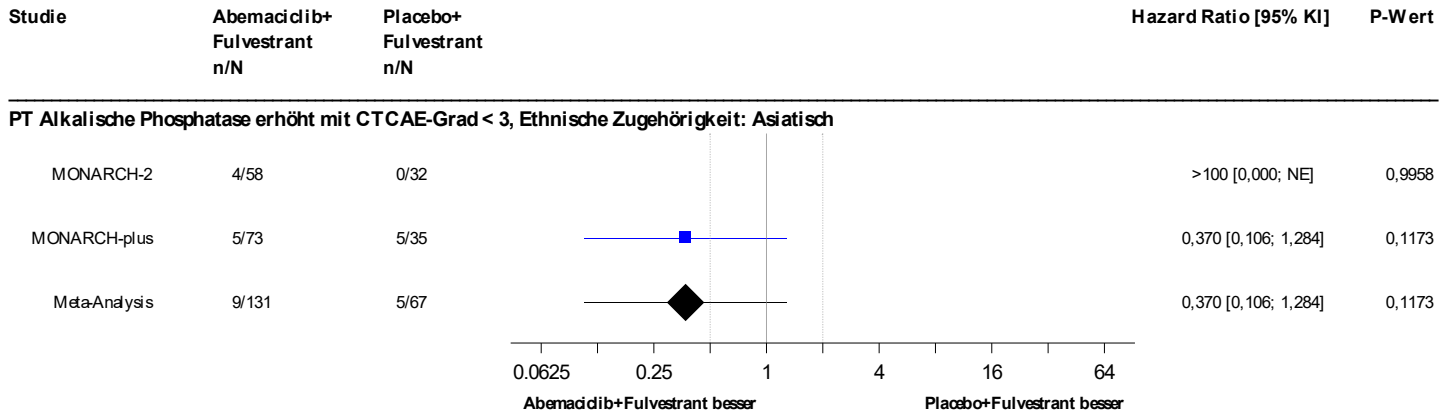
Abbildung 1450.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9955, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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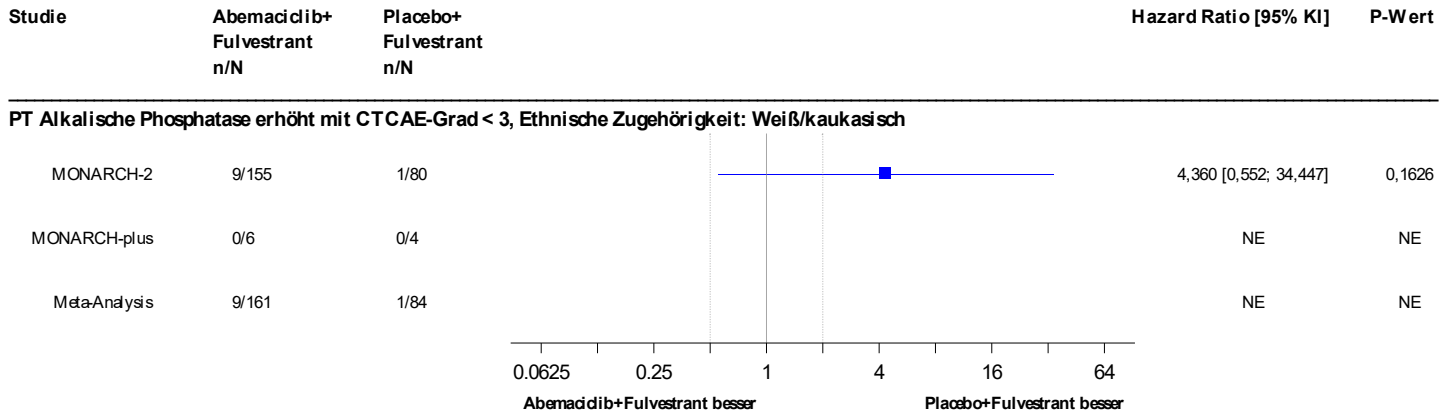
Abbildung 1450.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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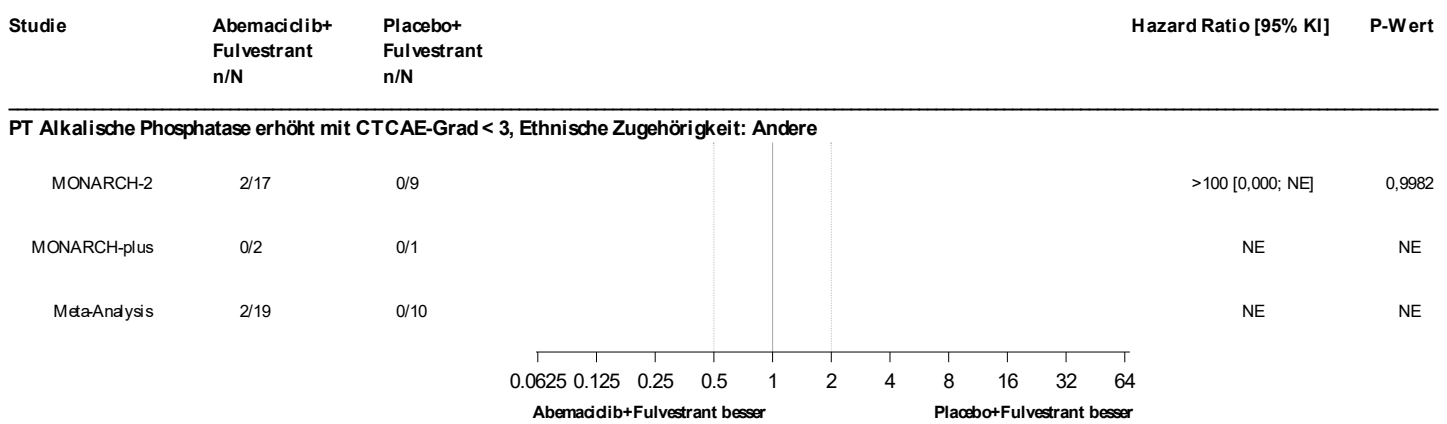
Abbildung 1450.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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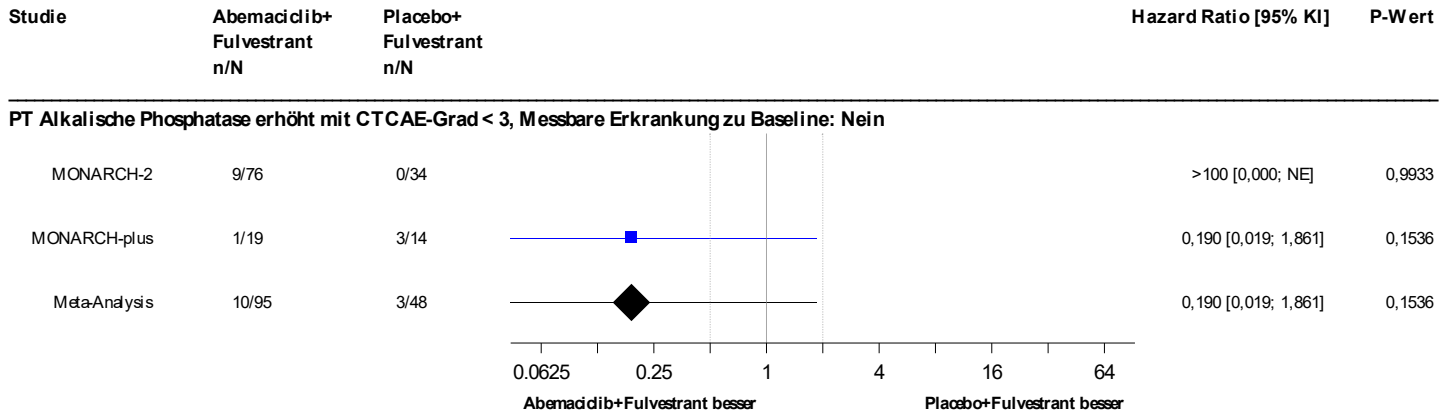
Abbildung 1450.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9927, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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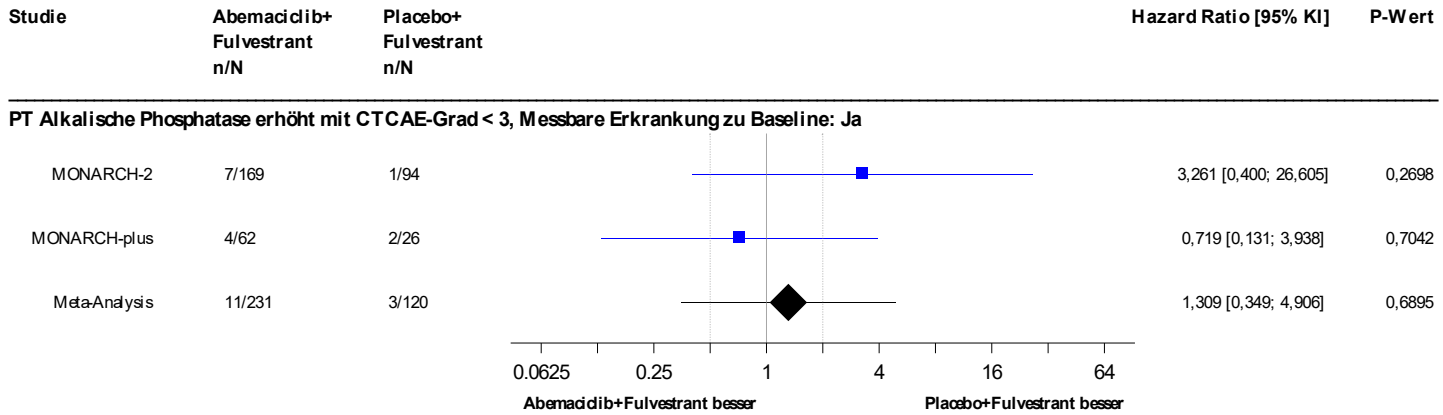
Abbildung 1450.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,2026, P-Wert=0,2728, I2 Index=16,8%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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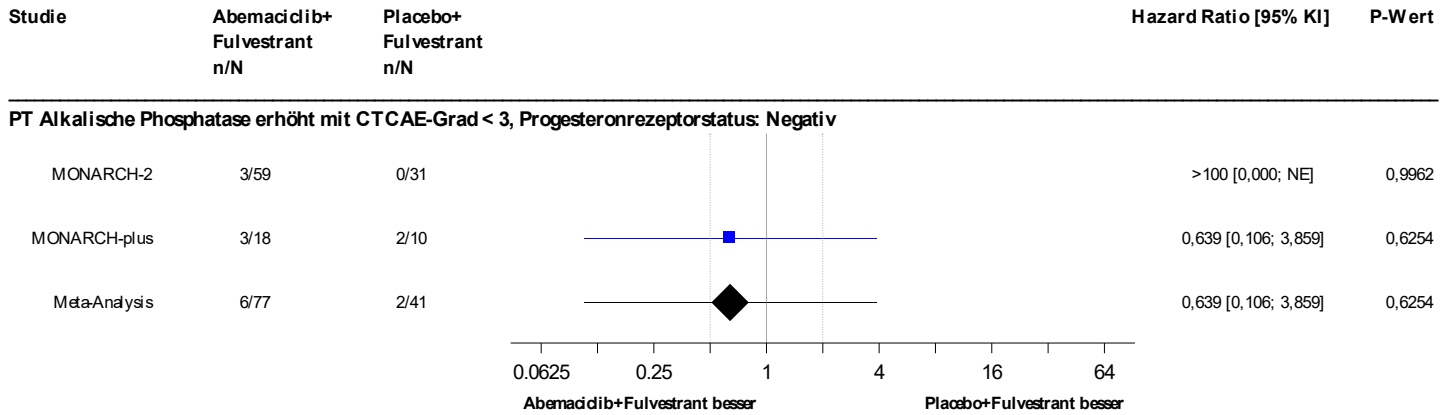
Abbildung 1450.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9961, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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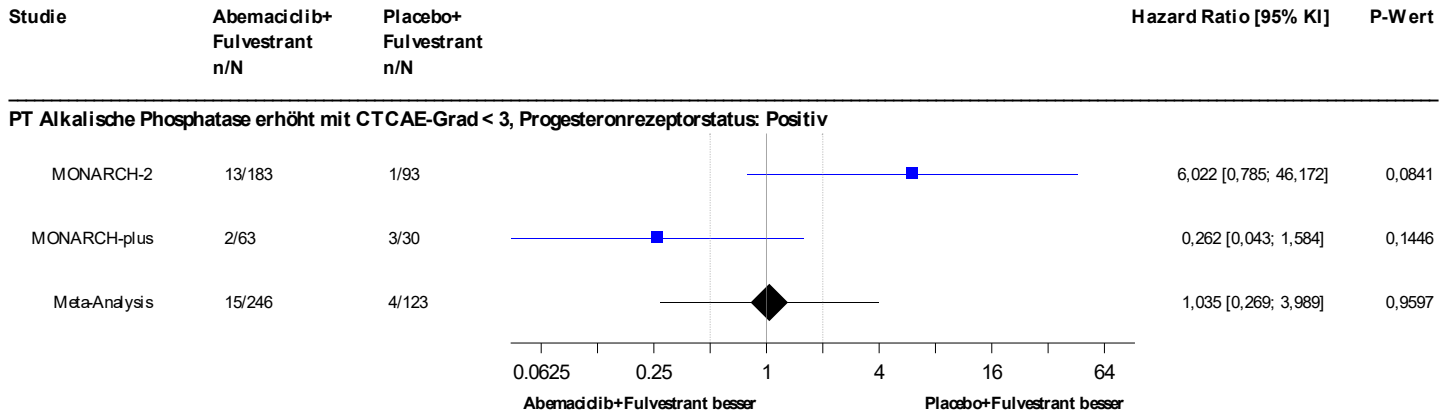
Abbildung 1450.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=5,1105, P-Wert=0,0238, I2 Index=80,4%
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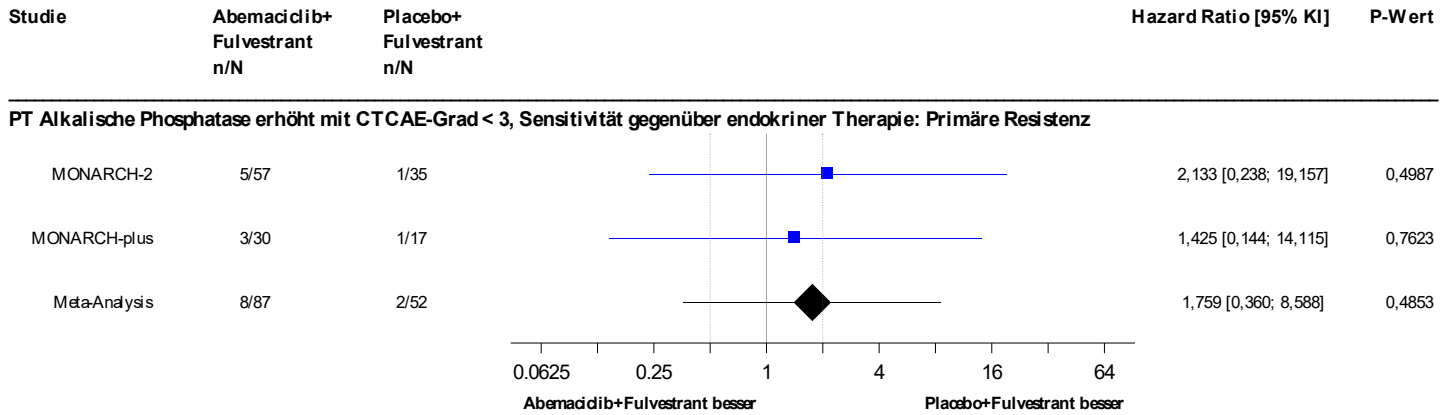
Abbildung 1450.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0621, P-Wert=0,8032, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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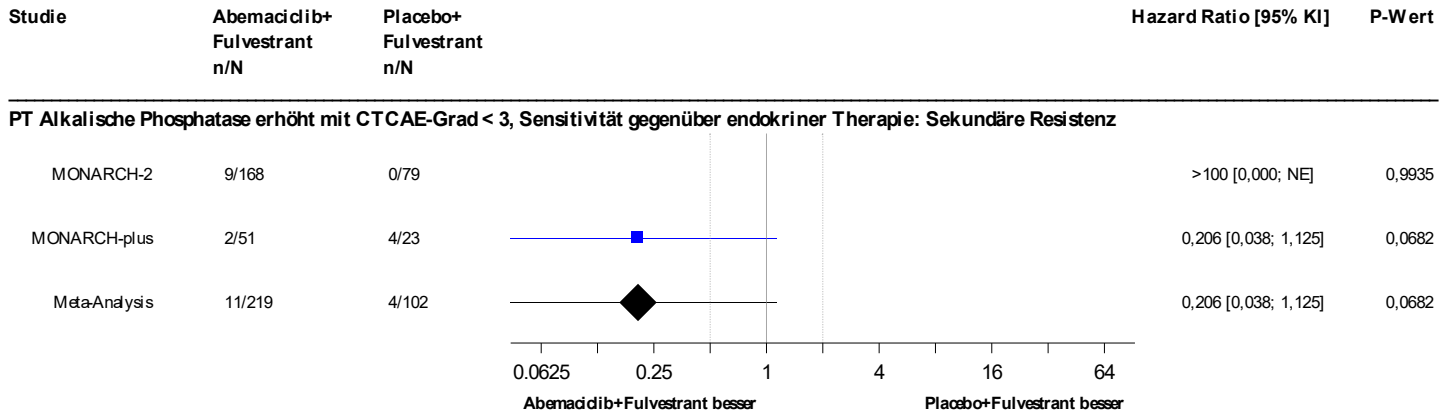
Abbildung 1450.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9929, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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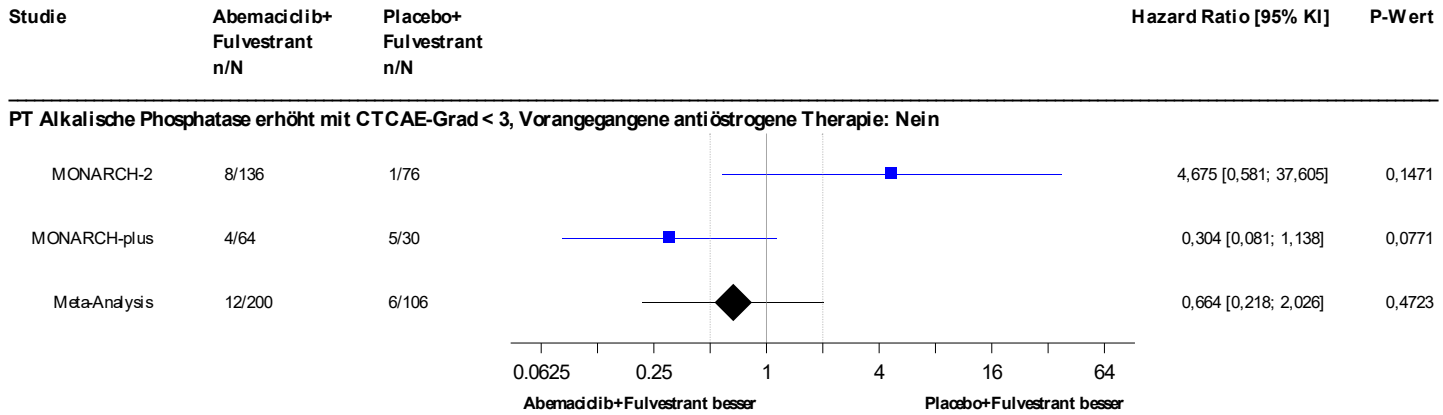
Abbildung 1450.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=4,7114, P-Wert=0,0300, I2 Index=78,8%
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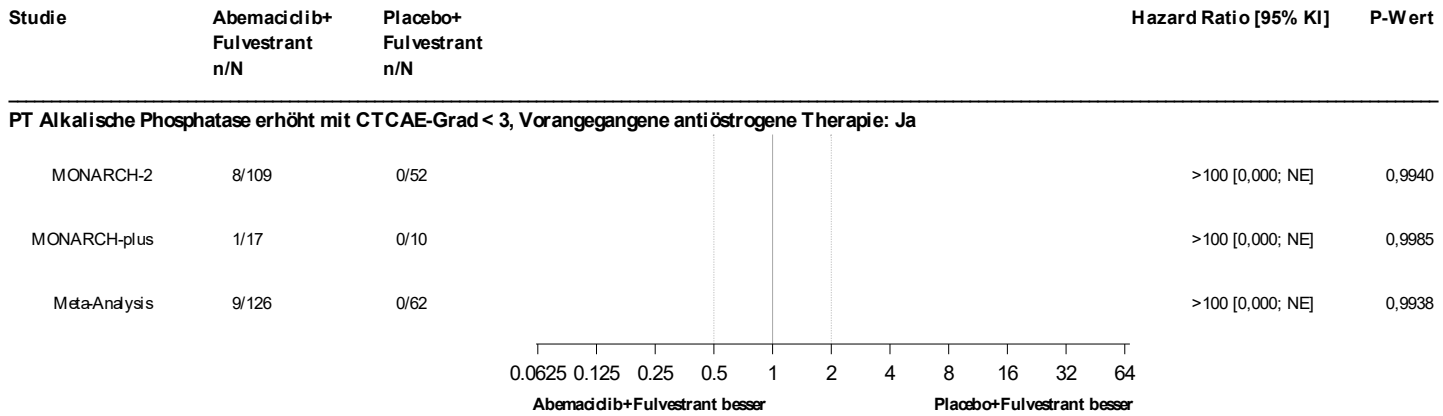
Abbildung 1450.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alkalische Phosphatase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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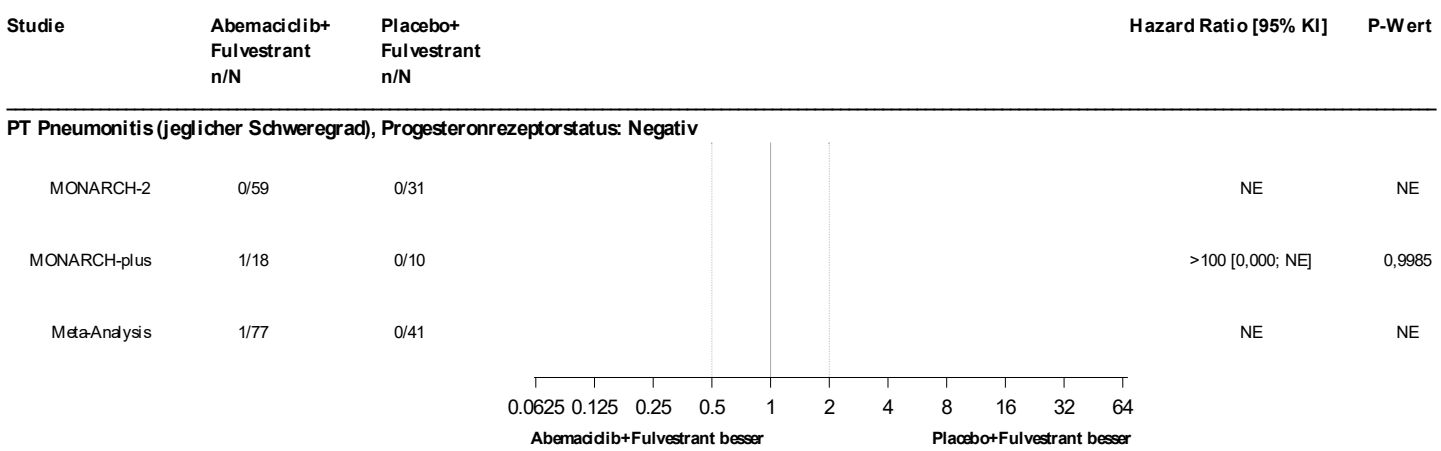
17SEP2021 / 07:48

Abbildung 1456.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Pneumonitis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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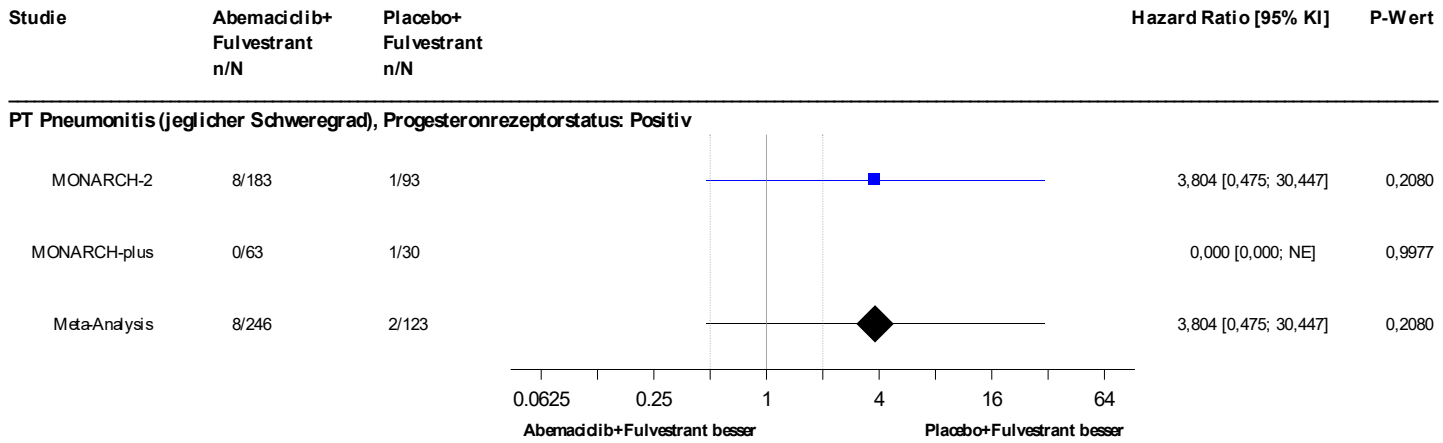
17SEP2021 / 07:48

Abbildung 1456.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Pneumonitis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9975, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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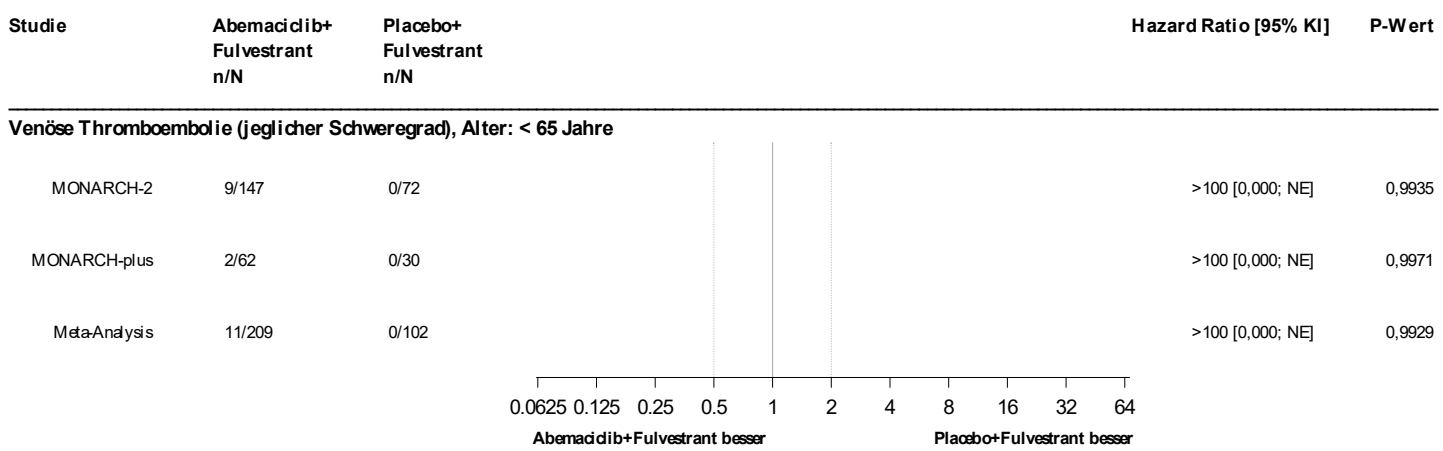
17SEP2021 / 07:48

Abbildung 1460.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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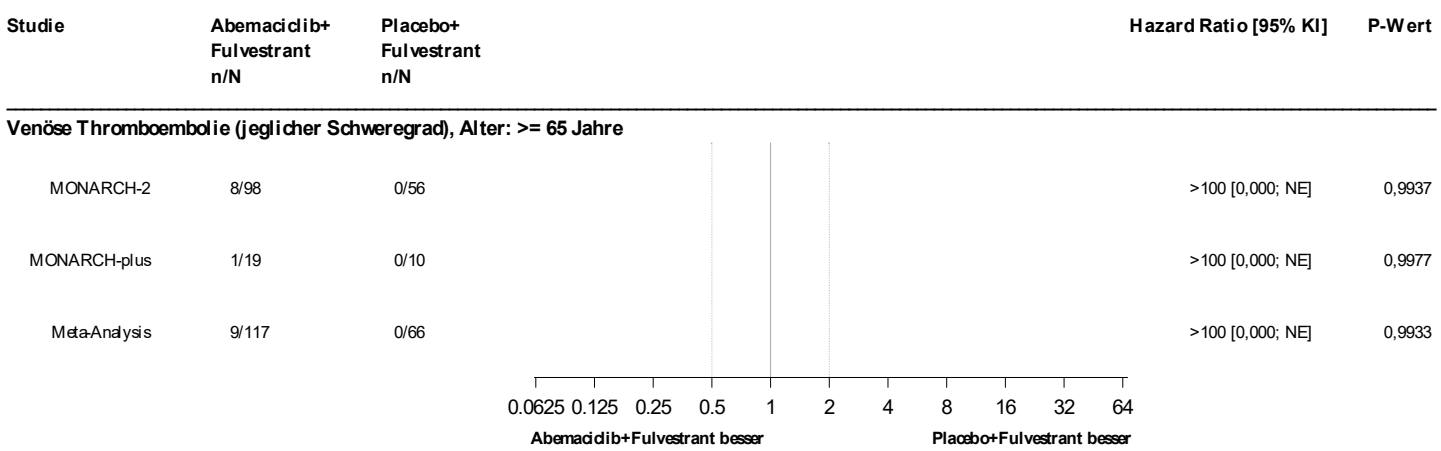
Abbildung 1460.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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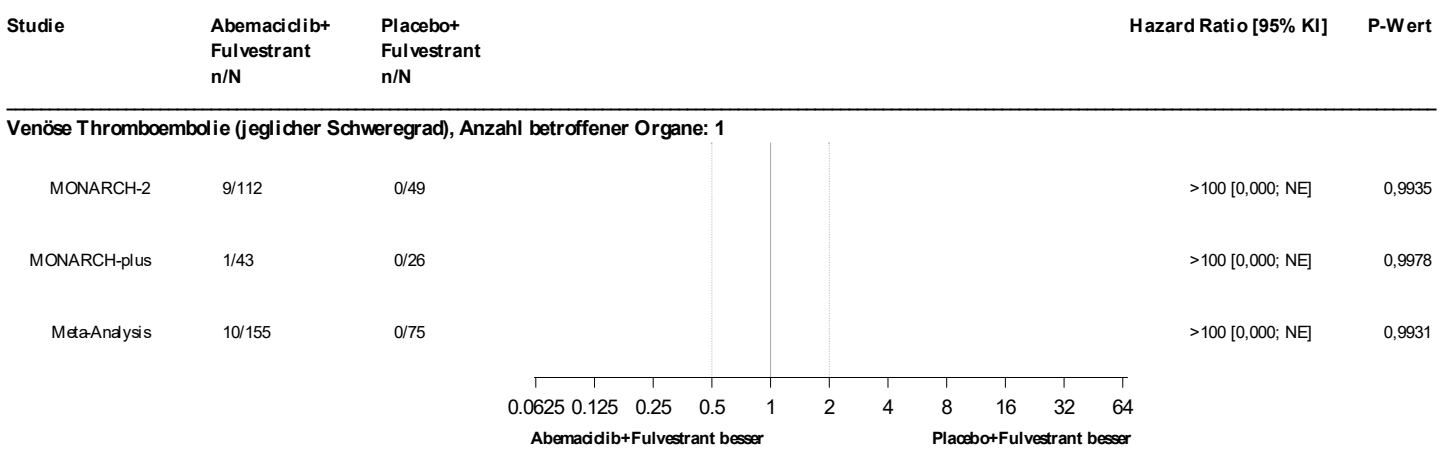
Abbildung 1460.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
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Abbildung 1460.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

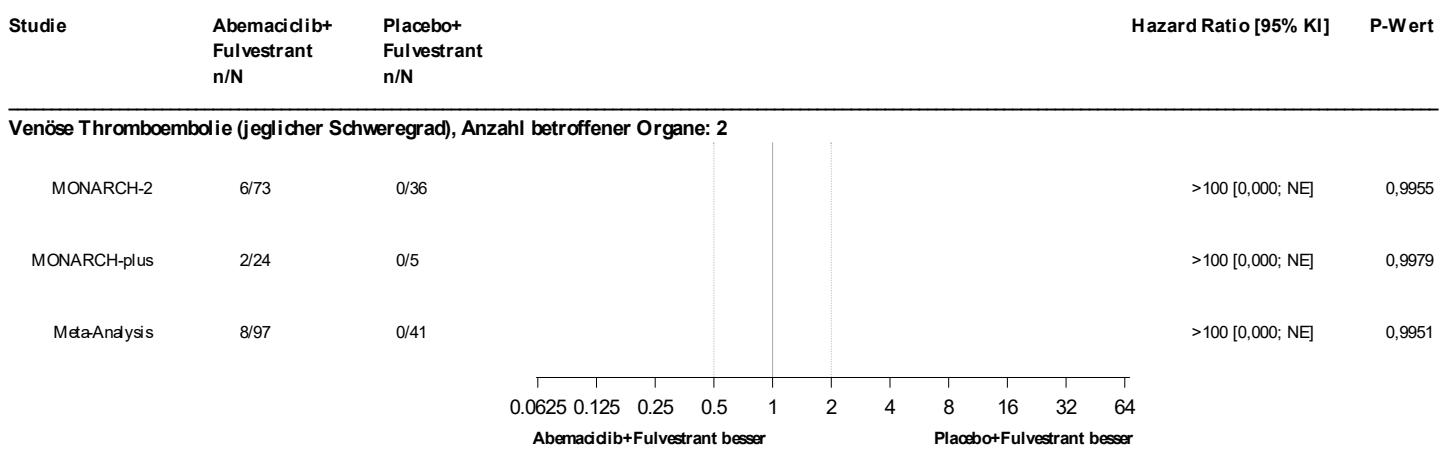

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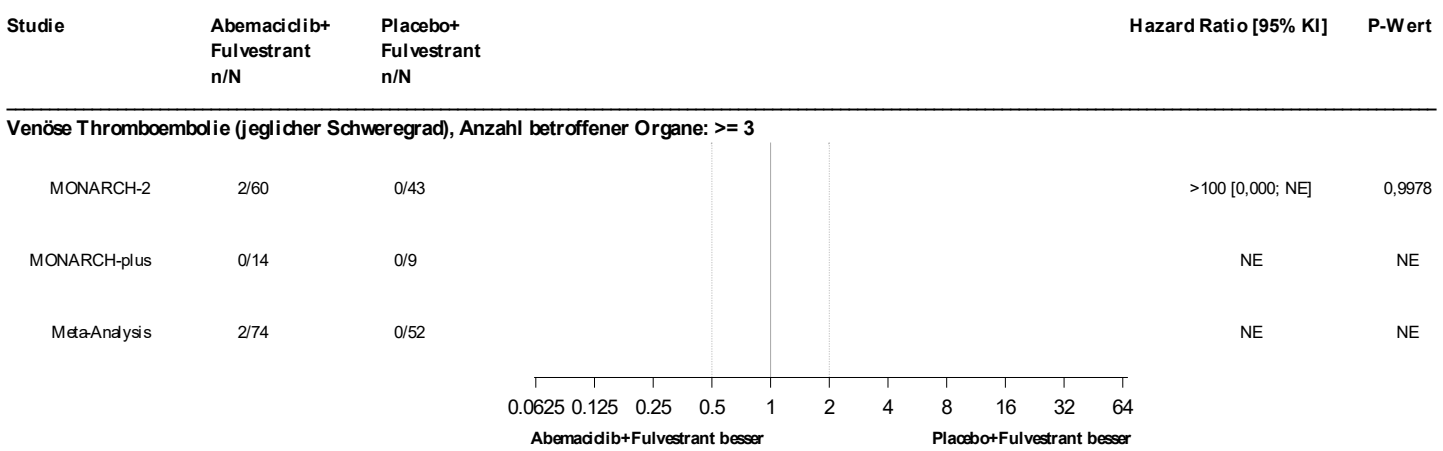
Abbildung 1460.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



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Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Abbildung 1460.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

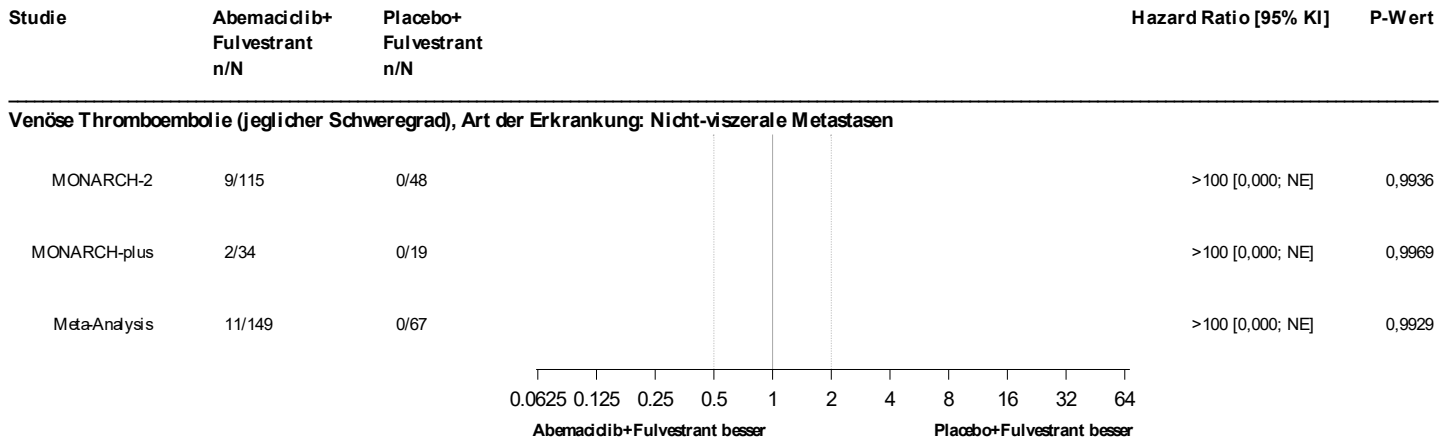

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Abbildung 1460.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

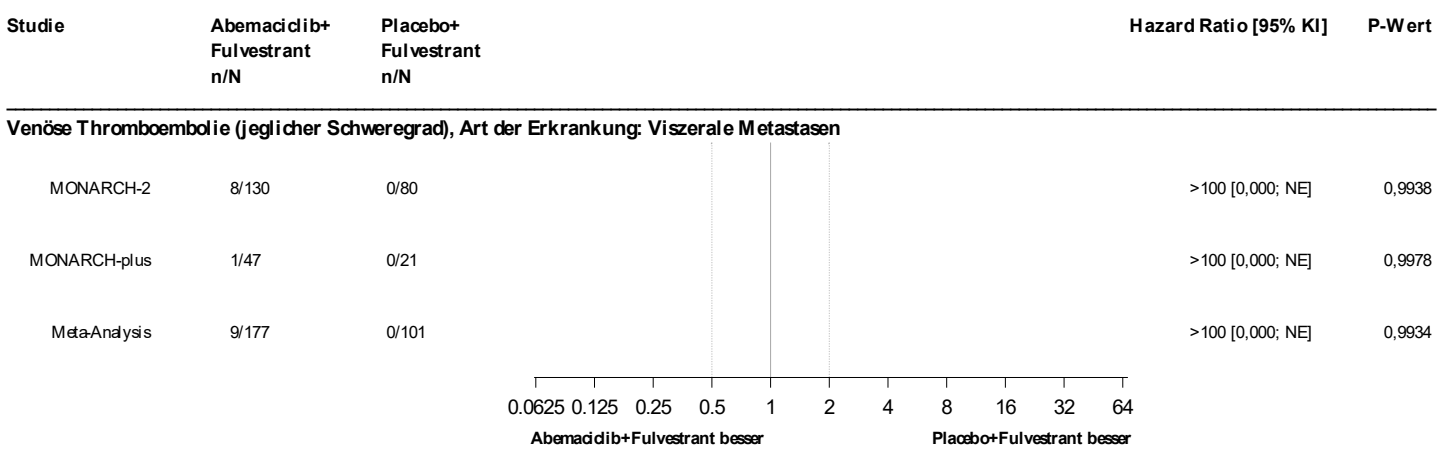

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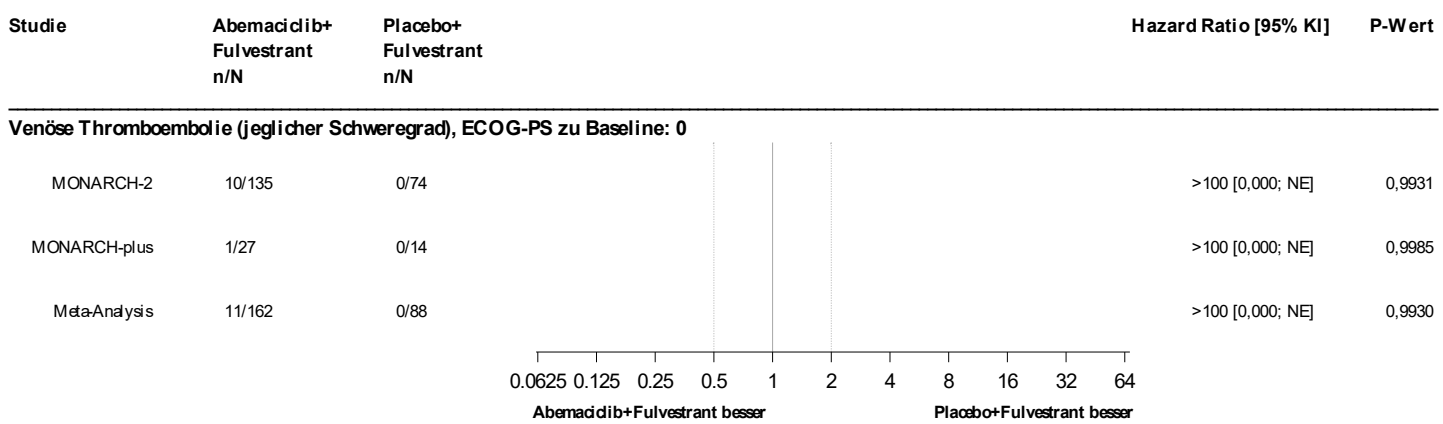
Abbildung 1460.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Abbildung 1460.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

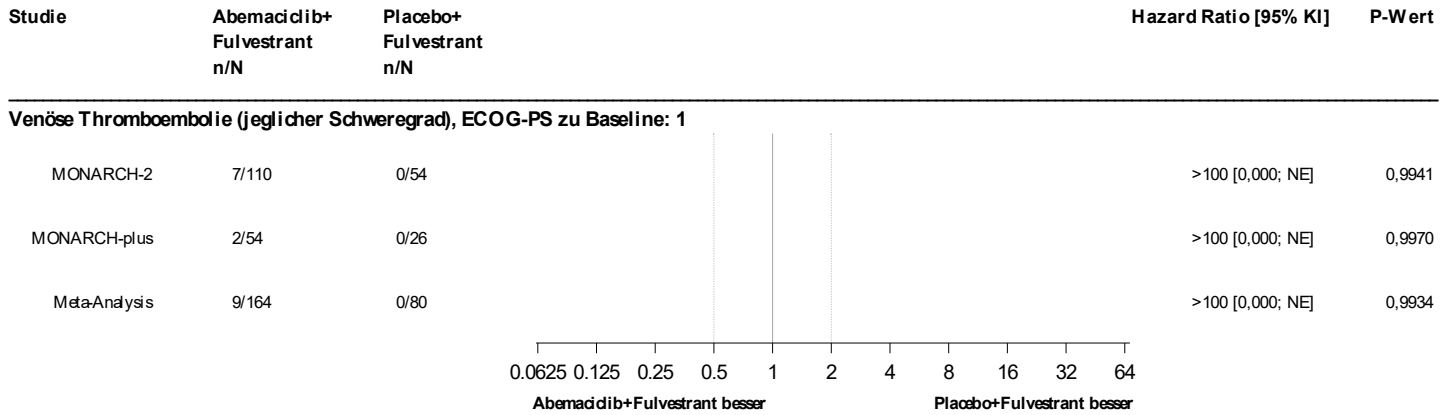

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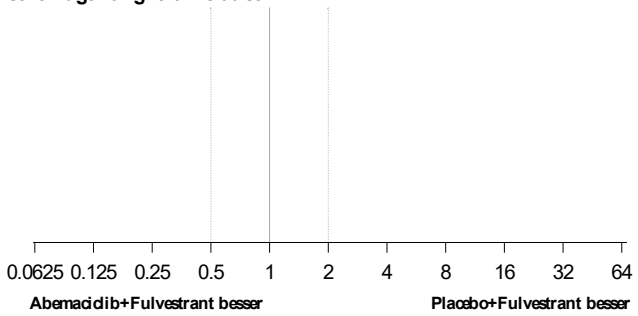
Abbildung 1460.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

Studie	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% KI]	P-Wert
Venöse Thromboembolie (jeglicher Schweregrad), Ethnische Zugehörigkeit: Asiatisch				
MONARCH-2	4/58	0/32	>100 [0,000; NE]	0,9953
MONARCH-plus	2/73	0/35	>100 [0,000; NE]	0,9972
Meta-Analysis	6/131	0/67	>100 [0,000; NE]	0,9945



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Abbildung 1460.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

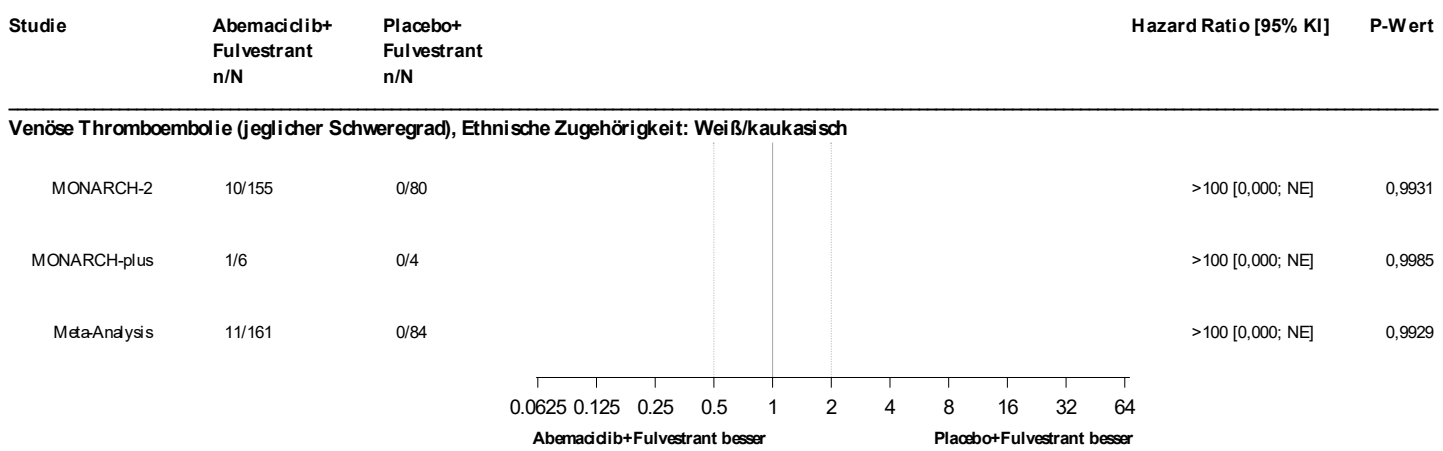

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Abbildung 1460.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

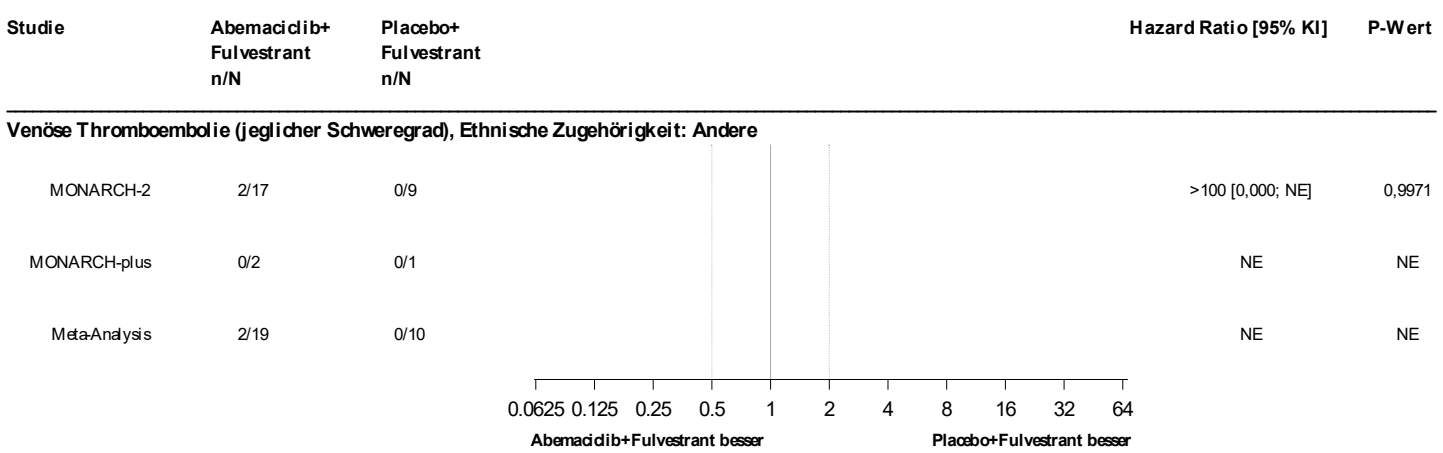

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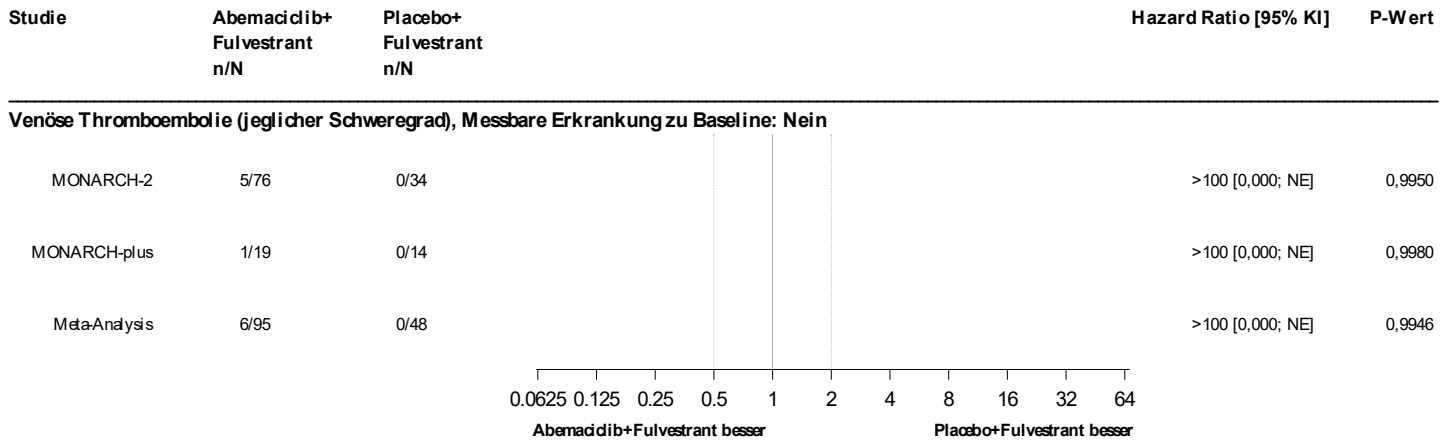
Abbildung 1460.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
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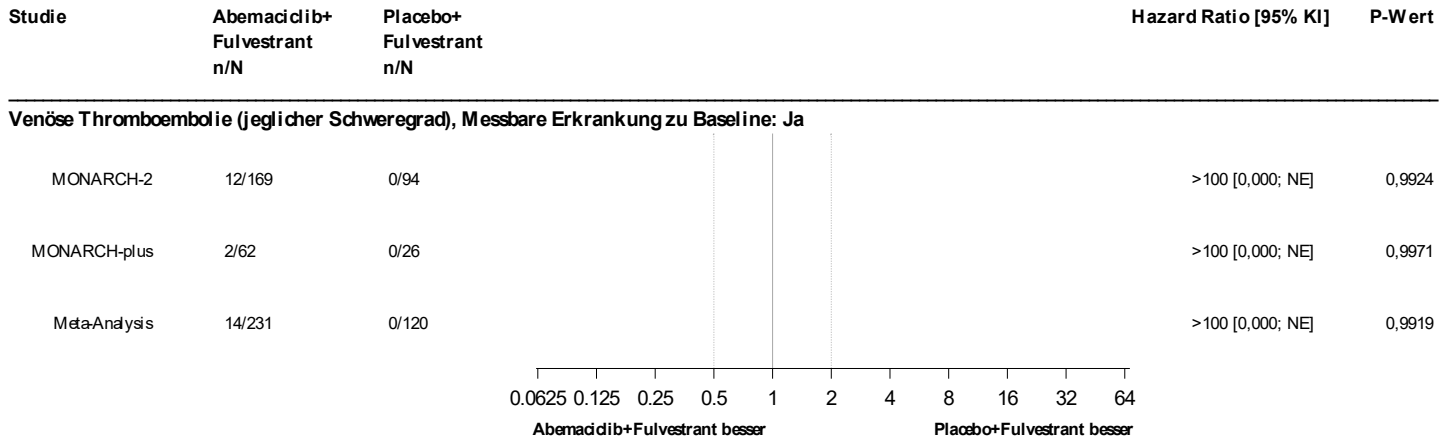
Abbildung 1460.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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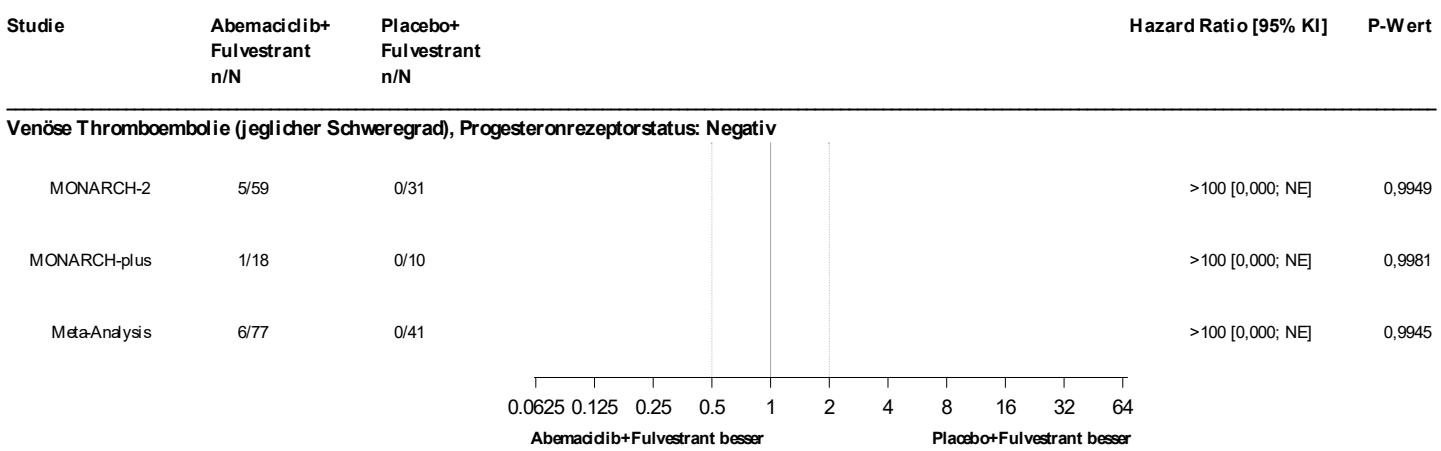
Abbildung 1460.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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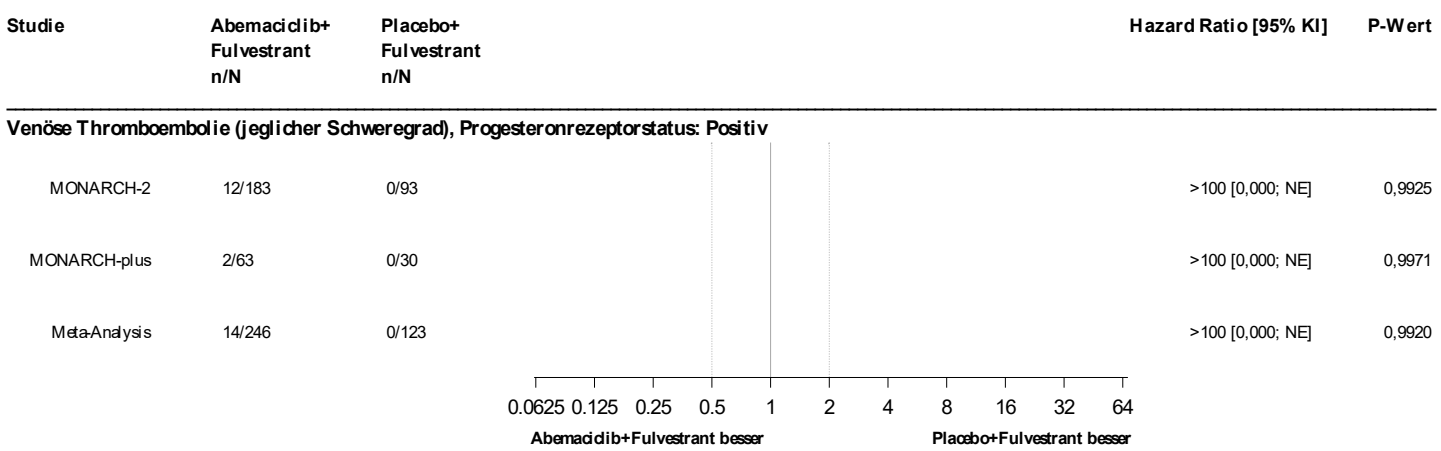
Abbildung 1460.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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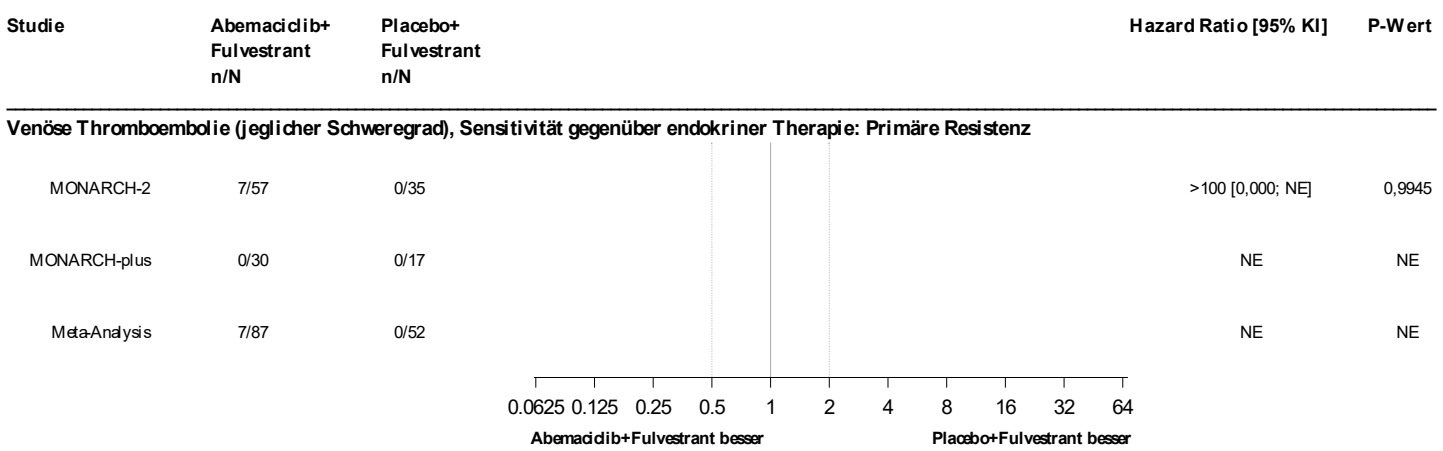
Abbildung 1460.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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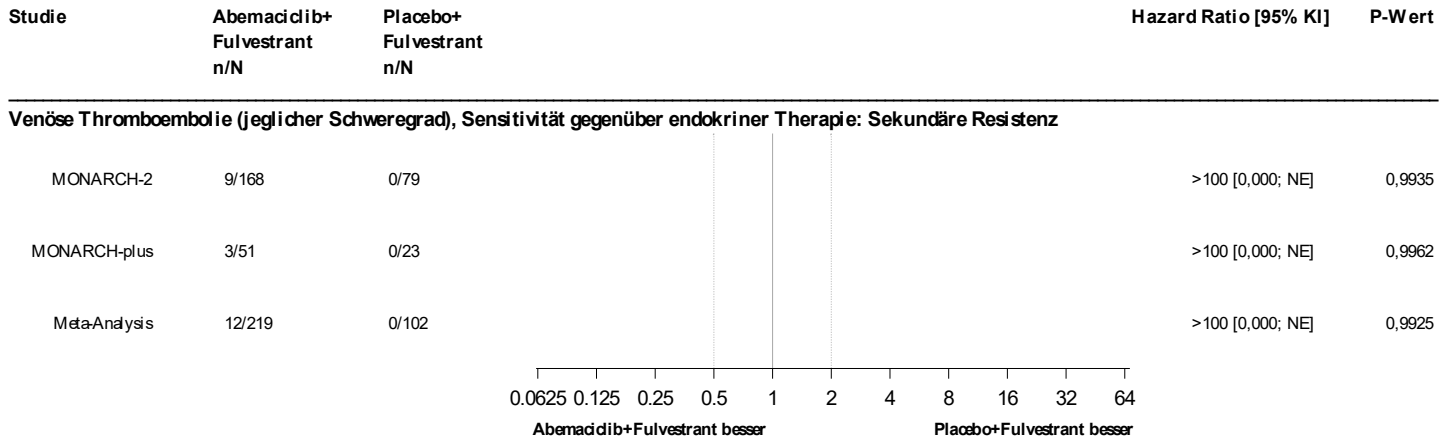
Abbildung 1460.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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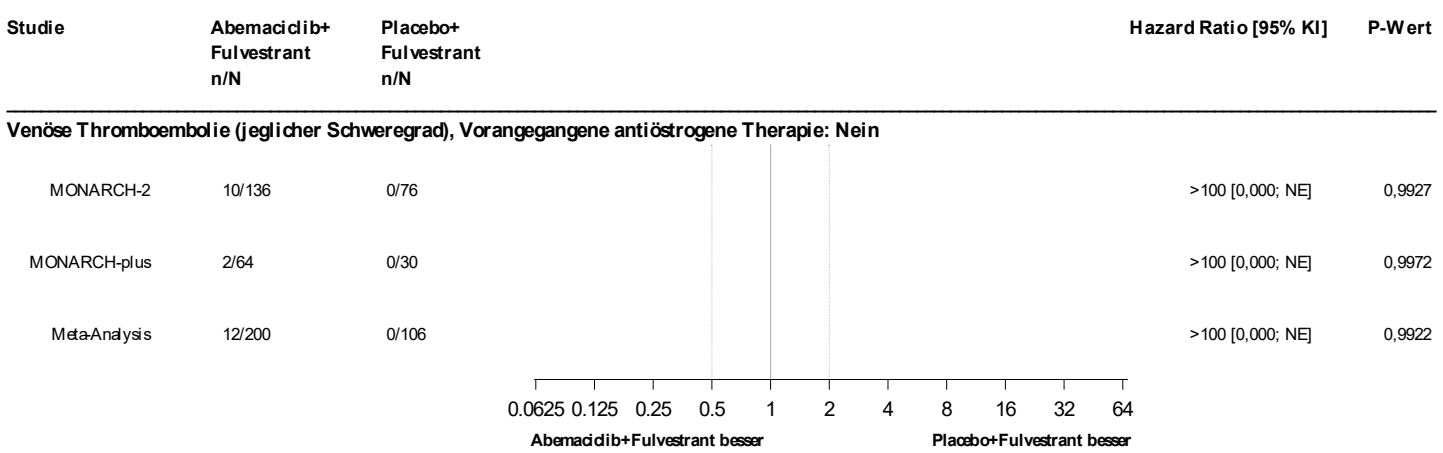
Abbildung 1460.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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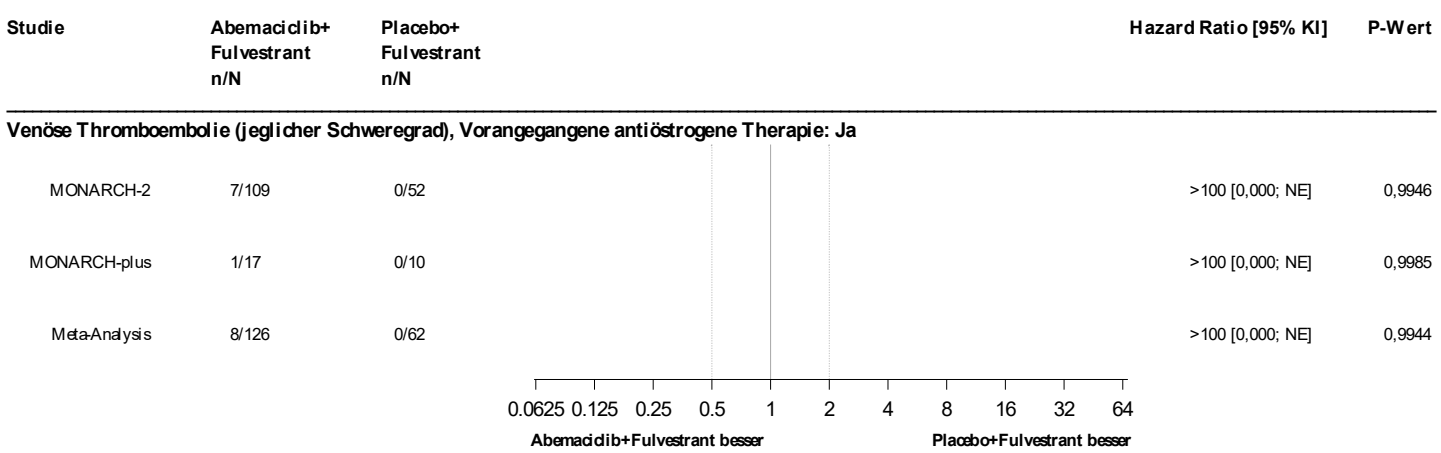
Abbildung 1460.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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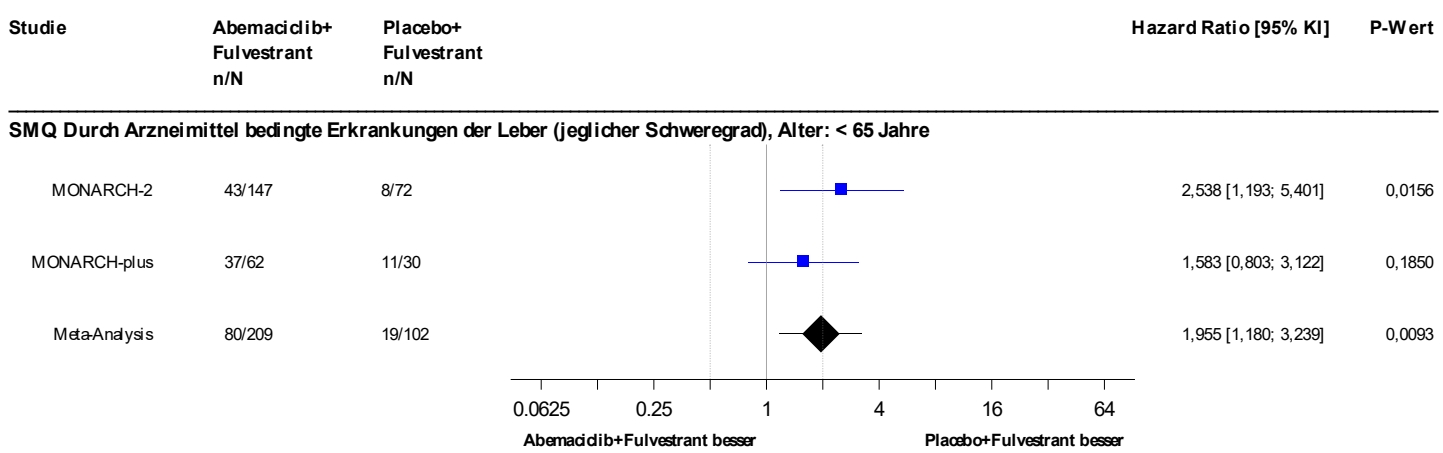
Abbildung 1464.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,8299, P-Wert=0,3623, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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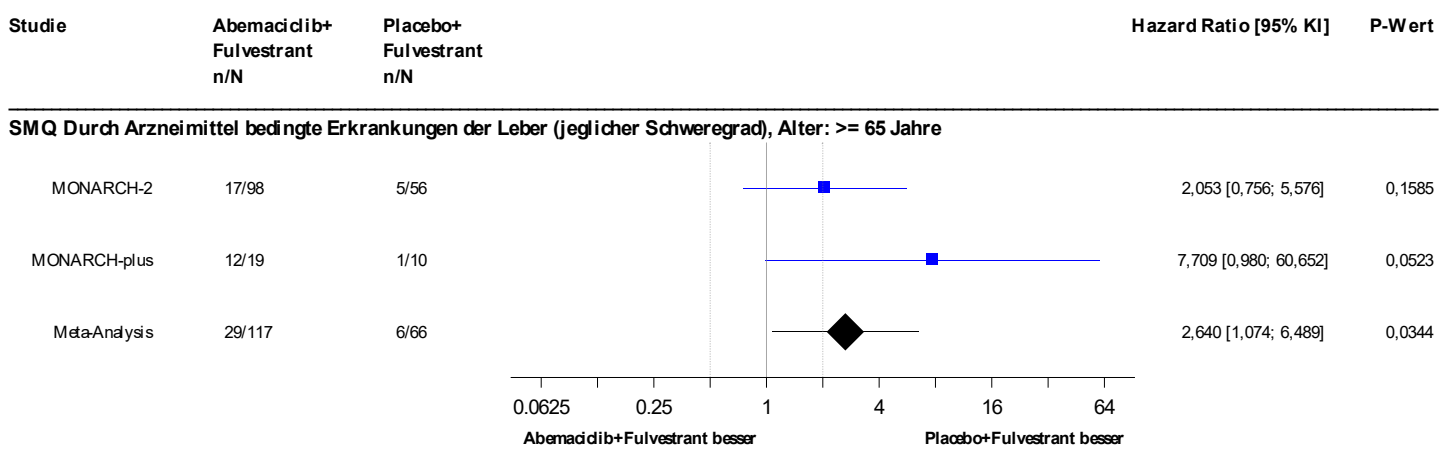
Abbildung 1464.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,2802, P-Wert=0,2579, I2 Index=21,9%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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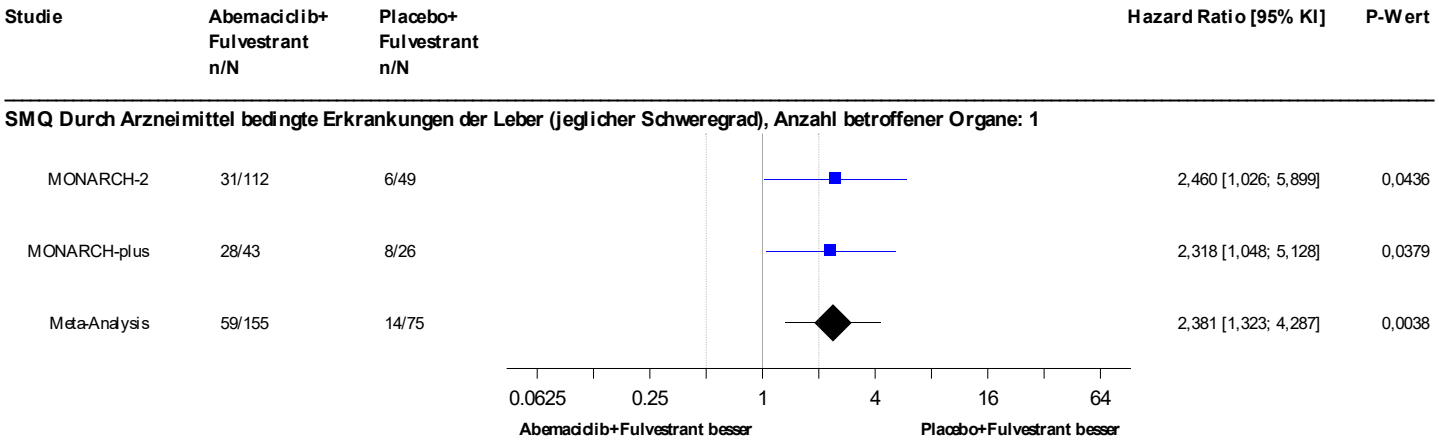
Abbildung 1464.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0097, P-Wert=0,9215, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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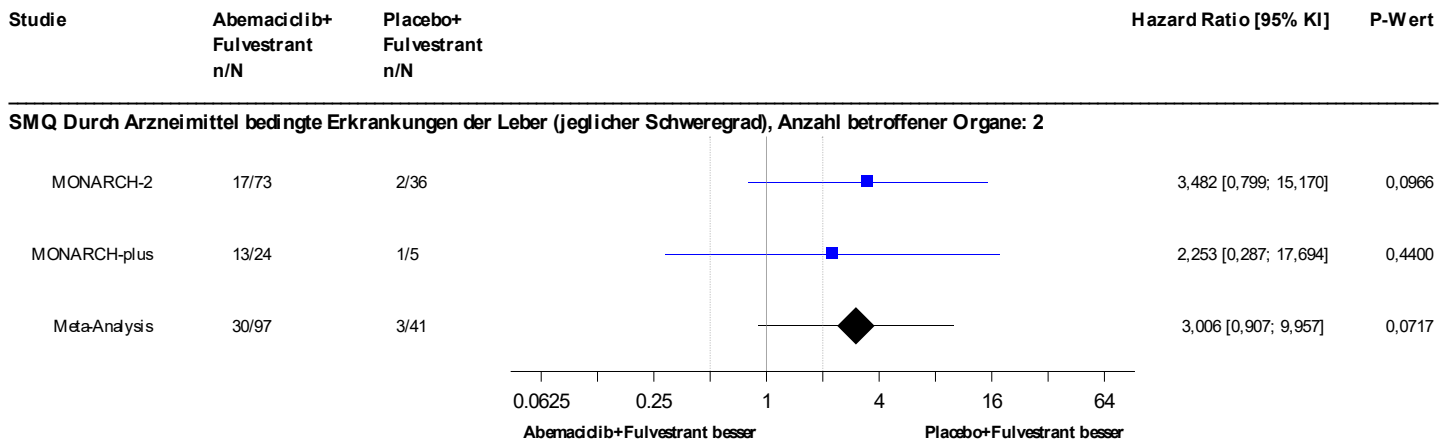
Abbildung 1464.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1136, P-Wert=0,7361, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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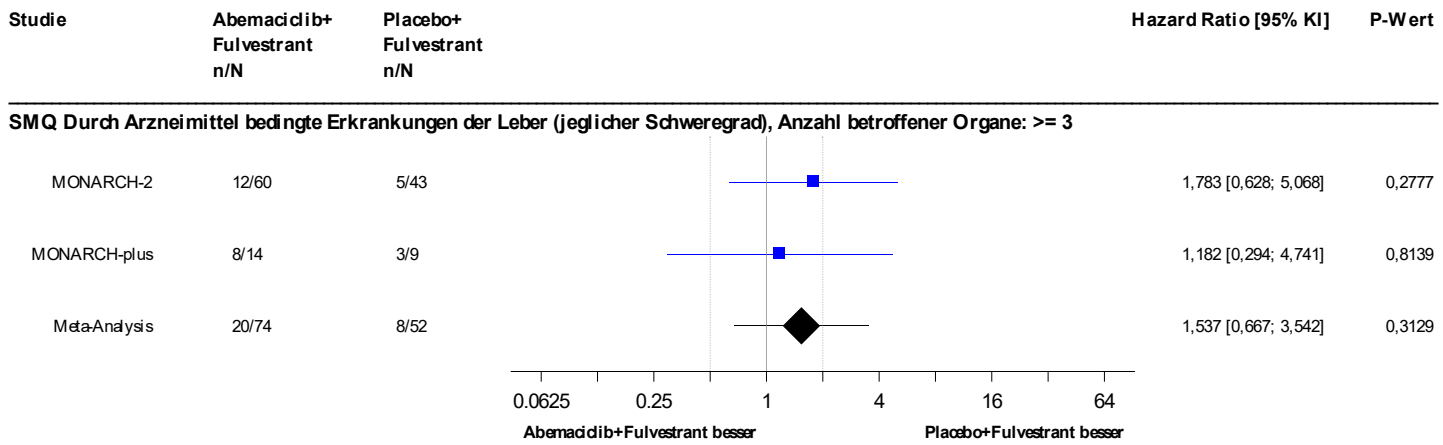
Abbildung 1464.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2154, P-Wert=0,6426, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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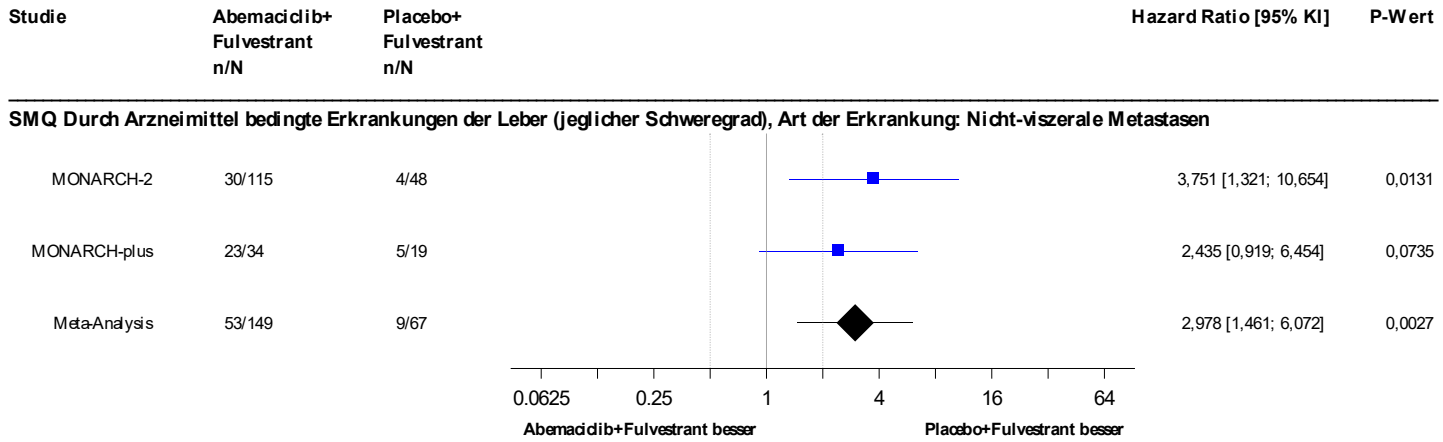
Abbildung 1464.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,3514, P-Wert=0,5533, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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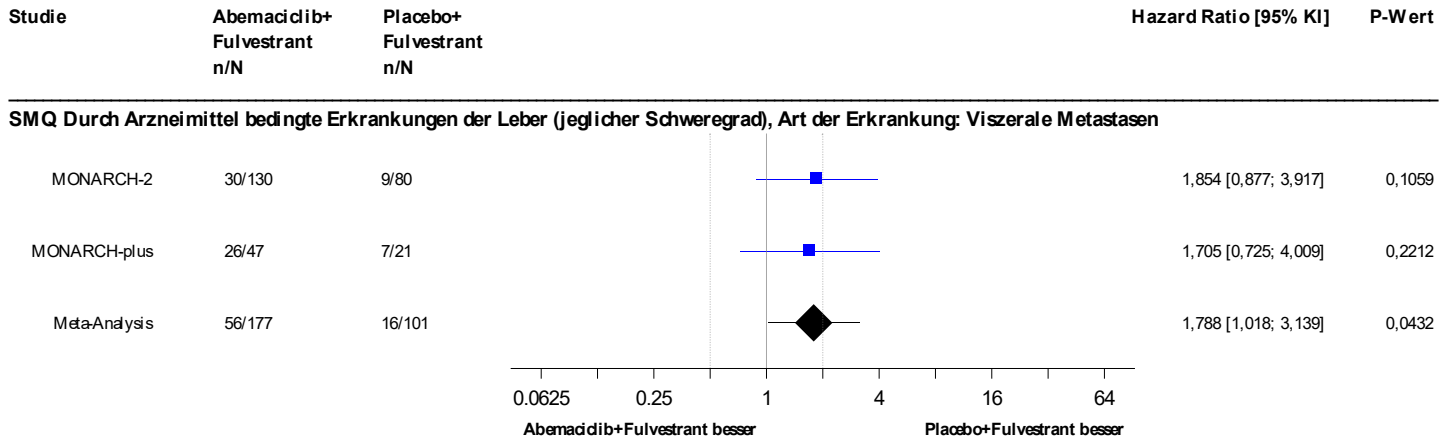
Abbildung 1464.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0207, P-Wert=0,8855, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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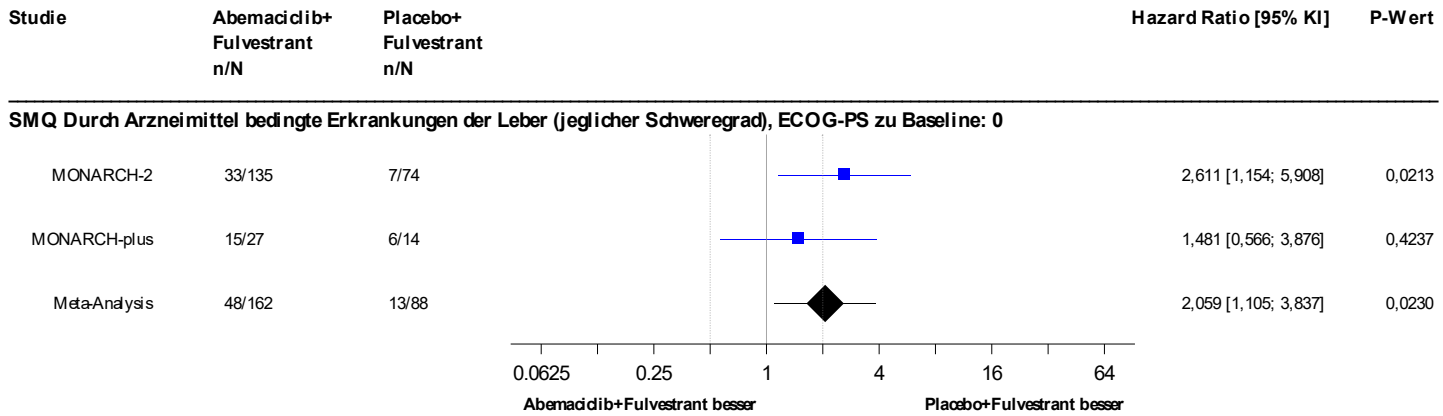
Abbildung 1464.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7754, P-Wert=0,3786, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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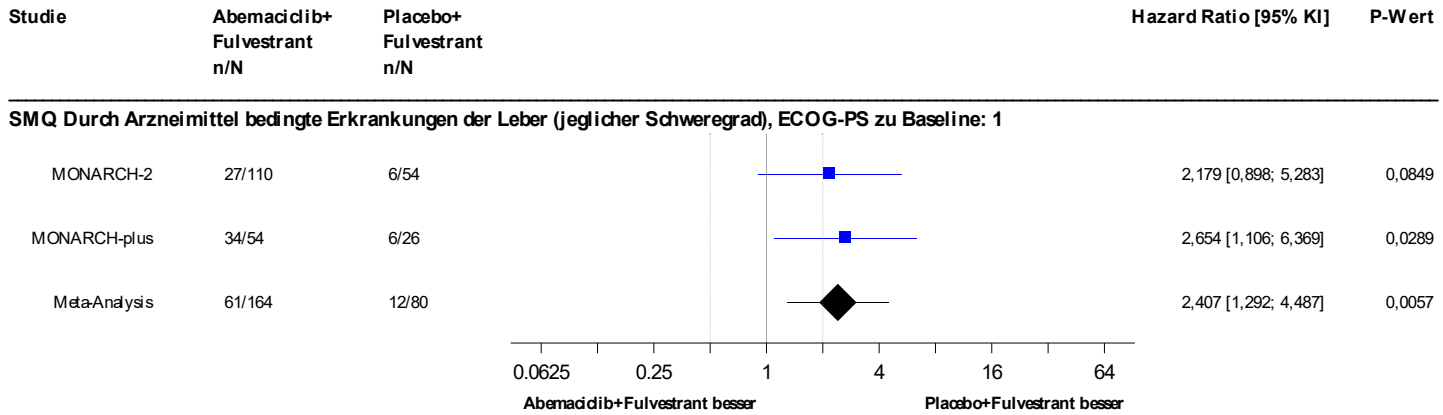
17SEP2021 / 07:48

Abbildung 1464.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0965, P-Wert=0,7561, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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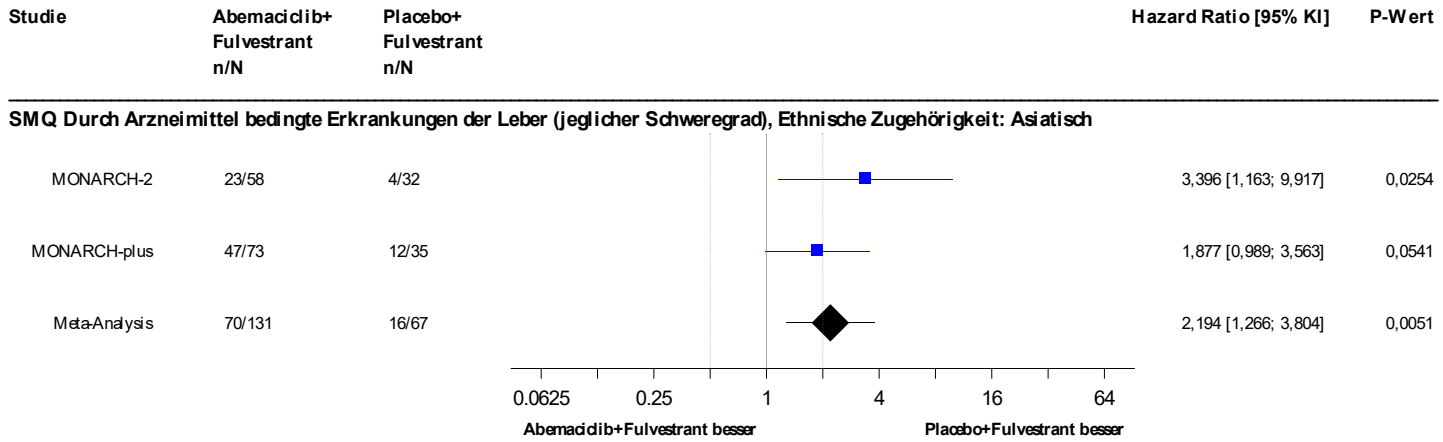
Abbildung 1464.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,8654, P-Wert=0,3522, I2 Index=0%
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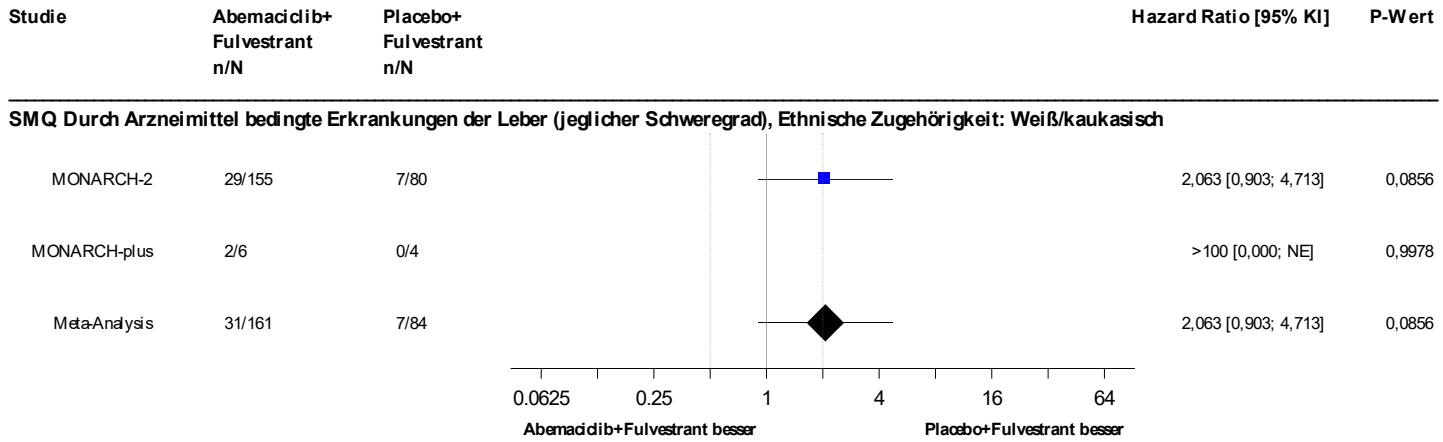
Abbildung 1464.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9979, I2 Index=0%
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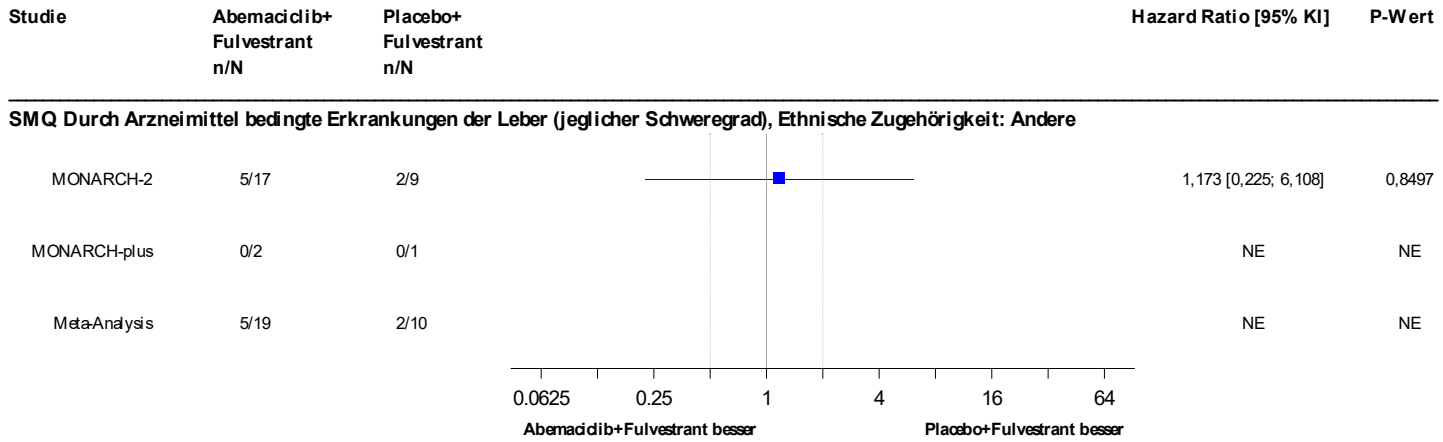
Abbildung 1464.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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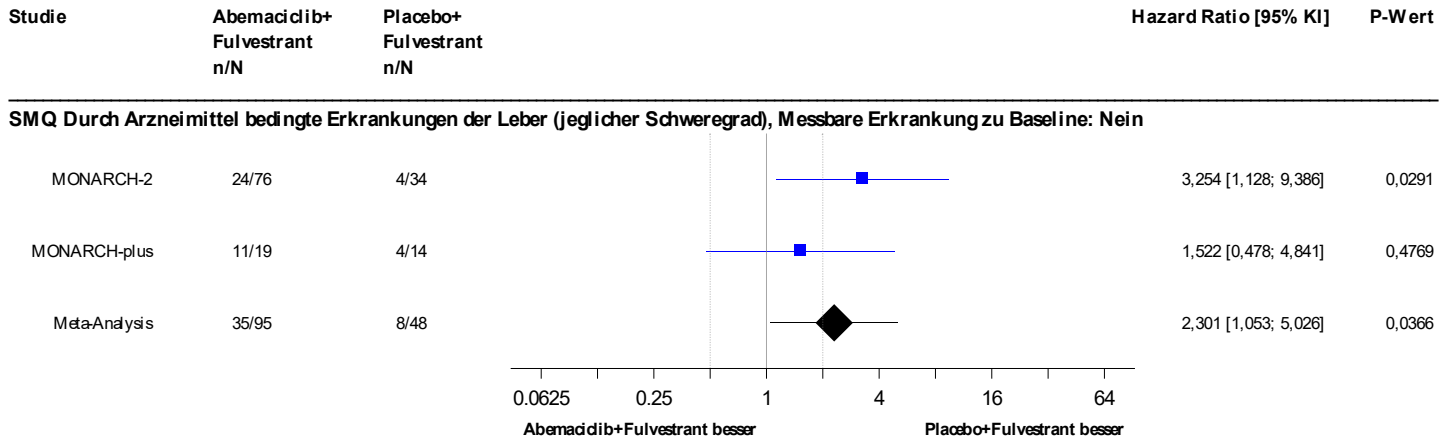
Abbildung 1464.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,9011, P-Wert=0,3425, I2 Index=0%
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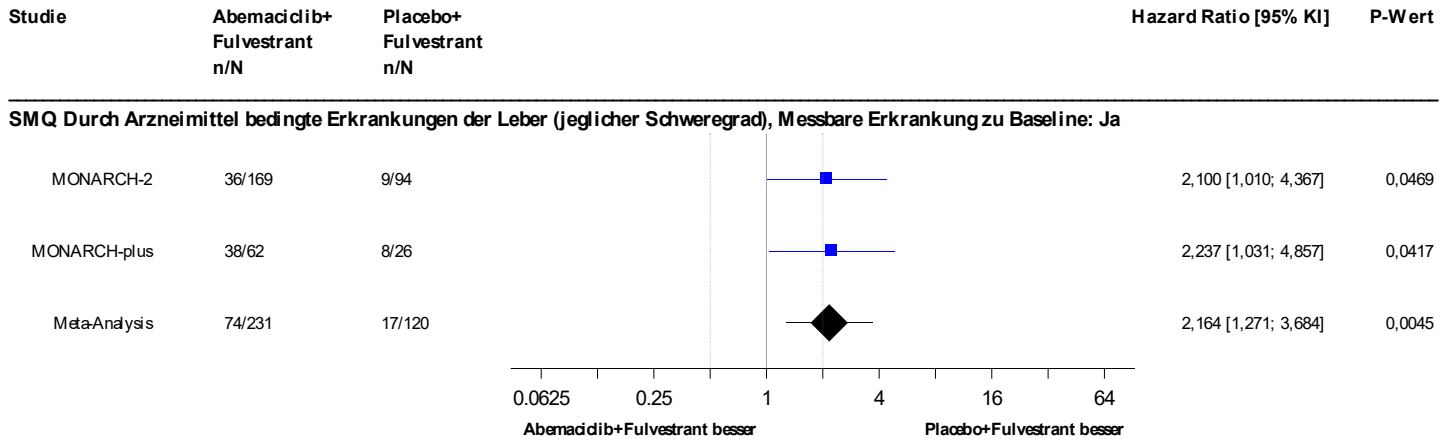
Abbildung 1464.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0135, P-Wert=0,9075, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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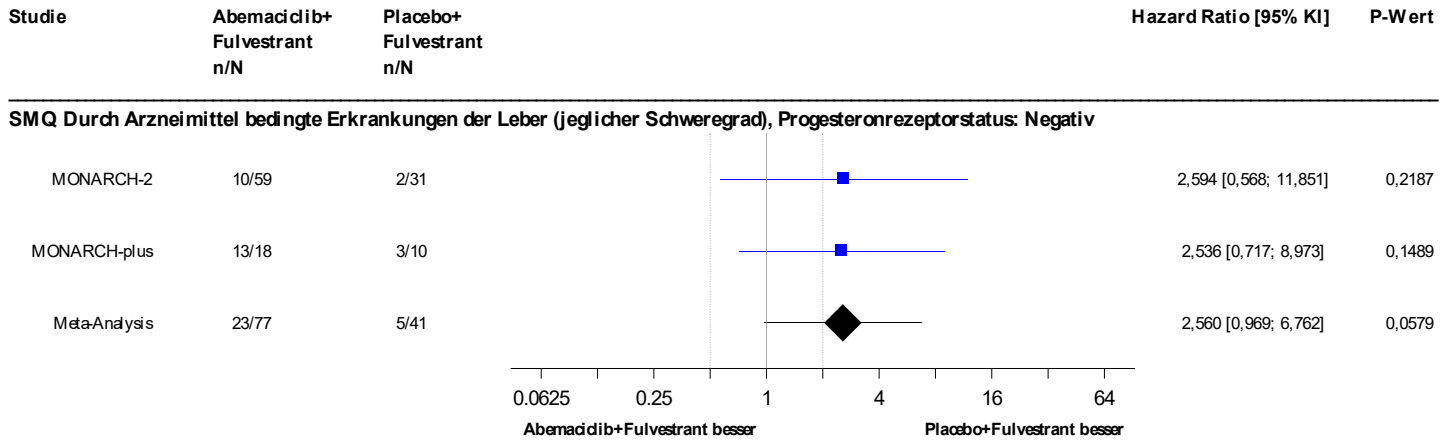
Abbildung 1464.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0005, P-Wert=0,9820, I2 Index=0%
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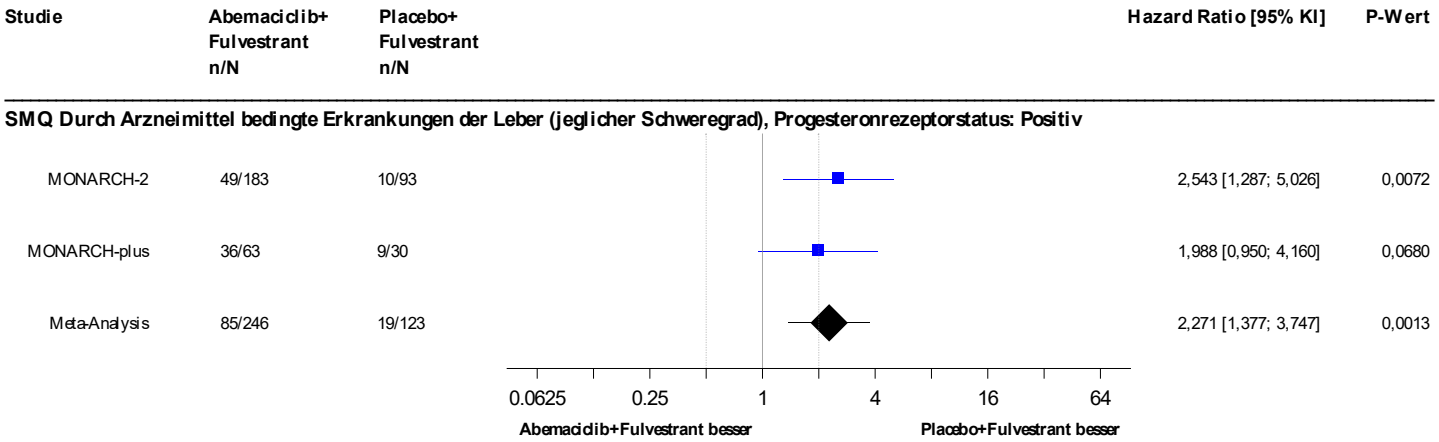
Abbildung 1464.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2307, P-Wert=0,6310, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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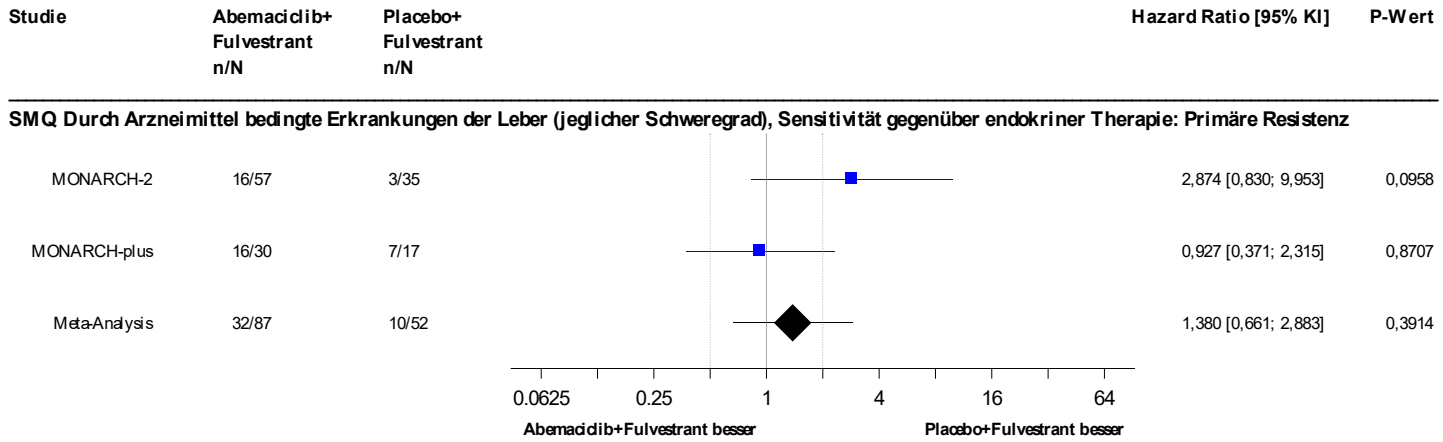
Abbildung 1464.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=2,0666, P-Wert=0,1506, I2 Index=51,6%
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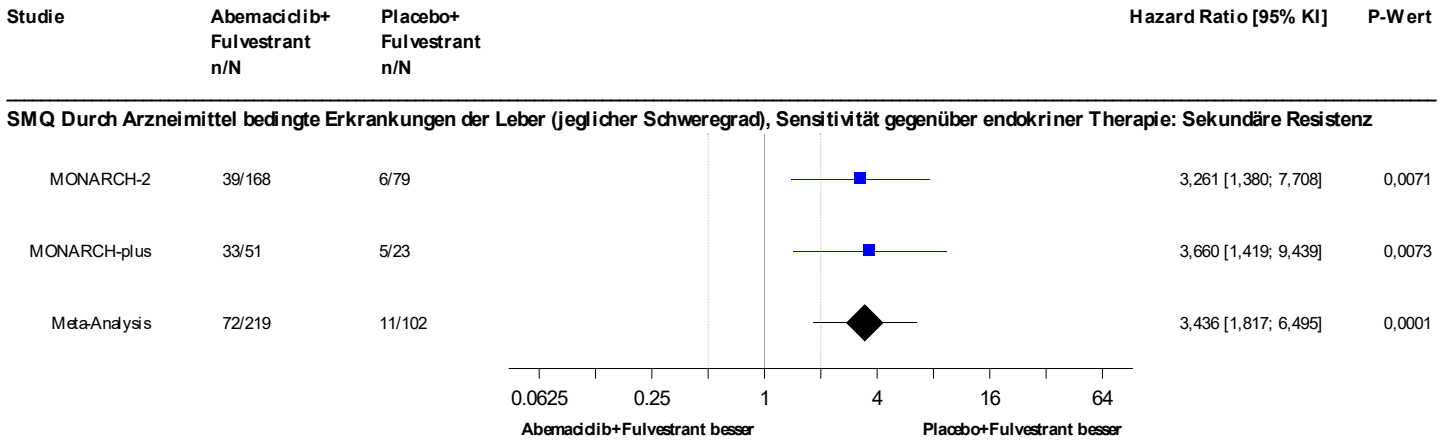
Abbildung 1464.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0312, P-Wert=0,8598, I2 Index=0%
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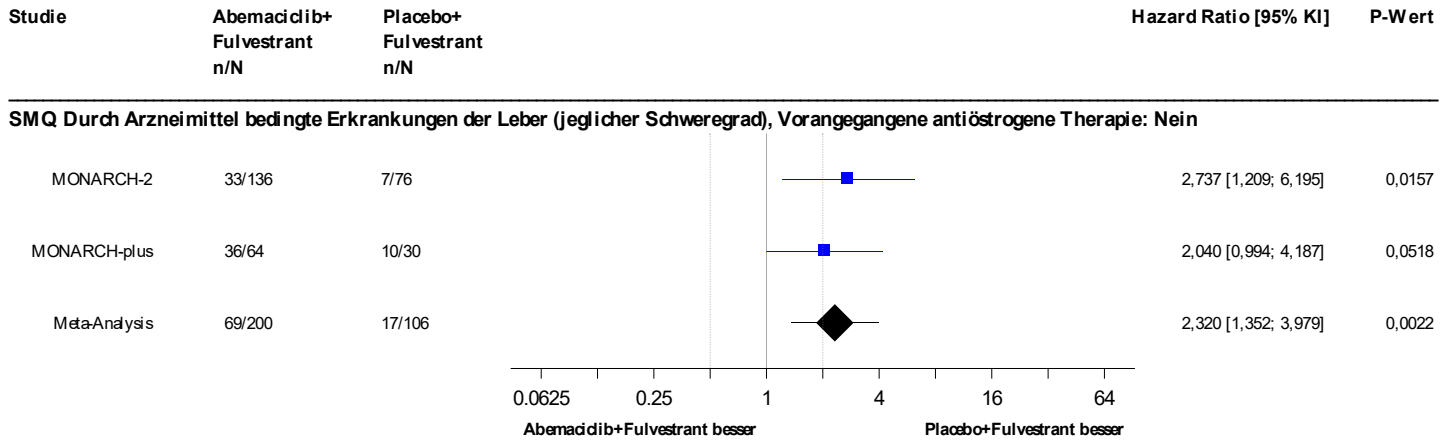
Abbildung 1464.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2800, P-Wert=0,5967, I2 Index=0%
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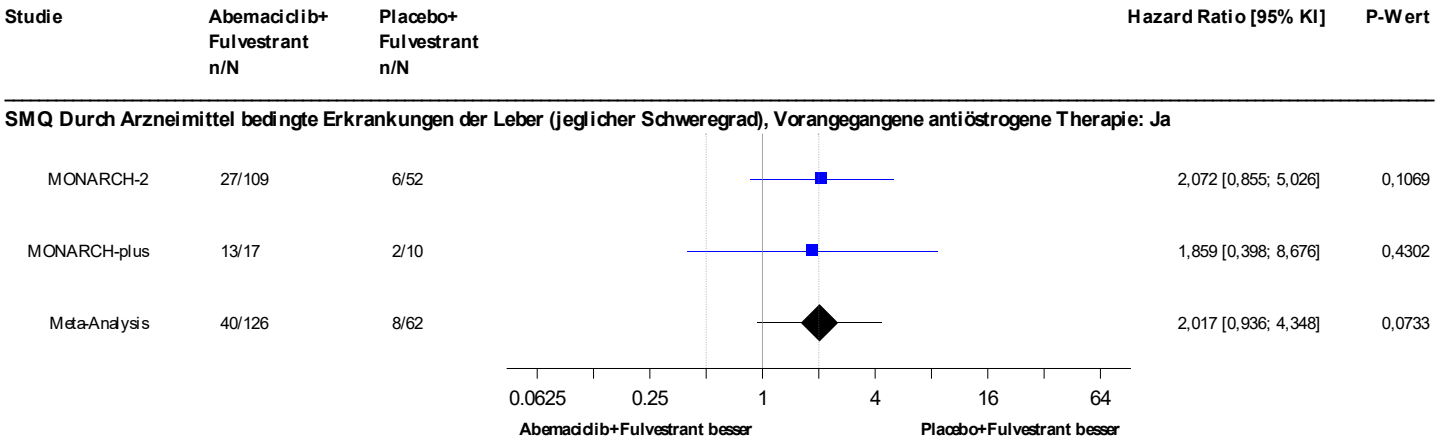
Abbildung 1464.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0144, P-Wert=0,9045, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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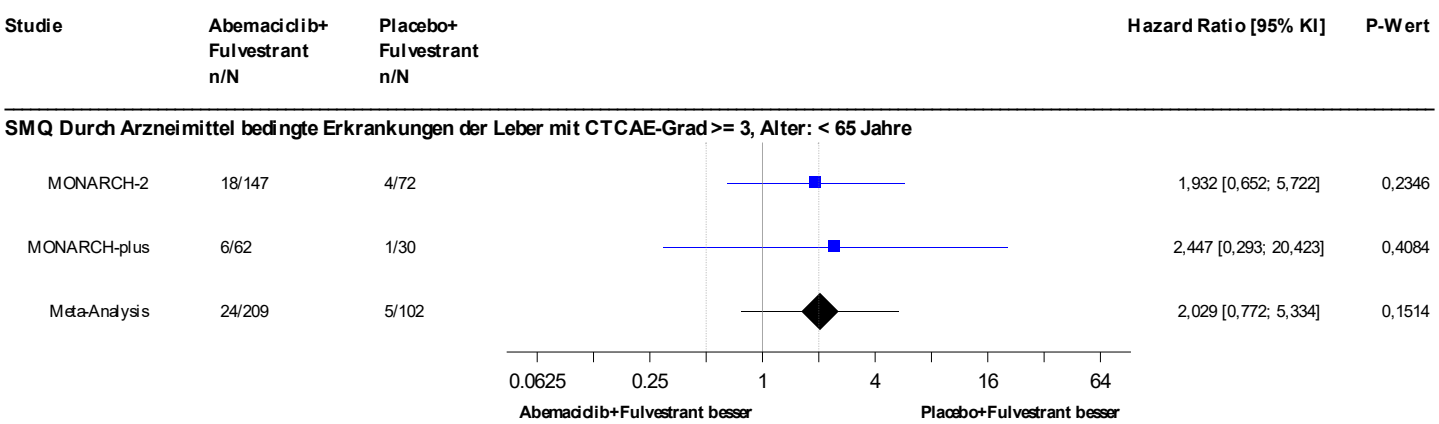
Abbildung 1465.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0378, P-Wert=0,8458, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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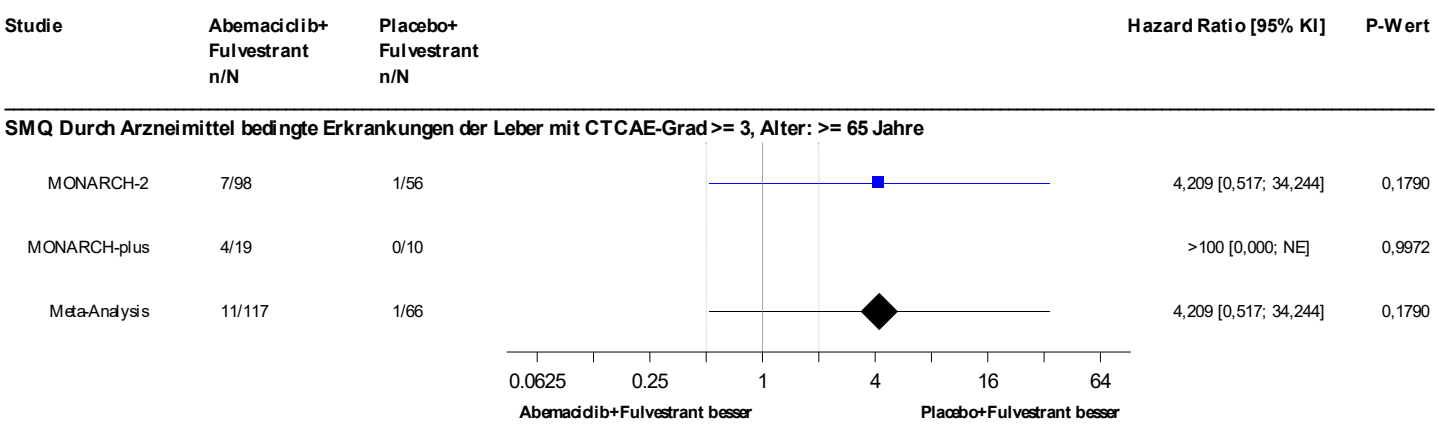
Abbildung 1465.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9974, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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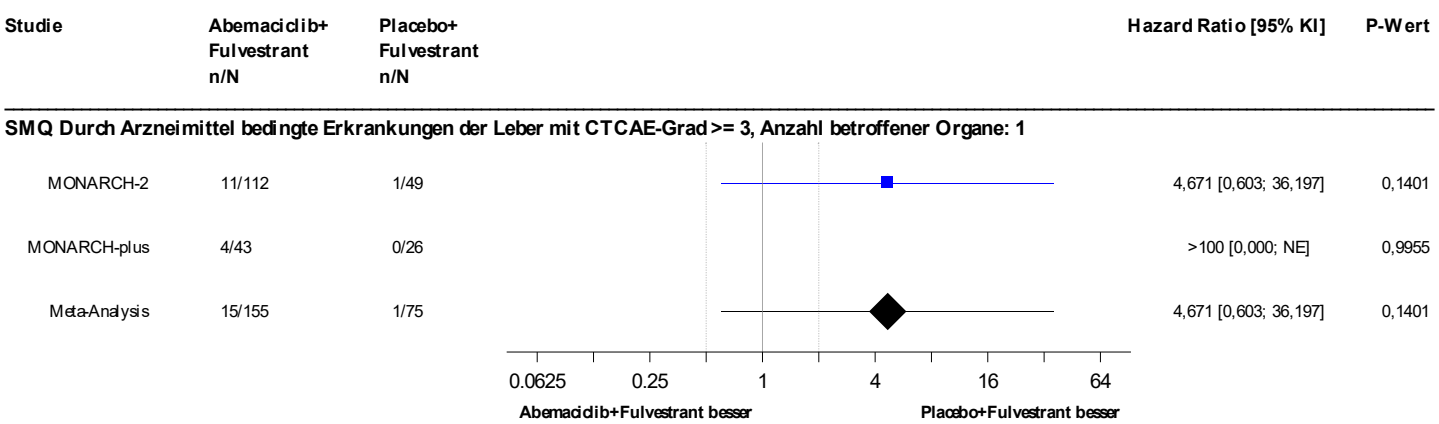
Abbildung 1465.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9959, I2 Index=0%
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Abbildung 1465.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

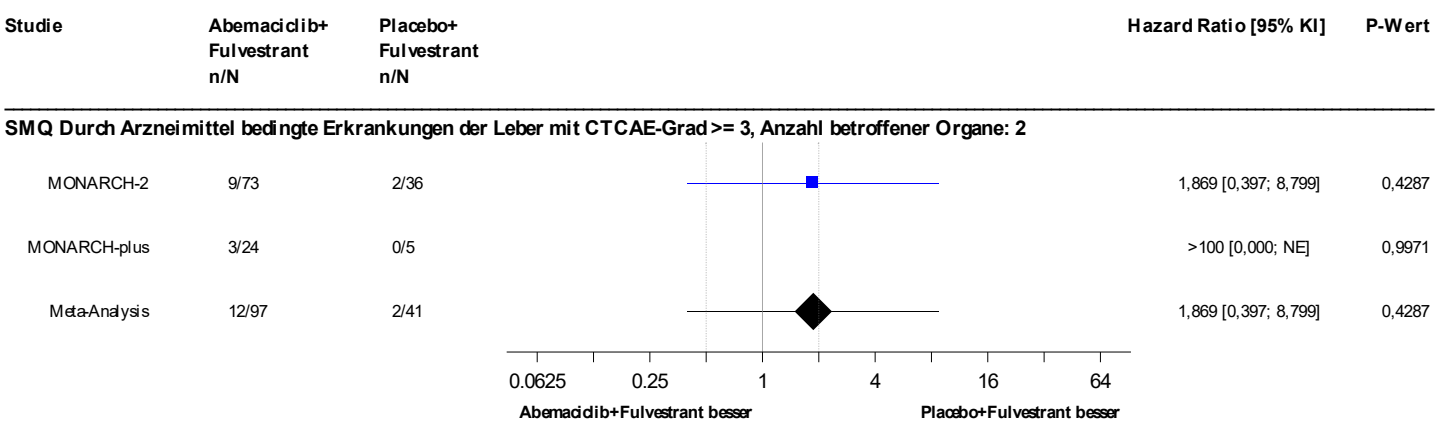

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Abbildung 1465.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

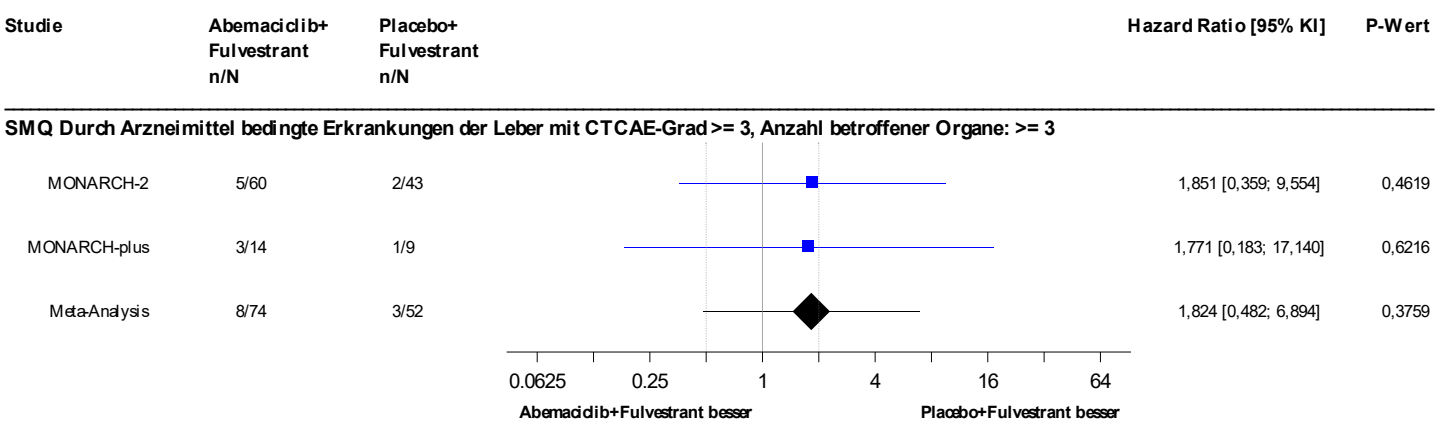

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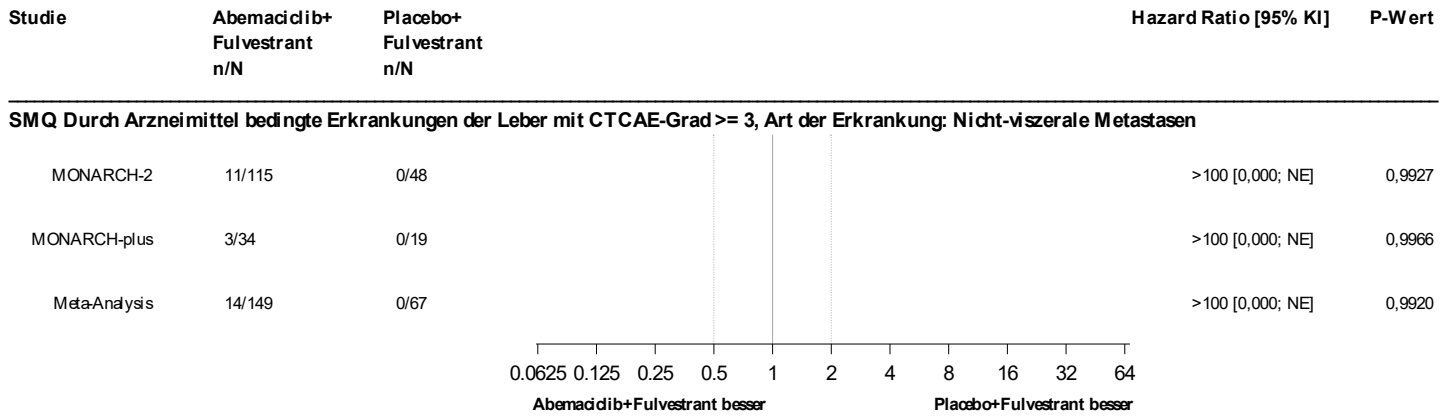
Abbildung 1465.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
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Abbildung 1465.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

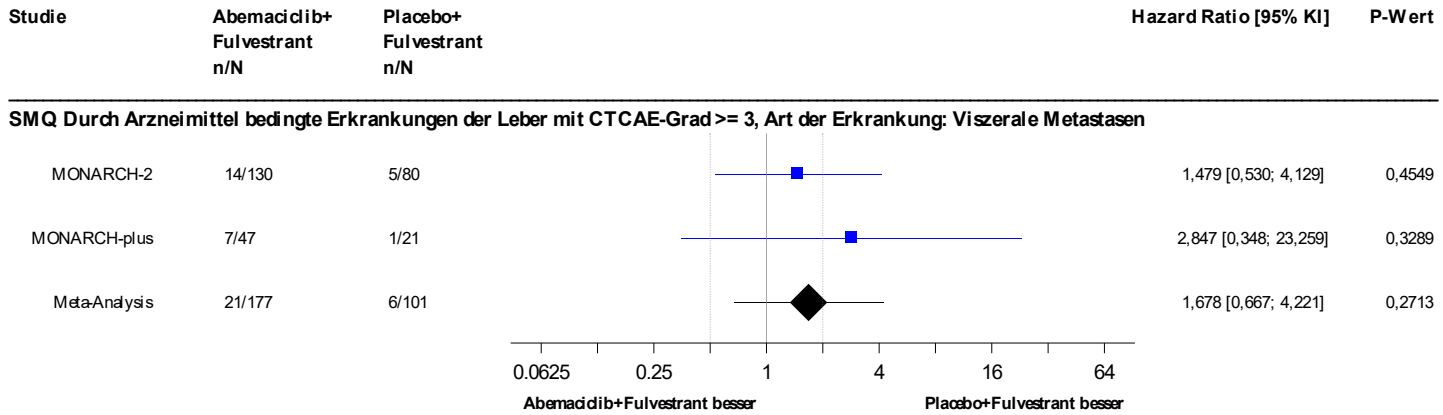

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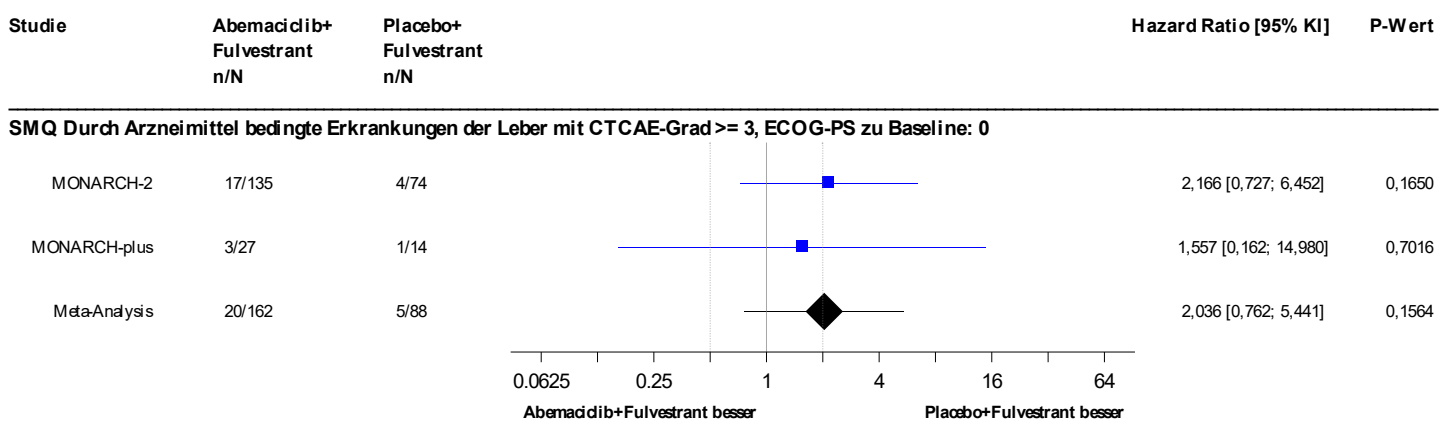
Abbildung 1465.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0664, P-Wert=0,7966, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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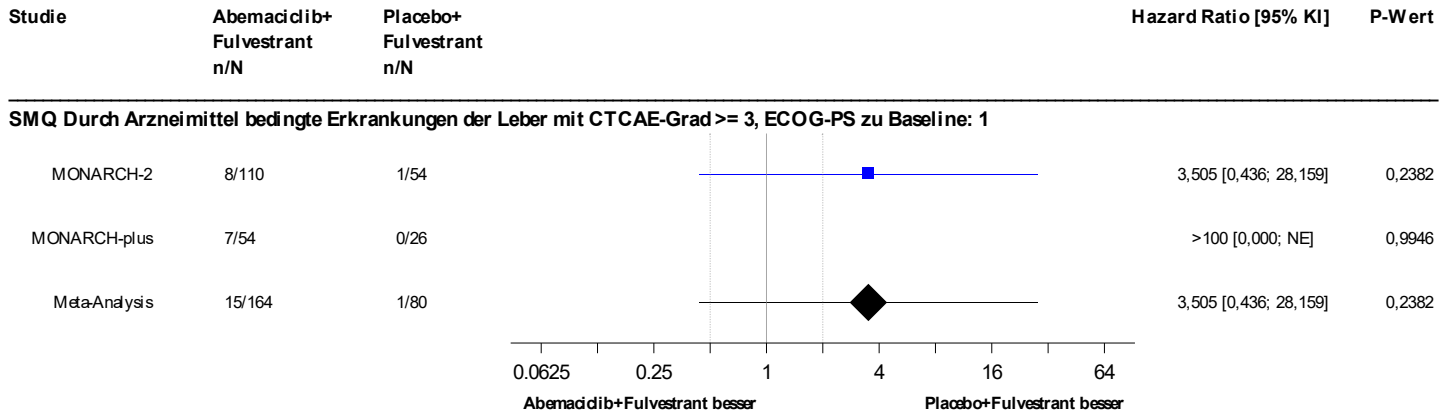
Abbildung 1465.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9950, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Abbildung 1465.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

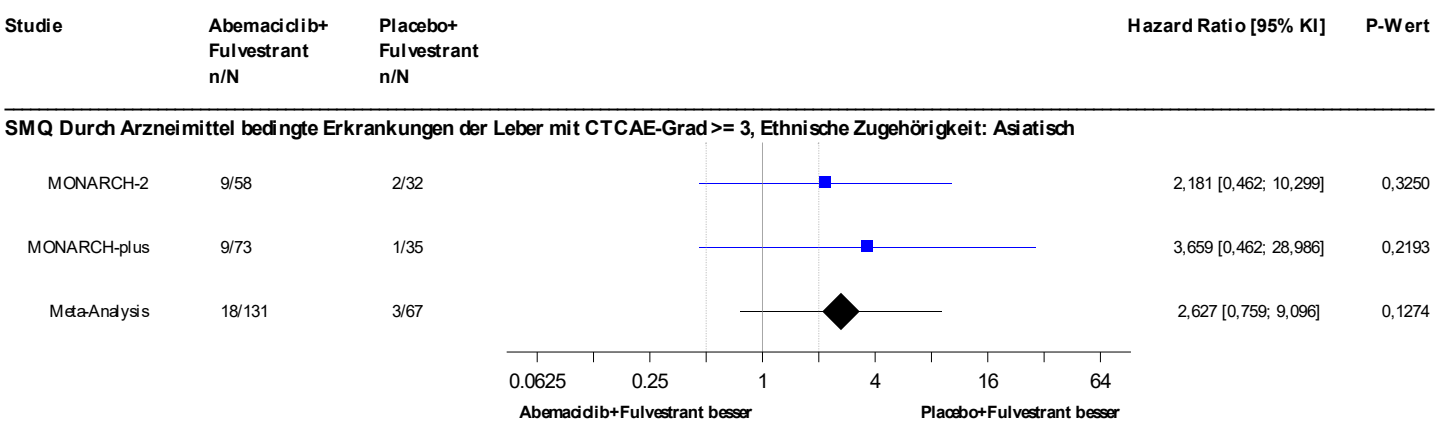

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Abbildung 1465.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)

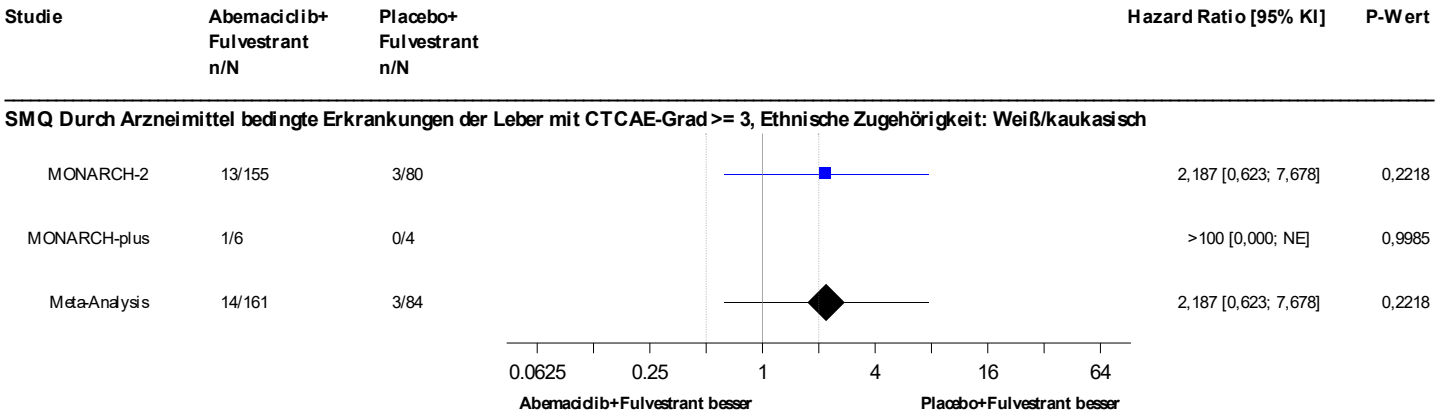

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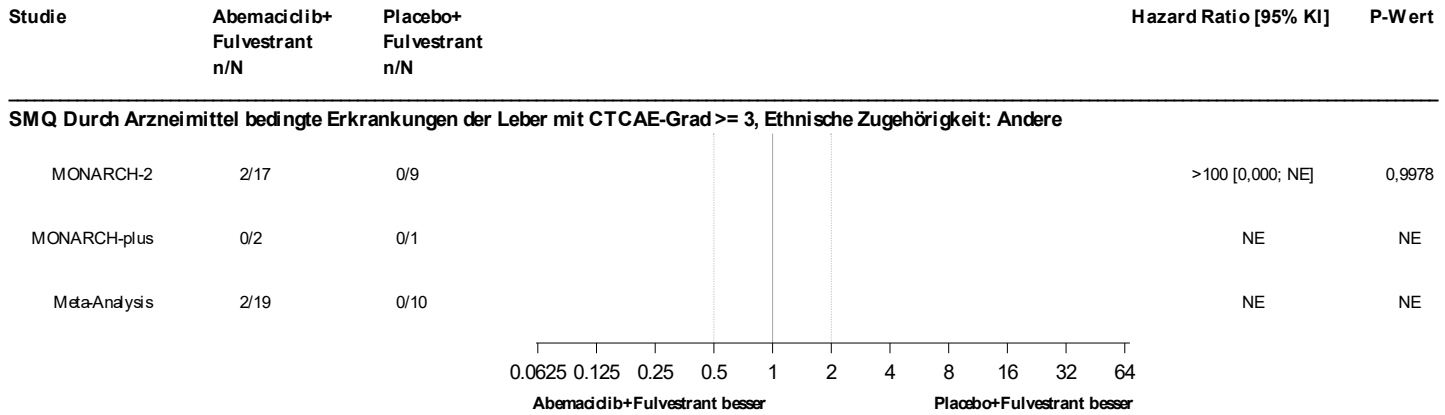
Abbildung 1465.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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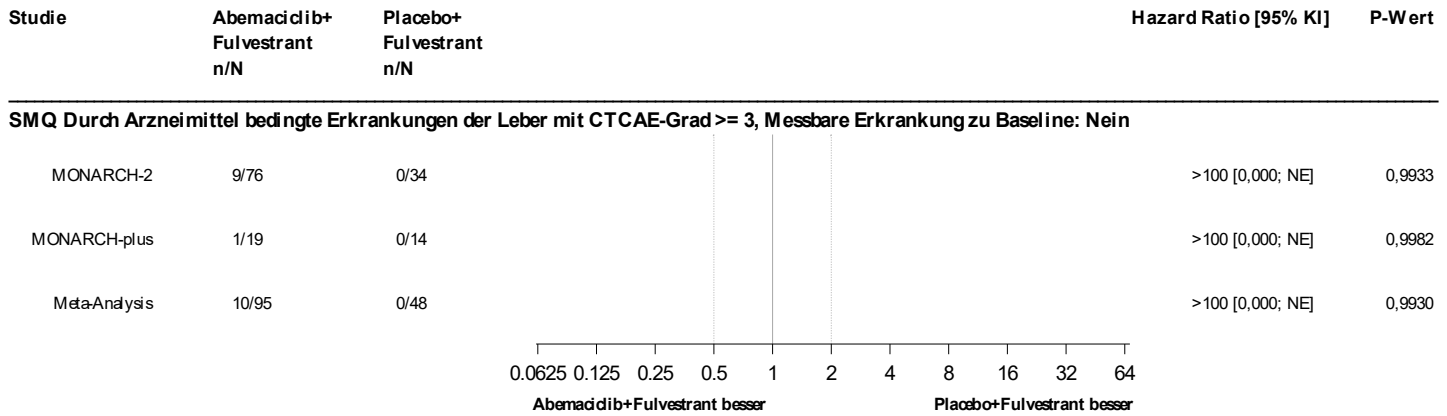
Abbildung 1465.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
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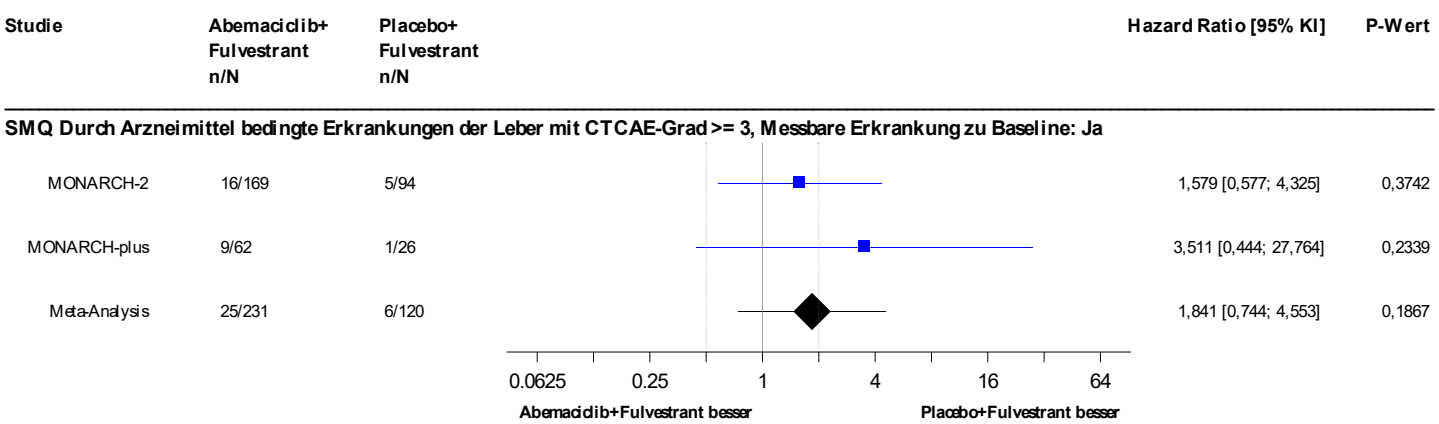
17SEP2021 / 07:48

Abbildung 1465.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



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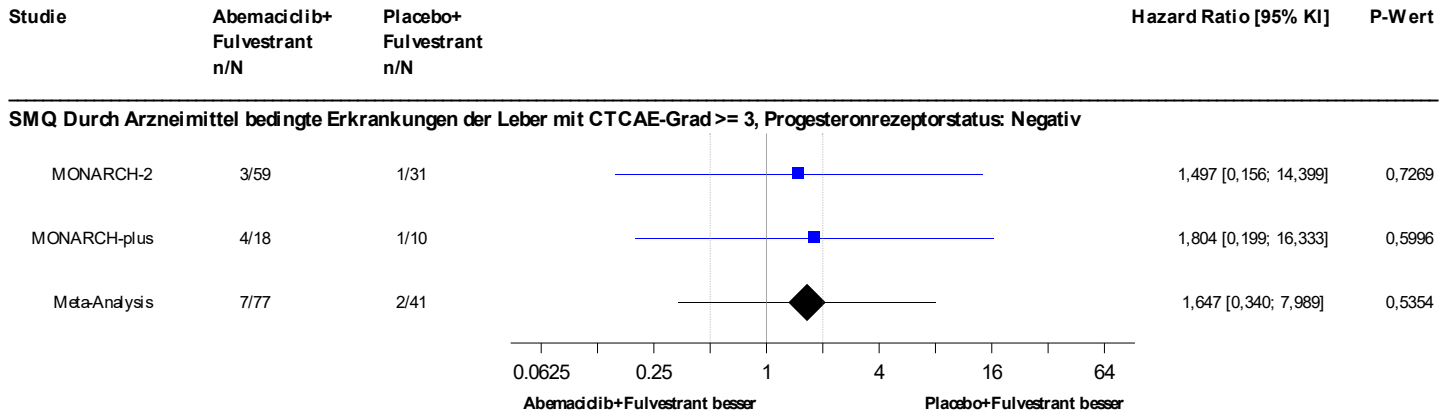
17SEP2021 / 07:48

Abbildung 1465.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0134, P-Wert=0,9078, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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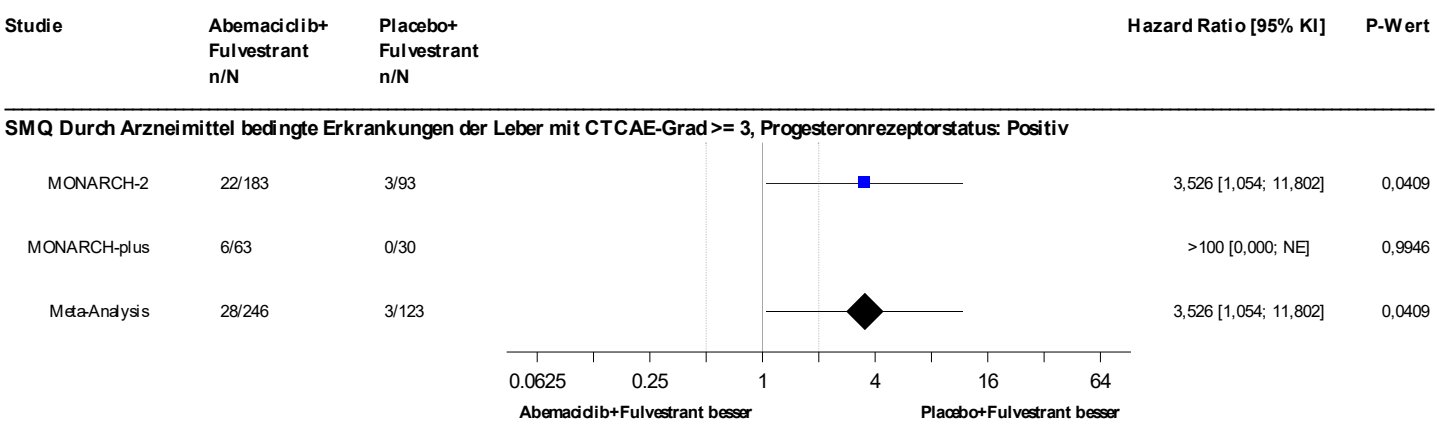
Abbildung 1465.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9950, I2 Index=0%
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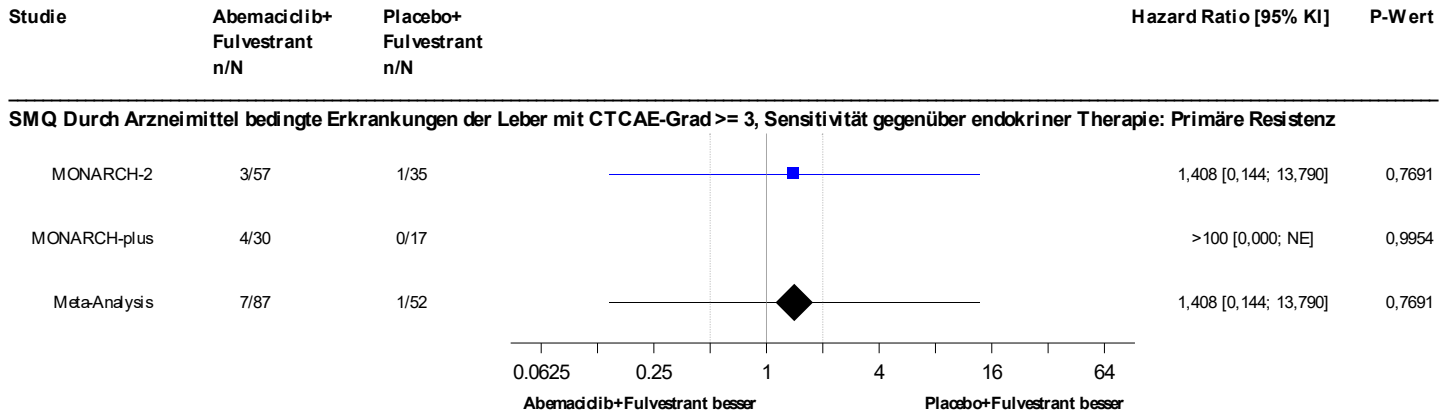
Abbildung 1465.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9955, I2 Index=0%
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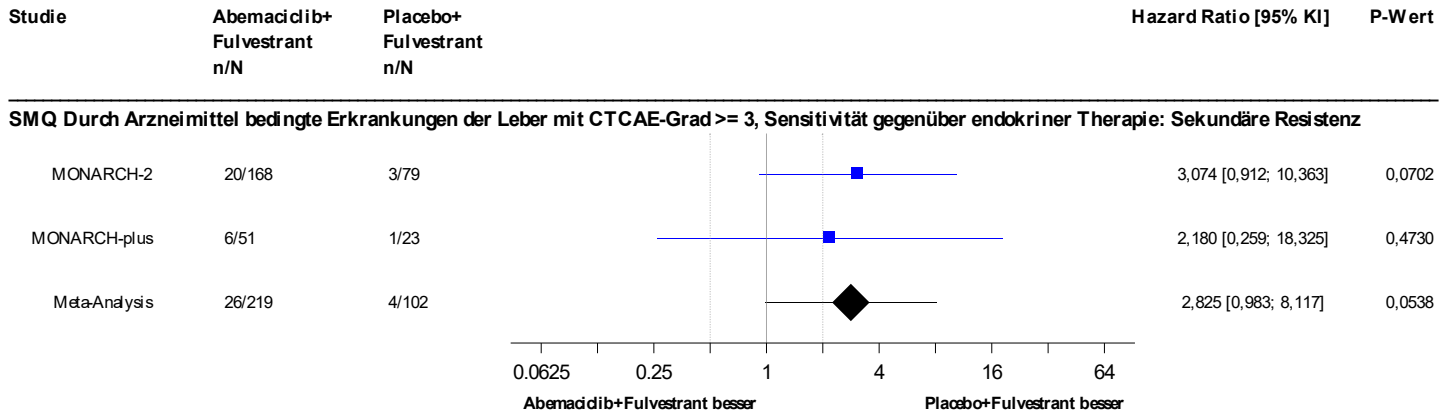
Abbildung 1465.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0754, P-Wert=0,7836, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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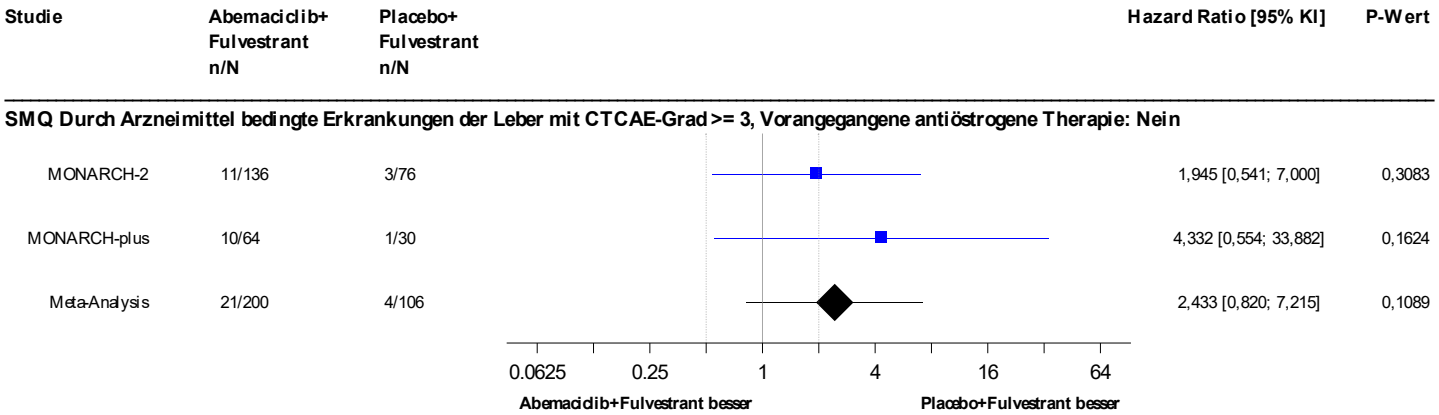
Abbildung 1465.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,4195, P-Wert=0,5172, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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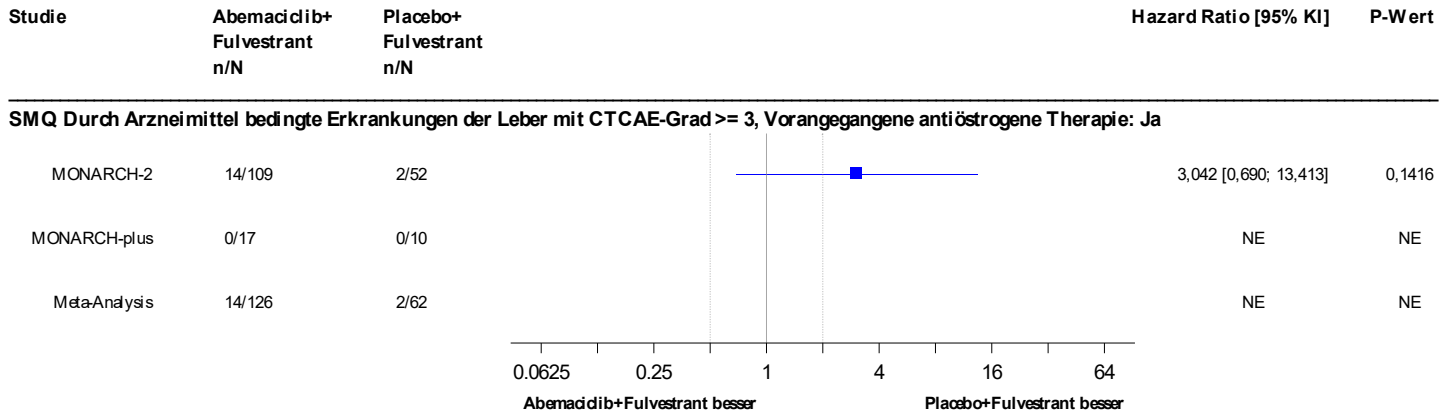
17SEP2021 / 07:48

Abbildung 1465.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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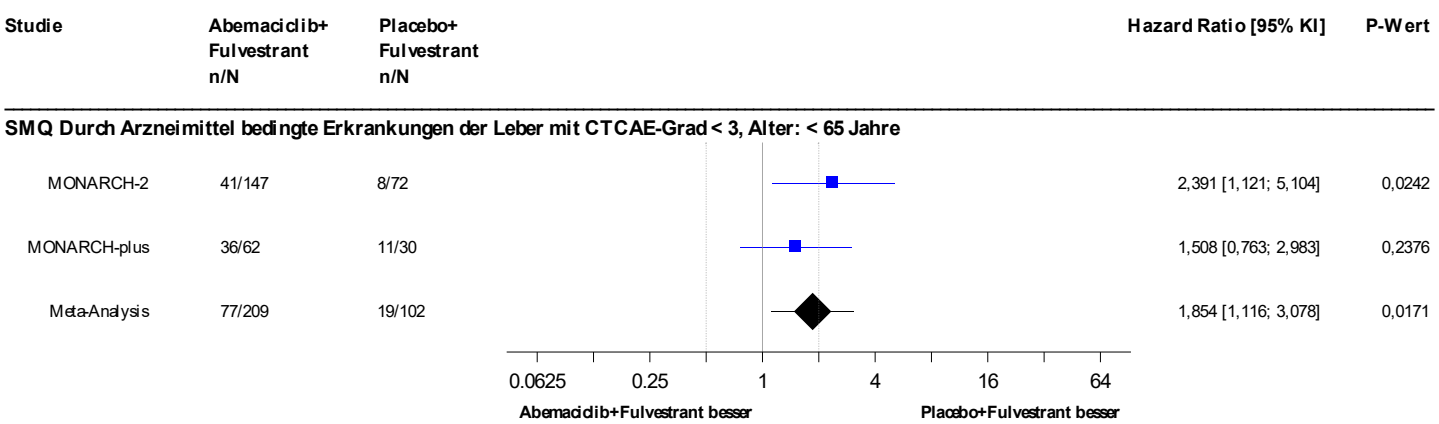
Abbildung 1466.1.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,7851, P-Wert=0,3756, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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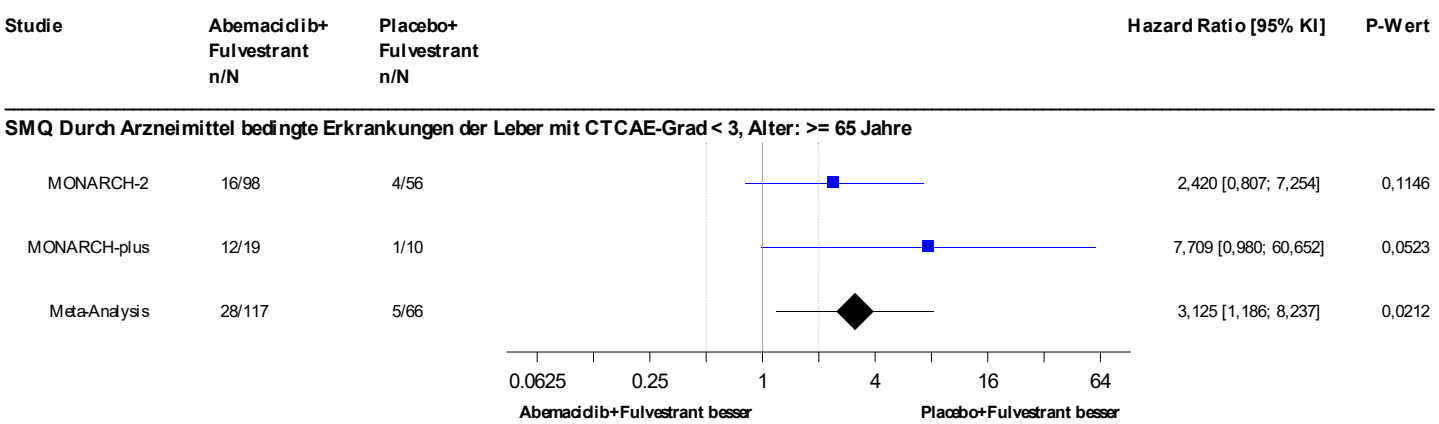
Abbildung 1466.1.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,9444, P-Wert=0,3312, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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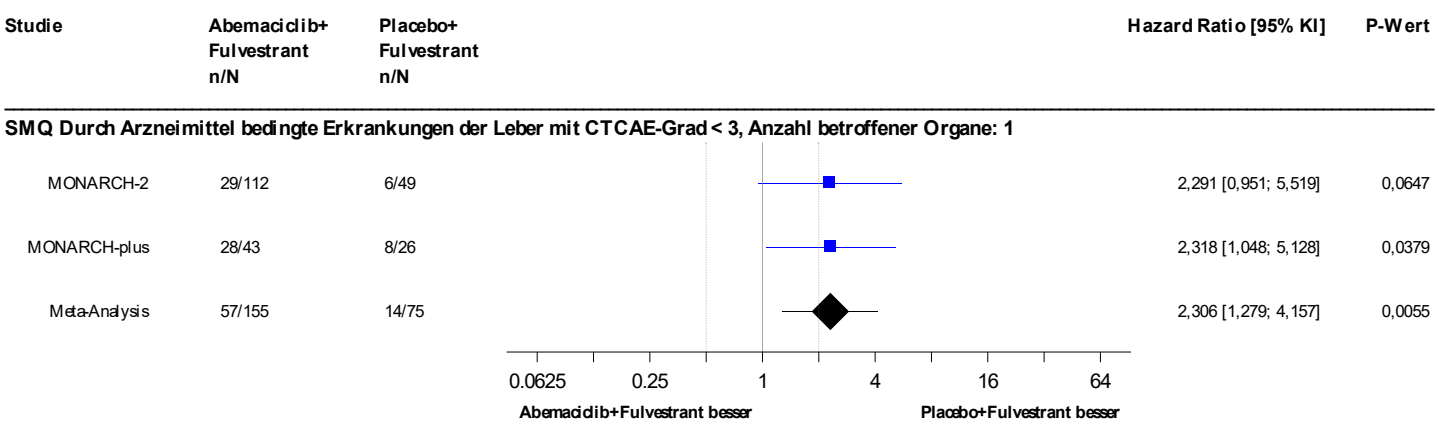
17SEP2021 / 07:48

Abbildung 1466.1.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0004, P-Wert=0,9841, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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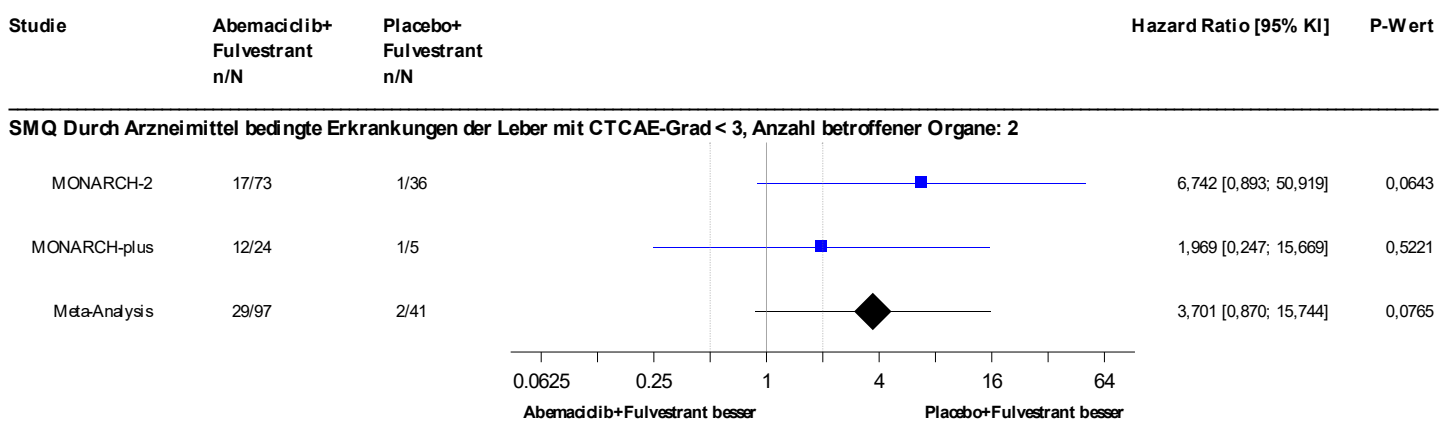
Abbildung 1466.1.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6937, P-Wert=0,4049, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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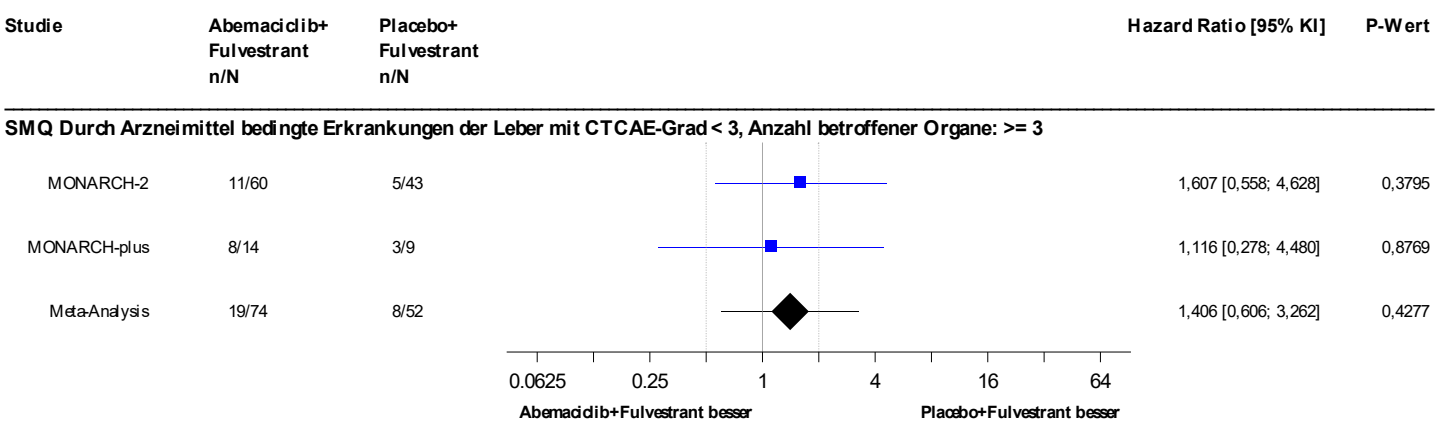
17SEP2021 / 07:48

Abbildung 1466.1.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1673, P-Wert=0,6825, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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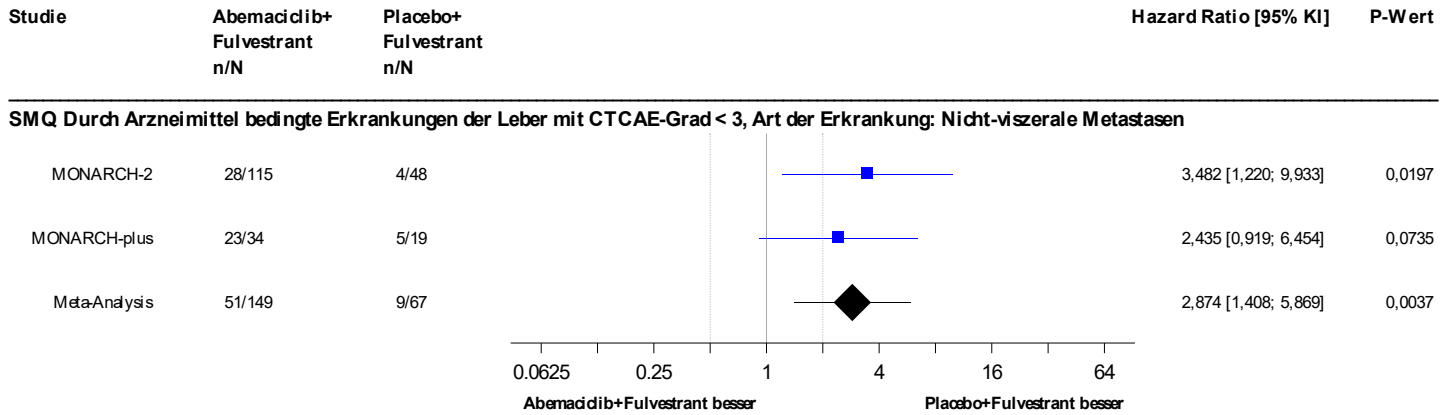
Abbildung 1466.1.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,2396, P-Wert=0,6245, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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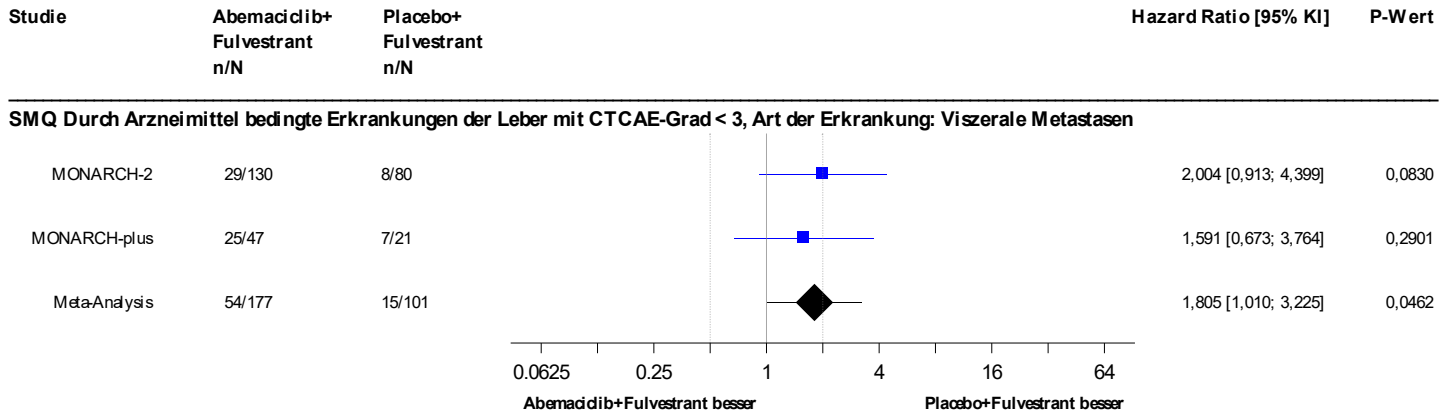
Abbildung 1466.1.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1504, P-Wert=0,6982, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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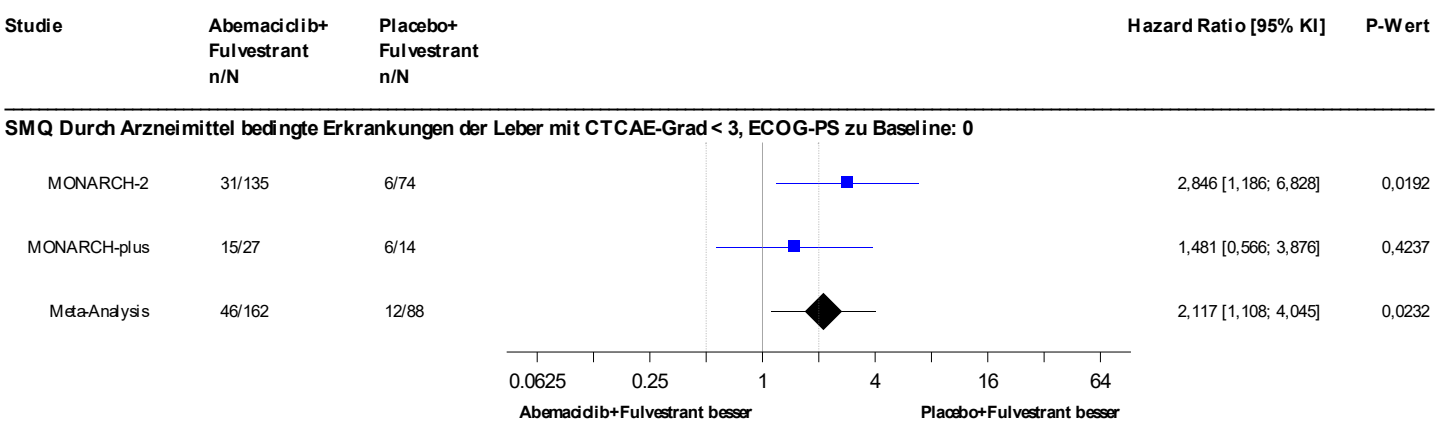
Abbildung 1466.1.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,9688, P-Wert=0,3250, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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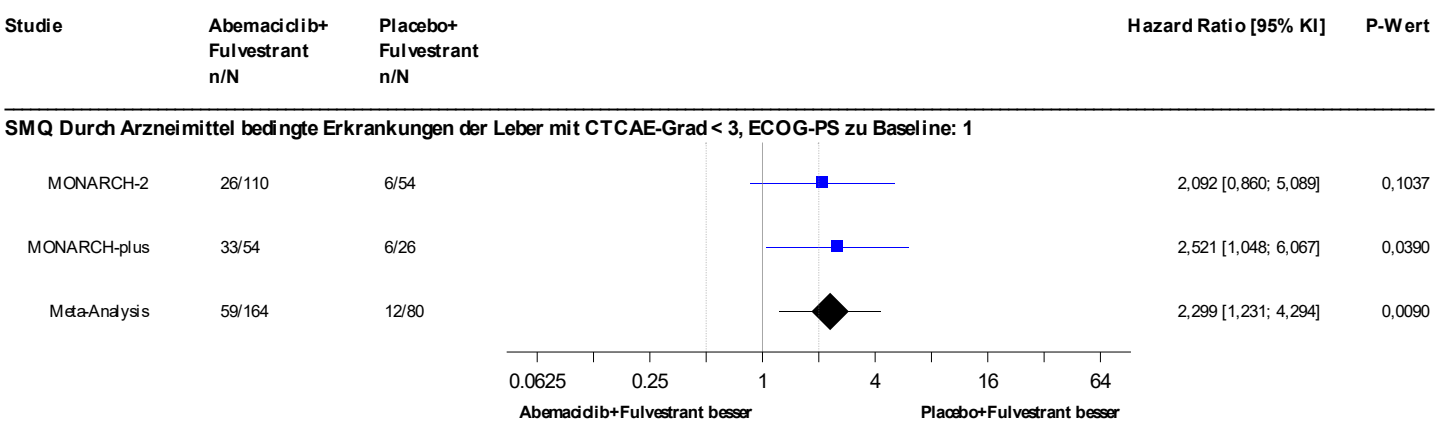
Abbildung 1466.1.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0857, P-Wert=0,7697, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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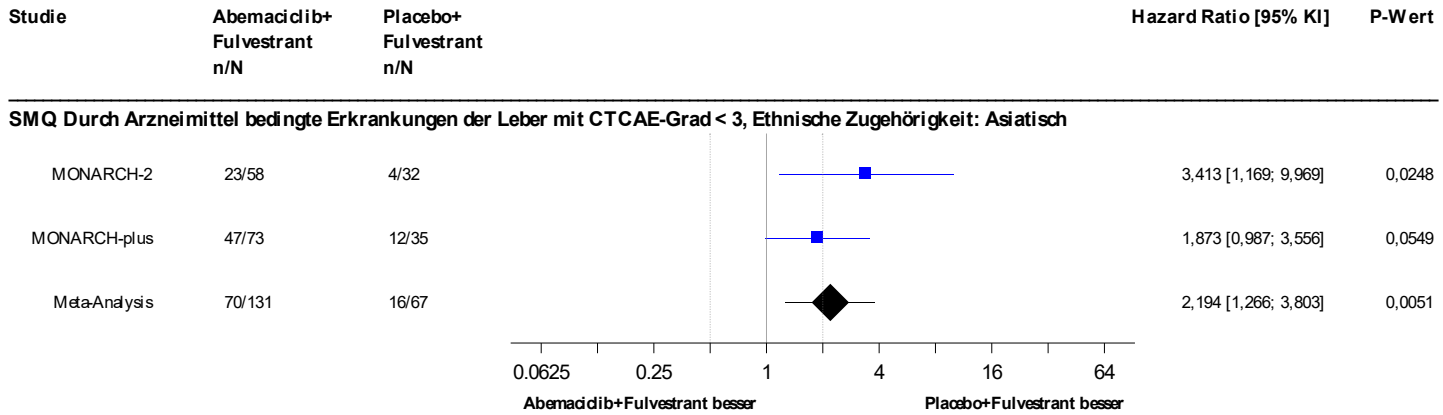
Abbildung 1466.1.5.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Asiatisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,8865, P-Wert=0,3464, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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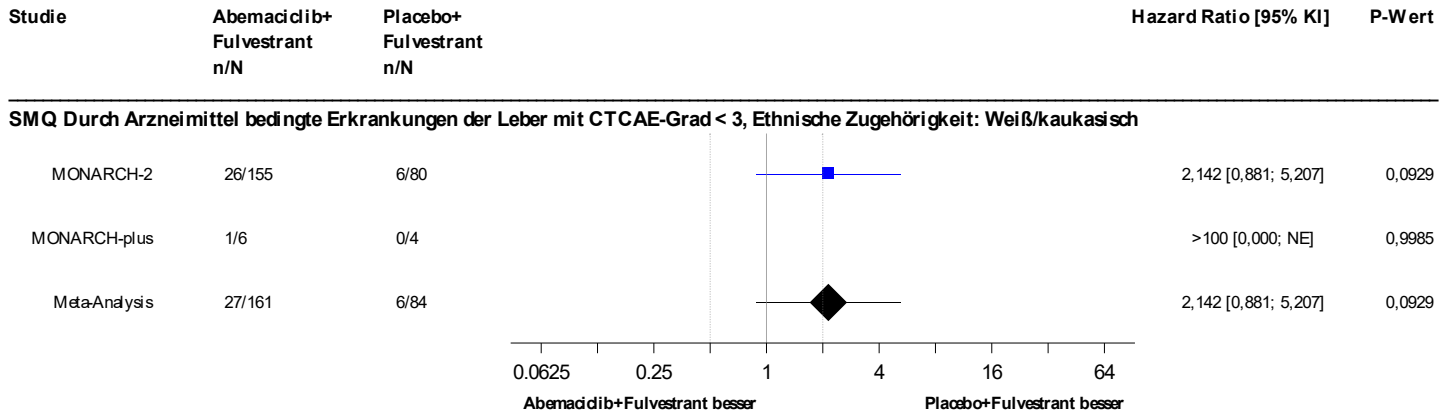
Abbildung 1466.1.5.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Weiß/kaukasisch
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9986, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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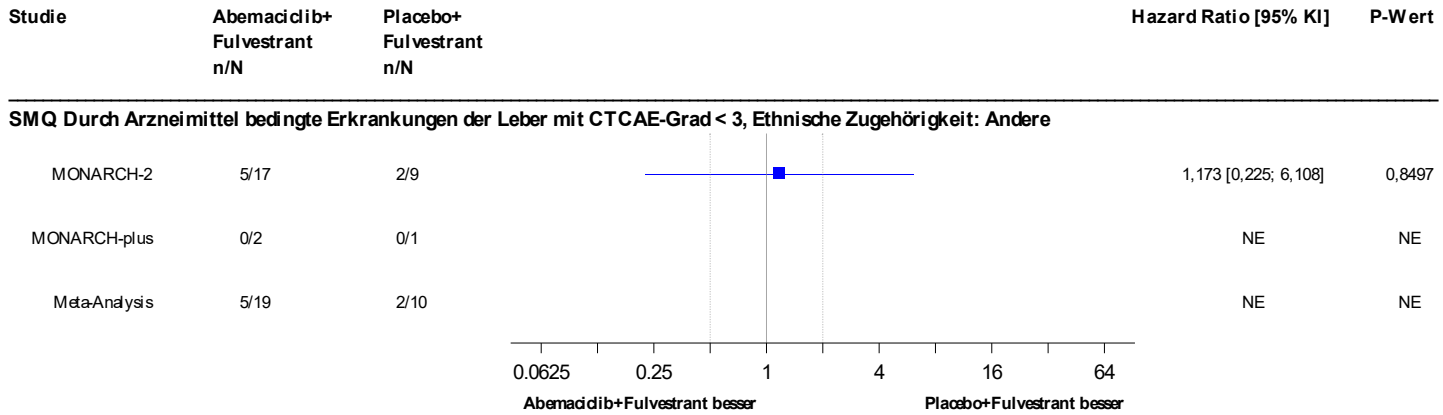
Abbildung 1466.1.5.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Ethnische Zugehörigkeit: Andere
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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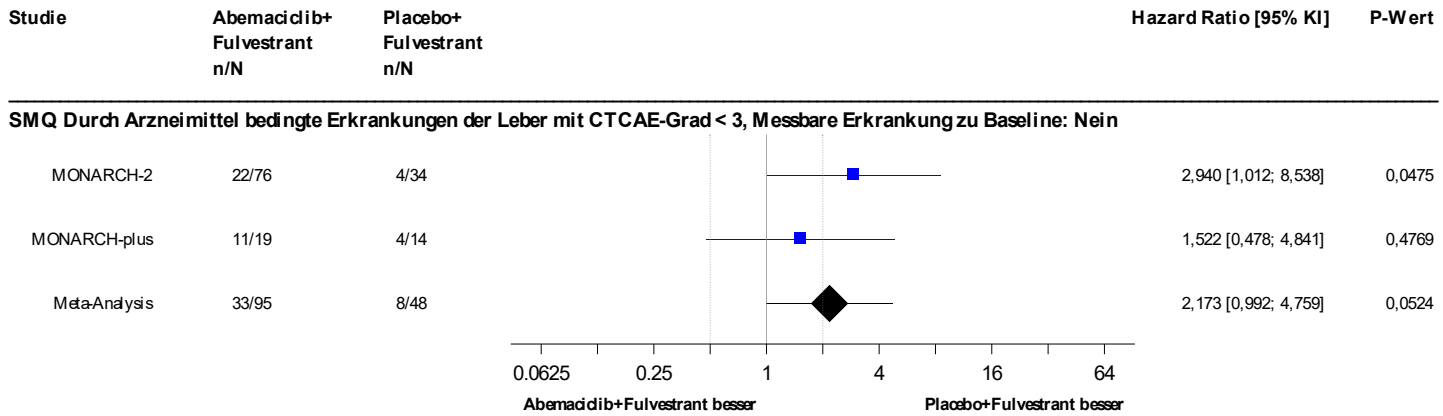
Abbildung 1466.1.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6724, P-Wert=0,4122, I2 Index=0%
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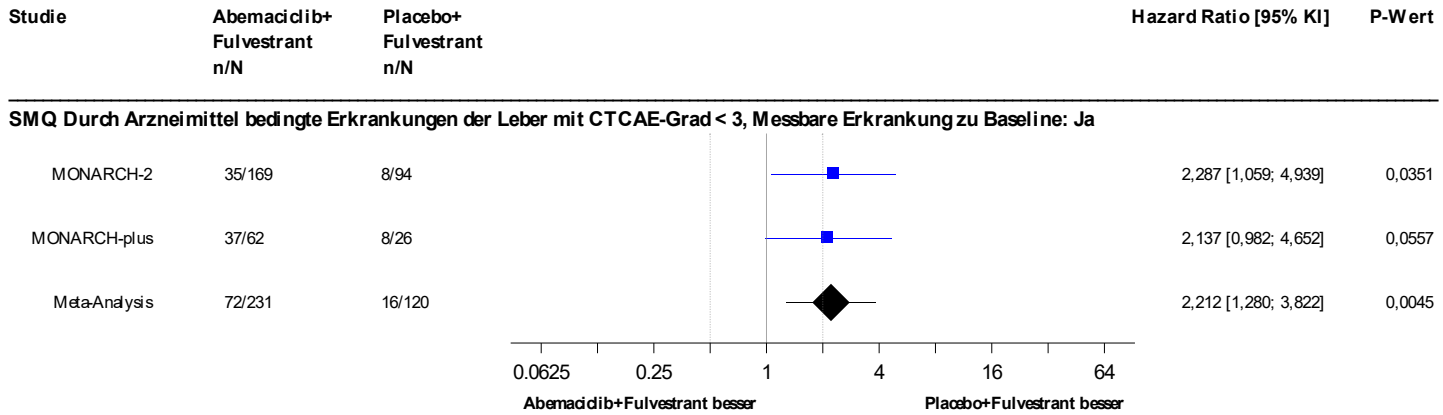
17SEP2021 / 07:48

Abbildung 1466.1.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0149, P-Wert=0,9029, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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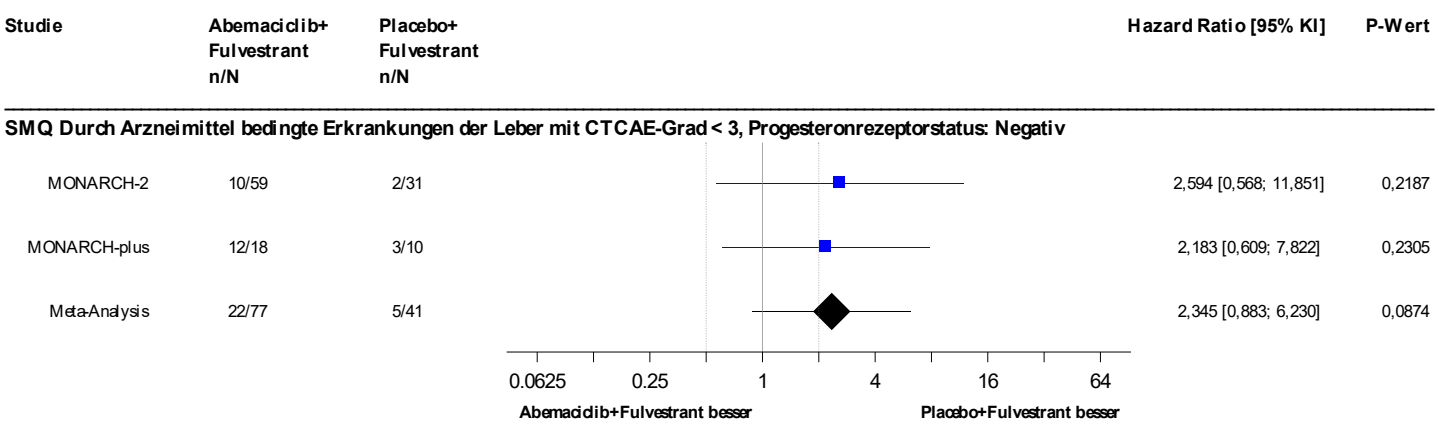
Abbildung 1466.1.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0290, P-Wert=0,8647, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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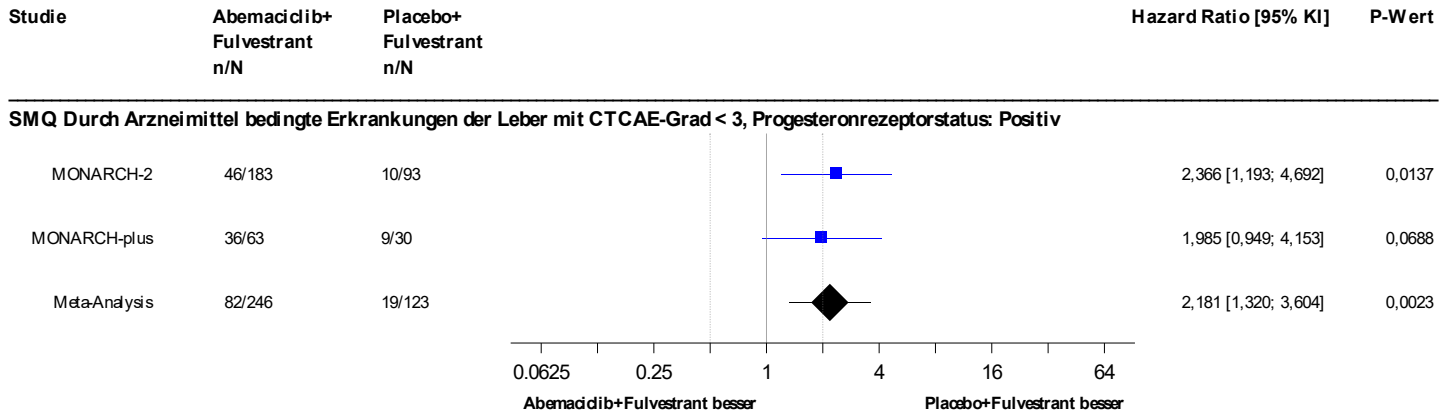
17SEP2021 / 07:48

Abbildung 1466.1.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,1167, P-Wert=0,7327, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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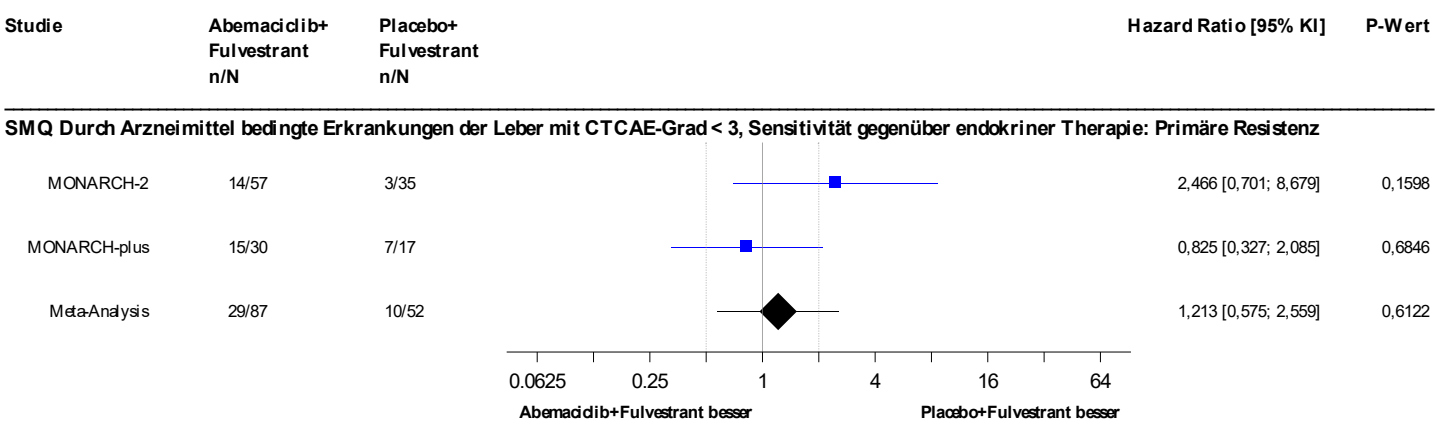
Abbildung 1466.1.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=1,8845, P-Wert=0,1698, I2 Index=46,9%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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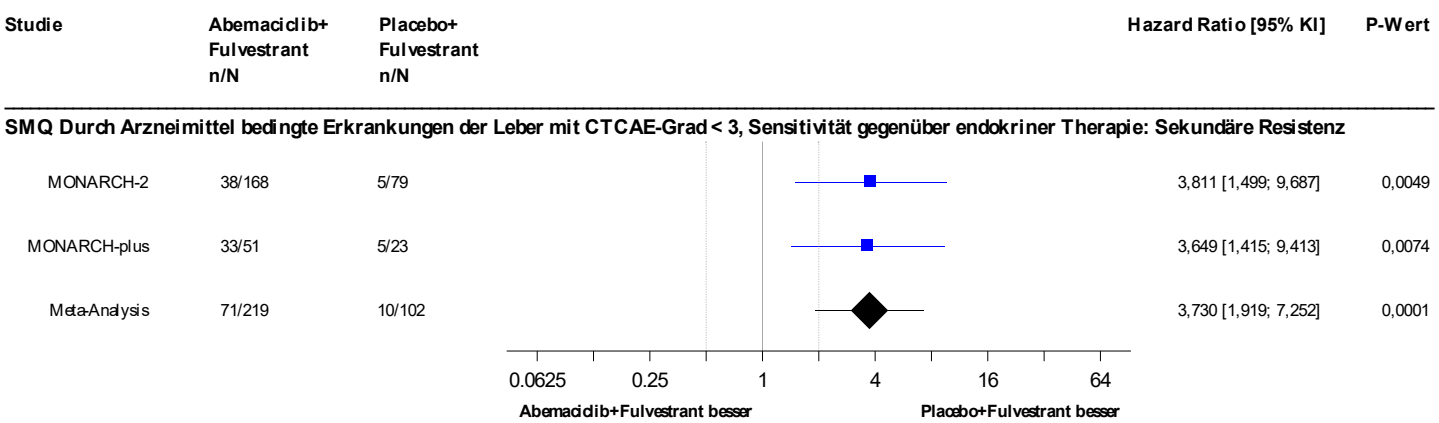
Abbildung 1466.1.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0041, P-Wert=0,9491, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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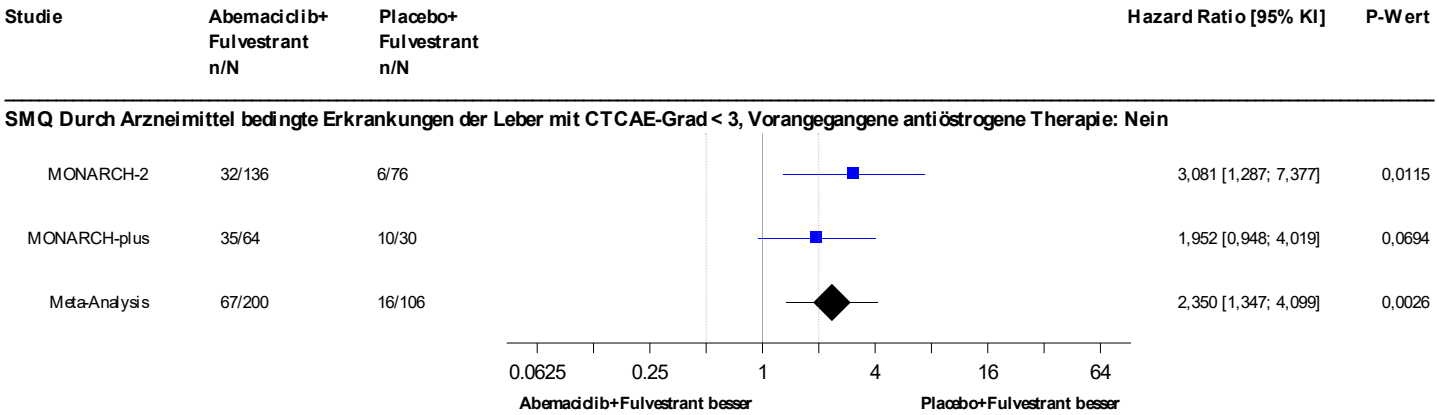
Abbildung 1466.1.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,6229, P-Wert=0,4300, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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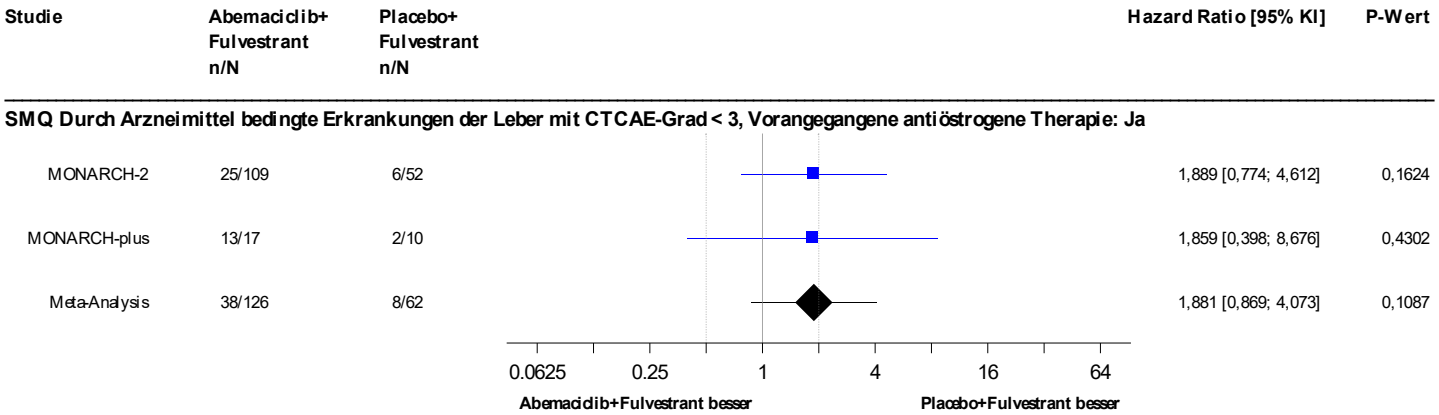
17SEP2021 / 07:48

Abbildung 1466.1.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal A1 (Erstlinie)



Heterogenität: Cochran Q-test=0,0003, P-Wert=0,9858, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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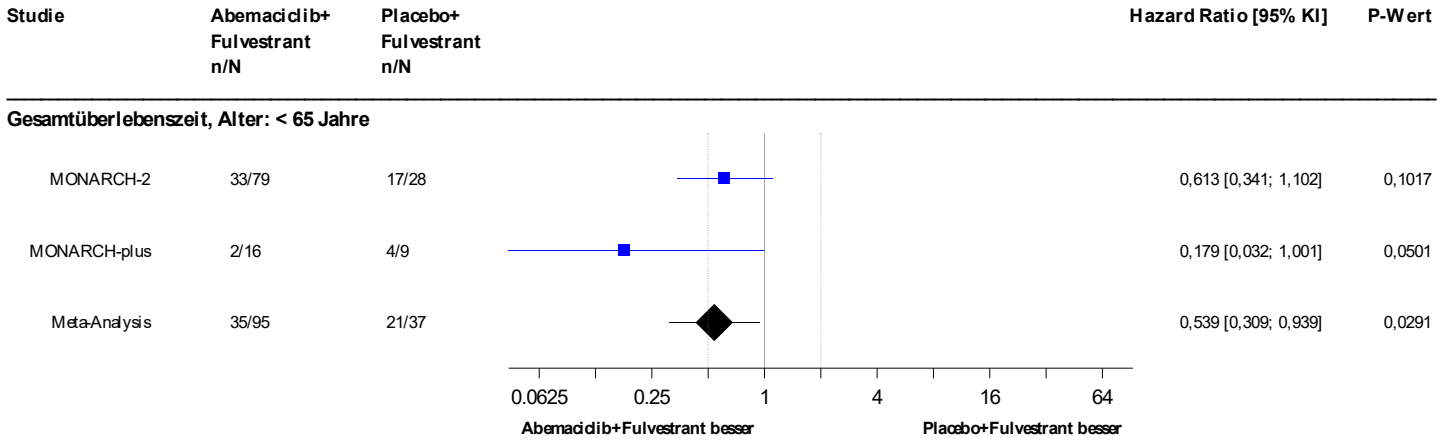
Abbildung 161 (Anhang): Ergebnisse der Subgruppenanalyse nicht interagierender Subgruppen (Metaanalyse der Studien MONARCH-2 und MONARCH-plus, B1)

Abbildung 1401.2.1.1: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,7574, P-Wert=0,1849, I2 Index=43,1%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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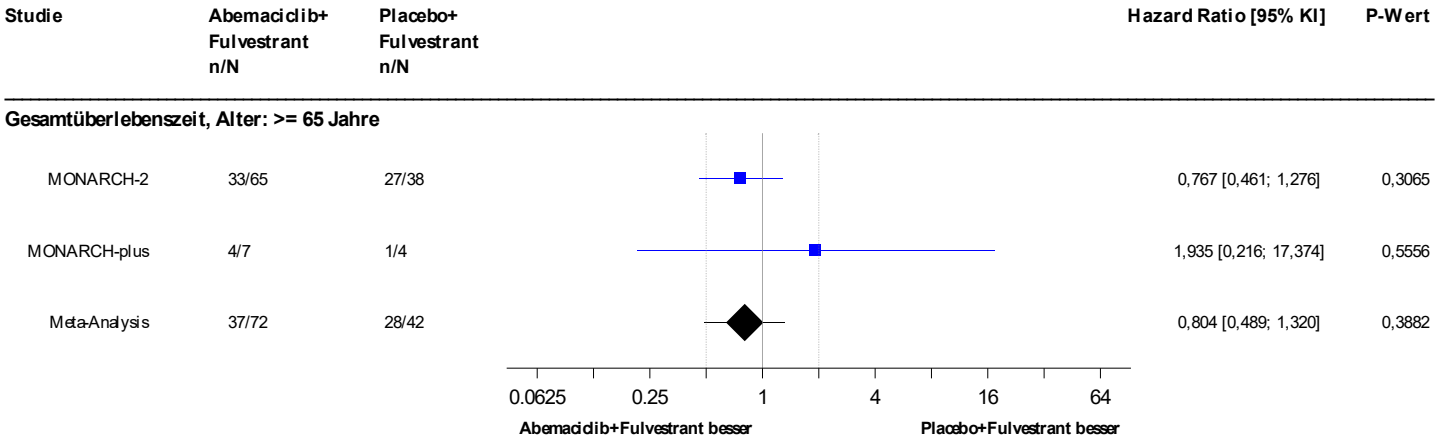
Abbildung 1401.2.1.2: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Alter: >= 65 Jahre Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,6487, P-Wert=0,4206, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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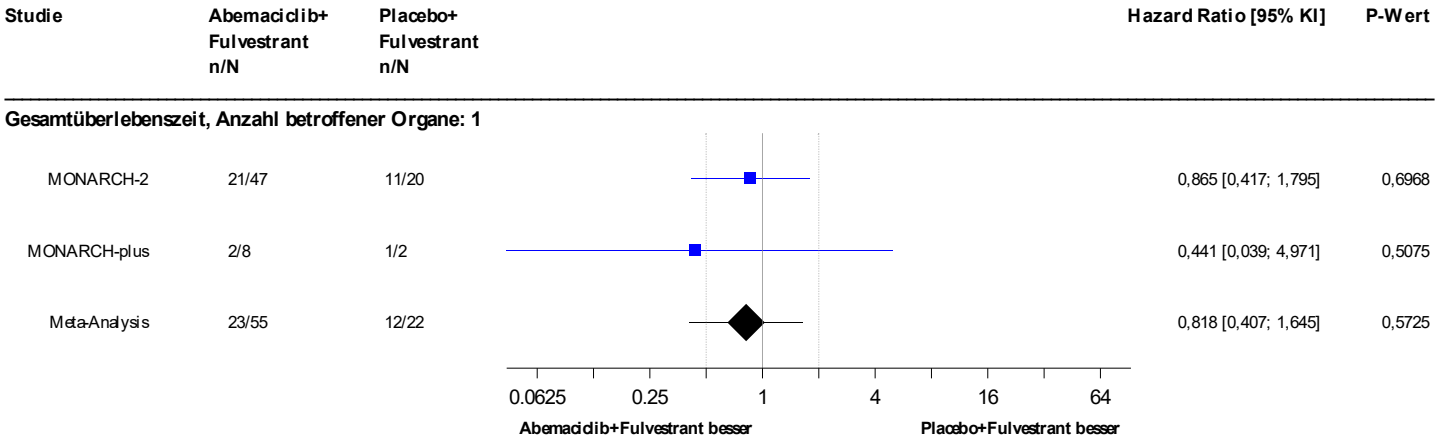
Abbildung 1401.2.2.1: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Anzahl betroffener Organe: 1 Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2727, P-Wert=0,6015, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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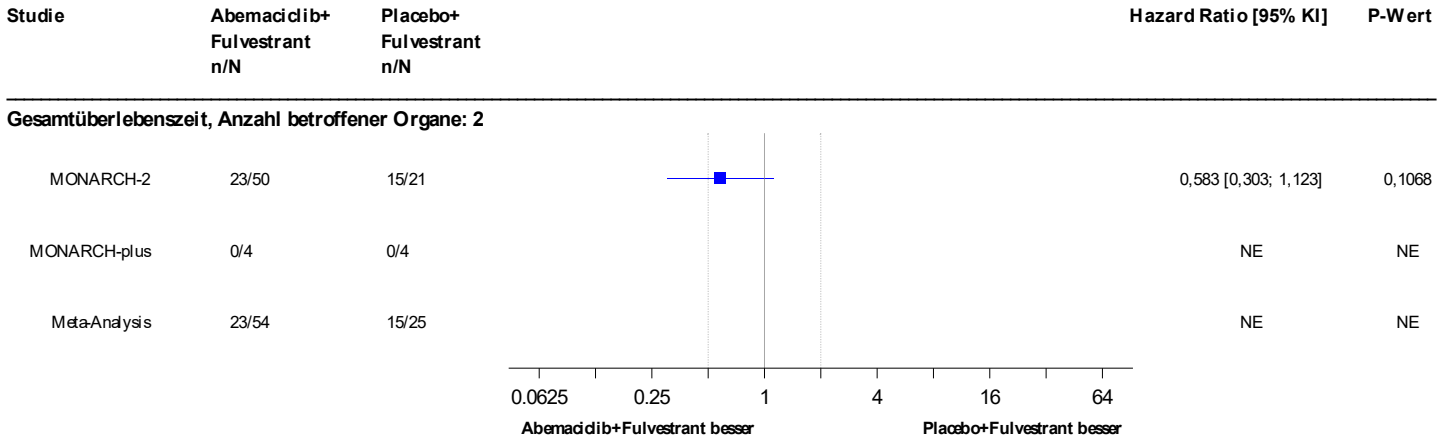
Abbildung 1401.2.2.2: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Anzahl betroffener Organe: 2 Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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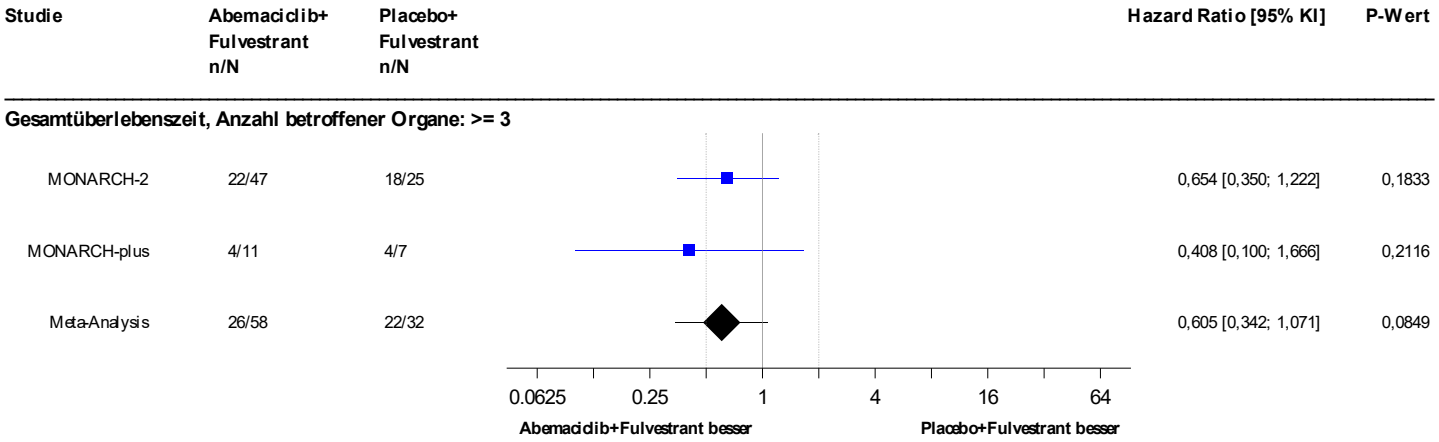
Abbildung 1401.2.2.3: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Anzahl betroffener Organe: >= 3 Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3626, P-Wert=0,5471, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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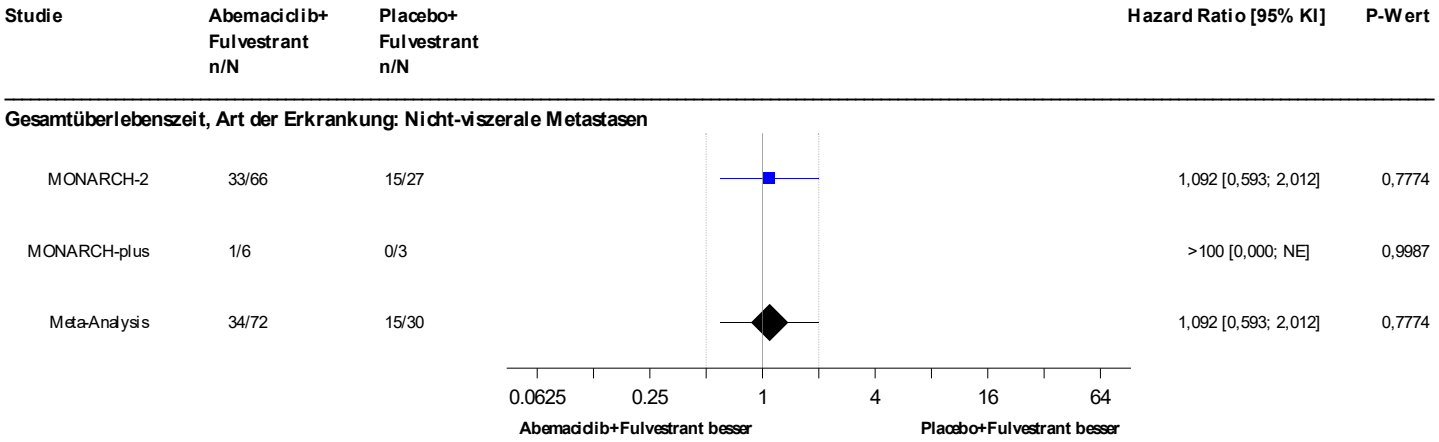
Abbildung 1401.2.3.1: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9987, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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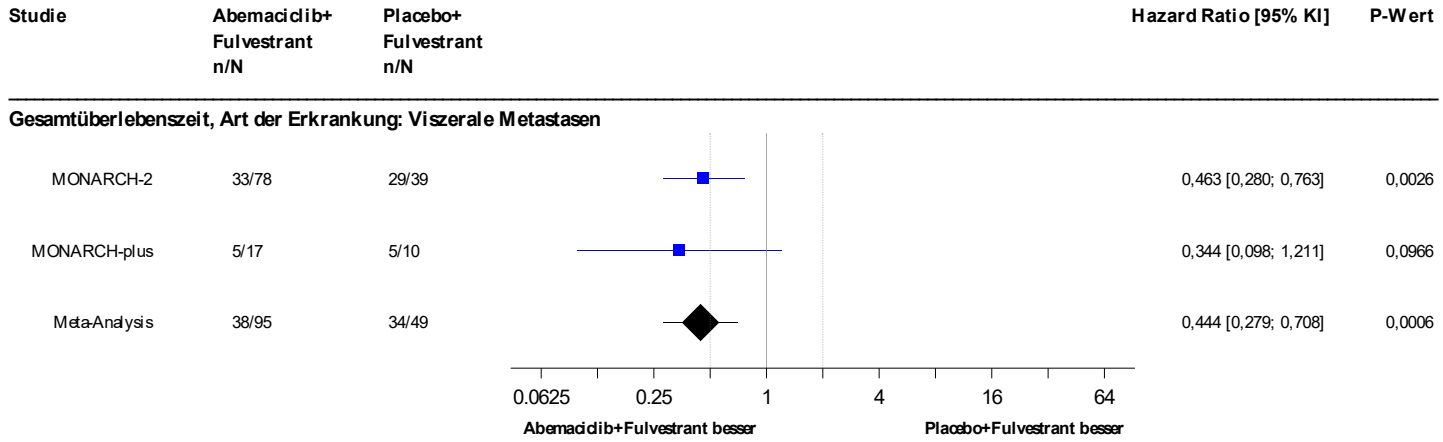
Abbildung 1401.2.3.2: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1833, P-Wert=0,6686, I2 Index=0%
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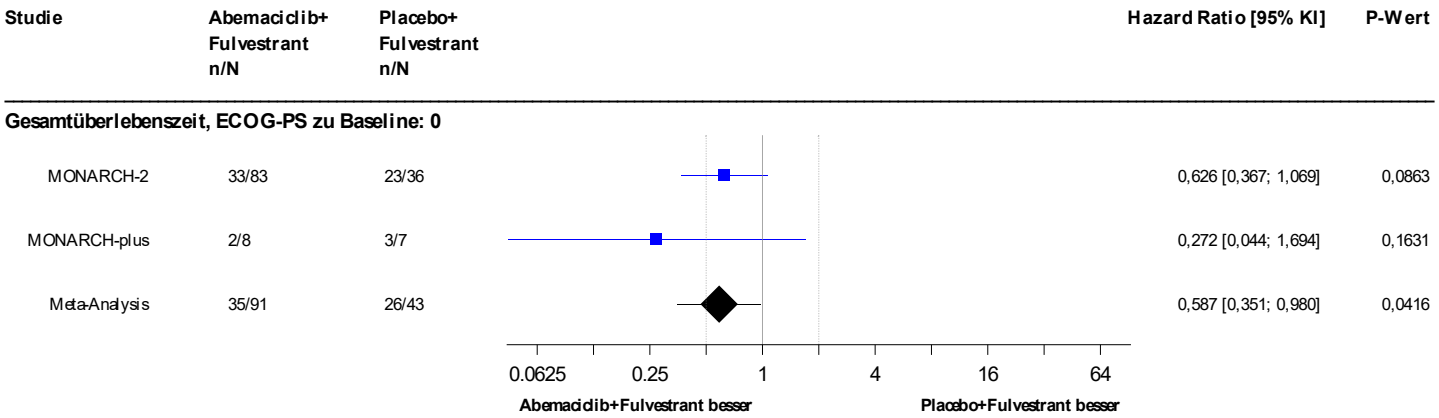
Abbildung 1401.2.4.1: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,7352, P-Wert=0,3912, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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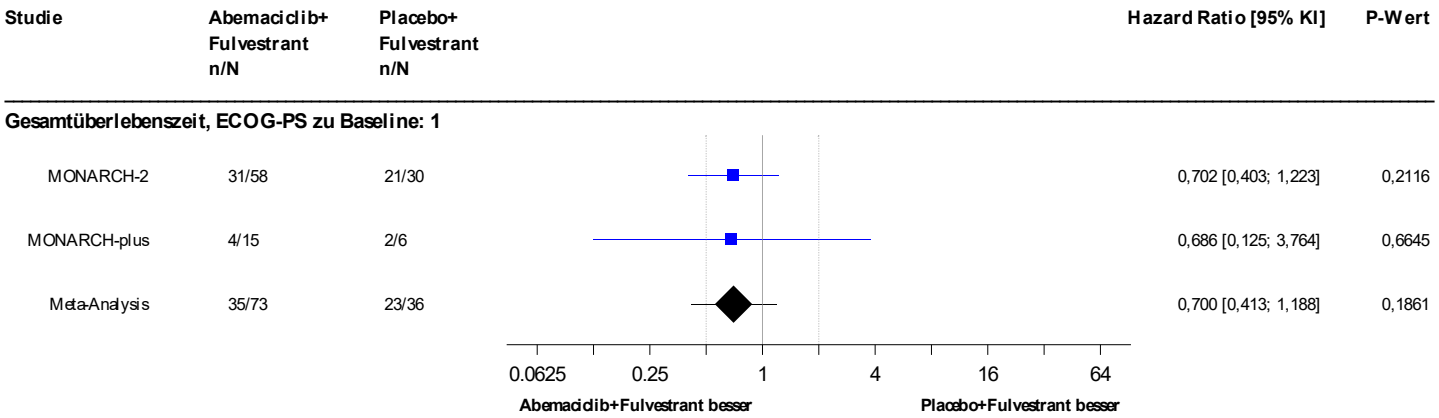
Abbildung 1401.2.4.2: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0006, P-Wert=0,9804, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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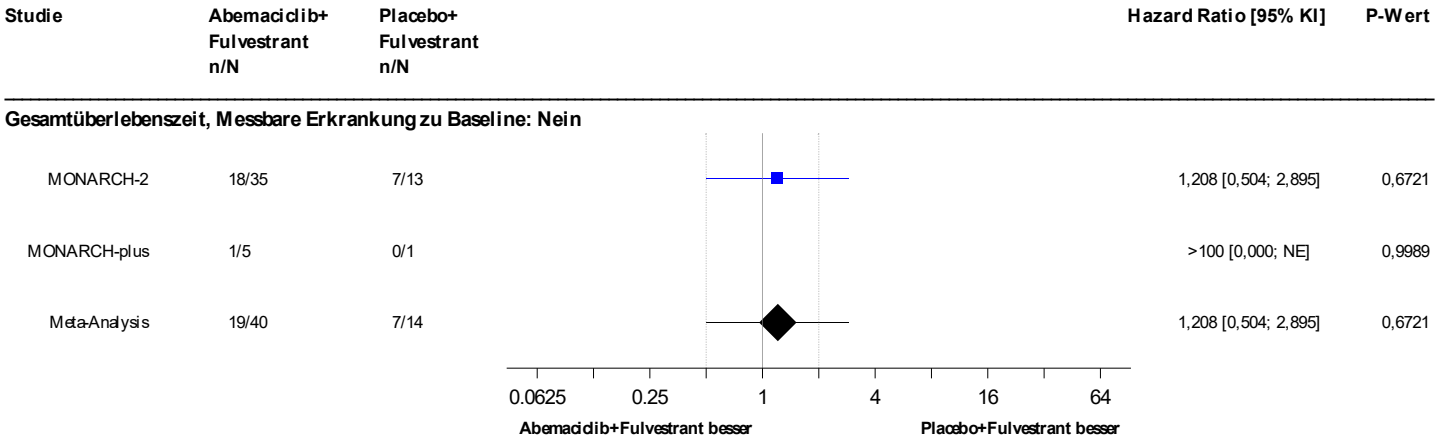
Abbildung 1401.2.6.1: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9989, I2 Index=0%
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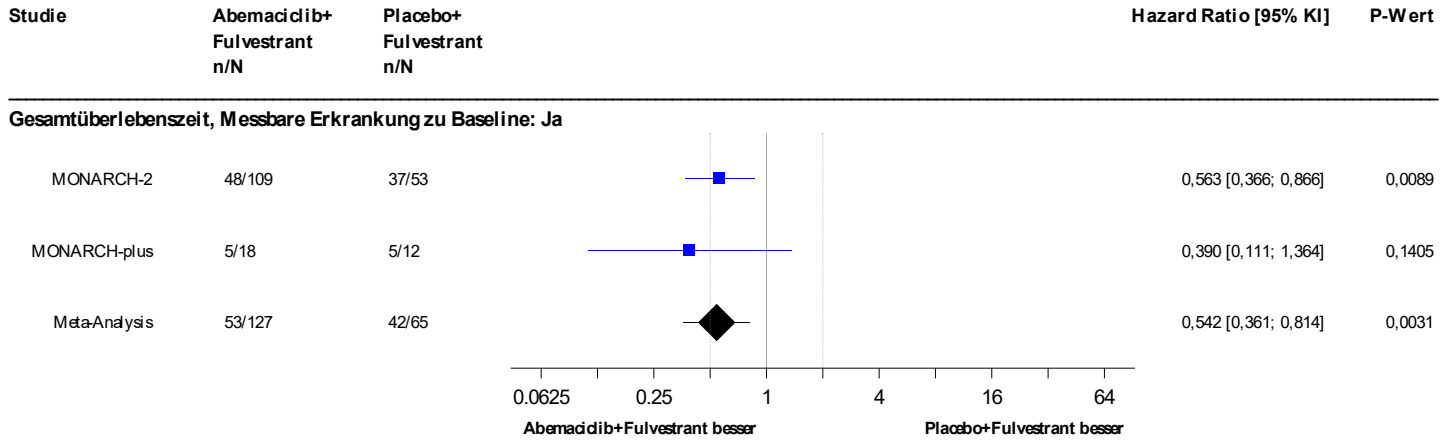
Abbildung 1401.2.6.2: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2965, P-Wert=0,5861, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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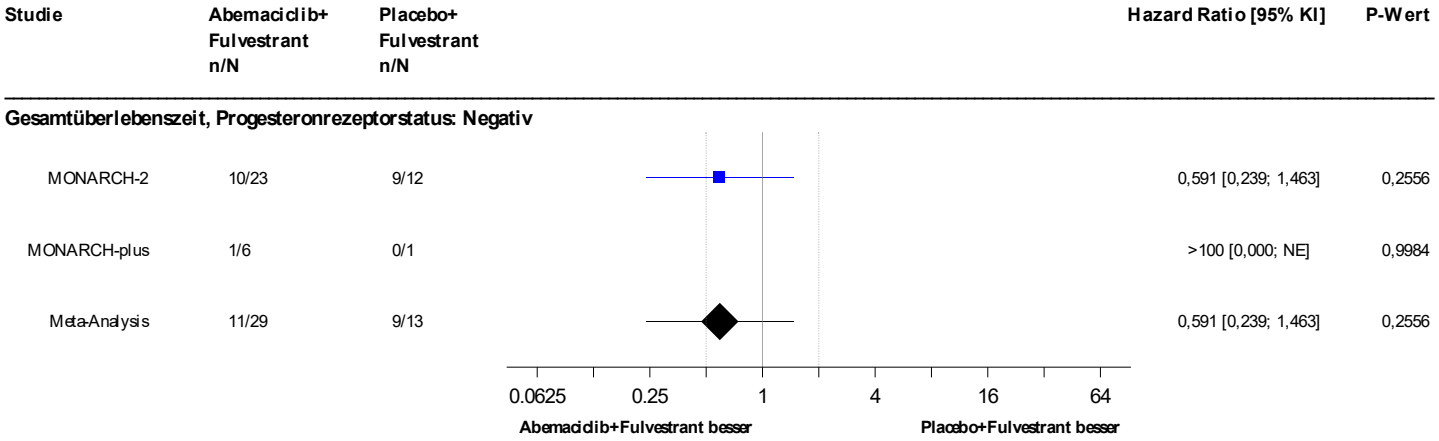
Abbildung 1401.2.7.1: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Progesteronrezeptorstatus: Negativ Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9984, I2 Index=0%
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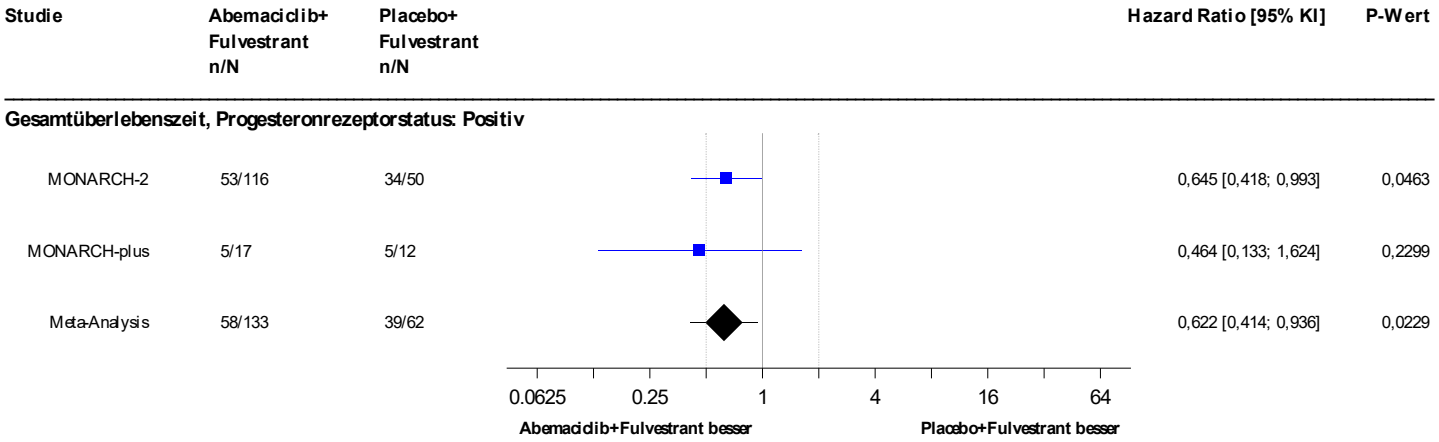
Abbildung 1401.2.7.2: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Progesteronrezeptorstatus: Positiv Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2356, P-Wert=0,6274, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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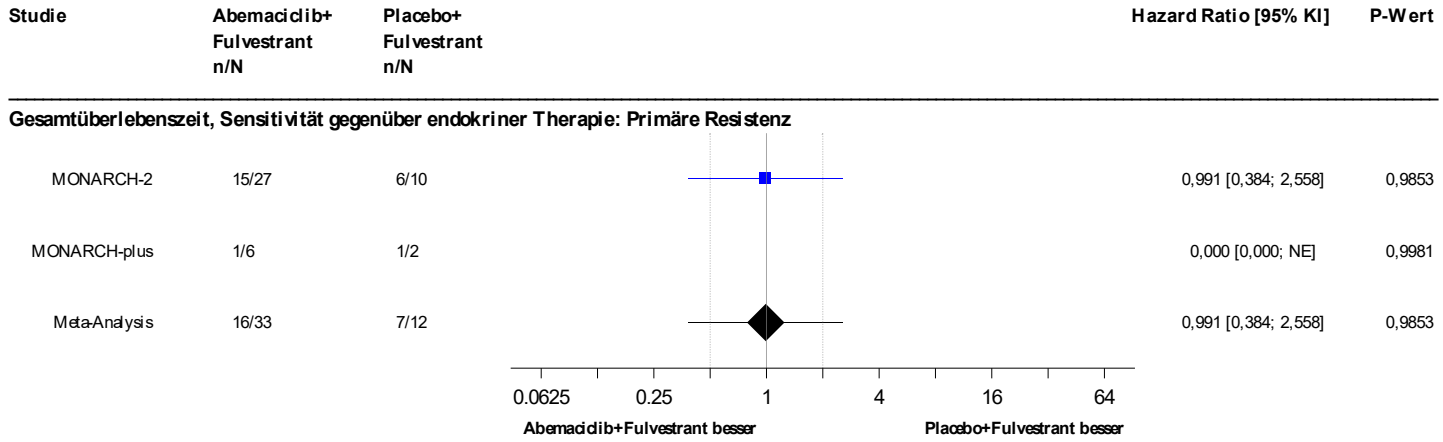
Abbildung 1401.2.8.1: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9981, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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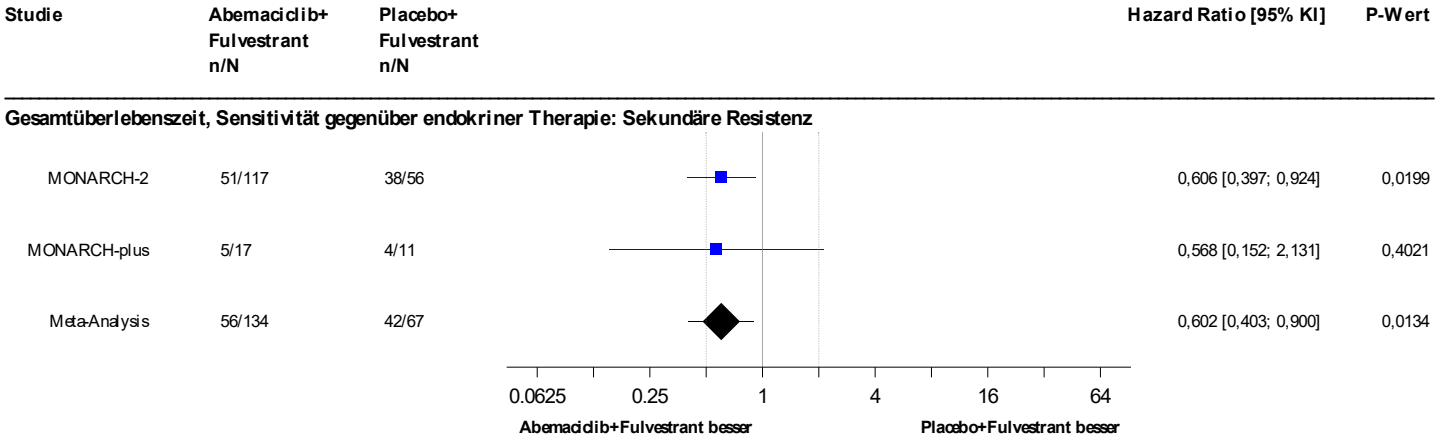
Abbildung 1401.2.8.2: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0080, P-Wert=0,9286, I2 Index=0%
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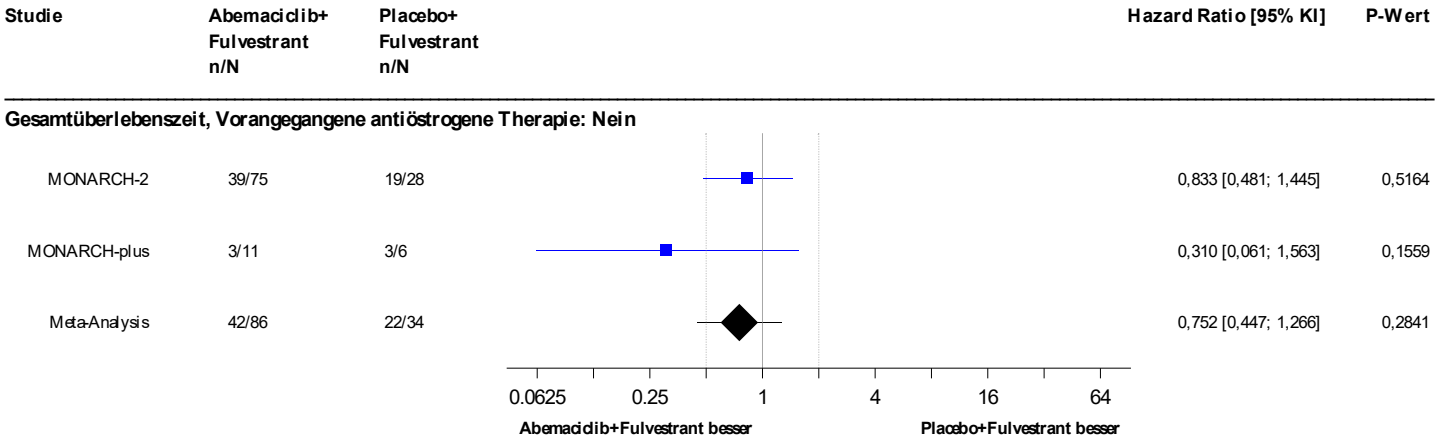
Abbildung 1401.2.9.1: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,2876, P-Wert=0,2565, I2 Index=22,3%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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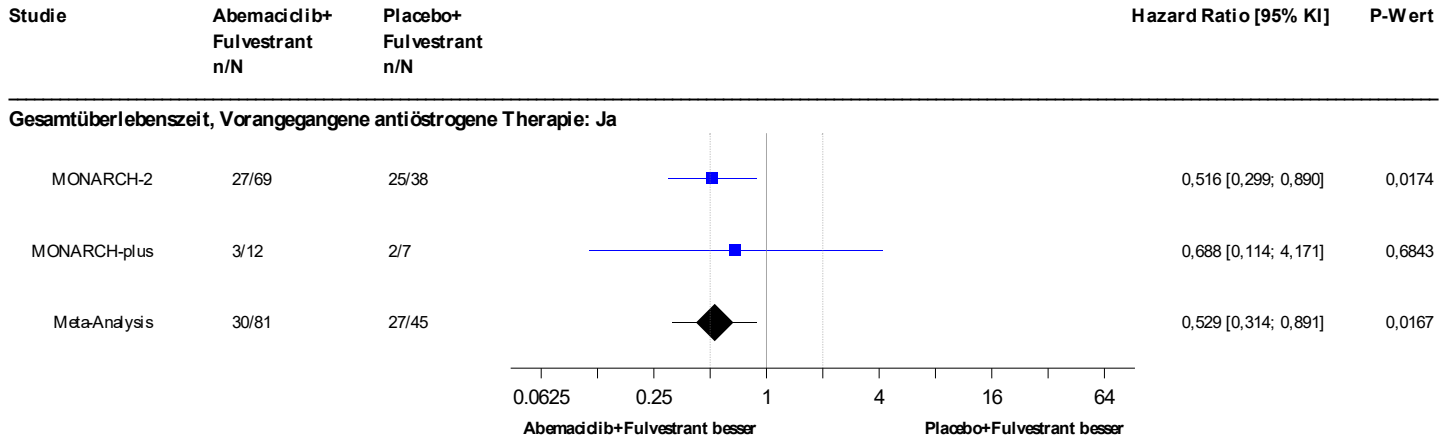
Abbildung 1401.2.9.2: Metaanalyse der Ergebnisse für Gesamtüberleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0896, P-Wert=0,7647, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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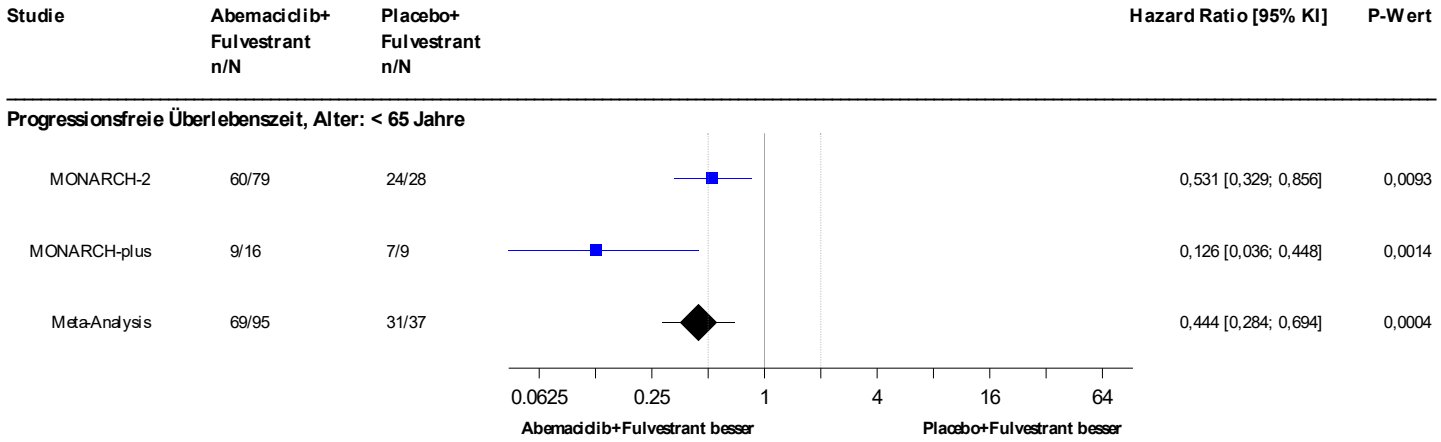
Abbildung 1402.2.1.1: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Alter: < 65 Jahre Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=4,3239, P-Wert=0,0376, I2 Index=76,9%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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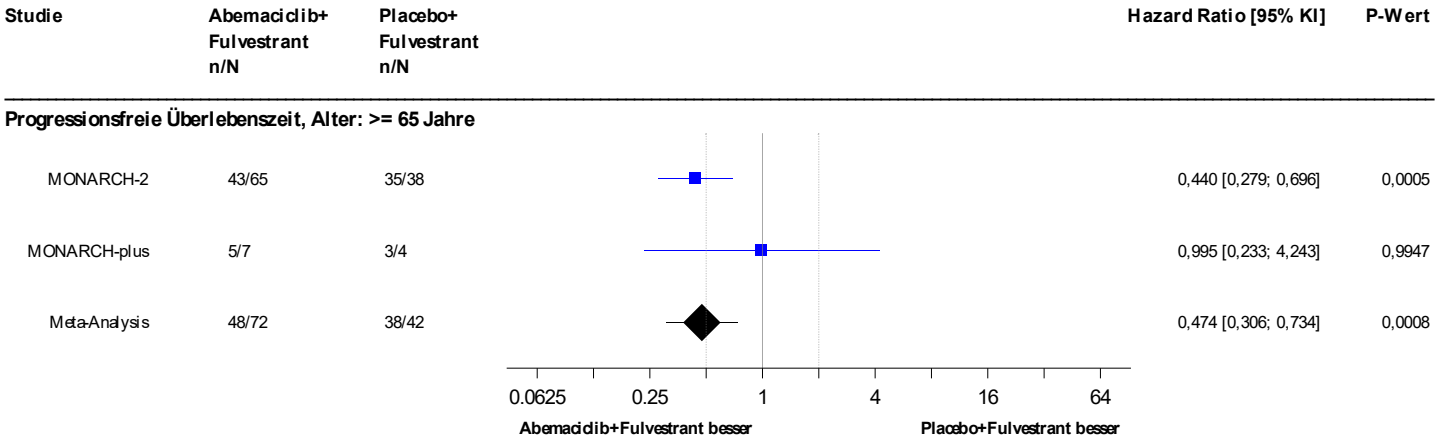
Abbildung 1402.2.1.2: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Alter: >= 65 Jahre Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,1032, P-Wert=0,2936, I2 Index=9,4%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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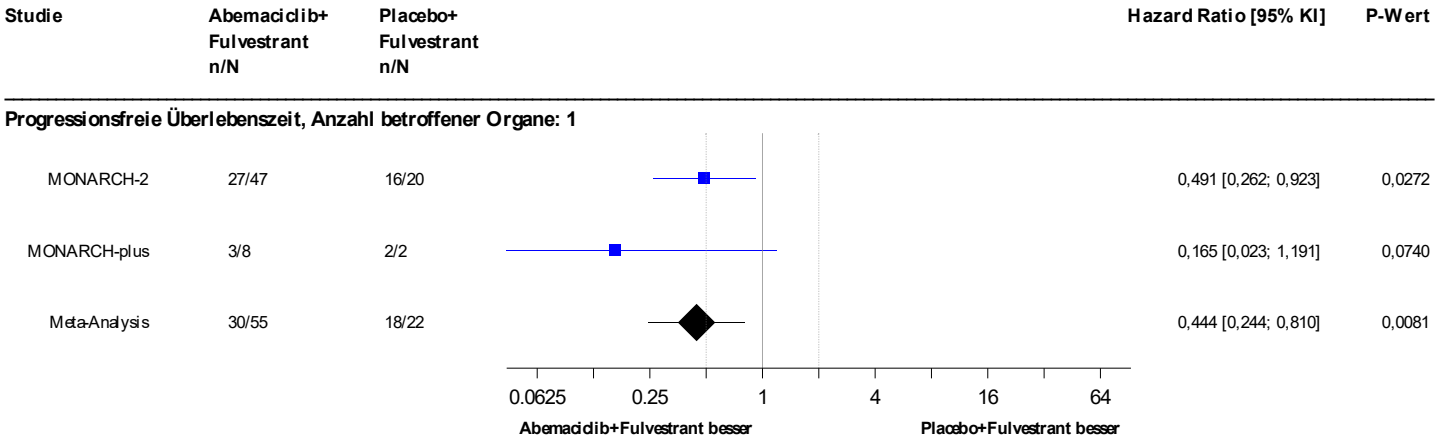
Abbildung 1402.2.2.1: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Anzahl betroffener Organe: 1 Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,0633, P-Wert=0,3025, I2 Index=5,9%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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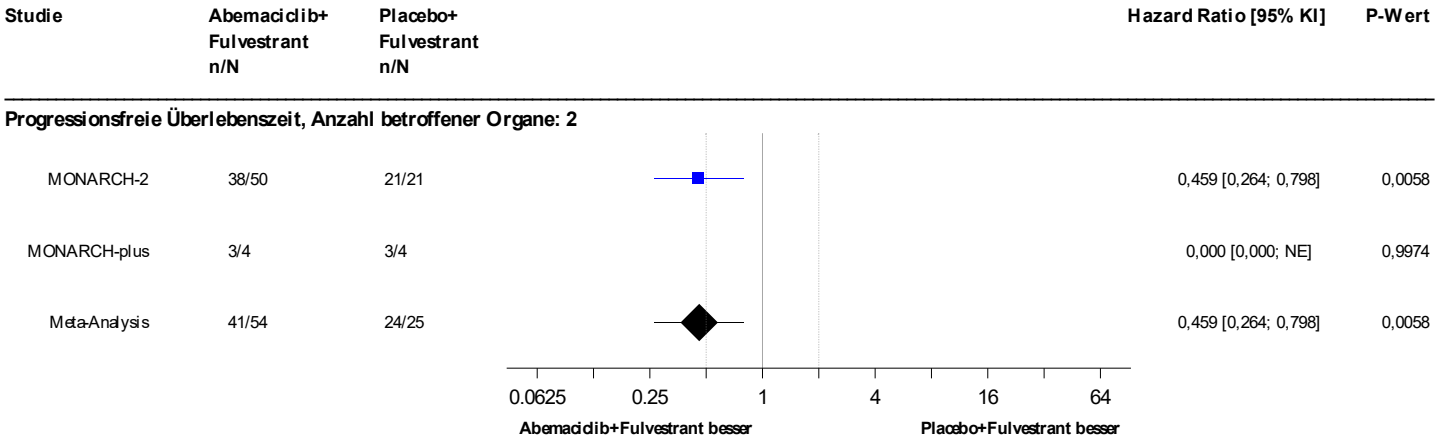
Abbildung 1402.2.2.2: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Anzahl betroffener Organe: 2 Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9975, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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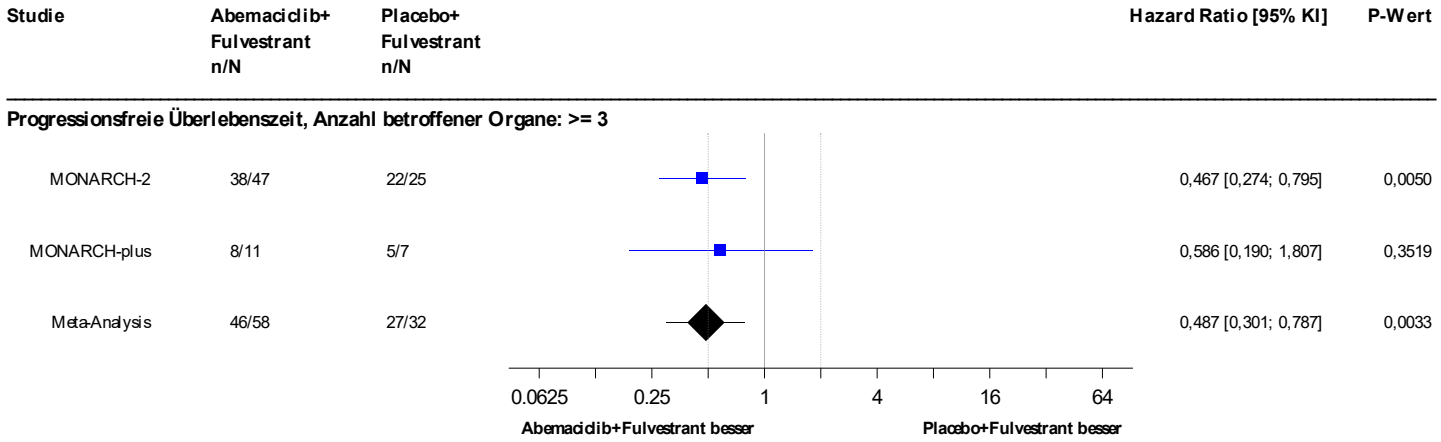
Abbildung 1402.2.2.3: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Anzahl betroffener Organe: >= 3 Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1270, P-Wert=0,7216, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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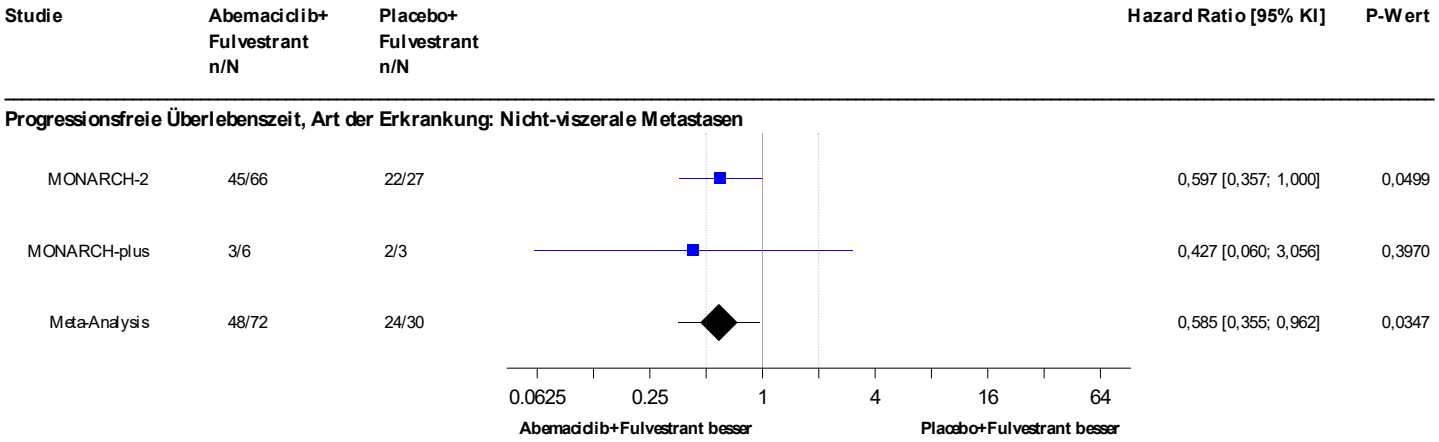
Abbildung 1402.2.3.1: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1042, P-Wert=0,7468, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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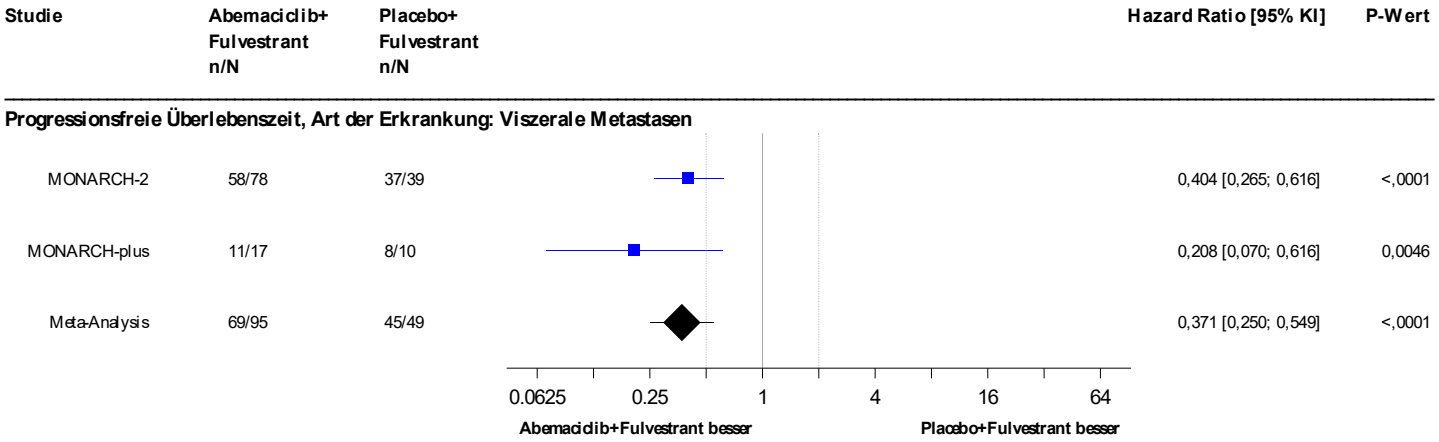
Abbildung 1402.2.3.2: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,2530, P-Wert=0,2630, I2 Index=20,2%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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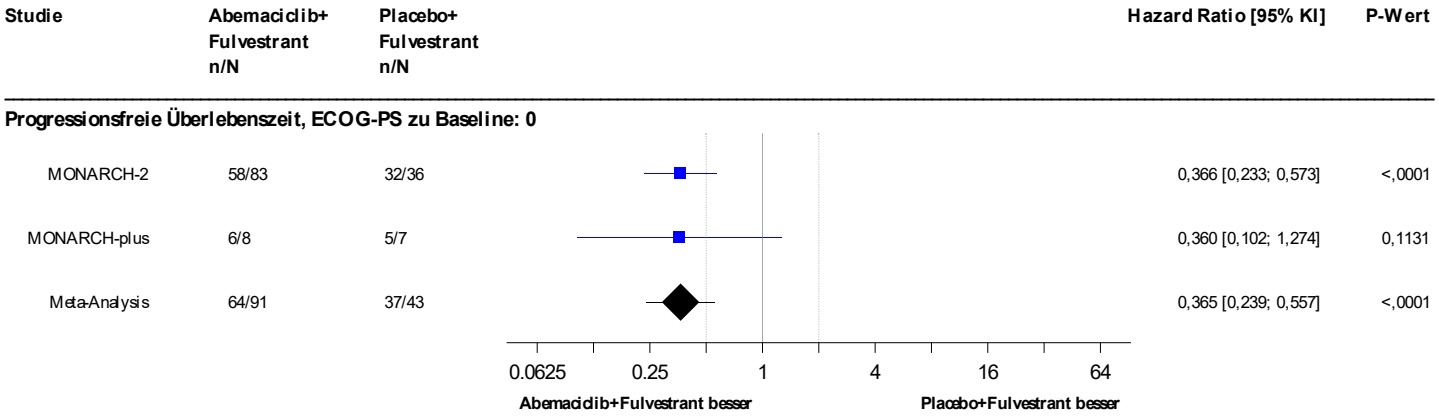
Abbildung 1402.2.4.1: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0005, P-Wert=0,9814, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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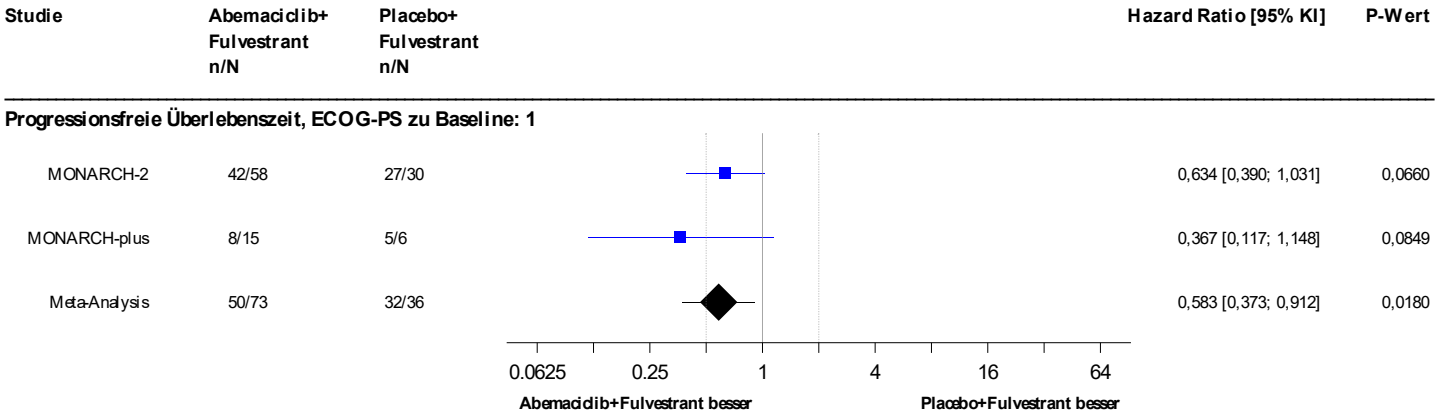
Abbildung 1402.2.4.2: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,7501, P-Wert=0,3865, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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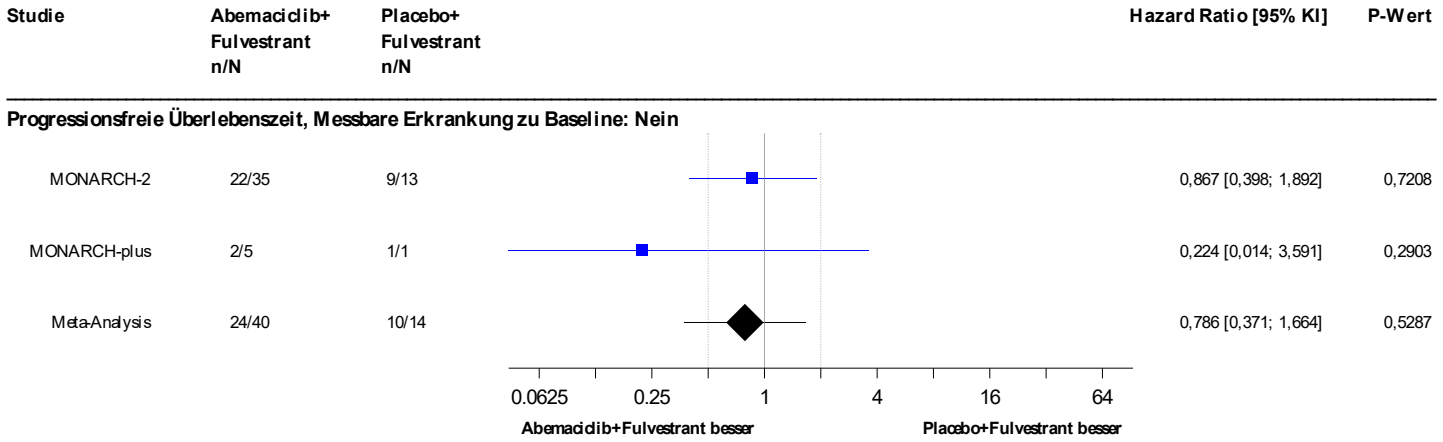
Abbildung 1402.2.6.1: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,8492, P-Wert=0,3568, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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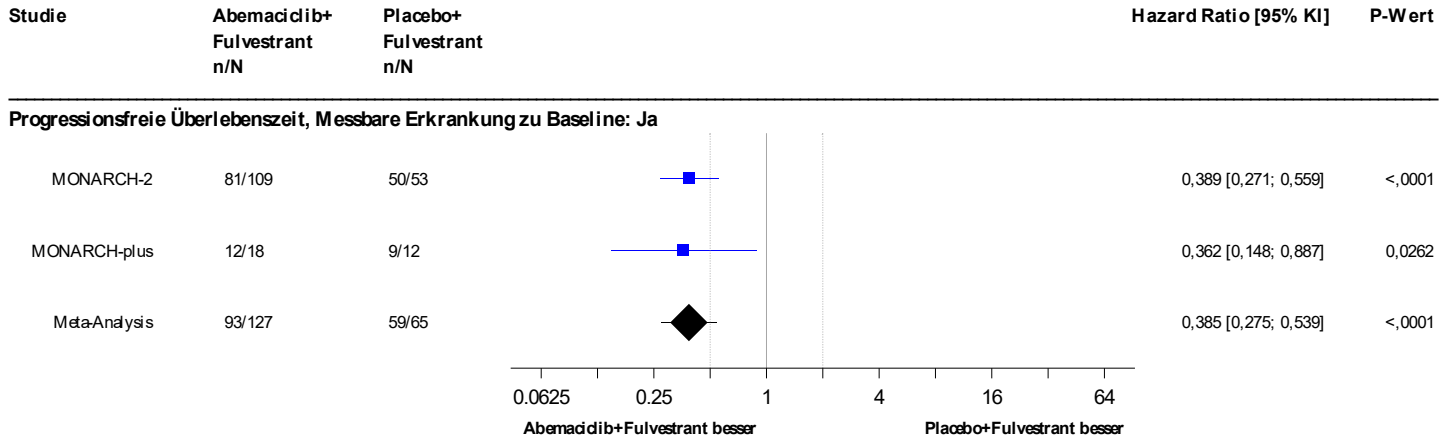
Abbildung 1402.2.6.2: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0205, P-Wert=0,8862, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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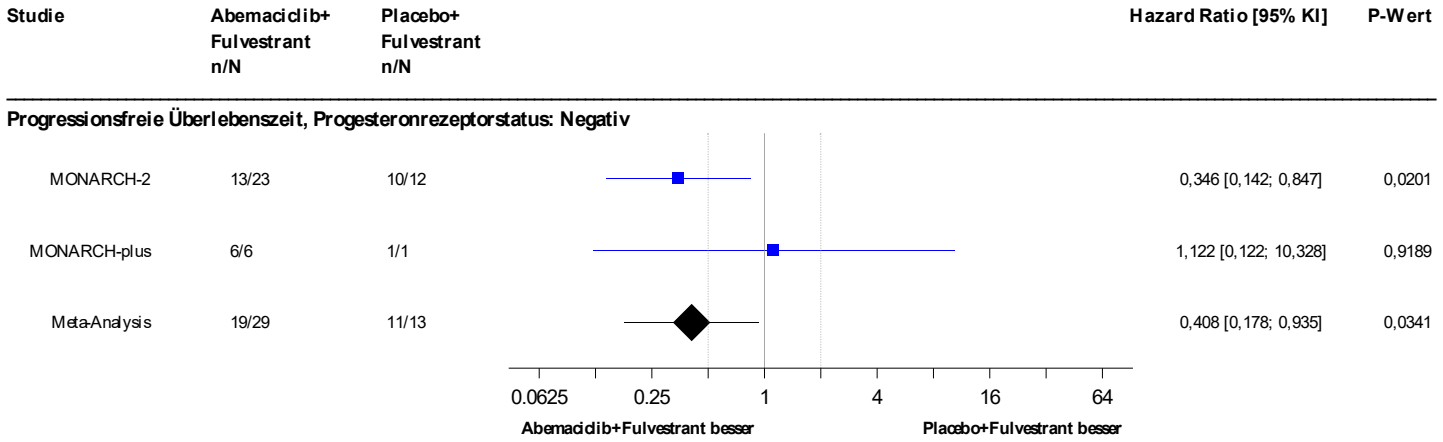
Abbildung 1402.2.7.1: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Progesteronrezeptorstatus: Negativ Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,9271, P-Wert=0,3356, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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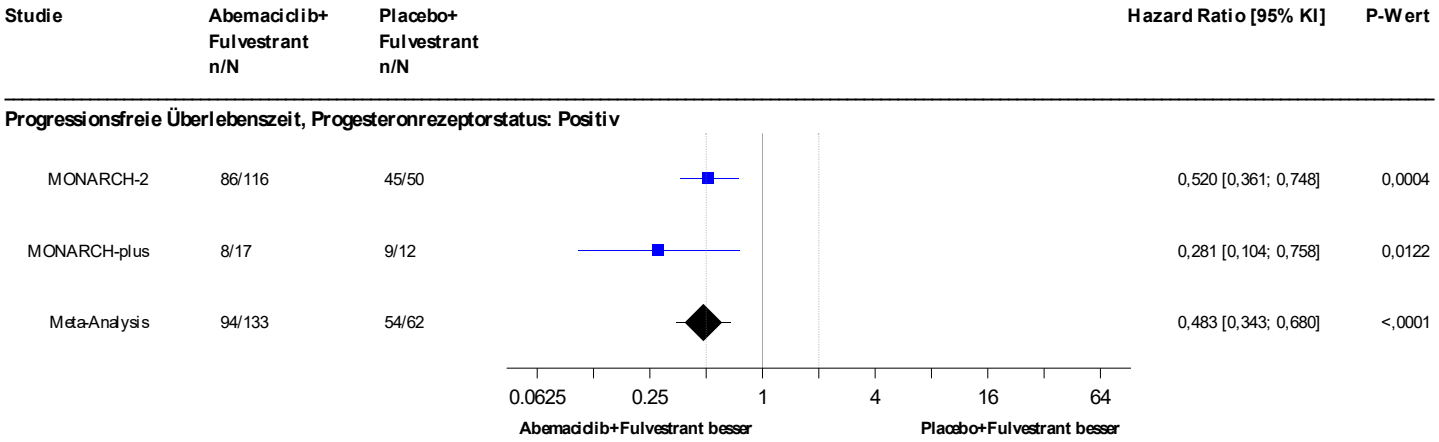
Abbildung 1402.2.7.2: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Progesteronrezeptorstatus: Positiv Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,3018, P-Wert=0,2539, I2 Index=23,2%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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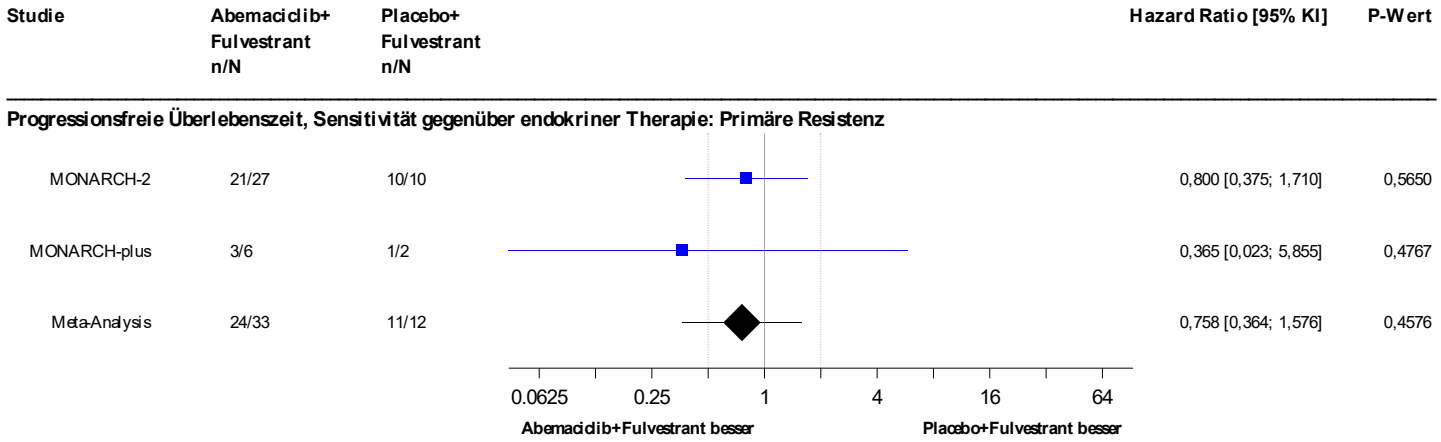
Abbildung 1402.2.8.1: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2857, P-Wert=0,5930, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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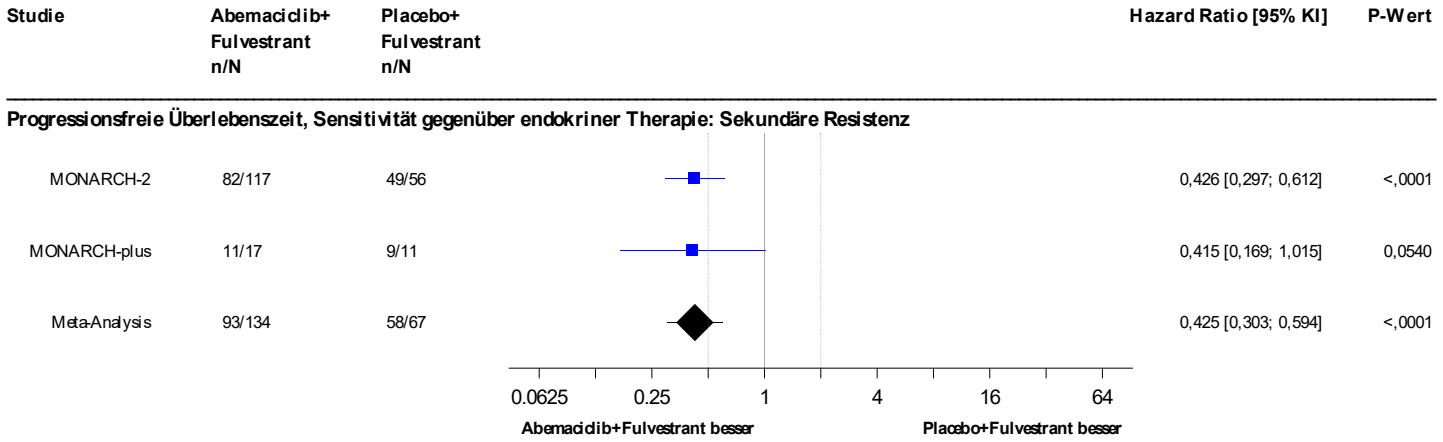
Abbildung 1402.2.8.2: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0031, P-Wert=0,9560, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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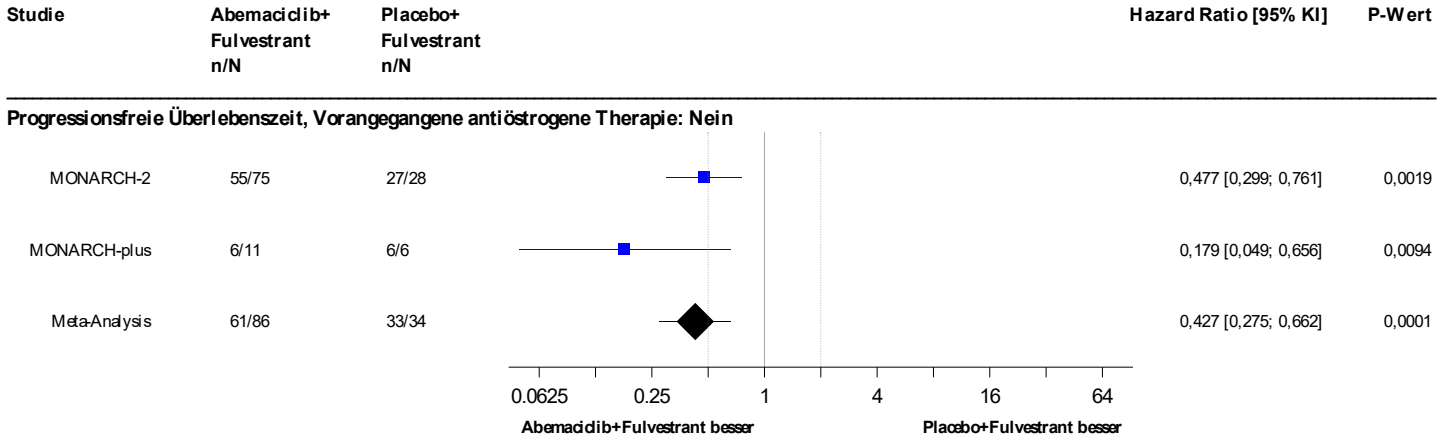
Abbildung 1402.2.9.1: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,9397, P-Wert=0,1637, I2 Index=48,4%
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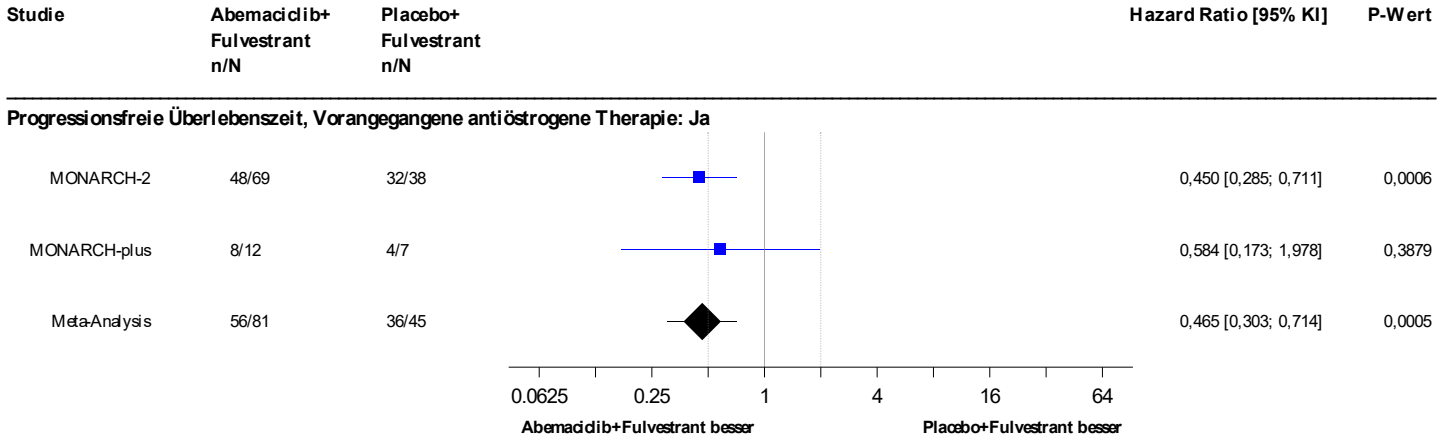
Abbildung 1402.2.9.2: Metaanalyse der Ergebnisse für progessionsfreies Überleben aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja Studien MONARCH-2 und MONARCH-plus - ITT Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1545, P-Wert=0,6943, I2 Index=0%
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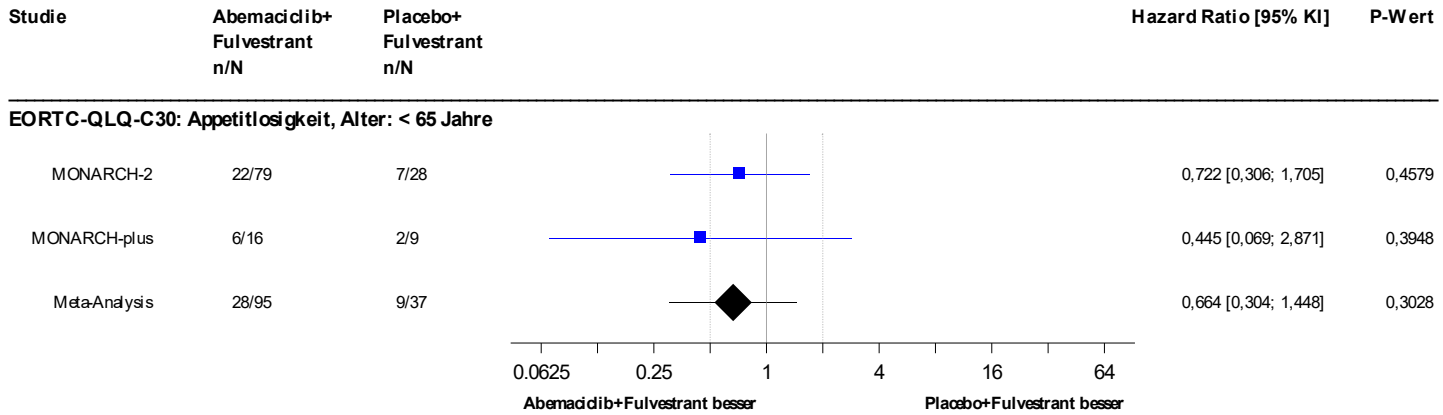
Abbildung 1403.2.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2136, P-Wert=0,6439, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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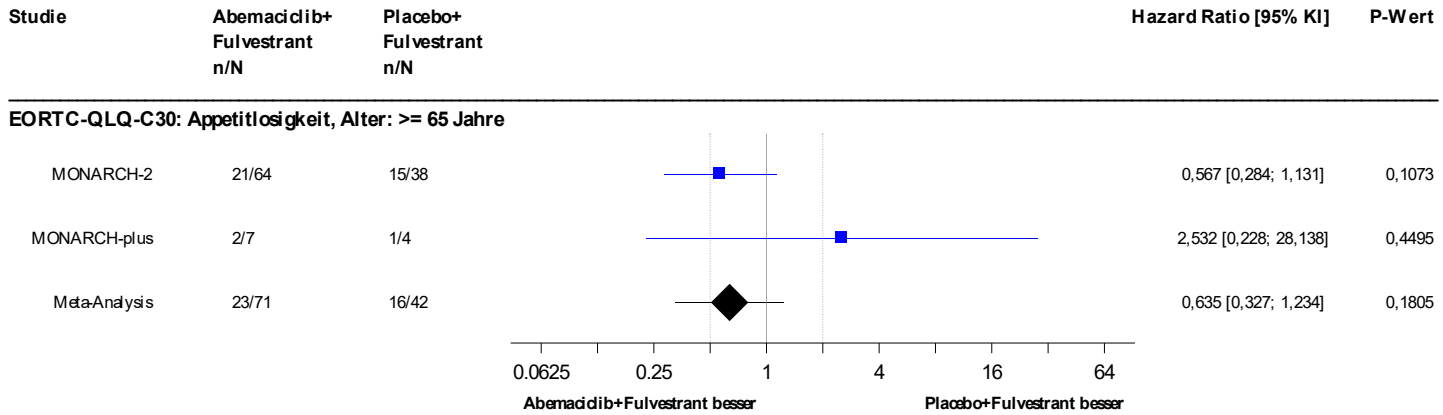
Abbildung 1403.2.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,3721, P-Wert=0,2415, I2 Index=27,1%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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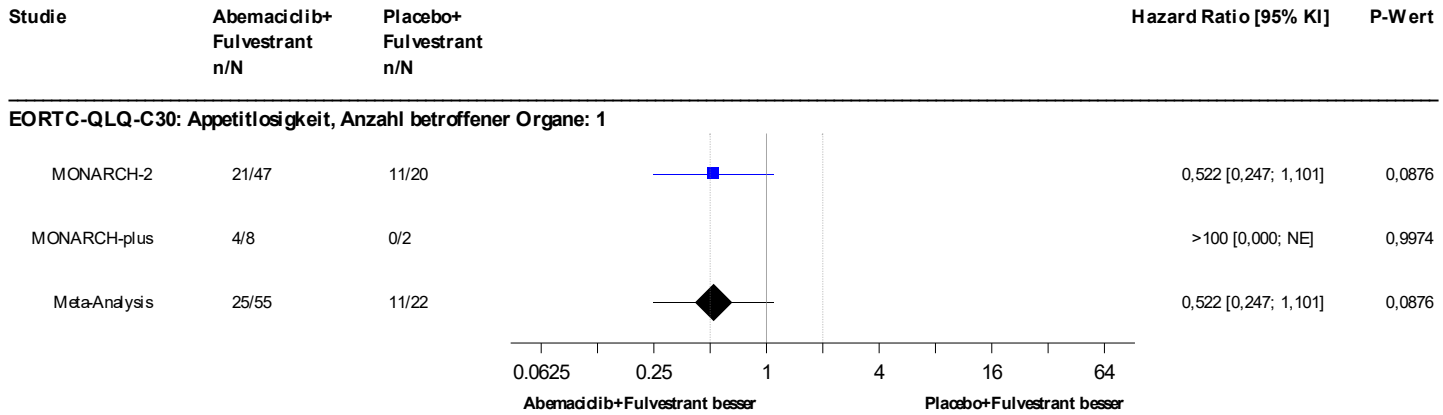
Abbildung 1403.2.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9972, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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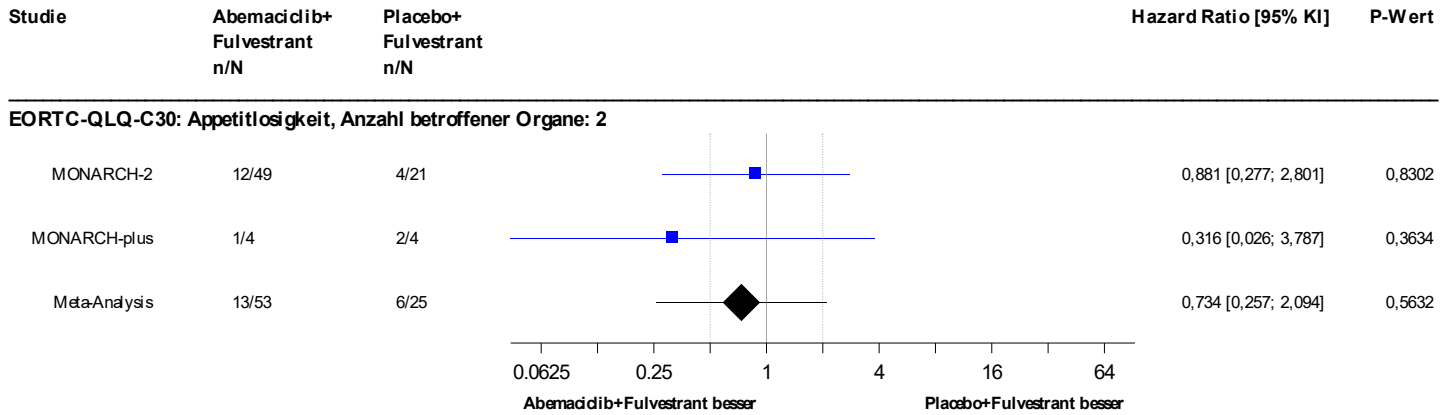
Abbildung 1403.2.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,5381, P-Wert=0,4632, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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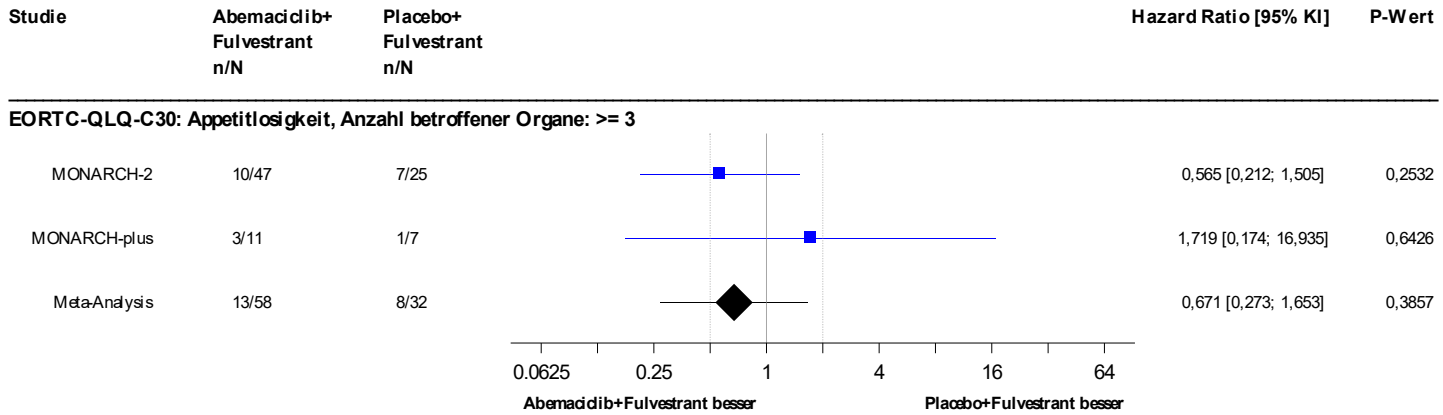
Abbildung 1403.2.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,7685, P-Wert=0,3807, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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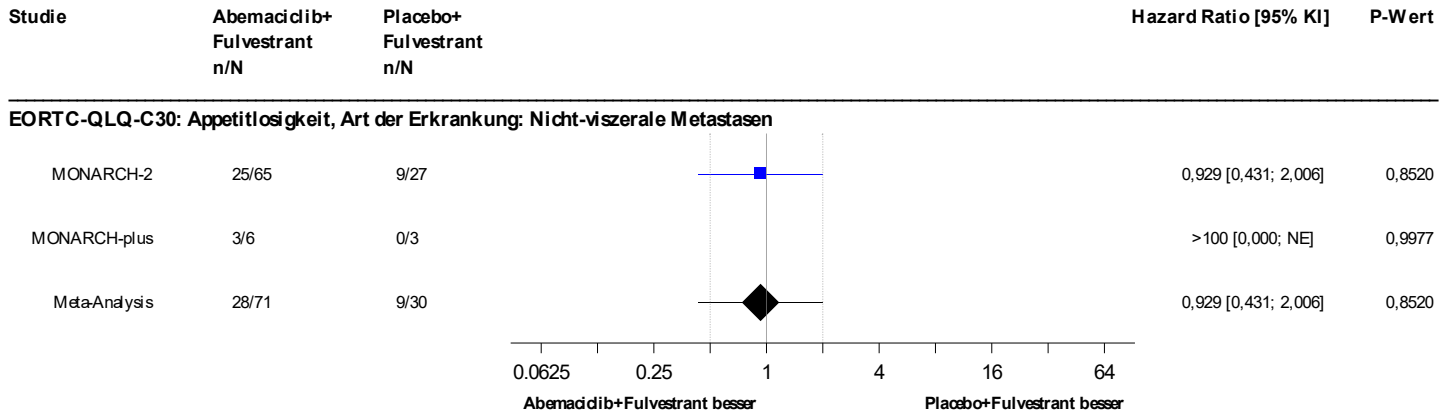
Abbildung 1403.2.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9977, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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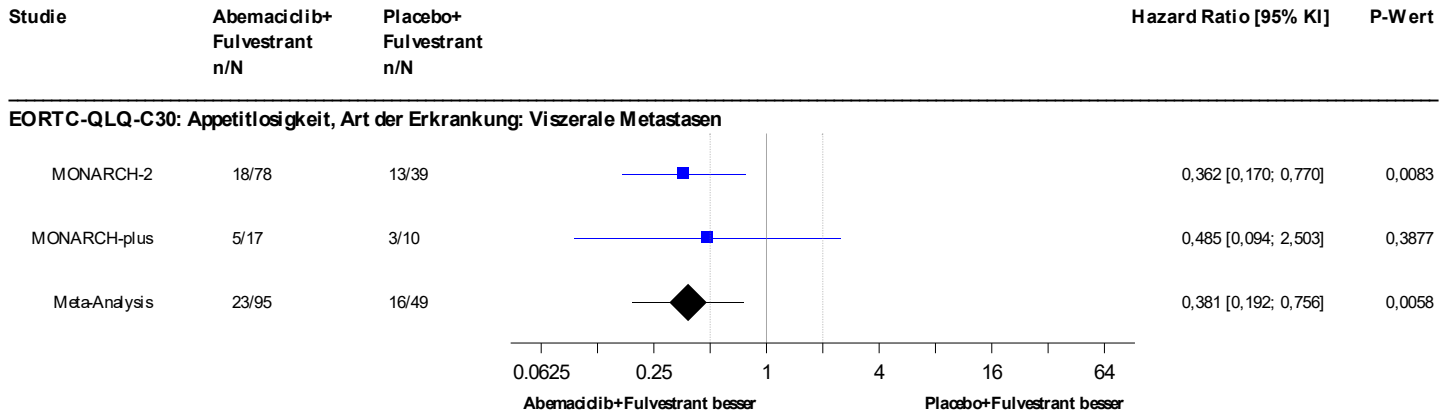
Abbildung 1403.2.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1012, P-Wert=0,7504, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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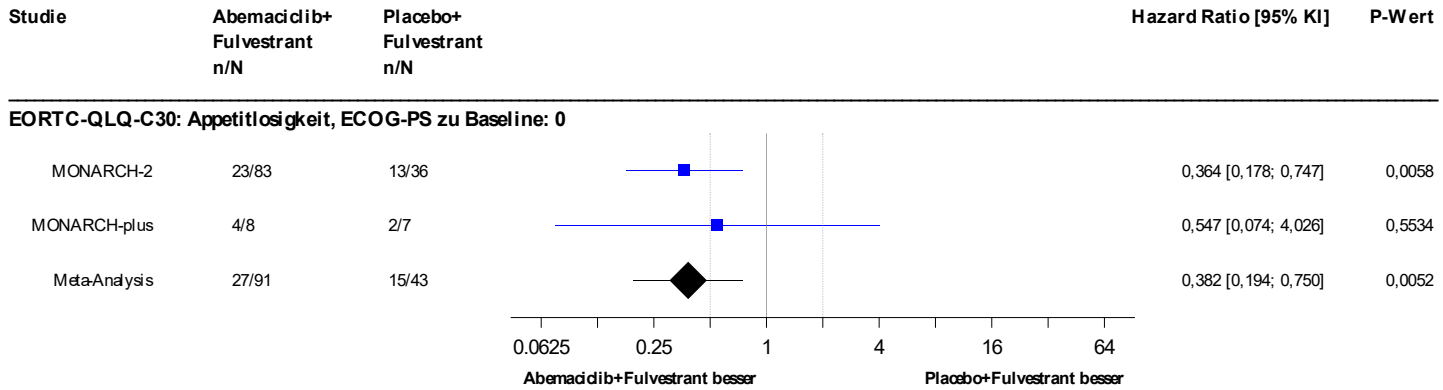
Abbildung 1403.2.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1409, P-Wert=0,7074, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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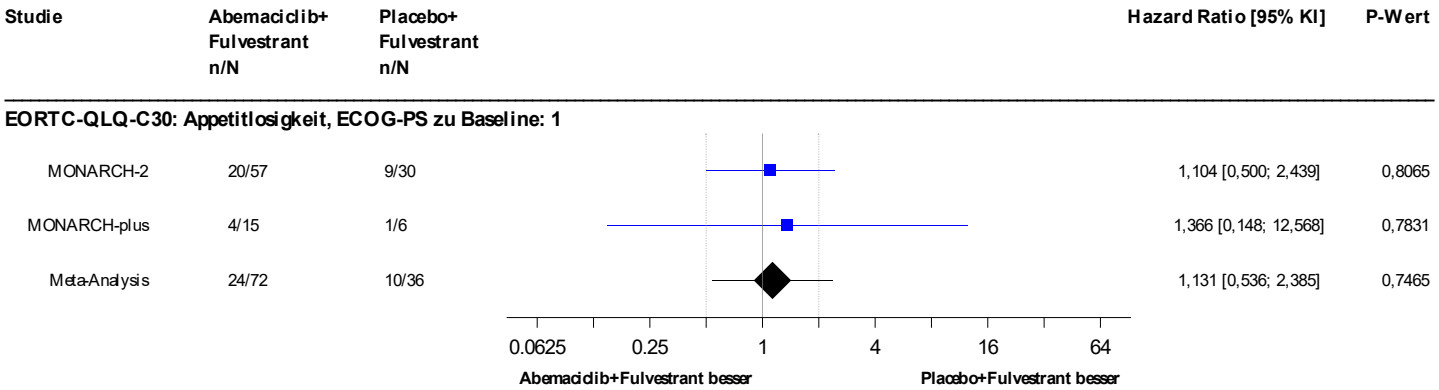
Abbildung 1403.2.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0313, P-Wert=0,8596, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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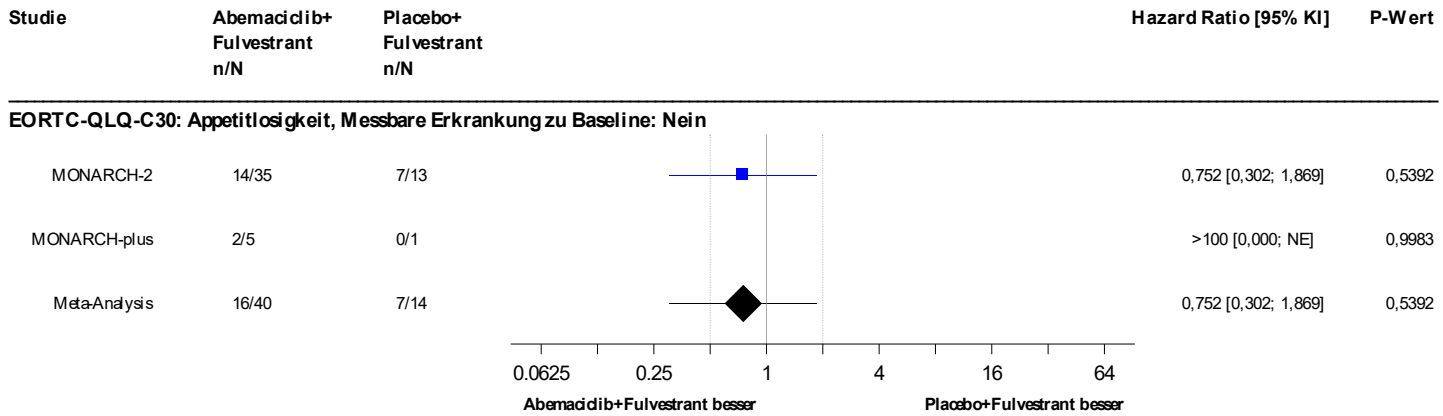
Abbildung 1403.2.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9983, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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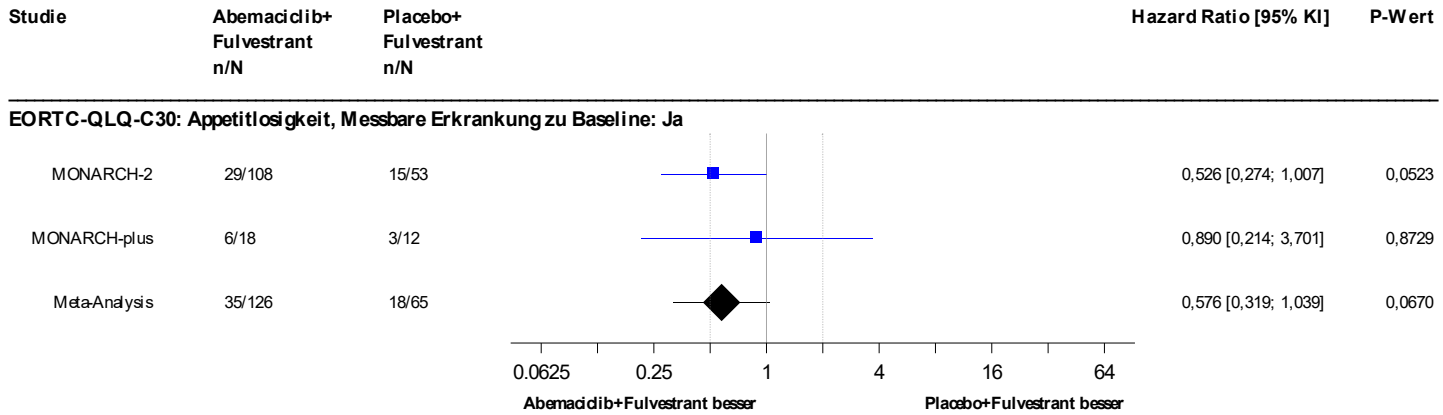
Abbildung 1403.2.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,4349, P-Wert=0,5096, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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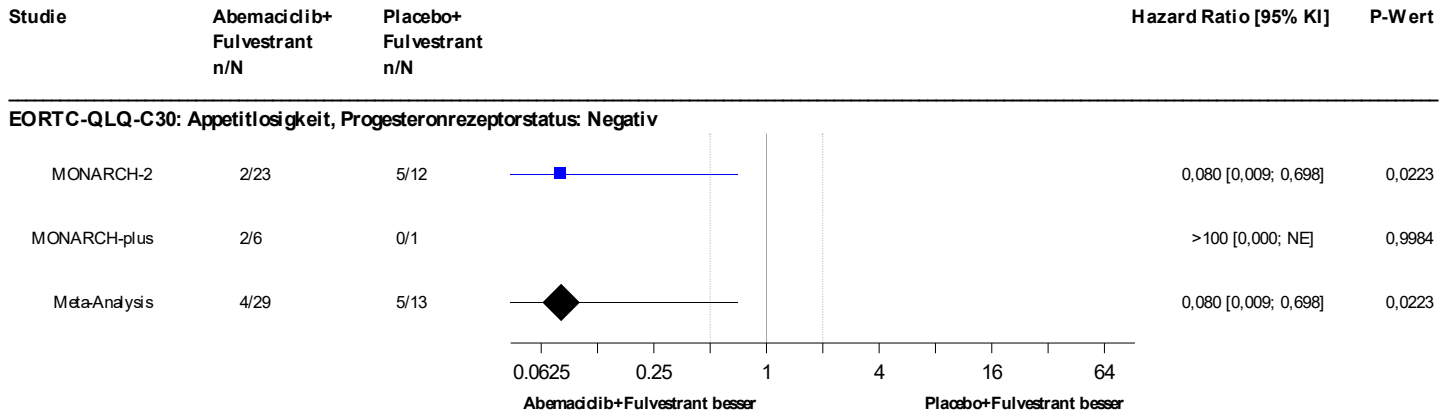
Abbildung 1403.2.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9982, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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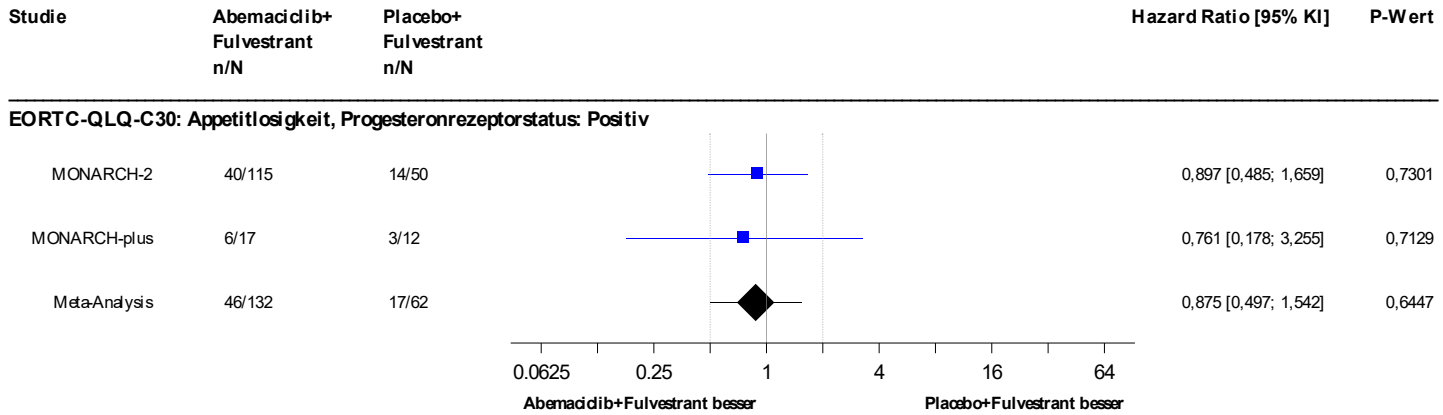
Abbildung 1403.2.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0418, P-Wert=0,8380, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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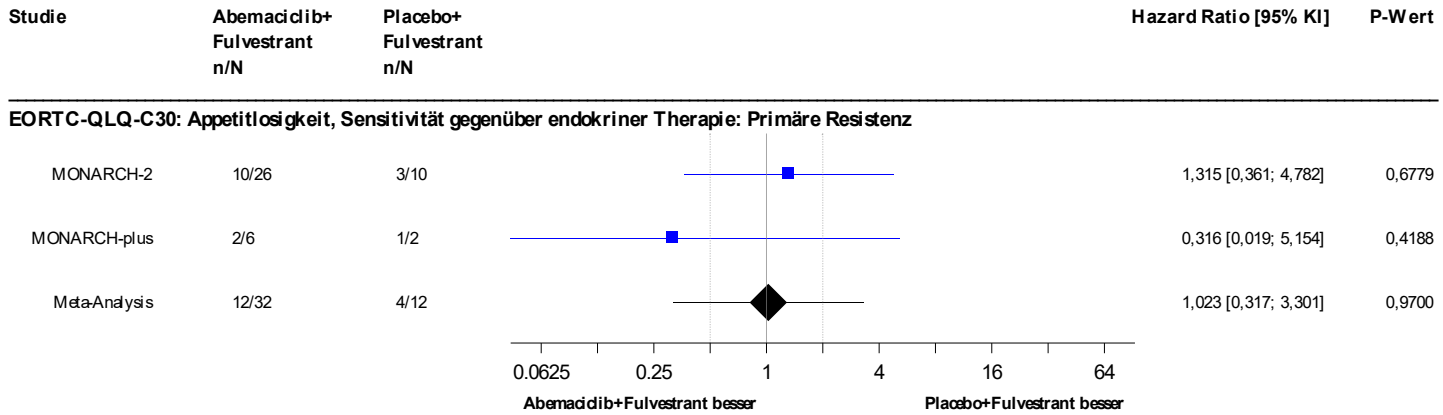
Abbildung 1403.2.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,8248, P-Wert=0,3638, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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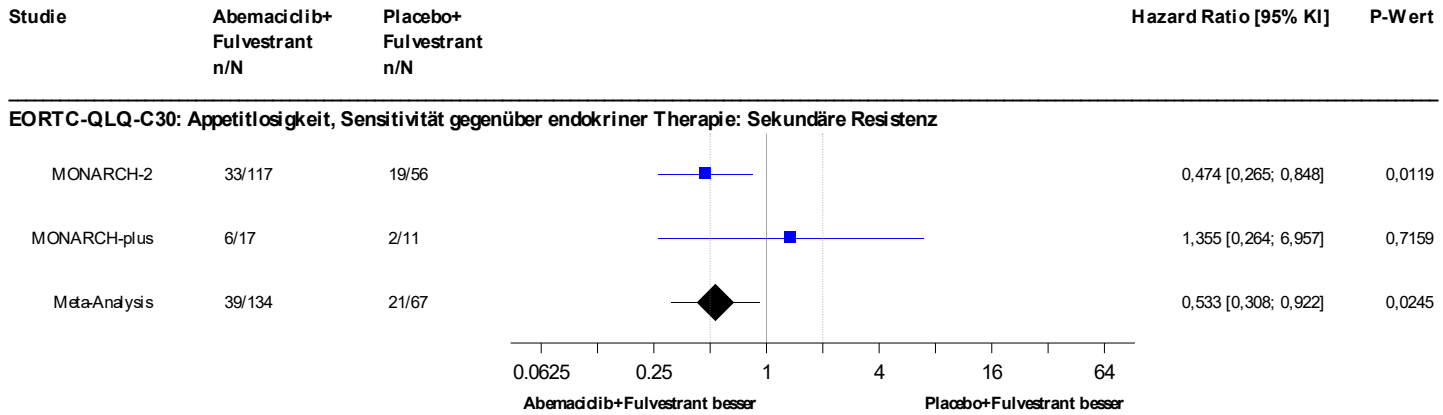
Abbildung 1403.2.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,4057, P-Wert=0,2358, I2 Index=28,9%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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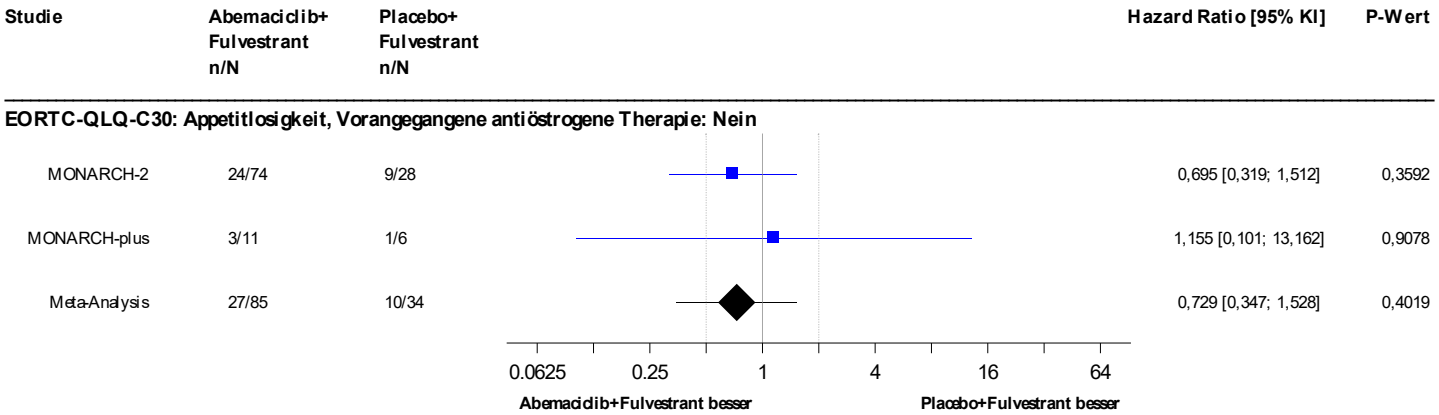
Abbildung 1403.2.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1516, P-Wert=0,6970, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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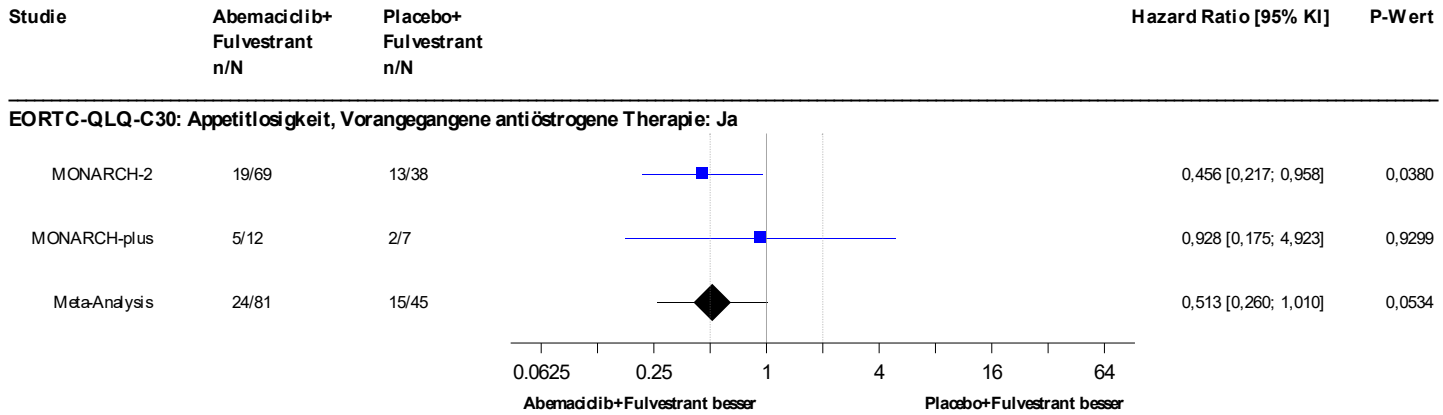
Abbildung 1403.2.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Appetitlosigkeit (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,5805, P-Wert=0,4461, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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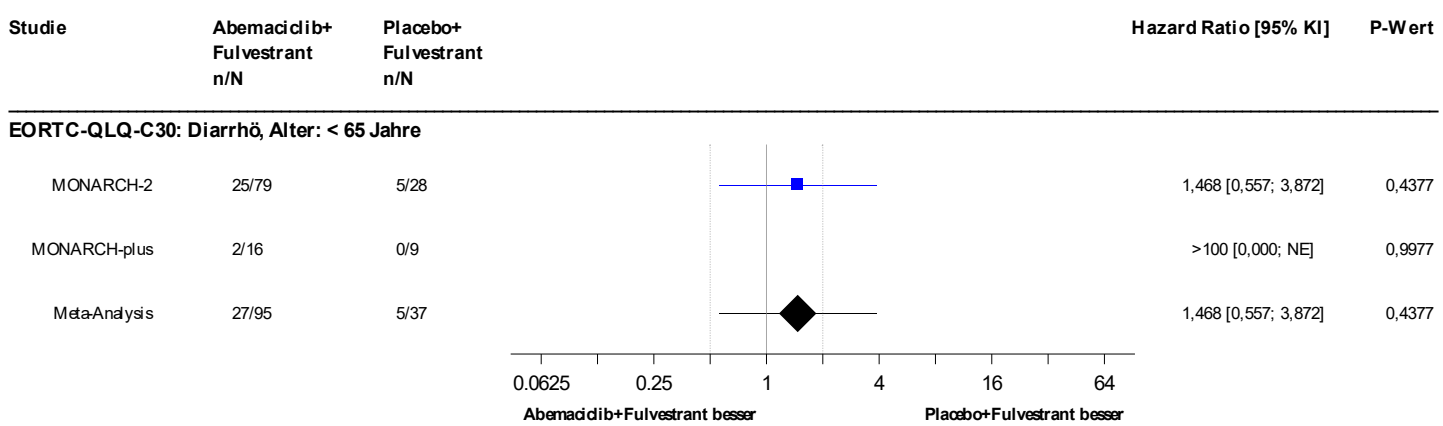
Abbildung 1404.2.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9978, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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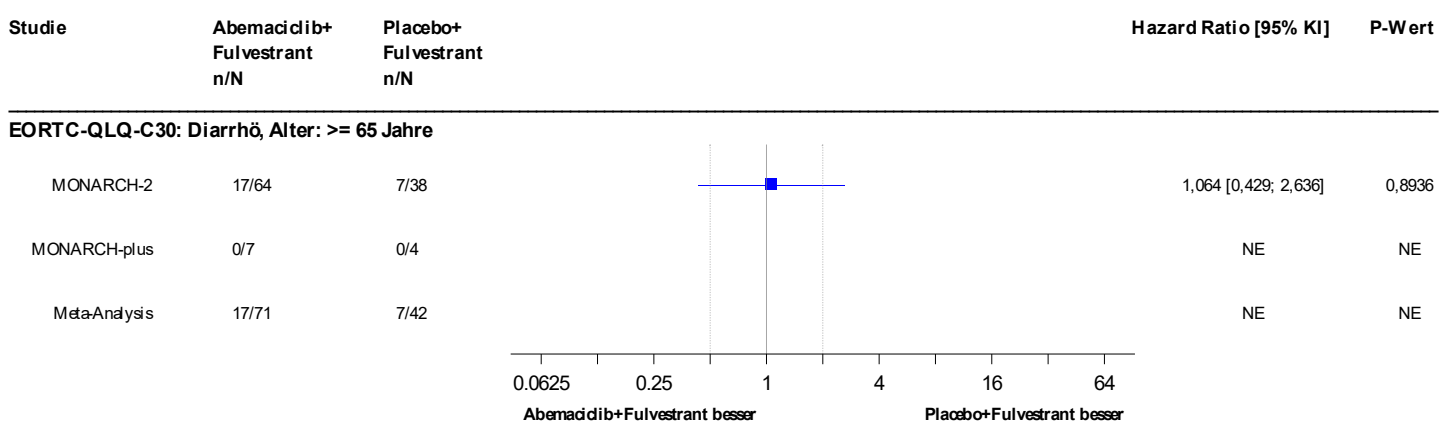
Abbildung 1404.2.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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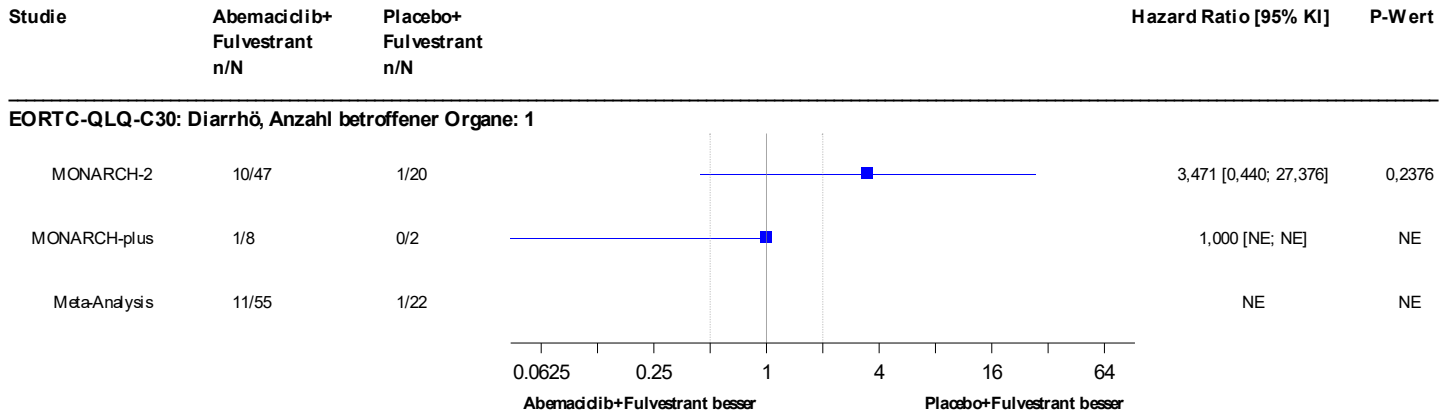
Abbildung 1404.2.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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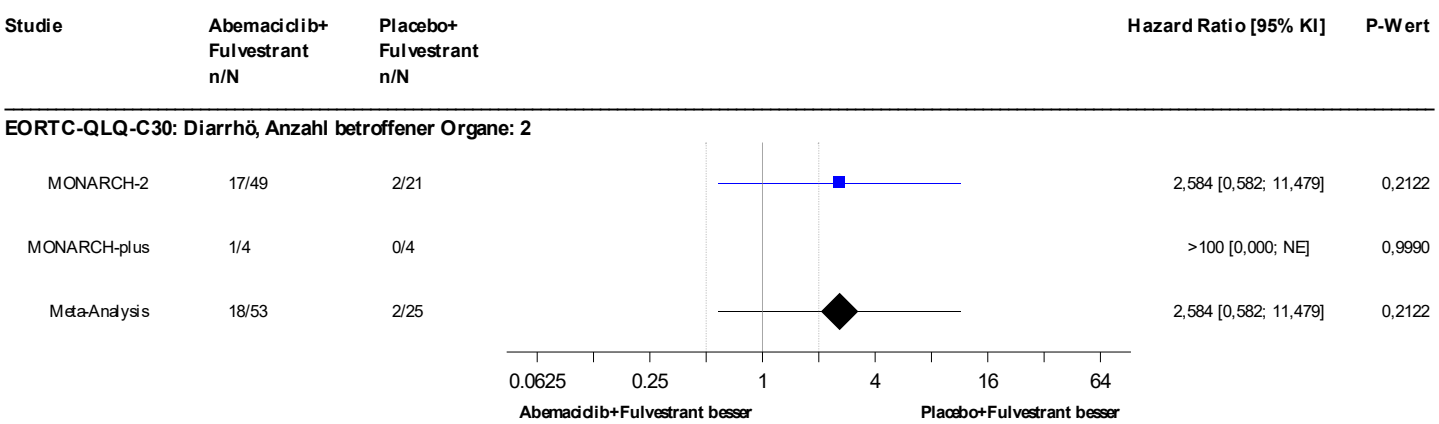
Abbildung 1404.2.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9990, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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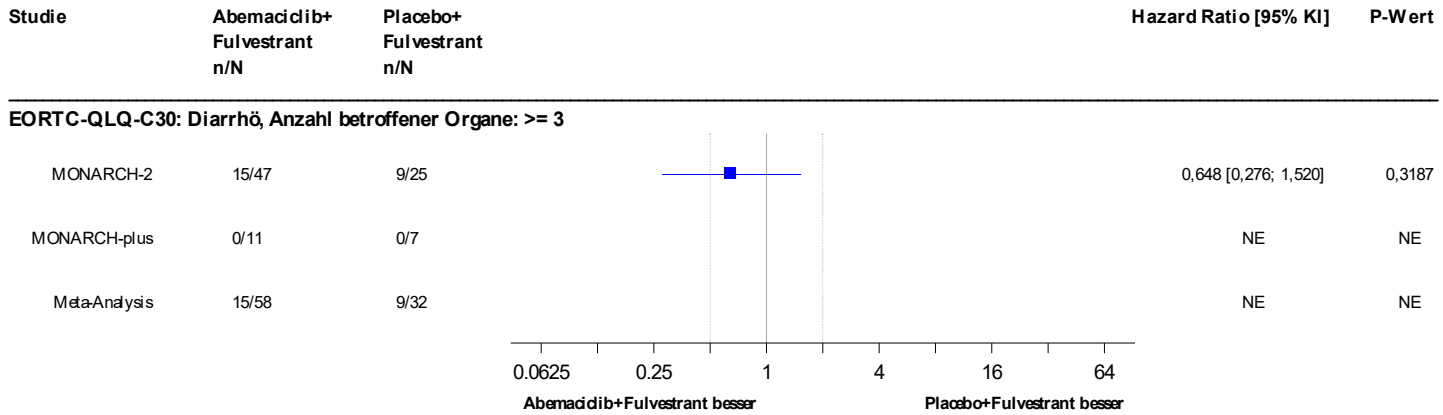
Abbildung 1404.2.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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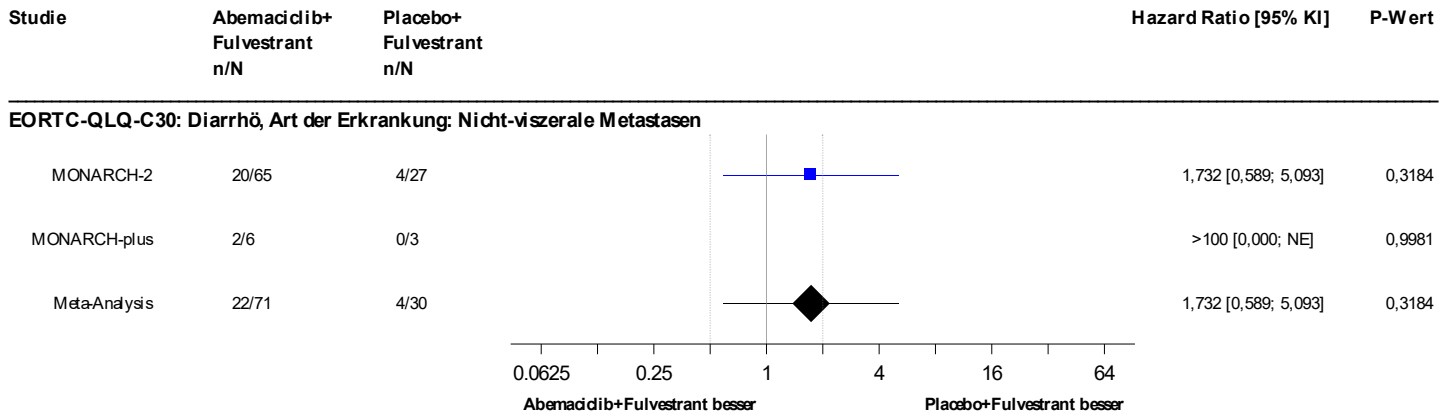
Abbildung 1404.2.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9981, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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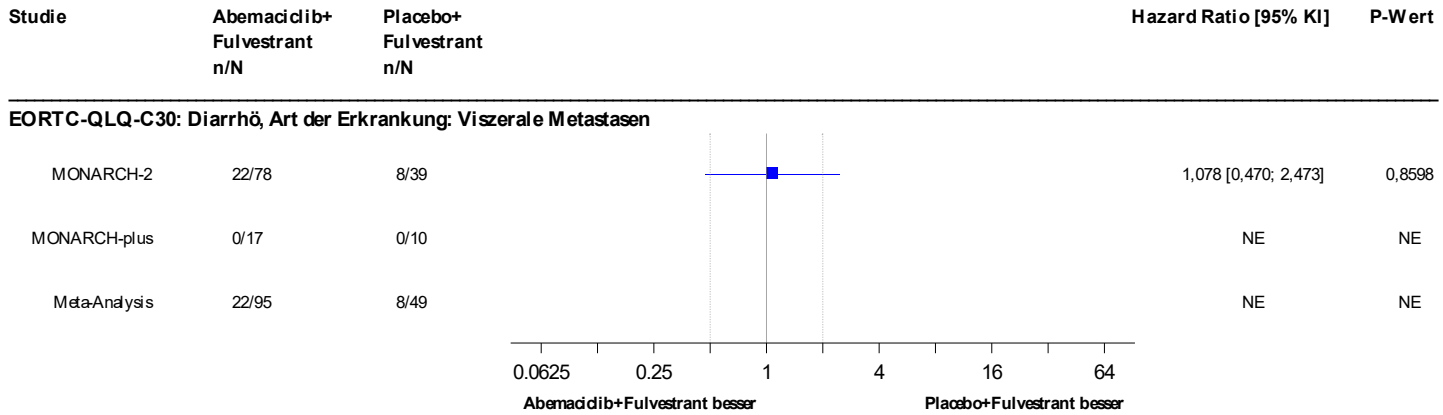
Abbildung 1404.2.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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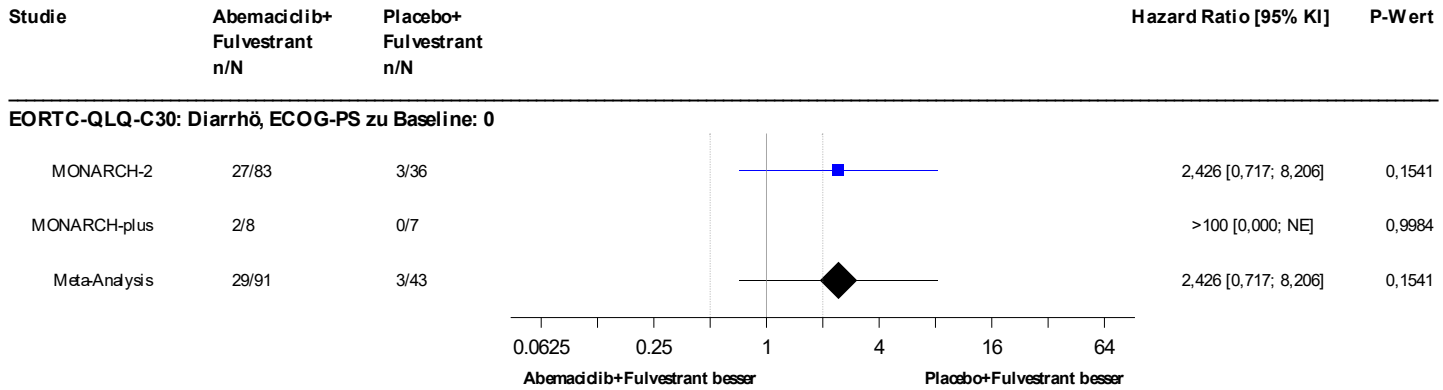
Abbildung 1404.2.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9985, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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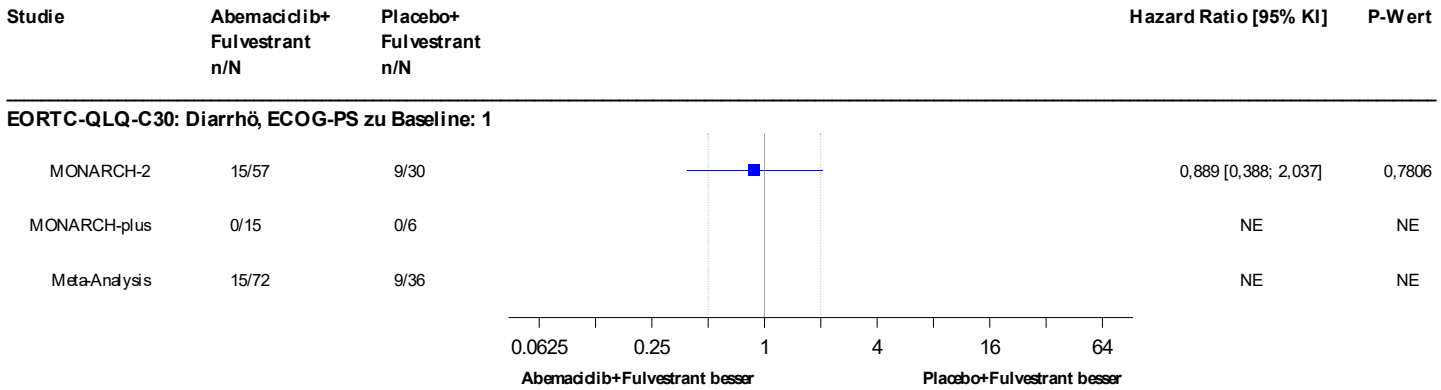
Abbildung 1404.2.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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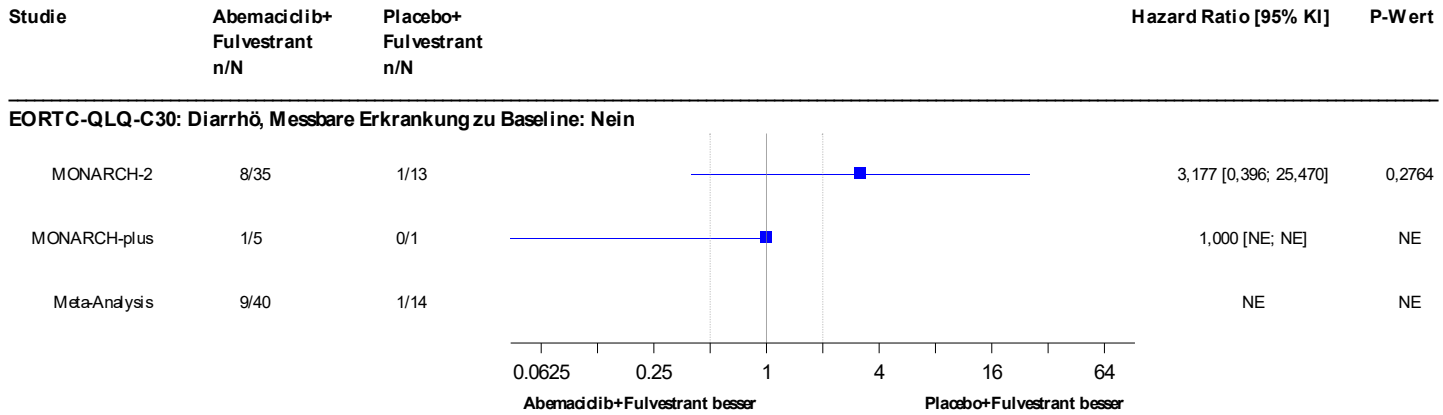
Abbildung 1404.2.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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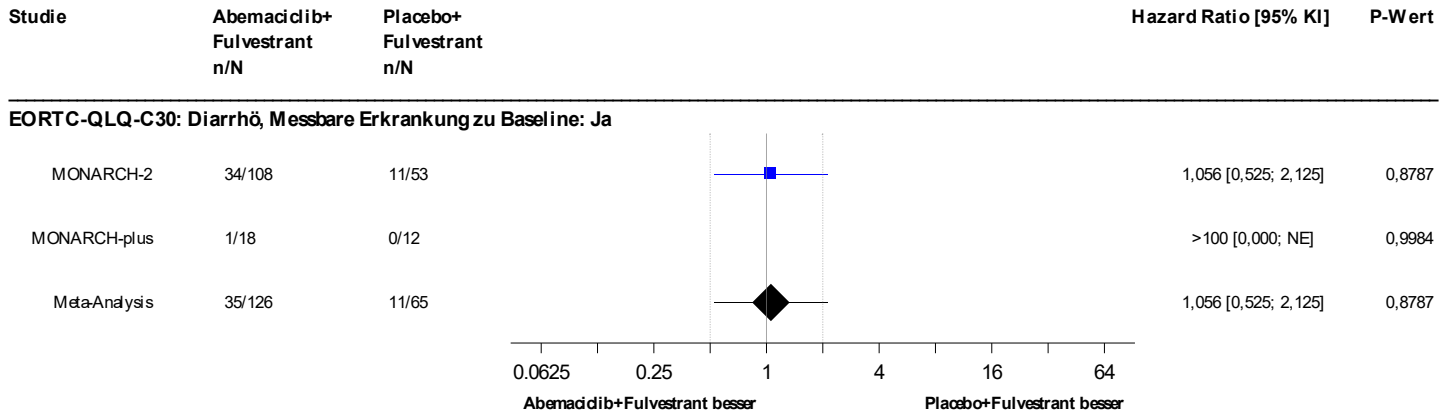
Abbildung 1404.2.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9984, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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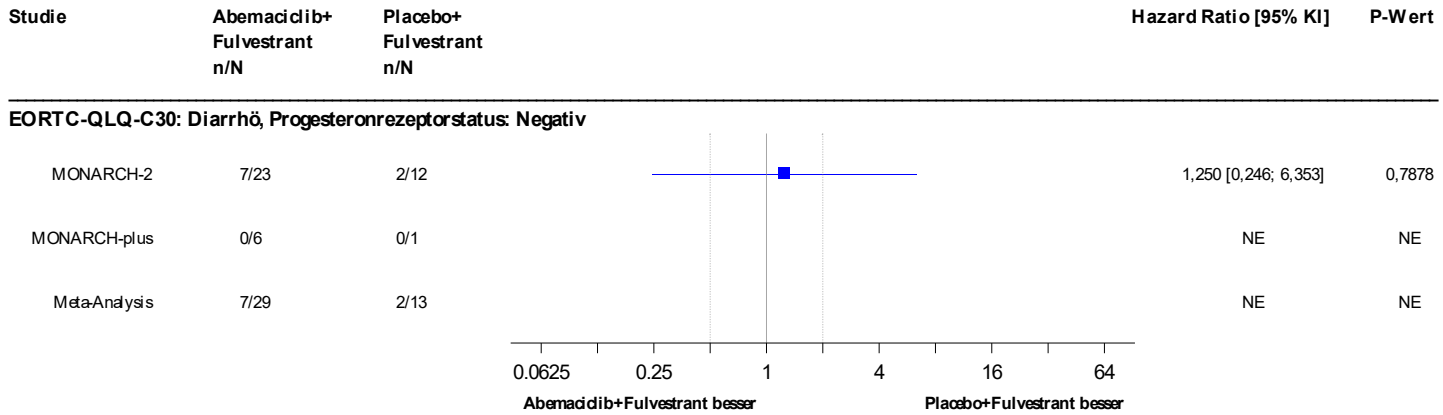
Abbildung 1404.2.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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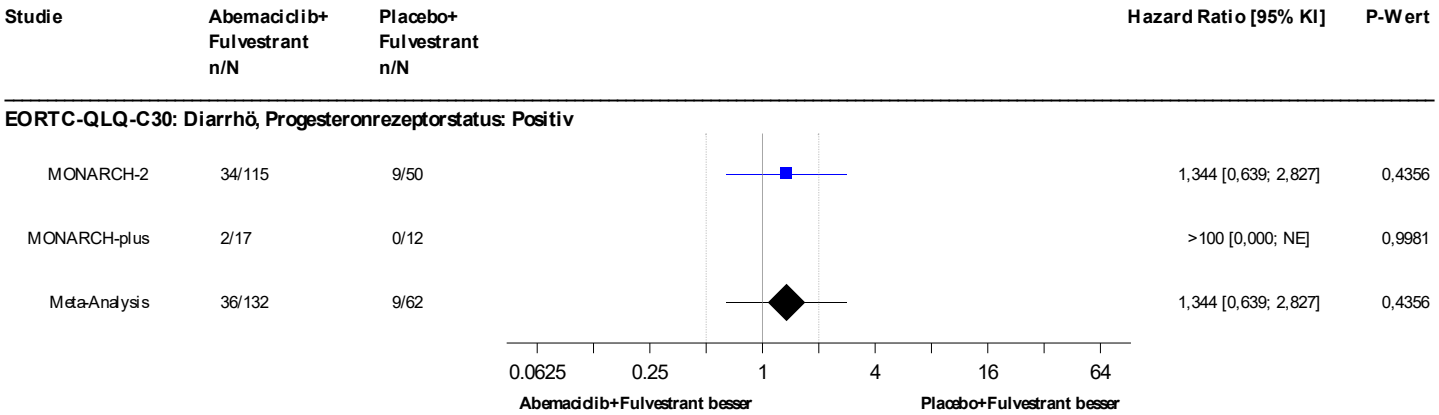
Abbildung 1404.2.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9981, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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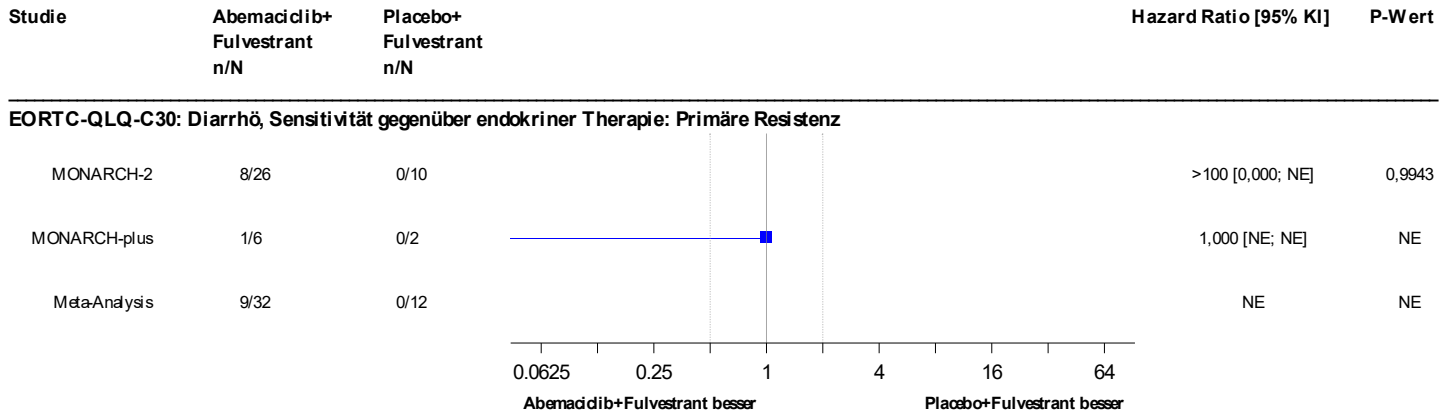
Abbildung 1404.2.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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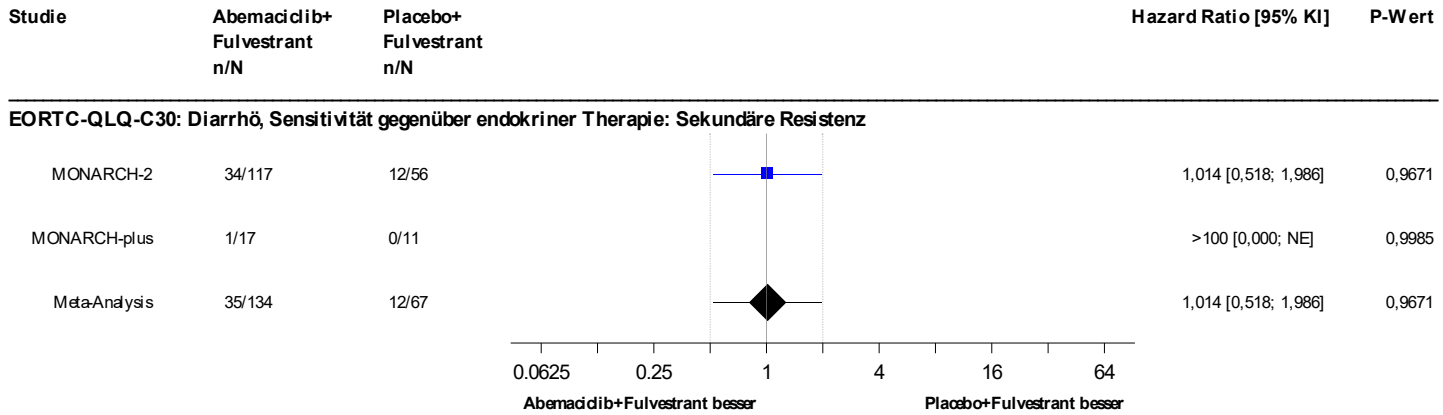
Abbildung 1404.2.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9985, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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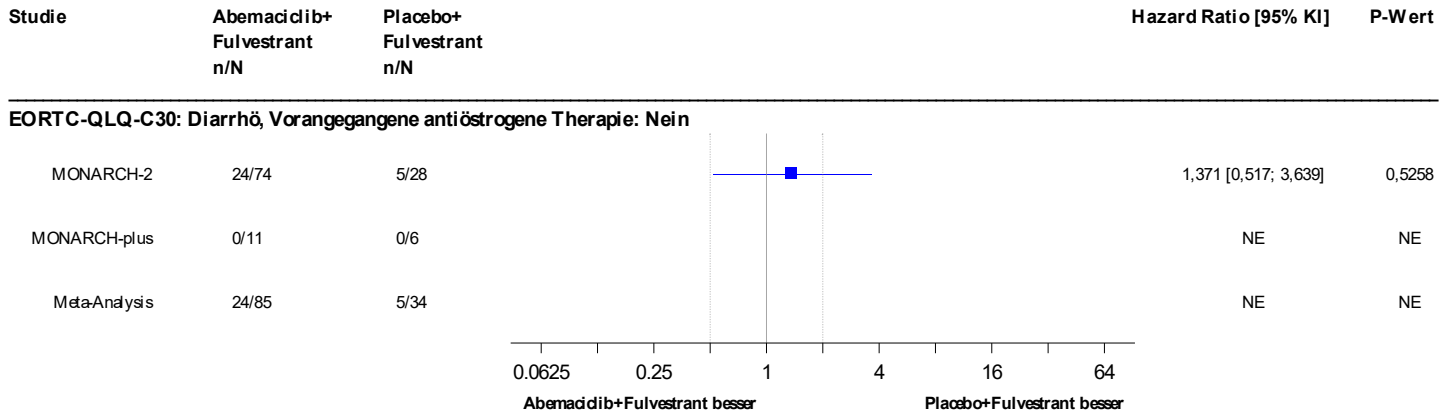
Abbildung 1404.2.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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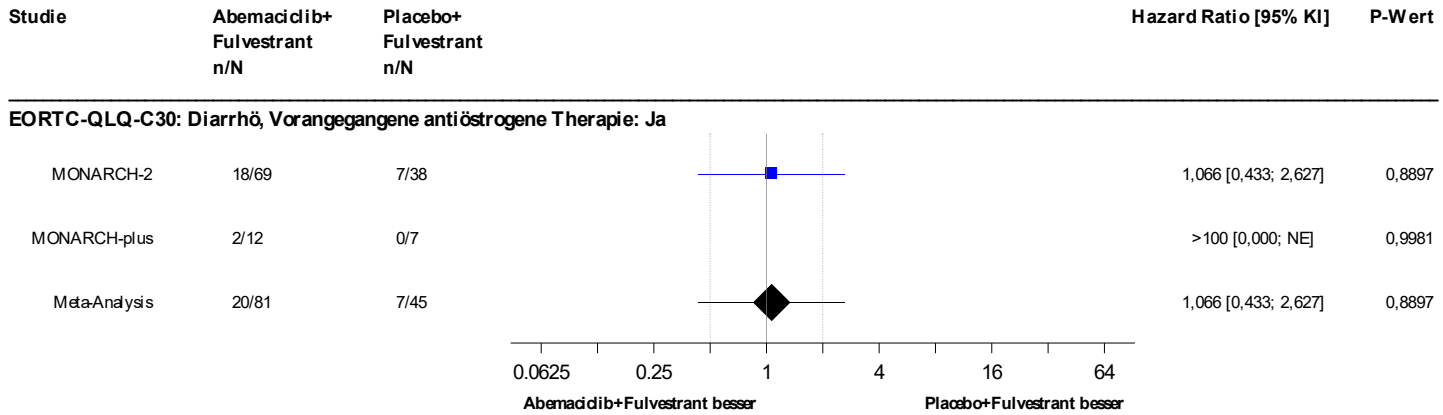
Abbildung 1404.2.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Diarrhö (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9981, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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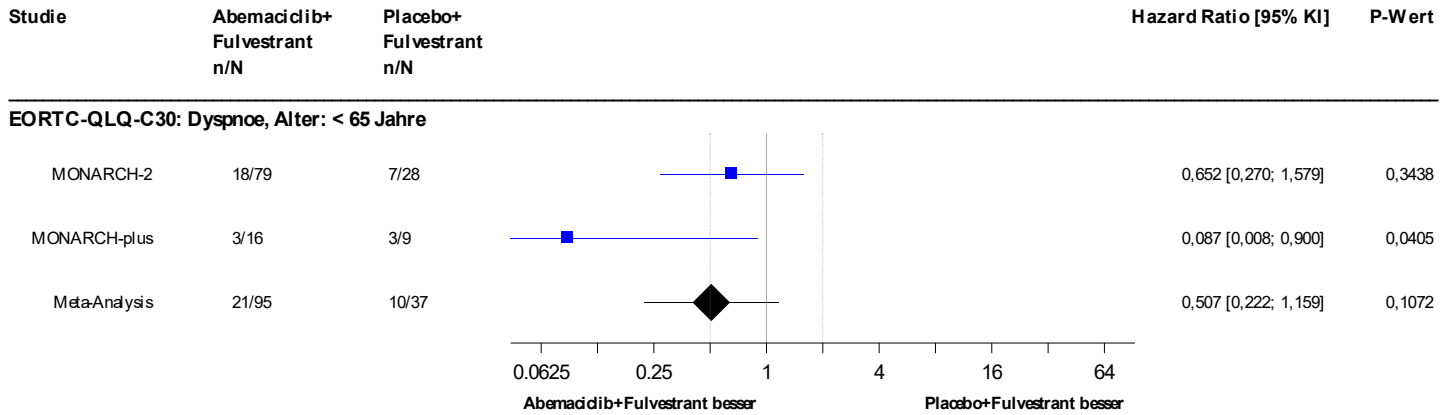
Abbildung 1405.2.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=2,4968, P-Wert=0,1141, I2 Index=59,9%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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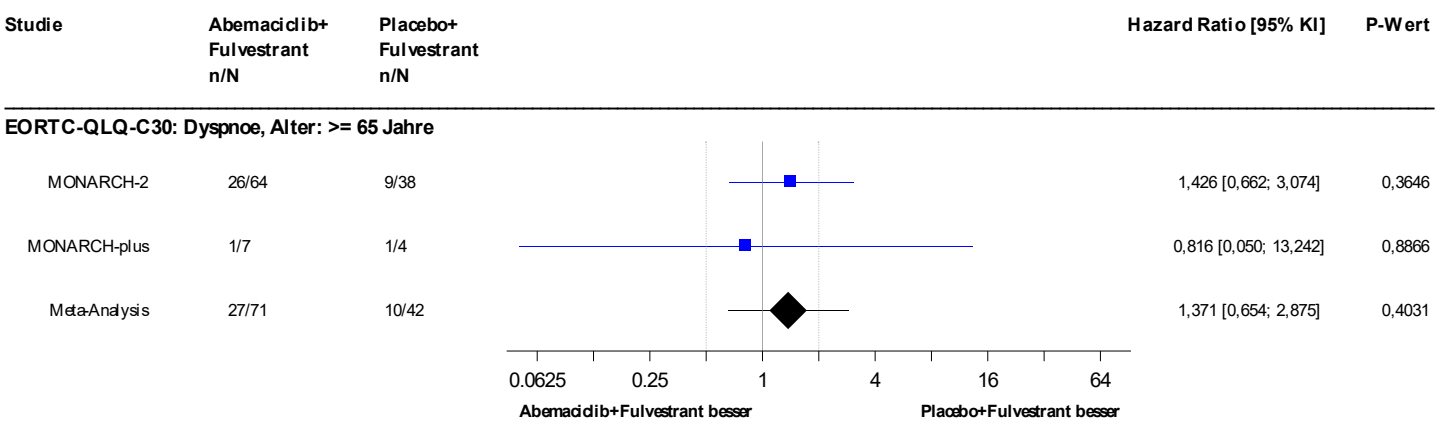
Abbildung 1405.2.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1431, P-Wert=0,7052, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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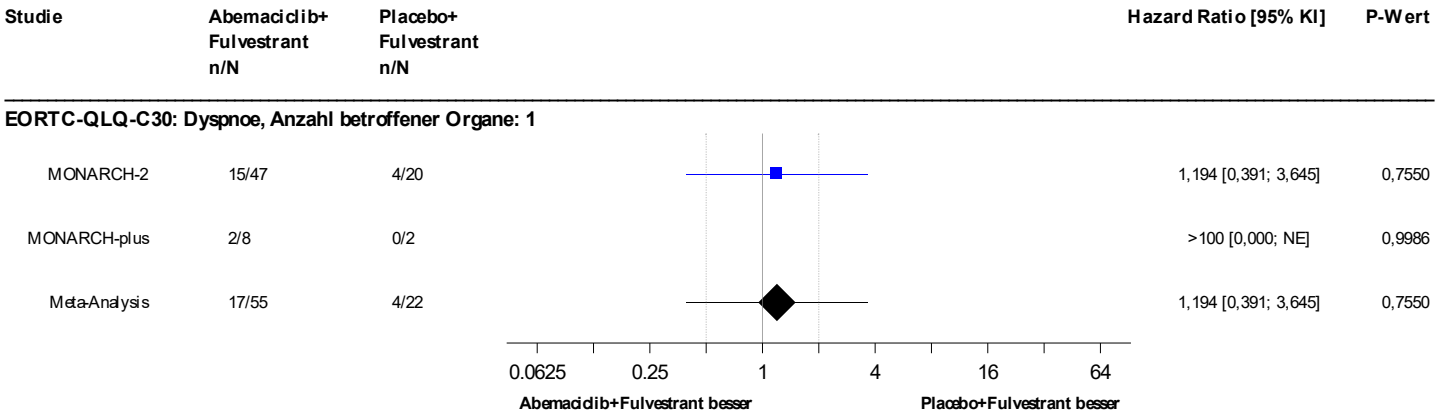
Abbildung 1405.2.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9986, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwdysp6_popa2_norggr_1.rtf
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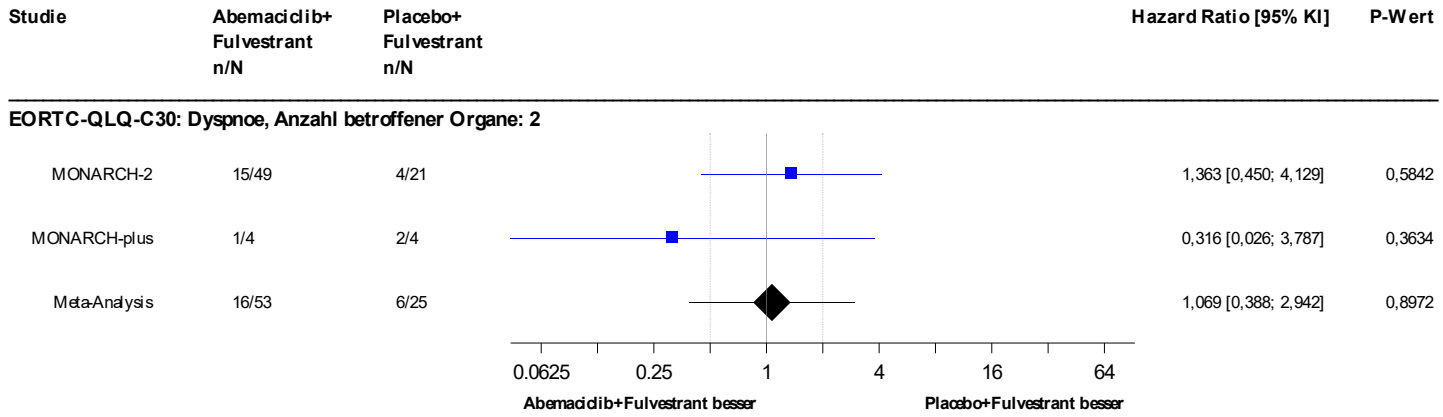
Abbildung 1405.2.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,1091, P-Wert=0,2923, I2 Index=9,8%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwdysp6_popa2_norggr_2.rtf
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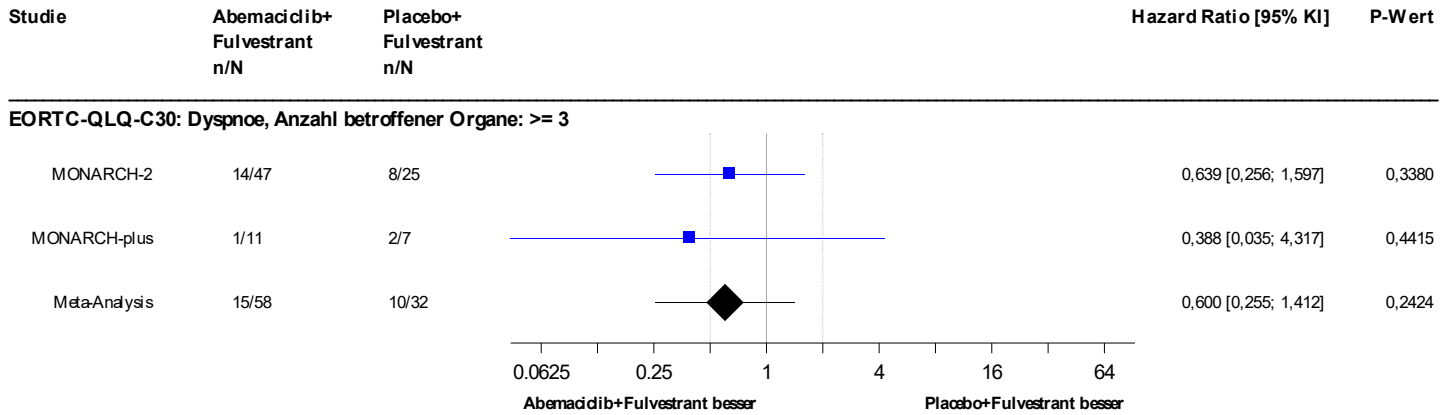
Abbildung 1405.2.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1437, P-Wert=0,7046, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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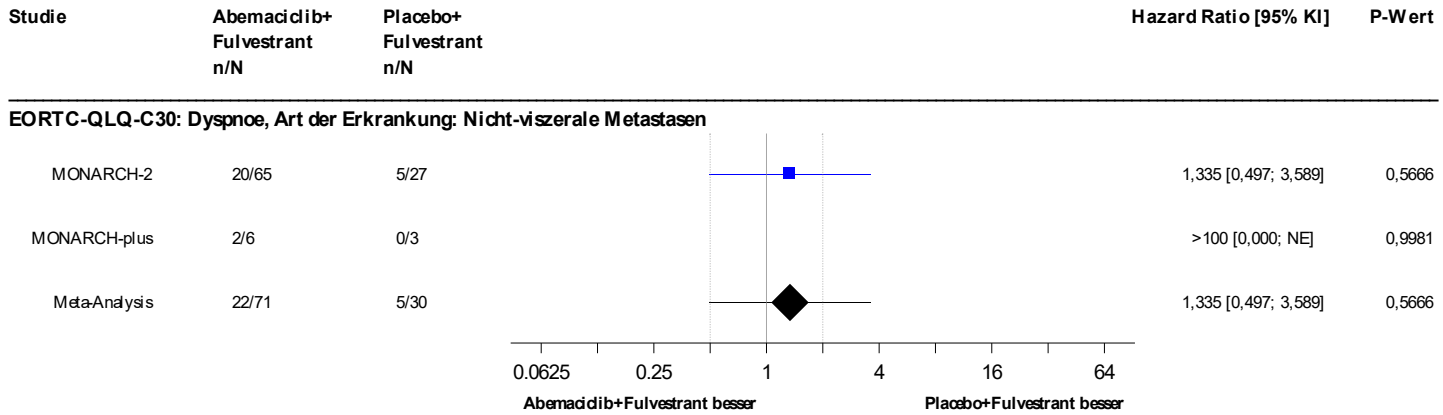
Abbildung 1405.2.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9981, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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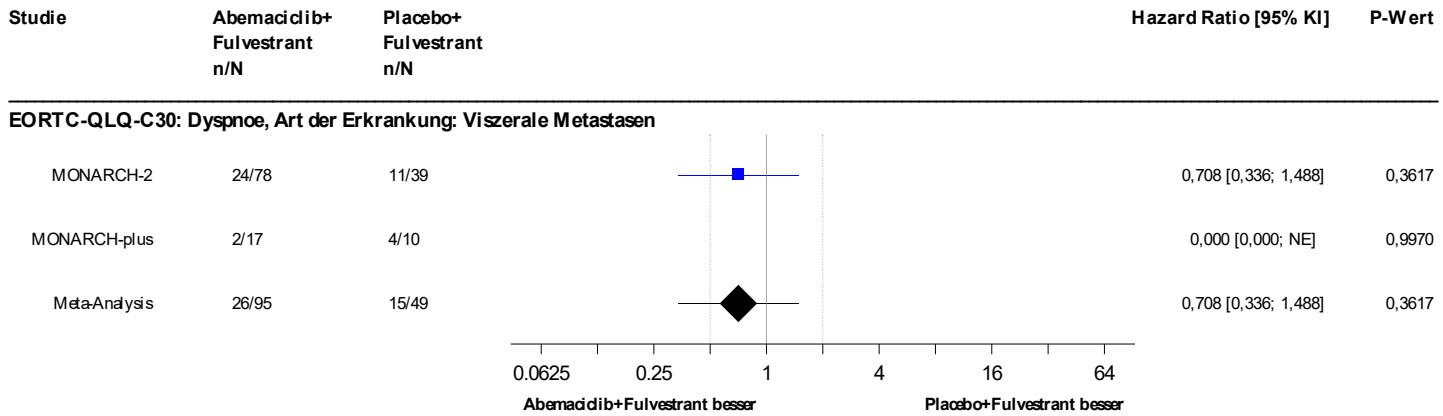
Abbildung 1405.2.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9971, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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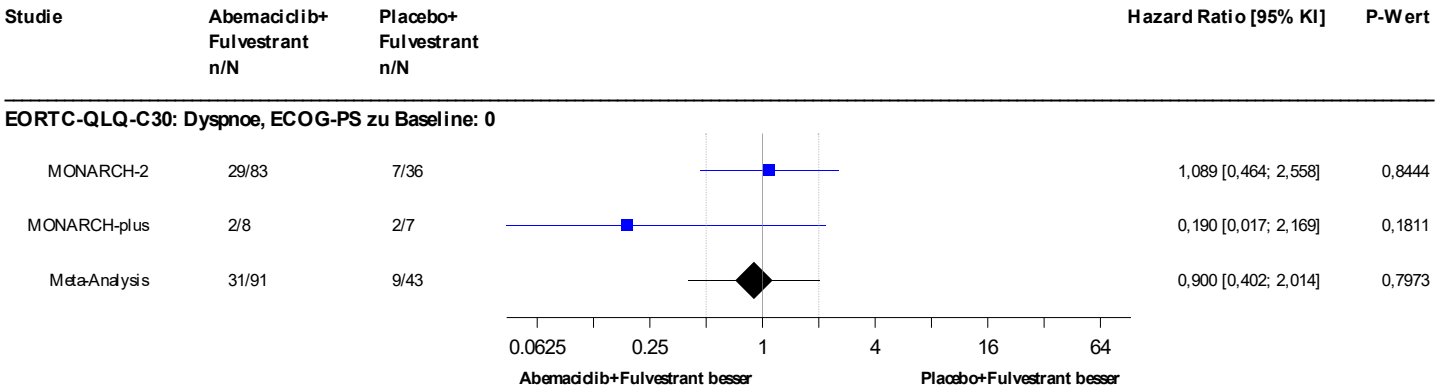
Abbildung 1405.2.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,7609, P-Wert=0,1845, I2 Index=43,2%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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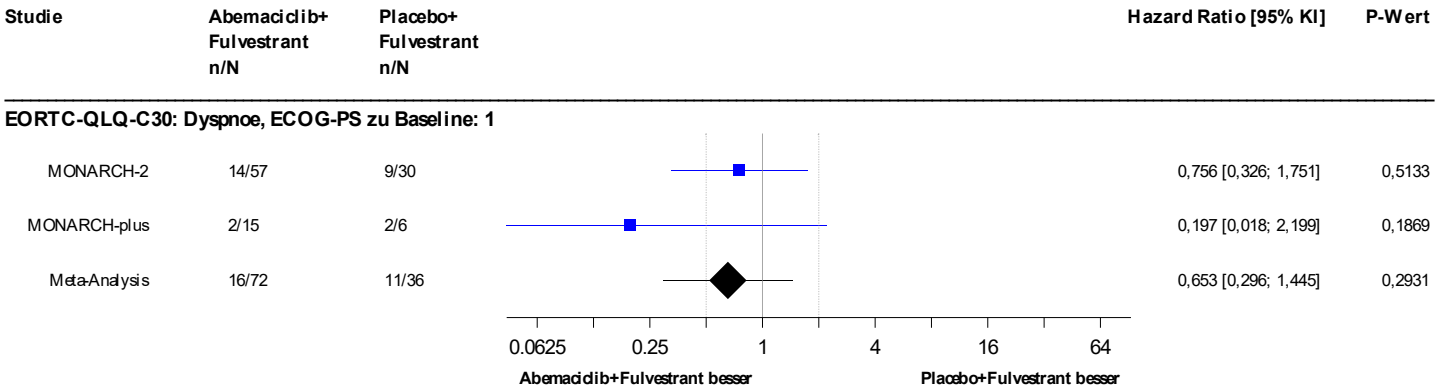
Abbildung 1405.2.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,0638, P-Wert=0,3024, I2 Index=6,0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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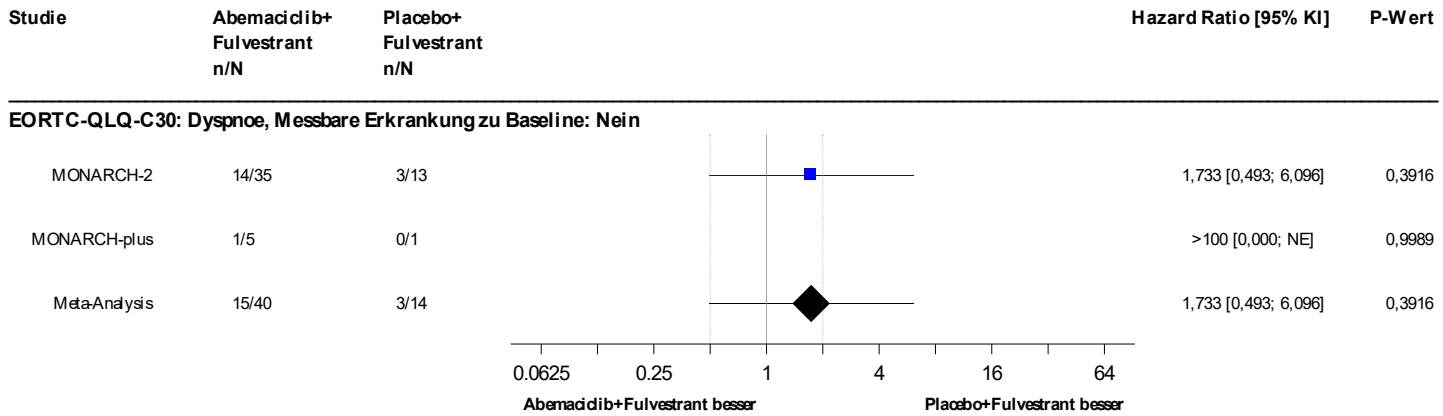
Abbildung 1405.2.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9990, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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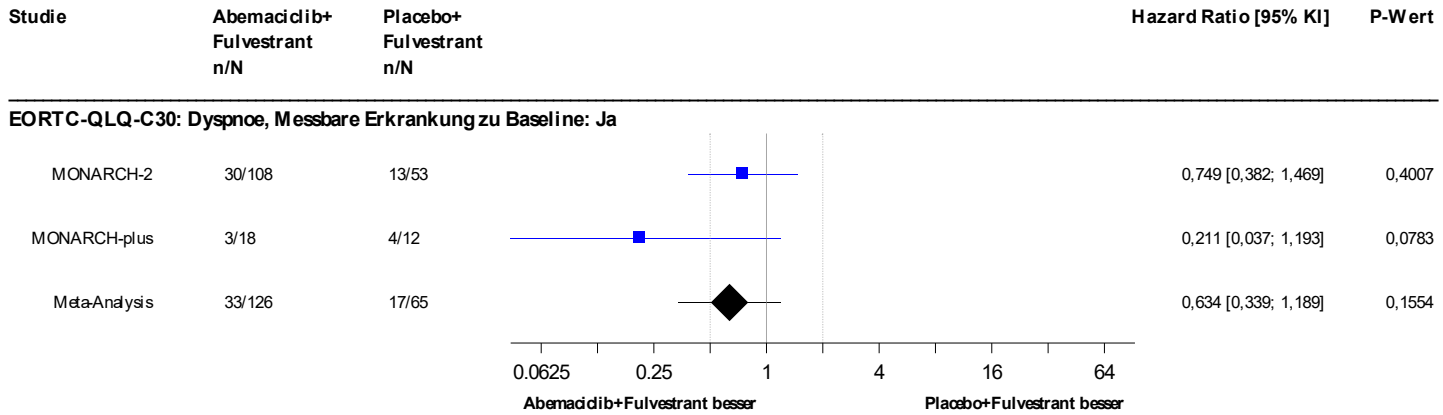
Abbildung 1405.2.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,7884, P-Wert=0,1811, I2 Index=44,1%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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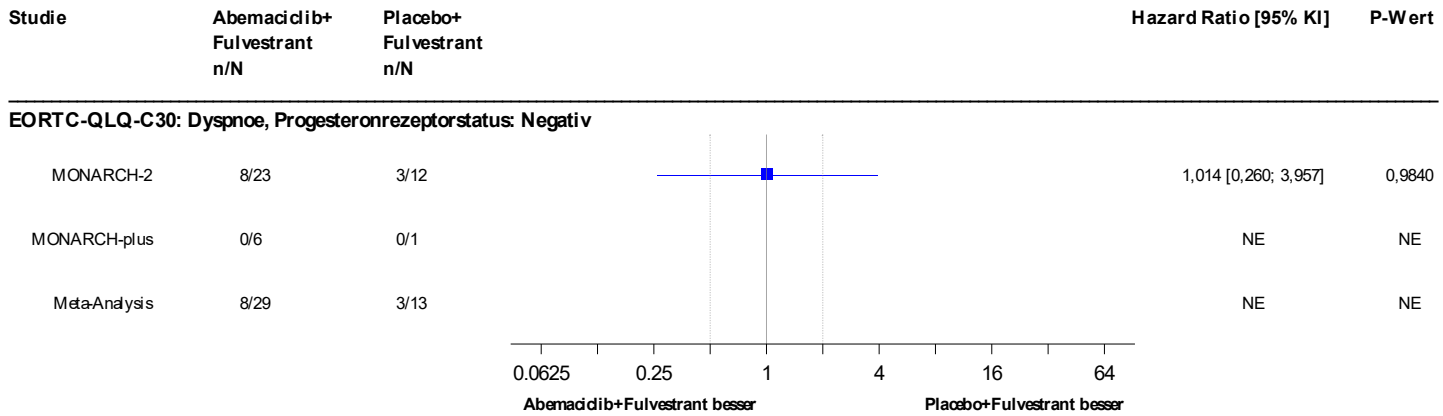
Abbildung 1405.2.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwdysp6_popa2_pgrstat_1.rtf
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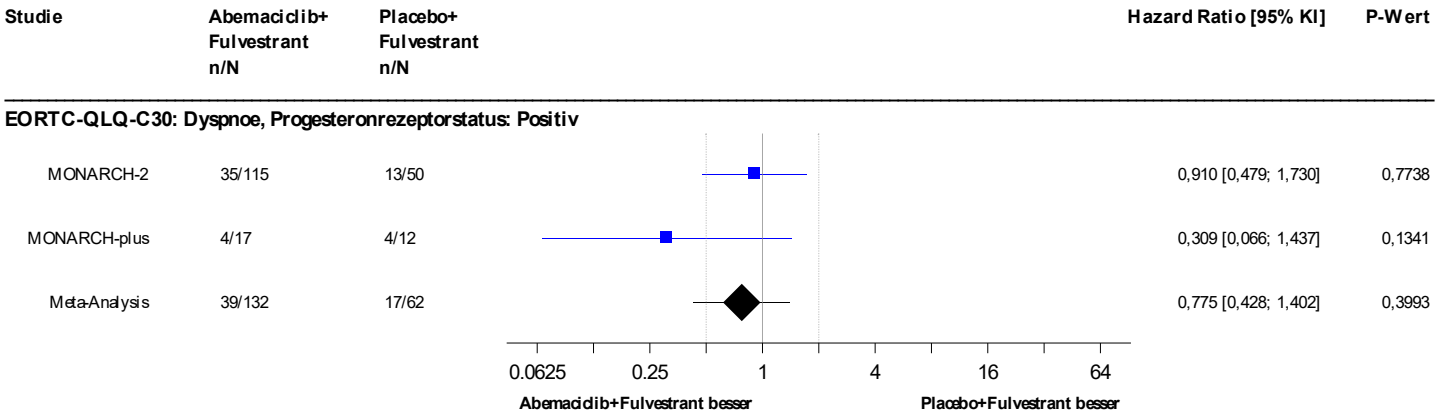
Abbildung 1405.2.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,6171, P-Wert=0,2035, I2 Index=38,2%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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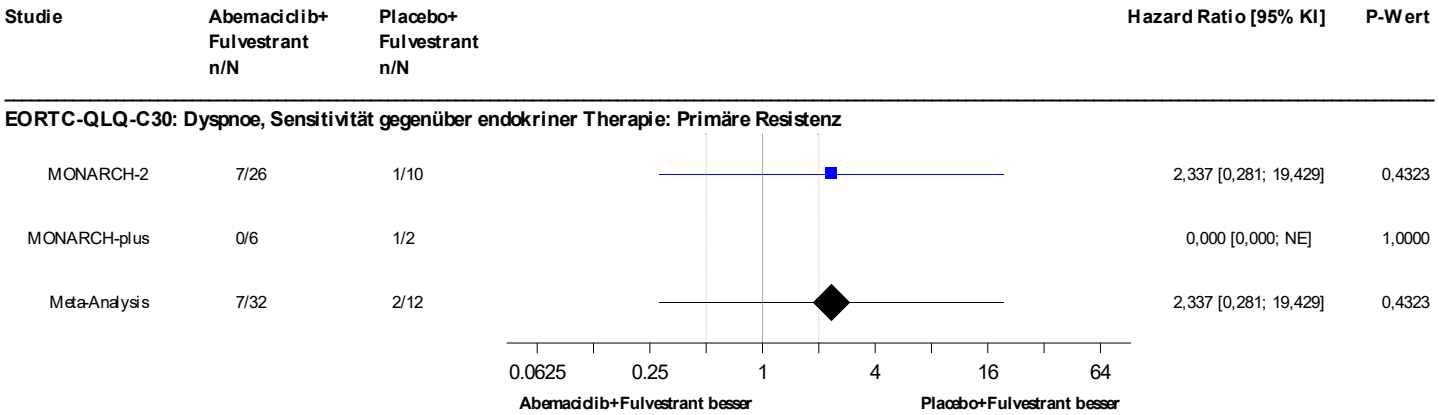
Abbildung 1405.2.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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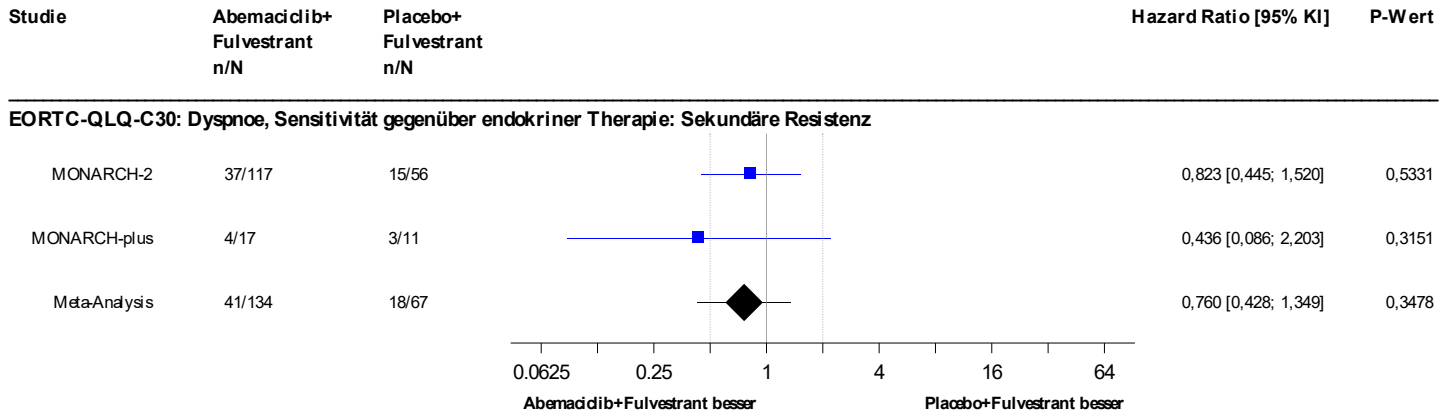
Abbildung 1405.2.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,5162, P-Wert=0,4725, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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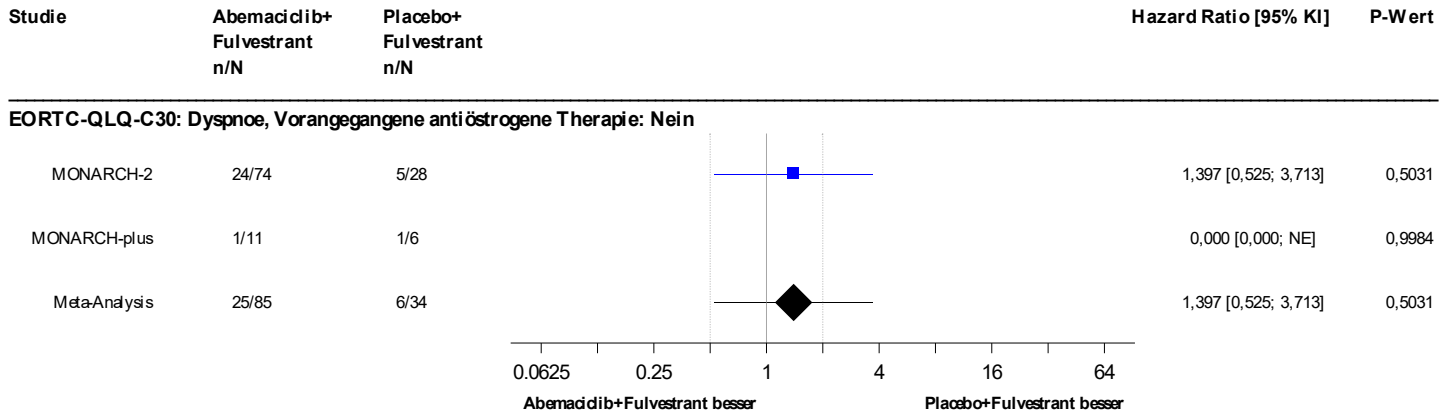
Abbildung 1405.2.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9984, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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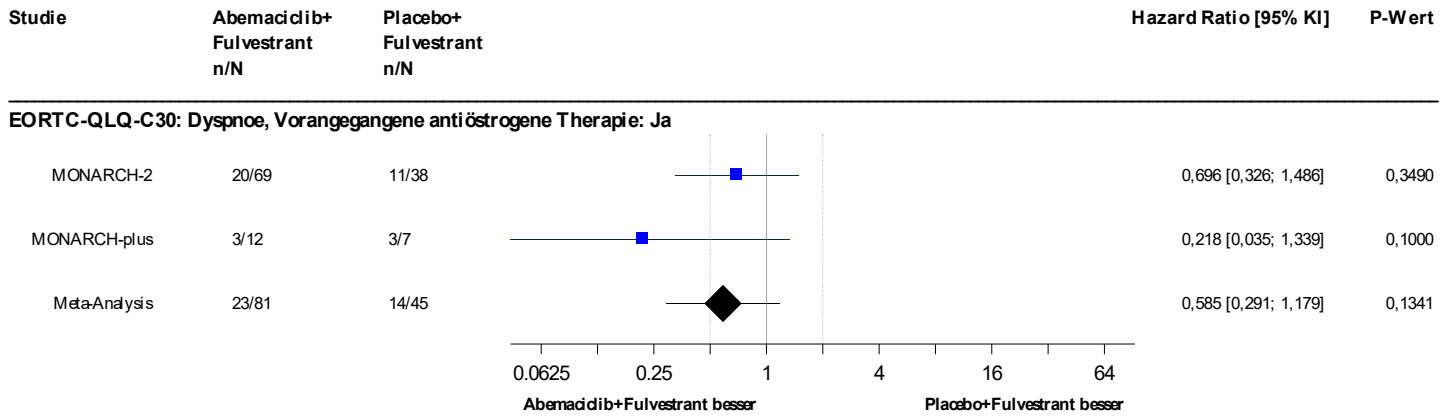
Abbildung 1405.2.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Dyspnoe (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,3384, P-Wert=0,2473, I2 Index=25,3%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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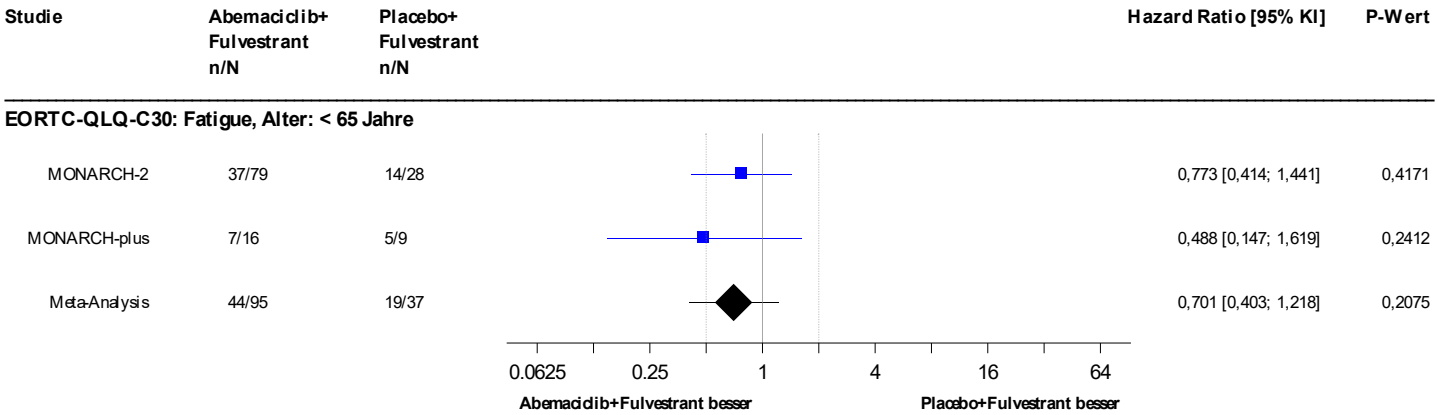
Abbildung 1406.2.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,4431, P-Wert=0,5056, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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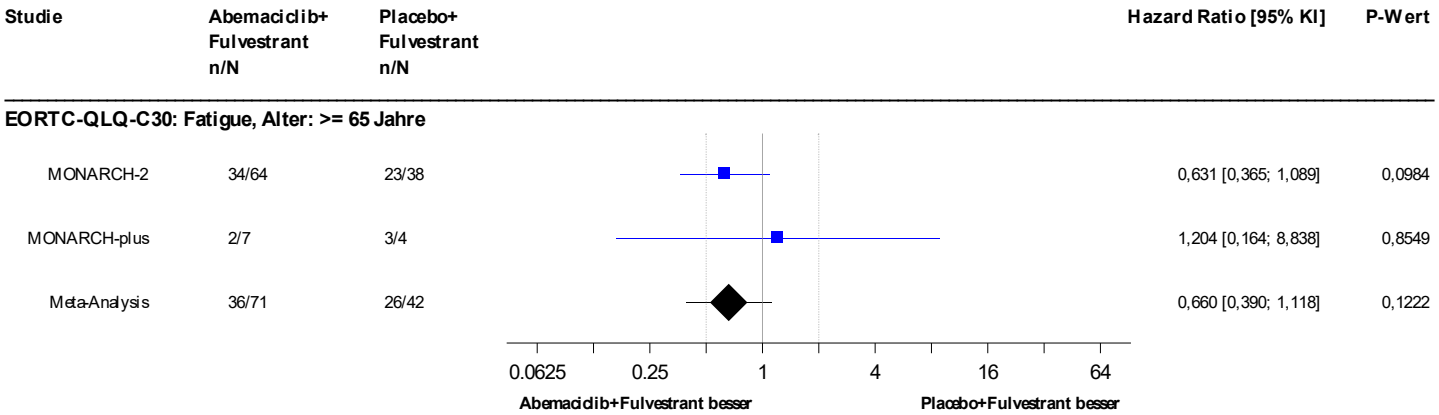
Abbildung 1406.2.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3764, P-Wert=0,5396, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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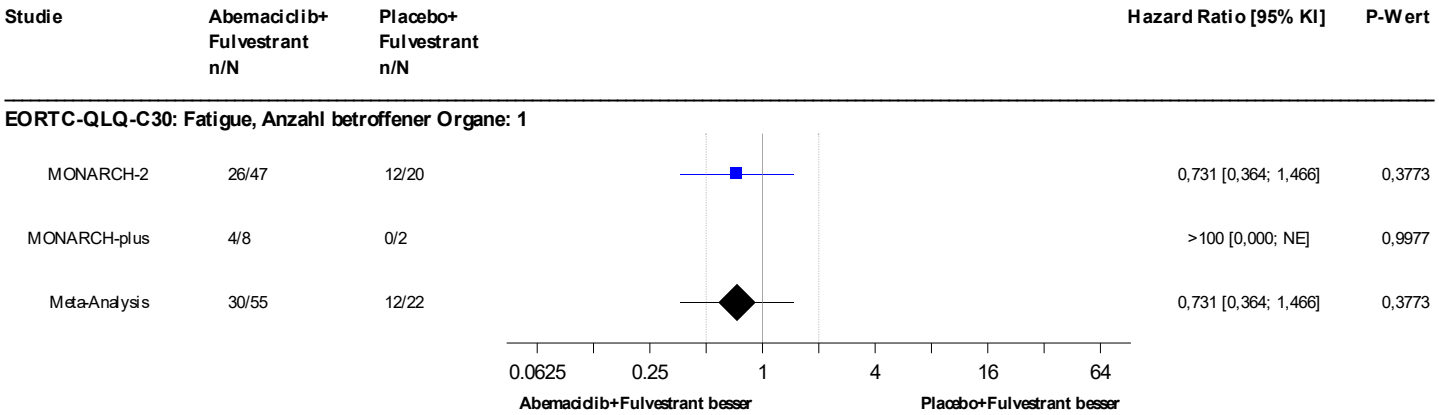
Abbildung 1406.2.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9977, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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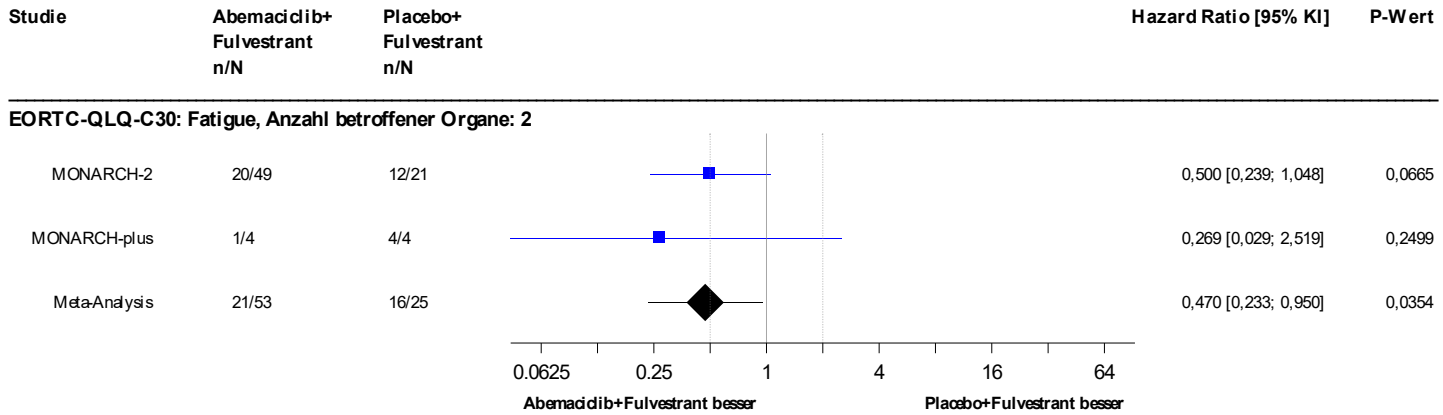
Abbildung 1406.2.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2662, P-Wert=0,6059, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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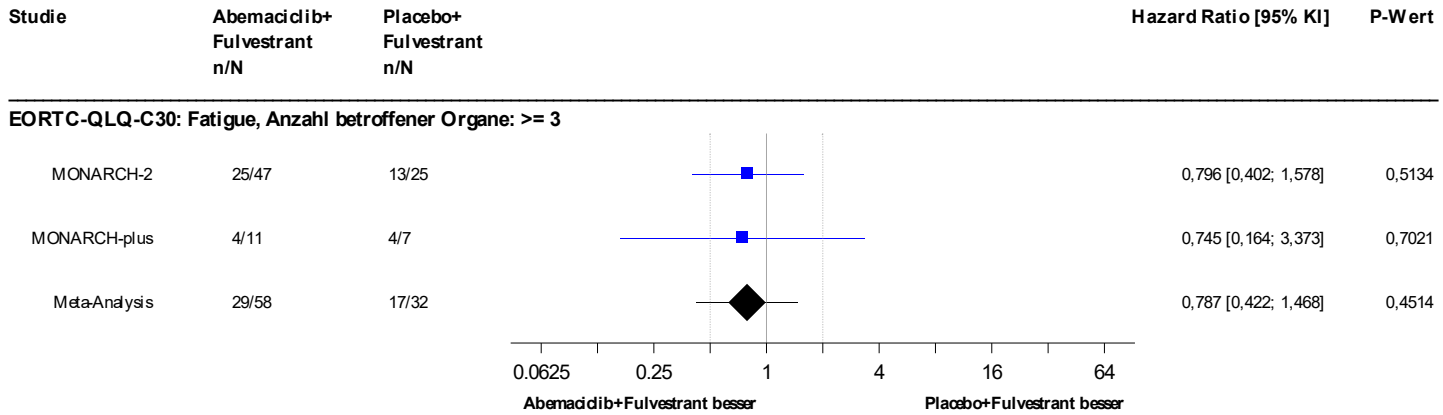
Abbildung 1406.2.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0062, P-Wert=0,9371, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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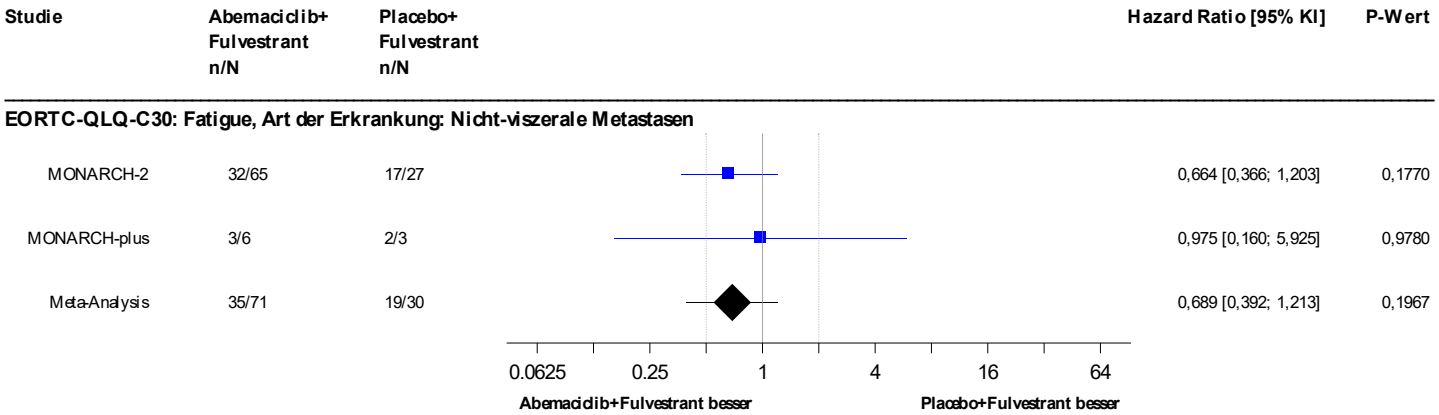
Abbildung 1406.2.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1570, P-Wert=0,6920, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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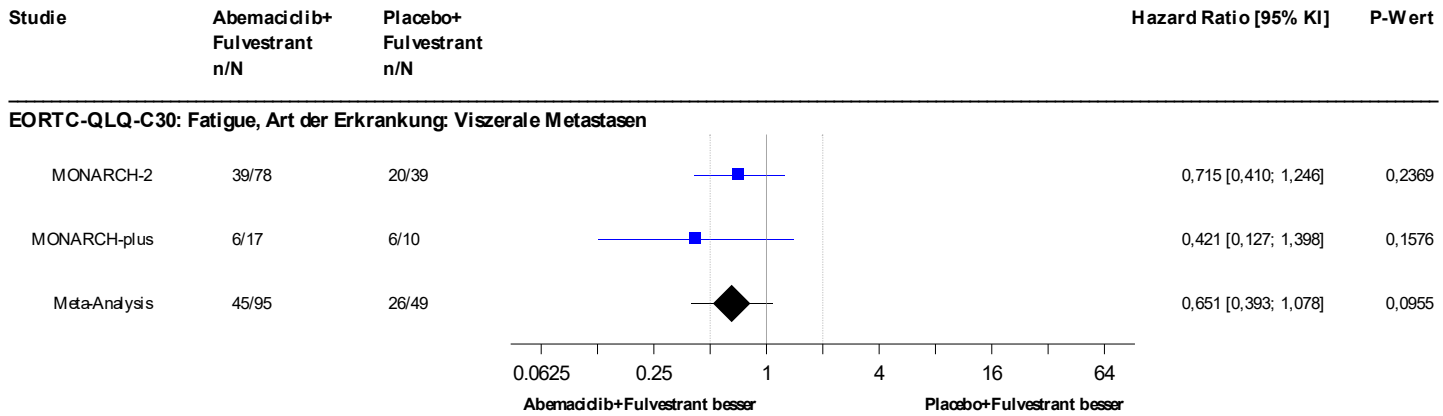
Abbildung 1406.2.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,6169, P-Wert=0,4322, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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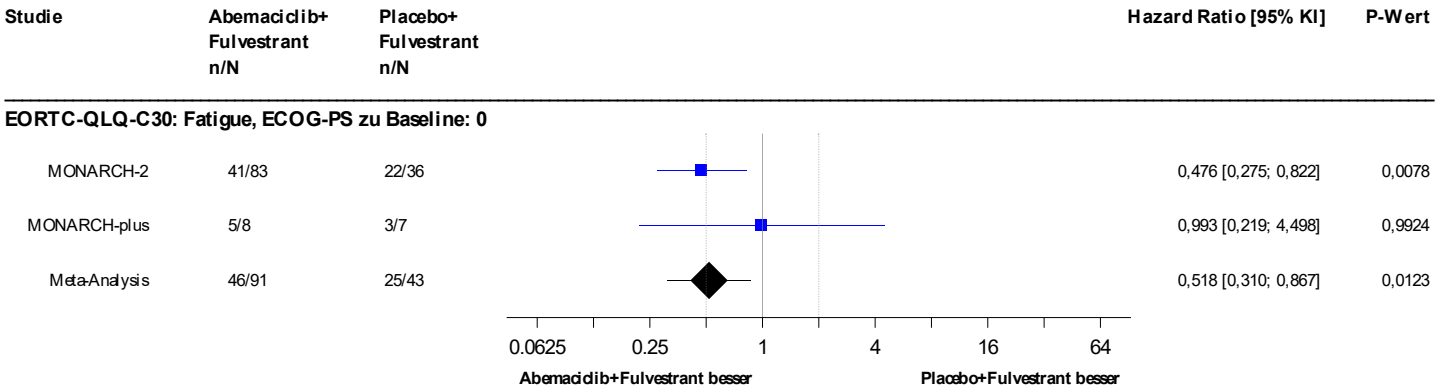
Abbildung 1406.2.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,8056, P-Wert=0,3694, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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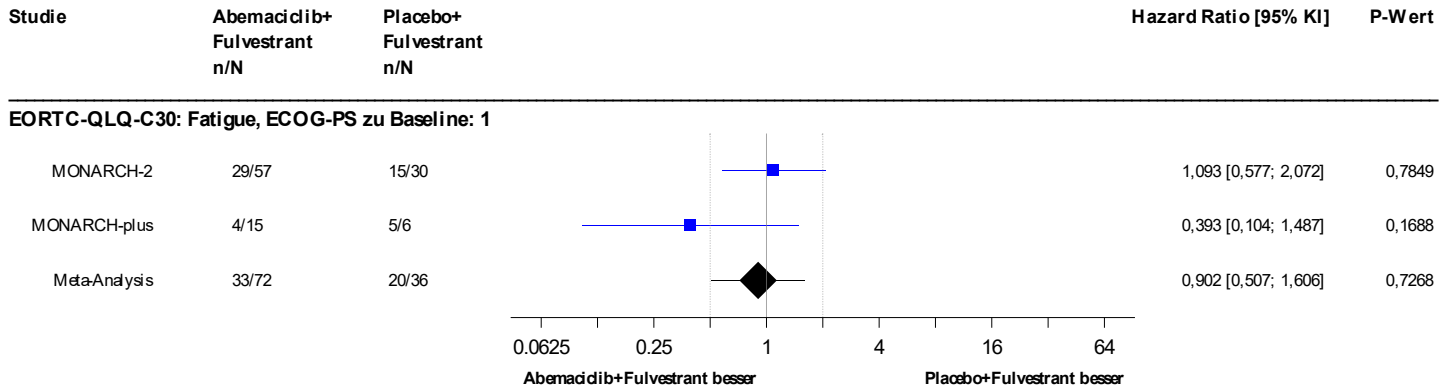
Abbildung 1406.2.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,8459, P-Wert=0,1743, I2 Index=45,8%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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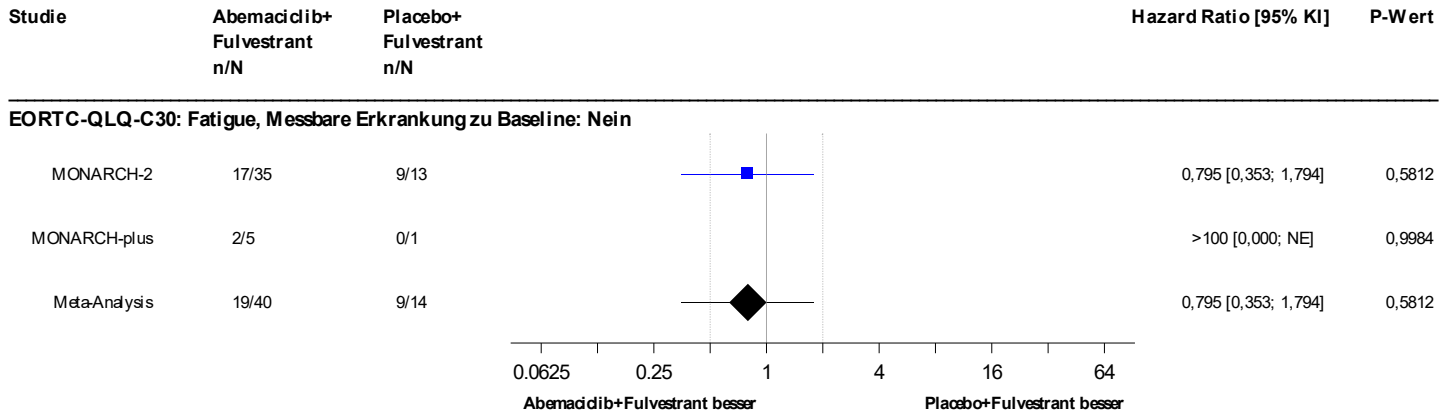
Abbildung 1406.2.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9984, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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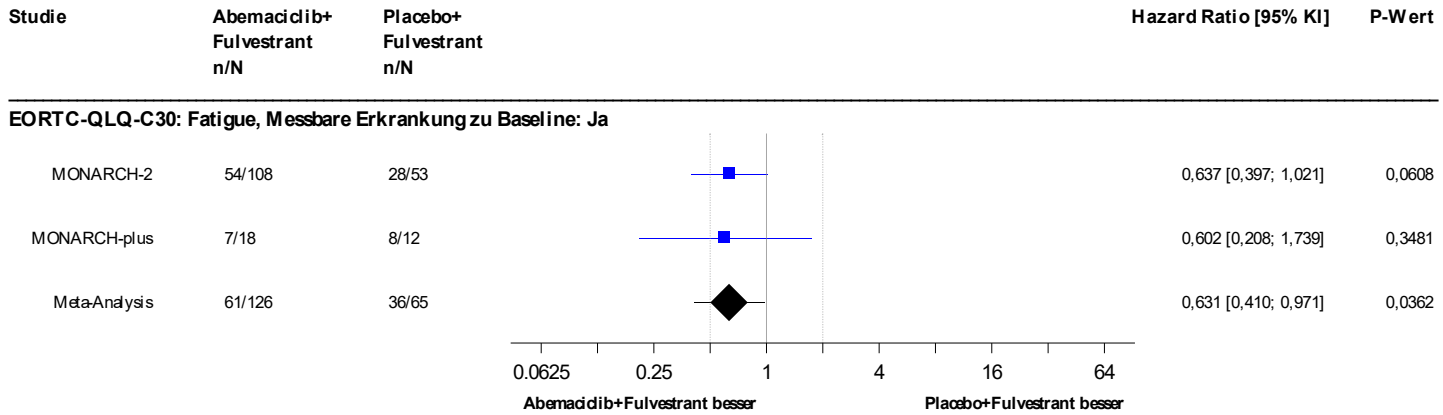
17SEP2021 / 07:48

Abbildung 1406.2.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0091, P-Wert=0,9238, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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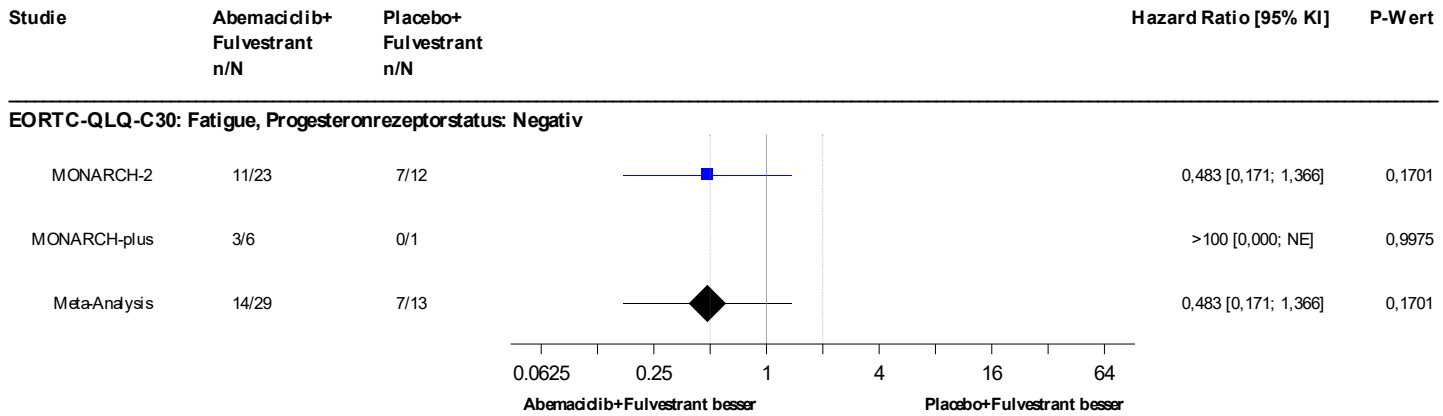
Abbildung 1406.2.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9974, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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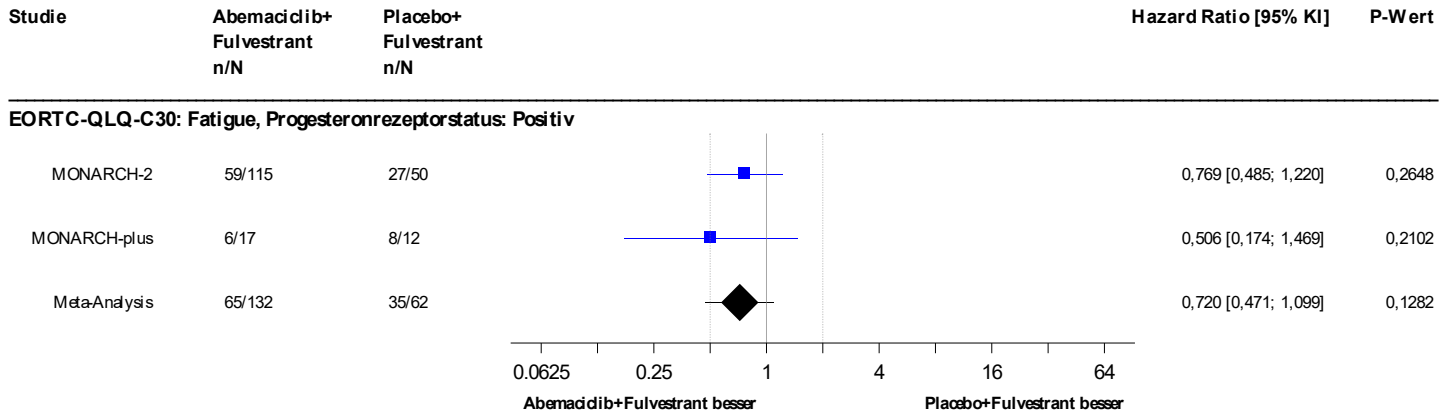
Abbildung 1406.2.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,4992, P-Wert=0,4799, I2 Index=0%
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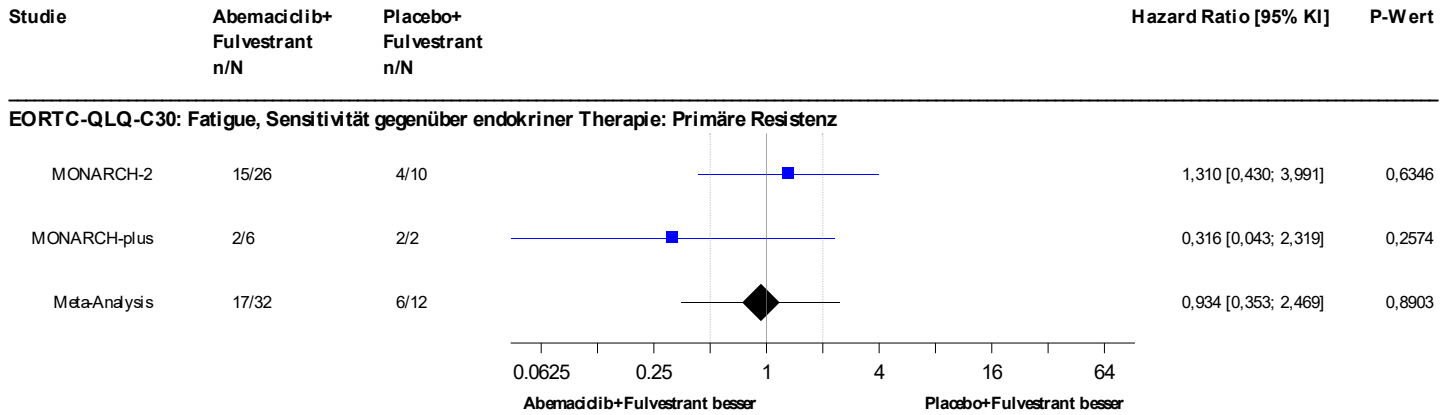
Abbildung 1406.2.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,4897, P-Wert=0,2223, I2 Index=32,9%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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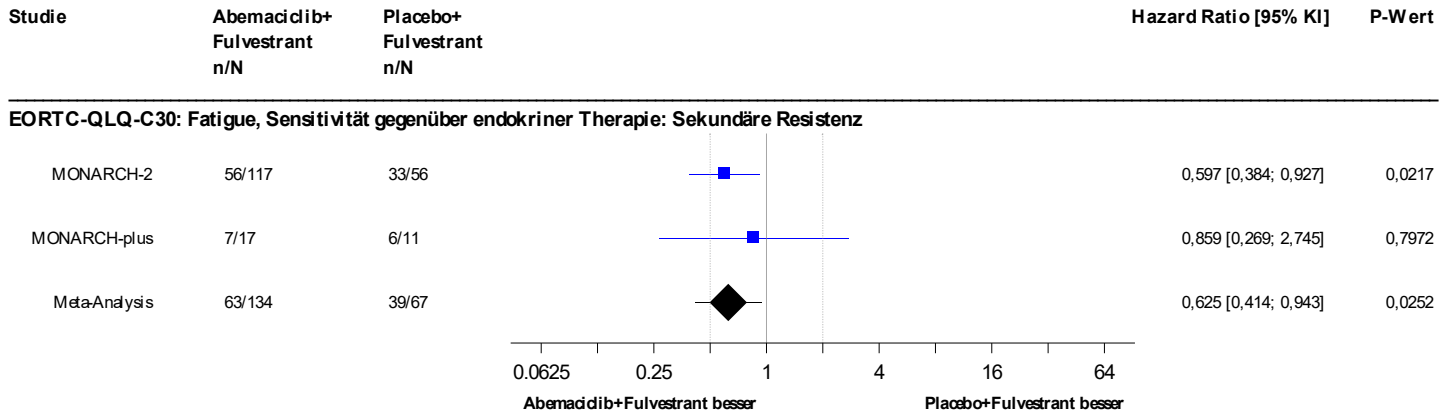
Abbildung 1406.2.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3288, P-Wert=0,5664, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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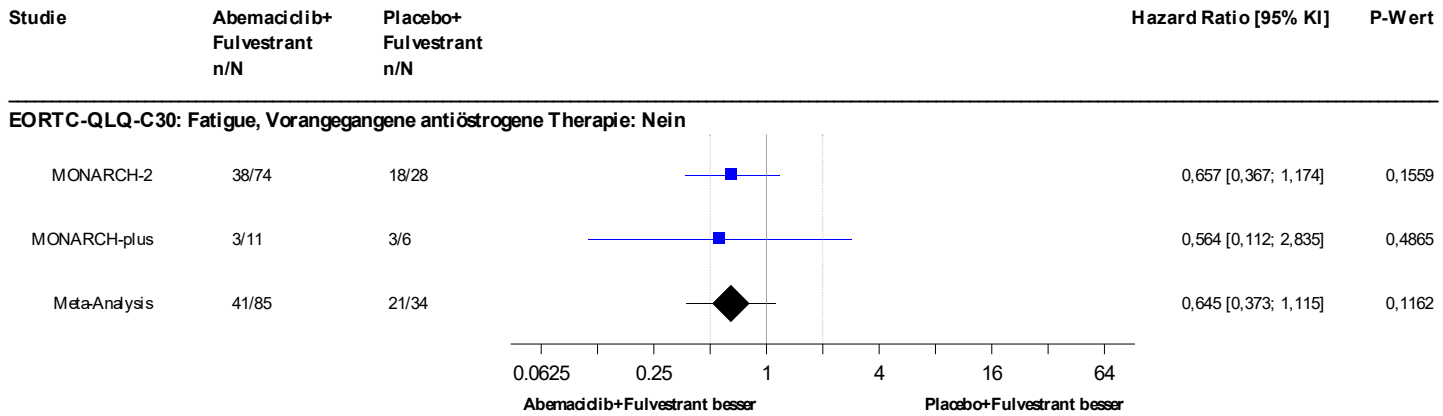
Abbildung 1406.2.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0304, P-Wert=0,8615, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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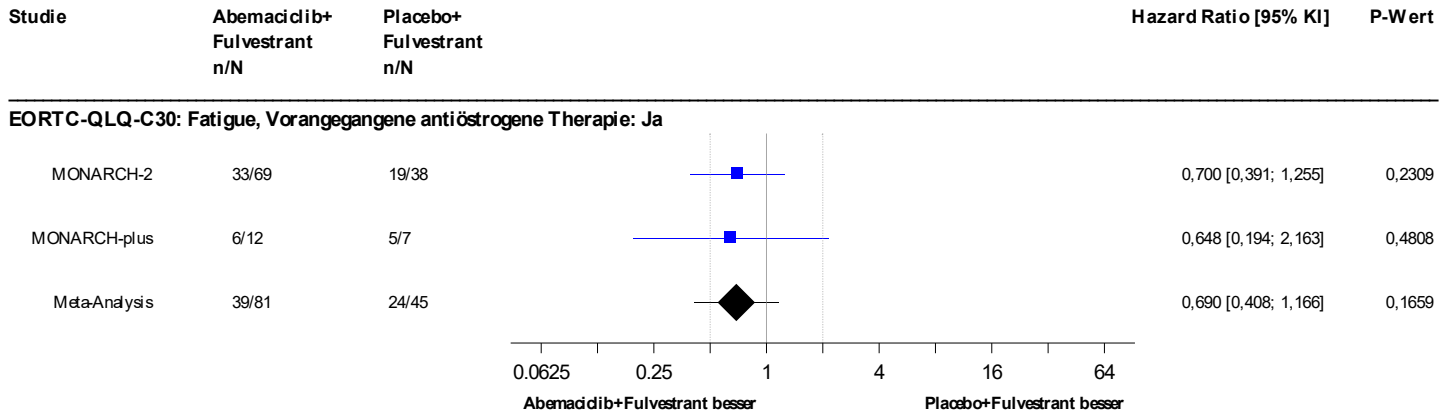
Abbildung 1406.2.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Fatigue (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0126, P-Wert=0,9106, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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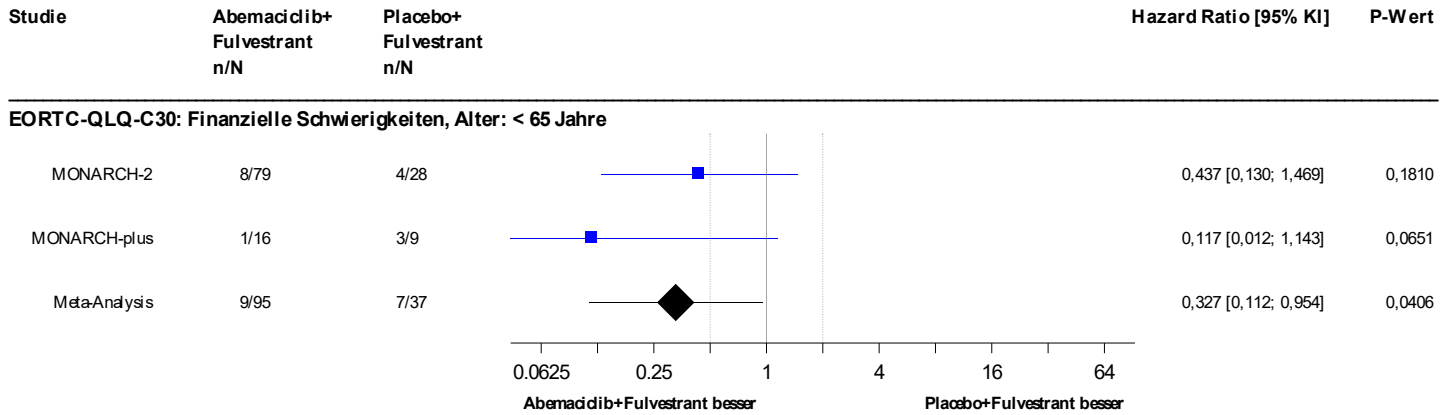
Abbildung 1407.2.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,0025, P-Wert=0,3167, I2 Index=0,2%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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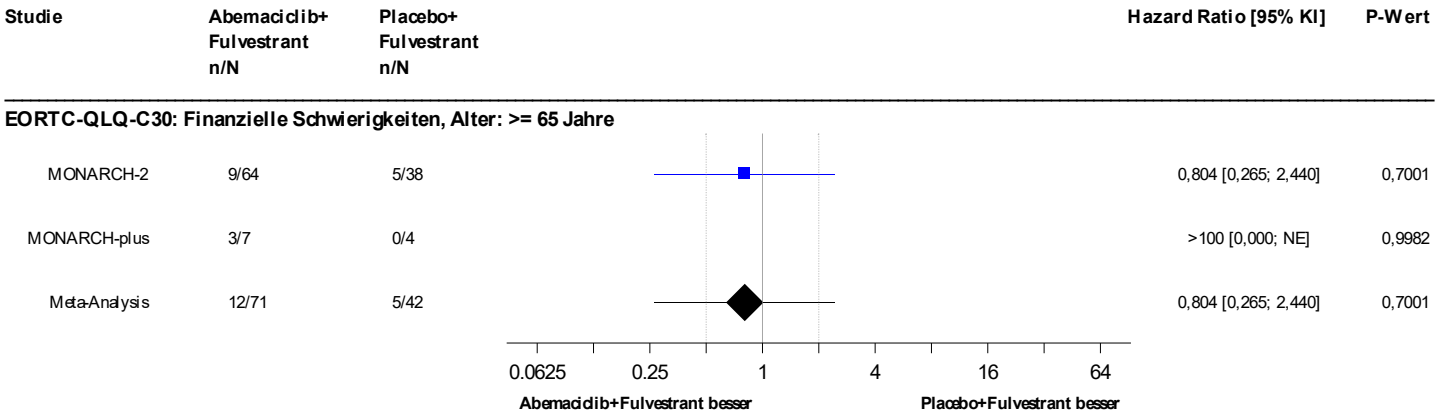
Abbildung 1407.2.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9982, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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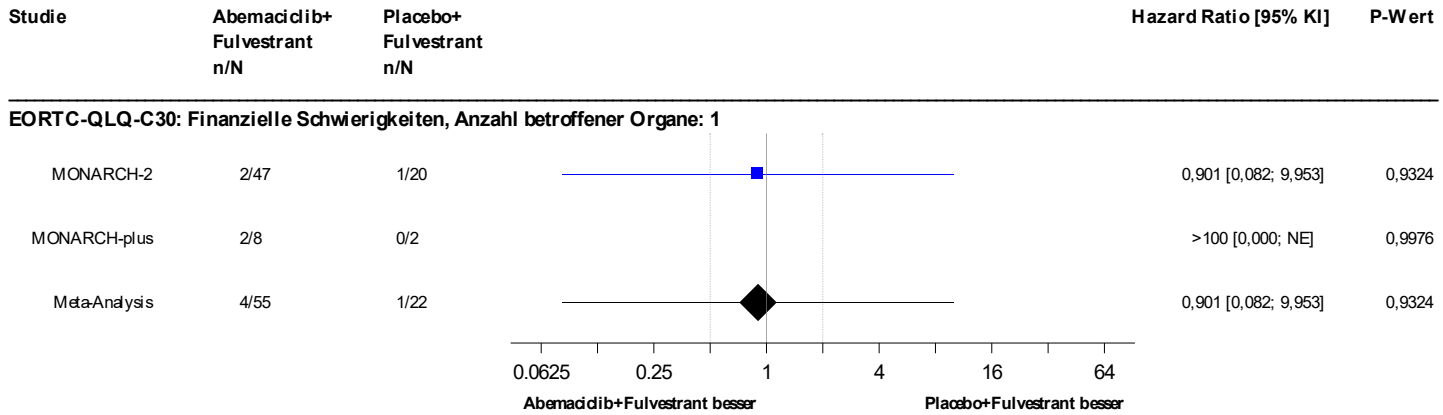
Abbildung 1407.2.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9976, I2 Index=0%
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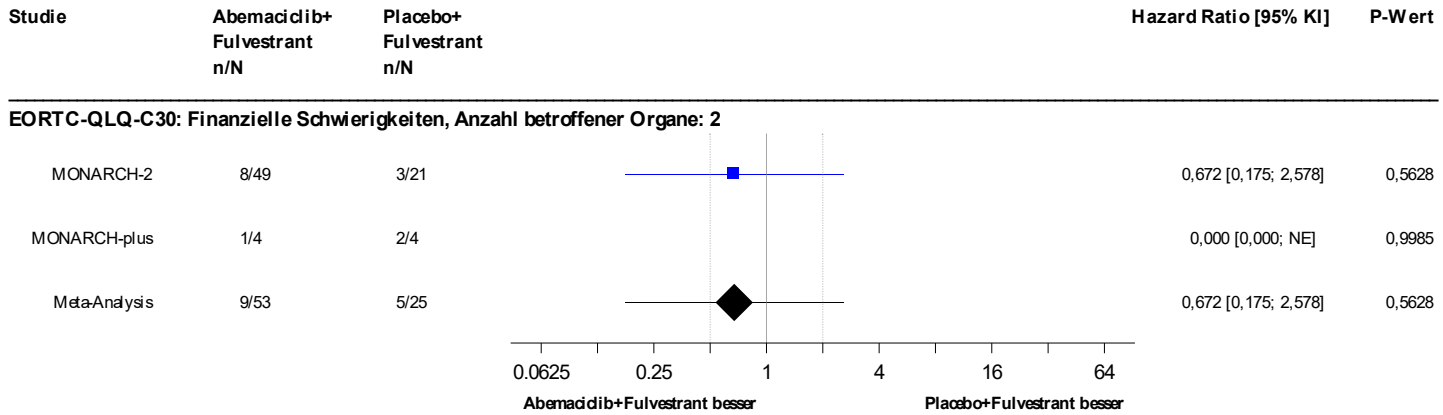
Abbildung 1407.2.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9986, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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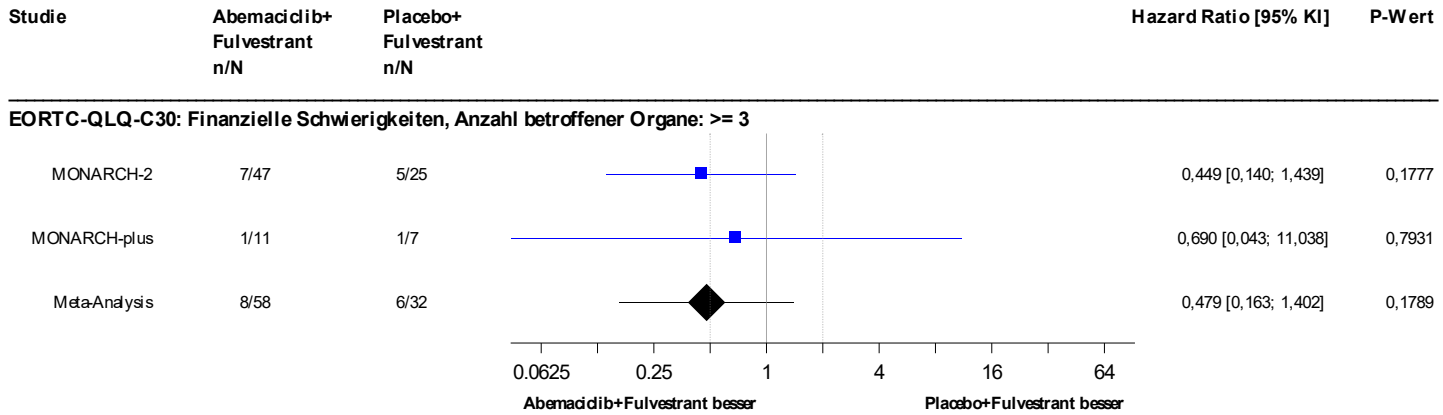
Abbildung 1407.2.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0787, P-Wert=0,7790, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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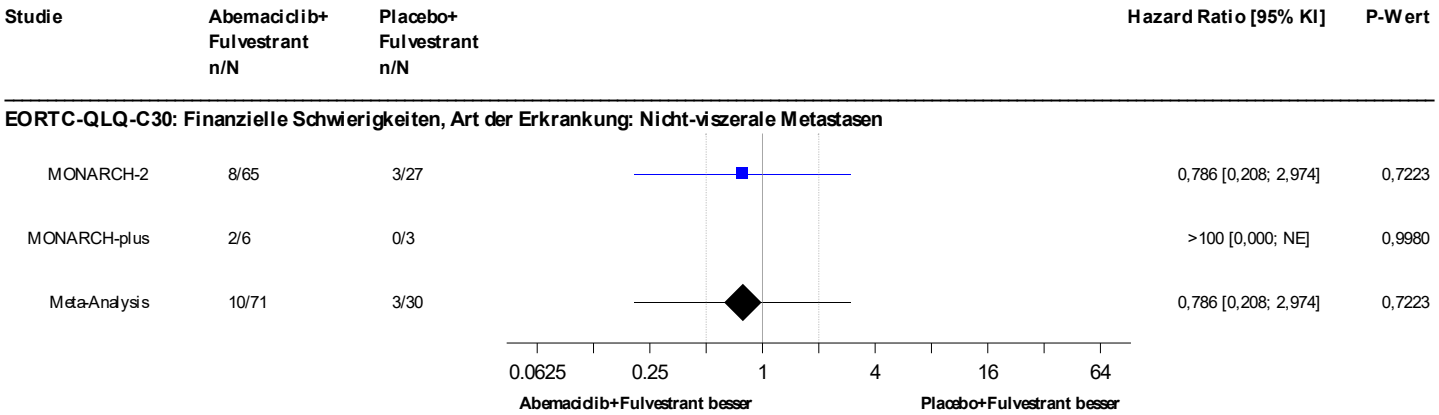
Abbildung 1407.2.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9980, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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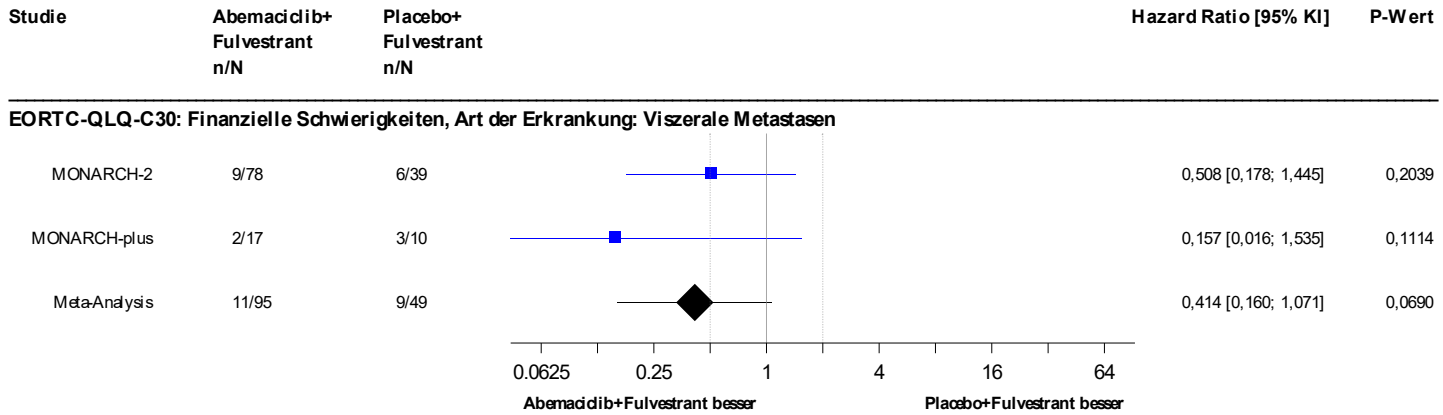
Abbildung 1407.2.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,8422, P-Wert=0,3588, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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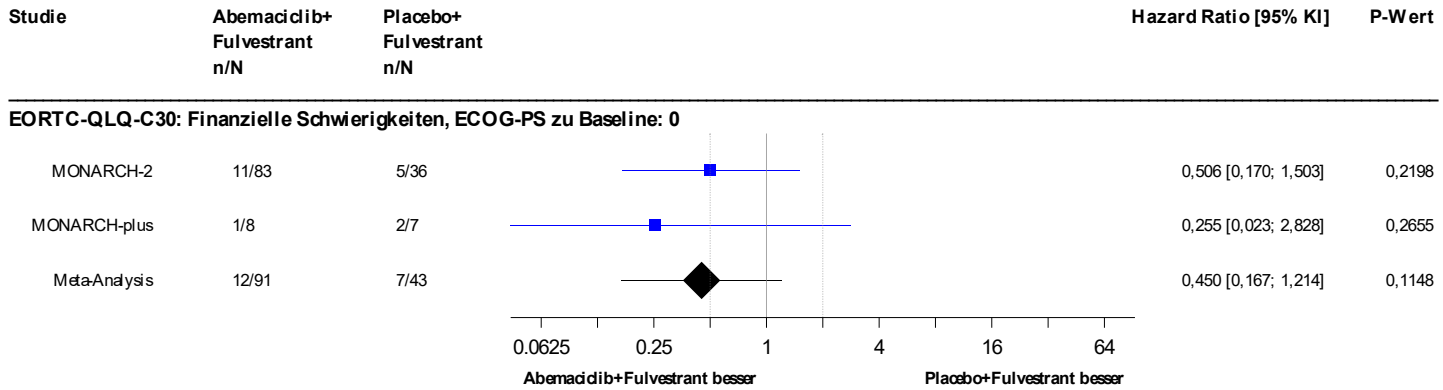
Abbildung 1407.2.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2584, P-Wert=0,6112, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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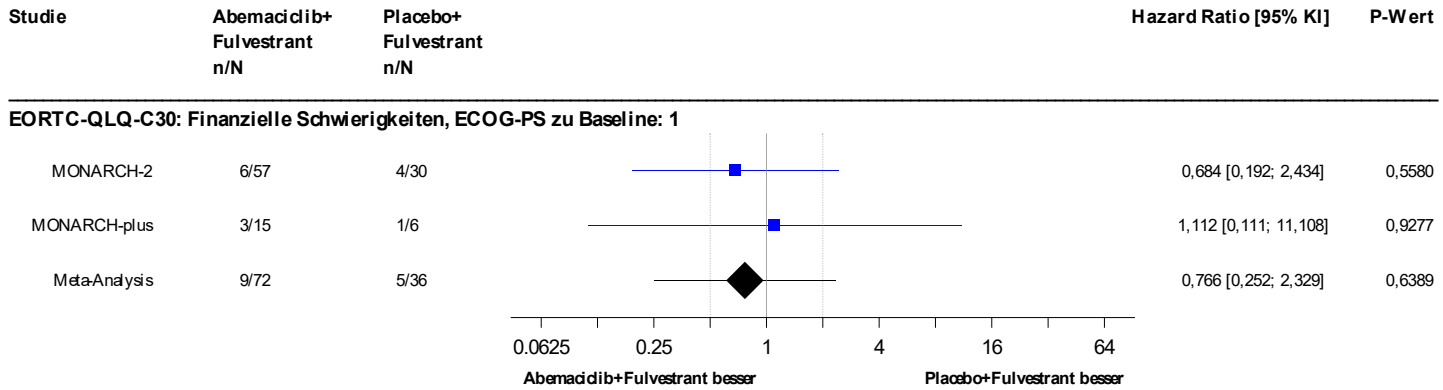
Abbildung 1407.2.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1313, P-Wert=0,7171, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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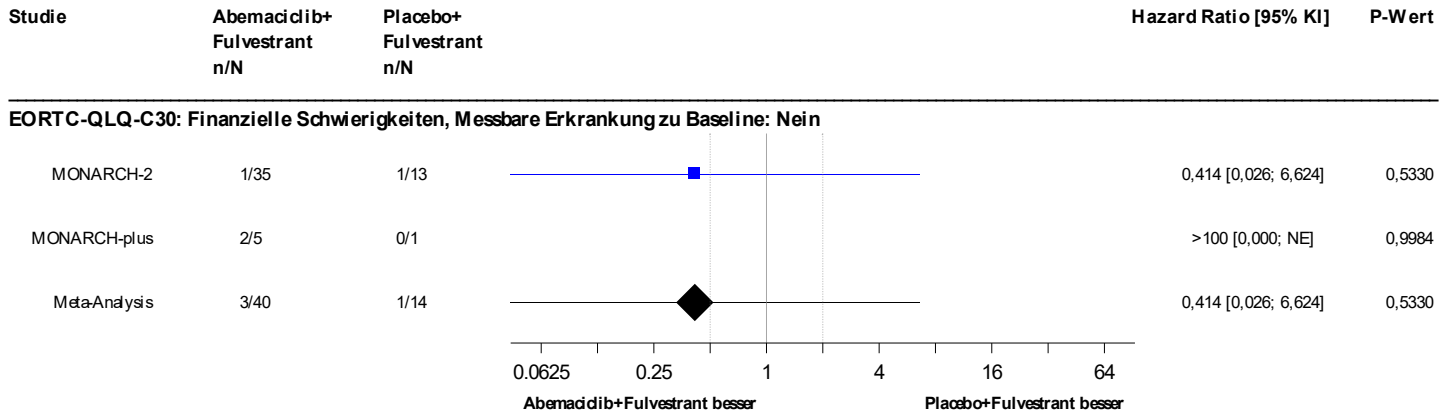
Abbildung 1407.2.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9983, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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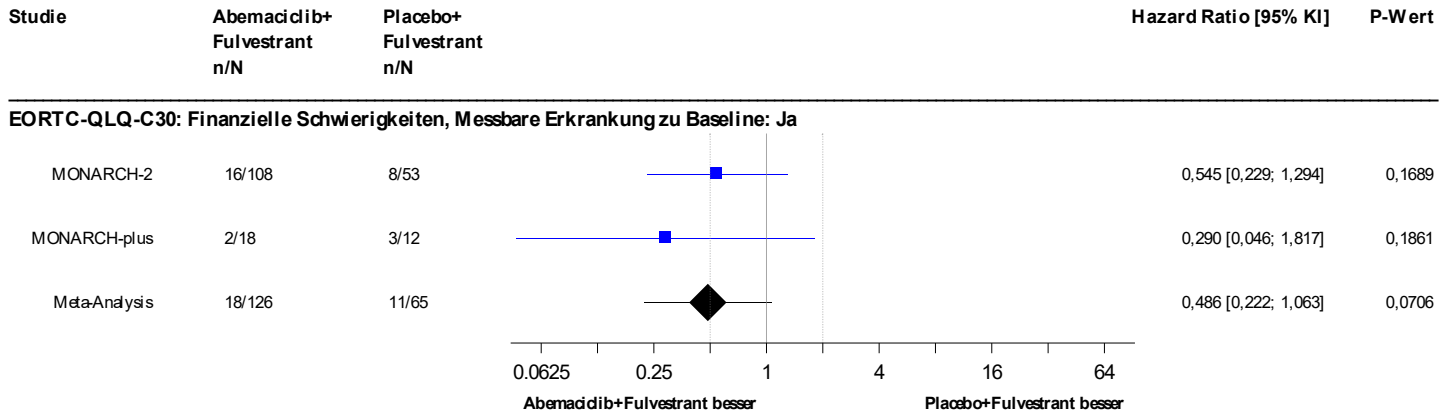
Abbildung 1407.2.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3710, P-Wert=0,5425, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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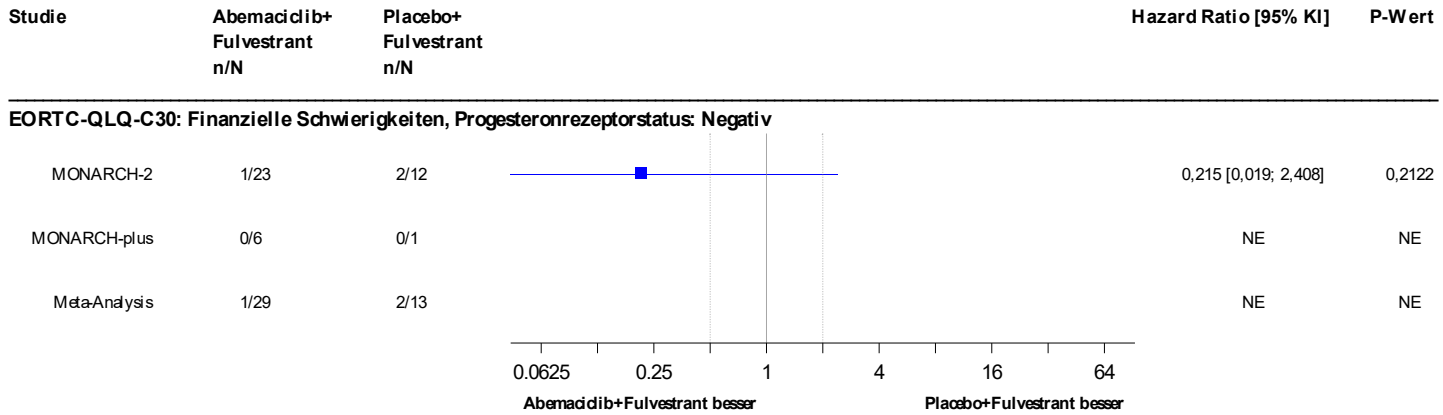
Abbildung 1407.2.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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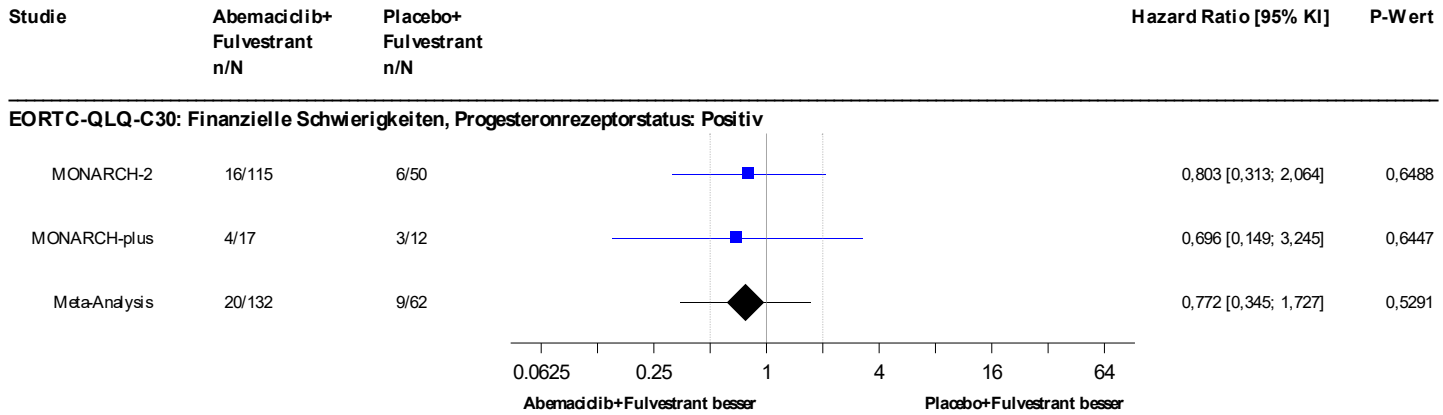
Abbildung 1407.2.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0241, P-Wert=0,8767, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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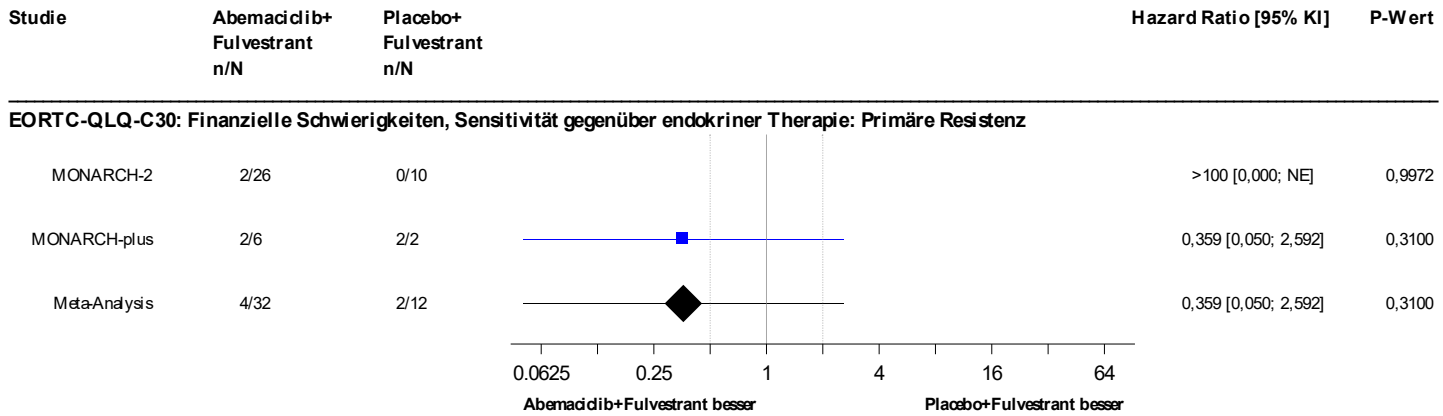
Abbildung 1407.2.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9970, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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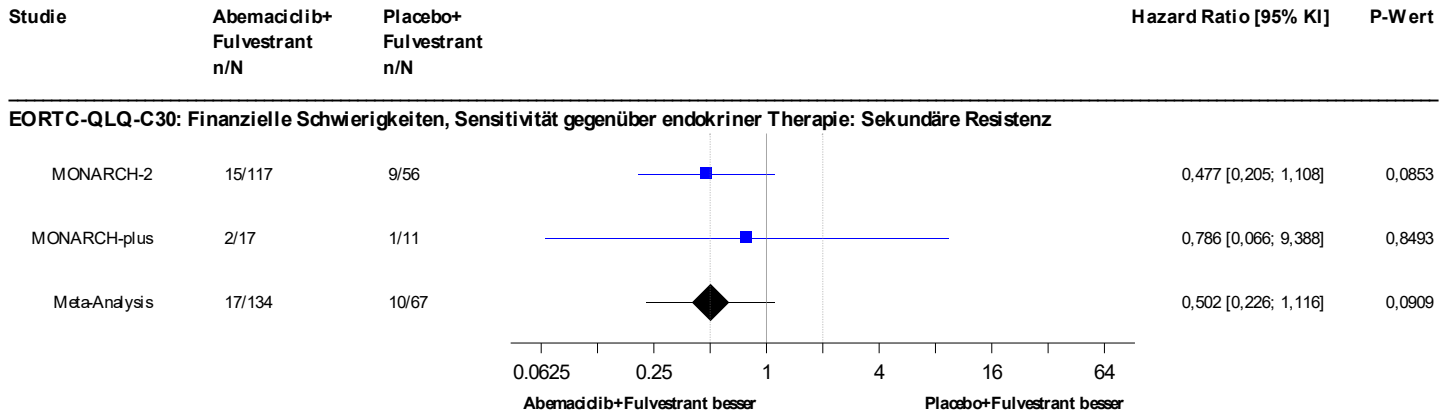
Abbildung 1407.2.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1398, P-Wert=0,7085, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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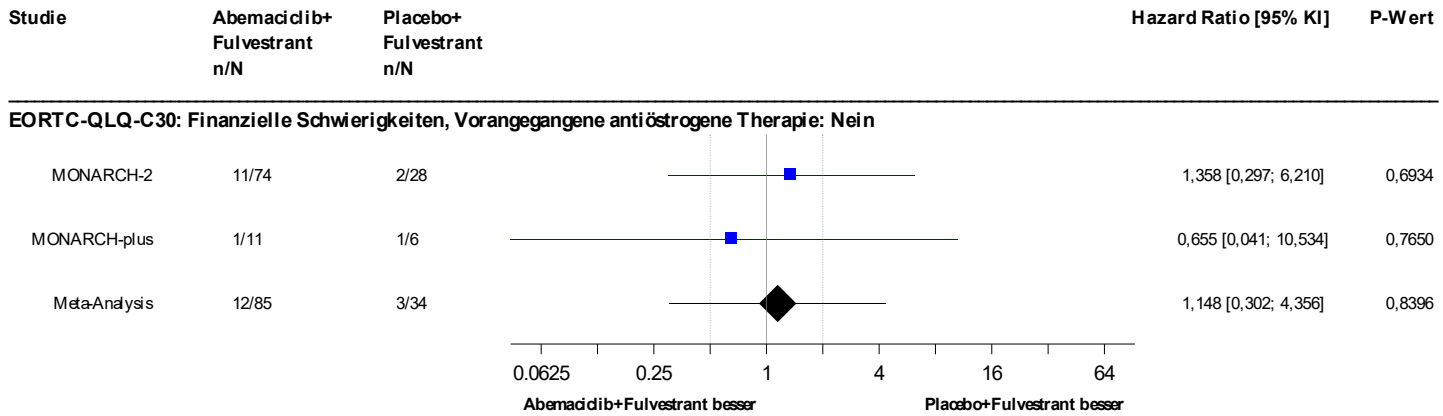
Abbildung 1407.2.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2038, P-Wert=0,6516, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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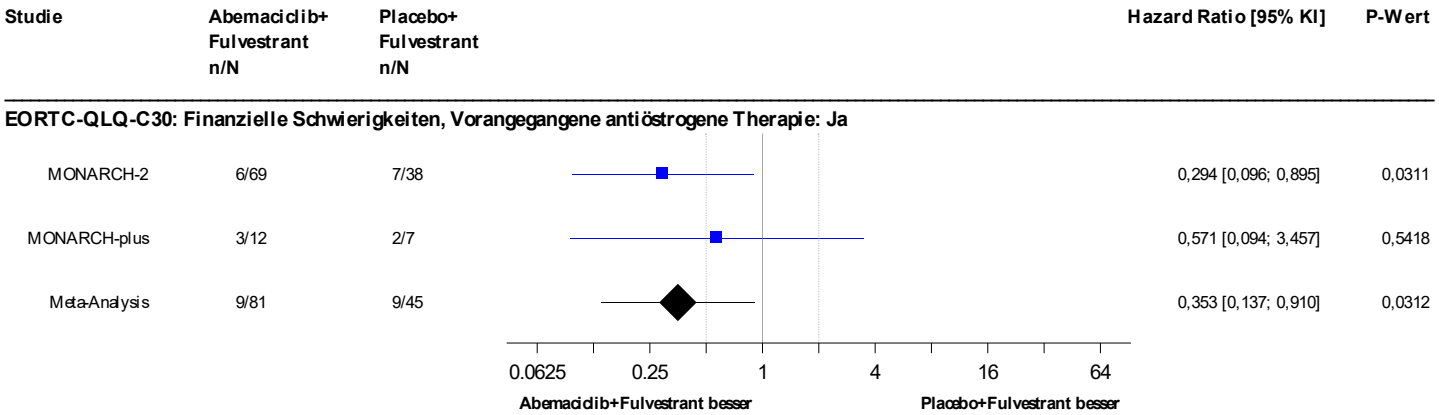
Abbildung 1407.2.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Finanzielle Schwierigkeiten (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3779, P-Wert=0,5387, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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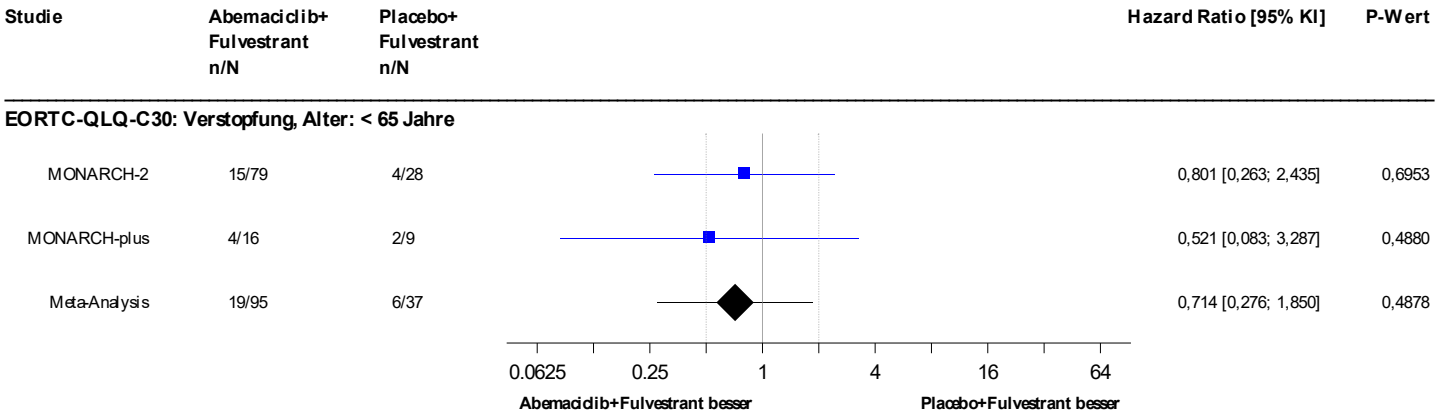
Abbildung 1408.2.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1529, P-Wert=0,6957, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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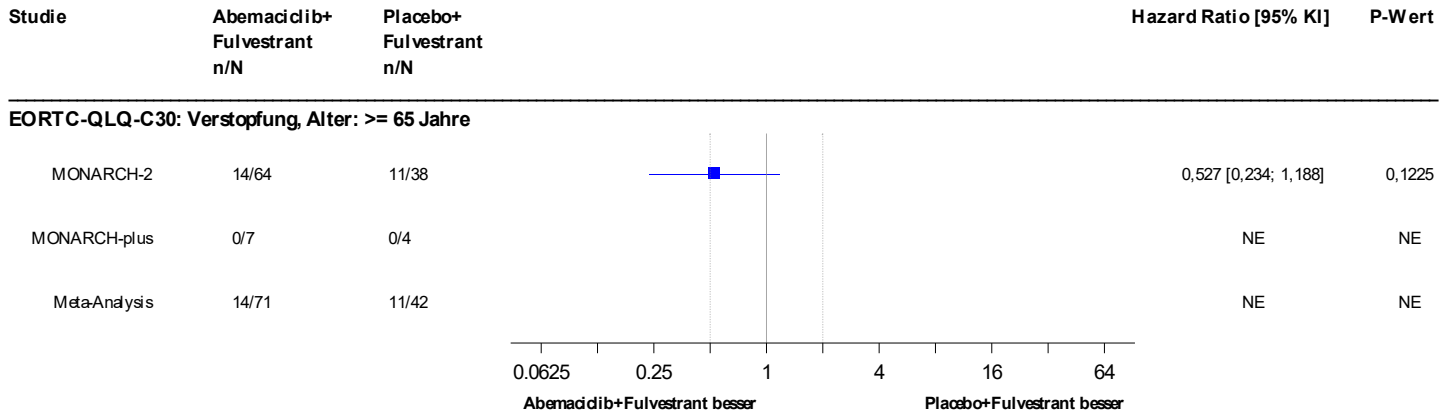
Abbildung 1408.2.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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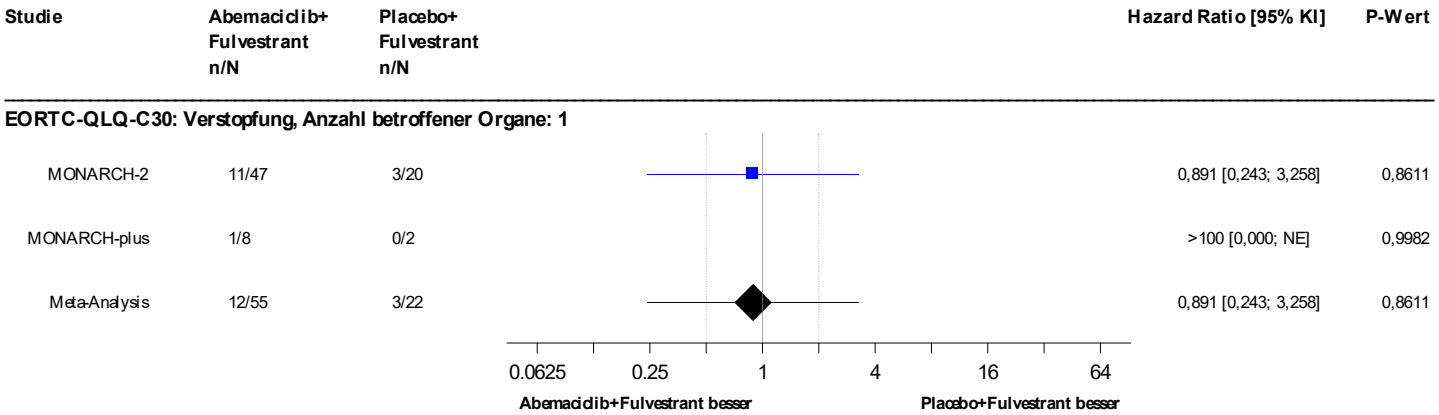
Abbildung 1408.2.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9982, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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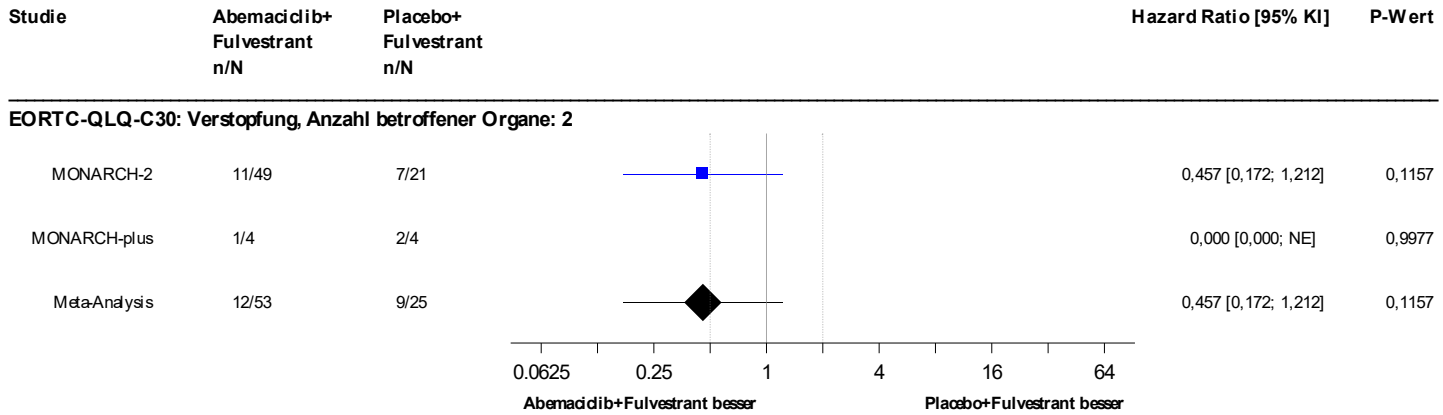
Abbildung 1408.2.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9978, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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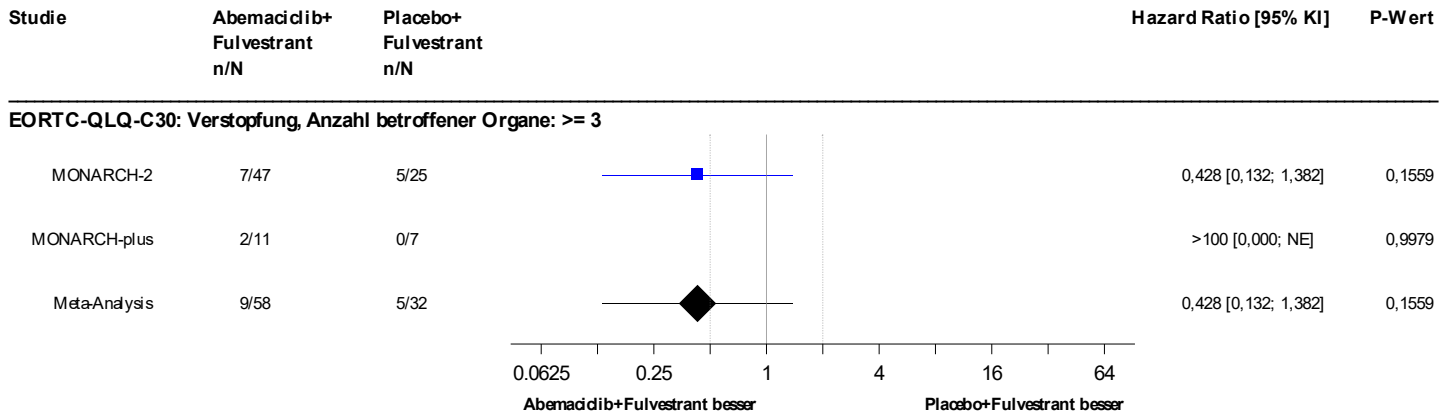
Abbildung 1408.2.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9979, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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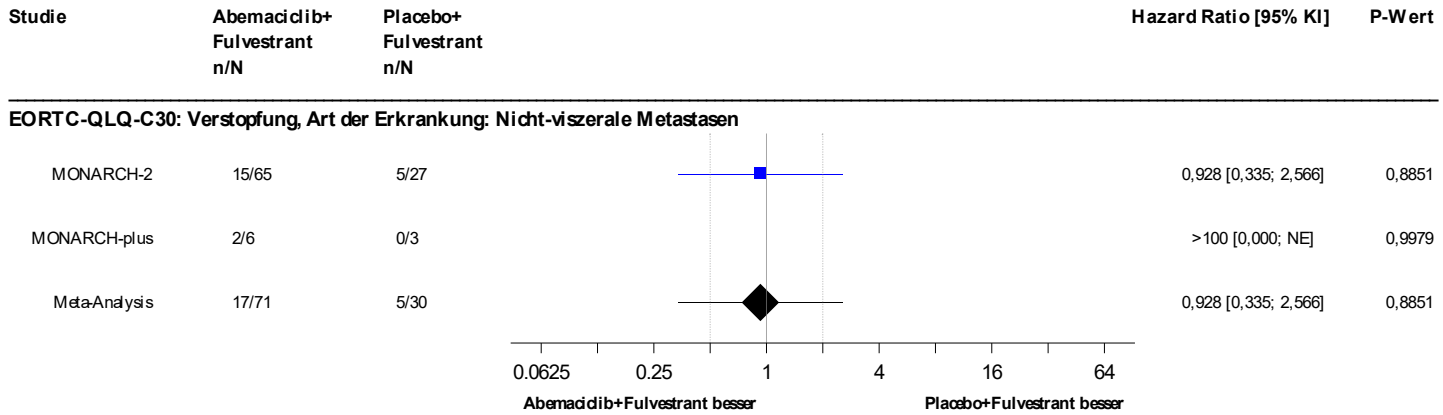
Abbildung 1408.2.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9979, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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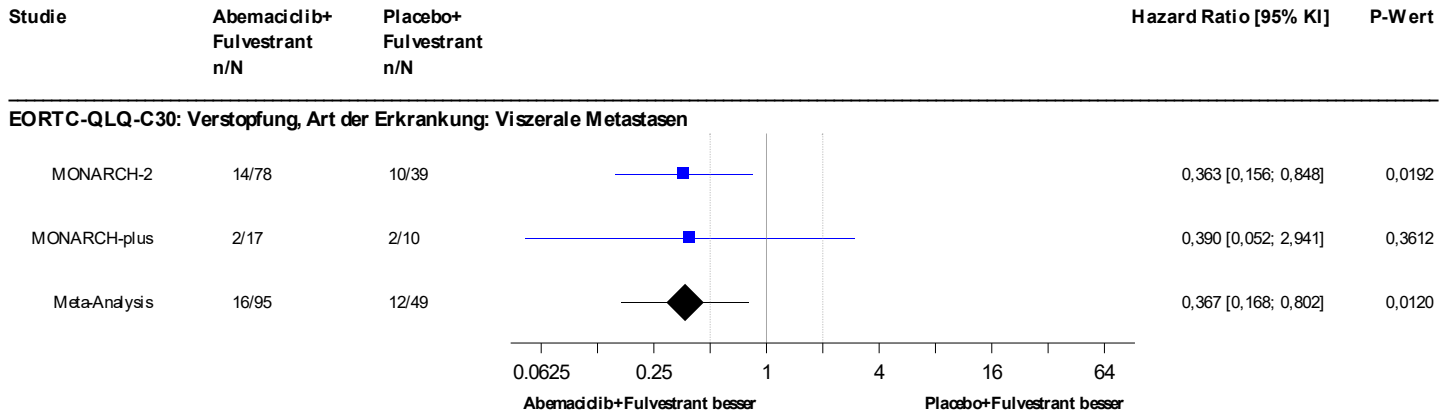
Abbildung 1408.2.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0041, P-Wert=0,9489, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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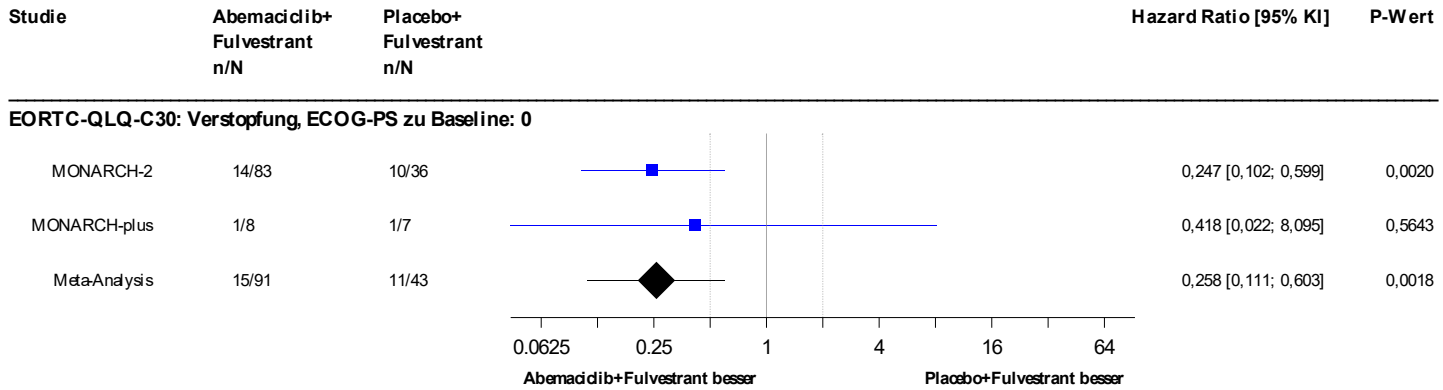
Abbildung 1408.2.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1111, P-Wert=0,7389, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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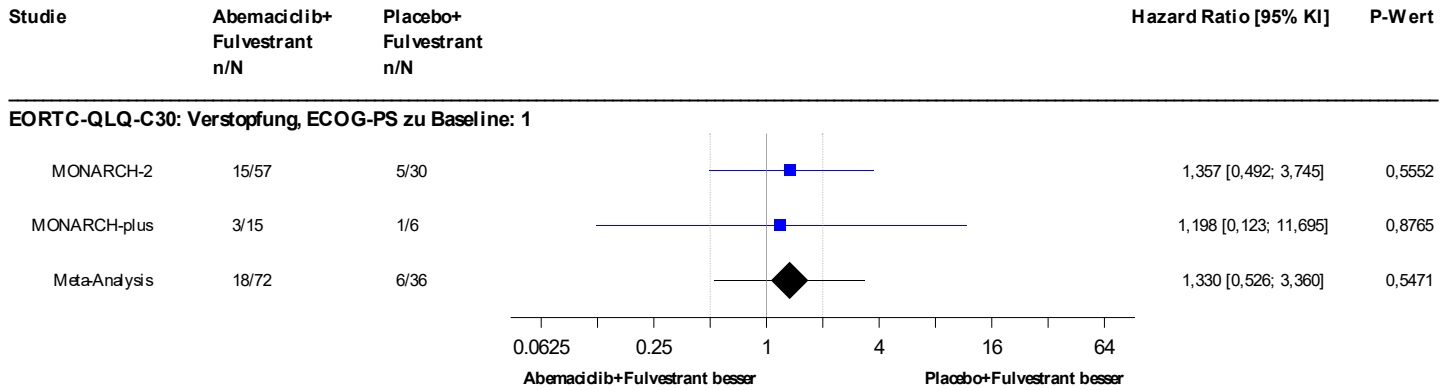
Abbildung 1408.2.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0096, P-Wert=0,9218, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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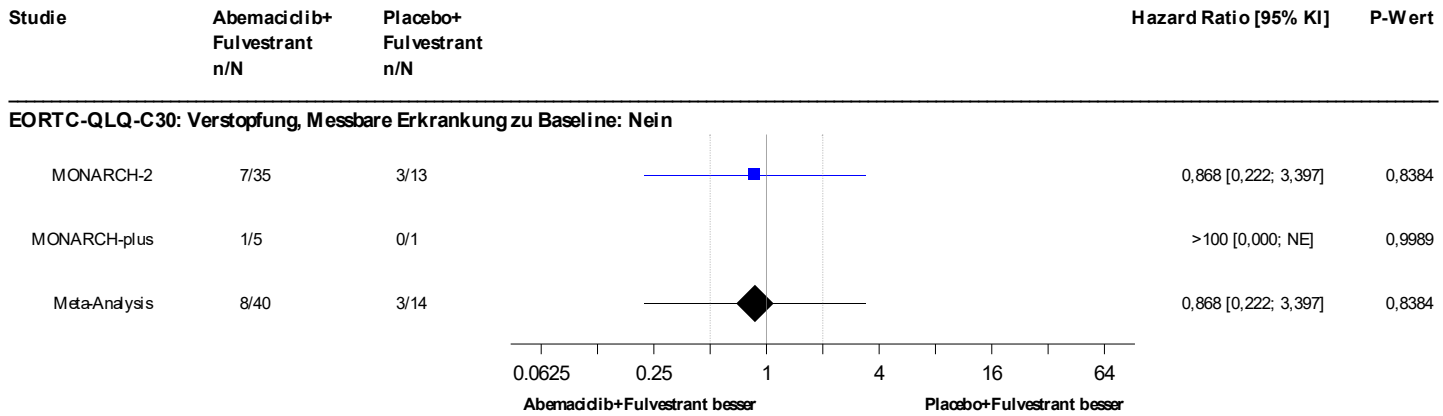
Abbildung 1408.2.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9989, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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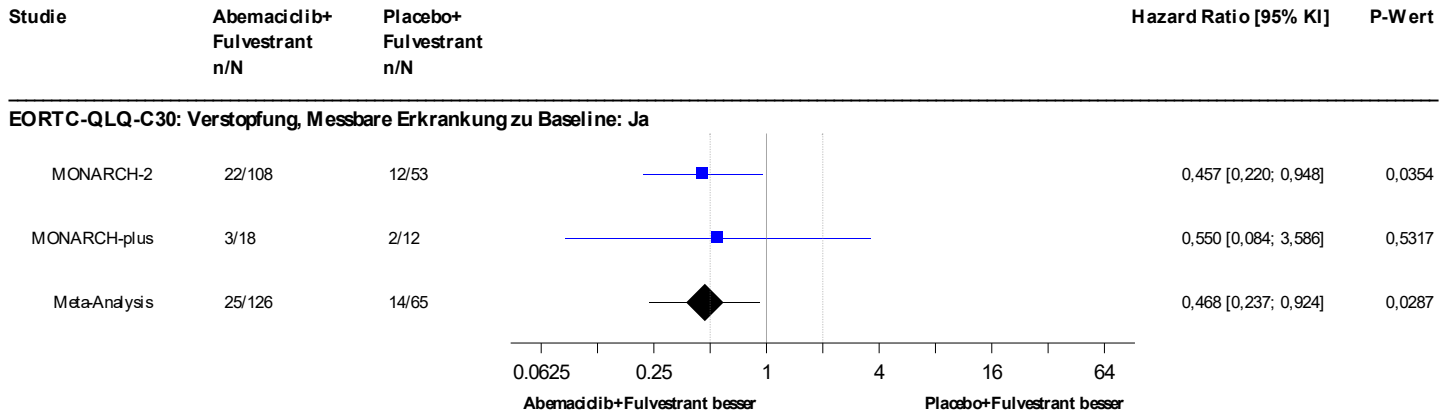
Abbildung 1408.2.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0324, P-Wert=0,8572, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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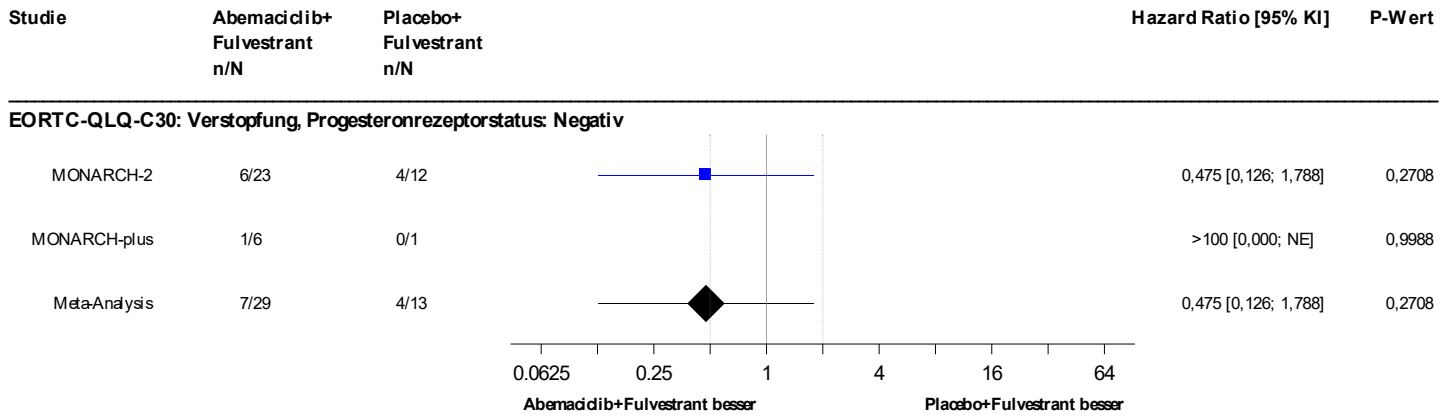
Abbildung 1408.2.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9988, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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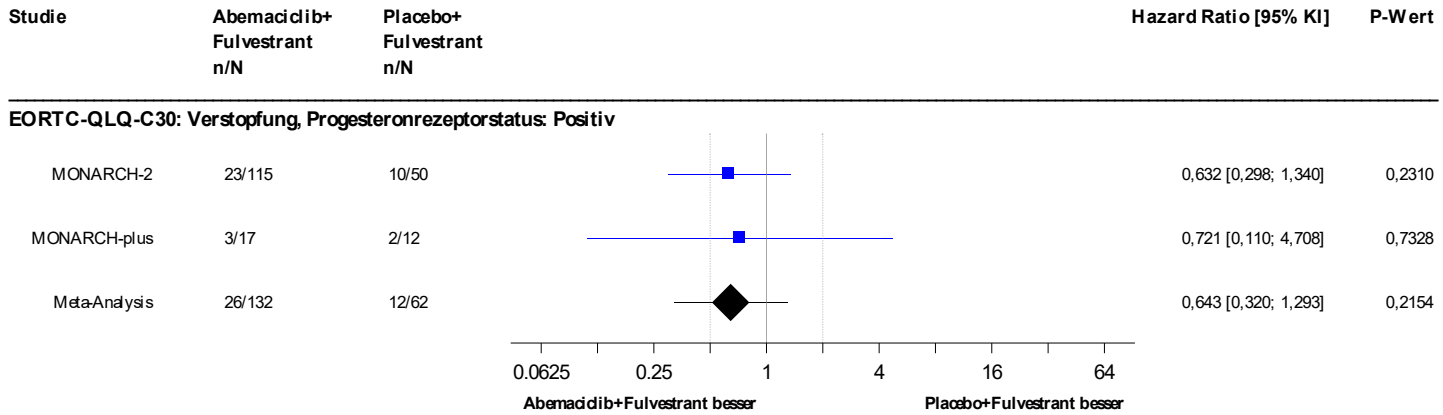
Abbildung 1408.2.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0166, P-Wert=0,8975, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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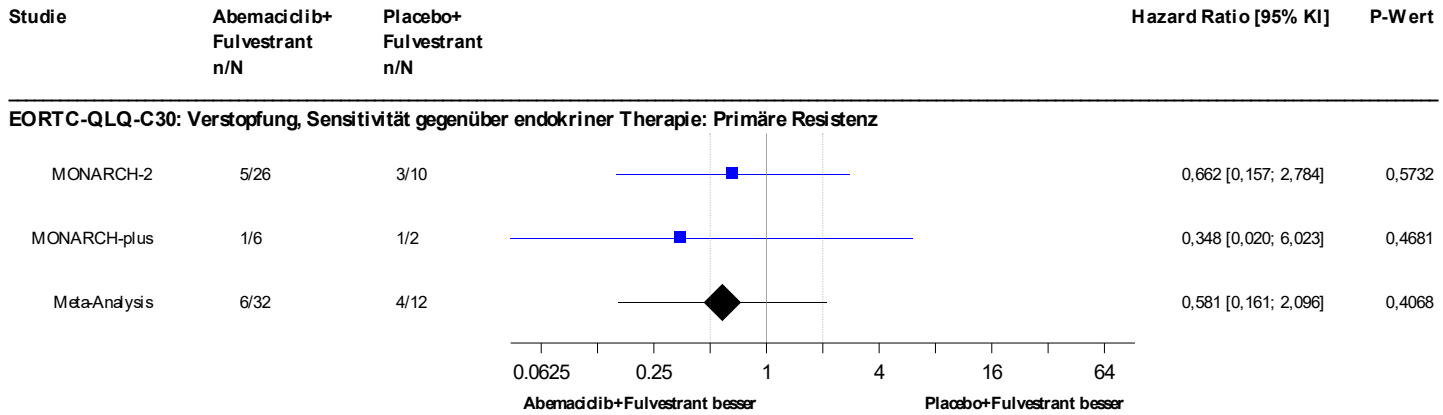
Abbildung 1408.2.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1555, P-Wert=0,6933, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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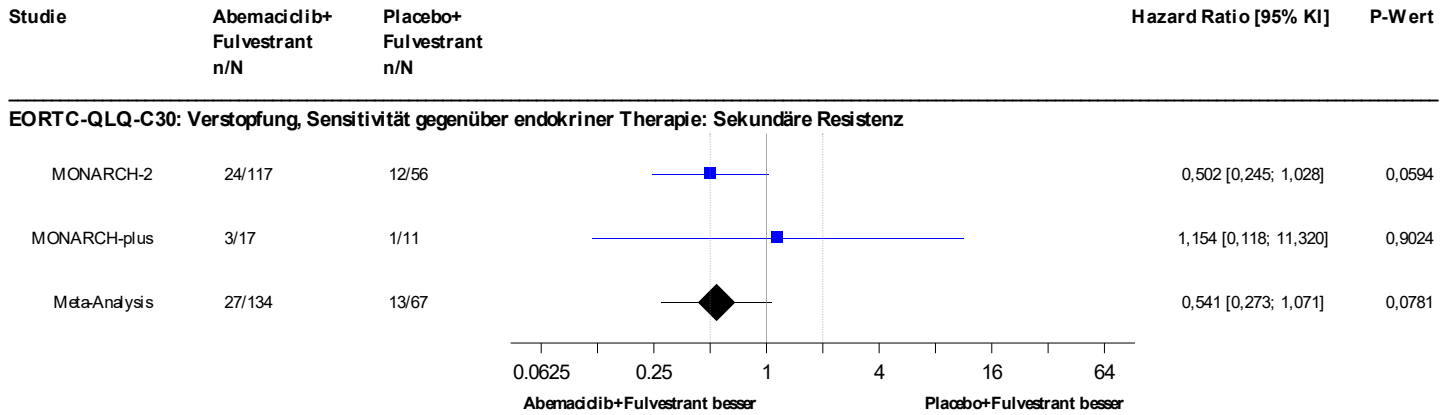
Abbildung 1408.2.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,4640, P-Wert=0,4957, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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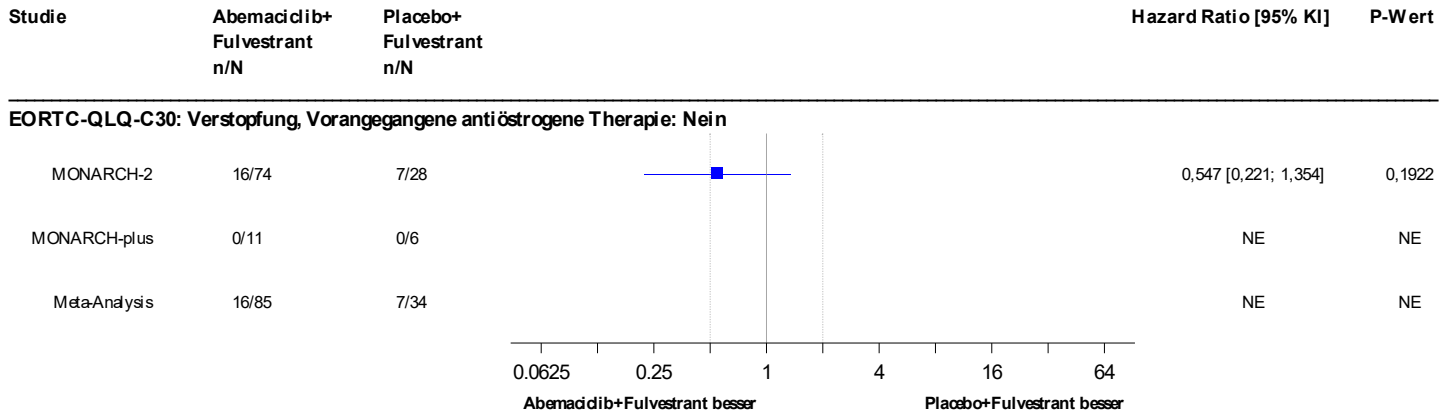
Abbildung 1408.2.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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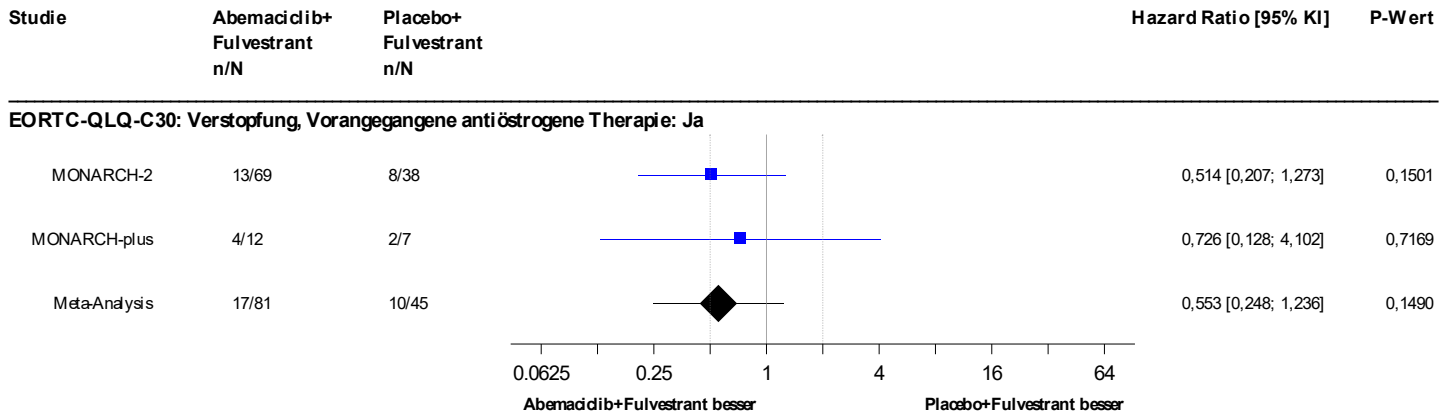
Abbildung 1408.2.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Verstopfung (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1204, P-Wert=0,7286, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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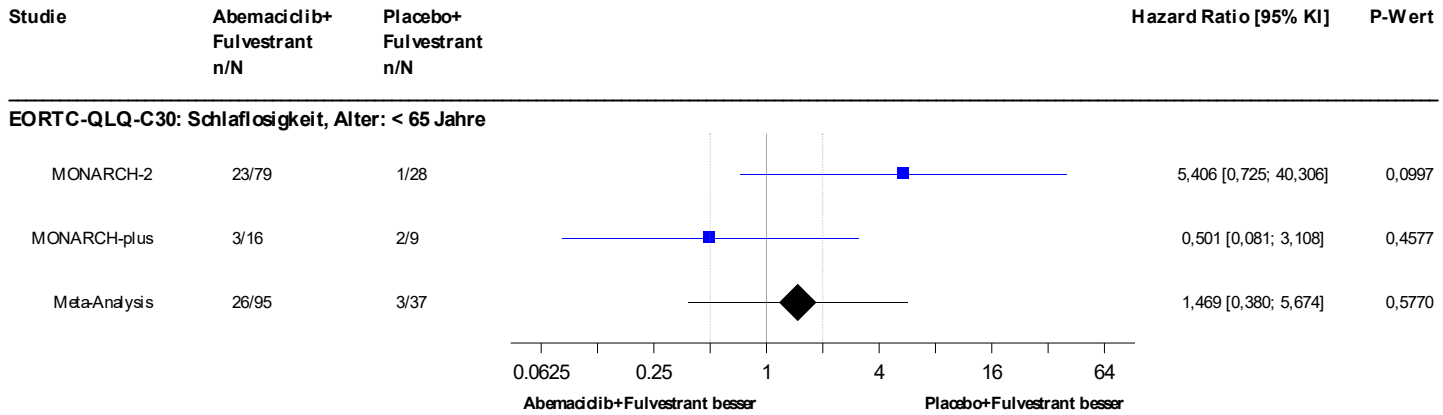
Abbildung 1409.2.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=2,9510, P-Wert=0,0858, I2 Index=66,1%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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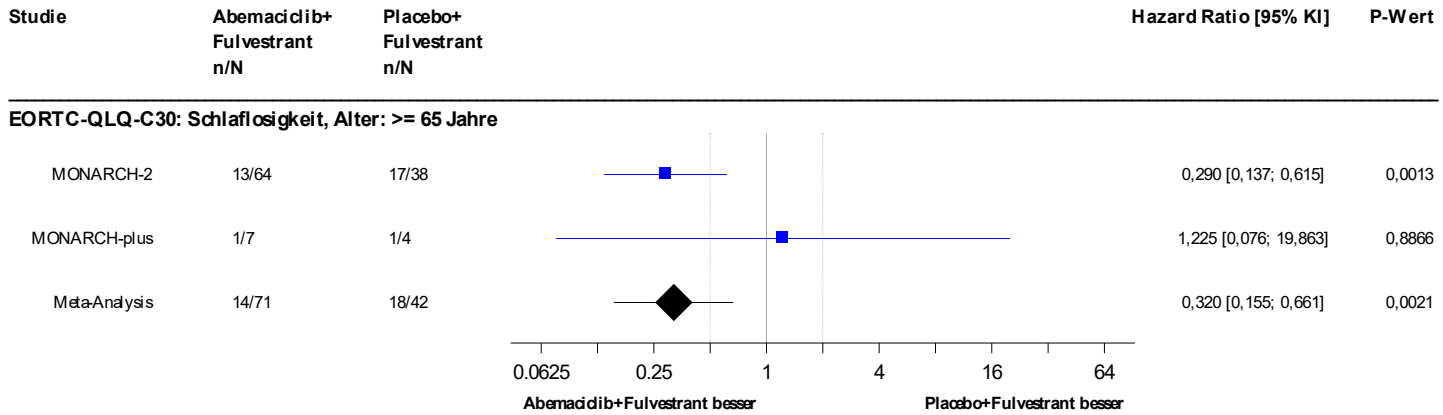
Abbildung 1409.2.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,9572, P-Wert=0,3279, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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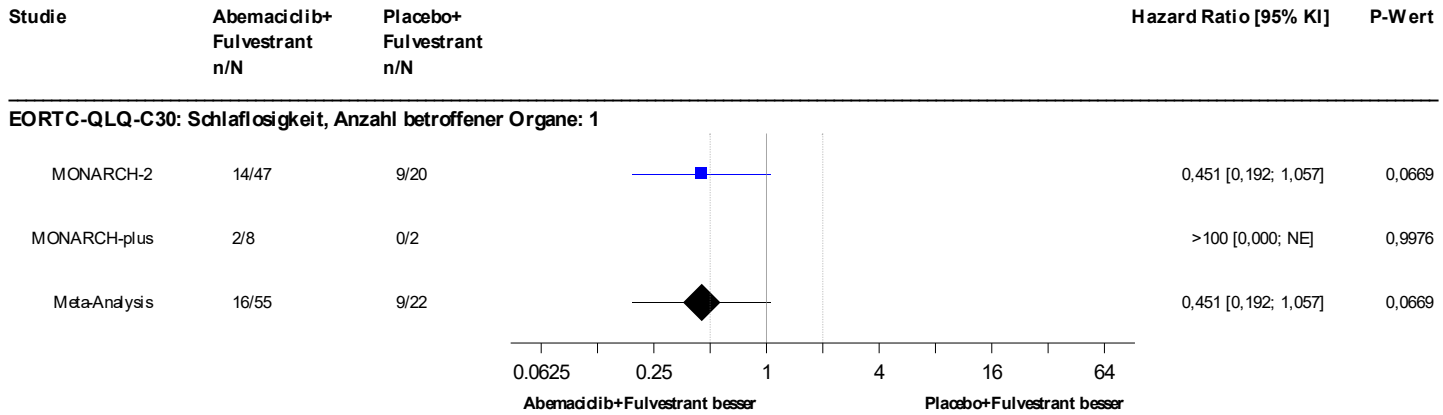
Abbildung 1409.2.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9975, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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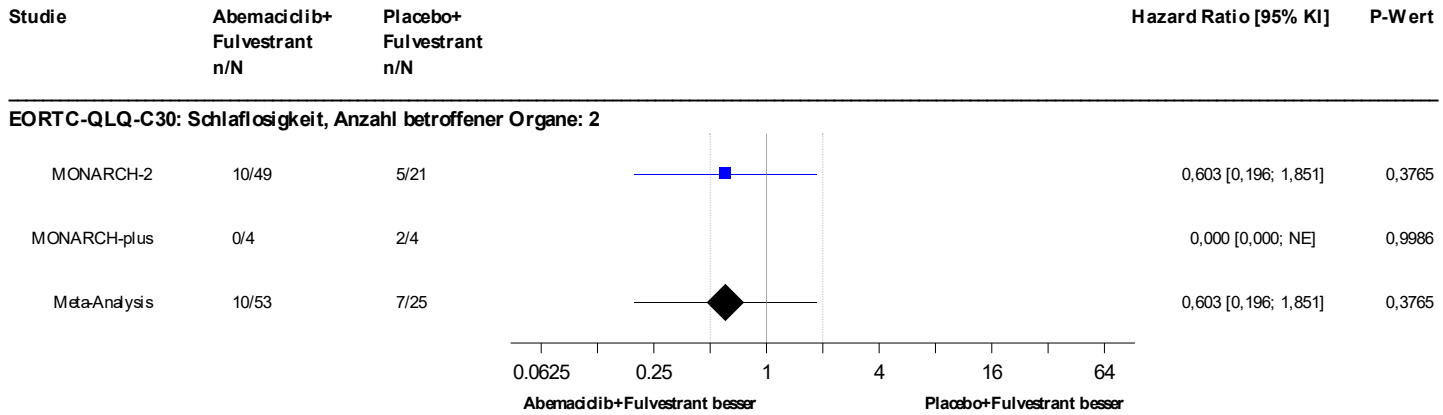
Abbildung 1409.2.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9986, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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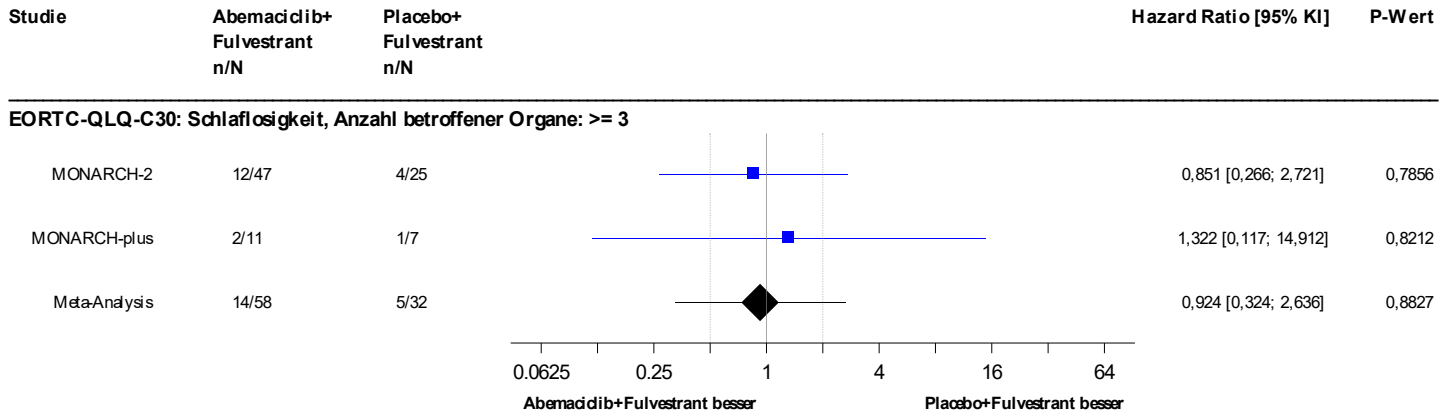
Abbildung 1409.2.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1033, P-Wert=0,7479, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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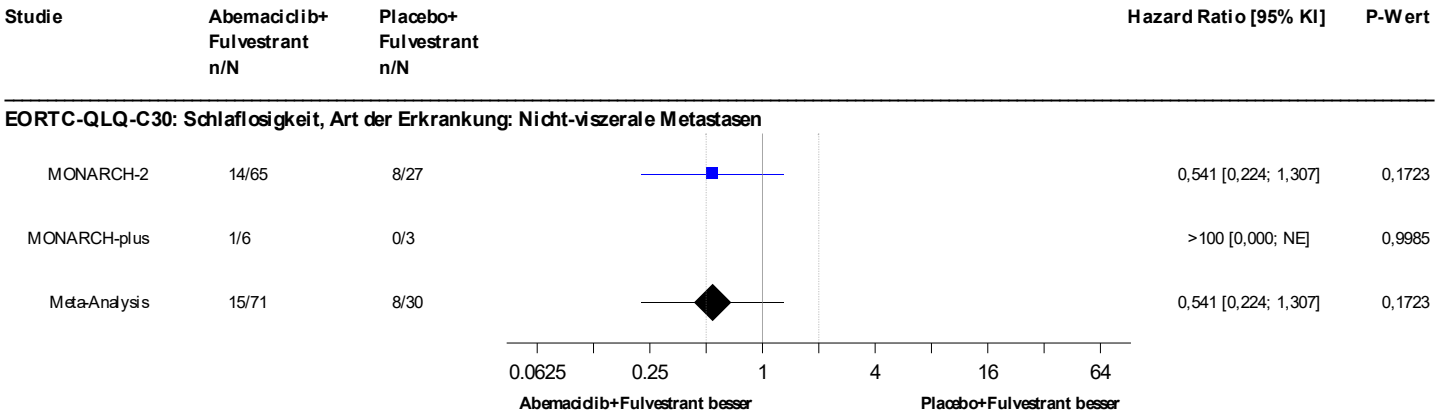
Abbildung 1409.2.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9985, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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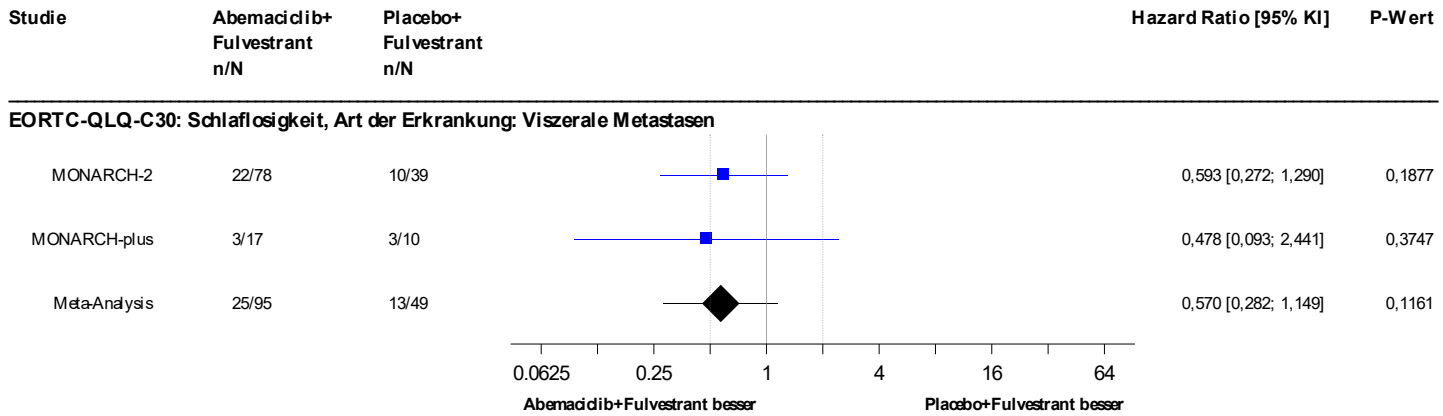
Abbildung 1409.2.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0549, P-Wert=0,8147, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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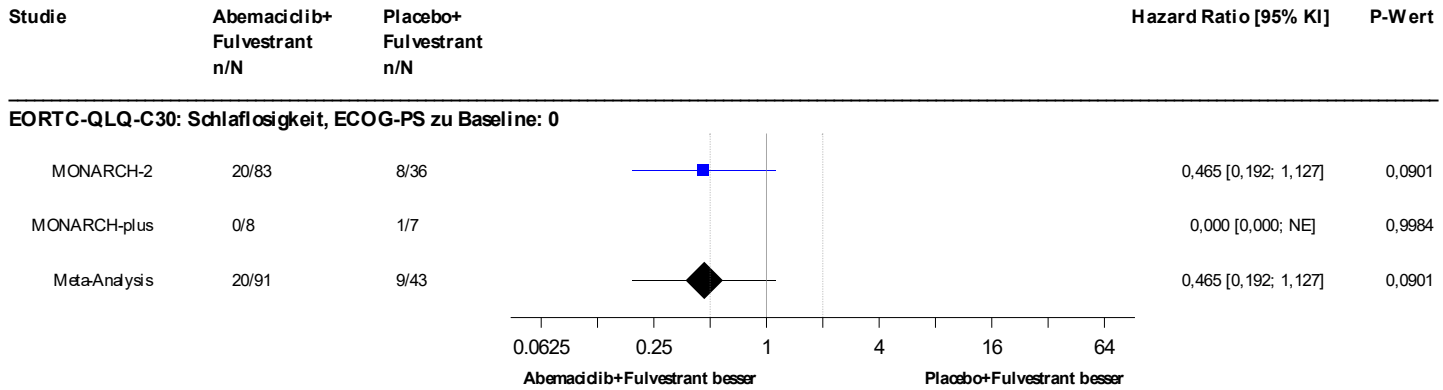
Abbildung 1409.2.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9985, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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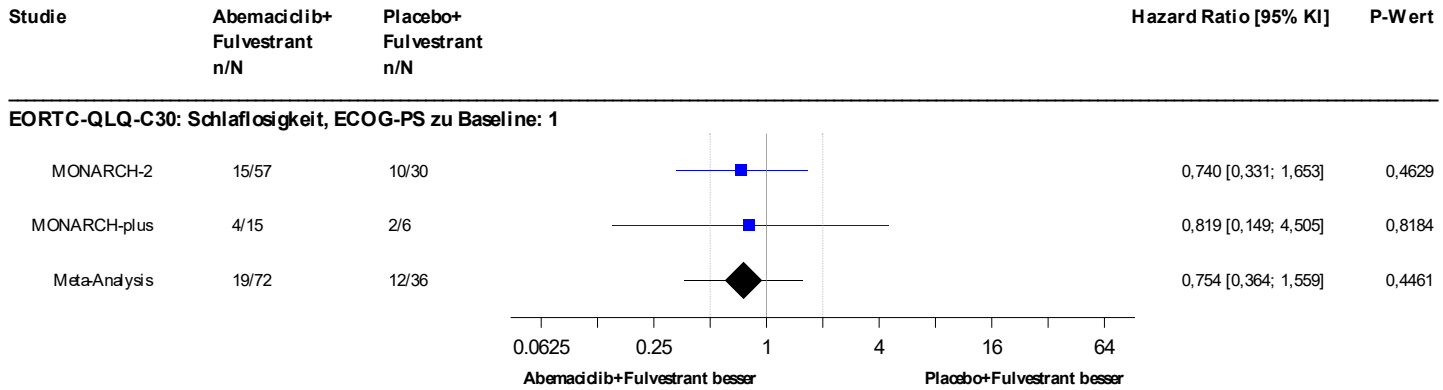
Abbildung 1409.2.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0111, P-Wert=0,9161, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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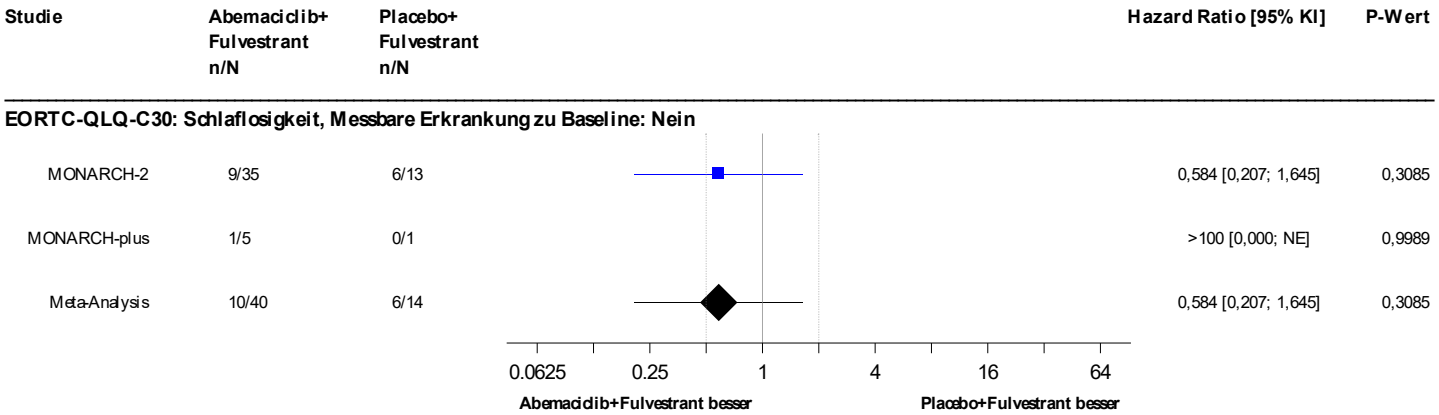
Abbildung 1409.2.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9989, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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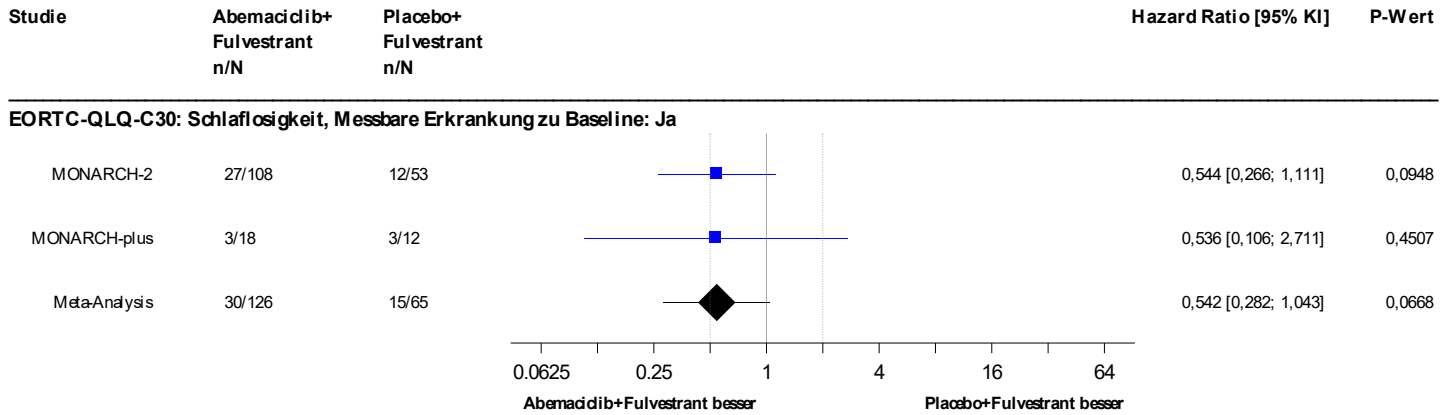
Abbildung 1409.2.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0003, P-Wert=0,9874, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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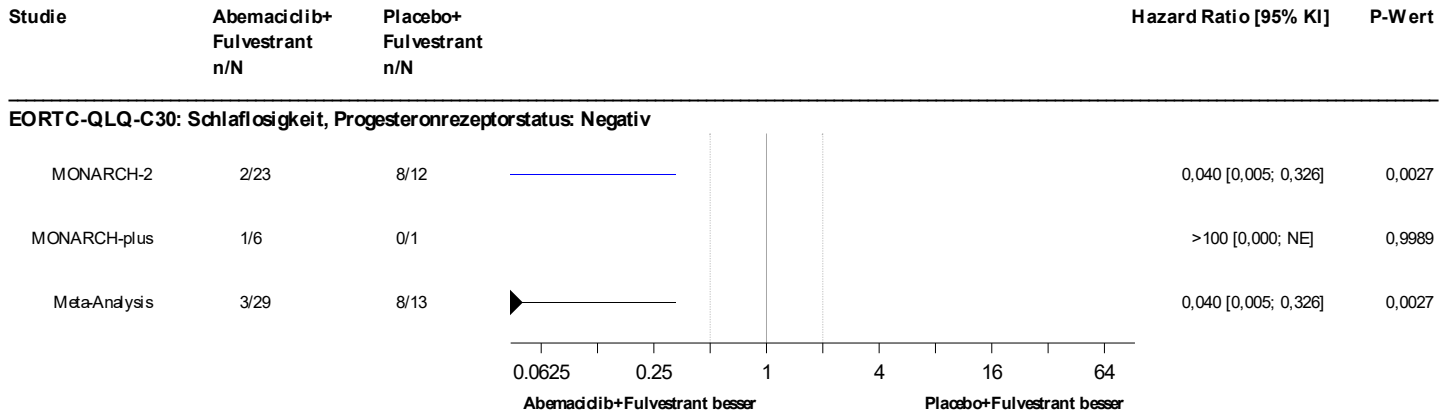
Abbildung 1409.2.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9987, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwinso6_popa2_pgrstat_1.rtf
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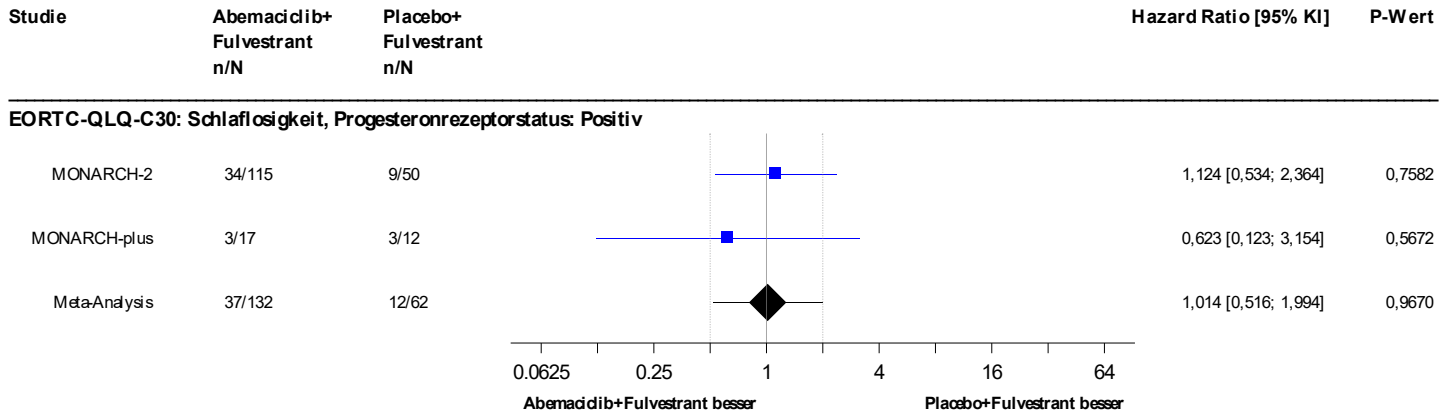
Abbildung 1409.2.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,4204, P-Wert=0,5167, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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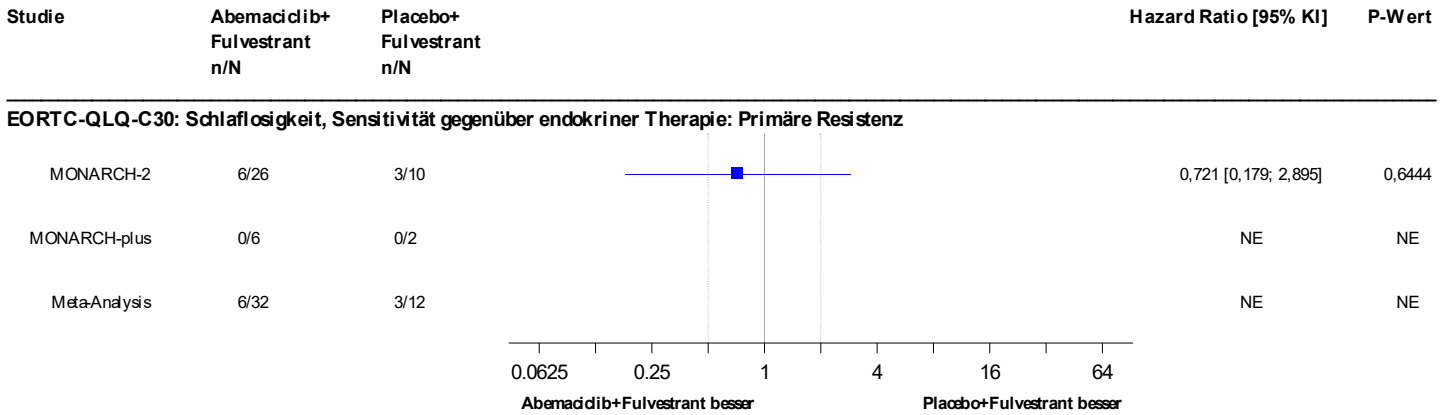
Abbildung 1409.2.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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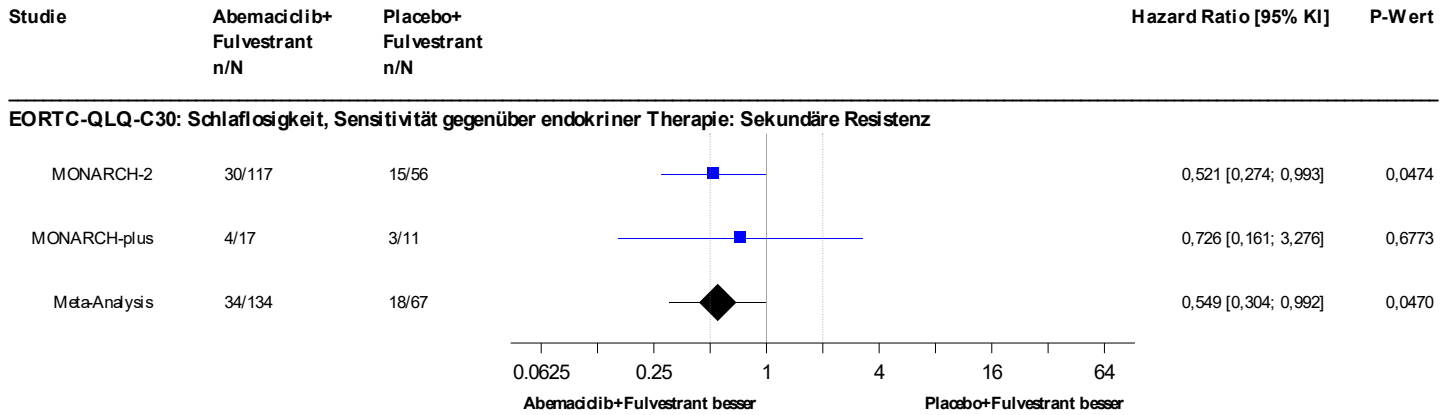
Abbildung 1409.2.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1572, P-Wert=0,6917, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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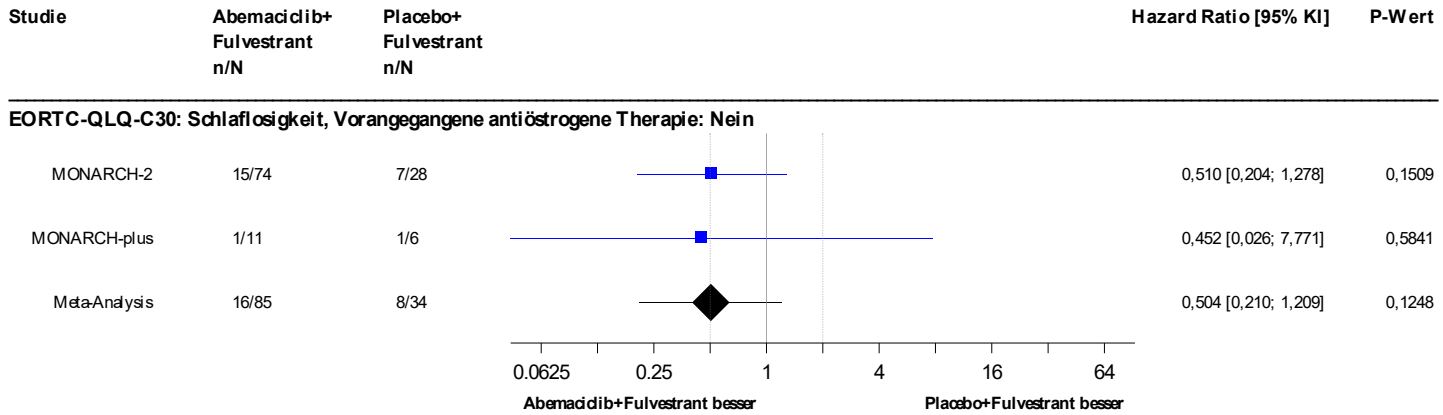
Abbildung 1409.2.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0063, P-Wert=0,9366, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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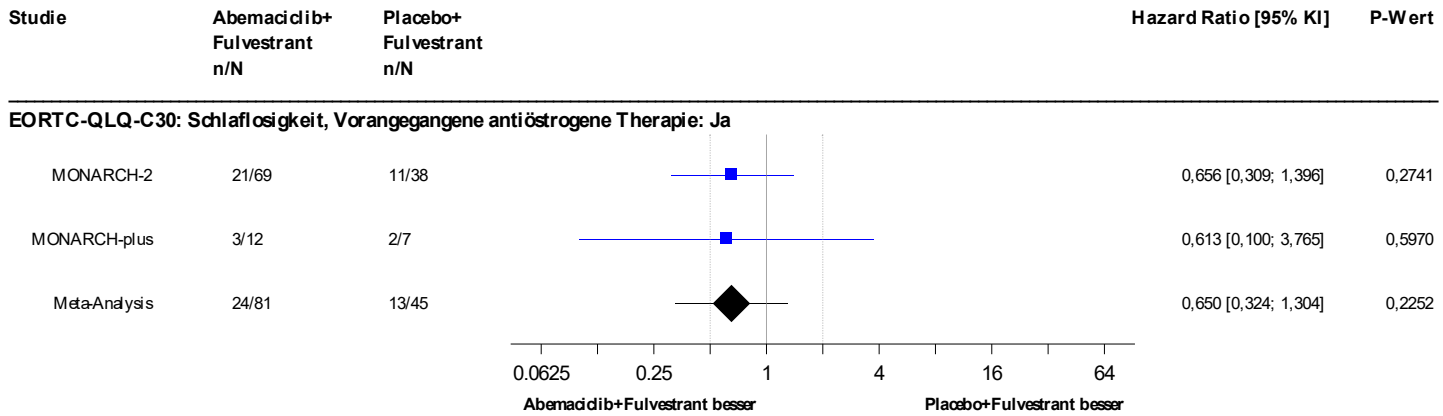
Abbildung 1409.2.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schlaflosigkeit (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0047, P-Wert=0,9453, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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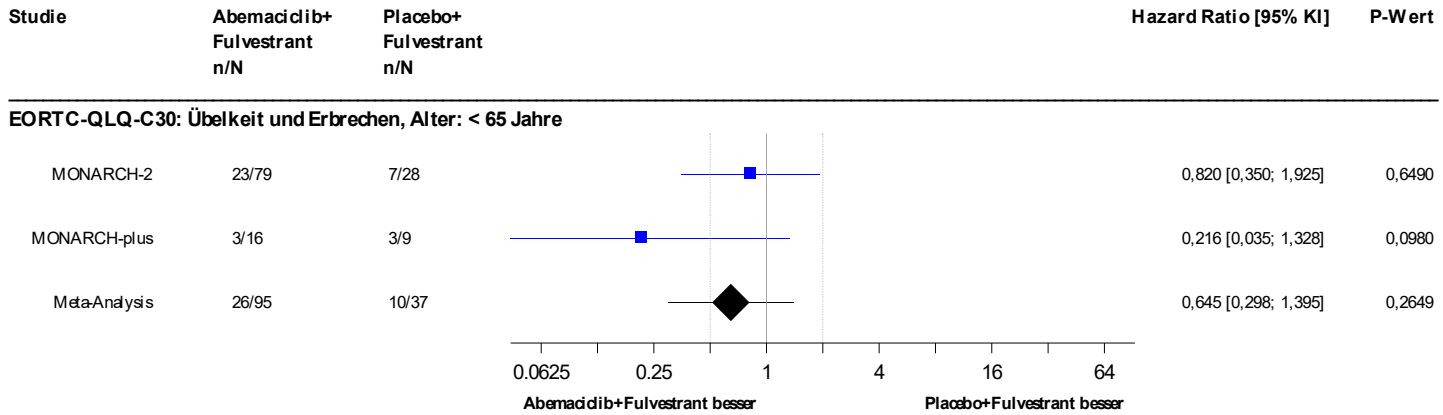
Abbildung 1410.2.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,7016, P-Wert=0,1921, I2 Index=41,2%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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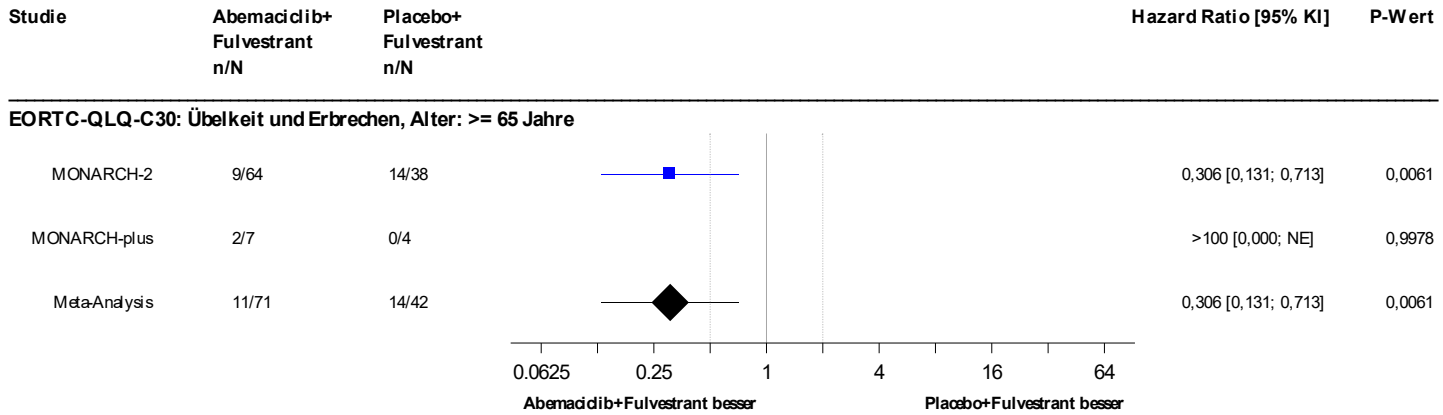
Abbildung 1410.2.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9976, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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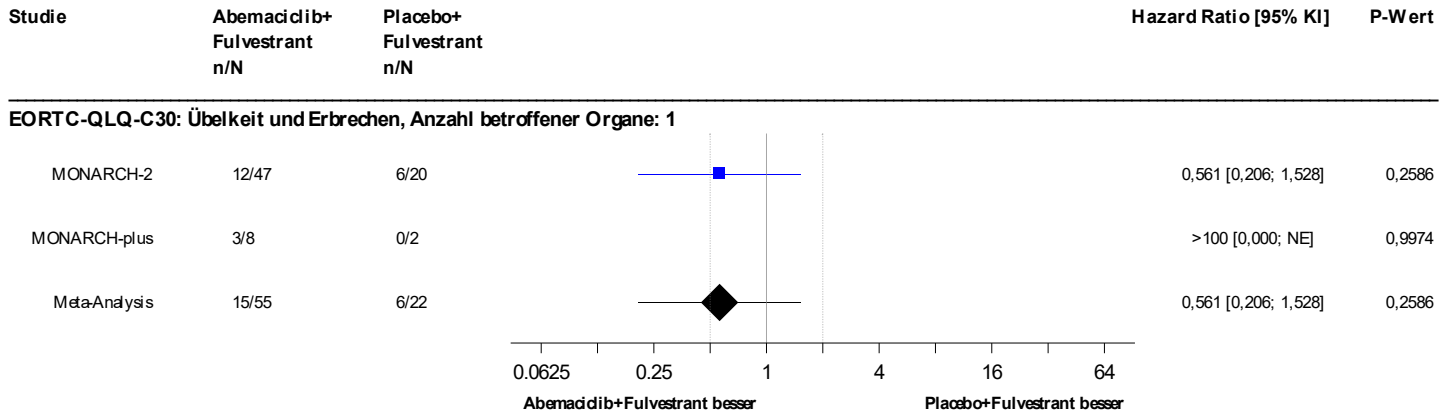
Abbildung 1410.2.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9973, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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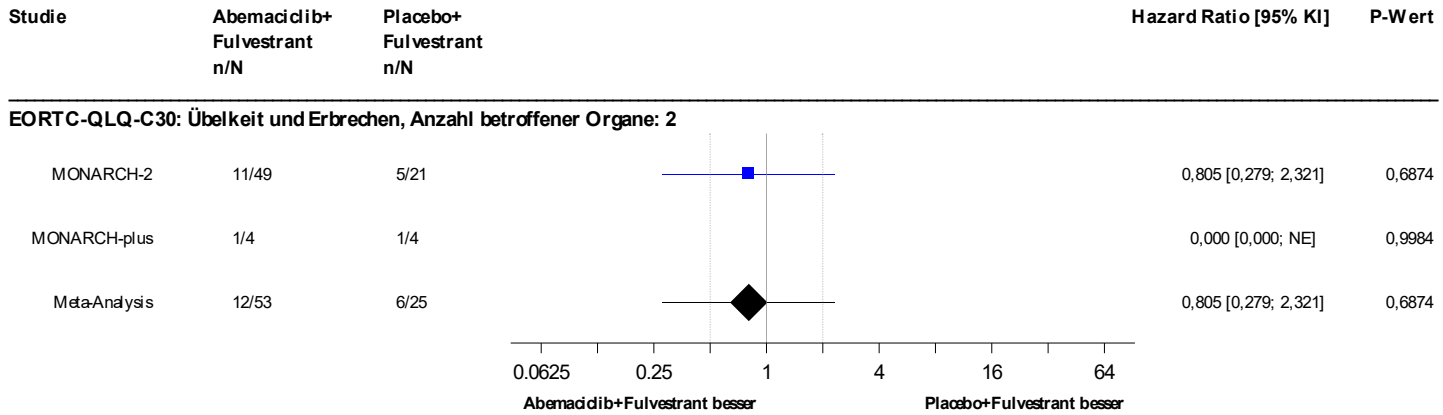
Abbildung 1410.2.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9984, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwnavo6_popa2_norggr_2.rtf
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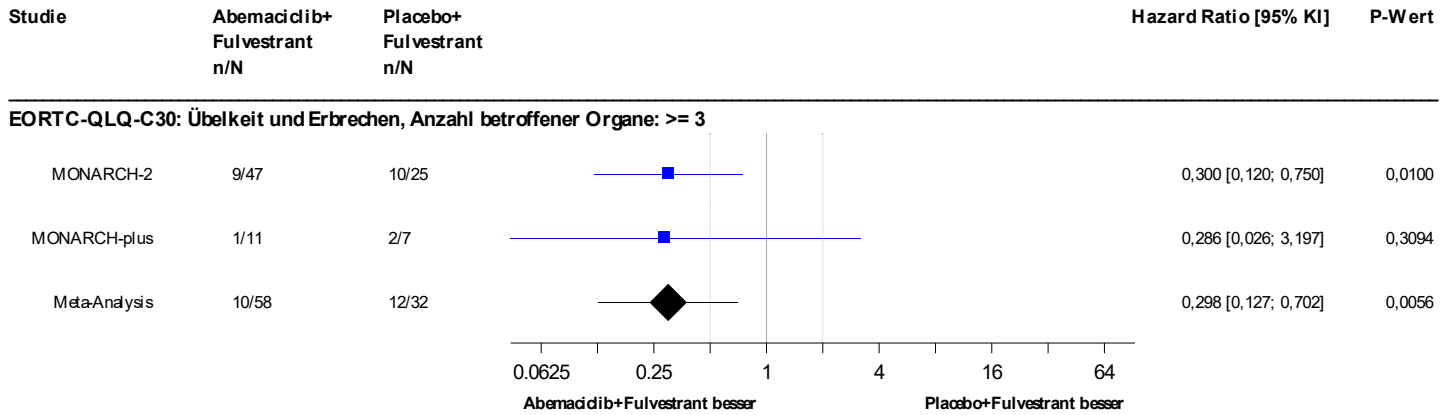
Abbildung 1410.2.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0014, P-Wert=0,9705, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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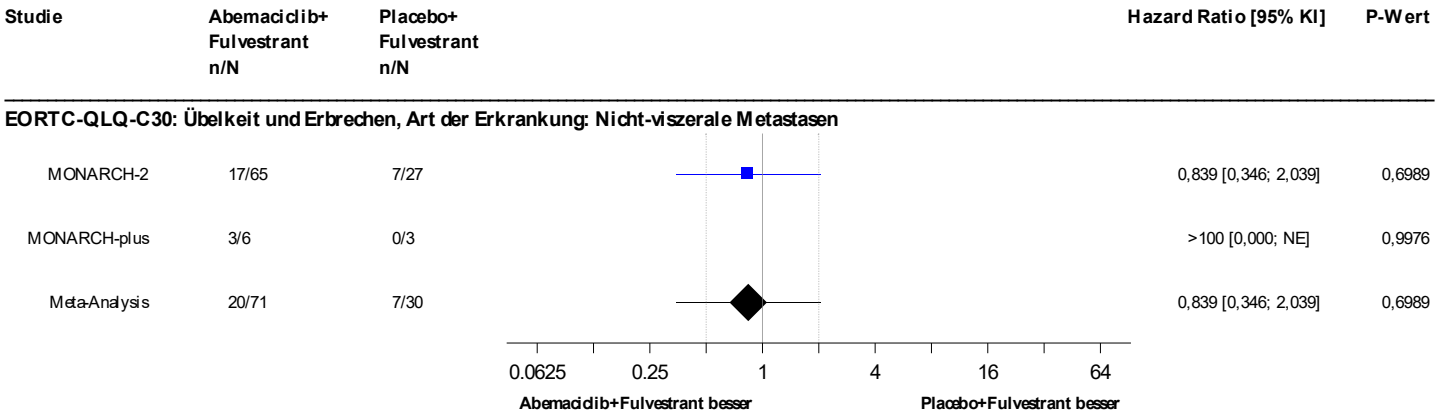
Abbildung 1410.2.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9976, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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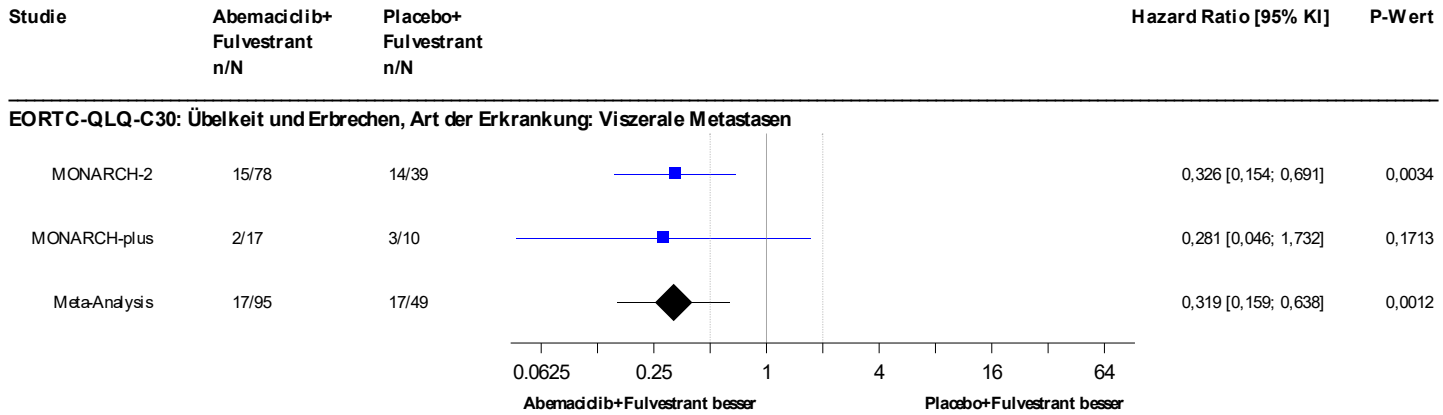
Abbildung 1410.2.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0216, P-Wert=0,8830, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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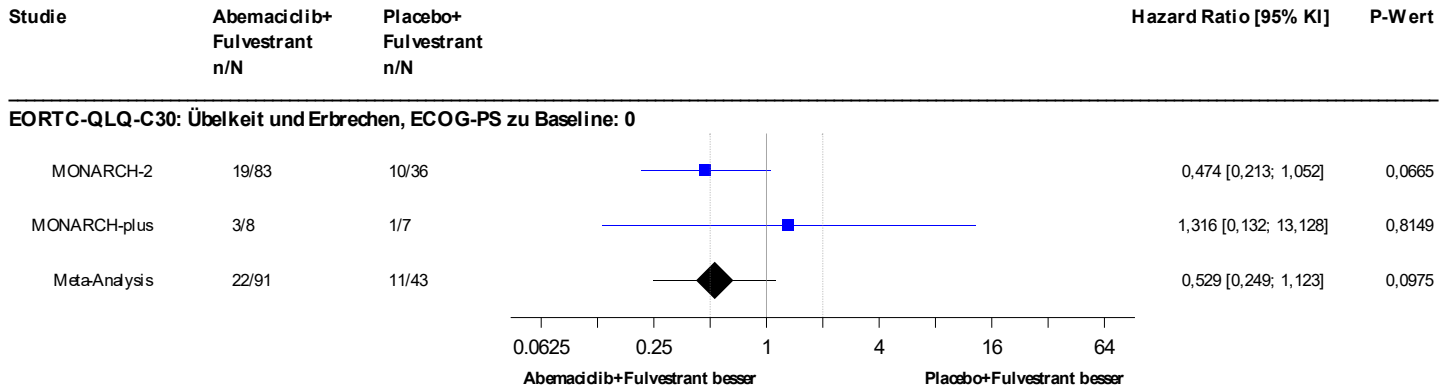
Abbildung 1410.2.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,6766, P-Wert=0,4108, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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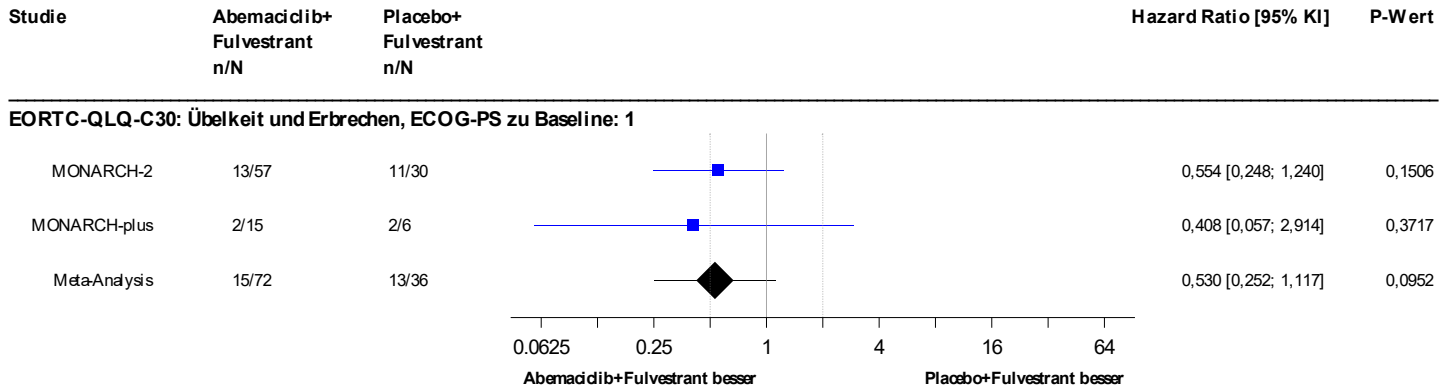
Abbildung 1410.2.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0792, P-Wert=0,7784, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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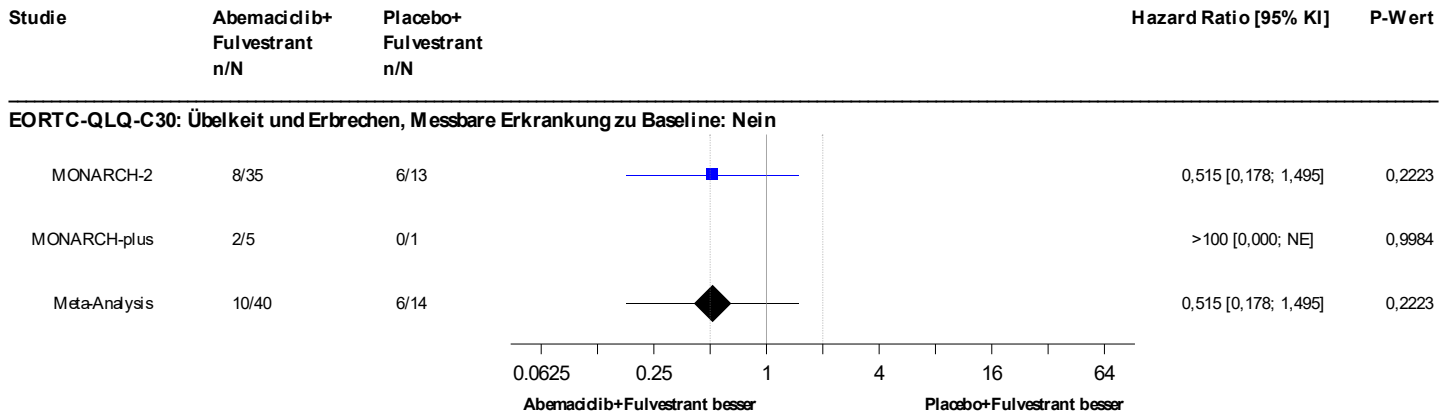
Abbildung 1410.2.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9983, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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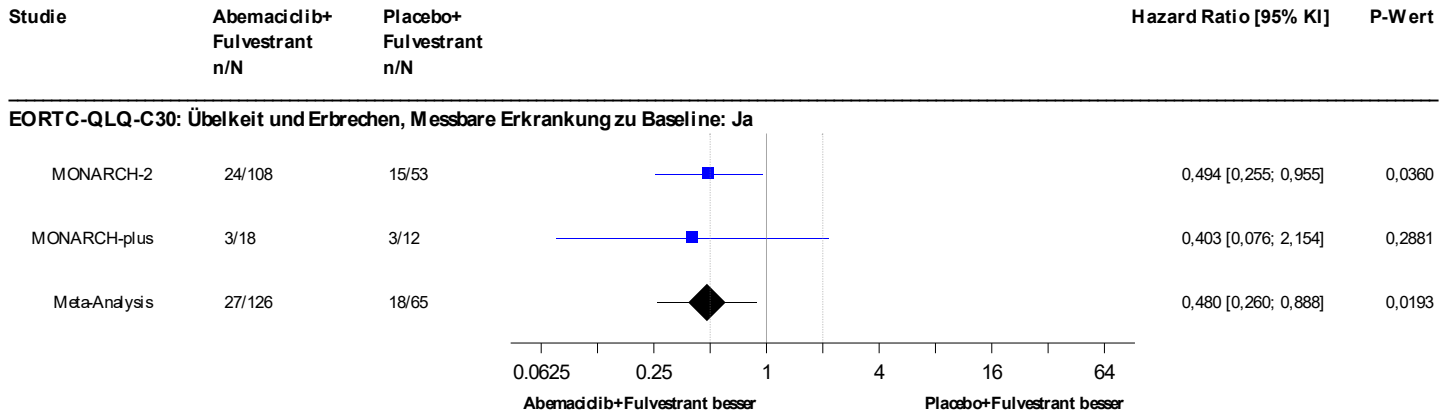
Abbildung 1410.2.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0484, P-Wert=0,8259, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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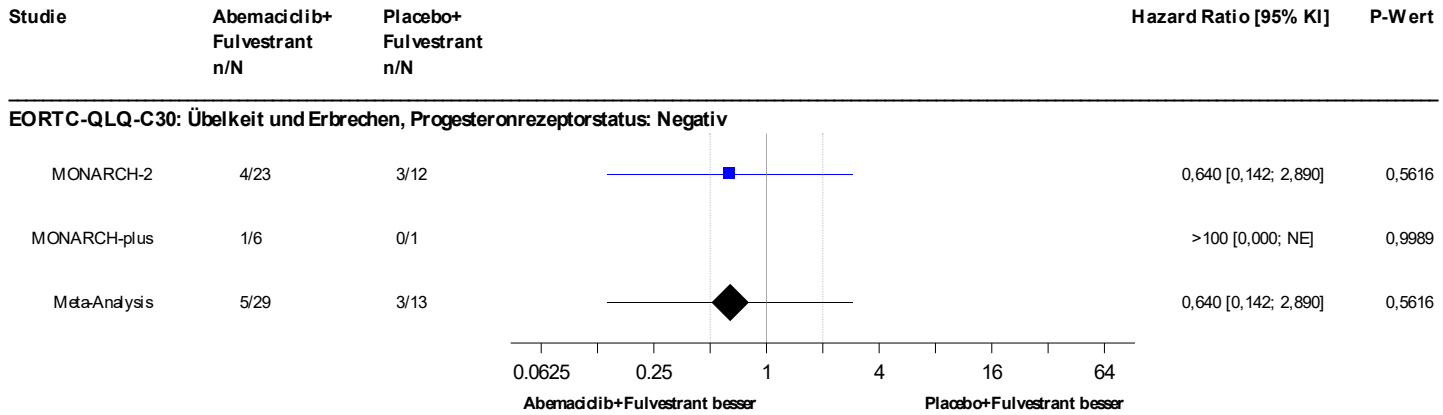
Abbildung 1410.2.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9989, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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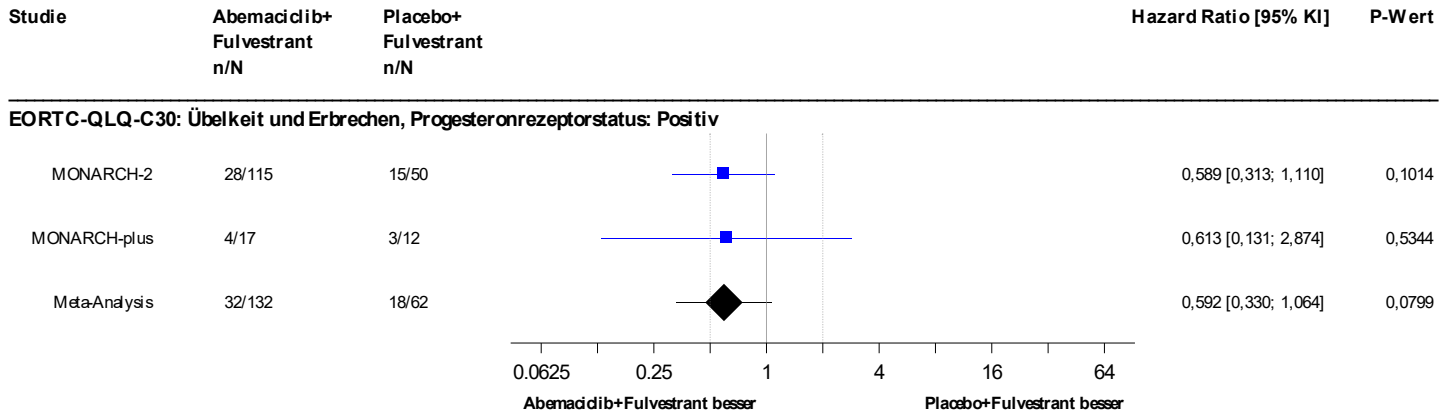
Abbildung 1410.2.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0021, P-Wert=0,9634, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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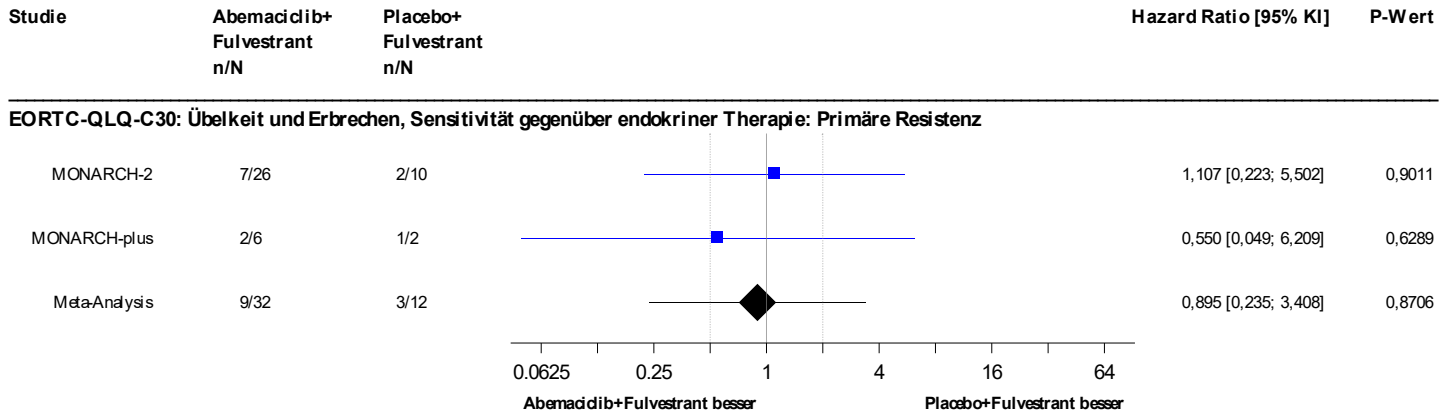
Abbildung 1410.2.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2224, P-Wert=0,6372, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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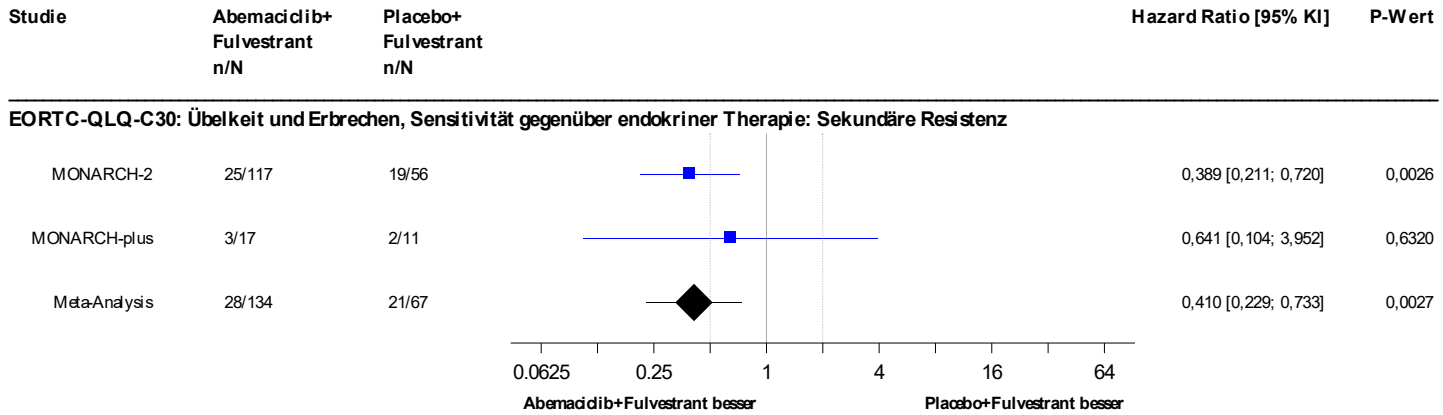
Abbildung 1410.2.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2596, P-Wert=0,6104, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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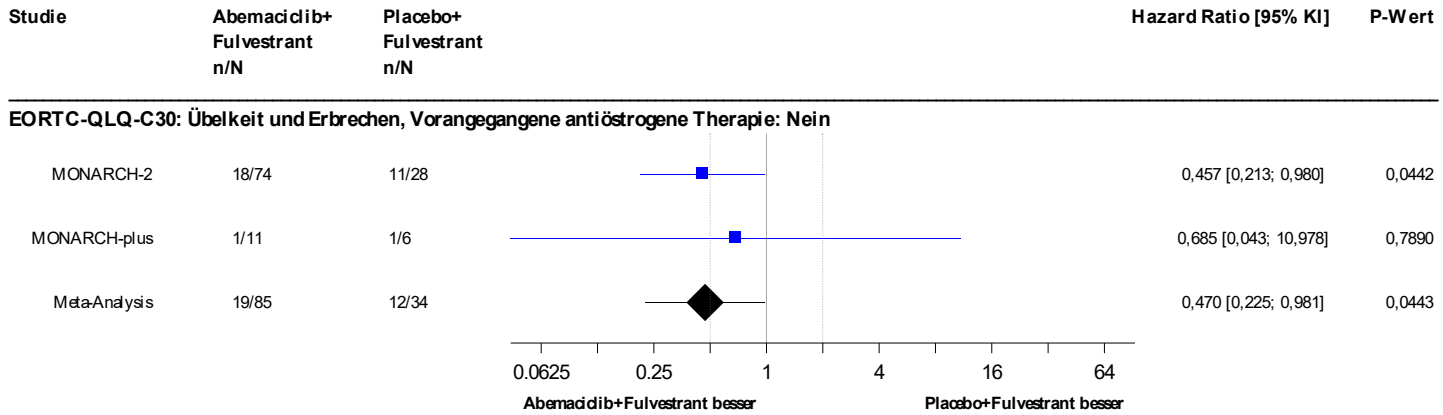
Abbildung 1410.2.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0762, P-Wert=0,7825, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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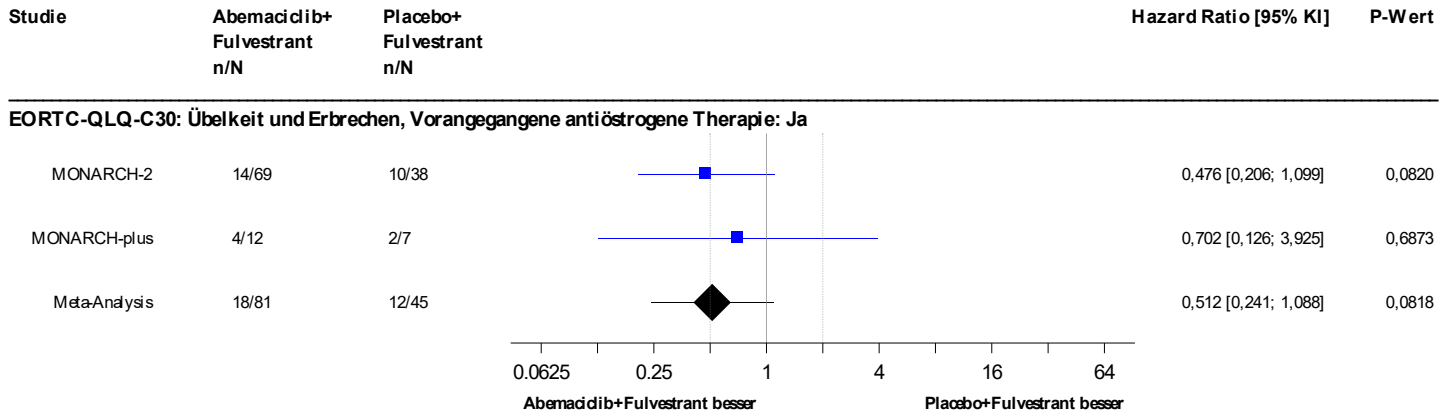
Abbildung 1410.2.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Übelkeit und Erbrechen (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1595, P-Wert=0,6896, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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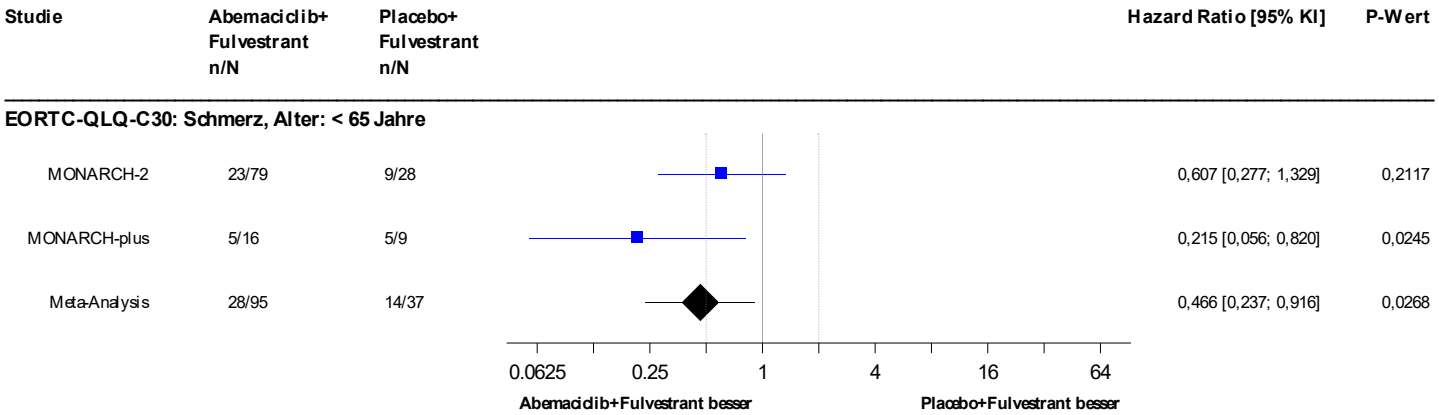
Abbildung 1411.2.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,7200, P-Wert=0,1897, I2 Index=41,9%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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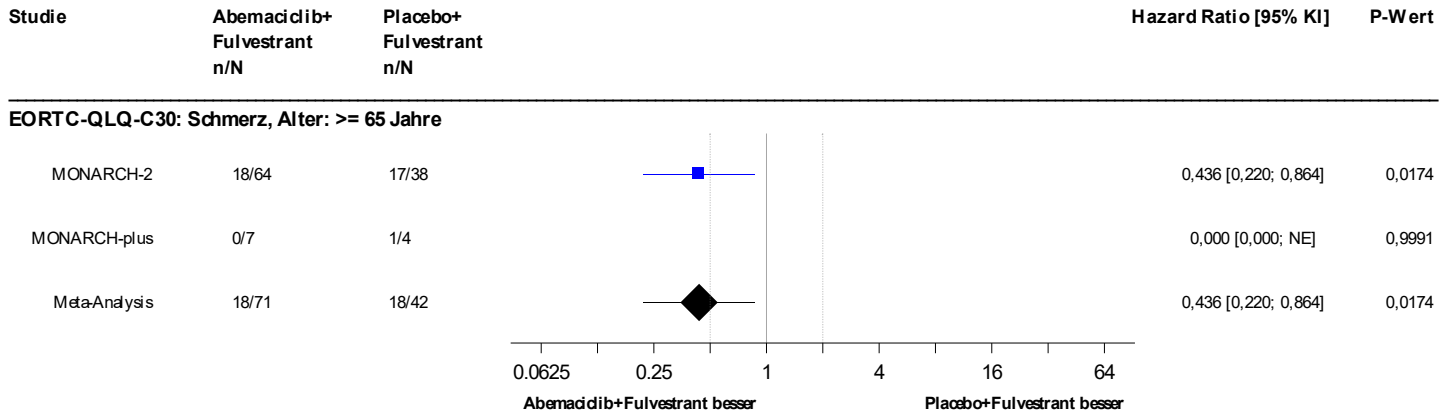
Abbildung 1411.2.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9991, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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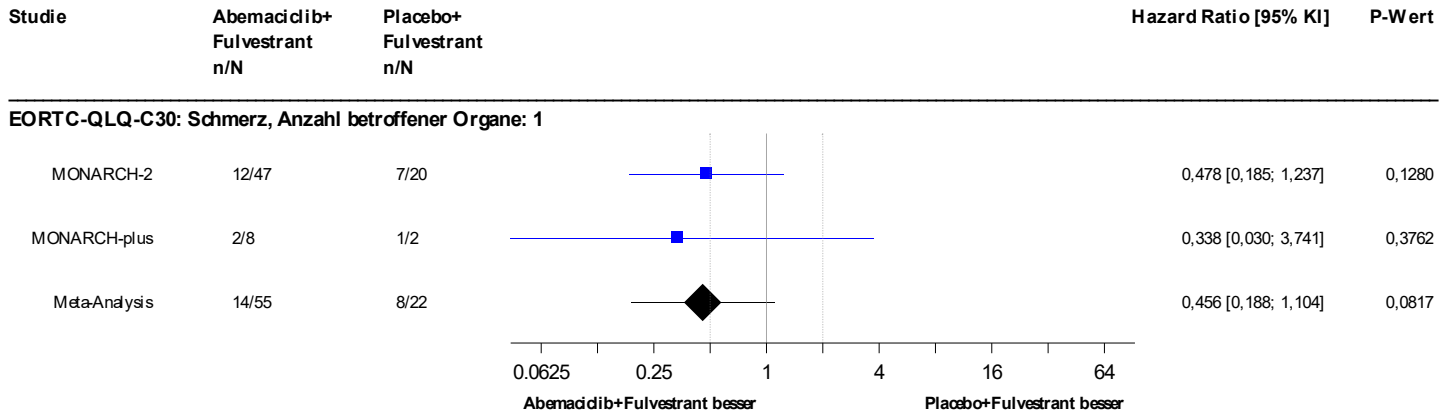
Abbildung 1411.2.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0694, P-Wert=0,7922, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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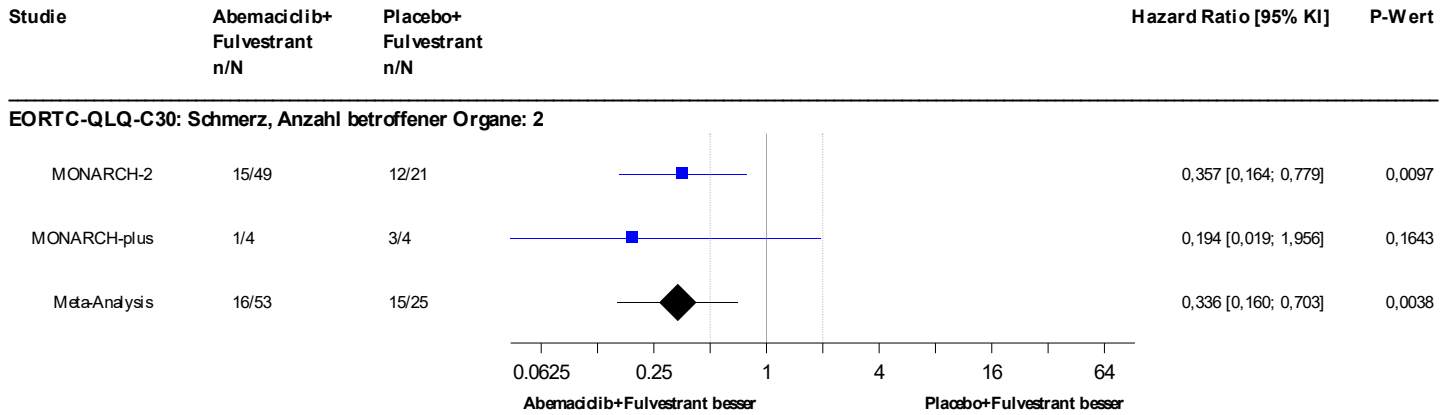
Abbildung 1411.2.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2408, P-Wert=0,6236, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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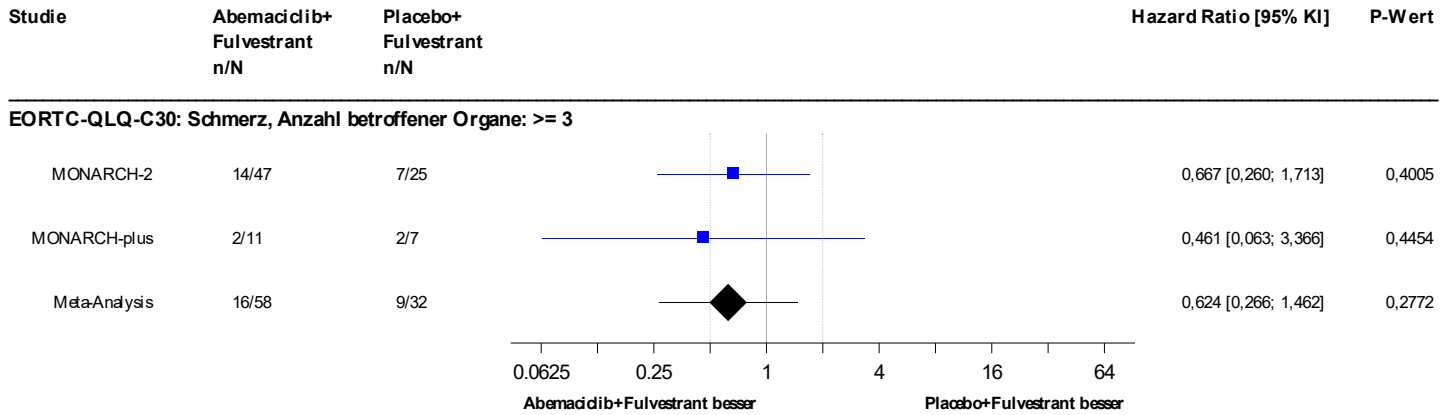
Abbildung 1411.2.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1083, P-Wert=0,7420, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwpain6_popa2_norggr_3.rtf
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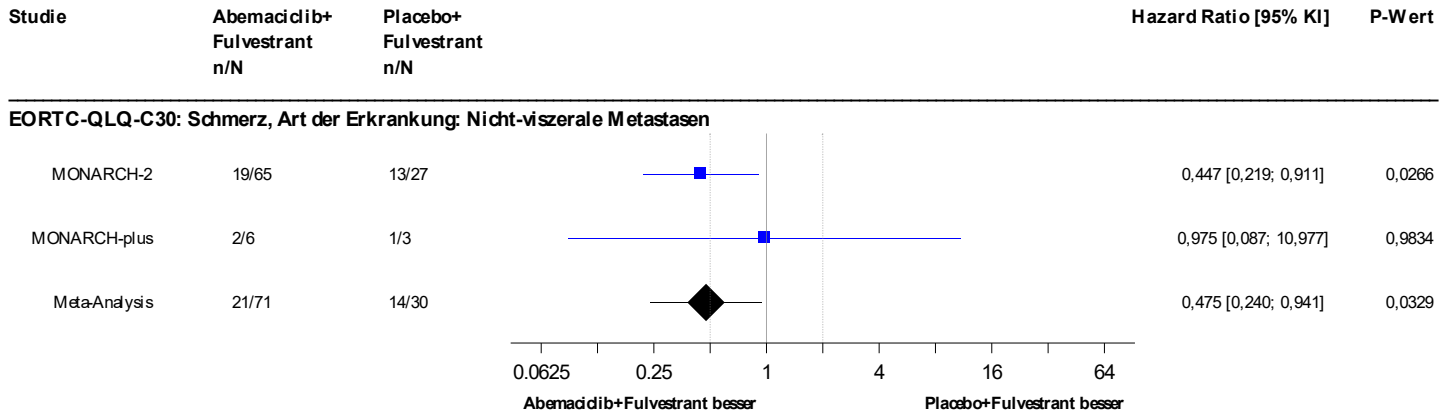
Abbildung 1411.2.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3672, P-Wert=0,5445, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwpain6_popa2_natdis2_1.rtf
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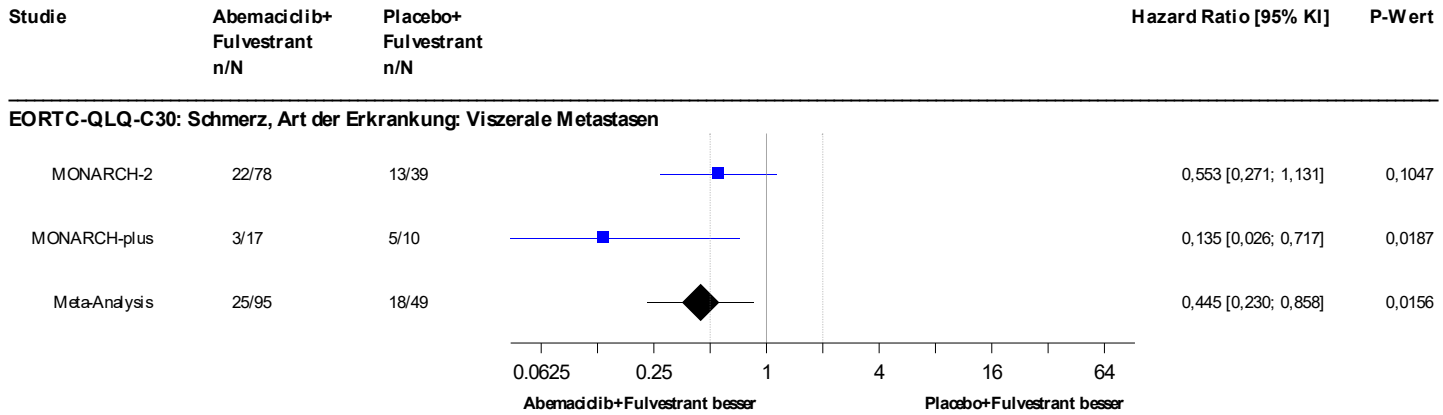
Abbildung 1411.2.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=2,3135, P-Wert=0,1283, I2 Index=56,8%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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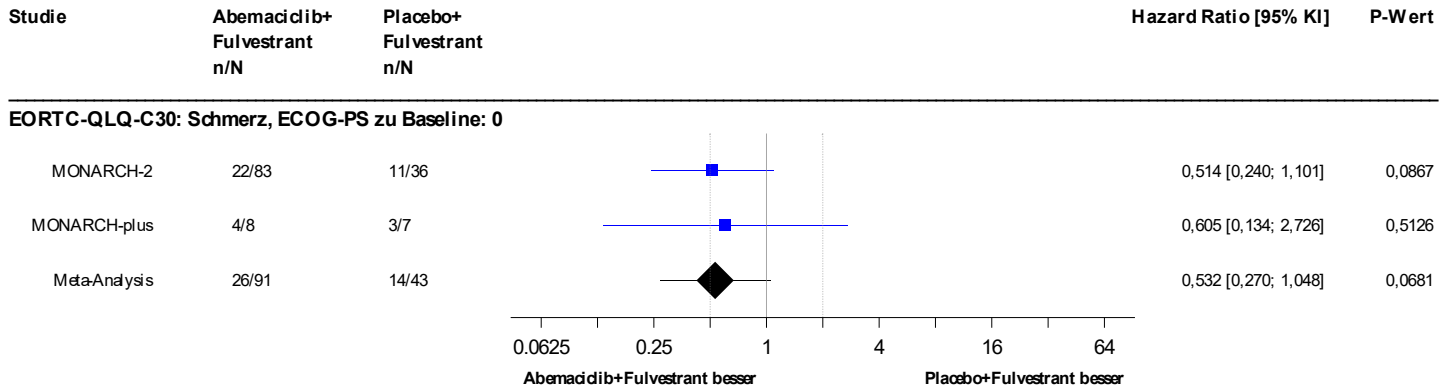
Abbildung 1411.2.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0352, P-Wert=0,8511, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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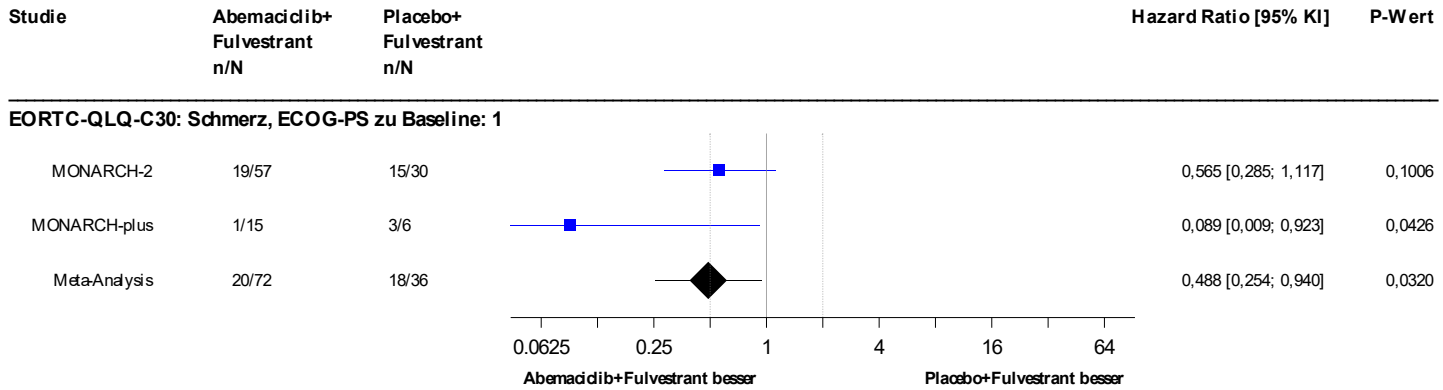
Abbildung 1411.2.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=2,2061, P-Wert=0,1375, I2 Index=54,7%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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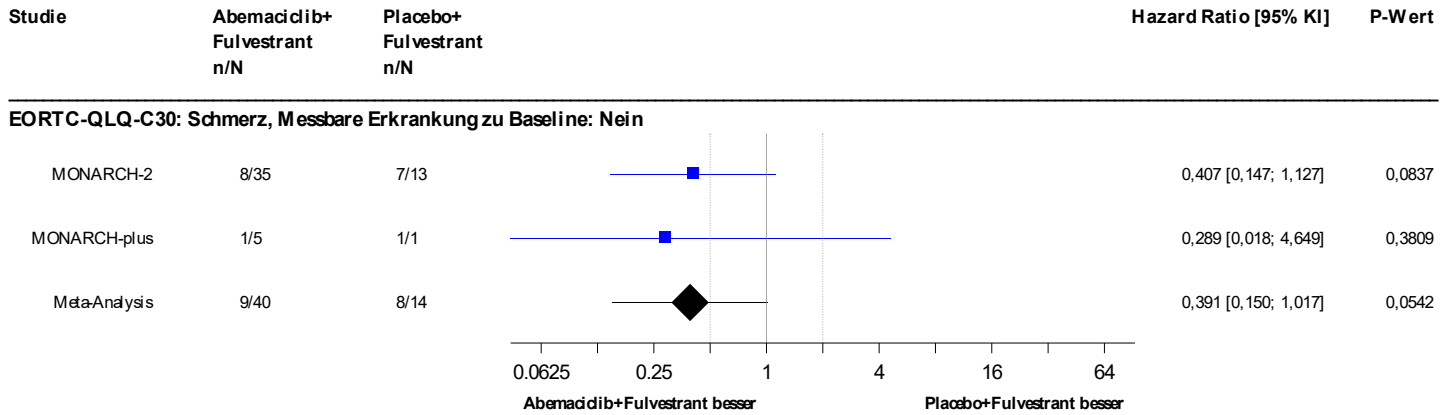
Abbildung 1411.2.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0516, P-Wert=0,8204, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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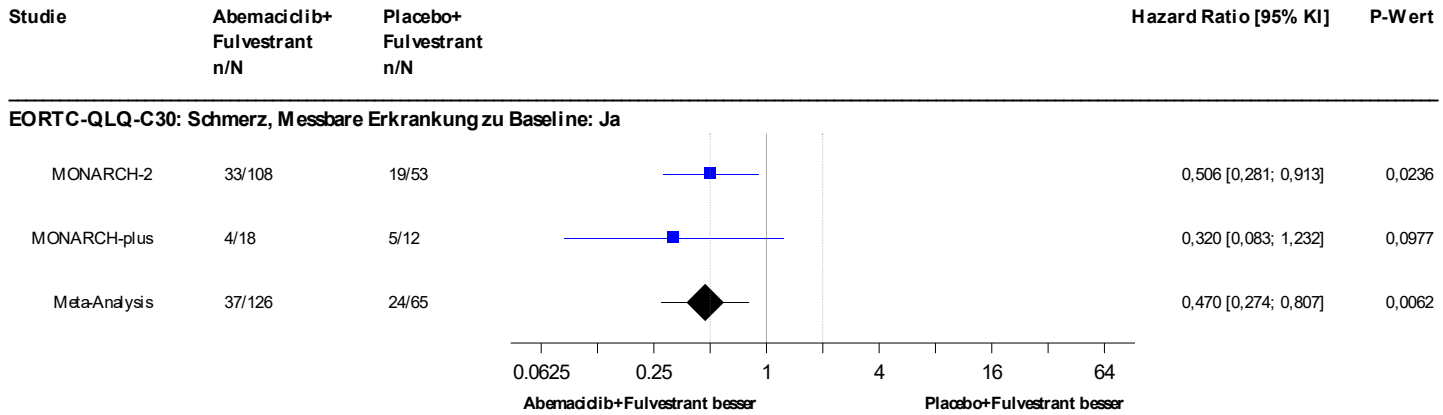
Abbildung 1411.2.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3729, P-Wert=0,5414, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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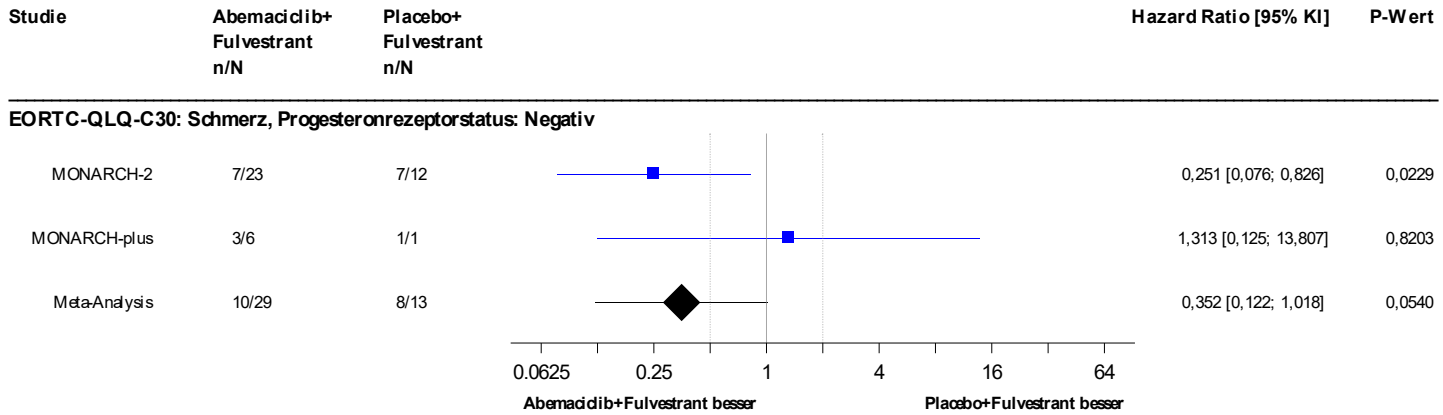
Abbildung 1411.2.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,5127, P-Wert=0,2187, I2 Index=33,9%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwpain6_popa2_pgrstat_1.rtf
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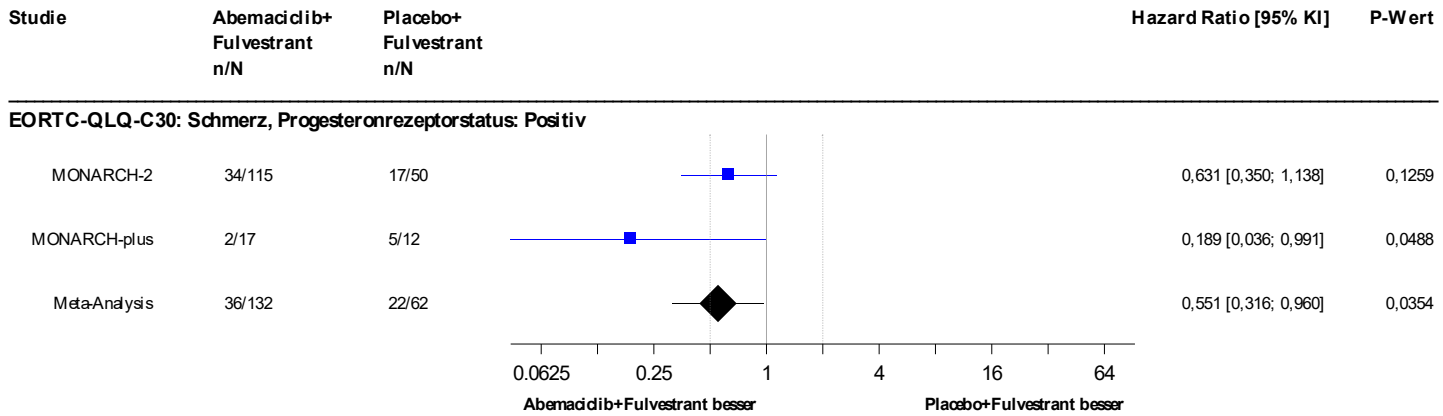
Abbildung 1411.2.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,8027, P-Wert=0,1794, I2 Index=44,5%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwpain6_popa2_pgrstat_2.rtf
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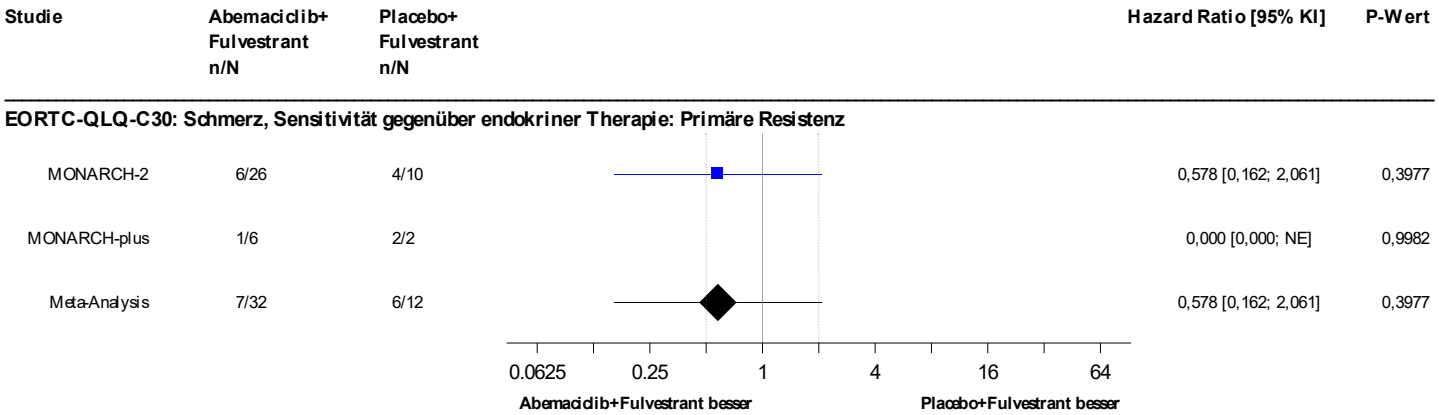
Abbildung 1411.2.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9982, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwpain6_popa2_snthr_1.rtf
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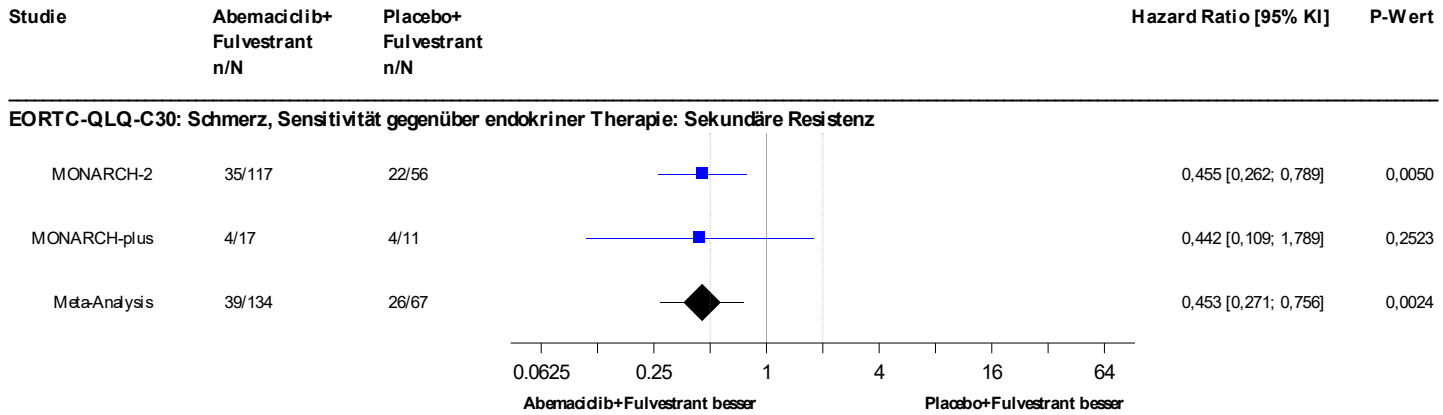
Abbildung 1411.2.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0014, P-Wert=0,9704, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwpain6_popa2_snthr_2.rtf
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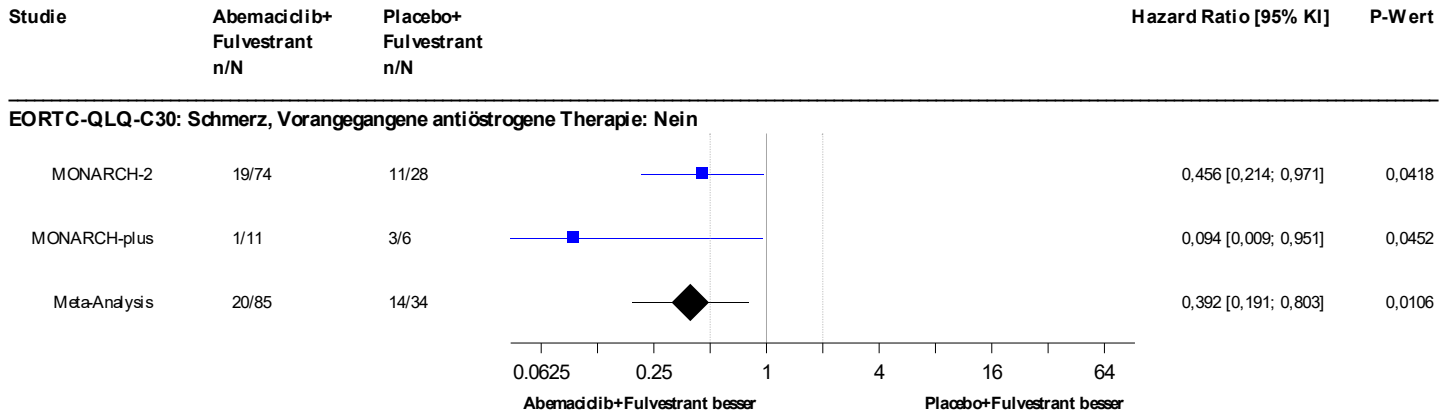
Abbildung 1411.2.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,6182, P-Wert=0,2033, I2 Index=38,2%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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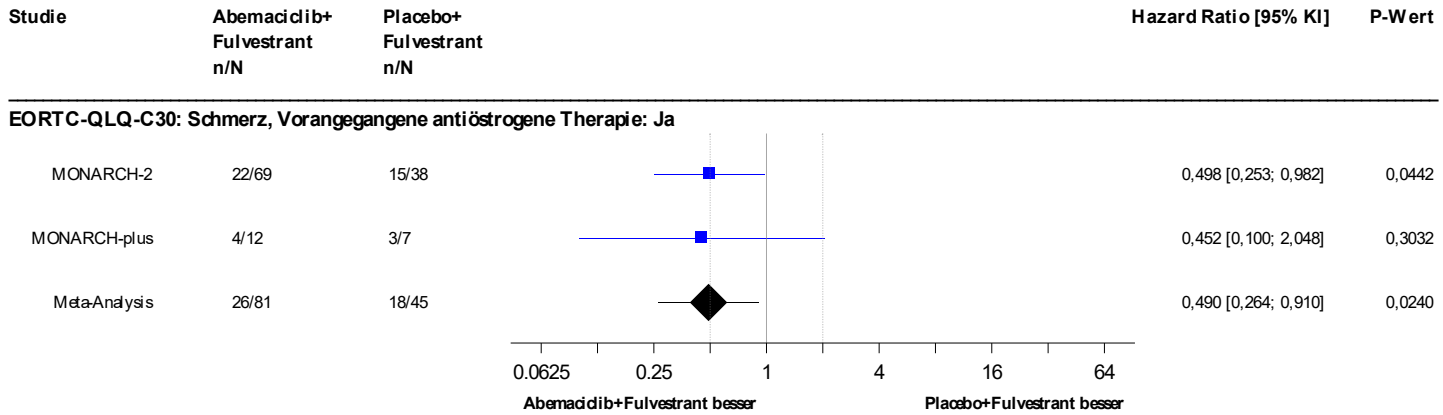
Abbildung 1411.2.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Symptomskala Schmerz (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0129, P-Wert=0,9095, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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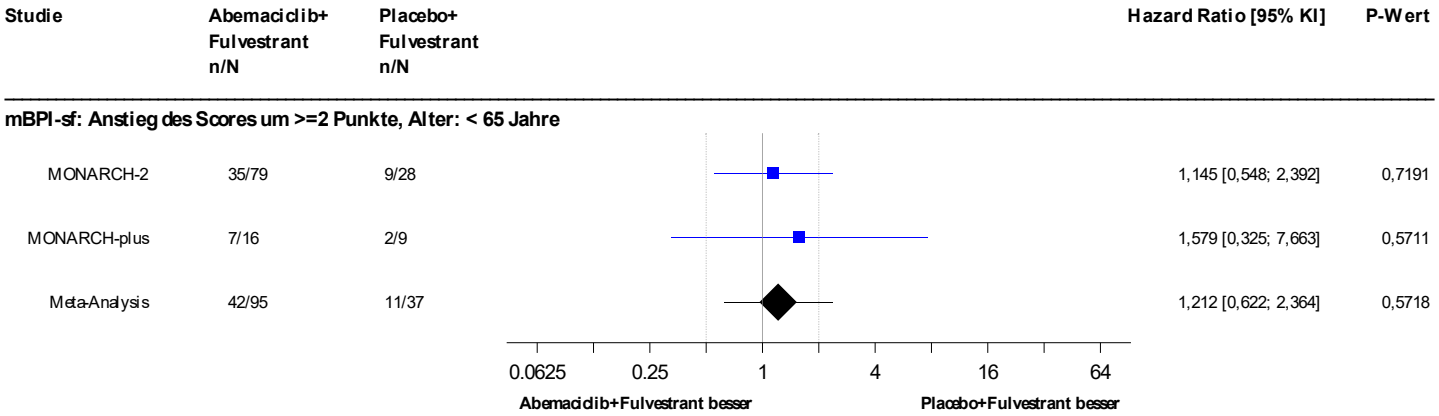
Abbildung 1412.2.1.1: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Alter: < 65 Jahre Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1305, P-Wert=0,7179, I2 Index=0%

Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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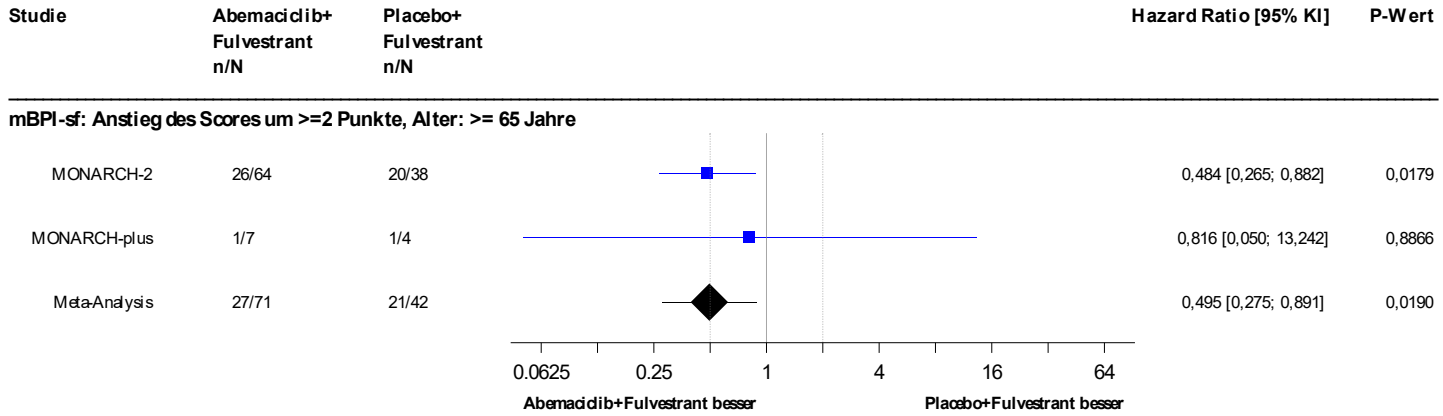
Abbildung 1412.2.1.2: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Alter: >= 65 Jahre Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1296, P-Wert=0,7188, I2 Index=0%

Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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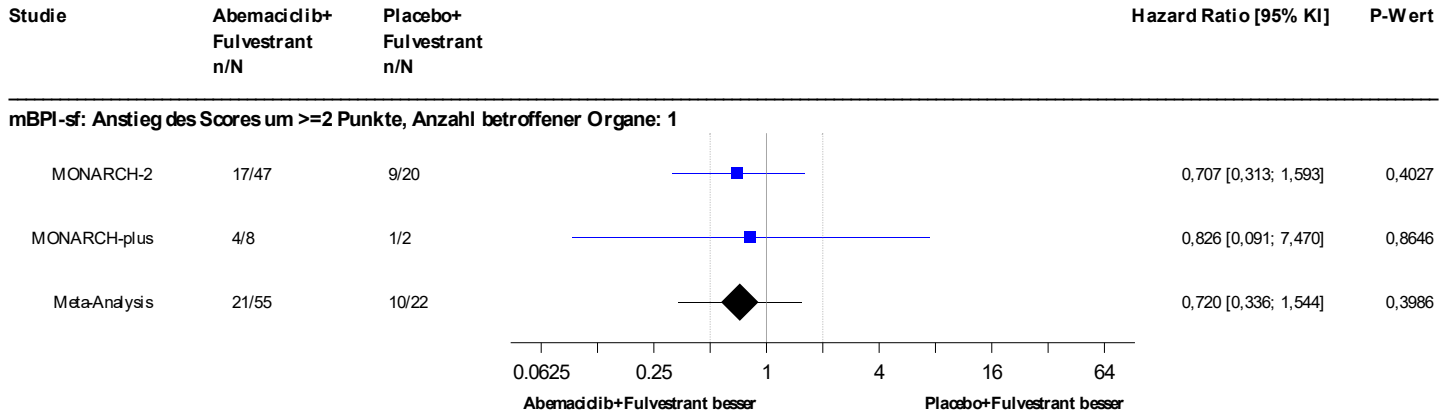
Abbildung 1412.2.2.1: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Anzahl betroffener Organe: 1 Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0168, P-Wert=0,8967, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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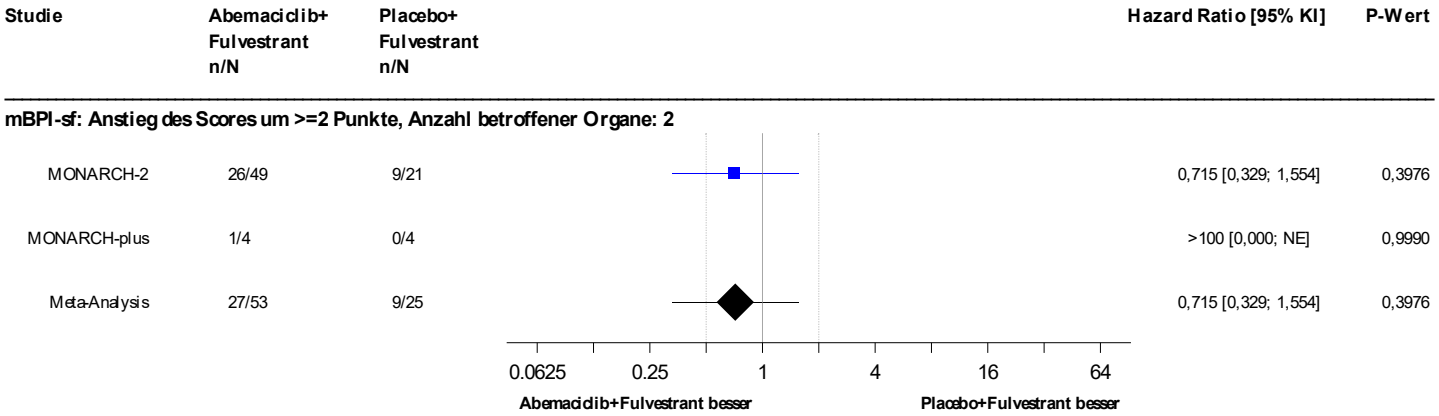
Abbildung 1412.2.2.2: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Anzahl betroffener Organe: 2 Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9989, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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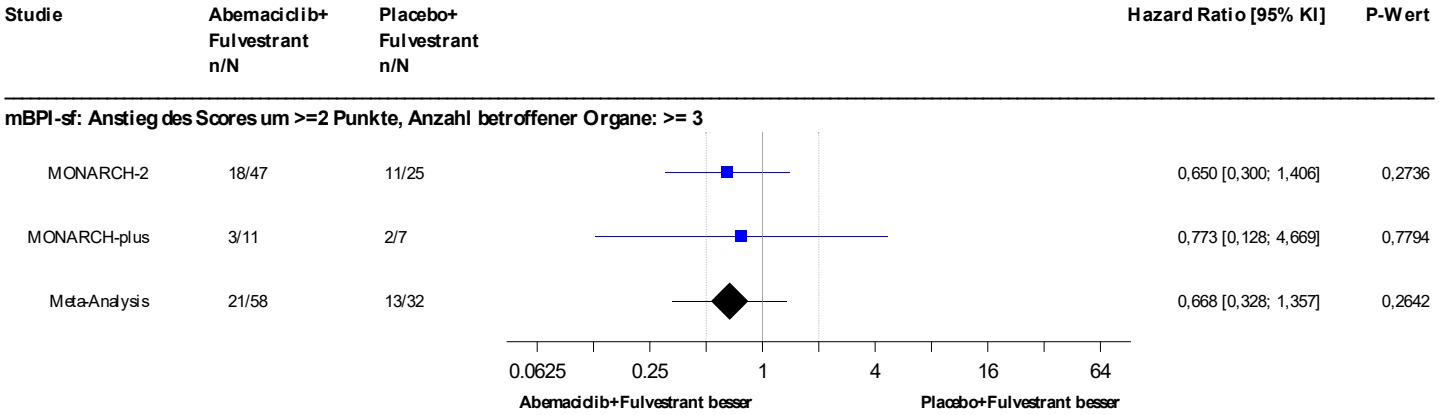
Abbildung 1412.2.2.3: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Anzahl betroffener Organe: >= 3 Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0304, P-Wert=0,8615, I2 Index=0%

Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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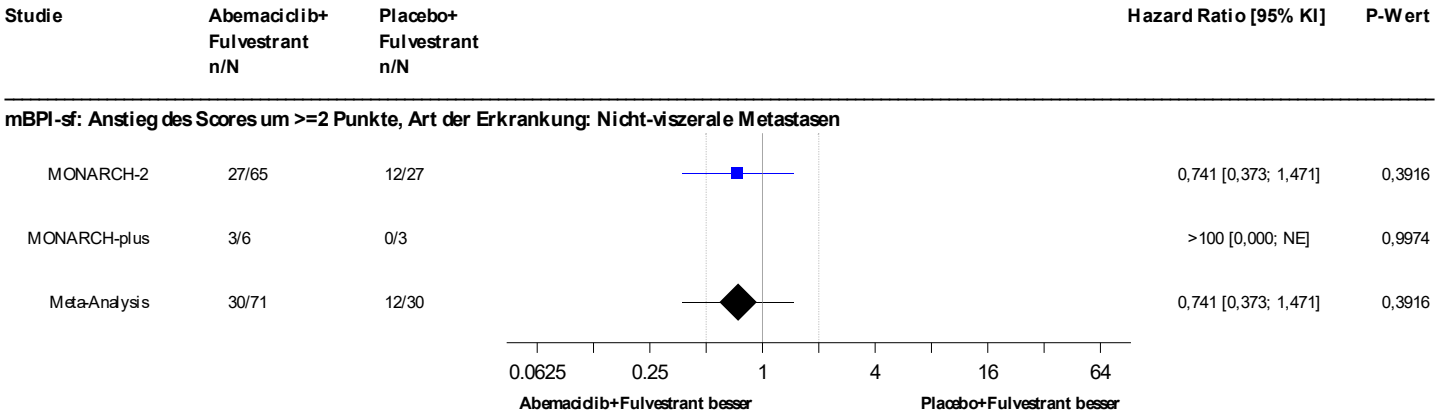
Abbildung 1412.2.3.1: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9974, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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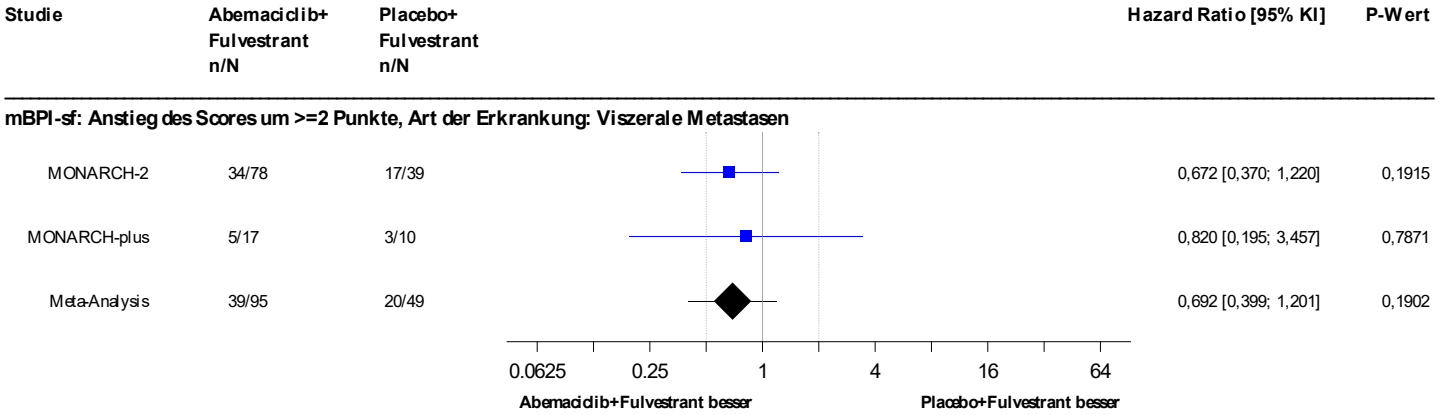
Abbildung 1412.2.3.2: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0631, P-Wert=0,8017, I2 Index=0%

Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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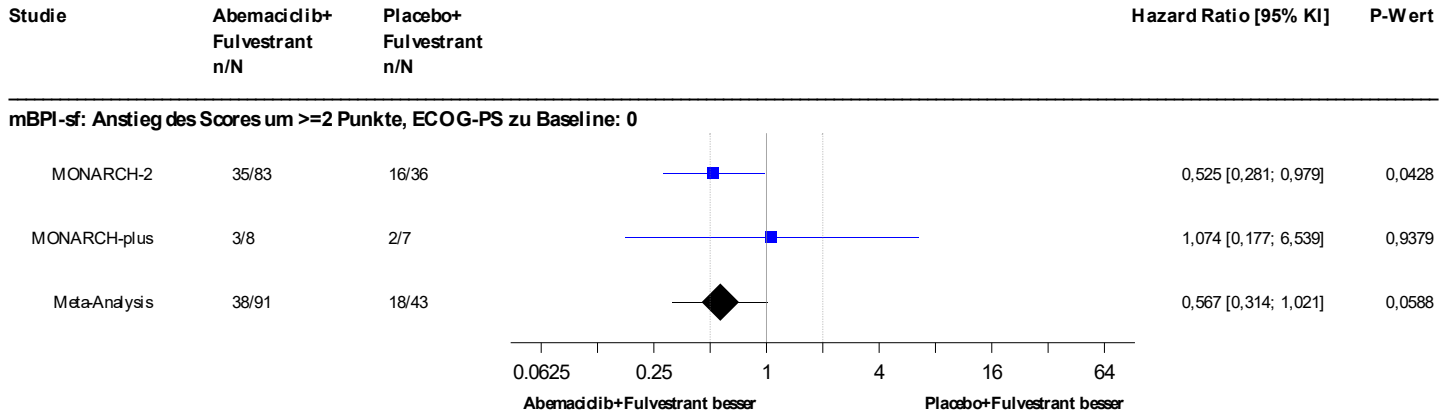
Abbildung 1412.2.4.1: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,5400, P-Wert=0,4625, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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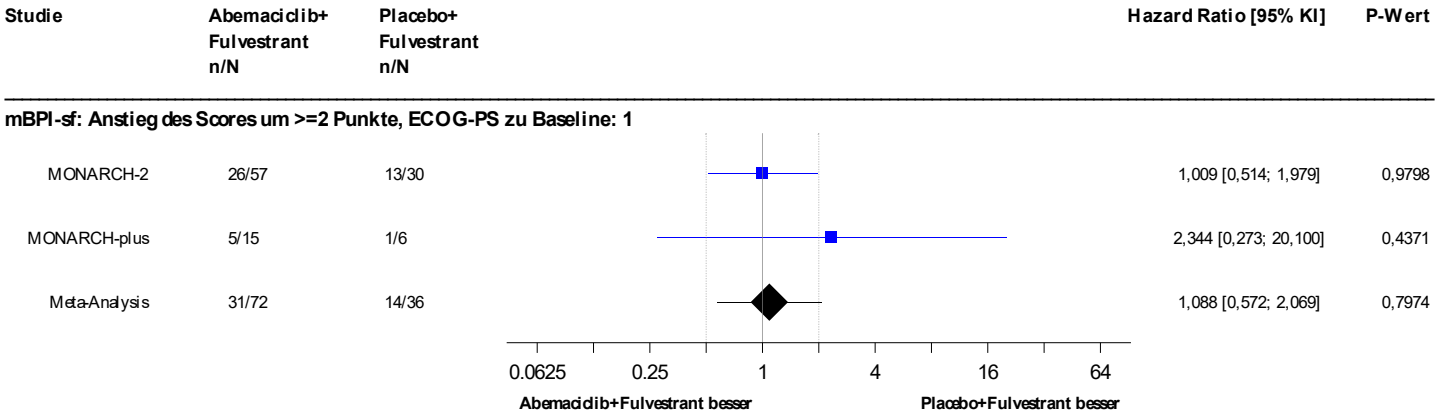
Abbildung 1412.2.4.2: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für ECOG-PS zu Baseline: 1 Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,5387, P-Wert=0,4630, I2 Index=0%

Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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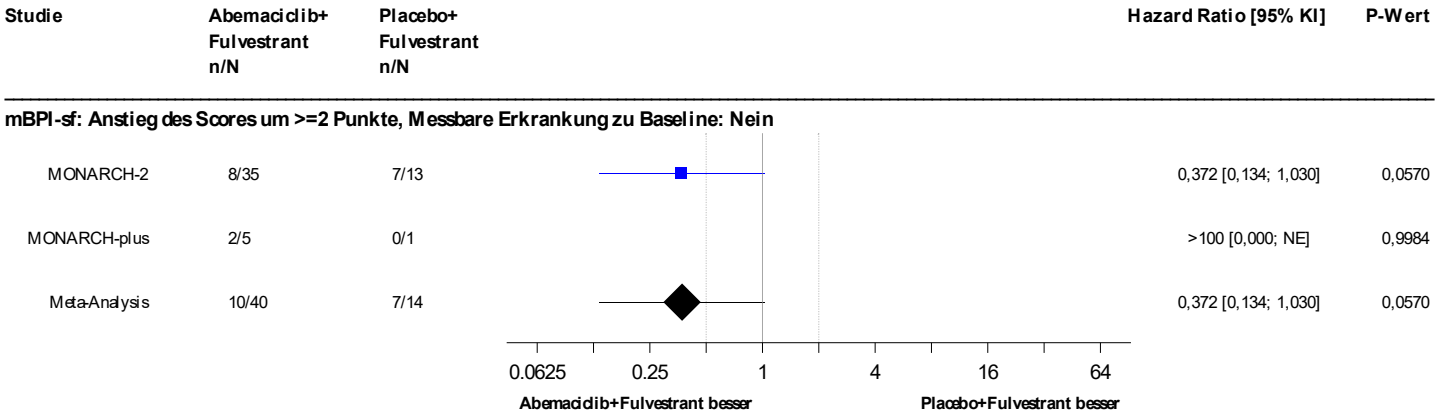
Abbildung 1412.2.6.1: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9983, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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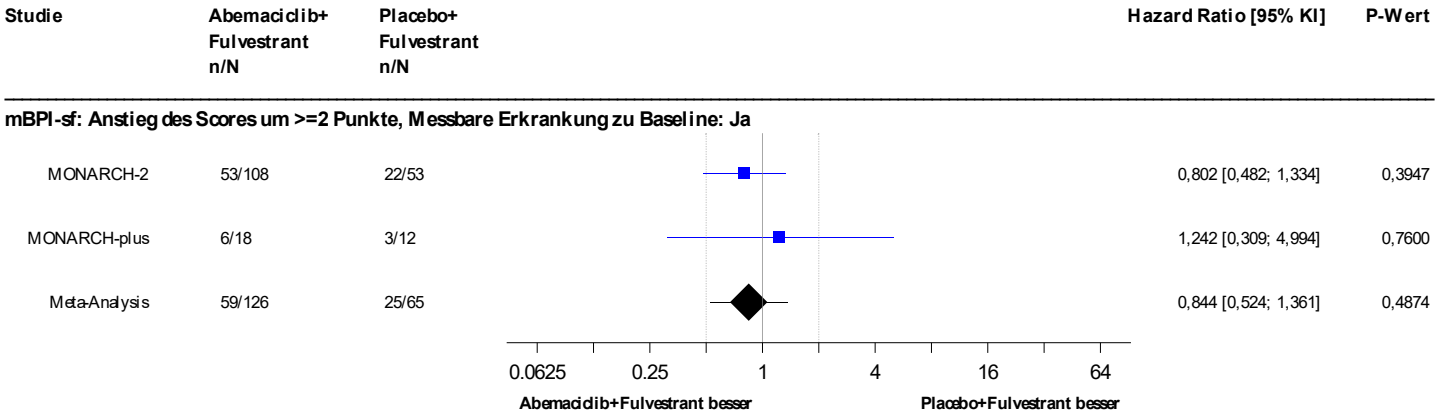
Abbildung 1412.2.6.2: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3355, P-Wert=0,5624, I2 Index=0%

Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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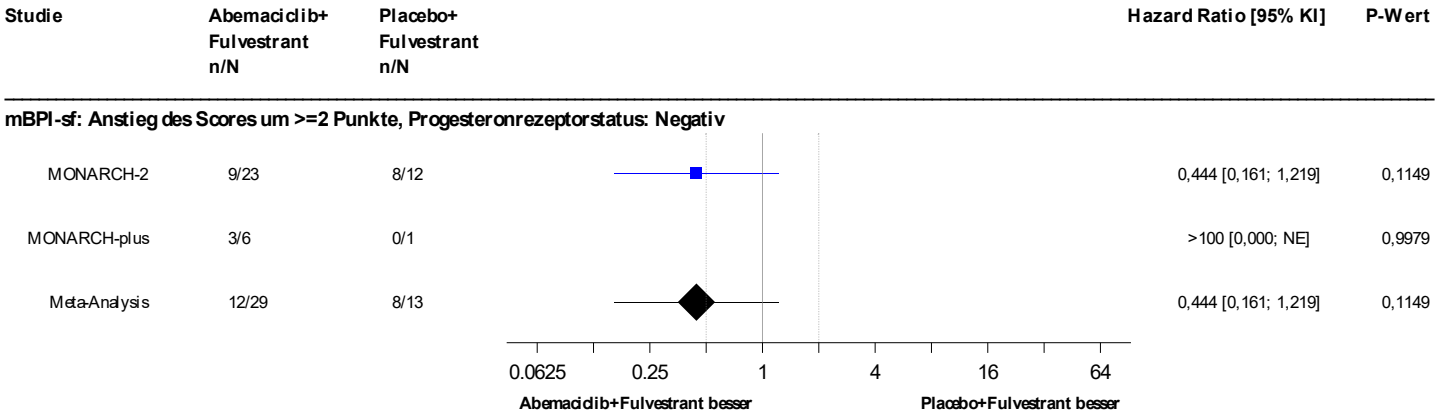
Abbildung 1412.2.7.1: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Progesteronrezeptorstatus: Negativ Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9978, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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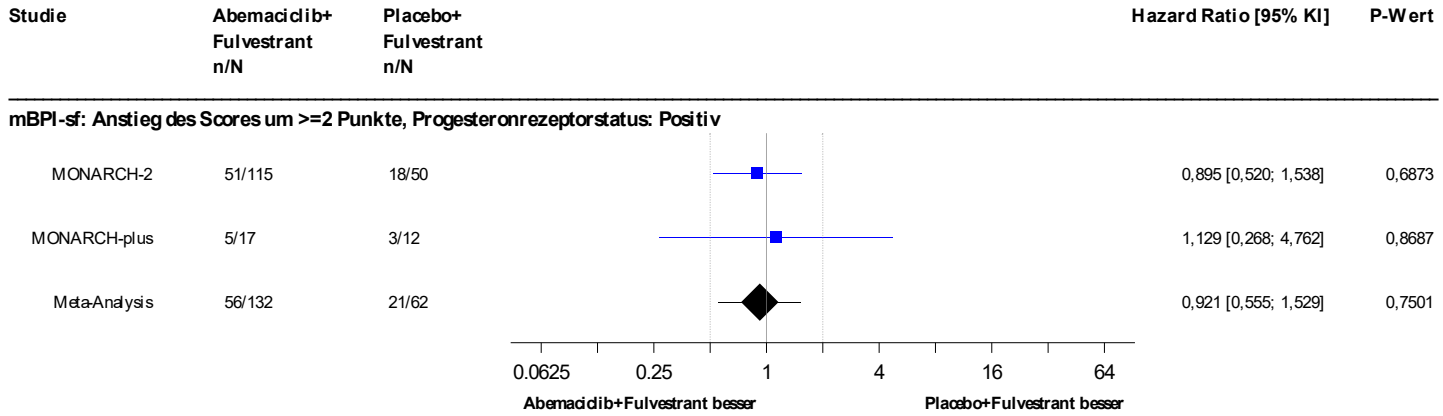
Abbildung 1412.2.7.2: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Progesteronrezeptorstatus: Positiv Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0879, P-Wert=0,7669, I2 Index=0%

Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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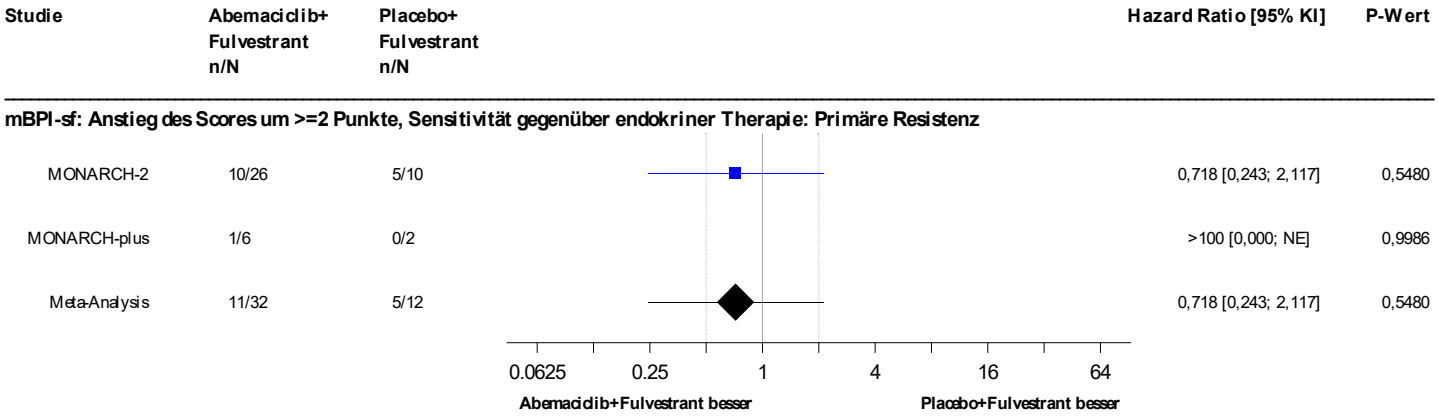
Abbildung 1412.2.8.1: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9986, I2 Index=0%

Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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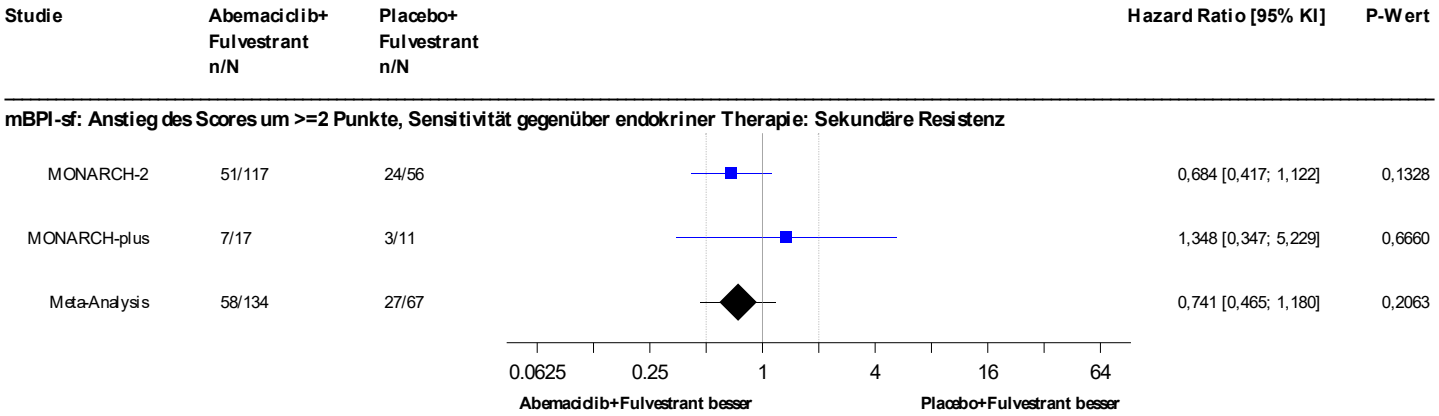
Abbildung 1412.2.8.2: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,8492, P-Wert=0,3568, I2 Index=0%

Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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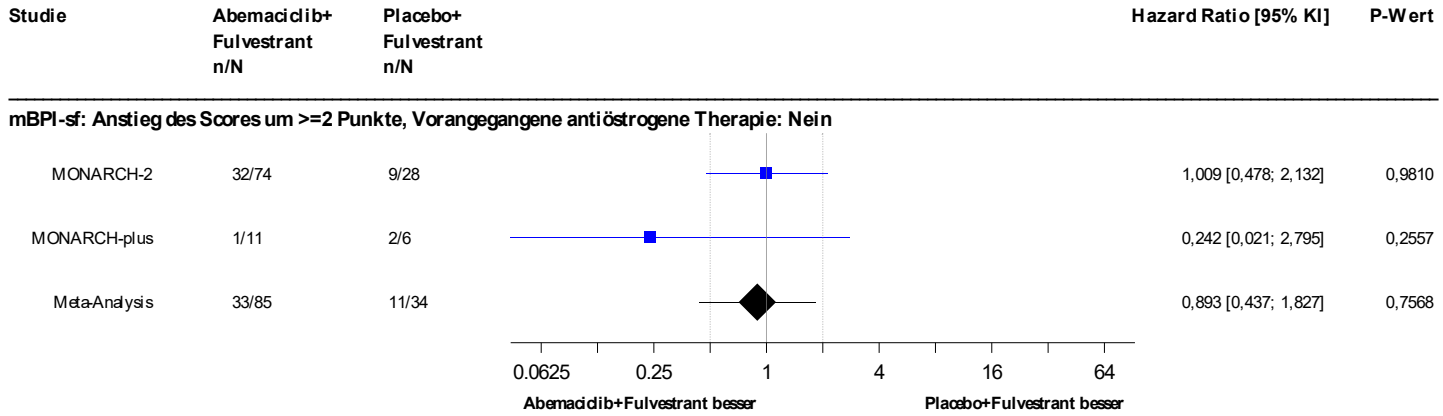
Abbildung 1412.2.9.1: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,1966, P-Wert=0,2740, I2 Index=16,4%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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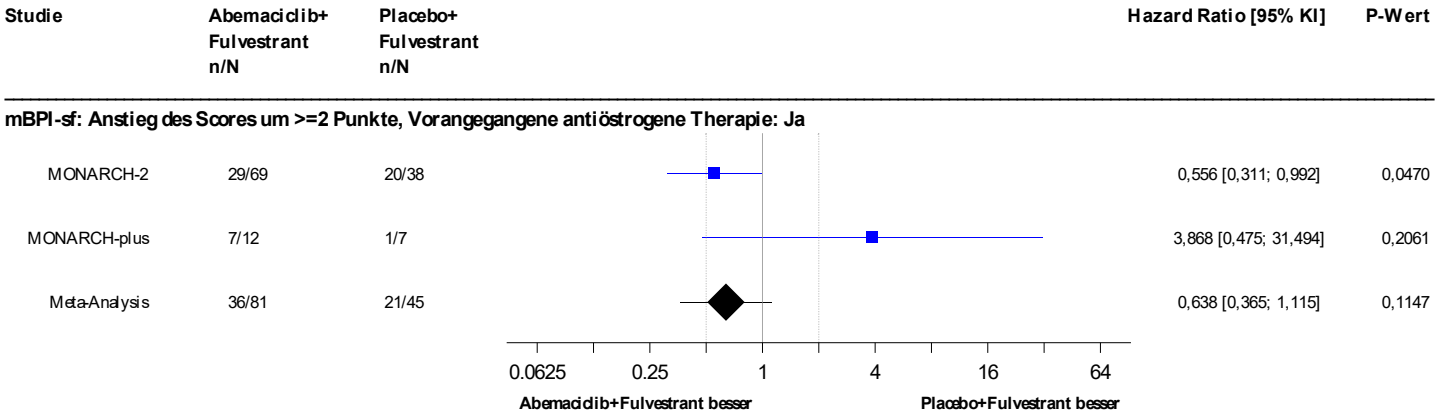
Abbildung 1412.2.9.2: Metaanalyse der Symptomskala des mBPI-sf „Stärkster Schmerz in den letzten 24 Stunden“ Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=3,0540, P-Wert=0,0805, I2 Index=67,3%
Abkürzungen: KI: Konfidenzintervall; mBPI-sf: Kurzfassung des modifizierten Fragebogens Schmerz; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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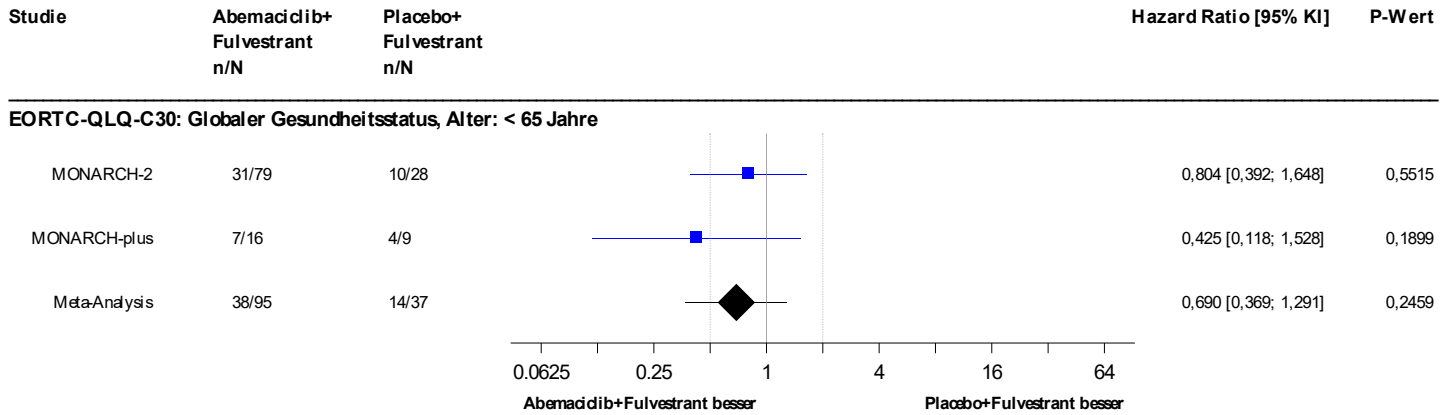
Abbildung 1413.2.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,7267, P-Wert=0,3940, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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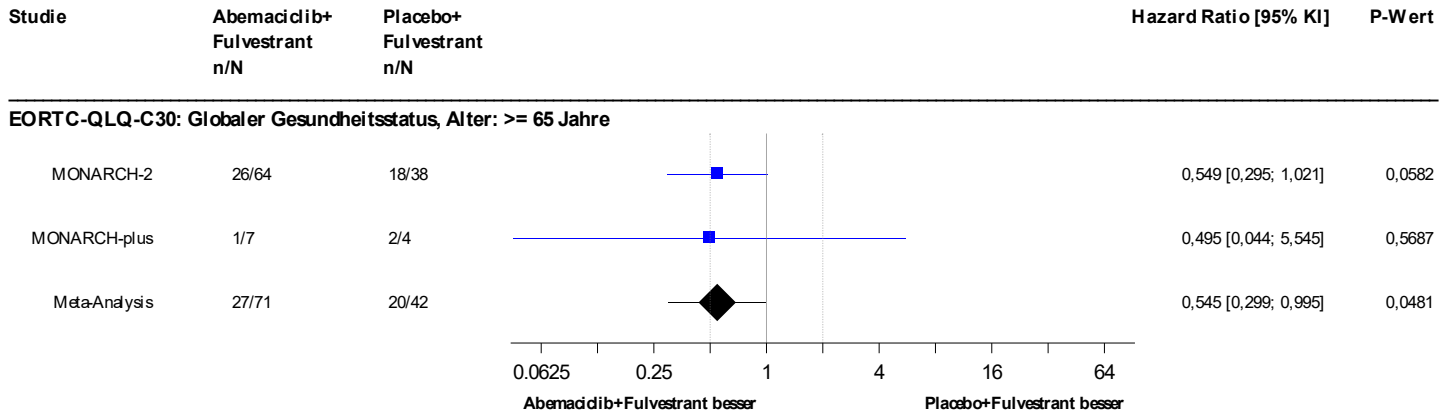
Abbildung 1413.2.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0065, P-Wert=0,9359, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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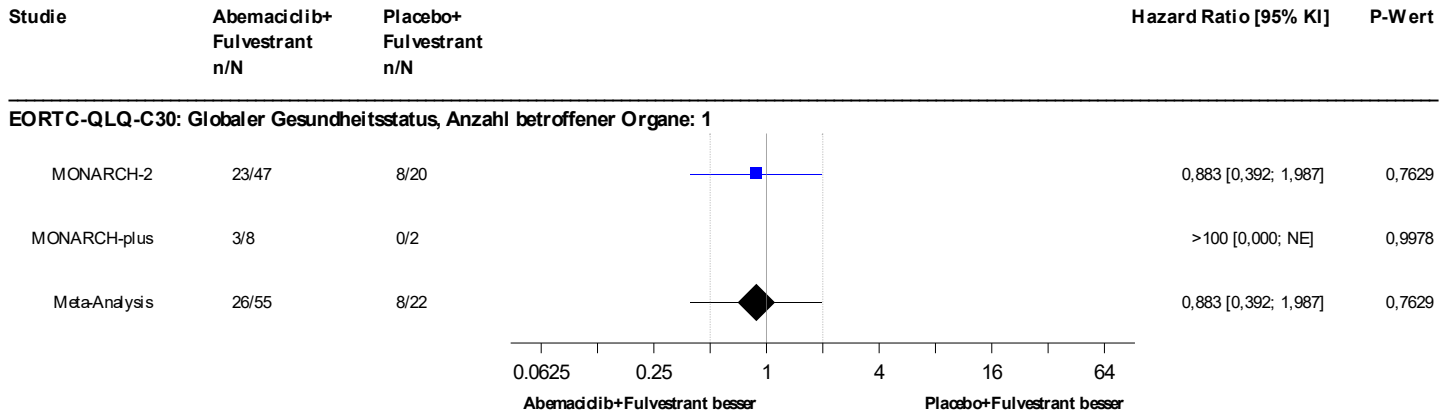
Abbildung 1413.2.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9978, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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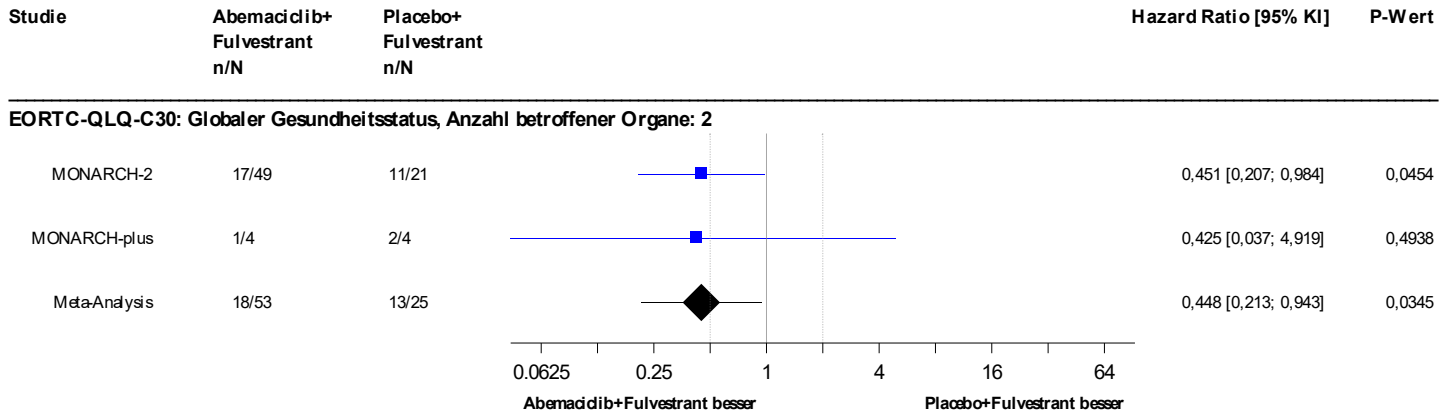
Abbildung 1413.2.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0020, P-Wert=0,9646, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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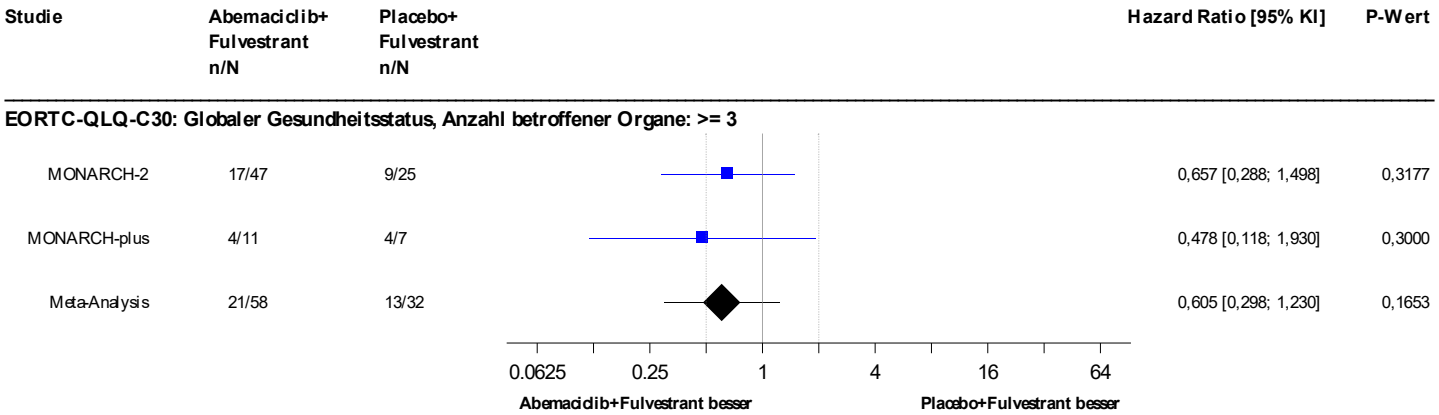
Abbildung 1413.2.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1475, P-Wert=0,7009, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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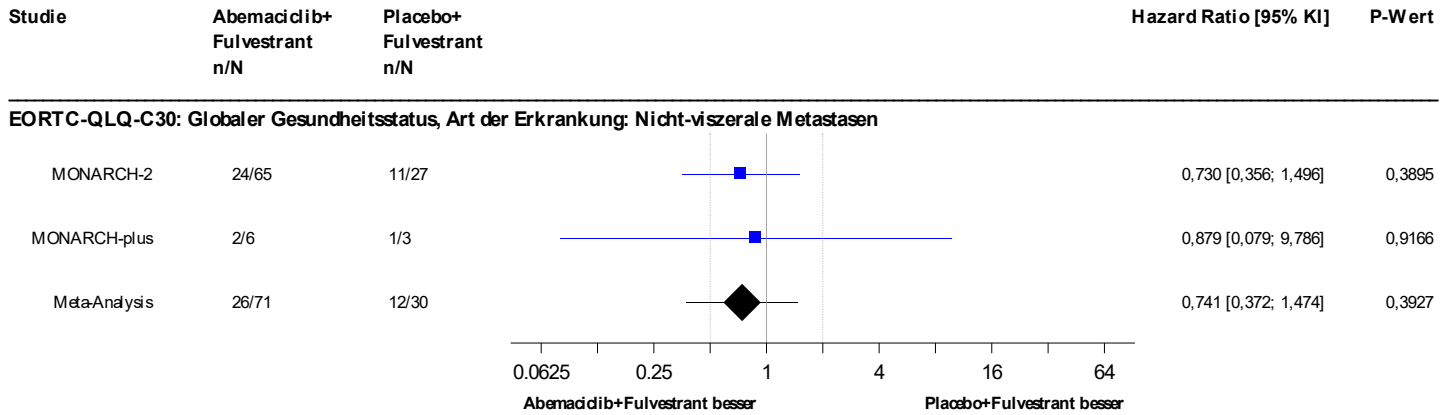
Abbildung 1413.2.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0211, P-Wert=0,8844, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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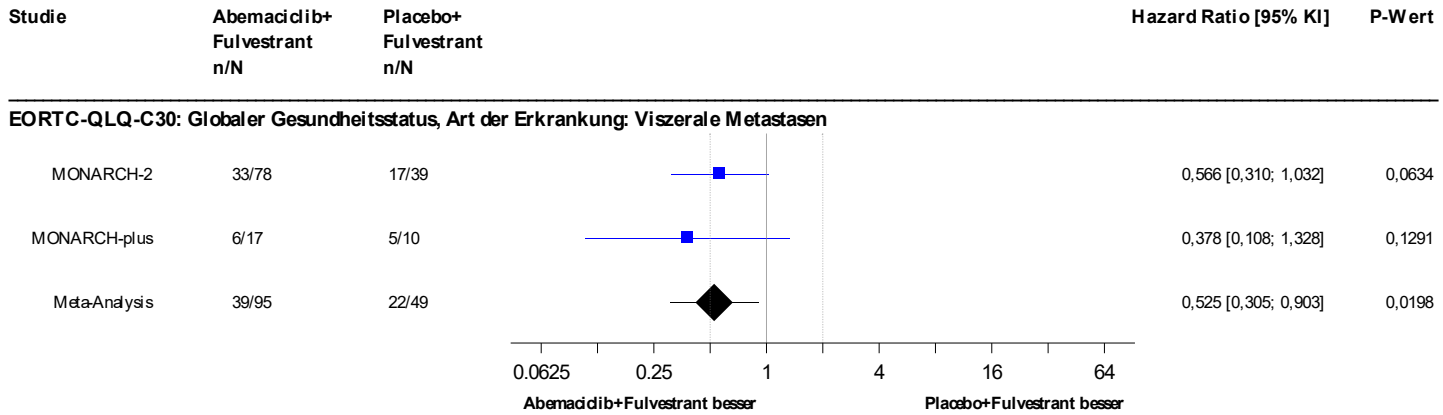
Abbildung 1413.2.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3234, P-Wert=0,5696, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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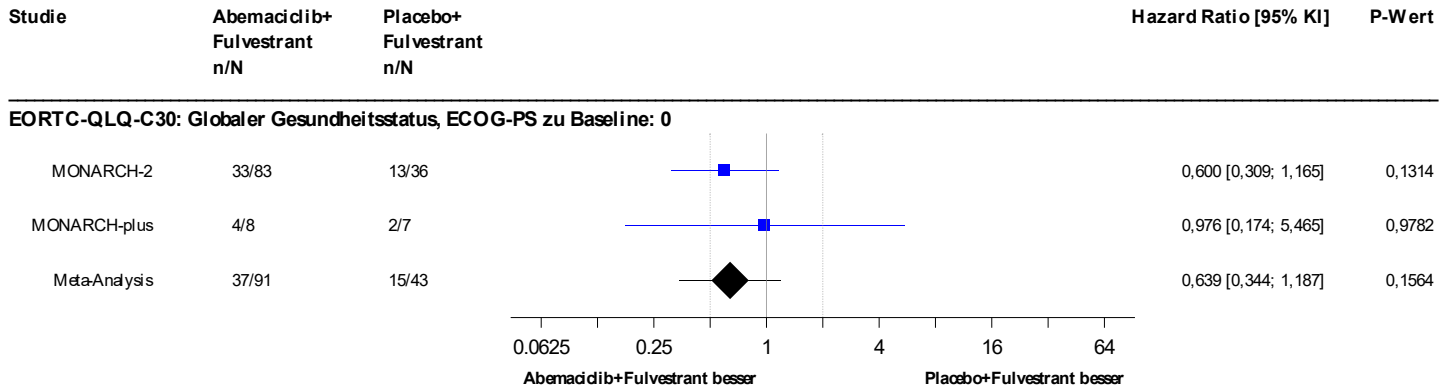
Abbildung 1413.2.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2676, P-Wert=0,6049, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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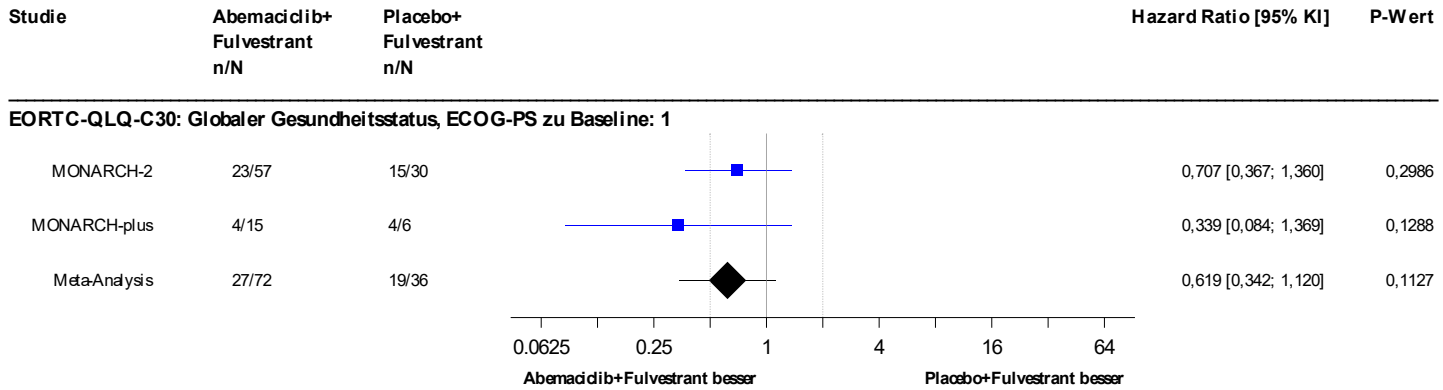
Abbildung 1413.2.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,8715, P-Wert=0,3505, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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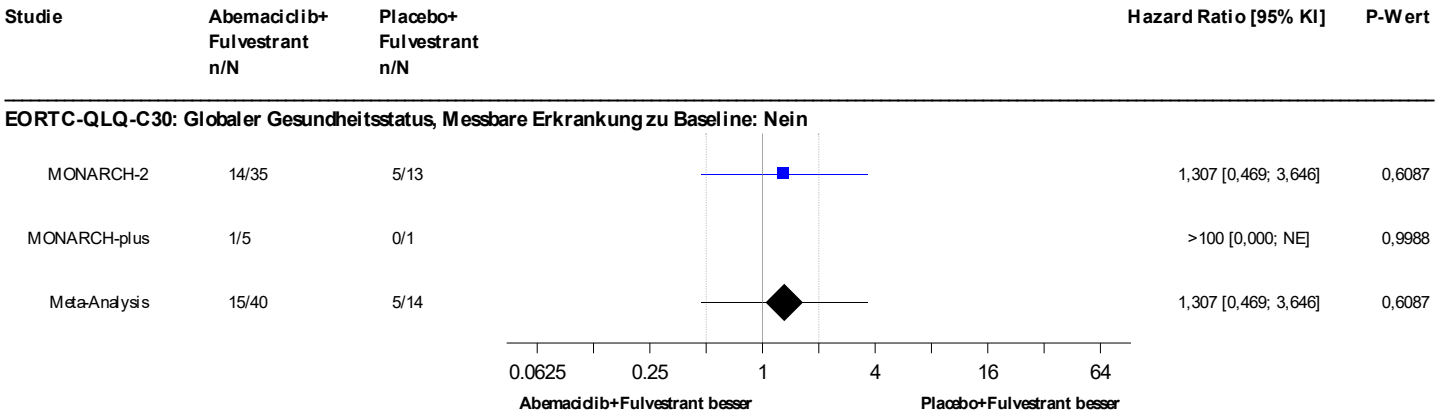
Abbildung 1413.2.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9988, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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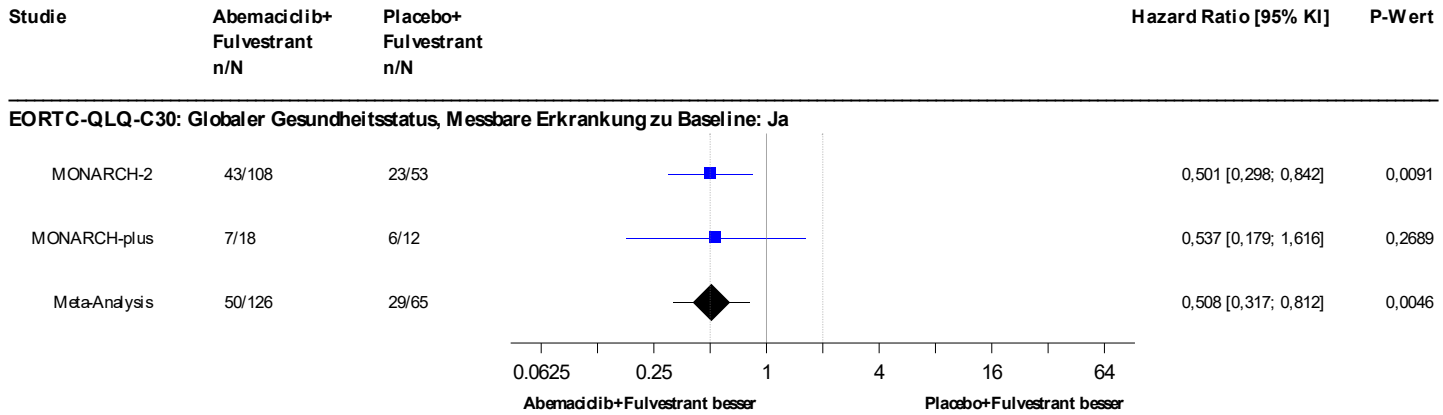
Abbildung 1413.2.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0126, P-Wert=0,9107, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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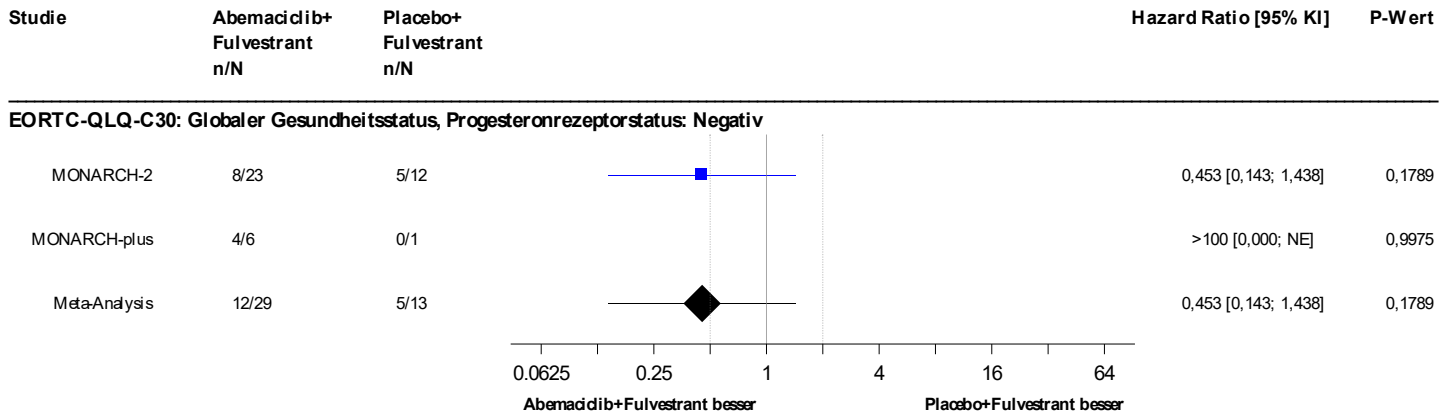
Abbildung 1413.2.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9974, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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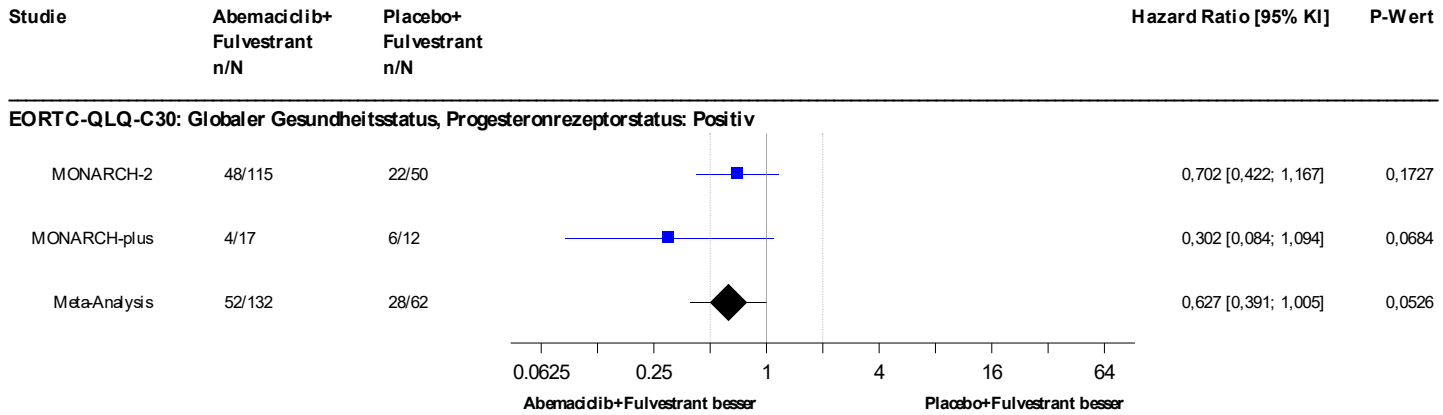
Abbildung 1413.2.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,4247, P-Wert=0,2326, I2 Index=29,8%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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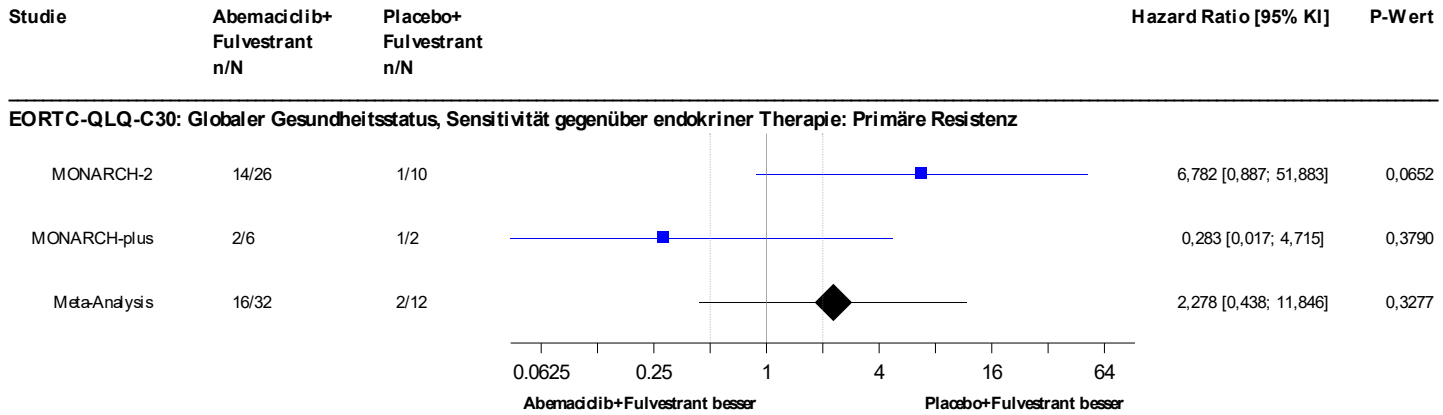
Abbildung 1413.2.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=3,2165, P-Wert=0,0729, I2 Index=68,9%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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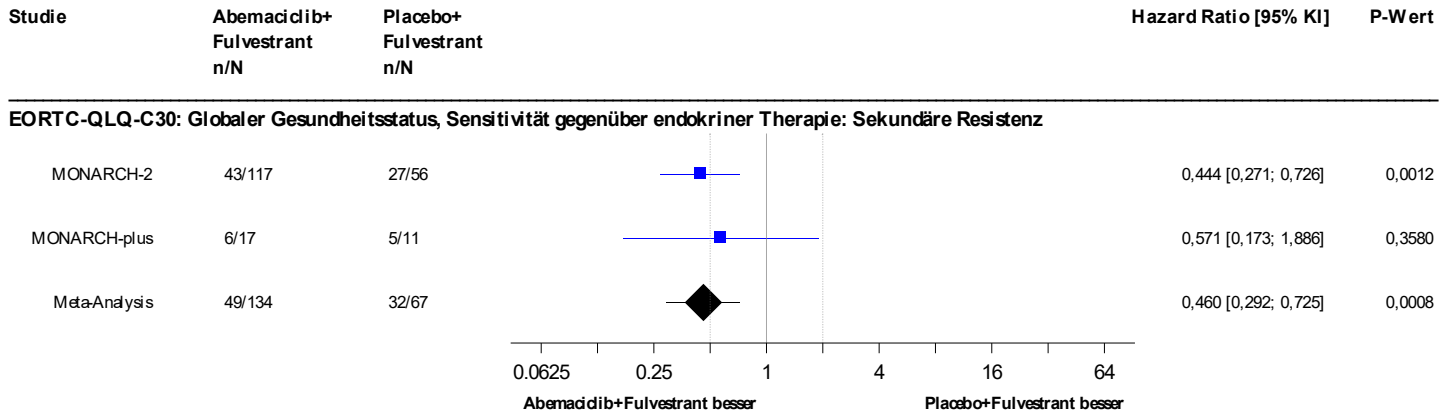
Abbildung 1413.2.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1466, P-Wert=0,7018, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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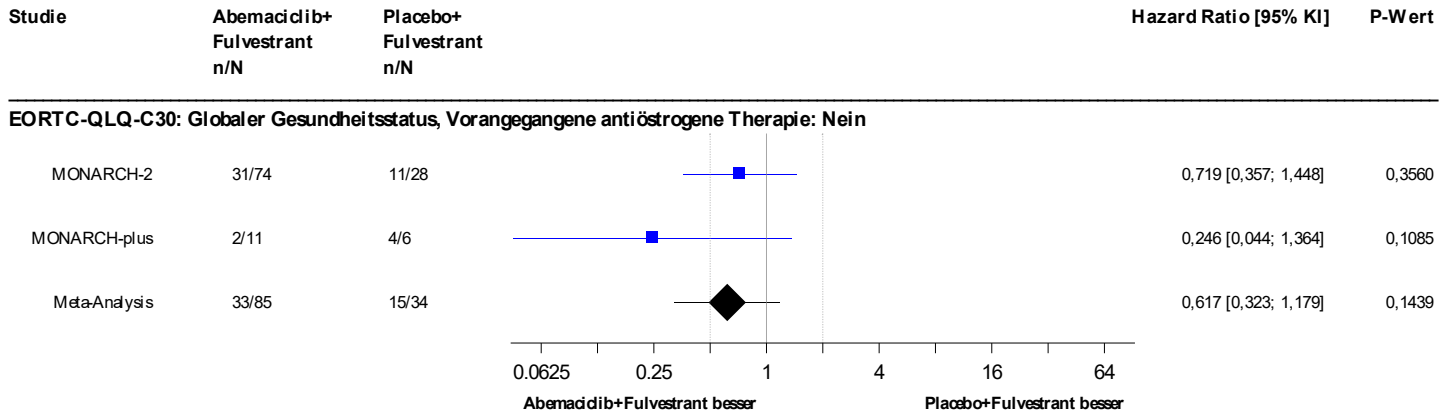
Abbildung 1413.2.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,2921, P-Wert=0,2557, I2 Index=22,6%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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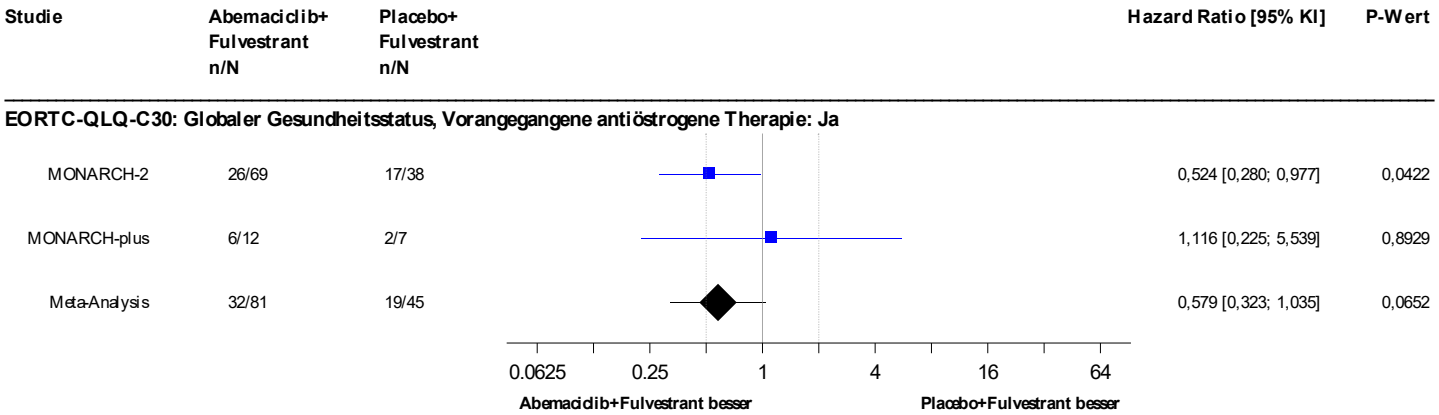
Abbildung 1413.2.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung des EORTC-QLQ-C30 globalen Gesundheitsstatus (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,7450, P-Wert=0,3881, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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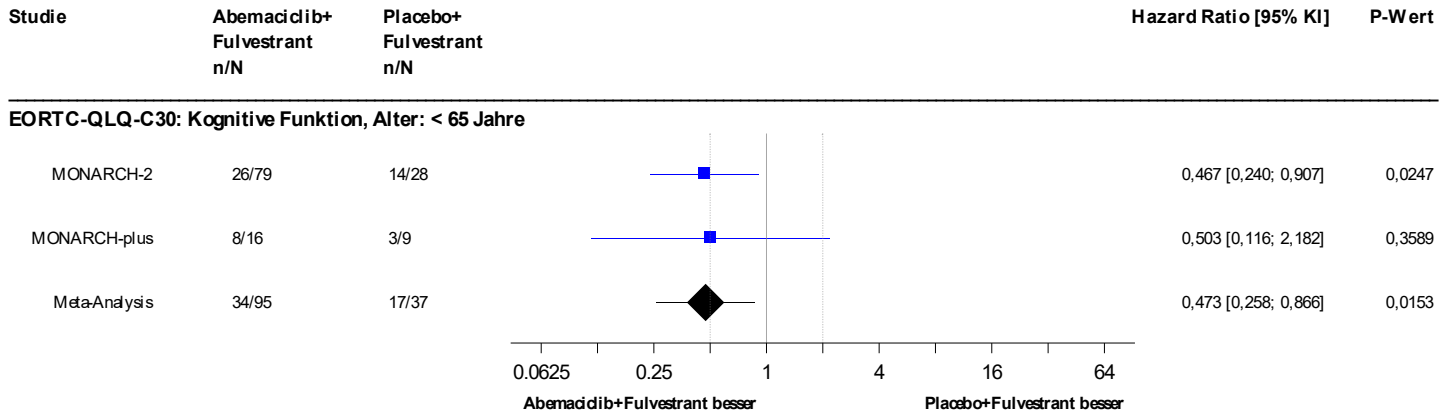
Abbildung 1414.2.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0083, P-Wert=0,9273, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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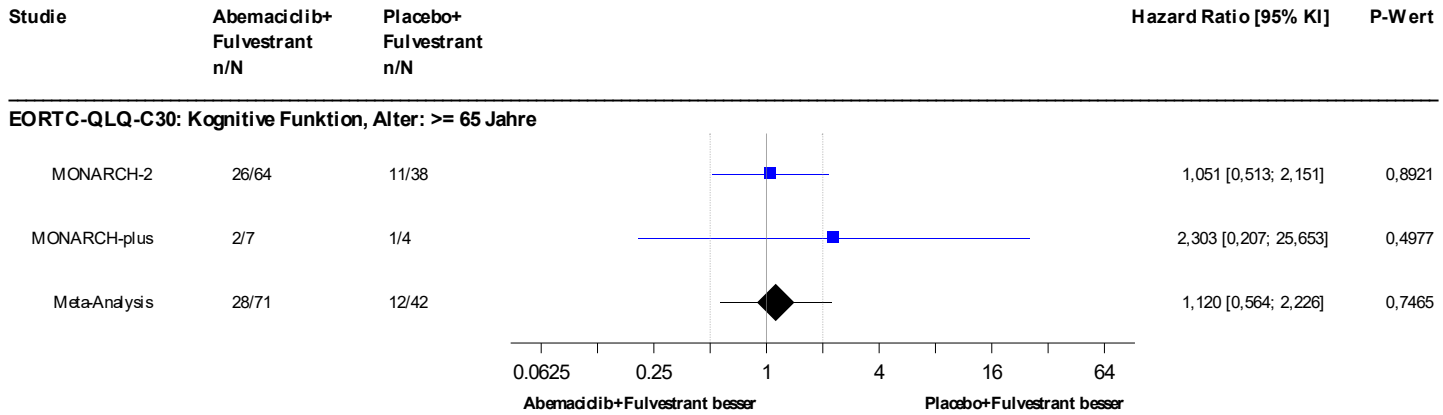
Abbildung 1414.2.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3738, P-Wert=0,5409, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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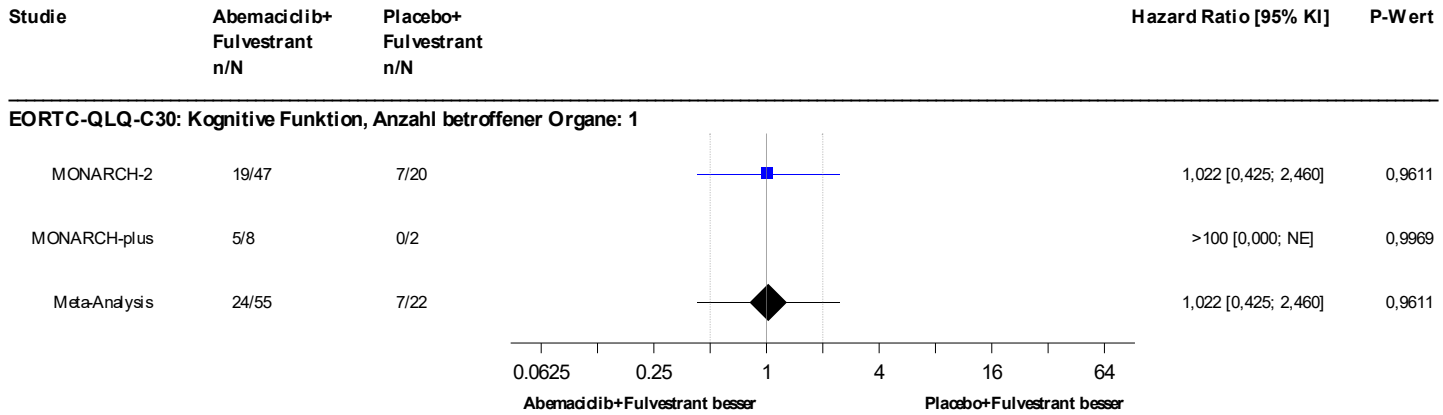
Abbildung 1414.2.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9969, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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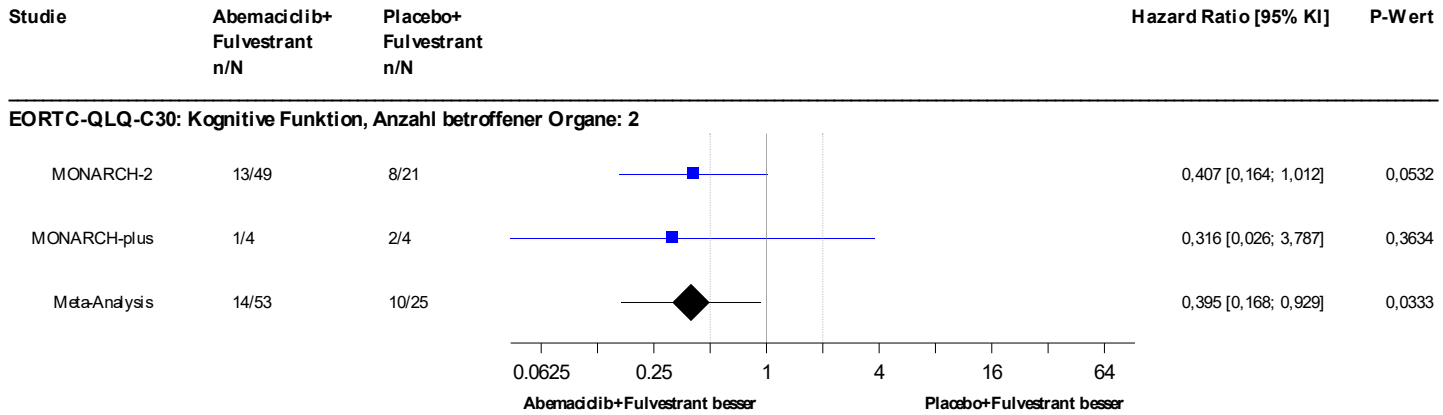
Abbildung 1414.2.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0351, P-Wert=0,8515, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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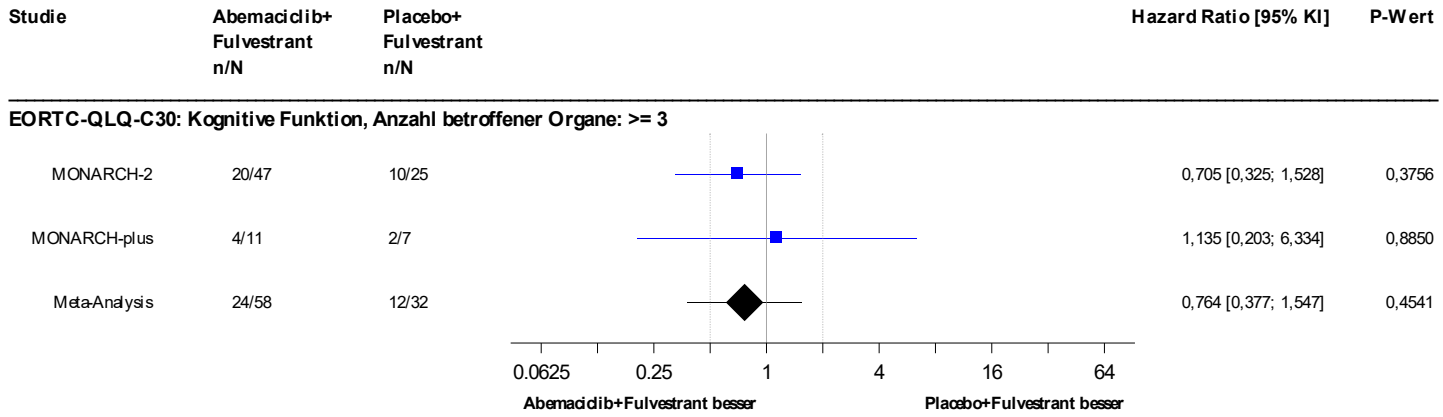
17SEP2021 / 07:48

Abbildung 1414.2.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2456, P-Wert=0,6202, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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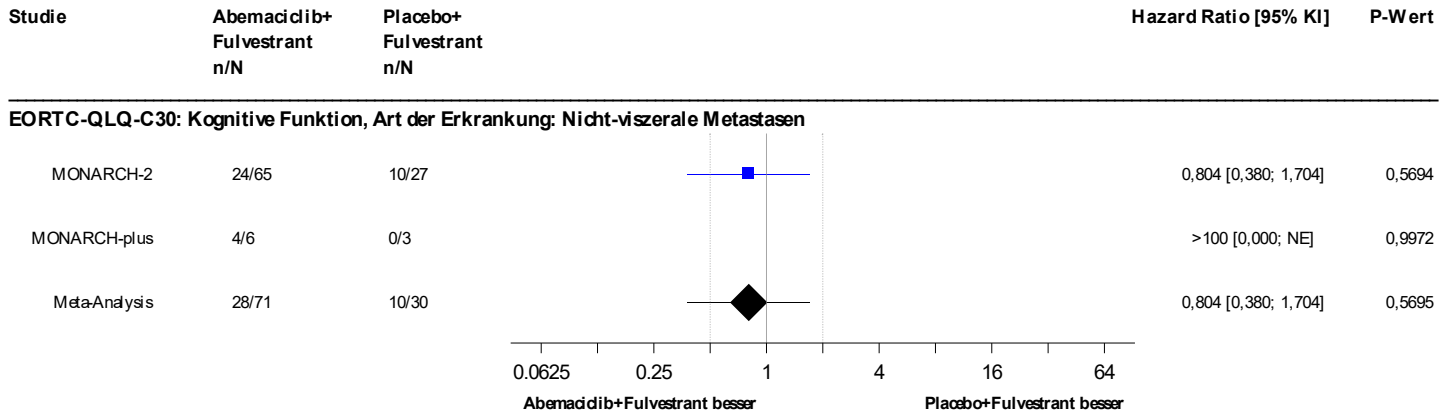
Abbildung 1414.2.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9971, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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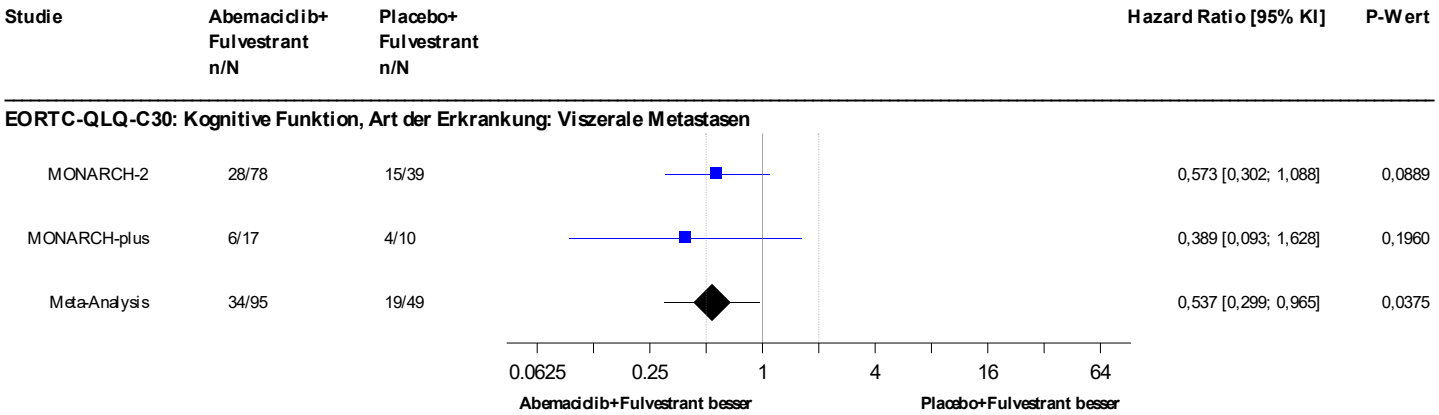
Abbildung 1414.2.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2362, P-Wert=0,6270, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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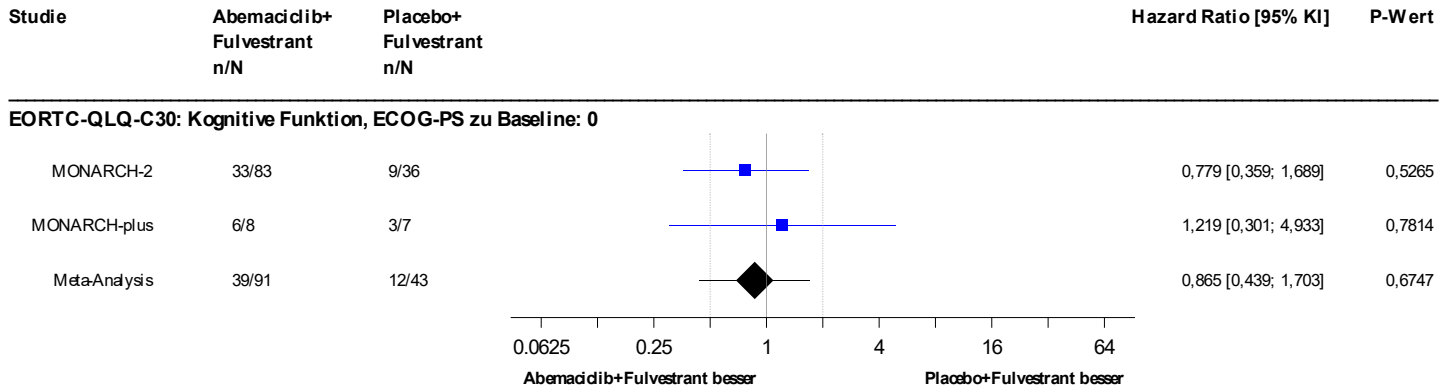
Abbildung 1414.2.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3020, P-Wert=0,5826, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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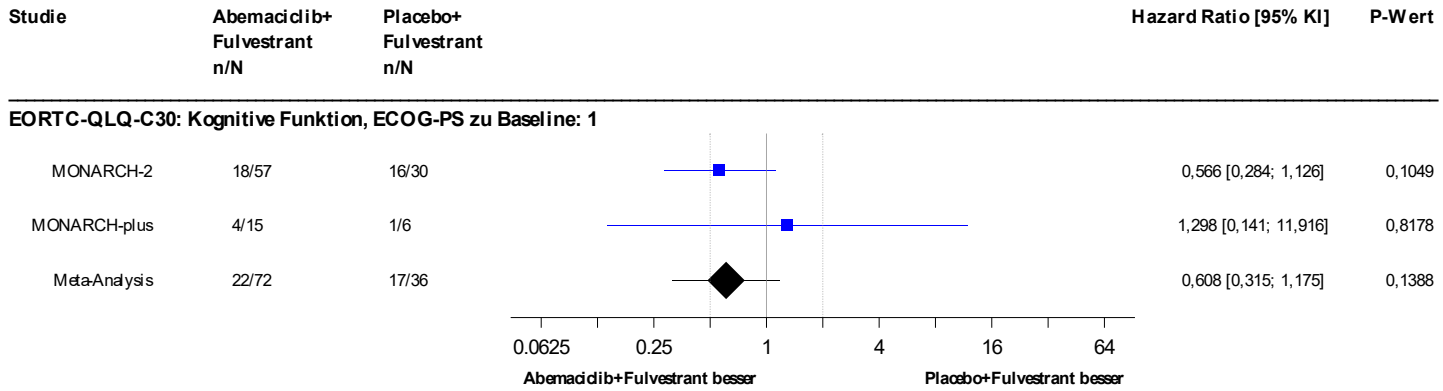
Abbildung 1414.2.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,4916, P-Wert=0,4832, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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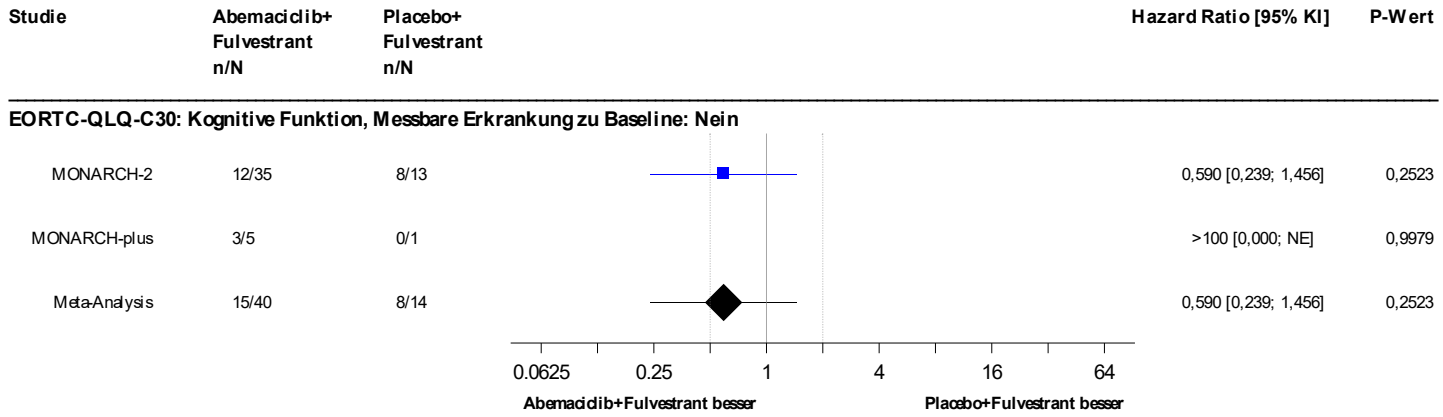
Abbildung 1414.2.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9979, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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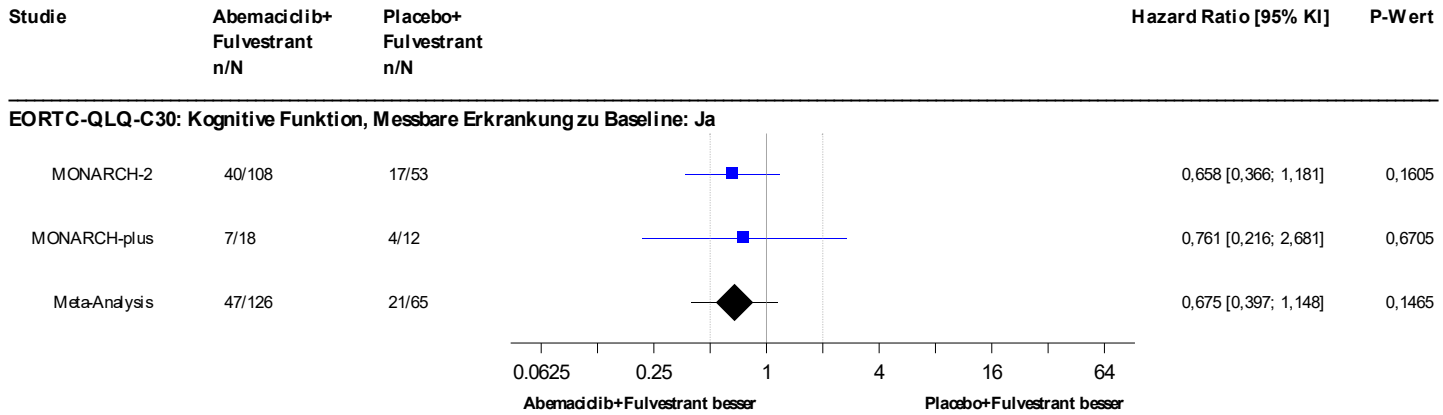
Abbildung 1414.2.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0423, P-Wert=0,8371, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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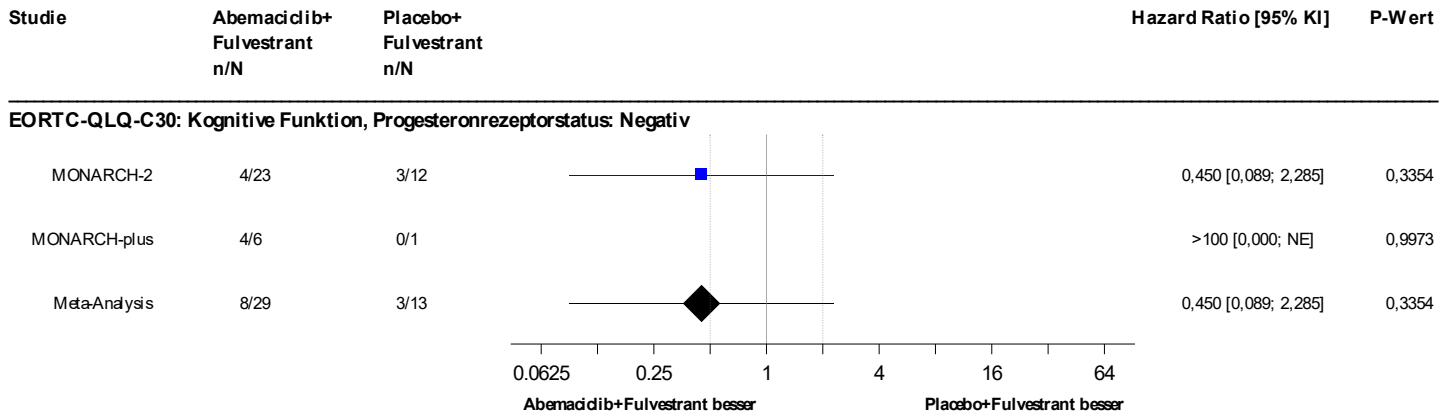
Abbildung 1414.2.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9972, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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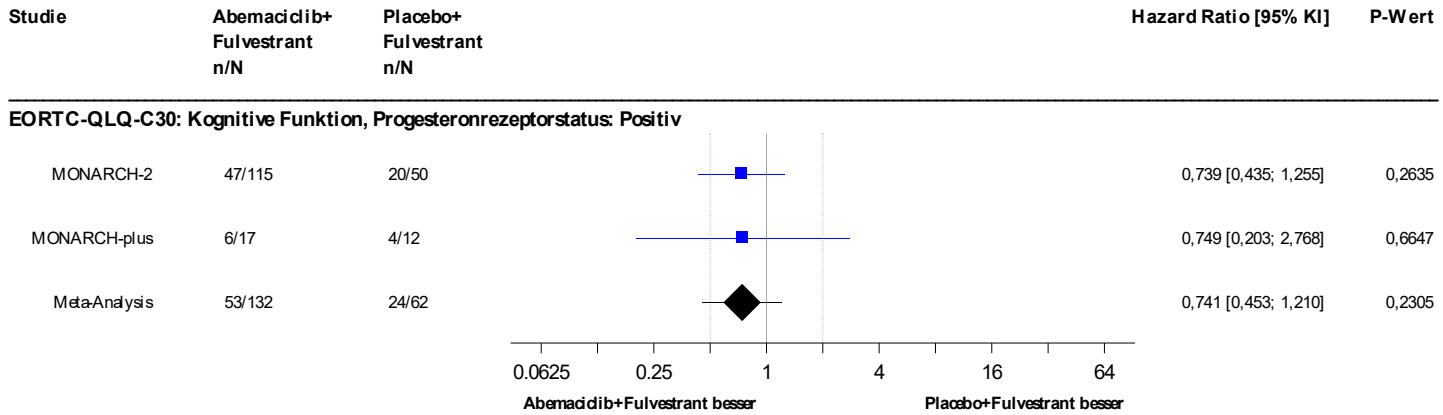
Abbildung 1414.2.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0003, P-Wert=0,9857, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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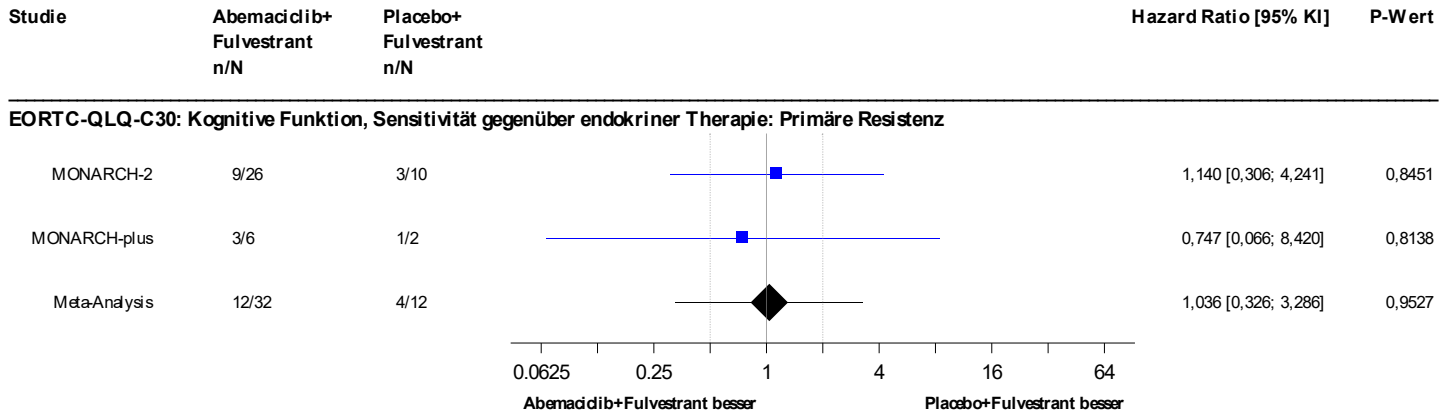
Abbildung 1414.2.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0901, P-Wert=0,7640, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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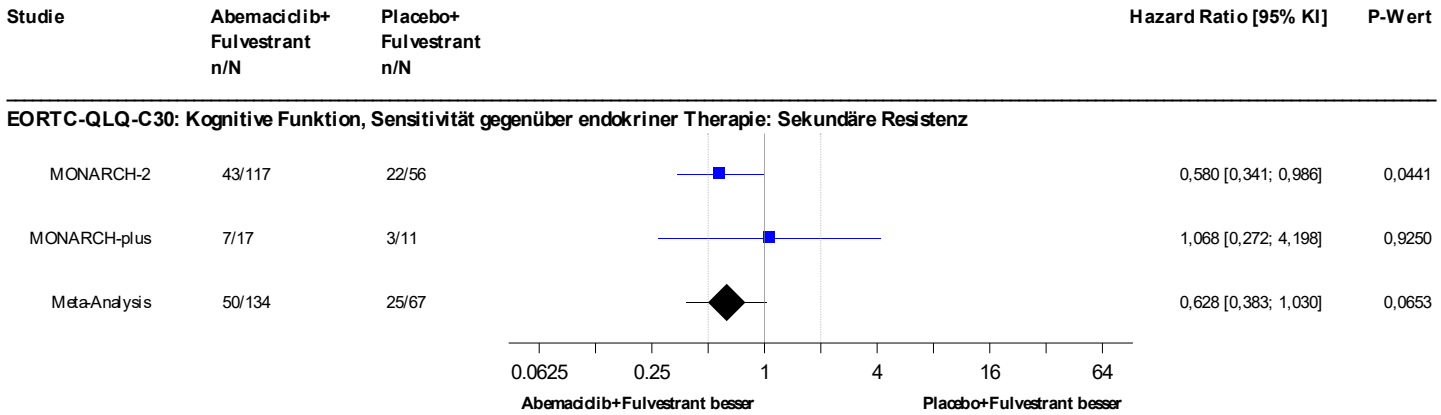
Abbildung 1414.2.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,6640, P-Wert=0,4151, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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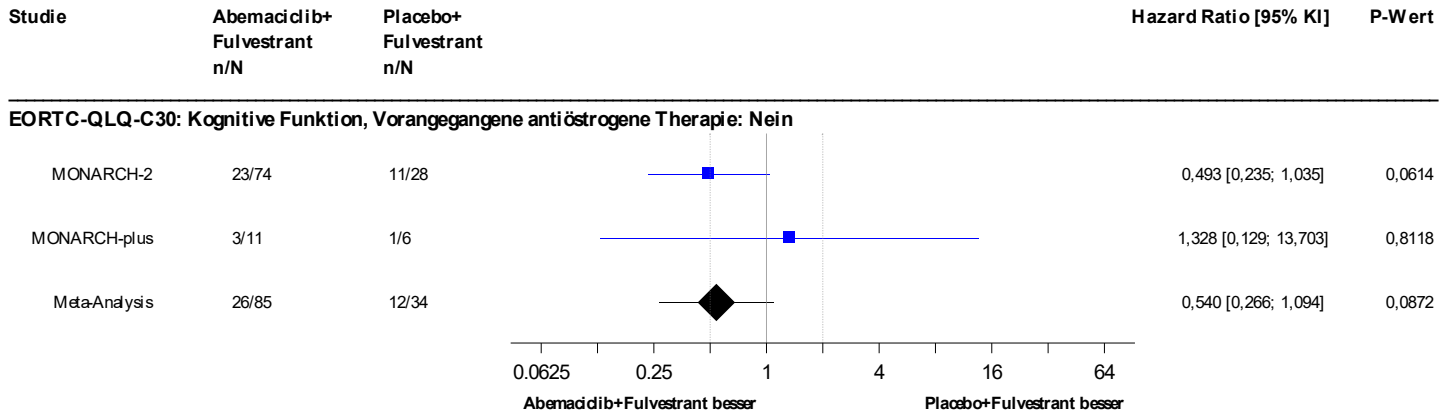
Abbildung 1414.2.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,6298, P-Wert=0,4274, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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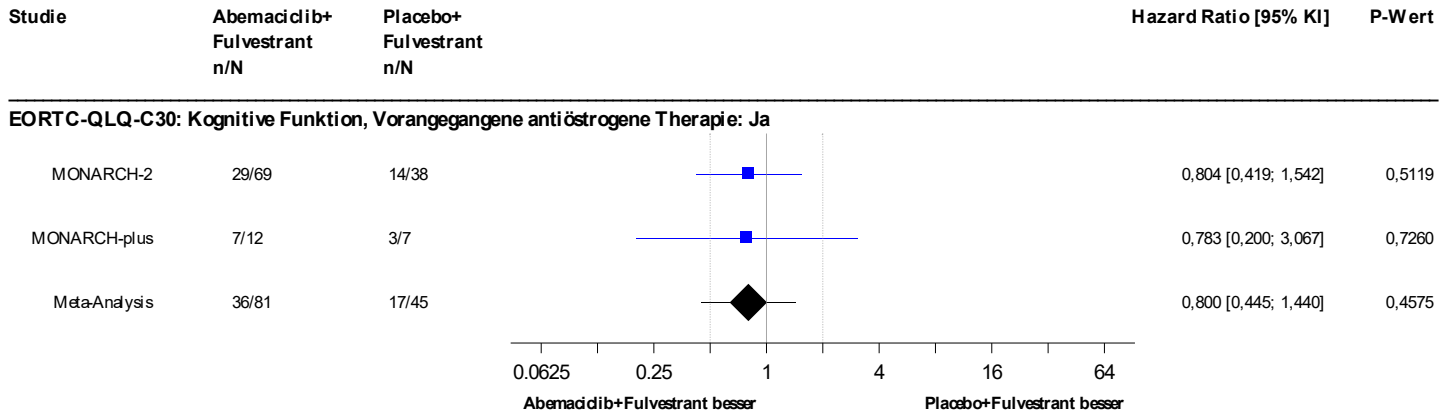
Abbildung 1414.2.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Kognitive Funktion (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0011, P-Wert=0,9730, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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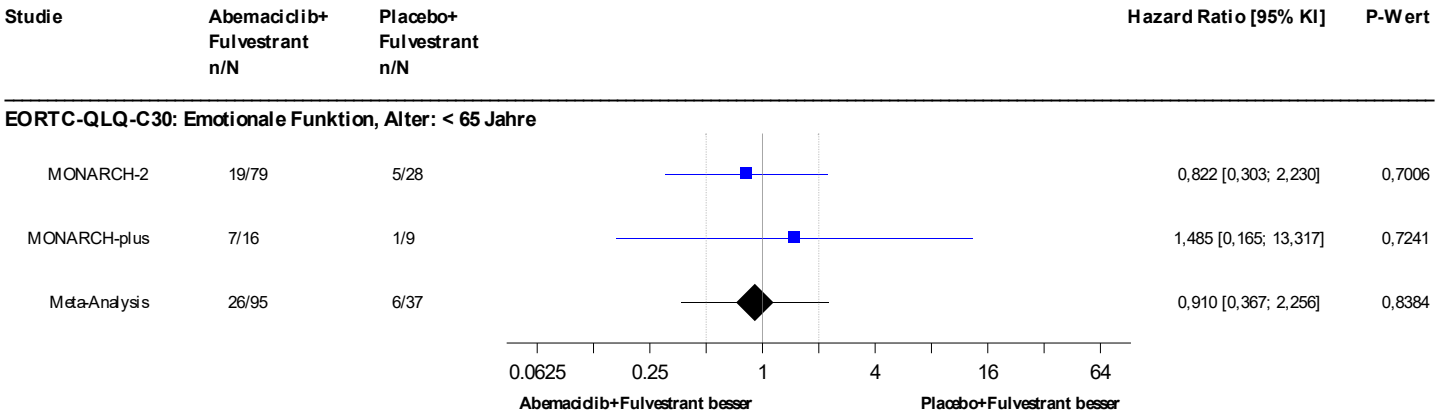
Abbildung 1415.2.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2309, P-Wert=0,6309, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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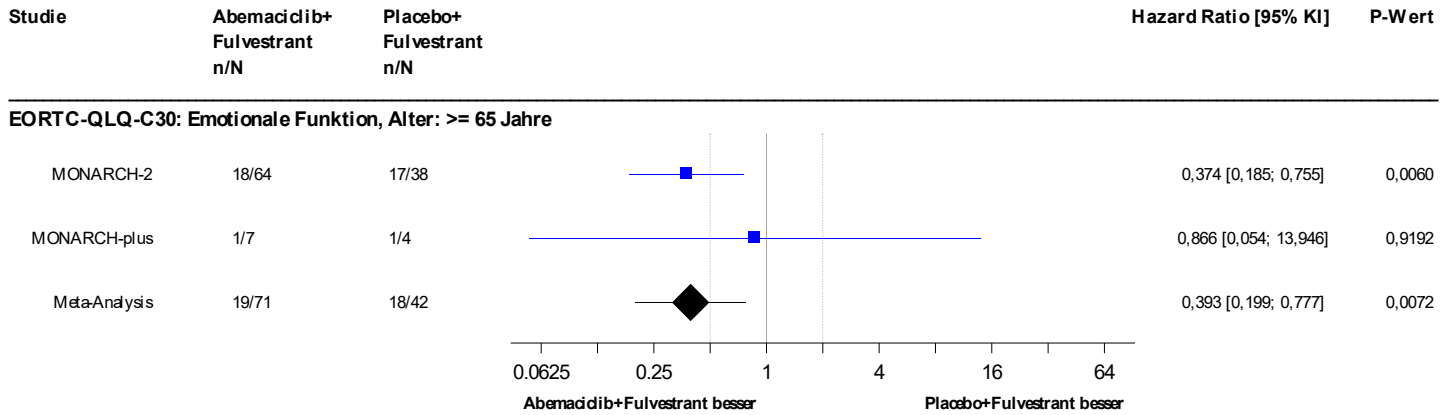
Abbildung 1415.2.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3298, P-Wert=0,5658, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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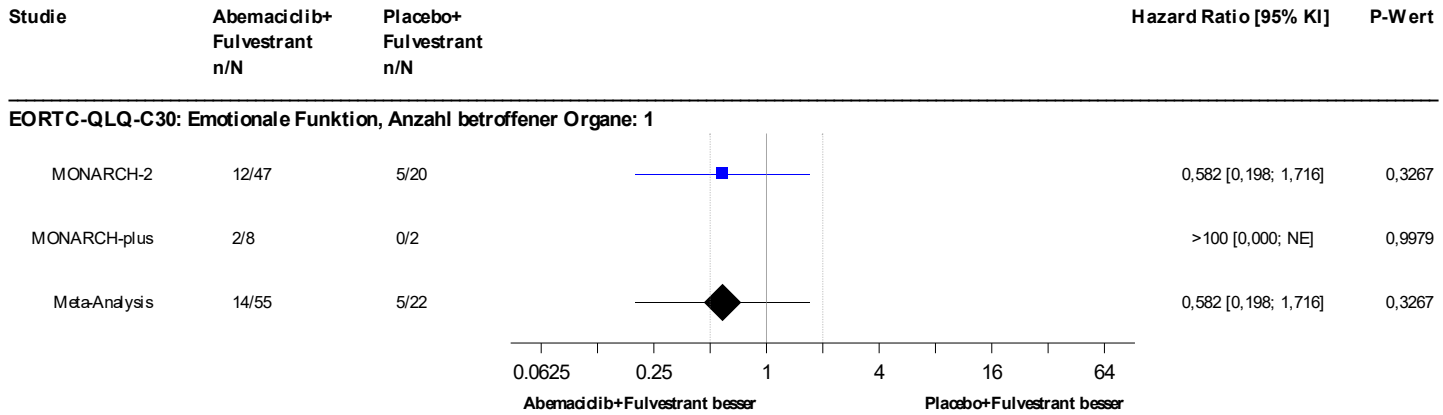
Abbildung 1415.2.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9978, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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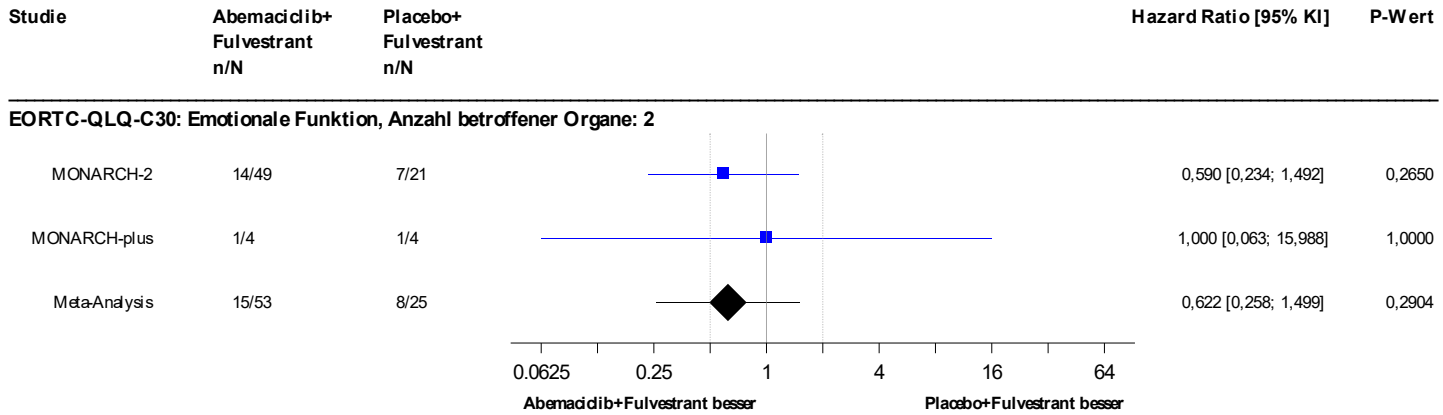
Abbildung 1415.2.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1250, P-Wert=0,7237, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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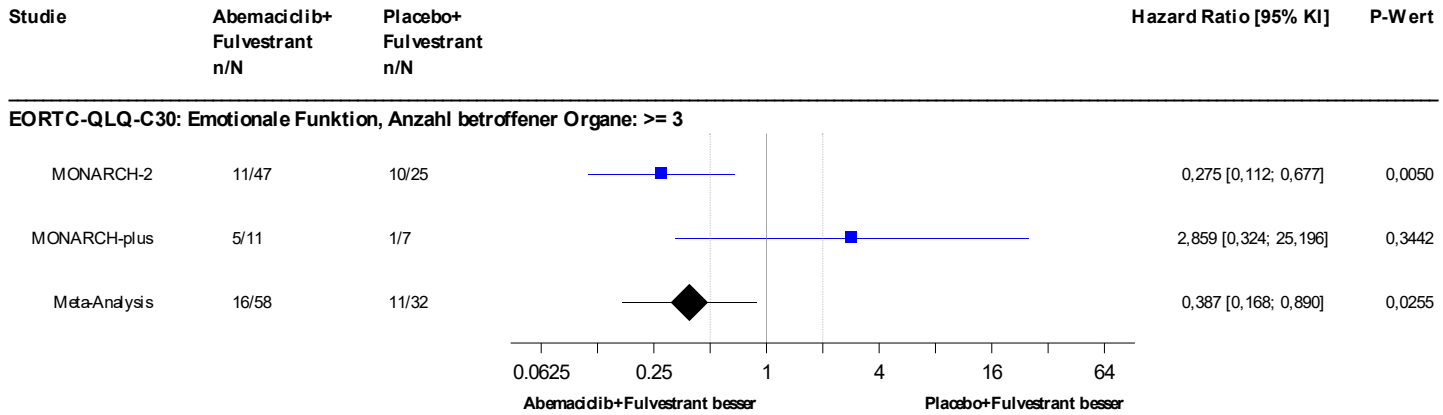
Abbildung 1415.2.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=3,7966, P-Wert=0,0514, I2 Index=73,7%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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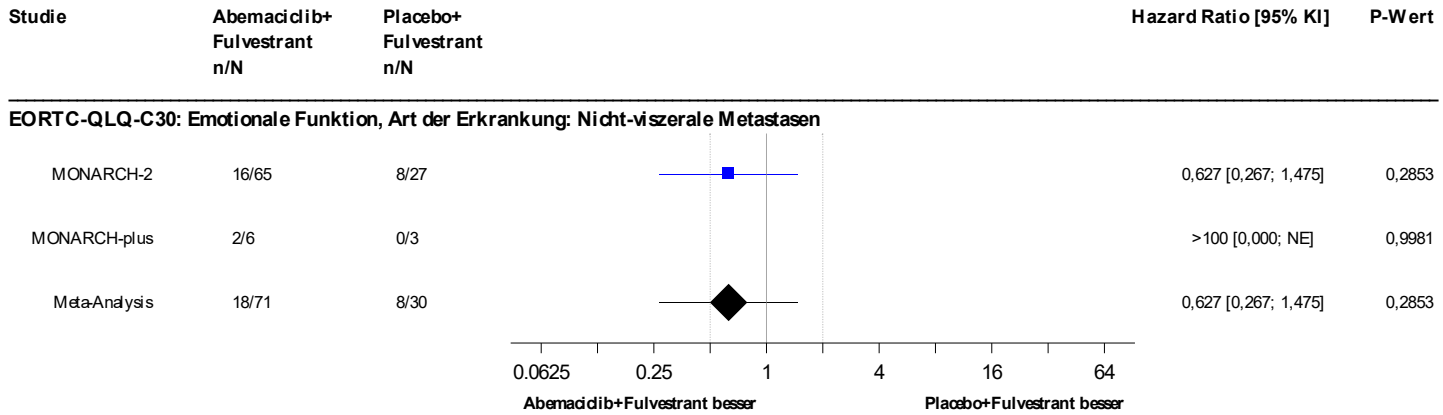
Abbildung 1415.2.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9981, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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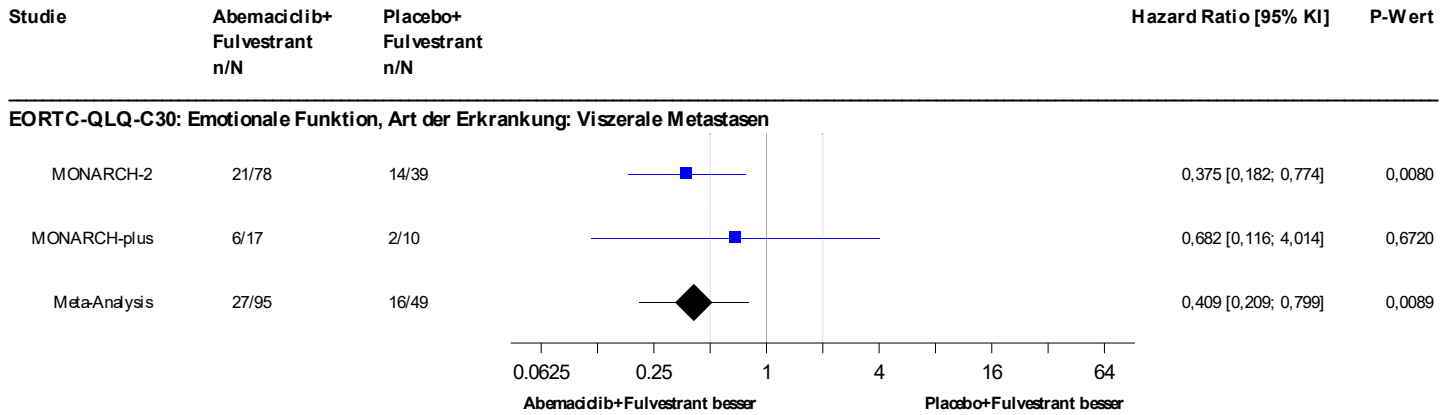
Abbildung 1415.2.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3733, P-Wert=0,5412, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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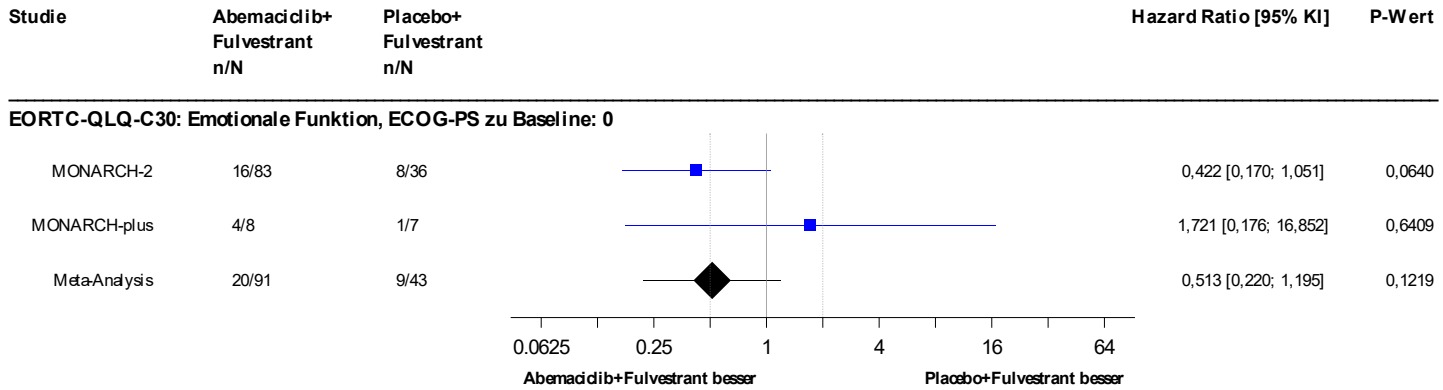
Abbildung 1415.2.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,2562, P-Wert=0,2624, I2 Index=20,4%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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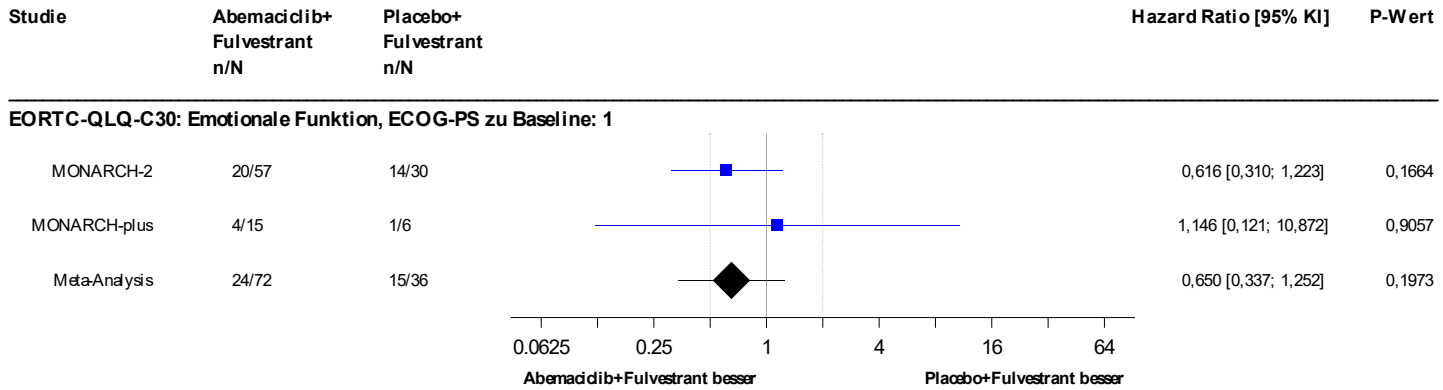
Abbildung 1415.2.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2670, P-Wert=0,6053, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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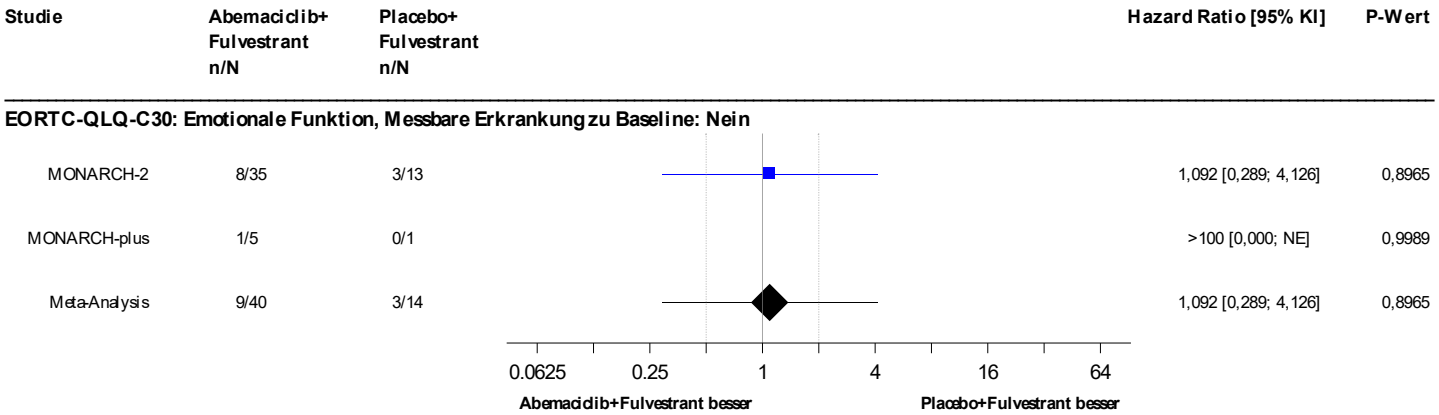
Abbildung 1415.2.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9989, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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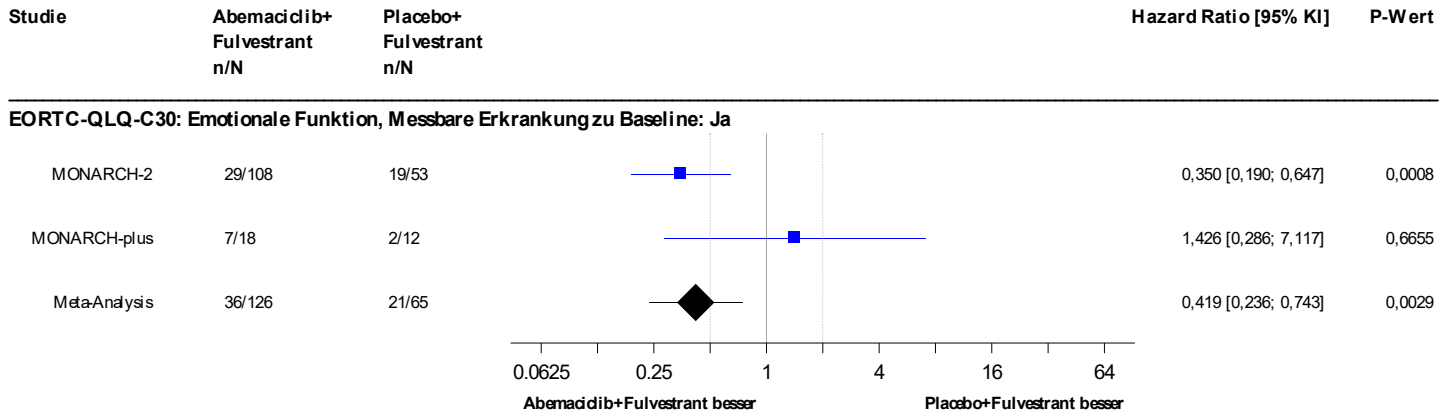
Abbildung 1415.2.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=2,5562, P-Wert=0,1099, I2 Index=60,9%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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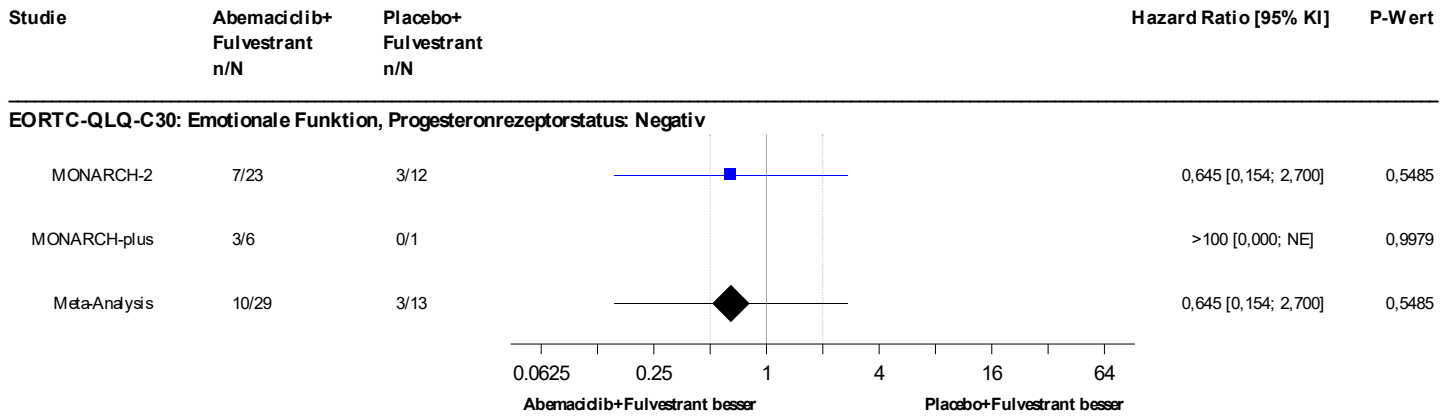
Abbildung 1415.2.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9979, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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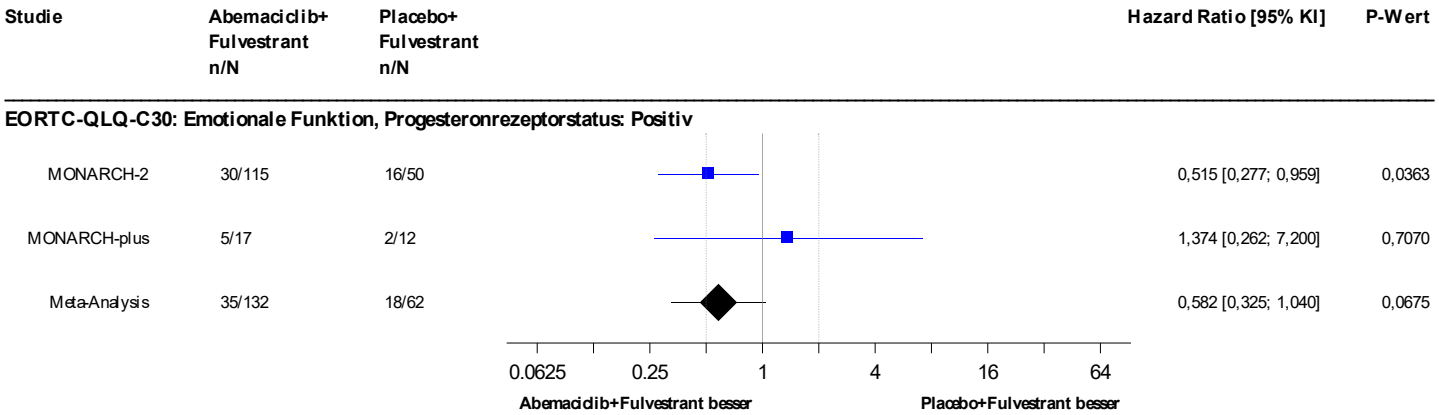
Abbildung 1415.2.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,1800, P-Wert=0,2773, I2 Index=15,3%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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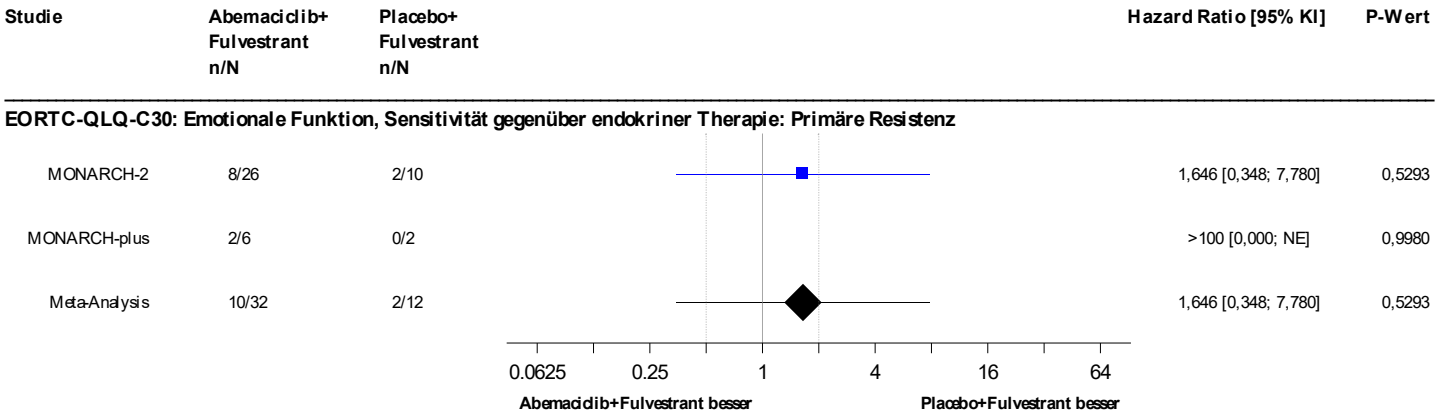
Abbildung 1415.2.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9981, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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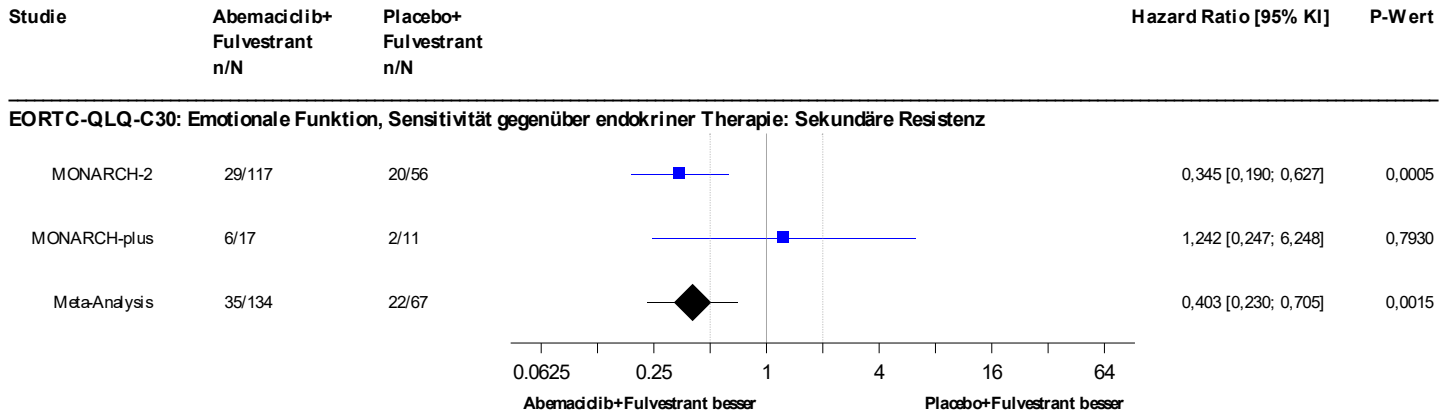
Abbildung 1415.2.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=2,1188, P-Wert=0,1455, I2 Index=52,8%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwemo6_popa2_snthr_2.rtf
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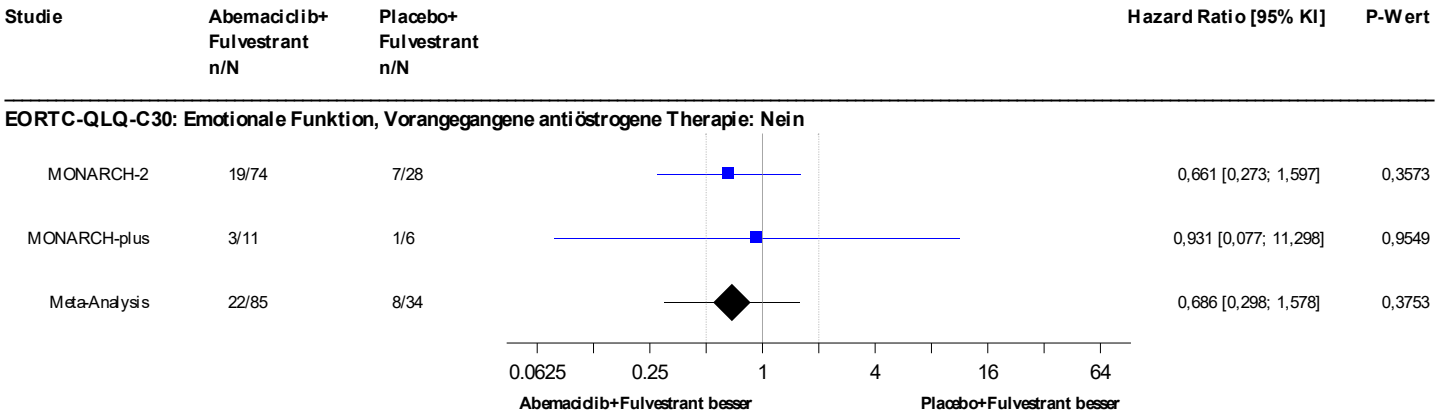
Abbildung 1415.2.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0643, P-Wert=0,7998, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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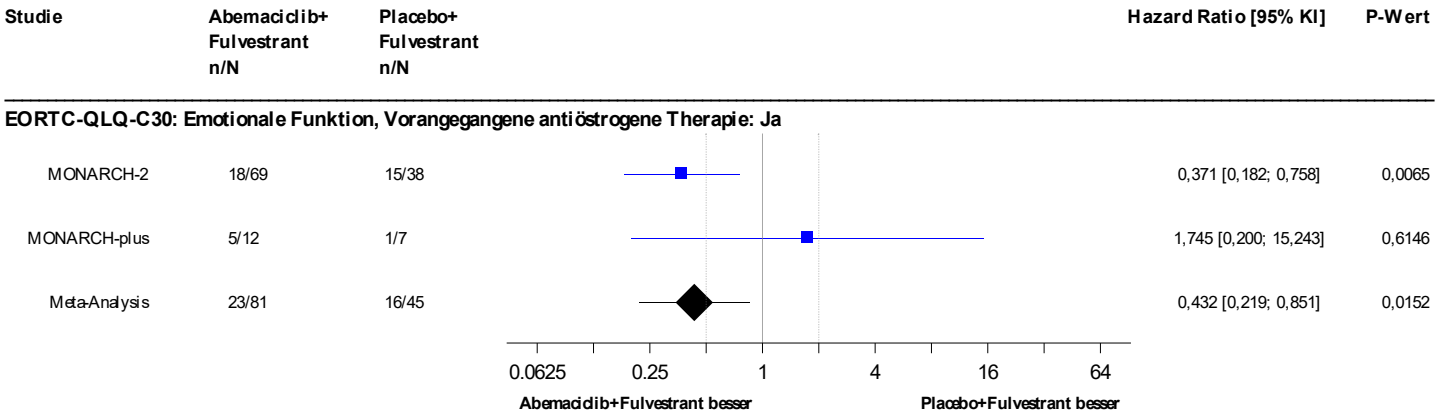
Abbildung 1415.2.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Emotionale Funktion (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,7668, P-Wert=0,1838, I2 Index=43,4%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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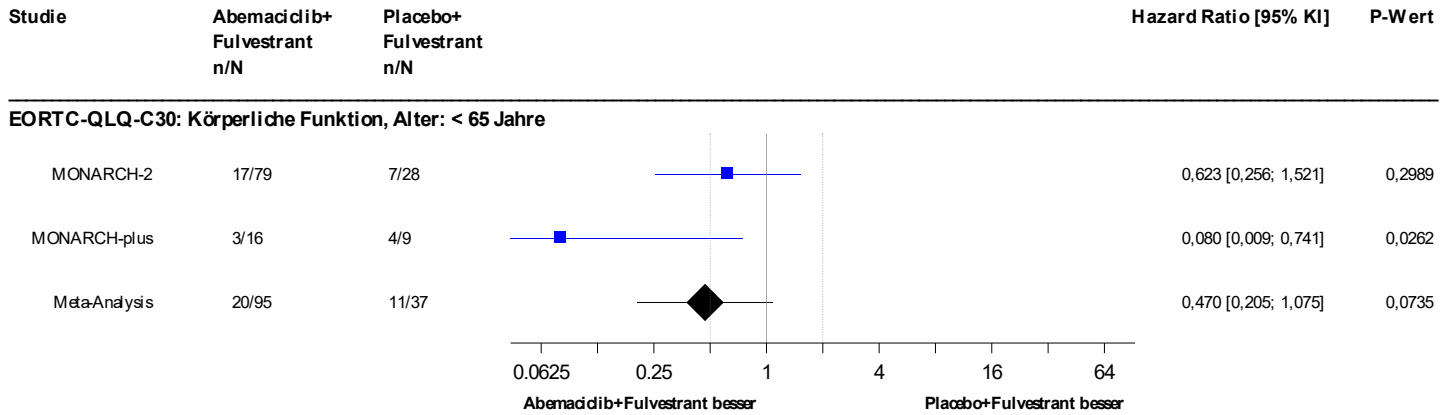
Abbildung 1416.2.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=2,8172, P-Wert=0,0933, I2 Index=64,5%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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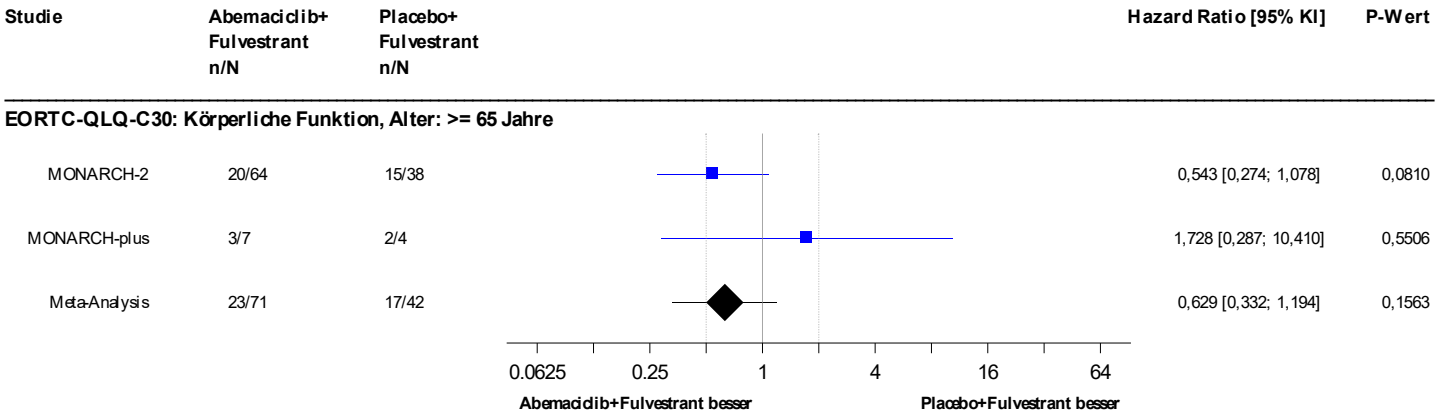
Abbildung 1416.2.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,3917, P-Wert=0,2381, I2 Index=28,1%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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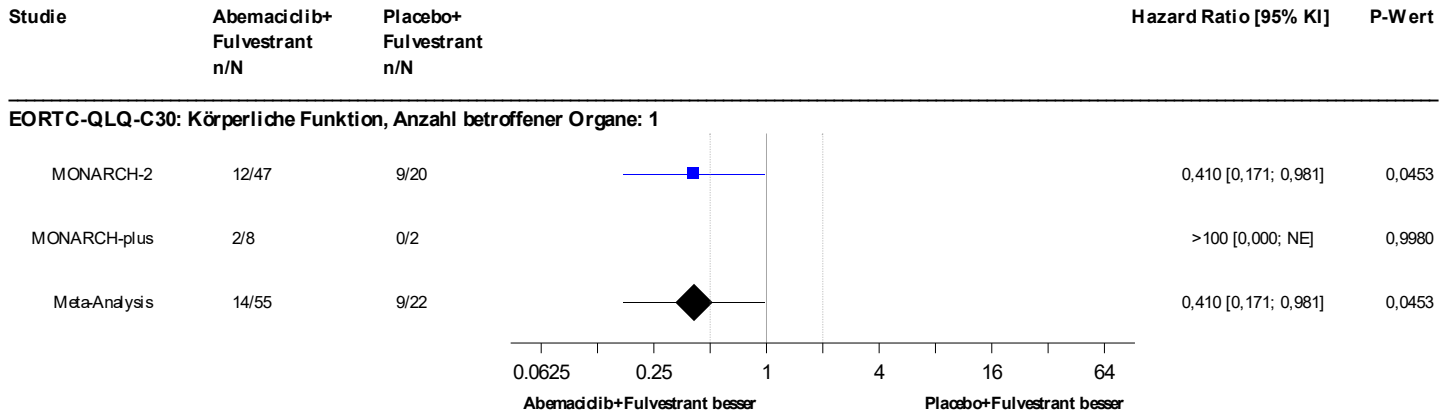
Abbildung 1416.2.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9979, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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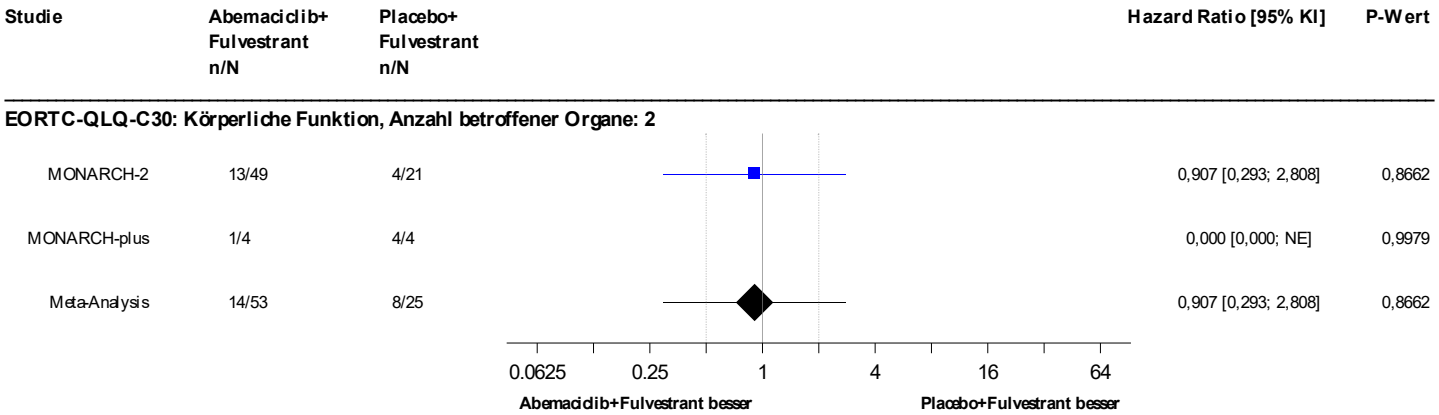
Abbildung 1416.2.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9980, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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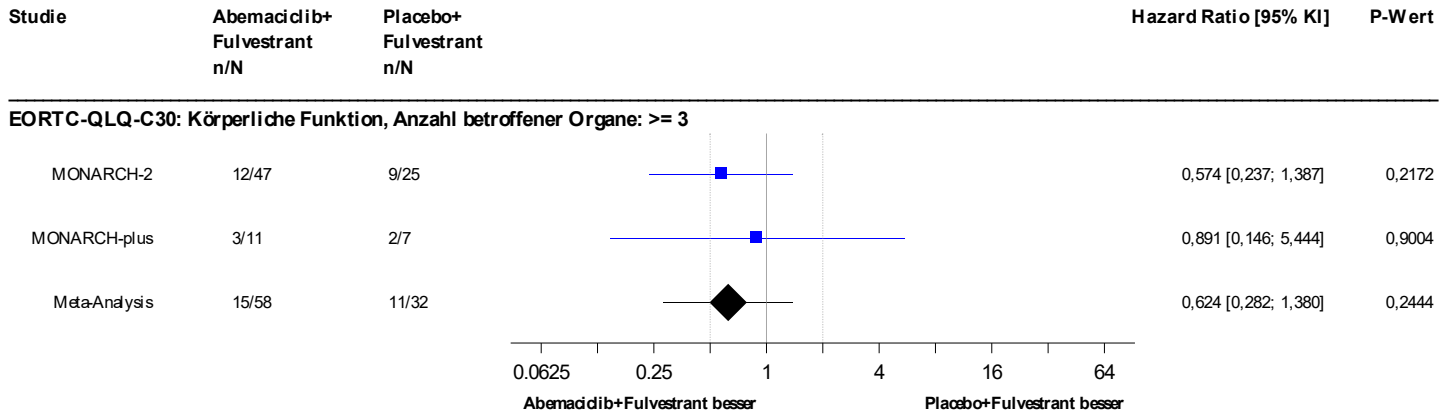
Abbildung 1416.2.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1834, P-Wert=0,6685, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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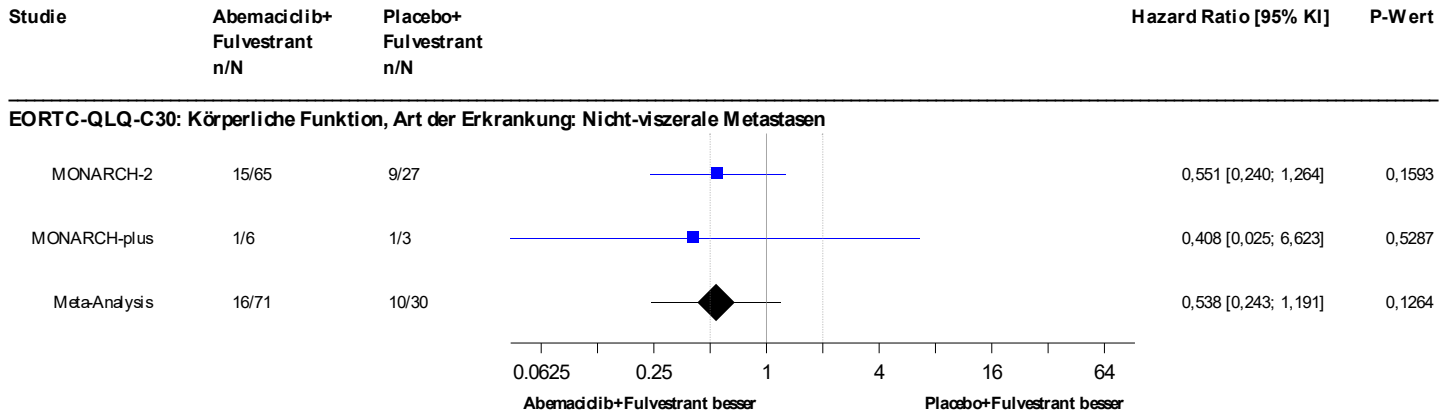
Abbildung 1416.2.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0407, P-Wert=0,8400, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwphys6_popa2_natdis2_1.rtf
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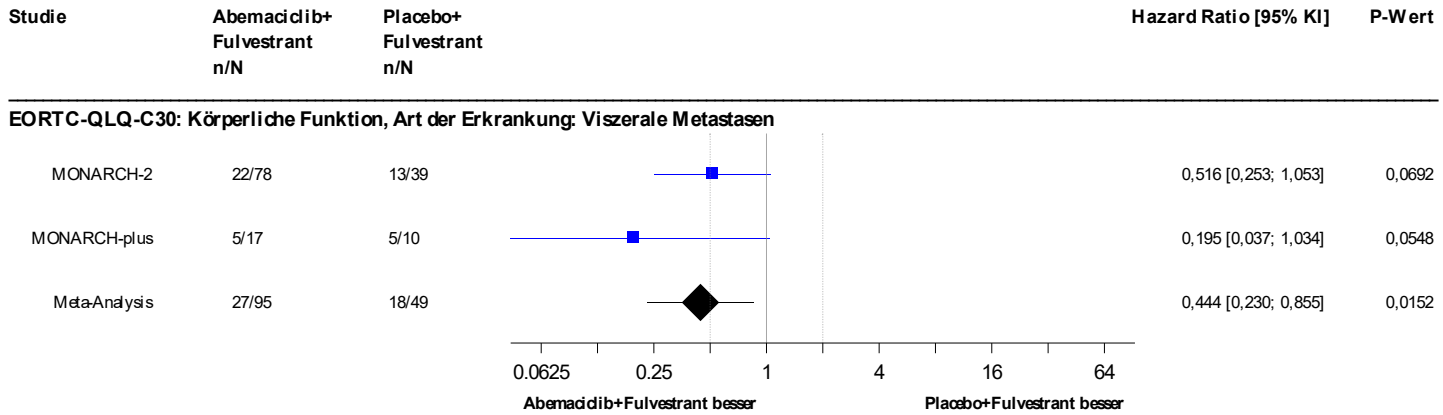
Abbildung 1416.2.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,1015, P-Wert=0,2939, I2 Index=9,2%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwphys6_popa2_natdis2_2.rtf
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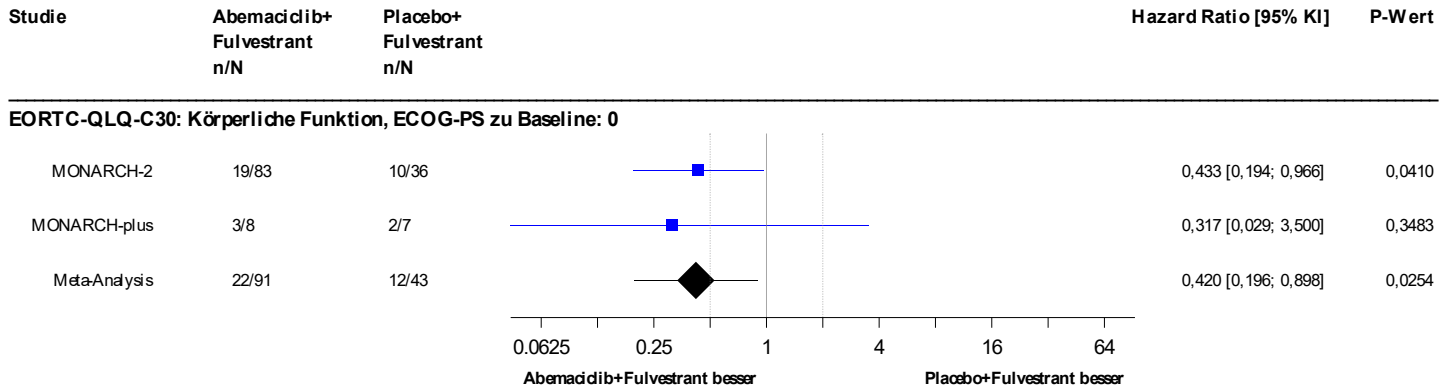
Abbildung 1416.2.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0585, P-Wert=0,8089, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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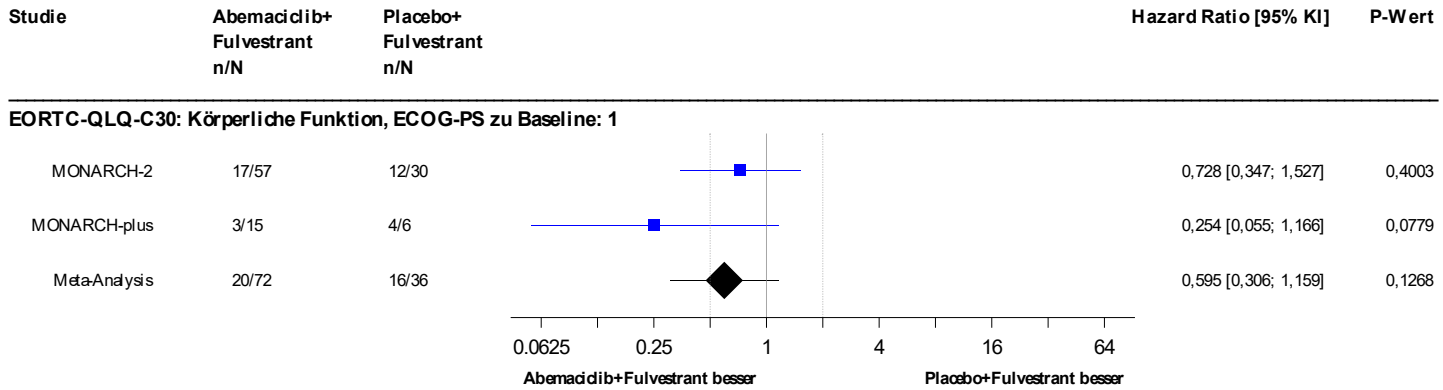
Abbildung 1416.2.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,4835, P-Wert=0,2232, I2 Index=32,6%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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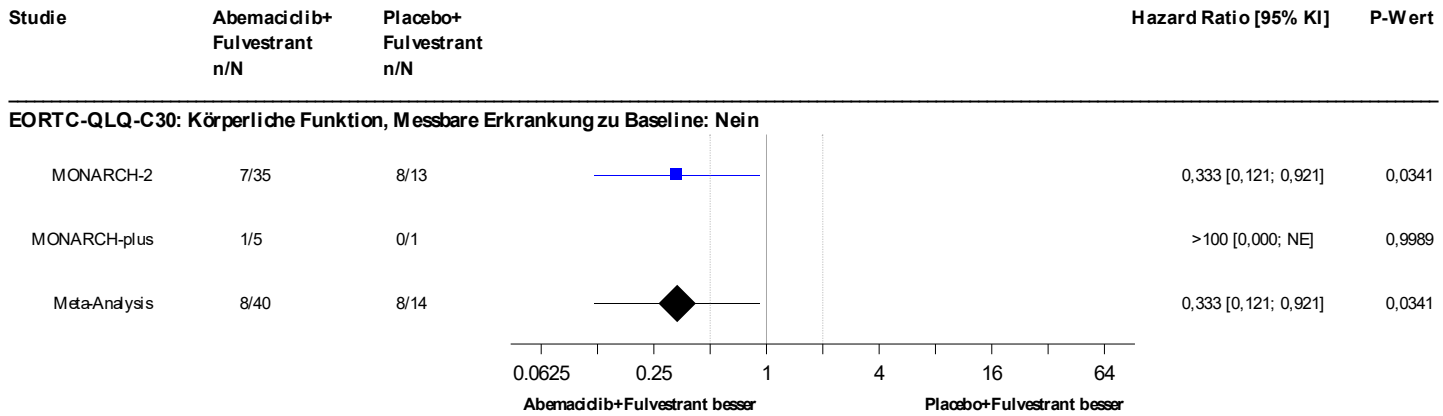
Abbildung 1416.2.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9988, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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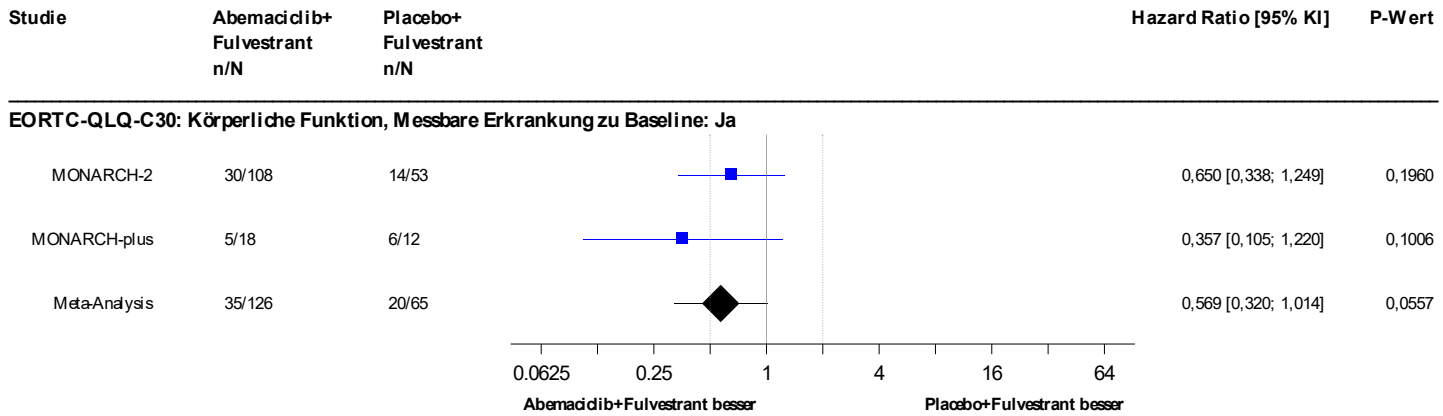
Abbildung 1416.2.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,7084, P-Wert=0,4000, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwphys6_popa2_measdis_2.rtf
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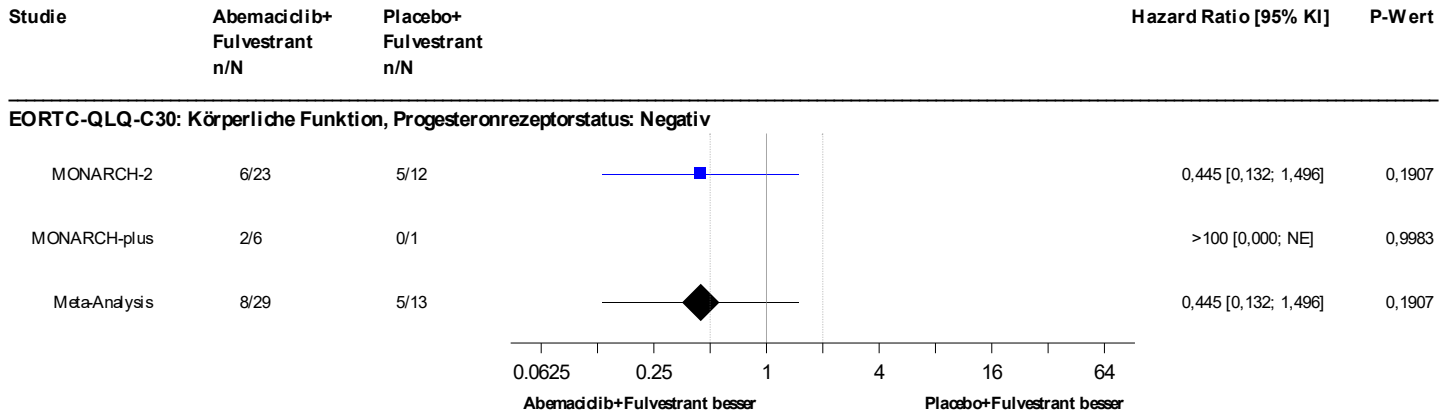
Abbildung 1416.2.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9982, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwphys6_popa2_pgrstat_1.rtf
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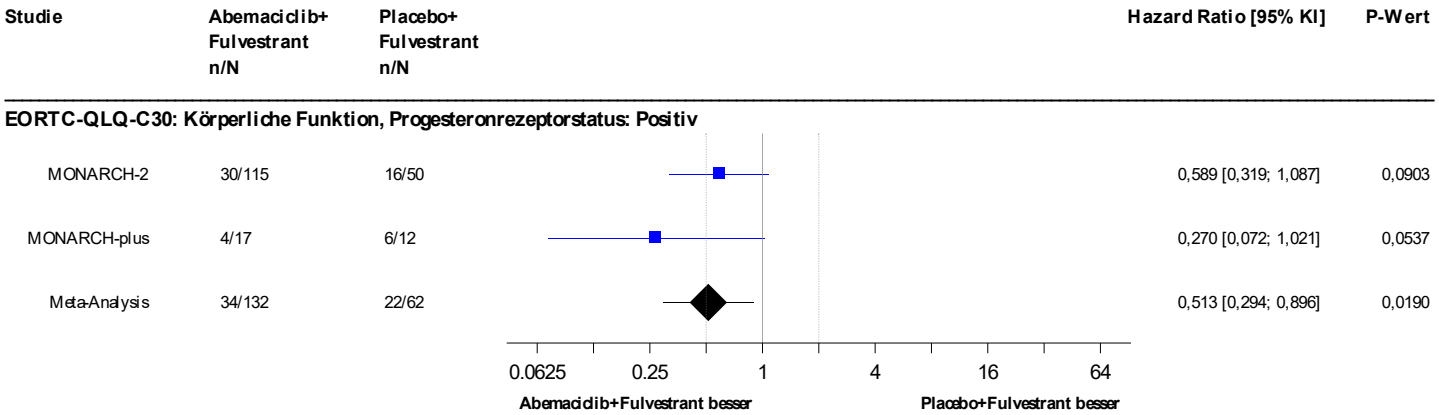
Abbildung 1416.2.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,0861, P-Wert=0,2973, I2 Index=7,9%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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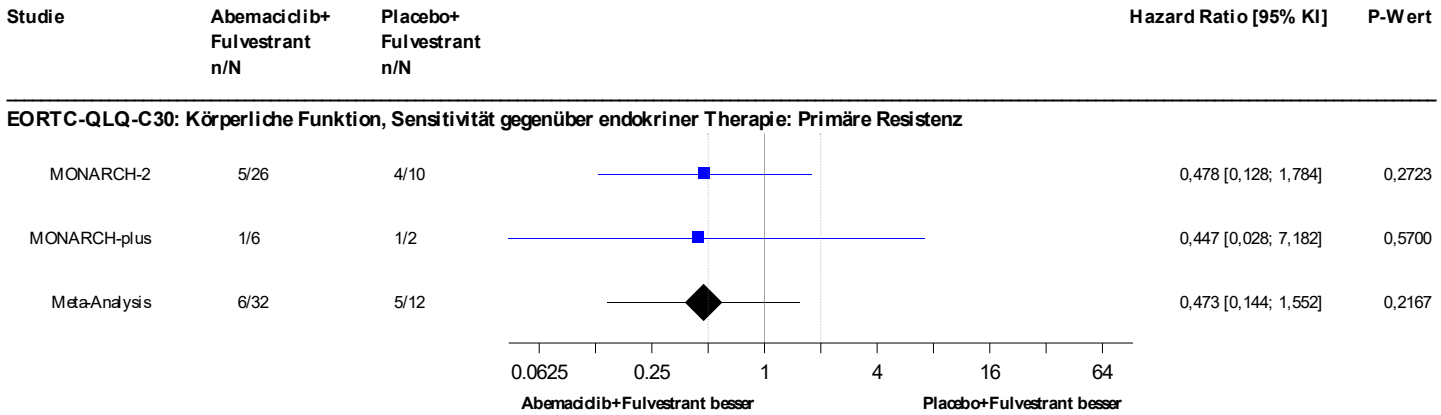
Abbildung 1416.2.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0018, P-Wert=0,9657, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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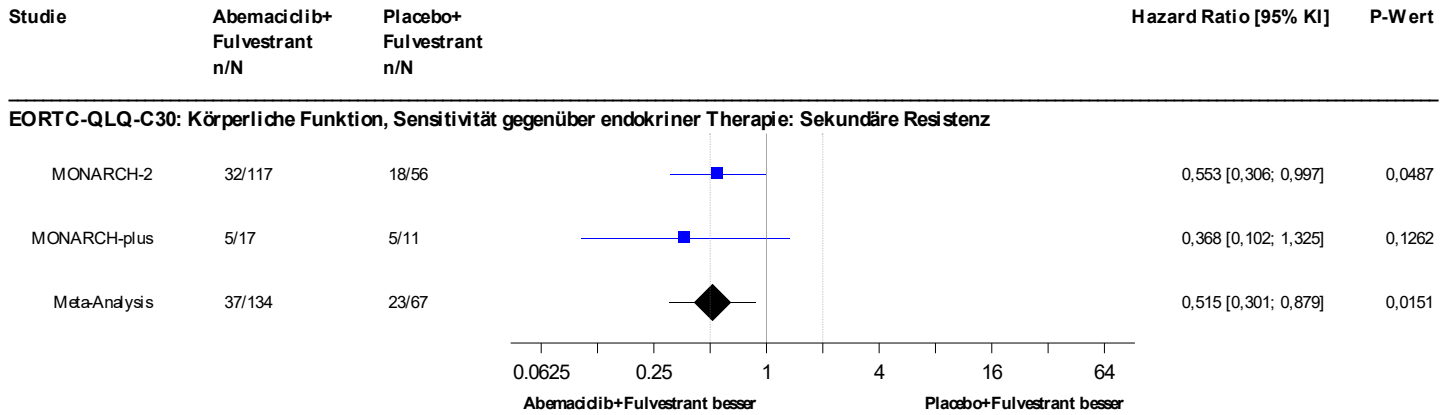
Abbildung 1416.2.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3202, P-Wert=0,5715, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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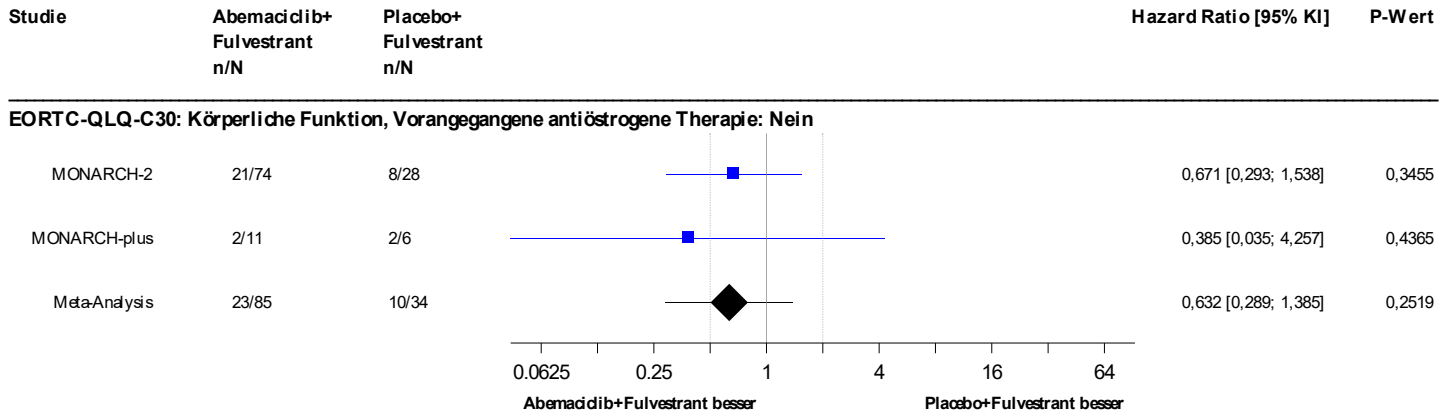
Abbildung 1416.2.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1828, P-Wert=0,6689, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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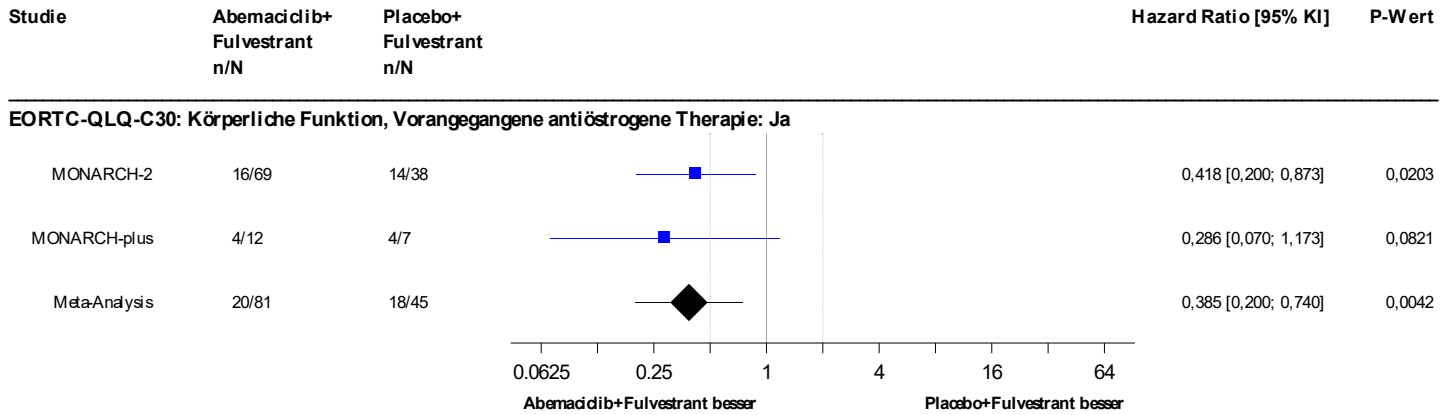
Abbildung 1416.2.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Körperliche Funktion (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2190, P-Wert=0,6398, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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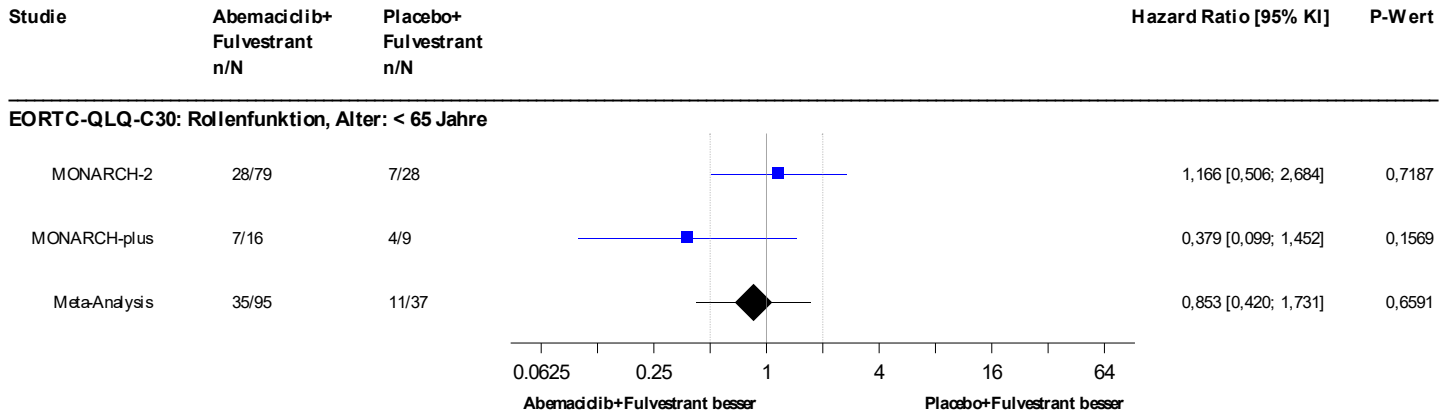
Abbildung 1417.2.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,9385, P-Wert=0,1638, I2 Index=48,4%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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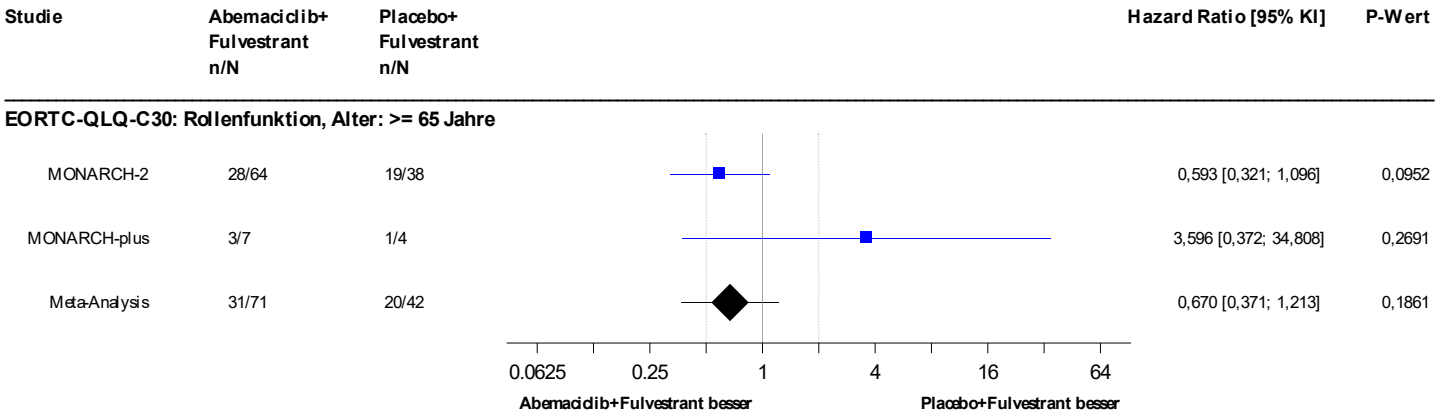
Abbildung 1417.2.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=2,2572, P-Wert=0,1330, I2 Index=55,7%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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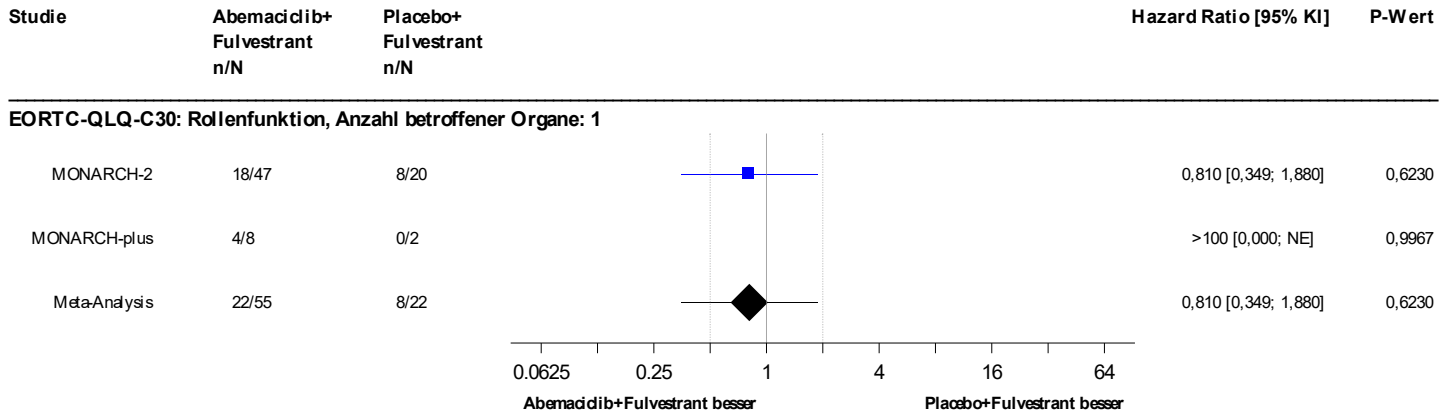
Abbildung 1417.2.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9967, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttwrole6_popa2_norggr_1.rtf
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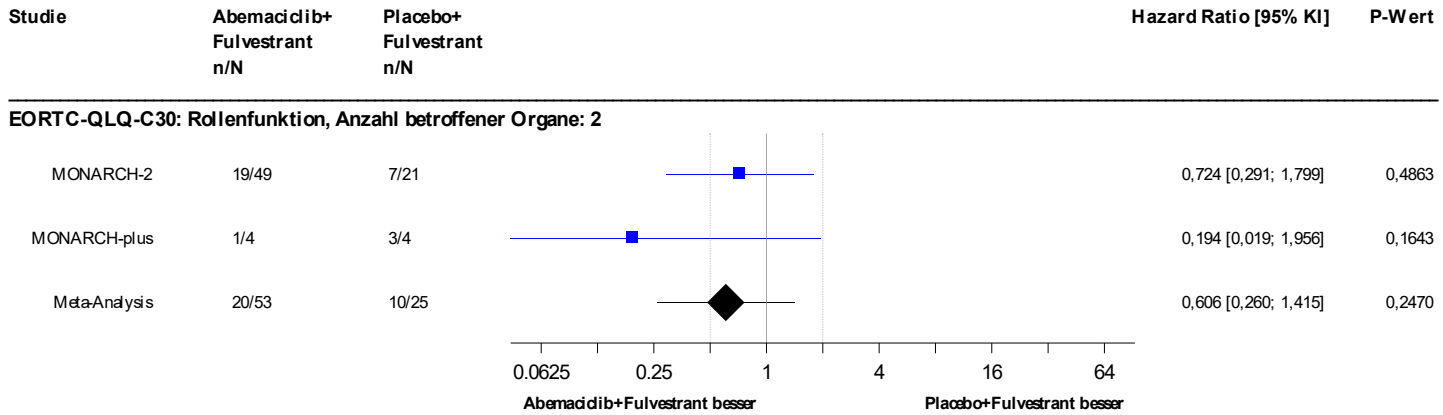
Abbildung 1417.2.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,0787, P-Wert=0,2990, I2 Index=7,3%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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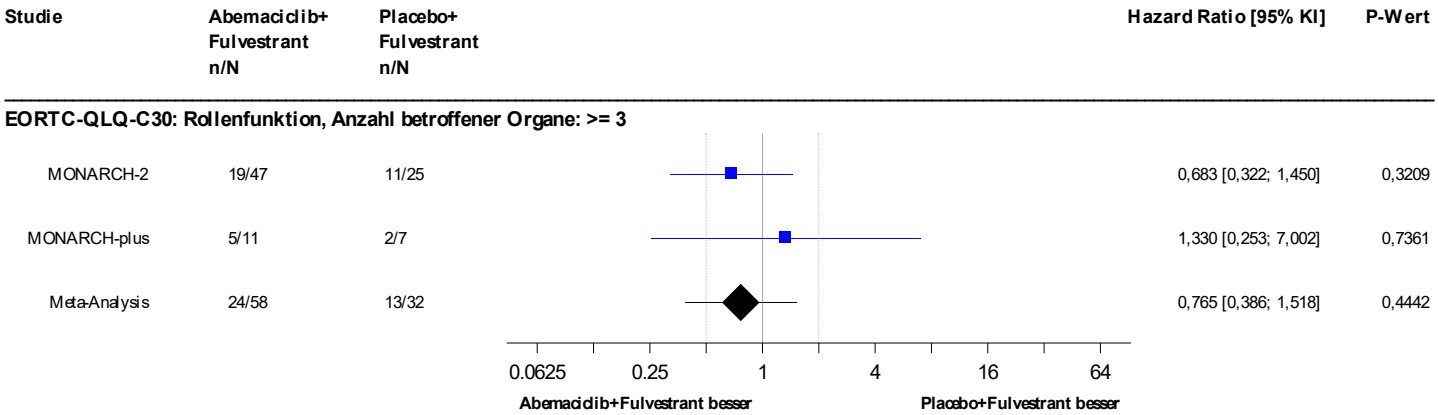
Abbildung 1417.2.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,5134, P-Wert=0,4737, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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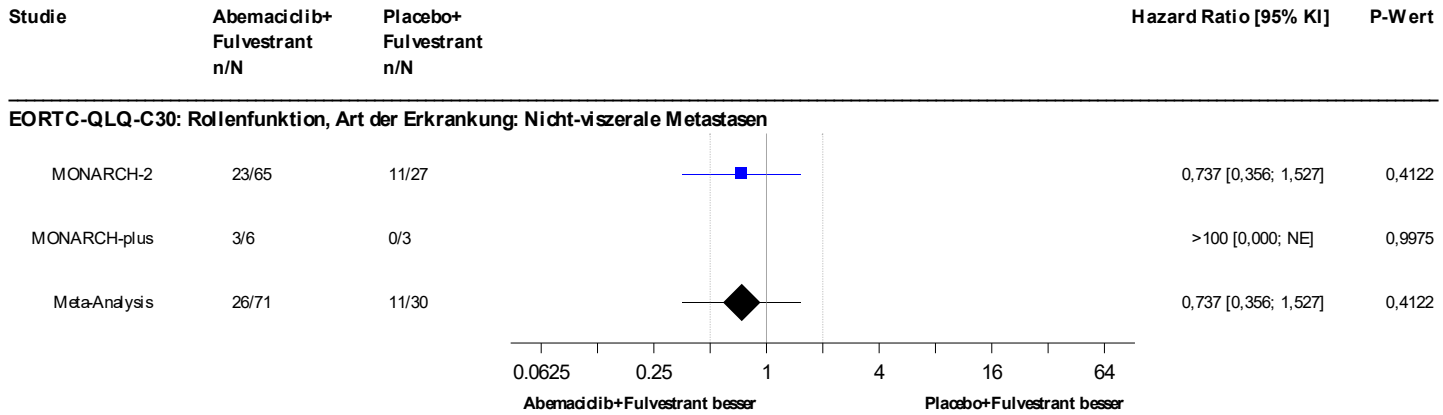
Abbildung 1417.2.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9975, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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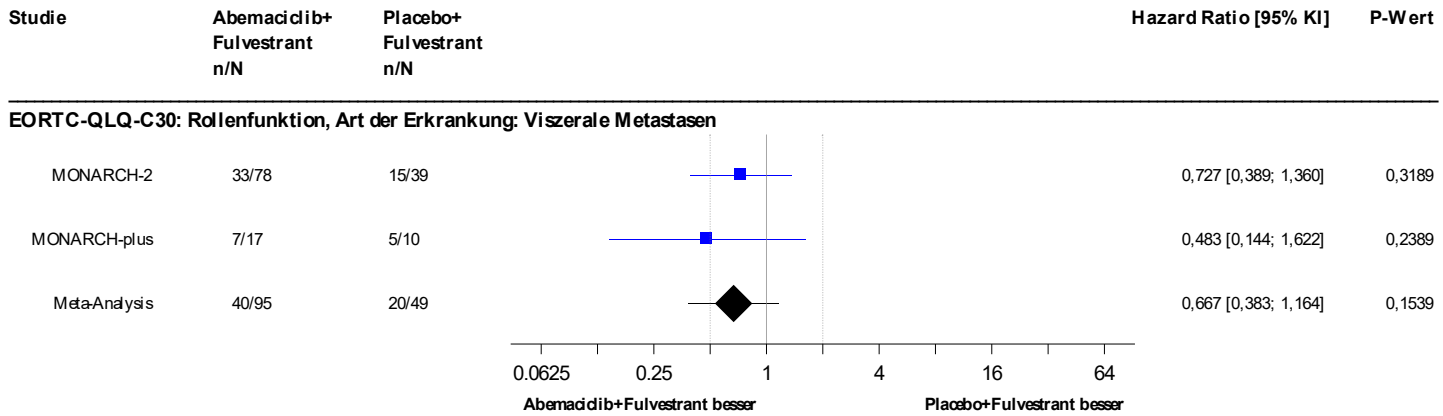
Abbildung 1417.2.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3473, P-Wert=0,5557, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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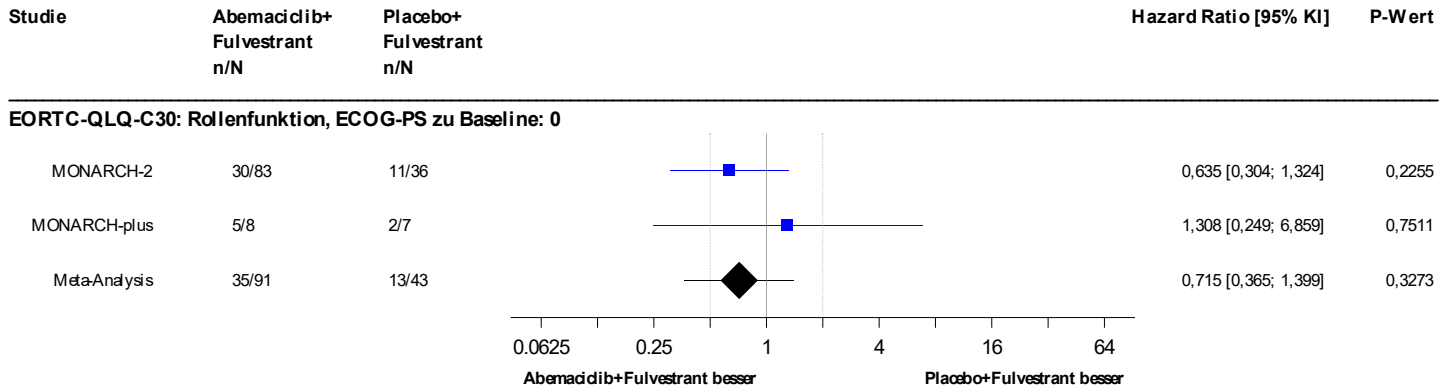
Abbildung 1417.2.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,6104, P-Wert=0,4346, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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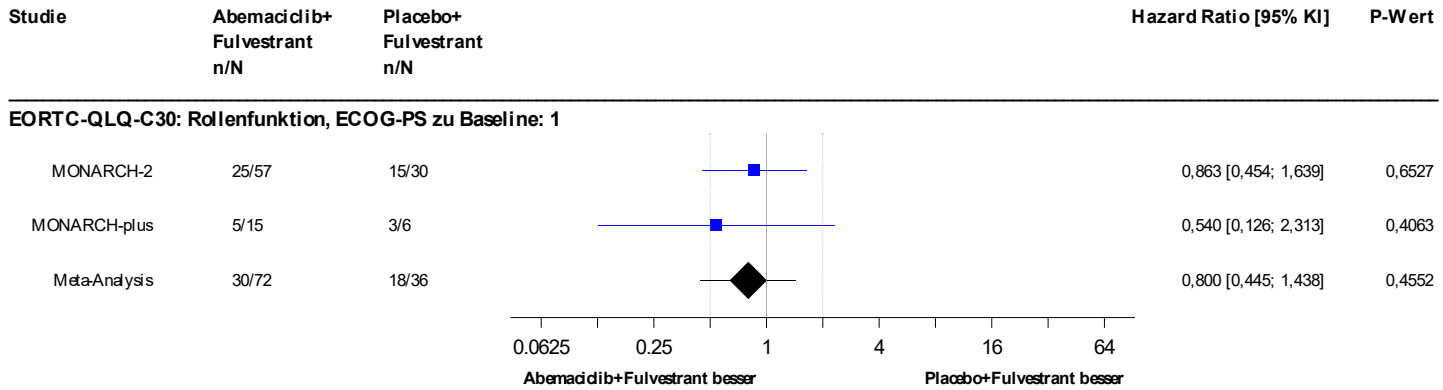
Abbildung 1417.2.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3344, P-Wert=0,5631, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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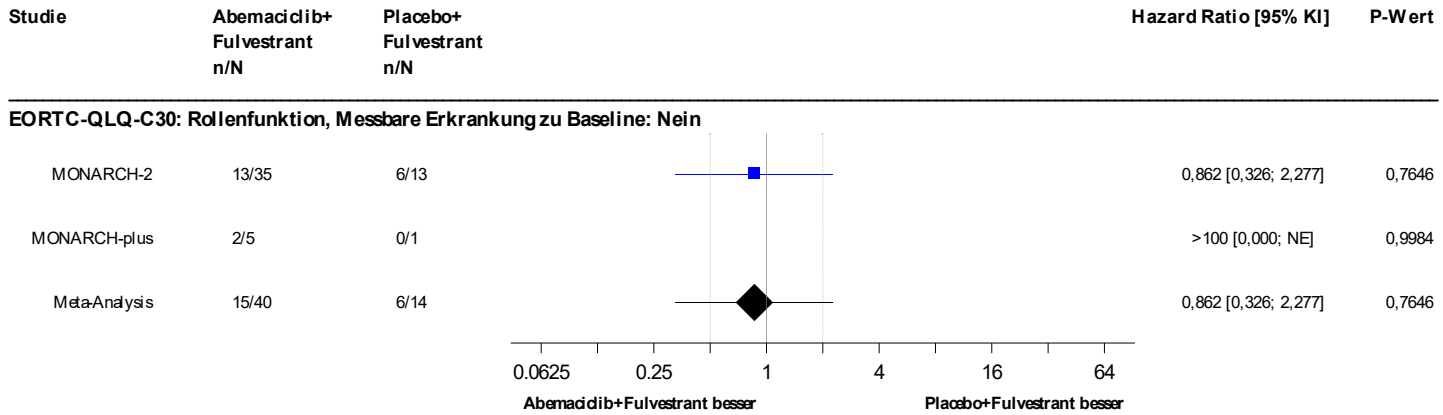
Abbildung 1417.2.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9984, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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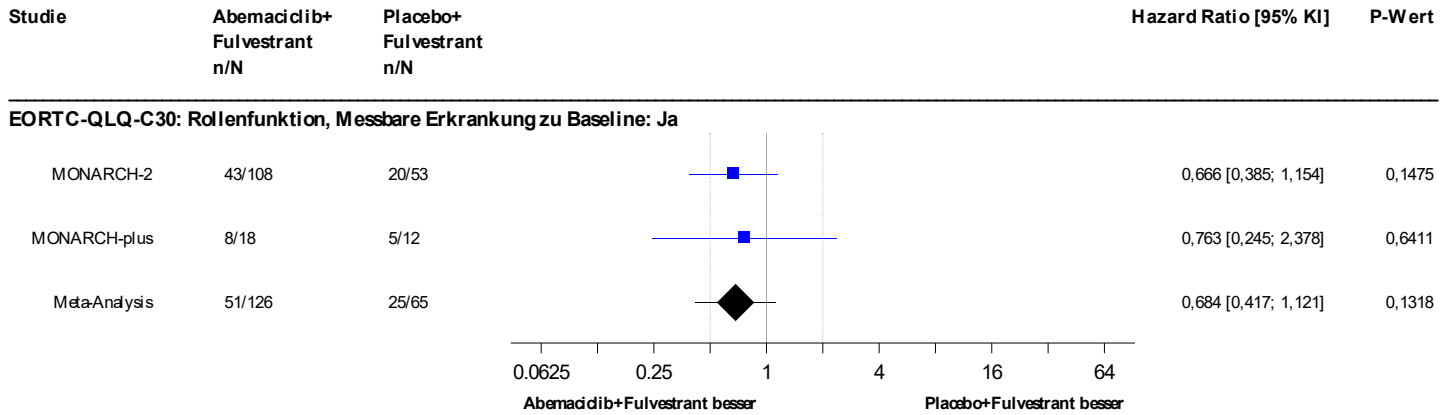
Abbildung 1417.2.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0444, P-Wert=0,8330, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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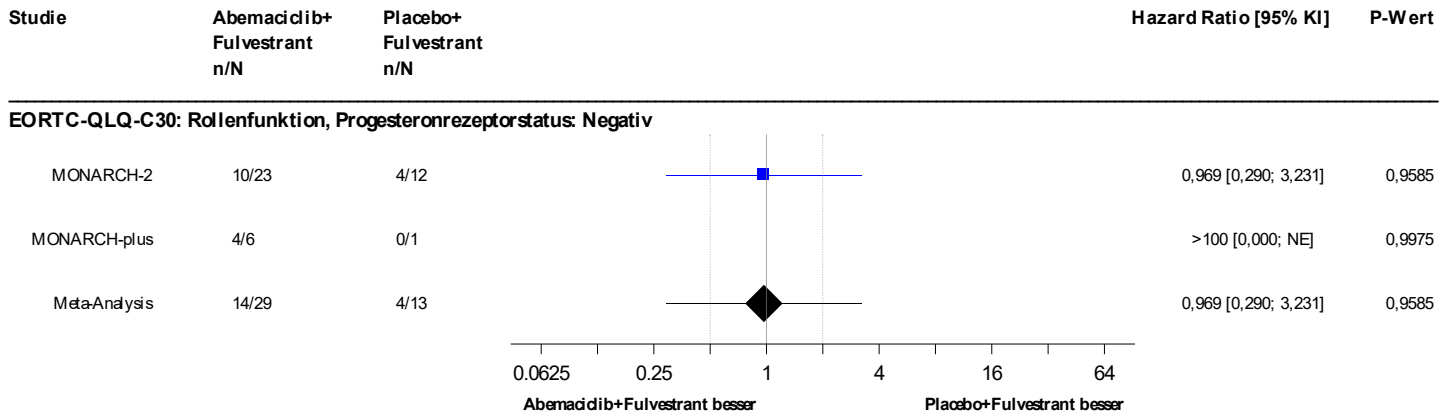
Abbildung 1417.2.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9975, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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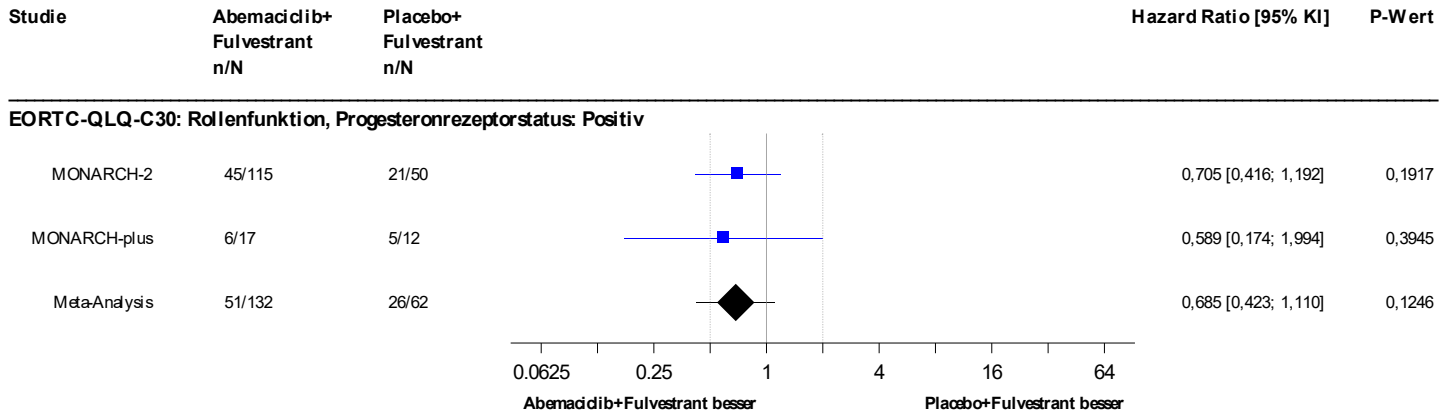
Abbildung 1417.2.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0704, P-Wert=0,7907, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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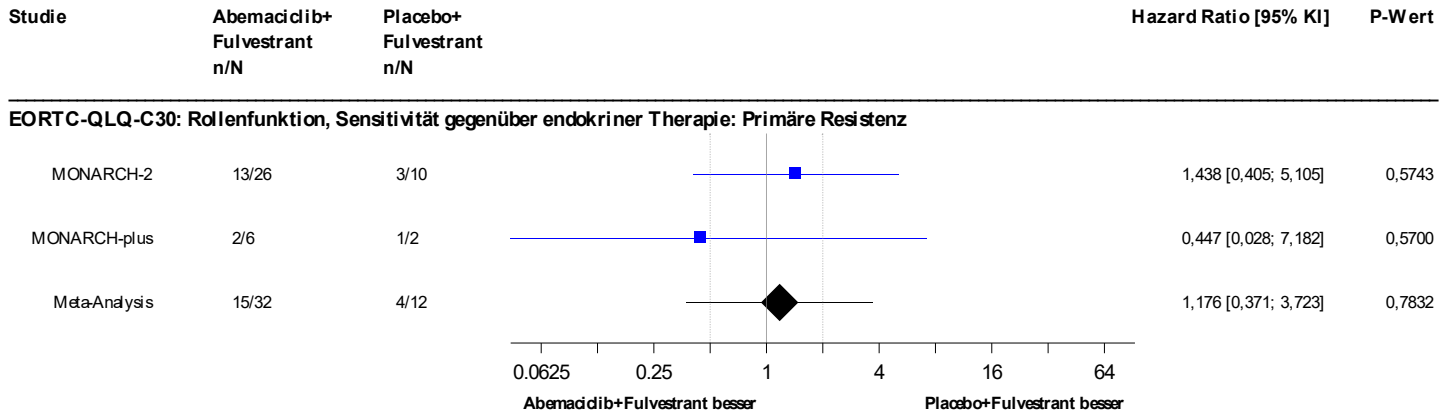
Abbildung 1417.2.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,5625, P-Wert=0,4532, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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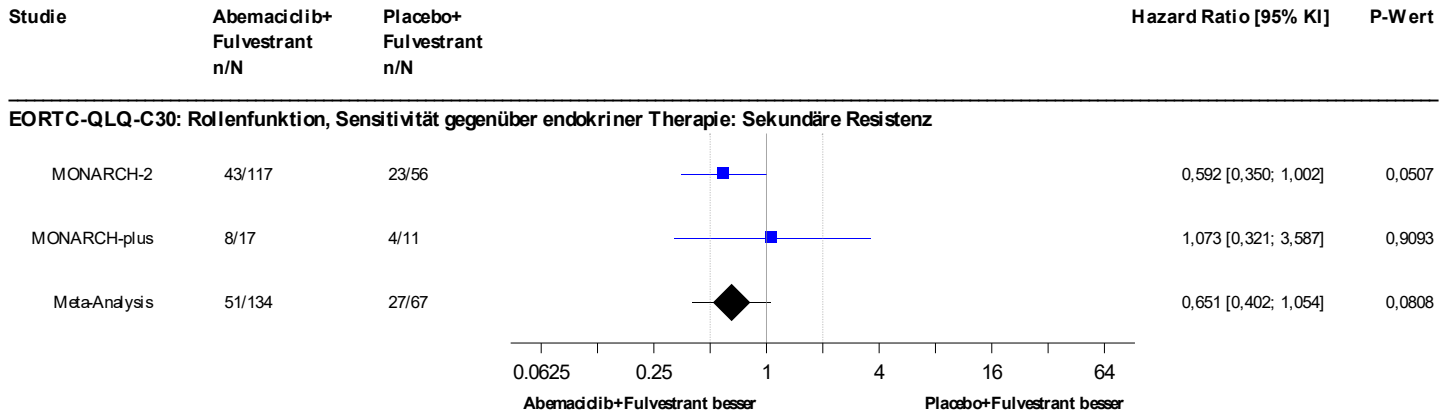
Abbildung 1417.2.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,7822, P-Wert=0,3765, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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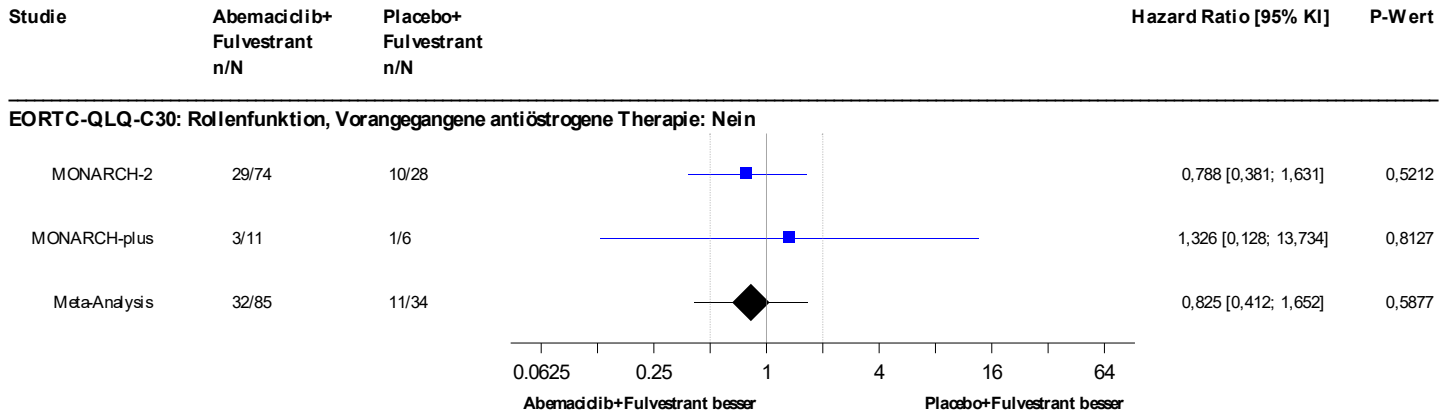
Abbildung 1417.2.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1737, P-Wert=0,6768, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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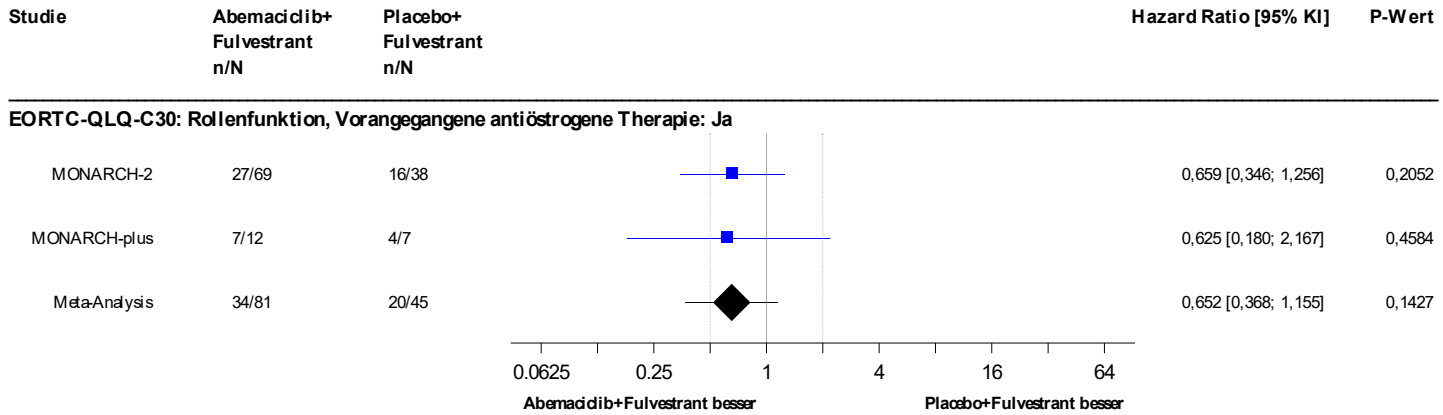
Abbildung 1417.2.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Rollenfunktion (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0057, P-Wert=0,9397, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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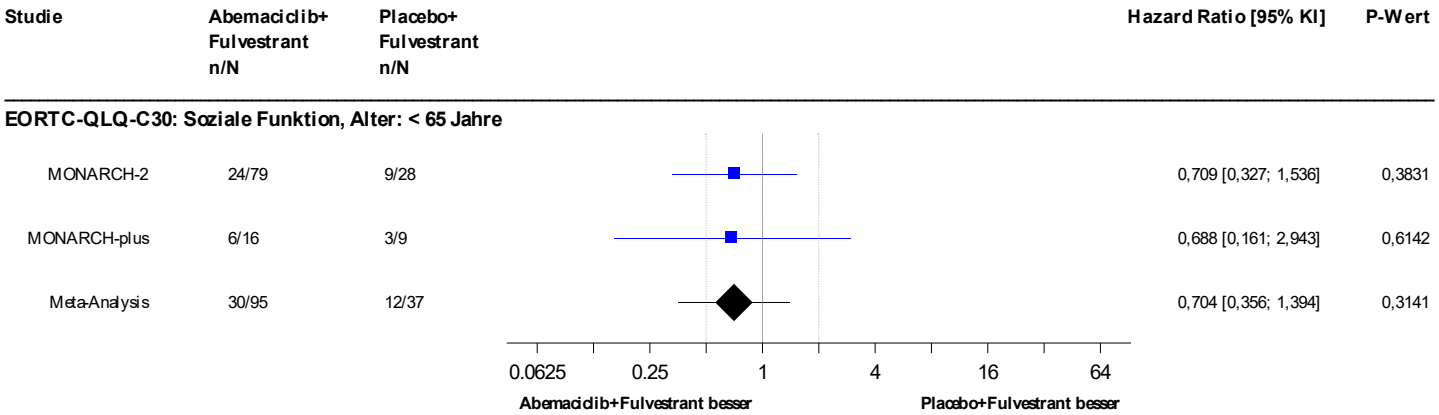
Abbildung 1418.2.1.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0012, P-Wert=0,9719, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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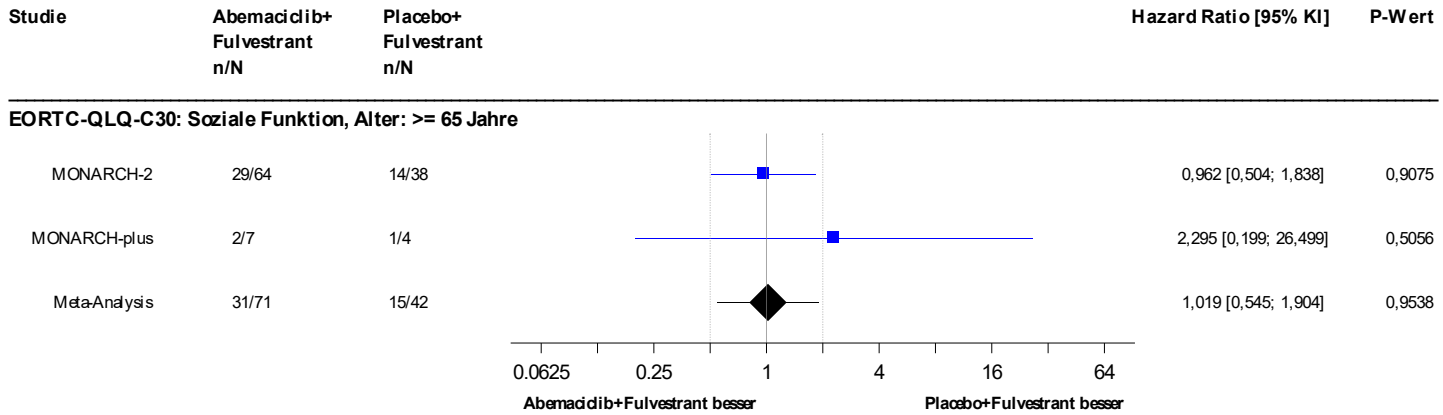
Abbildung 1418.2.1.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,4534, P-Wert=0,5007, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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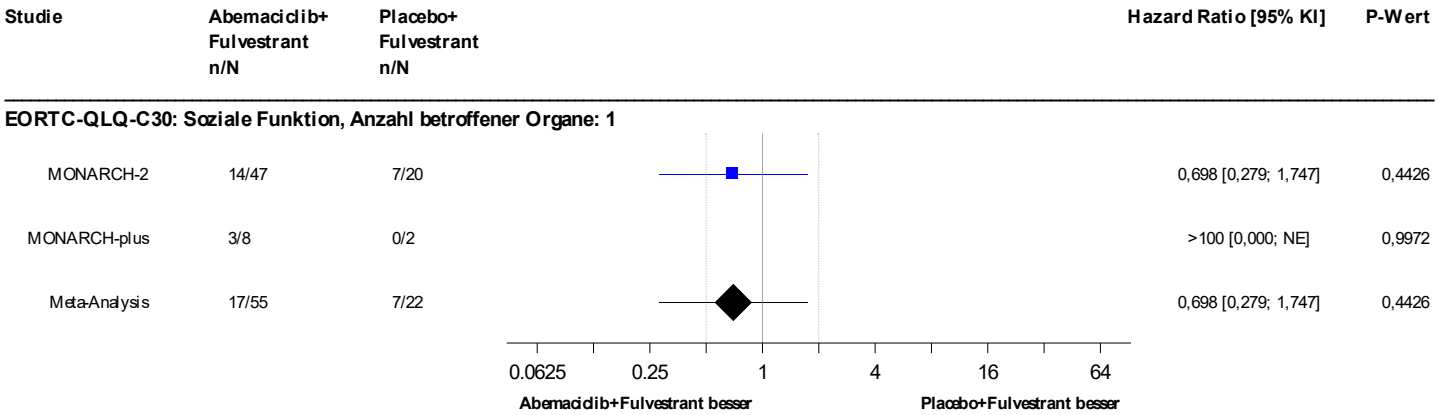
Abbildung 1418.2.2.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9971, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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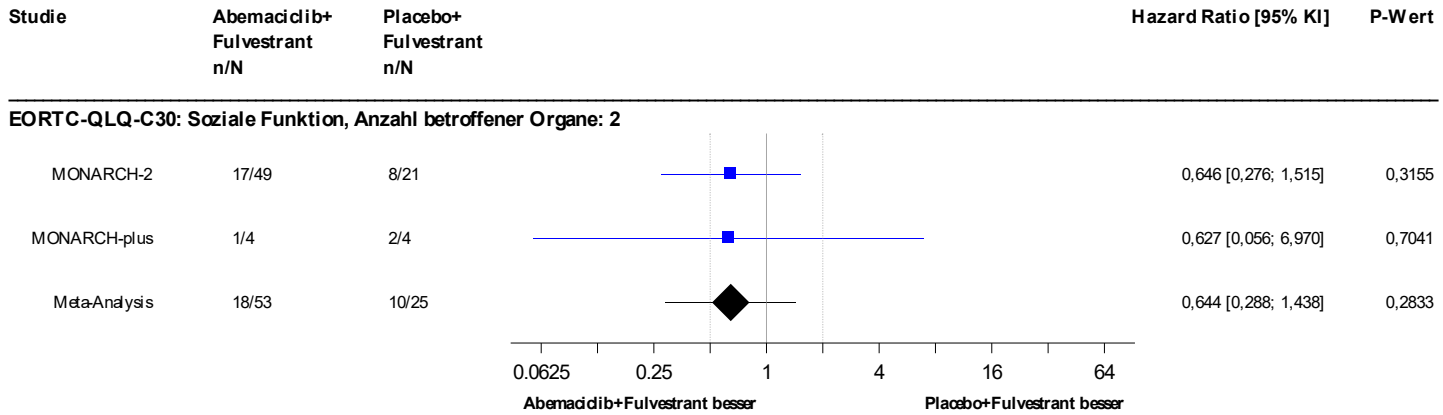
Abbildung 1418.2.2.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0005, P-Wert=0,9815, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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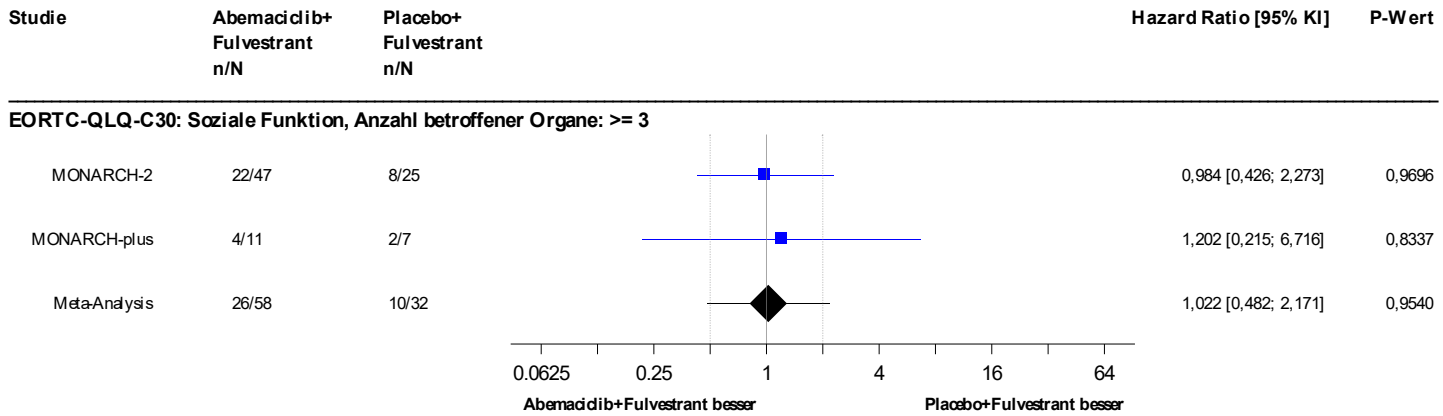
Abbildung 1418.2.2.3: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0422, P-Wert=0,8372, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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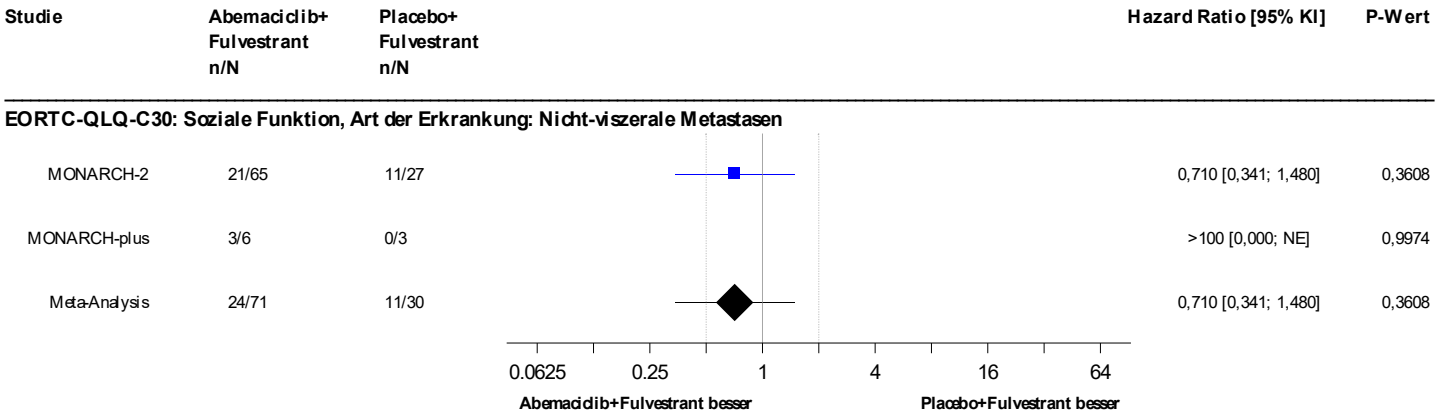
Abbildung 1418.2.3.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9974, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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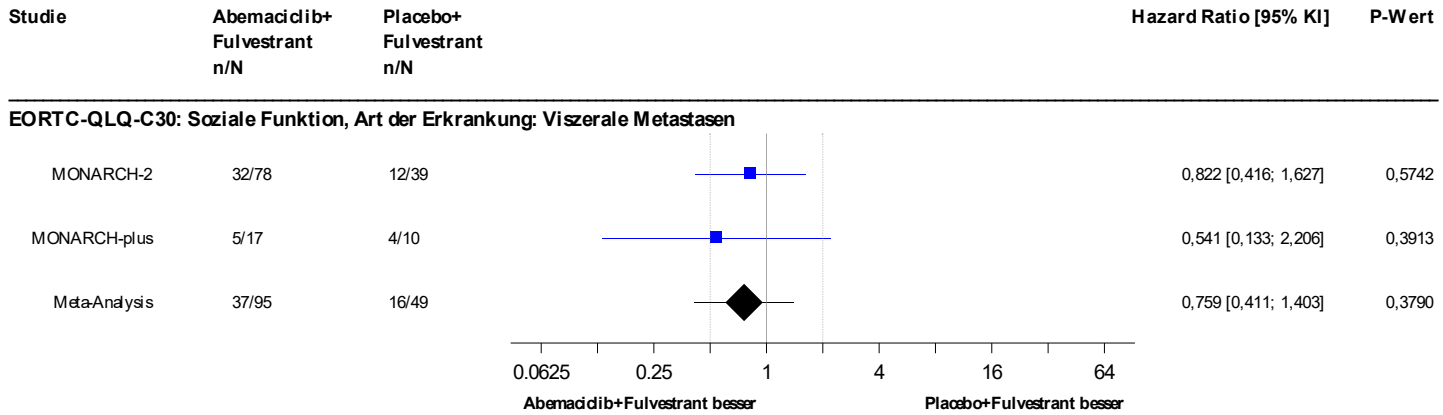
Abbildung 1418.2.3.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2766, P-Wert=0,5989, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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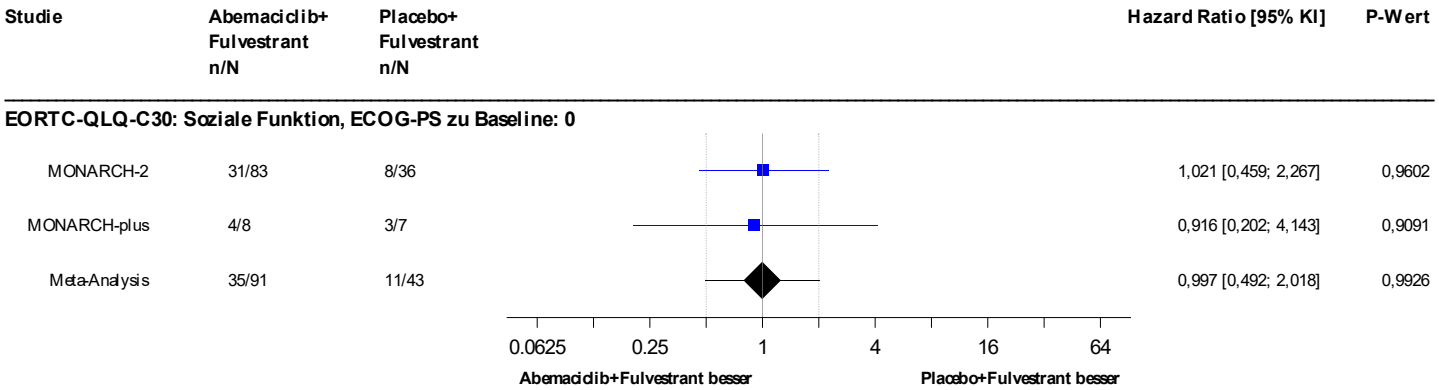
Abbildung 1418.2.4.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0154, P-Wert=0,9012, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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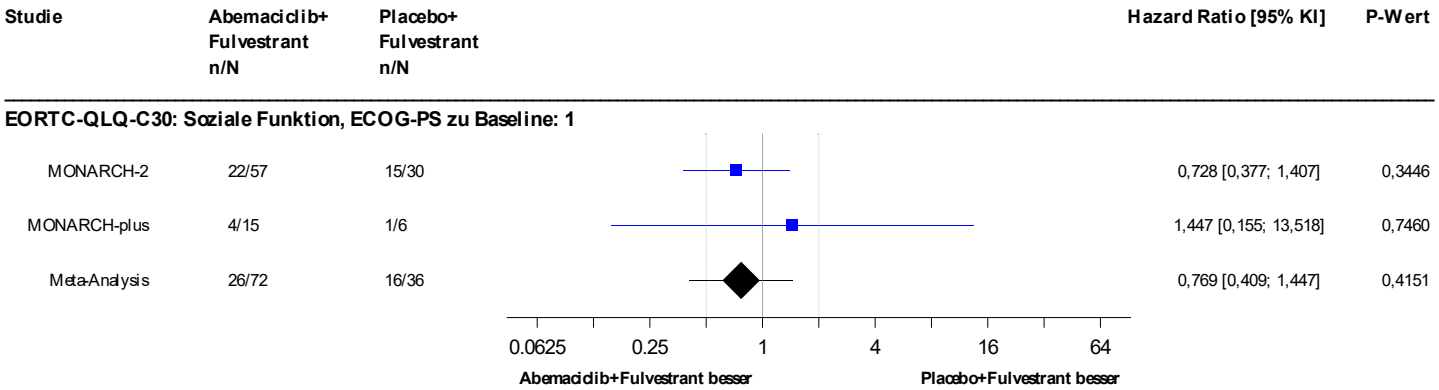
Abbildung 1418.2.4.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3340, P-Wert=0,5633, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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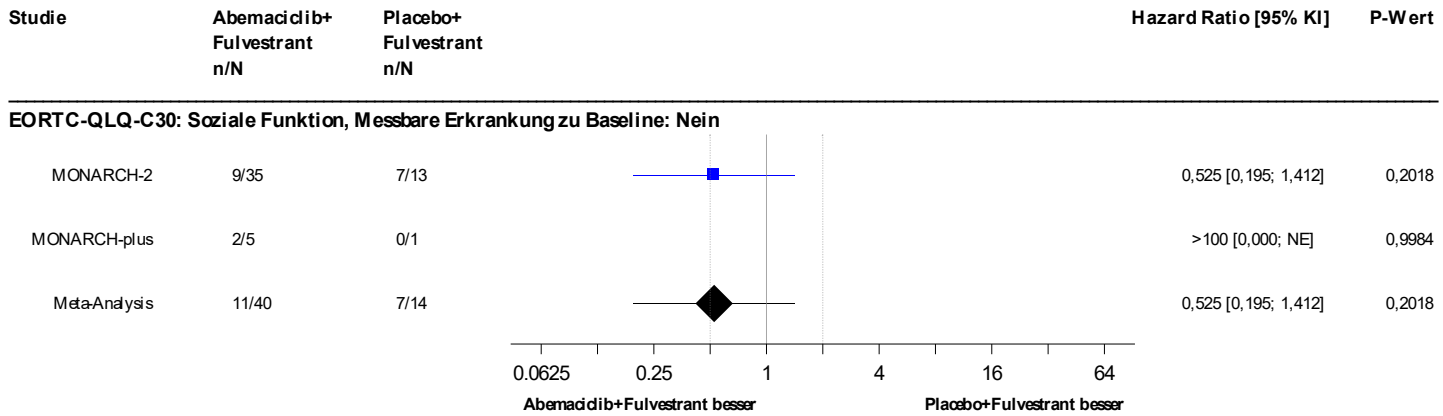
Abbildung 1418.2.6.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9983, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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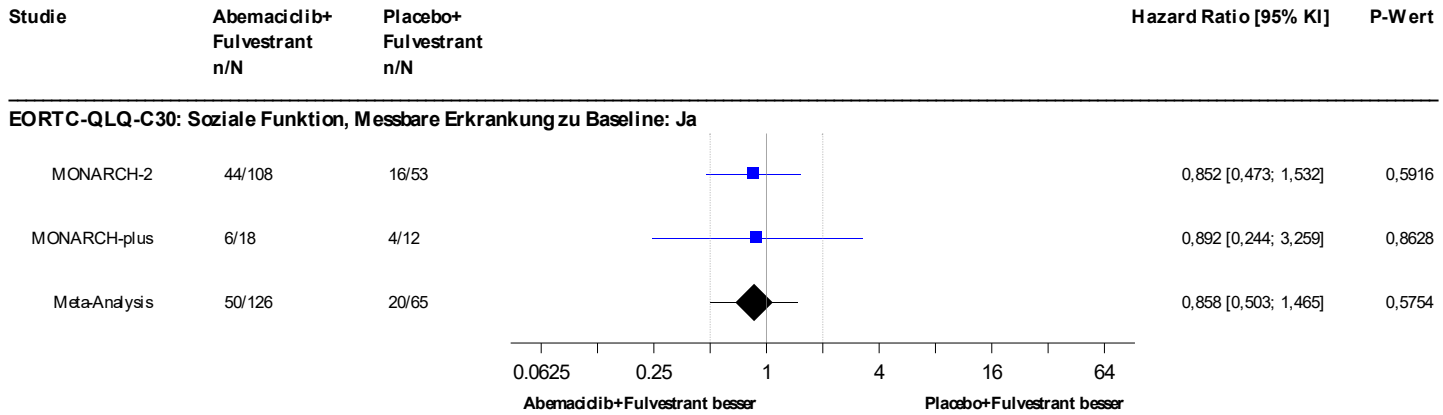
Abbildung 1418.2.6.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0041, P-Wert=0,9490, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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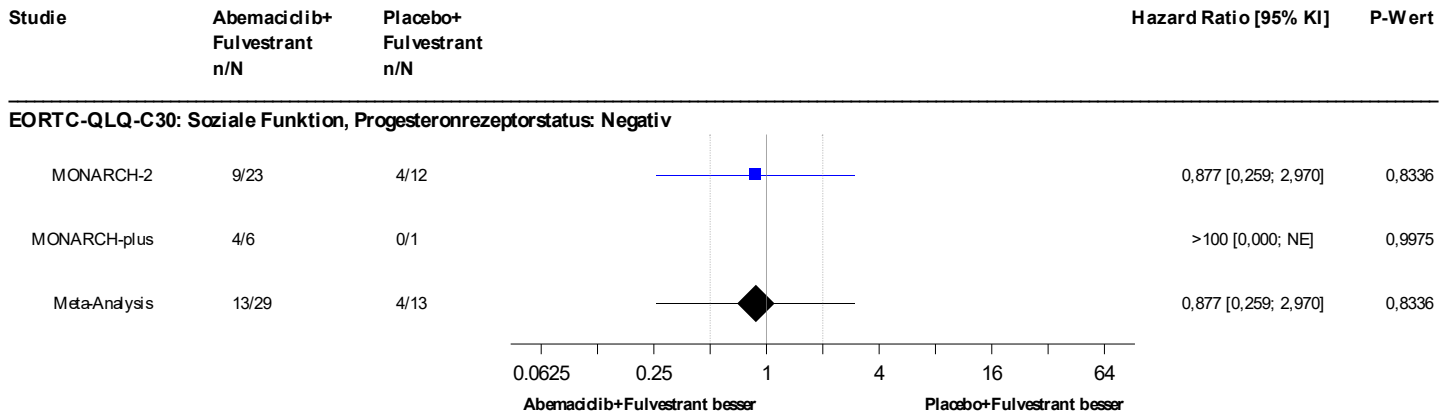
Abbildung 1418.2.7.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9975, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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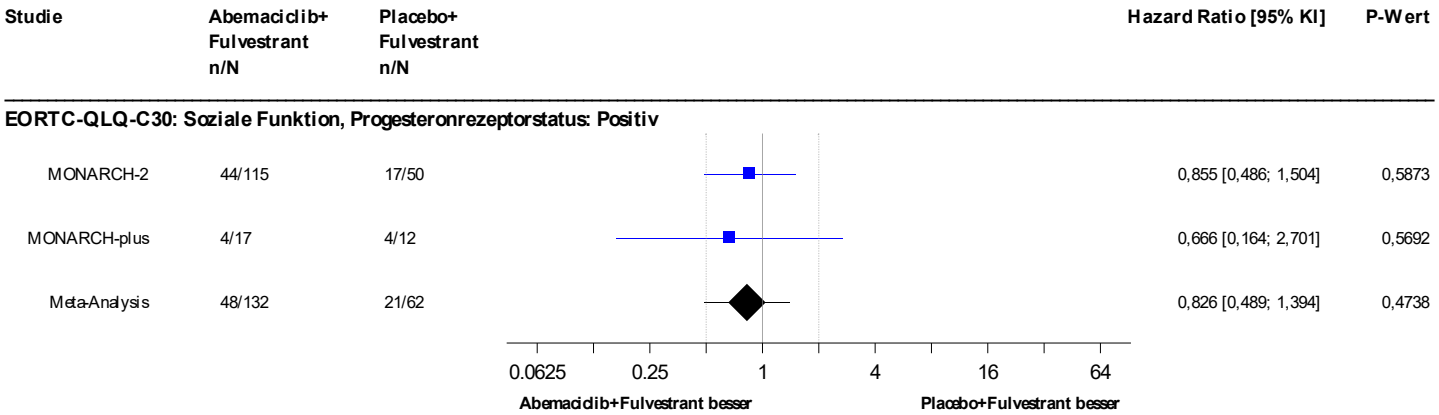
Abbildung 1418.2.7.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1057, P-Wert=0,7451, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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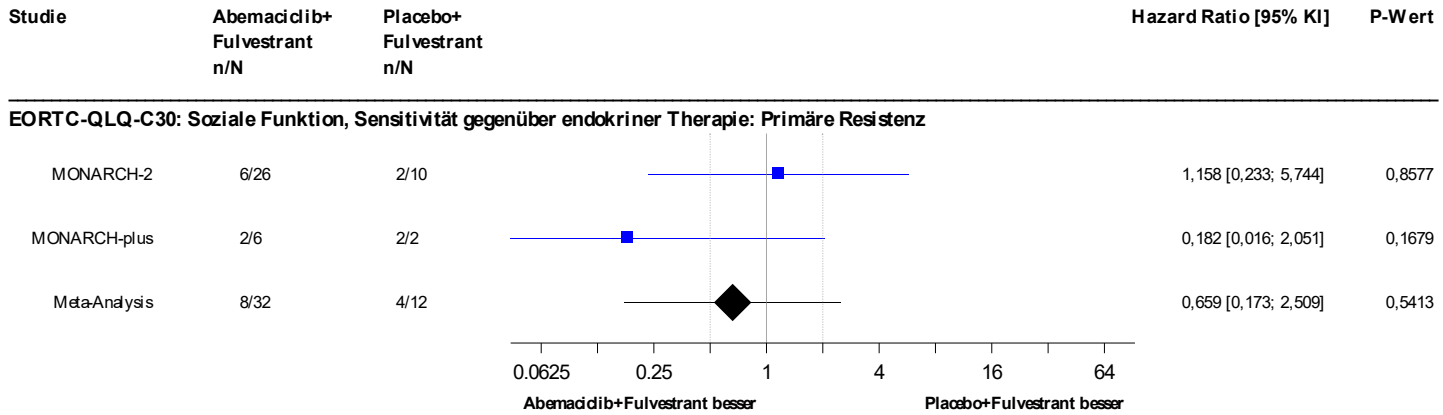
Abbildung 1418.2.8.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,5606, P-Wert=0,2116, I2 Index=35,9%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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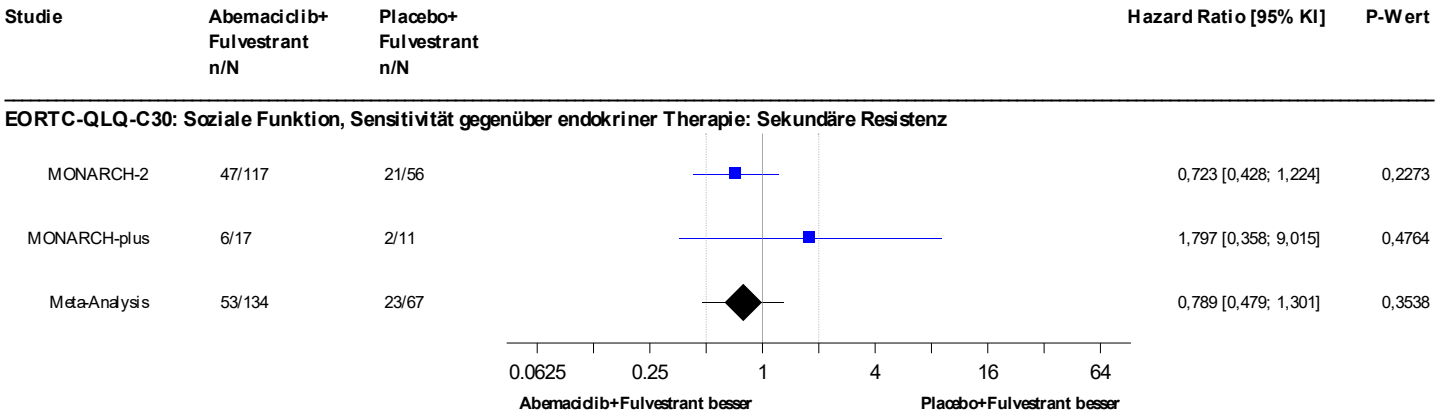
Abbildung 1418.2.8.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,1050, P-Wert=0,2932, I2 Index=9,5%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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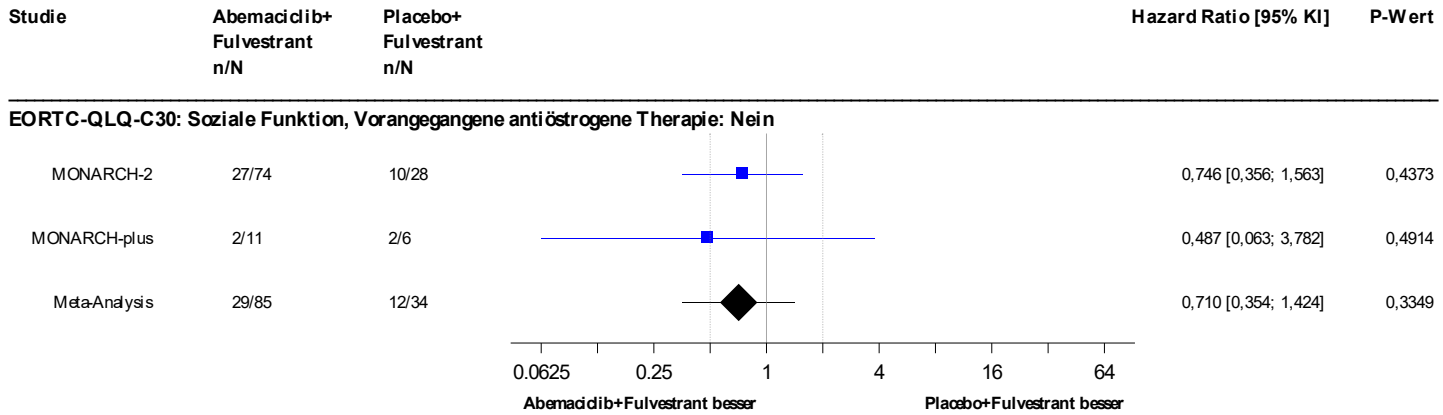
Abbildung 1418.2.9.1: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1470, P-Wert=0,7014, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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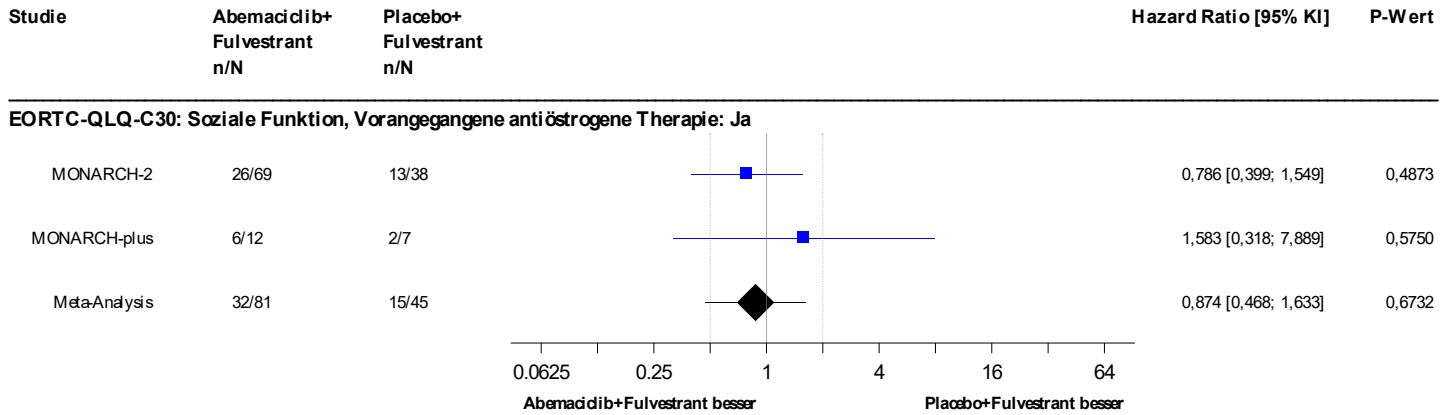
Abbildung 1418.2.9.2: Metaanalyse der Zeit bis zur dauerhaften Verschlechterung der EORTC-QLQ-C30 Funktionsskala Soziale Funktion (≥10 Punkte)
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,6190, P-Wert=0,4314, I2 Index=0%
Abkürzungen: EORTC: European Organisation for Research and Treatment of Cancer; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; QLQ-C30: Standardisiertes Instrument zur Messung der Lebensqualität.

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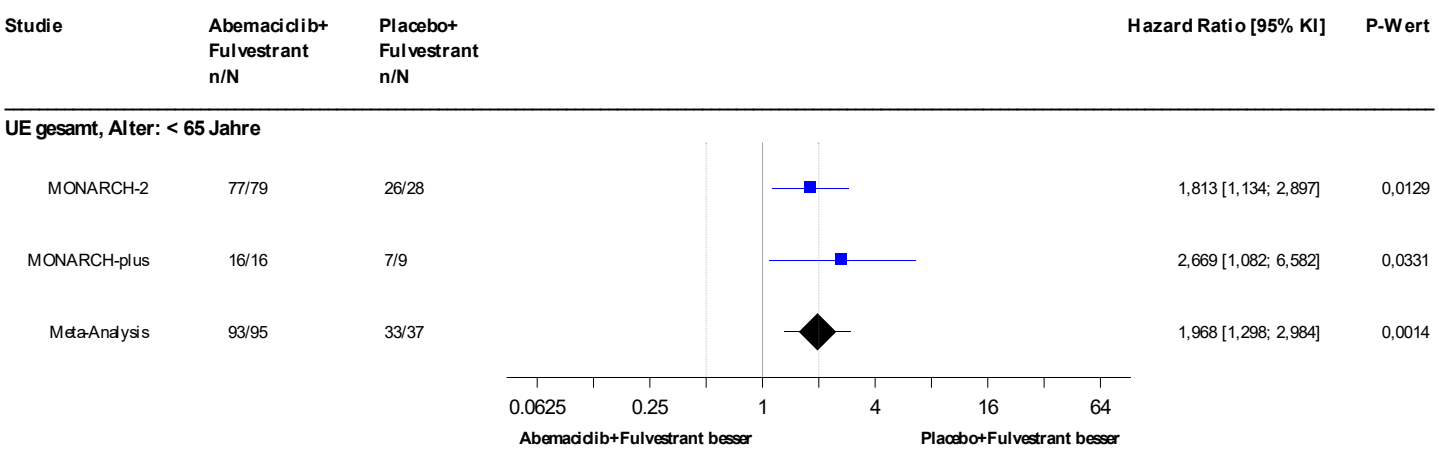
Abbildung 1419.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,5554, P-Wert=0,4561, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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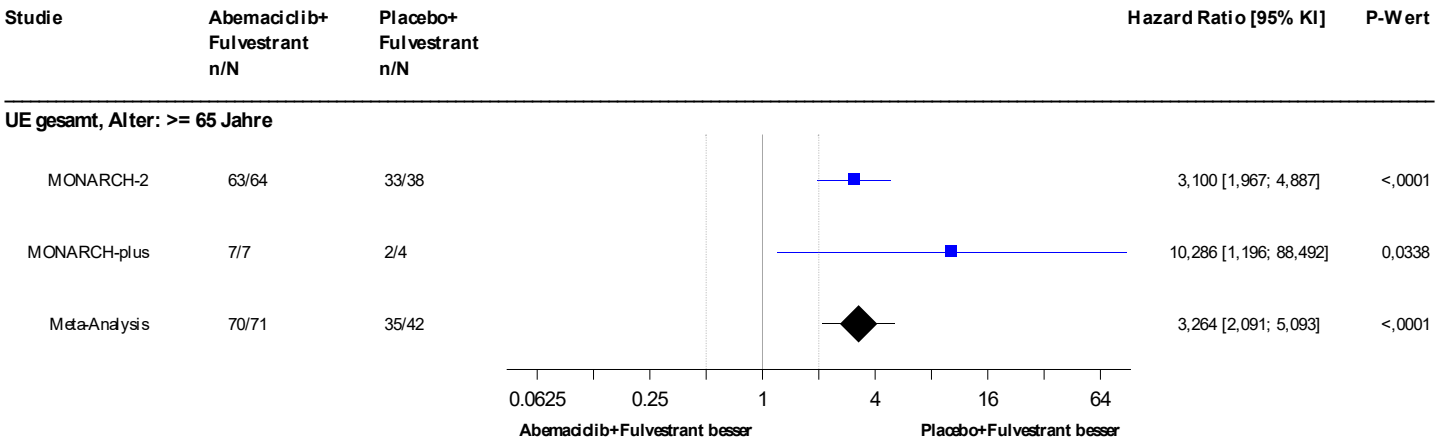
Abbildung 1419.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,1418, P-Wert=0,2853, I2 Index=12,4%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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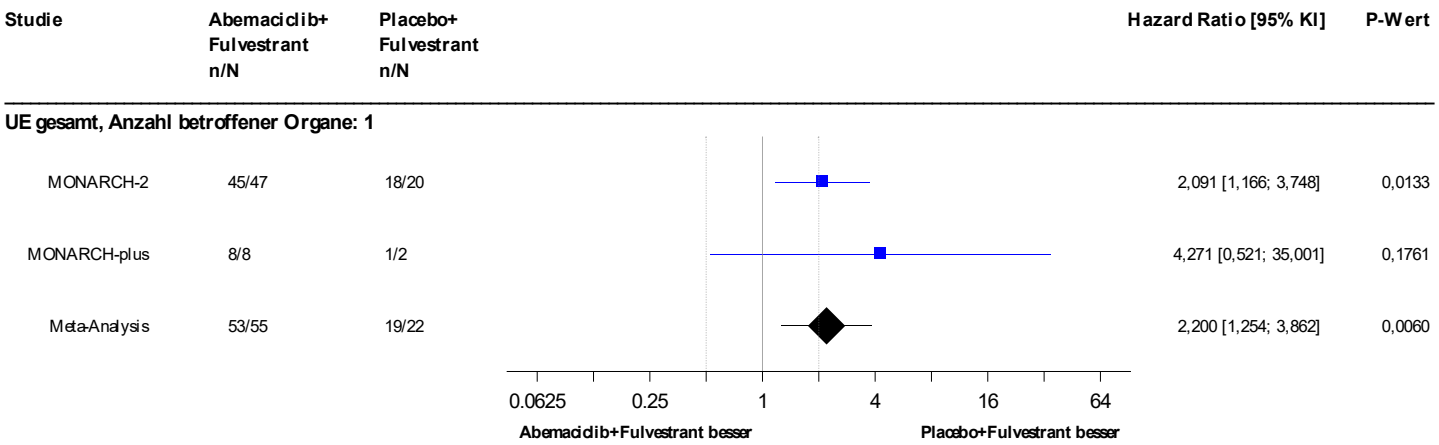
Abbildung 1419.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,4115, P-Wert=0,5212, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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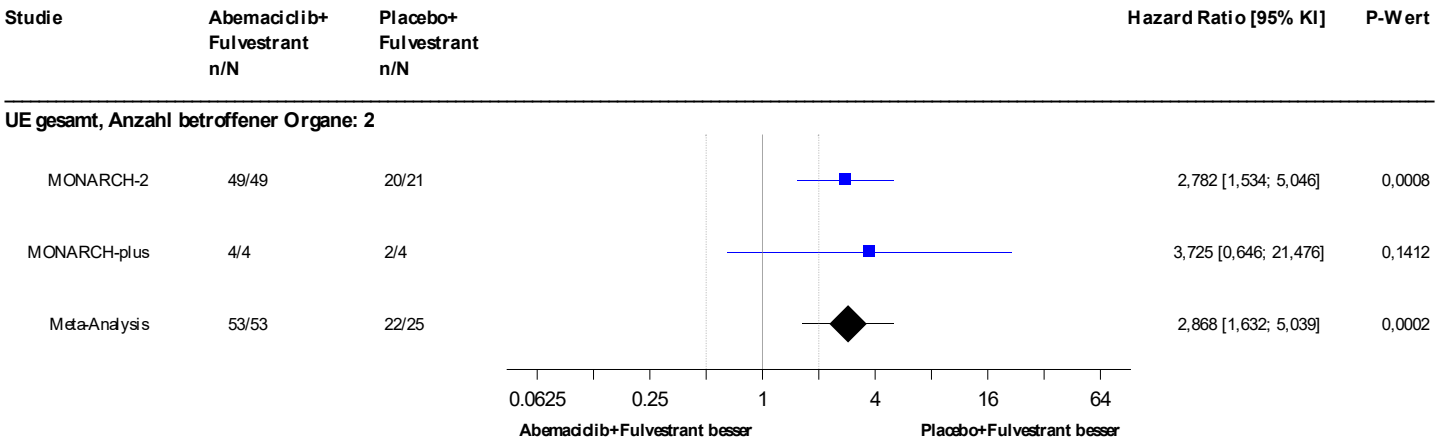
Abbildung 1419.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0956, P-Wert=0,7572, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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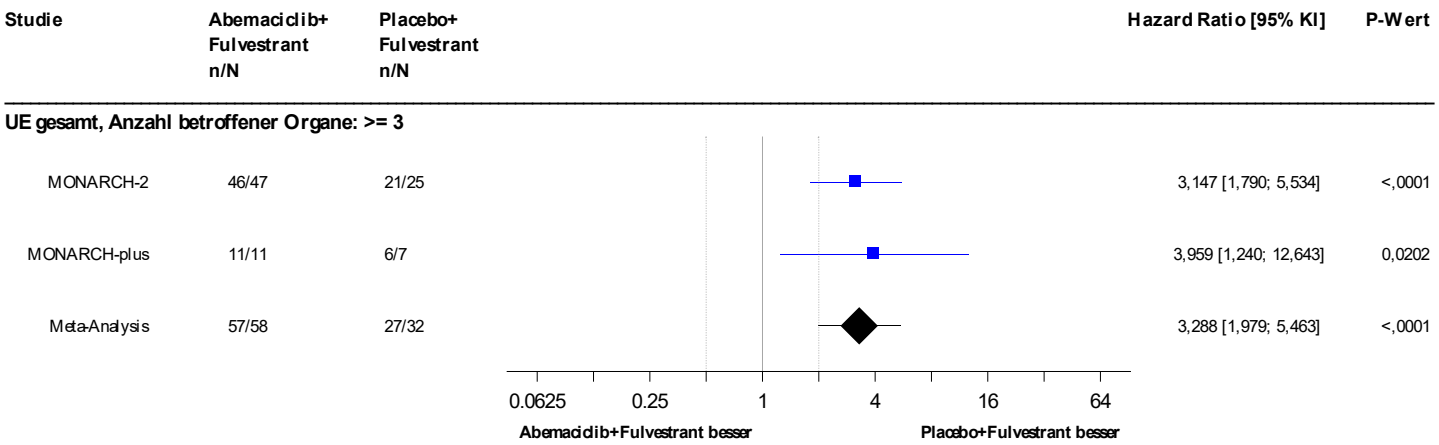
Abbildung 1419.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1213, P-Wert=0,7276, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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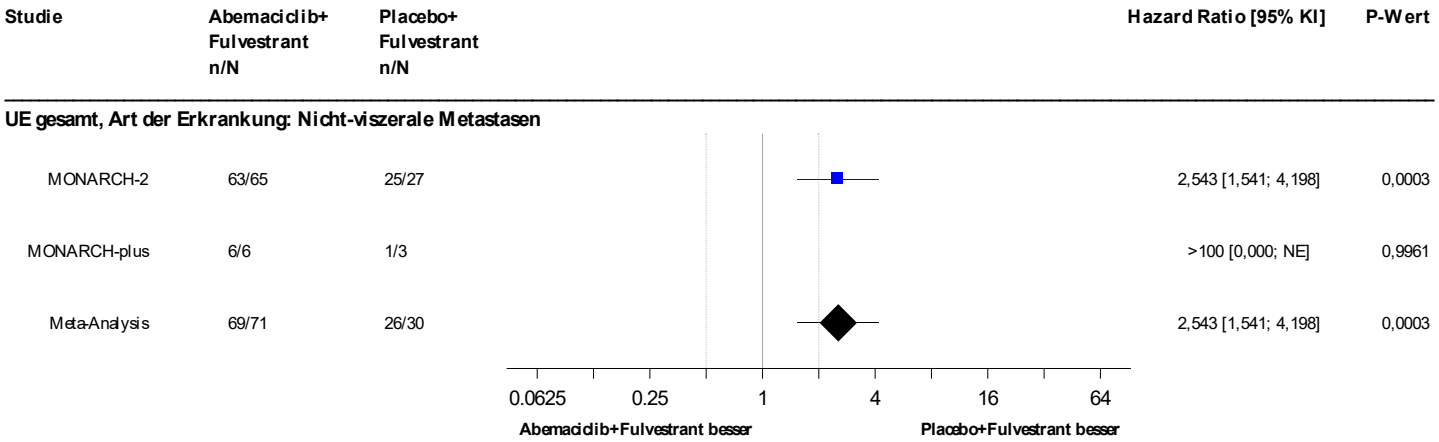
Abbildung 1419.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9963, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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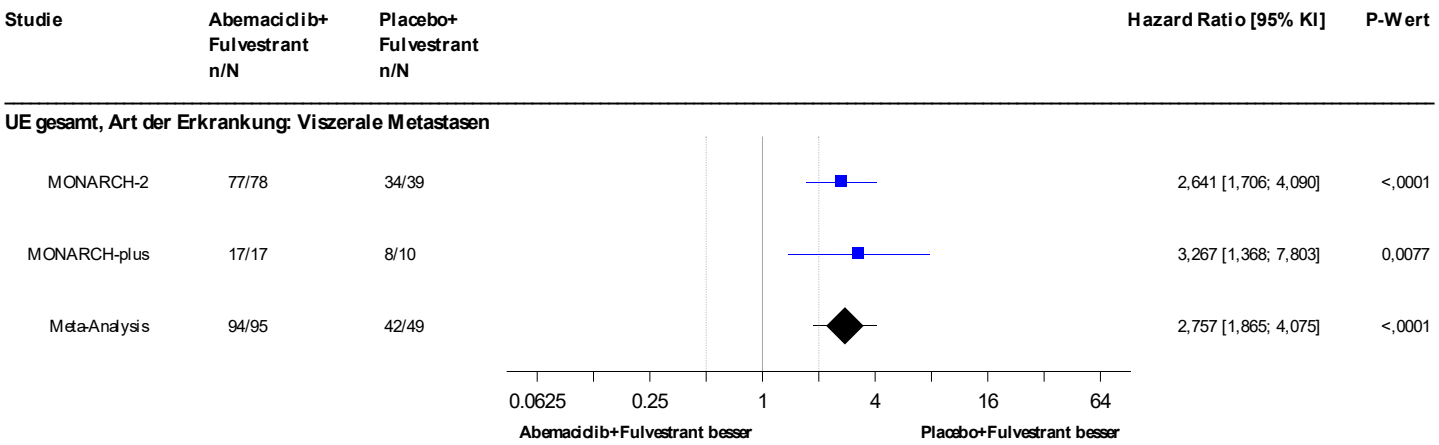
Abbildung 1419.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1830, P-Wert=0,6688, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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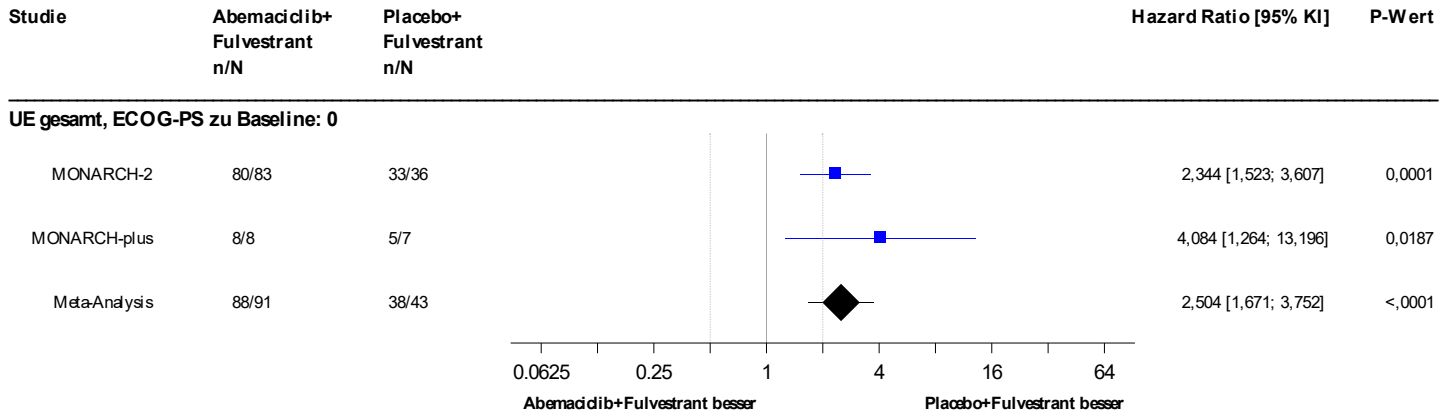
Abbildung 1419.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,7584, P-Wert=0,3838, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttteae_popa2_ecogbl_1.rtf
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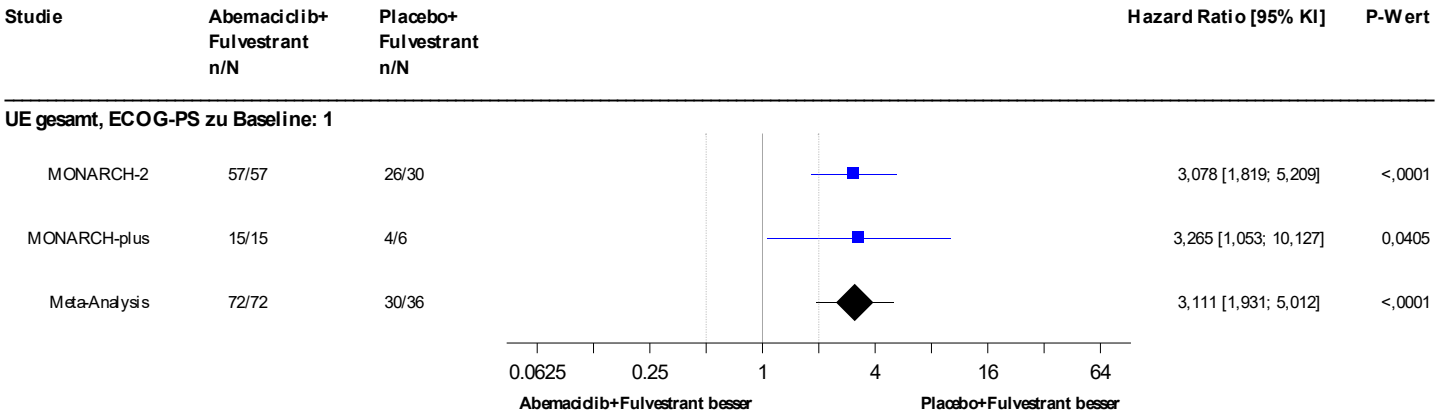
Abbildung 1419.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0085, P-Wert=0,9264, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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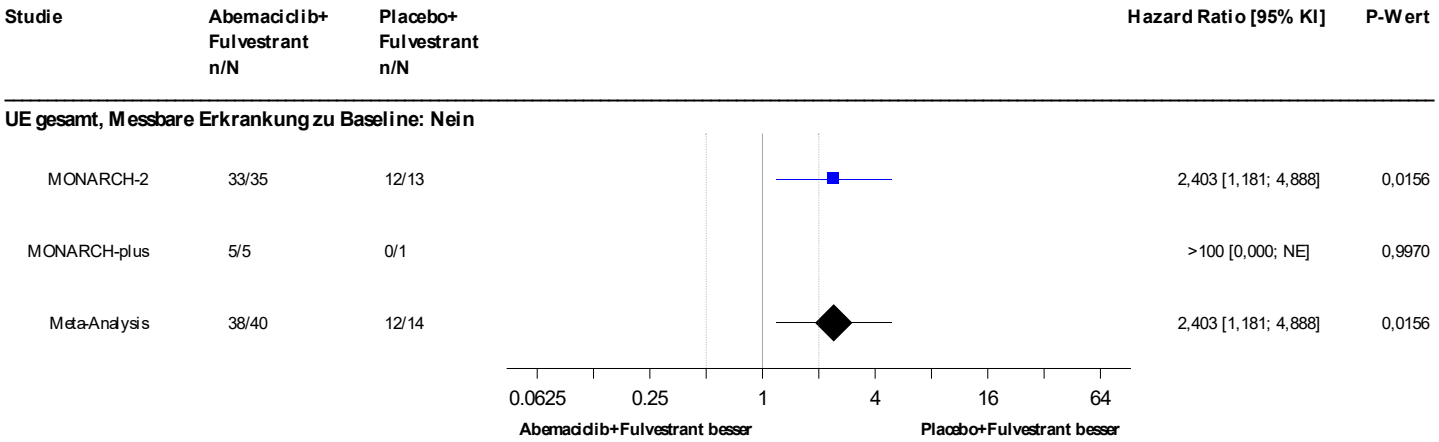
Abbildung 1419.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9971, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttteae_popa2_measdis_1.rtf
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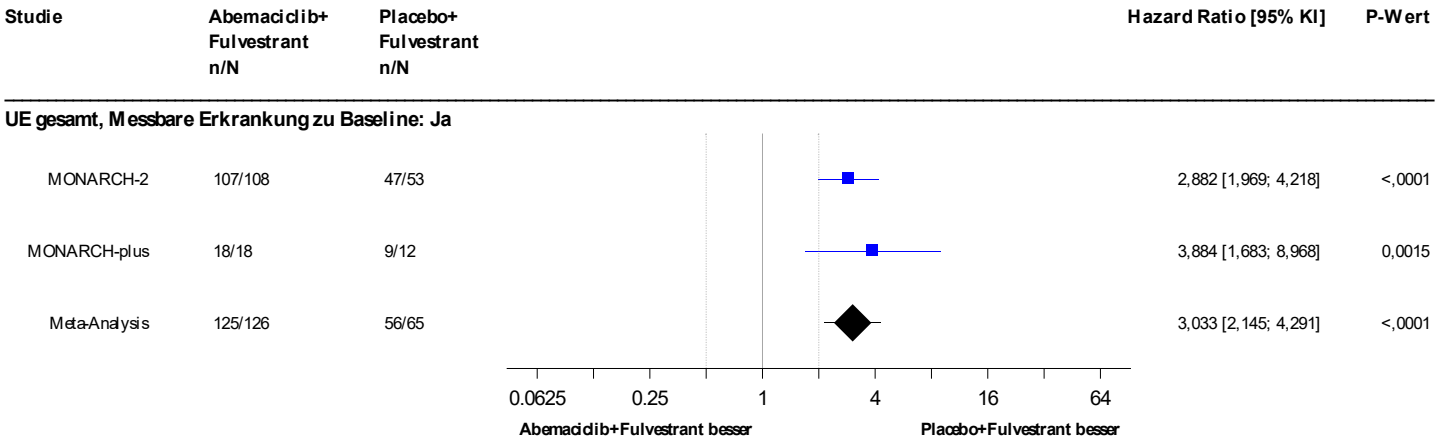
Abbildung 1419.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,4052, P-Wert=0,5244, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttteae_popa2_measdis_2.rtf
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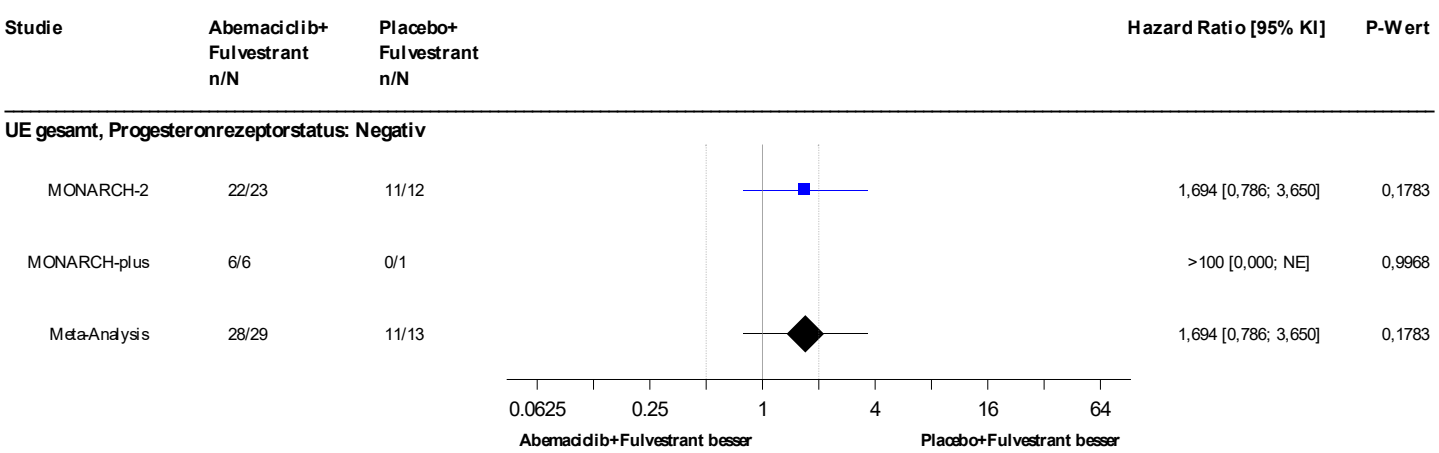
Abbildung 1419.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9969, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttteae_popa2_pgrstat_1.rtf
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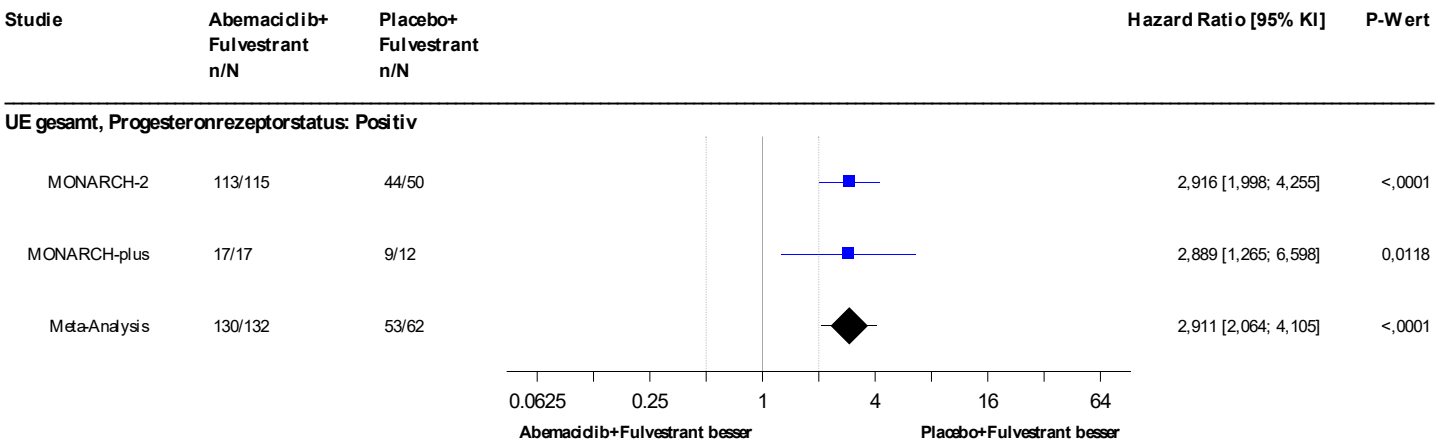
Abbildung 1419.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0004, P-Wert=0,9844, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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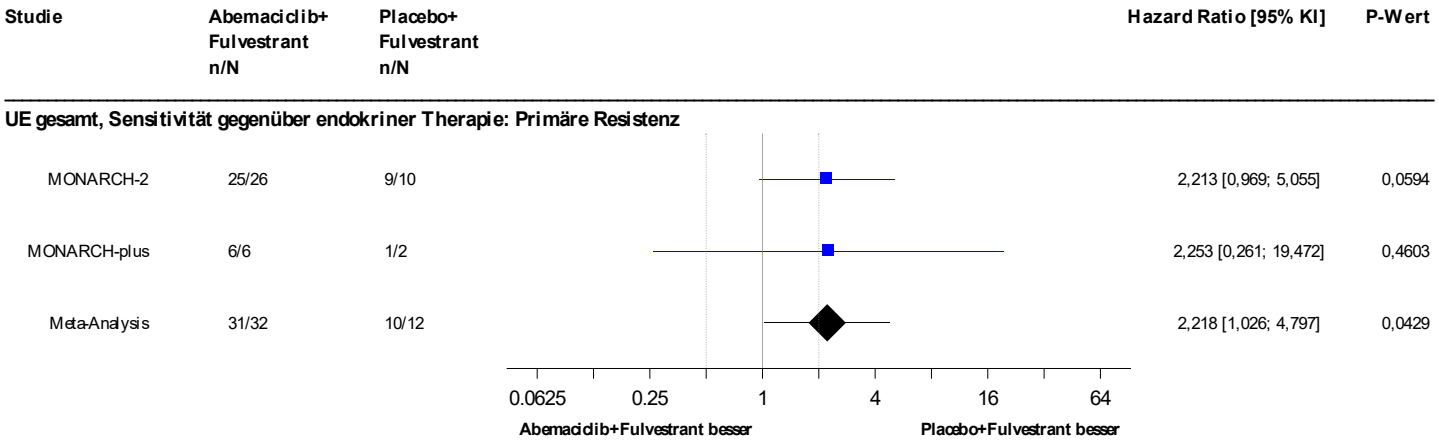
Abbildung 1419.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0002, P-Wert=0,9878, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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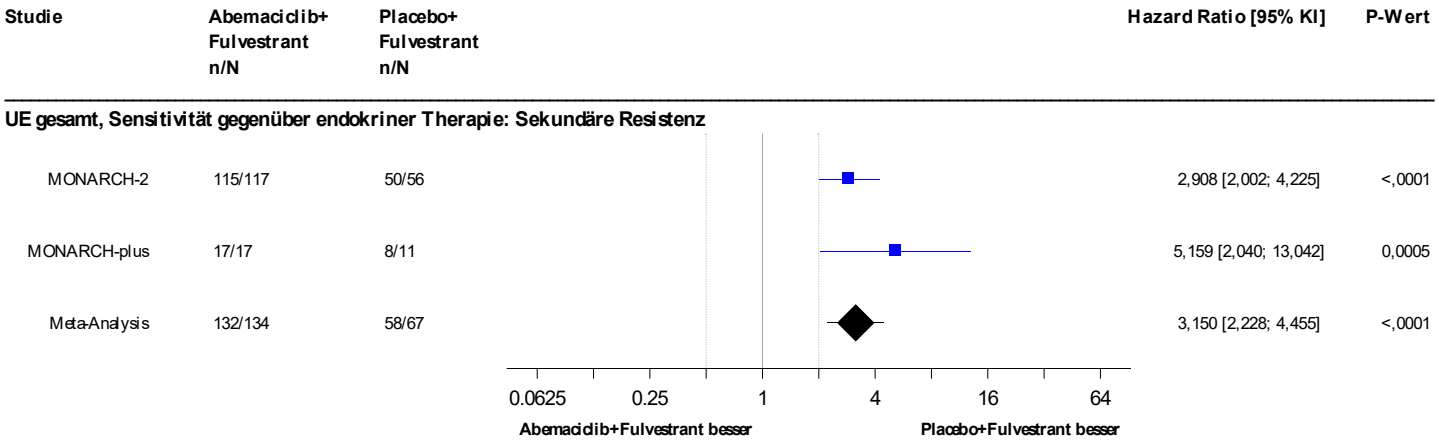
Abbildung 1419.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,2619, P-Wert=0,2613, I2 Index=20,8%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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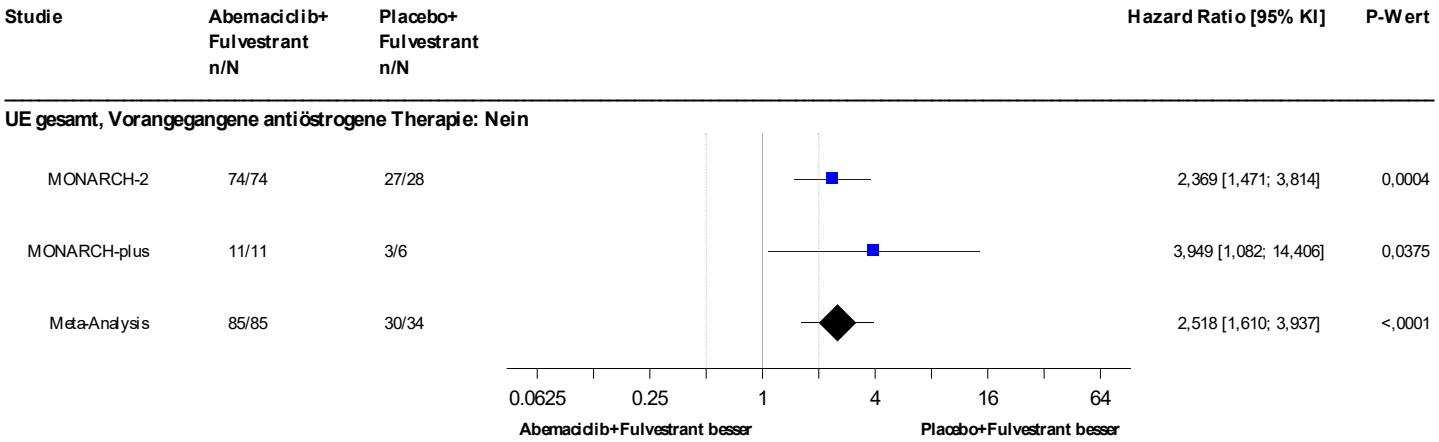
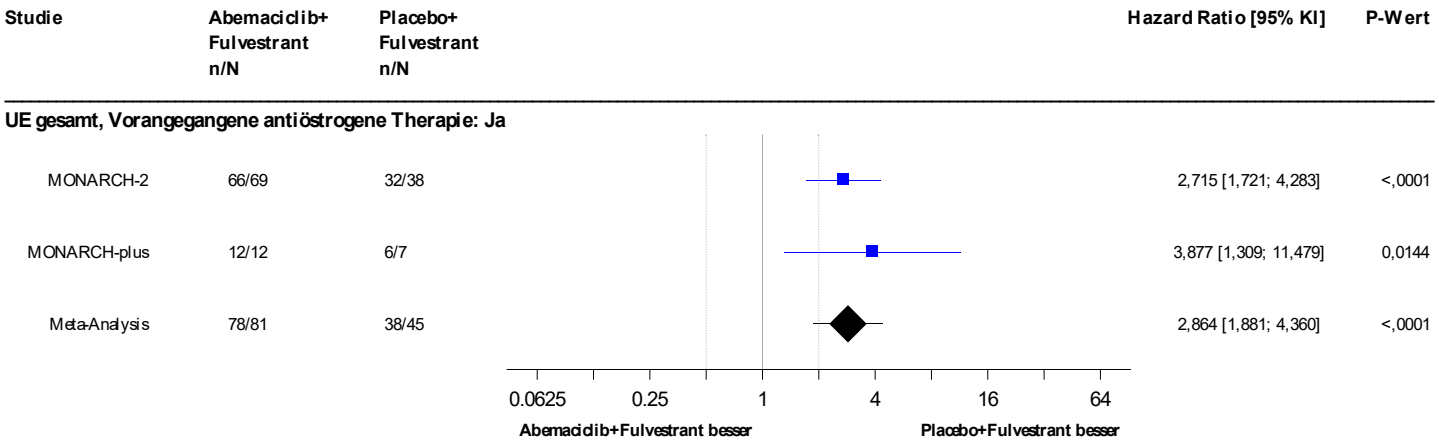
Abbildung 1419.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,5272, P-Wert=0,4678, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttteae_popa2_paet_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
17SEP2021 / 07:48

Abbildung 1419.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3515, P-Wert=0,5533, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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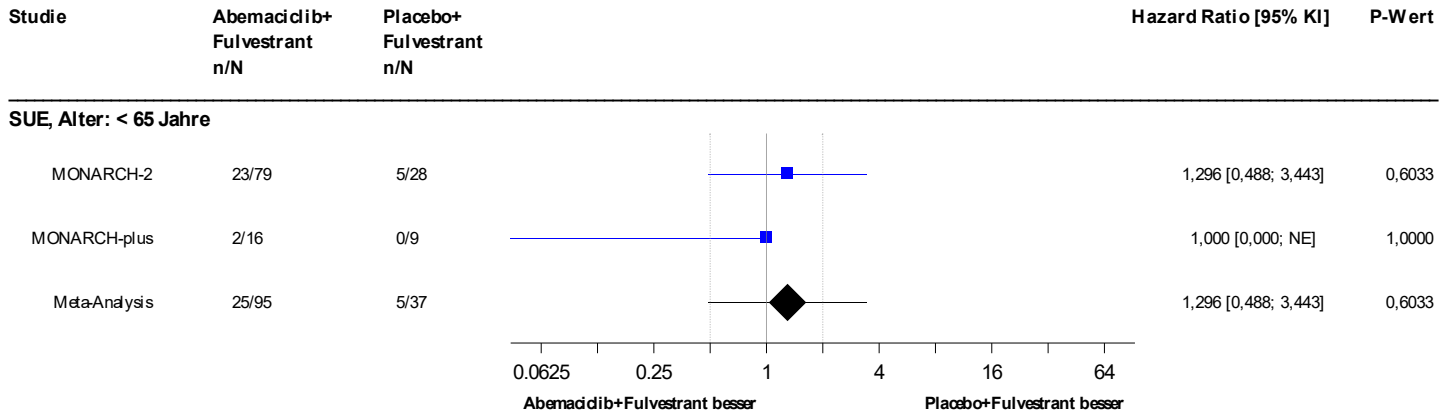
Abbildung 1420.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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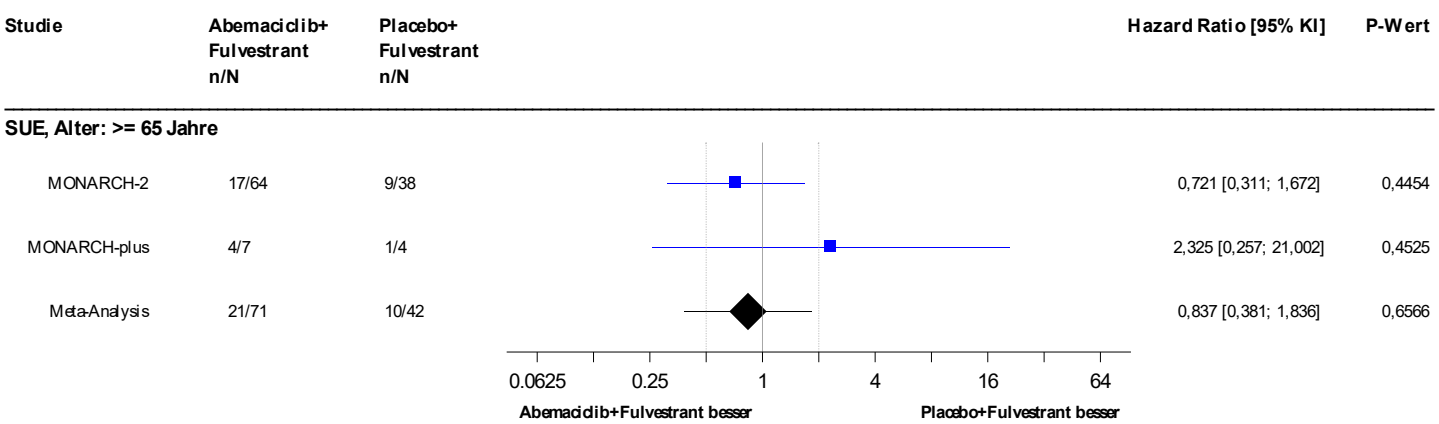
Abbildung 1420.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,9491, P-Wert=0,3300, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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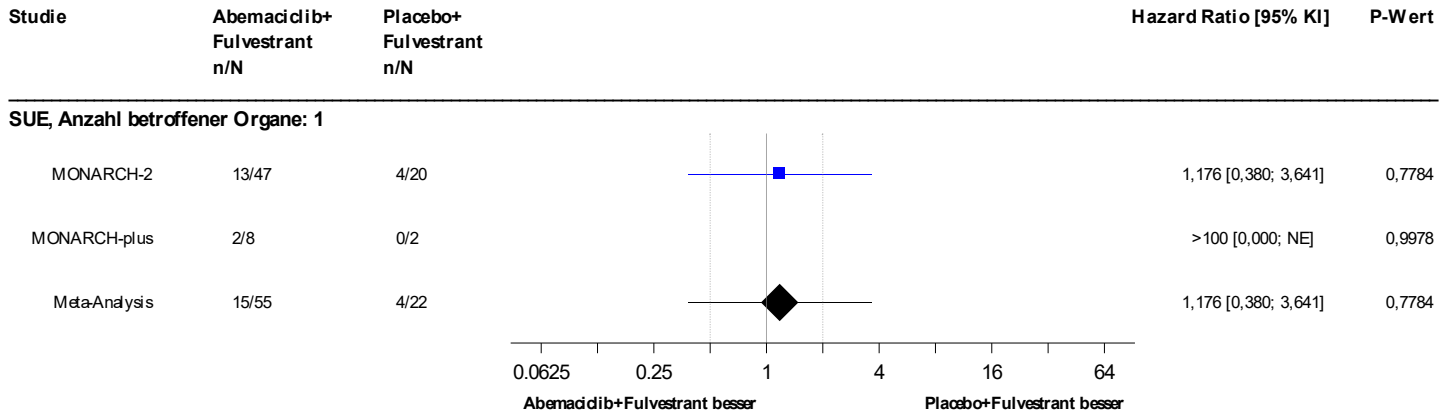
Abbildung 1420.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9979, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttsae_popa2_norggr_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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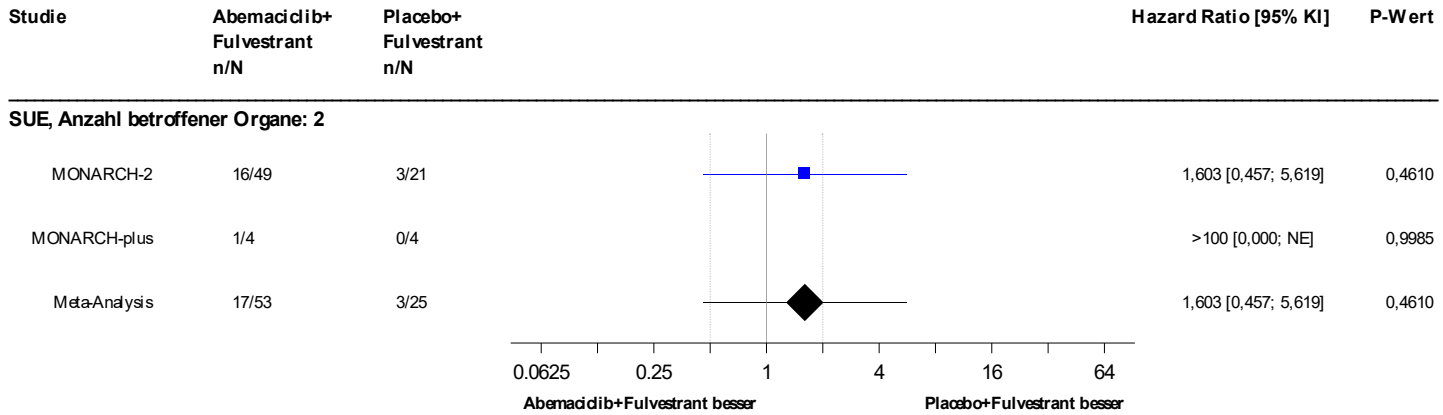
Abbildung 1420.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9986, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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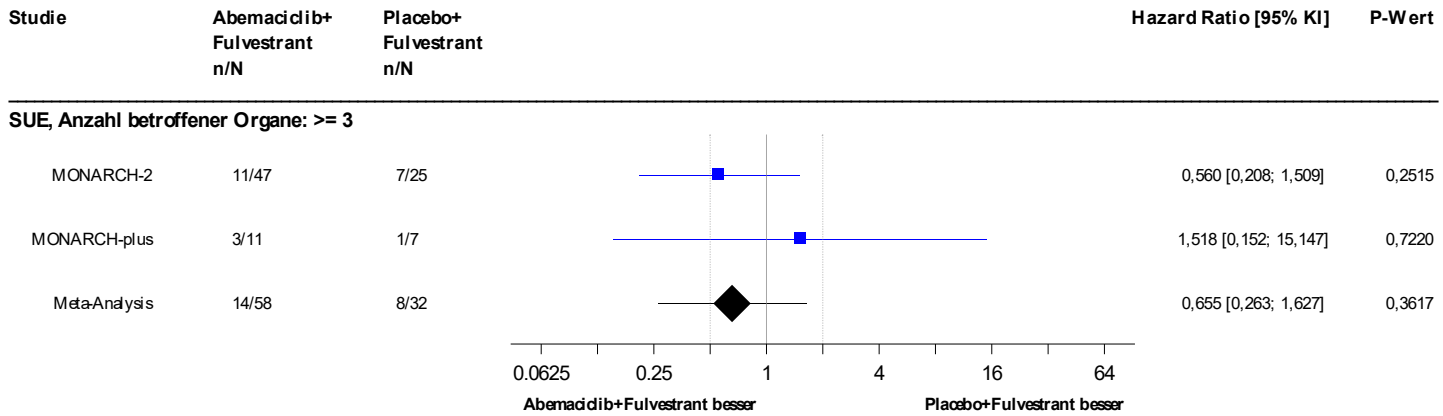
Abbildung 1420.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,6096, P-Wert=0,4350, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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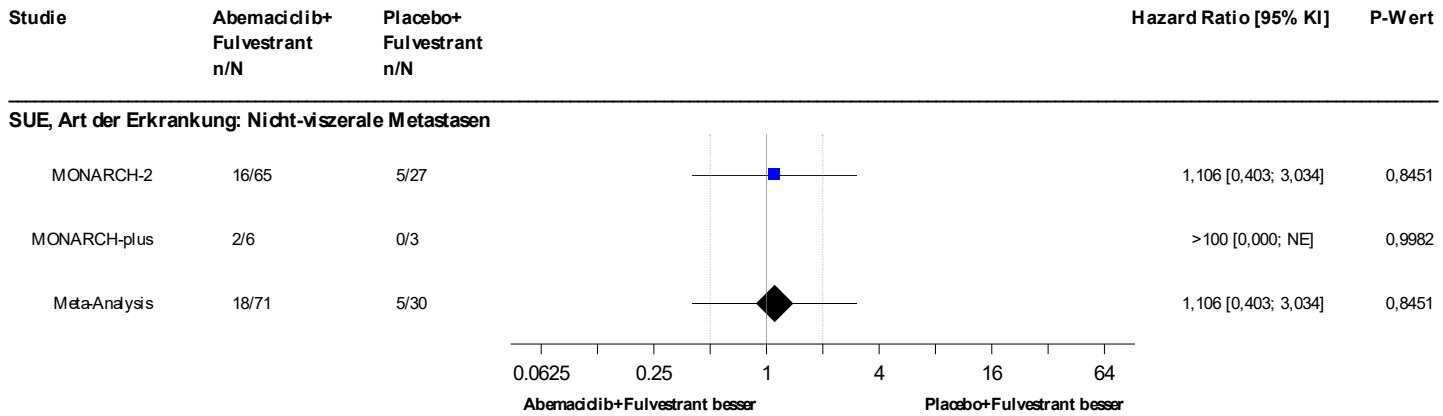
Abbildung 1420.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9982, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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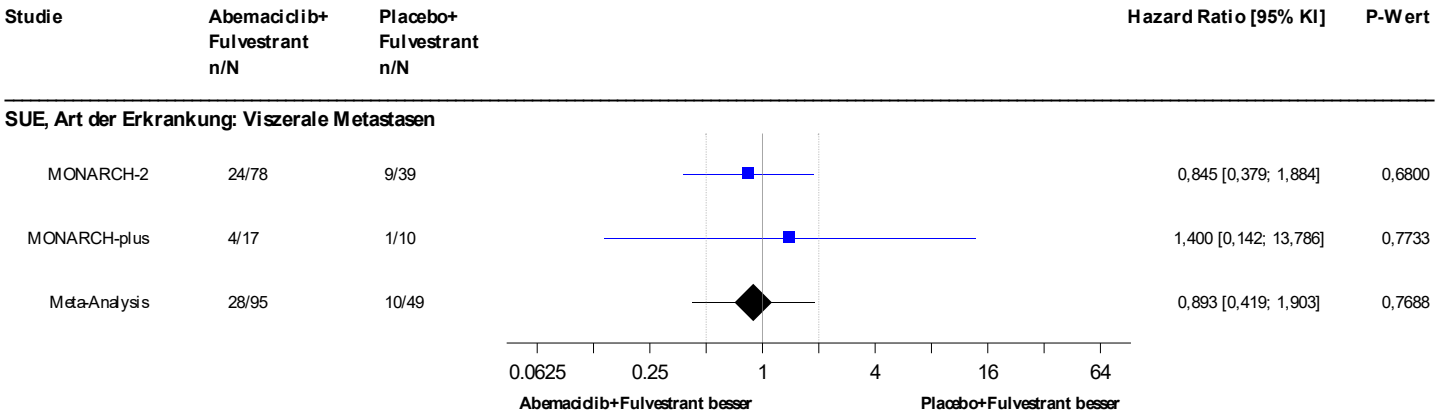
Abbildung 1420.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1667, P-Wert=0,6831, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttsae_popa2_natdis2_2.rtf
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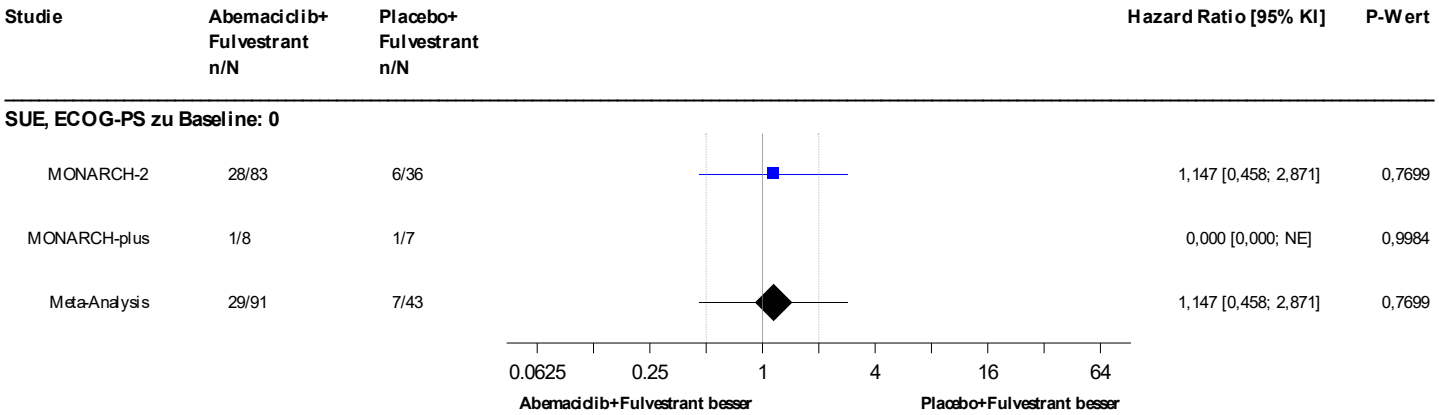
Abbildung 1420.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9984, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttsae_popa2_ecogbl_1.rtf
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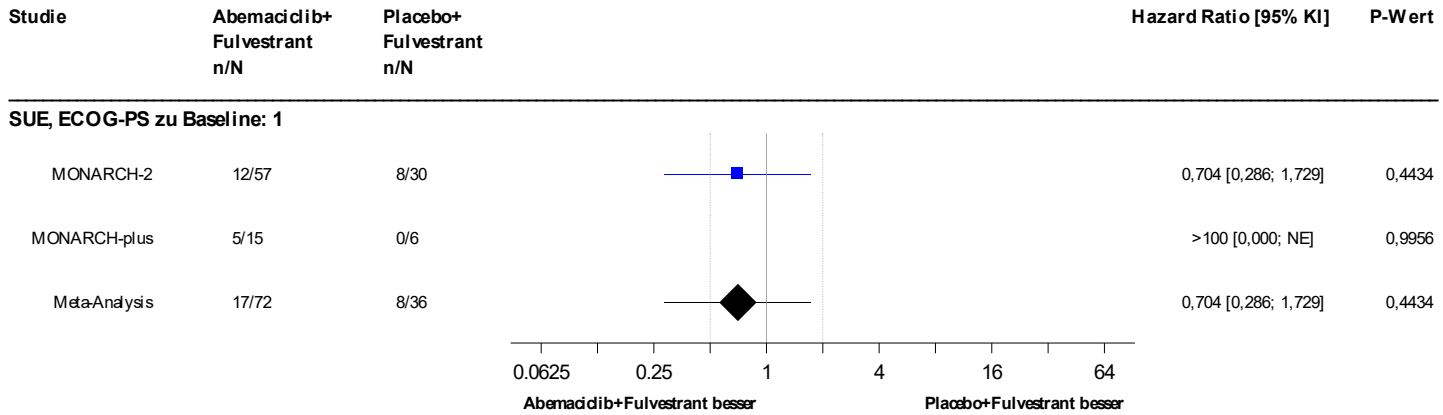
17SEP2021 / 07:48

Abbildung 1420.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9955, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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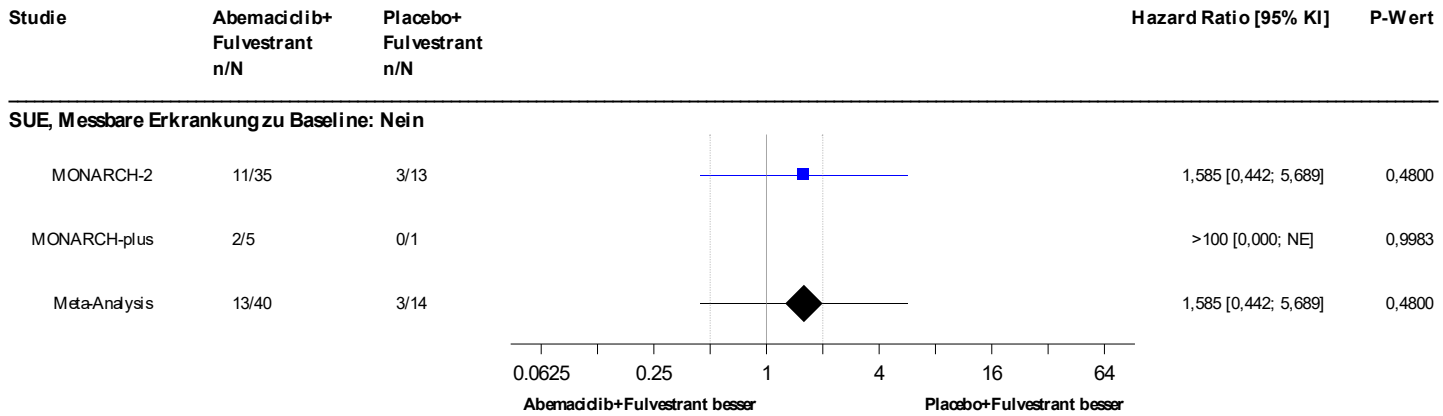
Abbildung 1420.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9984, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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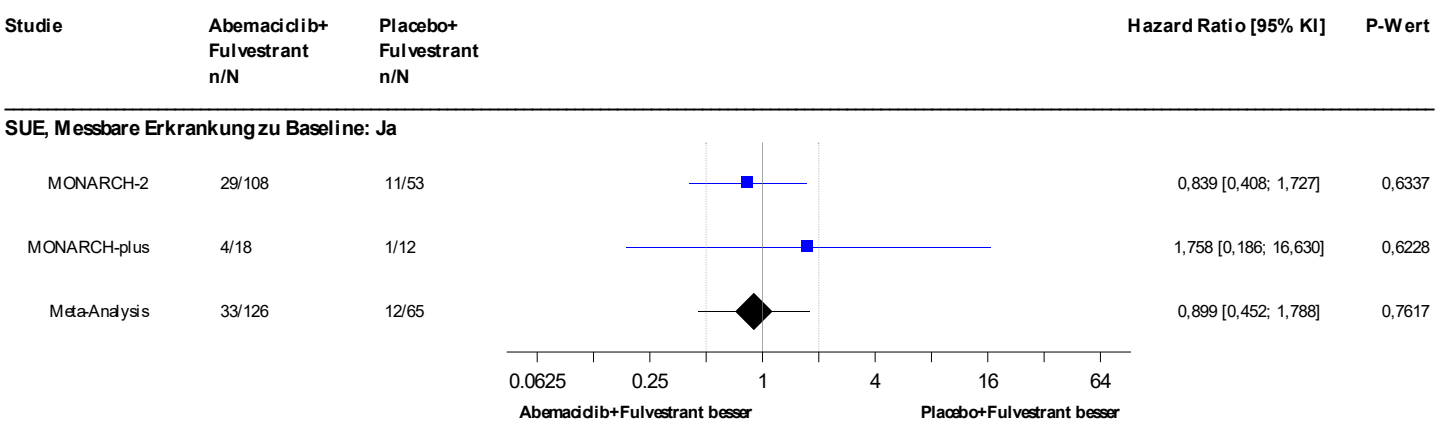
Abbildung 1420.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3772, P-Wert=0,5391, I2 Index=0%
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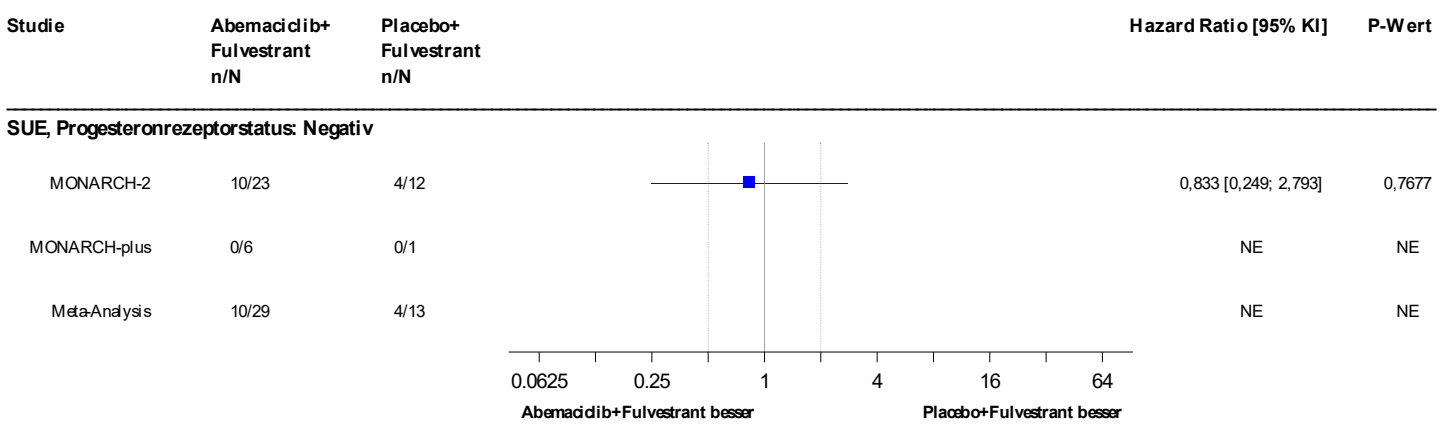
Abbildung 1420.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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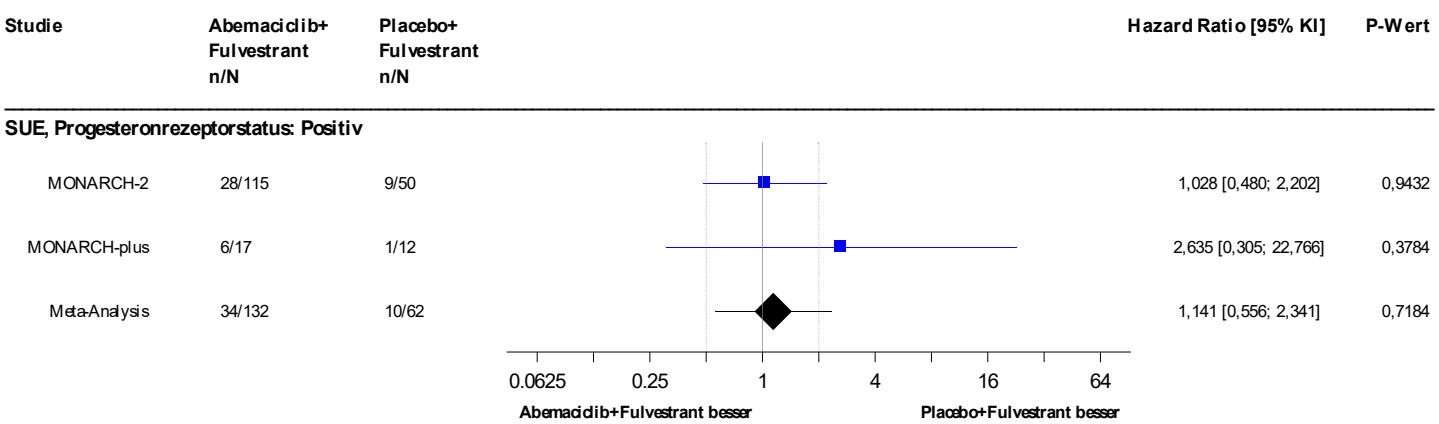
Abbildung 1420.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,6508, P-Wert=0,4198, I2 Index=0%
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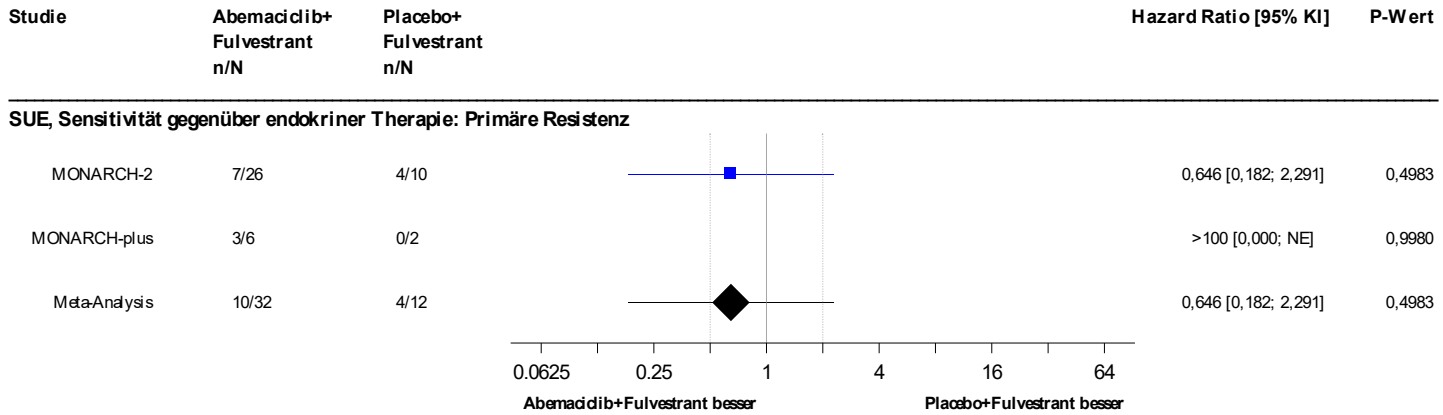
Abbildung 1420.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9979, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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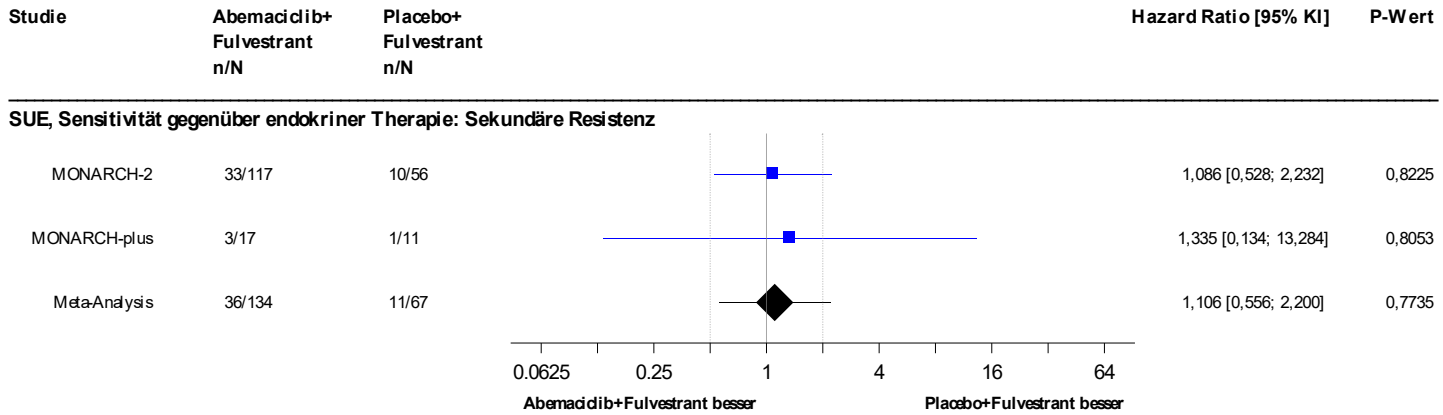
Abbildung 1420.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0282, P-Wert=0,8666, I2 Index=0%
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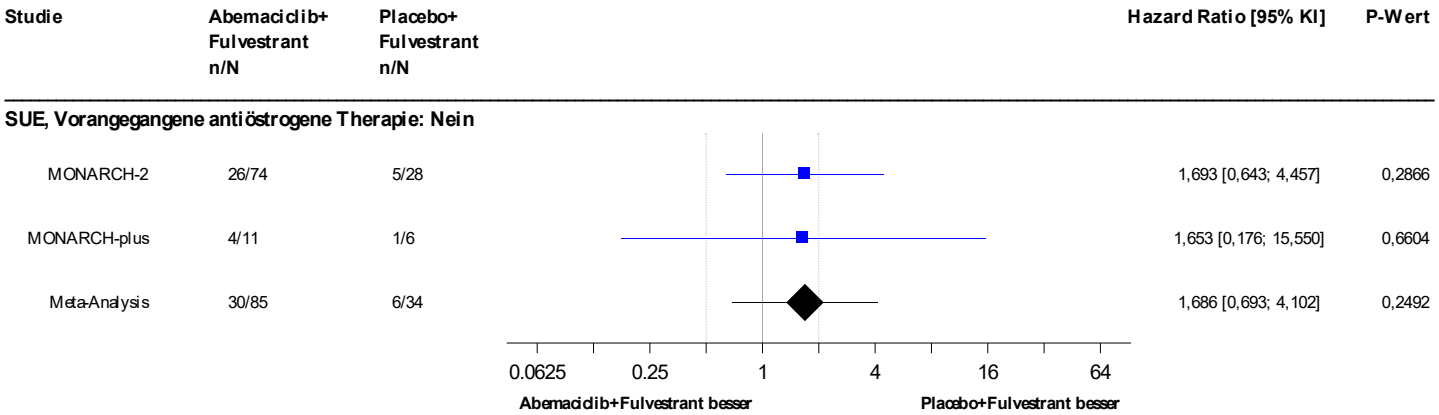
Abbildung 1420.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0004, P-Wert=0,9847, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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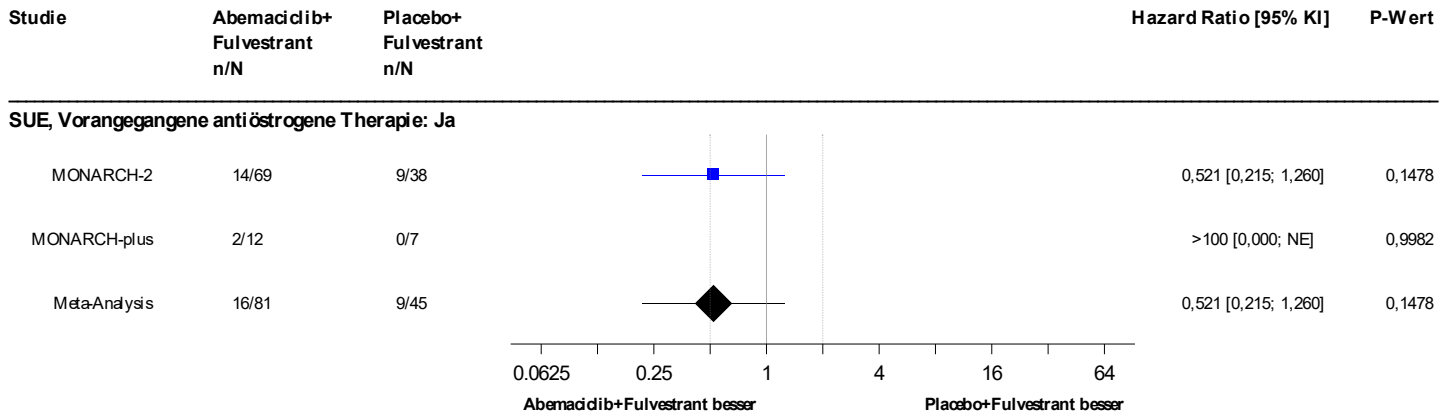
Abbildung 1420.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SUE: Schwerwiegendes unerwünschtes Ereignis.

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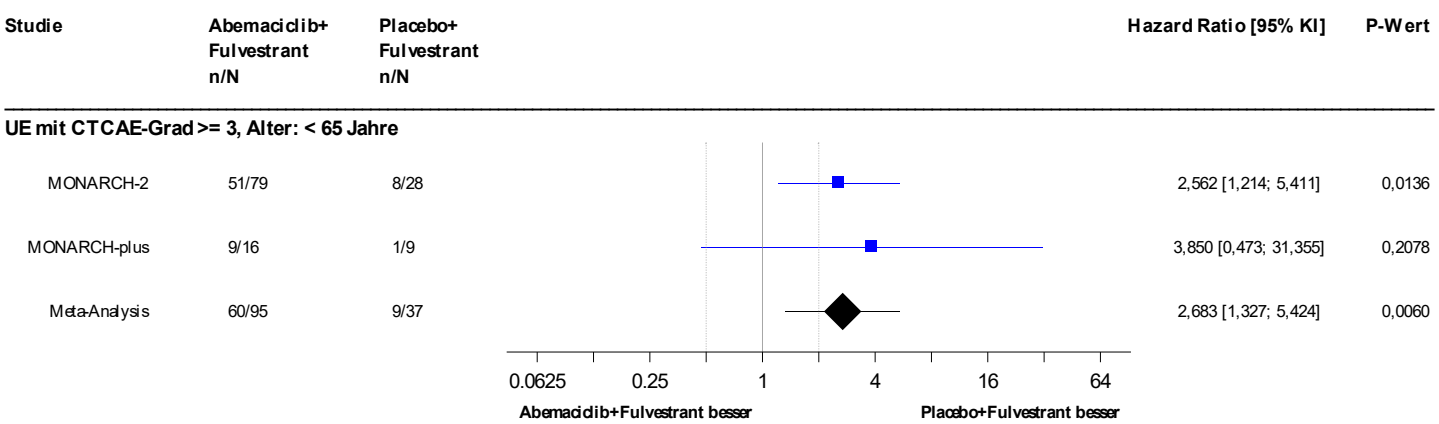
Abbildung 1421.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1284, P-Wert=0,7201, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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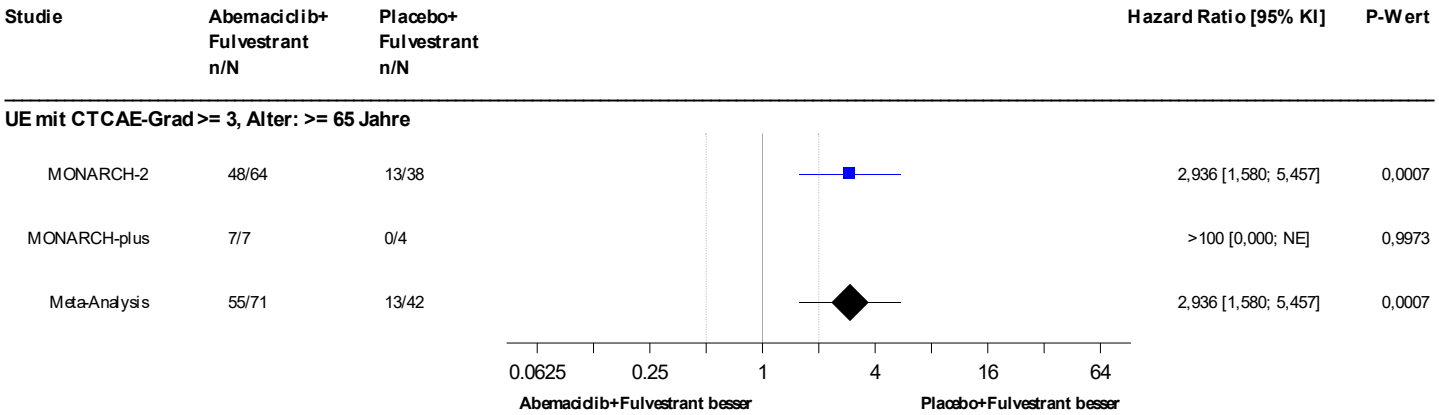
Abbildung 1421.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9974, I2 Index=0%
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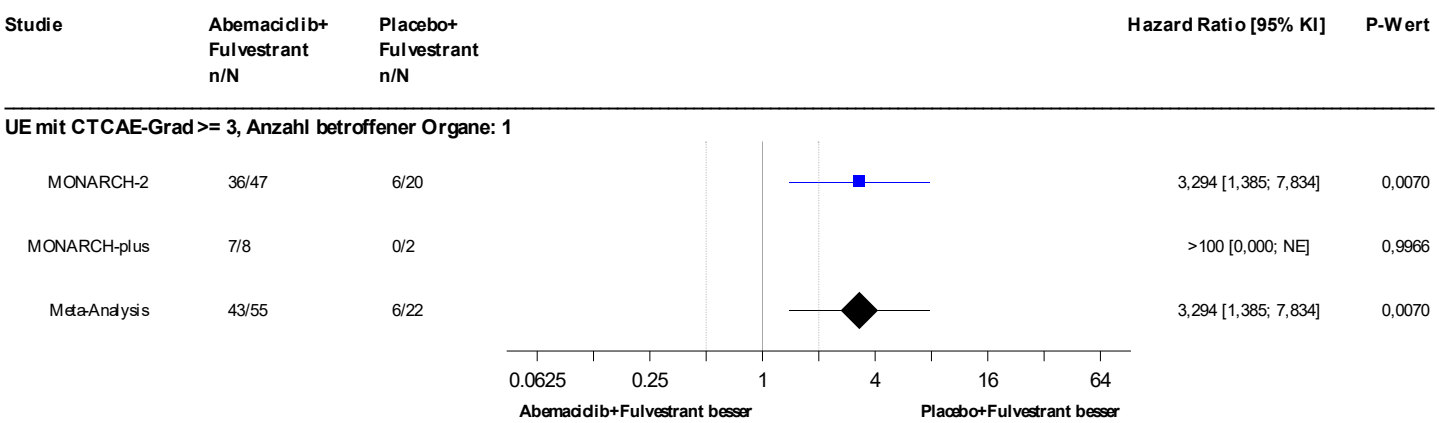
17SEP2021 / 07:48

Abbildung 1421.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9968, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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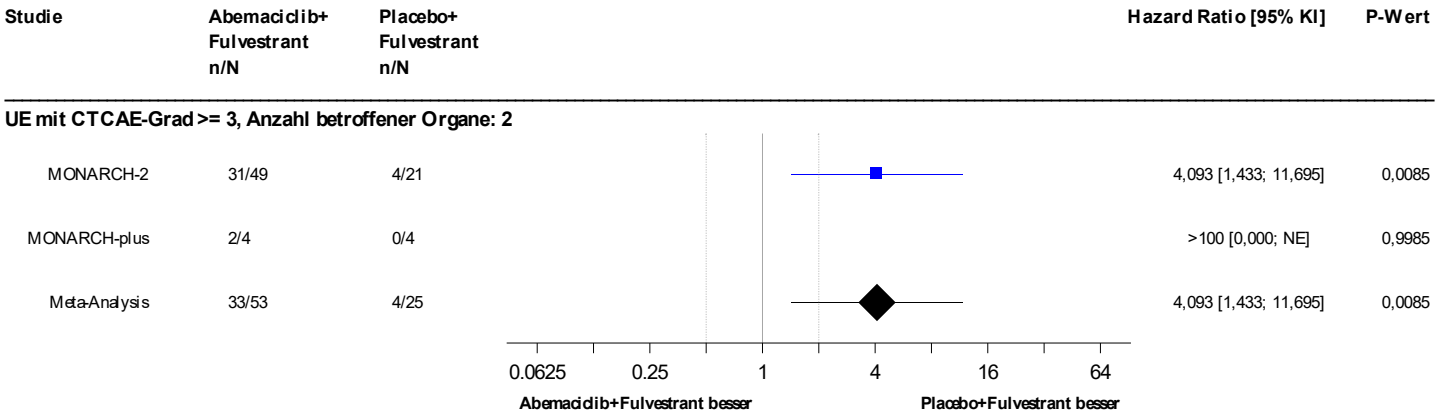
17SEP2021 / 07:48

Abbildung 1421.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9986, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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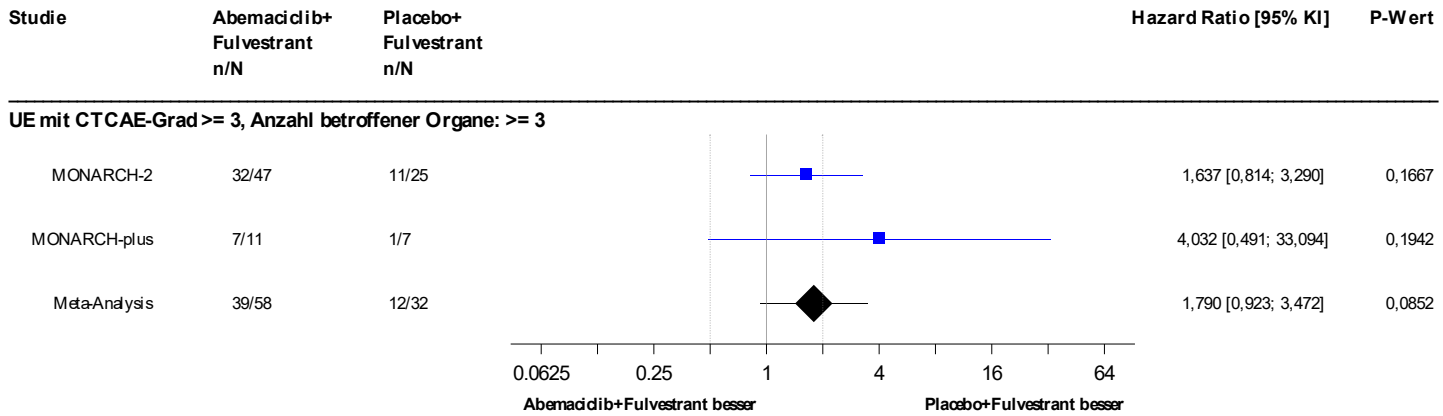
17SEP2021 / 07:48

Abbildung 1421.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,6349, P-Wert=0,4256, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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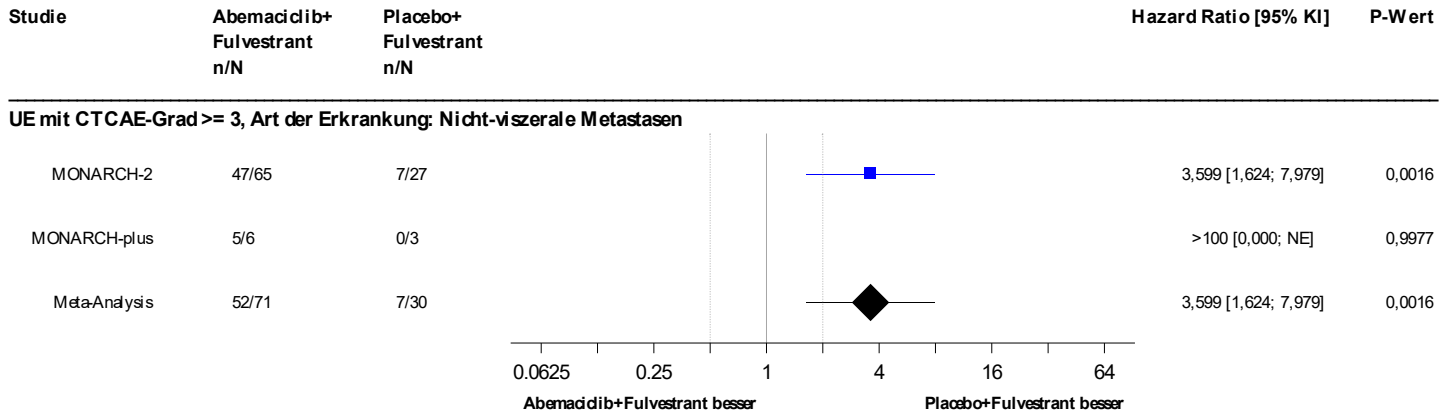
Abbildung 1421.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9979, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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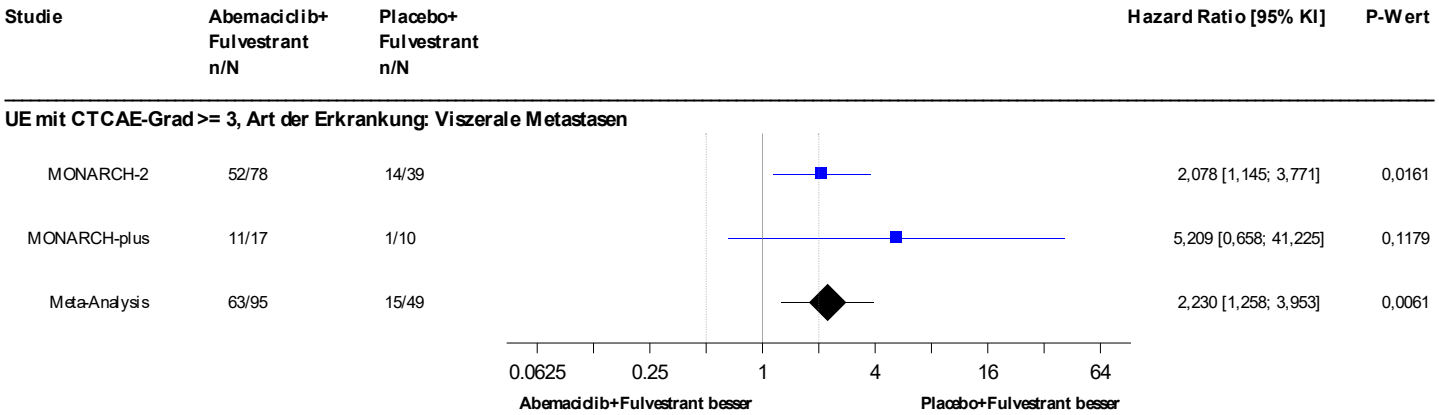
Abbildung 1421.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,6999, P-Wert=0,4028, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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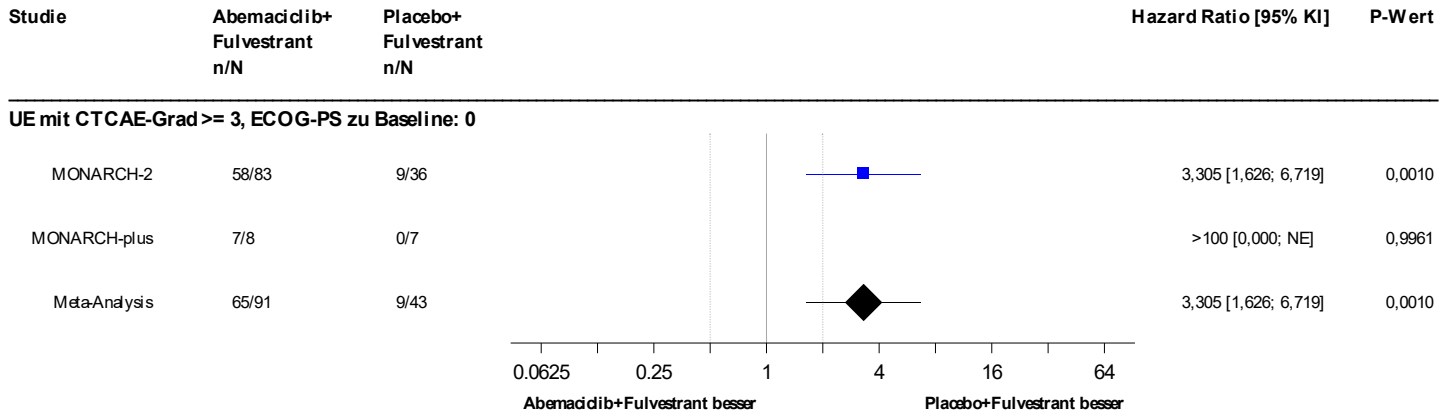
Abbildung 1421.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9963, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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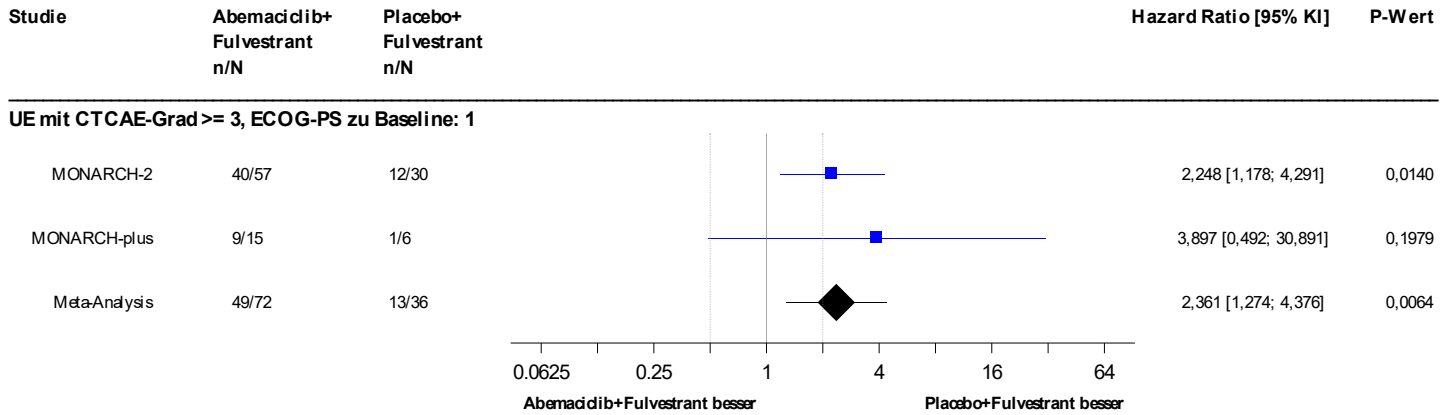
Abbildung 1421.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2469, P-Wert=0,6192, I2 Index=0%
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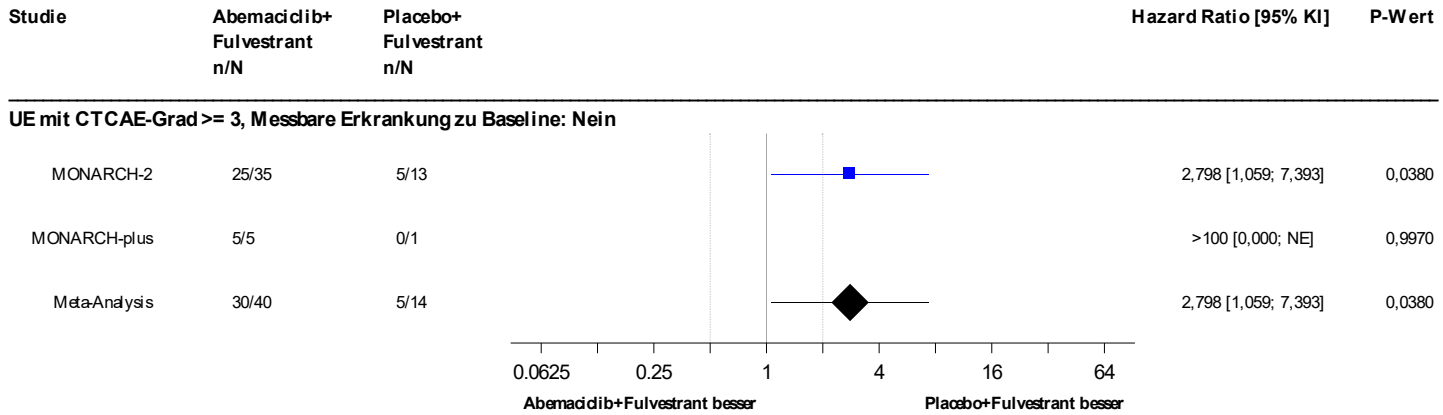
Abbildung 1421.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9971, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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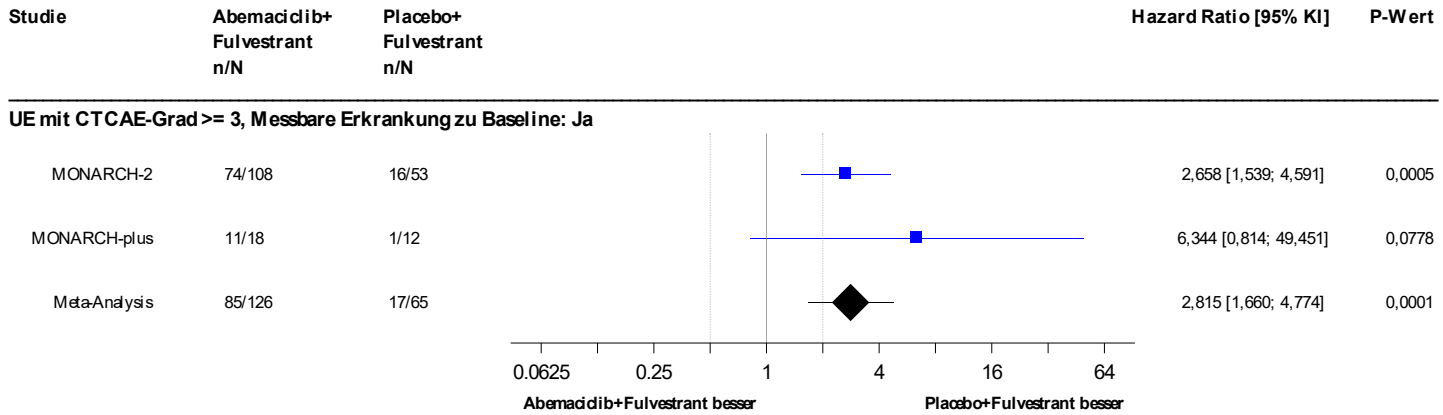
17SEP2021 / 07:48

Abbildung 1421.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,6440, P-Wert=0,4223, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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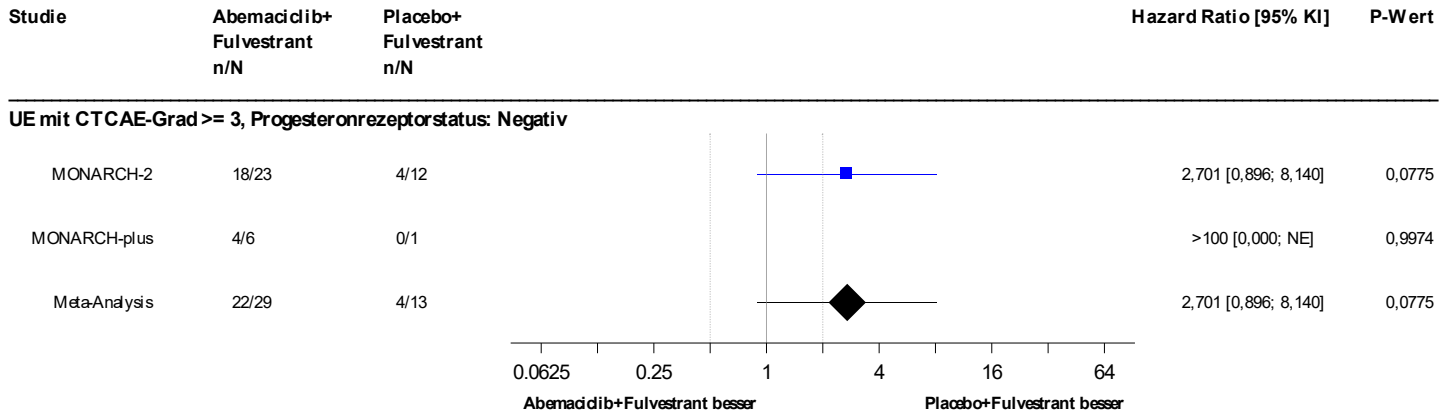
Abbildung 1421.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9976, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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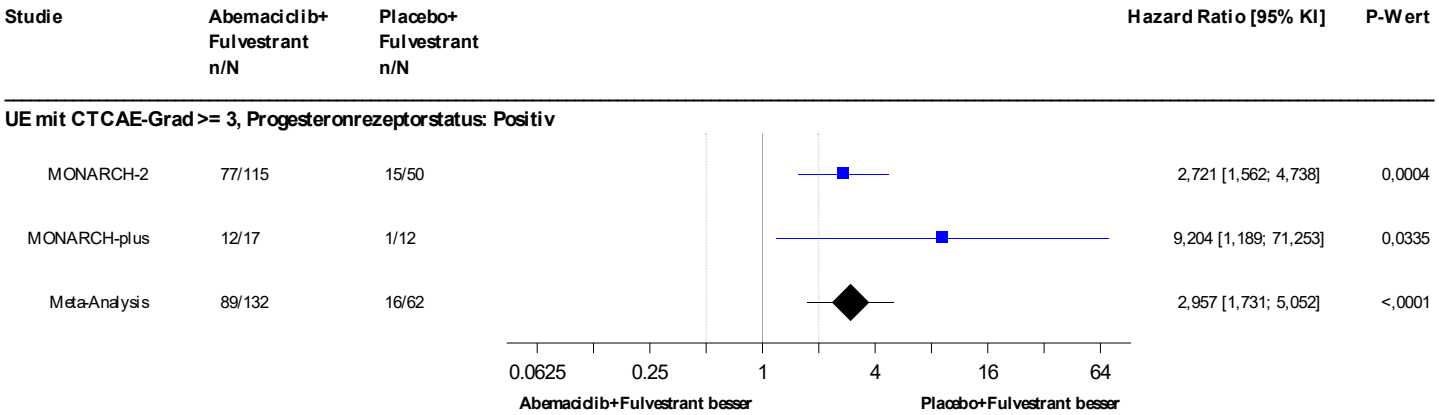
17SEP2021 / 07:48

Abbildung 1421.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,2689, P-Wert=0,2600, I2 Index=21,2%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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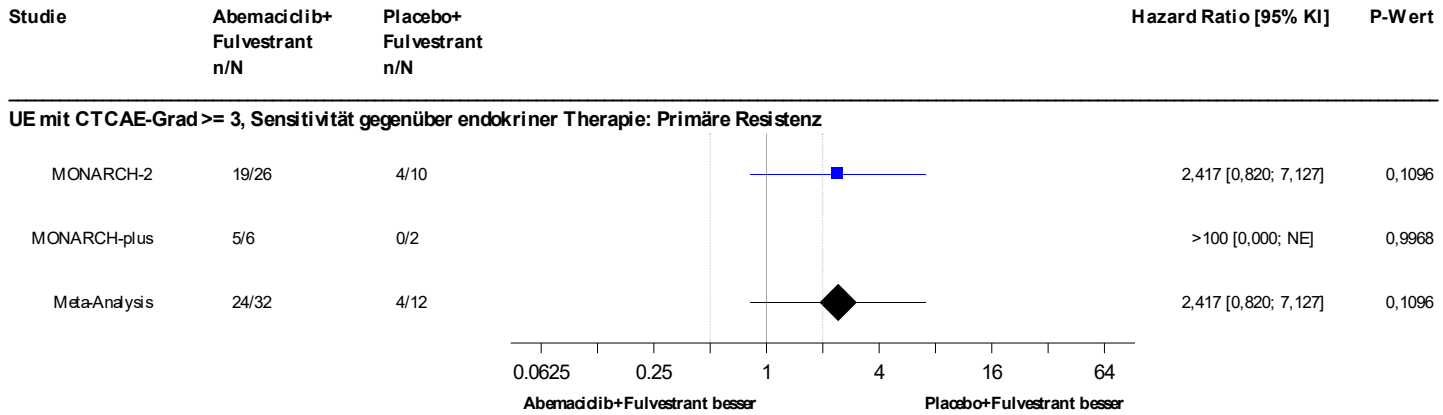
17SEP2021 / 07:48

Abbildung 1421.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9970, I2 Index=0%
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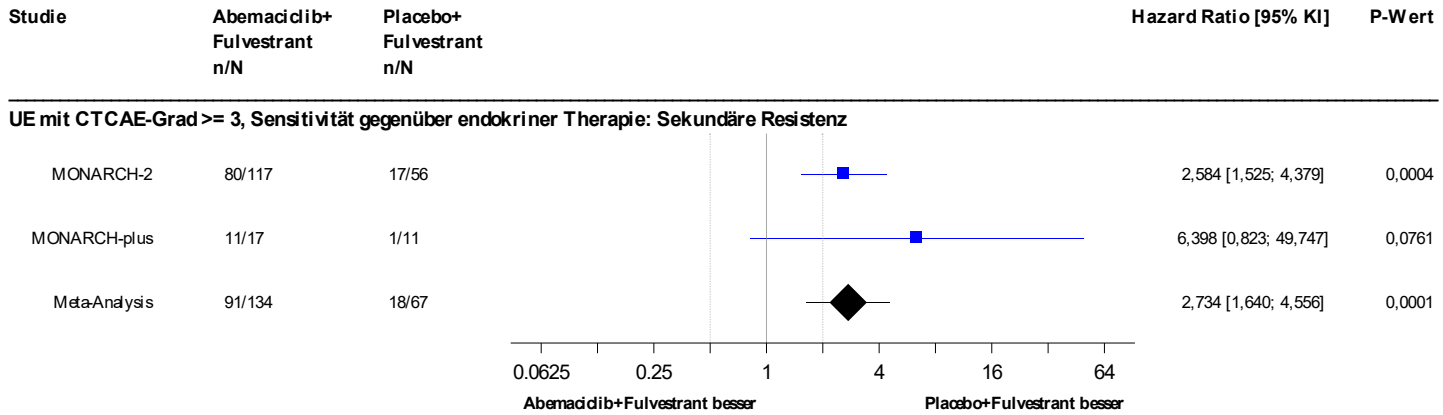
17SEP2021 / 07:48

Abbildung 1421.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,7038, P-Wert=0,4015, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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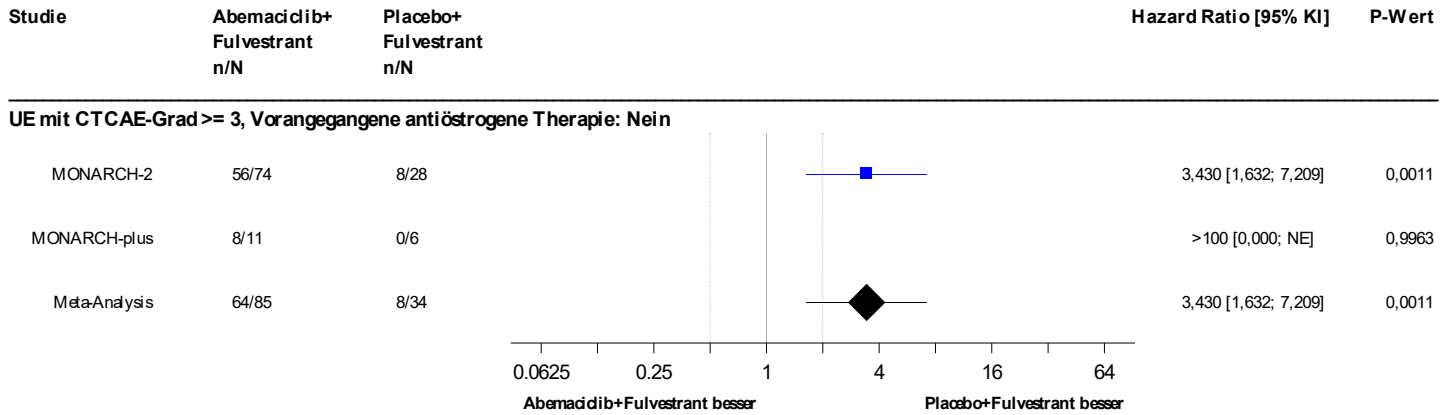
17SEP2021 / 07:48

Abbildung 1421.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9965, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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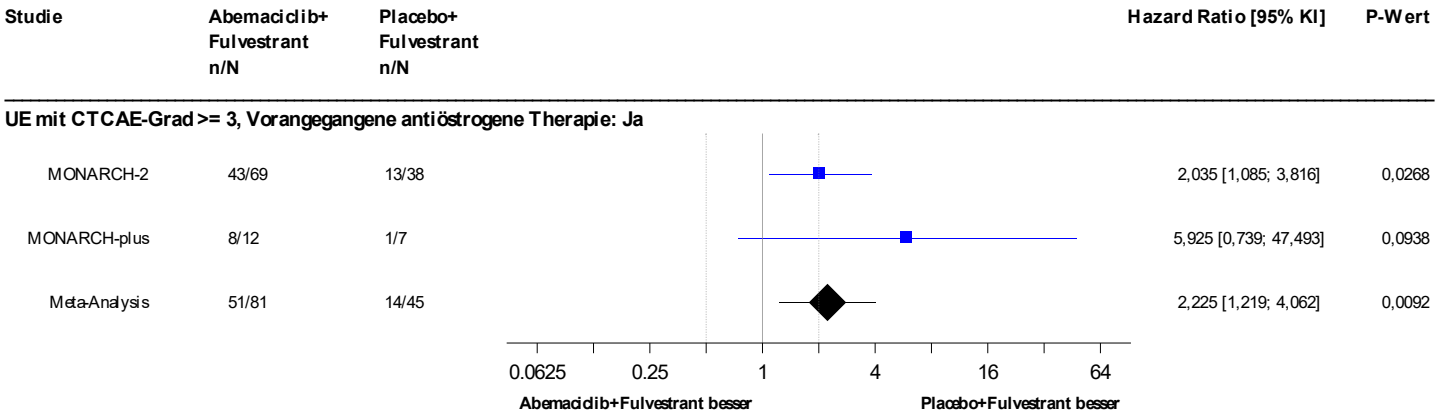
17SEP2021 / 07:48

Abbildung 1421.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3 aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,9282, P-Wert=0,3353, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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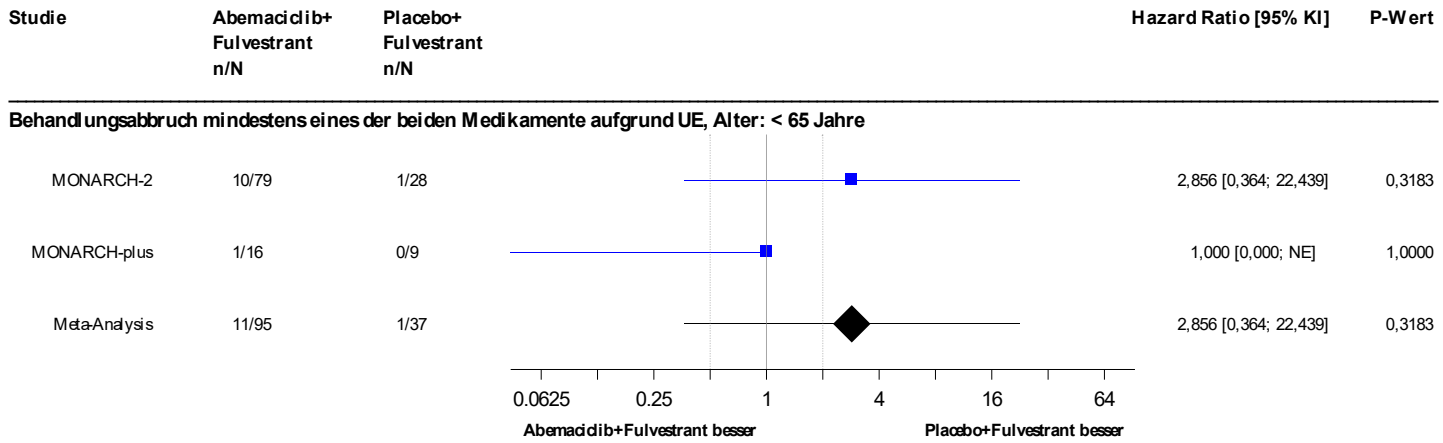
17SEP2021 / 07:48

Abbildung 1422.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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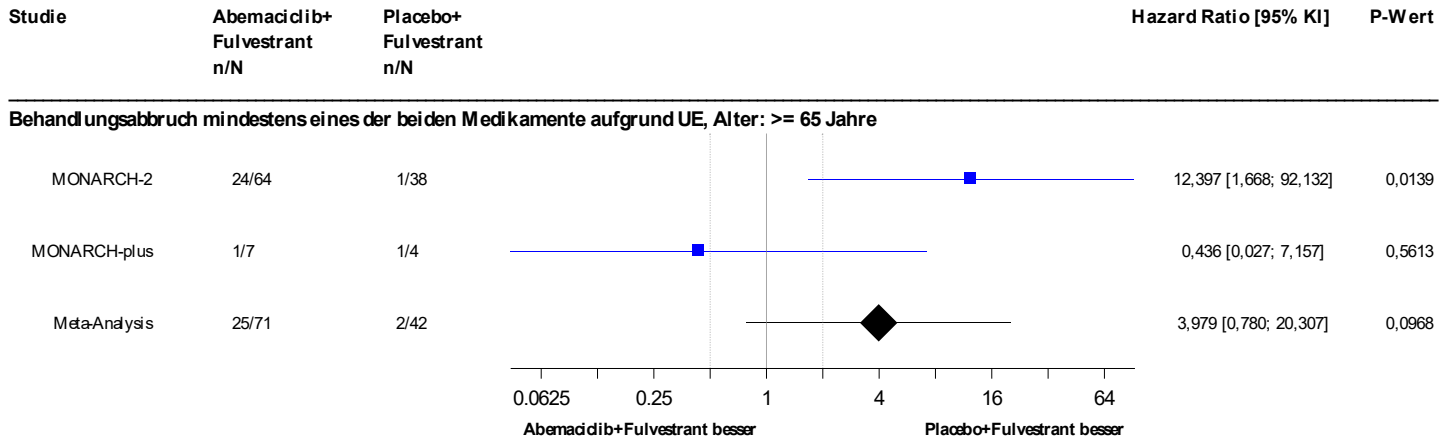
Abbildung 1422.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=3,6314, P-Wert=0,0567, I2 Index=72,5%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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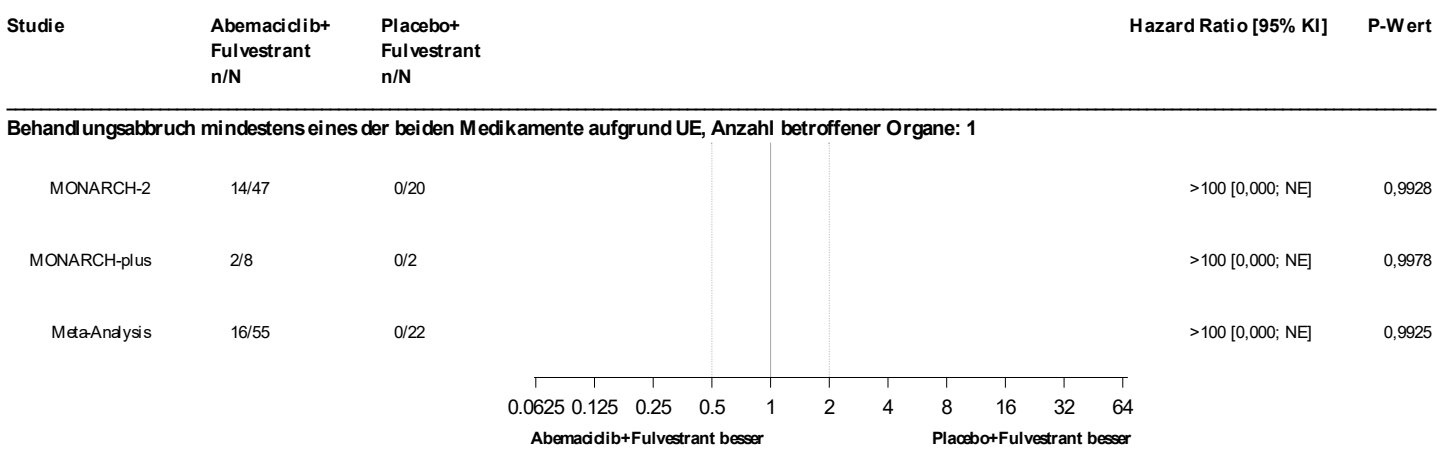
17SEP2021 / 07:48

Abbildung 1422.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9998, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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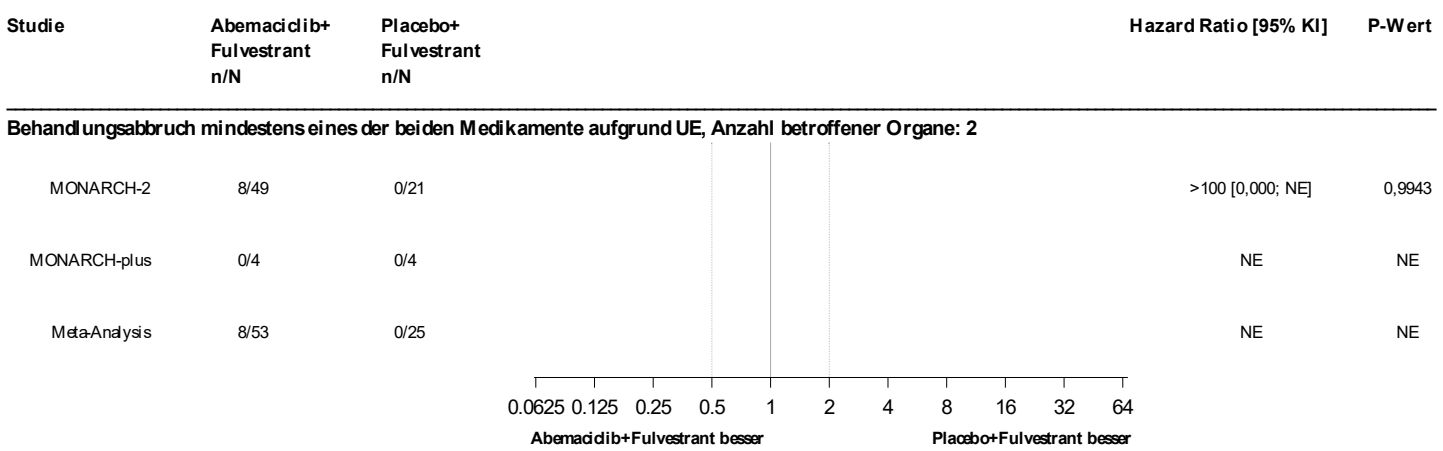
Abbildung 1422.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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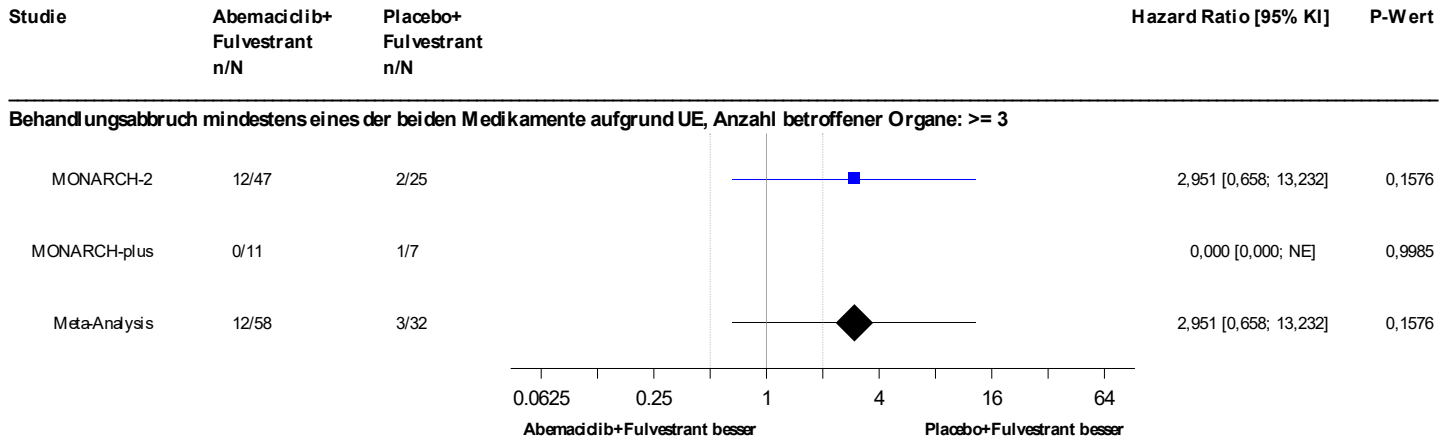
Abbildung 1422.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9984, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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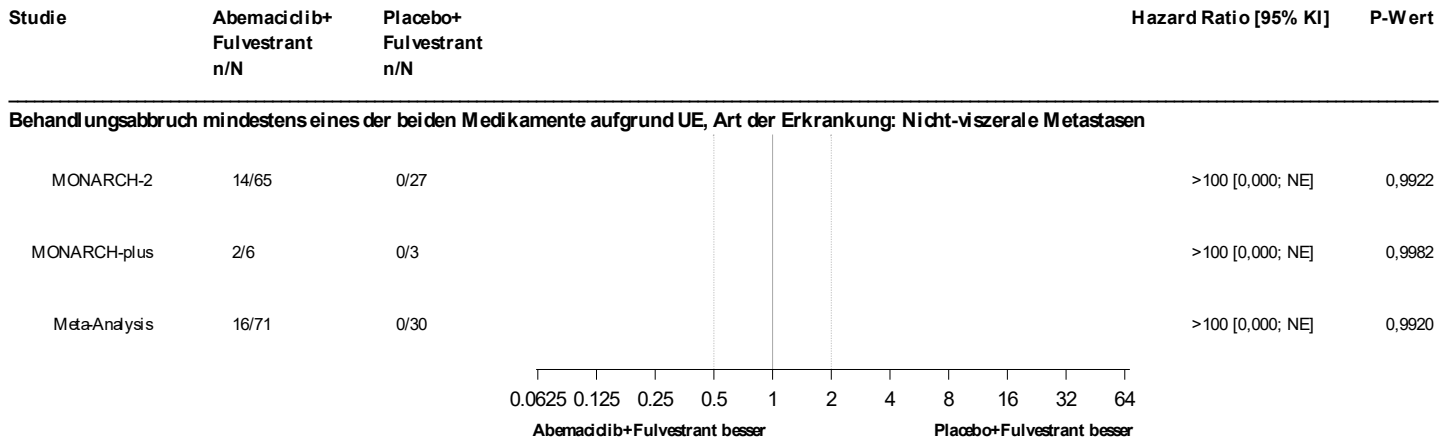
Abbildung 1422.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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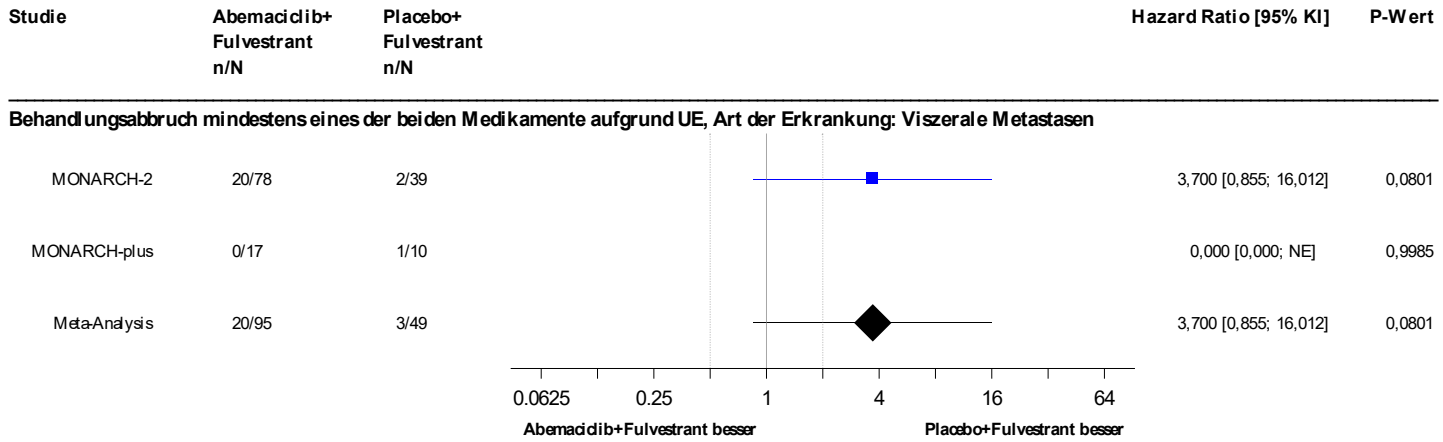
Abbildung 1422.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9984, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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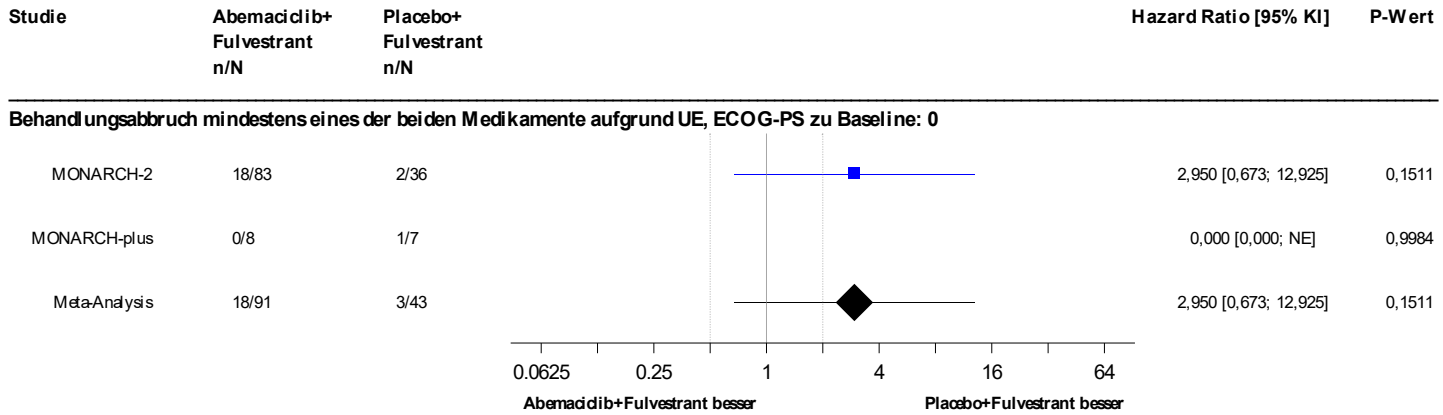
Abbildung 1422.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9983, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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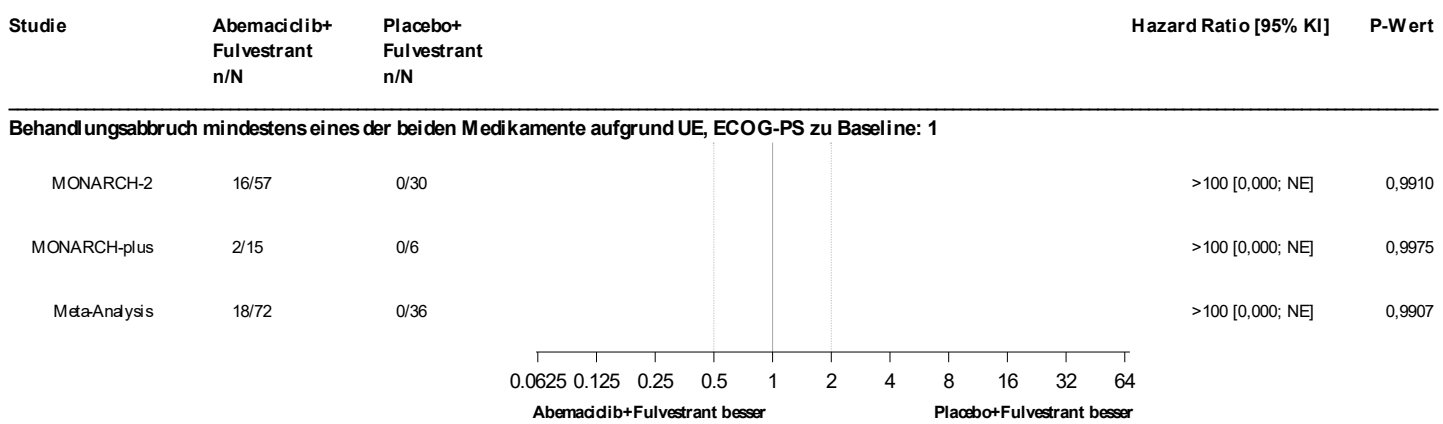
Abbildung 1422.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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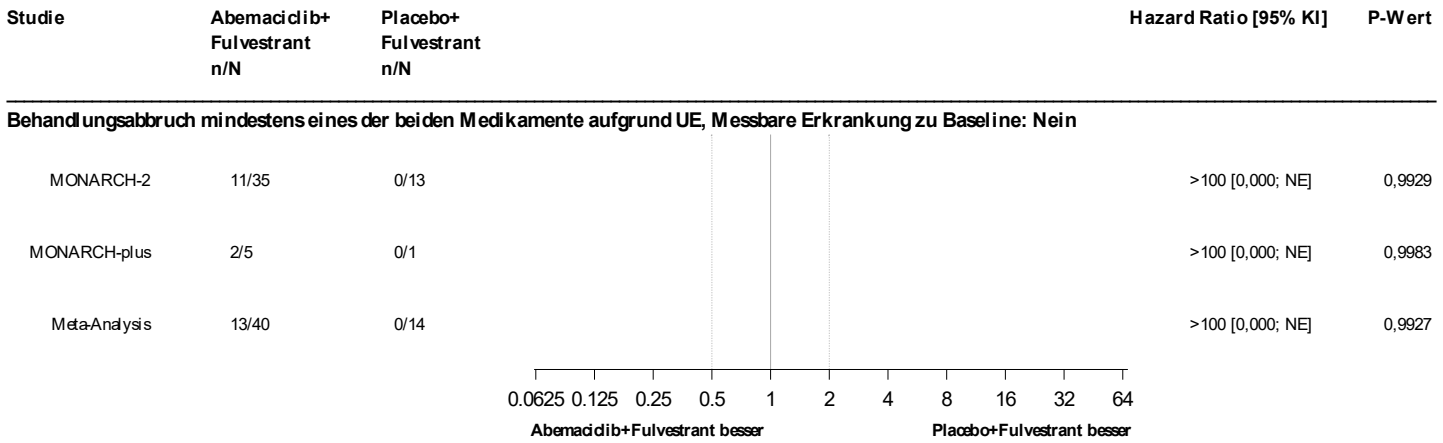
Abbildung 1422.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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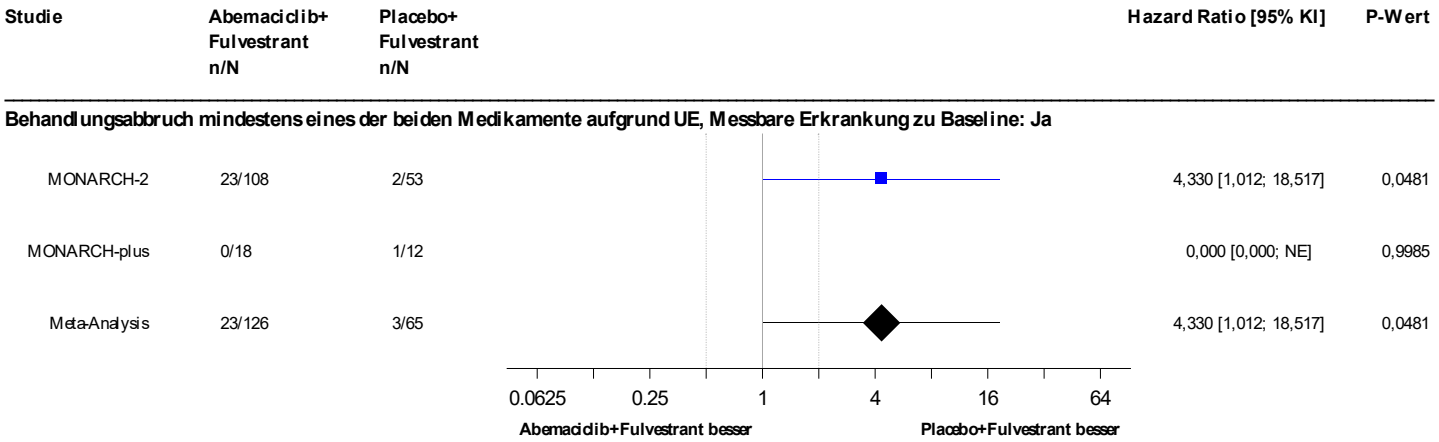
Abbildung 1422.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9983, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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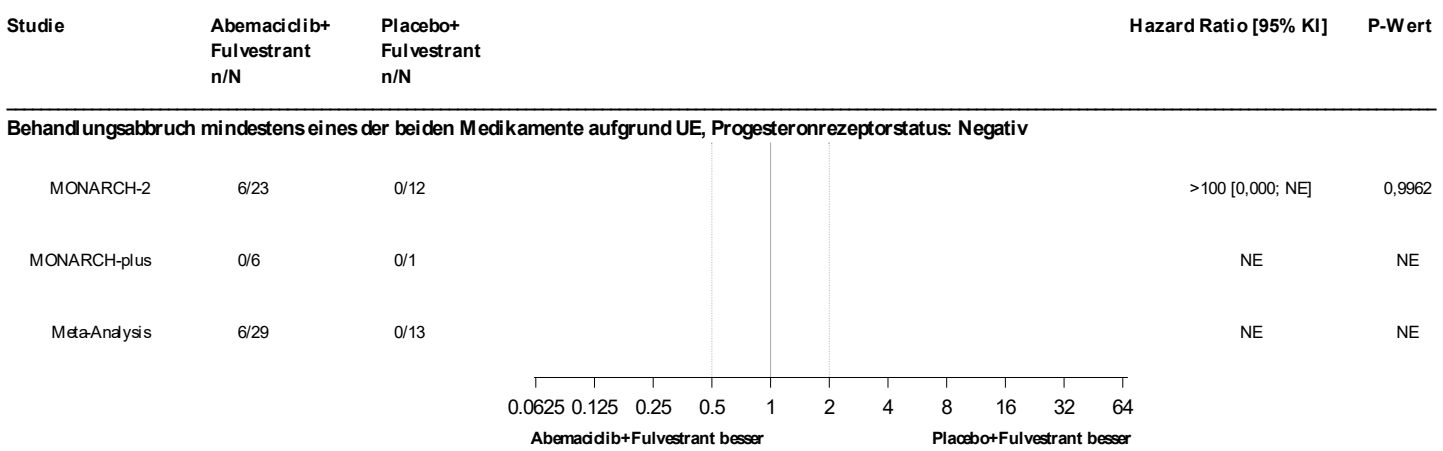
Abbildung 1422.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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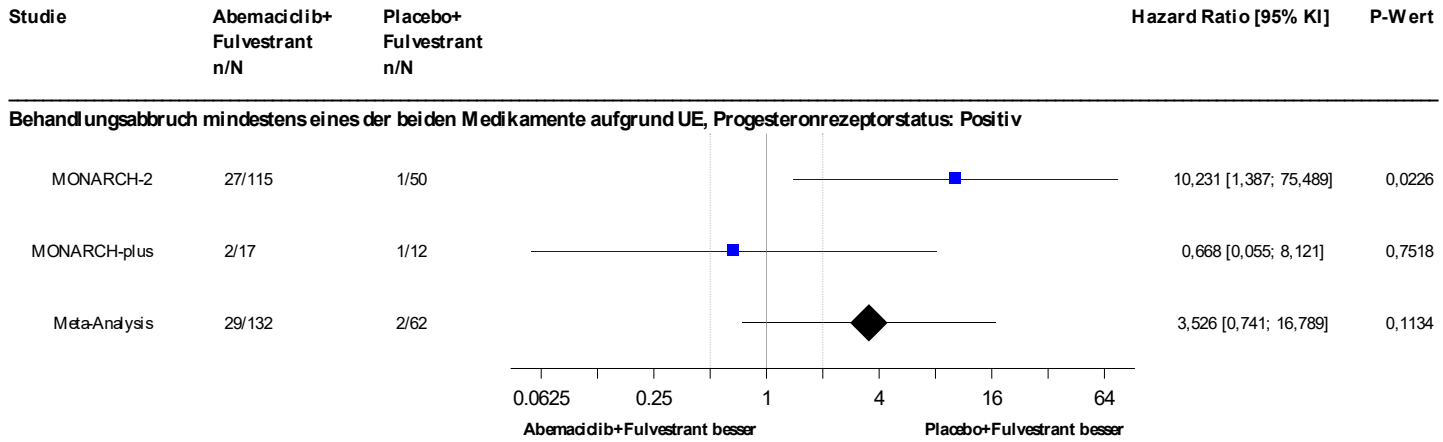
17SEP2021 / 07:48

Abbildung 1422.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=2,7951, P-Wert=0,0946, I2 Index=64,2%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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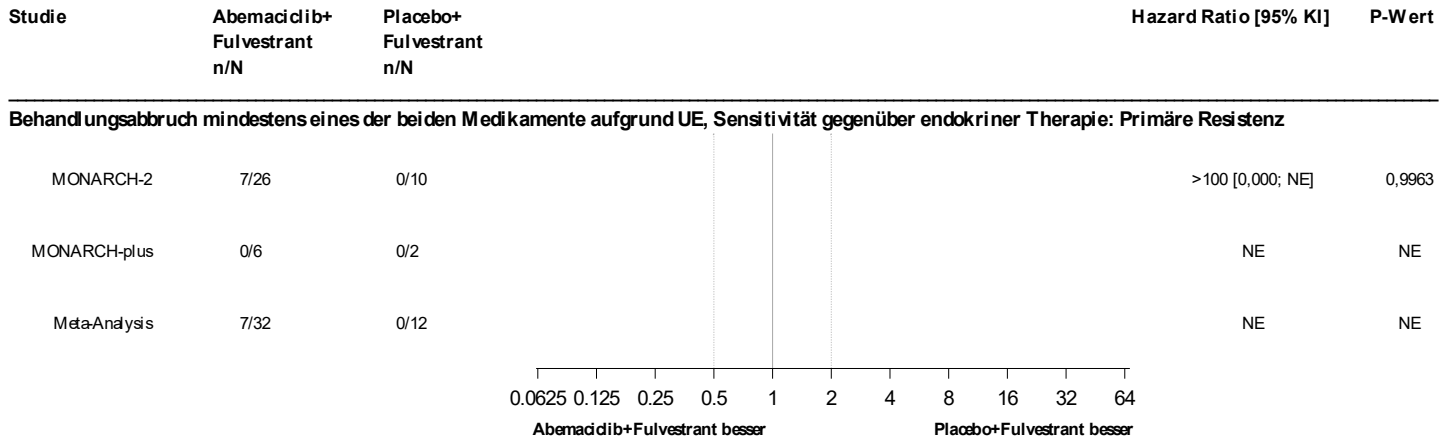
Abbildung 1422.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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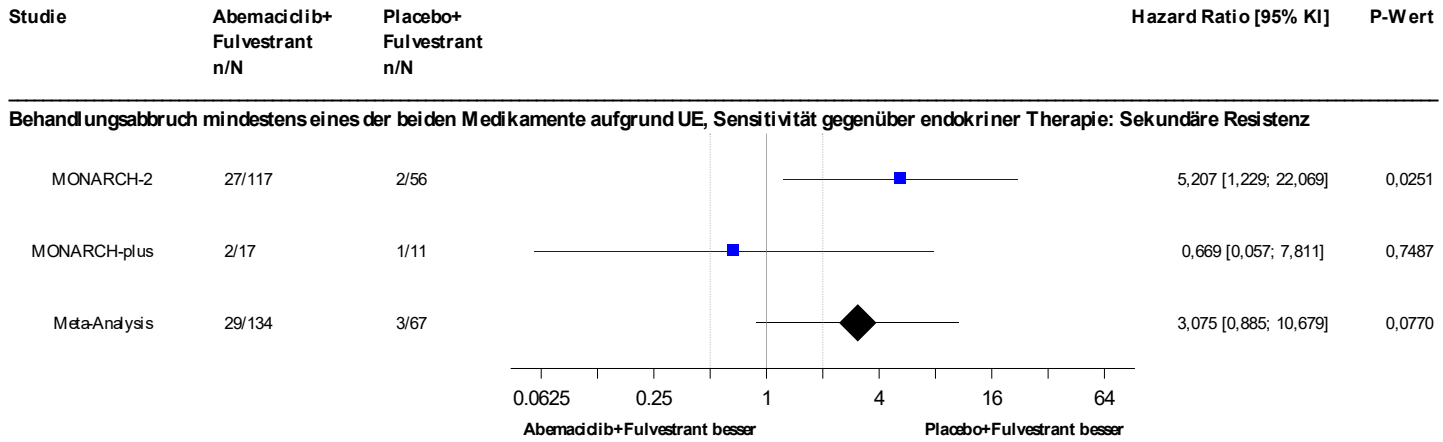
Abbildung 1422.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,9908, P-Wert=0,1583, I2 Index=49,8%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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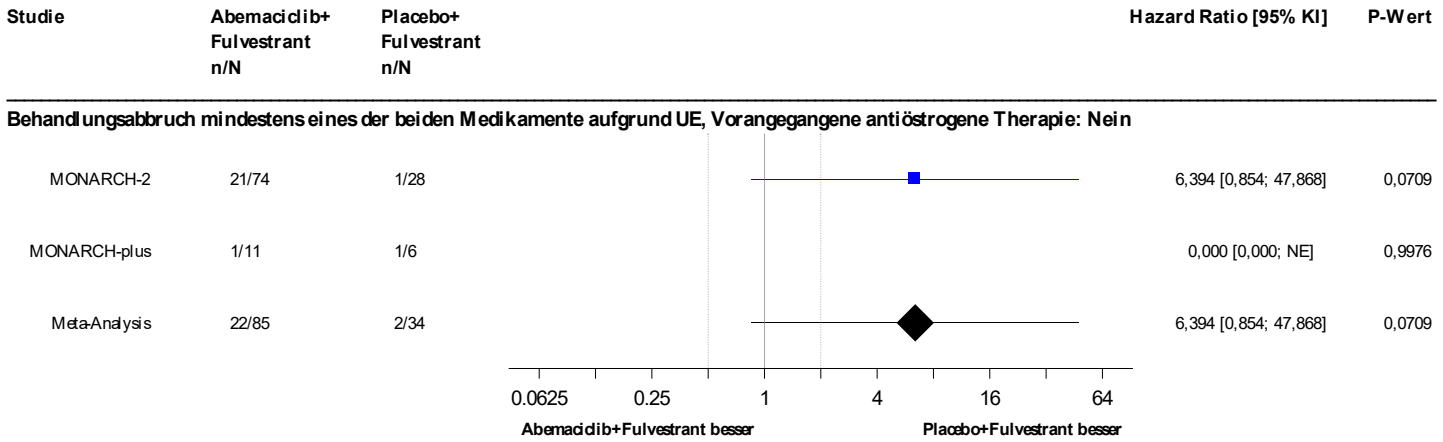
Abbildung 1422.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9973, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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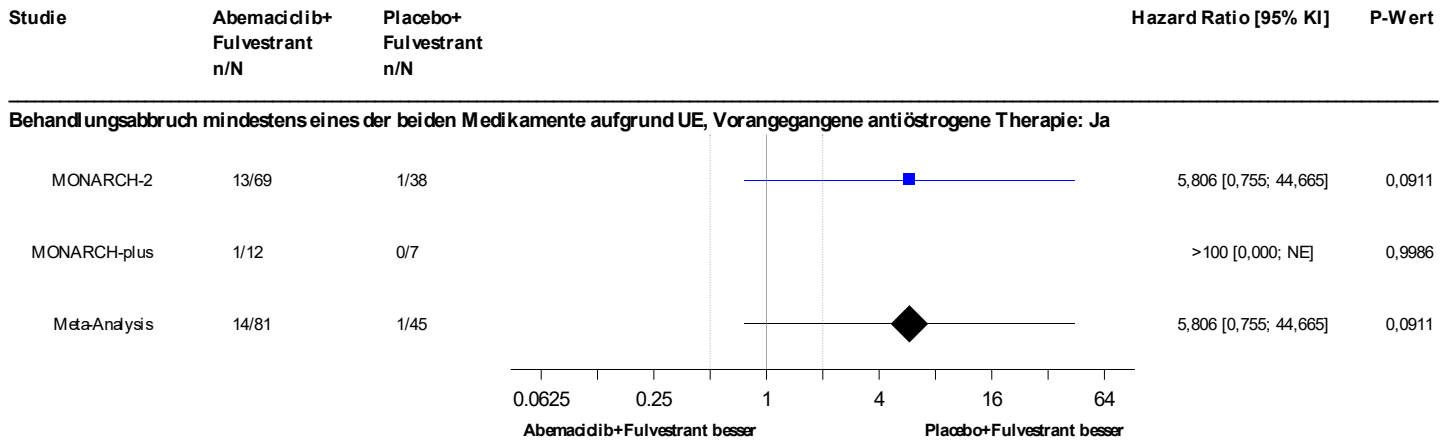
Abbildung 1422.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum Behandlungsabbruch mindestens eines der beiden Medikamente aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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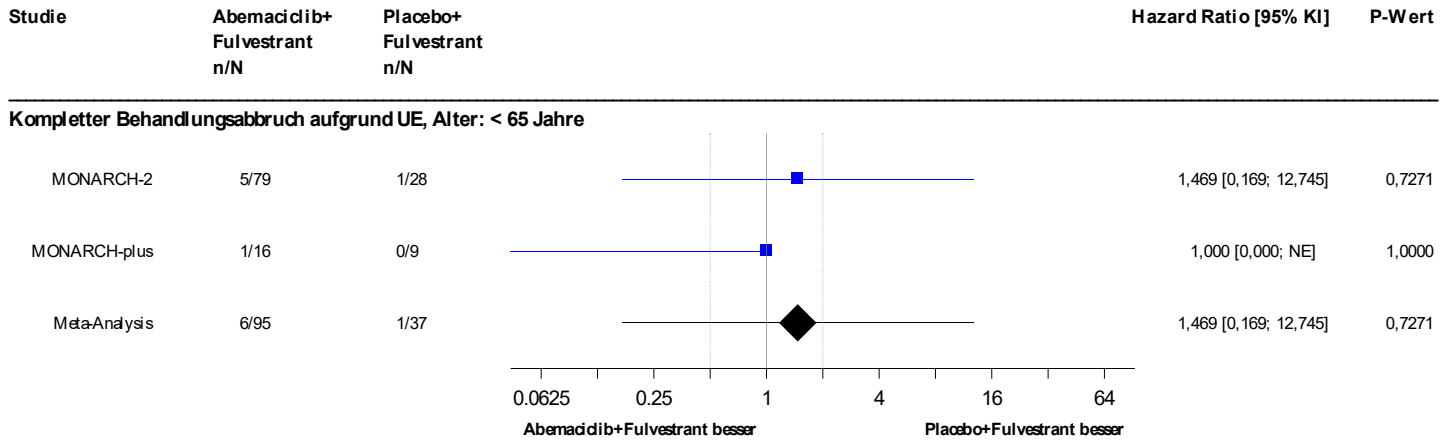
Abbildung 1423.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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Abbildung 1423.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

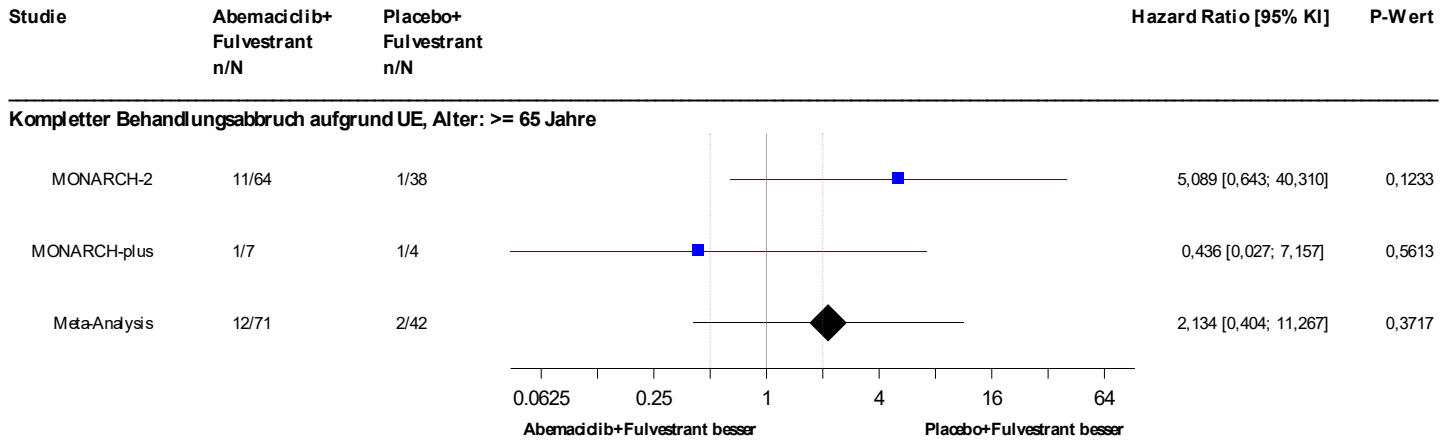

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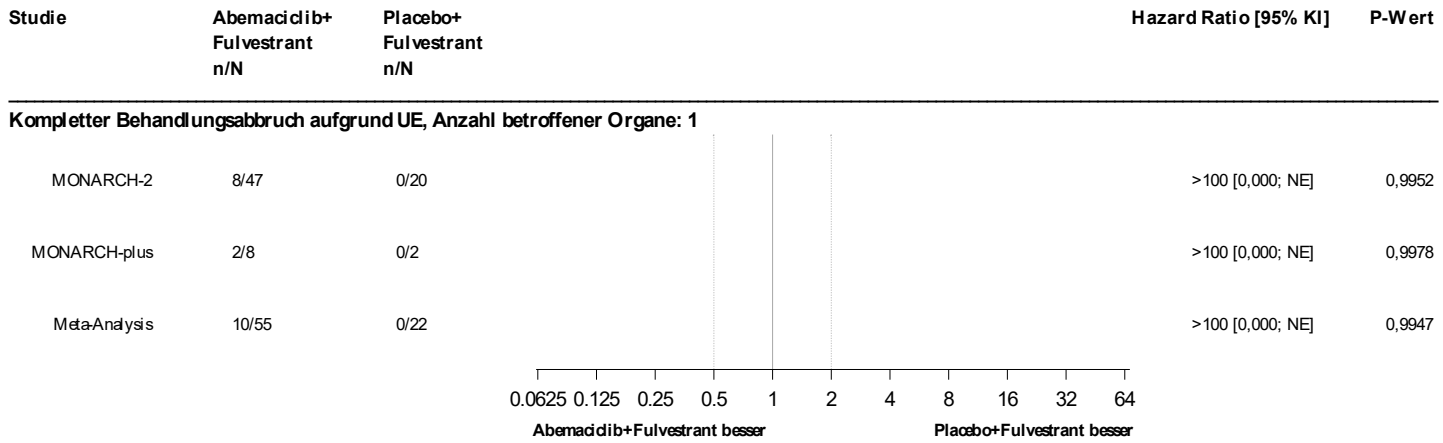
Abbildung 1423.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9998, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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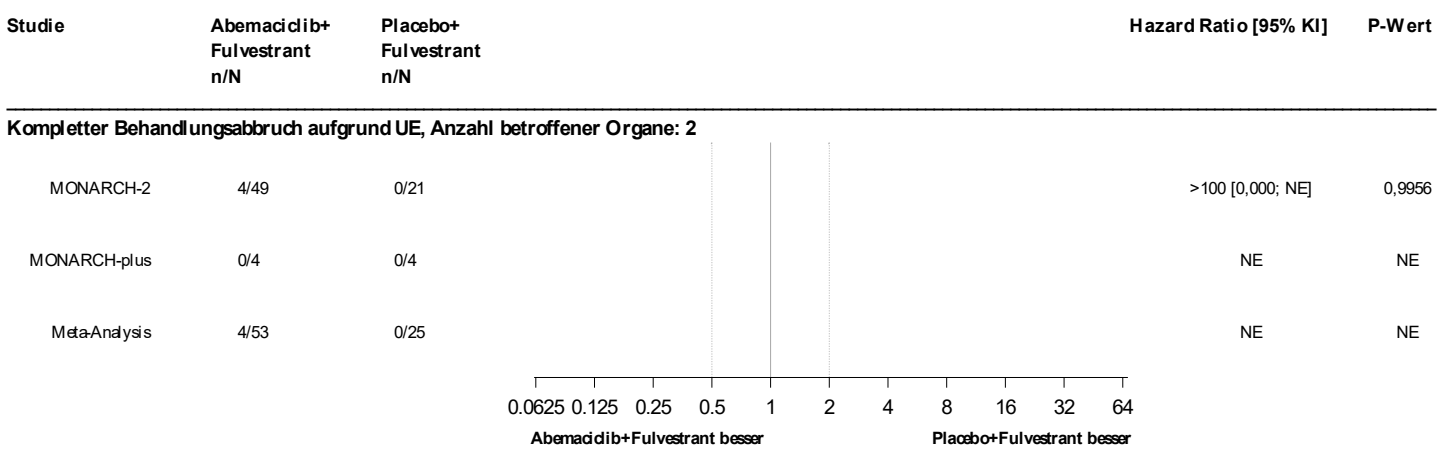
Abbildung 1423.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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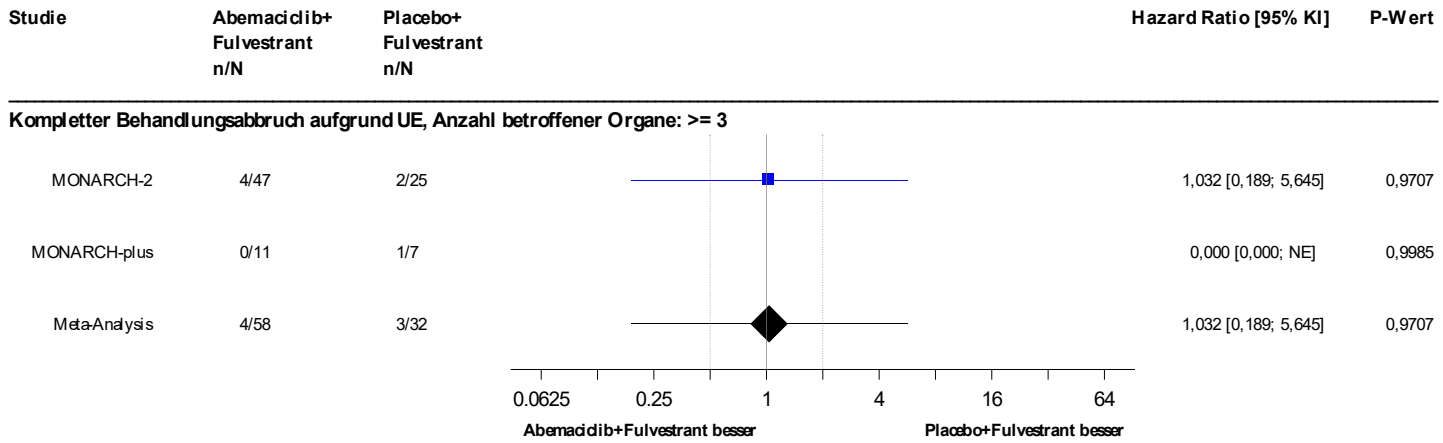
Abbildung 1423.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9985, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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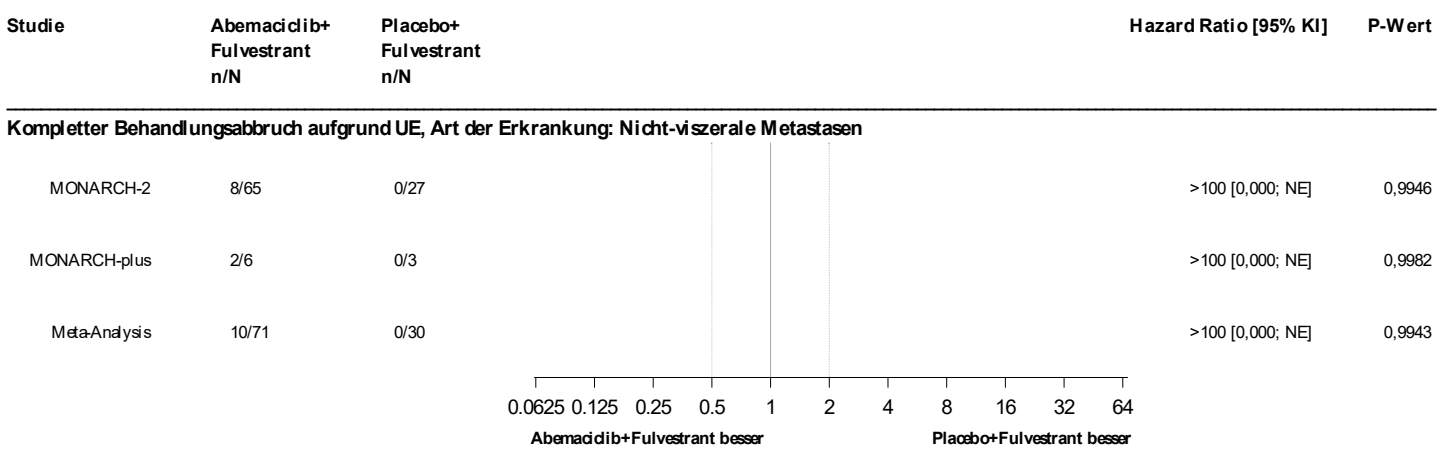
Abbildung 1423.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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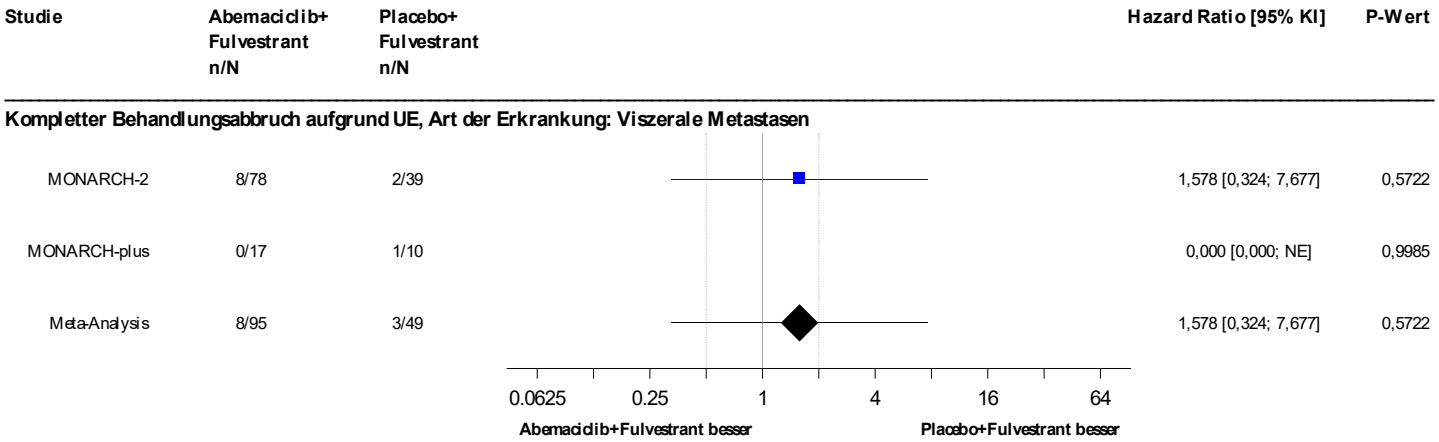
Abbildung 1423.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9985, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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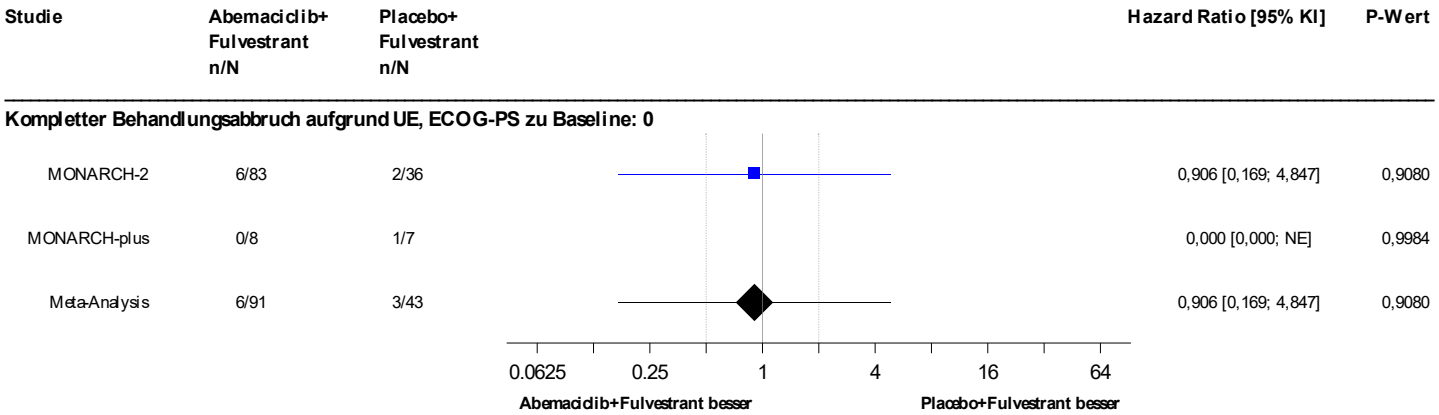
Abbildung 1423.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9984, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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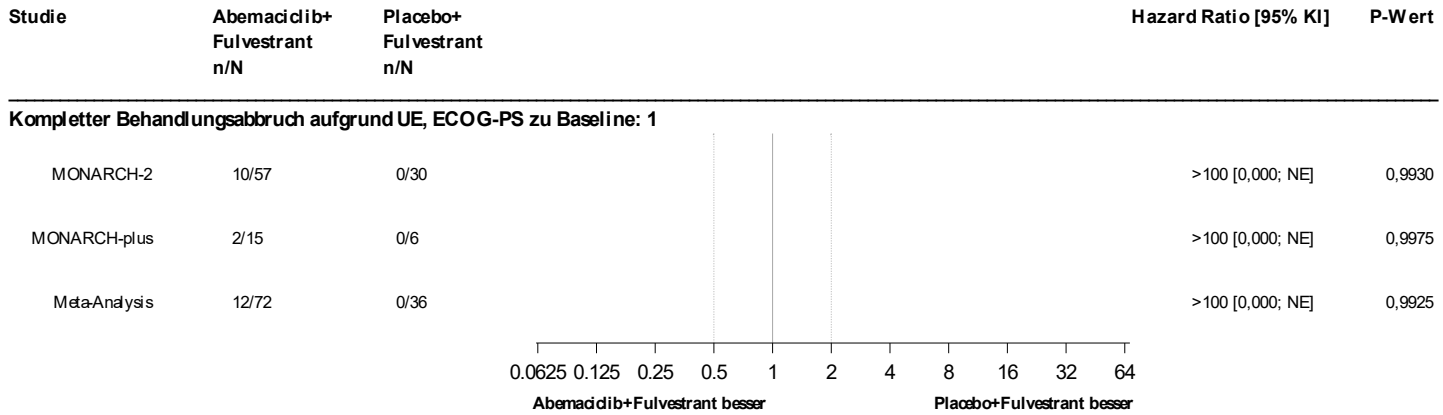
Abbildung 1423.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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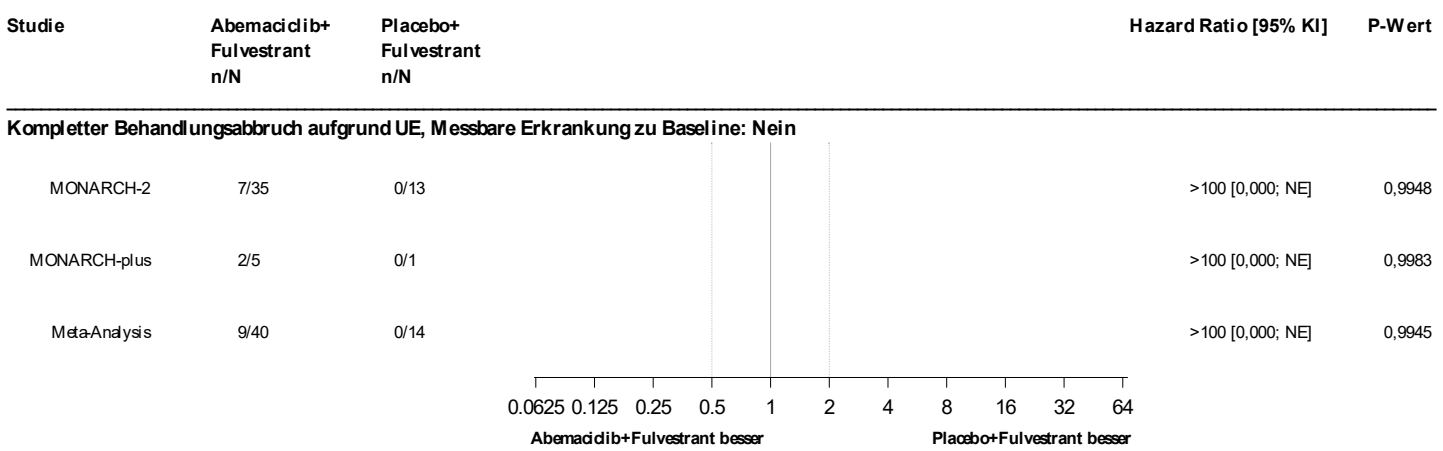
Abbildung 1423.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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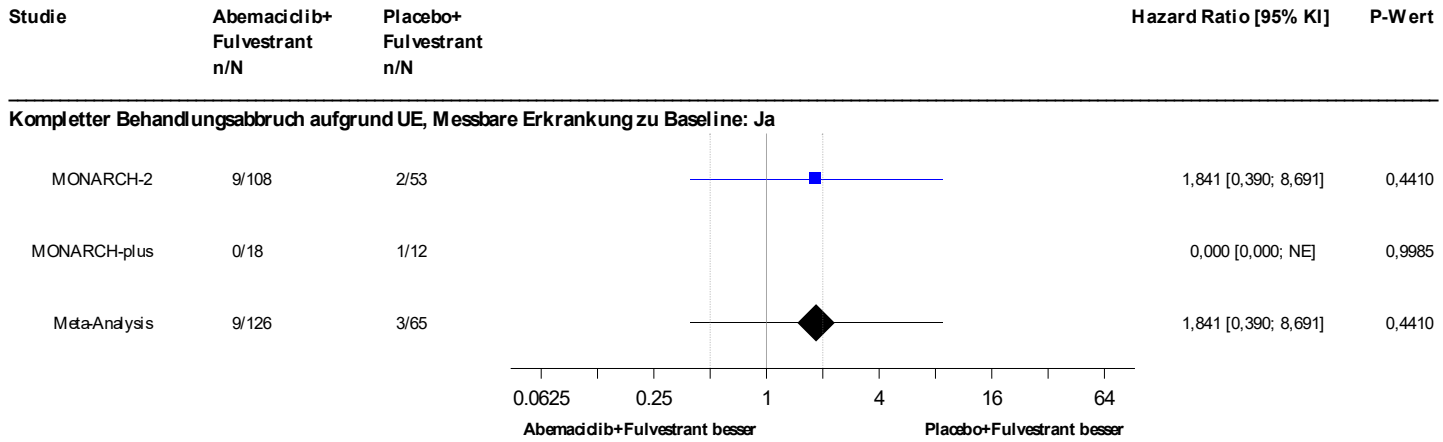
Abbildung 1423.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9984, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttdisca_popa2_measdis_2.rtf
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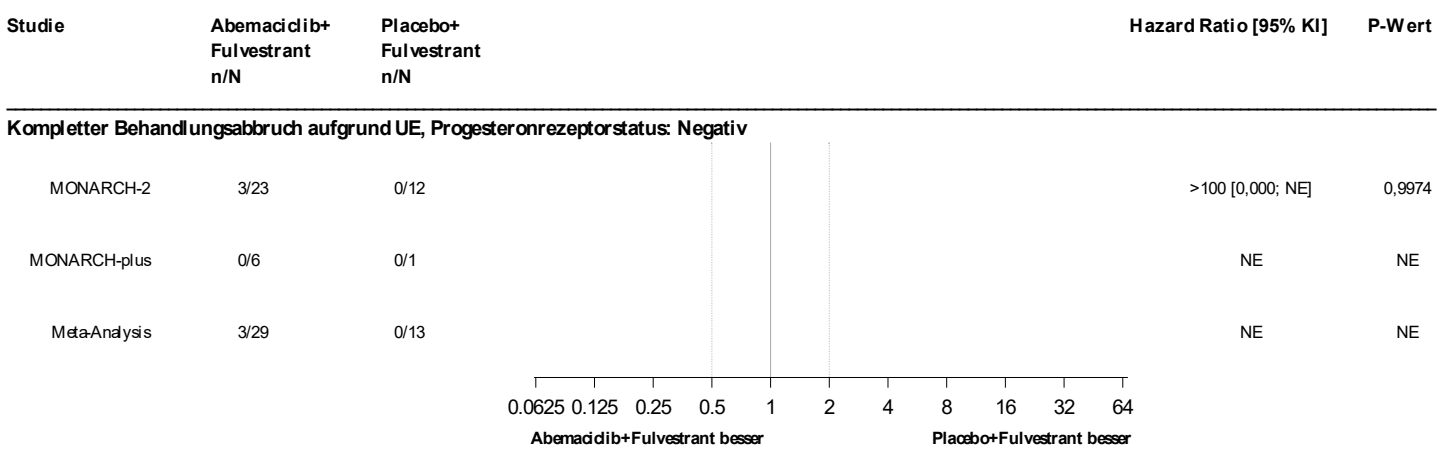
Abbildung 1423.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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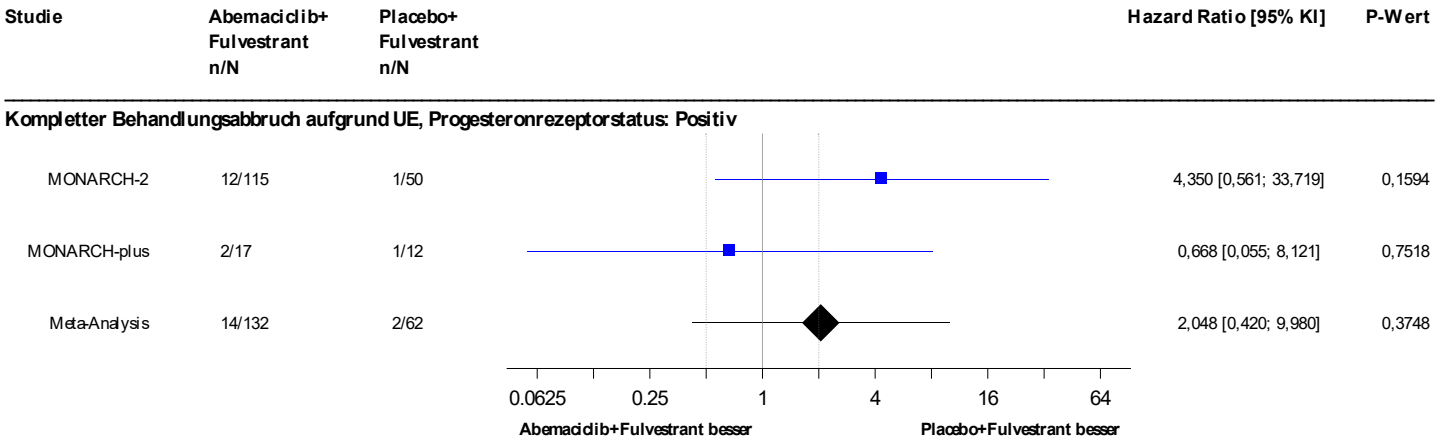
17SEP2021 / 07:48

Abbildung 1423.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,2920, P-Wert=0,2557, I2 Index=22,6%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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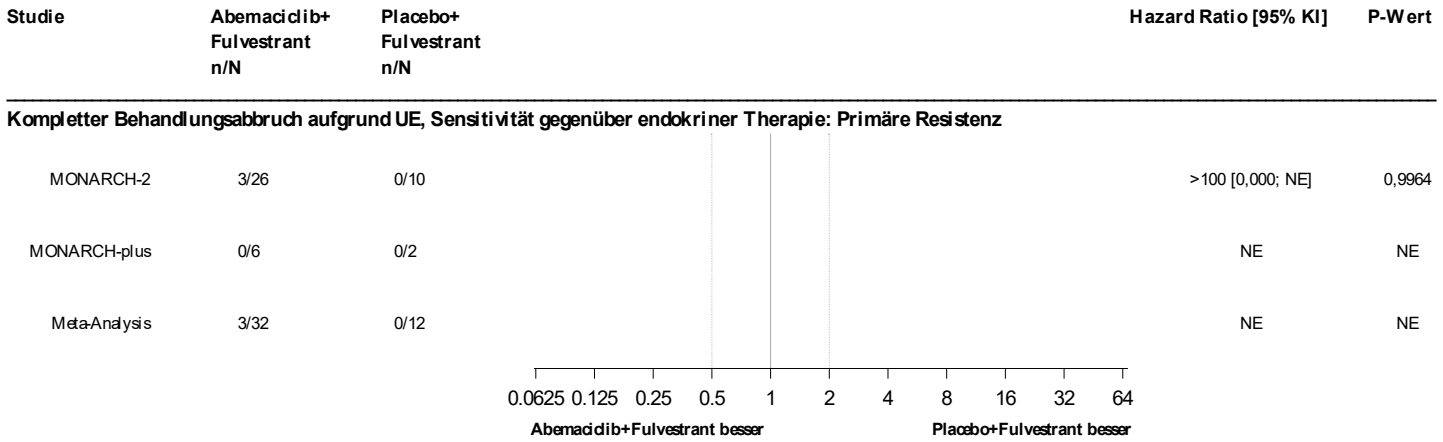
Abbildung 1423.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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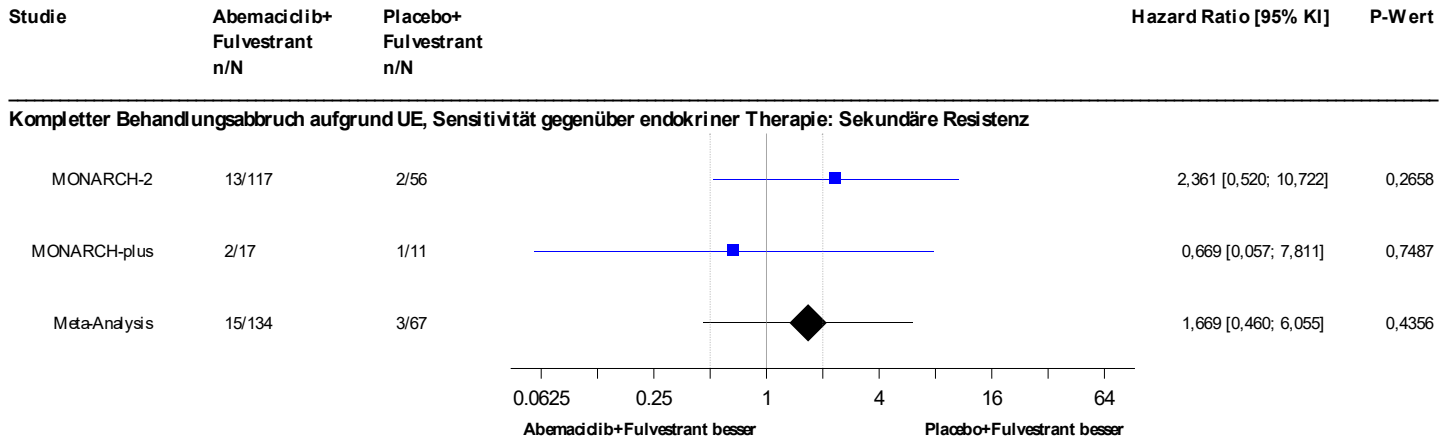
Abbildung 1423.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,7332, P-Wert=0,3918, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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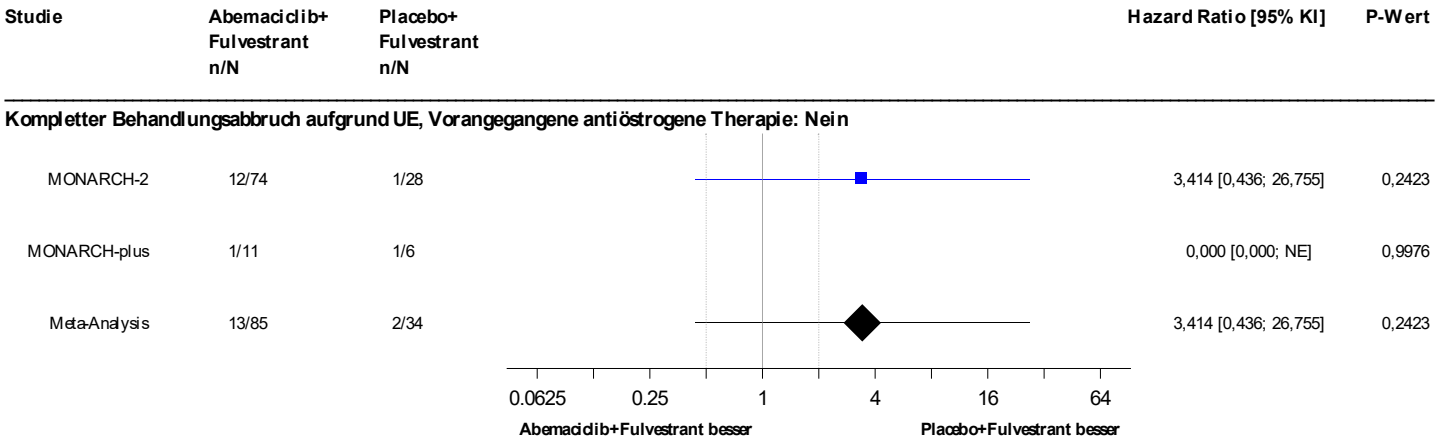
17SEP2021 / 07:48

Abbildung 1423.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9974, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

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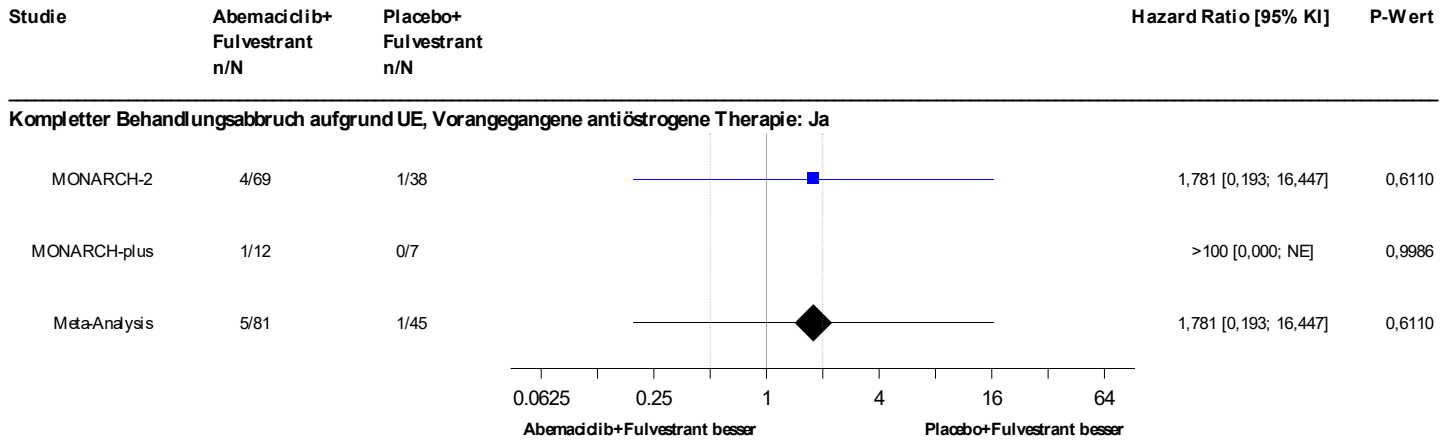
17SEP2021 / 07:48

Abbildung 1423.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum kompletten Behandlungsabbruch aufgrund unerwünschter Ereignisse aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9986, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; UE: Unerwünschtes Ereignis.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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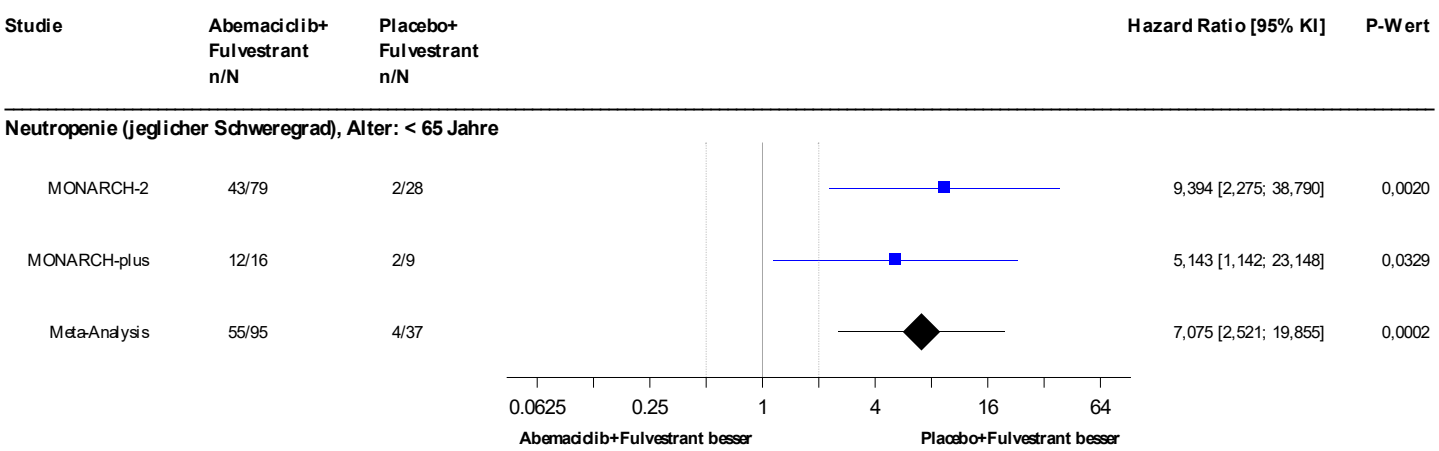
Abbildung 1424.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3263, P-Wert=0,5678, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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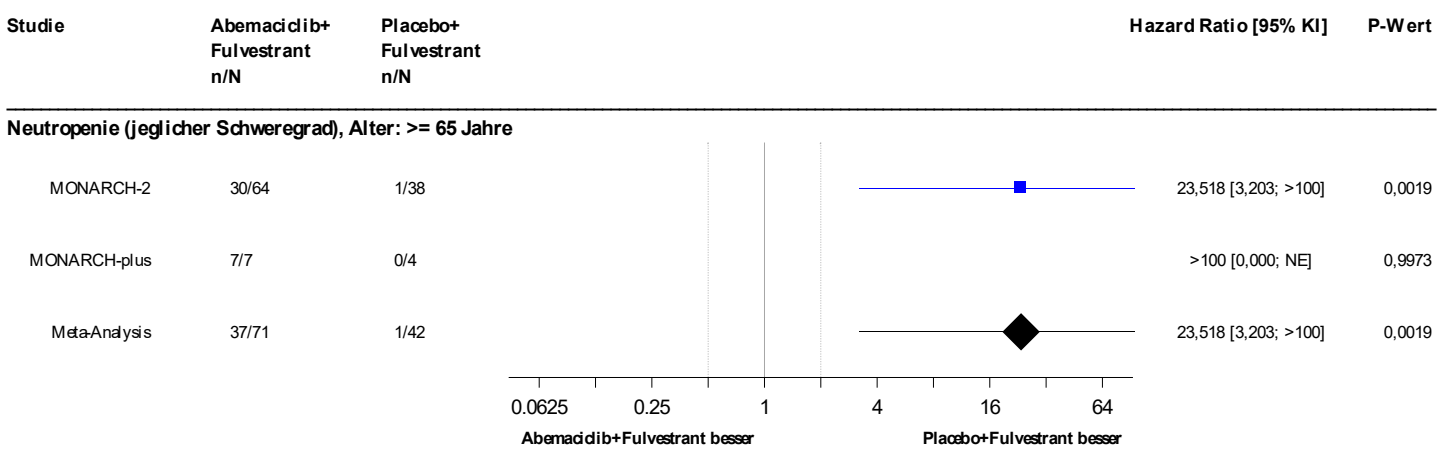
Abbildung 1424.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9977, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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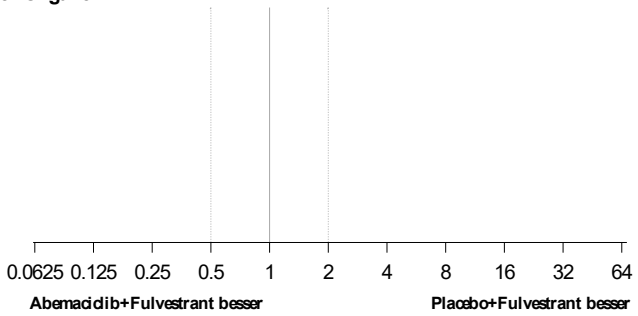
Abbildung 1424.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

Studie	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% KI]	P-Wert
Neutropenie (jeglicher Schweregrad), Anzahl betroffener Organe: 1				
MONARCH-2	21/47	0/20	>100 [0,000; NE]	0,9933
MONARCH-plus	8/8	0/2	>100 [0,000; NE]	0,9959
Meta-Analysis	29/55	0/22	>100 [0,000; NE]	0,9921



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttnpaesi_popa2_norggr_1.rtf
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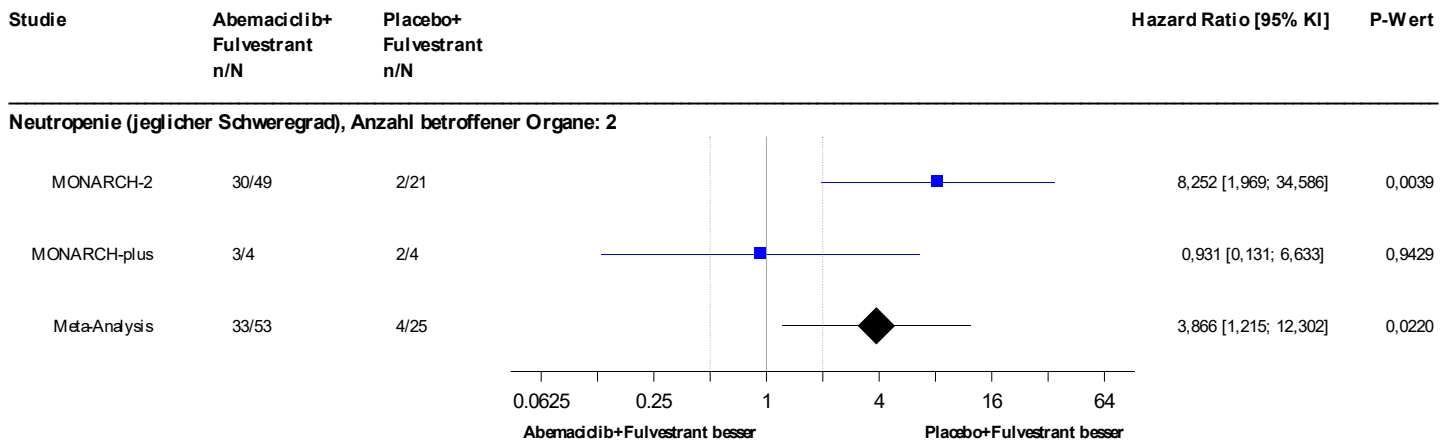
Abbildung 1424.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=3,0956, P-Wert=0,0785, I2 Index=67,7%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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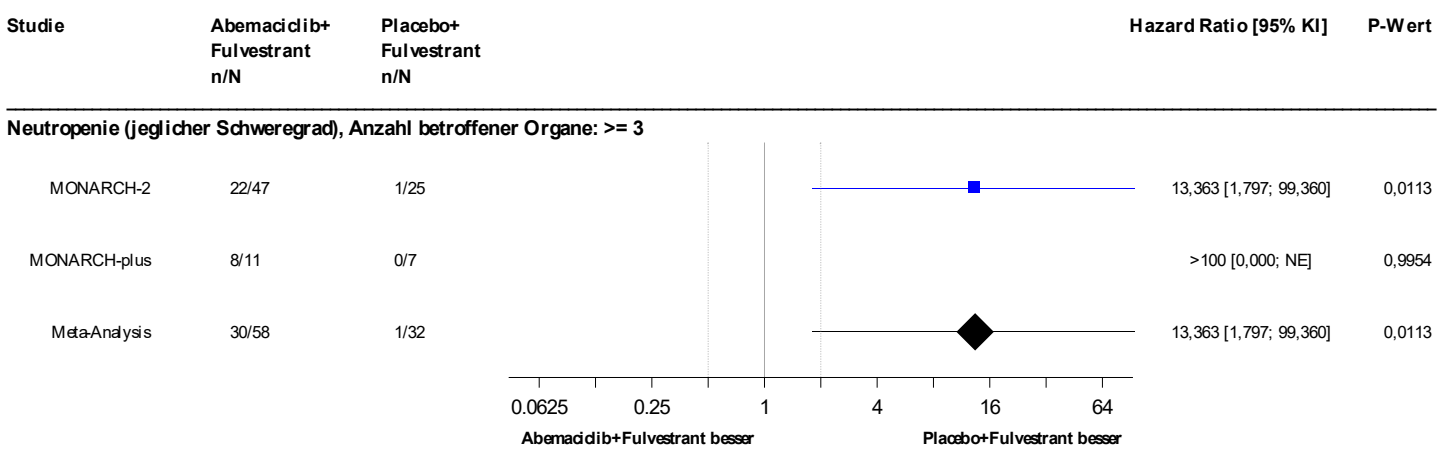
17SEP2021 / 07:48

Abbildung 1424.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9961, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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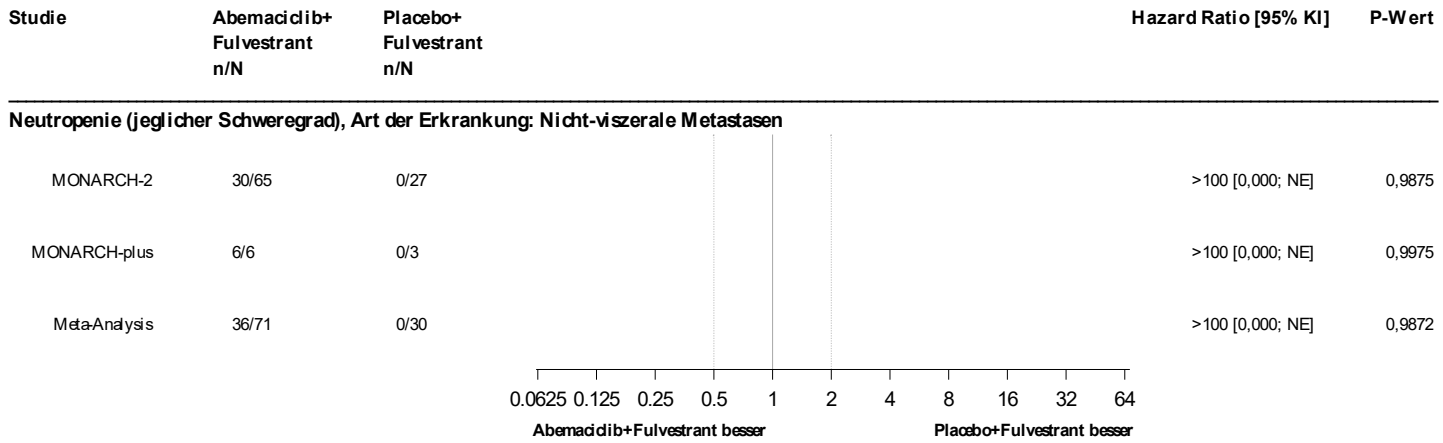
17SEP2021 / 07:48

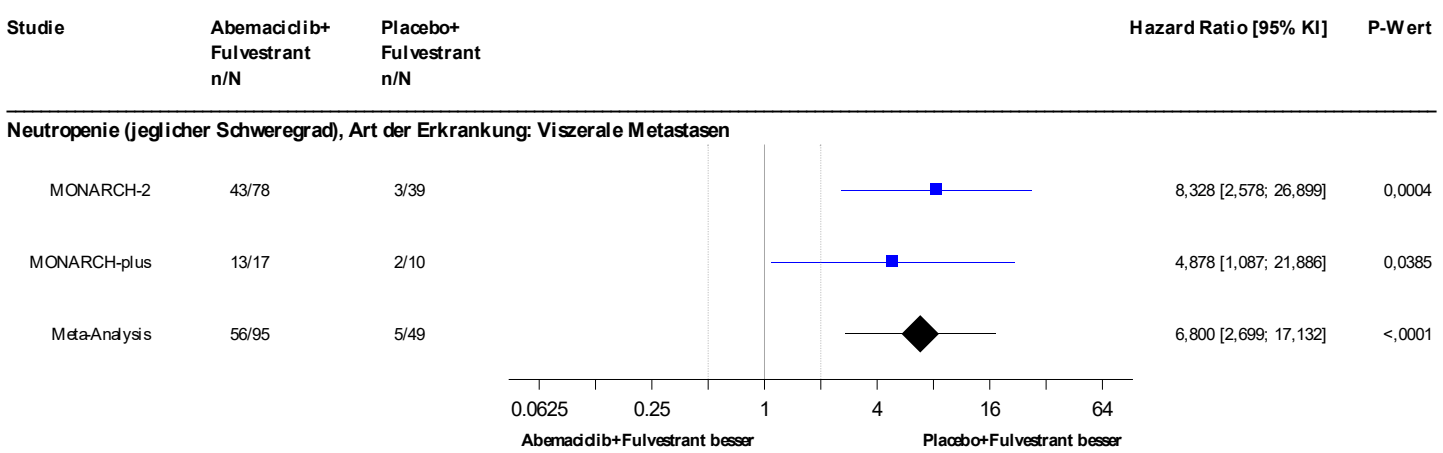
Abbildung 1424.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9997, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttnpaesi_popa2_natdis2_1.rtf
Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
17SEP2021 / 07:48

Abbildung 1424.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3028, P-Wert=0,5821, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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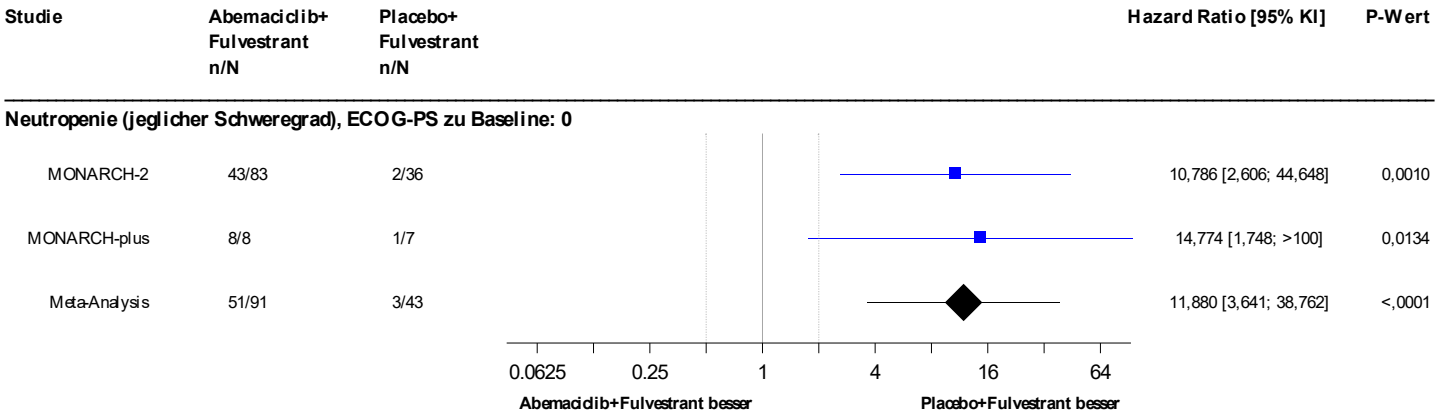
Abbildung 1424.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0578, P-Wert=0,8099, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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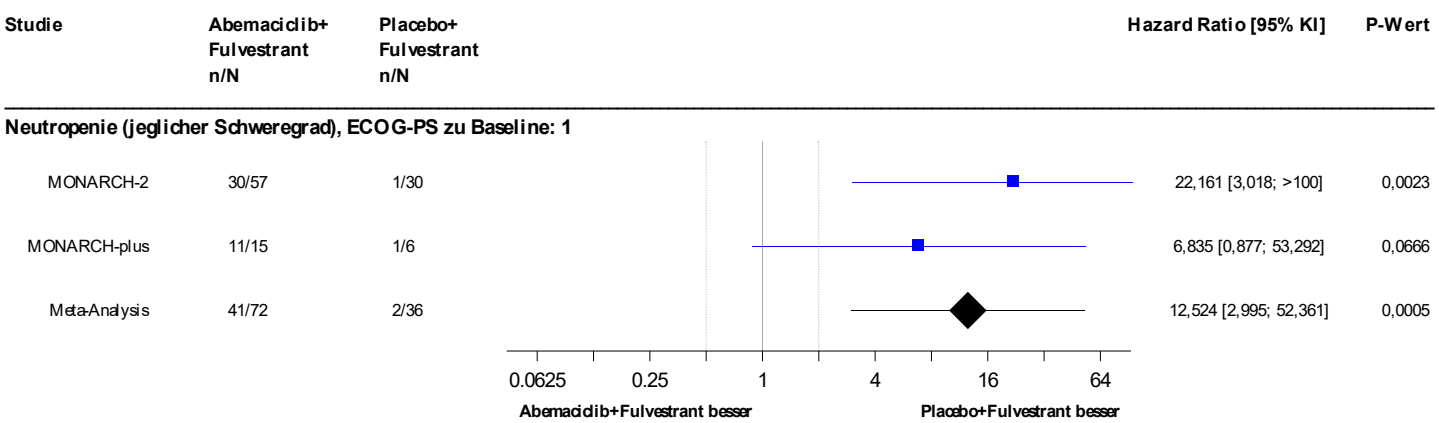
Abbildung 1424.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,6487, P-Wert=0,4206, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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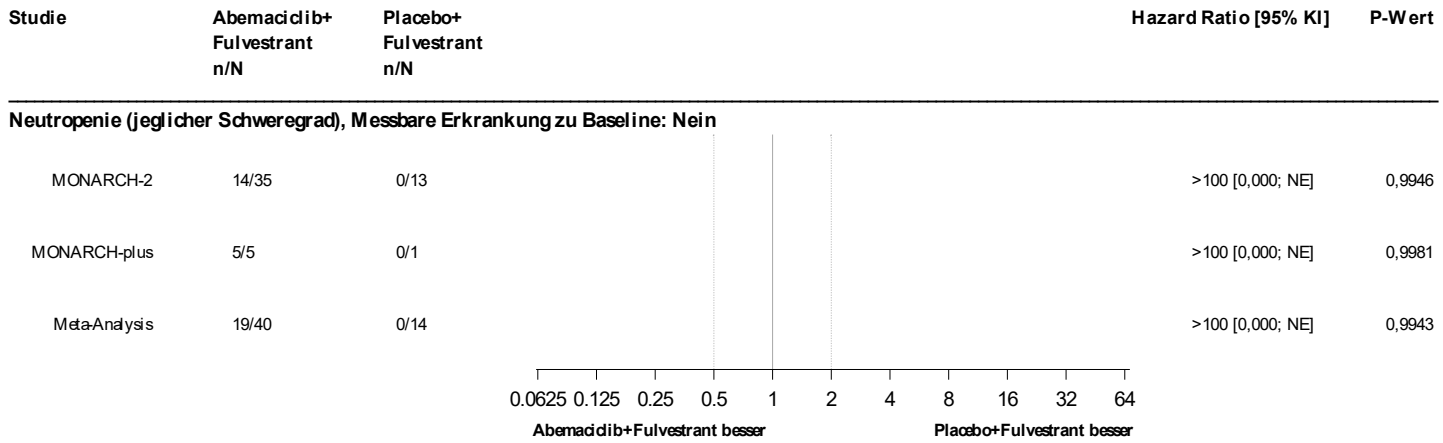
Abbildung 1424.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
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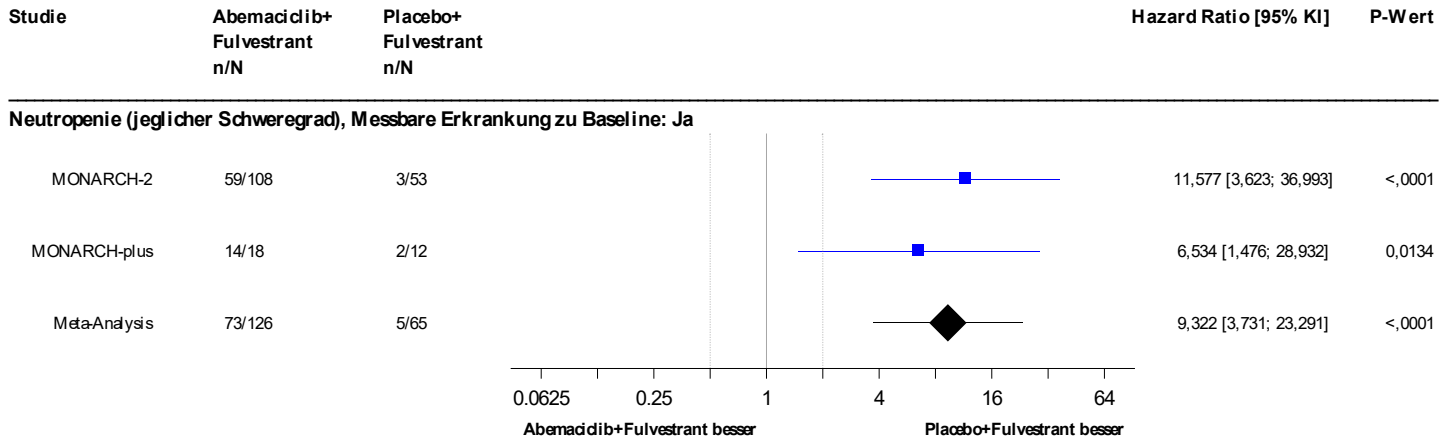
Abbildung 1424.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3527, P-Wert=0,5526, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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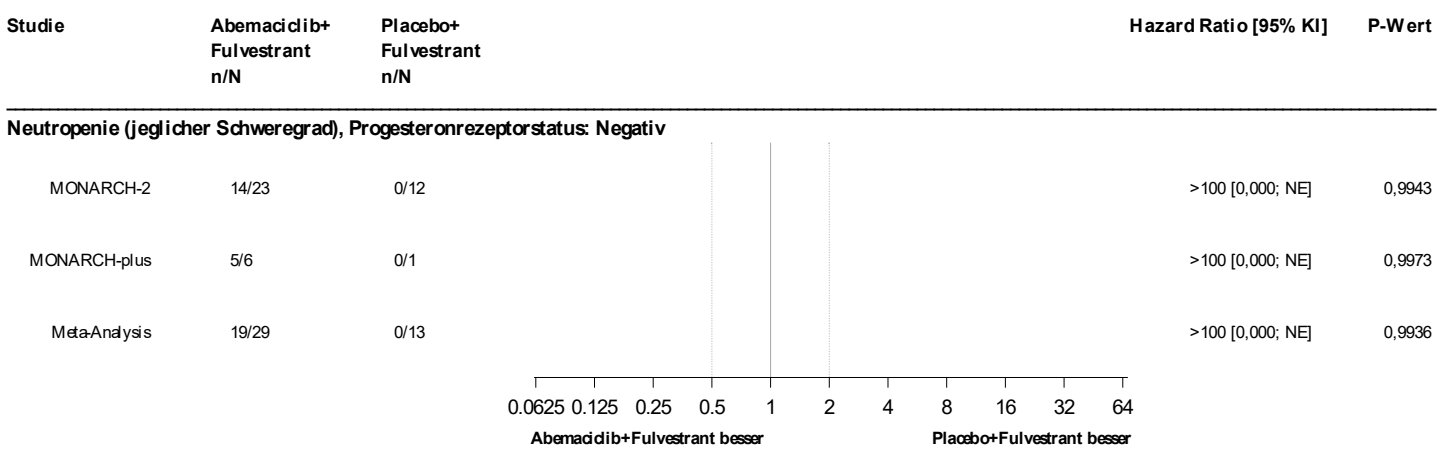
Abbildung 1424.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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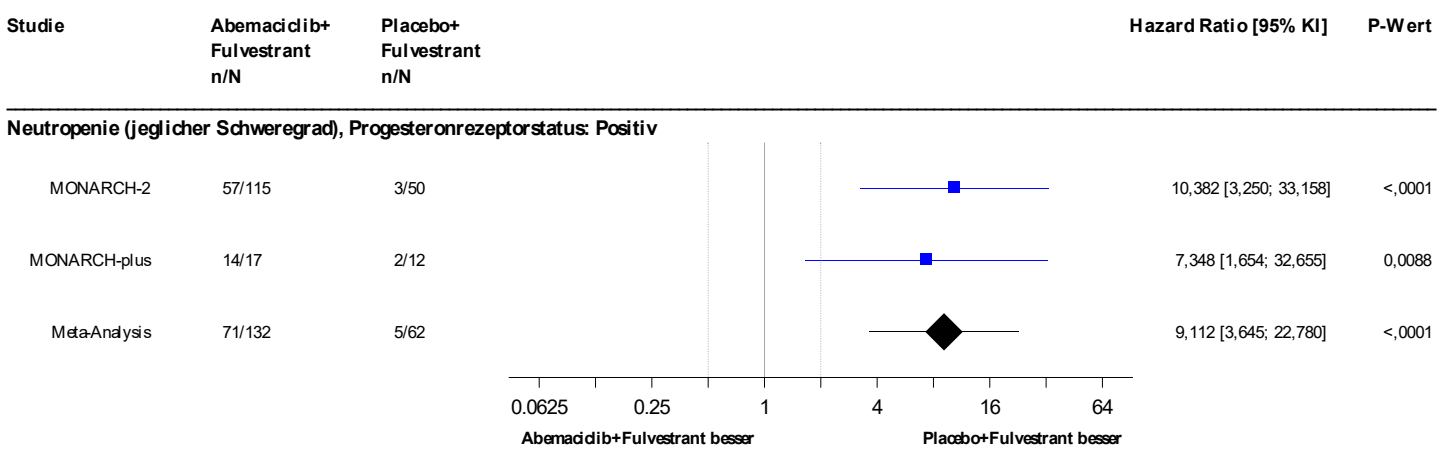
Abbildung 1424.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1284, P-Wert=0,7201, I2 Index=0%
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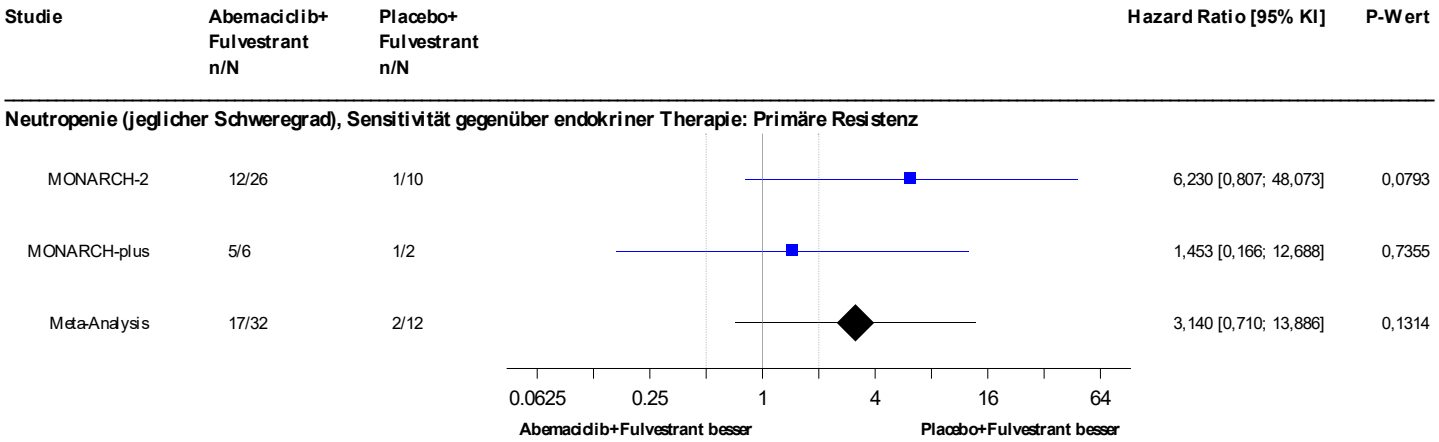
Abbildung 1424.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,9177, P-Wert=0,3381, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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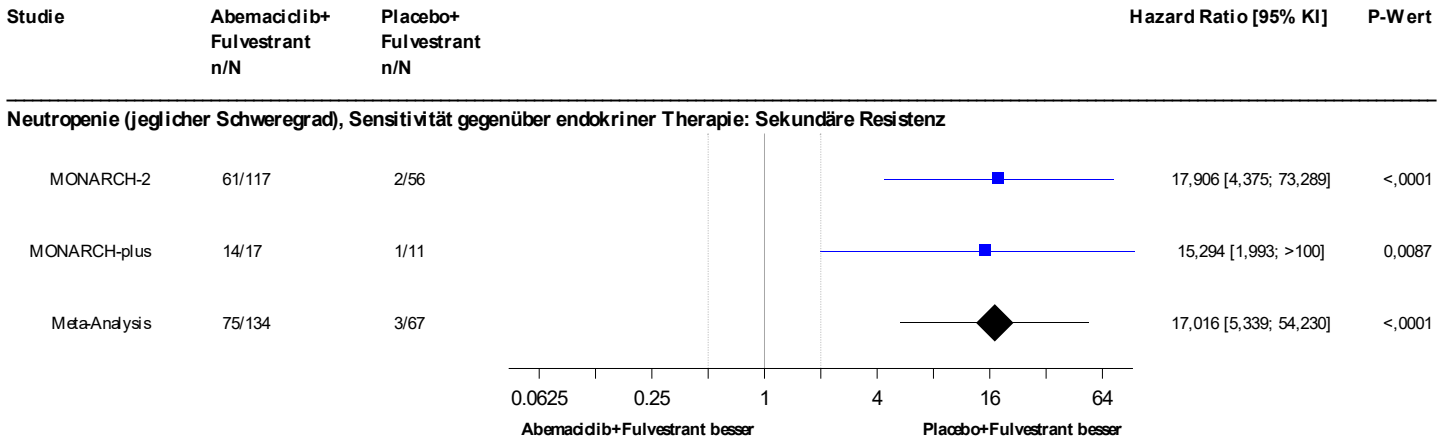
Abbildung 1424.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0156, P-Wert=0,9007, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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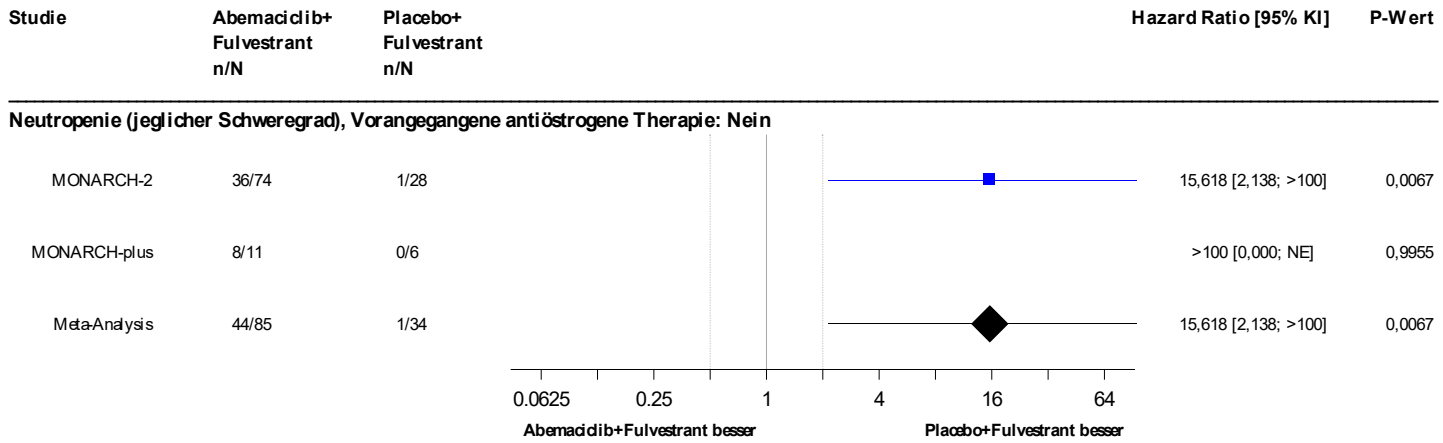
Abbildung 1424.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9962, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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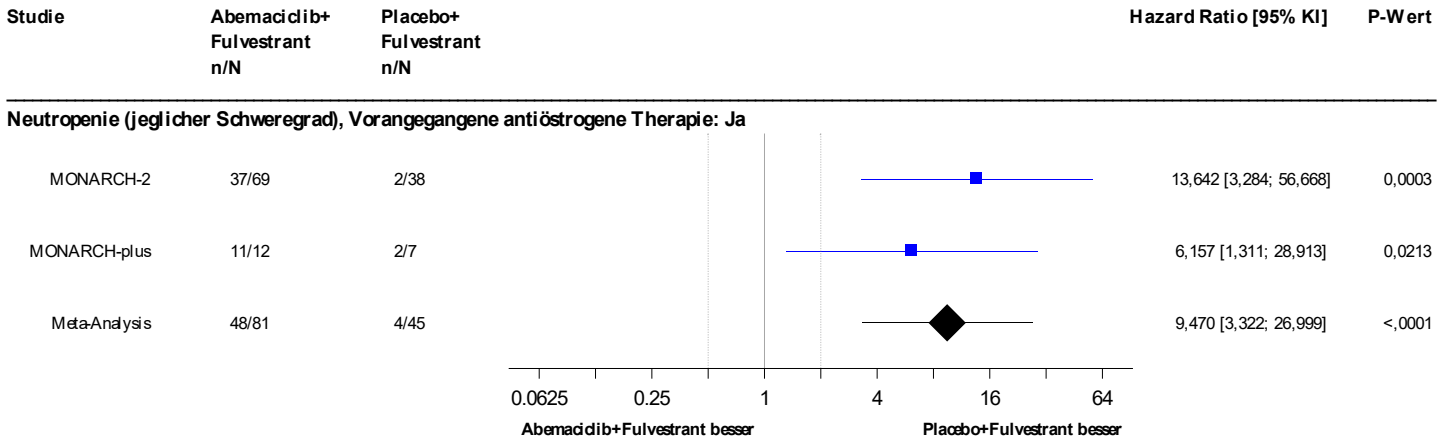
Abbildung 1424.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Neutropenie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,5502, P-Wert=0,4582, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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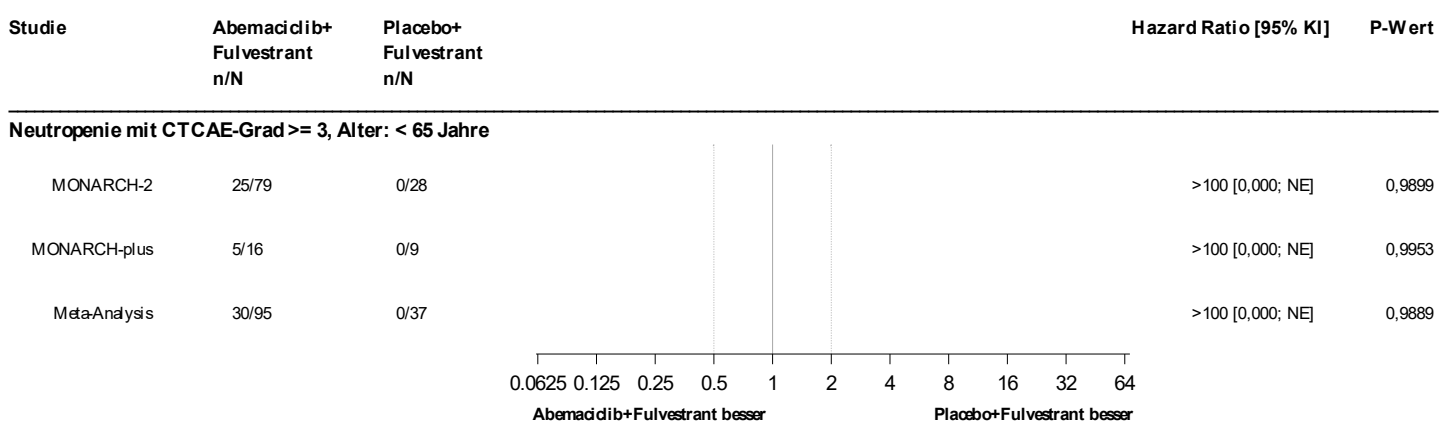
Abbildung 1425.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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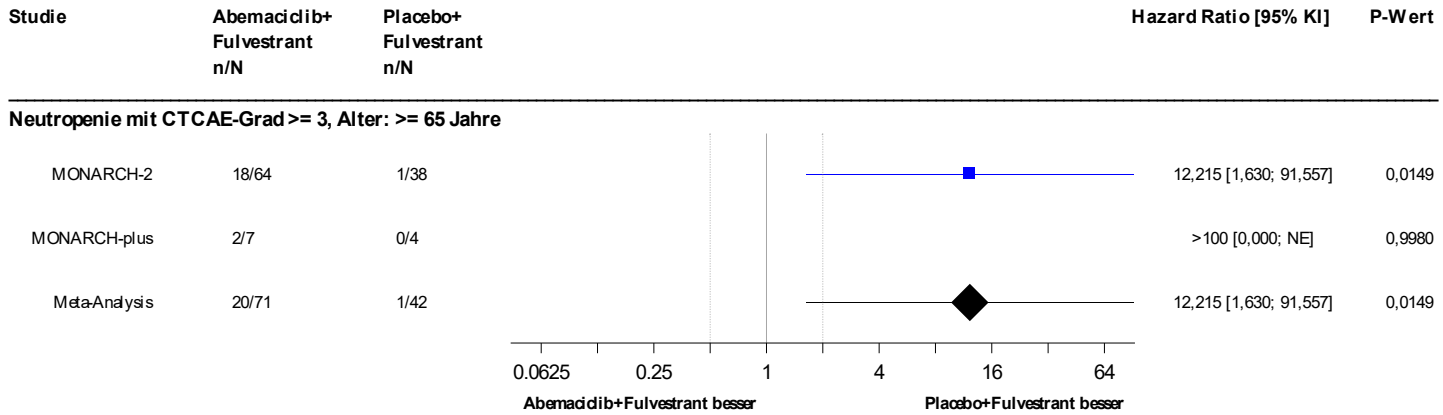
Abbildung 1425.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9983, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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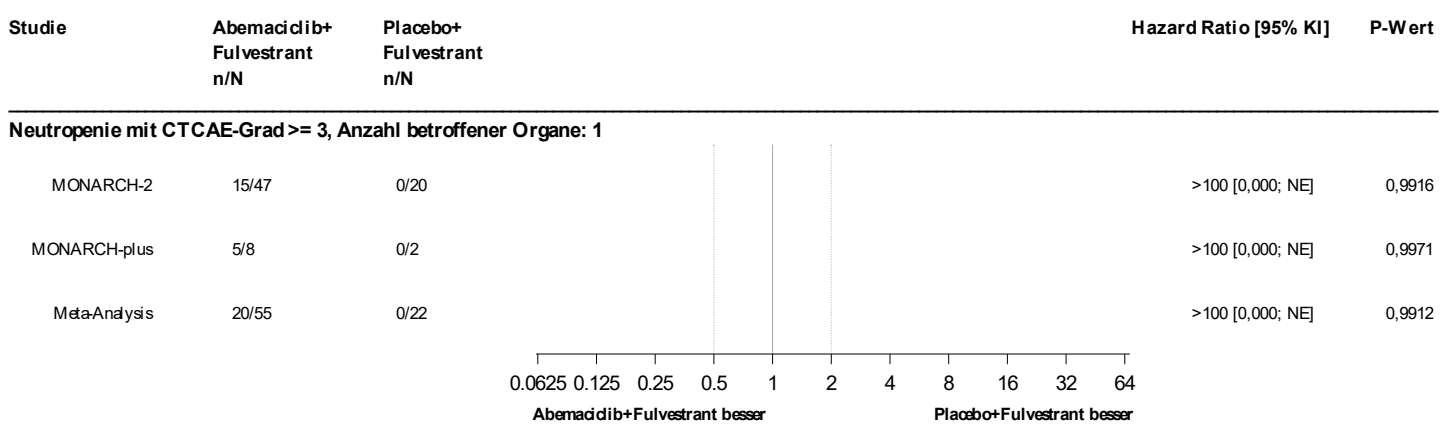
17SEP2021 / 07:48

Abbildung 1425.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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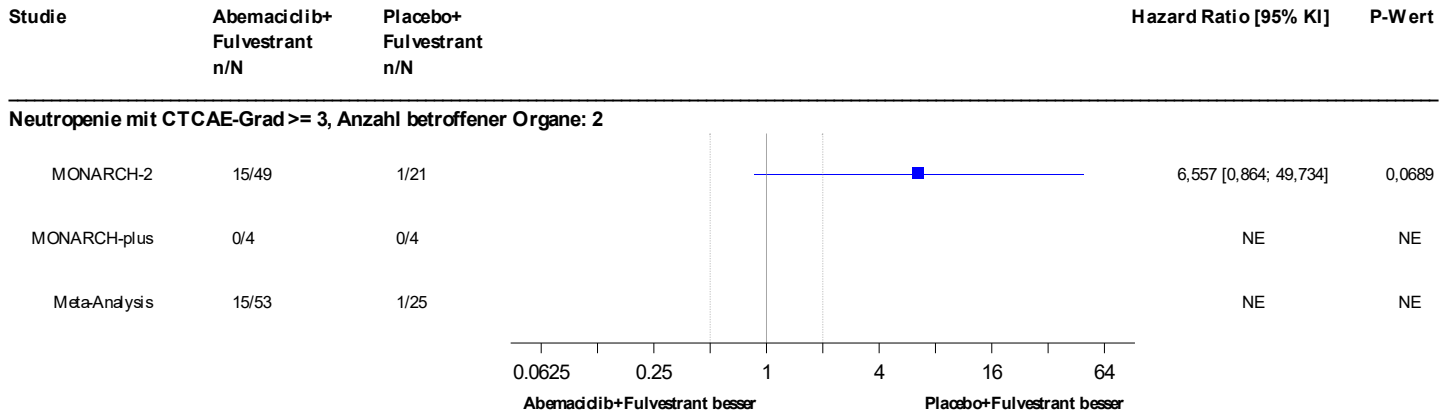
17SEP2021 / 07:48

Abbildung 1425.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Abbildung 1425.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

Studie	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% KI]	P-Wert
Neutropenie mit CTCAE-Grad >= 3, Anzahl betroffener Organe: >= 3				
MONARCH-2	13/47	0/25	>100 [0,000; NE]	0,9918
MONARCH-plus	2/11	0/7	>100 [0,000; NE]	0,9980
Meta-Analysis	15/58	0/32	>100 [0,000; NE]	0,9916

Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Abbildung 1425.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

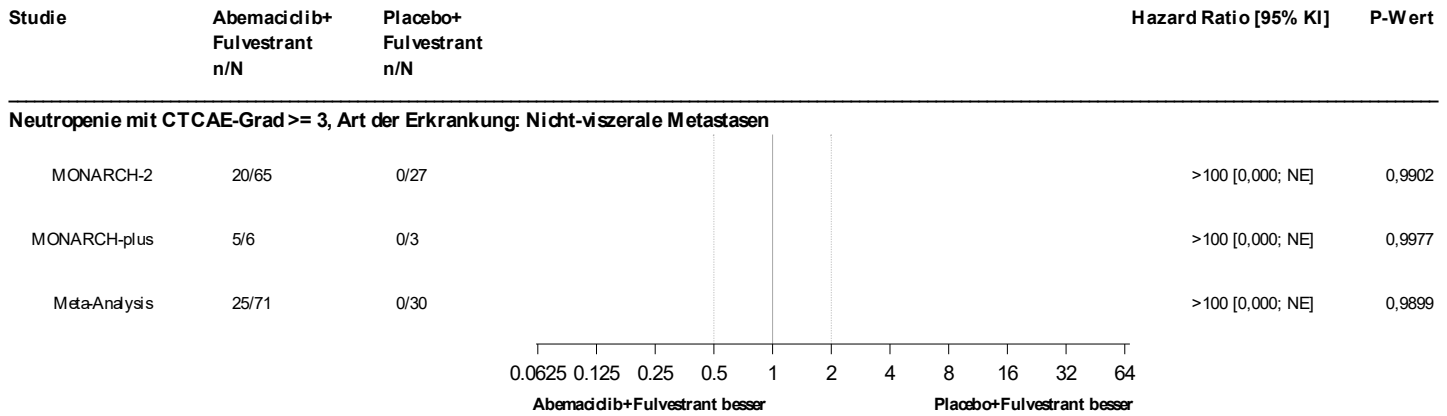

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Abbildung 1425.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

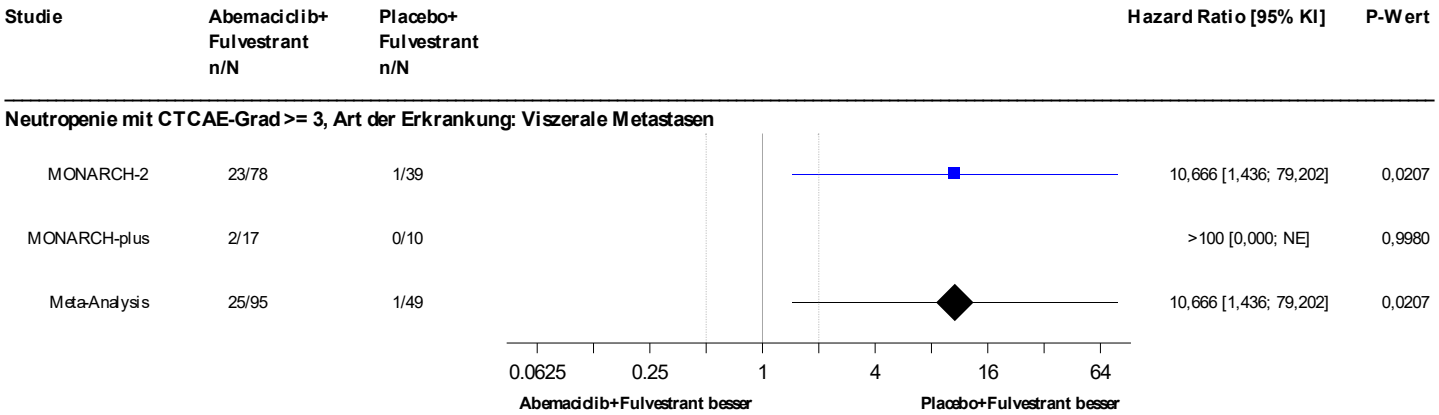

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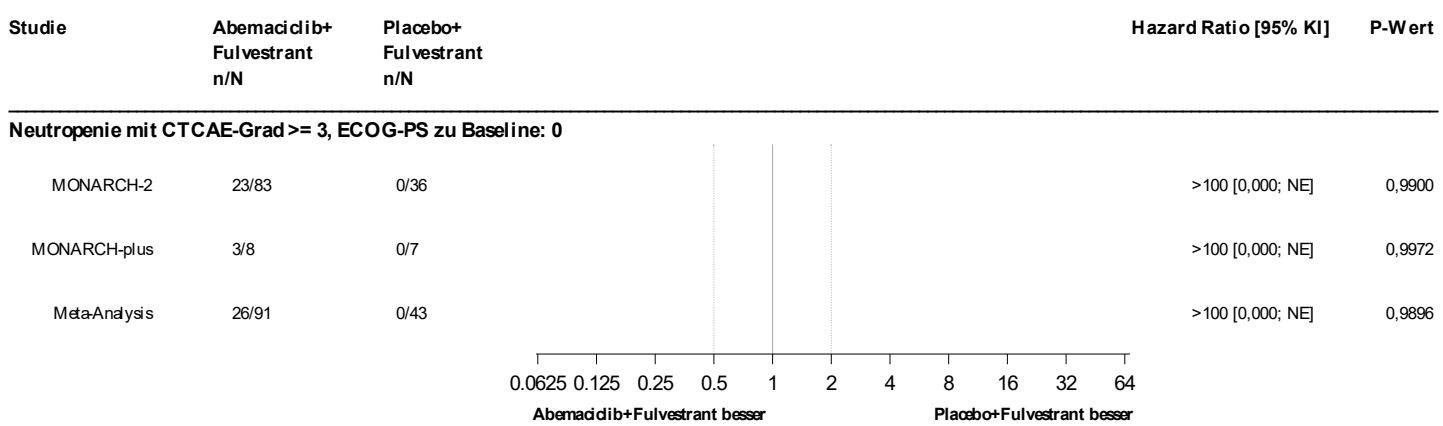
Abbildung 1425.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9998, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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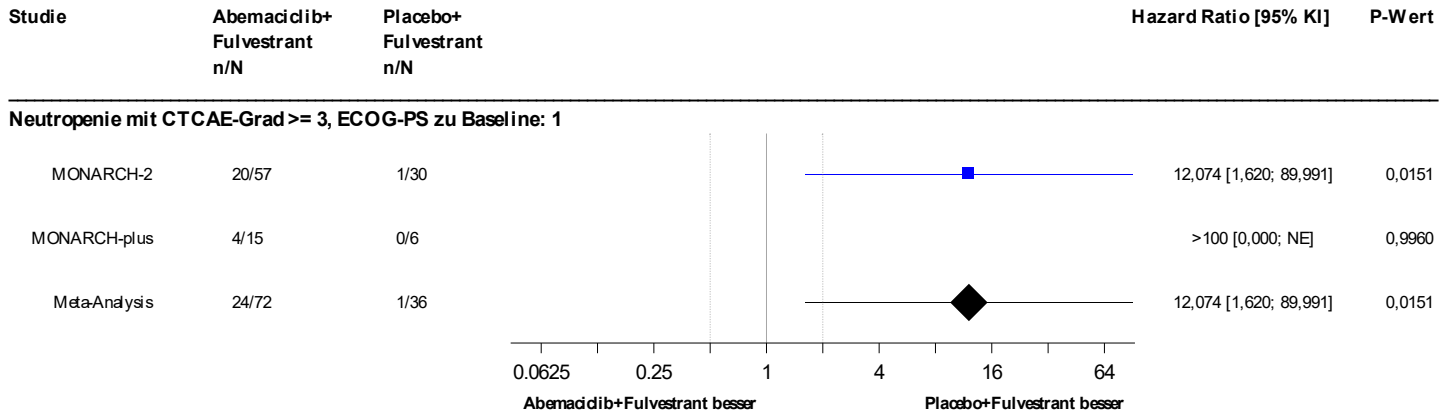
Abbildung 1425.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9966, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Abbildung 1425.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

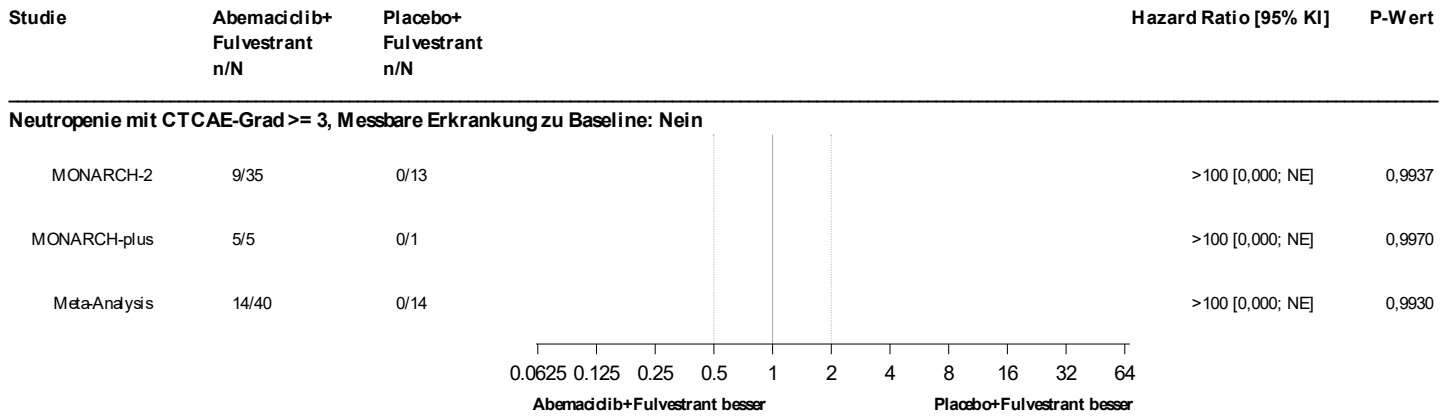

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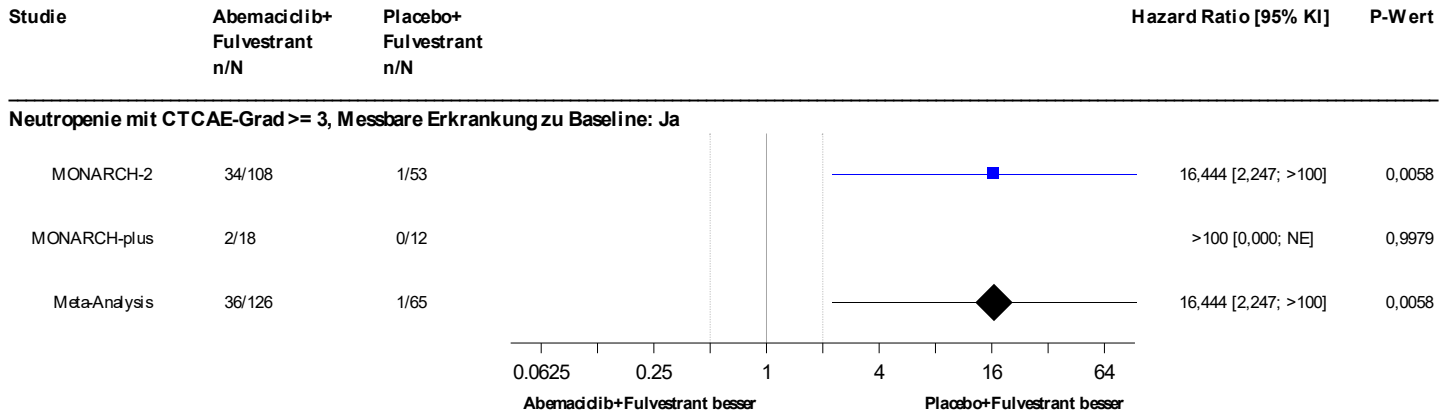
Abbildung 1425.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Abbildung 1425.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

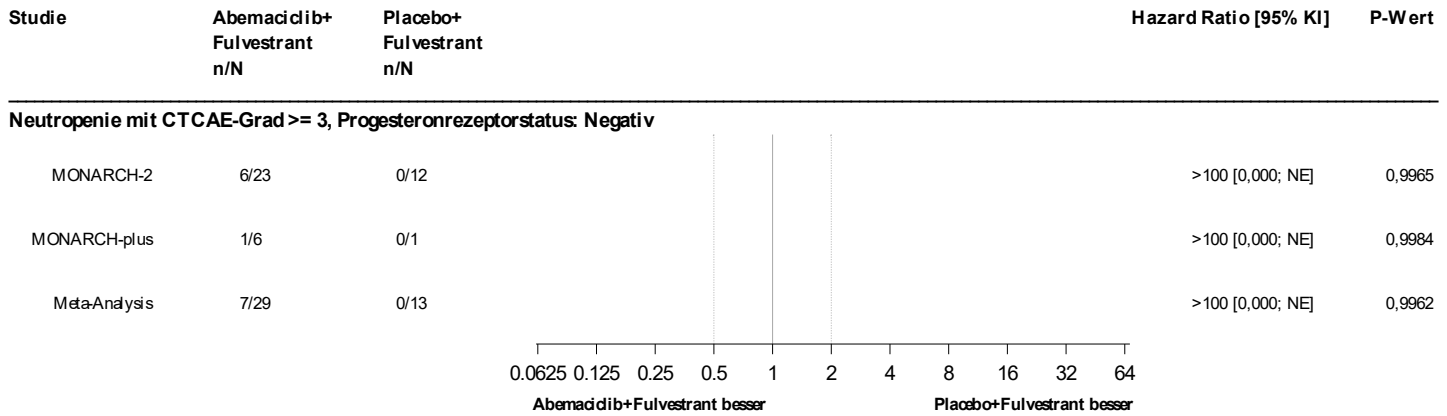

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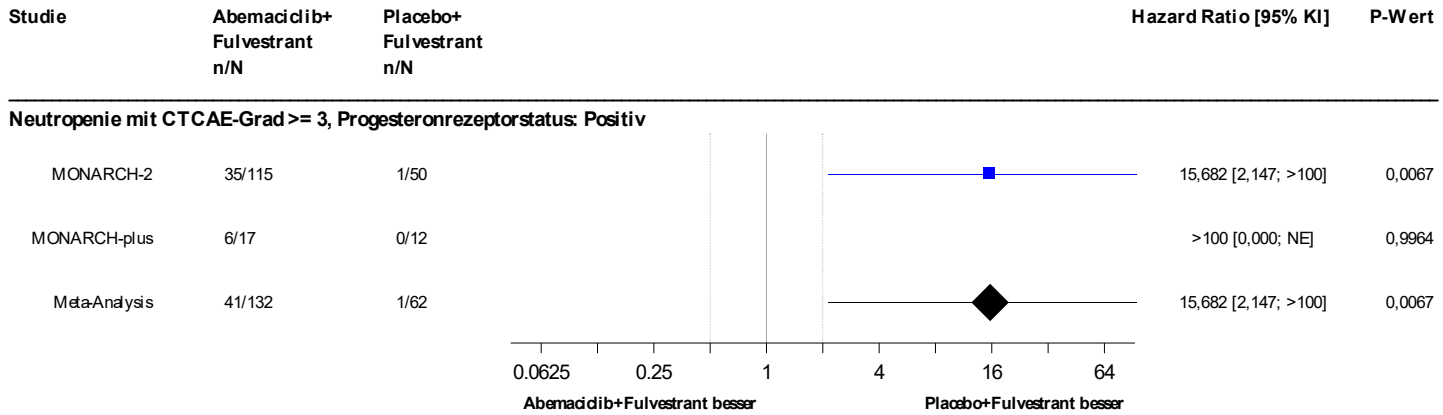
Abbildung 1425.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Abbildung 1425.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

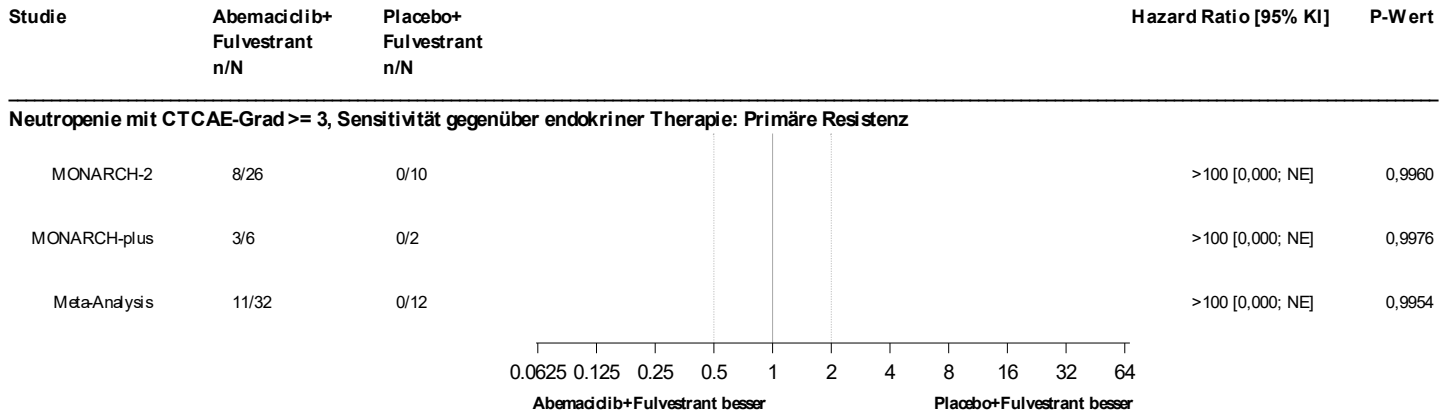

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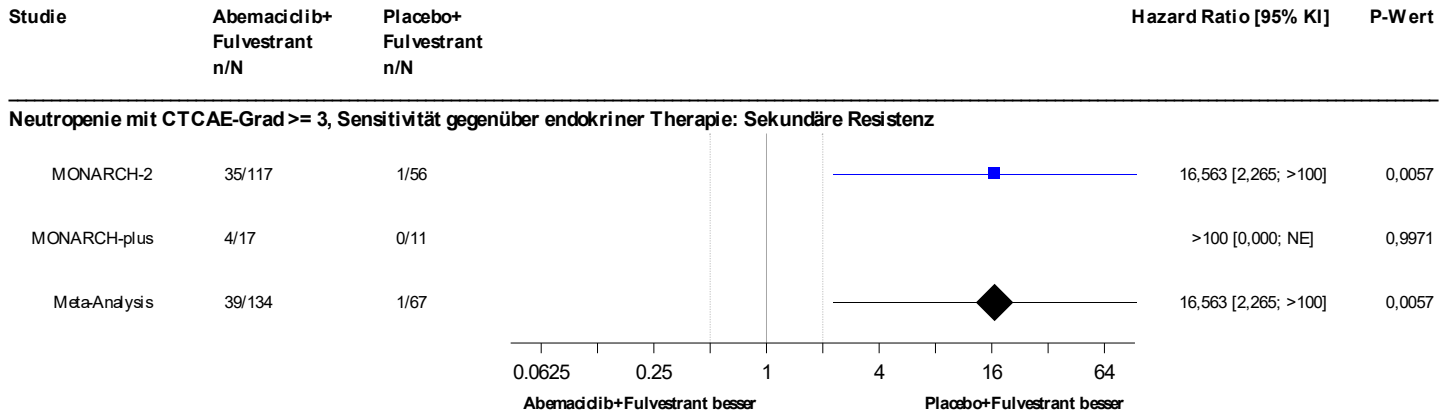
Abbildung 1425.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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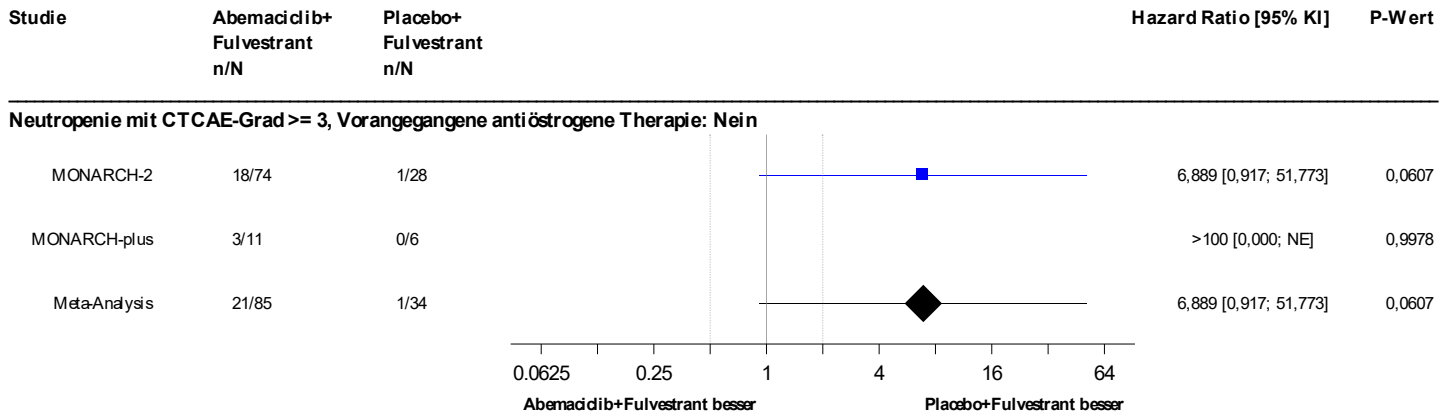
17SEP2021 / 07:48

Abbildung 1425.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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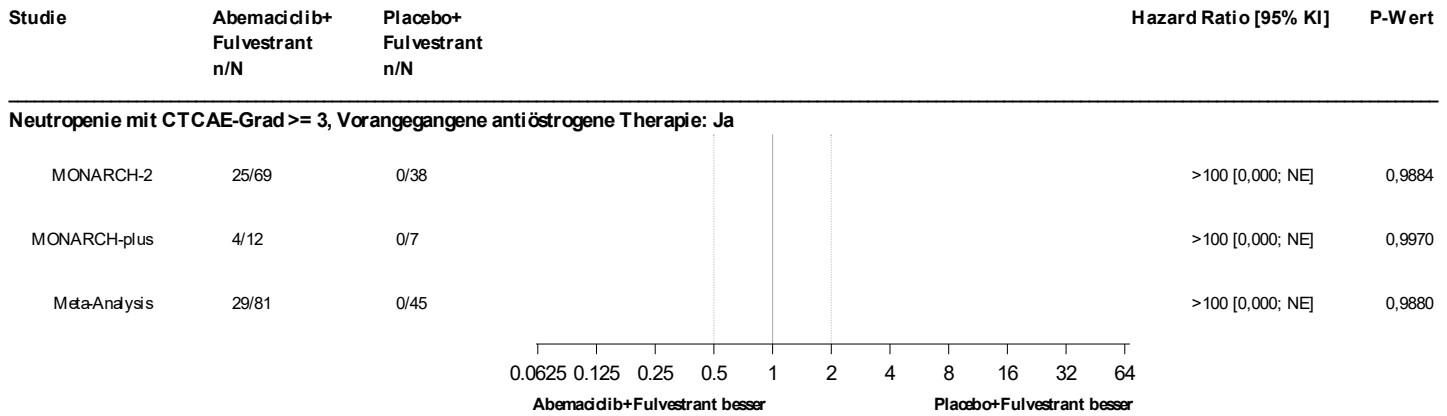
17SEP2021 / 07:48

Abbildung 1425.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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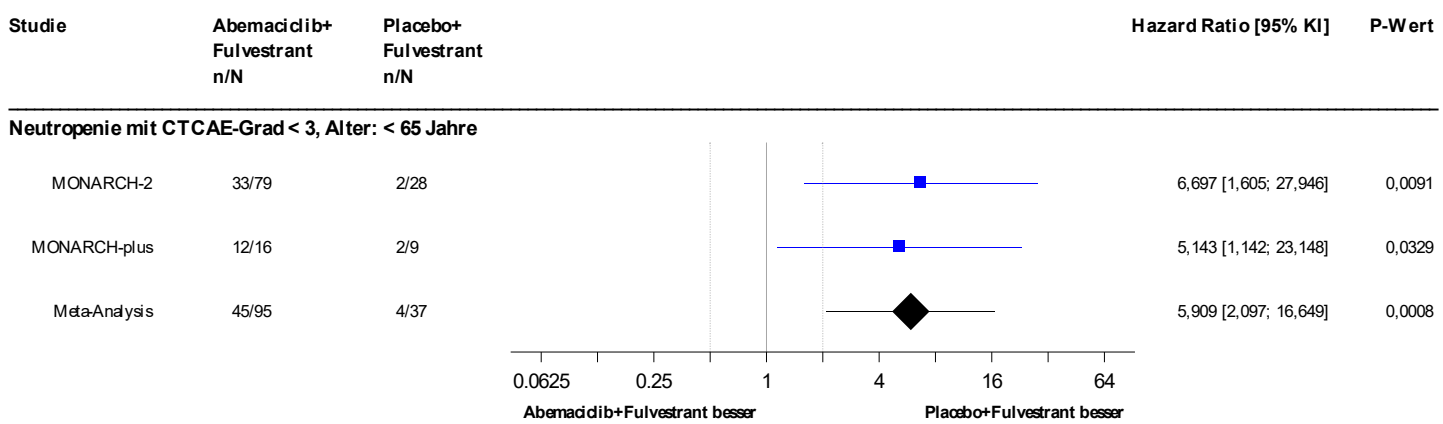
Abbildung 1426.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0622, P-Wert=0,8030, I2 Index=0%
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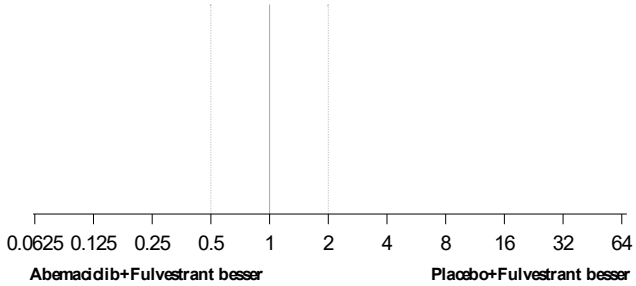
Abbildung 1426.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

Studie	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% KI]	P-Wert
Neutropenie mit CTCAE-Grad < 3, Alter: >= 65 Jahre				
MONARCH-2	24/64	0/38	>100 [0,000; NE]	0,9882
MONARCH-plus	7/7	0/4	>100 [0,000; NE]	0,9973
Meta-Analysis	31/71	0/42	>100 [0,000; NE]	0,9879



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9997, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Abbildung 1426.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

Studie	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% KI]	P-Wert
Neutropenie mit CTCAE-Grad < 3, Anzahl betroffener Organe: 1				
MONARCH-2	16/47	0/20	>100 [0,000; NE]	0,9910
MONARCH-plus	8/8	0/2	>100 [0,000; NE]	0,9959
Meta-Analysis	24/55	0/22	>100 [0,000; NE]	0,9901

Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9998, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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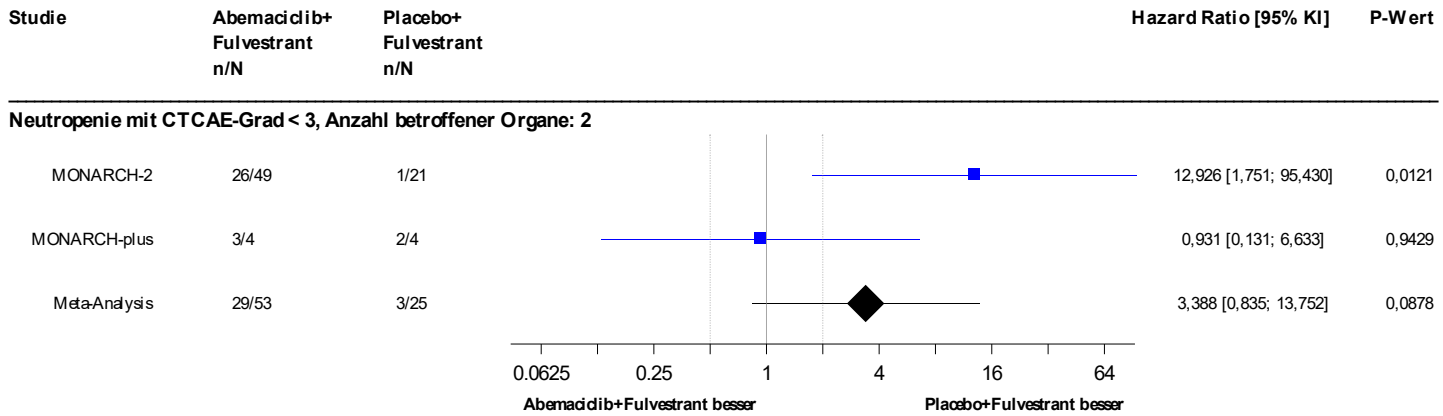
Abbildung 1426.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=3,3863, P-Wert=0,0657, I2 Index=70,5%
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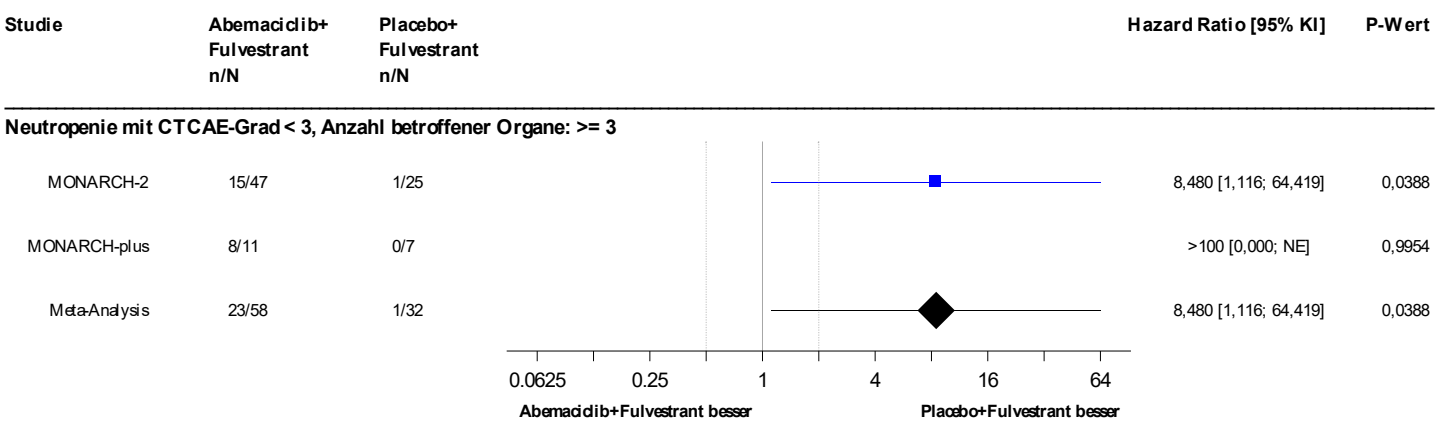
Abbildung 1426.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9960, I2 Index=0%
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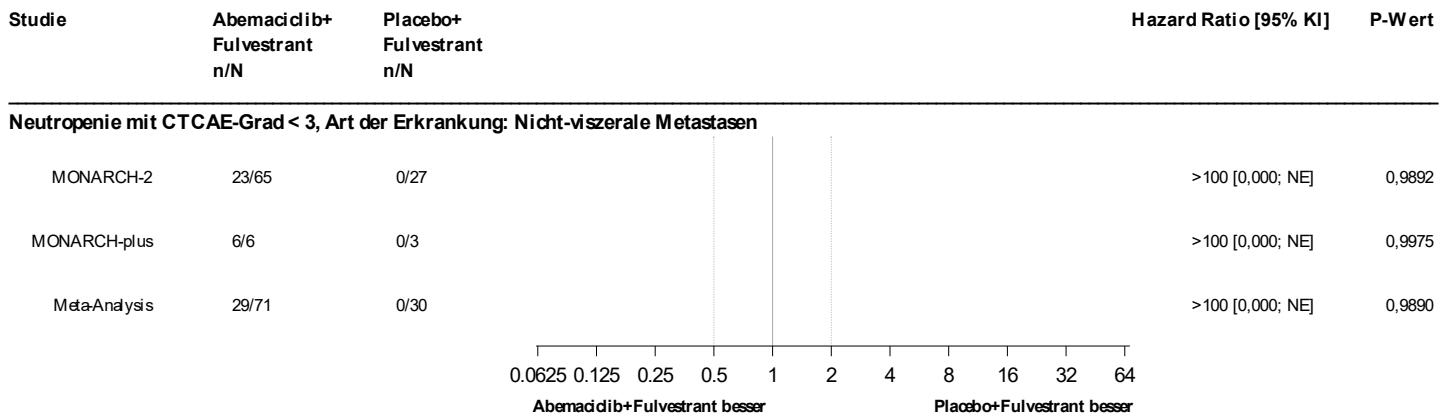
Abbildung 1426.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9996, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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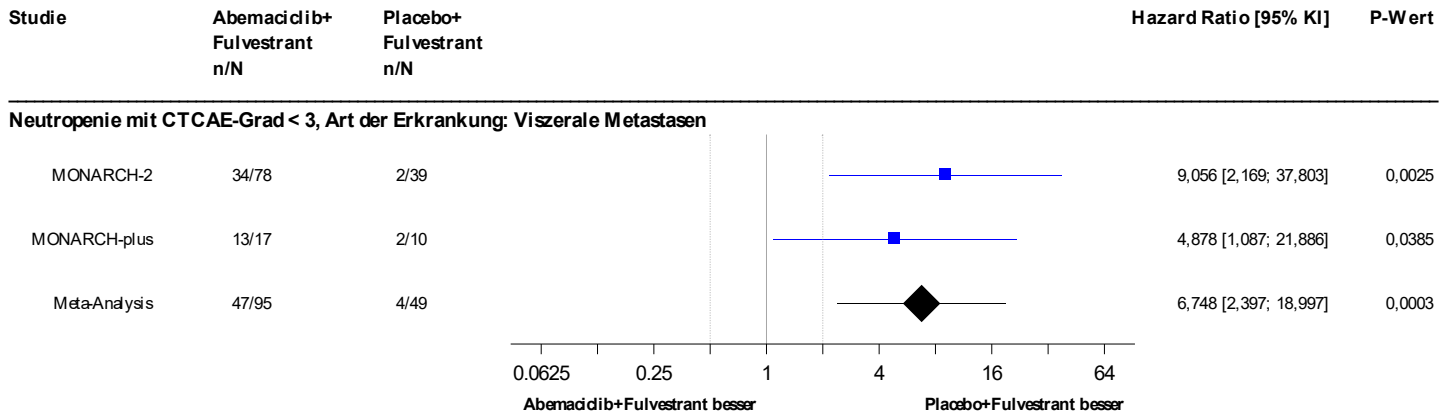
17SEP2021 / 07:48

Abbildung 1426.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3422, P-Wert=0,5586, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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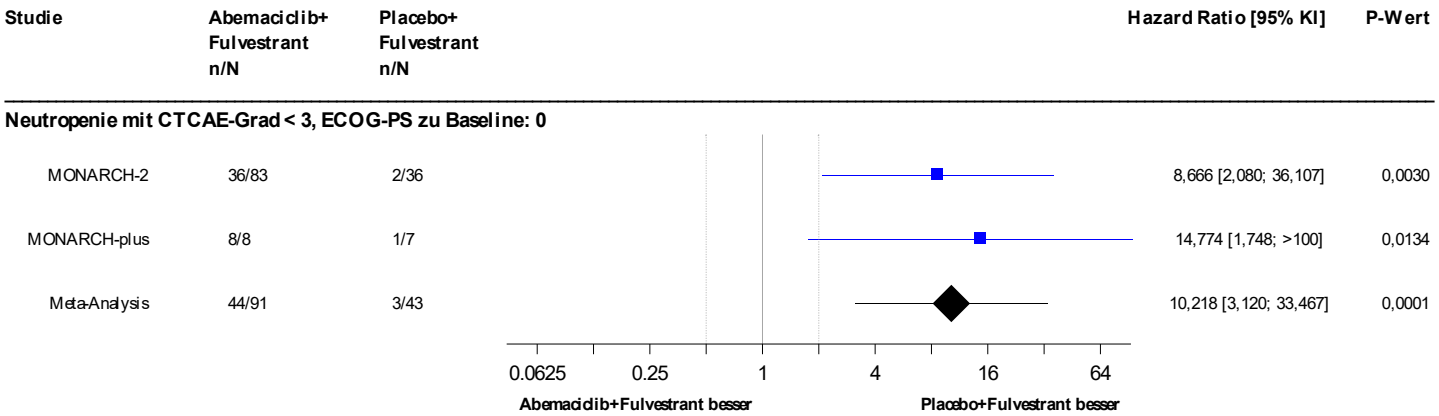
Abbildung 1426.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1659, P-Wert=0,6838, I2 Index=0%
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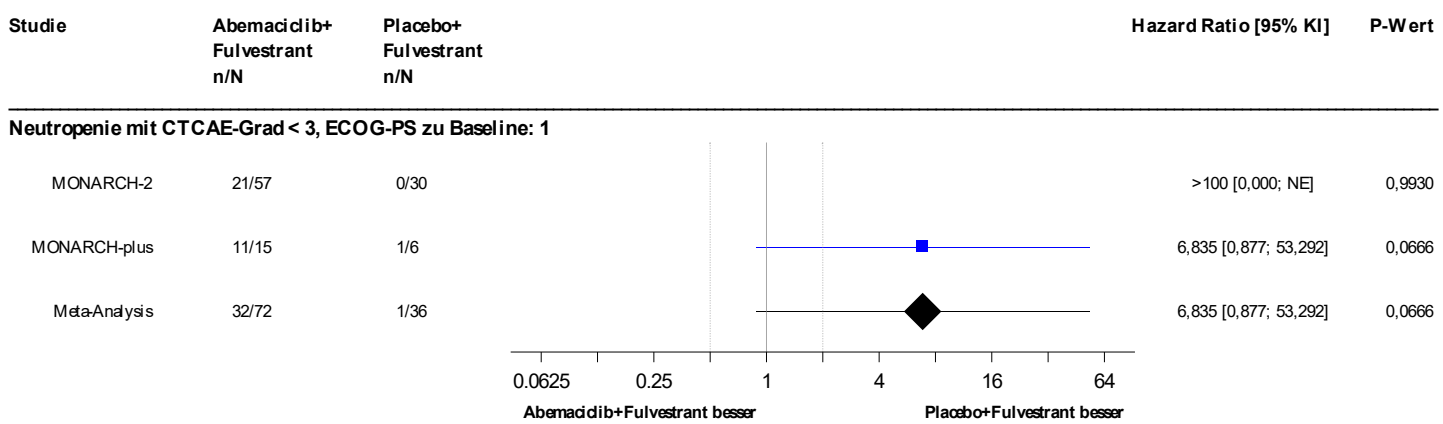
Abbildung 1426.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9937, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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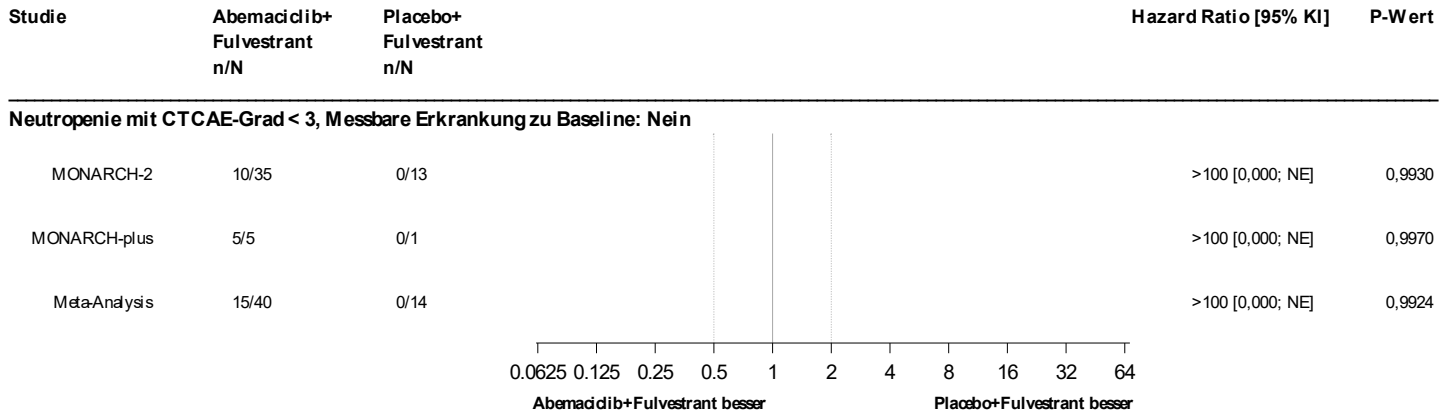
Abbildung 1426.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9998, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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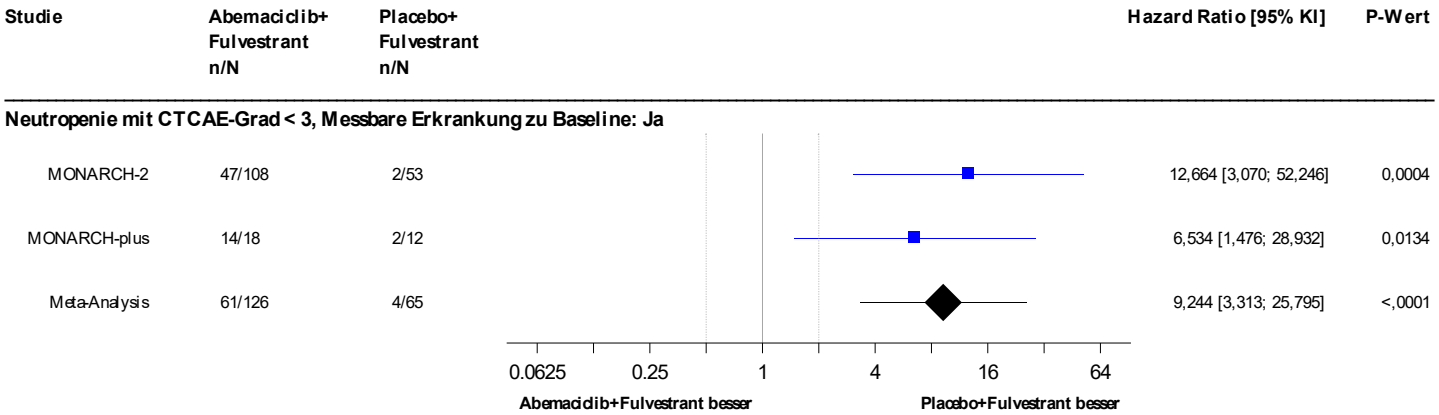
Abbildung 1426.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3983, P-Wert=0,5280, I2 Index=0%
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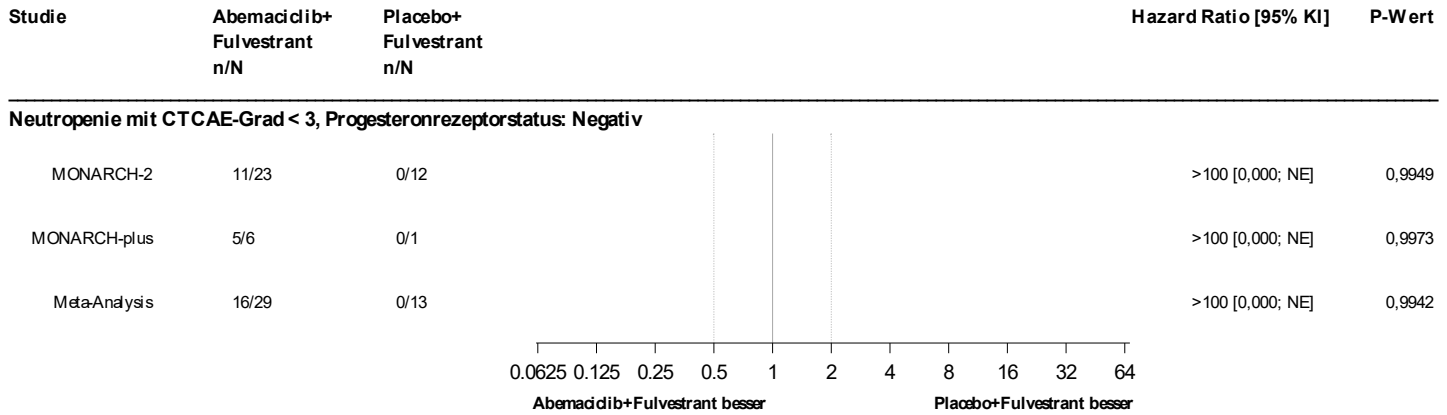
Abbildung 1426.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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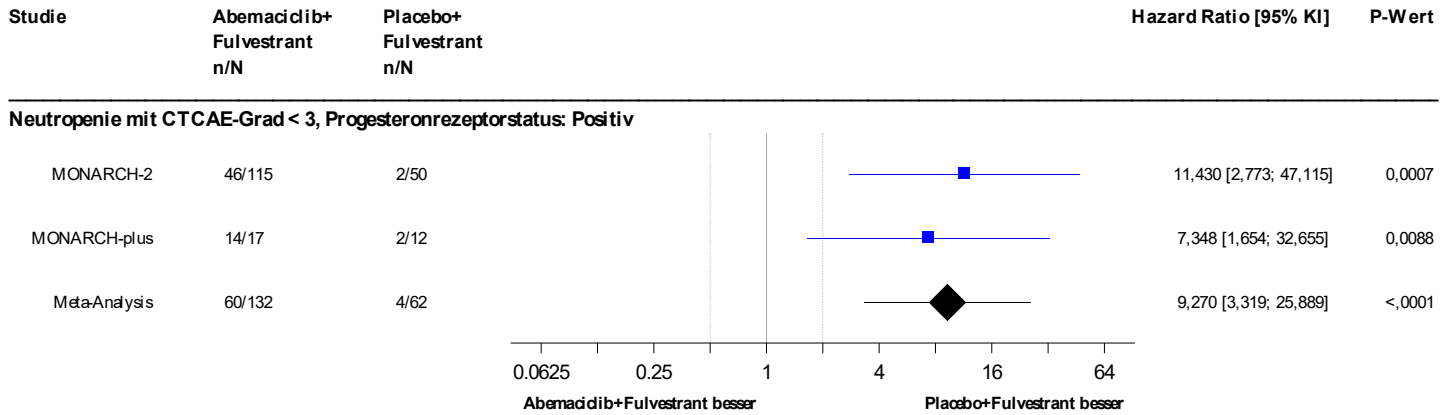
17SEP2021 / 07:48

Abbildung 1426.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1772, P-Wert=0,6738, I2 Index=0%
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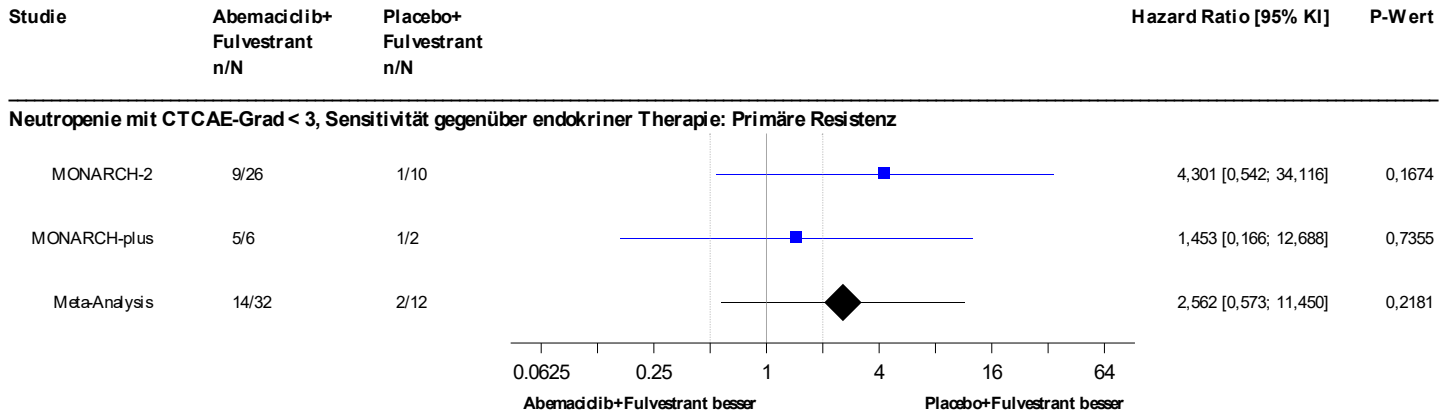
Abbildung 1426.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,5036, P-Wert=0,4779, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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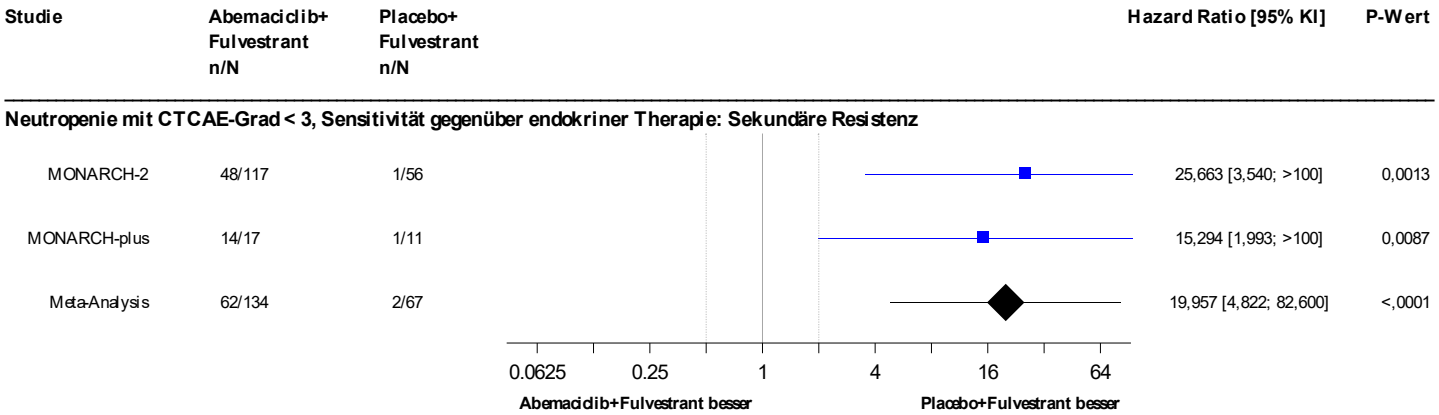
Abbildung 1426.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1274, P-Wert=0,7211, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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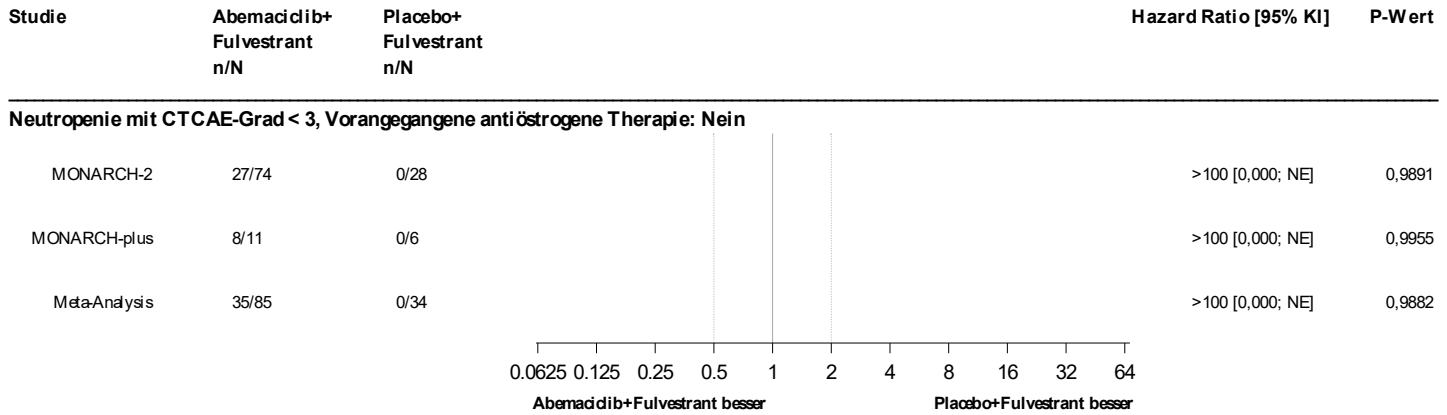
Abbildung 1426.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9996, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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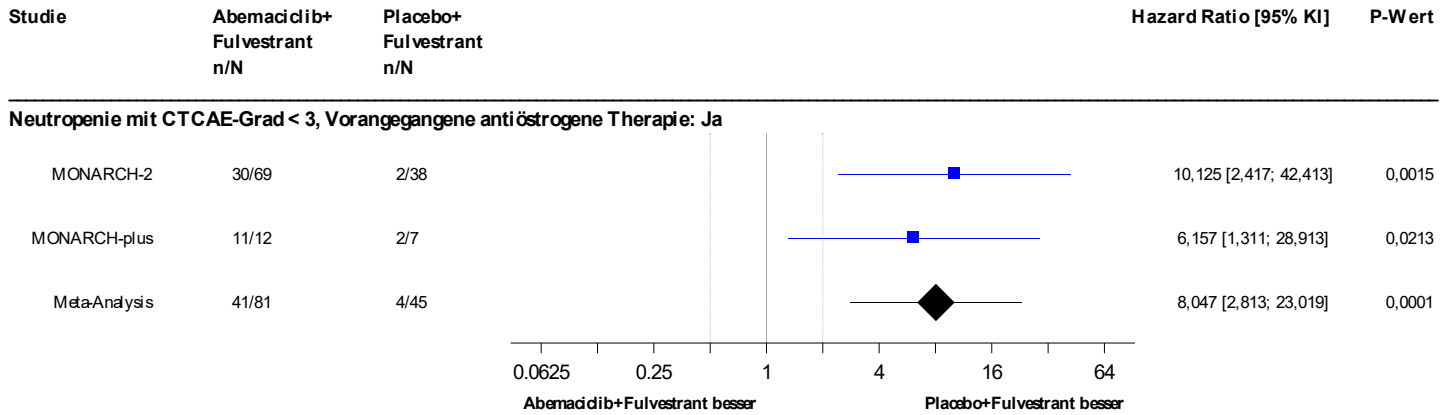
Abbildung 1426.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: Neutropenie aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2139, P-Wert=0,6437, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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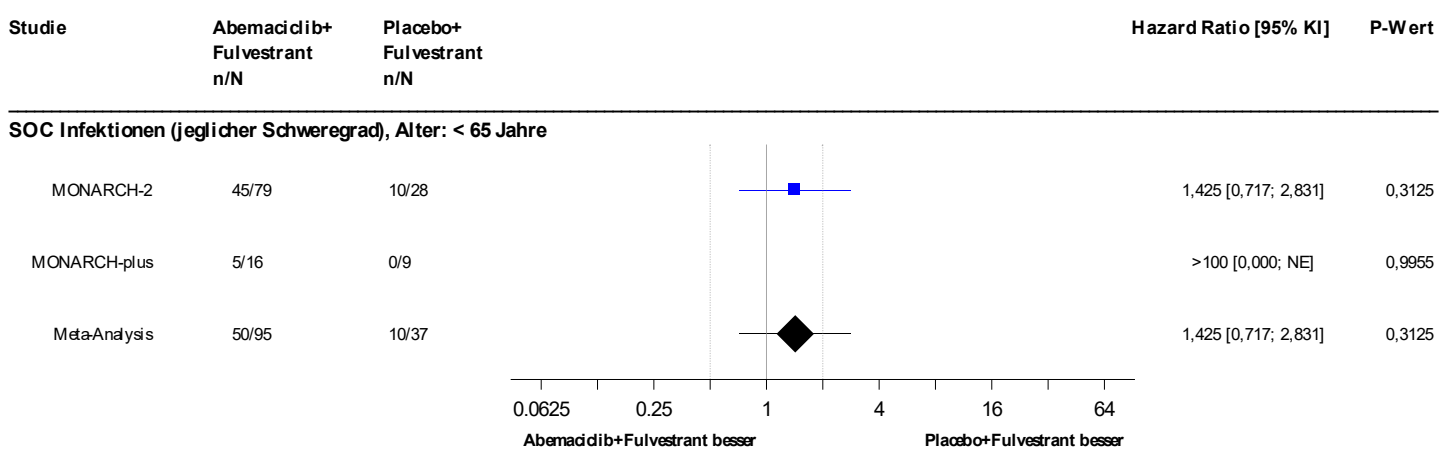
Abbildung 1428.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9956, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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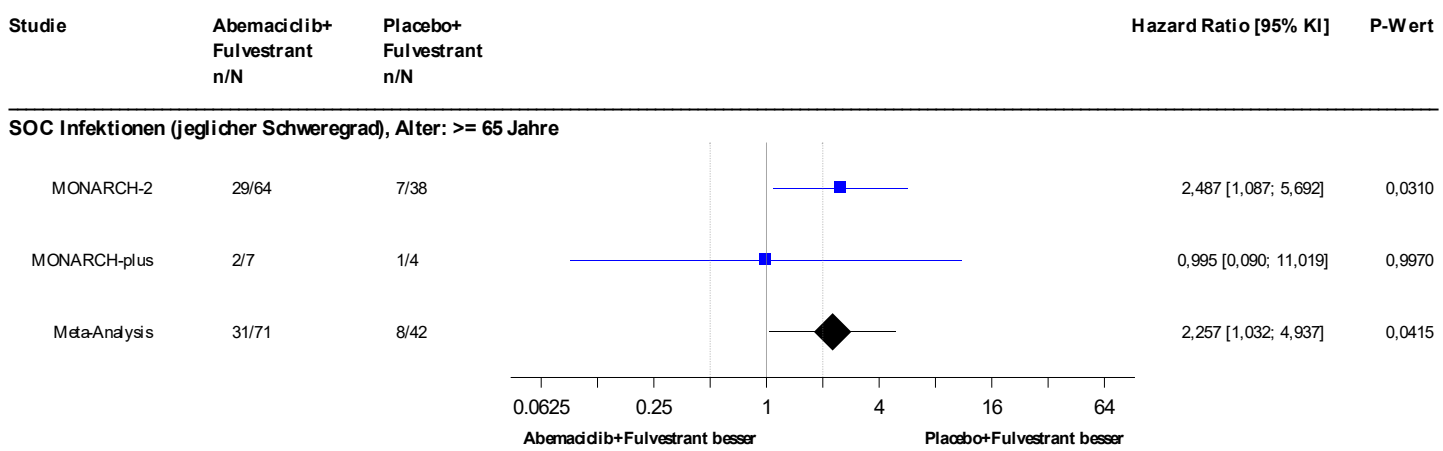
Abbildung 1428.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,4982, P-Wert=0,4803, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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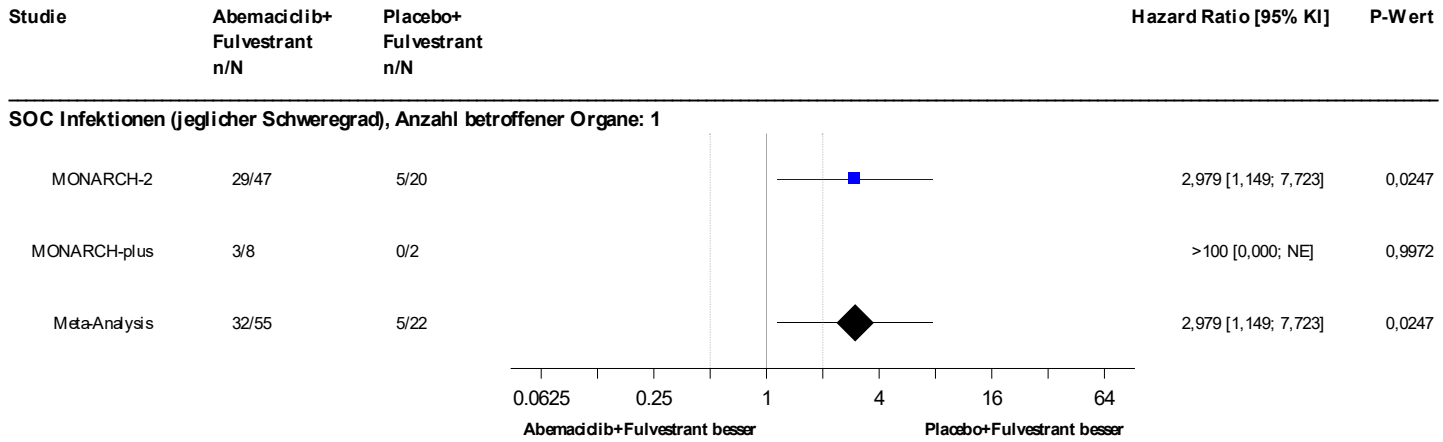
Abbildung 1428.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9974, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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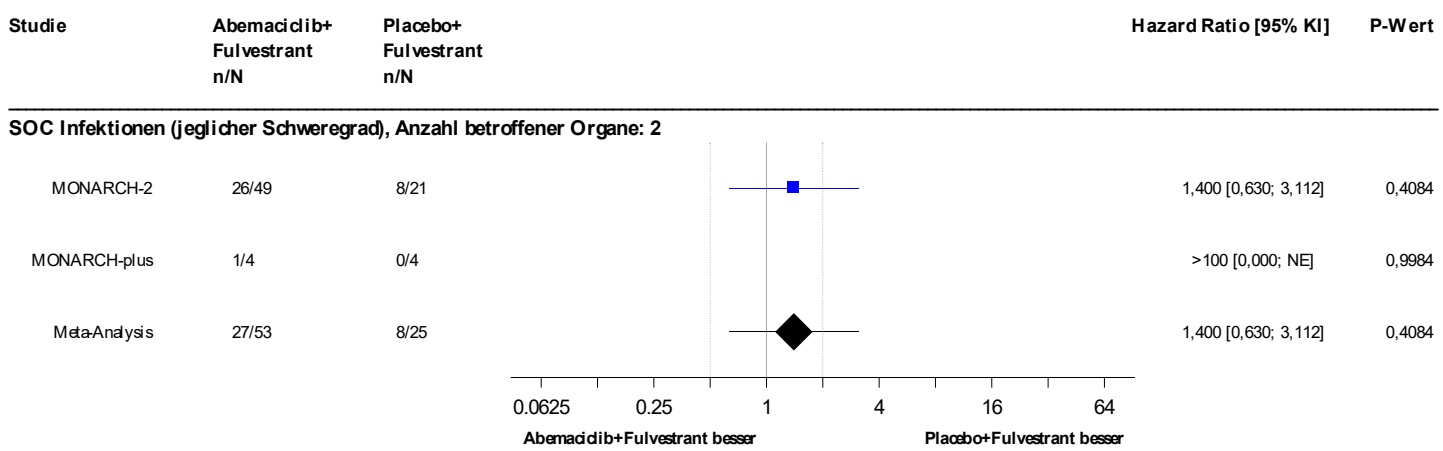
Abbildung 1428.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9984, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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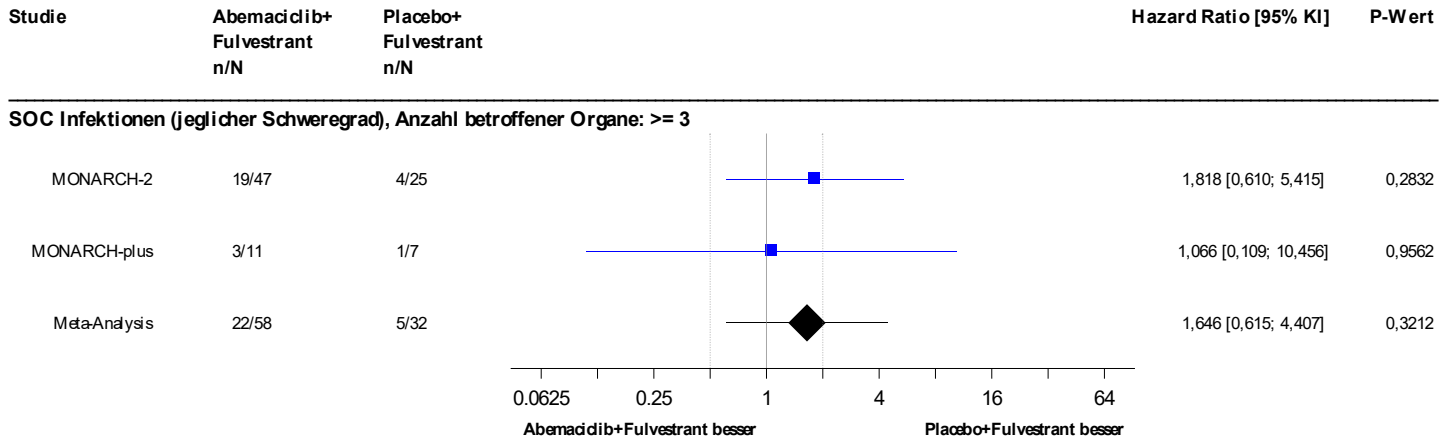
Abbildung 1428.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1708, P-Wert=0,6794, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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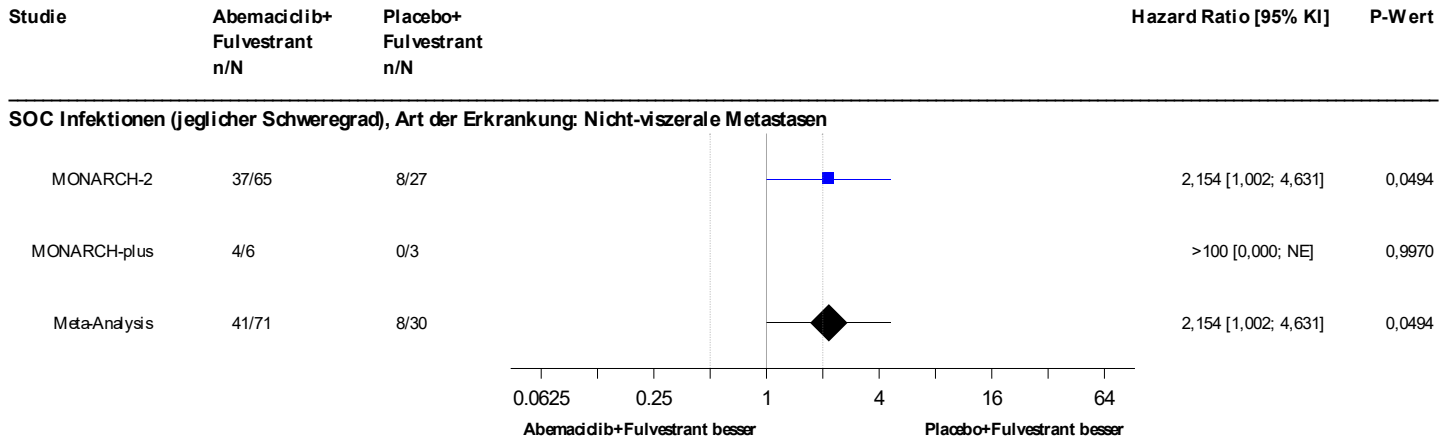
Abbildung 1428.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9971, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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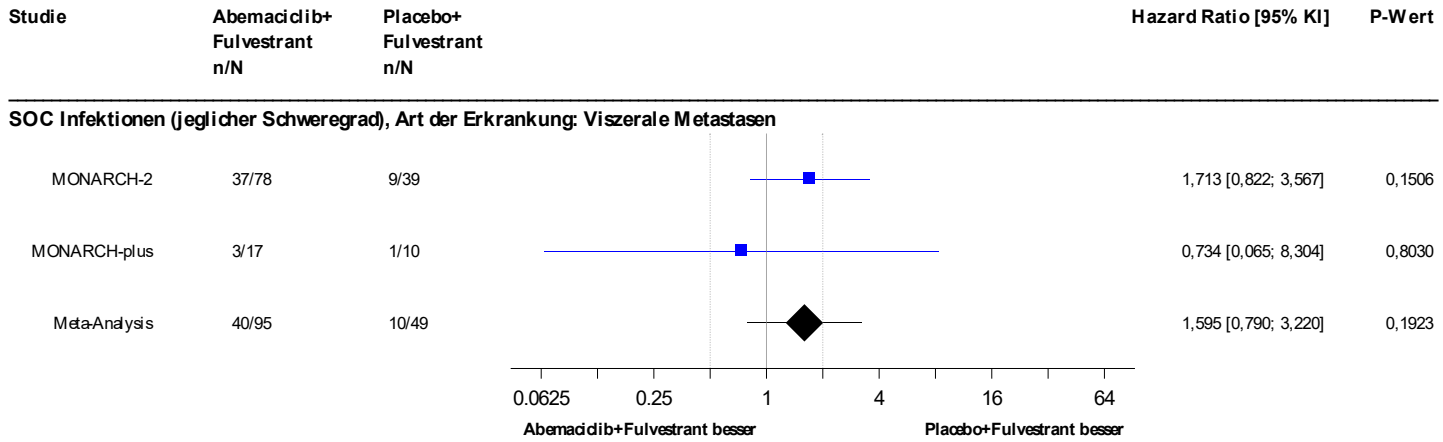
Abbildung 1428.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,4289, P-Wert=0,5125, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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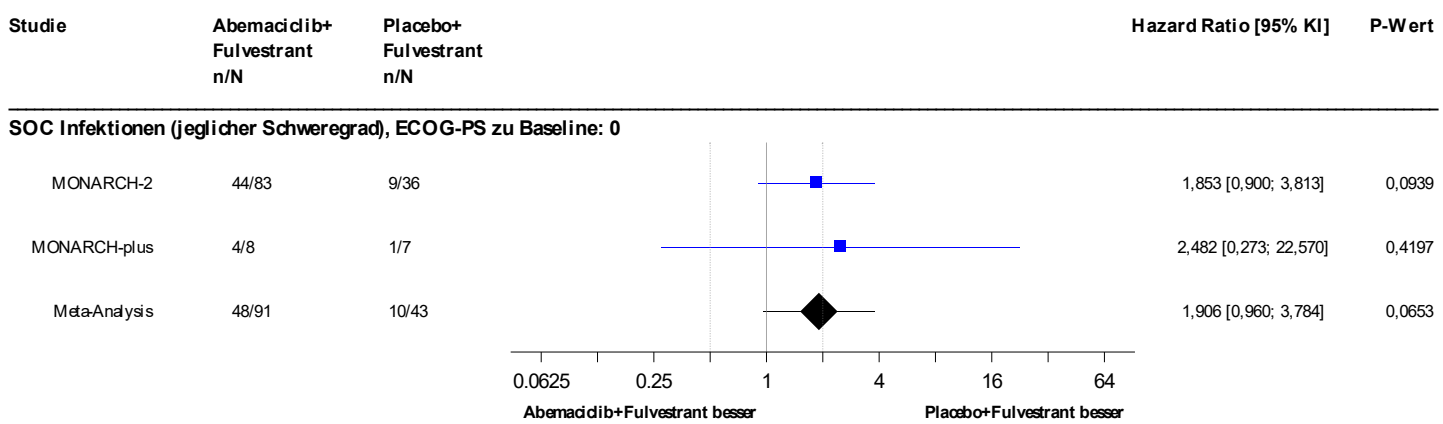
Abbildung 1428.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0608, P-Wert=0,8052, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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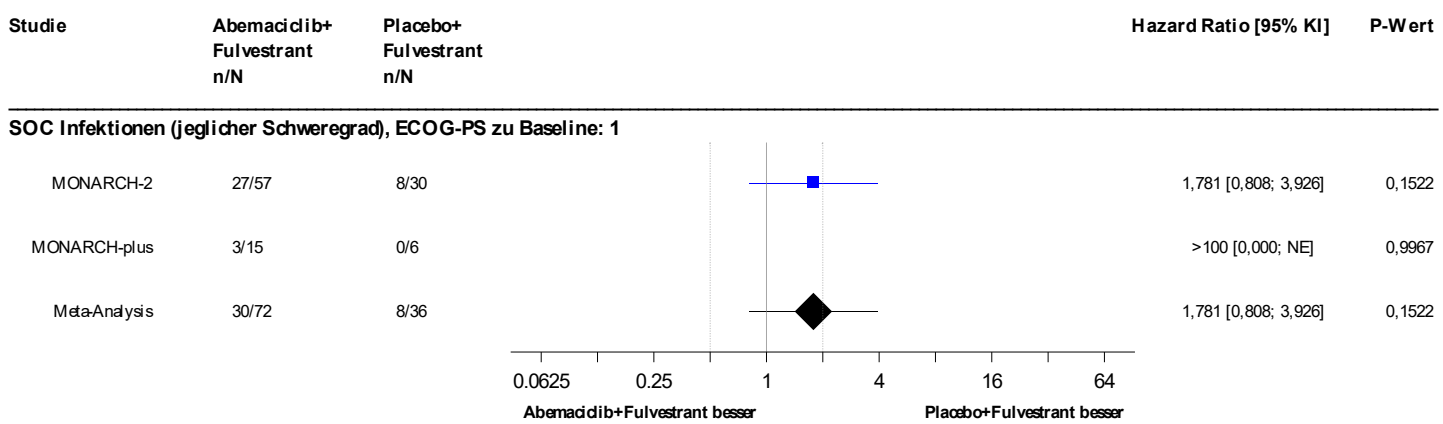
Abbildung 1428.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9968, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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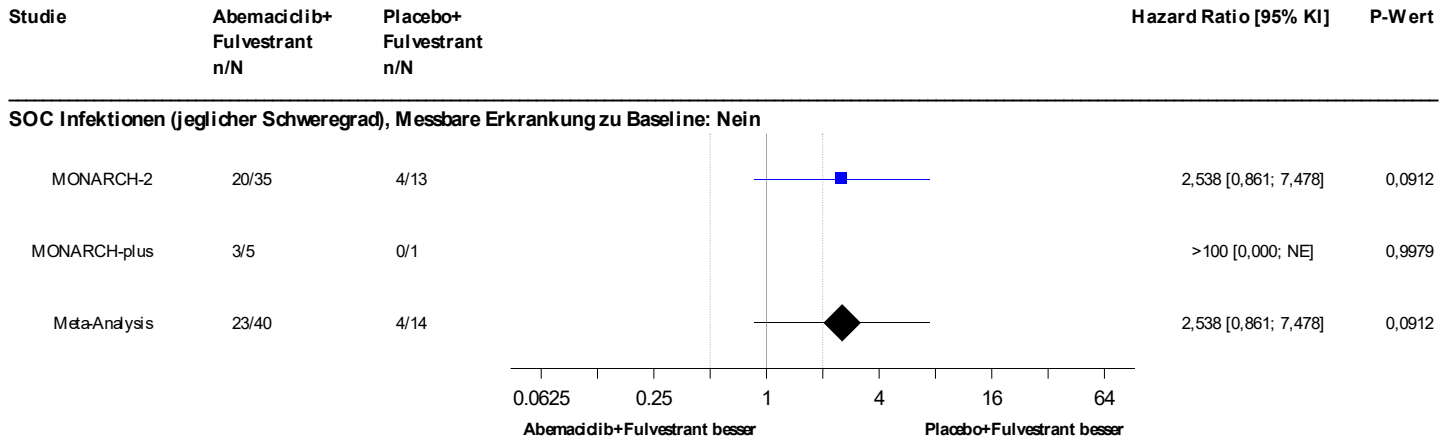
Abbildung 1428.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9980, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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Abbildung 1428.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

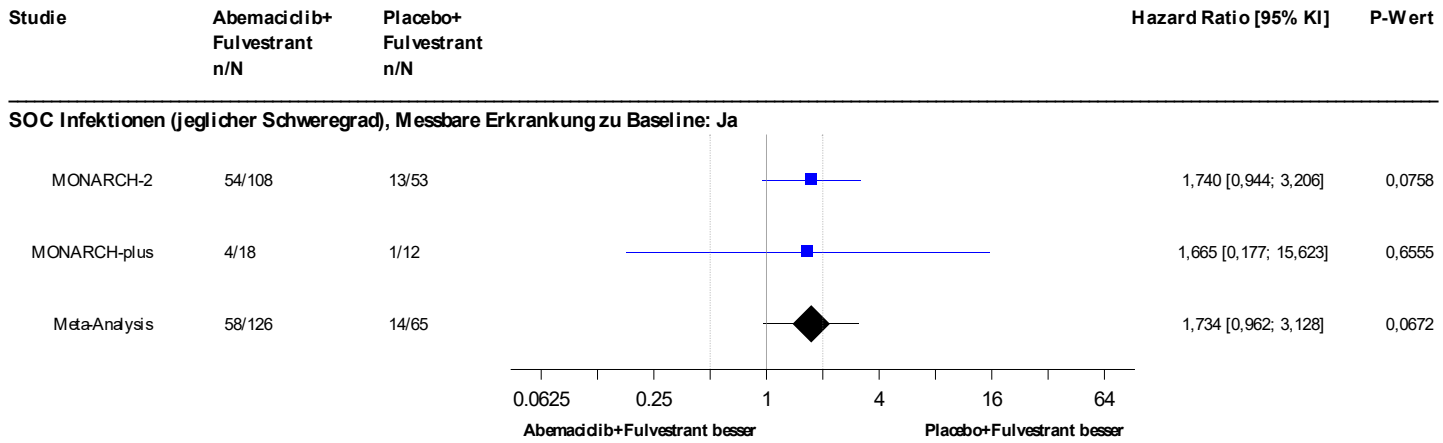

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Abbildung 1428.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

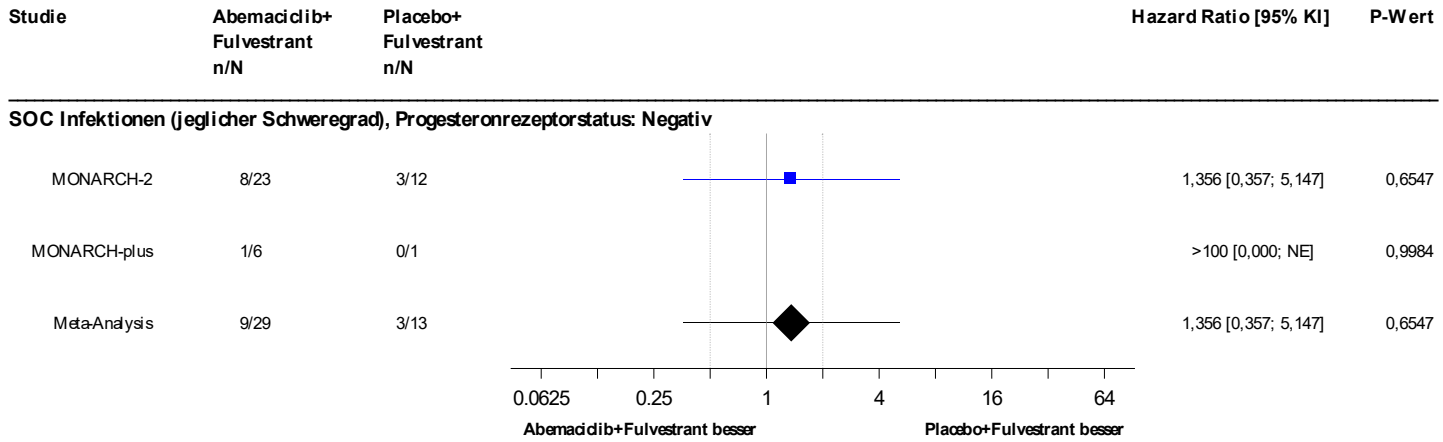

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Abbildung 1428.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

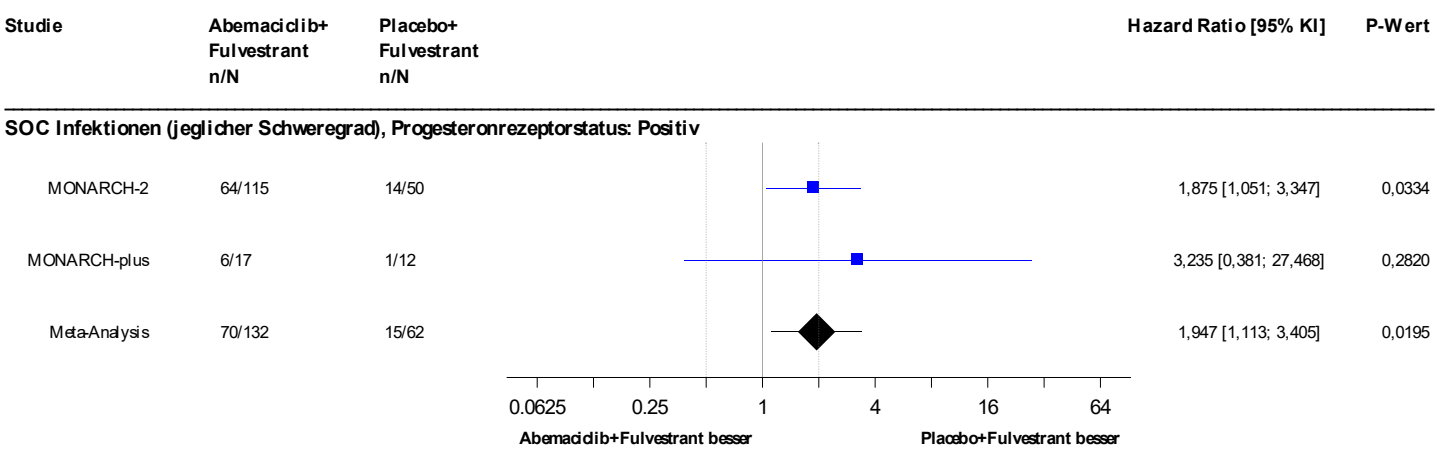

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Abbildung 1428.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

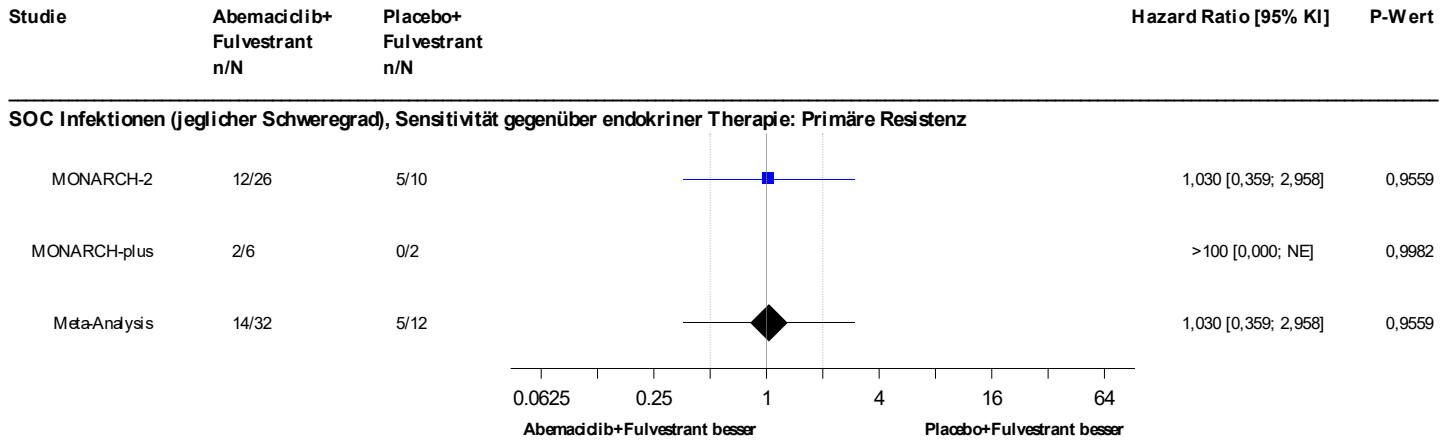

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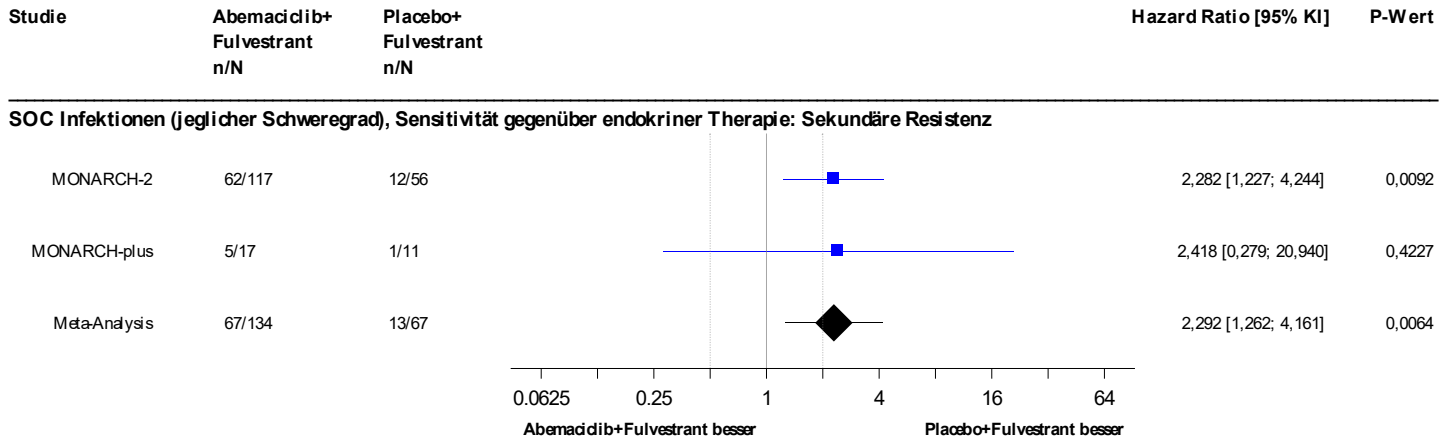
Abbildung 1428.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0026, P-Wert=0,9595, I2 Index=0%
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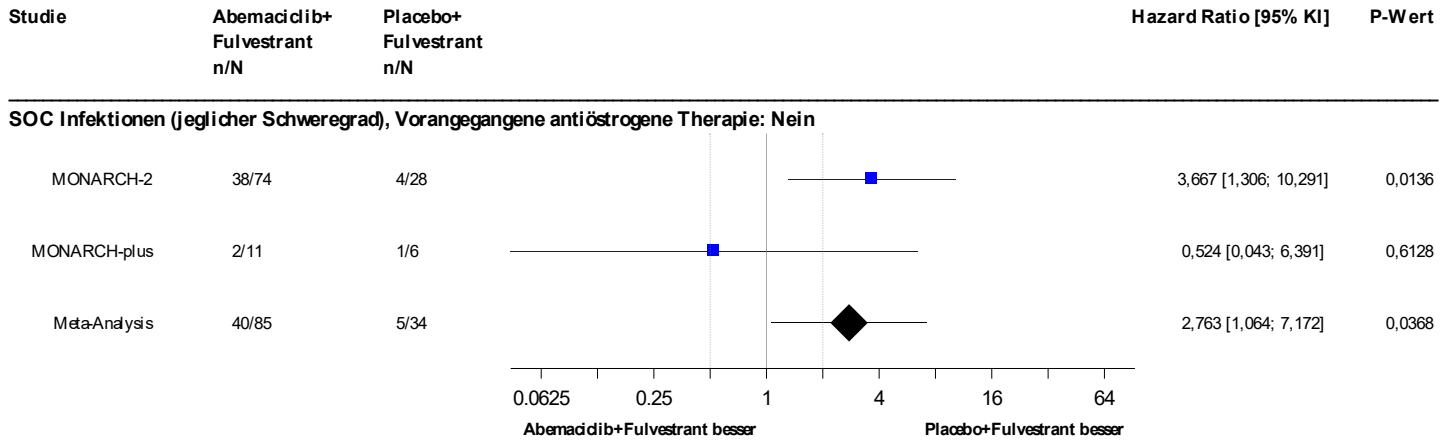
Abbildung 1428.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,9857, P-Wert=0,1588, I2 Index=49,6%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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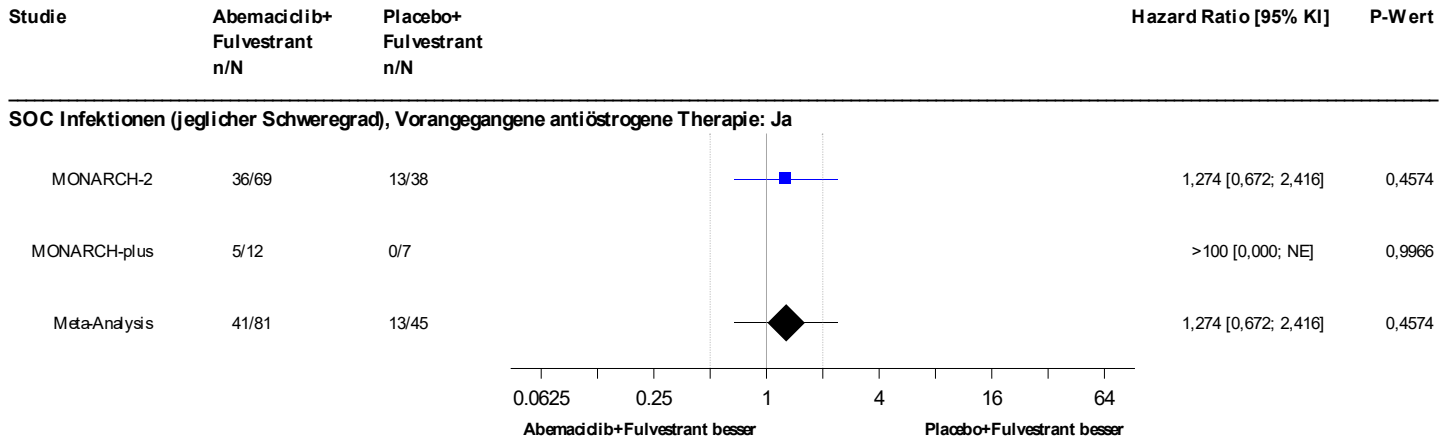
Abbildung 1428.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SOC Infektionen (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9967, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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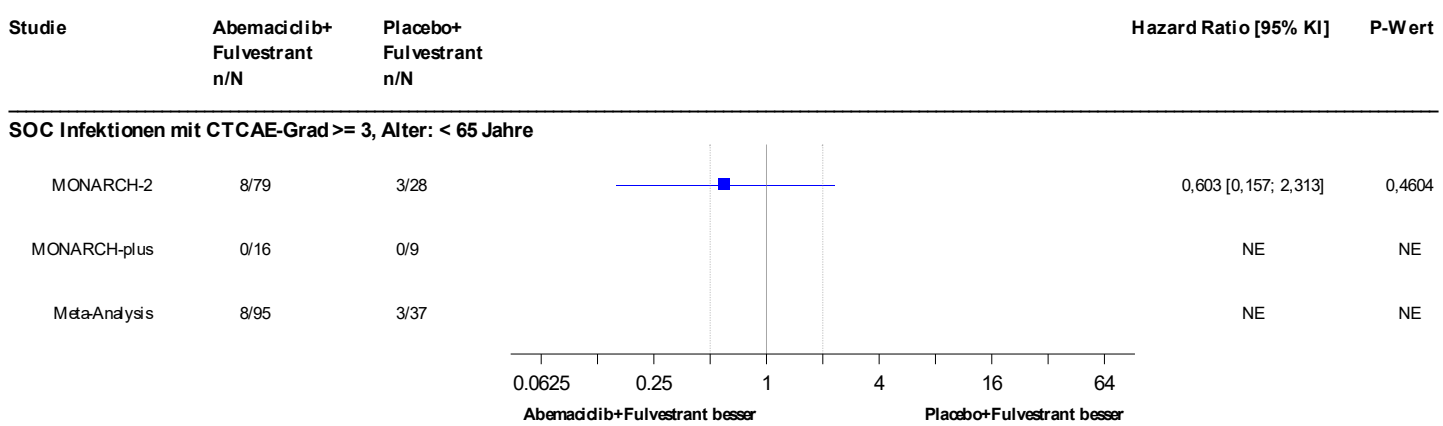
Abbildung 1429.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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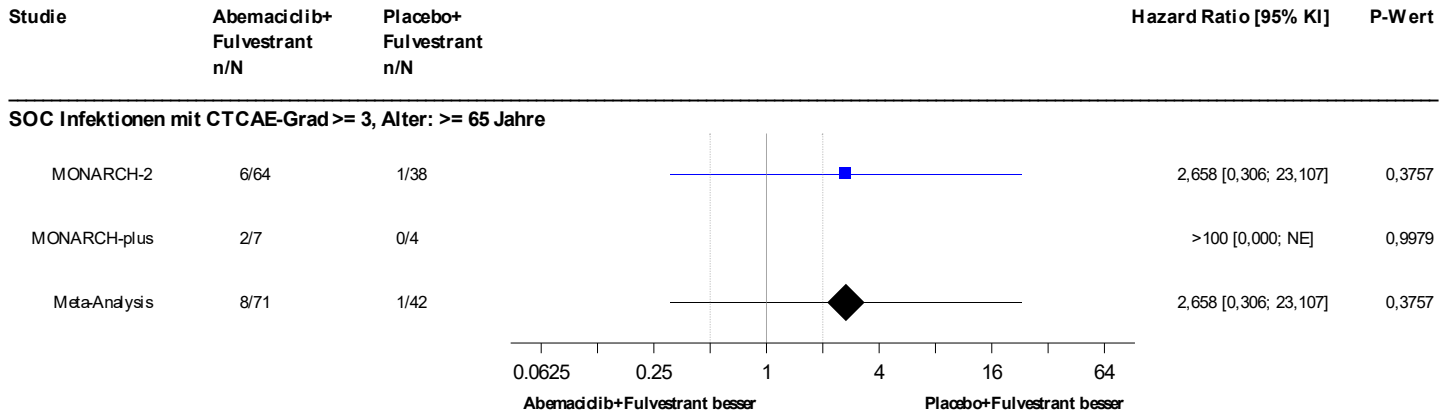
Abbildung 1429.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9980, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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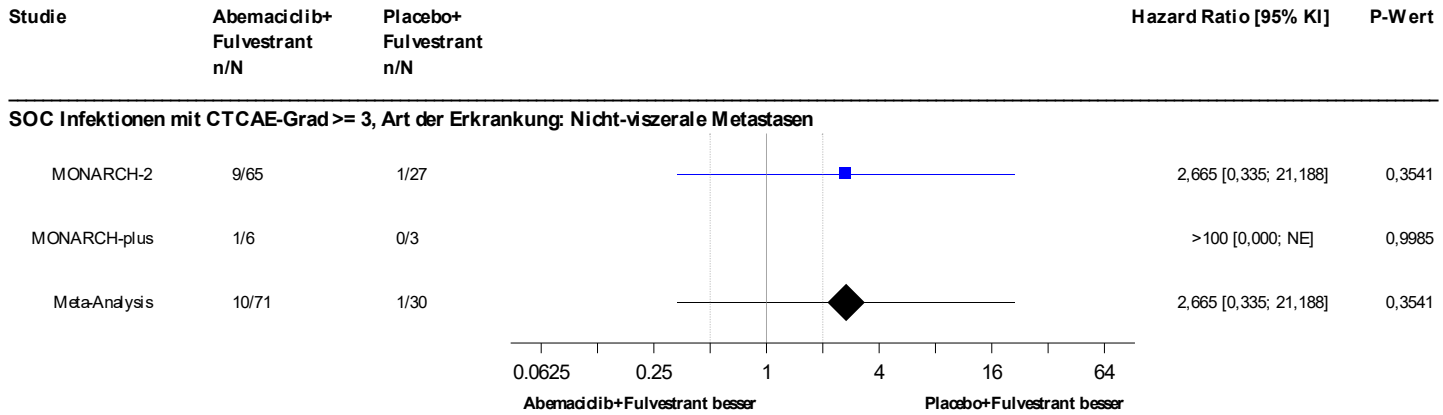
Abbildung 1429.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9986, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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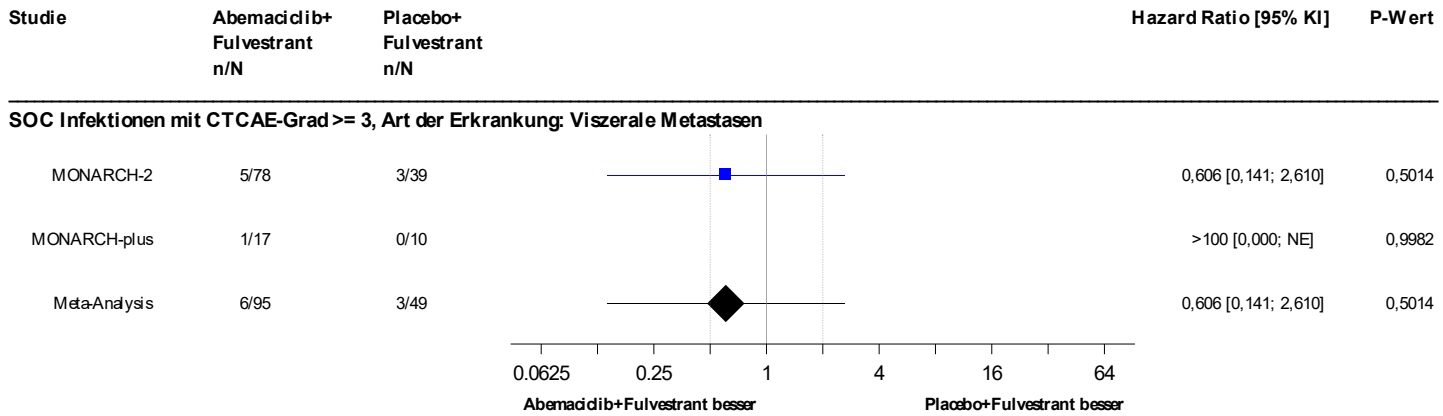
17SEP2021 / 07:48

Abbildung 1429.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9982, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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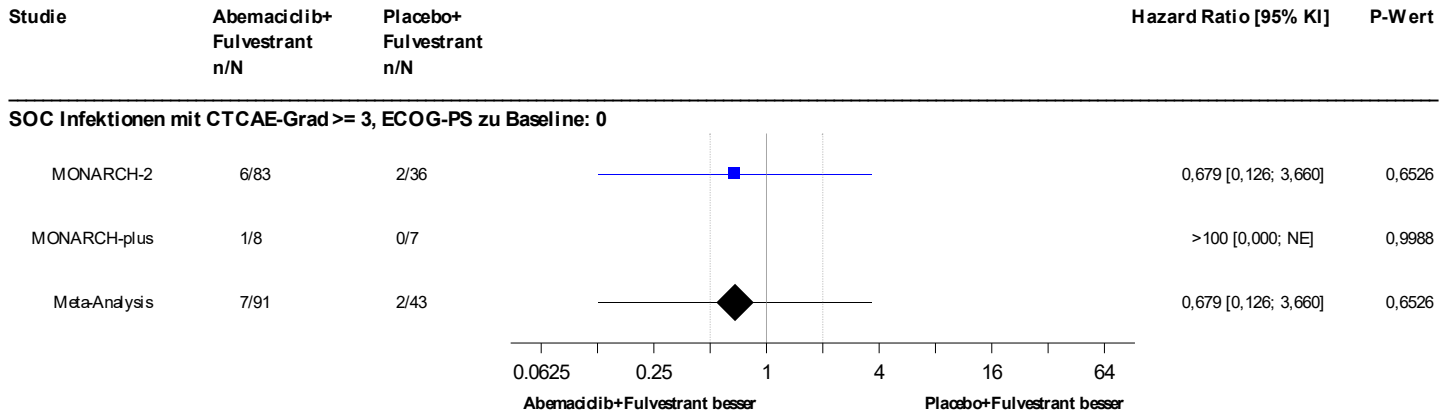
Abbildung 1429.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9987, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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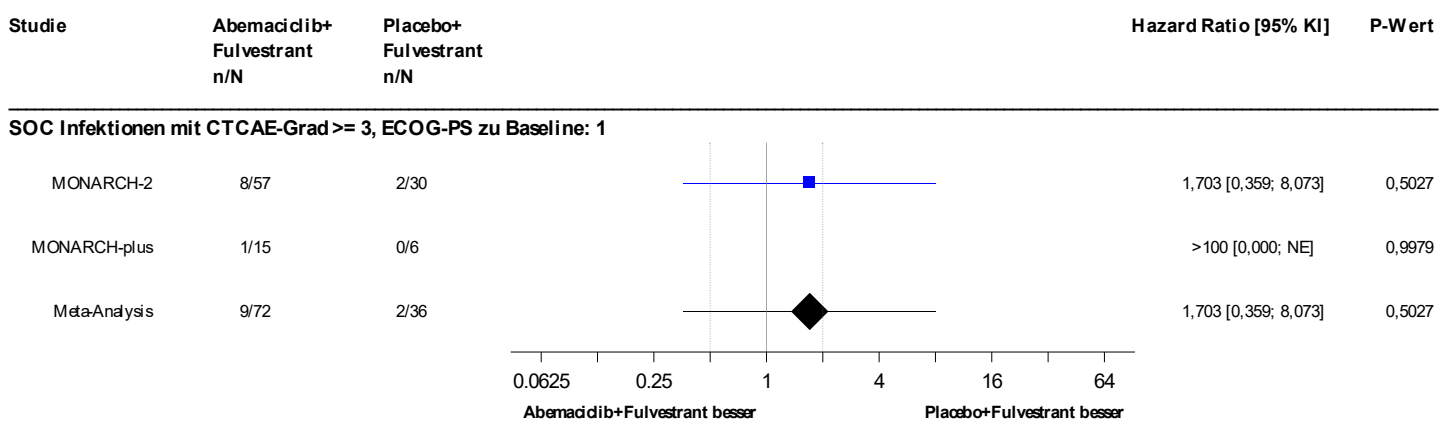
Abbildung 1429.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9979, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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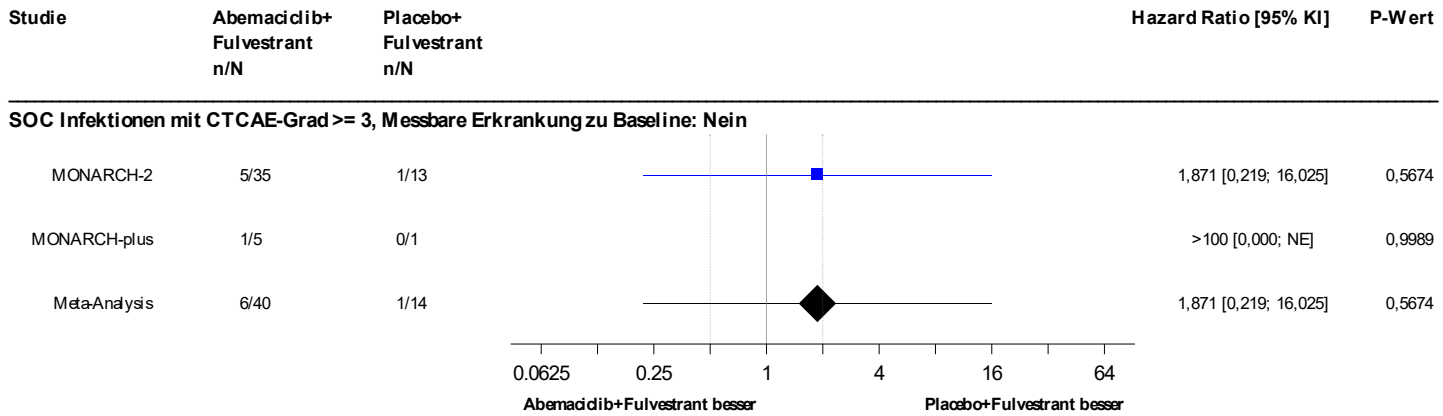
Abbildung 1429.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9990, I2 Index=0%
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Abbildung 1429.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

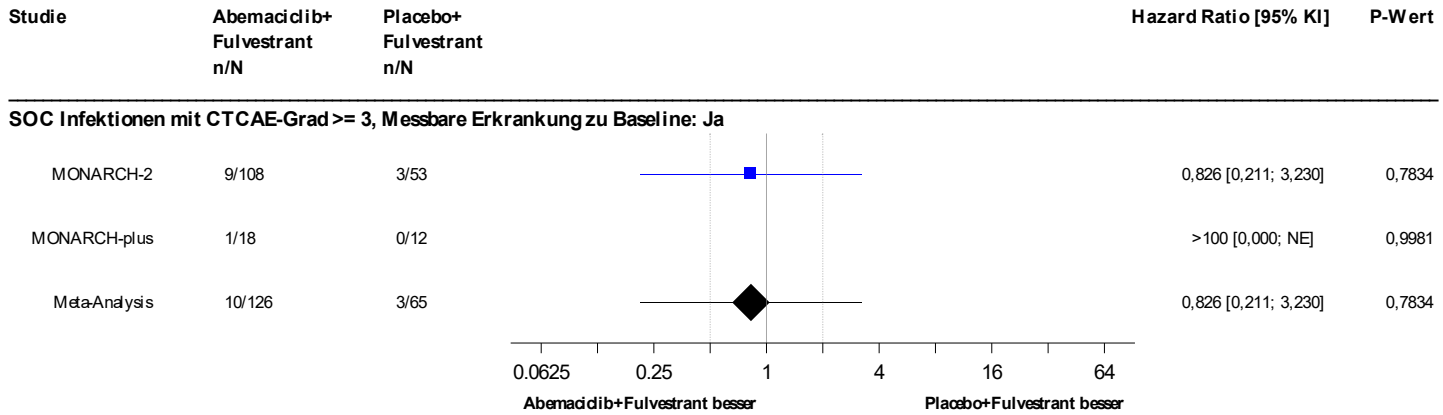

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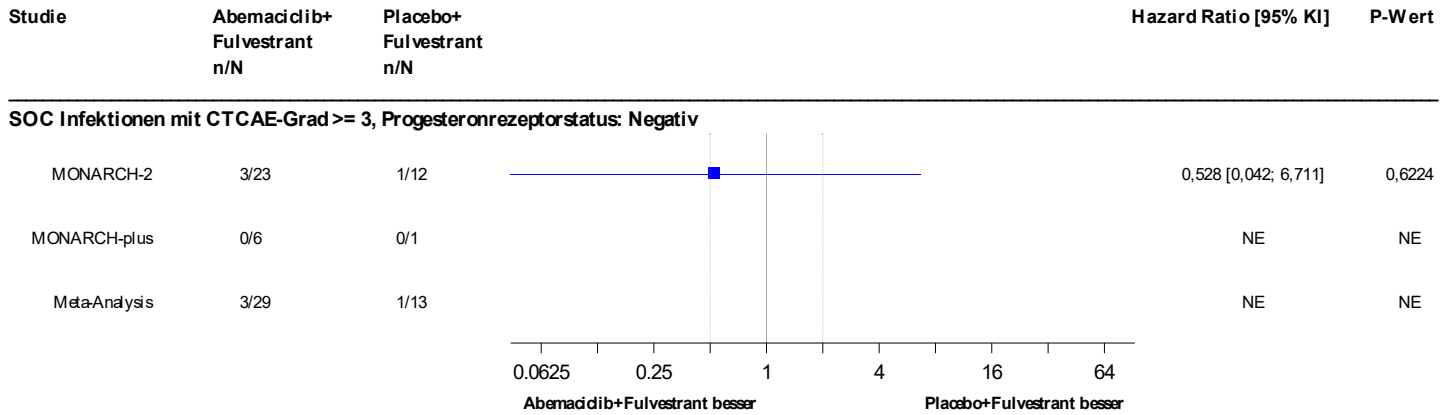
Abbildung 1429.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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Abbildung 1429.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

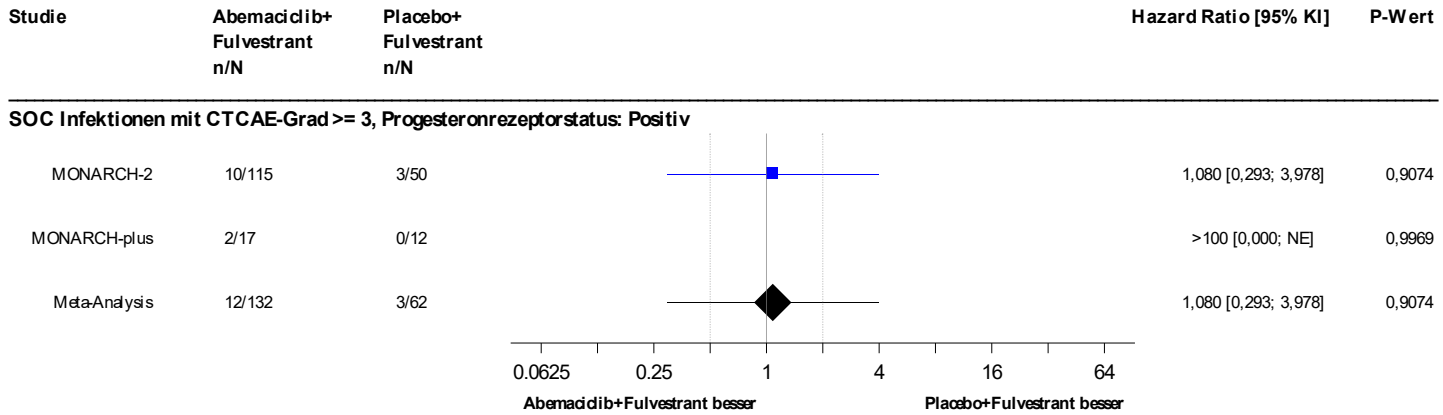

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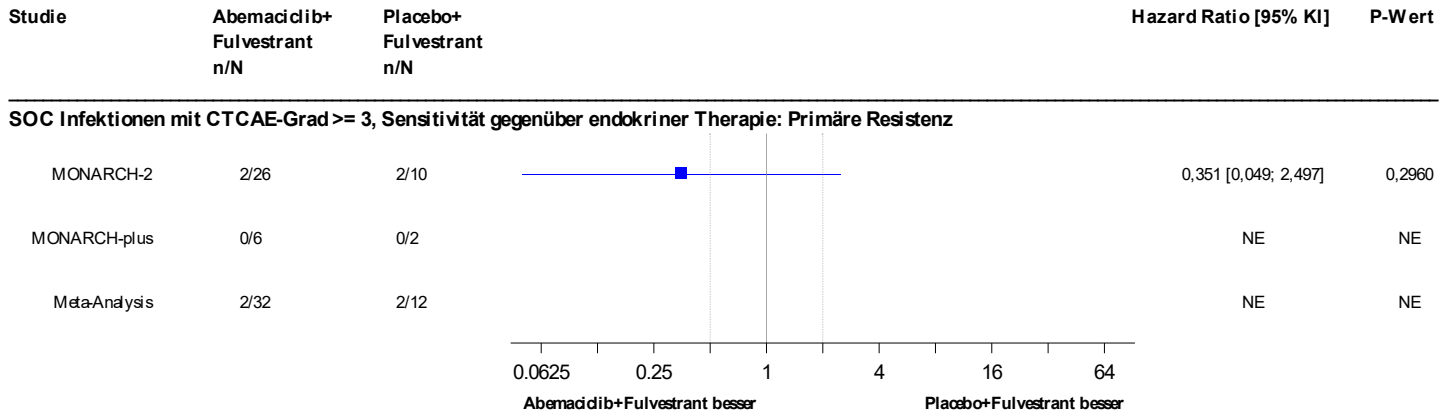
Abbildung 1429.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
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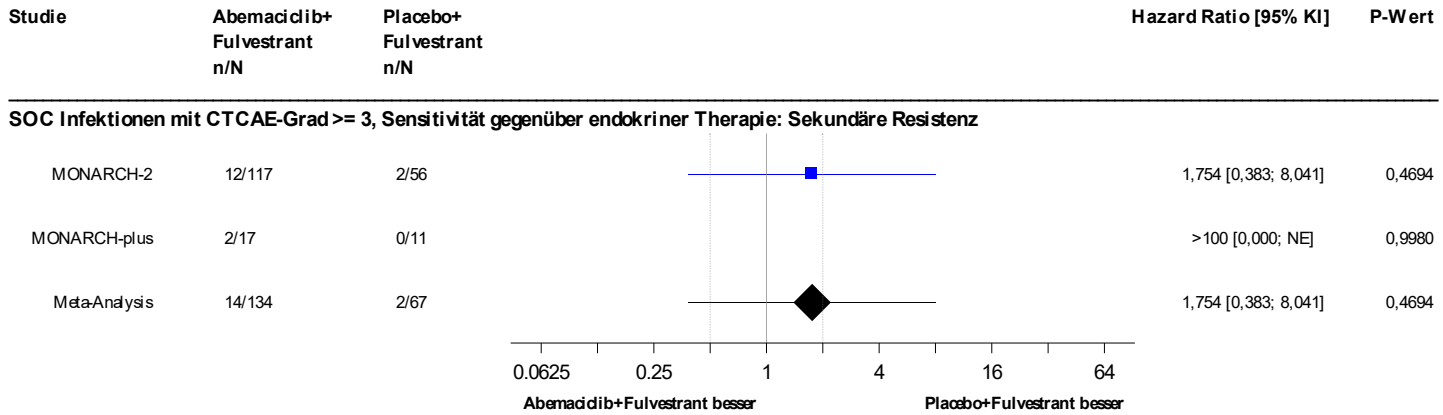
Abbildung 1429.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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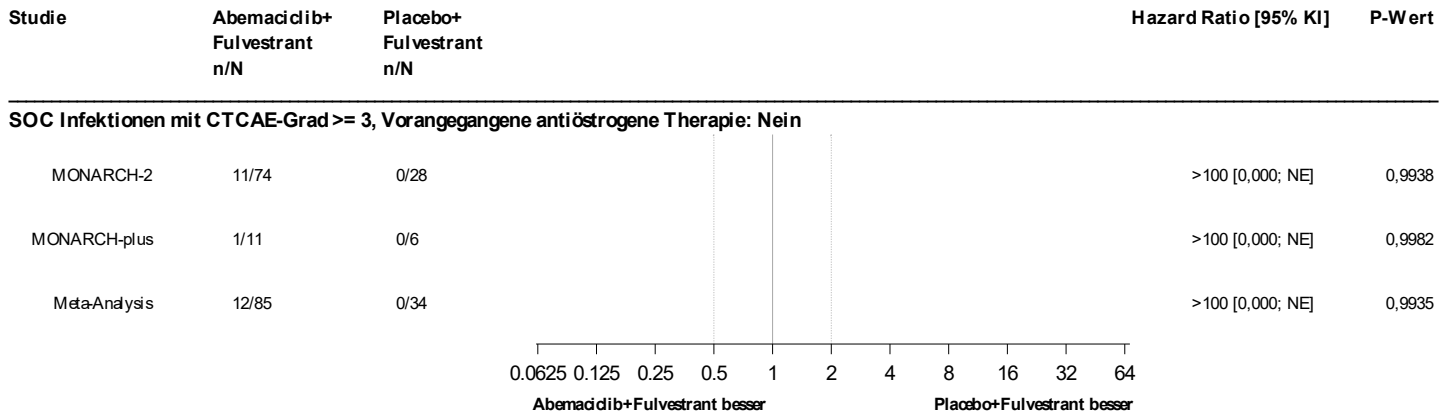
Abbildung 1429.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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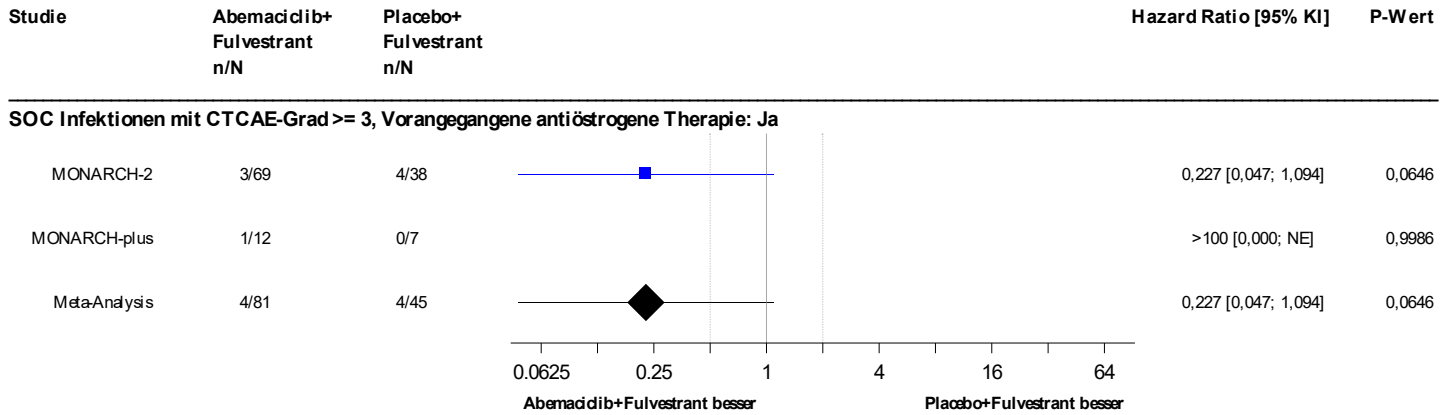
17SEP2021 / 07:48

Abbildung 1429.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9985, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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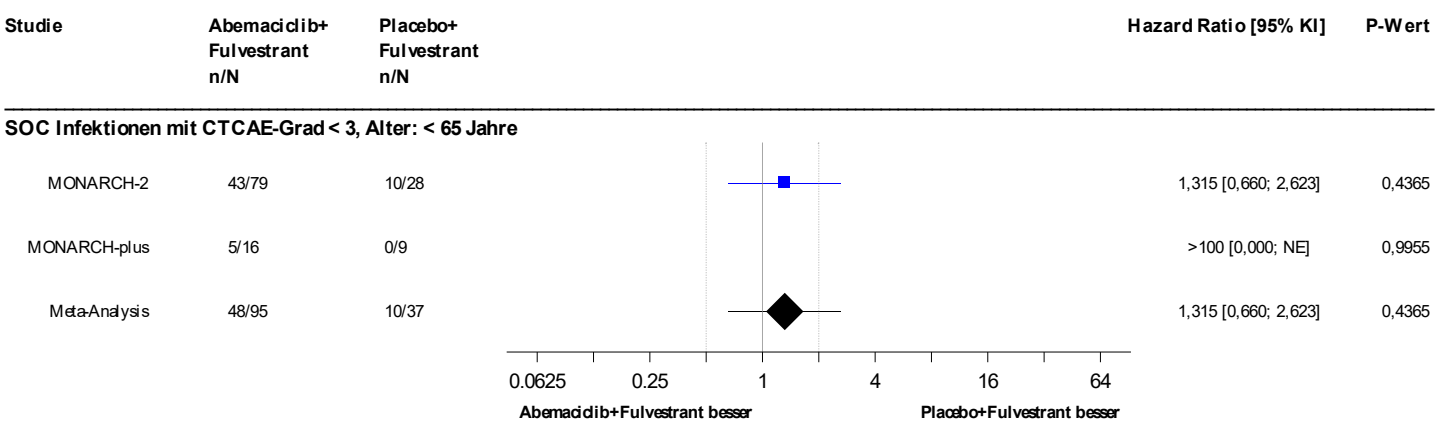
Abbildung 1430.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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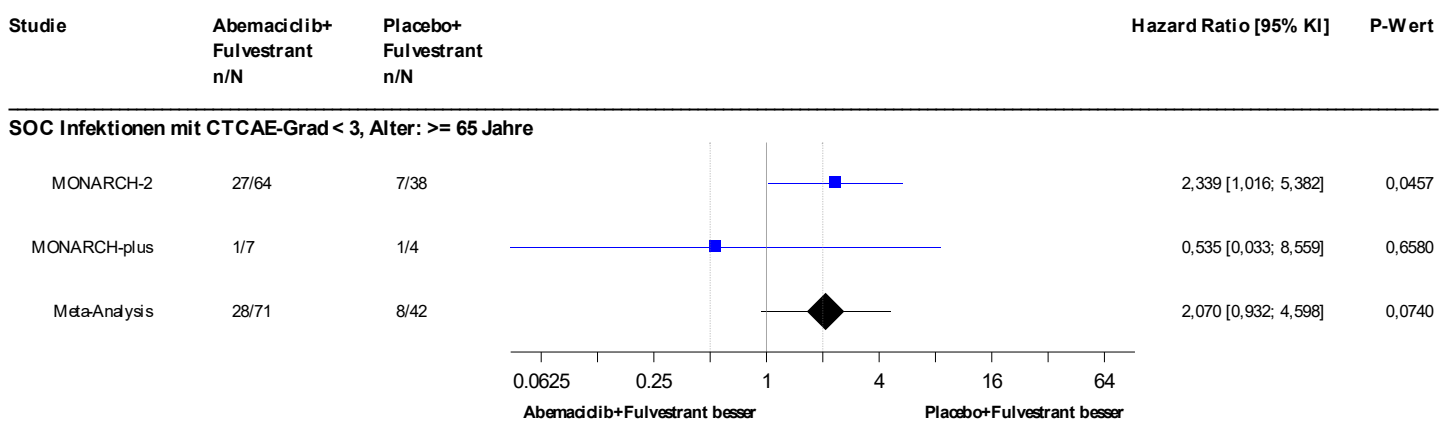
17SEP2021 / 07:48

Abbildung 1430.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,9980, P-Wert=0,3178, I2 Index=0%
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17SEP2021 / 07:48

Abbildung 1430.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

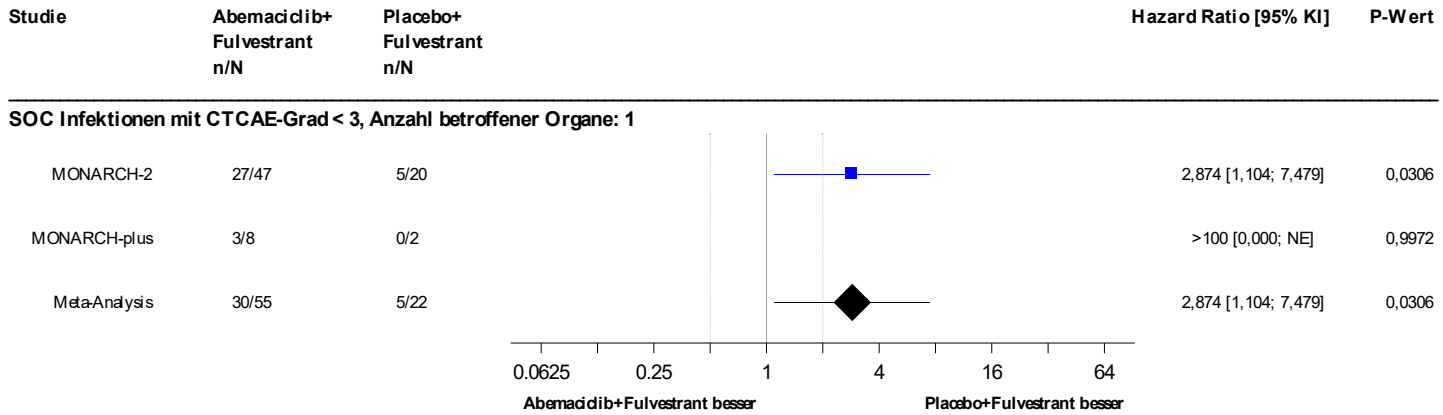

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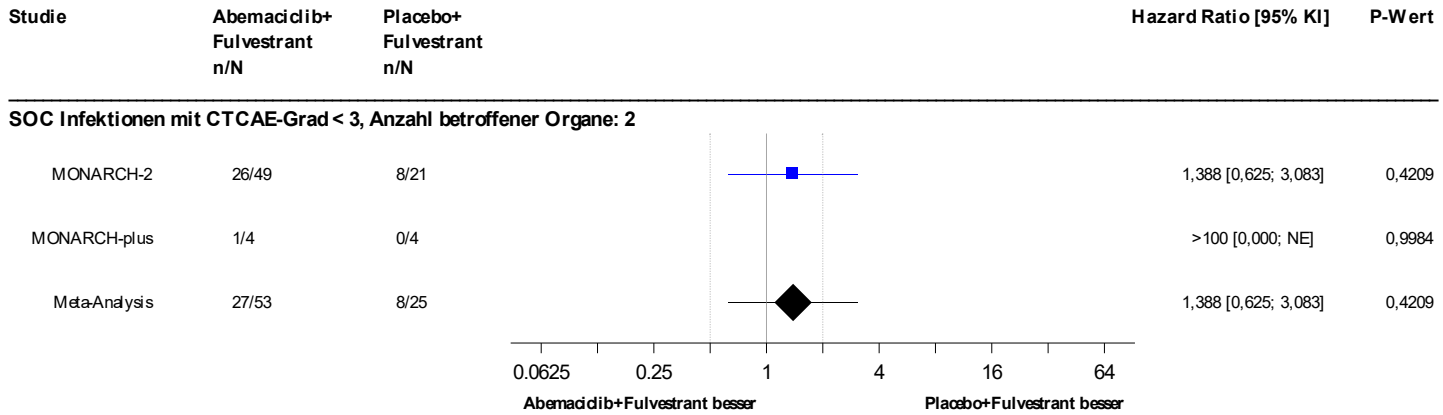
Abbildung 1430.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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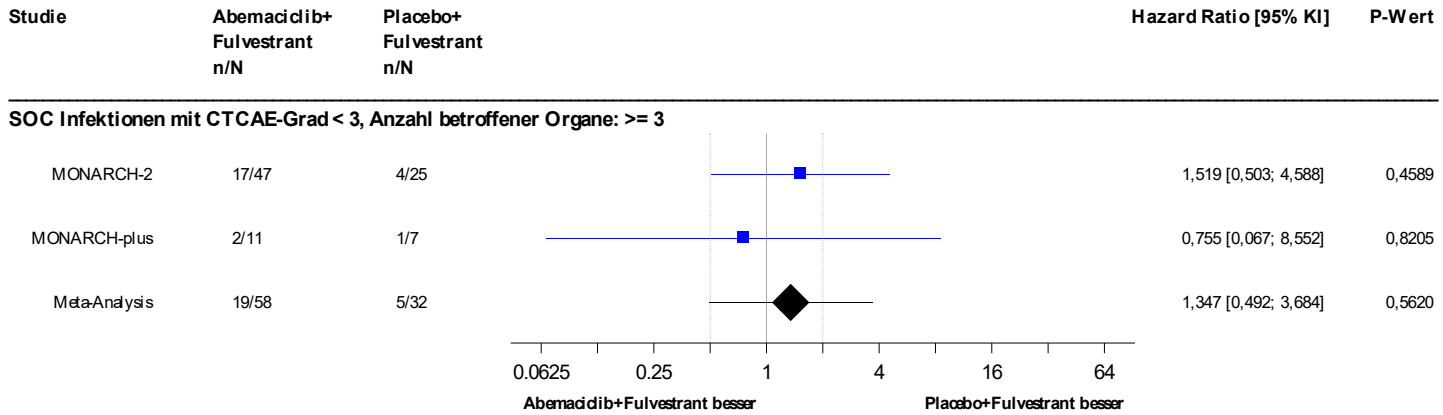
17SEP2021 / 07:48

Abbildung 1430.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2637, P-Wert=0,6076, I2 Index=0%
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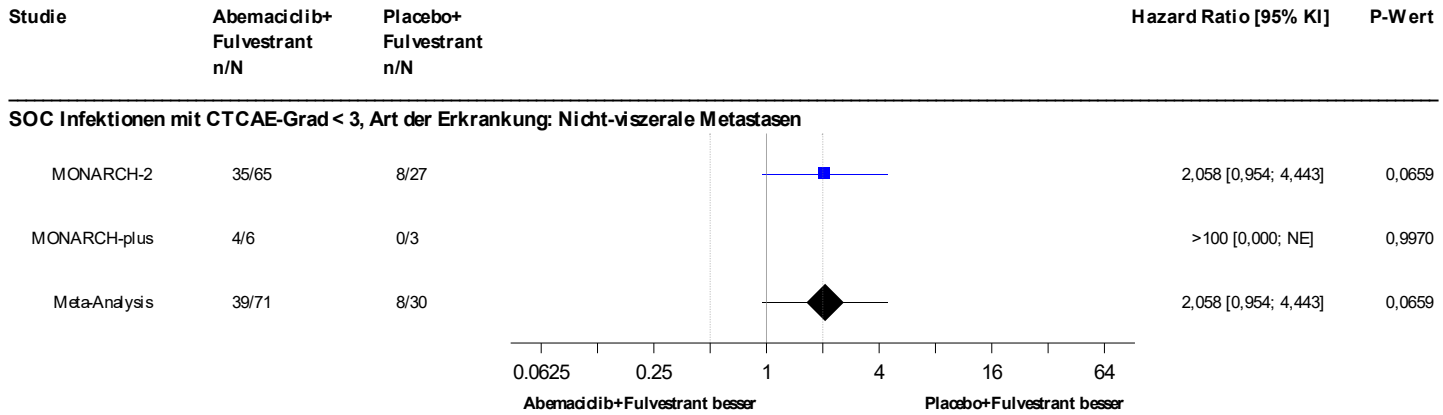
Abbildung 1430.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9971, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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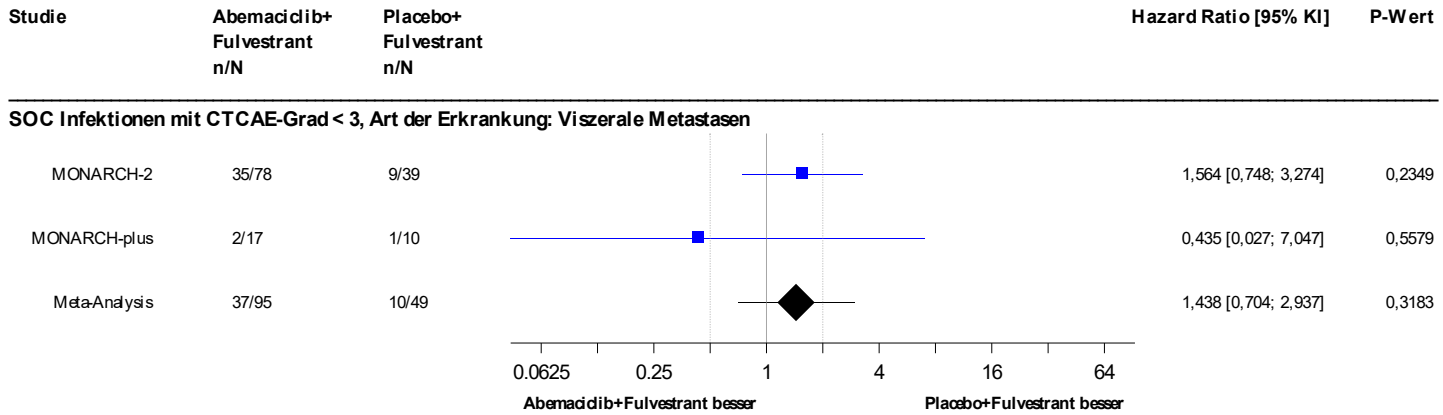
Abbildung 1430.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,7583, P-Wert=0,3839, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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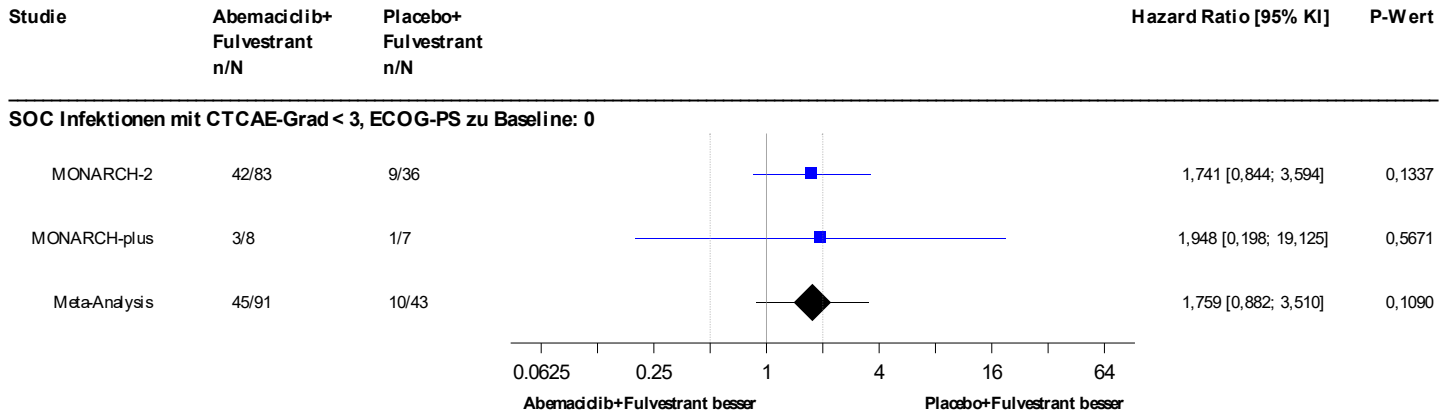
Abbildung 1430.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0084, P-Wert=0,9268, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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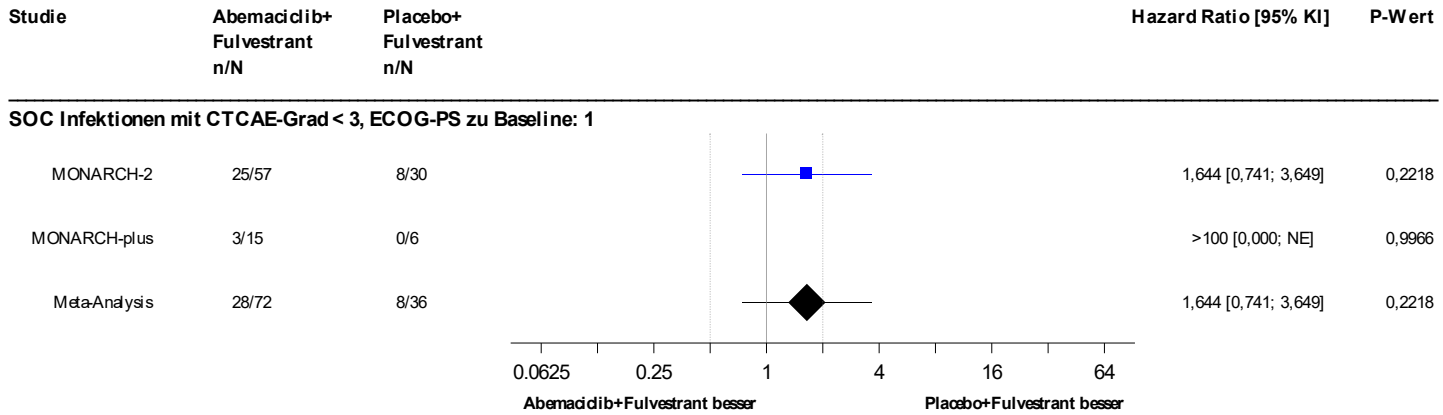
Abbildung 1430.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9967, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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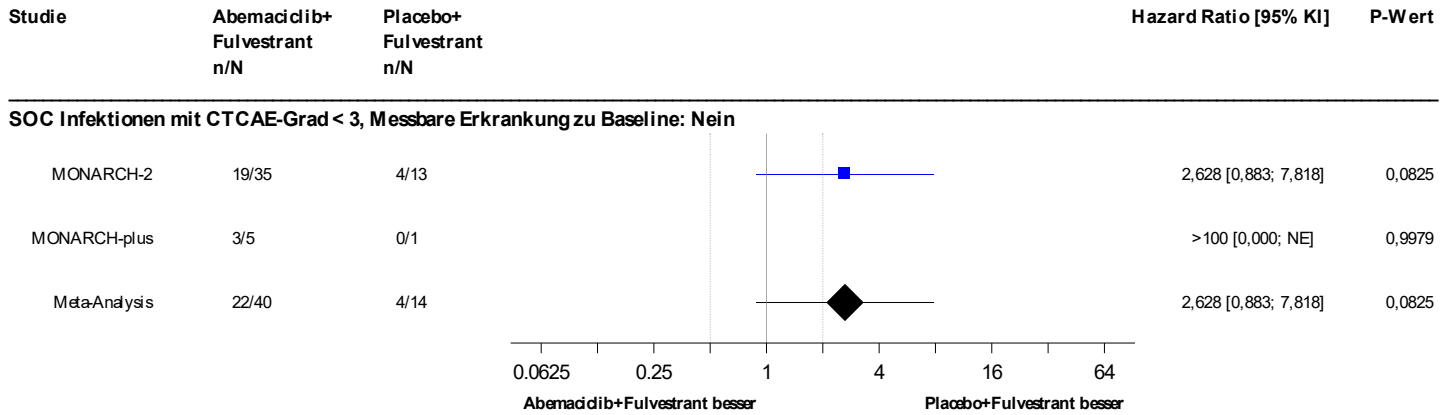
Abbildung 1430.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9981, I2 Index=0%
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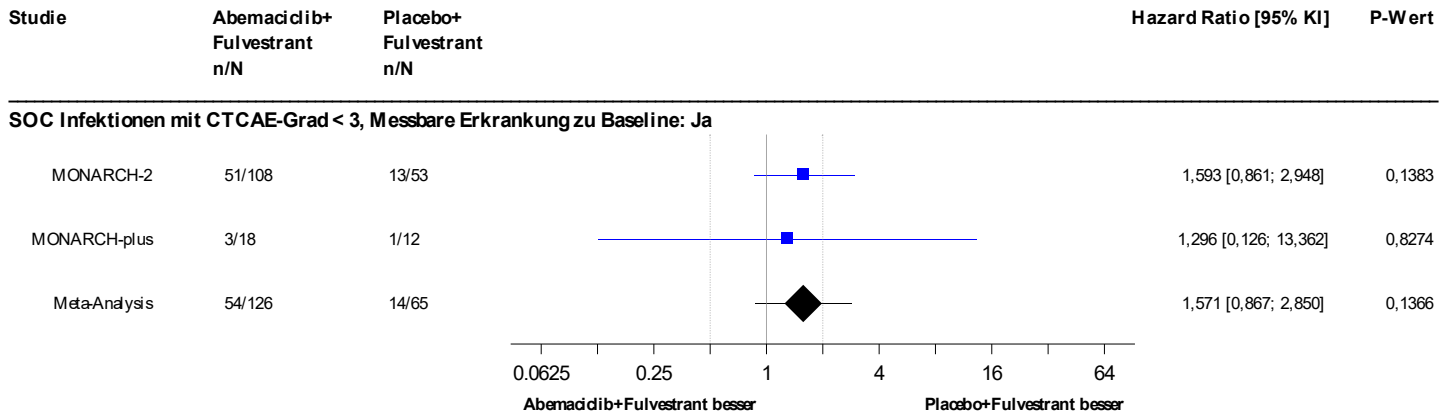
Abbildung 1430.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0280, P-Wert=0,8671, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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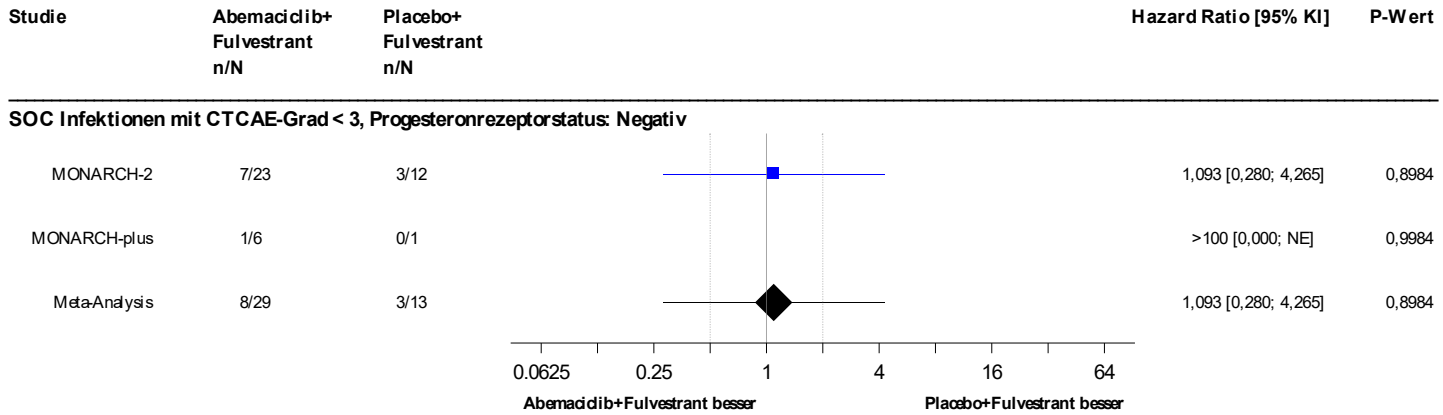
Abbildung 1430.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9984, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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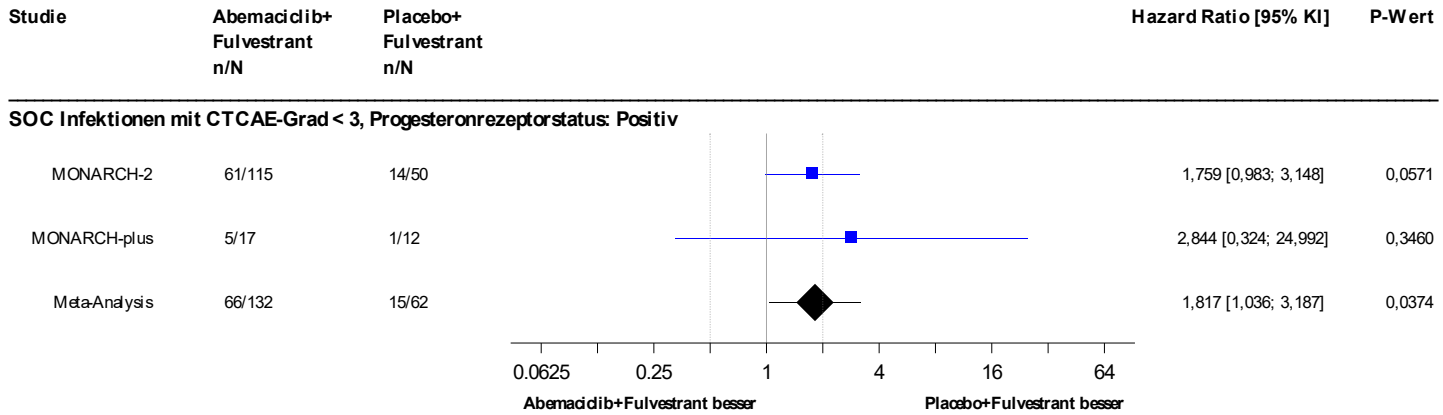
17SEP2021 / 07:48

Abbildung 1430.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1750, P-Wert=0,6757, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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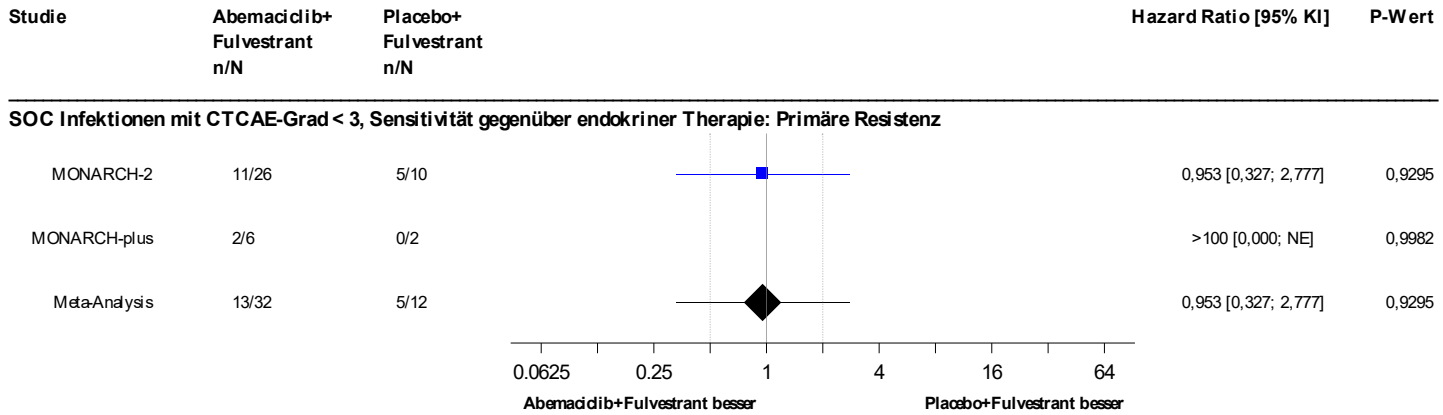
Abbildung 1430.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9982, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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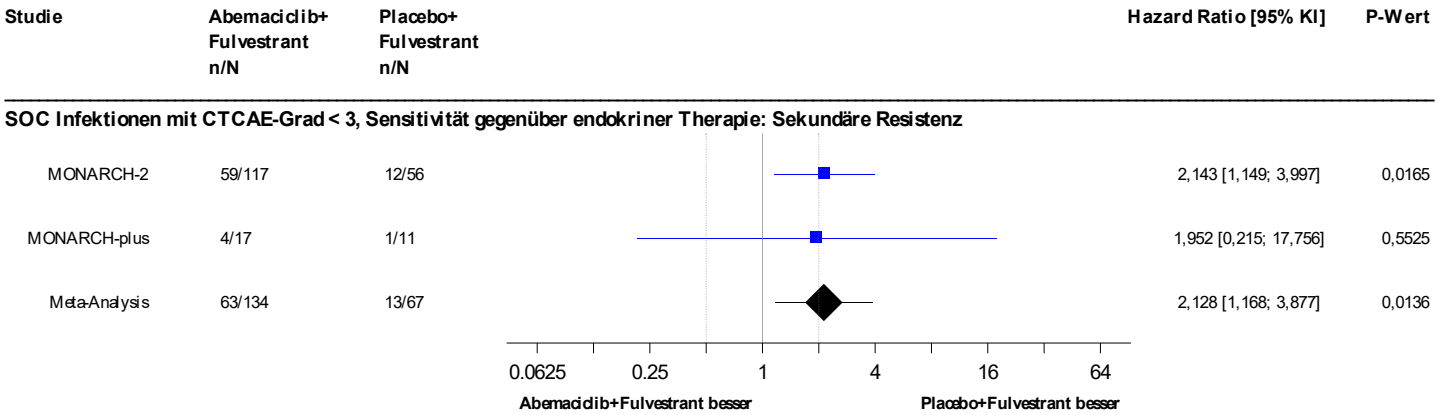
Abbildung 1430.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0063, P-Wert=0,9365, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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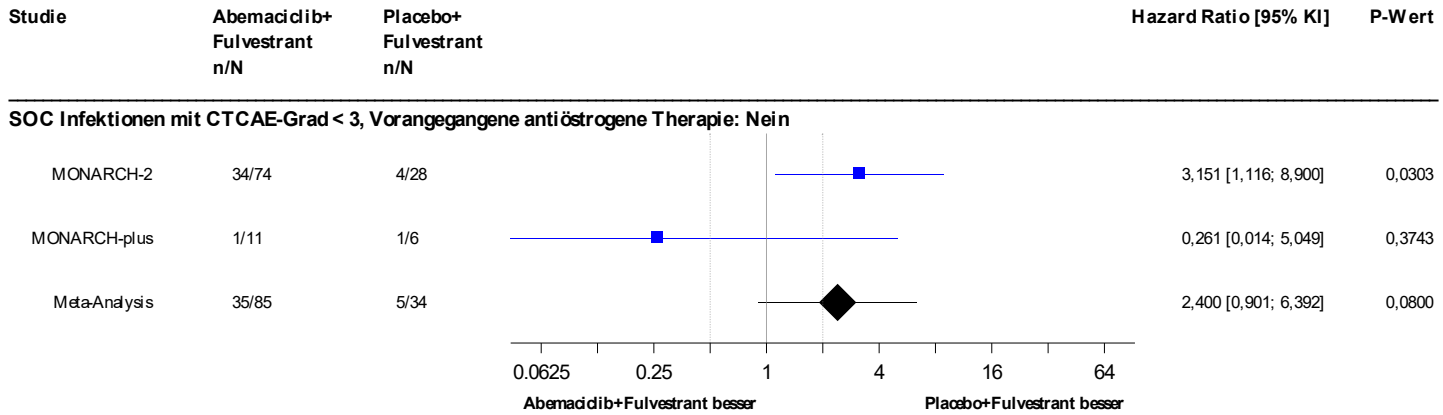
Abbildung 1430.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=2,4189, P-Wert=0,1199, I2 Index=58,7%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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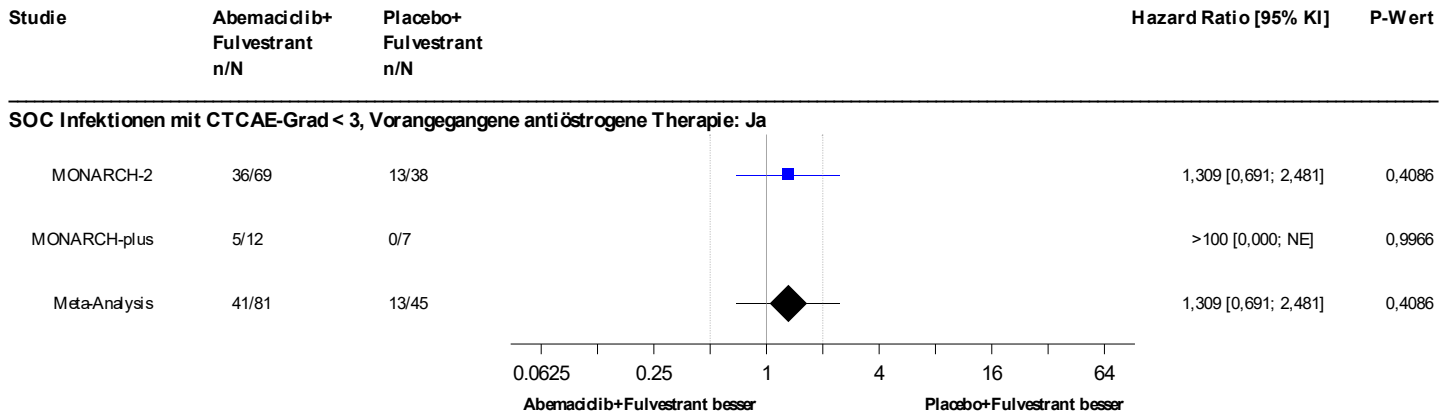
Abbildung 1430.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9967, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class.

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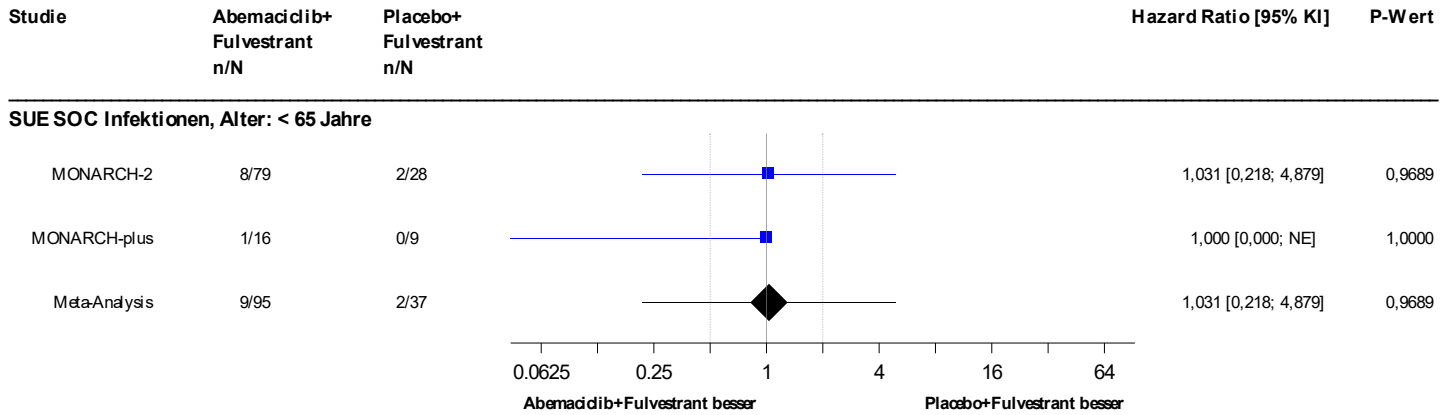
17SEP2021 / 07:48

Abbildung 1431.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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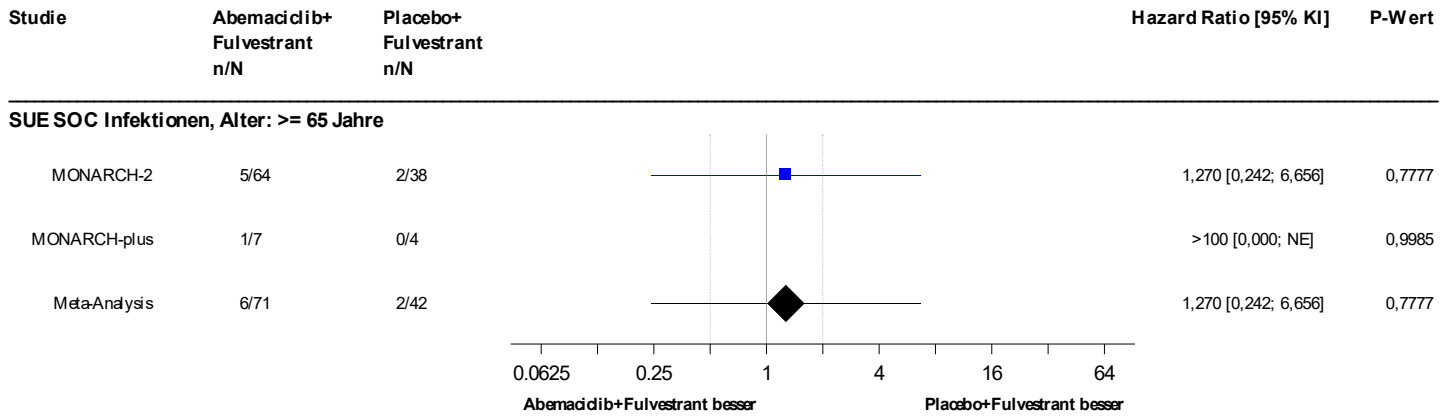
Abbildung 1431.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9986, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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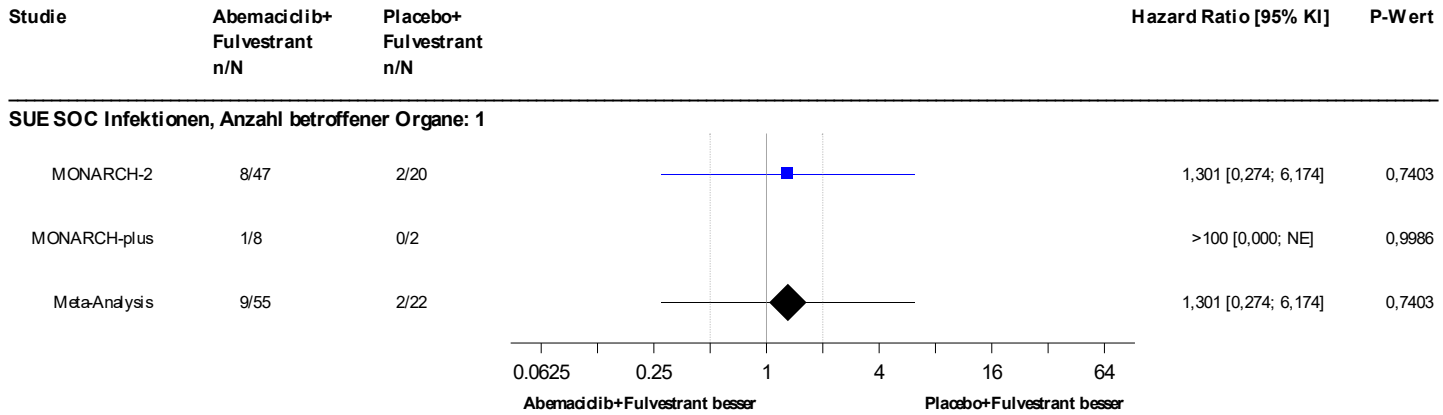
Abbildung 1431.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9986, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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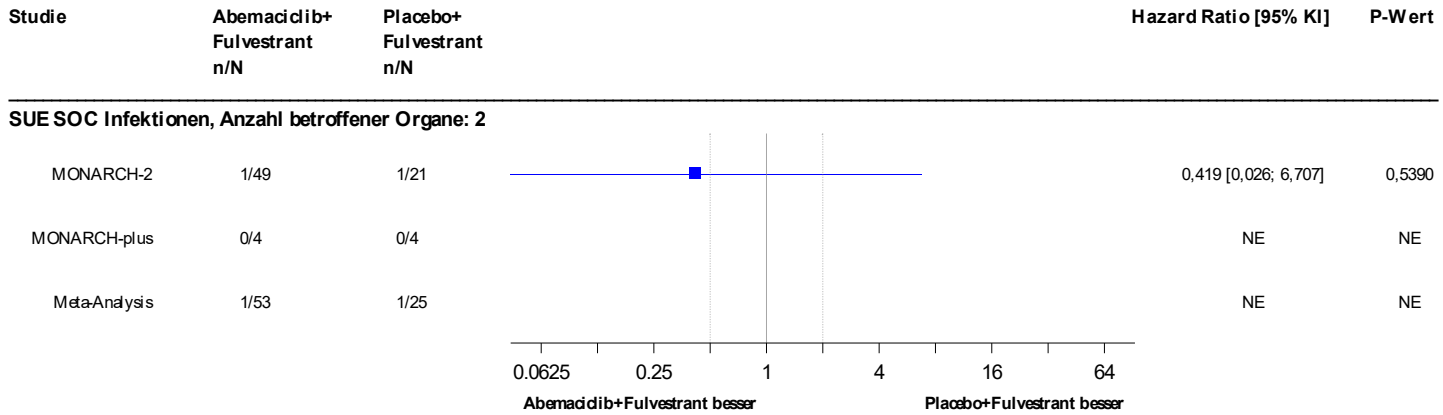
Abbildung 1431.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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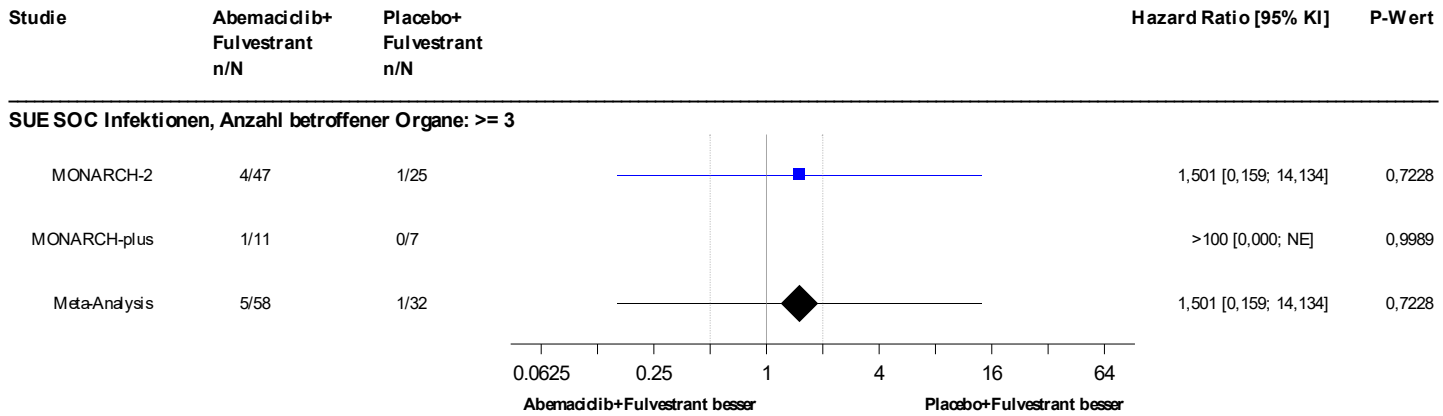
Abbildung 1431.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9989, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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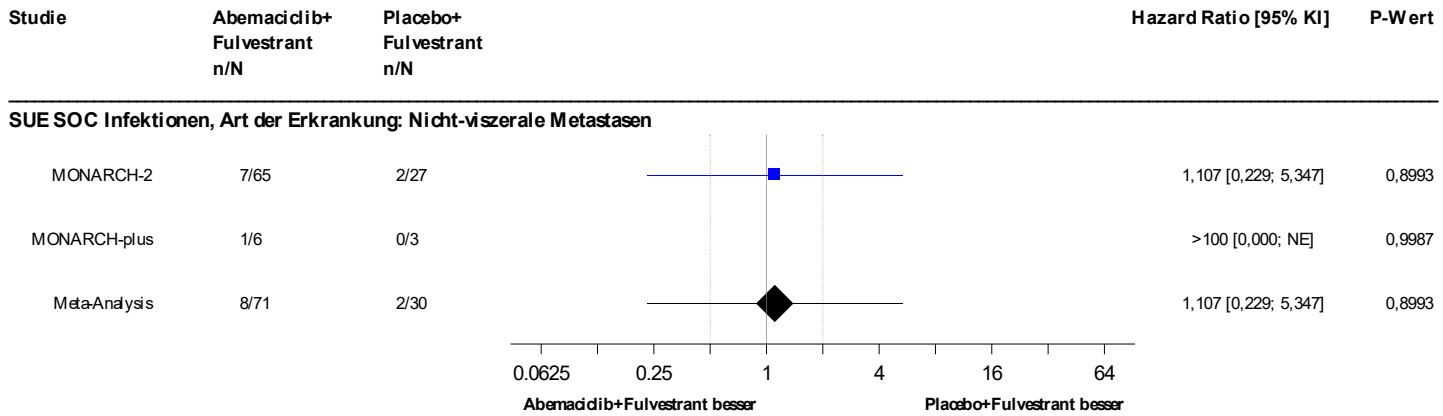
Abbildung 1431.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9987, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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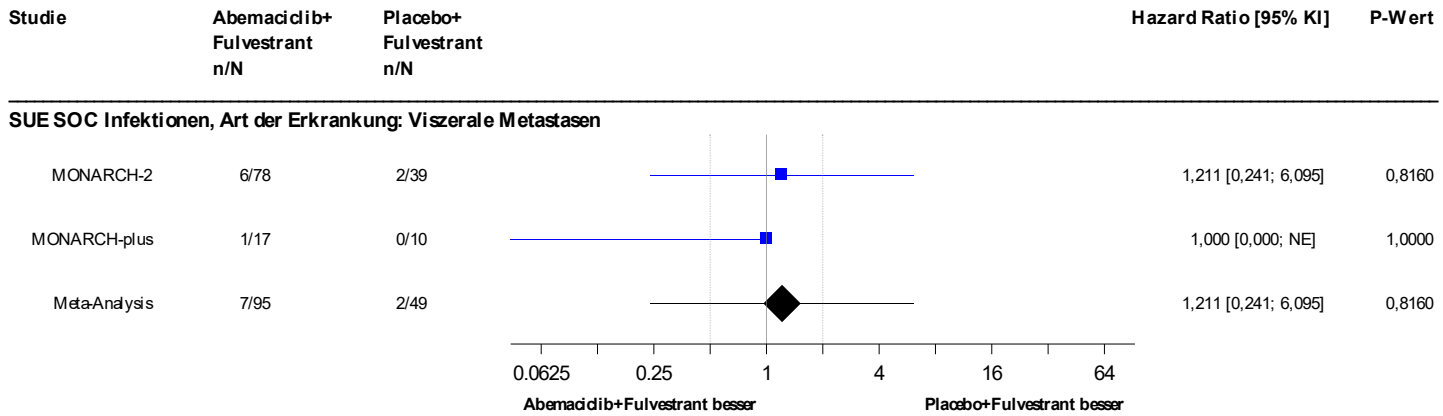
Abbildung 1431.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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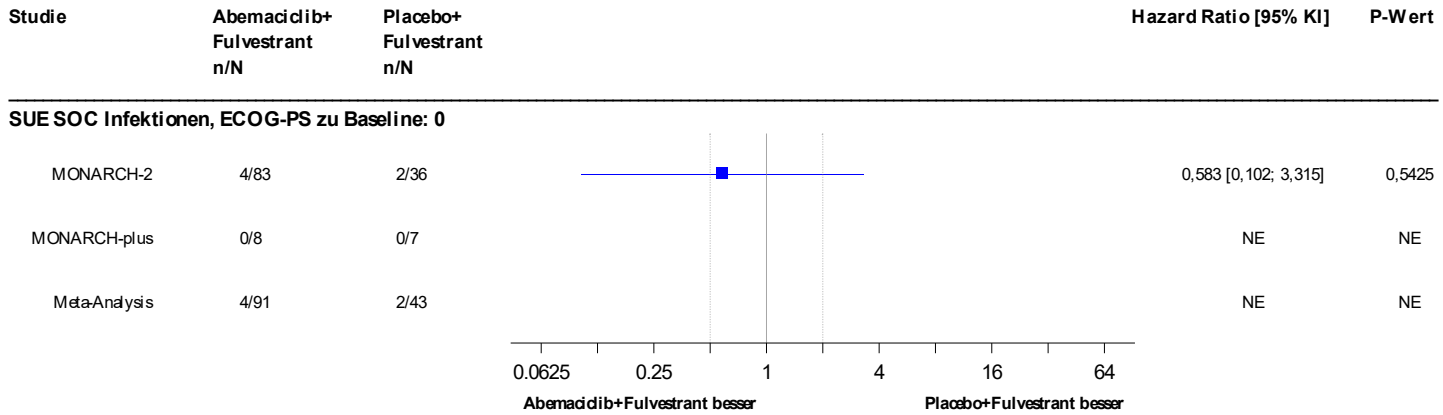
Abbildung 1431.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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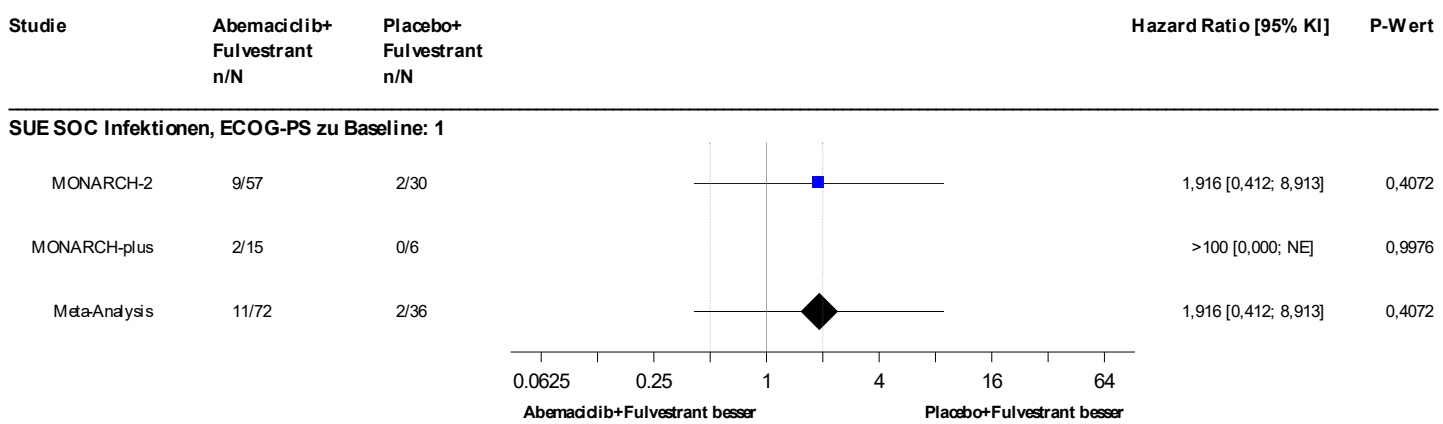
Abbildung 1431.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9977, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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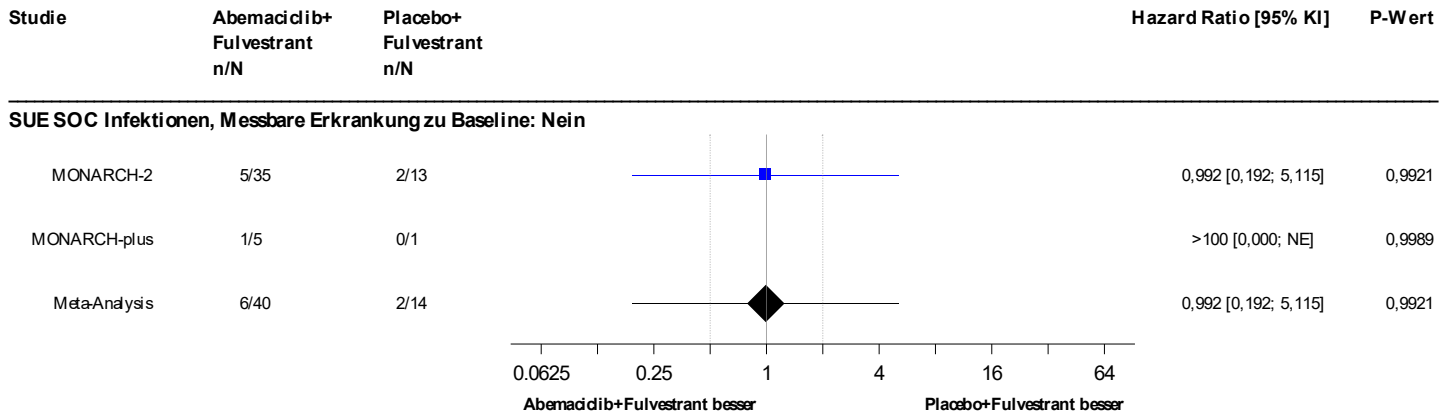
Abbildung 1431.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9989, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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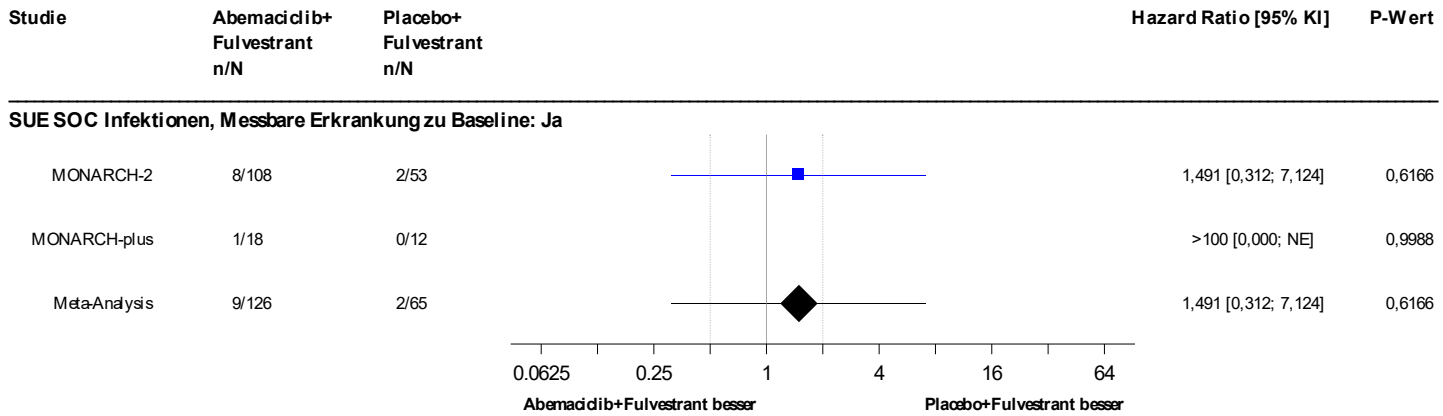
Abbildung 1431.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9988, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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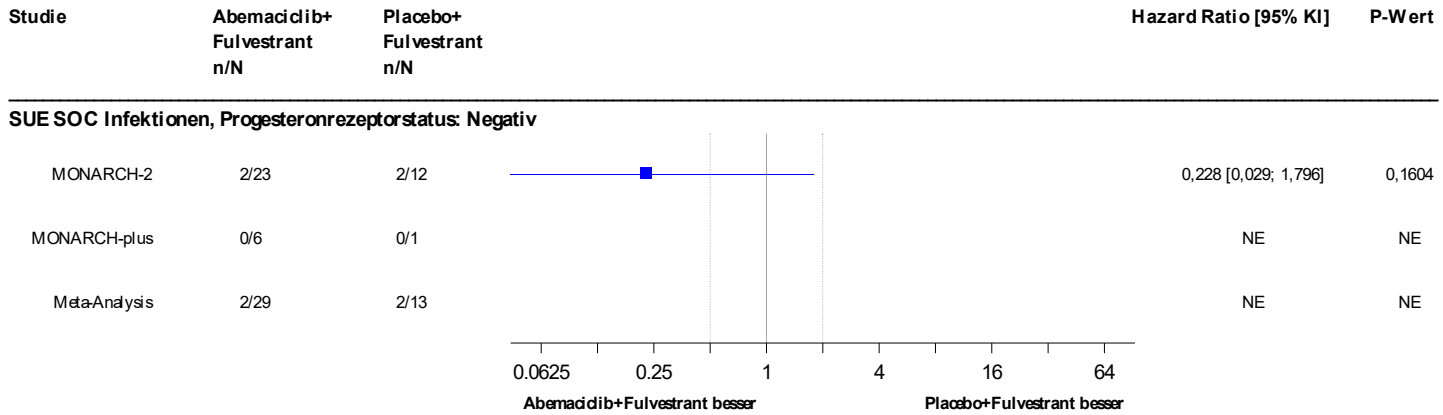
Abbildung 1431.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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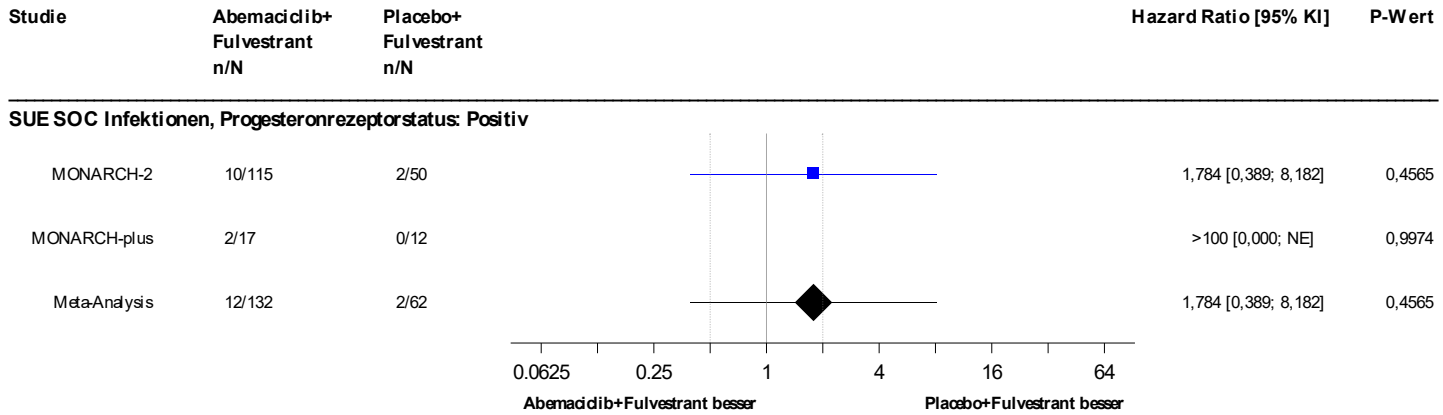
Abbildung 1431.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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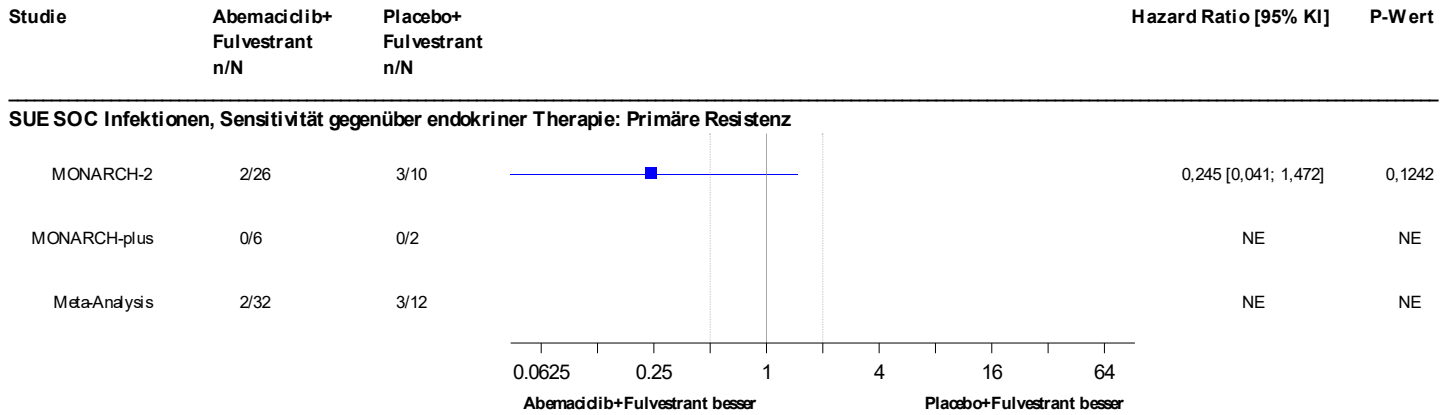
Abbildung 1431.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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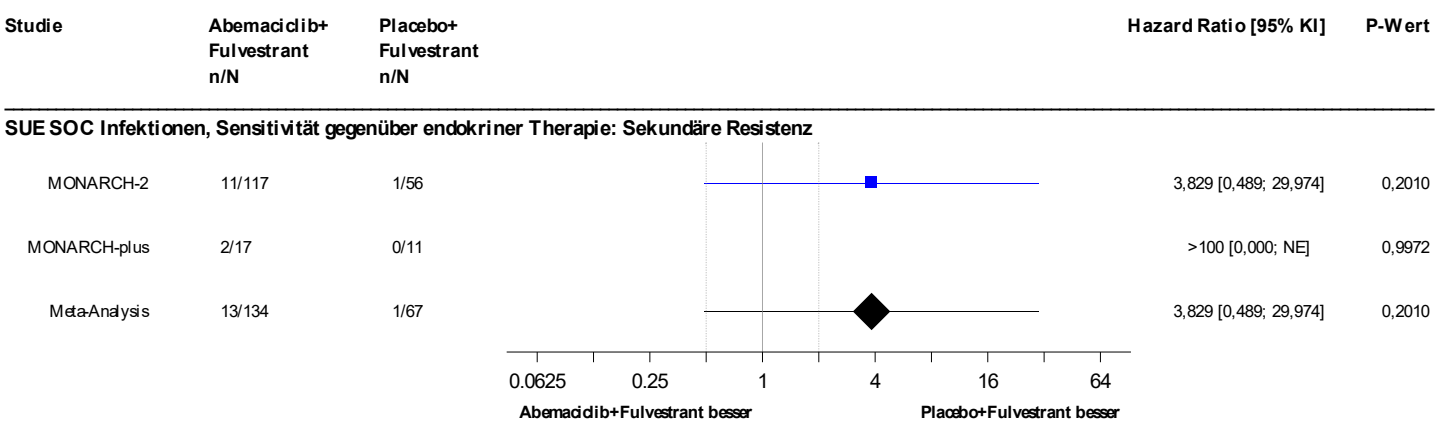
Abbildung 1431.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; SOC: System Organ Class; SUE: Schwerwiegendes unerwünschtes Ereignis.

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Abbildung 1431.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

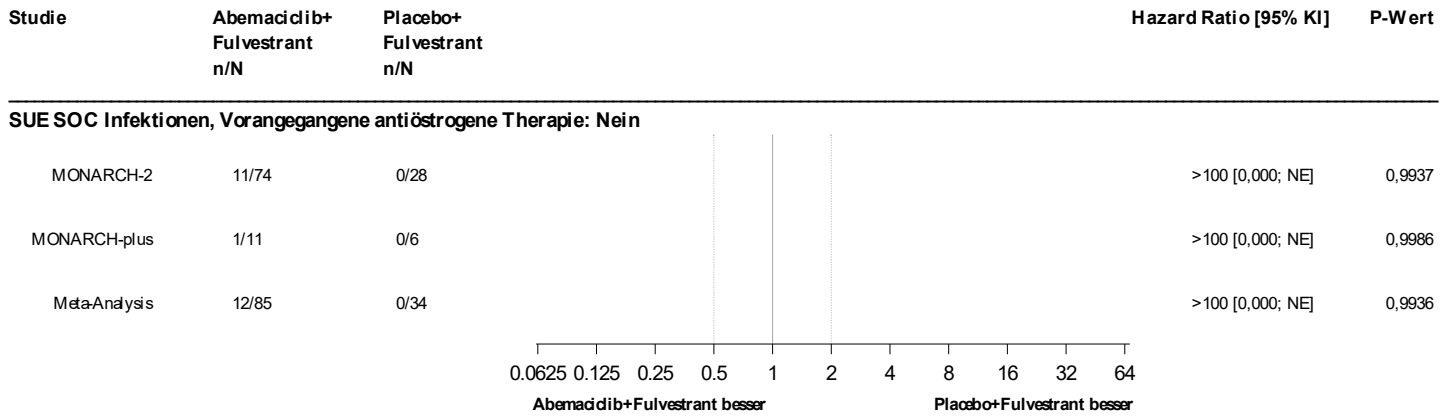

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Abbildung 1431.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten schwerwiegenden unerwünschten Ereignis: SOC Infektionen aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

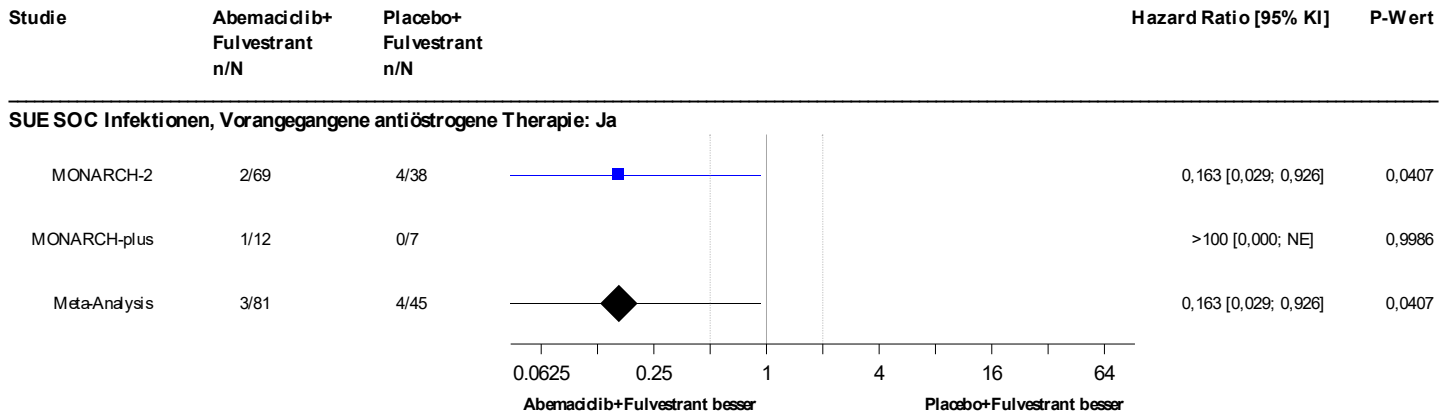

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Abbildung 1432.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

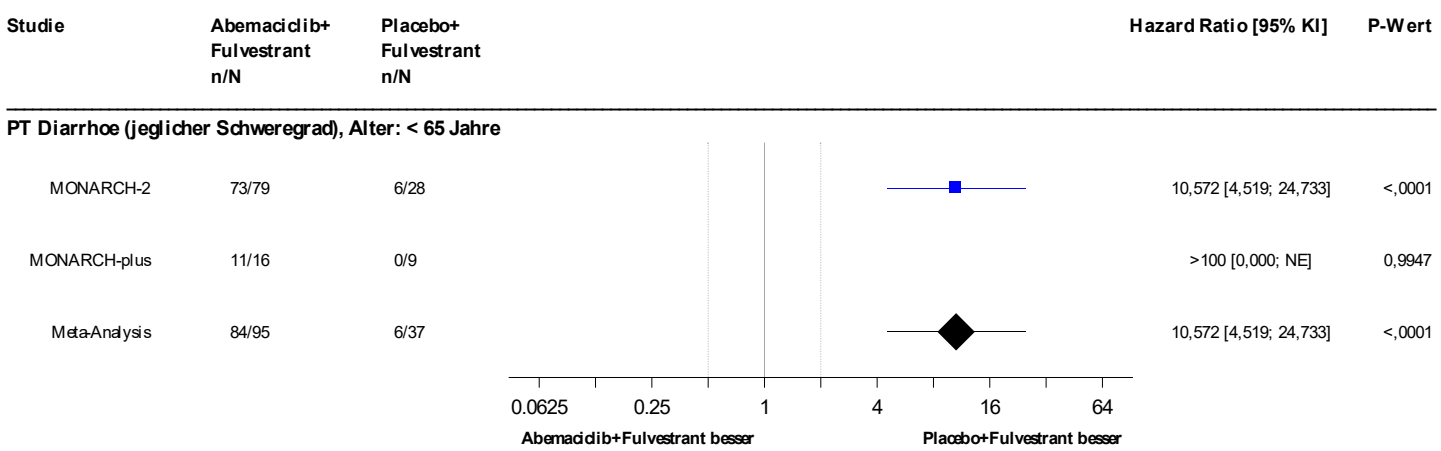

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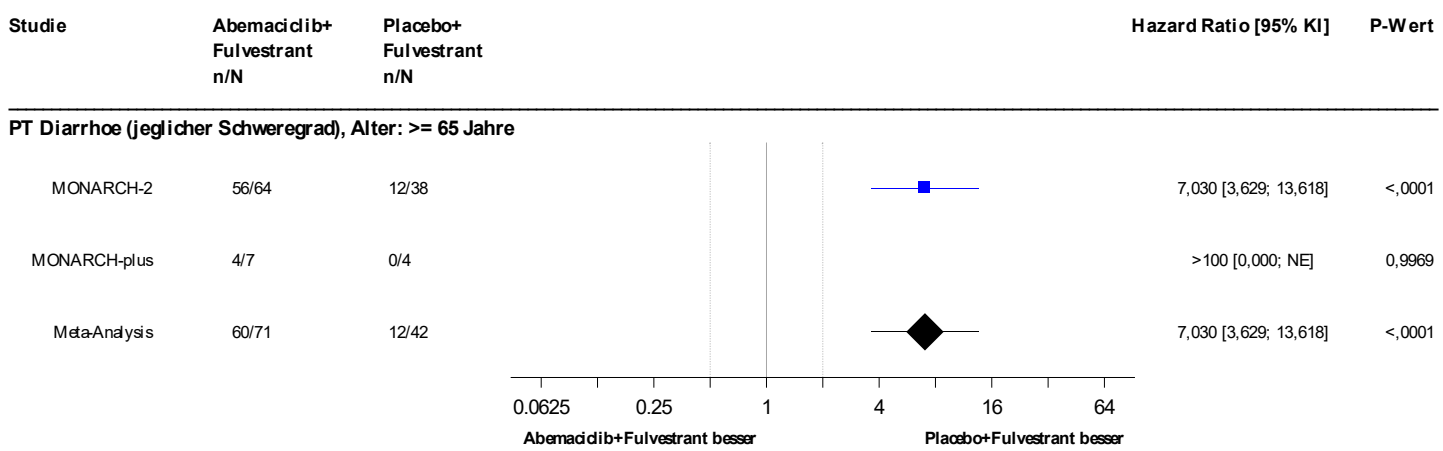
Abbildung 1432.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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17SEP2021 / 07:48

Abbildung 1432.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

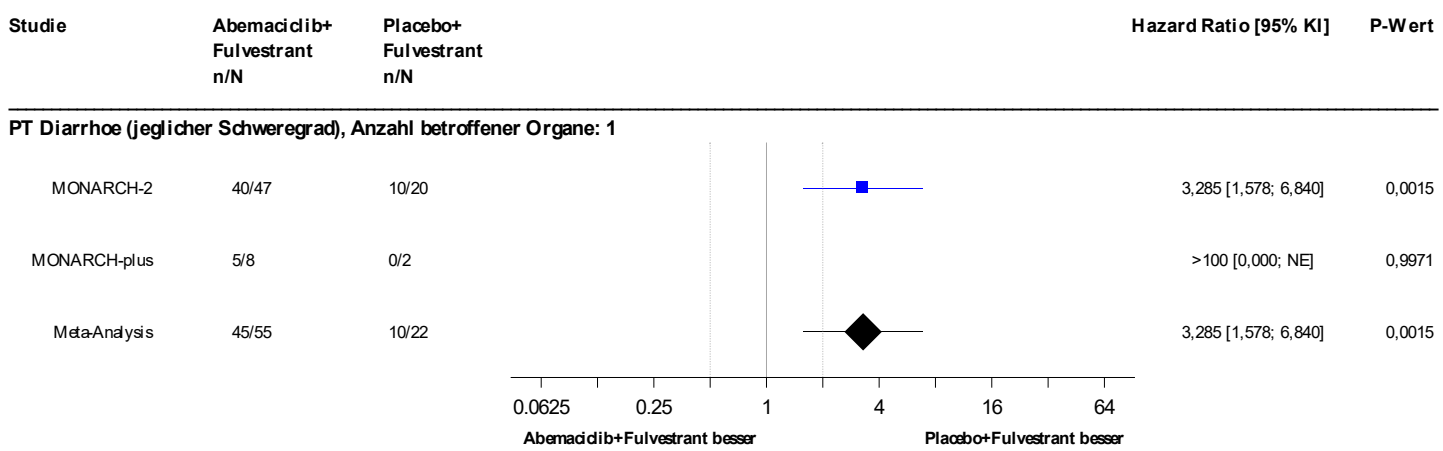

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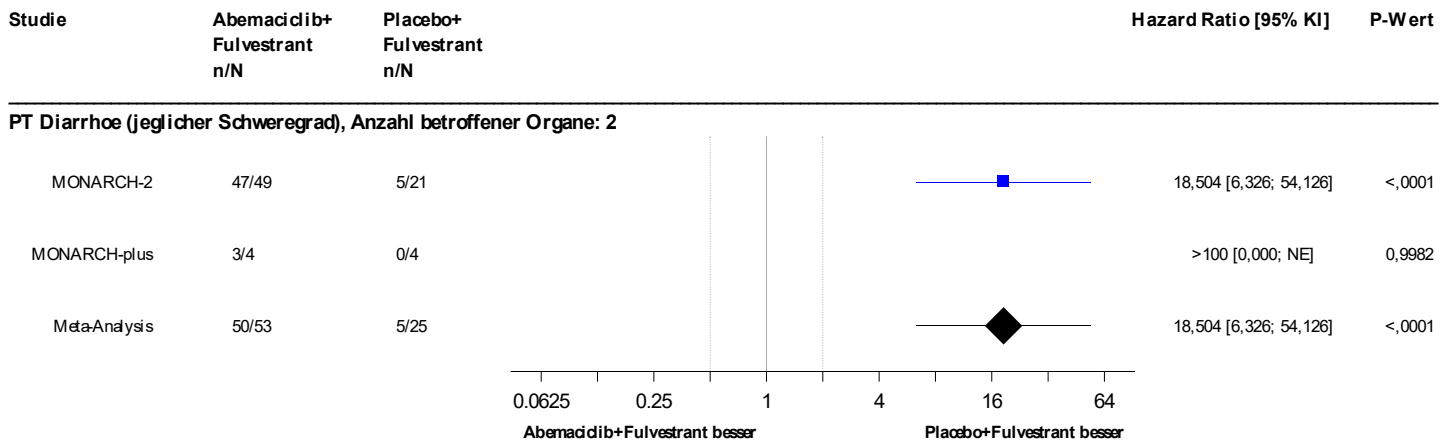
Abbildung 1432.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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Abbildung 1432.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

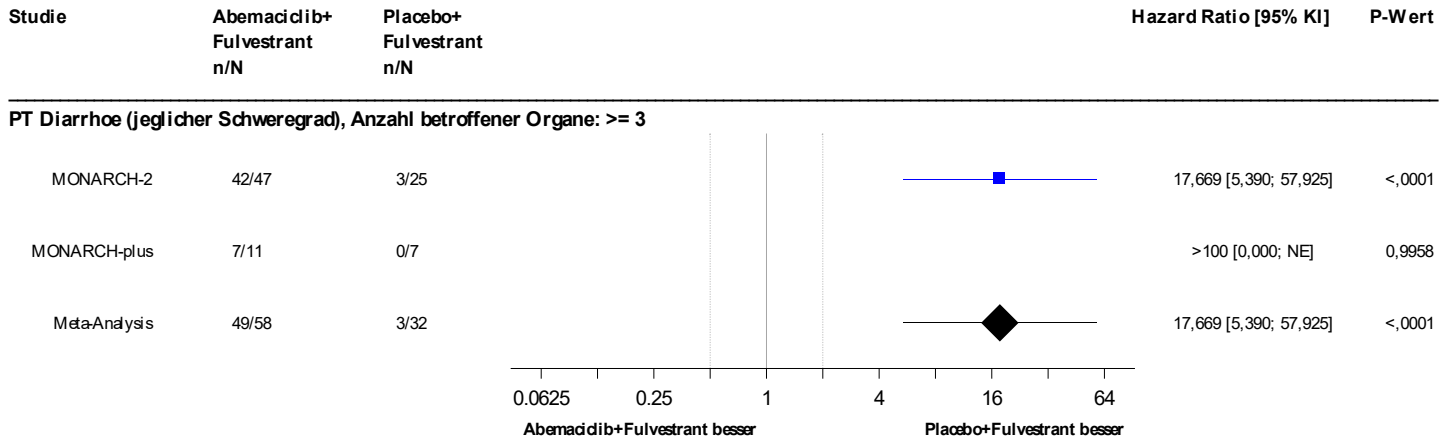

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Abbildung 1432.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

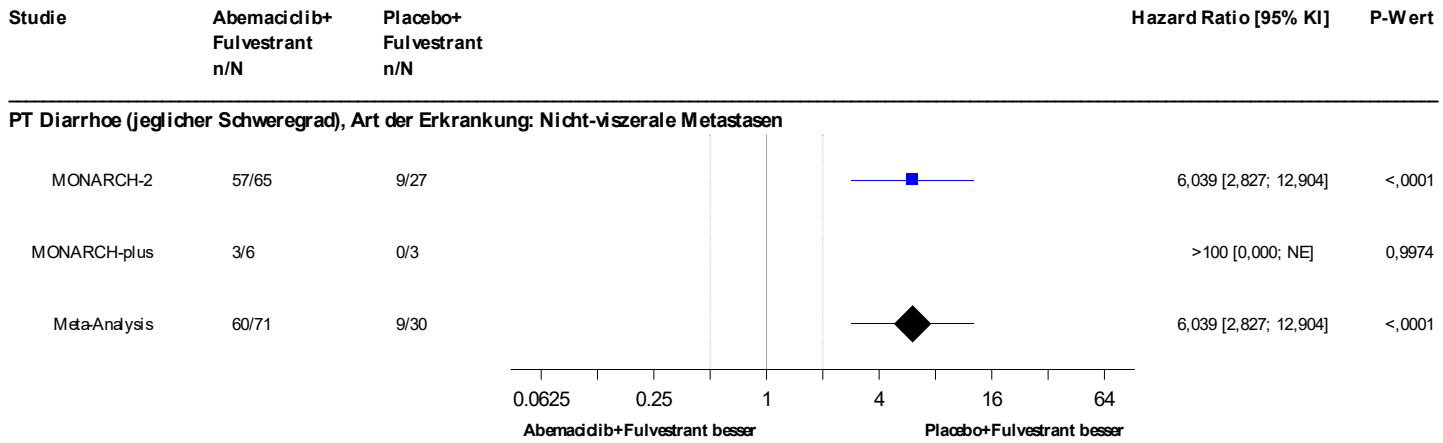

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Abbildung 1432.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

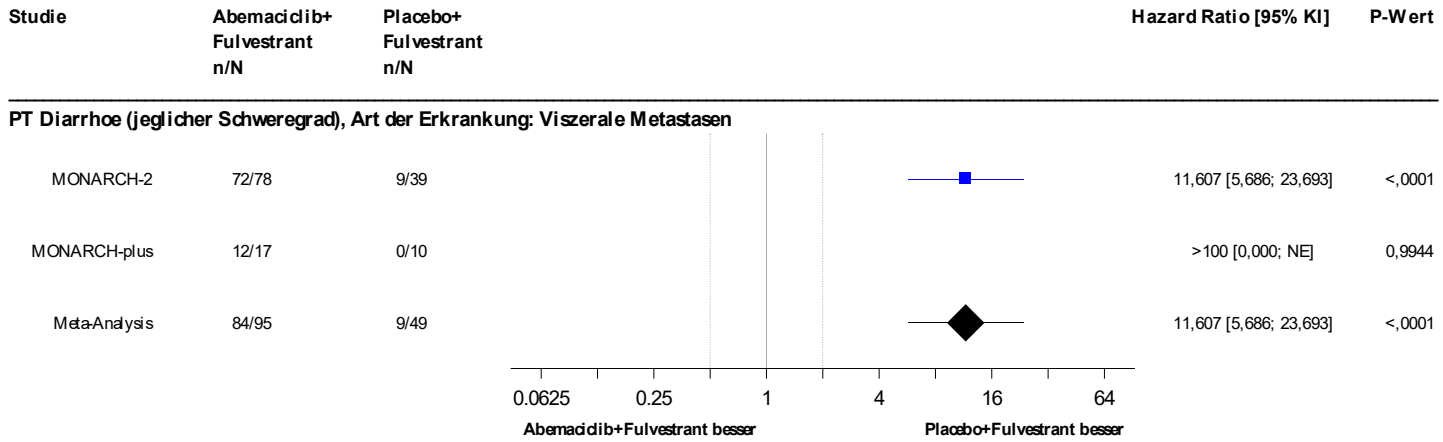

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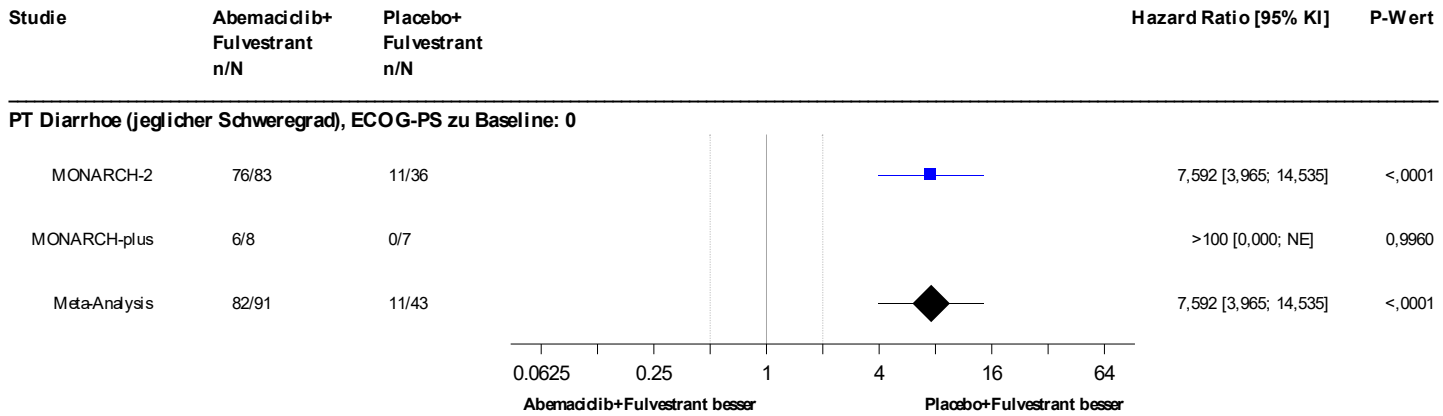
Abbildung 1432.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9965, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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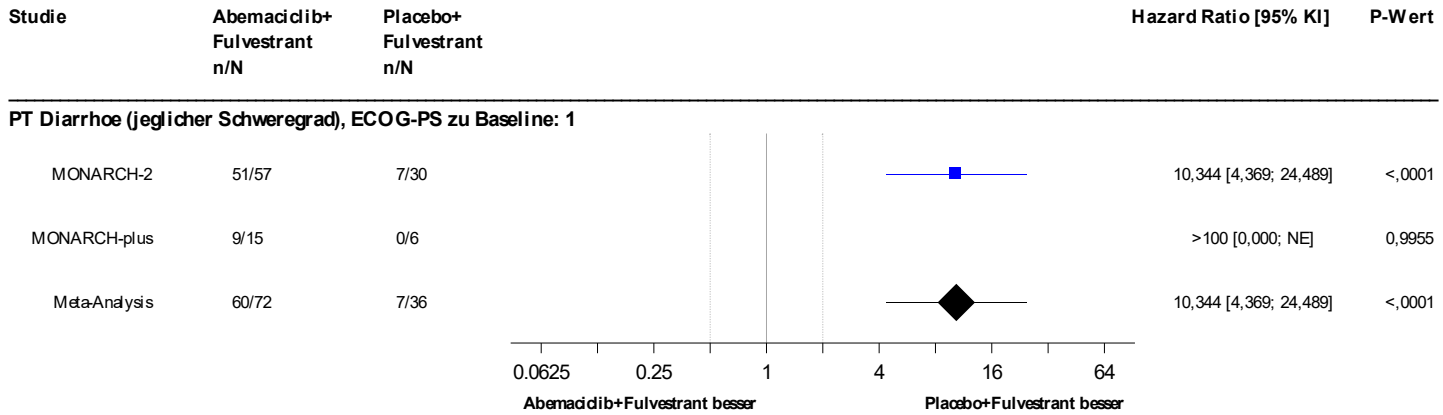
Abbildung 1432.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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Abbildung 1432.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

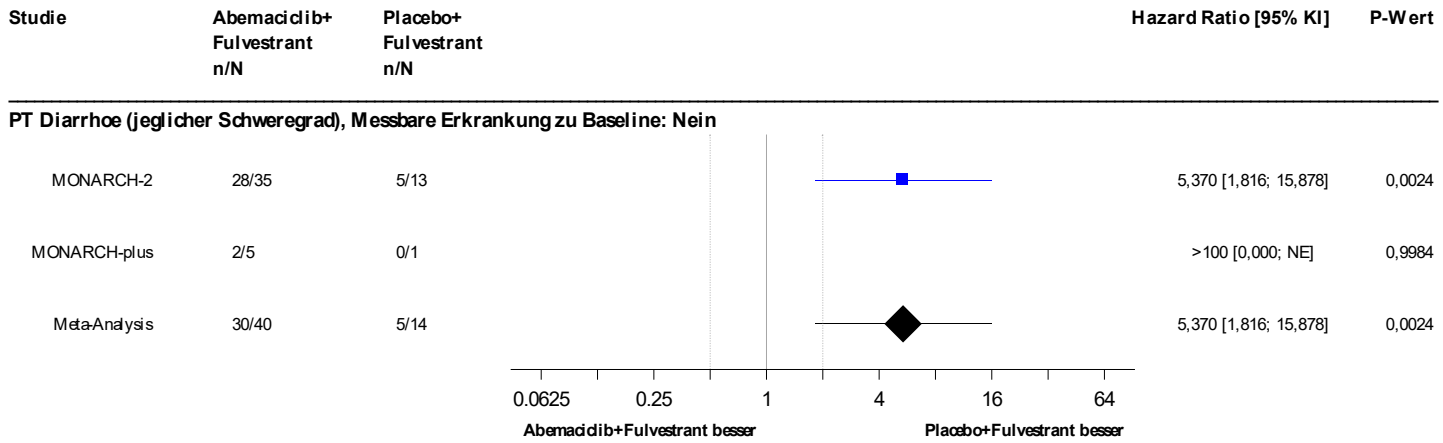

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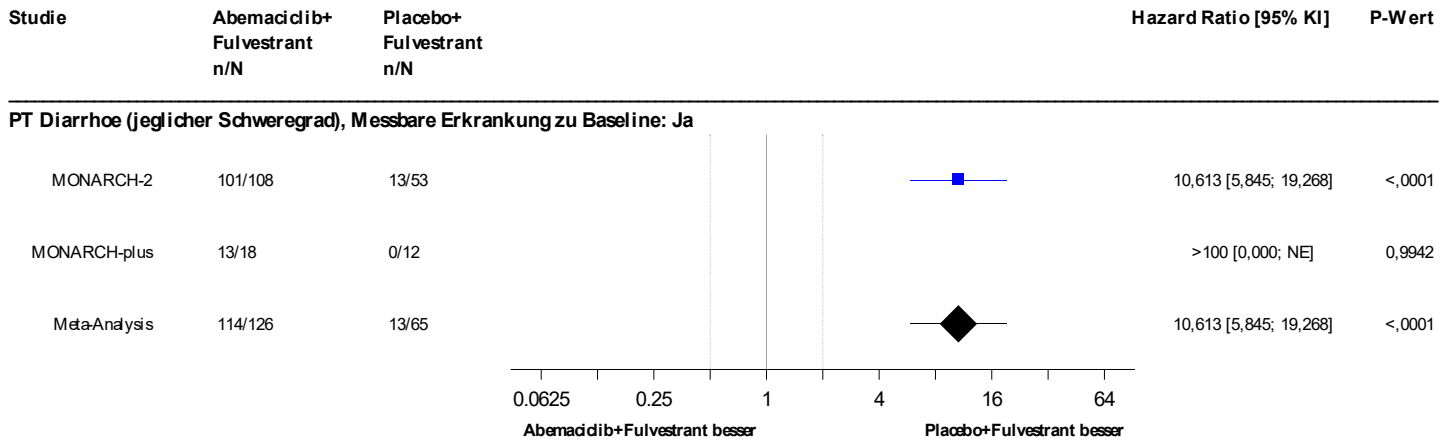
Abbildung 1432.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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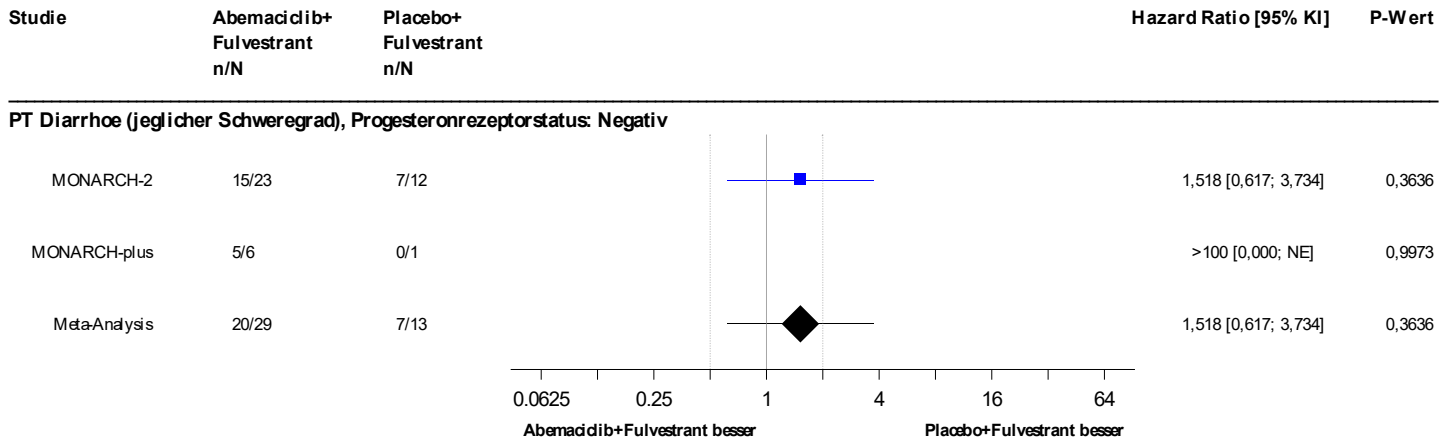
Abbildung 1432.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9973, I2 Index=0%
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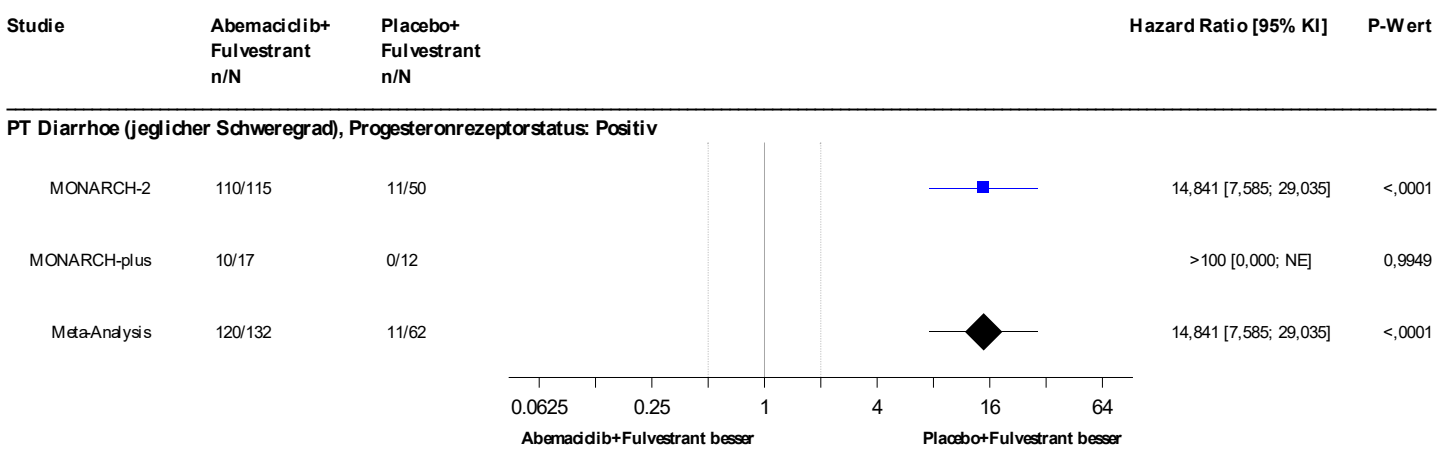
Abbildung 1432.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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17SEP2021 / 07:48

Abbildung 1432.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

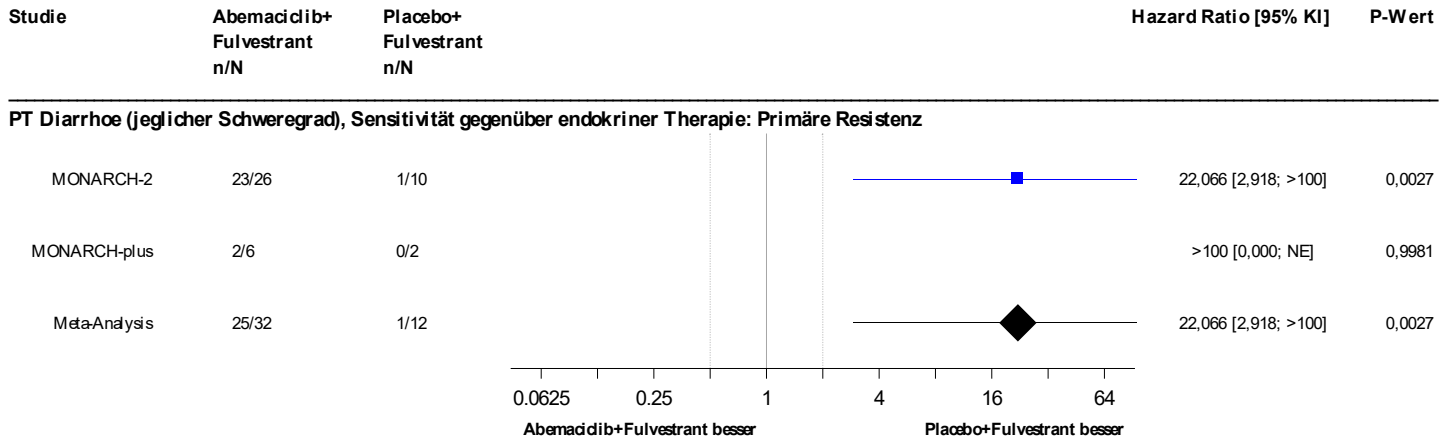

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Abbildung 1432.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

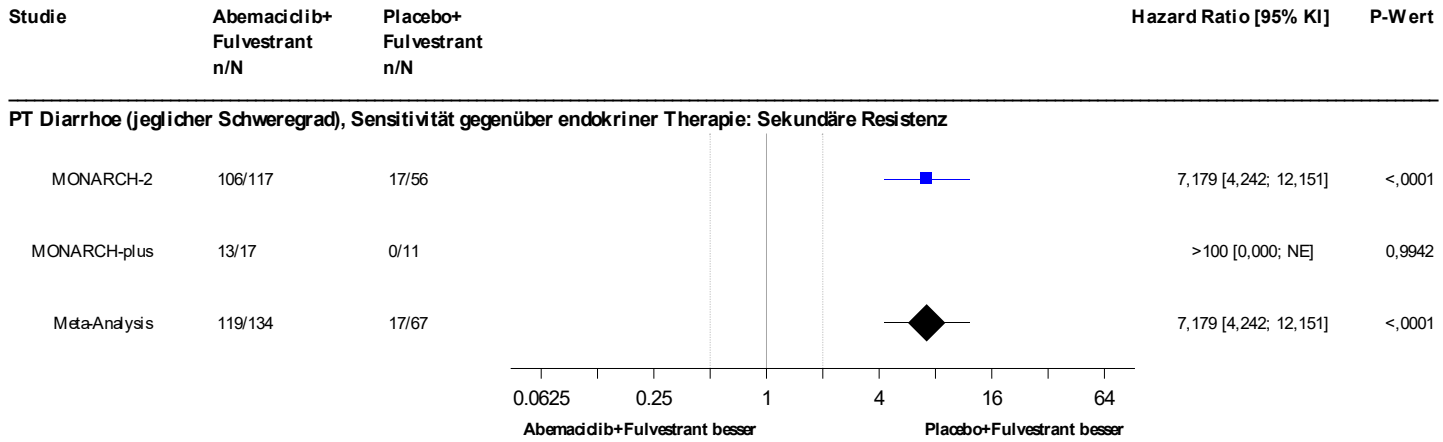

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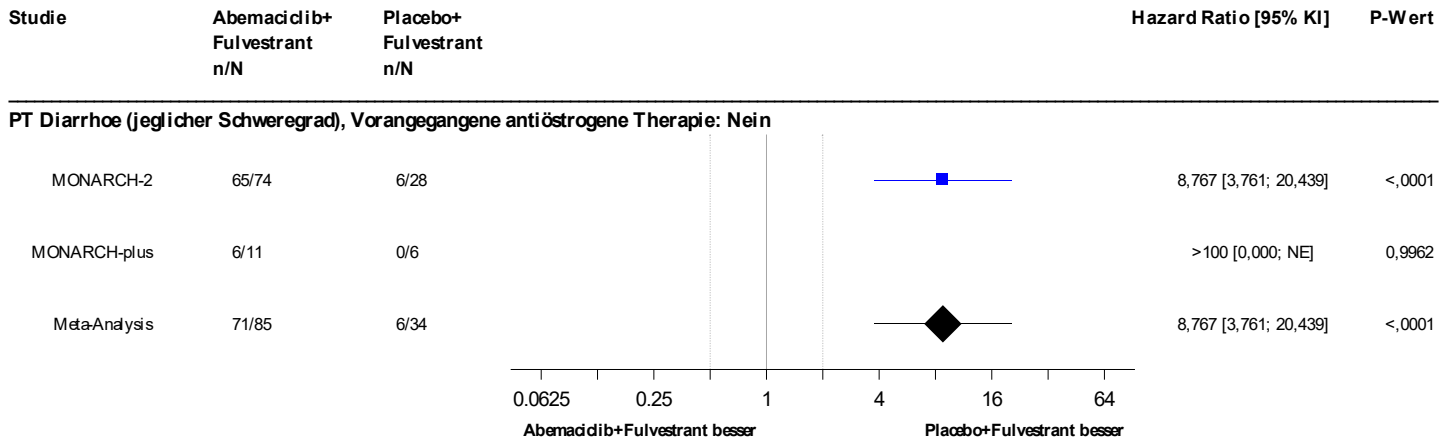
Abbildung 1432.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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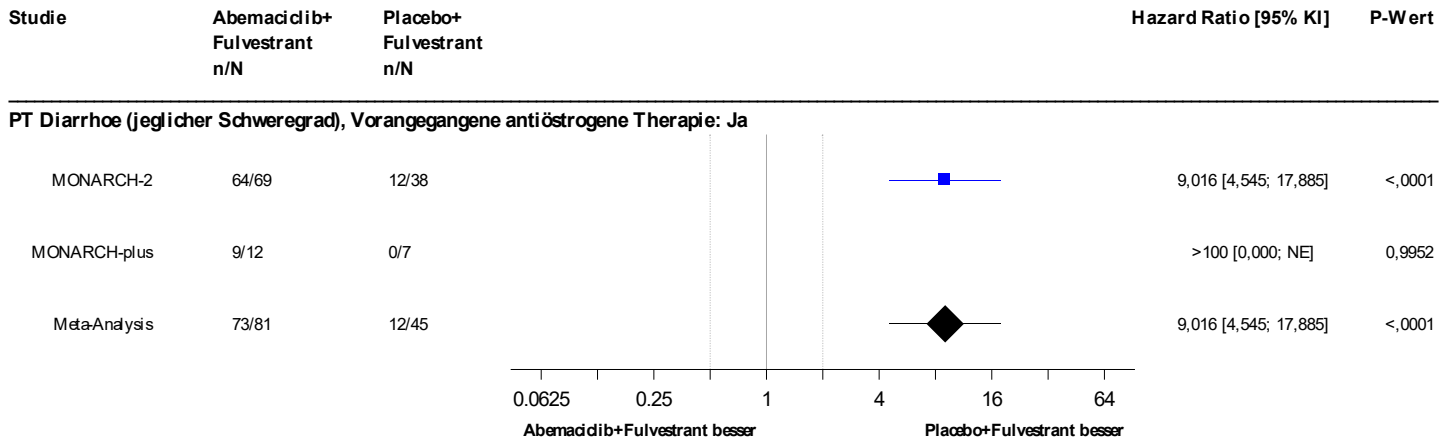
17SEP2021 / 07:48

Abbildung 1432.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Diarrhoe (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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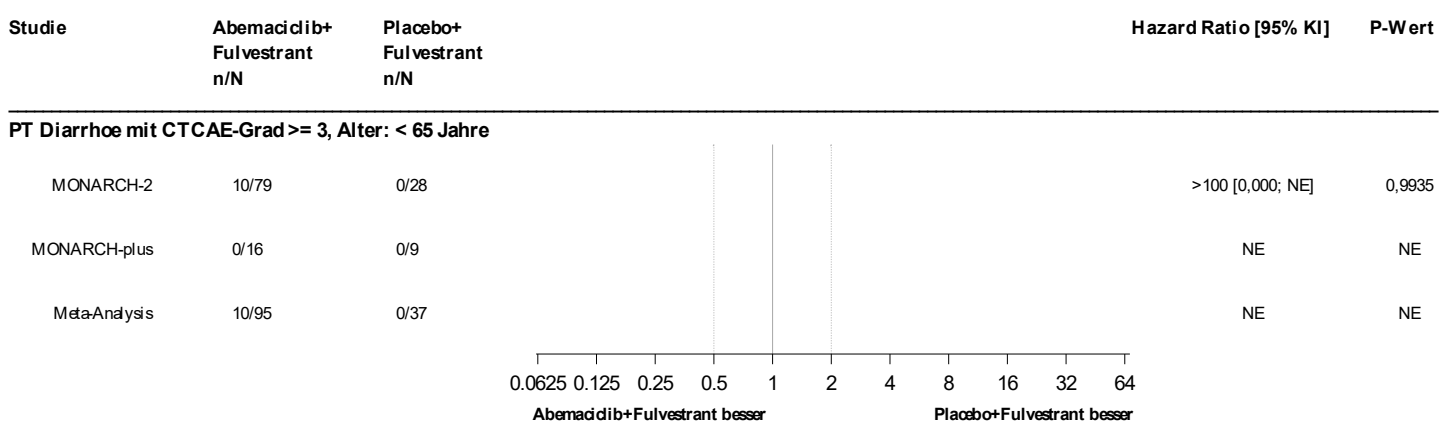
Abbildung 1433.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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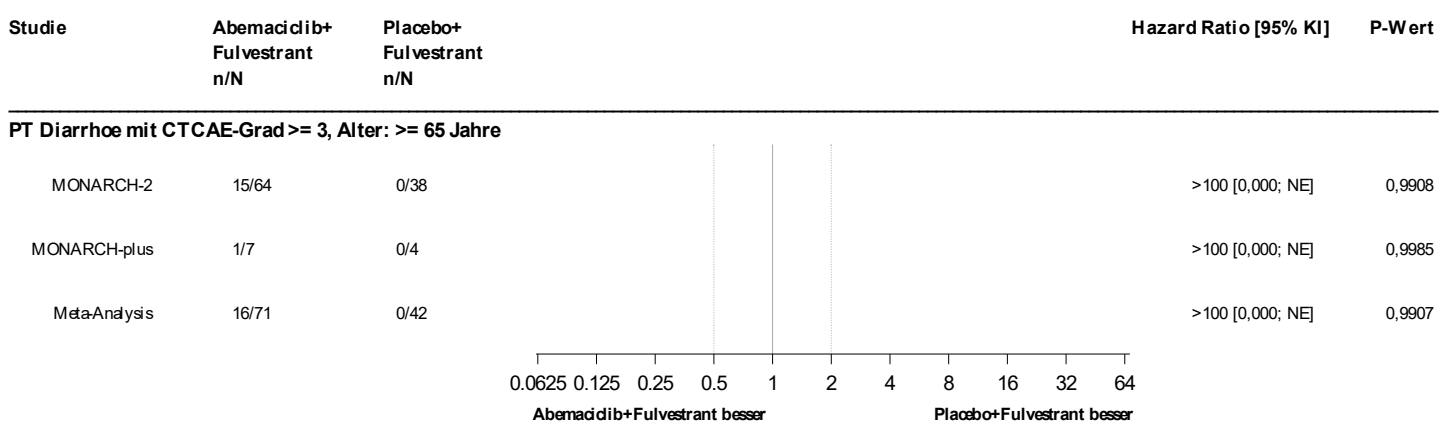
17SEP2021 / 07:48

Abbildung 1433.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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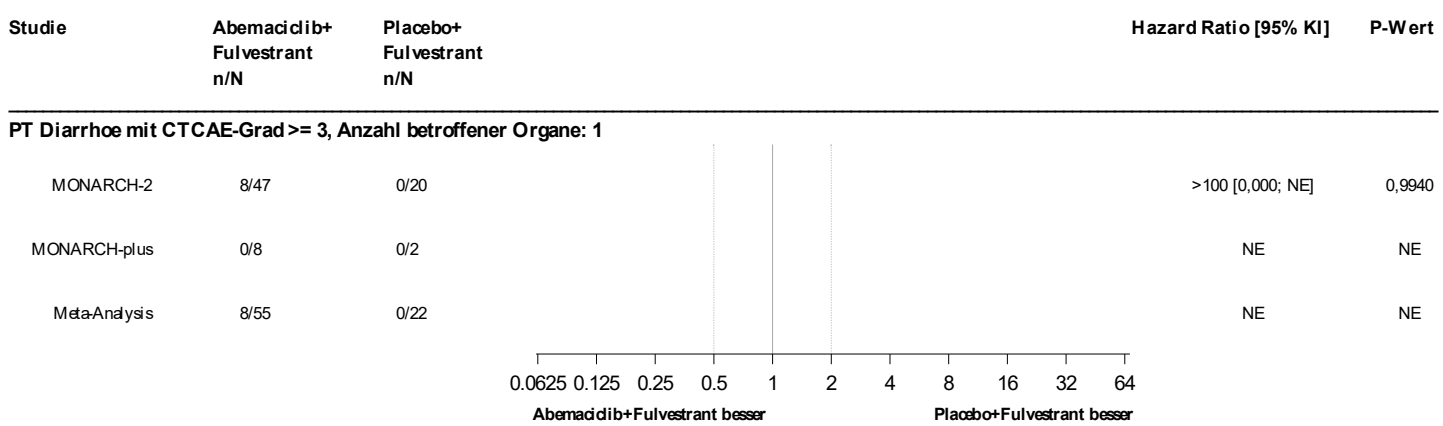
17SEP2021 / 07:48

Abbildung 1433.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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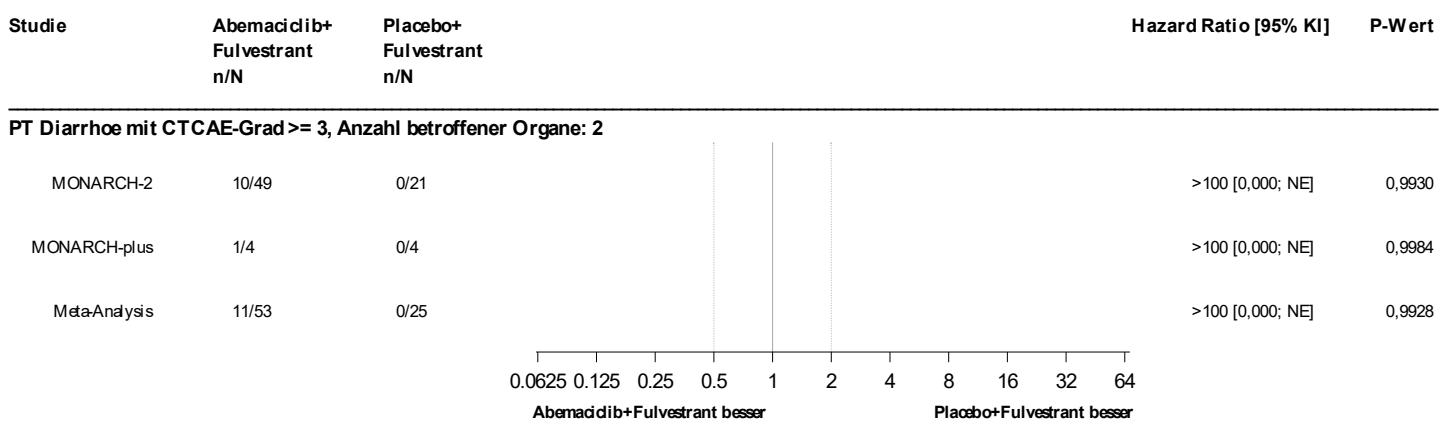
17SEP2021 / 07:48

Abbildung 1433.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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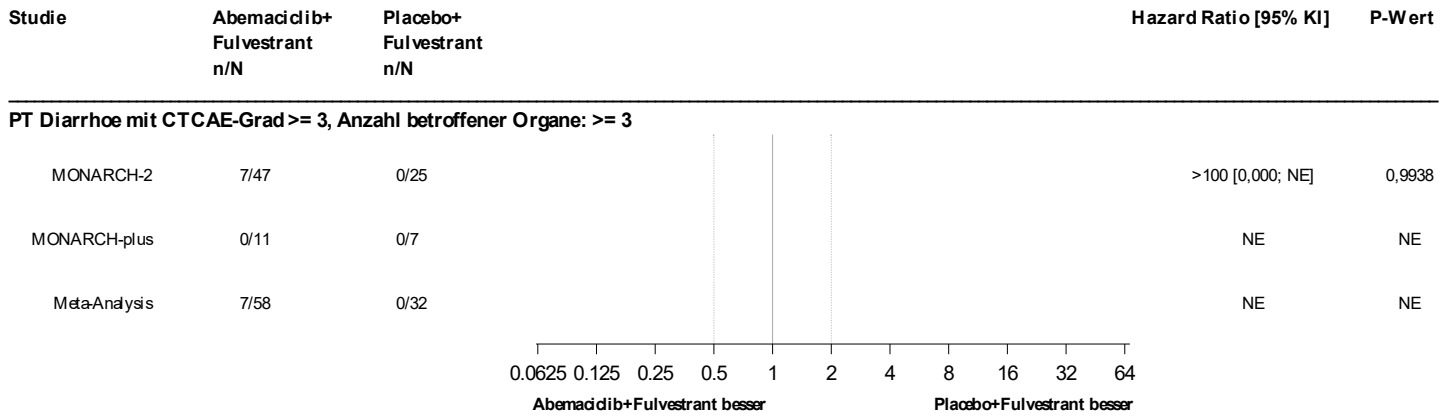
17SEP2021 / 07:48

Abbildung 1433.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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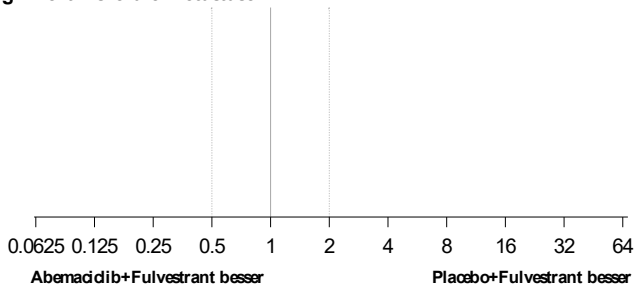
17SEP2021 / 07:48

Abbildung 1433.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

Studie	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% KI]	P-Wert
PT Diarrhoe mit CTCAE-Grad >= 3, Art der Erkrankung: Nicht-viszerale Metastasen				
MONARCH-2	14/65	0/27	>100 [0,000; NE]	0,9919
MONARCH-plus	0/6	0/3	NE	NE
Meta-Analysis	14/71	0/30	NE	NE



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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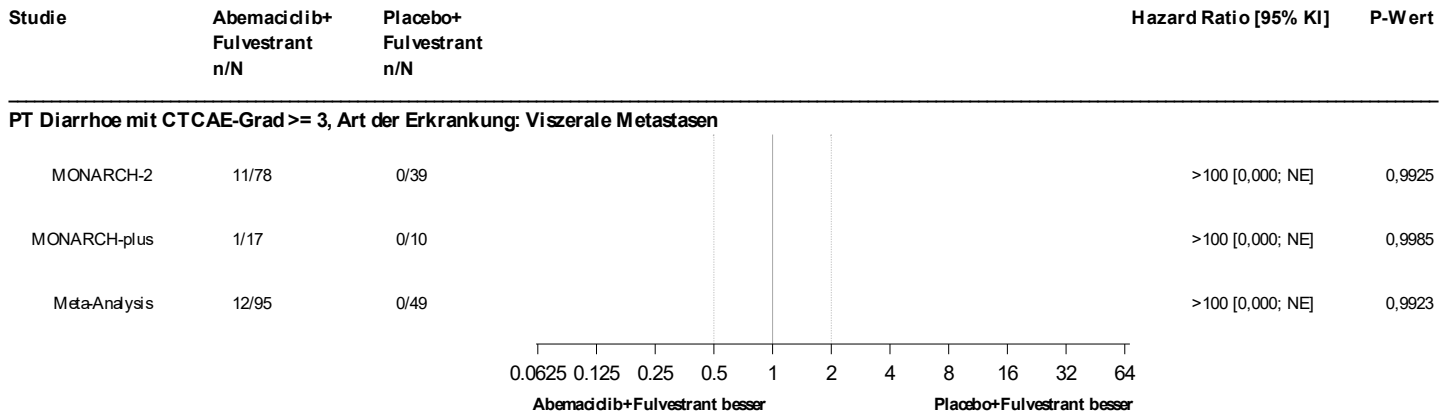
Abbildung 1433.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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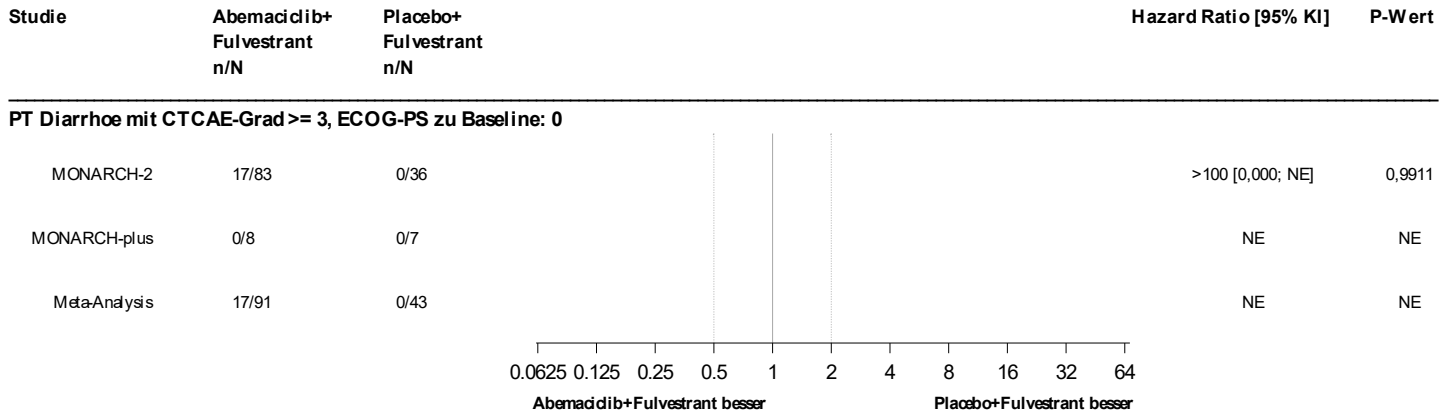
Abbildung 1433.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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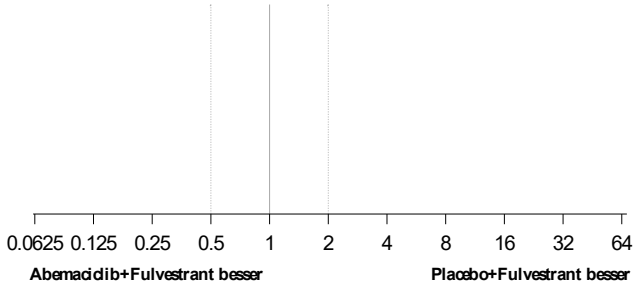
Abbildung 1433.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

Studie	Abemaciclib+ Fulvestrant n/N	Placebo+ Fulvestrant n/N	Hazard Ratio [95% KI]	P-Wert
PT Diarrhoe mit CTCAE-Grad >= 3, ECOG-PS zu Baseline: 1				
MONARCH-2	8/57	0/30	>100 [0,000; NE]	0,9935
MONARCH-plus	1/15	0/6	>100 [0,000; NE]	0,9979
Meta-Analysis	9/72	0/36	>100 [0,000; NE]	0,9932



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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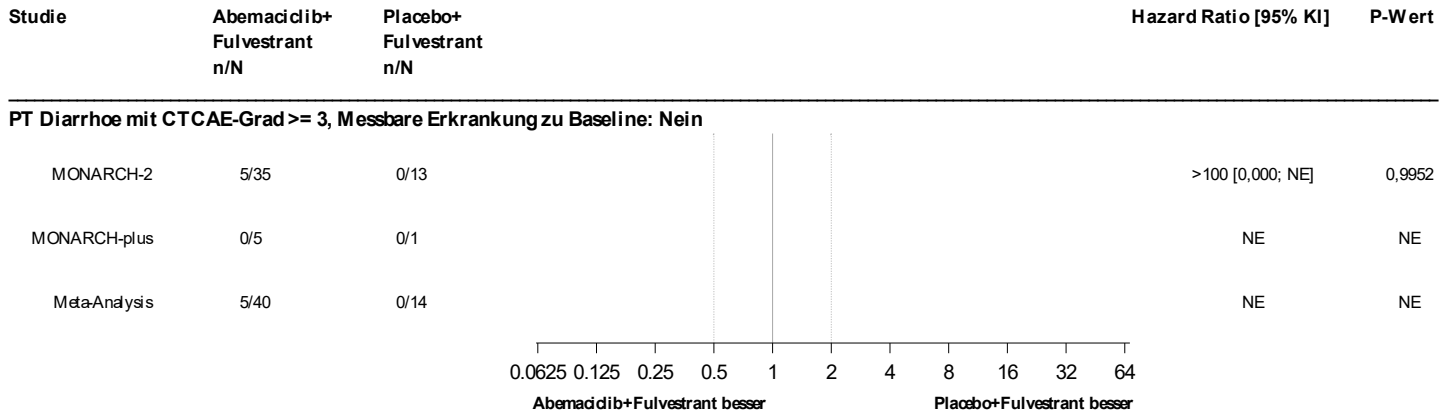
Abbildung 1433.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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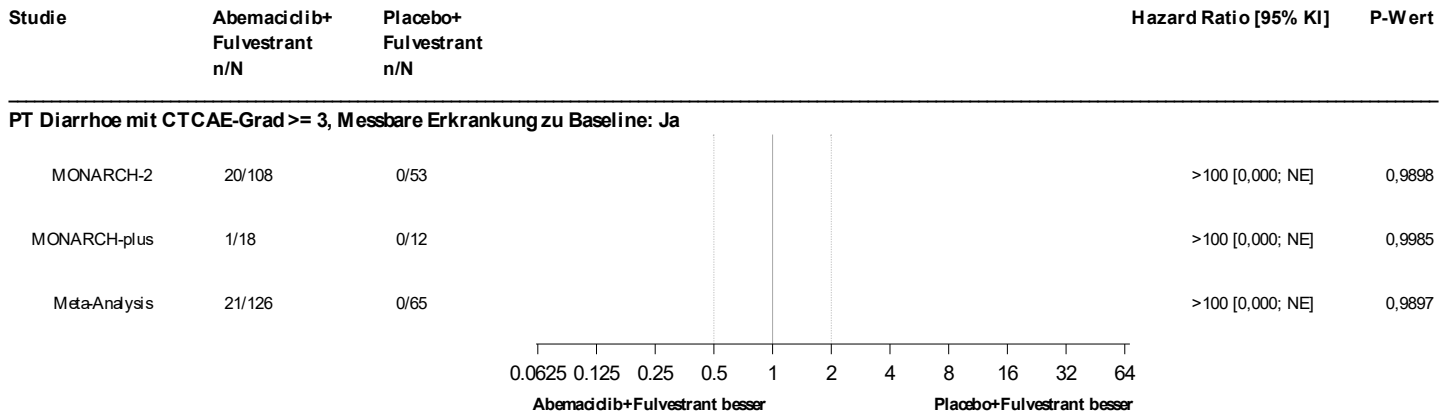
Abbildung 1433.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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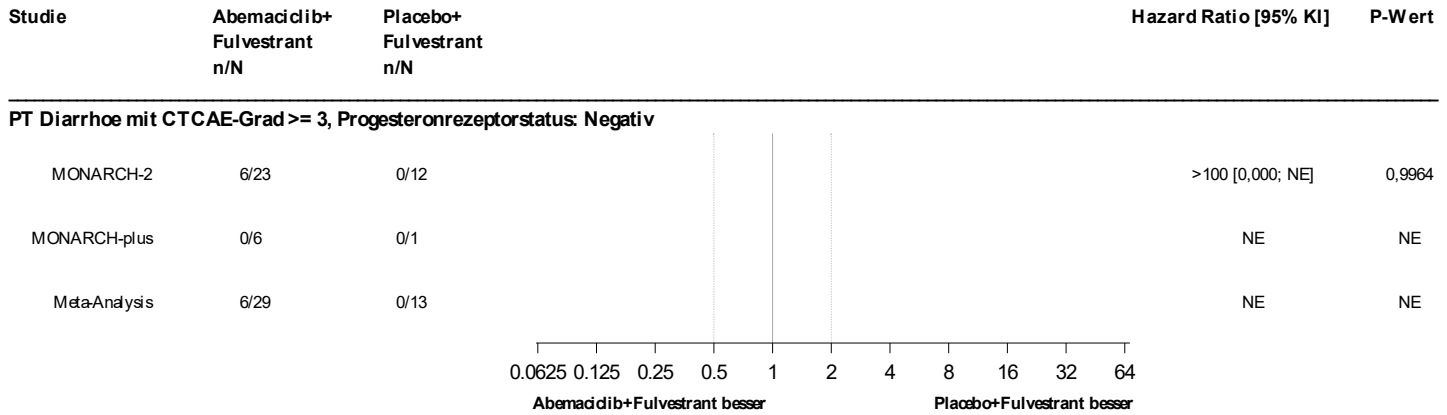
Abbildung 1433.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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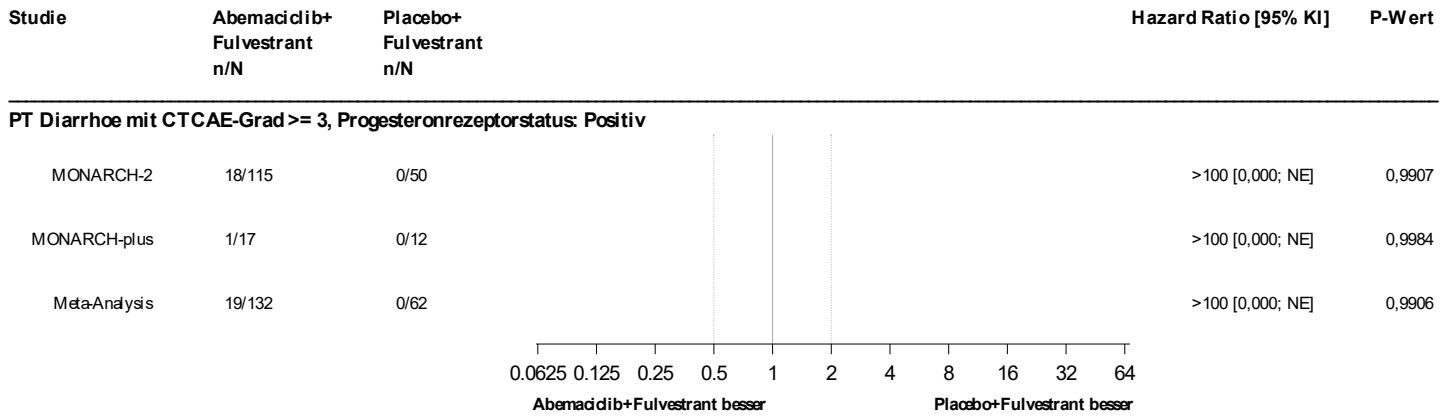
Abbildung 1433.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
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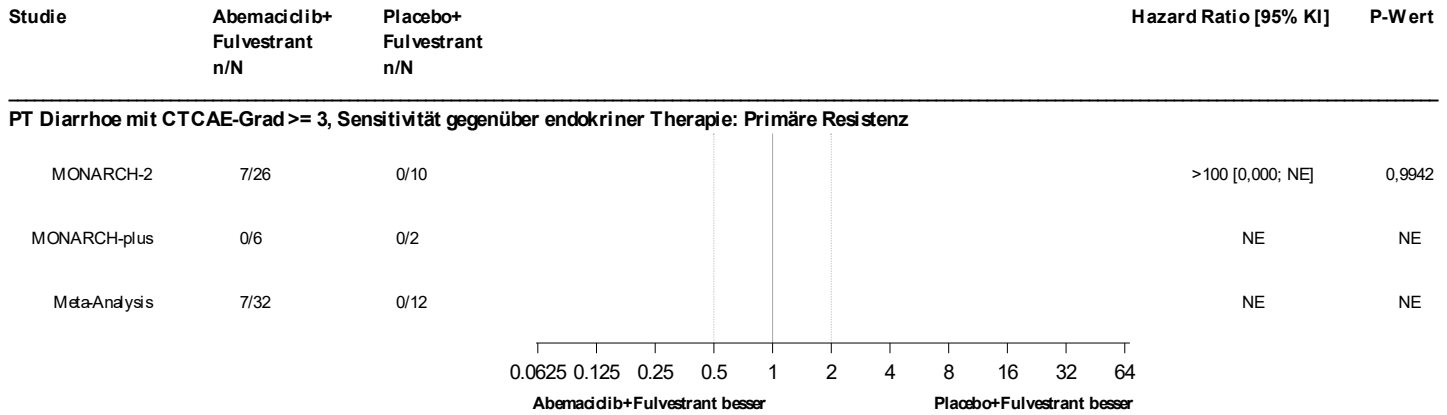
Abbildung 1433.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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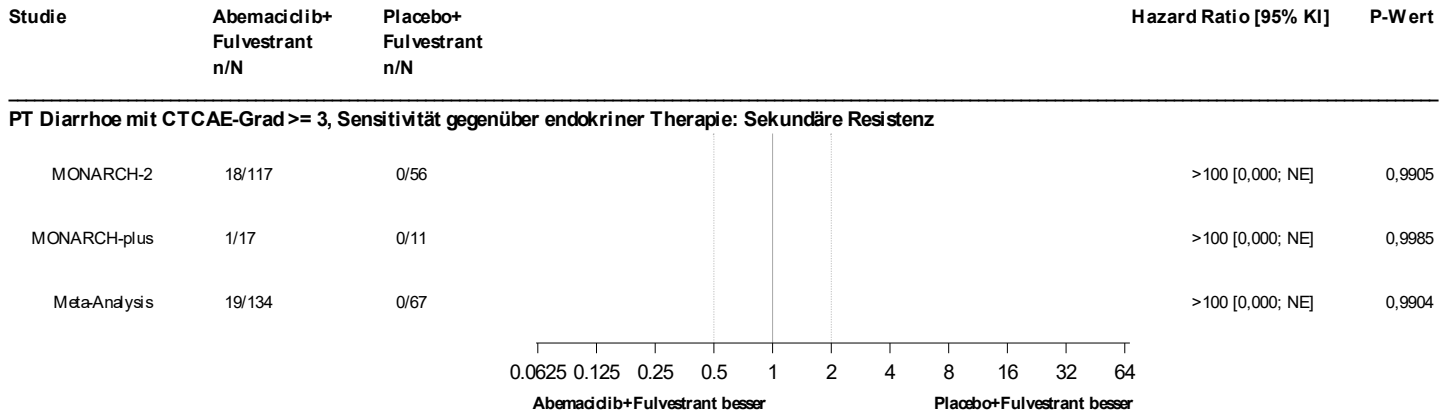
Abbildung 1433.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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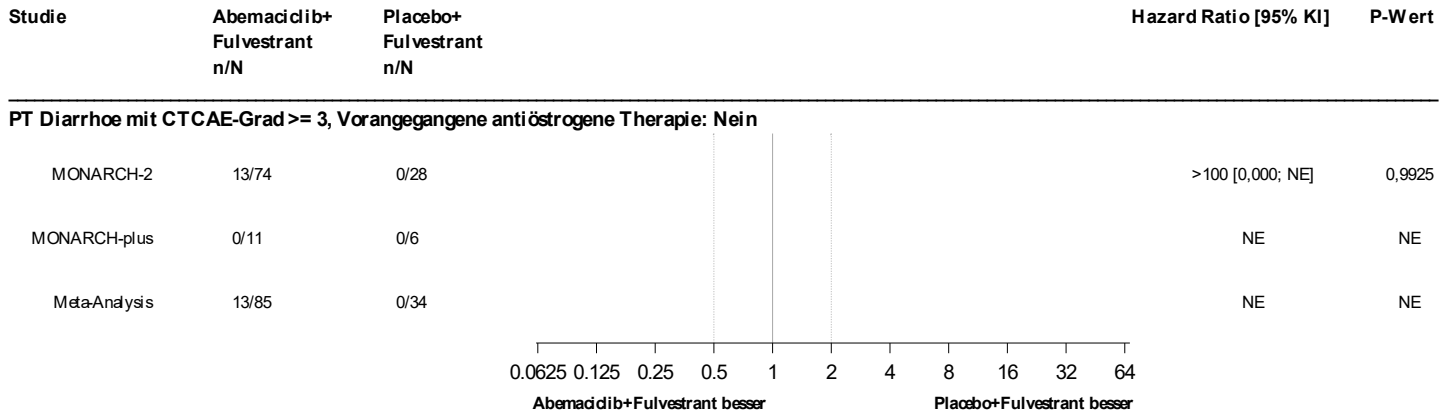
Abbildung 1433.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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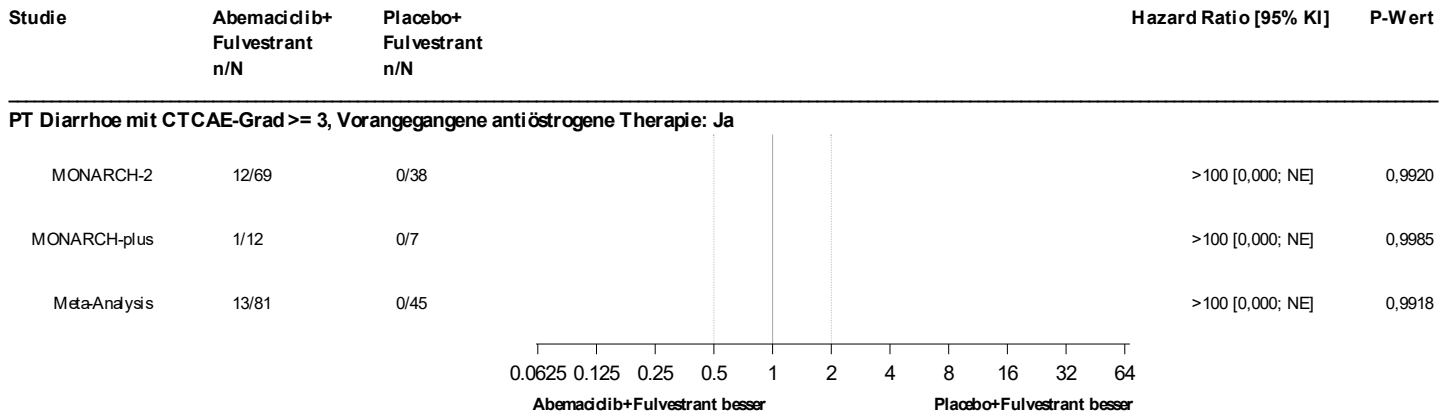
Abbildung 1433.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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Abbildung 1434.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

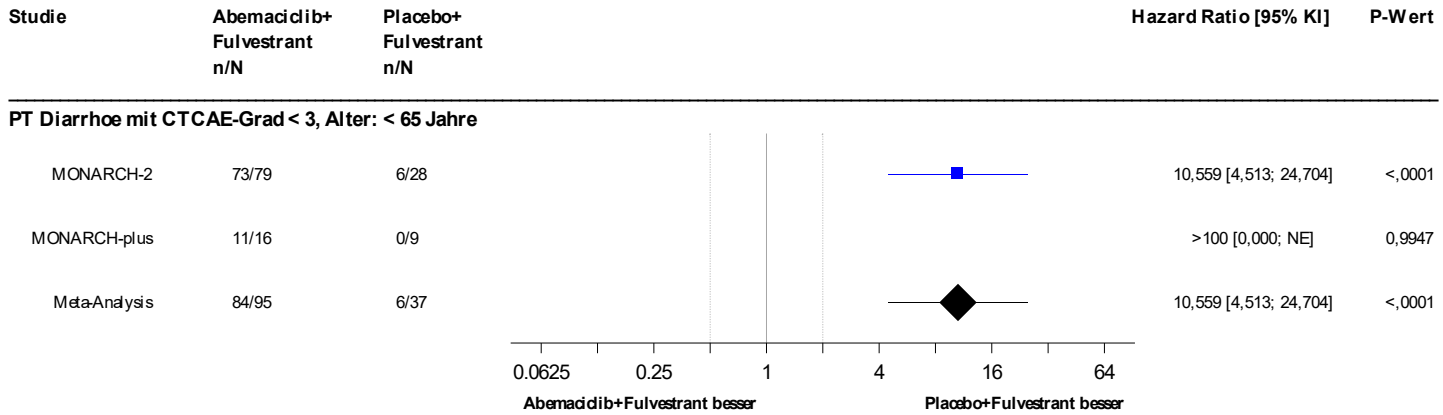

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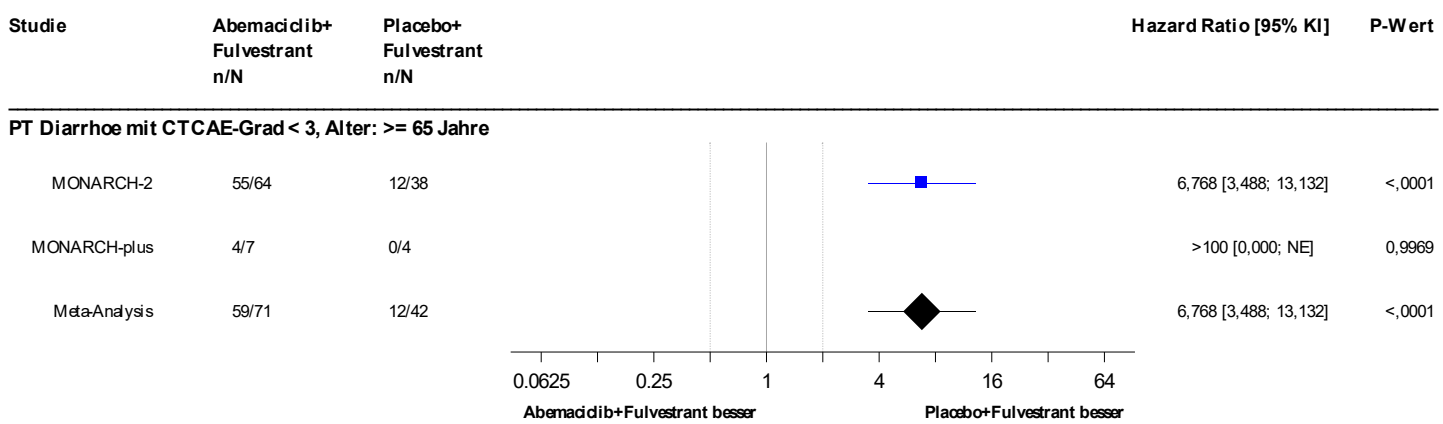
Abbildung 1434.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9972, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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Abbildung 1434.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

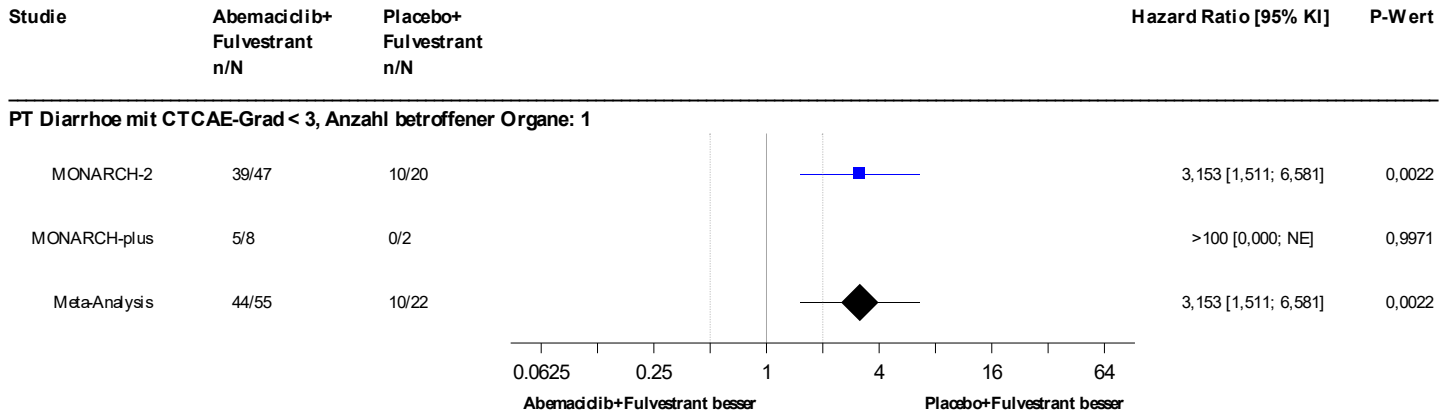

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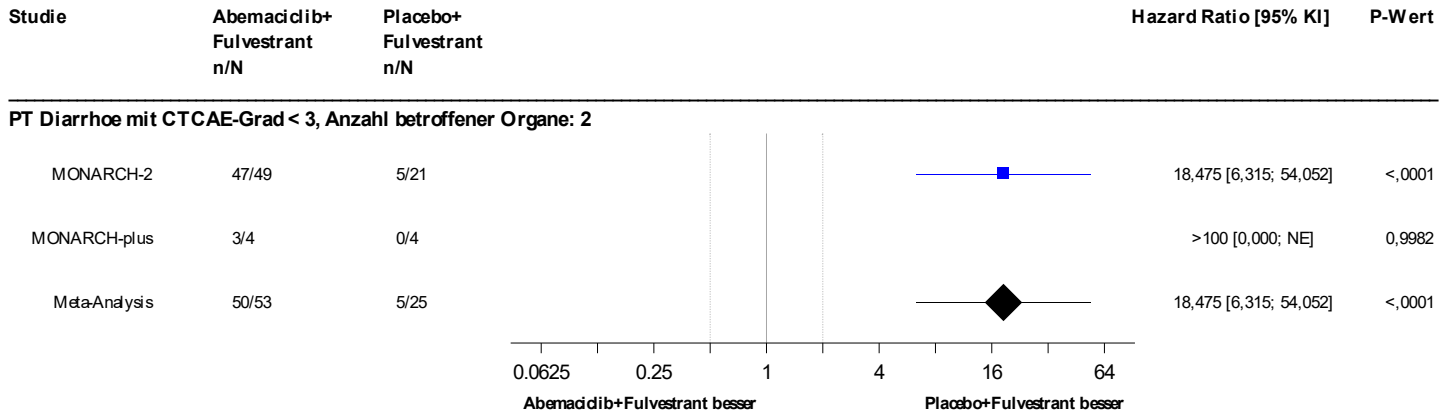
Abbildung 1434.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9985, I2 Index=0%
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Abbildung 1434.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

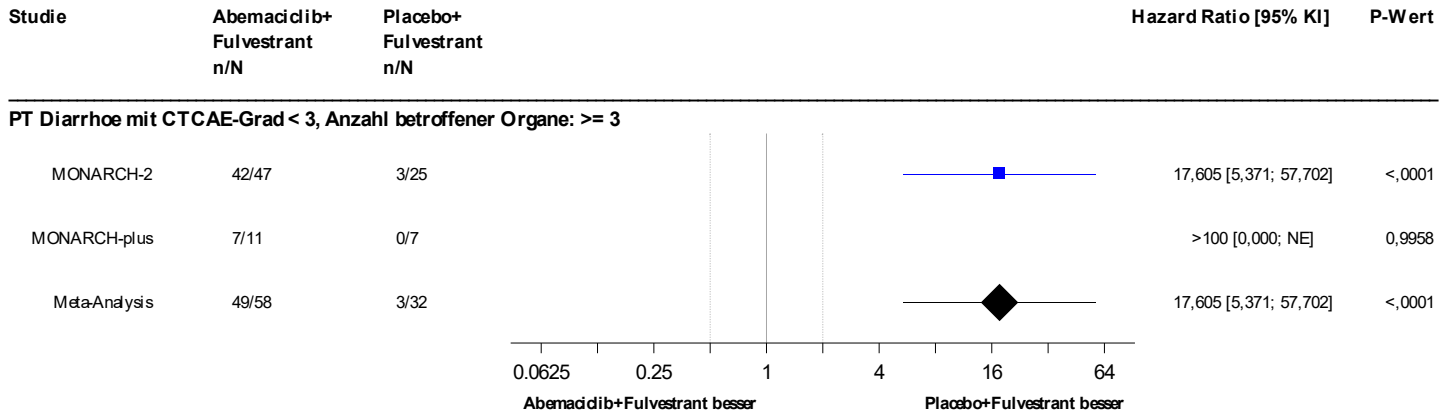

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Abbildung 1434.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

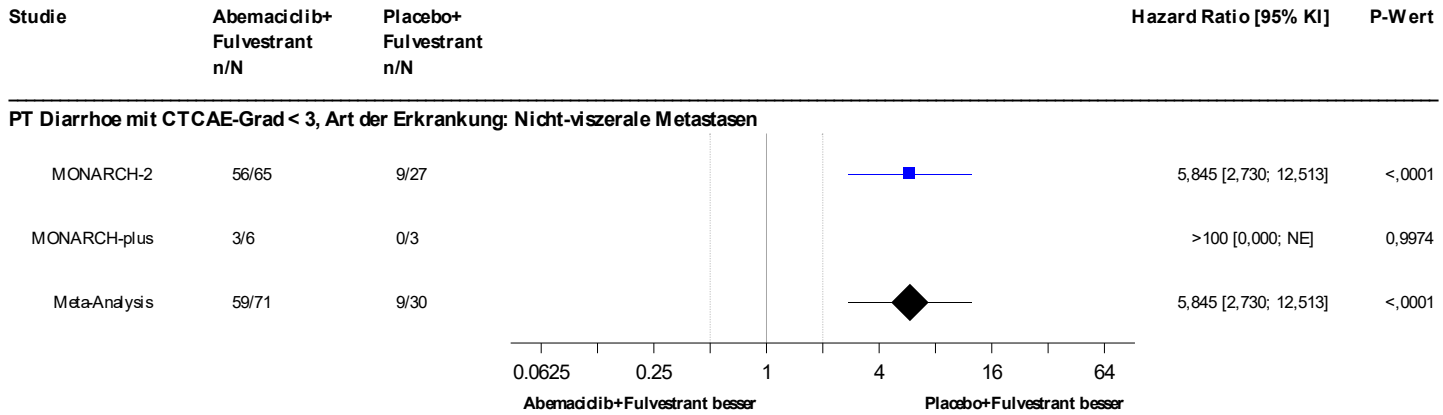

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Abbildung 1434.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

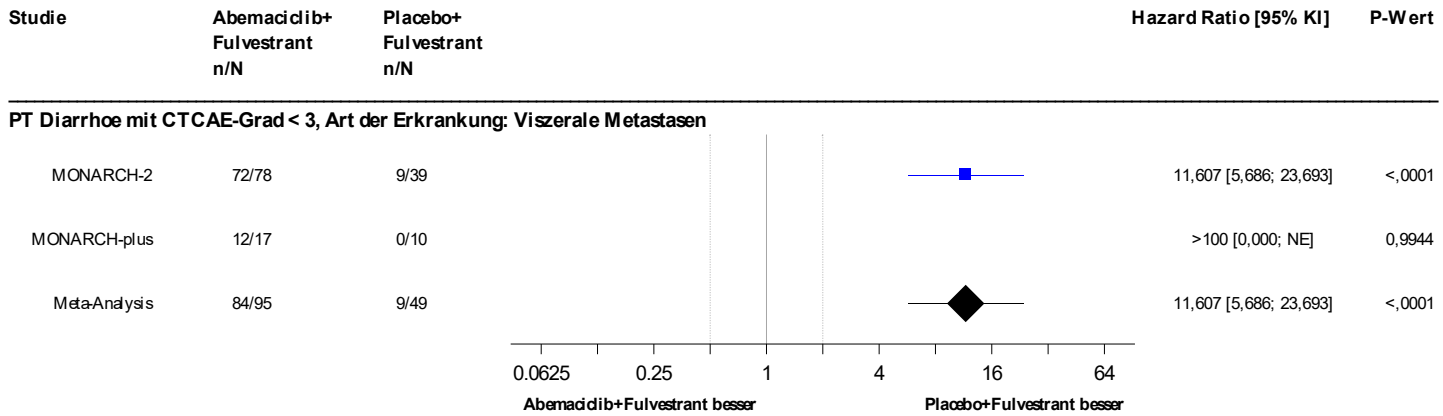

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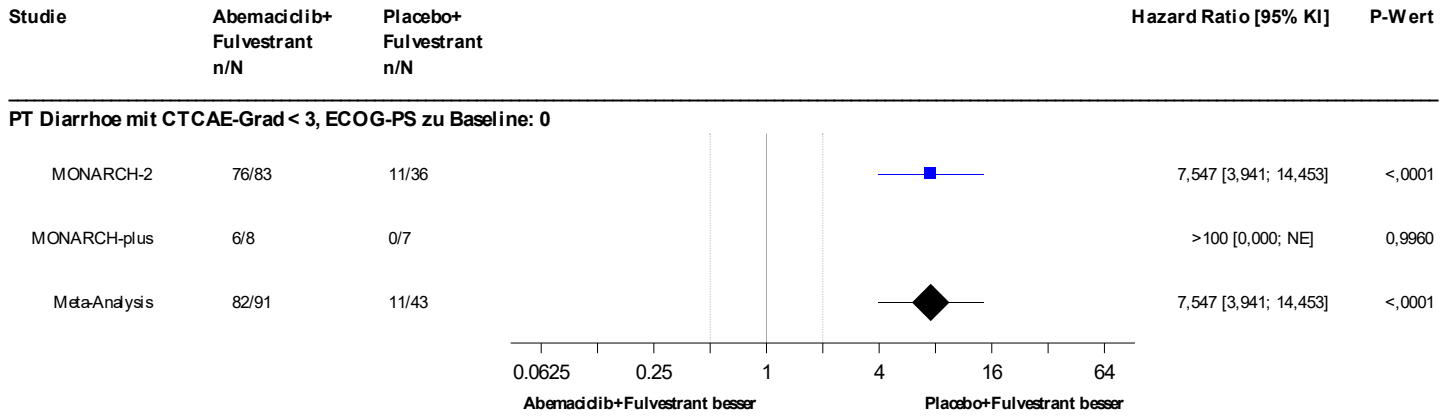
Abbildung 1434.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9965, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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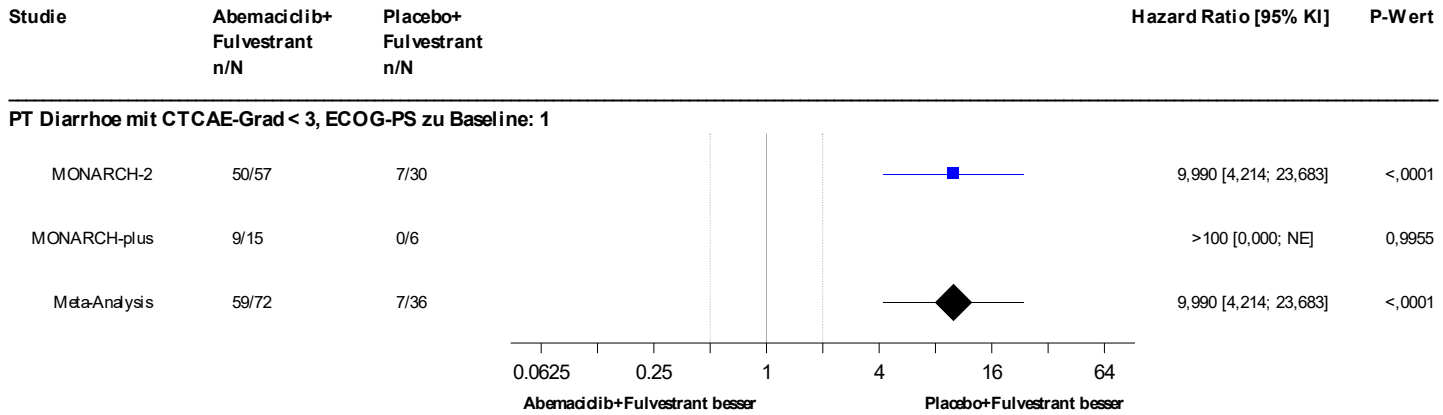
Abbildung 1434.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9961, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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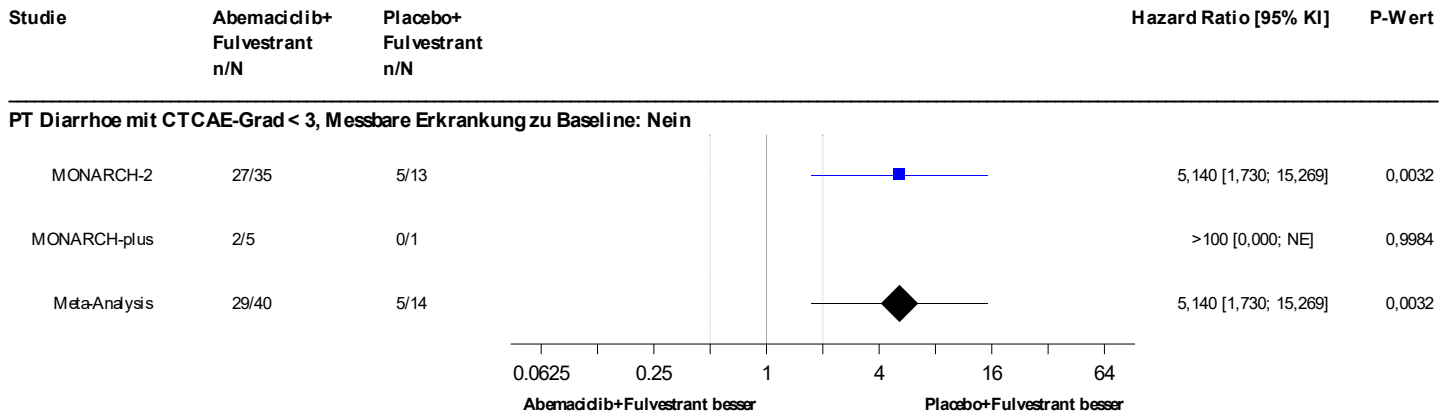
Abbildung 1434.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9986, I2 Index=0%
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Abbildung 1434.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

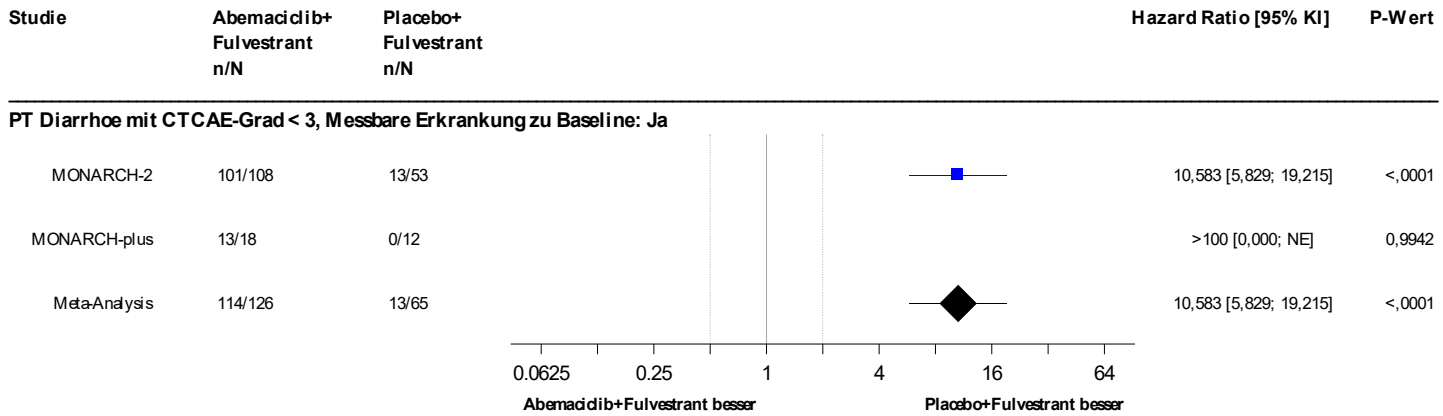

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Abbildung 1434.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

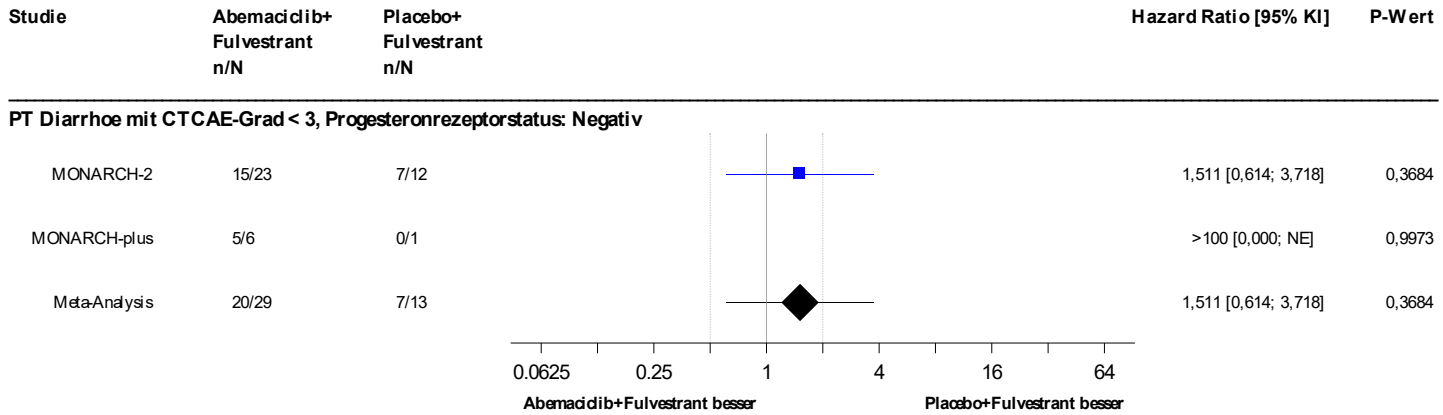

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Abbildung 1434.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

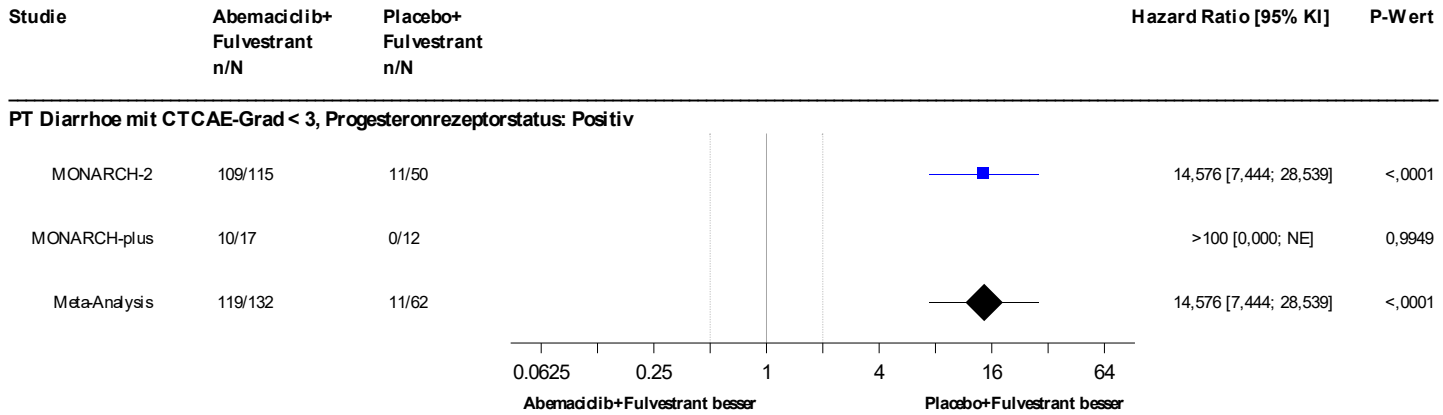

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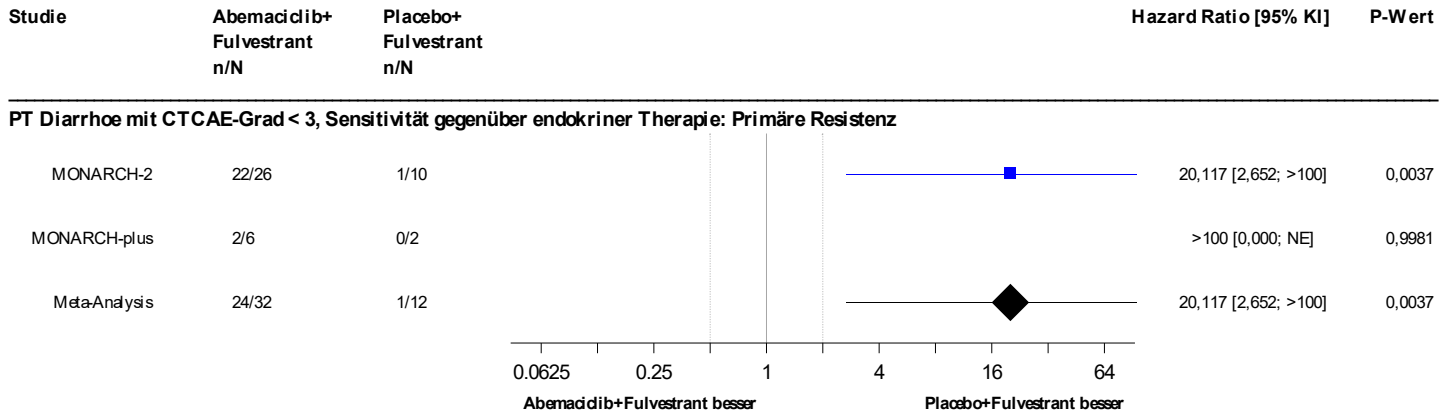
Abbildung 1434.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9984, I2 Index=0%
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Abbildung 1434.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

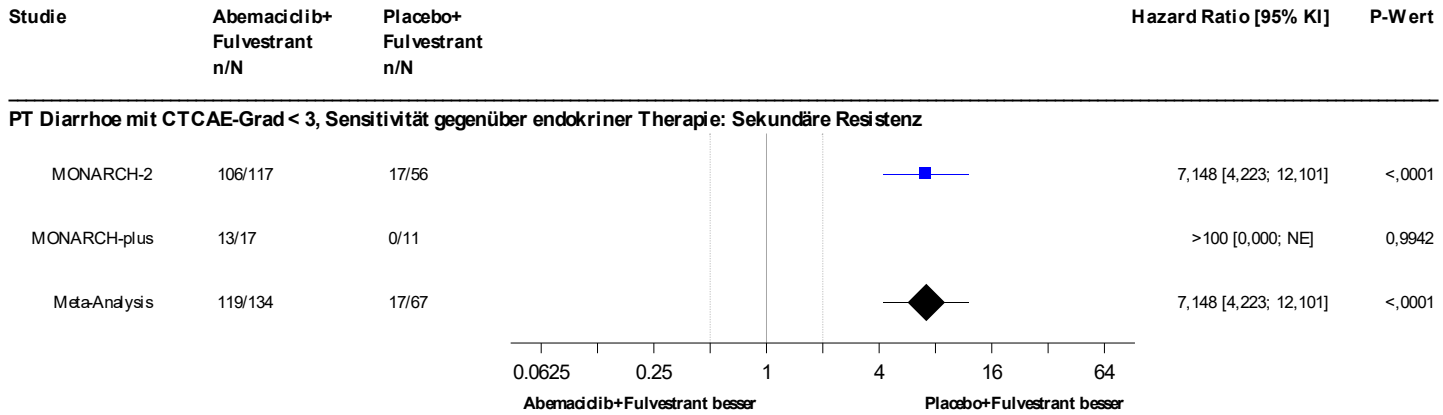

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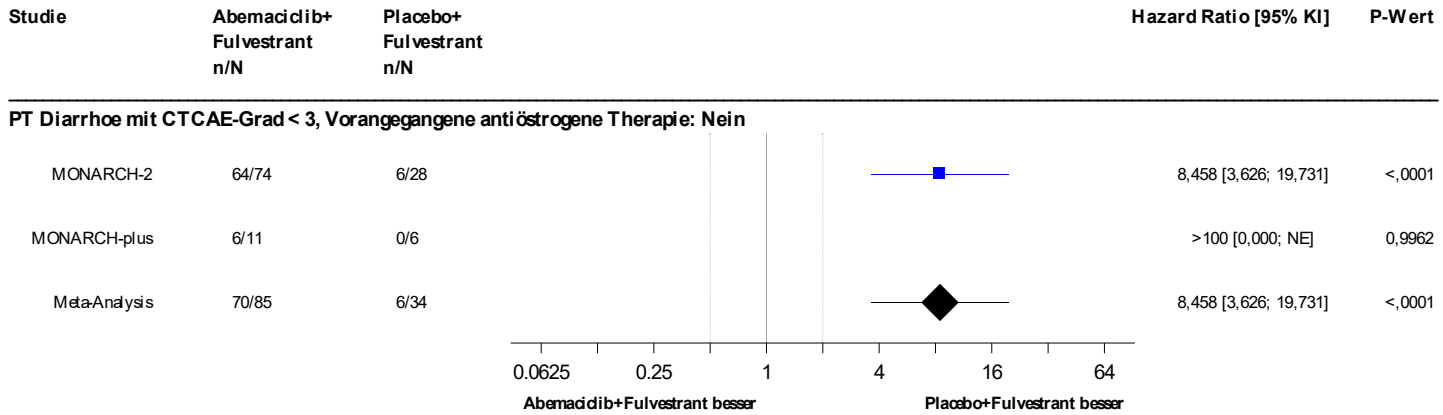
Abbildung 1434.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9966, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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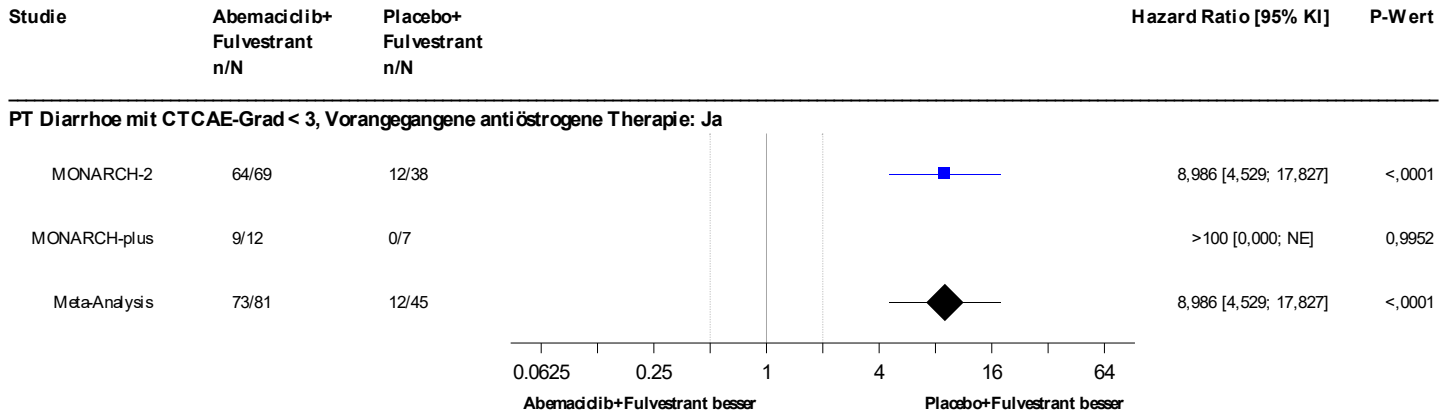
Abbildung 1434.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Diarrhoe aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9958, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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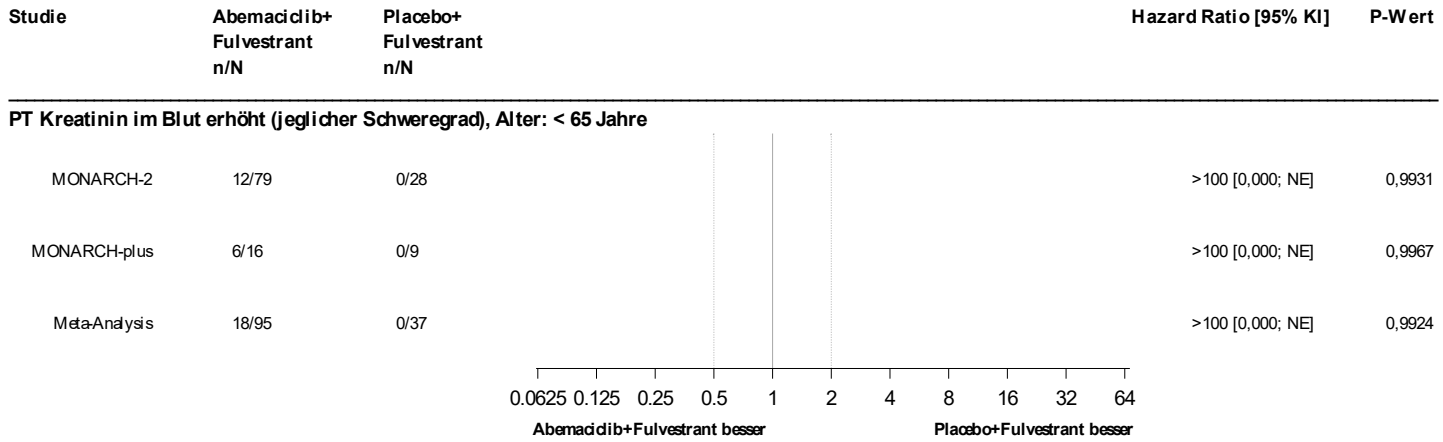
Abbildung 1436.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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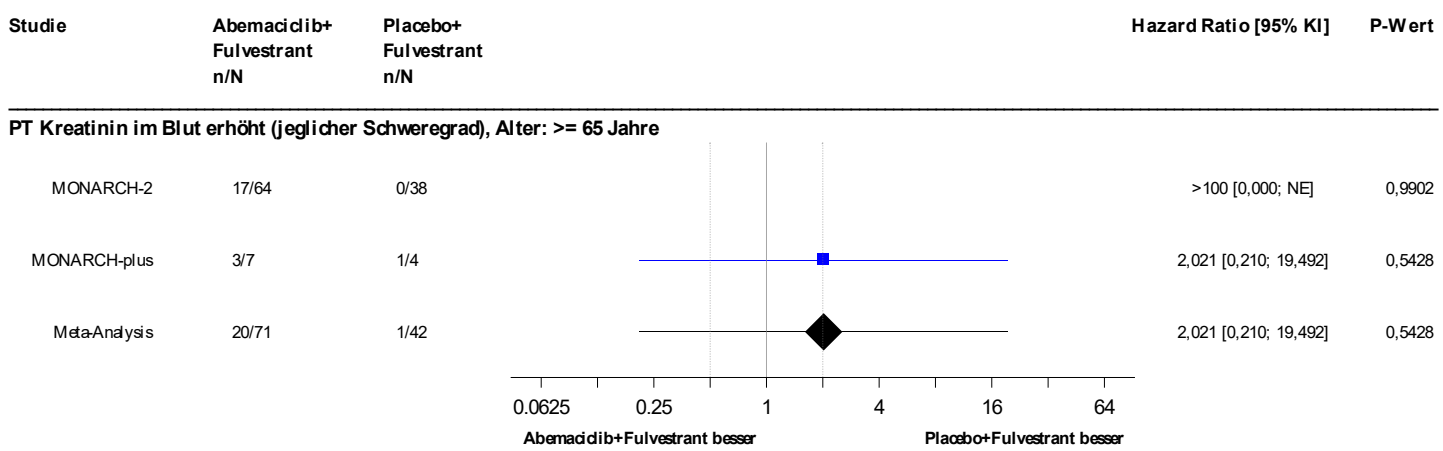
Abbildung 1436.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9906, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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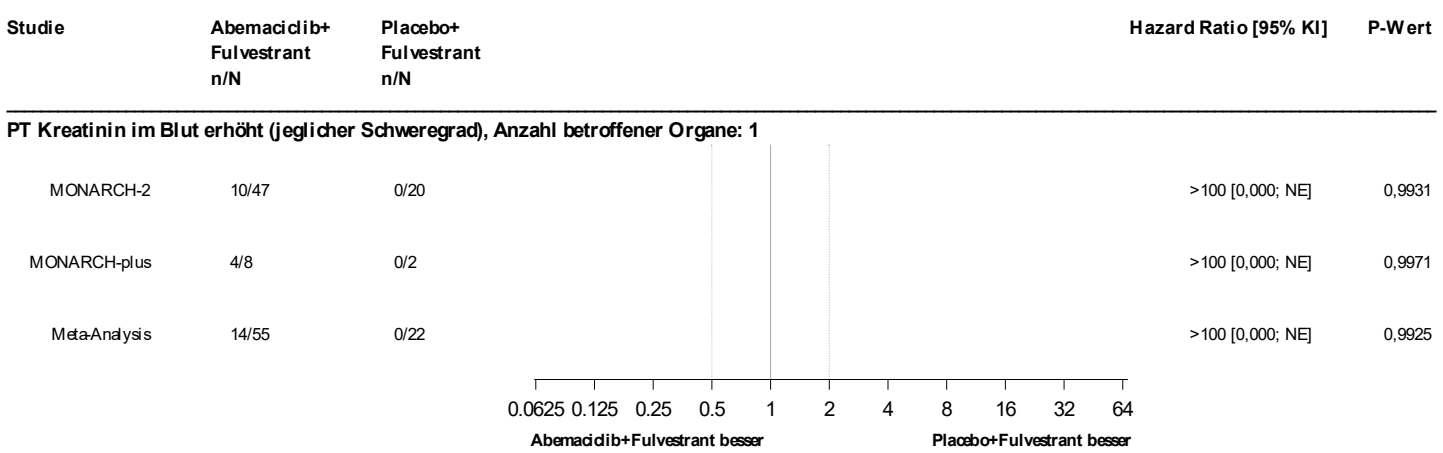
Abbildung 1436.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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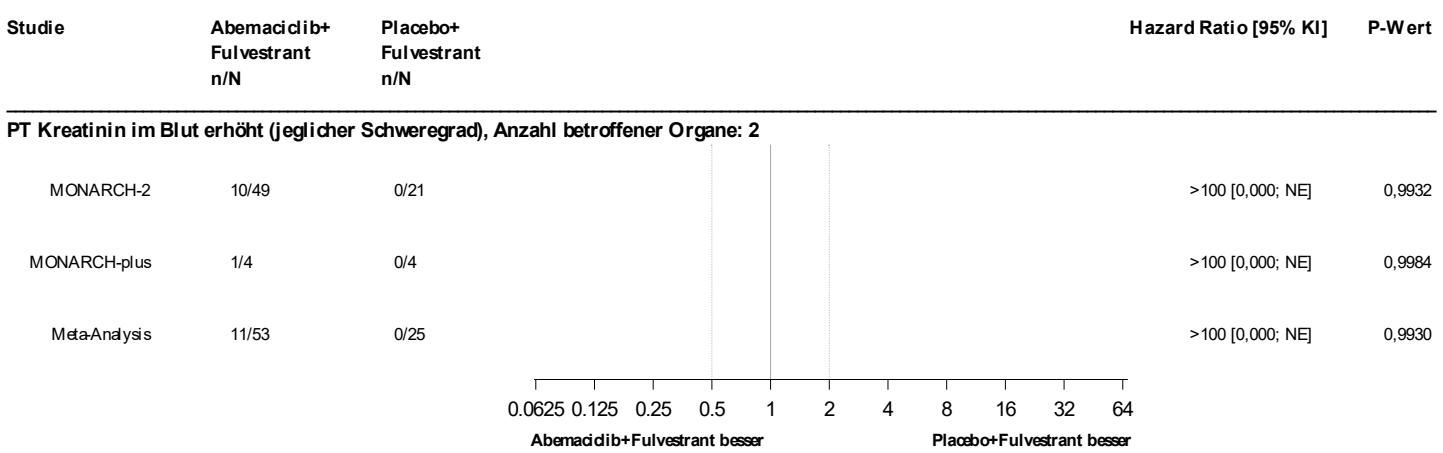
Abbildung 1436.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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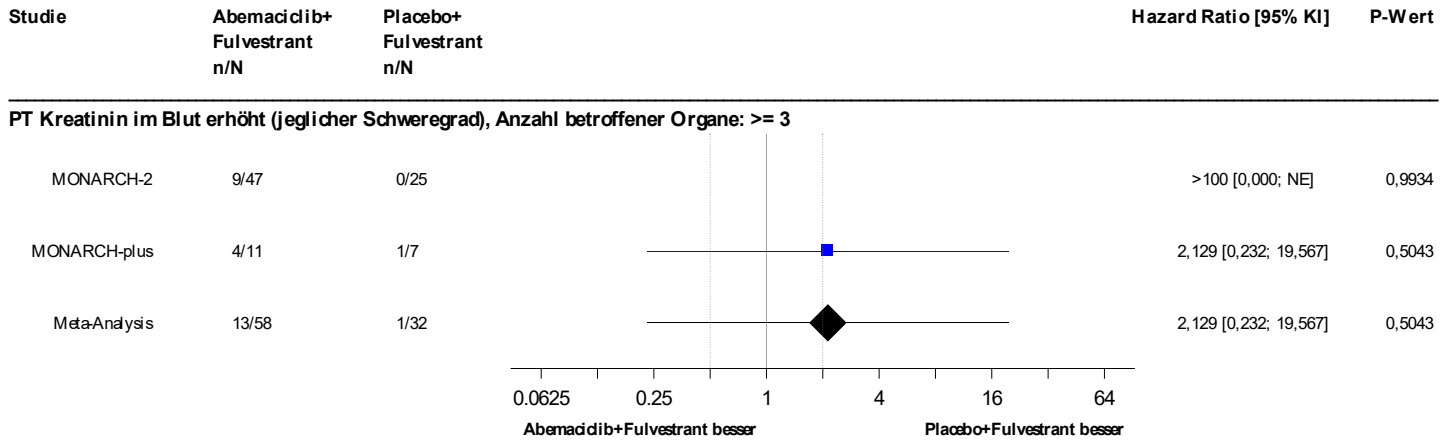
Abbildung 1436.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9937, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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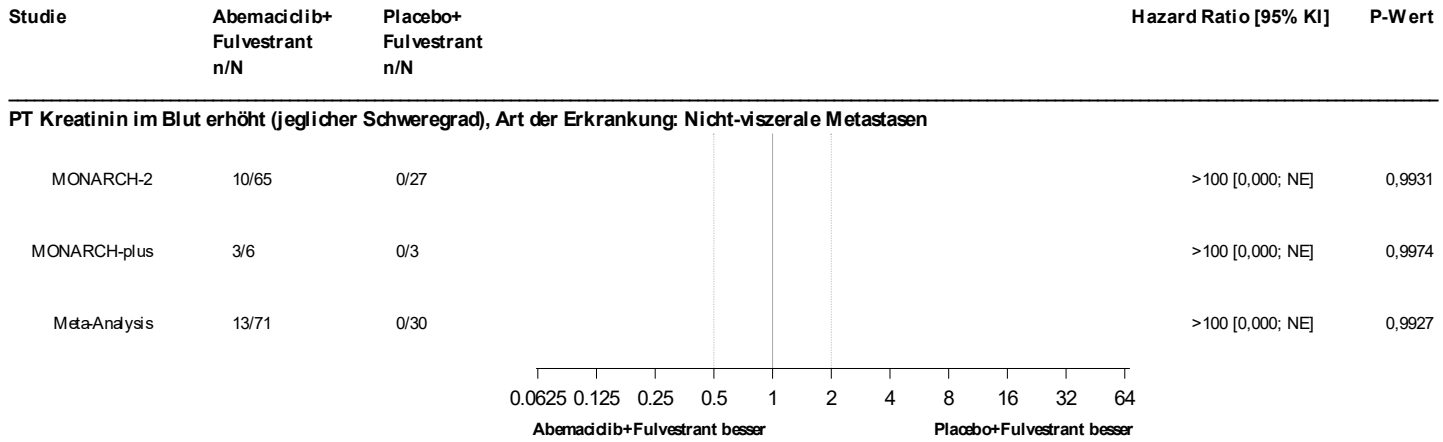
Abbildung 1436.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9998, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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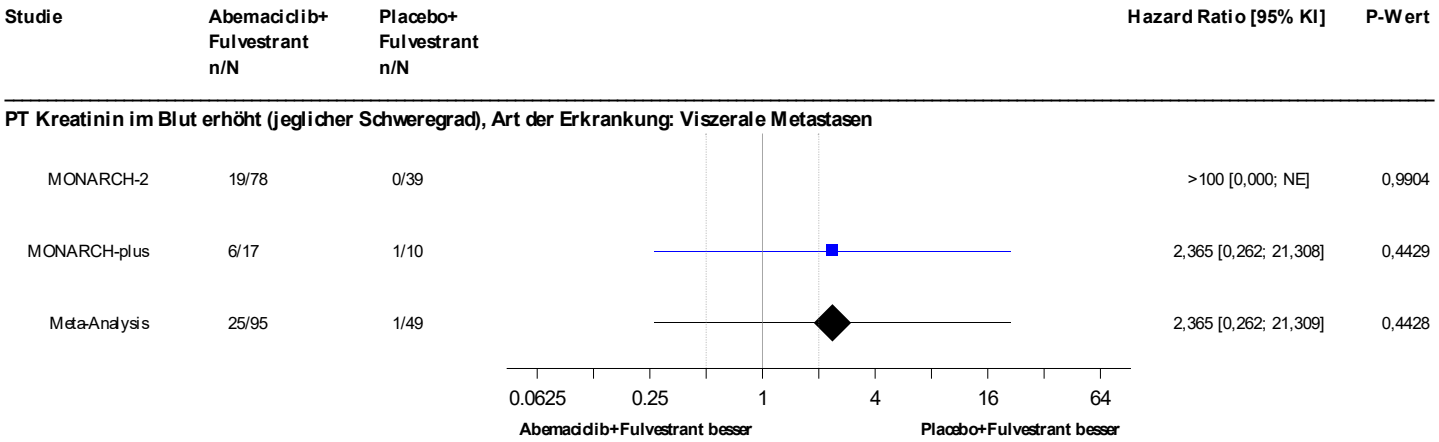
Abbildung 1436.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9909, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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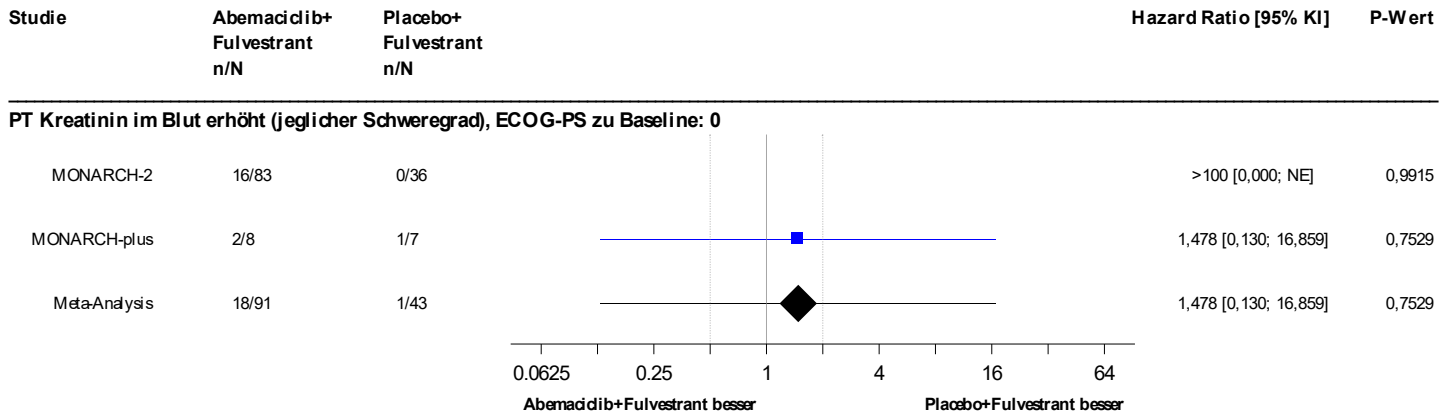
Abbildung 1436.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9917, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttcraesi_popa2_ecogbl_1.rtf
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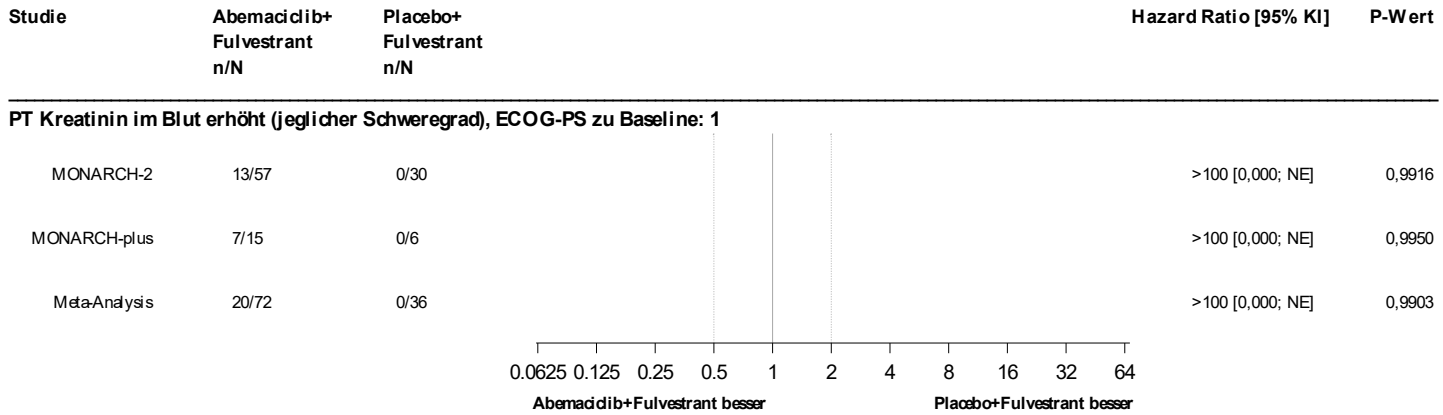
17SEP2021 / 07:48

Abbildung 1436.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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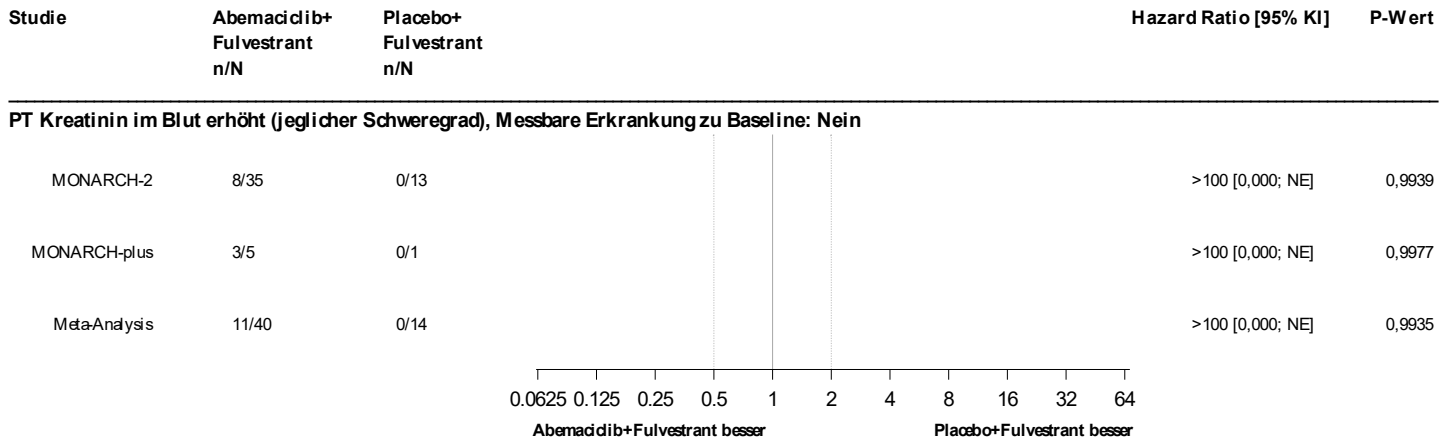
Abbildung 1436.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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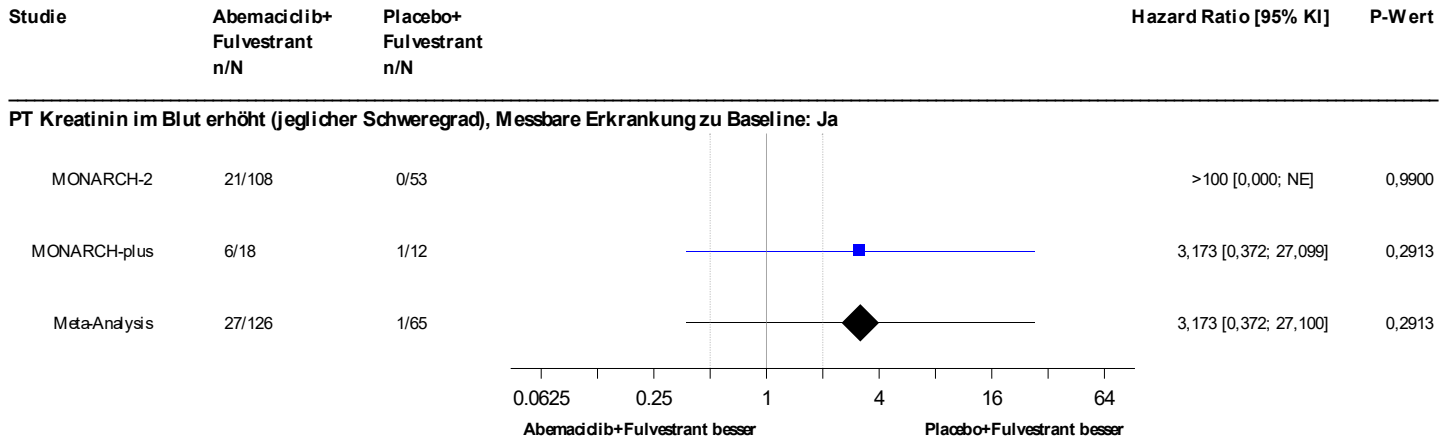
17SEP2021 / 07:48

Abbildung 1436.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9907, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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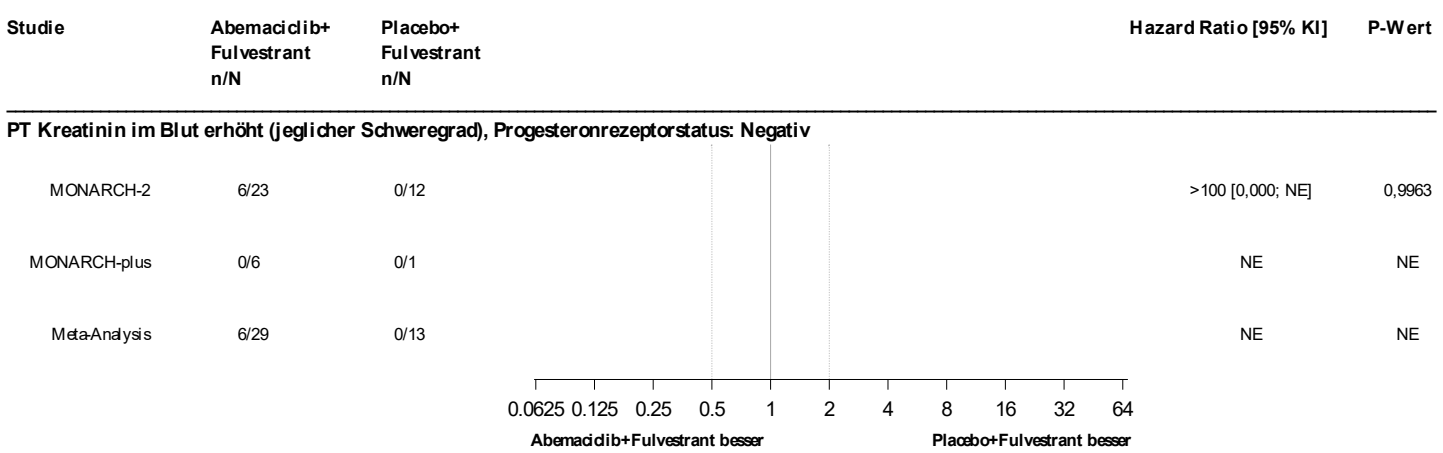
17SEP2021 / 07:48

Abbildung 1436.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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17SEP2021 / 07:48

Abbildung 1436.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

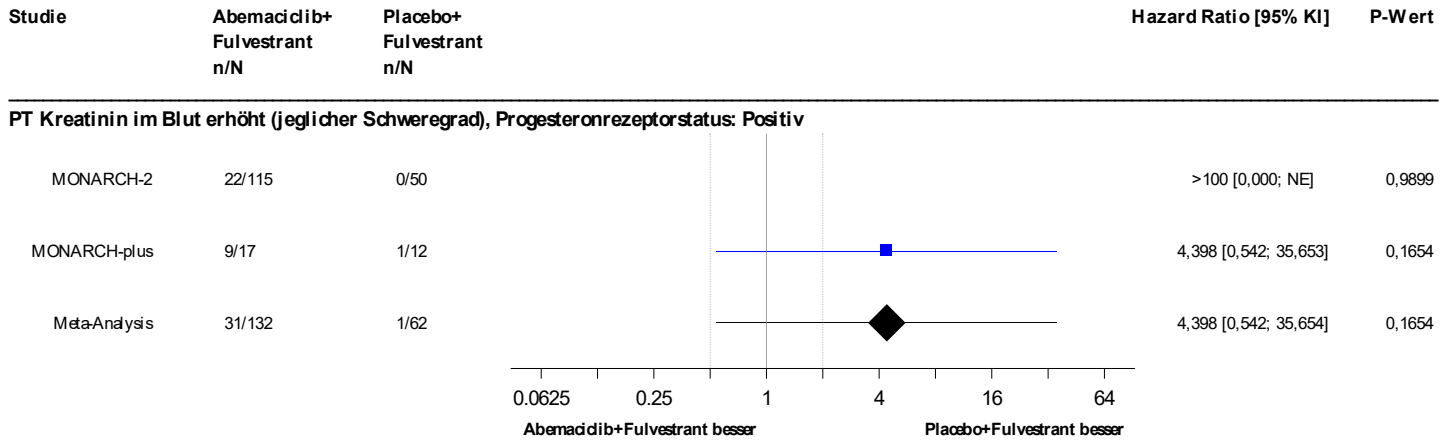

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Abbildung 1436.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

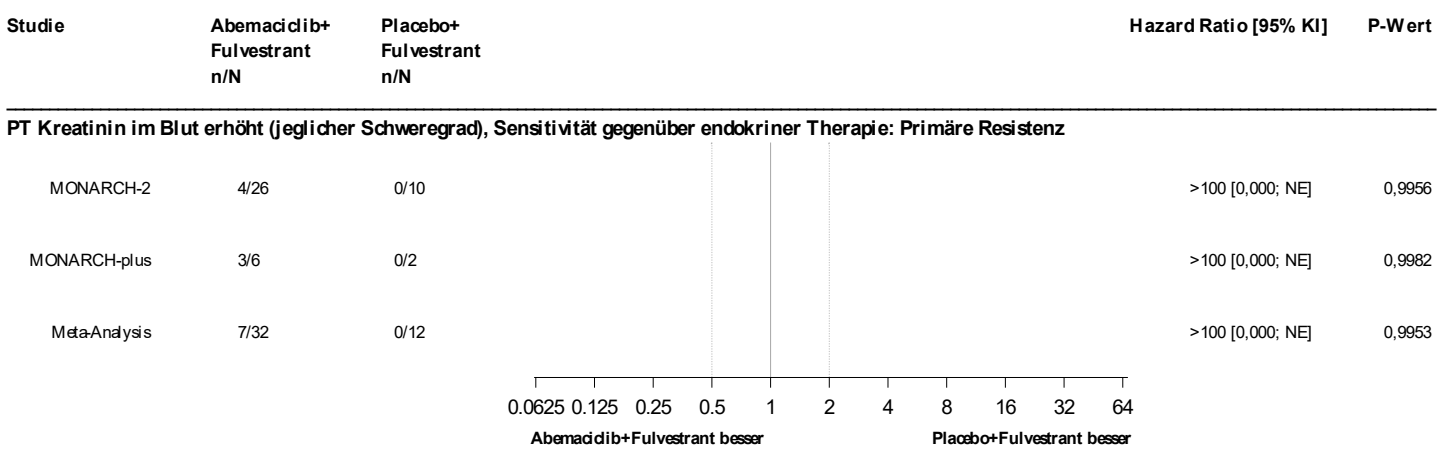

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Abbildung 1436.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

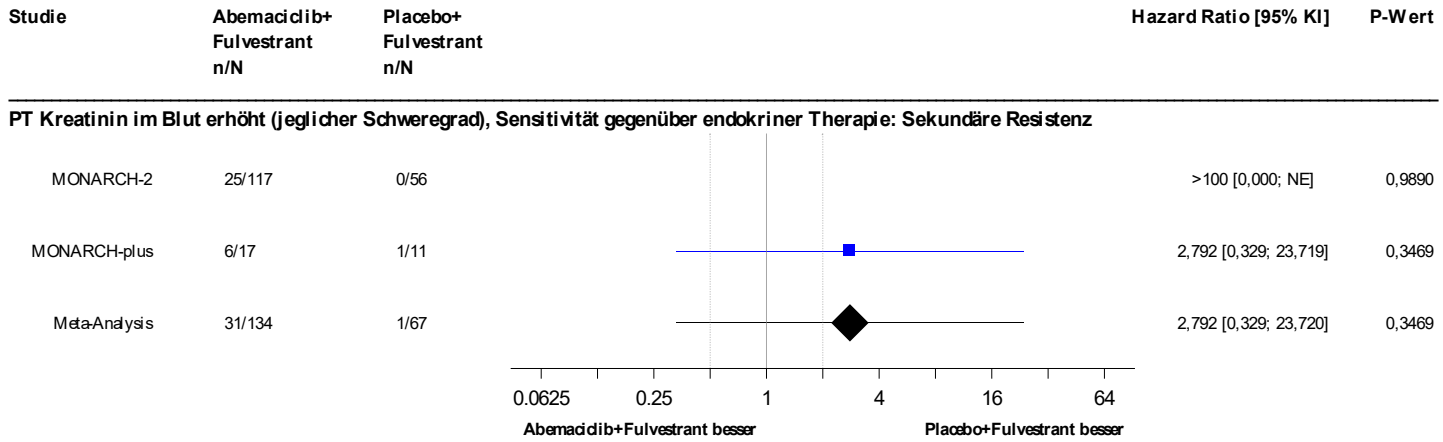

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Abbildung 1436.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

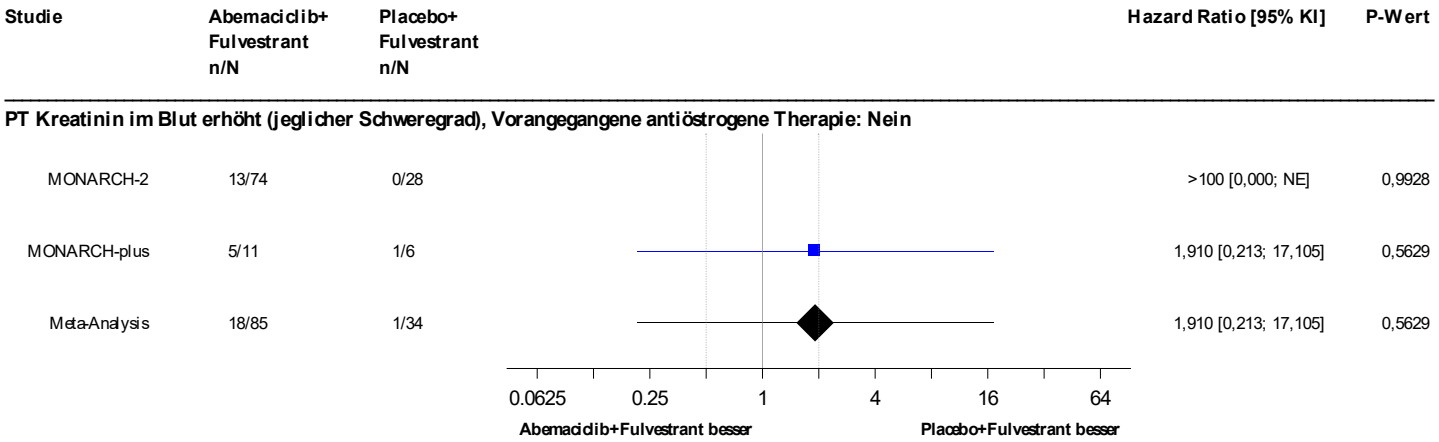

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Abbildung 1436.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Kreatinin im Blut erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

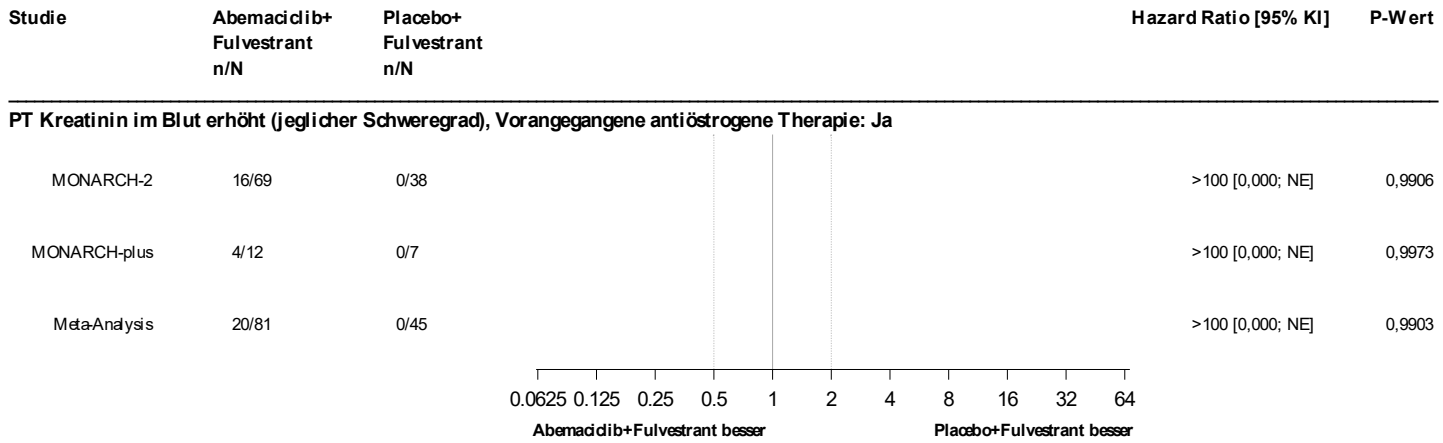

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Abbildung 1438.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

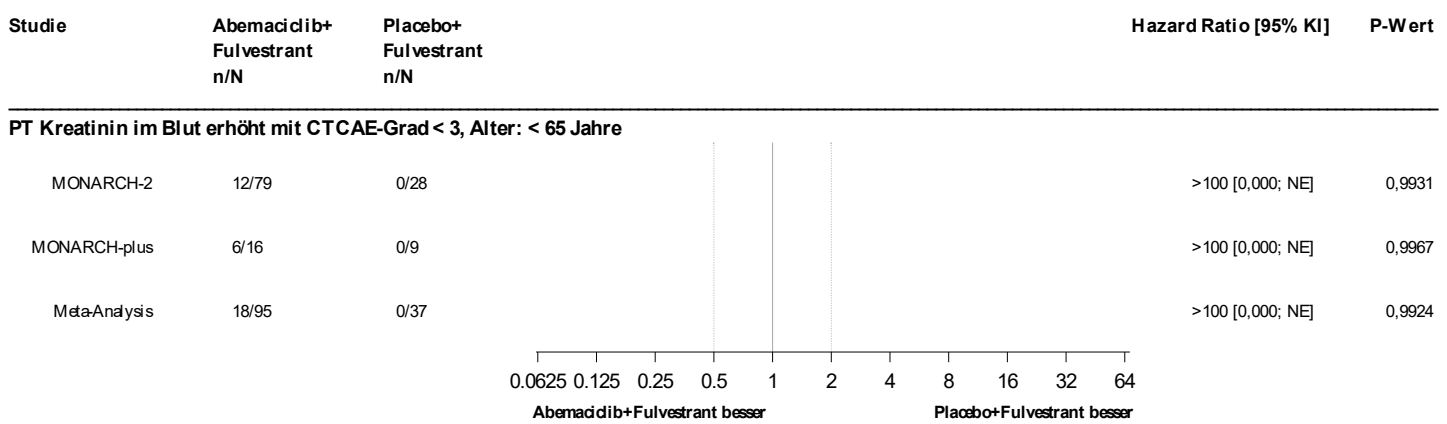

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Abbildung 1438.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

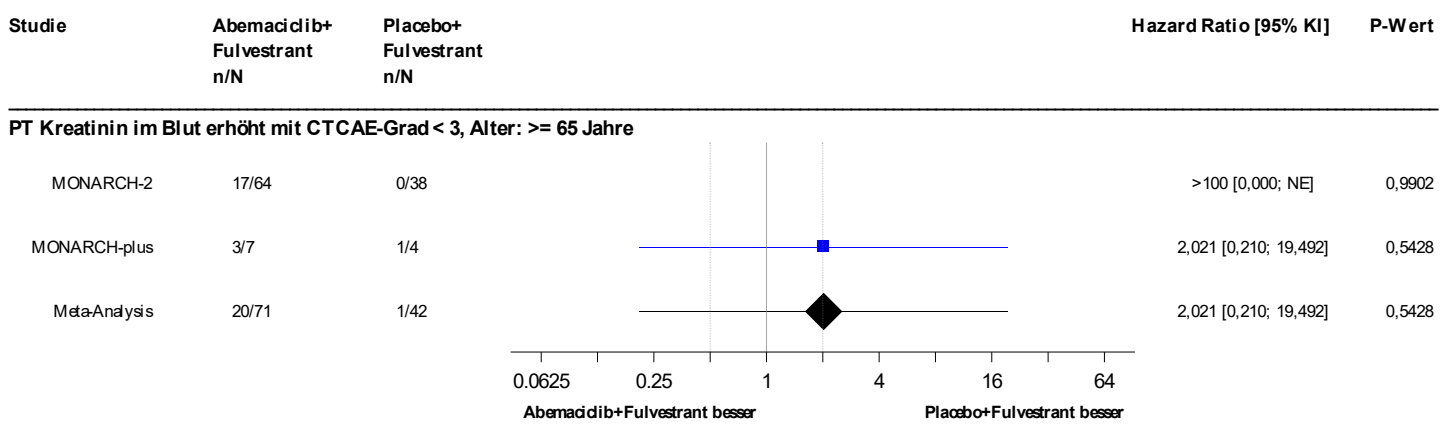

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Abbildung 1438.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

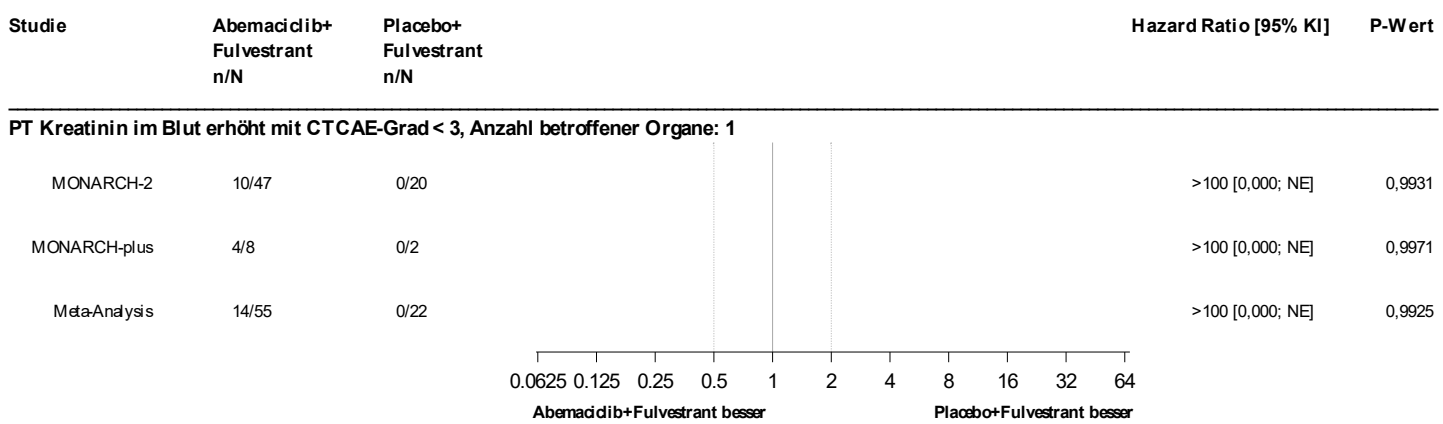

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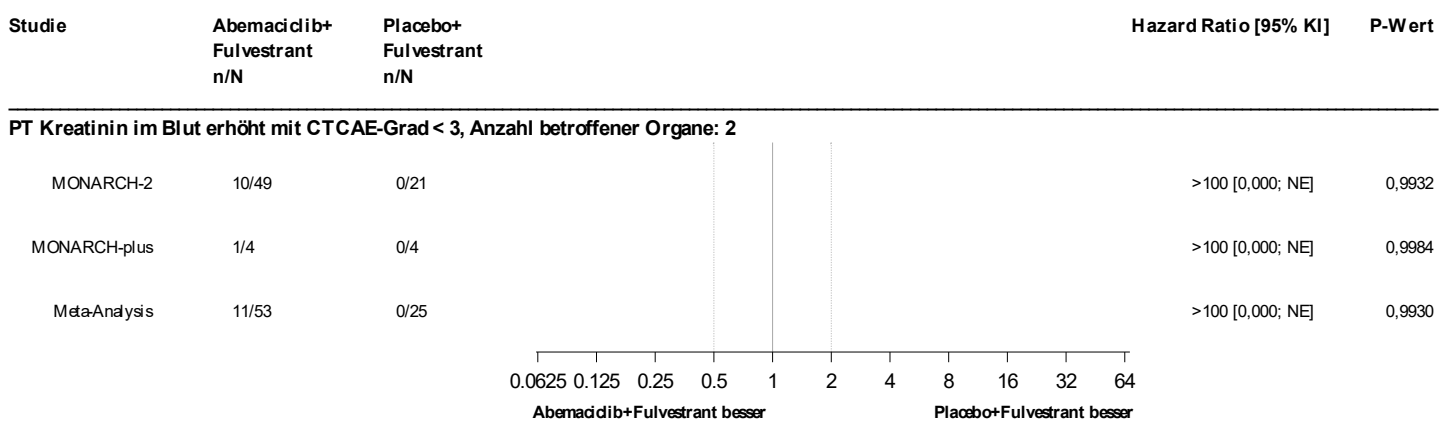
Abbildung 1438.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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17SEP2021 / 07:48

Abbildung 1438.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

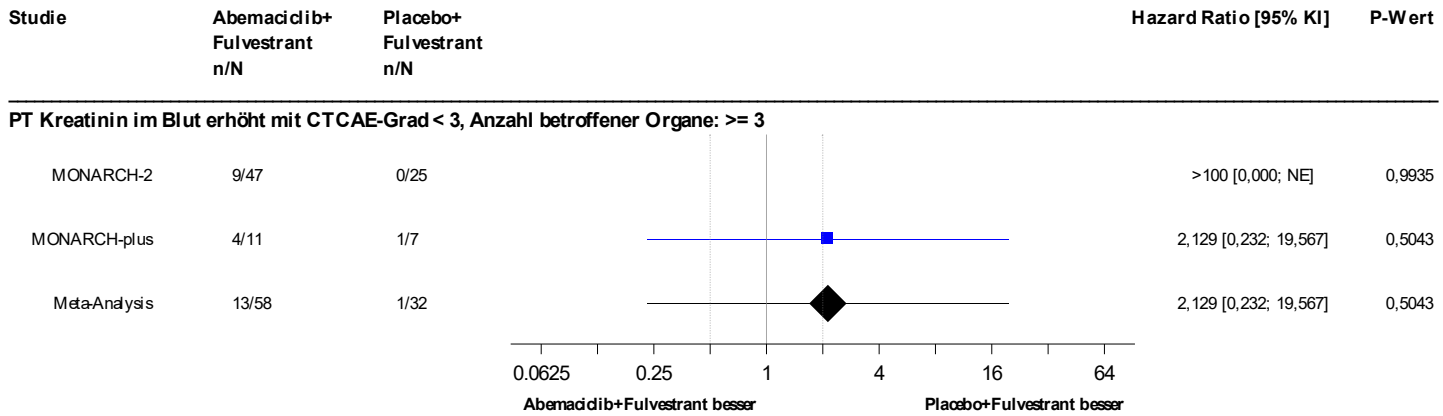

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Abbildung 1438.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

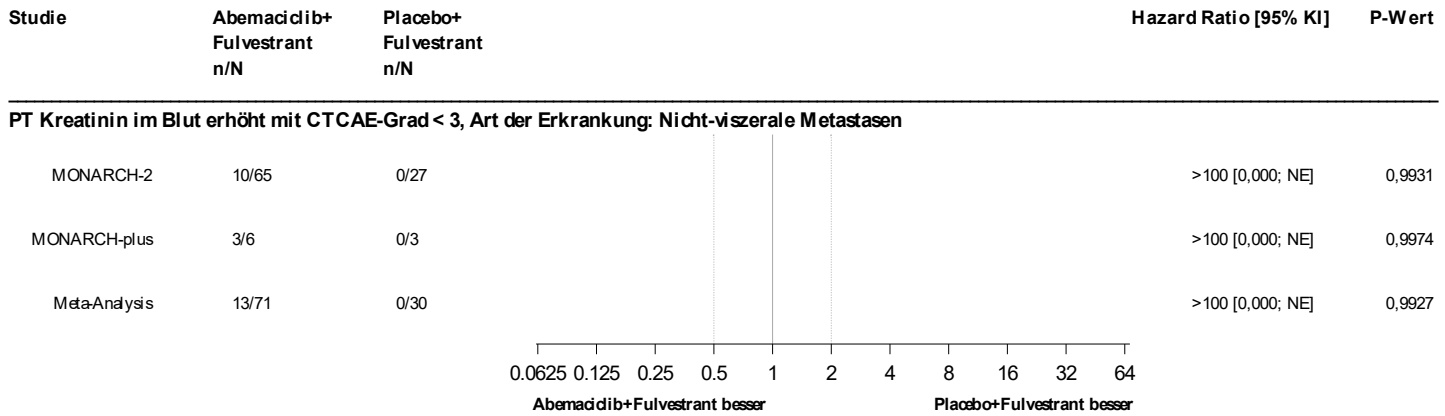

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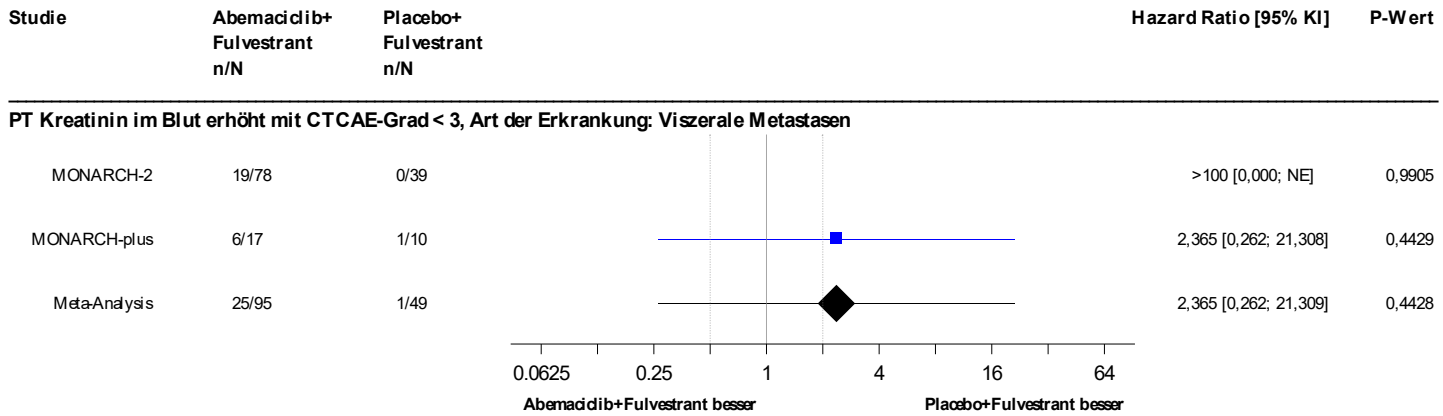
Abbildung 1438.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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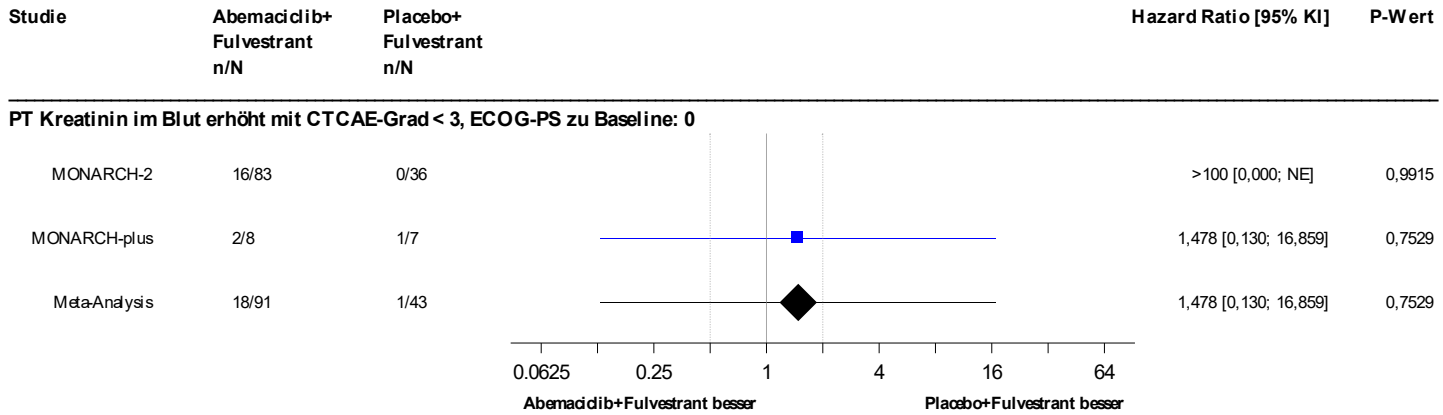
Abbildung 1438.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9917, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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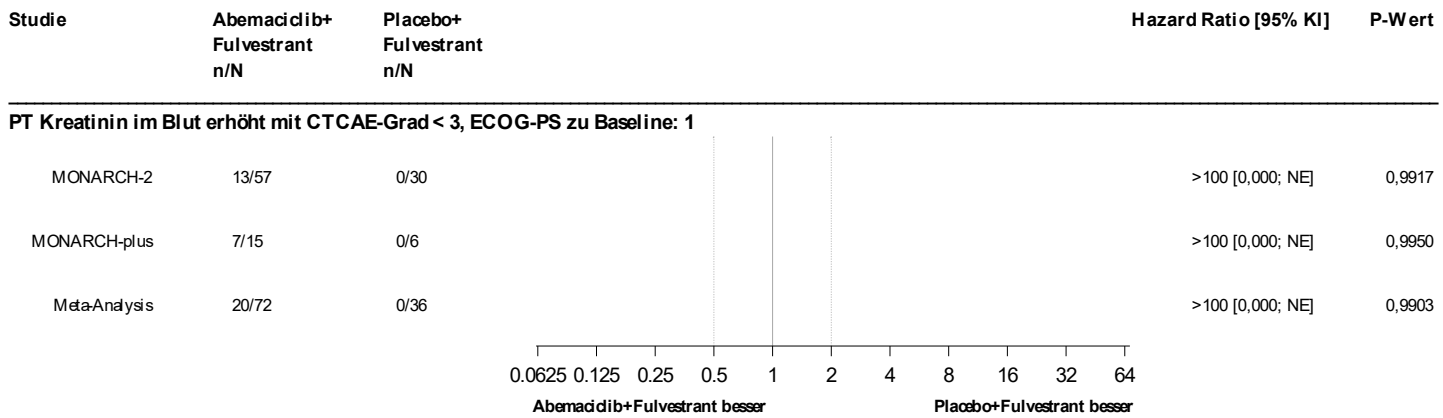
Abbildung 1438.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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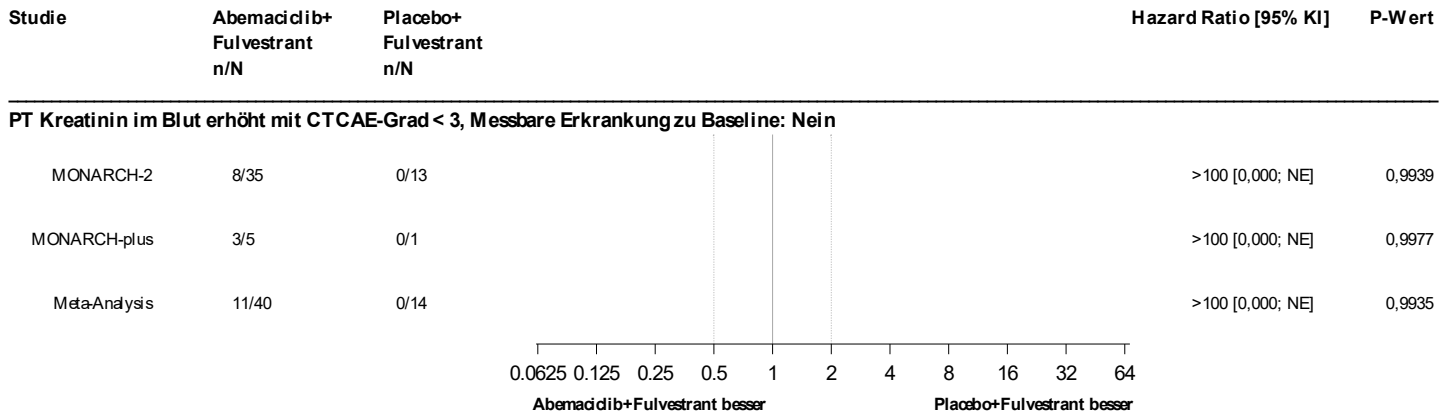
Abbildung 1438.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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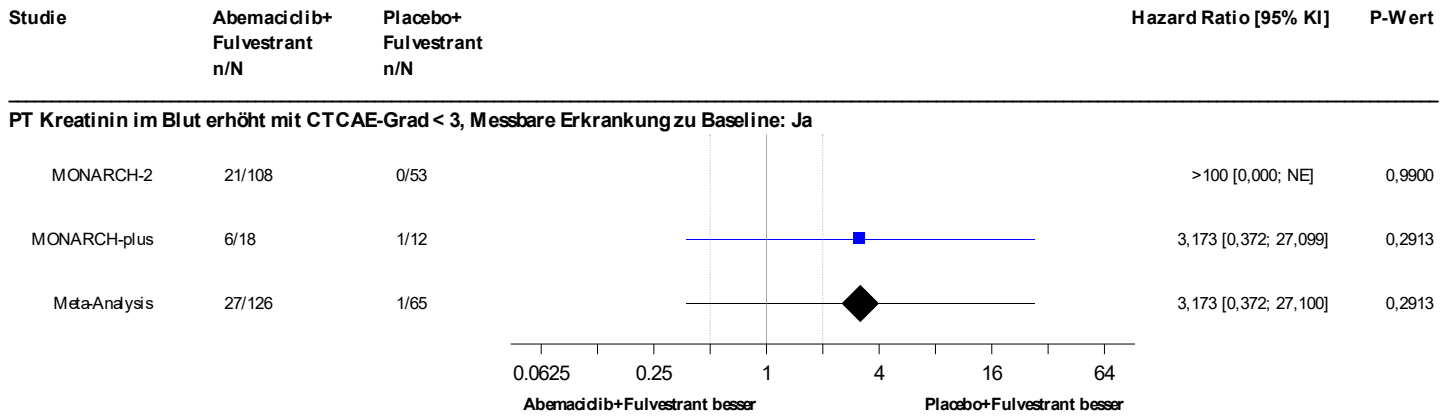
Abbildung 1438.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9907, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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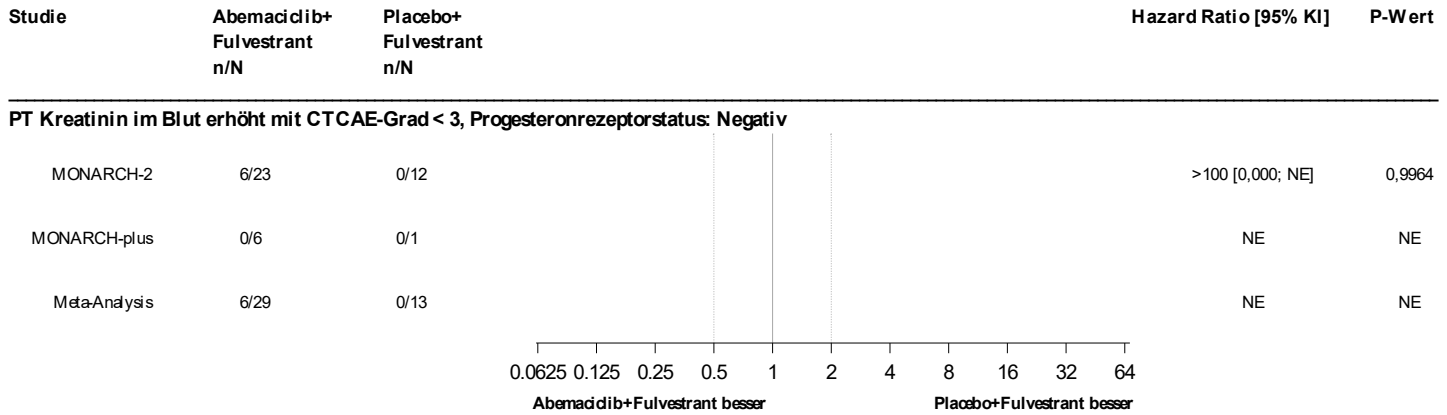
Abbildung 1438.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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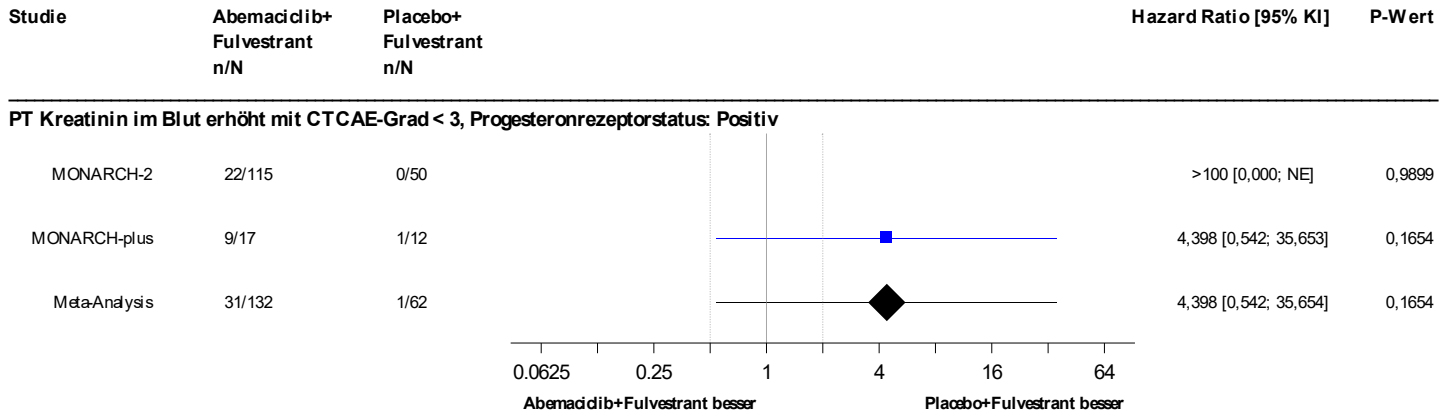
Abbildung 1438.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



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Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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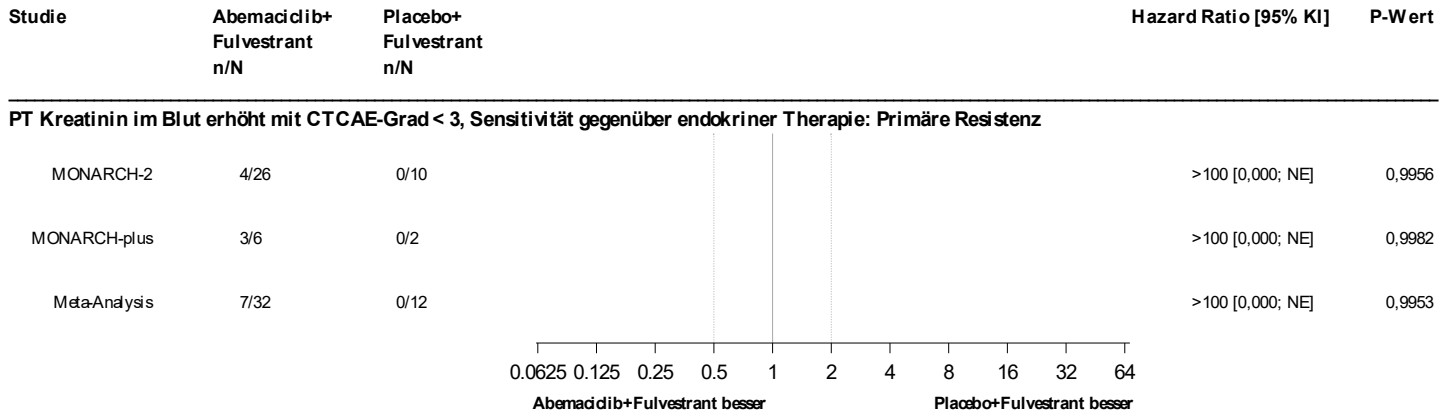
Abbildung 1438.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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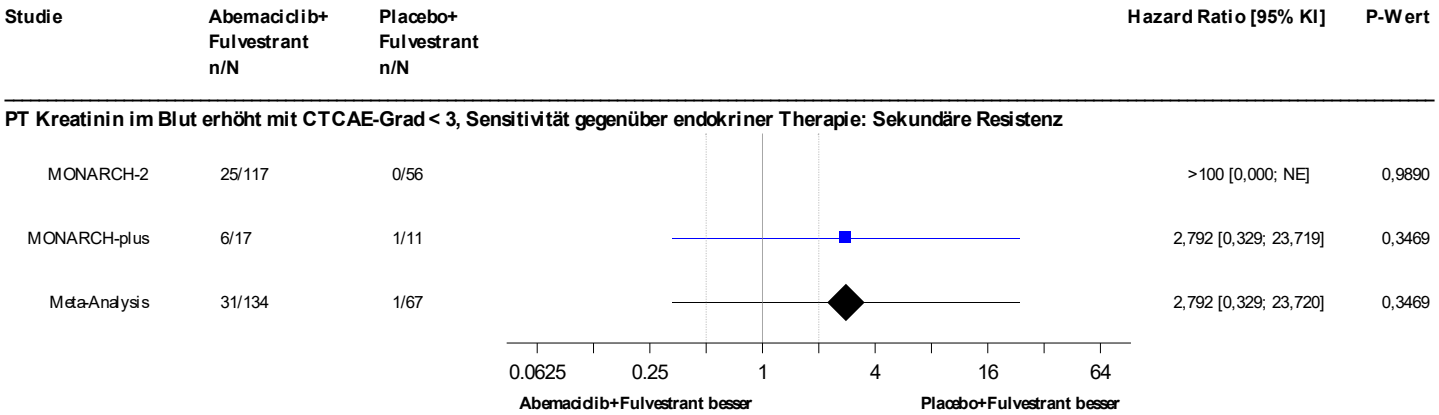
Abbildung 1438.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0002, P-Wert=0,9897, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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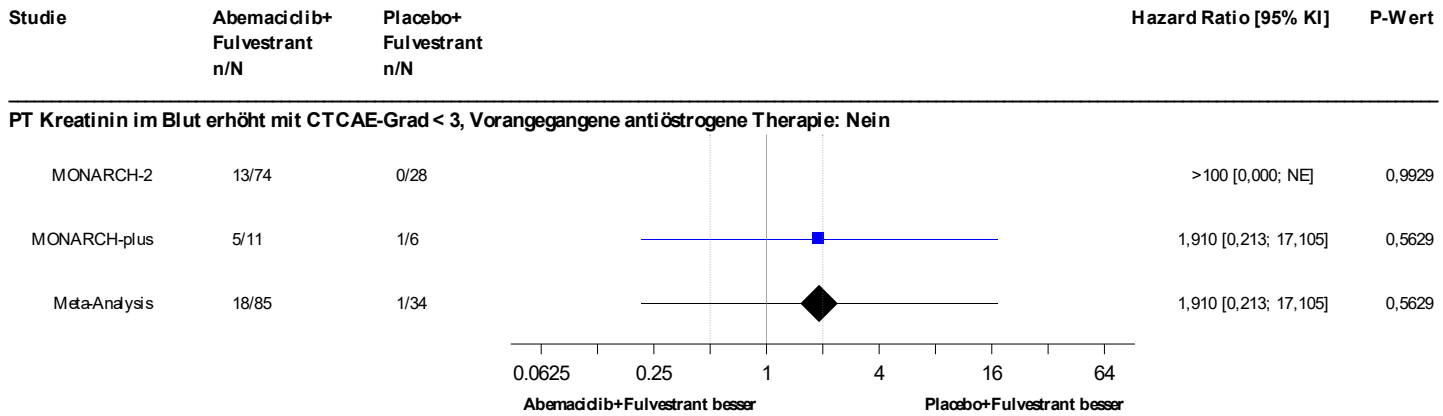
Abbildung 1438.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0001, P-Wert=0,9932, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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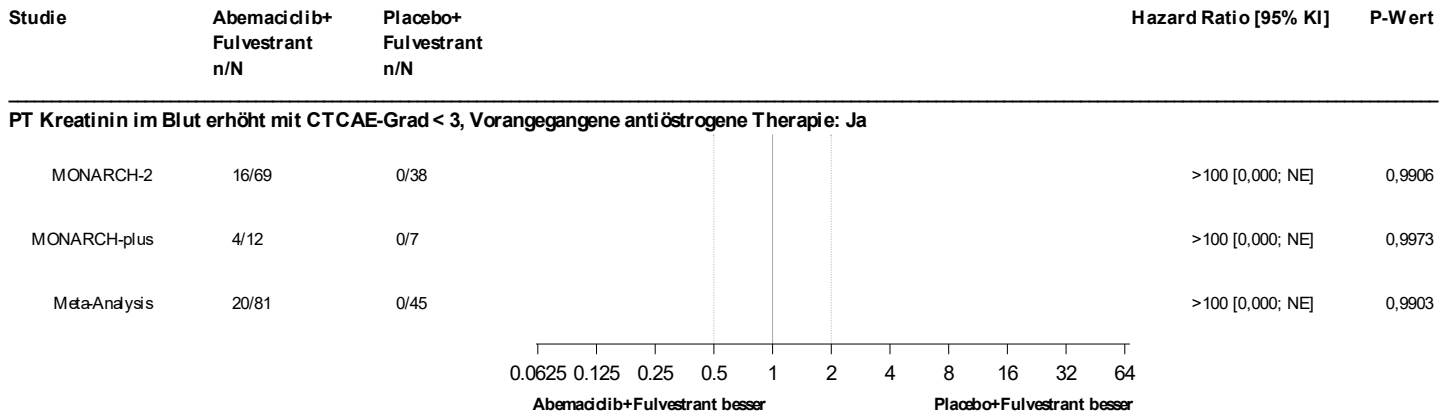
Abbildung 1438.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Kreatinin im Blut erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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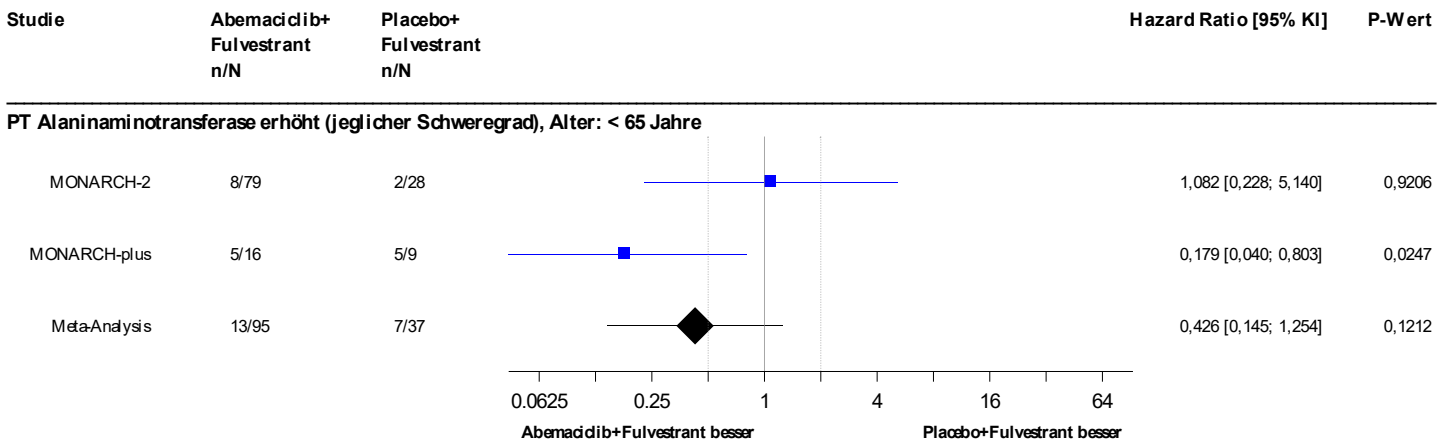
Abbildung 1440.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=2,6563, P-Wert=0,1031, I2 Index=62,4%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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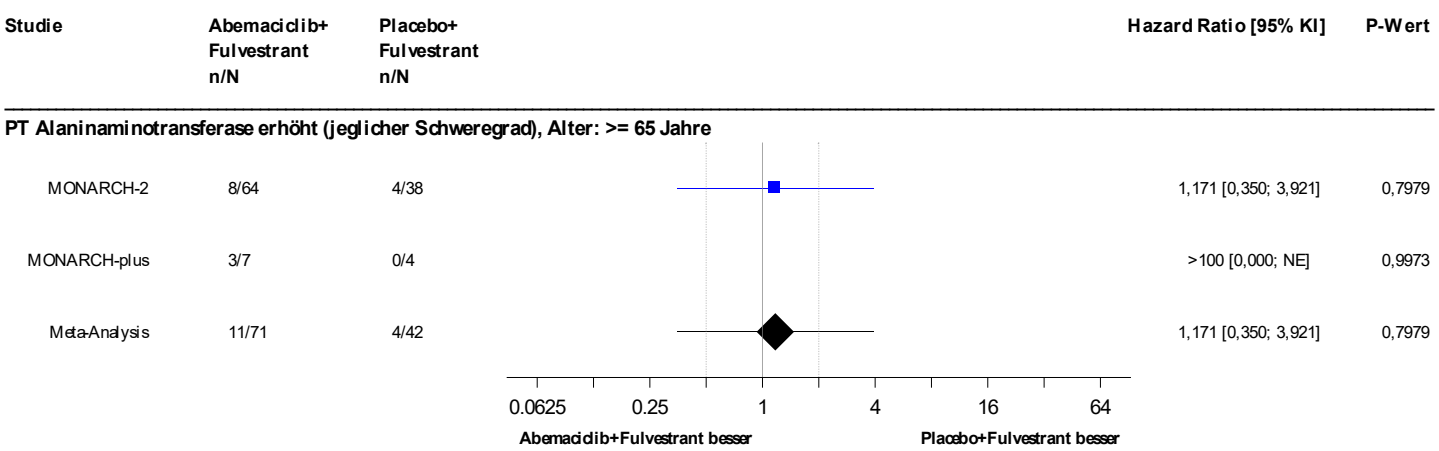
Abbildung 1440.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9973, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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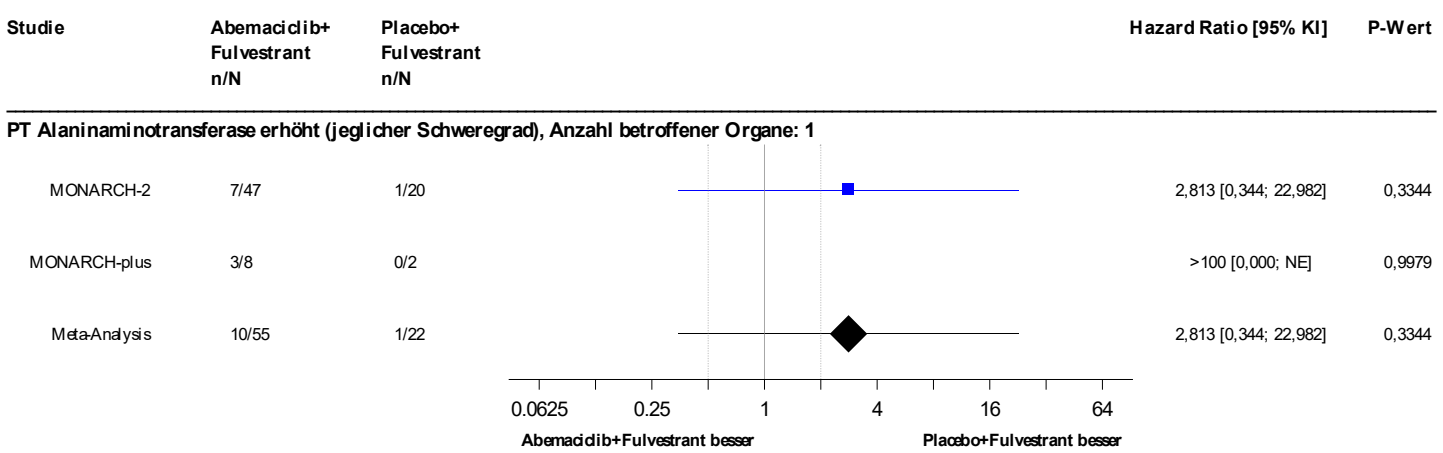
Abbildung 1440.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9981, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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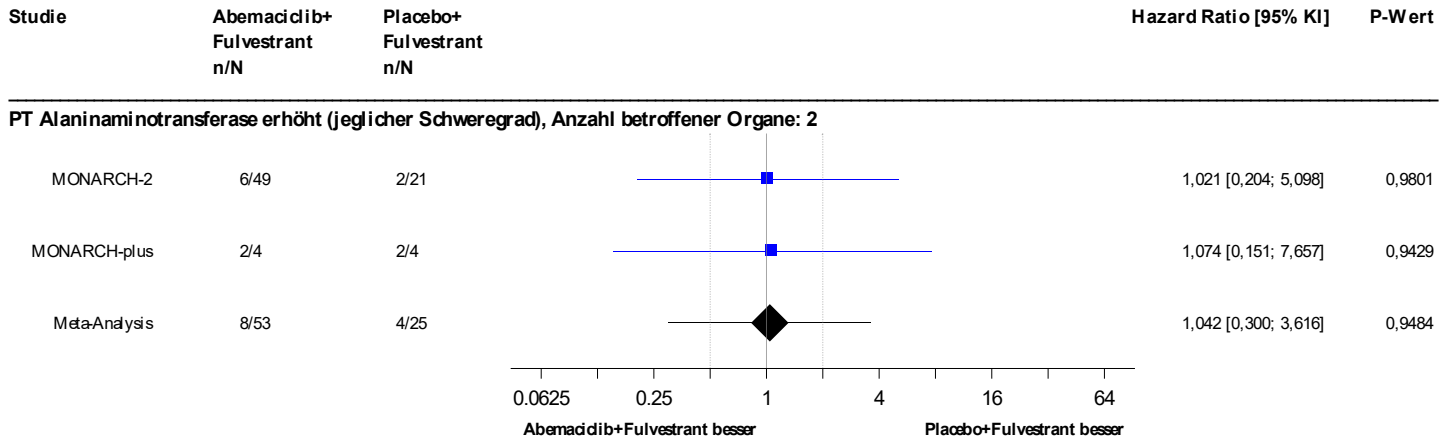
Abbildung 1440.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0016, P-Wert=0,9684, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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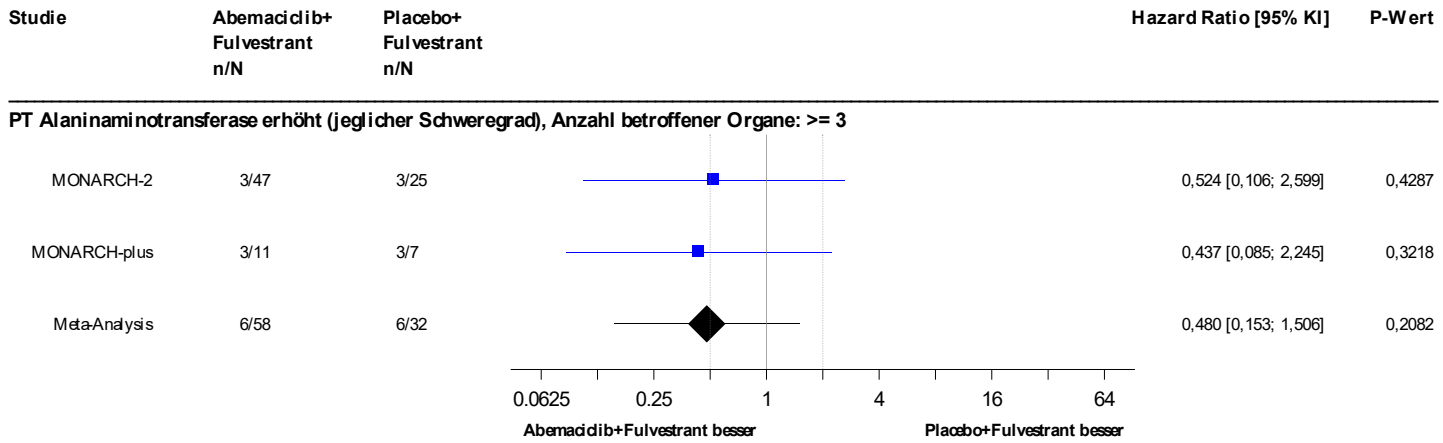
17SEP2021 / 07:48

Abbildung 1440.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0238, P-Wert=0,8774, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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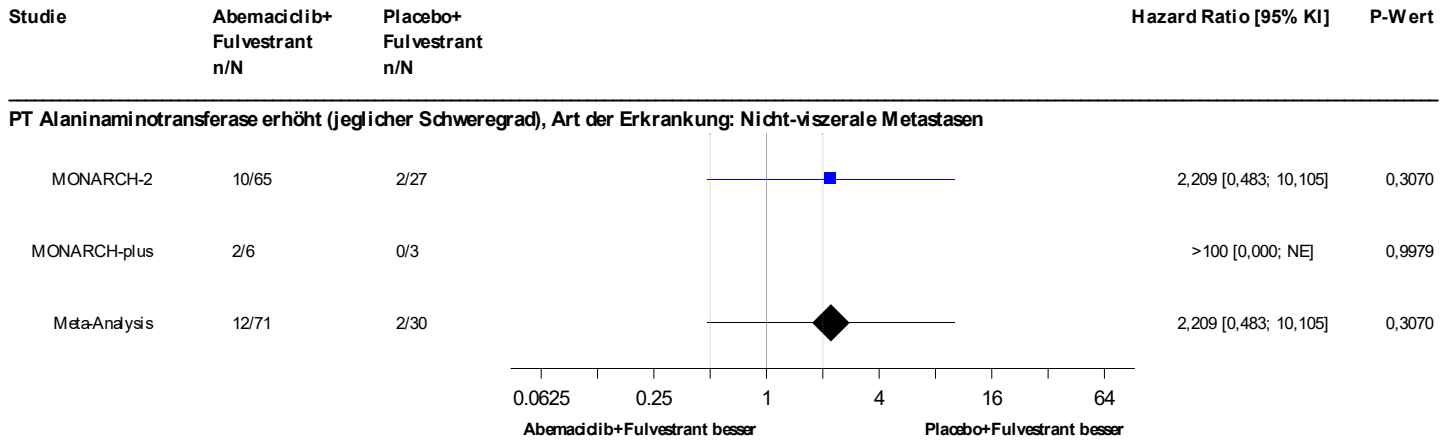
Abbildung 1440.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9980, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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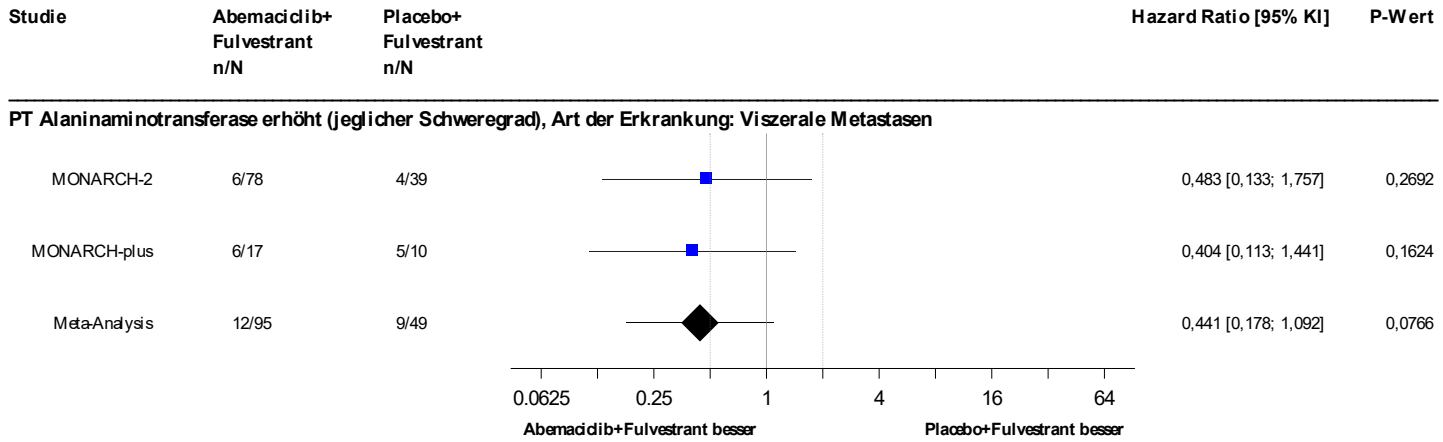
Abbildung 1440.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0372, P-Wert=0,8470, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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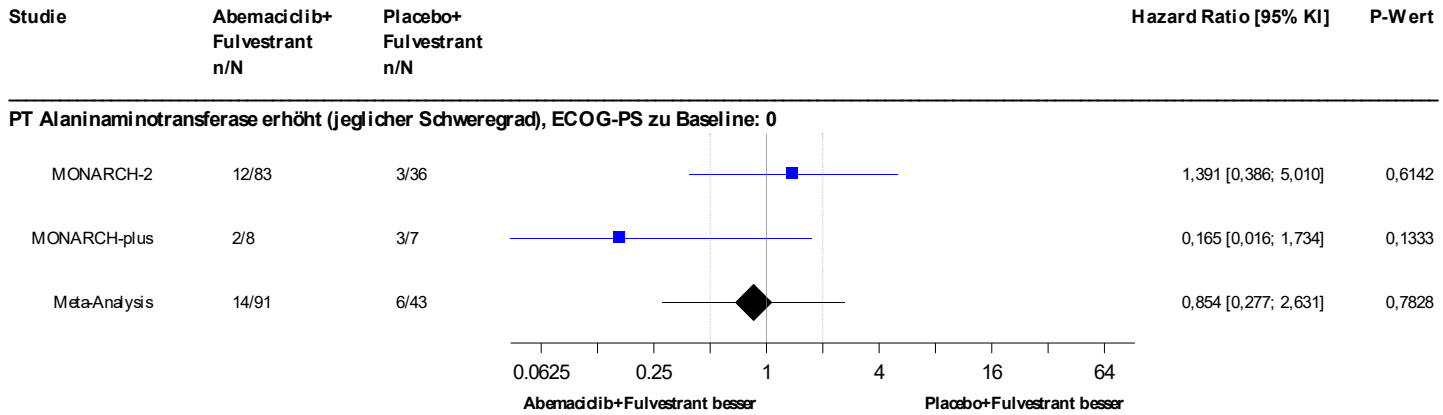
Abbildung 1440.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=2,4316, P-Wert=0,1189, I2 Index=58,9%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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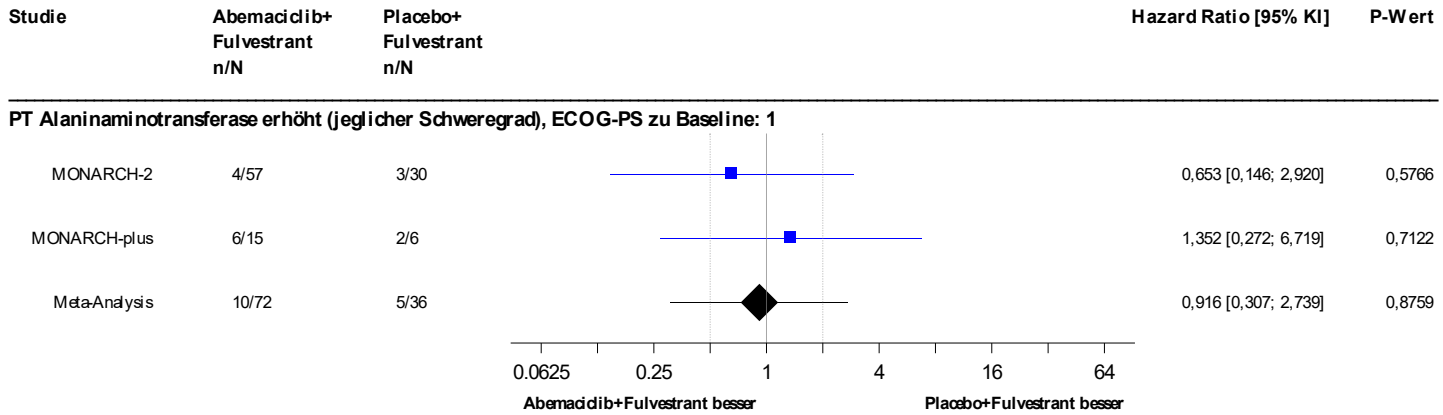
Abbildung 1440.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,4235, P-Wert=0,5152, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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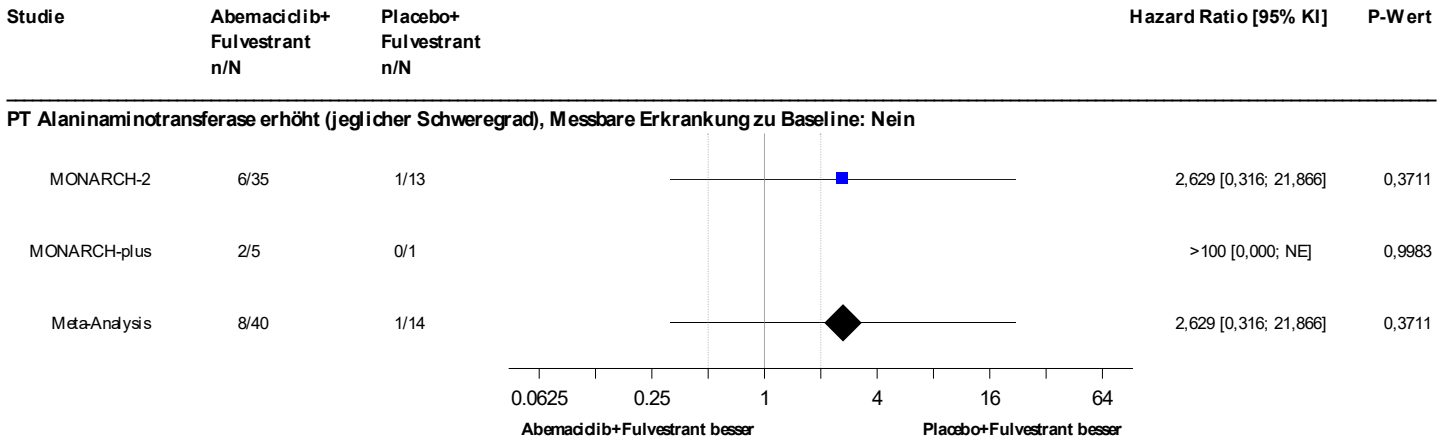
Abbildung 1440.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9984, I2 Index=0%
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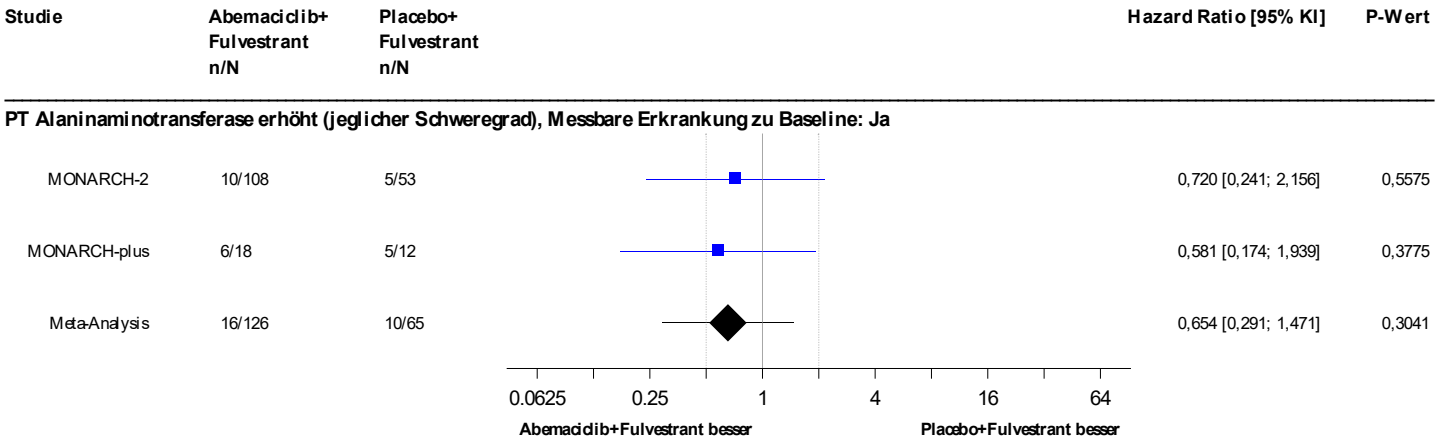
Abbildung 1440.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0666, P-Wert=0,7964, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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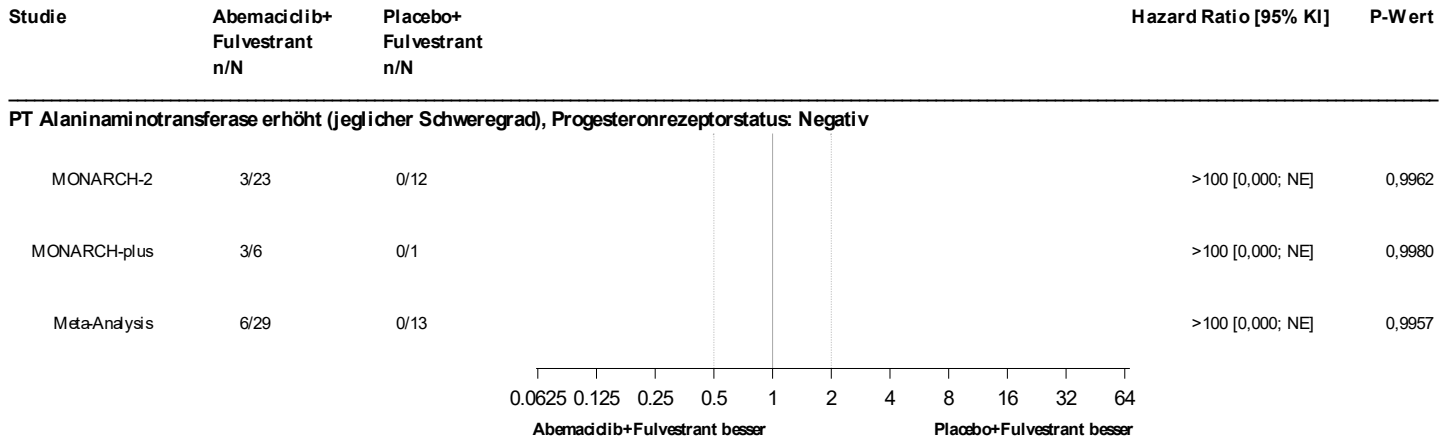
Abbildung 1440.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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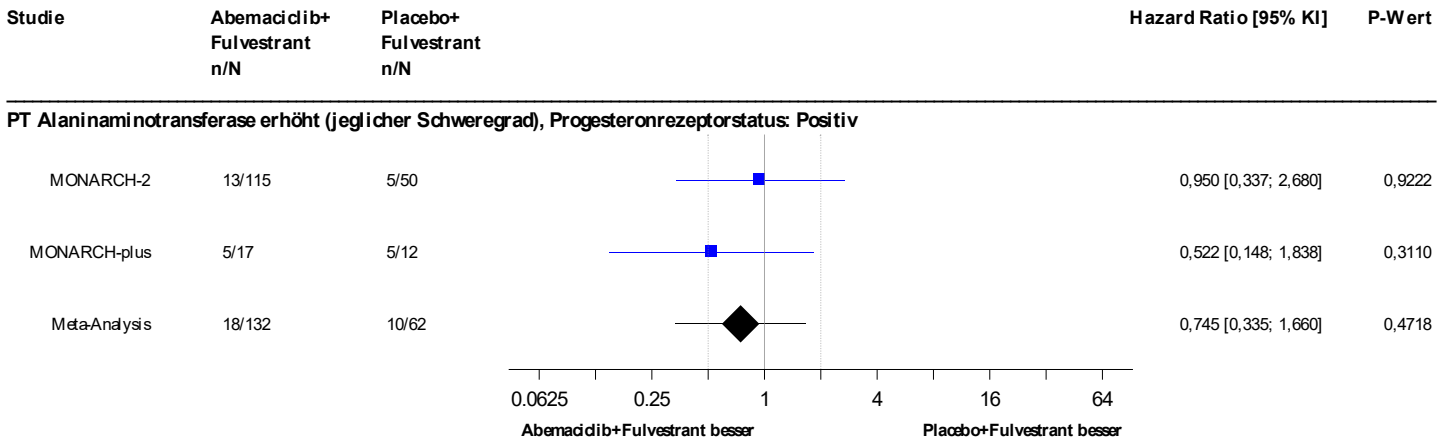
Abbildung 1440.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,5182, P-Wert=0,4716, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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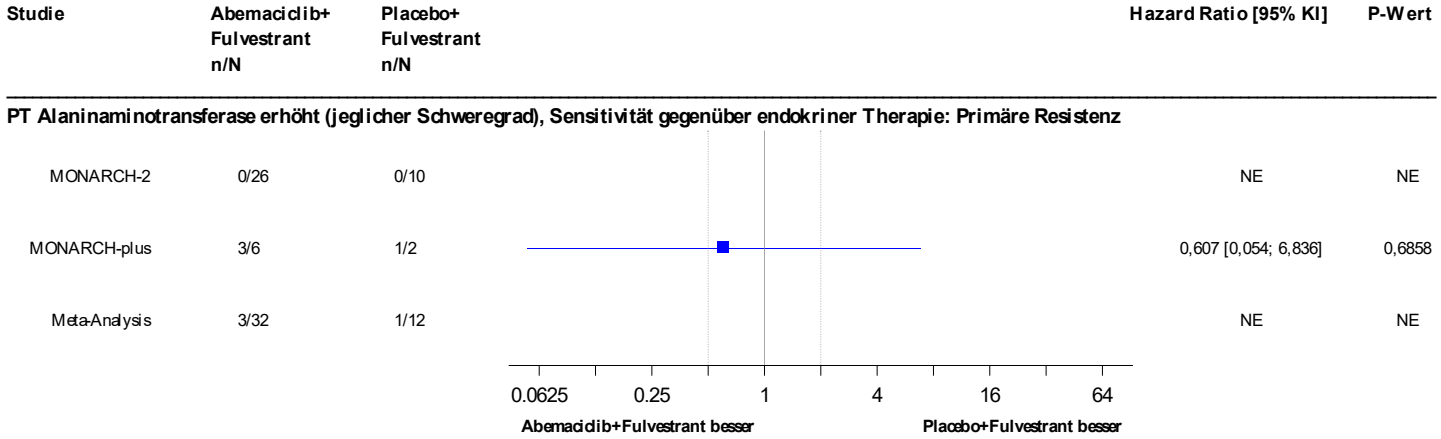
Abbildung 1440.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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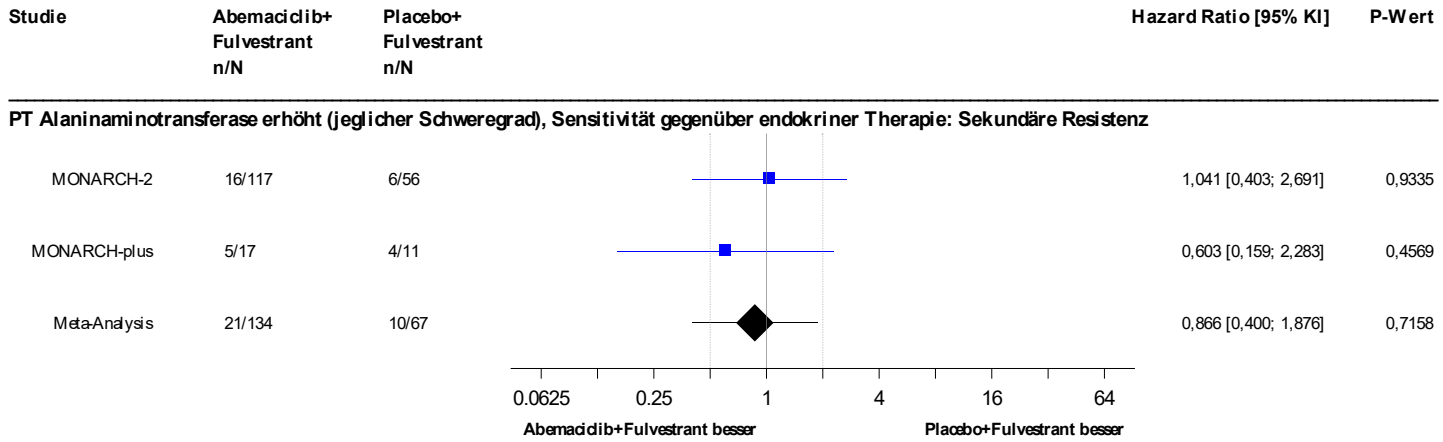
Abbildung 1440.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,4279, P-Wert=0,5130, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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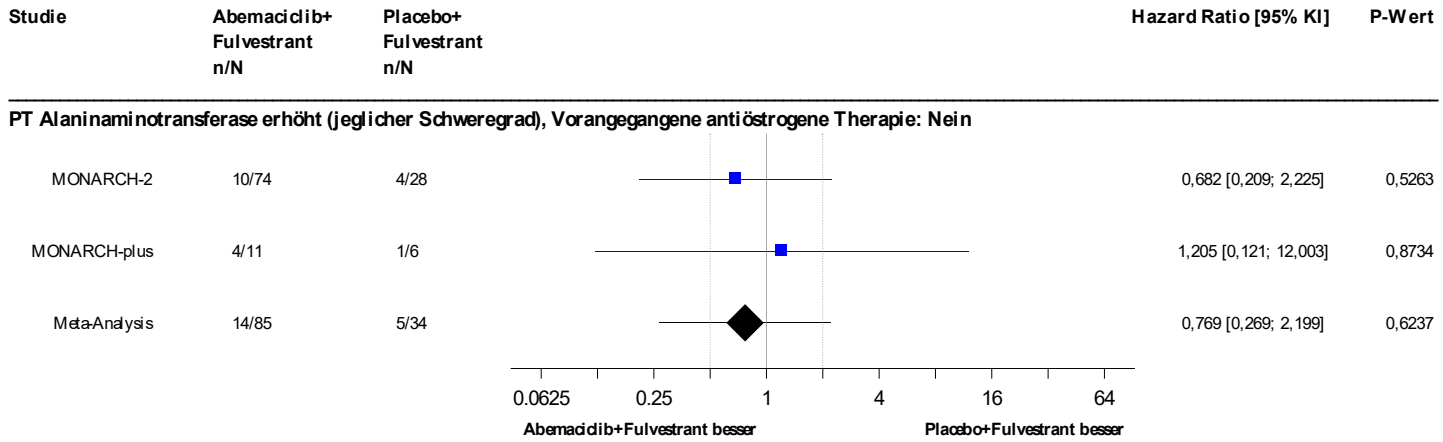
Abbildung 1440.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1862, P-Wert=0,6661, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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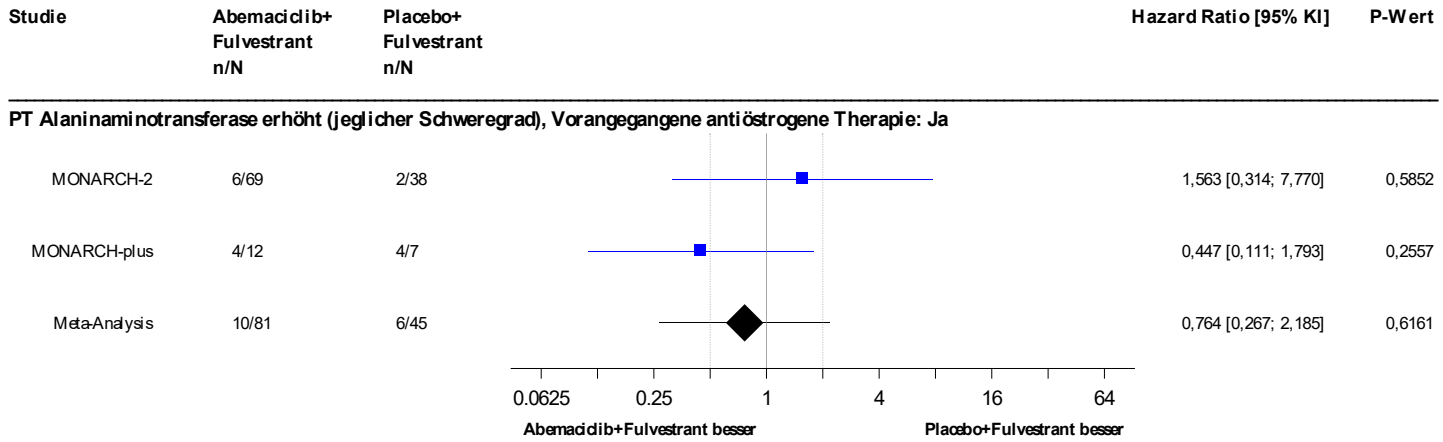
Abbildung 1440.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Alaninaminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,3385, P-Wert=0,2473, I2 Index=25,3%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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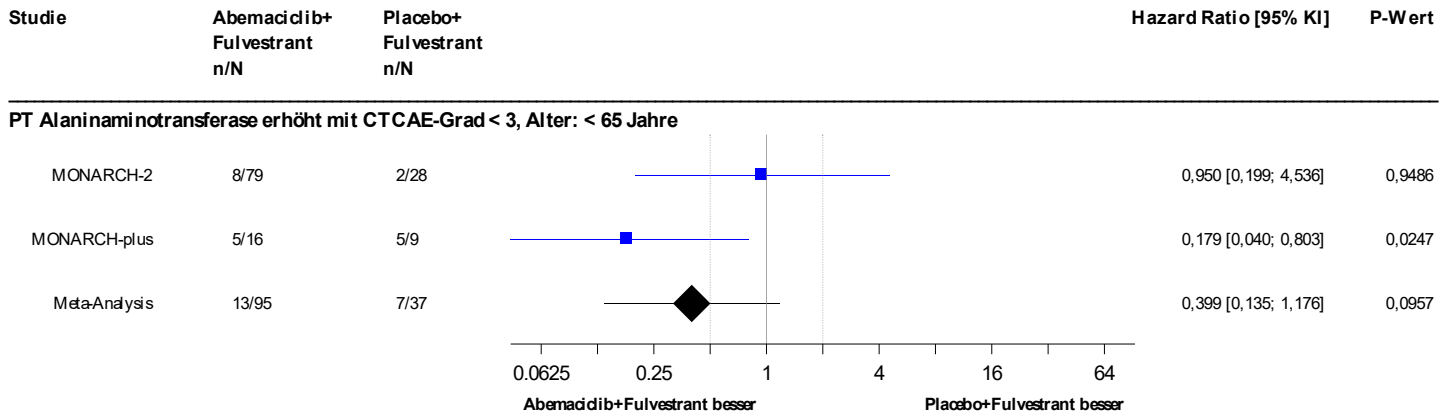
Abbildung 1442.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=2,2756, P-Wert=0,1314, I2 Index=56,1%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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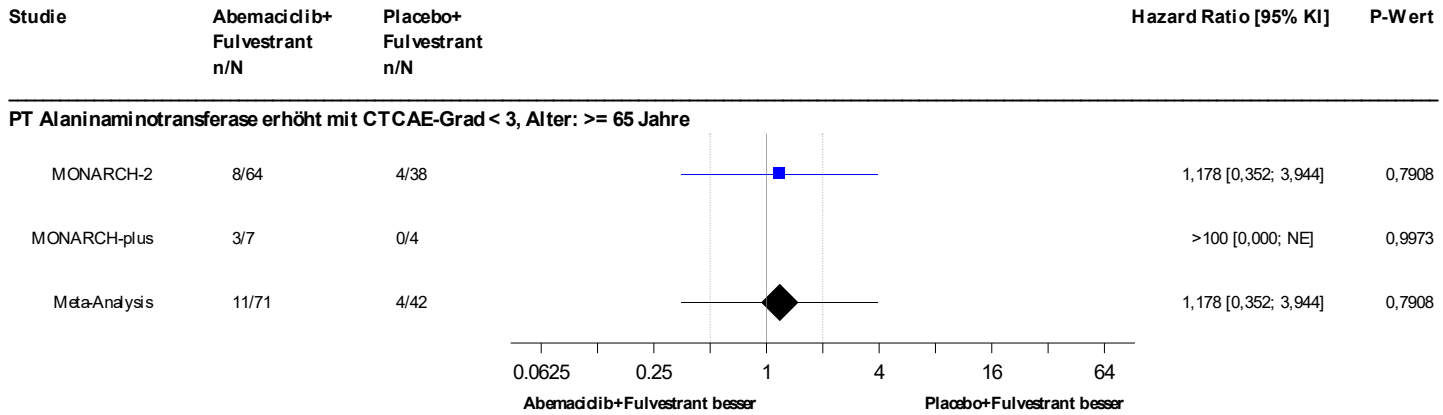
Abbildung 1442.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9973, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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Dataset Location: /lillyce/prd/ly2835219/i3y_mc_jpbl/misc5/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/data/analysis/shared/adam, /lillyce/prd/ly2835219/i3y_cr_jpbq/csr2/data/analysis/shared
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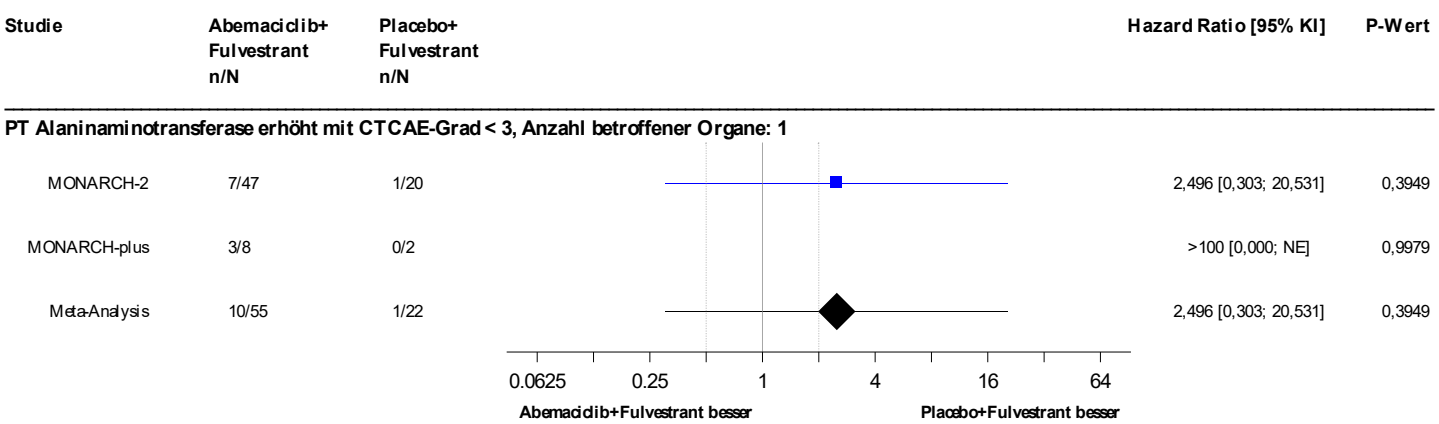
Abbildung 1442.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9980, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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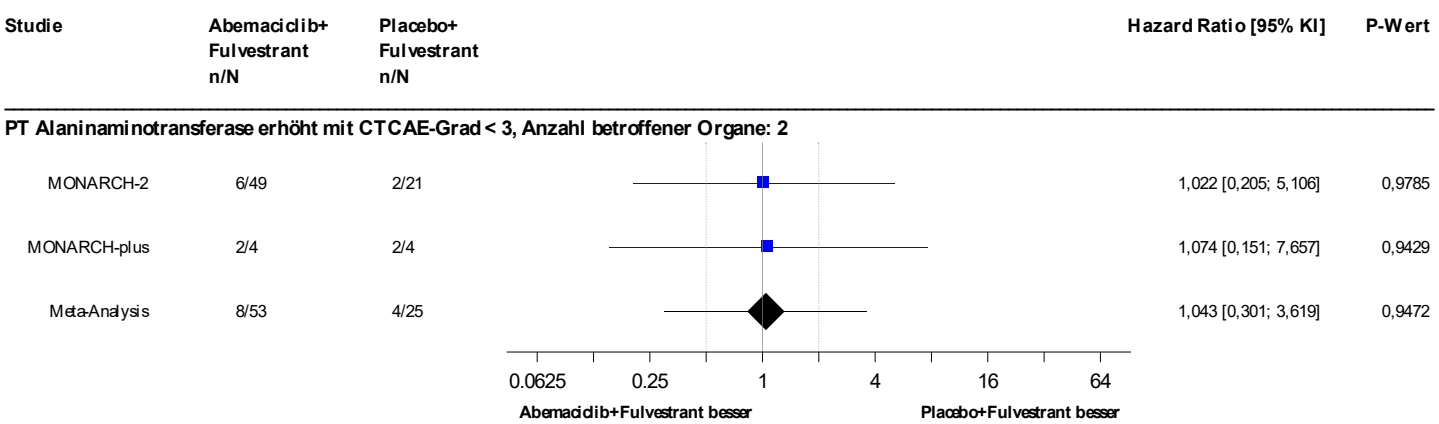
Abbildung 1442.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0015, P-Wert=0,9694, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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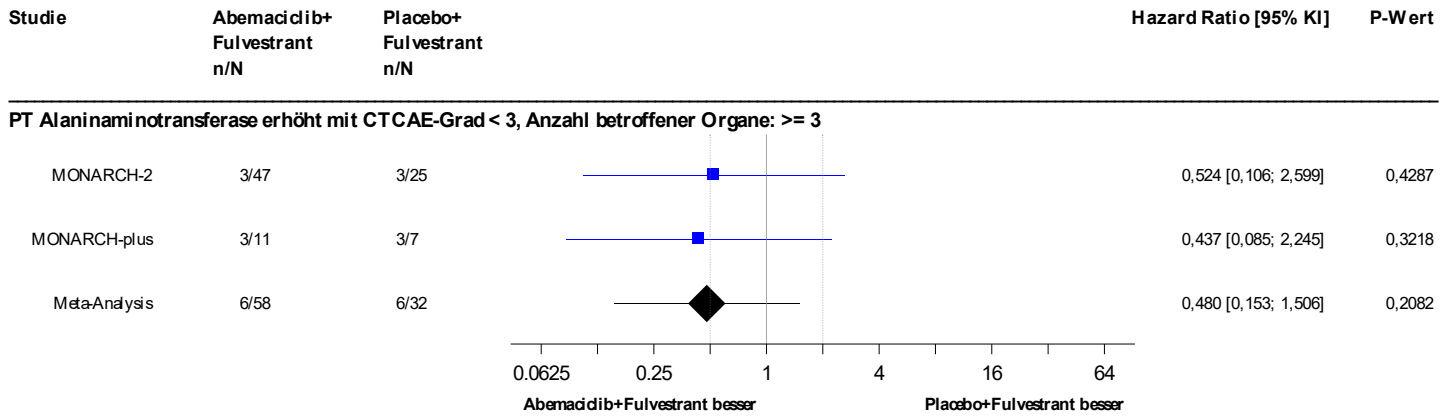
Abbildung 1442.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0238, P-Wert=0,8774, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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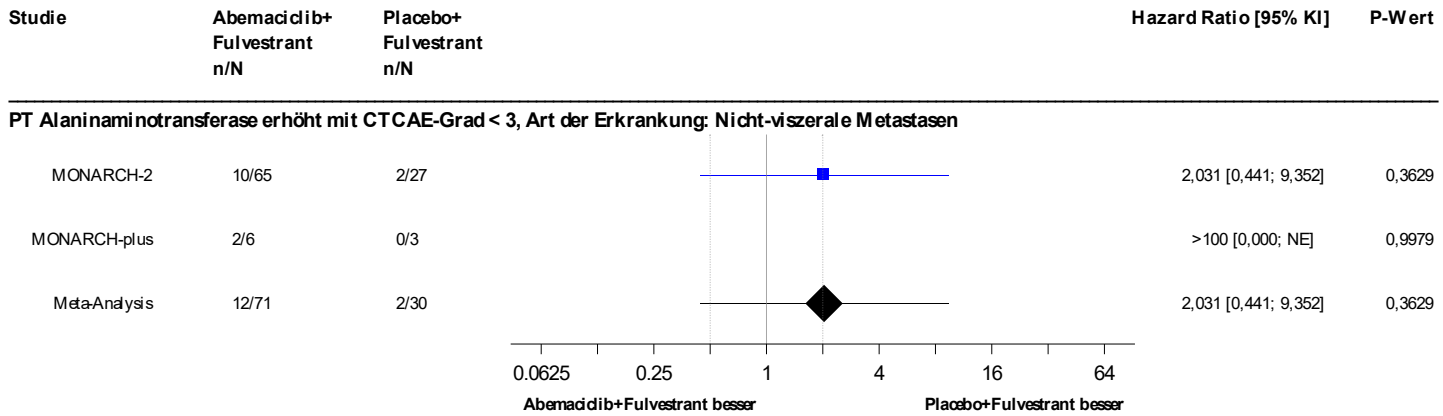
Abbildung 1442.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9980, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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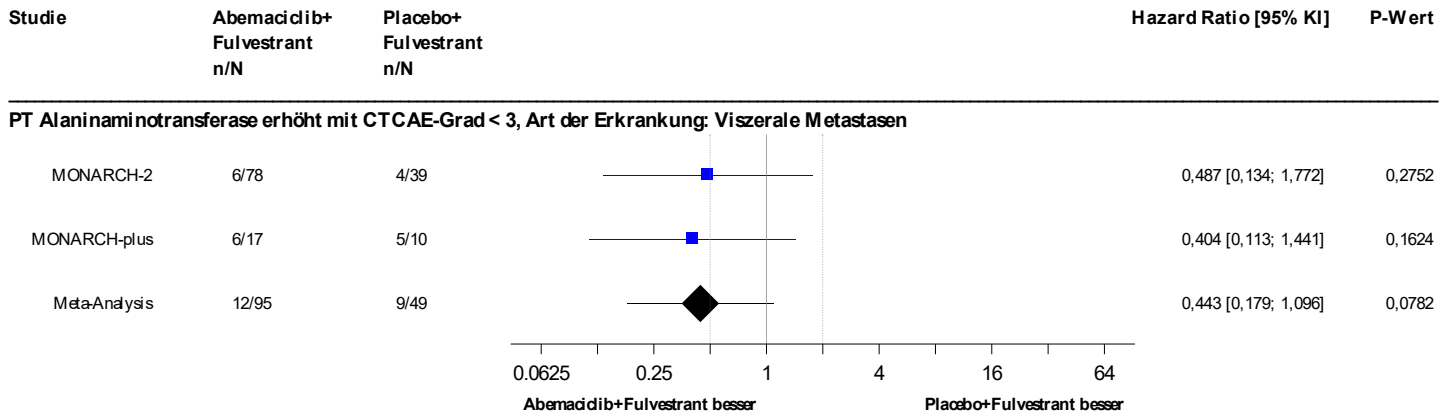
Abbildung 1442.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0413, P-Wert=0,8390, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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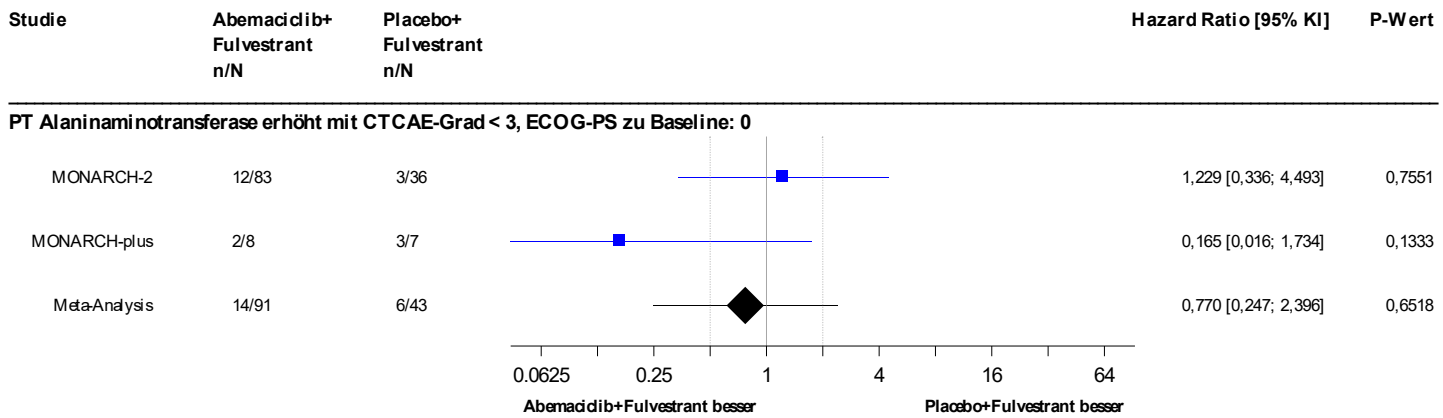
Abbildung 1442.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=2,1472, P-Wert=0,1428, I2 Index=53,4%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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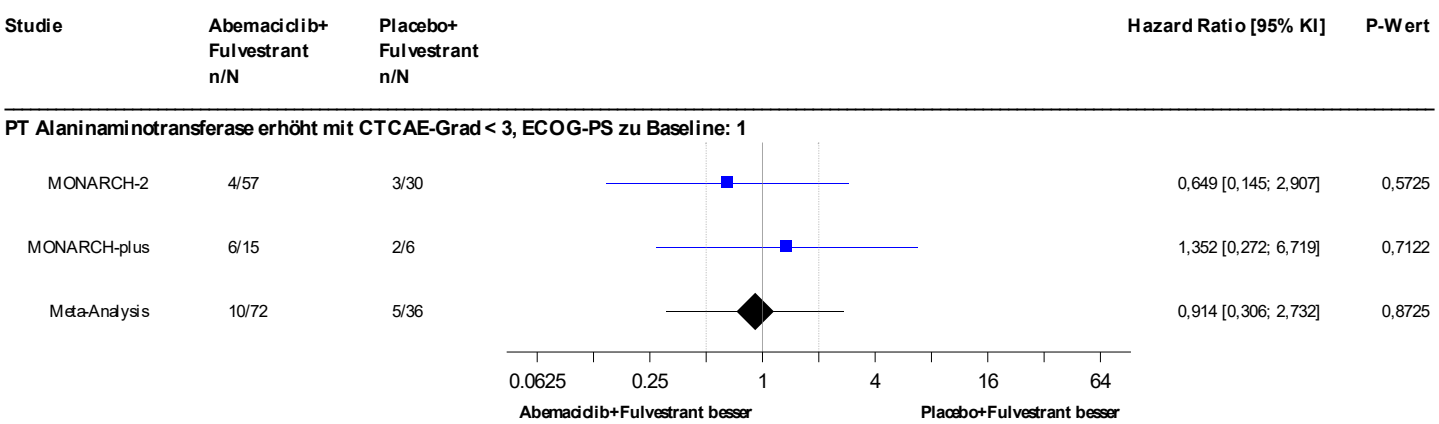
Abbildung 1442.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,4289, P-Wert=0,5125, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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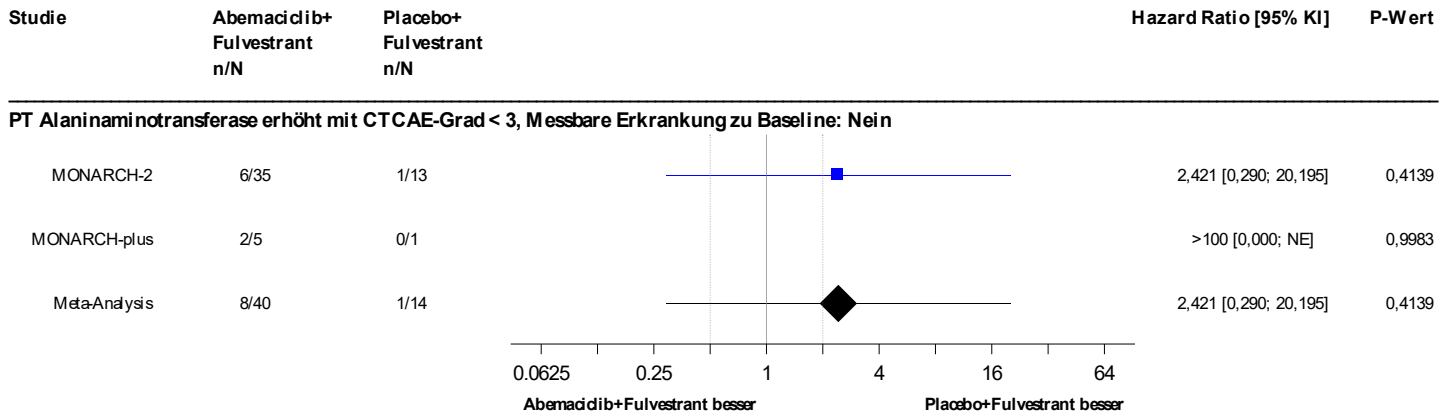
Abbildung 1442.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9984, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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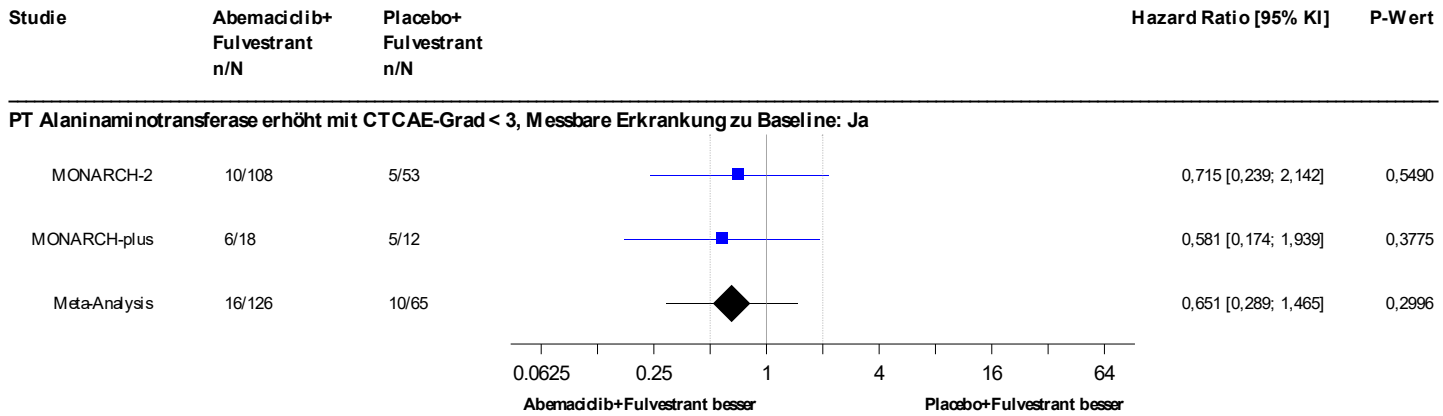
Abbildung 1442.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0620, P-Wert=0,8033, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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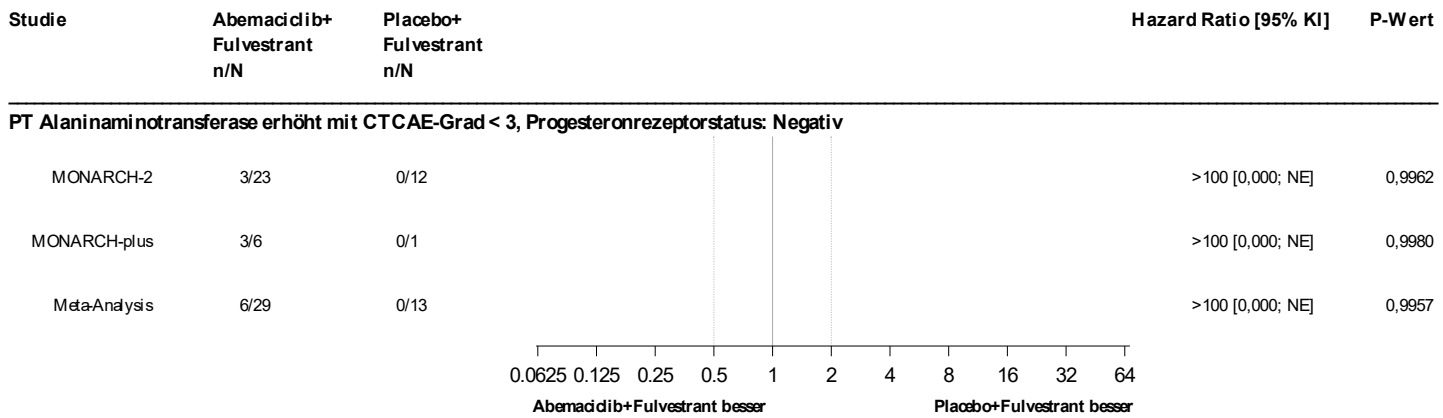
Abbildung 1442.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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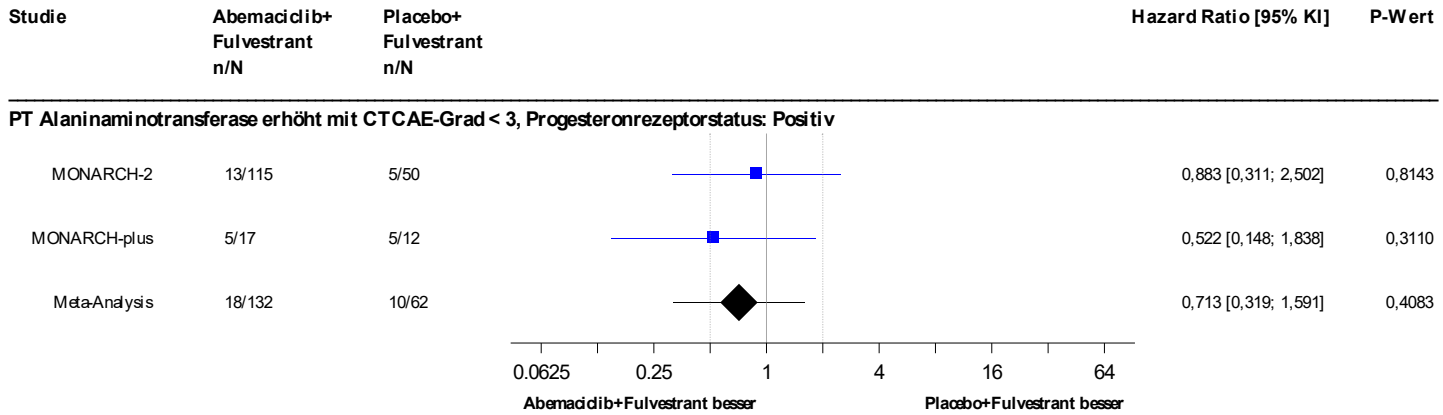
Abbildung 1442.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3979, P-Wert=0,5282, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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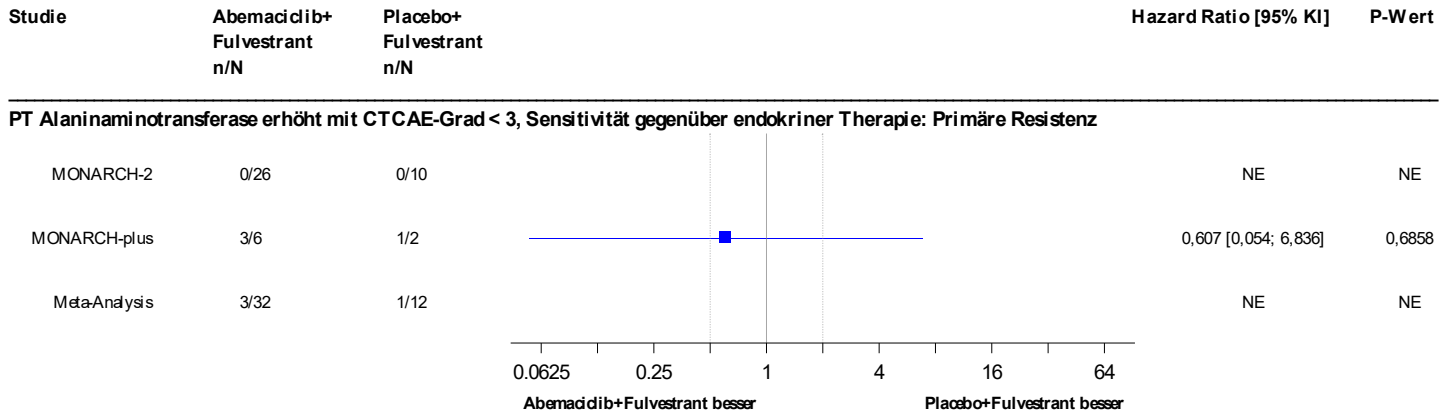
Abbildung 1442.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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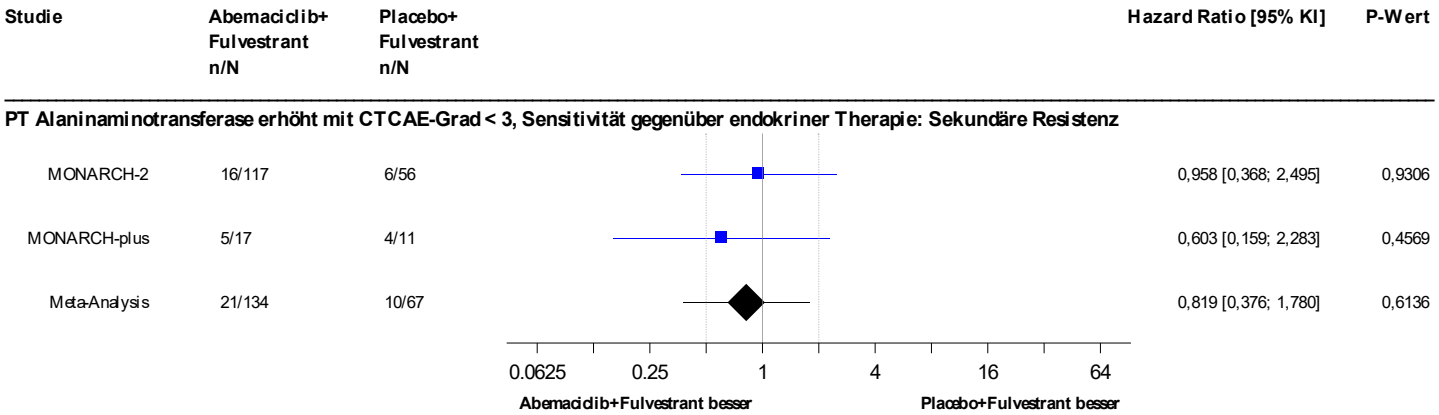
Abbildung 1442.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3061, P-Wert=0,5801, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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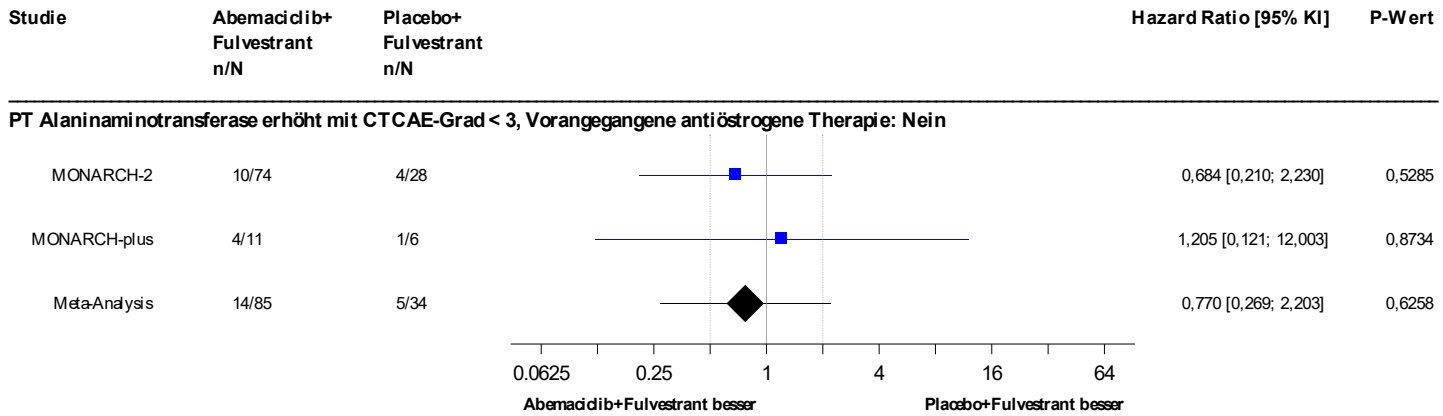
Abbildung 1442.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,1849, P-Wert=0,6672, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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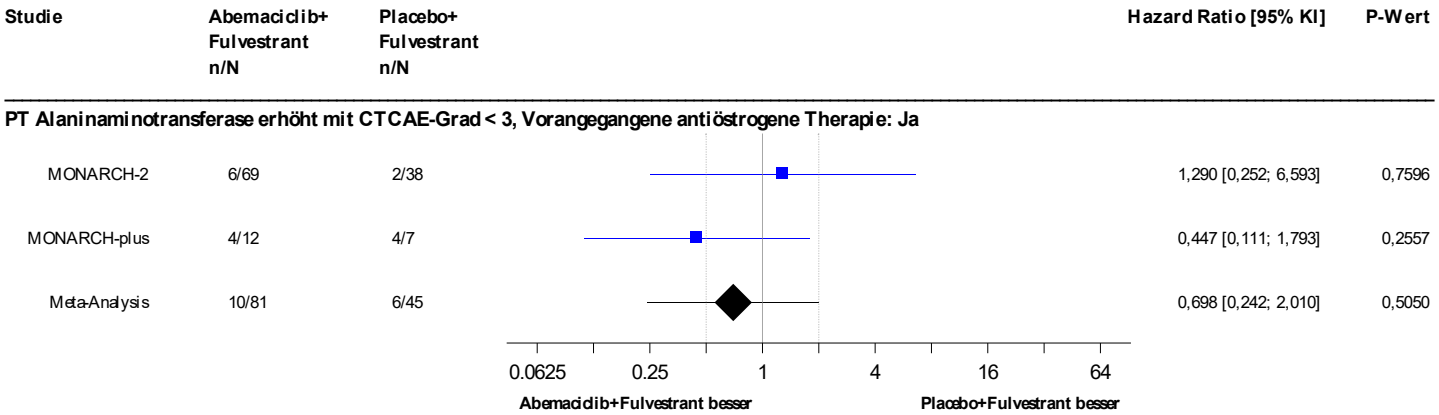
Abbildung 1442.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Alaninaminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,9414, P-Wert=0,3319, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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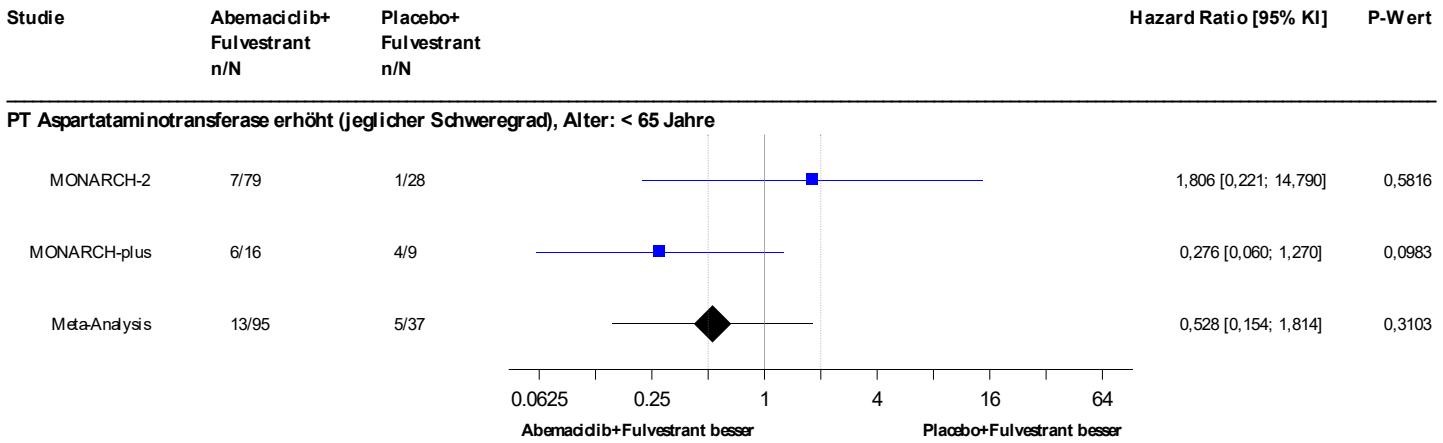
Abbildung 1444.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=2,0075, P-Wert=0,1565, I2 Index=50,2%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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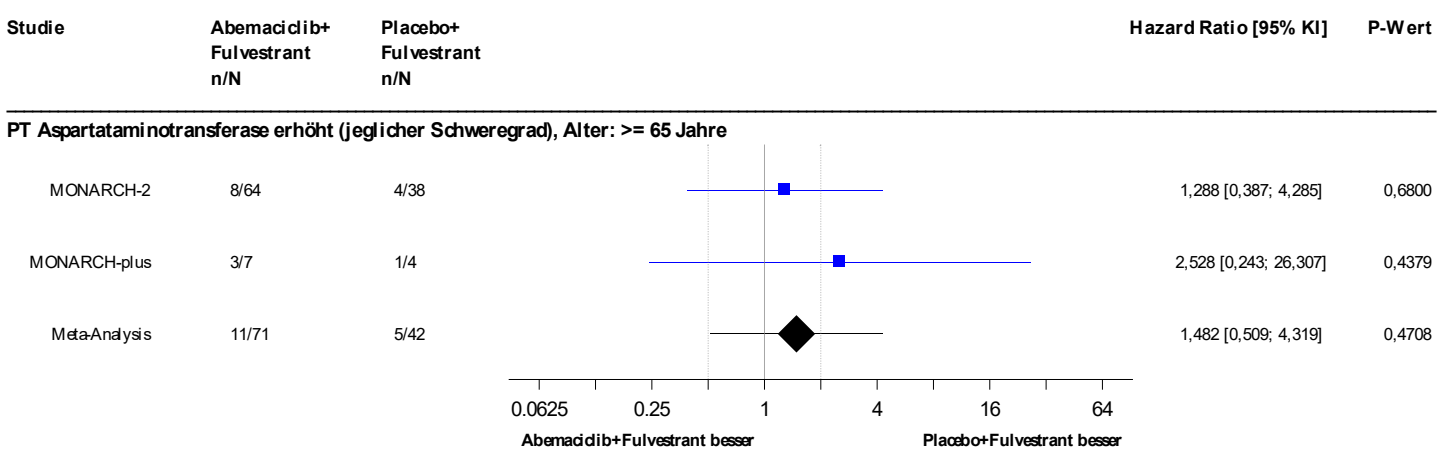
Abbildung 1444.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2519, P-Wert=0,6157, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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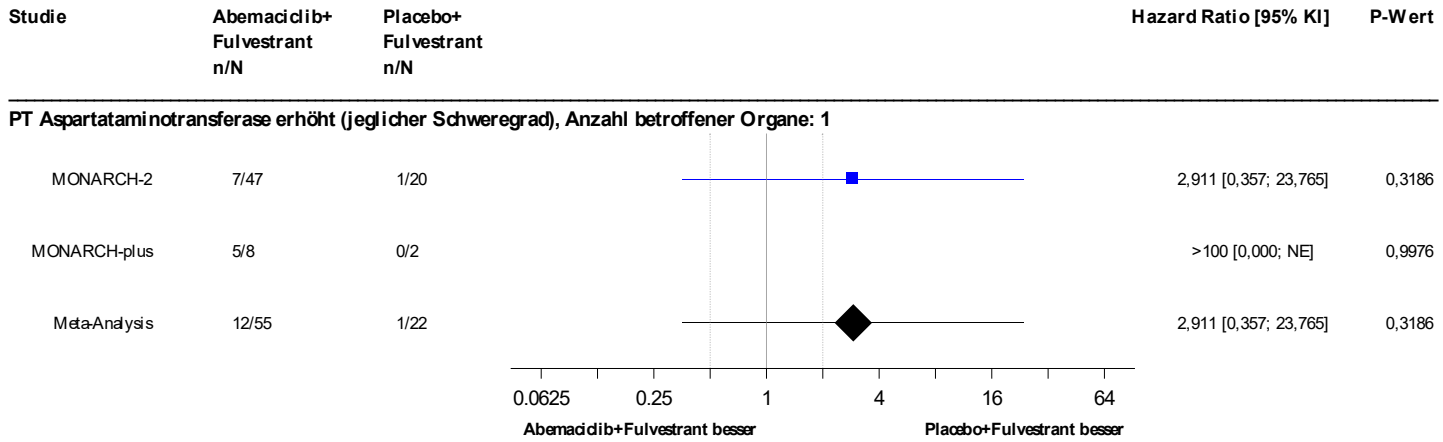
Abbildung 1444.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9977, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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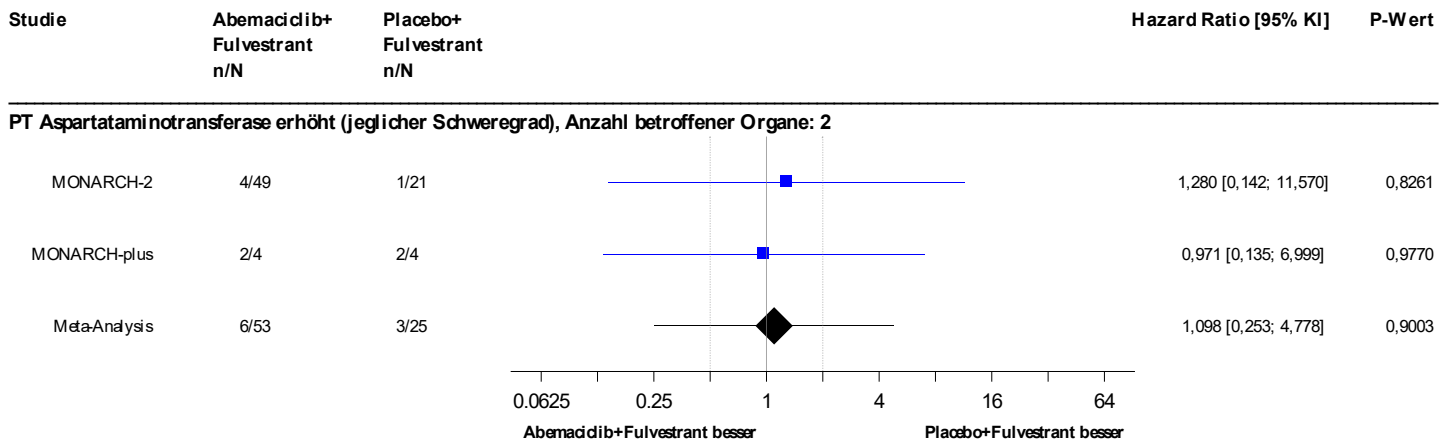
Abbildung 1444.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0334, P-Wert=0,8550, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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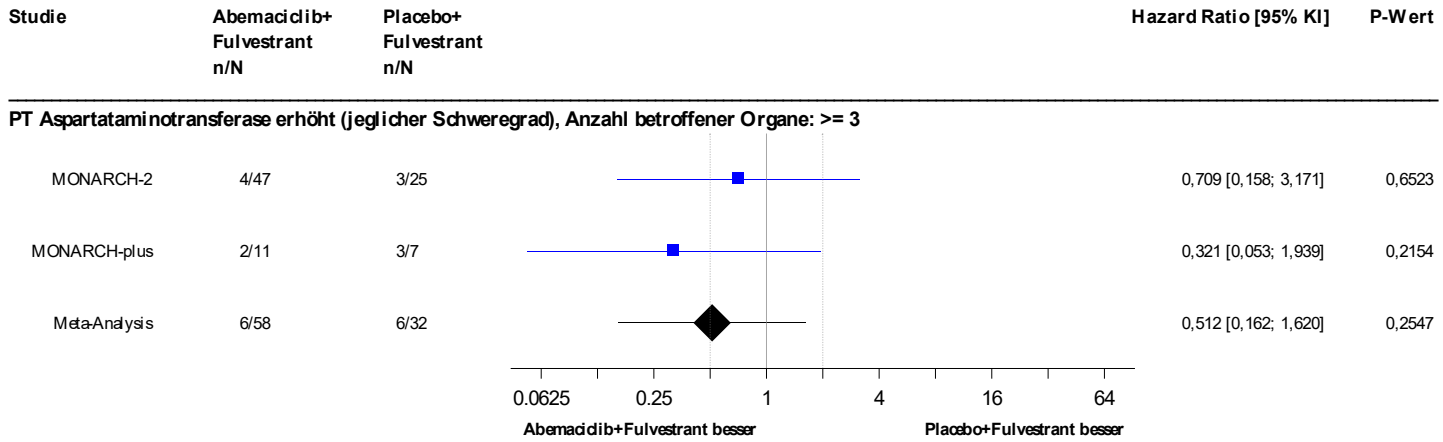
Abbildung 1444.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,4404, P-Wert=0,5069, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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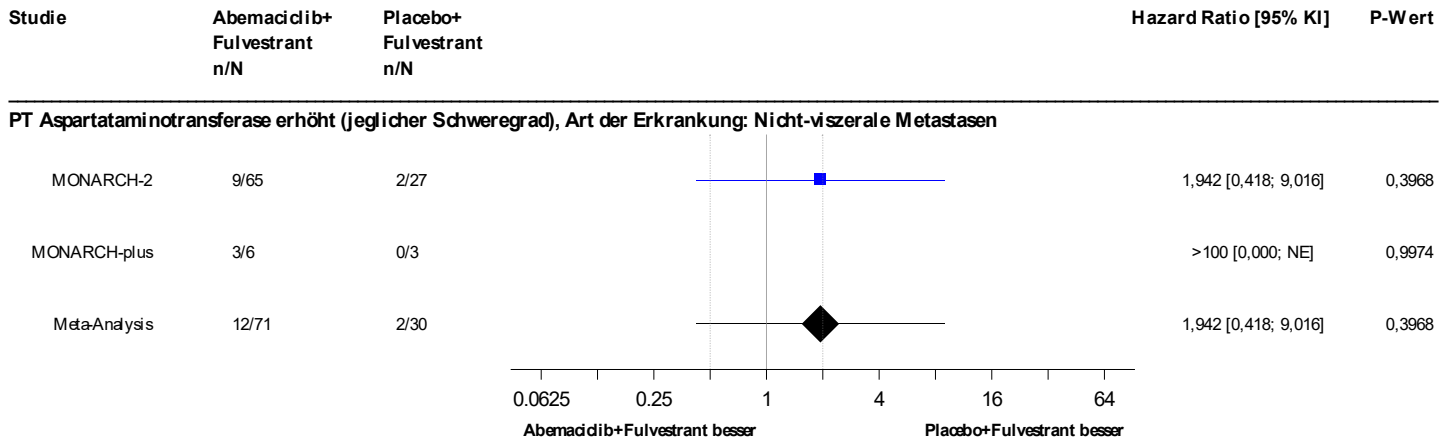
Abbildung 1444.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9975, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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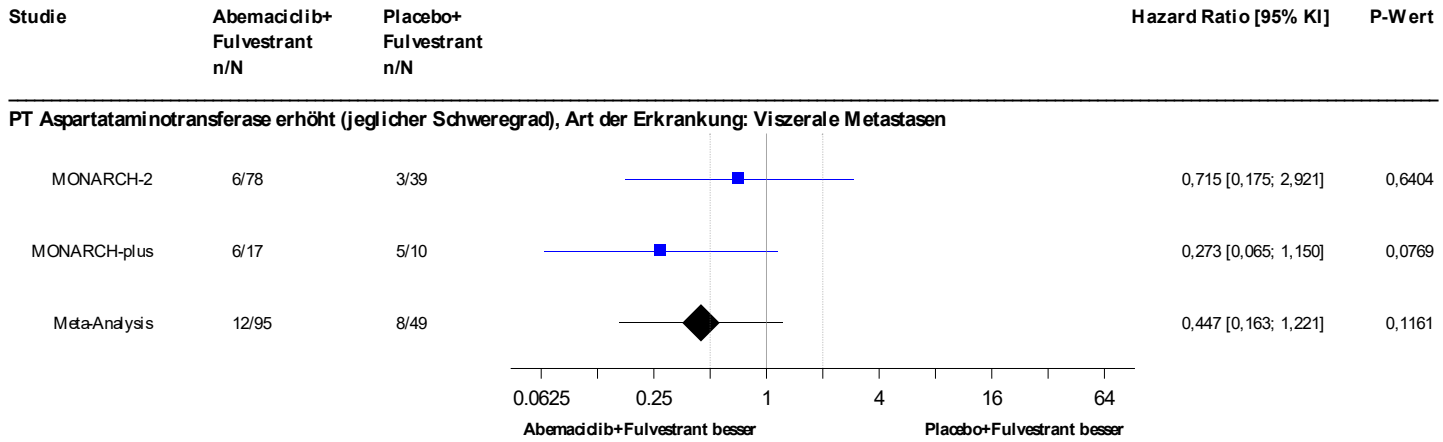
Abbildung 1444.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,8784, P-Wert=0,3486, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttasaesi_popa2_natdis2_2.rtf
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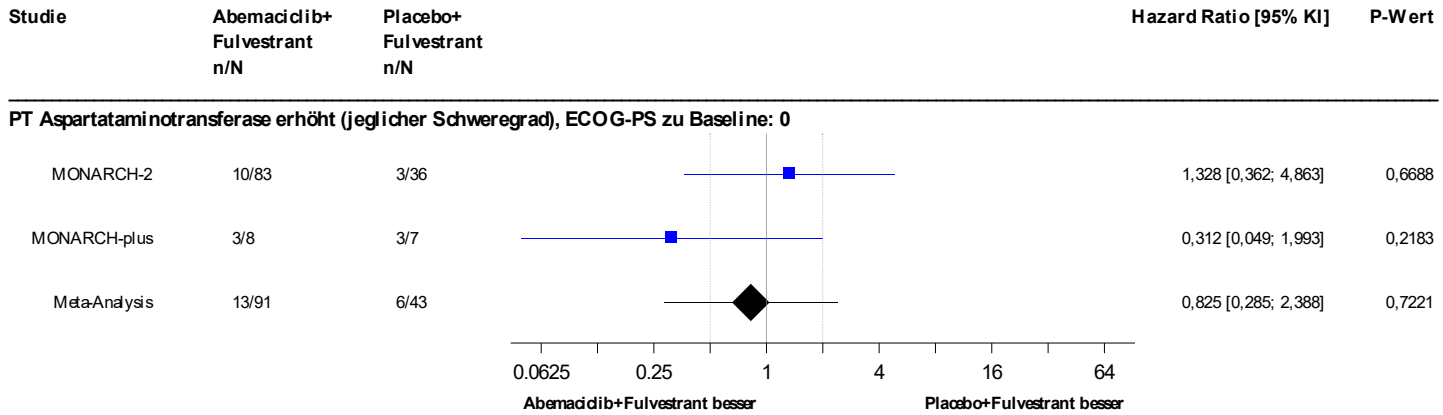
Abbildung 1444.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,5722, P-Wert=0,2099, I2 Index=36,4%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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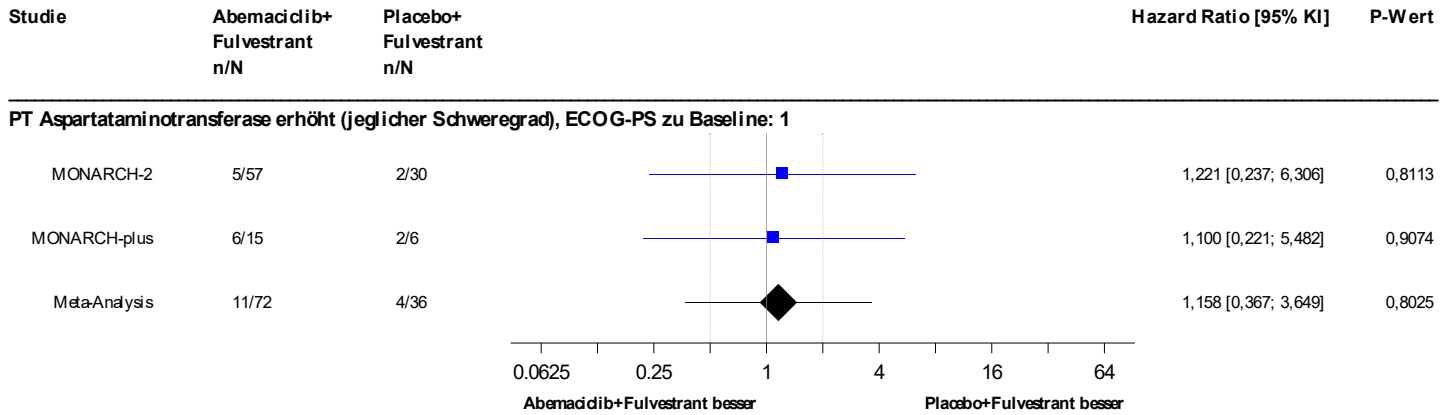
17SEP2021 / 07:48

Abbildung 1444.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0080, P-Wert=0,9288, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
Output Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/output/shared/tfl/german_dossier/metaout/t_meta_ttasaesi_popa2_ecogbl_2.rtf
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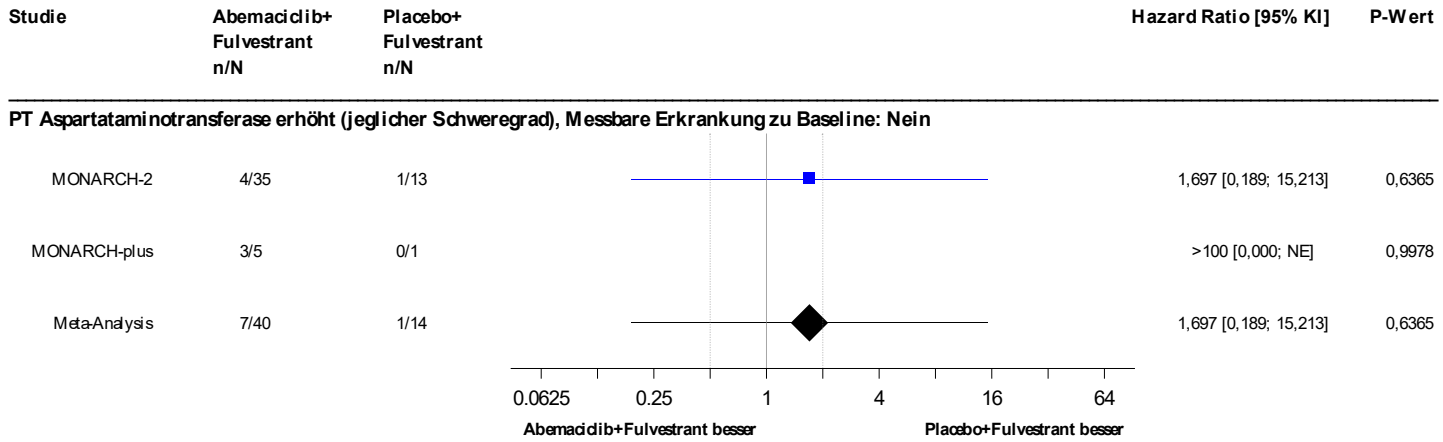
17SEP2021 / 07:48

Abbildung 1444.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9978, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

Program Location: /lillyce/prd/ly2835219/i3y_cr_jpbq/misc7/programs/stat/tfl/german_dossier/t_meta_tte_sub.sas
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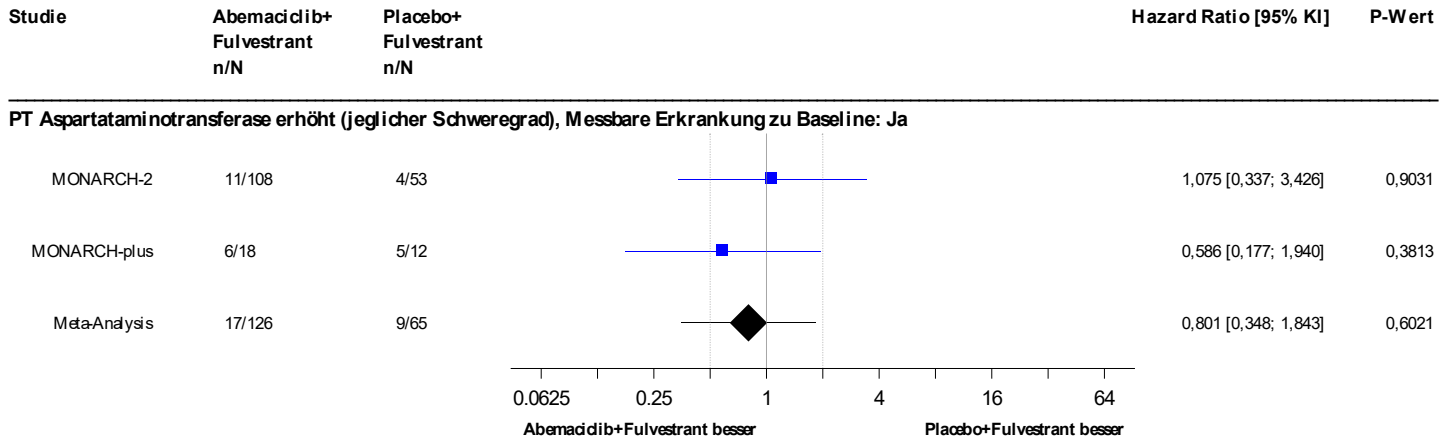
17SEP2021 / 07:48

Abbildung 1444.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,5096, P-Wert=0,4753, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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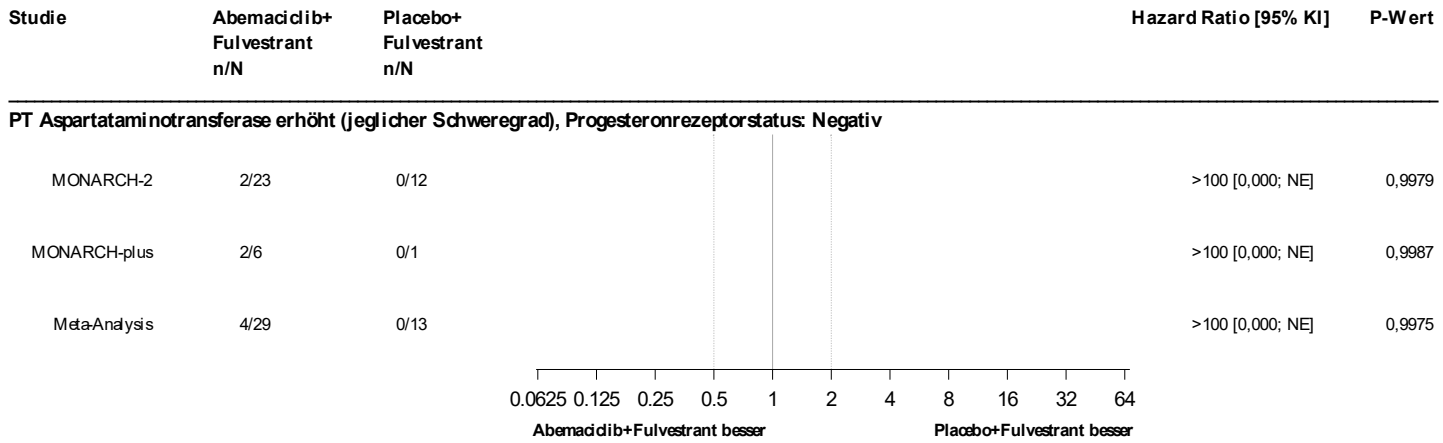
Abbildung 1444.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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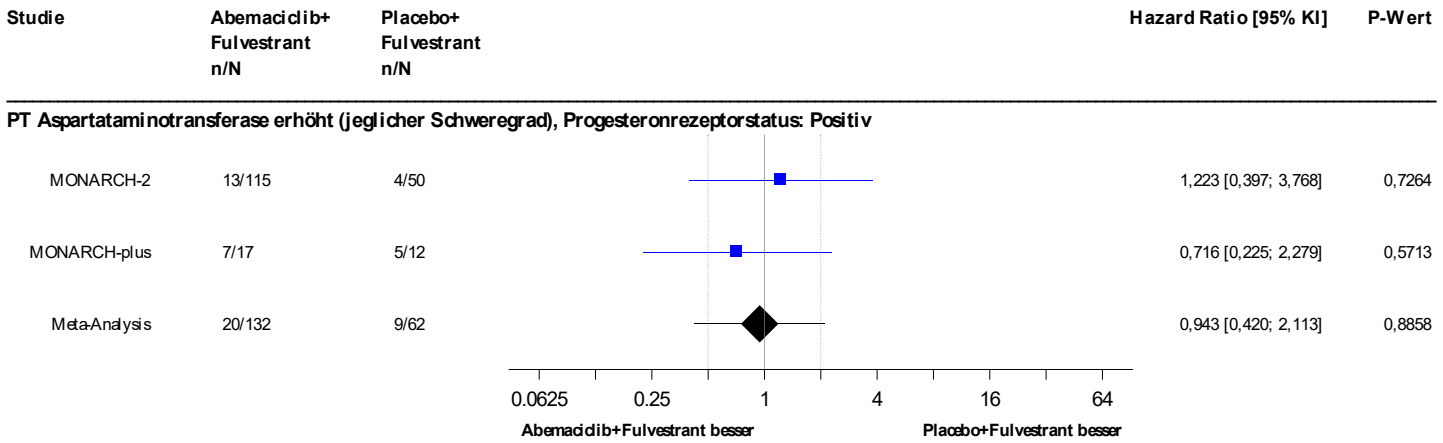
Abbildung 1444.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,4224, P-Wert=0,5158, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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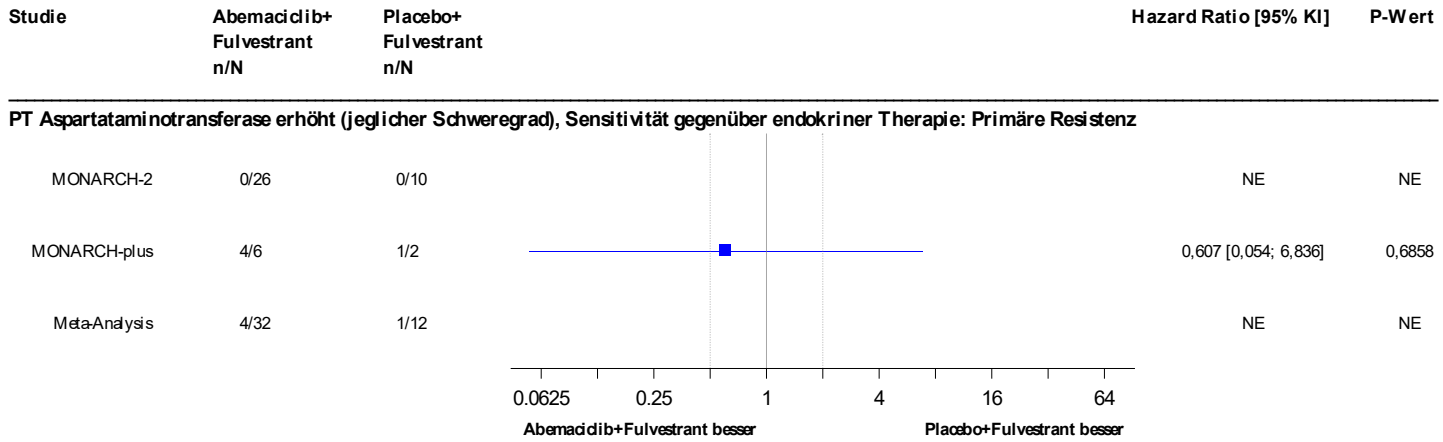
Abbildung 1444.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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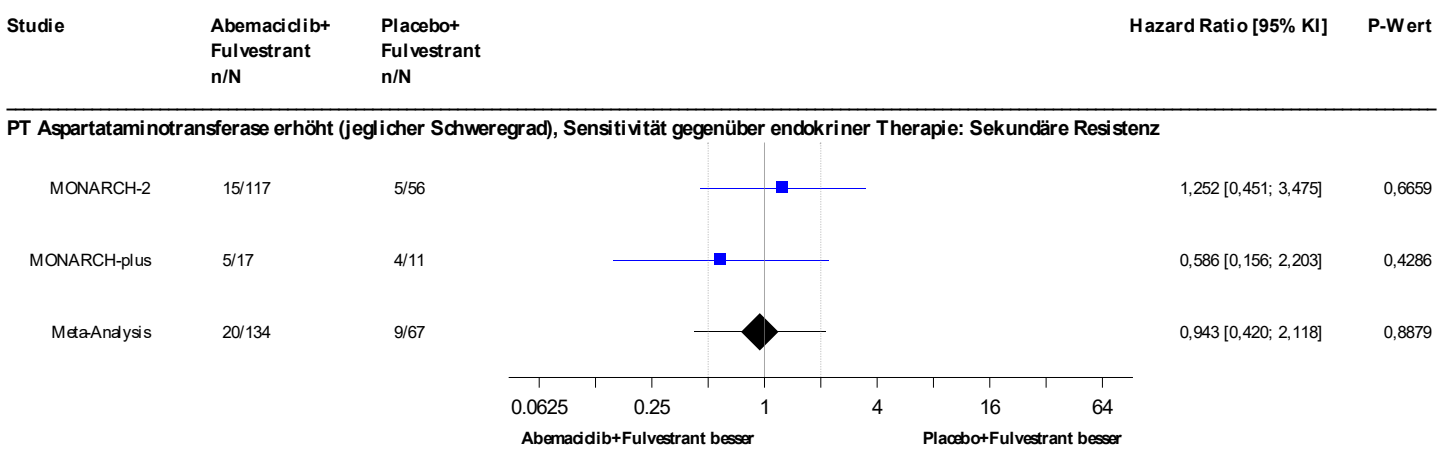
Abbildung 1444.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,7931, P-Wert=0,3732, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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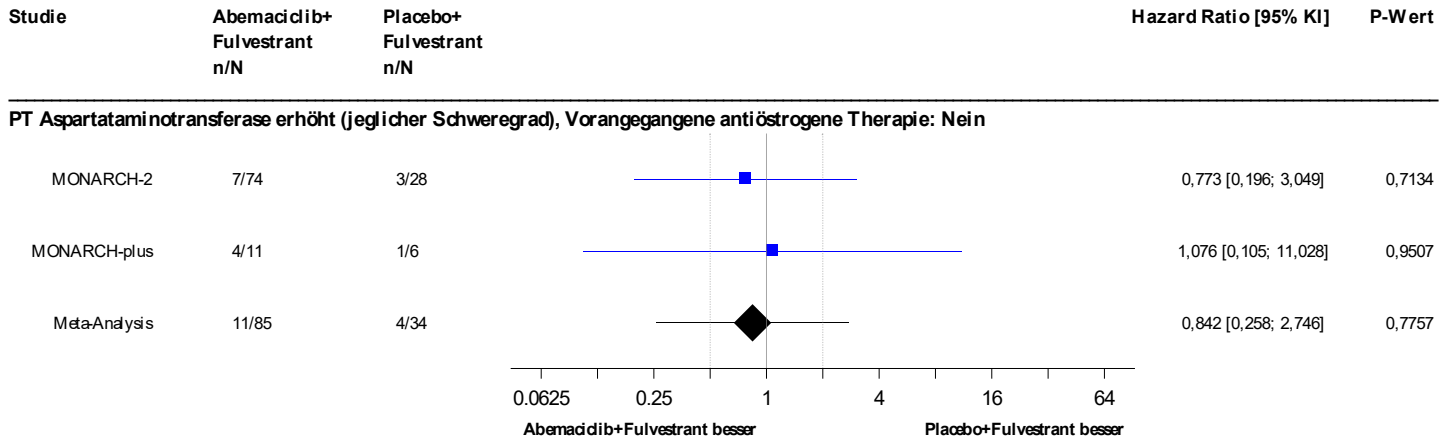
Abbildung 1444.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0575, P-Wert=0,8105, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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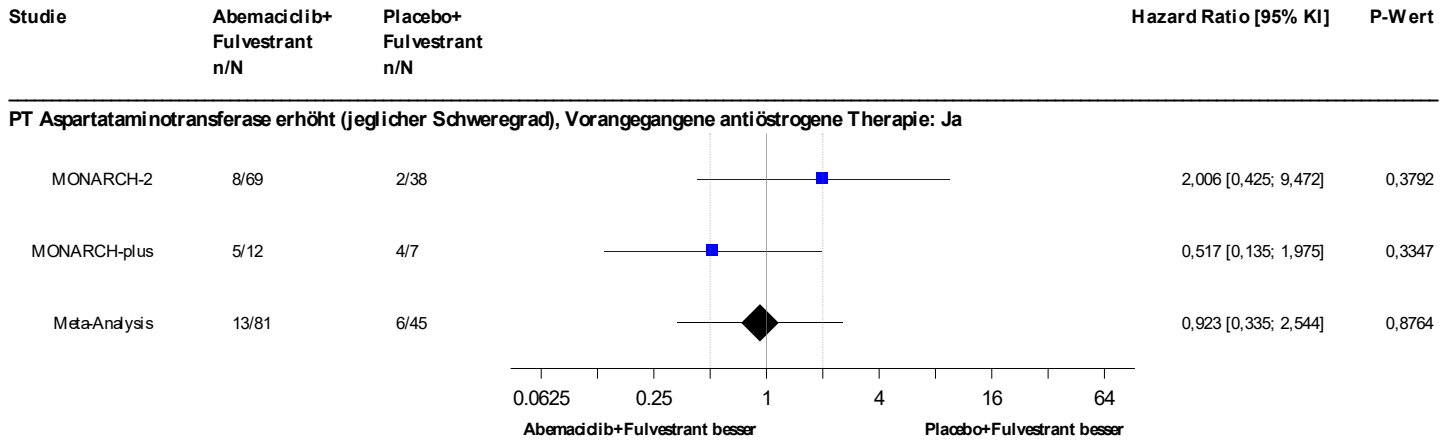
Abbildung 1444.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: PT Aspartataminotransferase erhöht (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,6797, P-Wert=0,1950, I2 Index=40,5%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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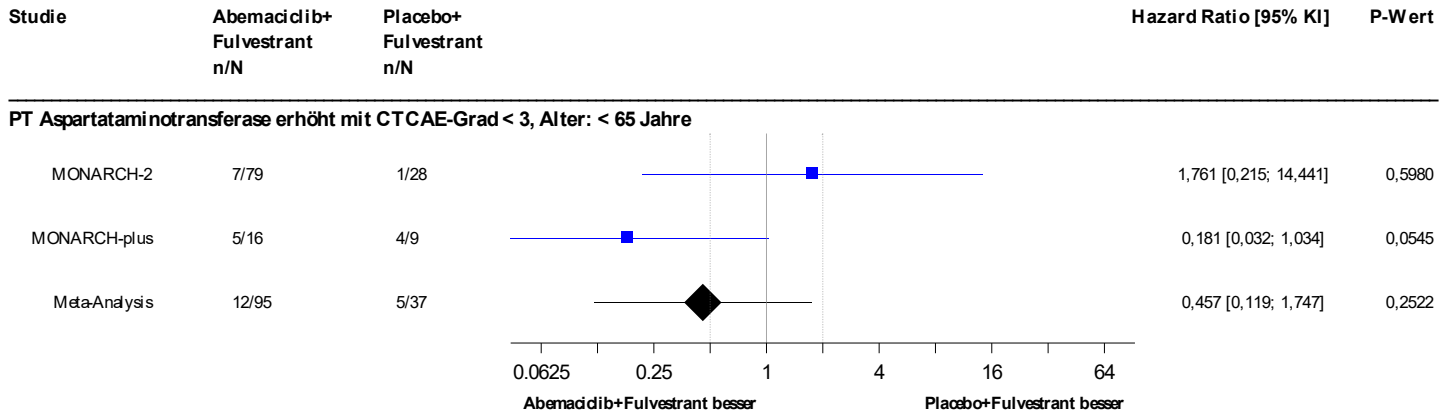
Abbildung 1446.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=2,6628, P-Wert=0,1027, I2 Index=62,4%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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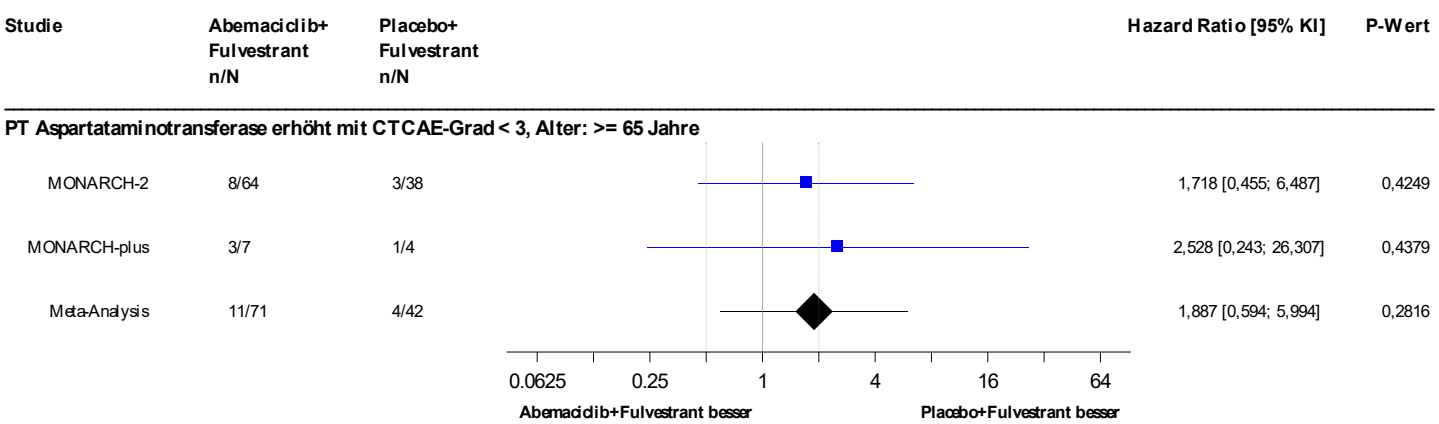
Abbildung 1446.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0790, P-Wert=0,7786, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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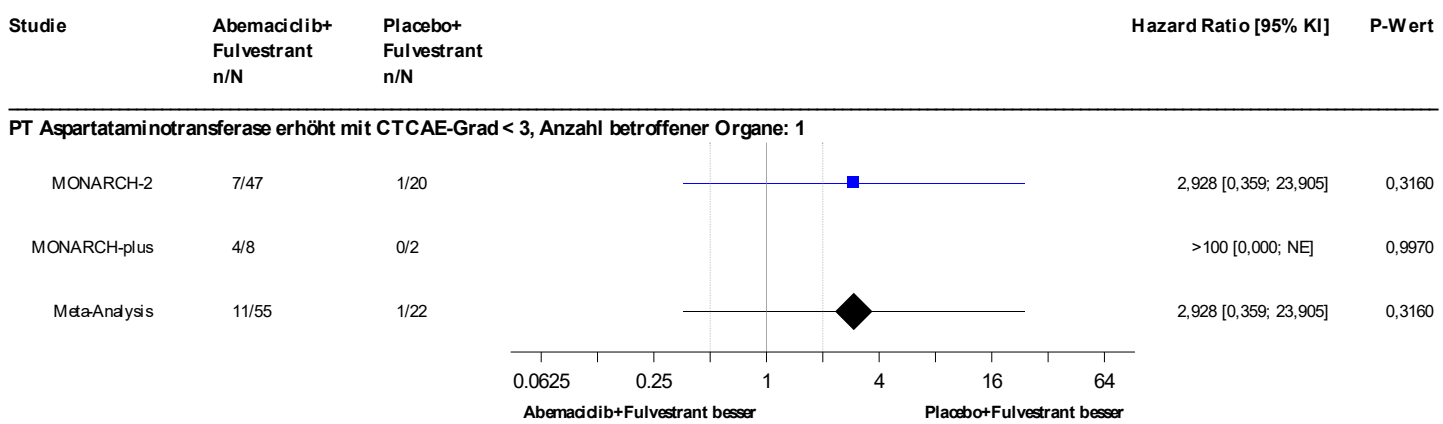
Abbildung 1446.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9972, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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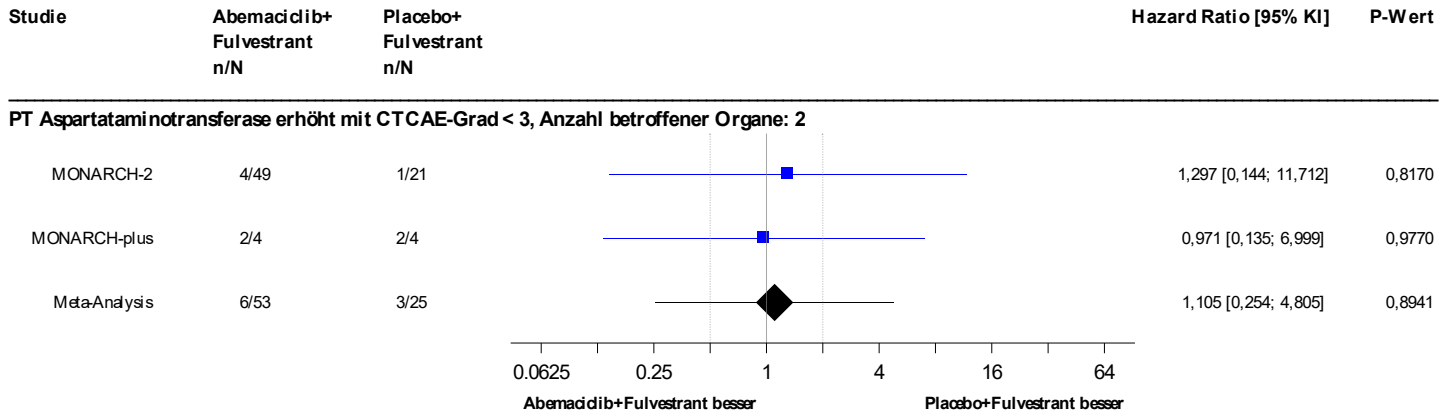
Abbildung 1446.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0366, P-Wert=0,8482, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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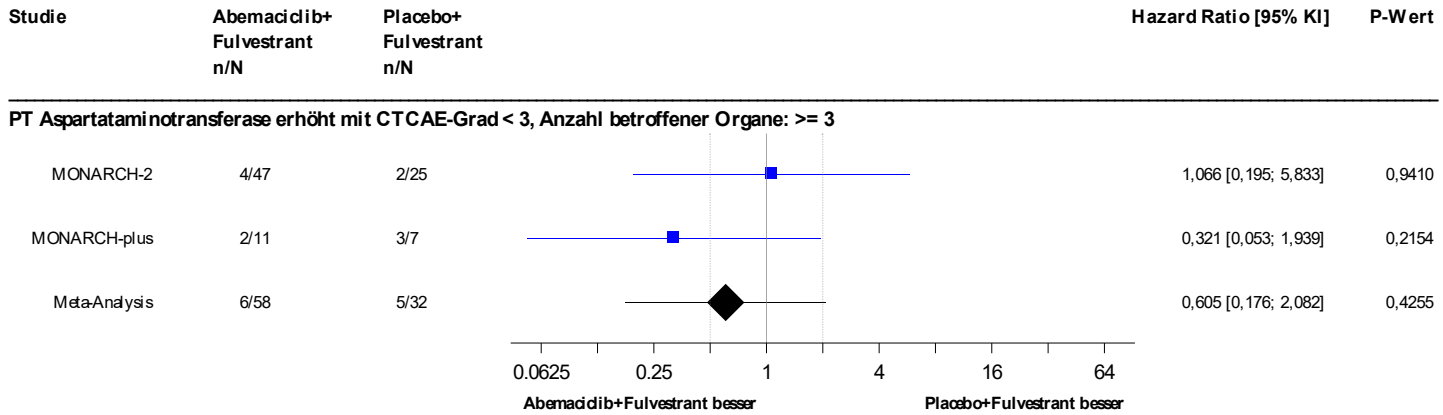
Abbildung 1446.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,9053, P-Wert=0,3414, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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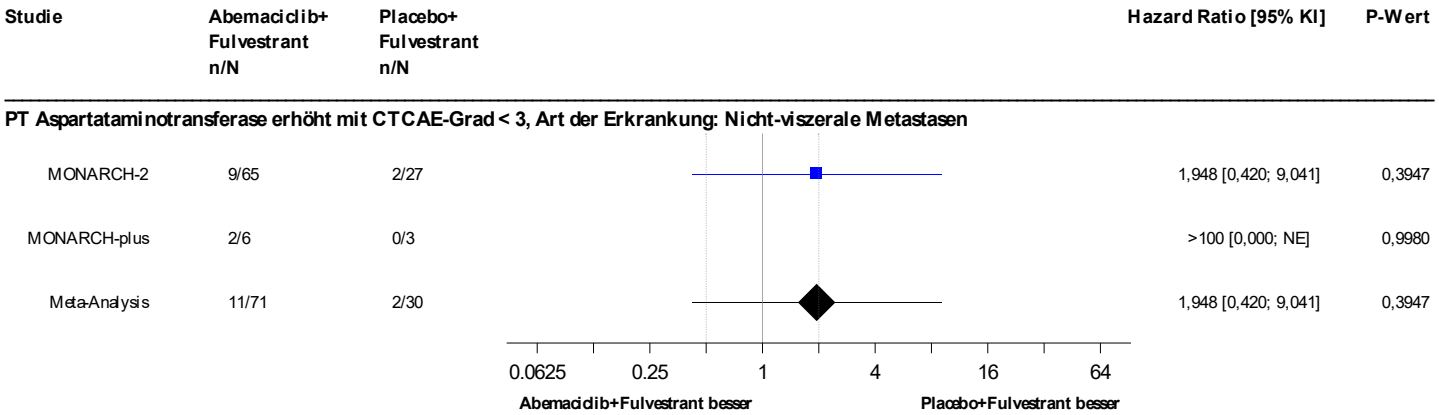
Abbildung 1446.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9981, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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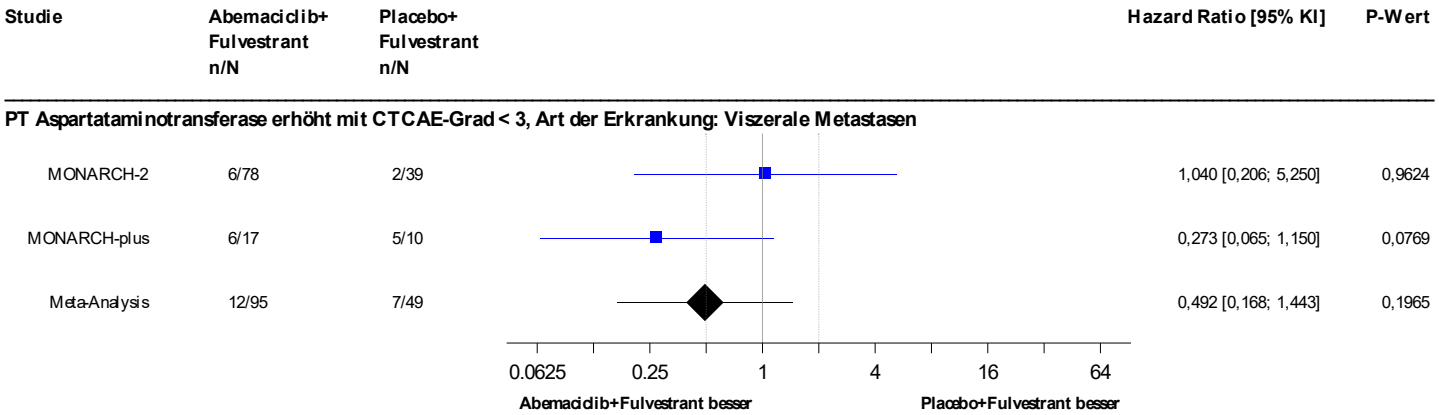
Abbildung 1446.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,4633, P-Wert=0,2264, I2 Index=31,7%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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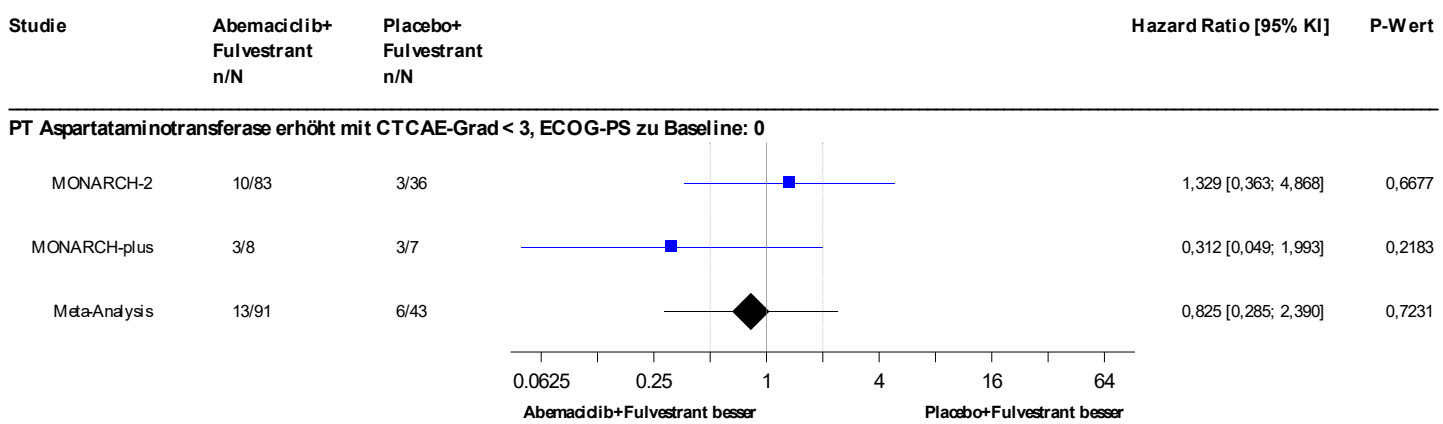
Abbildung 1446.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,5743, P-Wert=0,2096, I2 Index=36,5%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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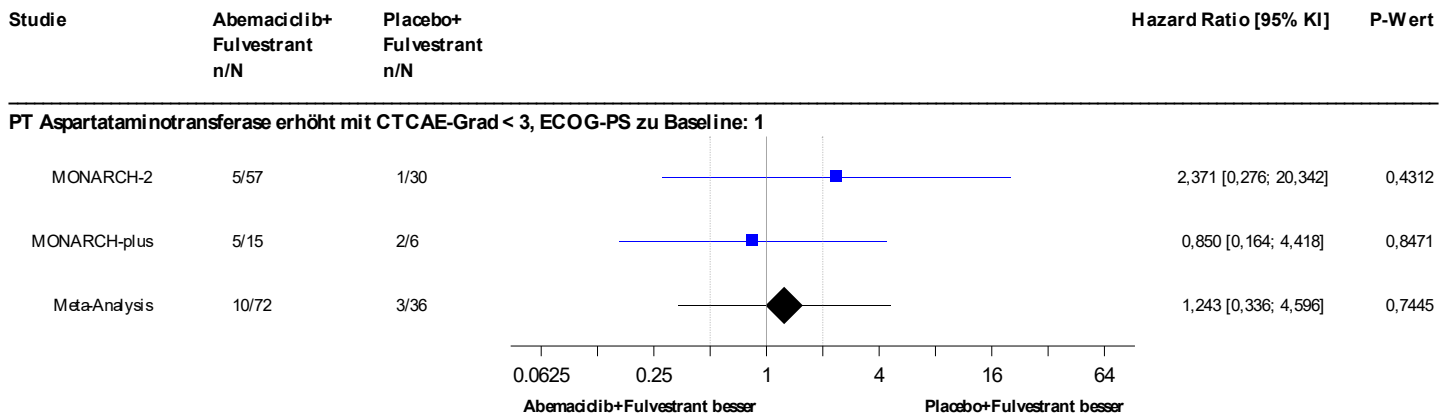
Abbildung 1446.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,5506, P-Wert=0,4581, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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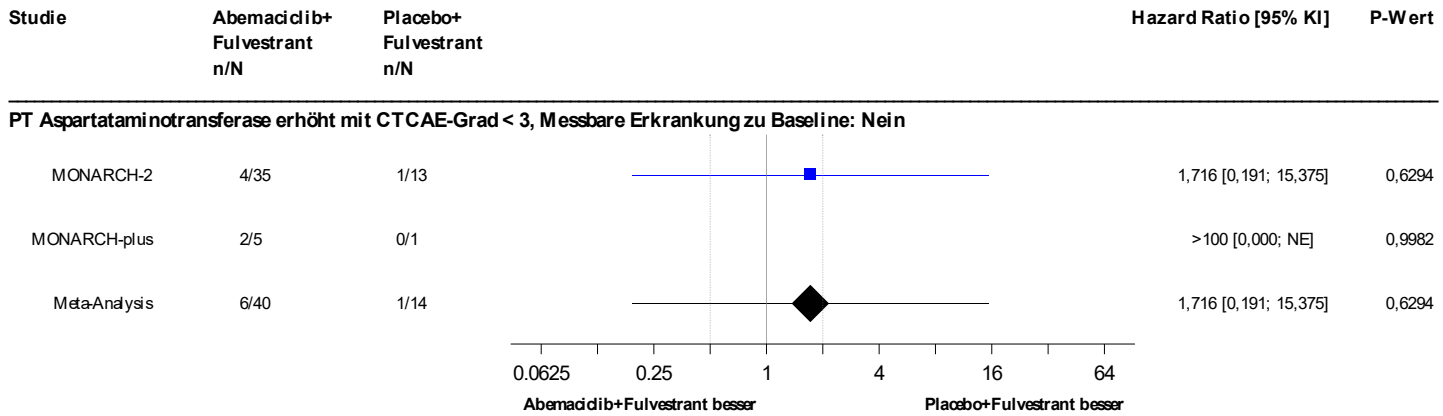
Abbildung 1446.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9983, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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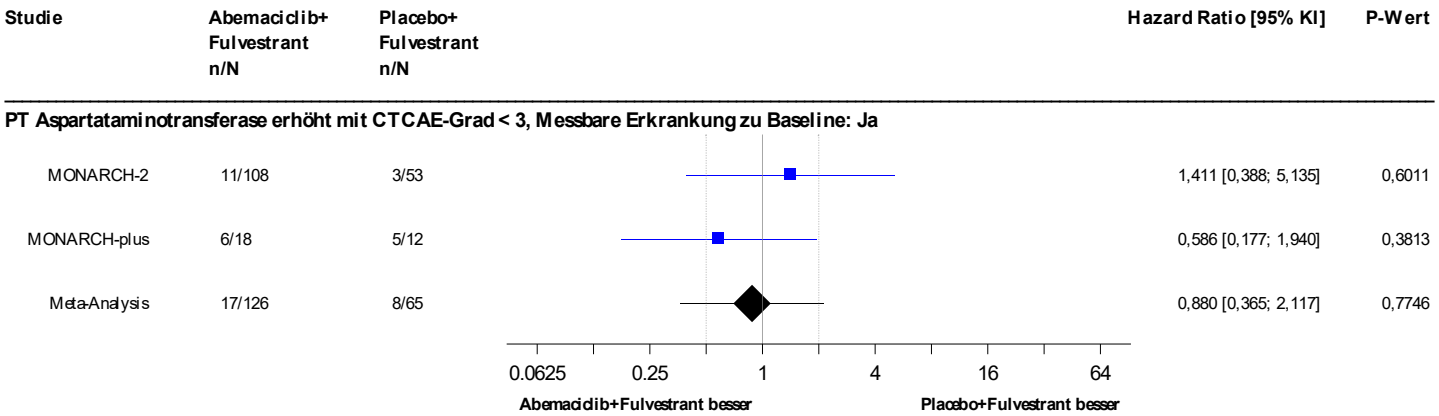
Abbildung 1446.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,9579, P-Wert=0,3277, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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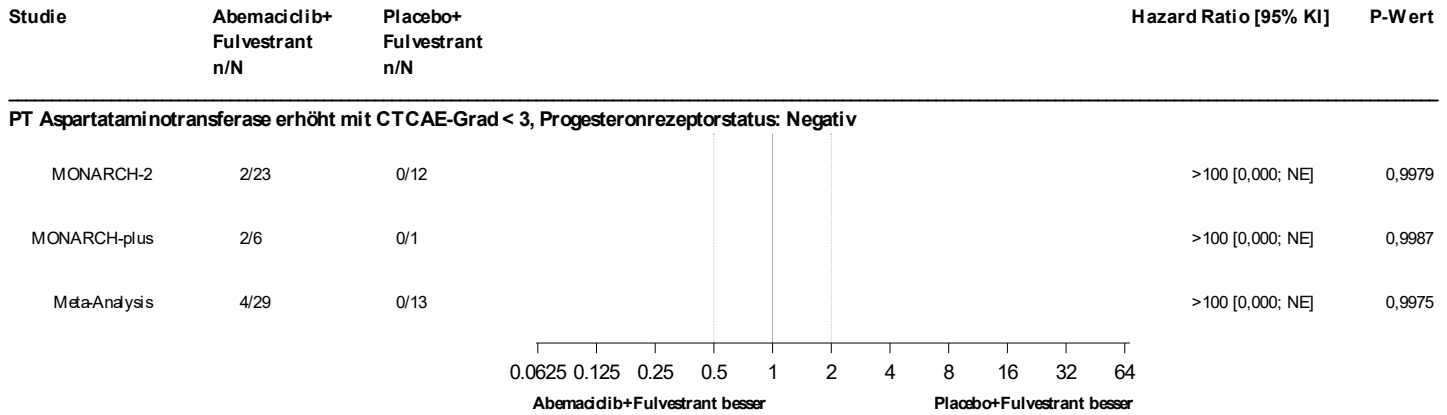
Abbildung 1446.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9999, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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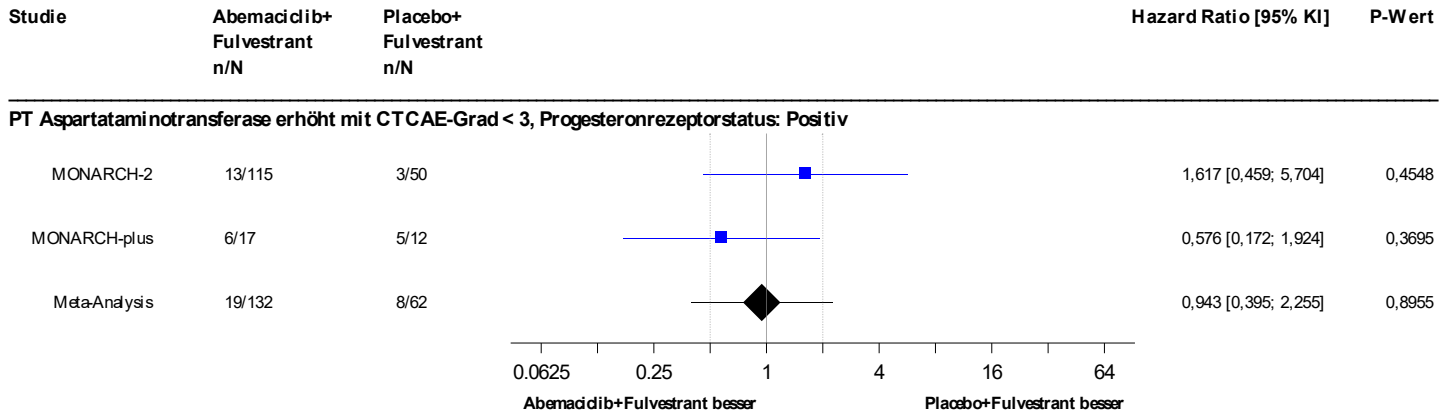
Abbildung 1446.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,3467, P-Wert=0,2459, I2 Index=25,7%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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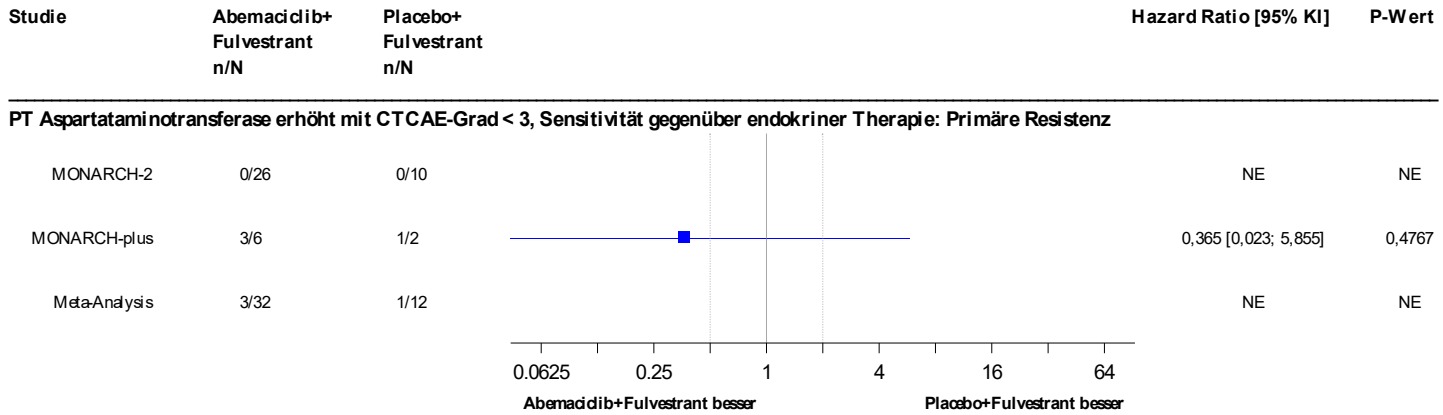
Abbildung 1446.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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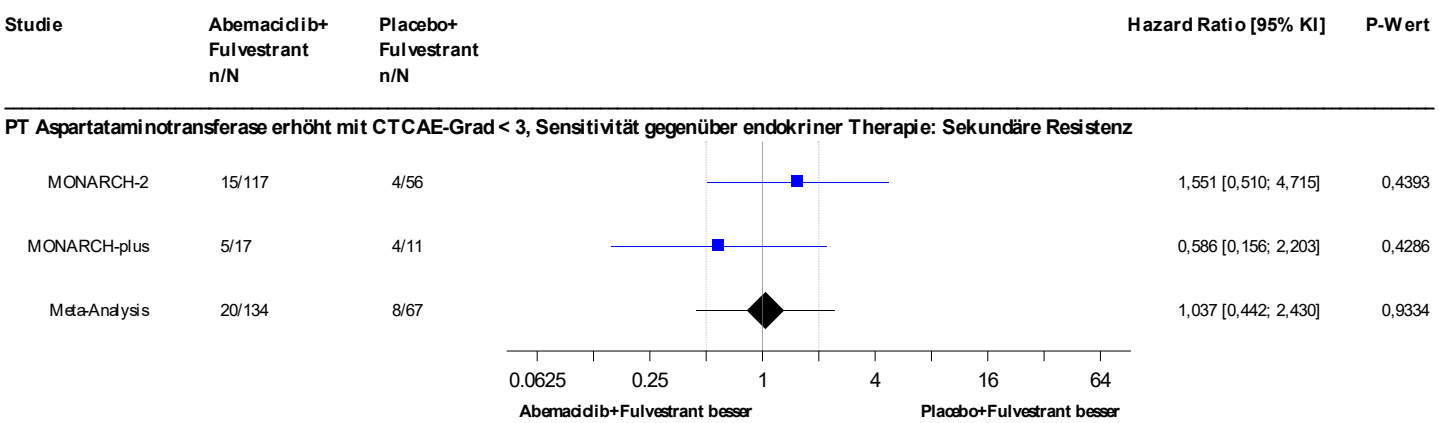
Abbildung 1446.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,2177, P-Wert=0,2698, I2 Index=17,9%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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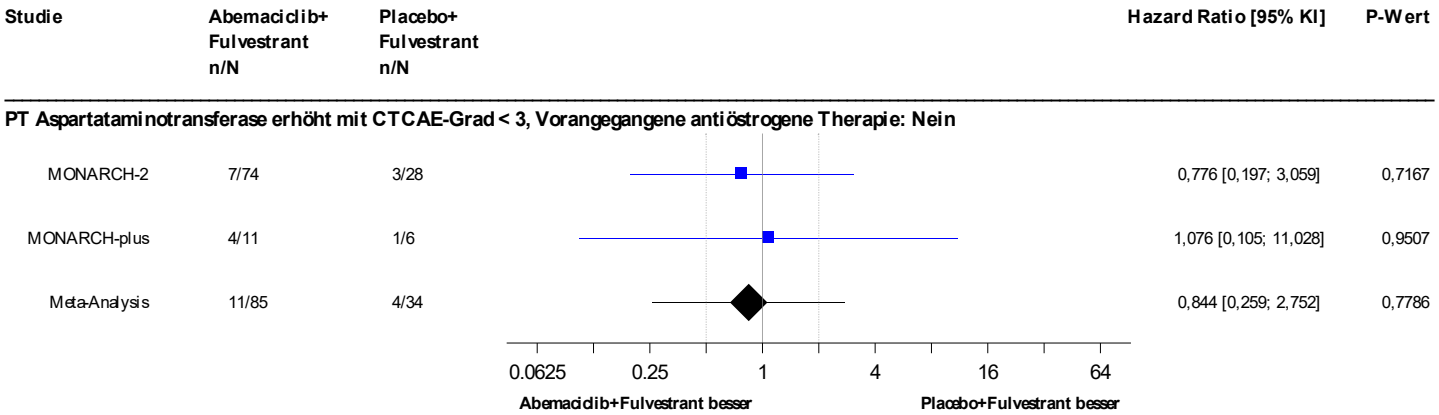
Abbildung 1446.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0565, P-Wert=0,8122, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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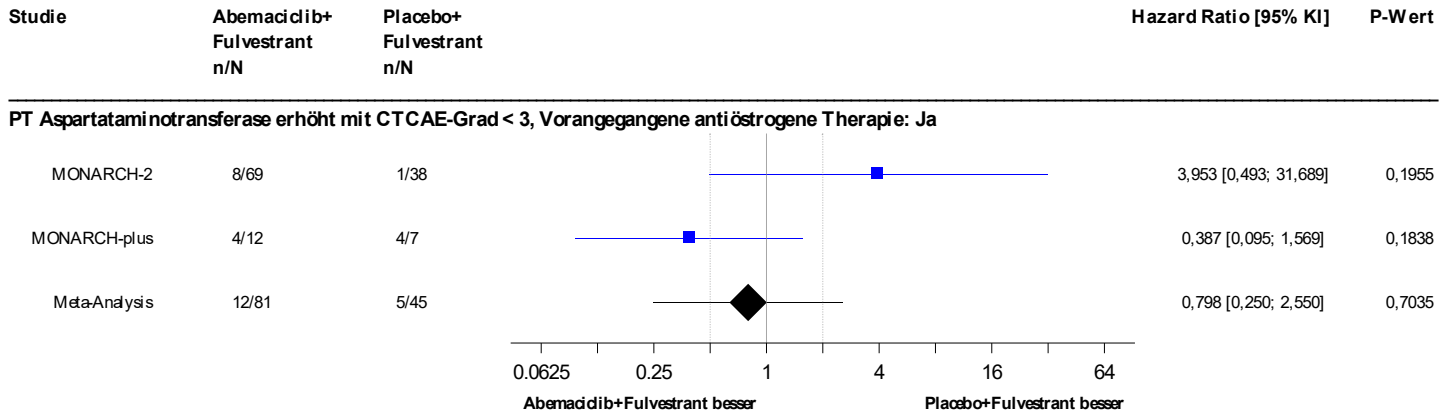
Abbildung 1446.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: PT Aspartataminotransferase erhöht aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=3,2974, P-Wert=0,0694, I2 Index=69,7%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar; PT: Preferred Term.

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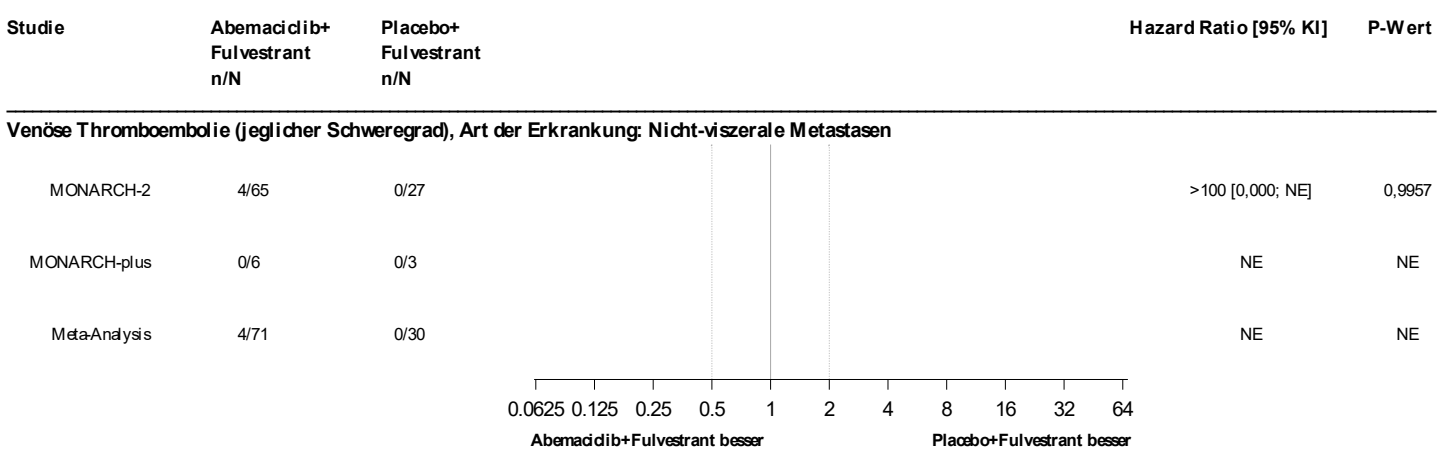
Abbildung 1460.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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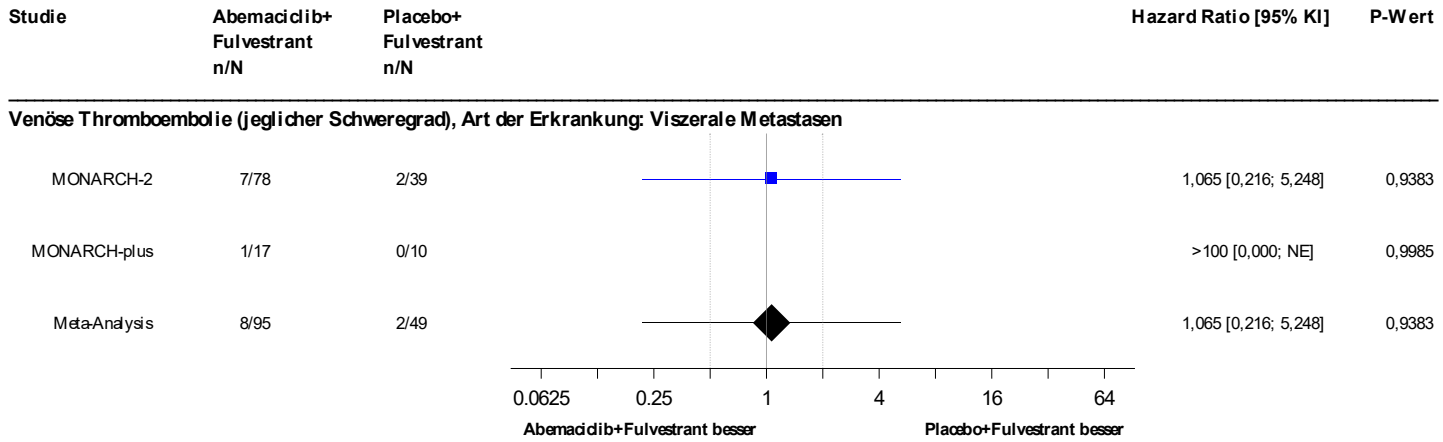
Abbildung 1460.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9985, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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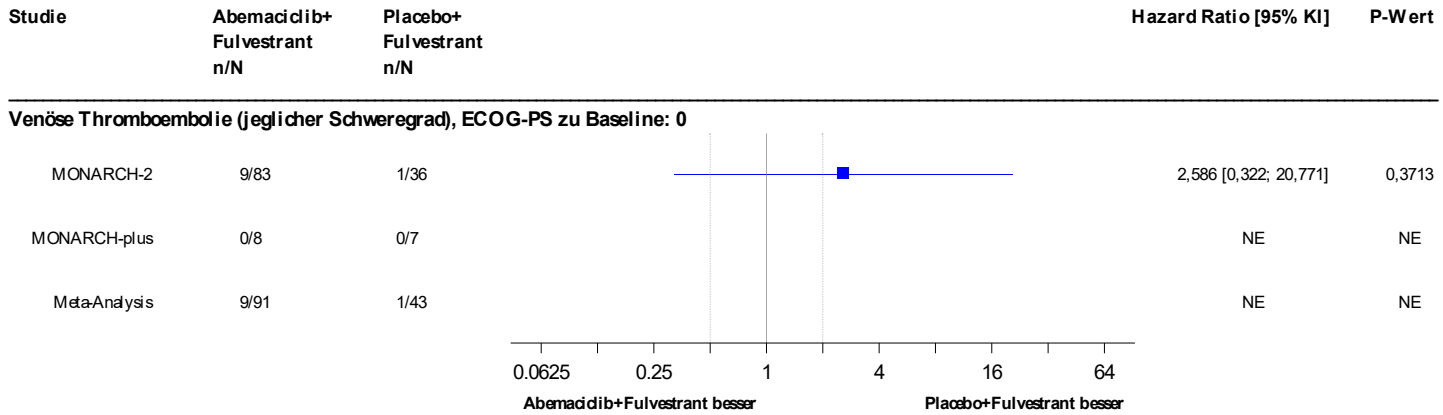
Abbildung 1460.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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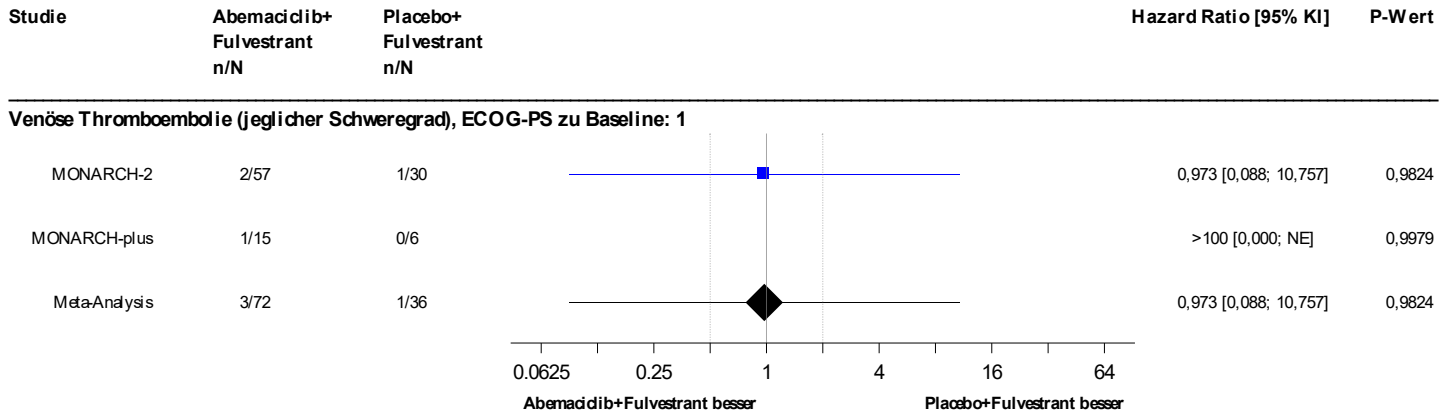
Abbildung 1460.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9979, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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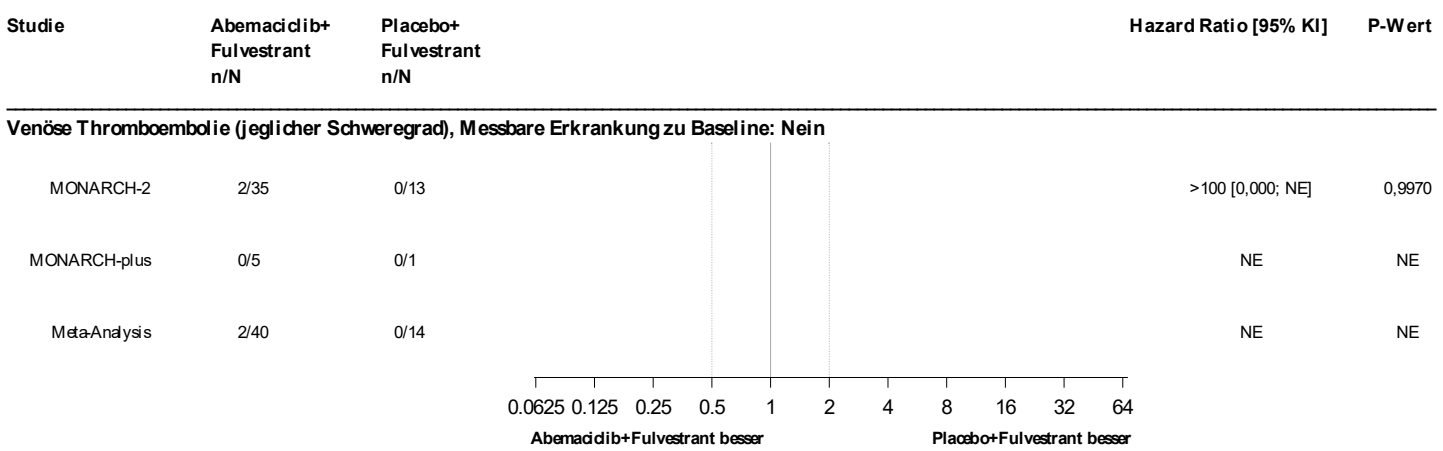
Abbildung 1460.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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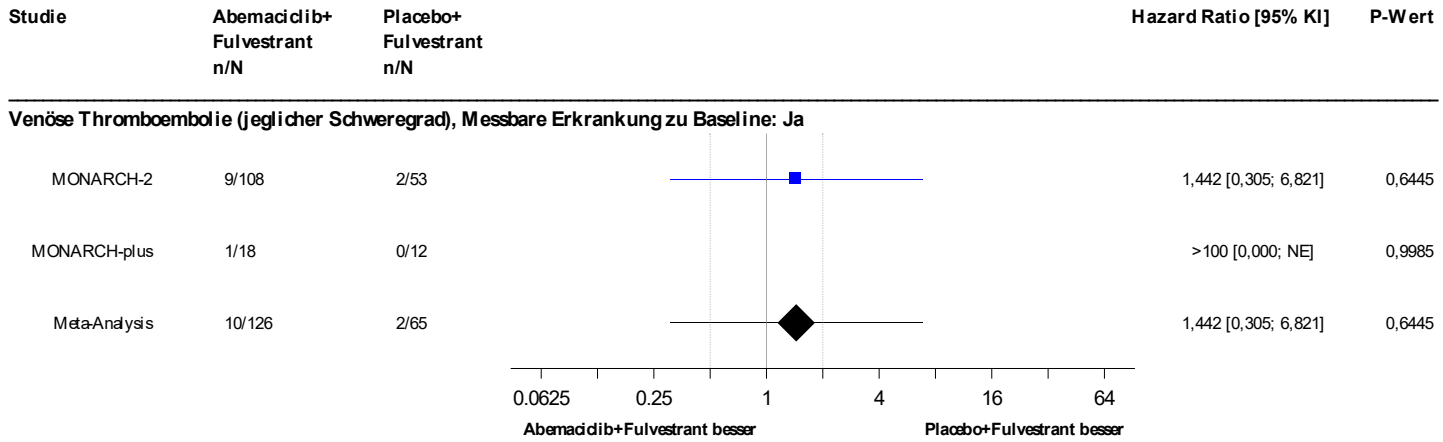
Abbildung 1460.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9985, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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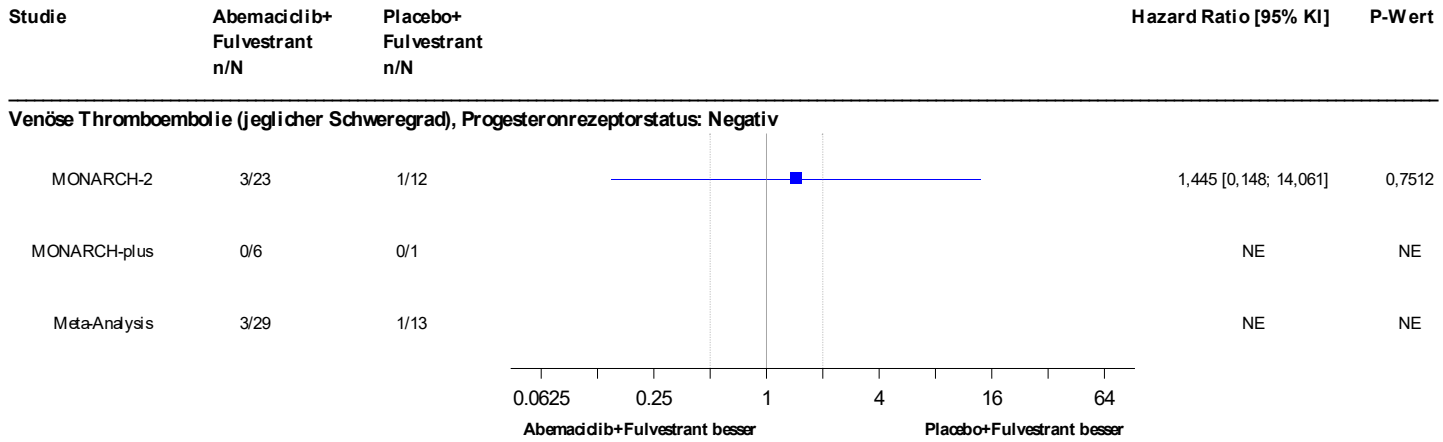
Abbildung 1460.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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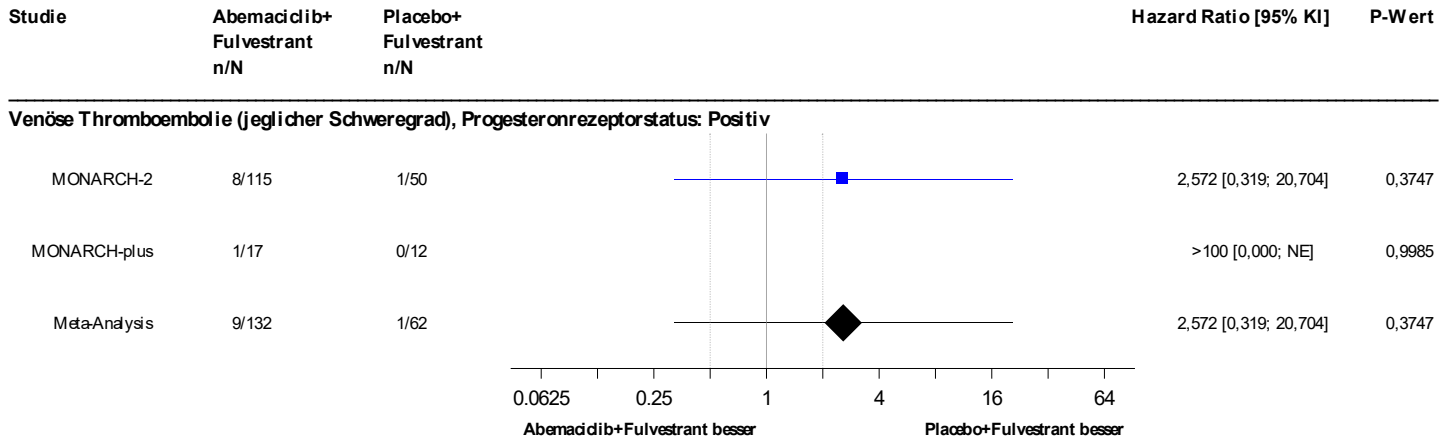
Abbildung 1460.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9985, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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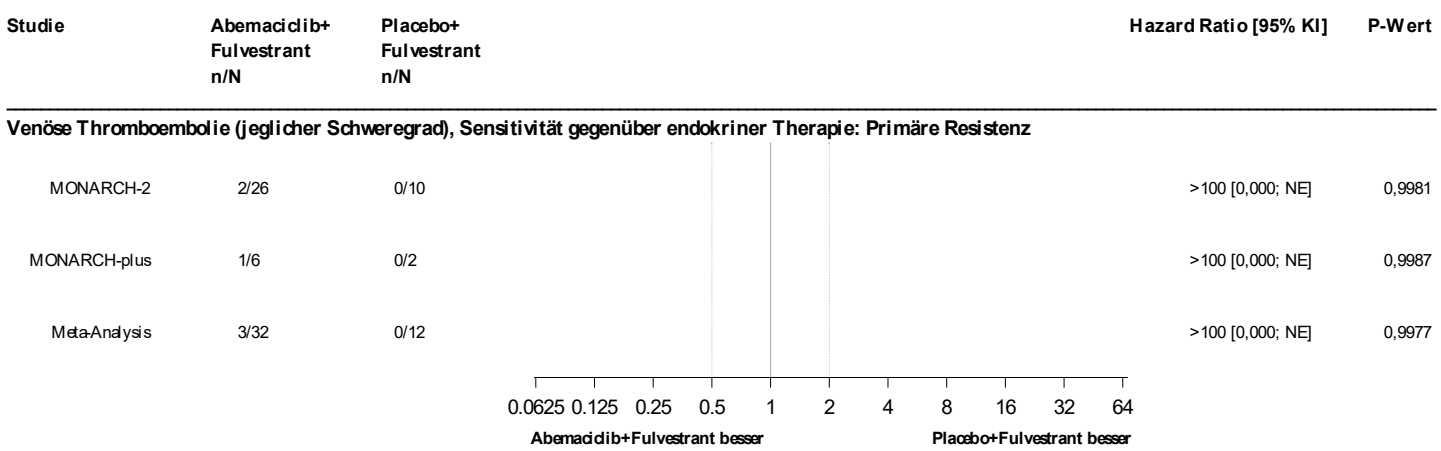
Abbildung 1460.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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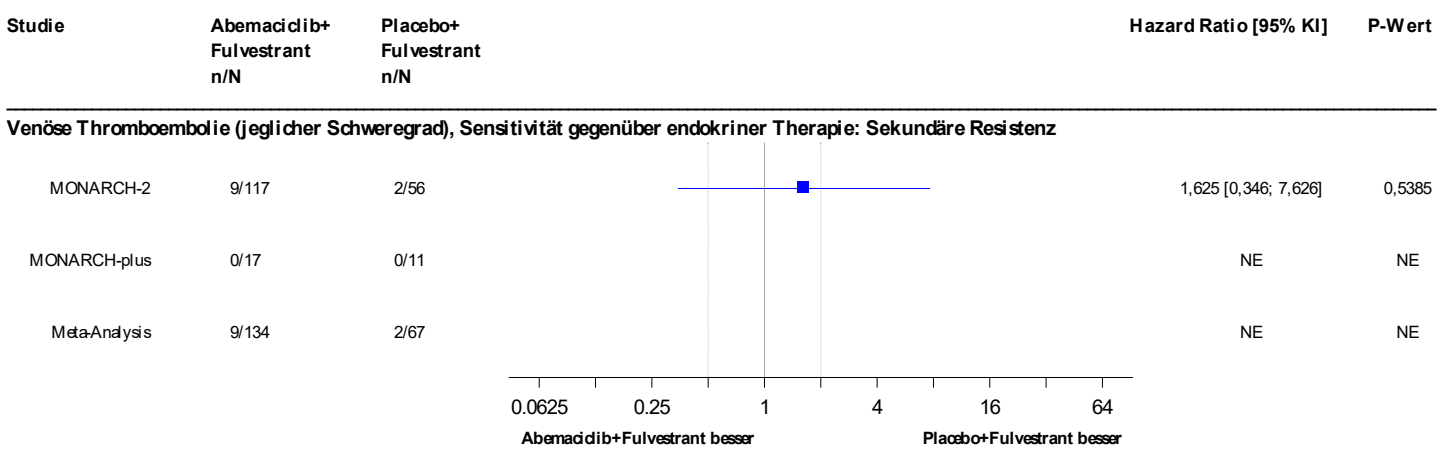
Abbildung 1460.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: Venöse Thromboembolie (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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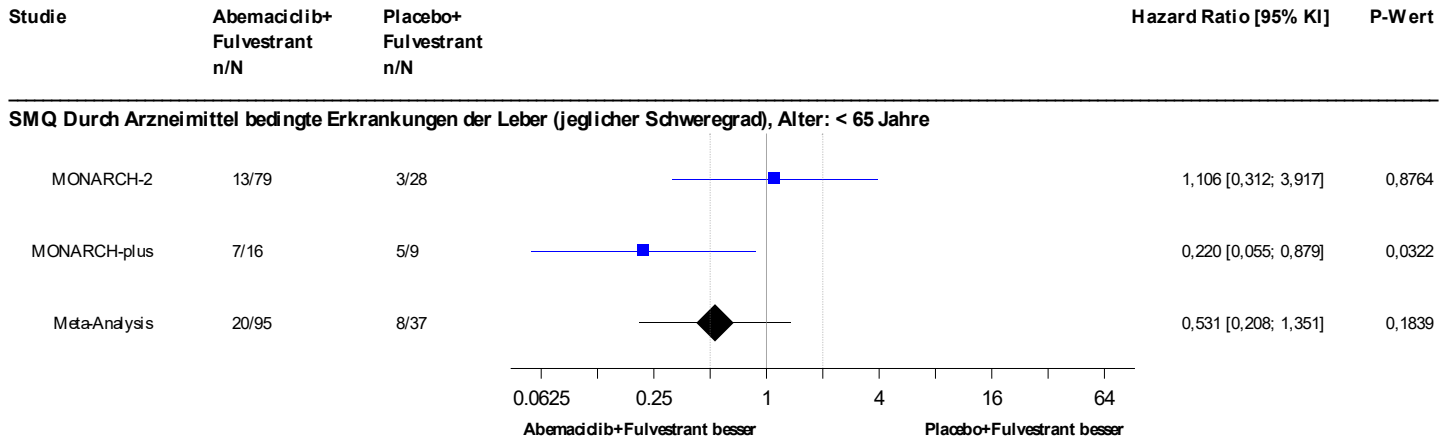
Abbildung 1464.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=2,8466, P-Wert=0,0916, I2 Index=64,9%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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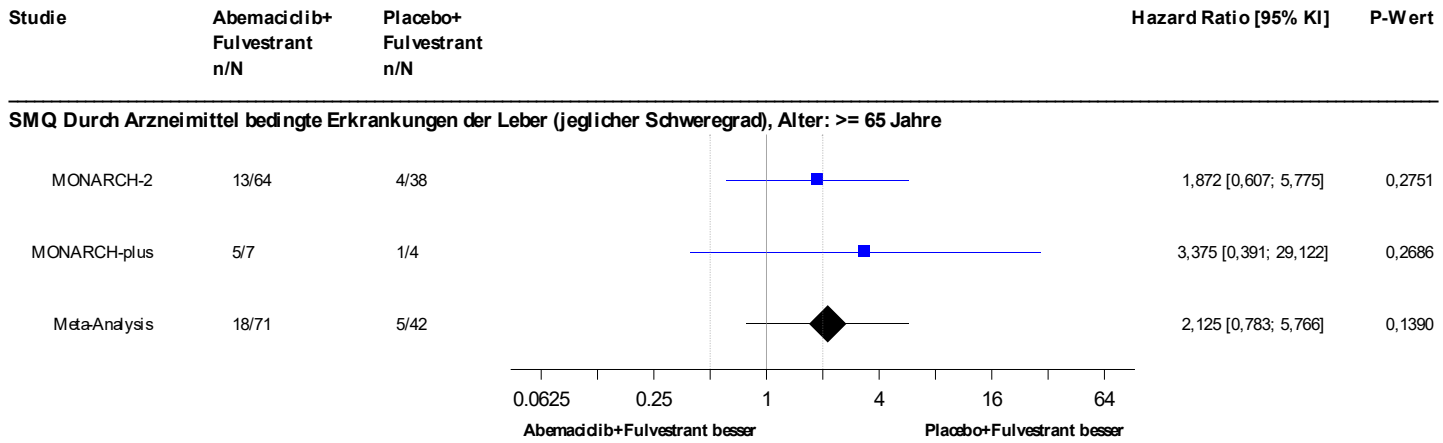
Abbildung 1464.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2256, P-Wert=0,6348, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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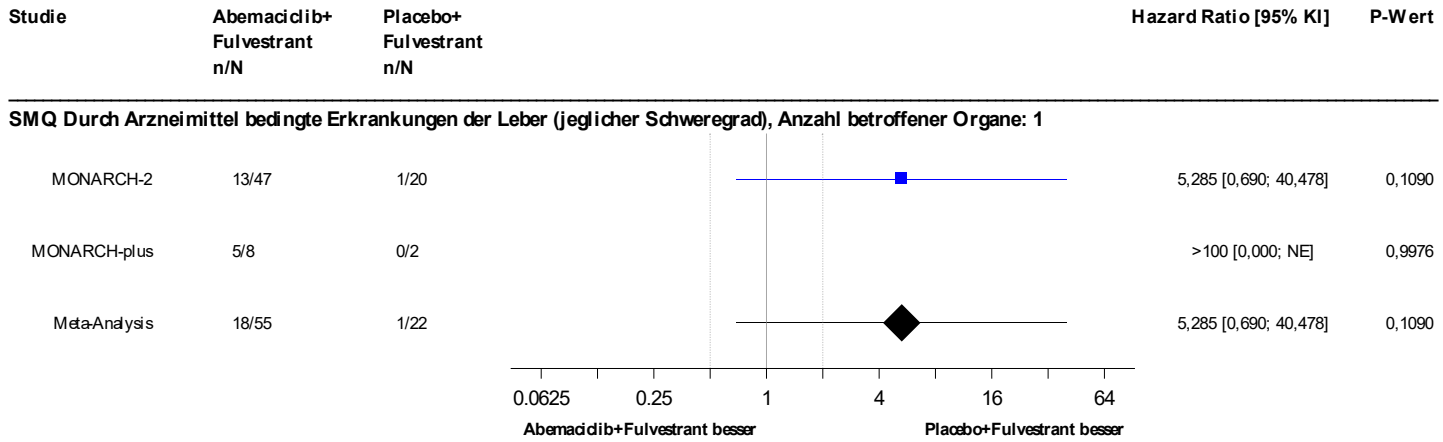
Abbildung 1464.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9978, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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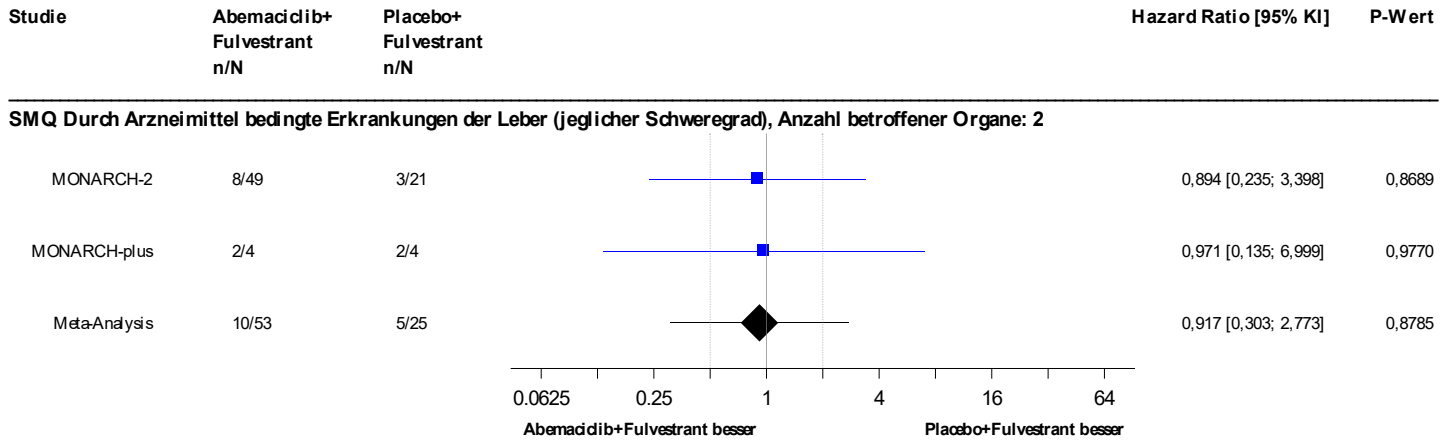
Abbildung 1464.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0047, P-Wert=0,9453, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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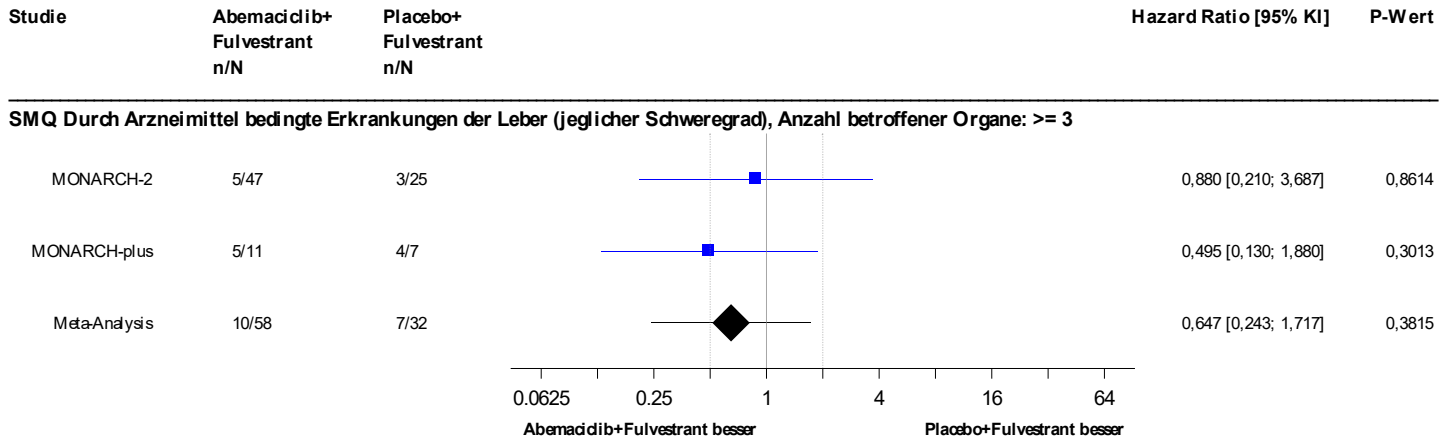
Abbildung 1464.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3330, P-Wert=0,5639, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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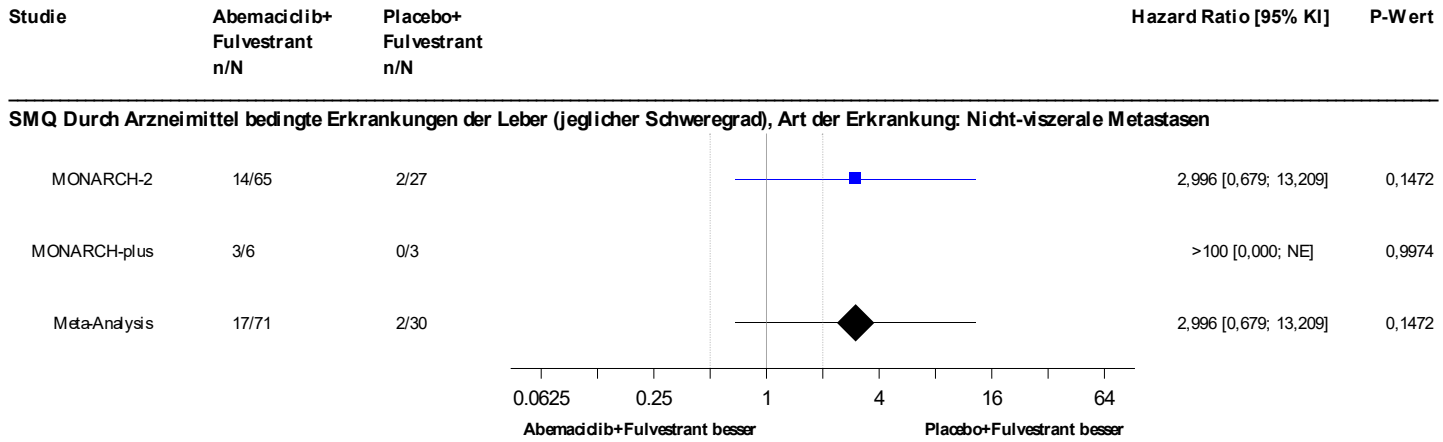
Abbildung 1464.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9976, I2 Index=0%
Abkürzungen: KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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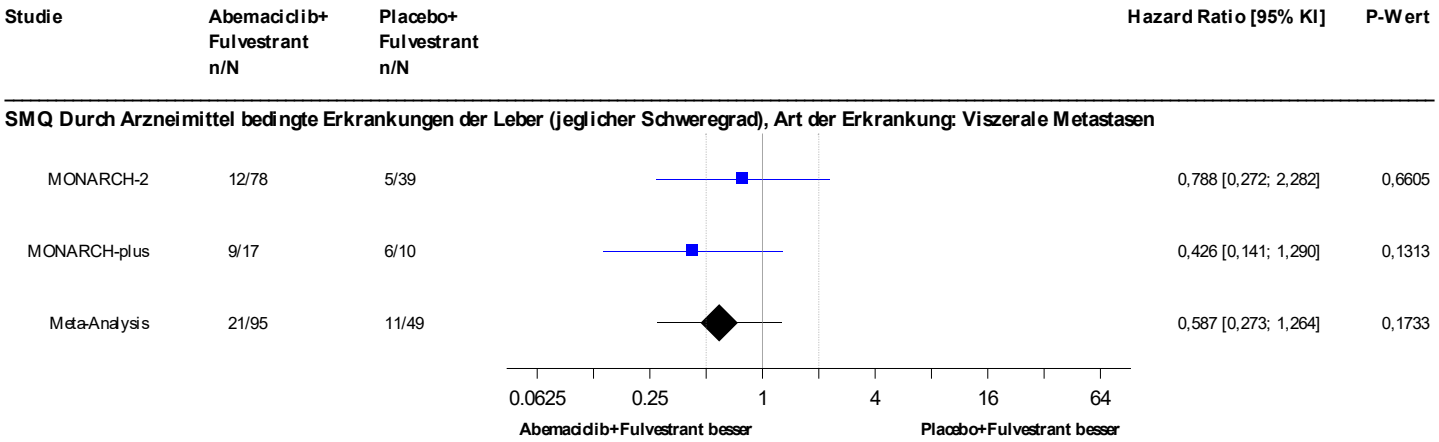
Abbildung 1464.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,6150, P-Wert=0,4329, I2 Index=0%
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Abbildung 1464.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
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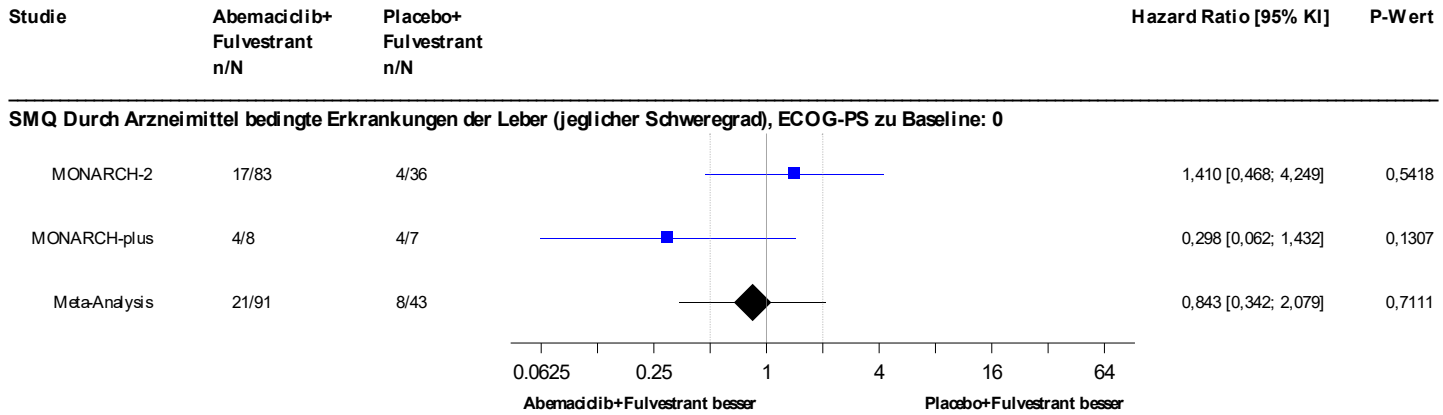

Heterogenität: Cochran Q-test=2,5187, P-Wert=0,1125, I2 Index=60,3%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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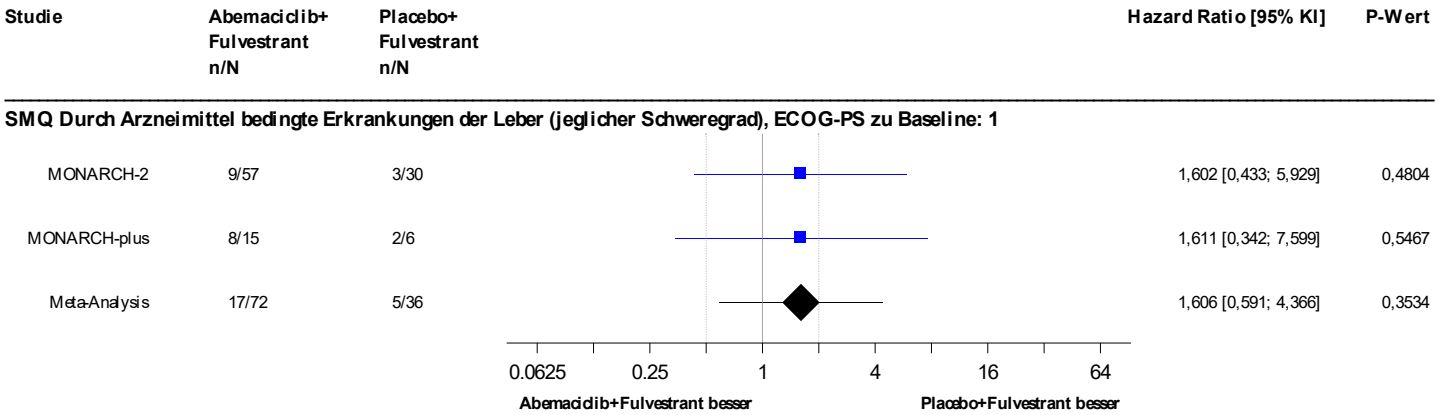
Abbildung 1464.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9956, I2 Index=0%
Abkürzungen: ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Abbildung 1464.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

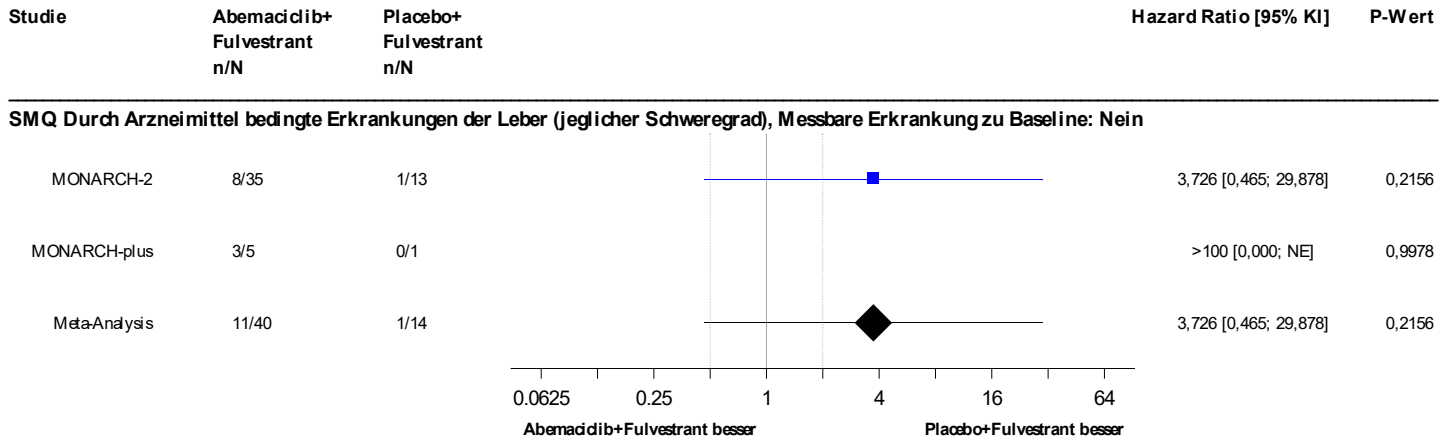

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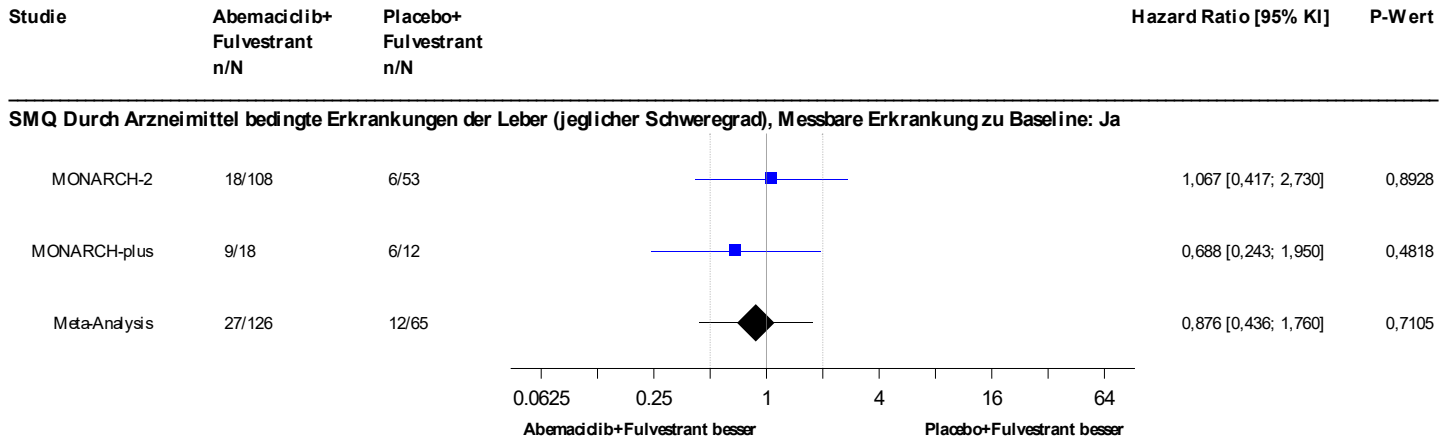
Abbildung 1464.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3752, P-Wert=0,5402, I2 Index=0%
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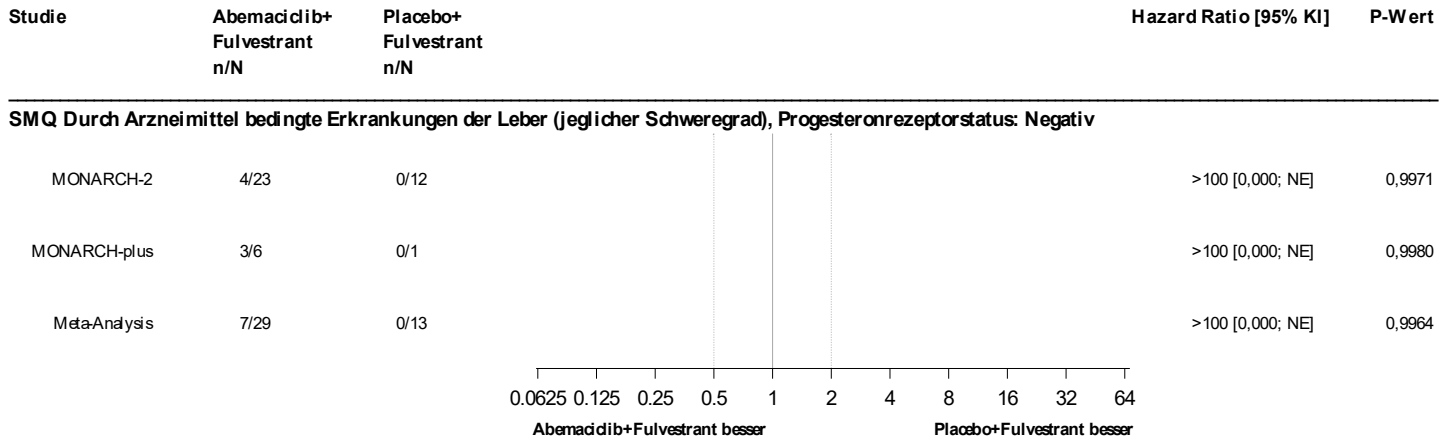
Abbildung 1464.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
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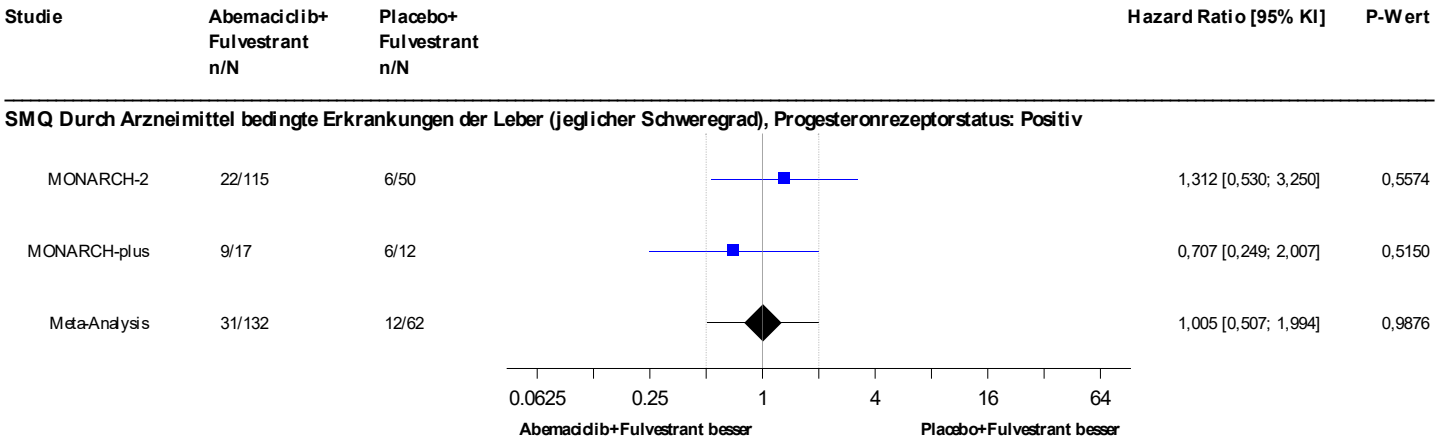
Abbildung 1464.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,7679, P-Wert=0,3809, I2 Index=0%
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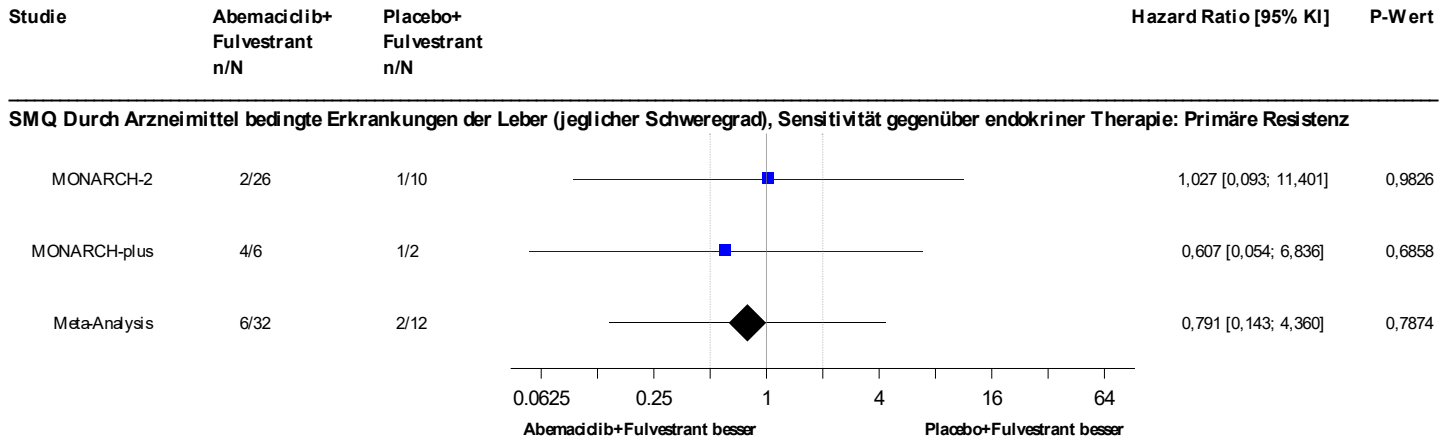
Abbildung 1464.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0914, P-Wert=0,7624, I2 Index=0%
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Abbildung 1464.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

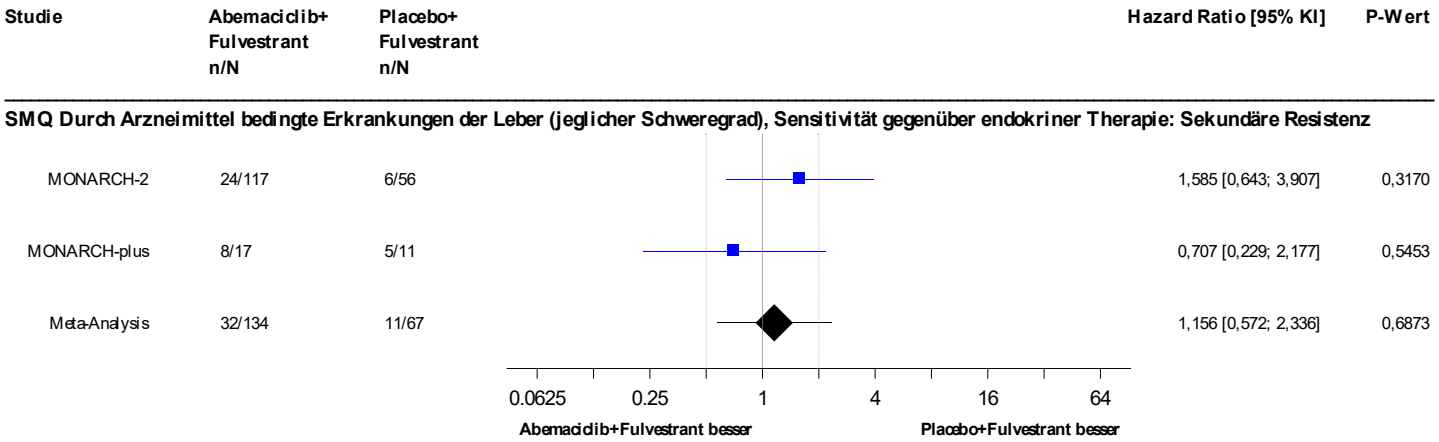

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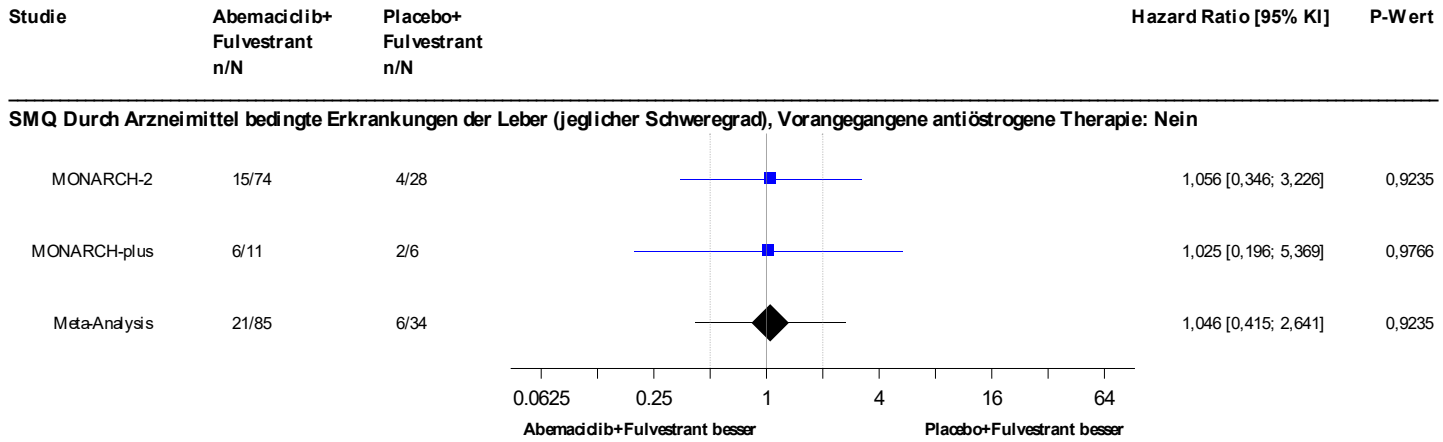
Abbildung 1464.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0009, P-Wert=0,9766, I2 Index=0%
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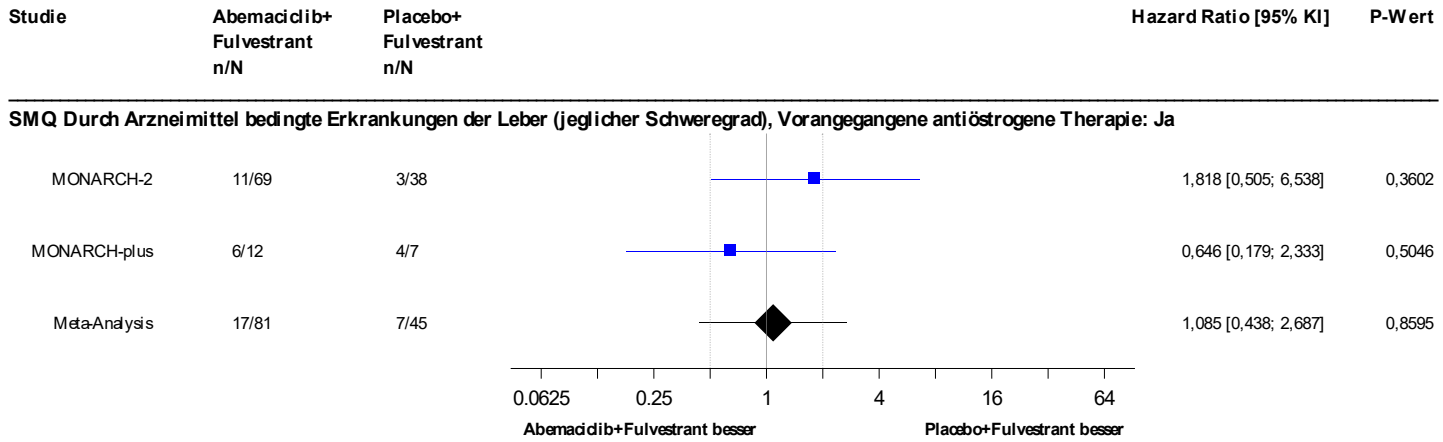
Abbildung 1464.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber (jeglicher Schweregrad) aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,2509, P-Wert=0,2634, I2 Index=20,1%
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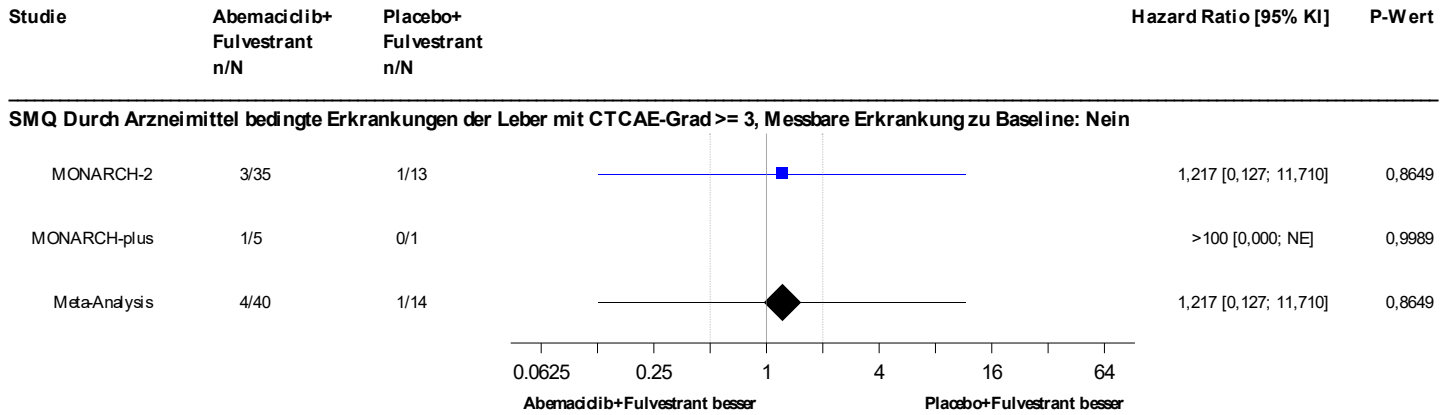
Abbildung 1465.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9989, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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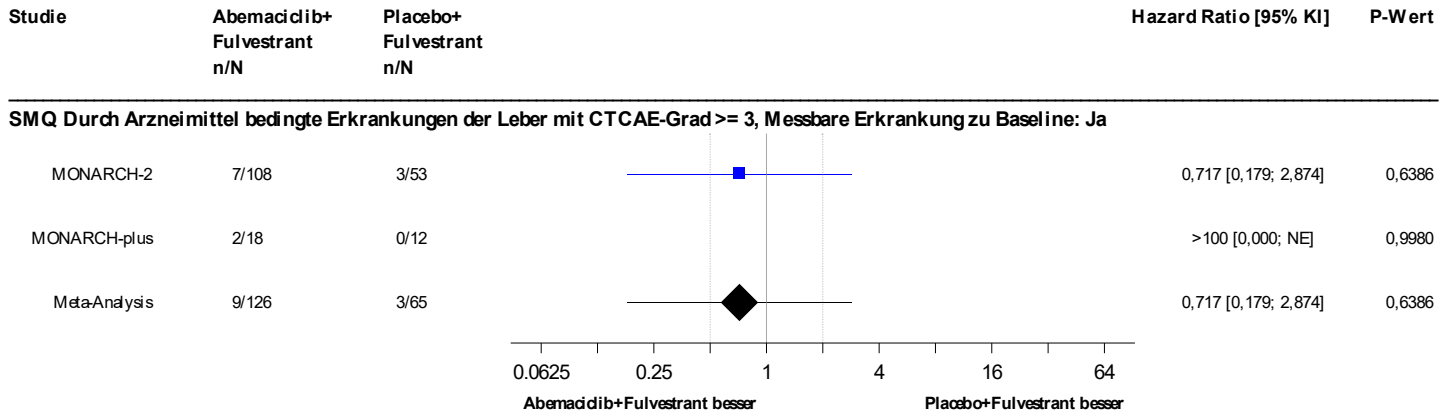
Abbildung 1465.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9980, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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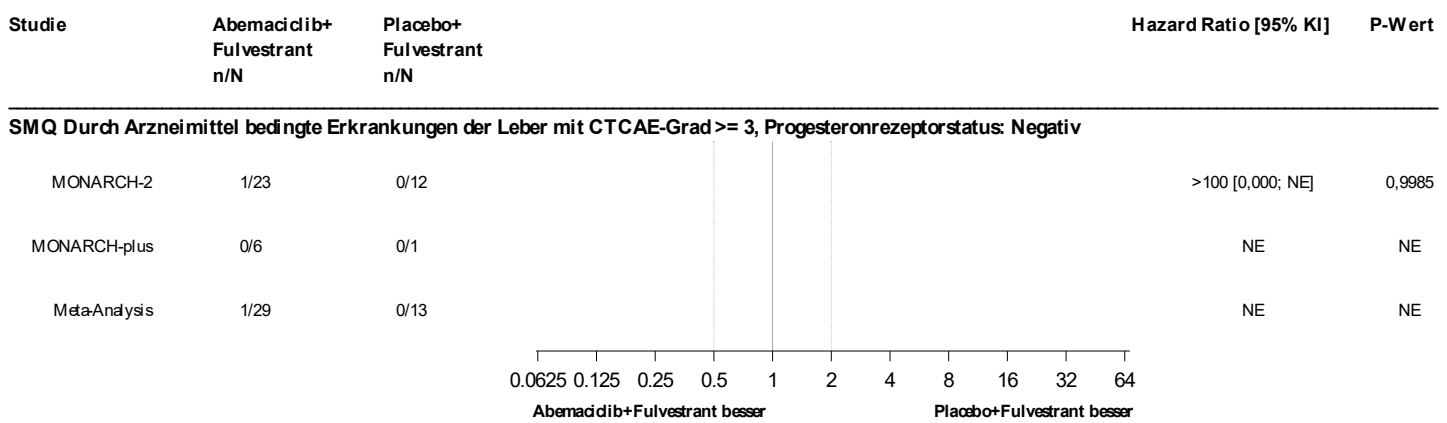
17SEP2021 / 07:48

Abbildung 1465.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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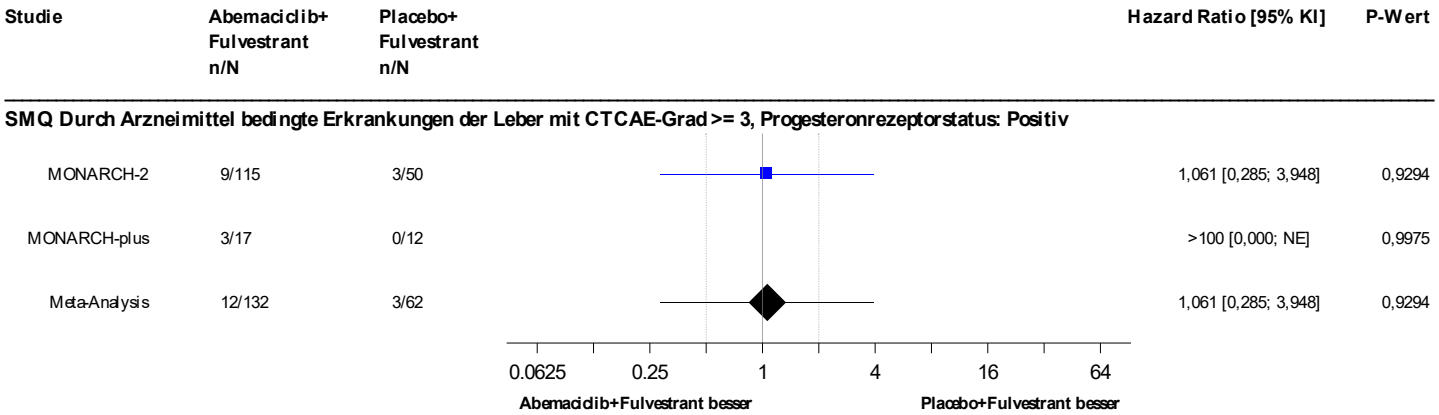
17SEP2021 / 07:48

Abbildung 1465.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9975, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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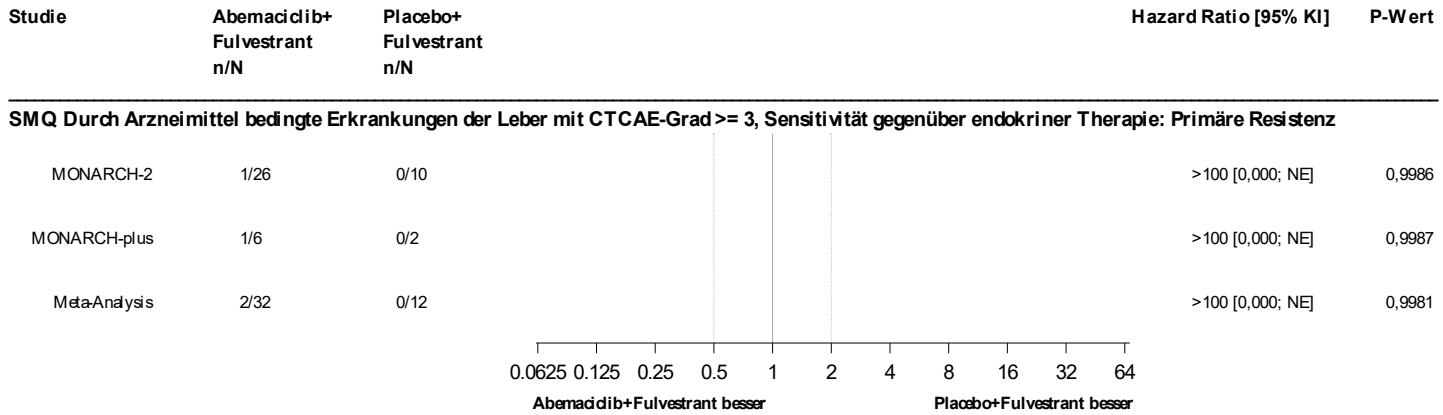
Abbildung 1465.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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Abbildung 1465.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)

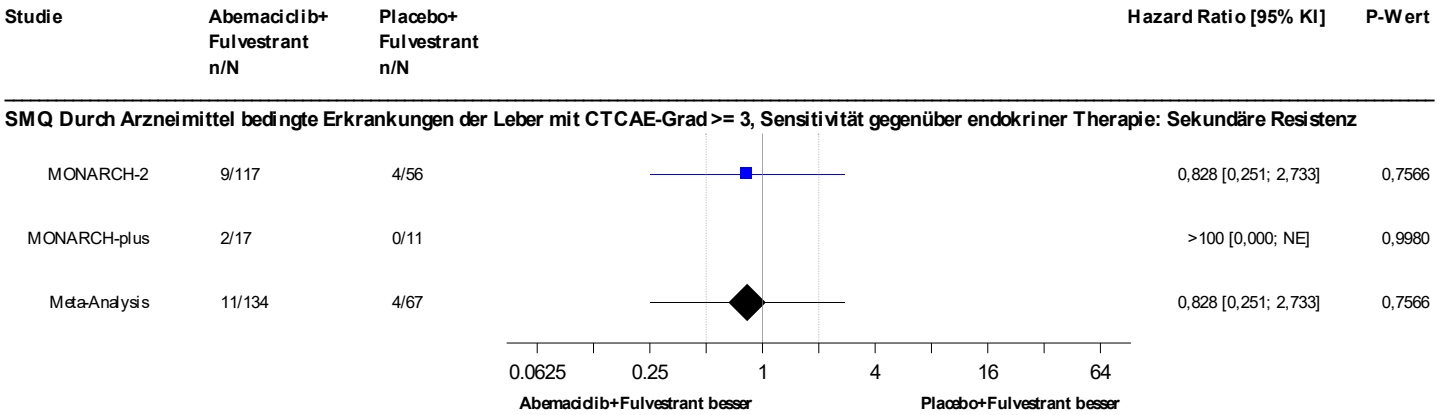

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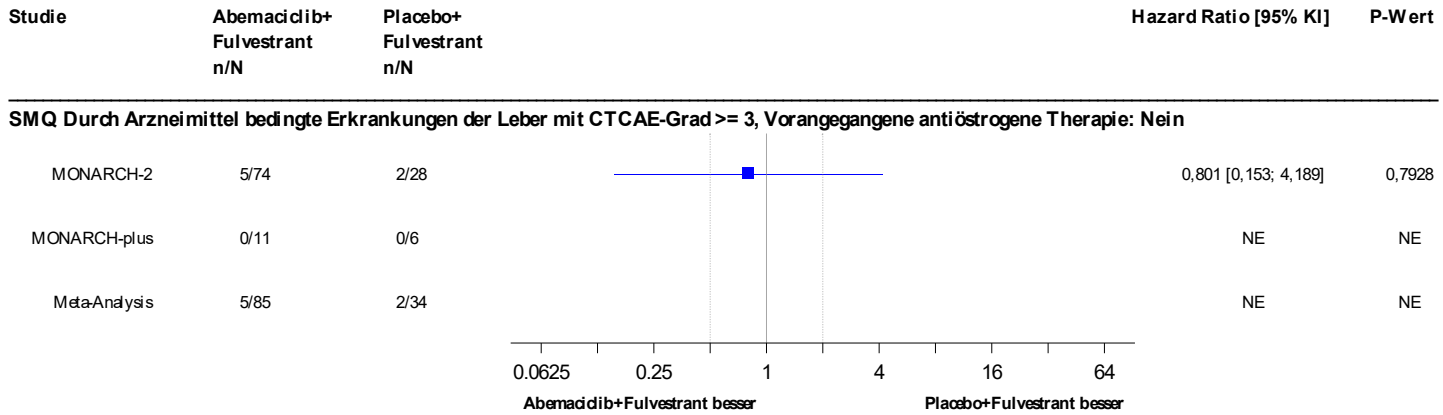
Abbildung 1465.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=NE, P-Wert=NE, I2 Index=NE
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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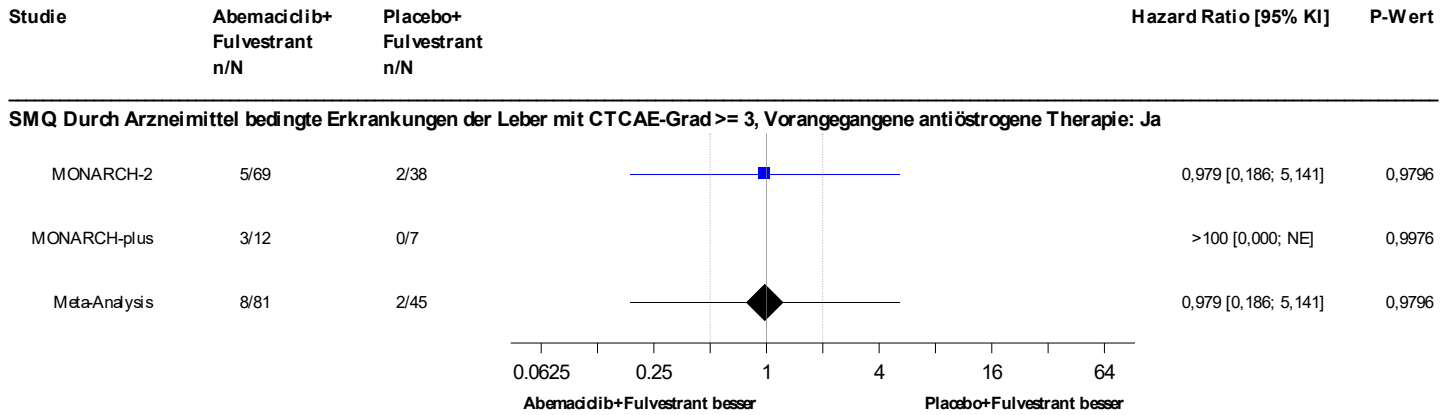
Abbildung 1465.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad ≥ 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9975, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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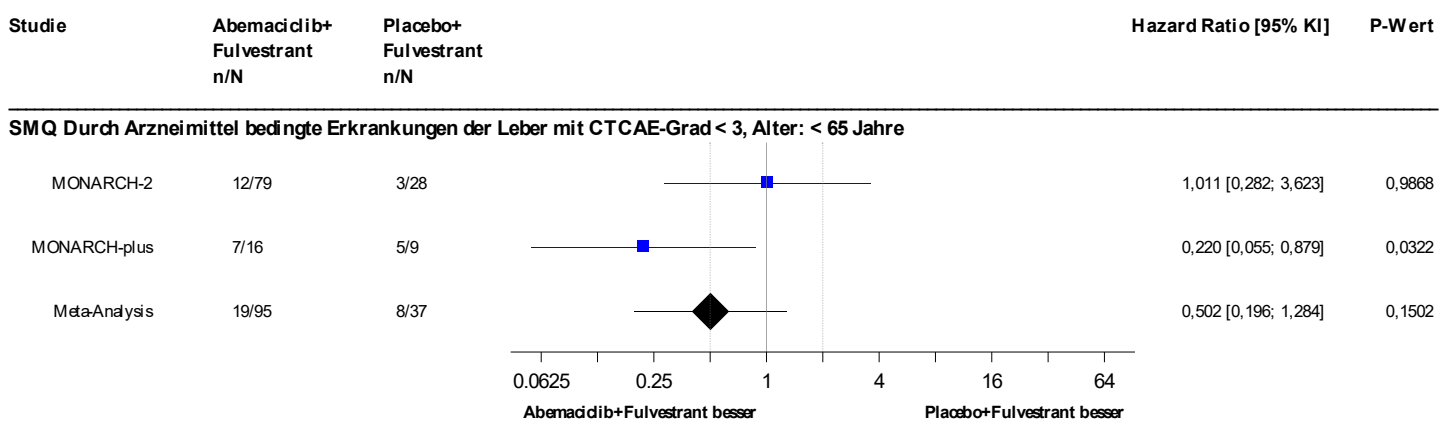
Abbildung 1466.2.1.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: < 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=2,5184, P-Wert=0,1125, I2 Index=60,3%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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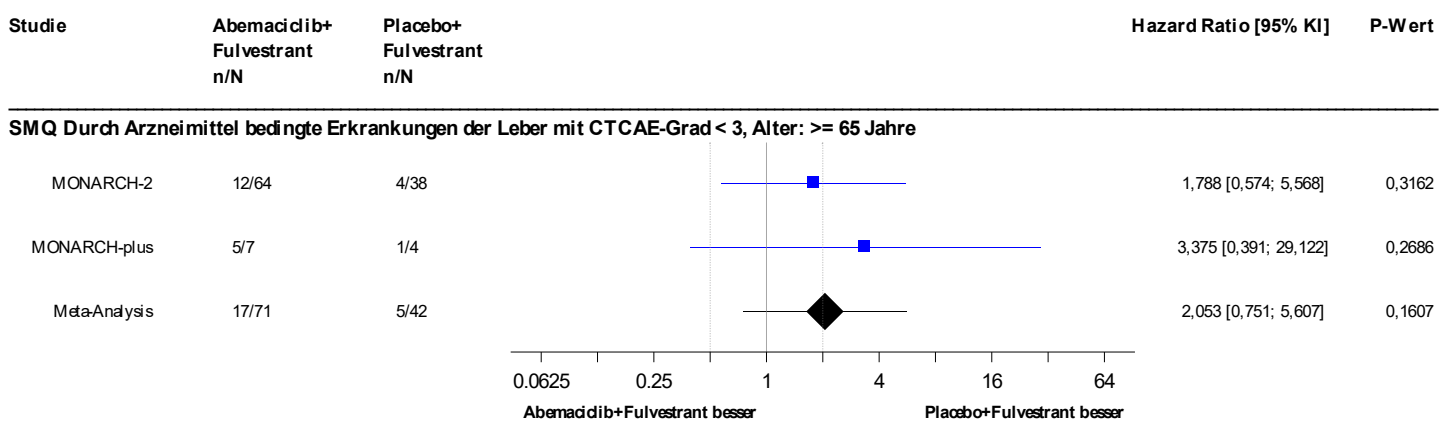
17SEP2021 / 07:48

Abbildung 1466.2.1.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Alter: >= 65 Jahre
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,2614, P-Wert=0,6092, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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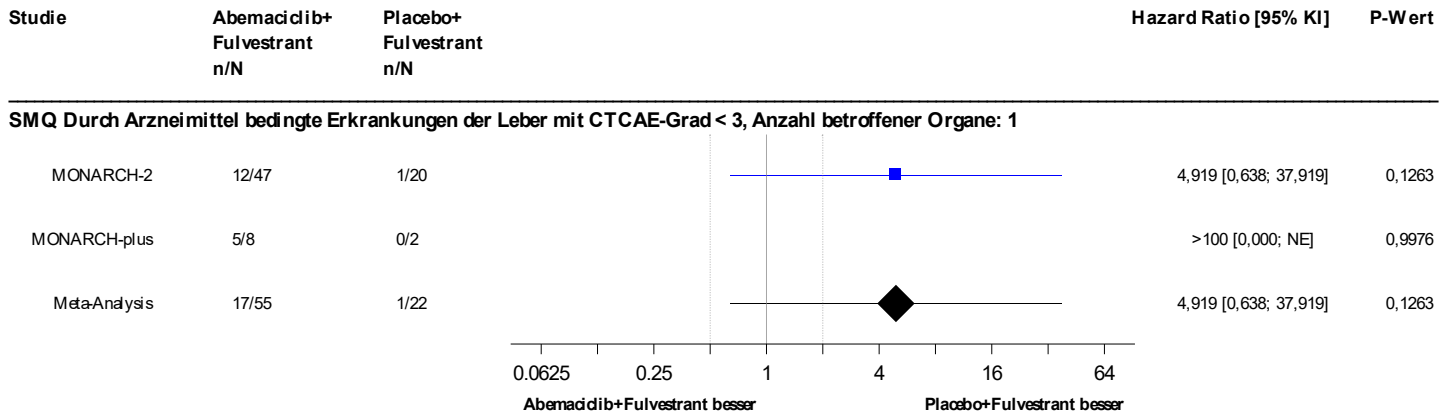
Abbildung 1466.2.2.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9978, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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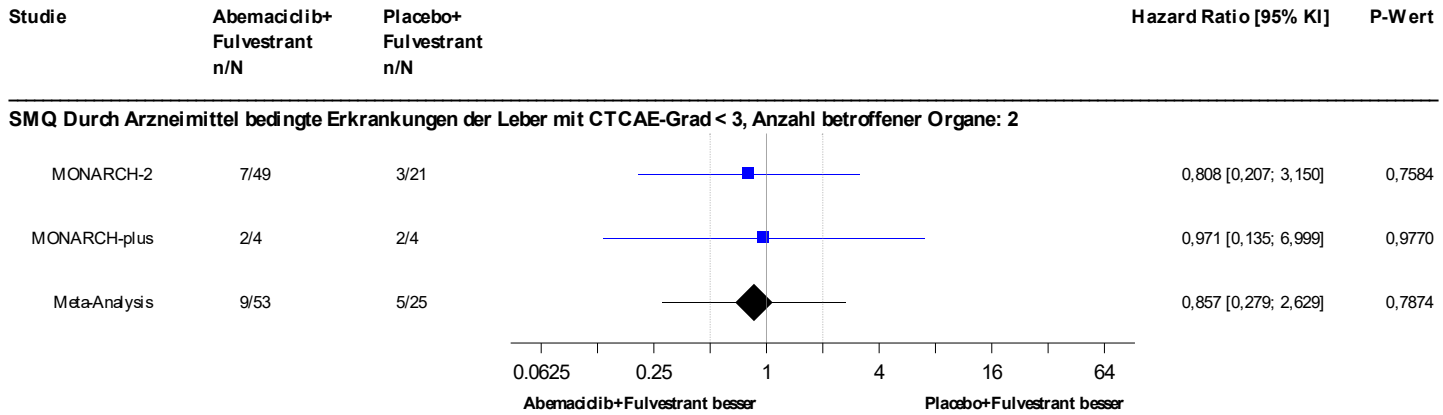
17SEP2021 / 07:48

Abbildung 1466.2.2.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: 2
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0228, P-Wert=0,8801, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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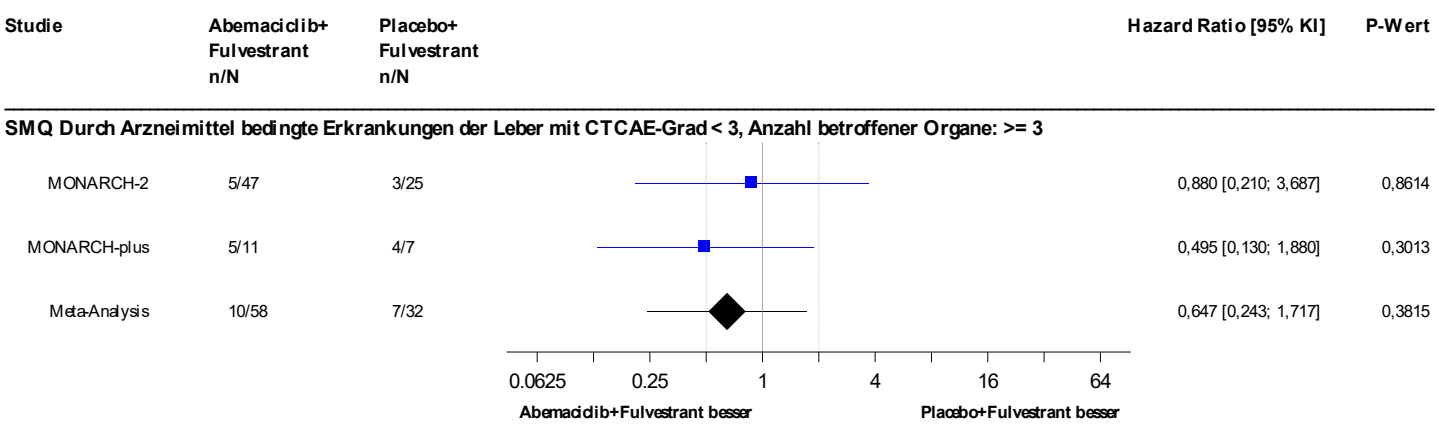
Abbildung 1466.2.2.3: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Anzahl betroffener Organe: >= 3
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3330, P-Wert=0,5639, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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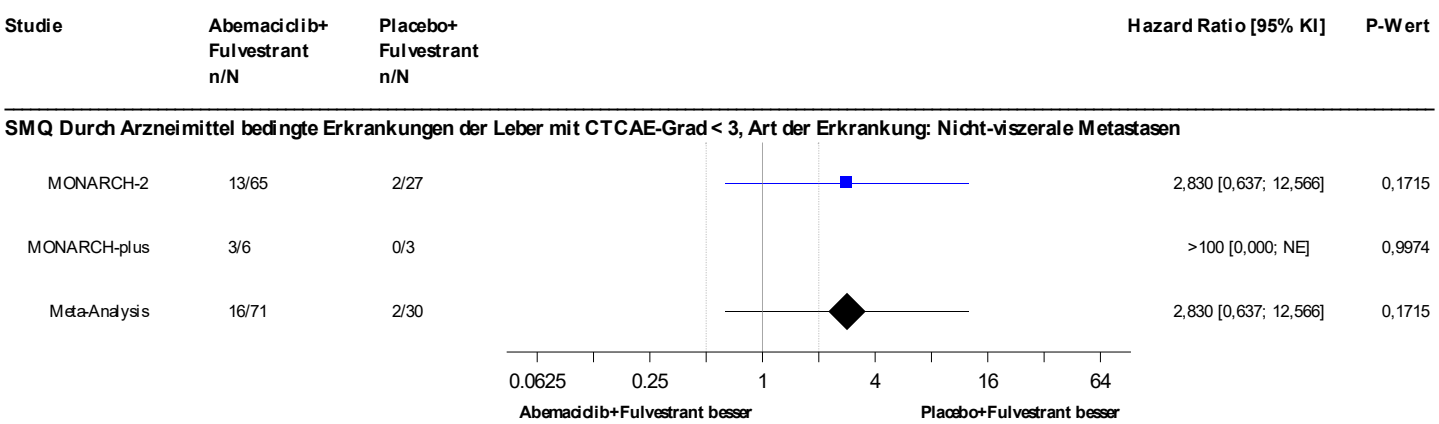
17SEP2021 / 07:48

Abbildung 1466.2.3.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Nicht-viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9976, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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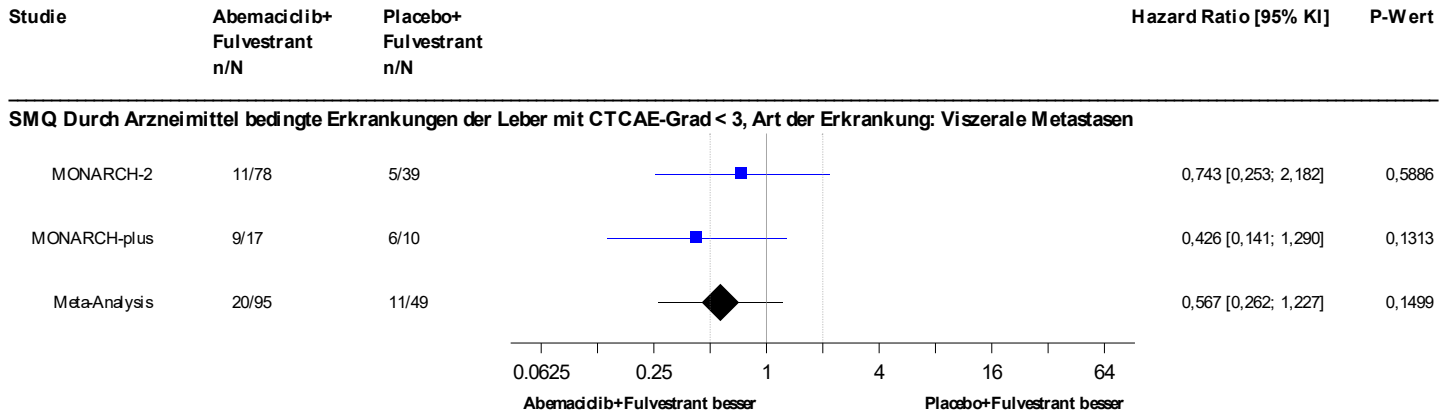
17SEP2021 / 07:48

Abbildung 1466.2.3.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Art der Erkrankung: Viszerale Metastasen
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,4958, P-Wert=0,4813, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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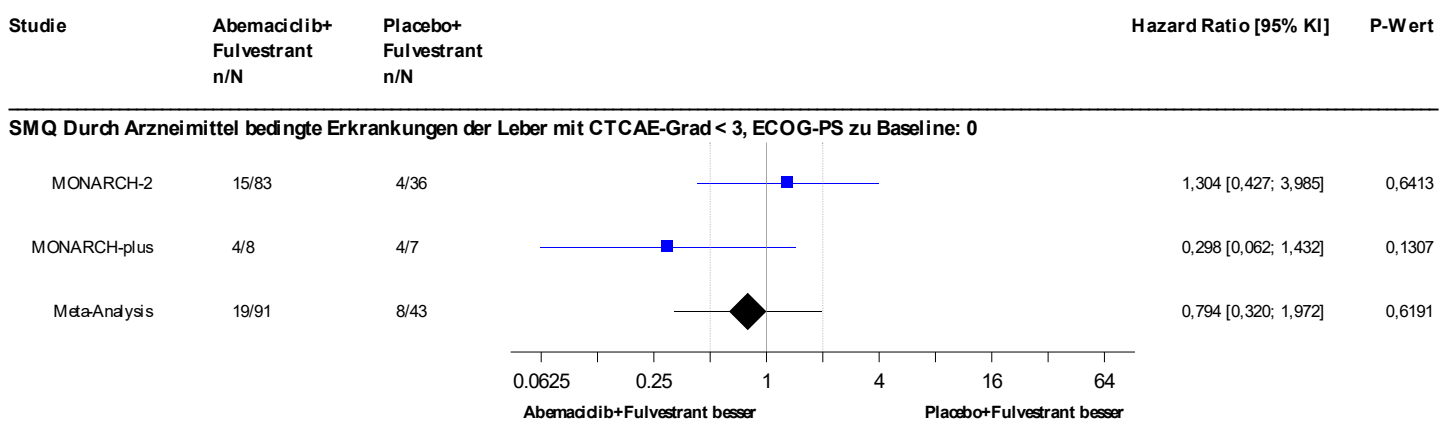
Abbildung 1466.2.4.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 0
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=2,2537, P-Wert=0,1333, I2 Index=55,6%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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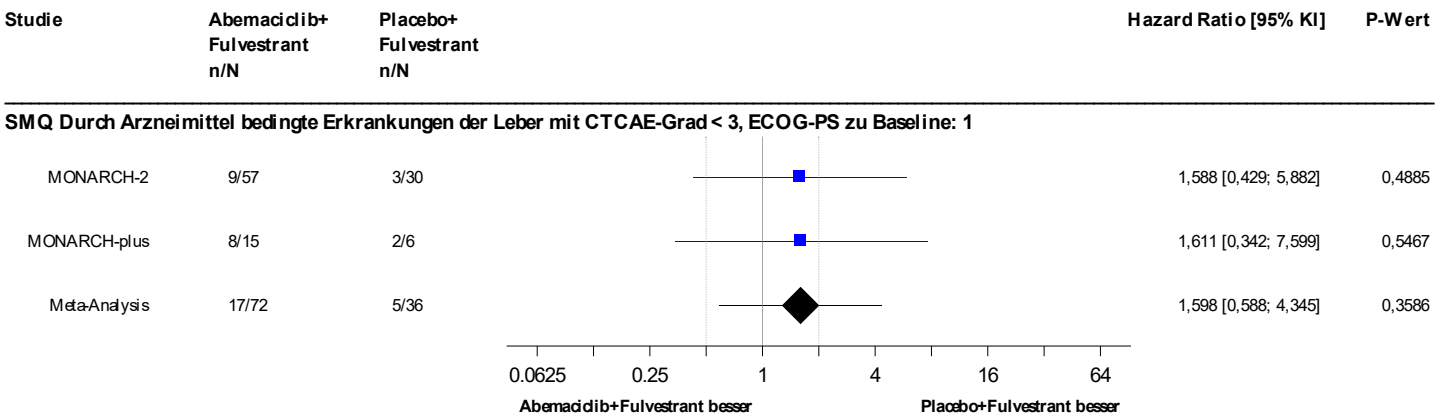
Abbildung 1466.2.4.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für ECOG-PS zu Baseline: 1
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0002, P-Wert=0,9890, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; ECOG-PS: Eastern Cooperative Oncology Group-Performance Status; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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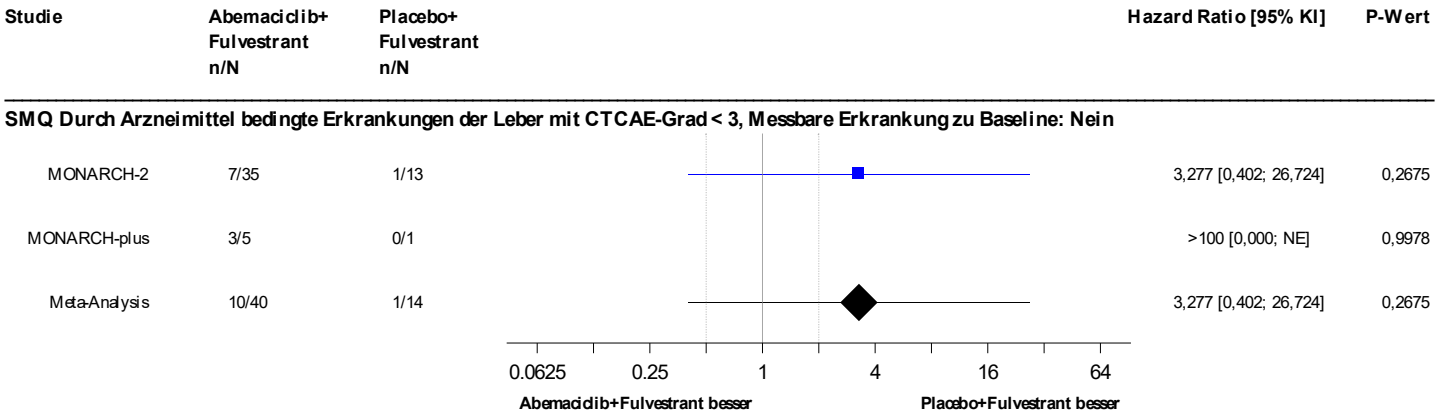
Abbildung 1466.2.6.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=0,9979, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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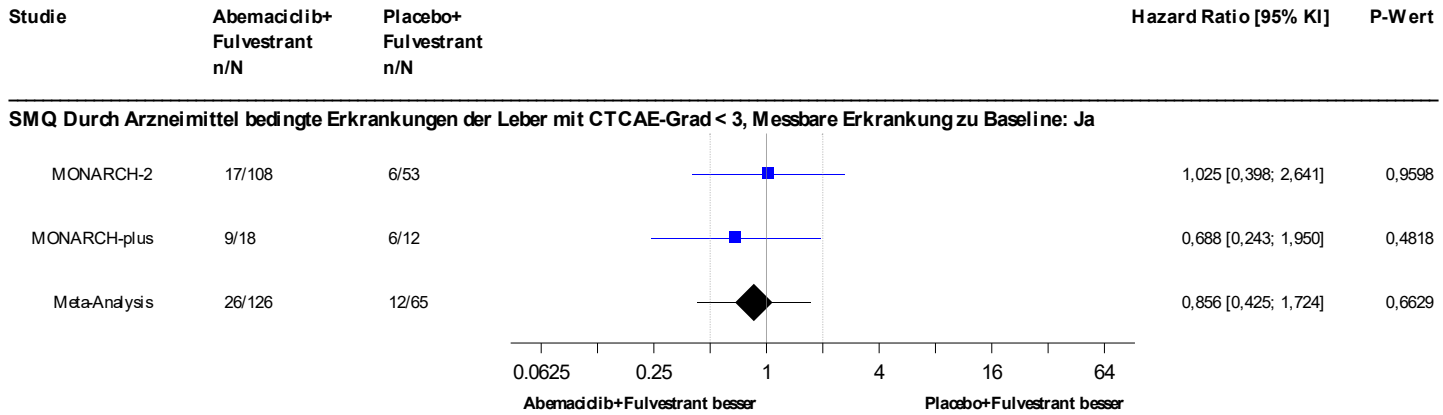
Abbildung 1466.2.6.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Messbare Erkrankung zu Baseline: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,3074, P-Wert=0,5793, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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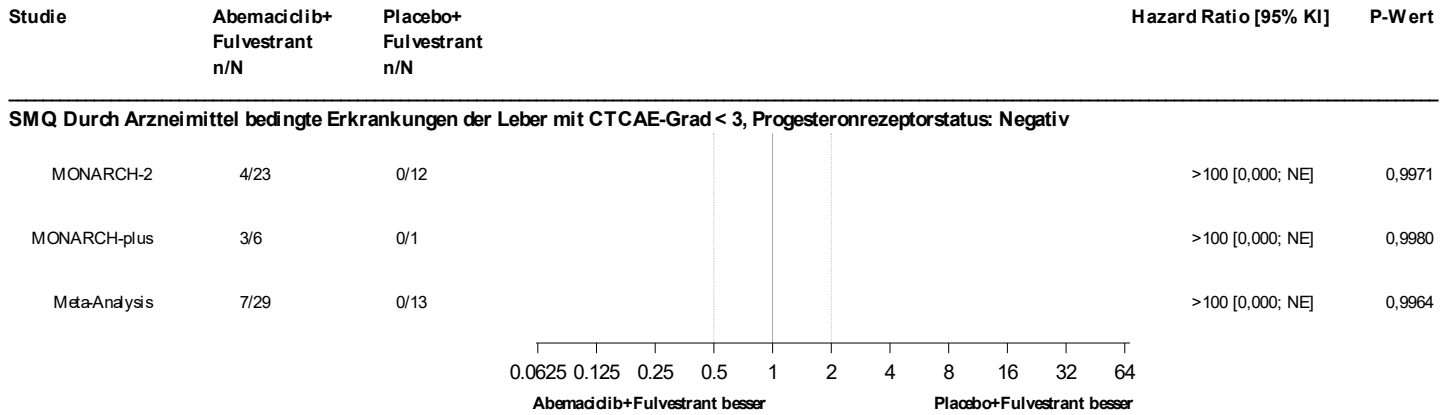
Abbildung 1466.2.7.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Negativ
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0000, P-Wert=1,0000, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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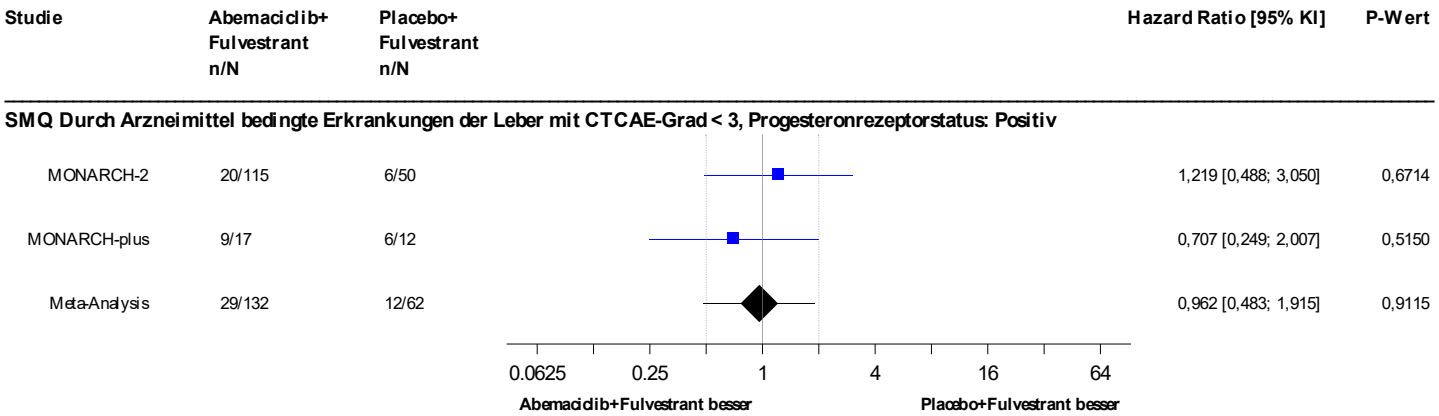
Abbildung 1466.2.7.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Progesteronrezeptorstatus: Positiv
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,5914, P-Wert=0,4419, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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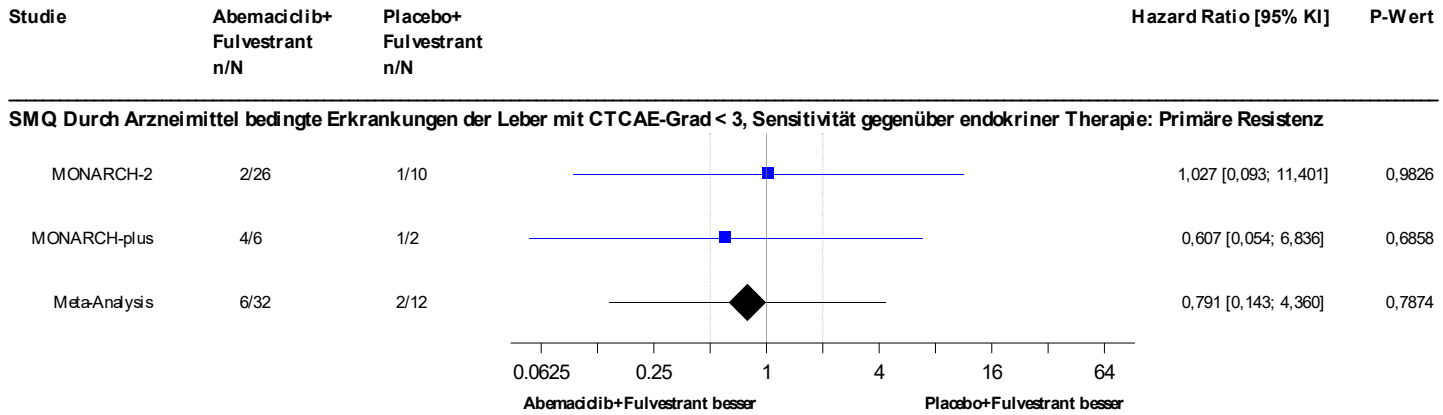
Abbildung 1466.2.8.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Primäre Resistenz
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0914, P-Wert=0,7624, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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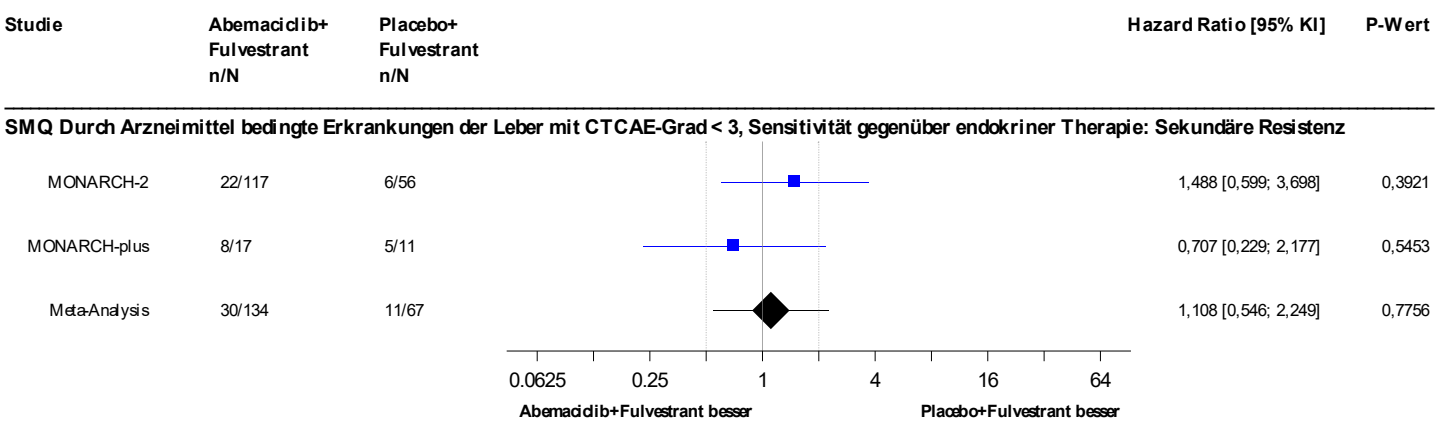
Abbildung 1466.2.8.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel Subgruppenanalyse für Sensitivität gegenüber endokriner Therapie: Sekundäre Resistenz Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=1,0168, P-Wert=0,3133, I2 Index=1,7%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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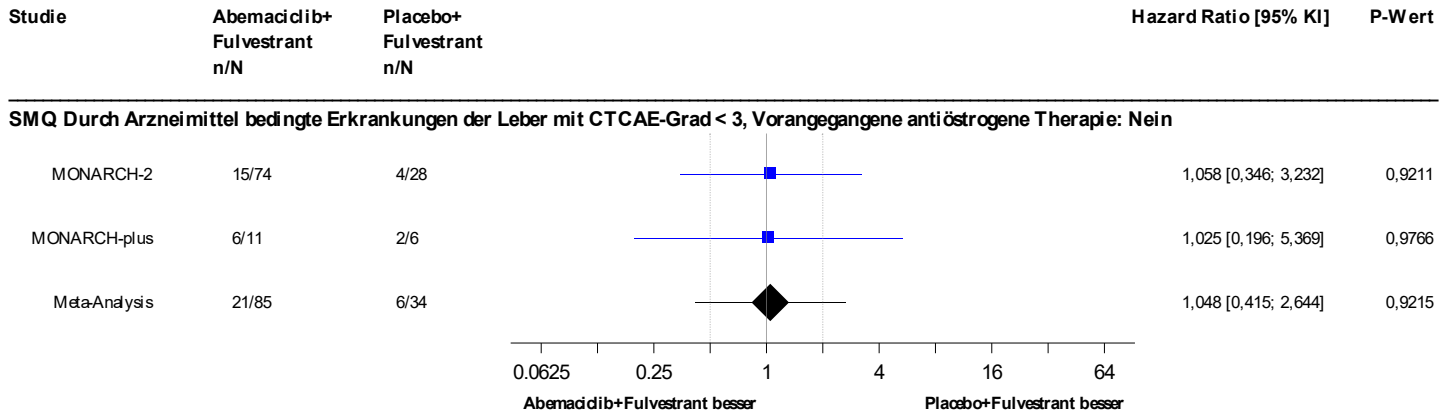
Abbildung 1466.2.9.1: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Nein
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,0010, P-Wert=0,9752, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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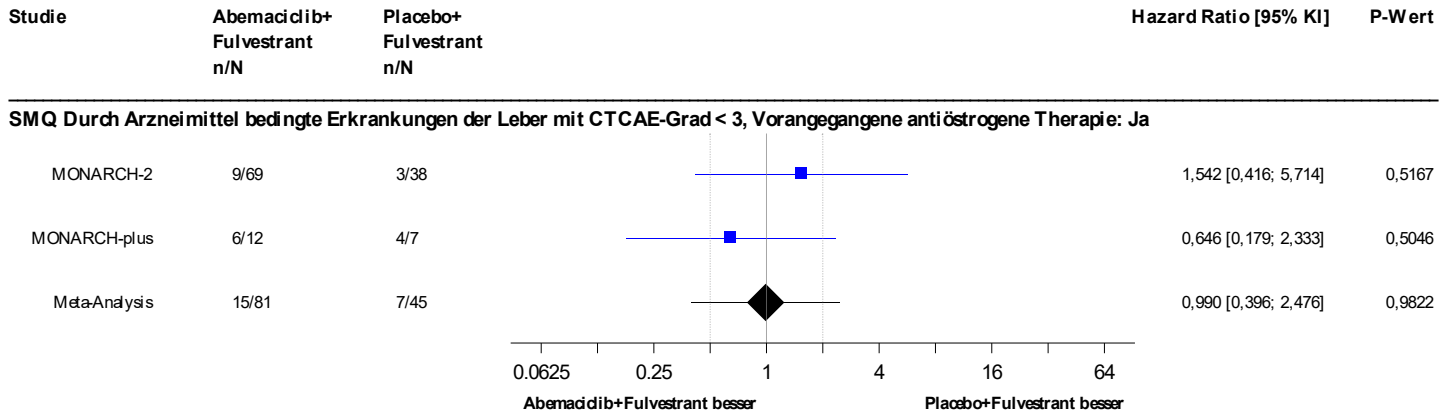
Abbildung 1466.2.9.2: Metaanalyse der Ergebnisse für die Zeit bis zum ersten unerwünschten Ereignis CTCAE Grad < 3: SMQ Durch Arzneimittel bedingte Erkrankungen der Leber aus RCT mit dem zu bewertenden Arzneimittel
Subgruppenanalyse für Vorangegangene antiöstrogene Therapie: Ja
Studien MONARCH-2 und MONARCH-plus - Safety Population - Postmenopausal B1 (Zweitlinie)



Heterogenität: Cochran Q-test=0,8652, P-Wert=0,3523, I2 Index=0%
Abkürzungen: CTCAE: Common Terminology Criteria for Adverse Events; KI: Konfidenzintervall; n: Anzahl Patienten mit Ereignis; N: Gesamtzahl der Patienten in der Analyse; NE: Nicht errechenbar.

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